# vaccibody

Annual report 2019

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# Management review

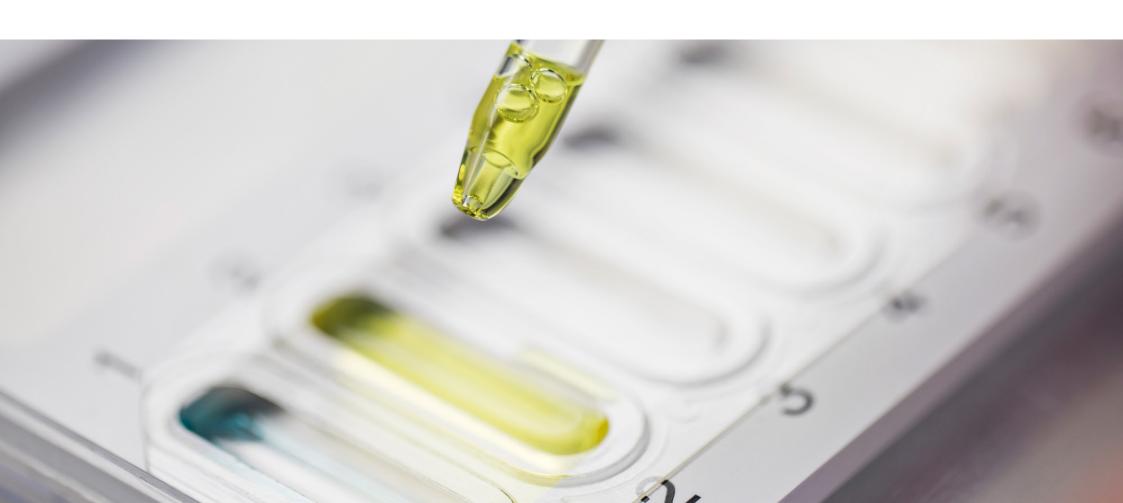
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# **Our business**



# Vaccibody in brief





# Vaccibody

Vaccibody is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies for cancer and infectious diseases. Founded in 2007, Vaccibody is using its vaccine technology platform to generate best-in-class therapeutics in indications/diseases with a significant unmet medical need. The Company is a leader in the rapidly evolving field of cancer vaccines and currently has two clinical-stage product candidates: a personalized cancer neoantigen vaccine and a vaccine against HPV16-related cervical cancer.

Vaccibody has 24 employees (end of 2019) located in Oslo, Norway, and collaborations with internationally renowned companies. Vaccibody's shares are traded on the NOTC\*.

# The Vaccibody vaccine technology platform at a glance

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.

# Vaccibody's lead products

The 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 currently being tested in a Phase II clinical trial.

# The advantages of the Vaccibody vaccine

Vaccibody's vaccine platform offers advantages with respect to a number of important parameters, such as safety, immunogenicity and clinical efficacy, speed of development, and rapid manufacturing and scalability. This may grant Vaccibody a favorable position as a leader in the field of cancer vaccines and in the fight against infectious diseases.

VB10.NEO is the first personalized neoantigen cancer vaccine to demonstrate induction of strong cancer-specific immune responses which lead to favorable clinical responses. This has been demonstrated in several patients with locally advanced or metastatic disease in several indications.

While the Company solidifies the value of its vaccine platform in immuno-oncology in the clinic, it continues to build the platform for other disease areas, strengthening the team and the partnerships required to bring these innovative treatments to patients worldwide.

# For more information, please visit www.vaccibody.com

\* NOTC is a marketplace for unlisted shares managed by NOTC AS, which is owned 100% by Oslo Børs ASA, the Oslo Stock Exchange.



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# Letter to shareholders

A transformative year characterized by important milestones and scientific validation

Dear shareholder.

2019 was a groundbreaking year for Vaccibody, with the successful achievement of a significant number of important milestones. The main focus of the Company in 2019 was to demonstrate the versatility and potential of our technology platform and to show the first compelling clinical data for VB10.NEO, our fully personalized neoantigen cancer vaccine and lead product candidate in Phase I/IIa clinical development. An absolute highlight, these strong data from VB10.NEO in the first 14 patients, across several indications, were presented in November 2019. In addition, we presented final Phase IIa data for VB10.16, our vaccine targeting HPV-induced cancers. The Company entered into an important partnership with Roche, jointly exploring VB10.16 in combination with Roche's checkpoint inhibitor Tecentrig® (atezolizumab) in patients with advanced late-stage HPV16-positive cervical cancer

The main focus of the Company in 2019 was to demonstrate the versatility and potential of our technology platform and to show the first compelling clinical data for VB10.NEO.

Furthermore, in February 2019, Vaccibody raised NOK 230 million (EUR 23.6 million) in a private placement to further advance its core assets, VB10.NEO and VB10.16, through clinical development. In addition, the Company continued growing its organization, onboarding additional talent and expertise in order to maintain a high momentum in effectively progressing product candidates toward the markets and patients, and building its development pipeline.

Vaccibody remains focused on exploring its unique and proprietary vaccine technology across multiple therapeutic settings with significant unmet medical needs. Our prime focus has so far been on addressing various cancers and establishing early proof of concept in other disease settings.

In the VB N-01 clinical trial (with VB10.NEO), we are evaluating our personalized neoantigen cancer vaccine in patients with renal cancer (RCC), metastatic melanoma, lung cancer (NSCLC), urothelial cancer and head & neck cancer (SCCHN). Interim data showed a favorable safety profile. Moreover, VB10.NEO demonstrated the ability to induce a highly specific immune response toward the patient-specific mutations selected by Vaccibody's proprietary neoantigen selection algorithm, NeoSELECTTM.















NeoSELECT<sup>TM</sup>, in combination with the Vaccibody vaccine, has shown a strong ability to identify immunogenic patient-specific mutations which not only boost pre-existing immune responses, but also induce de novo immune responses (i.e. immunogenicity, where no prior immune response existed). This results in best-inclass neoepitope-specific immune responses.

We believe that one of the key differentiating factors for a successful, fully personalized neoantigen cancer vaccine will be robustness, consistency and speed of manufacturing for each individualized product. Data from the VB N-01 clinical trial suggest that Vaccibody is well positioned on all these key differentiating parameters.

In our VB C-01 clinical trial (with VB10.16), enrolling patients with HPV16-positive high-grade precancerous cervical lesions, VB10.16 demonstrated a favorable safety profile and the ability to induce strong and rapid antigenspecific immune responses in all of the patients included in the clinical trial. Importantly, immune responses translated into and showed strong correlation with clinically meaningful responses for patients enrolled in the clinical study. The VB C-01 clinical trial served as the first in-human proof of concept for Vaccibody's proprietary vaccine technology.

In 2019, our organization grew from 19 to 24 employees. In October 2019, we were pleased to announce the recruitment of Siri Torhaug as Vaccibody's new Chief Medical Officer, effective January 1, 2020. Siri brings to Vaccibody the unique experience of working with immuno-oncology products, including cancer vaccines, as a clinical oncologist and investigator on several exploratory clinical trials at the Radiumhospital in Oslo, Norway. Furthermore, on September 1, 2019, Michael Engsig was promoted from his former position as Chief Operating Officer (COO) to Chief Executive Officer (CEO).

With the recently announced recruitment of Gunnstein Norheim, an internationally renowned scientist in infectious disease vaccines, we will explore activities in this field – another therapeutic area in which our technology may have game-changing potential. Vaccibody is excited to take the next significant steps in transforming the Company from being highly focused on oncology to expanding our strong proprietary technology platform outside oncology.

Looking ahead to 2020, the Company's most important clinical objective is currently to complete the enrolment of patients into our groundbreaking VB N-01 clinical trial and preparing the next steps in developing VB10.NEO toward the markets. A detailed overview of our clinical objectives for 2020 is provided on page 8.

On behalf of the Board of Directors and the Executive Management, we would like to thank all Vaccibody employees for their dedication and exceptional contribution in 2019. We would like to extend our sincere gratitude to our shareholders for their continued support of Vaccibody's cause. Furthermore, we thank the patients, their families and our investigators for helping us in our quest to develop medicines that matter.

We look forward to continuing our journey to develop cutting-edge, efficacious medicines and create value for the patients that need it the most.

April 15, 2020

Anders Tuv Michael Engsig
Chairman of the Board CEO

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# 2019 highlights









# February

Vaccibody enters into a collaboration with Roche to explore a combination of Vaccibody's VB10.16 and immune-checkpoint inhibitor atezolizumab (Tecentriq®) in advanced cervical cancer. Vaccibody successfully conducts a private placement, raising around NOK 230 million (EUR 23.6 million).



#### March

Vaccibody presents positive 12-month results from its Phase IIa clinical study in high-grade cervical dysplasia, providing proof of concept for its platform technology and drug candidate VB10.16.



# April

Vaccibody and Nektar Therapeutics present new preclinical data for VB10.NEO combined with bempegaldesleukin (NKTR-214) at the American Association for Cancer Research (AACR) Annual Meeting 2019.



#### June

Vaccibody reports strong neoantigen-specific T cell responses induced in the first four cancer patients with low mutational burden after VB10.NEO vaccination.



# August

Vaccibody announces the appointment of Michael Engsig as Chief Executive Officer.



# October

Vaccibody announces the appointment of Siri Torhaug, MD, as its new Chief Medical Officer.



### November

Vaccibody announces initial data showing positive clinical responses in patients with locally advanced or metastatic cancer treated with VB10.NEO and presents data at the Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2019).

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# 2019 key figures

NOK 1,000	2019	2018
Total revenue and other income	12,446	12,042
Total operating expenses	111,338	77,879
Operating profit (loss)	-98,892	-65,837
Net profit (loss) for the year	-95,956	-63,793
Net proceeds from equity issues	224,322	337
Net cash flow	135,077	-62,525
Cash and cash equivalents, year-end	279,625	144,547
Outstanding shares, year-end	54,973,080	48,479,880
Cash and cash equivalents/ total assets	96%	94%
Equity ratio	92%	91%
Equity	268,439	140,072
Total assets	292,254	153,338
Employees, average	23	16
Employees, year-end	24	19

# 2020 outlook and objectives

2





The Board of Directors and the Executive Management have a clear strategy for the year ahead. A detailed overview of Vaccibody's objectives for 2020 is provided in the table below. The primary clinical objective is to complete the enrolment of patients into the Company's VB N-01 clinical trial.

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.

# Financial review









# Income statement

The net result for the 2019 fiscal year was a net loss of NOK 96.0 million compared to a NOK 63.8 million loss in 2018. 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 12.4 million in 2019 (NOK 12.0 million in 2018) and consisted primarily of grants from the Research Council of Norway under the BIA program for user-driven research-based innovation and from SkatteFUNN, a Norwegian government R&D tax incentive program. Both amounts were at the same level as in 2018.

# Operating expenses

Total operating expenses amounted to NOK 111.3 million in 2019 compared to NOK 77.9 million in 2018. Employee expenses increased to NOK 29.4 million (2018: NOK 20.9 million). The increase was primarily caused by the planned increase in headcount from 19 to 24.

Other operating expenses amounted to NOK 81.8 million in 2019 (2018: NOK 56.9 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 2.9 million in 2019 compared to NOK 2.0 million in 2018.

The increase related to interest income on the Company's cash and cash equivalents, partly offset by net currency losses.

# Statement of financial position

#### Cash

At December 31, 2019, Vaccibody had a cash position of NOK 279.6 million compared to NOK 144.5 million at December 31, 2018. In February 2019, the Company closed a private placement with net proceeds of NOK 219.4 million.

# Equity

At December 31, 2019, total equity amounted to NOK 268.4 million compared to NOK 140.1 million at December 31, 2018. The change reflects the net result for the year plus share capital increases from the private placement in February 2019 and the exercise of warrants. Gross proceeds from the private placement in February 2019 amounted to NOK 230 million, while the net proceeds were NOK 219.4 million. The shares were placed at a price of NOK 40 per share.

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# The Vaccibody vaccine technology platform

Vaccibody's proprietary, targeted vaccine platform centers around the ability to induce a fast, strong and long-lasting specific immune response.

# The recombinant Vaccibody protein consists of three modules:

- A. The targeting unit, which targets and delivers the antigens to the immune system's Antigen Presenting Cells (APC). The targeting unit may be selected to optimize the antigen-specific immune response profile that correlates with protection for each specific disease.
- B. The dimerization unit, which joins the protein into the dimeric Vaccibody format.
- C. The antigens selected, to which a specific immune response is generated. These may be selected to fight a vast range of disease areas, including cancer and infectious diseases.

# C B

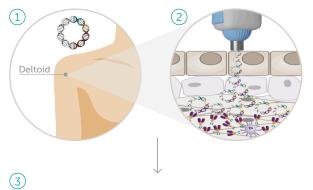
# **Technology platform**

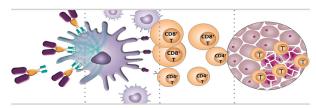
# A targeted vaccine

The Vaccibody vaccine is delivered as a DNA plasmid using a needle-free jet injector that injects the plasmids which are subsequently taken up into the patient's muscle cells. Inside the cells, the DNA plasmids provide the information to start producing the Vaccibody protein in the same way that cells produce other human proteins. The newly encoded Vaccibody proteins are then secreted from the cells, and target and deliver their antigens to the APC. The selected targeting unit determines the delivery of the antigen to specific subsets of APC, which ultimately affects the kinetics and immune response profile. The MIP-1 $\alpha$  targeting unit used in Vaccibody's two clinical products has been selected due to its ability to attract APC and induce rapid, strong and dominant CD8 killer T cell

responses combined with supporting CD4 helper T cell responses. The unique ability to induce a strong CD8 killer T cell response has been shown to be important for tumor cell killing and distinguishes the Vaccibody platform from both conventional vaccines, including non-targeted DNA vaccines, and RNA- and peptide-based vaccines.

The Vaccibody vaccine has demonstrated a favorable safety profile and has the potential to be used in a number of different disease areas, including cancer and infectious diseases. It can be optimized for each disease by matching the antigen of choice with a targeting unit providing an immune response profile correlating with protection.





- The DNA plasmid encoding the Vaccibody protein is injected into the muscle using a needle-free jet injector.
- The Vaccibody protein is produced in the muscle cells and secreted, and subsequently recruits and targets the APC.
- The APC process and present the antigens to the T cells. This results in an antigen-specific T cell response. Using MIP-1α, there will be a dominant cytotoxic T cell (CD8) response, which leads to killing of the tumor cells.







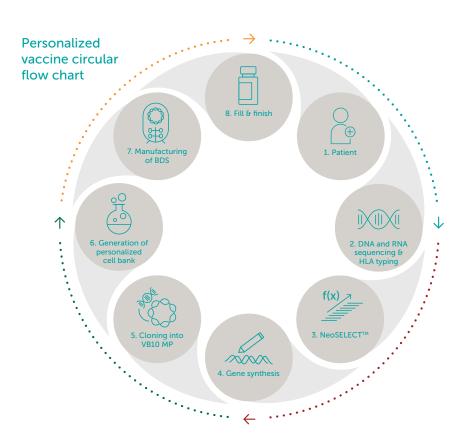


# Two vaccine concepts: the personalized vaccine and the off-the-shelf vaccine

# The Vaccibody vaccine may be:

- Off-the-shelf: An off-the-shelf (ready-made) vaccine that encodes for antigens shared among a large patient population, such as the VB10.16 vaccine that targets all HPV16-positive cancers.
- Personalized: The antigens may be selected from the individual patient's tumor, and a fully personalized vaccine is produced matching the optimal set of antigens identified in the tumor. Vaccibody's VB10.NEO program is such a fully personalized vaccine, targeting the patient's antigens based on tumor-specific mutations (i.e. distinctly non-self), so-called neoantigens.

The process and supply chain to produce an off-the-shelf vaccine has become a standard process in the industry. A fully personalized vaccine on the other hand is a much more complex process and requires a rapid turnaround time and robust processes across the entire value chain. Experience from the VB N-01 clinical trial testing VB10.NEO indicates that Vaccibody has a competitive advantage in the manufacturing process with a 100% success rate so far (i.e., all patients received a vaccine). The unique mechanism of action leading to rapid, strong and CD8-dominating responses has also led to highly encouraging immunological and clinical signs of efficacy in the first patients evaluated.



- **1.** The patient has a blood sample and tumor biopsy taken.
- 2. The samples are sequenced in order to identify the tumor-specific mutations and immune markers.
- 3. Vaccibody's proprietary neoantigen selection algorithm, NeoSELECT™, selects the optimal tumor-specific mutations (neoantigens) to be included in the vaccine.
- The vaccine is designed and synthesized.
- The patient's specific gene construct is cloned into a VB10.NEO master plasmid (MP).

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- **6.** The personalized cell bank is generated to be used in small-scale manufacturing.
- The drug substance is produced through recombinant microbial fermentation.
- The bulk drug substance (BDS) is sterilized and filled into vials to form the final drug product for use in one patient.

# Off-the-shelf vaccine flow chart











Vaccibody's in-house immunological expertise and proprietary bioinformatics are used to select the optimal antigens (e.g. from a virus) to include in the vaccine.



The vaccine is designed and synthesized.



The gene construct is cloned into a master plasmid.



The master cell bank is generated to be used in the manufacturing (large scale).



The bulk drug substance (BDS) is produced through recombinant microbial fermentation.



The drug substance is sterilized and filled into vials to form the final drug product for use with a large patient group.

# Therapeutic areas and clinical pipeline

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Vaccibody's technology platform may benefit the lives of patients across many disease areas. The ongoing clinical trials with VB10.NEO and VB10.16 cover six cancer indications in total, and both our products have the potential to cover many additional indications with a high unmet medical need. The VB N-01 study evaluates the personalized neoantigen vaccine, which is being tested in lung, urothelial, melanoma, head & neck and renal cancer. The VB C-02 study currently evaluates the VB10.16 vaccine, which is currently being tested in the advanced cervical cancer indication.

Vaccibody has a highly versatile vaccine technology platform and is a leader in the rapidly developing field of individualized cancer neoantigen vaccines.

Vaccibody has two clinical programs.

Program	Description	Discovery	Preclinical	Phase I	Phase II	Phase III	Collaborator
Oncology and precancer							
Personalized							
VB10.NEO  Melanoma, lung, bladder, renal, head & neck	An open-label Phase I/IIa basket study to evaluate the safety and efficacy of multiple dosing with VB10.NEO in patients with locally advanced or metastatic cancer. One study arm combines VB10.NEO with bempegaldesleukin (NKTR-214) in head & neck cancer patients.						Nektar Therapeutics
Off-the-shelf							
VB10.16  Precancerous cervical lesions	An open-label Phase I/IIa study to evaluate the safety and immunogenicity of VB10.16 in HPV16-positive patients with HSIL (CIN 2/3). The study was completed January 31, 2019, and the final report is available with positive 12-month data.						
VB10.16 Cervical	An open-label Phase II study to evaluate the safety and efficacy of multiple dosing with VB10.16 in combination with atezoluzimab (Tecentriq®) in HPV16-positive patients with advanced, non-resectable cervical cancer.						Roche
Infectious disease							
Undisclosed	Research is being conducted to leverage Vaccibody's vaccine technology to develop vaccines to prevent or treat infectious diseases.						

# Research and preclinical development

# Vaccibody's research organization is primarily focused on:

- Immuno-oncology research
- Developing algorithms for neoantigen selection
- · Clinical development

The Company is expanding its focus area outside oncology to include building an infectious disease unit. Gunnstein Norheim, former Director of the Vaccine Science Team at CEPI (Coalition for Epidemic Preparedness Innovations), recently joined Vaccibody and will play an important role in exploring the Company's potential in the infectious disease area.

The bioinformatics unit, which has developed the proprietary algorithm NeoSELECT<sup>TM</sup>, selecting the antigens from the patient-specific mutations, is also growing. Applying artificial intelligence and machine learning, Vaccibody has developed best-in-class antigen selection tools, which Vaccibody expects will be further optimized as it gains further insight and correlative patient data. This expertise may also be applied in other disease areas, such as vaccine design for shared cancer antigens and infectious diseases.

Furthermore, a range of formerly outsourced analysis procedures has been insourced, including immune monitoring. Through insourcing, Vaccibody obtains more flexibility, including the opportunity to build further competencies and insight into data that may yield further scientific advancements.

Vaccibody's patents and know-how are the foundation for creating long-term shareholder value. Vaccibody has an active patent strategy whereby the Company seeks to protect the IP that it believes is important for its business. The IP portfolio will increase further as the Company gains insight and expands its activities.



# Partnerships and collaborations

Vaccibody continuously considers collaborations with industry and academic groups to develop and strengthen the Company's strategic and competitive position as well as its technology platform and to offer better treatments to patients by combining Vaccibody's vaccine with other treatment modalities.

# Vaccibody's external collaborations and drug combinations include:

Company	Vaccibody program & trial	Cancer indication	Partner compound
Nektar Therapeutics	VB10.NEO / N-01	Advanced head & neck cancer	Bempegaldesleukin (NKTR-214)
Roche	VB10.16 / C-02	Advanced cervical cancer	Atezolizumab (Tecentriq®)



# **Management** review



# **Corporate governance**







The Board of Directors of Vaccibody is committed to maintaining good corporate governance standards. Vaccibody is not a publicly listed company (the Company's shares are registered on the NOTC), but the Company seeks direction from the guidelines and procedures stipulated in the Norwegian Code of Practice for Corporate Governance (issued October 17, 2018 (NCPCG)).

This Corporate governance section includes the measures implemented for the efficient management and control of Vaccibody's operations. The Board of Directors and the Executive Management of Vaccibody are committed to complying with the demands of shareholders and other stakeholders for efficient business operations, while at the same time being committed to running the Company independently.

#### Business

Vaccibody is a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies for cancer and infectious diseases.

The Company has established a set of guidelines that lay down the ethical standards for behavior toward colleagues, suppliers, patients, business partners and other relevant stakeholders. The Company has developed anti-corruption guidelines and instructions regarding the handling of waste materials that may impact the environment.

# General meetings

The Company's general meetings are open to all shareholders. The chairman of the meeting is elected by

the shareholders. This is considered sufficient to ensure the independence of the meeting chairman.

The Chairman of the Board and the Chairman of the Nomination Committee shall be present at the general meeting. The Company's independent auditors will attend the meeting if deemed necessary due to items on the agenda.

#### Nomination Committee

The Nomination Committee is appointed at the Company's general meeting pursuant to Article 8 of the Company's Articles of Association. The Nomination Committee is responsible for recommending candidates to the Board of Directors and the remuneration of the board members in accordance with the instructions for the Nomination Committee issued by the Board of Directors and sanctioned by the shareholders in general meeting.

The Company established its first Nomination Committee at the Annual General Meeting held on April 10, 2018. The current Nomination Committee consists of three members:

- Jonas Einarsson (Chairman) has over 30 years of experience in the pharmaceutical industry and is currently the CEO of Radforsk.
- Hans Petter Bøhn is a manager of the not-for-profit foundation Svanhild og Arne Musts Fond for Medisinsk Forskning as well as serving as an independent advisor to the Research Council of Norway, the Norwegian Cancer Society and a number of biotech start-ups.

 Jan Fikkan has international senior management experience from GE Healthcare and Amersham Health, among others.

The committee members were elected for a term of one year which expires at the Annual General Meeting in 2020. They are considered independent of the Board of Directors and the Executive Management.

Vaccibody has a set of corporate manuals and instructions that provide descriptions of the procedures relating to how the Company must conduct its operations, ensure sufficient funding and constantly evaluate relevant risks associated with its business.

# Board of Directors, composition and independence

Pursuant to Article 7 of the Articles of Association, the Board of Directors shall consist of between two and eight members. The current Board of Directors consists of eight members, of whom two are women and six are men.

All board members are elected for a term of one year from one annual general meeting to the next. The most recently elected board members were elected at the Extraordinary General Meeting held on January 20, 2020 (Einar J. Greve and Christian Åbyholm), and both will serve for the period ending at the Annual General Meeting to be held in 2021.







relating to clinical trials, IT operations, storage of data

The composition of the Board of Directors is compliant with the NCPCG, as the majority of its members are independent of the Executive Management and material business contacts, more than two members are independent of the main shareholders, and none of the Company's executive managers serve on the Board of Directors.

Jan Haudemann-Andersen, Anders Tuv and Christian Åbyholm represent shareholders holding at least 5% of the Company's shares, and they are therefore not considered independent board members. All other board members are considered independent of the Executive Management and do not represent any major (>5%) shareholders.

The work of the Board of Directors

The Board of Directors is responsible for providing strategic guidance to the Company and for monitoring the business operations of the Executive Management. At the meetings of the Board of Directors, which are held

every two months, the CEO updates the Board on the operational and financial developments of the Company.

The Board of Directors has also appointed a Remuneration Committee, which determines the compensation schemes of the Executive Management.

Discussions of matters of material importance in which the Chairman of the Board has been personally involved are chaired by another member of the Board.

The Board of Directors reviews and evaluates its work annually.

# Risk management and internal control

Vaccibody has implemented a set of corporate manuals and instructions that provide descriptions of the procedures relating to how the Company must conduct its operations. These include quality assurance guidelines (including GDPR compliance) and HR.

The Executive Management reports to the Board of Directors on a continual basis, ensuring that the Board is consistently updated on important risks and developments related to clinical studies, finance and strategy.

# Remuneration of the Board of Directors

The remuneration of the Board of Directors consists of an annual fee, based on the recommendation of the Nomination Committee

The Company has chosen to deviate from the recommendations of the NCPCG regarding warrants to the Board of Directors because the Company is at the development stage and due to international industry practice. The table on the left shows the number of shares and warrants in the Company held by each board member as of April 1, 2020.

# Remuneration of the Executive Management

The Company recognizes the importance of attracting and retaining key employees and executive managers, and the compensation package is regarded as an important tool in this respect. The Company has a warrant scheme which aims to align the long-term interests of the Executive Management with those of the shareholders. The warrants are granted subject to the achievement of defined targets for the past year. Warrants typically vest over a period of three years and are granted annually. Reference is made to note 5 to the financial statements (see page 35).

# **Auditors**

The Company's auditors, Deloitte AS, are considered to be independent of Vaccibody. The auditors provide a statement each year confirming their independence. The auditors attend the board meeting at which the Board of Directors discusses the annual financial statements, accounting principles and other relevant matters. At each year's annual general meeting, the Board of Directors discloses the fees paid to the auditors.

Board member	Board meetings attended in 2019	Served since	Election period ending	Number of outstanding warrants held <sup>1</sup>	Number of shares held <sup>1</sup>
Anders Tuv (Chairman) <sup>2</sup>	11	2012	AGM in 2020	160,000	0
Ingrid Alfheim	9	2007	AGM in 2020	60,000	90,200
Einar J. Greve	0	2020	AGM in 2021	30,000	325,000
Jan Haudemann-Andersen	11	2017	AGM in 2020	0	8,010,260
Lars Lund-Roland	11	2014	AGM in 2020	0	100,000
Bernd R. Seizinger	11	2014	AGM in 2020	0	120,000
Susanne Stuffers <sup>3</sup>	11	2019	AGM in 2020	23,333	12,000
Christian Åbyholm <sup>4</sup>	0	2020	AGM in 2021	20,000	336,944

<sup>4.</sup> Christian Åbyholm represents Andenæsgruppen, which holds 4,856,956 shares.

# Corporate social responsibility

# **Employees**

The primary focus of Vaccibody's corporate social responsibility (CSR) efforts is its employees. The Company has no formal policy on CSR but adheres to a set of guidelines in its Code of Conduct regarding employee health and safety, and conduct toward healthcare professionals, vendors and competitors.

There were no accidents or work-related injuries during the reporting period. The sick-leave rate of absence was 1.7% in 2019.

#### **Environment and climate**

Vaccibody may use hazardous materials in its laboratories and has put in place routines to handle such materials in a way that minimizes the impact on the environment. However, as the Company operates from rented facilities where services for the proper handling and disposal of hazardous materials are readily available and conducts its business in a highly regulated industry, Vaccibody's potential impact on the environment and climate is viewed as minimal. In other words, the Company does not pollute the environment. As a result, specific environment and climate policies have not currently been adopted.

### **Business ethics**

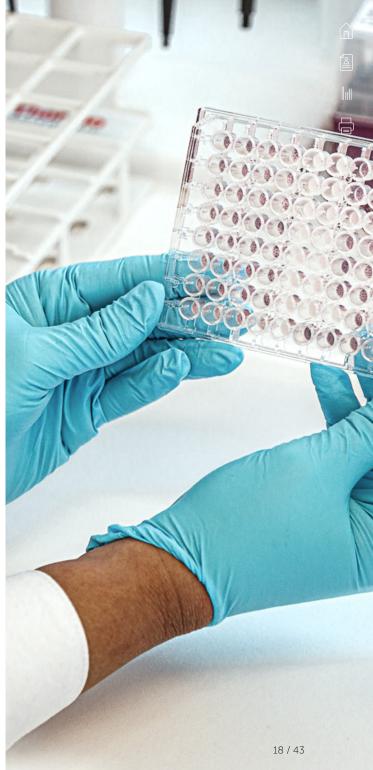
Vaccibody, in collaboration with its partners, conducts preclinical experiments in animals as well as clinical trials. The animal experiments are approved by the Norwegian governing body Mattilsynet. Vaccibody only uses R&D vendors and laboratories that are approved and have documented high standards and expertise in animal research. The clinical trials are performed in accordance with the ethical and scientific principles governing clinical research on human subjects, as set out in the Declaration of Helsinki and the International Conference on Harmonization (ICH) guidelines on Good Clinical Practice. Vaccibody collaborates with world-leading, competent service providers that specialize in these types of studies and consults with leading experts on trial design to optimize trial conduct.

Procedures for handling personal data in accordance with the General Data Protection Regulation (GDPR) have been implemented.

Vaccibody is committed to maintaining the highest standards of ethical conduct and will not tolerate the use of bribery or corruption to achieve its business objectives. The Company has established anti-corruption policies according to which all employees must decline any expensive gifts, money, trips or other such offerings from business contacts. The Company is working to apply these guidelines with its suppliers.

No incidents of bribery or whistleblowing were reported in 2019.

Key HR indicators	2019	2018
Full-time employees, year-end	24	19
Employees holding a scientific, advanced degree, Master or Ph.D., %	98%	100%
Lost-time injuries (LTIs), no.	0	0
Male/female gender diversity (M/F), %	29/71	41/59
Employee turnover, %	7%	6%
Gender diversity (M/F), Board of Directors, %	75/25	83/17



# **Risk management**









# Research and development

Developing novel pharmaceutical products inherently involves high risk. The Company seeks to mitigate risk through appropriate measures. The Company has a pipeline of candidates and clinical studies in various indications and designs its clinical studies according to best practice and in compliance with international regulations to minimize risk. Specialized Clinical Research Organizations (CRO) are contracted to help in these efforts. The clinical studies are carried out in collaboration with world-class international partners with solid experience in conducting such studies, and are conducted according to all applicable quality standards.

#### Commercial risk

Commercial risks include the time and costs involved in developing products, market competition, regulatory approvals, patent protection and the ability to attract partners. The Company focuses on ensuring sufficient patent protection, and works closely with external patent counsels to minimize the risk of patent infringement claims as well as to prepare any patent defense should this be necessary. Vaccibody has been successful in forming partnerships with leading companies in its field. They contribute both financially and with R&D expertise, thereby helping to reduce risk.

### Market risk

The financial success of the Company requires obtaining marketing authorizations and achieving acceptable reimbursement for its drugs. There can be no assurance that the Company's drugs will obtain cost-effective selling prices or reimbursement rates. The Company's products are subject to approvals from the U.S. Food and Drug Administration (FDA) to market its products in the U.S., and from the European Medicines Agency (EMA) to market its products in Europe, as well as equivalent regulatory authorities in other jurisdictions worldwide to commercialize products in those regions. The Company relies for its future earnings on the timely marketing authorization of its drugs for various indications.

#### Financial risk

Vaccibody is exposed to financial risk factors, including risks associated with cash management, the short-term liquidity profile of development programs, liquidity from partnerships and the ability to attract capital from financial markets.

The expected main sources of capital to secure future funding are the capital markets, potential new collaboration agreements with partners and potential soft funding from grant applications.

The Company is exposed to currency risk as much of its operating expenses for the clinical trials are paid in foreign currency, primarily in euro. The Company reduces its currency risk by holding parts of its cash reserves in the applicable currencies.

### Human resources

As a highly specialized and scientifically focused company, Vaccibody relies on its ability to attract and retain talent and expertise. The Company has implemented a compensation scheme and strives to be an attractive employer by offering an inspirational and flexible working environment.

#### IT risk

Vaccibody has implemented procedures for IT security and data management via its IT providers. These include firewalls and anti-virus programs. Server back-ups are run automatically at regular intervals.

# Risk management and internal controls

See section on corporate governance.











# Our people

Vaccibody's employees are essential for delivering on the Company's ambitions and goals. Vaccibody aspires to attract, develop and retain the best people in the sector. The Company strives to be a company where employees thrive and develop, regardless of their background or nationality.

The Company works continuously to ensure the wellbeing of and a safe and healthy work environment for its employees.

Vaccibody's office and laboratories in Oslo, Norway, serve as the Company's head office.

# **Board of Directors**











Anders Tuv is investment director of the early-stage life science investment company Radforsk, which is focused on immunotherapies and precision medicines. He is an experienced investment and business development professional with broad experience from the life science industry covering management positions, strategy and business development, research collaborations, licensing deals, M&A and IPOs. He holds several chairman and non-executive director positions in Norwegian biotech companies. He holds an MBE degree.



Ingrid Alfheim

Ingrid Alfheim is former CEO of Bio-Medisinsk Innovasjon AS, a serial founder of biomedical companies, including Vaccibody AS. She has more than 20 years of experience in basic and applied research within toxicology and biomedicine. Past employments include Euromed AS, Axis-Shield ASA and the Research Council of Norway. She has held and holds various positions as chair and board member of a number of listed and unlisted young biotech/biomedical companies. She holds a Ph.D. in environmental toxicology.



Einar J. Greve

Einar J. Greve works as a strategic advisor with Cipriano AS. He was previously a partner of Wikborg Rein & Co and a partner of Arctic Securities ASA. He has held and holds various positions as chairman and board member of both Norwegian and international listed and unlisted companies. He holds a master of law degree (cand.jur.) from the University of Oslo.



Jan Haudemann-Andersen

Jan Haudemann-Andersen is the sole owner of Datum AS and Datum Invest AS, and a major shareholder of Vaccibody. He has extensive investment experience from private and listed companies in Norway and abroad. He holds a business degree (siviløkonom) from the BI Norwegian Business School.

Continued on next page

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Lars Lund-Roland is a business and management consultant and has a background in pharmaceutical marketing and business. Past employments include managerial and marketing positions with Merck & Co. Inc., MSD Norway and Bringwell AB. He serves as chairman of the board of the Norwegian Life Science Cluster, Palion Medical AS, SonoClear AS and Nisonic AS. He holds a BSc degree in nursing and a graduate diploma in business and administration (Bedriftsøkonomisk Kandidat) from the BI Norwegian Business School.



Bernd R. Seizinger

Bernd R. Seizinger serves as chairman or board member of a number of public and private biotech companies in the U.S., Canada and Europe, including Oxford BioTherapeutics, Aprea, CryptoMedix and Oncolytics. In addition, he serves on the advisory board of Pureos Ventures (BB Biotech/Bank Bellevue, Zurich) and is senior advisor to Hadean Ventures (Stockholm and Oslo). Prior managerial positions include Opsona, GPC Biotech, Genome Therapeutics Corporation and Bristol-Myers Squibb. He is a medical doctor and holds a Ph.D. in neurobiology.



Susanne Stuffers

Susanne Stuffers is CEO and partner of P53 Invest AS, an investment company with a sole focus on healthcare investments. Her past employments and professional experience include equity research, consultancy, medical and commercial roles with Arctic Securities, EY, Novartis and OUS Ullevål. She holds a degree in medicine from Erasmus University Rotterdam (Netherlands) and a Ph.D. in cancer biomedicine from Oslo University Hospital (Radiumhospitalet).



Christian Åbyholm

Christian Åbyholm is a partner at Andenæsgruppen. His prior professional experience and past employments include M&A, business development and equity research with Norsk Hydro, Aker RGI, Morgan Stanley and Merrill Lynch. He is a CFA charterholder, has an MBA from IMD and a business degree (siviløkonom) from the Norwegian School of Economics and Business Administration. In addition, he completed the first two years of law school at the University of Oslo.

# **Executive Management**









Michael Engsig
Chief Executive Officer

Michael Engsig joined Vaccibody in March 2017. He is a broadly anchored pharmaceutical professional with extensive experience from early-stage drug discovery to late-stage development and product launches in biotech and pharma and across all major geographical areas, e.g. with Takeda and Nycomed. He holds a civil engineering (MSc) degree in chemistry specializing in biotechnology from the Technical University of Denmark, and a Graduate Diploma in Business Administration (HD) in organization and leadership from Copenhagen Business School (CBS).



**Agnete B. Fredriksen**President and Chief Scientific Officer

Agnete B. Fredriksen is a co-founder of Vaccibody. Her focus is on developing vaccines from idea to clinical development, having had prior roles at Affitech AS and Medinnova AS. She is the author of numerous scientific papers in the field of immunology, immunotherapy and vaccines, and has been awarded several patents in the field of immunotherapy. She is a board member of the Enabling Technologies portfolio of NRC, stimulating research in Norwegian industry. She holds an MSc and a Ph.D. from the Institute of Immunology, Rikshospitalet Medical Center in Oslo, where she designed and developed the first Vaccibody vaccine molecules. She received the King's Gold Medal of Merit for her Ph.D. thesis describing vaccibodies.



Mette Husbyn Chief Technical Officer

Mette Husbyn joined Vaccibody in 2017. Her professional experience spans CMC, drug development through all clinical stages from early research to NDA/MAA filings, including regulatory filings within both the antimicrobial and immune oncology programs, as well as diagnostic imaging. Past employments include Lytix Biopharma, Nycomed Pharma, Amersham Health and GE Healthcare. She holds a Ph.D. in peptide chemistry from the University of Oslo.



**Siri Torhaug** Chief Medical Officer

Siri Torhaug joined Vaccibody as Chief Medical Officer in January 2020. She has broad experience in clinical development and translational research. Furthermore, she has extensive experience in scientific and medical affairs covering relevant tumor areas, R&D and general management of cancer drug development as well as product launches and life cycle management for several oncology products. Past employments include Oslo University Hospital (Radiumhospitalet), one of the premier oncology hospitals in Europe, as well as Novartis and AstraZeneca. She is a medical doctor and a certified clinical specialist in oncology.

# **Shareholder information**









Vaccibody AS is a Norwegian limited liability company ("aksjeselskap") regulated by the Norwegian Private Limited Companies Act ("Lov om aksjeselskaper (aksjeloven)").

While being privately owned, the Company has adopted a provision in its Articles of Association to allow its shares to be freely traded. The acquisition of its shares is not subject to the consent of the Company, and shareholders do not have pre-emptive rights, which is otherwise a default provision of the Norwegian Private Limited Companies Act.

The Company's shares are registered with Verdipapirsentralen (VPS), Norway's central securities depository.

On January 27, 2020, the Company's shares were registered on the NOTC – a marketplace for unlisted shares managed by NOTC AS, which is wholly owned by Oslo Børs ASA.

As of December 31, 2019, one shareholder, Datum AS, held more than 10% of the shares and/or votes in Vaccibody. Datum AS is controlled by Jan Haudemann-Andersen (member of Vaccibody's Board of Directors) and holds 11.8% of the shares in the Company.

News releases made by the Company are always released through the NOTC information system at www.notc.no.

For further information about the Company's shares, reference is made to note 10 to the financial statements and to the corporate governance section.

# News









- February 13, 2019
   Vaccibody AS launches a private placement of new shares of NOK 230 million
- February 13, 2019
   Vaccibody AS announces collaboration to study VB10.16 and atezolizumab (Tecentriq®) in advanced cervical cancer
- February 13, 2019 Company presentation – February 2019
- February 14, 2019
   Vaccibody AS NOK 230 million (EUR 23.6 million)
   private placement successfully placed
- February 27, 2019
   Vaccibody AS to present data on VB10.NEO and VB10.16 at upcoming American Association for Cancer Research annual meeting
- March 25, 2019
   Positive 12-month results from Phase IIa clinical study in high-grade cervical dysplasia provides proof of concept for Vaccibody's immunotherapy platform and lead candidate VB10.16

- April 1, 2019
   Vaccibody AS and Nektar Therapeutics present
   new preclinical data from their immuno-oncology
   collaboration at the American Association for Cancer
   Research (AACR) annual meeting 2019
- May 7, 2019
   Vaccibody AS calls an annual general meeting
- May 24, 2019 Quarterly report – 2019 Q1
- June 26, 2019
   Vaccibody AS announces strong neoantigen-specific
   T cell responses induced in cancer patients with low mutational burden after VB10.NFO vaccination
- August 14, 2019Quarterly report 2019 Q2
- August 15, 2019
   Organizational changes at Vaccibody AS:
   Vaccibody AS appoints Michael Engsig as Chief Operating Officer
- August 28, 2019
   Organizational changes at Vaccibody AS:
   Vaccibody AS announces Martin Bonde to step down as
   Chief Executive Officer, Michael Engsig to take over

- October 7, 2019
   Vaccibody AS to present data on VB10.NEO at upcoming Society for Immunotherapy of Cancer annual meeting 2019
- October 9, 2019
   Call for an extraordinary general meeting
- October 11, 2019
   Vaccibody AS appoints new Chief Medical Officer
- November 2, 2019
   Vaccibody AS to host capital markets day in Oslo on November 12, 2019
- November 5, 2019
   Vaccibody AS announces initial positive clinical responses in patients with locally advanced or metastatic cancer treated with VB10.NEO neoantigen cancer vaccine
- December 12, 2019Quarterly report 2019 Q3
- December 13, 2019
   Call for an extraordinary general meeting

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# **Statement by the Board of Directors and the Chief Executive Officer**

# Oslo, April 15, 2020

The Board of Directors and the Chief Executive Officer have today considered and approved the Annual Report of Vaccibody AS for the fiscal year January 1 – December 31, 2019.

In our opinion, Vaccibody's financial statements provide a fair presentation of the assets, liabilities and financial

position at December 31, 2019, and of the results of operations and cash flows for the fiscal year January 1 – December 31, 2019.

In our opinion, the Annual Report provides a fair presentation of the development in the Company's operations and financial circumstances, the results for the

year and the overall financial position of Vaccibody as well as a description of the most significant risks and elements of uncertainty facing the Company.

We recommend that the financial statements be adopted at the Annual General Meeting on April 22, 2020.

# The Board of Directors of Vaccibody AS

Anders Tuv Chairman of the Board **Ingrid Alfheim**Board member

Jan Haudemann-Andersen Board member **Lars Lund-Roland**Board member

Bernd R. Seizinger Board member **Einar J. Greve** Board member

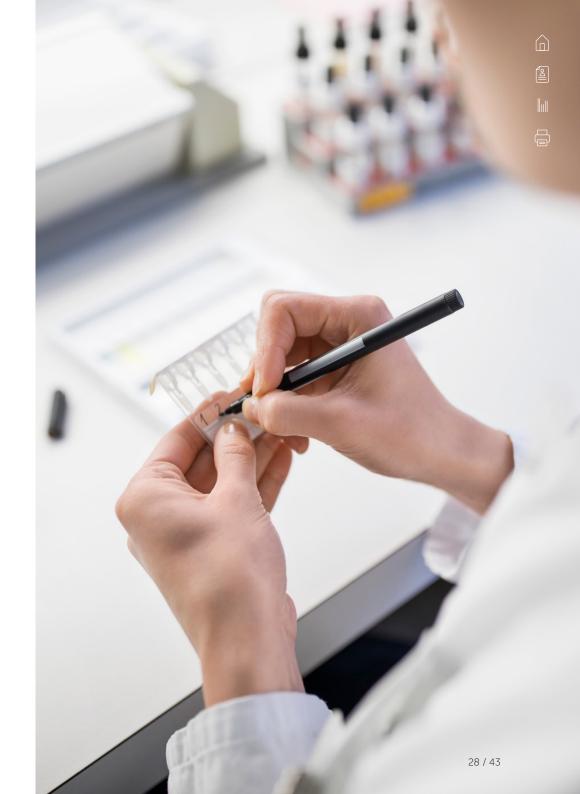
Susanne Stuffers Board member Christian Åbyholm Board member Michael Thyring Engsig Chief Executive Officer

# **Financial statements**



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- 33 Notes to the financial statements
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# **Income** statement

Year ending December 31







2018

Note	NON 1,000	2019	2010
	OPERATING REVENUE AND EXPENSES		
	Operating revenue		
1	Revenue	489	129
2	Other operating income	11,957	11,913
	Total operating revenue	12,446	12,042
	Operating expenses	,	,
5	Employee expenses	29,355	20,882
6	Depreciation and amortization expenses	136	58
5	Other operating expenses	81,847	56,939
	Total operating expenses	111,338	77,879
	OPERATING PROFIT (LOSS)	-98,892	-65,837
	FINANCIAL INCOME AND EXPENSES		
	Financial income		
	Change in market value of financial current assets	215	0
3	Other interest	3,502	1,809
8	Other financial income	568	2,597
	Total financial income	4,284	4,406
	Financial expenses		
	Change in market value of financial current assets	0	335
	Other interest	212	80
8	Other financial expenses	1,137	1,947
	Total financial expenses	1,349	2,363
	NET FINANCIAL INCOME AND EXPENSES	2,936	2,044
	PROFIT (LOSS) FROM ORDINARY OPERATIONS BEFORE TAX	-95,956	-63,793
9	Tax	0	0
	Net profit (loss) for the year	-95,956	-63,793
	APPLICATION AND ALLOCATION		
10	Uncovered loss	-95,956	-63,793
	TOTAL APPLICATION AND ALLOCATION	-95,956	-63,793

2019

Vaccibody Annual report 2019

Note NOK 1,000

# **Statement of** financial position

At December 31

Note	NOK 1,000	2019	2018
	ASSETS		
	FIXED ASSETS		
	Intangible assets		
7	Concessions, patents, licenses, trademarks	300	300
	Total intangible assets	300	300
	Tangible assets		
6	Plant and machinery	519	4
6	Fixtures, office equipment, etc.	122	107
	Total tangible assets	641	110
	Financial fixed assets		
	Other long-term receivables	36	75
	Total financial fixed assets	36	75
	TOTAL FIXED ASSETS	976	485
	CURRENT ASSETS		
	Receivables		
2	Other short-term receivables	11,653	8,306
	Total receivables	11,653	8,306
	Investments		
3	Other quoted financial instruments	190,369	112,106
	Total investments	190,369	112,106
4	Bank deposits, cash in hand, etc.	89,256	32,441
	TOTAL CURRENT ASSETS	291,277	152,854
	TOTAL ASSETS	292,254	153,338













# Statement of financial position

At December 31



# Signed by the Board of Directors of Vaccibody AS

Oslo, April 3, 2020

<b>Anders Tuv</b> Chairman of the Board	<b>Ingrid Alfheim</b> Board member	<b>Jan Haudemann-</b> <b>Andersen</b> Board member	<b>Lars Lund-Roland</b> Board member	Bernd R. Seizinger Board member	Einar J. Greve Board member
Susanne Stuffers Board member	<b>Christian Åbyholm</b> Board member	Michael Thyring Engsig Chief Executive Officer			

# **Cash flow** statement

Year ending December 31

	Ш
	(2)

279,625

144,547

Note	NOK 1,000	2019	2018

	Loss for the year	-95,956	-63,793
	Adjustments for:		
6	Depreciation	136	58
2	Change in receivables	-3,346	-1,348
	Change in trade payables	7,841	-564
	Change in other long-term receivables	39	-29
	Change in other current liabilities	2,708	2,892
	Net cash flow from operating activities	-88,578	-62,783
6	Purchase of tangible fixed assets	-667	-79
	Net cash flow from investing activities	-667	-79
10	Proceeds from equity issues	224,322	337
	Net cash flow from financing activities	224,322	337
	Net change in cash and cash equivalents	135,077	-62,525
	Cash and cash equivalents at January 1	144,547	207,073



Cash and cash equivalents at December 31

# Notes to the financial statements







# Note 1 | Accounting policies

The financial statements are prepared in accordance with the Norwegian Accounting Act and generally accepted accounting principles for small enterprises in Norway.

### Revenue

Revenue from sale of goods is recognized at the time of delivery. Services are recognized as the services are provided. All work performed has been invoiced at December 31. Public support income is recognized as it accrues. Governmental grants are recorded gross as other operating income.

### Current assets / Current liabilities

Current assets and current liabilities include items that are due for payment within one year after the balance sheet date, and items related to the business cycle. Current assets are valued at the lower of nominal cost and estimated fair value. Current liabilities are recognized at their nominal value.

#### Fixed assets

Fixed assets are assets intended for permanent ownership and use. Fixed assets are stated at cost. Tangible assets are depreciated over the remaining useful life. Tangible assets are written down to fair value if impairment is not expected to be temporary. Impairment is reversed when the impairment situation no longer exists.

# Intangible assets

Expenses related to the development of intangible assets are expensed directly. Purchased intangible assets are capitalized at cost. Intangible assets acquired through acquisition of a business are capitalized at cost when the criteria for capitalization are met. Intangible assets with finite useful life are amortized systematically. Intangible assets are written down to the recoverable amount if the expected financial benefits do not cover the carrying amount and any outstanding production costs.

#### Receivables

Trade receivables and other receivables are recognized at face value less provision for bad debts. Provision for bad debts is made on the basis of an individual assessment of each receivable.

#### Financial instruments

Financial instruments, including units in money market funds that are classified as current assets, are valued at fair value at the balance sheet date. Other investments are recognized at the lower of average cost and fair value at the balance sheet date

#### Tax

Tax in the income statement comprises tax payable for the period, tax becoming payable in the next period, and the change in deferred tax. Deferred tax is calculated at the prevailing tax rate at the end of the fiscal year (22%), based on the temporary differences that exist between the book values and the tax-related values, together with cumulative tax losses carried forward at the end of the fiscal year. Temporary differences, both positive and negative, which will or are likely to reverse in the same period, are recorded as a net amount. Deferred tax assets are recognized in the statement of financial position if future utilization is likely.

# Share-based compensation

In accordance with generally accepted accounting principles for small enterprises in Norway, share-based compensation is not expensed except for the payroll tax accrued on the taxable benefit to personnel from purchase of shares at less than market value, e.g. in the event of an exercise of warrants.



# Note 2 | Public grants

Vaccibody AS receives grants from various public sources:

Ν	ОК	1	$\cap$	$\cap$	١

Grant sources	2019	2018
SkatteFUNN¹	5,080	5,092
BIA, Research Council of Norway (Norges Forskningsråd)	6,766	6,461
Other grants:	75	238
SAPHIR (EU)	-	158
NRC, other	75	80
Total grants	11,921	11,790
1. SkatteFUNN project no. 266518	2019	2018
Amounts granted	5,080	5,092

NOK 1,000	2019	2018
Nordea Likviditet III, acq. cost + reinvested interest	157,224	64,332
Net unrealized gains	306	554
KLP Pengemarked, acq. cost + reinvested interest	32,947	47,457
Net unrealized gains	-108	-238
TOTAL	190,369	112,106

The Company has a credit line at Nordea for entering into currency risk-hedging instruments. The Company's holding of money market funds in Nordea Likviditet III has been pledged as collateral for this credit line at Nordea.

# Note 4 | Restricted bank deposits

Note 3 | Market-based financial assets

NOK 1,000	2019	2018
Restricted bank account for employees' withheld taxes at Dec. 31	2,237	945

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# Note 5 | Employees, salaries, auditor, share warrants





The Company had an equivalent of 23 full-time employees during the fiscal year. The Company is subject to the rules for mandatory occupational pension plans, and the Company's (OTP) pension scheme meets the statutory requirements.

# Warrants:

The warrants listed below have been issued as of December 31, 2019:

# NOK 1,000

Specification of employee expenses	2019	2018
Salaries	26,247	17,413
Employer's social security contributions	2,075	2,717
Pension costs	500	346
Other employee expenses	533	405
Total	29,355	20,882
Remuneration to directors and auditor	2019	2018
Chief Executive Officer, up to Sept. 1, 2019:	5,538	2,831
Chief Executive Officer, from Sept. 1, 2019:	940	0
Remuneration to the Board of Directors	731	613
Remuneration to auditor (excl. VAT), consisting of:		
Audit fee	141	89
Services relating to VAT	109	0
Other services rendered	59	42
Total remuneration to auditor	309	131

# **Employees**

Warrant holder	Issued	Maturity	Strike (NOK)	Number
Agnete B. Fredriksen	06/21/2016	12/31/2020	4.000	49,500
Agnete B. Fredriksen	05/02/2017	12/31/2021	12.500	41,580
Agnete B. Fredriksen	05/02/2017	12/31/2021	12.500	243,000
Agnete B. Fredriksen	12/20/2017	12/20/2022	1.696	176,800
Agnete B. Fredriksen	12/20/2017	12/20/2022	2.500	55,200
Agnete B. Fredriksen	12/20/2017	12/20/2022	2.625	32,800
Agnete B. Fredriksen	12/20/2017	12/20/2022	12.500	217,600
Agnete B. Fredriksen	05/13/2019	05/13/2021	3.235	66,000
Caspar Foghsgaard	05/13/2019	12/31/2022	35.000	77,600
Elisabeth Stubsrud	06/21/2016	12/31/2020	4.000	61,000
Hedda Wold	04/10/2018	12/31/2022	20.000	68,000
Karoline Schjetne	05/02/2017	12/31/2021	12.500	93,573
Mette Husbyn	12/20/2017	12/20/2022	12.500	51,000
Mette Husbyn	04/10/2018	12/31/2022	20.000	187,000
Michael Engsig	10/16/2019	12/31/2023	44.000	582,000
Siri Torhaug	10/16/2019	12/31/2023	47.000	250,000
Stine Granum	06/21/2016	12/31/2020	4.000	61,000
SUBTOTAL				2,313,653

The CEO has a compensation package that includes an annual bonus payment of up to 25% of the fixed annual salary. The bonus is determined by the Board of Directors, based on assessment of target achievement.

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# Note 5 | Employees, salaries, auditor, share warrants

Board of Directors				
Warrant holder	Issued	Maturity	Strike (NOK)	Number
Anders Tuv	05/02/2017	12/31/2021	12.500	20,000
Anders Tuv	05/02/2017	12/31/2021	12.500	60,000
Bernd R. Seizinger	06/21/2016	12/31/2020	4.000	20,000
Bernd R. Seizinger	05/02/2017	12/31/2021	12.500	20,000
Bernd R. Seizinger	05/02/2017	12/31/2021	12.500	60,000
Bernd R. Seizinger	05/13/2019	05/13/2021	3.235	20,000
Erlend Skagseth	05/02/2017	12/31/2021	12.500	20,000
Erlend Skagseth	05/02/2017	12/31/2021	12.500	60,000
Ingrid Alfheim	06/21/2016	12/31/2020	4.000	20,000
Ingrid Alfheim	05/02/2017	12/31/2021	12.500	20,000
Ingrid Alfheim	05/02/2017	12/31/2021	12.500	60,000
Ingrid Alfheim	05/13/2019	05/13/2021	3.235	20,000
Jan Haudemann- Andersen	12/20/2017	12/31/2021	12.500	46,660
Lars Lund-Roland	06/21/2016	12/31/2020	4.000	20,000
Lars Lund-Roland	05/02/2017	12/31/2021	12.500	20,000
Lars Lund-Roland	05/02/2017	12/31/2021	12.500	60,000
Susanne Stuffers	05/13/2019	12/31/2021	40.000	23,333
SUBTOTAL				569,993

Other				
Warrant holder	Issued	Maturity	Strike (NOK)	Number
Martin Bonde (former CEO)	10/23/2015	08/10/2020	4.000	13,200
Martin Bonde (former CEO)	05/02/2017	08/28/2020	12.500	354,000
Tom Pike (former Chairman)	05/02/2017	12/31/2021	12.500	168,000
Tom Pike (former Chairman)	05/13/2019	05/13/2021	3.235	66,000
SUBTOTAL				601,200
TOTAL				3,484,846

The Company and the individual warrant holders have entered into separate warrant agreements to regulate plans for the vesting of the warrants issued, etc.

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# Note 6 | Tangible fixed assets

# Note 8 | Other financial items







NOK 1,000	Plant and machinery	Fixtures, office equipment, etc.	Total
Acquisition cost at Jan. 1, 2019	223	153	376
+ Additions	599	68	667
Acquisition cost at Dec. 31, 2019	822	221	1,043
Cumulative depreciation at Jan. 1, 2019	219	47	266
+ Ordinary depreciation	83	53	136
Cumulative depreciation at Dec. 31, 2019	303	99	402
Net book value at Dec. 31, 2019	519	122	641
Annual depreciation rates (%)	20-33	20-33	

NOK 1,000		
Specification of other financial income	2019	2018
Currency gains	568	2,553
Other financial income	0	44
TOTAL	568	2,597
NOK 1,000		
Specification of other financial expenses	2019	2018
Currency losses	1,083	1,926
Other financial expenses	53	21
TOTAL	1,137	1,947

# Note 7 | Intangible assets

The item "Concessions, patents, licenses, trademarks" in the statement of financial position consists of acquired patents and project rights. Book value equals acquisition value.

The Board of Directors' view is that the Company will succeed in developing products based on these assets, or otherwise realize their value. Ongoing operational costs for patents are expensed directly, due to uncertainty as to whether and when products based on these assets can be launched for sale.

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# Note 10 | Equity / shareholders







# Note 9 | Taxes

Temporary differences and

+ Fixed assets incl. goodwill

- Tax losses carried forward

Total negative tax-decreasing differences

Differences not included in calculation of

deferred tax (asset)

deferred tax

NOK 1,000		
Tax base	2019	
Profit (loss) before tax	-95,956	
Permanent and other differences	-15,722	
Change in temporary differences	-48	
Tax base for the year	-111,725	
Tax cost for the year	2019	2018
Tax payable	0	0
Total ordinary tax costs	0	0

Due to uncertainty as to whether tax losses carried forward will be utilized in future years,
the deferred tax asset is not recognized in the statement of financial position.

NOK 1,000	Share capital	Share premium	Other equity	Total equity
At Jan. 1, 2019	2,424	287,775	-150,126	140,072
Net profit (loss) for the year	0	0	-95,956	-95,956
Share issue	288	219,133	0	219,420
Exercise of warrants	37	4,824	0	4,861
Share issue to Inven2*	0	0	41	41
At Dec. 31, 2019	2,749	511,731	-246,041	268,439

<sup>\*</sup> Paid December 2019, but entered in the Register of Business Enterprises (Foretaksregisteret) on January 17, 2020.

The share capital consists of 54,973,080 shares with a face value of NOK 0.05. The total share capital is NOK 2,748,654.

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2018

-53

186,231

186,284

186,284

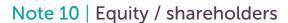
2019

-6

297,956

297,962

297,962









# Largest 20 shareholders at December 31, 2019

Name	Shares	<u>%</u>
DATUM AC	C 404 F00	11.00
DATUM AS	6,484,500	11.80
SARSIA SEED AS	4,874,800	8.90
RADFORSK	4,811,400	8.80
AS TANJA	2,290,000	4.20
PORTIA AS	1,850,000	3.40
NORRON SICAV – TARGET FUND	1,739,700	3.20
SKØIEN AS	1,670,800	3.00
OM HOLDING AS	1,652,000	3.00
NORDA ASA	1,633,956	3.00
verdipapirfondet norge Selektiv	1,606,408	2.90
VATNE EQUITY AS	1,550,000	2.80
ARCTIC FUNDS PLC	1,100,075	2.00
JOH JOHANNSON EIENDOM AS	875,000	1.60
CRESSIDA AS	840,000	1.50
DUKAT AS	813,700	1.50
HORTULAN AS	796,239	1.40
ADRIAN AS	794,020	1.40
ALTITUDE CAPITAL AS	793,570	1.40
SKIPS AS TUDOR	725,000	1.30
CHRISTIANIA SKIBS AS	720,000	1.30
Other	17 351 912	31.60
Total	54,973,080	100.00

Direct or indirect shareholdings among the Board of Directors at Decemb	er 31. 2019

Name:	Position	Shares	%
Ingrid Alfheim	Board member	50,200	0.09
Einar J. Greve	Board member	250,000	0.45
Jan Haudemann-Andersen	Board member	6,863,600	12.49
Susanne Stuffers	Board member	12,000	0.02
Christian Åbyholm	Board member	336,944	0.61

# Note 11 | Significant events after the reporting date

Subsequent to the reporting date, the COVID-19 pandemic has occurred. This may affect the Company's operations in the following ways:

- The Company has ongoing and planned clinical trials at several European hospitals. The COVID-19 pandemic may cause the clinical sites to reprioritize in ways that delay the recruitment of patients to the Company's clinical trials.
- The Company's clinical trials are dependent on timely supply of the vaccines to be given
  to the patients in the clinical trials. The COVID-19 pandemic may adversely affect the
  supply chains for these vaccines and thereby the progress of the trials.
- The Company has research activities ongoing in its own laboratories. Restrictions
  on access to facilities and working procedures in general may adversely affect the
  Company's ability to maintain progress in these research activities.

The Company is in a development stage, involving negative cash flow. General conditions in the capital markets have been adversely affected by the COVID-19 pandemic, which may adversely affect the Company's ability to attract financing of its operations in the intermediate and long term.

The company had 317 shareholders at December 31, 2019.

# Independent auditor's report









# Report on the Audit of the Financial Statements

# Opinion

We have audited the financial statements of Vaccibody AS showing a loss of NOK 95,956,000. The financial statements comprise the balance sheet as at 31 December 2019, the income statement and cash flow statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying financial statements are prepared in accordance with law and regulations and give a true and fair view of the financial position of the Company as at 31 December 2019, and its financial performance and its cash flows for the year then ended in accordance with the Norwegian Accounting Act and accounting standards and practices generally accepted in Norway.

# **Basis for Opinion**

We conducted our audit in accordance with laws, regulations, and auditing standards and practices generally accepted in Norway, including International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the Company as required by laws and regulations, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Other information

Management is responsible for the other information. The other information comprises information in the annual report, except the financial statements and our auditor's report thereon.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

# Responsibilities of the Board of Directors and the Managing Director for the Financial Statements

The Board of Directors and the Managing Director (management) are responsible for the preparation in accordance with law and regulations, including fair presentation of the financial statements in accordance with the Norwegian Accounting Act and accounting standards and practices generally accepted in Norway,

and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern. The financial statements use the going concern basis of accounting insofar as it is not likely that the enterprise will cease operations.

# Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with laws, regulations, and auditing standards and practices generally accepted in Norway, including ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

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As part of an audit in accordance with laws, regulations, and auditing standards and practices generally accepted in Norway, including ISAs, we exercise professional judgment and maintain professional scepticism throughout the

 identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error. We design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

audit. We also:

- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- conclude on the appropriateness of management's use
  of the going concern basis of accounting and, based
  on the audit evidence obtained, whether a material
  uncertainty exists related to events or conditions that
  may cast significant doubt on the Company's ability
  to continue as a going concern. If we conclude
  that a material uncertainty exists, we are required to
  draw attention in our auditor's report to the related
  disclosures in the financial statements or, if such
  disclosures are inadequate, to modify our opinion. Our
  conclusions are based on the audit evidence obtained
  up to the date of our auditor's report. However, future
  events or conditions may cause the Company to cease
  to continue as a going concern.
- evaluate the overall presentation, structure and content
  of the financial statements, including the disclosures,
  and whether the financial statements represent the
  underlying transactions and events in a manner that
  achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

# Report on Other Legal and Regulatory Requirements

Opinion on Registration and Documentation Based on our audit of the financial statements as described above, and control procedures we have considered necessary in accordance with the International Standard on Assurance Engagements (ISAE) 3000, Assurance Engagements Other than Audits or Reviews of Historical Financial Information, it is our opinion that management has fulfilled its duty to produce a proper and clearly set out registration and documentation of the Company's accounting information in accordance with the law and bookkeeping standards and practices generally accepted in Norway.

Oslo, 3 April 2020 Deloitte AS

# Sylvi Bjørnslett

State Authorised Public Accountant (Norway)









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# **Corporate** information







# Vaccibody

Gaustadalleen 21 0349 Oslo Norway

Phone: +47 22 95 81 93 E-mail: info@vaccibody.com

Organization number: N-990 646 066 MVA

www.vaccibody.com

# Annual General Meeting

The Annual General Meeting will be held on April 22, 2020, at Oslo Research Park, Gaustadalleen 21, 0349 Oslo, Norway

# Commercial bank

Nordea Bank Abp, filial i Norge Essendrops gate 7 0107 Oslo Norway

# Auditor

Deloitte AS Dronning Eufemias gate 14 0191 Oslo Norway

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# Glossary

# Antigen

An antigen is a molecule recognized by the immune system. "Non-self" antigens are identified as intruders and attacked by the immune system.

# APC

Antigen Presenting Cells (APC) are part of the immune system and are cells that display antigens on their surfaces and present them to T cells.

### CD4+ T cells

Immune cells able to activate and help other immune cells by releasing signaling molecules, thereby orchestrating an optimal immune response, also known as helper T cells.

#### CD8+ T cells

Immune cells able to kill cancer or virus-infected cells, also known as cytotoxic T cells.

#### CIN

Cervical Intraepithelial Neoplasia (CIN) is the premalignant transformation and dysplasia of squamous cells on the surface of the cervix caused by HPV infection.

#### DNA

Deoxyribonucleic acid (DNA) is the hereditary material found in every cell and is unique for each individual. DNA consists of genes that encode for proteins.

# DNA vaccine

Vaccines are made to induce an immune response to an antigen, to boost the immune system. When the antigen is delivered as a DNA molecule (plasmid), it is called a DNA vaccine.

#### HPV

Human papillomavirus. There are several strains, and HPV16 is the strain that is most associated with cancer.

#### HSIL

High-grade squamous intraepithelial lesions of the cervix. This corresponds to cervical intraepithelial neoplasia grade 2/3 (CIN 2/3).

# Immuno-oncology

Cancer immunotherapy, also called immuno-oncology, is a type of cancer treatment that helps the immune system fight cancer.

#### ΙP

Intellectual property such as patents and know-how.

#### MIP-1α

A chemokine that attracts APC and ensures binding to receptors on the surface of APC. It is used as a targeting module in Vaccibody vaccines.

#### Mutation

A change or alteration that occurs in the DNA. Mutations may lead to cancer, and these mutations may be identified and recognized by the immune system.

#### Neoantigen

Novel tumor-specific antigens derived from somatic gene mutations in cancer cells that are solely expressed on a patient's tumor. These mutations may be regarded as truly foreign by the immune system.

# NKTR-214

NKTR-214, or bempegaldesleukin, is an immunotherapeutic drug in clinical development by Nektar Therapeutics.

#### Off-the-shelf vaccine

Ready-made vaccine that may be used to treat larger patient groups.

### Personalized vaccine

On-demand vaccine designed and manufactured specifically for each individual patient.

#### Plasmid

A small DNA molecule carrying genes that can be expressed as proteins within a host cell.

#### Phase I/IIa

Early-phase clinical trials intended to evaluate safety/tolerability and initial clinical effect.

#### R&D

Research and development.

### RNA

Ribonucleic acid (RNA) is a polymeric molecule essential in various biological roles in coding, decoding, regulation and expression of genes. All of the RNA in a natural cell is made by DNA transcription.

#### T cell

Immune cells of key importance to the immune system to tailor the immune response to specific pathogens or cancer.

#### Vaccibody technology platform

A proprietary vaccine delivery platform intended to make more efficacious vaccines by targeting the antigen to APC.

#### VB10.16

Vaccibody drug candidate targeting HPV16-induced malignancies such as cervical cancer.

#### VB10.NEO

Vaccibody drug candidate where each vaccine is personalized and designed by identifying each patient's specific gene alterations (mutations).

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