vaccibody

## Company overview

*Vaccibody AS is a privately held vaccine company based on the technology conceived at the University of Oslo and Oslo University Hospital in the laboratories of Professors Bjarne Bogen and Inger Sandlie. Vaccibody AS has developed a unique and innovative vaccine platform with the aim to treat and prevent pre-cancerous diseases or cancer as well as infectious diseases. Through its innovative design Vaccibody AS's proprietary vaccine platform generates rapid, durable and broad antibody and T cell responses leading to remarkably potent vaccines.*

*Vaccibody has developed compelling preclinical data and initiated the first clinical trial with VB10.16, a therapeutic vaccine against cervical precancerous lesion. Also, Vaccibody has initiated development of neoantigen-based individualized cancer vaccines and is using the Vaccibody technology to generate first-in-class therapeutics to treat cancers with a high unmet medical need.*

## Highlights for the 2nd quarter 2017 (April-June)

- Clinical Trial VB C-01:
  - 12 months data from the phase I trial was released with the following results:
    - Well tolerated. No Serious Adverse Events (SAEs).
    - Transient or long-term reduction in lesion size and CIN regression observed in majority of patients
    - Direct correlation of strength of immune response with size reduction plus clear trend with CIN regression
  - A protocol amendment adding a 4th vaccination and extending the immunomonitoring program was approved

- VB10.NEO Neoantigen-based individualized cancer vaccine program:
  - Generation of highly encouraging preclinical data showing that combination of VB10.NEO and checkpoint inhibitor immunotherapy can lead to eradication of large, established tumours - with induction of long-term memory responses able to prohibit any signs of tumour growth after a second tumour challenge.
  - Development of a VB10.NEO specific neoepitope prediction model based on key features identified to be important for immunogenicity.
  - Completed development and pilot batch manufacturing of VB10.NEO DNA vaccines under GMP at selected Contract Manufacturing Organization (CMO)
  - Selection of clinical CRO to support the execution of the VB N-01 clinical trial.
  - Completion of key documents for the Clinical Trial Protocol (Investigator's Brochure and Investigational Medicinal Product Dossier). *(**Post Q2 note**: the Clinical Trial Application (CTA) was filed with German regulators at the Paul Ehrlich Institute on August 3rd).*

| Key figures | 2nd quarter | | 6 months | | Full year |
|---|---|---|---|---|---|
| *Amounts in NOK 1,000* | 2017 | 2016 | 2017 | 2016 | 2016 |
| Total revenue and other income | 2 494 | 1 884 | 4 502 | 3 174 | 8 999 |
| Total operating expenses | 9 635 | 5 216 | 16 138 | 11 037 | 25 407 |
| **Operating profit (loss)** | **-7 141** | **-3 332** | **-11 637** | **-7 863** | **-16 408** |
| **Net profit (loss) for the period** | **-6 310** | **-3 304** | **-10 690** | **-7 767** | **-16 220** |
| | | | | | |
| Net proceeds from equity issues | 0 | 106 | 498 | 106 | 23 945 |
| Net cash flow | -5 616 | -4 117 | 197 506 | -8 378 | 7 914 |
| Cash and cash equivalents, end of period | 222 509 | 8 711 | 222 509 | 8 711 | 25 002 |
| | | | | | |
| Outstanding shares, beginning of period | 2 409 649 | 1 215 349 | 1 215 349 | 1 197 819 | 1 215 349 |
| Outstanding shares, end of period | 2 417 064 | 1 220 639 | 2 417 064 | 1 220 639 | 1 529 649 |
| | | | | | |
| Employees, end of period | 12 | 6 | 12 | 6 | 8 |

**VB10.16 Clinical Development**

The Company's core focus in the VB10.16 trial in Q2 2017 has been to complete the analysis of the long-term (1 year) data from the dosing phase (phase I) of the first-in human study for VB10.16 with the title "An exploratory, safety and immunogenicity study of the human papillomavirus (HPV16) immunotherapy VB10.16 in women with high grade cervical intraepithelial neoplasia (HSIL; CIN 2/3)".

The treatment with VB10.16 was well tolerated. No serious adverse advents (SAEs) have been reported. The most common AEs were transient mild to moderate local site reactions at the administration site.

Immunological analyses of the peripheral blood demonstrated a strong induction of HPV16-specific T cell immune responses in 12 of 14 patients evaluated. The short interval immunization regimen in Cohort 1 induced a more rapid, stronger and longer-lasting T cell response than seen with the schedule with longer intervals used in Cohort 2. Therefore, and as earlier reported, the immunization regimen in Cohort 1 was chosen for the expansion phase of the study (clinical phase IIa), which was initiated in Q1 2017.

The strength of the immune response correlates directly with reduction in the size of the lesions and shows a clear trend with CIN regression as well as HPV16 clearance. In Cohort 1 reduction in the size of the lesions after 12 months was observed in 4 of 6 patients (two patients chose to be conizated during the course of the study and were thus excluded from the 12-month analysis). Histopathological regression to low grade neoplasia (CIN 1) or no disease was seen in 3 of 6 patients. During the course of the 12-months study/follow up period, however, all 6 of 6 patients at some point in time has shown histopathological regression to CIN 1 or no disease and simultaneously 5 out of 6 presented with reduction in lesion size. Both co-infection with other high-risk HPV infections and a transient upregulation of the checkpoint inhibitor PD-L1 were observed in the patients without complete long-term

responses and may play a role in these findings. The observed HPV16-specific T cell responses peaked after 2 months in Cohort 1 and in order to improve the chances of long-term regression of lesions, the phase IIa immunization scheme will be supplemented with an extra vaccination at 16 weeks to increase and prolong the T cell response that seem to correlate directly with clinical responses.

The company has also been focusing on initiation of the clinical phase IIa of the VB10.16 trial. The first patient was vaccinated in March and patients are now being enrolled into 4 clinical centers in Germany.

Vaccibody will enroll 15-20 additional patients with CIN 2/3 in this expansion phase.

**VB10.NEO Preclinical and Clinical Development**

Vaccibody continued the generation of strong preclinical data to support filing of a Clinical Trial Application (CTA) for VB10.NEO.

A combination study of VB10.NEO and anti-PD-1 checkpoint inhibitor immunotherapy in a mouse model showed impressive results which lead to eradication of large, established tumour and long-term memory responses able to inhibit growth of a new tumour implantation. Data supporting the use of 10 to 20 neoepitopes per patient in the VB10.NEO format was generated. These data were instrumental in the final clinical protocol design process.

A careful and thorough process to identify and select a Clinical Research Organisation (CRO) to support Vaccibody in the VB10.NEO clinical trial was undertaken in Q2.

A Scientific Advice Meeting with the German regulatory agency at the Paul Ehrlich Institute (PEI) was successfully conducted in April. This formed the basis for completion of Clinical Trial Application (CTA), the Investigator's Brochure (IB) and the Investigational Medicinal Product Dossier (IMPD).

The CTA supports a multicenter phase I/IIa clinical trial evaluating the safety, feasibility and efficacy of VB10.NEO in combination with standard of care checkpoint inhibitor therapy. The clinical trial will enroll patients with locally advanced or metastatic non-small cell lung cancer, melanoma, renal cancer, bladder or head&neck cancer. A total of 40 patients is planned to be enrolled in the phase I part of the trial. *(**Post Q2 note**: the Clinical Trial Application (CTA) was filed with German regulators at the Paul Ehrlich Institute on August 3).*

**Phibro Agreement**

Phibro Animal Health Corporation has terminated the global exclusive license agreement with Vaccibody, which had granted Phibro a right to develop, market and sell novel vaccines for the

poultry market using the Vaccibody platform technology. Thus, Phibro has no further rights to Vaccibody's technology under the Agreement. The termination will neither influence the development of the human vaccines currently being pursued by Vaccibody (VB10.16 for precancerous lesions of the cervix and VB10.NEO for various advanced solid cancers) nor have any financial impact going forward.

**Financial review**

*Profit and loss statement*
*Revenue* in the first six months of 2017 of KNOK 486 relates to an R&D collaboration of limited scope which was completed in the 2nd quarter 2017. *Other income* in the first six months of 2017 was KNOK 4,015 compared to KNOK 3,168 in the first six months of 2016. Grants from the Norwegian Research Council under the BIA programme is higher in 2017 than for 2016 in line with the increased R&D expenses of the Neo-antigen project.

*Total operating expenses* increased to KNOK 16,138 in the first six months of 2017 from KNOK 11,037 in the same period in 2016. *Payroll and related expenses* increased to KNOK 5,033 compared to KNOK 3,115 in 2016 due to the planned increase in staff. *Procurement of R&D services and IP expenses* increased to KNOK 7,146 in the first six months of 2017 compared to KNOK 5,298 in the same period in 2016. Expenses on the Neo-antigen project increased as planned, including preparations for the clinical trial application and pre-clinical studies, whereas expenses on the VB10.16 clinical trial was reduced due to the delayed inclusion of patients in the expansion phase IIa of the study. *Other operating expenses* increased to KNOK 3,920 in the first six months of 2017 compared to KNOK 2,575 in the same period in 2016, mainly due to increased internal lab expenses, recruitment expenses, more traveling activity and general and administration expenses relating to increased staff.

*Statement of financial position*
On June 30, 2017, Vaccibody had total assets of KNOK 229,826, hereunder *Cash and cash equivalents* of KNOK 222,509 and *Receivables* of KNOK 6,912. *Receivables* include mainly grants earned and to be received during the year in accordance with the applicable payment schedules. *Shareholders' equity* was KNOK 224,209.

## Outlook

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

- Clinical Trial VB C-01 (VB10.16)
  - Conclude enrolment of the expansion phase (Phase IIa)
  - Interim reporting from the expansion phase (Phase IIa)

- Clinical Trial for cancer neoantigen vaccine (VB10.NEO)
  - Approval of the clinical trial application (CTA) for a clinical phase I/IIa in cancer patients within indications with high unmet medical need
  - Initiation of phase I/IIa clinical trial evaluating the safety, feasibility and efficacy of VB10.NEO in combination with standard of care checkpoint inhibitor therapy.

- 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* | **2017** | **2016** | **2017** | **2016** | **2016** |
| Revenue | 486 | - | 486 | 6 | 243 |
| Other income | 2 008 | 1 884 | 4 015 | 3 168 | 8 755 |
| | | | | | |
| Payroll and related expenses | 2 511 | 1 114 | 5 033 | 3 115 | 8 507 |
| Procurement of R&D services and IP expenses | 4 913 | 2 807 | 7 146 | 5 298 | 11 153 |
| Depreciation | 21 | 18 | 39 | 48 | 84 |
| Other operating expenses | 2 190 | 1 277 | 3 920 | 2 575 | 5 662 |
| **Total operating expenses** | **9 635** | **5 216** | **16 138** | **11 037** | **25 407** |
| | | | | | |
| **Operating profit (loss)** | **-7 141** | **-3 332** | **-11 637** | **-7 863** | **-16 408** |
| | | | | | |
| **Net financial items** | **832** | **28** | **946** | **96** | **188** |
| | | | | | |
| **Profit (loss) before income tax** | **-6 310** | **-3 304** | **-10 690** | **-7 767** | **-16 220** |
| Income tax | - | - | - | - | - |
| **Net profit (loss) for the period** | **-6 310** | **-3 304** | **-10 690** | **-7 767** | **-16 220** |

| Statement of financial position | | | | | | | |
|---|---|---|---|---|---|---|---|
| *NOK 1,000* | **30.06.17** | **31.03.17** | **31.12.16** | **30.09.16** | **30.06.16** | **31.03.16** | **31.12.15** |
| Intangible assets | 300 | 300 | 300 | 300 | 300 | 300 | 300 |
| Property, plant and equipment | 105 | 79 | 97 | 122 | 134 | 152 | 117 |
| **Total non-current assets** | **405** | **379** | **397** | **422** | **434** | **452** | **417** |
| | | | | | | | |
| Receivables | 6 912 | 6 153 | 226 608 | 6 845 | 5 597 | 4 116 | 3 917 |
| Cash and cash equivalents | 222 509 | 228 125 | 25 002 | 26 941 | 8 711 | 12 828 | 17 088 |
| **Total current assets** | **229 421** | **234 278** | **251 611** | **33 786** | **14 308** | **16 944** | **21 005** |
| | | | | | | | |
| **Total assets** | **229 826** | **234 657** | **252 008** | **34 208** | **14 742** | **17 396** | **21 422** |
| | | | | | | | |
| Share capital | 2 417 | 2 410 | 1 530 | 1 521 | 1 221 | 1 215 | 1 215 |
| Share premium | 287 445 | 286 954 | 78 784 | 78 563 | 55 254 | 55 154 | 55 154 |
| Other paid in equity | - | - | - | - | - | - | - |
| Unregistered share issue | - | 498 | 209 050 | - | - | - | - |
| Retained earnings (accumulated losses) | -65 653 | -59 343 | -54 962 | -51 819 | -46 509 | -43 205 | -38 742 |
| **Shareholders' equity** | **224 209** | **230 519** | **234 402** | **28 264** | **9 966** | **13 164** | **17 627** |
| | | | | | | | |
| Accounts payable | 2 811 | 1 466 | 3 411 | 2 423 | 1 420 | 408 | 1 293 |
| Other current liabilities | 2 806 | 2 672 | 14 195 | 3 520 | 3 356 | 3 824 | 2 502 |
| **Current liabilities** | **5 617** | **4 138** | **17 606** | **5 943** | **4 776** | **4 232** | **3 795** |
| | | | | | | | |
| **Total liabilities** | **5 617** | **4 138** | **17 606** | **5 943** | **4 776** | **4 232** | **3 795** |
| | | | | | | | |
| **Total Equity and Liabilities** | **229 826** | **234 657** | **252 008** | **34 208** | **14 742** | **17 396** | **21 422** |

| Statement of changes in equity | | | | | |
|---|---|---|---|---|---|
| *NOK 1,000* | | | | | |
| | **Share capital** | **Share premium** | **Accumulated losses** | **Other equity** | **Total equity** |
| **Balance at 01.01.2016** | **1 215** | **55 154** | **-38 742** | | **17 627** |
| Loss for the period | | | -16 220 | | -16 220 |
| Issue of ordinary shares | 314 | 23 631 | | | 23 945 |
| Issue of ordinary shares, not registered | | | | 209 050 | 209 050 |
| **Balance at 31.12.2016** | **1 530** | **78 784** | **-54 962** | **209 050** | **234 402** |
| | | | | | |
| **Balance at 01.01.2017** | **1 530** | **78 784** | **-54 962** | **209 050** | **234 402** |
| Loss for the period | | | -10 690 | | -10 690 |
| Registration of share issue | 880 | 208 170 | | -209 050 | 0 |
| Warrants exercised | 7 | 490 | | | 498 |
| **Balance at 30.06.2017** | **2 417** | **287 445** | **-65 653** | **-** | **224 209** |

| Statement of cash flow<br>*NOK 1,000* | *6 months*<br>**2017** | <br>**2016** | *Full year*<br>**2016** |
|---|---|---|---|
| **Loss for the period** | **-10 690** | **-7 767** | **-16 220** |
| *Adjustments for:* | | | |
| Interest income | -637 | -225 | -356 |
| Interest expenses | 1 | 104 | 160 |
| Depreciation | 39 | 48 | 84 |
| Change in trade receivables | 212 | 74 | -290 |
| Change in trade payables | -600 | 127 | 2 118 |
| Change in receivables related to grants | -516 | -1 754 | -2 402 |
| Change in other current liabilities | -439 | 854 | 743 |
| **Net cash flow from operating activities** | **-12 630** | **-8 540** | **-16 163** |
| Purchase of property, plant and equipment | -47 | -65 | -65 |
| Interest income | 637 | 225 | 356 |
| **Net cash flow from investing activities** | **590** | **161** | **292** |
| Interest expenses | -1 | -104 | -160 |
| Proceeds from equity issues | 209 548 | 106 | 23 945 |
| **Net cash flow from financing activities** | **209 546** | **2** | **23 786** |
| **Net change in cash and cash equivalents** | **197 506** | **-8 378** | **7 914** |
| Cash and cash equivalents at begining of period | 25 002 | 17 088 | 17 088 |
| **Cash and cash equivalents at end of period** | **222 509** | **8 711** | **25 002** |

## Notes to the Quarterly Financial Statement

### Note 1 Accounting policies

The financial statements of Vaccibody AS for 2016 and 2017 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 received a grant from the Norwegian Research Council under the BIA-programme for the development of VB10.16 at a total of MNOK 15.5 for the period 2012-2016. The Company recognized MNOK 0.4, 4.4, 6.4, 2.7 and 1.5 of the grant in 2012, 2013, 2014, 2015 and 2016 respectively.

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 and MNOK 2.0 in the first six months of 2017.

Vaccibody AS is eligible for grant under the Norwegian Skattefunn programme. The Company has recognized MNOK 1.77, 2.8 and 3.9 of the grant in 2014, 2015 and 2016 respectively, and MNOK 2.1 in the first six months of 2017.

**Note 3 Share capital and shareholders**

Table of shareholders as of June 30, 2017:

| Shareholder | Shares | Ownership |
|---|---|---|
| SARSIA SEED AS | 336 240 | 13,9 % |
| RADIUMHOSPITALETS FORSKNINGSSTIFTELSE | 253 070 | 10,5 % |
| ARCTIC FUNDS PLC | 196 457 | 8,1 % |
| DATUM INVEST AS | 167 700 | 6,9 % |
| NORDA ASA | 141 600 | 5,9 % |
| NORRON SICAV - TARGET | 112 000 | 4,6 % |
| PORTIA AS | 103 500 | 4,3 % |
| INVEN2 AS *(1)* | 100 020 | 4,1 % |
| KREFTFORENINGEN | 97 280 | 4,0 % |
| OM HOLDING AS | 73 850 | 3,1 % |
| *OTHERS* | *835 347* | *34,6 %* |
| **Total** | **2 417 064** | 100,0 % |

*(1) Inven2 AS holds 33 000 shares on behalf of the inventors of the Company's technology, Bjarne Bogen, Inger Sandlie and Agnete B. Fredriksen.*

The Company has 172,248 warrants outstanding to inventors, key employees, former 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.*