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 as well as 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 2nd quarter 2018 (April-June)

- VB10.NEO Neoantigen-based individualized cancer vaccine program:
  - First patient enrolled in the neoantigen clinical phase I/IIa trial. This trial is now enrolling patients with locally advanced or metastatic melanoma, non-small cell lung carcinoma, clear renal cell carcinoma and, urothelial or squamous cell carcinoma off head and neck.
  - Approval by the German regulatory authority Paul Ehrlich Institute of an amendment to the clinical trial application (CTA) allowing for CT-guided biopsies enabling more precise assessment of deep tumors.
  - Submission to the German regulatory authority Paul Ehrlich Institute of an amendment seeking to allow the use of a 2nd Contract Manufacturing Organization to produce the VB10.NEO vaccines in order to expand production capacity (**Post Quarter Event:** Amendment approved August 13).

- Clinical Trial VB C-01:
  - Immunogenicity data for phase IIa, showed a vaccine-induced increased immune response in 16 out of 17 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.
  - Continued treatment of patients with CIN2/3 in the expansion phase (Phase IIa). On track to report 6 months data in Q3, 2018.

Key figures	2nd quarter		6 months		Full year
Amounts in NOK 1,000	**2018**	**2017**	**2018**	**2017**	**2017**
Total revenue and other income	2 883	2 494	5 846	4 502	9 763
Total operating expenses	15 055	9 635	30 318	16 138	43 731
Operating profit (loss)	**-12 172**	**-7 141**	**-24 472**	**-11 637**	**-33 968**
Net profit (loss) for the period	**-11 902**	**-6 310**	**-24 037**	**-10 690**	**-31 371**
Net proceeds from equity issues	337	209 548	337	209 548	209 548
Net cash flow	-12 394	-5 616	-29 231	197 506	182 070
Cash and cash equivalents, end of period	177 842	222 509	177 842	222 509	207 073
Outstanding shares, beginning of period (*)	48 396 480	2 409 649	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	15	12	15	12	15

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

VB10.NEO Preclinical and Clinical Development

Preclinical experiments to further substantiate that the Vaccibody vaccine platform technology can be used to generate dominating CD8+ killer T cells responses have been carried out. Importantly, the ability to delay tumor growth and eliminate tumors in mice have been shown to be fully dependent on the Vaccibody-induced neoantigen-specific CD8+ killer T cell response. Knowledge gained from such preclinical experiments continue to support the platform and provide an important foundation for the optimization of the selection of neoepitopes in the clinical trial.

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 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 and urothelial or squamous cell carcinoma off head and neck.

In order to enable a more precise access to and assessment of deep tumors, an amendment was submitted to the German regulatory authority Paul Ehrlich Institute seeking the use of CT-guided biopsies. The approval was obtained in Q2. Furthermore, an amendment seeking approval to use a 2nd Contract Manufacturing Organization (CMO) in order to expand the production capacity of the VB10.NEO vaccines was submitted (**Post Quarter Event:** Amendment approved on August 13).

The collaboration with the three highly renowned clinical oncology sites (Heidelberg, Munich and Frankfurt) is now fully up to speed: Site Initiation Visits have taken place at all sites and enrolment of patients are on-going at all sites.

Manufacturing of the individual patient's personalized VB10.NEO vaccine is ongoing with a tight quality control system and dedicated tracking system in place.

VB10.16 Clinical Development

Immunogenicity data for the first 17 patients in phase IIa, showed a vaccine-induced increased immune response in 16 out of 17 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.

Treatment of patients with CIN2/3 in the expansion phase (phase IIa) was continued in Q2. The clinical study is on track to report 6 months data in Q3, 2018.

Financial review

Profit and loss statement
Other income in the first six months of 2018 was KNOK 5,856 compared to KNOK 4,015 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. The Company had no *revenue* in the first six months of 2018, compared to KNOK 486 in the same period of 2017 which related to an R&D collaboration of limited scope.

Total operating expenses increased to KNOK 30,318 in the first six months of 2018 from KNOK 16,138 in the same period of 2017. *Payroll and related expenses* increased to KNOK 8,235 compared to KNOK 5,033 in 2017 due to the planned increase in staff. *Procurement of R&D services and IP expenses* increased to KNOK 15,273 in the first six months of 2018 compared to KNOK 7,146 in the same period of 2017. Expenses on the Neo-antigen project increased as planned, including preparations for the clinical trial and the associated manufacturing, 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 6,783 in the first six months of 2018 compared to KNOK 3,920 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 June 30, 2018, Vaccibody had total assets of KNOK 187,463, hereunder *Cash and cash equivalents* of KNOK 177,842 and *Receivables* of KNOK 9,244. *Receivables* include mainly grants earned and to be received within a year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 179,829.

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	*2nd quarter*		*6 months*		*Full year*
NOK 1,000	**2018**	**2017**	**2018**	**2017**	**2017**
Revenue	-	486	-	486	486
Other income	2 883	2 008	5 846	4 015	9 277
Payroll and related expenses	3 827	2 511	8 235	5 033	14 372
Procurement of R&D services and IP expenses	7 528	4 913	15 273	7 146	21 180
Depreciation	12	21	28	39	82
Other operating expenses	3 689	2 190	6 783	3 920	8 097
Total operating expenses	**15 055**	**9 635**	**30 318**	**16 138**	**43 731**
Operating profit (loss)	**-12 172**	**-7 141**	**-24 472**	**-11 637**	**-33 968**
Net financial items	**270**	**832**	**435**	**946**	**2 597**
Profit (loss) before income tax	**-11 902**	**-6 310**	**-24 037**	**-10 690**	**-31 371**
Income tax	-	-	-	-	-
Net profit (loss) for the period	**-11 902**	**-6 310**	**-24 037**	**-10 690**	**-31 371**

Statement of financial position							
NOK 1,000	**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
Property, plant and equipment	77	74	89	109	105	79	97
Total non-current assets	**377**	**373**	**389**	**408**	**405**	**379**	**397**
Receivables	9 244	8 611	7 004	7 593	6 912	6 153	226 608
Cash and cash equivalents	177 842	190 235	207 073	213 813	222 509	228 125	25 002
Total current assets	**187 086**	**198 846**	**214 077**	**221 406**	**229 421**	**234 278**	**251 611**
Total assets	**187 463**	**199 219**	**214 466**	**221 815**	**229 826**	**234 657**	**252 008**
Share capital	2 424	2 420	2 417	2 417	2 417	2 410	1 530
Share premium	287 775	287 580	287 445	287 445	287 445	286 954	78 784
Unregistered share issue	-	-	-	-	-	498	209 050
Retained earnings (accumulated losses)	-110 370	-98 467	-86 333	-74 352	-65 653	-59 343	-54 962
Shareholders' equity	**179 829**	**191 532**	**203 529**	**215 509**	**224 209**	**230 519**	**234 402**
Accounts payable	2 926	2 666	6 084	3 155	2 811	1 466	3 411
Other current liabilities	4 709	5 021	4 853	3 150,557	2 806	2 672	14 195
Current liabilities	**7 634**	**7 687**	**10 937**	**6 305**	**5 617**	**4 138**	**17 606**
Total liabilities	**7 634**	**7 687**	**10 937**	**6 305**	**5 617**	**4 138**	**17 606**
Total Equity and Liabilities	**187 463**	**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 01.01.2018	**2 417**	**287 445**	**-86 333**	**-**	**203 529**
Loss for the period			-24 037		-24 037
Warrants exercised	7	330			337
Balance at 30.06.2018	**2 424**	**287 775**	**-110 370**	**-**	**179 829**

Statement of cash flow *NOK 1,000*	*6 months* **2018**	 **2017**	*Full year* **2017**
Loss for the period	**-24 037**	**-10 690**	**-31 371**
Adjustments for:			
Interest income	-888	-637	-1 584
Interest expenses	53	1	14
Depreciation	28	39	82
Change in trade receivables	73	212	-75
Change in trade payables	-3 159	-600	2 674
Change in receivables related to grants	-2 313	-516	-321
Change in other current liabilities	-144	-439	1 608
Net cash flow from operating activities	**-30 387**	**-12 630**	**-28 973**
Purchase of property, plant and equipment	-16	-47	-74
Interest income	888	637	1 584
Net cash flow from investing activities	**872**	**590**	**1 509**
Interest expenses	-53	-1	-14
Proceeds from equity issues	337	209 548	209 548
Net cash flow from financing activities	**284**	**209 546**	**209 534**
Net change in cash and cash equivalents	**-29 231**	**197 506**	**182 070**
Cash and cash equivalents at begining of period	207 073	25 002	25 002
Cash and cash equivalents at end of period	**177 842**	**222 509**	**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 3.2 in the first six 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 grant in 2015, 2016 and 2017 respectively, and MNOK 2.5 in the first six months of 2018.

Note 3 Share capital and shareholders

Table of shareholders as of June 30, 2018:

Shareholder	Shares	Ownership
SARSIA SEED AS	6 074 800	12,5 %
RADIUMHOSPITALETS FORSKNINGSST.	4 811 400	9,9 %
DATUM INVEST AS	4 152 600	8,6 %
ARCTIC FUNDS PLC	3 929 140	8,1 %
NORDA ASA	3 235 600	6,7 %
PORTIA AS	2 110 000	4,4 %
KREFTFORENINGEN	1 945 600	4,0 %
Norron Sicav - Target	1 930 000	4,0 %
OM Holding AS	1 477 000	3,0 %
INVEN2 AS	1 340 400	2,8 %
OTHERS	*17 473 340*	*36,0 %*
Total	**48 479 880**	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 4,128,369 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.