# vaccibody

Vaccibody 2Q 2021 August 26, 2021

# **Presenting Team**



Michael Engsig



M.Sc. Biochemistry and G.D.Bus.Admin.

More than 20 years professional experience in biotech and pharma:

- KLIFO
- PPD
- Takeda and Nycomed

#### Chief Innovation & Strategy Officer

#### Agnete B. Fredriksen



M.Sc. in Molecular Biology and Ph.D. in Immunology

Designed and created the first Vaccibody™ molecules. Co-founder of Vaccibody AS (2007)

• Served as CSO 2007-2021, leading the scientific strategy



M.Sc. in Shipping, Trade and Finance , and MSc in Marine Engineering and Naval Architecture

Long career in the field of finance. Most recently as CFO in Flex LNG, listed on both the New York Stock Exchange and the Oslo Stock Exchange



# Forward-looking statement

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

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



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#### Introduction to Vaccibody

Vaccibody Platform Technology

#### Project update

- VB10.NEO
- VB10.16
- VB10.COV2
- Autoimmune disorders

#### Financials

Organizational update

# **Overview of Vaccibody**

• Leading vaccine platform taking advantage of differentiated technology to address a broad range of diseases

• Targeting antigens to antigen presenting cells, generating unique rapid, strong and long-lasting immune response

• Highly advanced oncology pipeline with two Phase 2 assets including VB10.NEO, an individualized vaccine targeting tumor specific epitopes, as well as VB10.16, an off the shelf vaccine

• Significant collaboration with Genentech to support development of key oncology assets

• 2-arm COVID-19 vaccine strategy focused on providing protection against current and future Variants of Concern

• Collaboration with Adaptive Biotechnologies to generate broadly protective T cell based immunity against multiple SARS-CoV-2 antigens

Highly experienced management team with track record of success
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# Vaccibody's Strategy

Leveraging Vaccibody's validated technology platform for maximum value generation

Vaccibody aim to become the world's leading vaccine technology company with an ability to address a range of diseases by executing on the core tenets of its strategy:



Rapidly advance existing assets through the clinic



Further leverage the technology platform to expand pipeline



Seek strategic partnerships to compliment our strengths

# **Pipeline**

Broad oncology coverage and strong partnerships. Leveraging platform within infectious diseases

Program	Indication	Discovery	Preclinical	Phase 1	Phase ll	Phase III	Partnerships	
Individualized								
VB10.NEO	Melanoma, lung, bladder, renal, head & neck	$\bigcirc$					Genentech <sup>1</sup> Nektar <sup>2</sup> Therapeutics <sup>2</sup>	
VB10.NEO	Locally advanced and metastatic tumors	$\bigcirc$					Genentech <sup>1,3</sup>	
Off the shelf								
VB10.16	HPV16 positive cervical cancer <sup>4</sup>	$\bigcirc$						
Undisclosed	Undisclosed targets within shared antigens							
VB10.COV2	SARS-CoV-2	$\bigcirc$	$\bigcirc$		$\bigcirc$	$\bigcirc$	Adaptive Biotechnologies <sup>5</sup>	
Undisclosed	Undisclosed targets within infectious disease							

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1) Genentech has an exclusive license to VB10.NEO; 2) Collaboration with Nektar Therapeutics on combining NKTR-214 (bempegaldesleukin) with VB10.NEO in trial arm 5B (SCCHN); 3) In combination with atezolizumab; 4) Roche supplies atezolizumab; 5) SARS-CoV-2 T cell epitopes excl. licensed from Adaptive



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# Flexible Vaccibody<sup>™</sup> format can fuel multiple products customized for each indication

The Vaccibody™ technology platform is developed based on the concept of **targeting antigen to Antigen Presenting Cells (APCs)** in order to create more efficacious vaccines



The Vaccibody IP covers the 3 combined and interchangeable functional modules irrespective of delivery format (eg DNA, mRNA, viral vector, protein)

Applicable to develop specific and optimized vaccine products for cancer, infectious diseases and autoimmunity

# Vaccibody mechanism of action

The APC targeting vaccine technology platform creates unique rapid, strong and broad immune responses that can be tailored to each disease



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Internalization & presentation to CD4 and CD8 T cells Killing of cancer cells or pathogen-infected cells

Neutralization

## In house bioinformatics applied for optimal vaccine design across therapeutic areas

#### NeoSELECT

Identification of patient-specific neoepitopes



#### sharedSELECT

Identification of shared cancer antigens for off-the-shelf vaccines



Identification of epitopes across patient

population/cancer indication epitope epitope HI A-A HLA-DR HLA-DP HLA-B HLA-DQ Hotspots with epitopes predicted to bind across population scale MHC I/II Proteosomal processing Self similarity TCR reactivity Patient safety Optimized vaccine construct design

epiC-PATH





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# VB10.NEO: Fully individualized neoantigen based cancer vaccine



- Finalized enrollment VB N-01; 5 indications, <50 pt
- Landmark deal with partner of choice Genentech (200m\$ upfront & near term, 515m\$ additional milestones and low double digit royalties)
- Initiated VB N-02, in collaboration with Genentech; > 10 indications, 2 doses, combo with atezolizumab, ~40 patients
- Demonstrated ability to raise broad and strong patient-by-patient neoantigenspecific immune responses
- Correlation between vaccine-induced immune responses and clinical responses



Correlation with incorporation of high-quality neoepitopes

#### **Genentech** A Member of the Roche Group





# VB10.NEO: VB N-02, combination trial with Genentech's atezolizumab (Tecentriq<sup>®</sup>)

#### Study purpose and design

- 2 doses. Safety, biomarkers, and antitumor activity of VB10.NEO in combination with Genentech's atezolizumab
- Up to 40 patients with locally advanced, recurrent or metastatic solid tumors (more than 10 indications)
- The trial will recruit patients in US, Germany, and Spain (NCT05018273)



# VB10.16: Off the shelf therapeutic HPV vaccine

- Finalized Phase I/IIa study with VB10.16 monotherapy in HPV16+ precancerous cervical lesions
- Demonstrated ability to induce strong HPV16 specific T cell responses
- Strong correlation between vaccine induced T cell responses and lesion size reduction
  - Data from PD-L1 upregulation in monotherapy study provide scientific rationale for combination of anti-PD-1/PD-L1
- Phase II study of VB10.16 + atezolizumab in advanced cervical cancer has been initiated and interim safety analysis support continuation
  - release of interim clinical data expected Q1 2022
  - Potential to expand scope to several HPV driven cancer types, including head and neck cancer
- Fully owned by Vaccibody

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# VB10.16: VB C-02, combination trial with Genentech's atezolizumab (Tecentriq<sup>®</sup>)

#### Study purpose and design

- Purpose is to assess the safety/tolerability, immunogenicity and the efficacy of multiple doses of VB10.16 immunotherapy in combination with Genentech's atezolizumab
- Up to 50 patients with advanced or recurrent, non-resectable HPV16+ cervical cancer
- The trial is recruiting patients in Europe in 6 countries: Belgium, Bulgaria, Czech Republic, Germany, Norway and Poland (NCT04405349)

_		12 months	12 months	
Advanced or recurrent, non- resectable HPV16- positive cervical cancer	Vaccination induction	Vaccination maintenance	Follow-up	

## Key Strengths of Vaccibody Infectious Disease Platform

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- Rapid onset of immunogenicity
- Vaccine platform enabling complex and multiple antigen design
- Attractive manufacturing, formulation, distribution and administration
- Tailored to each disease's correlate of protection

Well-tolerated

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# **Unmet need for improved COVID-19 vaccines**

#### **Emerging data support unmet need for improved COVID-19 vaccines:**

- Neutralizing antibodies induced by the marketed Wuhan based vaccines wane over time
- Further reduced efficacy against Variants of concern (VoC)
  - Most significant against beta B1.351

A matter of time before emerging variants escape immunity from current vaccines based on the original Wuhan WA1/2020 spike sequence?

#### Vaccibody's 2<sup>nd</sup> generation vaccine candidate:

- A RBD beta based vaccine harboring the most significant mutations
- Preclinical data support potential to offer rapid, strong and long-lasting neutralizing antibody responses across multiple VoC



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Tartof et al., 2021

Adapted from Cox et al., Yadav et al., Hoffmann et al., Garcia-Beltran et al., Tarke, et al., Redd et al., and Madhi, et al., Stephens et al.

# Strong rationale for T cell focused Covid-vaccines

#### Increasing evidence of the importance of broad T cell responses against COVID-19

- T cell response in vaccinated human subjects coincide with early protection
- A higher proportion of CD8<sup>+</sup> T cell responses is observed in mild disease
- Reduced positive cases associated with strong T cell responses
- Not sensitive to mutations in the current VoC

#### Vaccibody's 3<sup>rd</sup> generation vaccine candidate:

- A vaccine with the most clinically relevant and conserved SARS-CoV-2 T cell epitopes identified in clinical material by Adaptive Biotechnologies
- Vaccine design and preclinical data support potential for rapid and long-lasting immunity across all population groups and across current and future variants
- Rapid onset of broad T cell-based immunity opens potential for safe, effective, easy-toadminister therapeutic product to reduce severity of illness and clear infection

Peng et al 2020 https://www.nature.com/articles/s41590-020-0782-6 Wyllie et al SIREN study UK https://www.medrxiv.org/content/10.1101/2020.11.02.20222778v1.full-text



# Vaccibody's SARS-CoV-2 vaccines

• Exploit the protective role of both the humoral and cellular immune system



## **RBD candidate VB2129 induces potent virus neutralization responses across VoC**



One dose Two doses

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# Adaptive is the partner of choice for T cell vaccines



Adaptive applied its immune medicine platform to identify and validate immuno-dominant T-cell epitope hotspots



Sequence information using samples from more than 6500 patients impacted by COVID-19 plus 150,000+ SARS-CoV-2 specific TCR-antigen pairs across the viral genome



Launched T-Detect<sup>™</sup> COVID, which is the first-in-class T-cell-based clinical test for Covid-19 with FDA Emergency Use Authorization



# Unique clinical data set to map T cell responses to the antigens



- Library of 150,000+ SARS-CoV-2 specific TCR-antigen pairs across virus genome from over a hundred patient samples
- Validate SARS-CoV-2 specific of immuno-dominant T-cell epitope 'hotspots'
- Prioritization of epitopes are used to inform vaccine design

# Strong immunogenicity of VB2210 in 3 mouse models



- VB2210 induces strong responses post 1 vaccination against HLA specific epitopes in humanized HLA tg mice
- The strong T cell responses observed in two additional mice models show the breadth of the T cell response independent of MHC selection

#### Position of immunodominant epitopes in RBD



CD4

\*

peptides

4000

3000

2000

1000

400

200

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SFU/10<sup>6</sup> splenocytes

## **VB10.COV2** induces broad and **CD8 dominated T** cell responses

Strong, dominating CD8 T cell responses against RBD in VB2060

- 4 distinct CD8 epitopes
  - 1 described by others\*
- 3 distinct CD4 epitopes ٠
  - 2 described by others\*

Consistent with Vaccibody's platform data MIP-1 $\alpha$  targeting ensures processing of presentation of a broader set of epitopes than seen with other vaccine technologies.

Norheim 2020

\*

# VB-D-01 investigating two candidates as prime in vaccine naive and a booster in previously vaccinated subjects



A Phase 1/2, open label, dose escalation trial to determine safety and immunogenicity of two SARS CoV-2 virus vaccine candidates (C1) and (C2) in healthy adult volunteers



# Modular platform providing opportunities within infectious diseases

- Rapid onset of immune responses
  - Potential for one dose and therapeutic efficacy
- Allows for incorporation of multiple antigens in one vaccine
  - Potential for broader protection and pan-pathogen vaccines
- Tailored products to each disease and it's correlate of protection
  - Create vaccines with unique, controlled immune response profile
- Standard manufacturing process and easy distribution, painless administration



### Targeting unit offers unique ability to explore Agspecific immune tolerance





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## **Income Statement**

Amounts in USD '000	Q2 2021	Q2 2020	YTD 2021	YTD 2020	FY 2020
Revenue from contracts with customers	1,607	-	2,054	-	215,000
Other income	291	117	625	252	695
Total revenue and other income	1,898	117	2,679	252	215,695
Employee benefit expenses	2,714	2,509	6,576	2,964	16,049
Other operating expenses	6,765	3,906	11,054	7,542	21,078
Depreciation	103	62	205	131	303
Operating profit (loss)	-7,684	-6,360	-15,156	-10,385	178,265
Finance income	379	118	595	1,514	3,815
Finance costs	272	317	1,242	552	1,176
Profit (loss) before tax	-7,577	-6,559	-15,803	-9,423	180,905
Income tax expense	-1,330	-	-3,048	-	31,130
Profit (loss) for the period	-6,247	-6,559	-12,755	-9,423	149,774

#### **Revenue from contracts with customers**

- Revenues under the Genentech agreement
- \$1.6m and \$2.1m recognized in the 2<sup>nd</sup> guarter and 1<sup>st</sup> half of 2021, respectively, relating to R&D activities
- \$215m recognized in 2020 relating to the license component of the agreement

#### Other income

 Government grants from SkatteFUNN and Research Council of Norway

#### **Employee benefit expenses**

• Increase in 2021 mainly due to planned increase in headcount and expenses related to the share option program

#### Other operating expenses

 Increase in 2021 mainly due to increased R&D activities

#### **Finance income and Finance costs**

 Mainly related to movements in foreign currency exchange rates and fair value adjustments of financial instruments

# **Balance Sheet**

Amounts in USD '000	30/06/2021	31/12/2020
ASSETS		
Non-current assets		
Property, plant and equipment	132	131
Right-of-use assets	98	277
Intangible assets	32	32
Other long-term receivables	530	556
Total non-current assets	792	996
Current assets		
Trade receivables	3,750	3,750
Other receivables	2,804	1,487
Contract assets	9,554	15,000
Other current financial assets	20,774	24,944
Cash and cash equivalents	174,378	183,851
Total current assets	211,260	229,032
TOTAL ASSETS	212,052	230,028

#### Cash and cash equivalents

• Strong cash position of \$174.4m as per June 30, 2021

#### Other current financial assets

• Money market funds of \$20.8m as per June 30, 2021

#### **Trade receivables**

• Amounts invoiced under the Genentech agreement

#### **Contract assets**

• Revenue earned but not invoiced under the Genentech agreement

# Balance Sheet - contd.

Amounts in USD'000	30/06/2021	31/12/2020
EQUITY AND LIABILITIES		
Equity		
Share capital	329	327
Share premium	61,224	60,348
Other capital reserves	5,945	4,419
Other components of equity	-3,112	-3,113
Retained earnings	104,114	116,869
Total equity	168,501	178,850
Non-current liabilities		
Non-current lease liabilities	7	8
Non-current provisions	5,950	6,859
Deferred tax liabilities	27,993	31,130
Total non-current liabilities	33,950	37,997
Current liabilities		
Government grants	161	-
Current lease liabilities	96	276
Trade and other payables	5,564	9,183
Current provisions	3,780	3,722
Total current liabilities	9,601	13,181
Total liabilities	43,551	51,178
TOTAL EQUITY AND LIABILITIES	212,052	230,028
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#### Equity

Total equity of \$168.5m, representing equity ratio of 79%



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#### **Organizational update**

# Significant ramp up of organization to execute on growth strategy and shareholder value creation



1 Jan '21



# Accomplishments and news flow guidance

#### **Selected accomplishments**

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#### July 2020

First patient dosed in VB C-02 Phase II trial of VB10.16 in combination with Roche's atezolizumab in advanced cervical cancer

#### October 2020

Worldwide, exclusive collaboration with Genentech on VB10.NEO

**December 2020** Launch of Infectious Disease strategy

#### July 2021:

VB10.NEO - initiation of VB N-02, Phase Ib trial VB10.CoV2 - Adaptive Biotechnologies - exclusive T cell epitope agreement, and pre-clinical update

#### **News flow guidance**

#### 2H 2021:

VB10.16 - fully enrolled VB C-02 trial in cervical cancer

#### **2H 2021:** First patient dosed COVID-vaccine trial, VB-D-01

#### 1H 2022:

VB10.16 - interim clinical data for first patients from VB C-02 trial in cervical cancer

# **Key investment highlights**

- Unique, leading and proprietary vaccine platform with potential to fuel future pipeline across multiple diseases
- Validated through clinical data and collaborations with partners of choice
- Solid oncology pipeline addressing broad range of tumor types as well as novel next-generation Covid-19 vaccine candidates
- Key catalysts within next 12 months
- Well capitalized to execute growth strategy and maximize value generation



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