

Report 1st quarter 2020

Highlights:

- Vaccibody AS is registered on the NOTC-list as of January 27, 2020

Highlights after March 31st, 2020:

- Vaccibody AS announces the expansion of its strategic focus to include Infectious Diseases
- Vaccibody AS announces the appointment of Gunnstein Norheim, Ph.D., as its new Director Infectious Diseases leading this new initiative

Michael Engsig, Chief Executive Officer at Vaccibody, comments:

“The First quarter 2020 was important for Vaccibody, with the expansion of our strategic focus into infectious diseases. Further, our attention has been on operational execution, safety and mitigation in the light of Covid-19.”

Key financial figures

Key figures	1st quarter		Full year
	2020	2019	2019
<i>Amounts in NOK 1,000</i>			
Total revenue and other income	1 287	2 904	12 446
Total operating expenses	43 462	22 932	111 338
Operating profit (loss)	-42 174	-20 028	-98 892
Net profit (loss) for the period	-31 421	-19 902	-95 956
Net proceeds from equity issues	8 016	219 420	224 322
Net cash flow	-25 062	196 604	135 077
Cash and cash equivalents, end of period	254 562	341 151	279 625
Outstanding shares, end of period	56 351 680	54 229 880	54 973 080
Cash and cash equivalents/total assets	96 %	97 %	96 %
Equity ratio	92 %	97 %	92 %
Equity	245 034	339 590	268 439
Total assets	266 434	350 591	292 254
Employees, average	26	21	23
Employees, end of period	26	21	24



R&D update

VB10.NEO

VB10.NEO is a personalized neoantigen cancer vaccine:

- Clinical status: Phase I/IIa
- Indications: Melanoma, lung, head & neck, renal, bladder

Status and highlights

Despite the Covid-19 situation the active sites have continued to screen and enroll patients. As per 31 March, 38 patients have been enrolled in the study. Patients have been enrolled across all respective indications.

The effort to increase the number of enrolling sites has been successful and Vaccibody reached seven sites as per first quarter 2020. Two additional sites are expected to open in 2Q/3Q.

Vaccibody received approval from the German authorities (PEI) to incorporate circulating tumor DNA analysis for its neoepitope selection, which is a novel tool to assess tumor specific mutations from a blood sample providing a representative view of the total prevalence of each mutation in all lesions.

The best in class 100% manufacturing success has been preserved and Vaccibody continues to focus on developing a robust and fast turnaround time for its fully personalized vaccines.

Vaccibody's internal GCLP immune monitoring lab went live during the first quarter which is an important step in controlling critical process steps.

VB10.16: VB C-02

The clinical trial is based on VB10.16 + atezolizumab in advanced cervical cancer:

- Clinical status: Phase II
- Indications: HPV16+ advanced, non-resectable cervical cancer

Status and highlights

The study has received Ethics approval and approval from the Competent Authorities from the majority of the countries. 24 sites have been selected for participation, and despite the Covid-19, the trial is expected to open up for select site activations and enrolment within the next months.



CMC efforts are developing according to the planned timelines.

Financial review

Income statement

The net result for 1Q20 was a net loss of NOK 31.4 million compared to a NOK 19.9 million loss in 1Q19. The increased loss was caused mainly by an increase in clinical development activities relating primarily to the inclusion and treatment of patients in VB N-01, a larger number of sites for accelerated patient recruitment, and expenses for preparations for the VB C-02 program.

Operating income

Total operating income amounted to NOK 1.3 million in 1Q20 (NOK 2.9 million in 1Q19) and consisted primarily of accrued grants from SkatteFUNN, a Norwegian government R&D tax incentive program.

Operating expenses

Total operating expenses amounted to NOK 43.5 million in 1Q20 compared to NOK 22.9 million in 1Q19. Employee expenses increased to NOK 8.1 million (1Q19: NOK 6.3 million). The increase was primarily caused by the planned increase in headcount. Other operating expenses amounted to NOK 35.4 million in 1Q20 (1Q19: NOK 16.6 million), primarily due to a ramp-up of the ongoing VB N-01 program as well as expenses for preparations for the VB C-02 clinical development program.

Net financial income and expenses

Net financial income and expenses increased to NOK 10.8 million in 1Q20 compared to NOK 0.1 million in 1Q19. The increase related primarily to currency gains on the Company's cash held in EUR.

Statement of financial position

Cash

At March 31, 2020, Vaccibody had a cash position of NOK 254.6 million compared to NOK 341.1 million at March 31, 2019. The change reflects mainly the net results of the Company and cash received from the exercise of warrants.

Equity

At March 31, 2020, total equity amounted to NOK 245.0 million compared to NOK 339.6 million at March 31, 2019. The change reflects the net result and the exercise of warrants.



Outlook

An overview of Vaccibody's objectives for the remainder of 2020 is provided in the table below. The primary clinical objectives are to complete the enrolment of patients into the Company's VB N-01 clinical trial including the basket arm 5B which investigates VB10.NEO in combination with Nektar Therapeutic's bempegaldesleukin (NKTR-214), and to initiate enrolment in the VB C-02 trial investigating VB10.16 in combination with atezolizumab in patients with advanced or recurrent cervical cancer. Further, Vaccibody will lay out its strategy for the Infectious Disease area during the course of 2020. Last, the Company is in continuous dialogue with academic and industrial entities and will announce new key collaborations and partnerships when they may occur.

Program	Clinical trial	Activity	Comments
VB10.NEO	VB N-01	Updated immune response data	Follow-up and expansion from the first data release in June 2019.
VB10.NEO	VB N-01	Dosing of first patient in NKTR-214 combo	Collaboration with Nektar Therapeutics combining VB10.NEO with bempegaldesleukin (NKTR-214 or bempeg), a CD122-preferential IL-2 pathway agonist in advanced head & neck cancer patients.
VB10.NEO	VB N-01	Updated clinical data	Follow-up and expansion from the first data release in November 2019.
VB10.NEO	VB N-01	Finalization of patient enrolment	The VB N-01 clinical trial is a basket trial with six different arms, including the NKTR-214 combination arm. It is estimated that 50 patients will be enrolled.
VB10.16	VB C-02	First patient dosed	Clinical trial testing VB10.16 in up to 50 patients with advanced cervical cancer.
VB10.16	VB C-02	Safety data for first patients	First safety data from the trial.



Results and financial position - 1Q20

Profit and loss statement <i>NOK 1,000</i>	<i>1st quarter</i>		<i>Full year</i>
	2020	2019	2019
Revenue	1	-	489
Other income	1 286	2 904	11 957
Employee expenses	8 053	6 341	29 355
Depreciation	51	15	136
Other operating expenses	35 358	16 576	81 847
Total operating expenses	43 462	22 932	111 338
Operating profit (loss)	-42 174	-20 028	-98 892
Net financial income and expenses	10 754	126	2 936
Profit (loss) before income tax	-31 421	-19 902	-95 956
Income tax	-	-	-
Net profit (loss) for the period	-31 421	-19 902	-95 956

Statement of financial position <i>NOK 1,000</i>	31.03.20	31.12.19	30.09.19	30.06.19	31.03.19	31.12.18
Intangible assets	300	300	300	300	300	300
Plant, machinery, fixtures etc	697	641	664	677	95	110
Other long term receivables	36	36	36	36	36	36
Total fixed assets	1 033	976	999	1 013	430	446
Receivables	10 839	11 653	10 250	9 700	9 009	8 345
Cash and cash equivalents	254 562	279 625	298 635	322 021	341 151	144 547
Total current assets	265 402	291 277	308 884	331 721	350 160	152 893
Total assets	266 434	292 254	309 883	332 733	350 591	153 338
Share capital	2 818	2 749	2 711	2 711	2 711	2 424
Share premium reserve	517 661	511 731	506 907	506 907	506 907	287 775
Other paid in equity	-	-	-	-	-	-
Unregistered share issue	2 058	41	-	-	-	-
Uncovered loss	-277 503	-246 082	-212 170	-189 274	-170 028	-150 126
Total equity	245 034	268 439	297 449	320 344	339 590	140 072
Accounts payable	18 734	13 362	5 697	5 867	3 609	5 521
Other current liabilities	2 666	10 453	6 738	6 522	7 391	7 745
Total current liabilities	21 400	23 815	12 435	12 389	11 000	13 266
Total liabilities	21 400	23 815	12 435	12 389	11 000	13 266
Total equity and liabilities	266 434	292 254	309 883	332 733	350 591	153 338

Key figures by quarter

Key figures	2020	2019			
	1Q20	4Q19	3Q19	2Q19	1Q19
<i>Amounts in NOK 1,000</i>					
Total revenue and other income	1 287	3 481	3 232	2 829	2 904
Total operating expenses	43 462	37 729	27 837	22 840	22 932
Operating profit (loss)	-42 174	-34 248	-24 605	-20 011	-20 028
Net profit (loss) for the period	-31 421	-33 912	-22 896	-19 246	-19 902
Net proceeds from equity issues	8 016	4 902	-	-	219 420
Net cash flow	-25 062	-19 011	-23 386	-19 130	196 604
Cash and cash equivalents, end of period	254 562	279 625	298 635	322 021	341 151
Outstanding shares, end of period	56 351 680	54 973 080	54 229 880	54 229 880	54 229 880
Cash and cash equivalents/total assets	96 %	96 %	96 %	97 %	97 %
Equity ratio	92 %	92 %	96 %	96 %	97 %
Equity	245 034	268 439	297 449	320 344	339 590
Total assets	266 434	292 254	309 883	332 733	350 591
Employees, average	26	25	24	22	21
Employees, end of period	26	24	26	23	21

Key financial figures (five years)

Key figures	2019	2018	2017	2016	2015
	<i>Amounts in NOK 1,000</i>				
Total revenue and other income	12 446	12 042	9 763	8 999	5 623
Total operating expenses	111 338	77 879	43 731	25 407	18 931
Operating profit (loss)	-98 892	-65 837	-33 968	-16 408	-13 308
Net profit (loss) for the period	-95 956	-63 793	-31 371	-16 220	-13 091
Net proceeds from equity issues (2)	224 322	337	209 548	23 945	556
Net cash flow (2)	135 077	-62 525	182 070	7 914	-12 289
Cash and cash equivalents, end of period (2)	279 625	144 547	207 073	25 002	17 088
Outstanding shares, end of period (1, 2)	54 973 080	48 479 880	2 417 064	1 529 649	1 215 349
Cash and cash equivalents/total assets (2)	96 %	94 %	97 %	10 %	92 %
Equity ratio	92 %	91 %	95 %	94 %	95 %
Equity	268 439	140 072	203 529	234 402	17 627
Total assets	292 254	153 338	214 466	248 128	18 625
Employees, average	23	16	12	7	4
Employees, end of period	24	19	15	8	5

Overview of shareholders as per March 31, 2020

Share capital and shareholders

Table of shareholders as of March 31, 2020:

Shareholder	Shares	Stake
DATUM OPPORTUNITY AS	5 000 000	8,87 %
RASMUSSENGRUPPEN AS	4 825 000	8,56 %
RadForsk	4 811 400	8,54 %
AS TANJA	2 290 000	4,06 %
NORDA ASA	1 746 956	3,10 %
SKØIEN AS	1 695 660	3,01 %
OM Holding AS	1 635 300	2,90 %
VERDIPAPIRFONDET NORGE SELEKTIV	1 606 408	2,85 %
VATNE EQUITY AS	1 562 500	2,77 %
DATUM AS	1 484 500	2,63 %
Others	29 693 952	52,69 %
Total	56 351 676	100,00 %

At March 31, 2020, the Company had 3,191,646 active warrants outstanding to key employees and members of the board. 206,660 of these warrants are exercised and were effectively registered as converted to shares as of April 1, 2020.

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.



Contact

CEO Michael Engsig
Vaccibody AS
Cell: +45 6173 1509
E: mengsig@vaccibody.com

About Vaccibody

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. Further, the Company has initiated research on infectious diseases.

Vaccibody is developing cutting-edge, targeted DNA vaccines for clinical use, based on a deep understanding of immunological principles. Vaccibody's vaccines specifically target Antigen Presenting Cells (APC), which are essential for inducing rapid, strong and specific immune responses and elicit efficacious clinical responses. By intelligent design, Vaccibody's vaccines can be tailored to induce the desired immune response profile correlating with protection for each specific disease with any given antigen. Hence, the Vaccibody vaccine platform has the potential to address many disease areas with a high unmet medical need such as cancer and infectious diseases. In addition, Vaccibody has collaborations with Roche and Nektar Therapeutics.

Vaccibody's lead product candidates are VB10.NEO, a personalized therapeutic cancer neoantigen vaccine currently being evaluated in a Phase I/IIa clinical trial, and VB10.16, a therapeutic cancer vaccine against HPV16-related cancers that is currently being tested in a Phase II clinical trial.

Vaccibody's shares are traded on NOTC, a marketplace for unlisted shares managed by NOTC AS, which is owned 100% by Oslo Børs ASA, the Oslo Stock Exchange.

Further information about the Company may be found at <http://www.vaccibody.com>

* * * * *