vaccibody

Report 3rd 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 been finalized and has reported positive 12 months data. Vaccibody has started a collaboration with Roche, which will explore VB10.16 in combination with PD-L1 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 3rd quarter 2019

VB10.NEO Neoantigen-based individualized cancer vaccine program:

- 28 patients have been enrolled in the neoantigen clinical phase I/IIa (DIRECT-01) 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.
- Post Quarter Event: In November Vaccibody presented a poster with its positive and promising, first preliminary safety, efficacy and immunogenicity results at the Society for Immunotherapy of Cancer (SITC) Annual Meeting 2019. VB10.NEO is the first neoantigen cancer vaccine to demonstrate induction of strong cancer-specific immune responses which leads to clinical responses in several patients with locally advanced or metastatic disease.
- The planning for starting the NKTR-214 VB10.NEO combination arm continues. VB expects to receive approval for the study from the German competent authorities in Q4 2019.
- Additional six new study sites have been selected and the first has been activated. Activation of the remaining sites is expected during Q4 bringing the total number of clinical sites to nine.

VB10.16 HPV16 vaccine program:

- Vaccibody has been invited to present a poster on the positive and strongly encouraging 12M data from the phase IIa clinical study in HPV16+ high grade cervical dysplasia (CIN2/3) at European Gynaecological Oncology Congress from November 2-5, 2019 in Athens, Greece.

- The pre-screening of sites for the VB C-02 Phase II study exploring VB10.16 in combination with Roche's checkpoint inhibitor atezolizumab (Tecentriq®) in up to 50 patients with advanced or recurrent cervical cancer has started and submissions to the Ethics committees and regulatory authorities have been done for five out of six countries.

Key figures	***3rd quarter***		***9 months***		***Full year***
Amounts in NOK 1,000	**2019**	**2018**	**2019**	**2018**	**2018**
Total revenue and other income	3 232	3 126	8 965	8 972	12 042
Total operating expenses	27 837	20 190	73 305	50 508	77 879
Operating profit (loss)	**-24 605**	**-17 064**	**-64 341**	**-41 536**	**-65 837**
Net profit (loss) for the period	**-22 896**	**-16 903**	**-61 741**	**-40 940**	**-63 793**
Net proceeds from equity issues	-	-	219 420	337	337
Net cash flow	-23 386	-12 915	154 087	-42 146	-62 525
Cash and cash equivalents, end of period	298 635	164 927	298 635	164 927	144 547
Outstanding shares, beginning of period (*)	54 229 880	48 479 880	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	27	17	27	17	19

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

VB10.NEO: Clinical Development and Nektar collaboration

The third quarter has had four key focus areas:

1) Enrollment. The patient enrollment process in the neoantigen clinical phase I/IIa trial started in April 2018. Vaccibody has enrolled 28 patients and patient treatment is on-going. Enrolment has been slower than expected in 2019, 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 new cohorts. Per end of Q3, we had four sites recruiting patients and will expand to a total of nine sites.

2) NKTR-214 arm in head & neck cancer. The discussions with the German regulators (PEI) regarding the protocol amendment and updated Investigators Brochure (IB) for the NKTR-214 arm has been a key focus point and patient enrolment is expected to start in Q4, 2019.

3) CMC. Progress has been made in the continuous efforts towards bringing down the turn-around time from biopsy to vaccination.

- SITC poster on VB10.NEO phase 1/2a (DIRECT-01) study. Vaccibody released its positive and promising, first preliminary safety, efficacy and immunogenicity results at the Society for Immunotherapy of Cancer (SITC) Annual Meeting 2019. VB10.NEO is the first neoantigen cancer vaccine to demonstrate induction of strong cancer-specific immune responses which leads to clinical responses in several patients with locally advanced or metastatic disease. Interim results from phase I/IIa clinical trial suggests a clear link between selection of high-quality neoepitopes, generation of strong neoepitope-specific CD8+ T cell responses and clinical responses.

VB10.16: Clinical Development

The core focus in the VB10.16 program in Q3, 2019 was on preparations for the VB C-02 trial in advanced cervical cancer. Submissions to the regulatory authorities have been made for five out of the six countries. The first responses from regulatory authorities is expected throughout Q4 2019.

The VB C-01 study - 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) – will have a poster on the positive 12M data at the European Gynaecological Oncology Congress from November 2-5, 2019 in Athens, Greece. The poster is available online on the Congress'webpage.

Financial review

Profit and loss statement

Other income in the first nine months of 2019 was KNOK 8,562 compared to KNOK 8,843 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 73,305 in the first nine months of 2019 from KNOK 50,508 in the same period of 2018. *Payroll and related expenses* increased to KNOK 19,824 compared to KNOK 13,780 in 2018 due to the planned increase in staff. *Procurement of R&D services and IP expenses* increased to KNOK 44,866 in the first nine months of 2019 compared to KNOK 26,911 in the same period of 2018, mainly relating to expenses on the Neo-antigen project where the first patient was enrolled in April 2018 and preparations for the phase II study of Vaccibody's VB10.16 in combination with Roche's atezolizumab

(Tecentriq®) in patients with advanced cervical cancer. *Other operating expenses* was slightly reduced to KNOK 8,524 in the first nine months of 2019 compared to KNOK 9,776 in the same period of 2018.

Statement of financial position
On September 30, 2019, Vaccibody had total assets of KNOK 309,883, hereunder *Cash and cash equivalents* of KNOK 298,635 and *Receivables* of KNOK 10,285. *Receivables* include mainly grants earned and to be received within a year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 297,752.

Outlook

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

- Clinical Trial for cancer neoantigen vaccine (VB10.NEO)
  - Continue 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. (Post Quarter Note: This was released in November.)

- 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 in collaboration with Roche
  - 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.

Profit and loss statement	3rd quarter		9 months		Full year
NOK 1,000	**2019**	**2018**	**2019**	**2018**	**2018**
Revenue	403	129	403	129	129
Other income	2 829	2 997	8 562	8 843	11 913
Payroll and related expenses	8 350	5 545	19 824	13 780	20 882
Procurement of R&D services and IP expenses	17 147	11 310	44 866	26 911	43 428
Depreciation	44	13	91	41	58
Other operating expenses	2 296	3 321	8 524	9 776	13 512
Total operating expenses	**27 837**	**20 190**	**73 305**	**50 508**	**77 879**
Operating profit (loss)	**-24 605**	**-17 064**	**-64 341**	**-41 536**	**-65 837**
Net financial items	**1 709**	**161**	**2 600**	**596**	**2 044**
Profit (loss) before income tax	**-22 896**	**-16 903**	**-61 741**	**-40 940**	**-63 793**
Income tax	-	-	-	-	-
Net profit (loss) for the period	**-22 896**	**-16 903**	**-61 741**	**-40 940**	**-63 793**

Statement of financial position								
NOK 1,000	**30.09.19**	**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	300
Property, plant and equipment	664	677	95	110	99	77	74	89
Total non-current assets	**963**	**977**	**395**	**410**	**399**	**377**	**373**	**389**
Receivables	10 285	9 735	9 046	8 381	10 251	9 244	8 611	7 004
Cash and cash equivalents	298 635	322 021	341 151	144 547	164 927	177 842	190 298	207 073
Total current assets	**308 920**	**331 756**	**350 197**	**152 928**	**175 177**	**187 086**	**198 909**	**214 077**
Total assets	**309 883**	**332 733**	**350 592**	**153 338**	**175 576**	**187 463**	**199 283**	**214 466**
Share capital	2 711	2 711	2 711	2 424	2 424	2 424	2 420	2 417
Share premium	506 907	506 907	506 907	287 775	287 775	287 775	287 580	287 445
Unregistered share issue	-	-	-	-	-	-	-	-
Retained earnings (accumulated losses)	-211 867	-188 971	-169 725	-150 126	-127 273	-110 370	-98 404	-86 333
Shareholders' equity	**297 752**	**320 647**	**339 893**	**140 072**	**162 926**	**179 829**	**191 595**	**203 529**
Accounts payable	5 697	5 867	3 610	5 521	8 472	2 926	2 666	6 084
Other current liabilities	6 434	6 219	7 088	7 745	4 179	4 709	5 021	4 853
Current liabilities	**12 131**	**12 086**	**10 698**	**13 266**	**12 651**	**7 634**	**7 687**	**10 937**
Total liabilities	**12 131**	**12 086**	**10 698**	**13 266**	**12 651**	**7 634**	**7 687**	**10 937**
Total Equity and Liabilities	**309 883**	**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			-61 741		-61 741
Share issue	288	219 133			219 420
Balance at 30.09.2019	**2 711**	**506 907**	**-211 867**	**-**	**297 752**

Statement of cash flow *NOK 1,000*	*9 months* **2019**	 **2018**	*Full year* **2018**
Loss for the period	**-61 741**	**-40 940**	**-63 793**
Adjustments for:			
Interest income	-2 425	-1 245	-1 518
Interest expenses	135	73	100
Depreciation	91	41	58
Change in trade receivables	242	-204	-430
Change in trade payables	176	2 387	-564
Change in receivables related to grants	-2 146	-3 043	-946
Change in other current liabilities	-1 311	-674	2 892
Net cash flow from operating activities	**-66 979**	**-43 603**	**-64 200**
Purchase of property, plant and equipment	-644	-51	-79
Interest income	2 425	1 245	1 518
Net cash flow from investing activities	**1 781**	**1 193**	**1 438**
Interest expenses	-135	-73	-100
Proceeds from equity issues	219 420	337	337
Net cash flow from financing activities	**219 285**	**264**	**236**
Net change in cash and cash equivalents	**154 087**	**-42 146**	**-62 525**
Cash and cash equivalents at begining of period	144 547	207 073	207 073
Cash and cash equivalents at end of period	**298 635**	**164 927**	**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 4.8 in the first nine 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 3.8 in the first nine months of 2019.

Note 3 Share capital and shareholders

Table of shareholders as of September 30, 2019:

Shareholder	**Shares**	**Ownership**
Sarsia Seed AS	4 874 800	8,99 %
Radiumhospitalets Forskningsstiftelse	4 811 400	8,87 %
Datum Invest AS	3 982 600	7,34 %
Arctic Funds PLC	2 529 140	4,66 %
Tanja A/S	2 290 000	4,22 %
Portia AS	2 125 000	3,92 %
Norron Sicav - Target	1 810 000	3,34 %
Verdipapirfondet DNB Norge	1 591 790	2,94 %
OM Holding AS	1 552 000	2,86 %
Norda ASA	1 502 956	2,77 %
Others	*27 160 194*	*50,08 %*
Total	**54 229 880**	100,00 %

At September 30th, 2019, the Company had 3,432,670 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.