



# vaccibody -

**3rd Quarter 2020 Report** 





# Report 3<sup>rd</sup> quarter 2020

# **Highlights:**

- Dosing of the first patient in VB C-02 Phase II clinical trial with VB10.16 in combination with Roche's immune-checkpoint inhibitor atezolizumab in advanced cervical cancer
- Vaccibody and Nektar Therapeutics dose first patient in Phase I/IIa trial arm evaluating VB10.NEO in combination with bempegaldesleukin (NKTR-214) and immune-checkpoint inhibitor in patients with head and neck cancer
- Finalization of patient enrolment in VB N-01 Phase I/IIa clinical trial with VB10.NEO neoantigen cancer vaccine in locally advanced or metastatic cancer patients

#### Highlights after September 30th, 2020:

- On October 1, Vaccibody announced that they have entered into an agreement with Genentech, a member of the Roche Group, for the development and commercialization of DNA-based individualized neoantigen cancer vaccines, including VB10.NEO. Under the terms of the agreement, Vaccibody receives USD 200 million in initial upfront and nearterm payments, and is eligible to receive up to a further USD 515 million in potential payments and milestones, and low double-digit tiered royalties on sales of commercialized products arising from the partnership
- On November 6, Vaccibody announced closing of the worldwide license and collaboration agreement with Genentech. All antitrust contingencies required to close the agreement with Genentech, regarding the development of individualized neoantigen cancer vaccines, have been satisfied and the agreement is now effective





- Vaccibody announces expanded R&D focus and strategy: Accelerated development of
  existing pipeline product candidates, discovery of novel approaches based on the
  Company's own technology; Expansion of technology platform to additional therapeutic
  areas and therapeutic modalities outside of current cancer and infectious disease focus;
  and Pursuit of further strategic partnerships to maximize the value of its technology
  platform
- Vaccibody listed on Oslo Stock Exchange's trading platform, Merkur Market, and was admitted trading from October 7. (The ticker code is VACC-ME)

### Michael Engsig, Chief Executive Officer at Vaccibody, comments:

"This has been a transformative quarter for Vaccibody. With the collaboration agreement with Genentech announced on October 1st, we have teamed up with our partner of choice for VB10.NEO and a pioneer in individualized neoantigen cancer vaccines. It is a tremendous third-party validation of the Vaccibody vaccine platform and we are very proud and excited. The agreement enables us to further leverage our unique technology platform by accelerating and expanding our pipeline, primarily with vaccine product candidates for cancer and infectious diseases; exploiting our vaccine technology and core expertise in new areas outside cancer and infectious diseases; and to form new partnerships and collaborations to complement our strengths."

## **Key financial figures**

Key figures	3rd quarter		9 mon	Full year	
Amounts in NOK 1,000	2020	2019	2020	2019	2019
Total revenue and other income	1,298	3,232	3,880	8,965	12,446
Total operating expenses	46,143	27,837	141,279	73,609	111,338
Operating profit (loss)	-44,845	-24,605	-137,399	-64,644	-98,892
Net profit (loss) for the period	-44,180	-22,896	-127,893	-62,044	-95,956
Net proceeds from equity issues	2,728	-	10,744	219,420	224,322
Net cash flow	-40,859	-23,386	-117,746	154,087	135,077
Cash and cash equivalents, end of period	161,878	298,635	161,878	298,635	279,625
Outstanding shares, end of period (*)	283,627,680	54,229,880	283,627,680	54,229,880	54,973,080
Cash and cash equivalents/total assets	93 %	96 %	93 %	96 %	96 %
Equity ratio	87 %	96 %	87 %	96 %	92 %
Equity	151,289	297,449	151,289	297,449	268,439
Total assets	173,756	309,883	173,756	309,883	292,254
Employees, average	33	24	35	24	23
Employees, end of period	36	26	36	26	24

<sup>(\*)</sup> The share was split 1:5 in July 2020





# Strategy update and Expanded R&D focus

The collaboration agreement with Genentech marks the beginning of an exciting new journey for Vaccibody. The potential for the Vaccibody technology to prevent and treat a wide range of diseases across multiple therapeutic areas stems from the platform's versatility in tailoring the immune response. The three underlying strategic pillars are:

- Accelerate and expand the pipeline: Vaccibody will focus on advancing and expanding its pipeline of product candidates in the areas of oncology (e.g. shared antigen cancer vaccines) and vaccines against infectious diseases
- Further leverage the technology platform: Vaccibody has developed a robust and
  flexible technology validated by multiple partners. The Company will use its molecular
  biology and technology know how to explore new therapeutic areas and different
  therapeutic modalities. Patents are being filed around these discoveries and more
  details will be made available after these applications have published
- Seek strategic partnerships to complement our strengths: Vaccibody has a dedicated strategy to form partnerships when this supports the value-creation. The partnerships may take three forms: Early strategic partnerships with the aim to more rapidly leverage and expand the use of Vaccibody's platform; Product partnering of Vaccibody's pipeline products; and Access complimentary technologies

For further information, please refer to the Vaccibody webcast from October 1<sup>st</sup> which is available on the Company's website.

## **R&D** update

#### VB10.NEO

VB10.NEO is an individualized neoantigen cancer vaccine:

- Clinical program VB N-01:
  - Clinical stage: Phase I/IIa
  - Cancer indications: Melanoma, non-small cell lung cancer (NSCLC), clear renal cell carcinoma, urothelial cancer or squamous cell carcinoma of the head and neck (SCCHN)

## Status and highlights

As announced on October 1, 2020, Vaccibody and Genentech entered into an agreement for the development and commercialization of DNA-based individualized neoantigen vaccines. Through this partnership, Vaccibody and Genentech will progress Vaccibody's investigational product candidate, VB10.NEO, into clinical trials in the U.S. and in Europe. Following





completion of a planned Phase 1b trial, Genentech will be responsible for and bear all costs for clinical, regulatory, manufacturing and commercialization activities.

Going forward, Vaccibody will be reporting on its receipt of financial milestones whereas other VB10.NEO communication will be at the discretion of Genentech.

#### **VB10.16**

VB10.16 is a therapeutic HPV vaccine directed against HPV16+ induced pre-malignancies and malignancies:

- Clinical program VB C-02:
  - Clinical stage: Phase II
  - o Indication: HPV16+ advanced, non-resectable cervical cancer

#### Status and highlights

Enrolment continues and more patients have been dosed. However, the second wave of the COVID-19 pandemic has introduced a new level of uncertainty and we are monitoring the situation closely to mitigate the impact on patient enrolment. The VB10.16 - safety data for the first patients is expected to be reported in 1H 2021 (compared to the earlier expectation by year-end 2020).

#### **Infectious Diseases**

Vaccibody's infectious disease initiative continues to generate supportive pre-clinical data. The strategy process is on track for the Company's presentation of its infectious disease strategy later in 2020.





#### **Financial review**

(Figures in brackets = same period 2019 unless stated otherwise)

#### *Income statement*

The net result for YTD 2020 was a net loss of NOK 127.9 million compared to a NOK 62.0 million net loss YTD 2019. The increased loss was caused mainly by a continued increase in clinical development activities relating primarily to the inclusion and treatment of patients in the VB N-01 trial (with VB10.NEO), a larger number of sites for accelerated patient recruitment, and expenses for the conduct of the VB C-02 trial (with VB10.16).

### Operating income

Total operating income amounted to NOK 3.9 million YTD 2020 (NOK 9.0 million) and consisted primarily of accrued grants from SkatteFUNN, a Norwegian government R&D tax incentive program.

#### Operating expenses

Total operating expenses amounted to NOK 141.2 million YTD 2020 compared to NOK 73.6 million YTD 2019. Employee expenses increased to NOK 28.1 million (NOK 19.8 million). The increase was primarily caused by the planned increase in employees. Other operating expenses amounted to NOK 112.9 million YTD 2020 (NOK 53.7 million), primarily due to the conduct of the ongoing VB N-01 trial (with VB10.NEO) as well as expenses for the conduct of the VB C-02 trial (with VB10.16).

#### Net financial income and expenses

Net financial income and expenses increased to NOK 9.5 million YTD 2020 compared to NOK 2.6 million YTD 2019. The increase related primarily to currency gains on the Company's cash held in EUR.

#### Statement of financial position

#### Cash

At September 30, 2020, Vaccibody had a cash position of NOK 161.9 million compared to NOK 298.6 million at September 30, 2019.

#### Equity

At September 30, 2020, total equity amounted to NOK 151.3 million compared to NOK 297.4 million at September 30, 2019.





#### Outlook

Three major clinical objectives for 2020 have been reached in third quarter, namely:

- 2 July: Dose the first patient in the C-02 trial of VB10.16 in combination with atezolizumab in advanced cervical cancer patients
- 12 August: Dose the first patient in the VB N-01 study arm with VB10.NEO in combination with Nektar Therapeutics' bempegaldesleukin (NKTR-214)
- 21 August: Complete the enrolment of patients into the Company's VB N-01 clinical trial

Expected 2020/2021 outlook and news flow regarding Vaccibody's clinical trial R&D pipeline:

2H 2020	Infectious disease – Strategy update			
	Further news flow may arise from the infectious disease strategy			
1H 2021	VB10.16 - Safety data for first patients			
1H 2021	VB10.NEO - Initiation of VB N-02, Phase 1b trial			
2H 2021	VB10.16 – Fully enrolled VB C-02 trial in cervical cancer			
2H 2021	VB10.16 – Interim clinical data for first patients from VB C-02 trial in			
	cervical cancer			

Going forward, the Company will have a strong cash position and no debt following the USD 200 million upfront and near-term payments from Genentech.

The Company is in continuous dialogue with academic and industrial entities and will announce new key collaborations and partnerships if or when they may occur.

The COVID-19 pandemic may impact timelines and operations.





# Results and financial position - 3Q20

The interim report is unaudited.

Profit and loss statement	3rd qu	ıarter	9 mon	ths	Full year
NOK 1,000	2020	2019	2020	2019	2019
Revenue	-	403	1	403	489
Other income	1,298	2,829	3,879	8,562	11,957
Employee expenses	8,184	8,350	28,154	19,824	29,355
Depreciation	68	44	182	91	136
Other operating expenses	37,891	19,443	112,943	53,694	81,847
Total operating expenses	46,143	27,837	141,279	73,609	111,338
Operating profit (loss)	-44,845	-24,605	-137,399	-64,644	-98,892
Net financial income and expenses	664	1,709	9,505	2,600	2,936
Profit (loss) before income tax	-44,180	-22,896	-127,893	-62,044	-95,956
Income tax	-	-	-	-	-
Net profit (loss) for the period	-44,180	-22,896	-127,893	-62,044	-95,956

Statement of financial po	Statement of financial position							
NOK 1,000	30/09/20	30/06/20	31/03/20	31/12/19	30/09/19	30/06/19	31/03/19	31/12/1
Intangible assets	300	300	300	300	300	300	300	300
Plant, machinery, fixtures etc	1,039	803	697	641	664	677	95	110
Other long term receivables	84	36	36	36	36	36	36	36
Total fixed assets	1,423	1,138	1,033	976	999	1,013	430	446
Receivables	10,454	11,514	10,839	11,653	10,250	9,700	9,009	8,345
Cash and cash equivalents	161,878	202,738	254,562	279,625	298,635	322,021	341,151	144,547
Total current assets	172,332	214,251	265,402	291,277	308,884	331,721	350,160	152,893
Total assets	173,756	215,389	266,434	292,254	309,883	332,733	350,591	153,338
Share capital	2,836	2,828	2,818	2,749	2,711	2,711	2,711	2,424
Share premium reserve	521,678	519,709	517,661	511,731	506,907	506,907	506,907	287,775
Unregistered share issue	750	, -	2,058	41	-	-	-	-
Uncovered loss	-373,976	-329,795	-277,503	-246,082	-212,170	-189,274	-170,028	-150,126
Total equity	151,289	192,742	245,034	268,439	297,449	320,344	339,590	140,072
Accounts payable	18,627	10,057	18,734	13,362	5,697	5,867	3,609	5,521
Other current liabilities	3,839	12,591	2,666	10,453	6,738	6,522	7,391	7,745
Total current liabilities	22,466	22,648	21,400	23,815	12,435	12,389	11,000	13,266
Total liabilities	22,466	22,648	21,400	23,815	12,435	12,389	11,000	13,266
Total equity and liabilities	173,756	215,389	266,434	292,254	309,883	332,733	350,591	153,338





# **Key figures by quarter**

Key figures	2020				20:	19	
Amounts in NOK 1,000	3Q20	2Q20	1Q20	4Q19	3Q19	2Q19	1Q19
Total revenue and other income	1,298	1,295	1,287	3,481	3,232	2,829	2,904
Total operating expenses	46,143	51,675	43,462	37,729	27,837	22,840	22,932
Operating profit (loss)	-44,845	-50,380	-42,174	-34,248	-24,605	-20,011	-20,028
Net profit (loss) for the period	-44,180	-52,292	-31,421	-33,912	-22,896	-19,246	-19,902
Net proceeds from equity issues	2,728	0	8,016	4,902	-	-	219,420
Net cash flow	-40,859	-51,825	-25,062	-19,011	-23,386	-19,130	196,604
Cash and cash equivalents, end of period	161,878	202,738	254,562	279,625	298,635	322,021	341,151
Outstanding shares, end of period (*)	283,627,680	56,558,340	56,351,680	54,973,080	54,229,880	54,229,880	54,229,880
Cash and cash equivalents/total assets	93 %	94 %	96 %	96 %	96 %	97 %	97 %
Equity ratio	87 %	89 %	92 %	92 %	96 %	96 %	97 %
Equity	151,289	192,742	245,034	268,439	297,449	320,344	339,590
Total assets	173,756	215,389	266,434	292,254	309,883	332,733	350,591
Employees, average	33	30	26	25	24	22	20
Employees, end of period	36	30	26	24	26	23	21

<sup>(\*)</sup> The share was split 1:5 in July 2020

# **Key financial figures (five years)**

Key figures					
Amounts in NOK 1,000	2019	2018	2017	2016	2015
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

<sup>(1)</sup> The share was split 1:20 in 1Q18

<sup>(2)</sup> A share issue committed and approved in an EGM in December 2016 was paid in and registered in 1Q17





# Overview of shareholders as per September 30, 2020

## Share capital and shareholders

Table of shareholders as of September 30, 2020:

Shareholder	Shares	Stake
DATUM OPPORTUNITY AS	25 000 000	8.81 %
RASMUSSENGRUPPEN AS	24 125 000	8.51 %
RADFORSK	24 057 000	8.48 %
AS TANJA	11 450 000	4.04 %
NORDA ASA	10 696 755	3.77 %
SKØIEN AS	10 025 000	3.53 %
OM Holding AS	8 148 291	2.87 %
VATNE EQUITY AS	7 812 500	2.75 %
PORTIA AS	7 500 000	2.64 %
DATUM AS	7 422 500	2.62 %
Others	147 390 634	51.97 %
Total	283 627 680	100.00 %

At September 30, 2020, the Company had 15 538 930 active warrants outstanding to key employees and members of the board.

## **Disclaimer**

This announcement and any materials distributed in connection with this announcement may contain certain forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they reflect the company's current expectations and assumptions as to future events and circumstances that may not prove accurate.

A number of material factors could cause actual results and developments to differ materially from those expressed or implied by these forward-looking statements.





## **About Vaccibody**

Vaccibody is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies. The Company is using the Vaccibody technology platform to generate best-in-class therapeutics against cancers and infectious diseases with a high unmet medical need.

Vaccibody is developing cutting-edge, targeted DNA vaccines for clinical use, based on a deep understanding of immunological principles. Vaccibody's vaccines specifically targets antigens to 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. Vaccibody has collaborations with Roche and Genentech, and Nektar Therapeutics and will pursue further collaborations and strategic partnerships to maximize the value of its technology platform.

Vaccibody's shares are traded on Merkur Market, a trading platform operated and wholly owned by Oslo Børs ASA, the Oslo Stock Exchange. The ticker code is VACC-ME.

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

\* \* \* \* \*





# vaccibody

# **Contact for Vaccibody:**

CEO Michael Engsig Vaccibody AS info@vaccibody.com www.vaccibody.com