## nykode therapeutics

## 1H 2022 Financial Results Presentation

August 24, 2022



## **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.



## **Today's presenters from Nykode management**

International management team with solid drug development experience



**MICHAEL ENGSIG** 

Chief Executive Officer

Wide-ranging experience from leading early-stage drug discovery through late-stage and commercial development

- Takeda and Nycomed
- PPD
- KLIFO





#### AGNETE FREDRIKSEN

Chief Business Officer & Co-founder

More than 20 years experience with APC-targeted vaccines from drug discovery to clinical development in various leadership positions at

Vaccibody/Nykode





#### HARALD GURVIN

Chief Financial Officer

Long career in the field of finance including:

- Flex LNG
- SFL Corporation

### **Overview**

### 

### VISION

 To build the leading immunotherapy company developing game changing medicine across an expanding range of therapeutic areas

### UNIQUE THERAPEUTIC APPROACH

- Proprietary Vaccibody<sup>™</sup> immunotherapy platform uniquely targets APCs to induce a broad and strong CD8 T cell response
- Adaptable platform can quickly target new diseases
- Pipeline of oncology and infectious disease vaccines which includes partnered programs and wholly-owned clinical candidates

### 

### NEXT GENERATION PLATFORM AND PIPELINE

- Dual-focus on the further potential in its differentiated modular platform and clinical projects
- Developing an antigen-specific immune tolerance
   platform



### STRONG VALIDATING PARTNERSHIPS

 Potentially > \$1.64B in payments + additional royalties from top-tier partners Regeneron, Genentech and Adaptive

### R

### CLINICALLY VALIDATED TECHNOLOGY

 Including recent positive interim results from Phase 2 HPV16+ cervical cancer program



### **STRONG FINANCIAL POSITION**

 Well capitalized with multiple significant catalysts in near-to-medium term

## 1H 2022 highlights

### **Technology and clinical programs**

• Nykode Therapeutics announced positive interim results from its Phase II trial with VB10.16 in combination with atezolizumab in heavily pre-treated patients with advanced cervical cancer

- · Enhanced ORR and DCR with long-lasting response
- Efficacy observed in both PD-L1 positive and PD-L1 negative, as well as non-inflamed tumors
- Association of immune responses and clinical responses
- Nykode presented preclinical data from its second generation Vaccibody™ vaccine technology at AACR Annual Meeting
  - Allowing further enhancement and control of T cell and antibody responses
- Nykode presented supportive preclinical data at its Capital Markets Day on its immune tolerance program for use in autoimmune disorders
  - increase antigen specific T regulatory cells and shift the cytokine balance towards immune suppression

## 1H 2022 highlights

### Finance

• Nykode converted to public limited liability company and uplisted to the main list of the Oslo Stock Exchange

### Organization

- Elaine Sullivan and Anne Whitaker elected to join the Board of Directors at the Company's AGM on May 12, 2022
- Nykode appointed Klaus Edvardsen as Chief Development Officer
- Nykode appointed Louise Stubbe as Chief Legal Officer (After June 30, 2022)
- Company continued on boarding of new talent reaching 142 employees by August 15, 2022

## VB10.16 interim data C-02

Nykode's off the shelf vaccine targeting HPV16+ cancers

Nykode Therapeutics | Webcast | Non-confidential

## **VB C-02:** VB10.16 in combination with atezolizumab in advanced cervical cancer

A Multi-Centre, Single Arm, Open-label Phase 2a Trial of the Combination of VB10.16 and atezolizumab in Patients with Advanced or Recurrent, Non-resectable HPV16 Positive Cervical Cancer (NCT04405349)

- Objectives: safety/tolerability, immunogenicity and efficacy
- Primary endpoints: incidence/severity of AEs, ORR (based on RECIST 1.1 by blinded independent central review)
- Fully enrolled with 52 patients
- Conducted in Europe in 6 countries (Germany, Belgium, Bulgaria, Czech Republic, Poland and Norway)
- Enrolled patients received treatment with 3 mg VB10.16 in combination with 1200 mg atezolizumab for up to 48 weeks



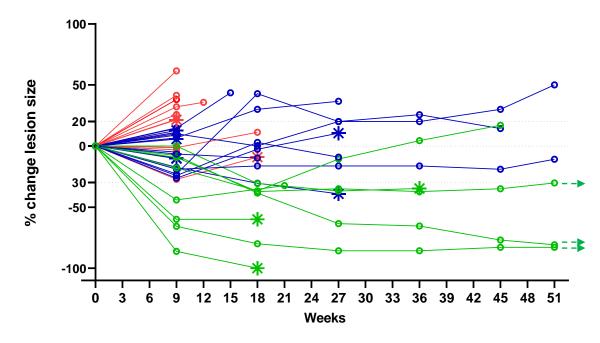


## **Baseline characteristics of EAS population**

C-02 included a heavily pre-treated population with advanced cervical cancer

Characteristic	N (%)	Characteristic	N (%)
Age (mean) Age (median)	48.9 yrs 47.0 yrs	ECOG 0	22 (56%)
Ethnicity (White)	39 (100%)	1	17 (44%)
Prior systemic treatment lines 1 2 3 4	12 (31%) 15 (39%) 9 (23%) 1 (2%)	PD-L1 status at baseline TIC 0 (<5%) TIC 1 (5-10%) TIC 2 (>10%) Missing	3 (8%) 19 (49%)
5	2 (5%)	Histology	
Prior surgery Y N	19 (49%) 20 (51%)	Squamous cell Adenocarcinoma Missing/unknown	8 (21%)
Prior radiotherapy Y N	31 (80%) 8 (20%)	Metastases* Liver Lung Other	7 (18%) 17 (44%) 19 (49%)
Prior chemotherapy Y N	39 (100%) 0 (0%)	Extra-pelvic metastases present         Yes         35 (90%)           No         4 (10%)	

## VB10.16 in combination with atezolizumab showed promising efficacy with durable responses



- Complete/Partial Response
- Stable Disease
- Progressive Disease

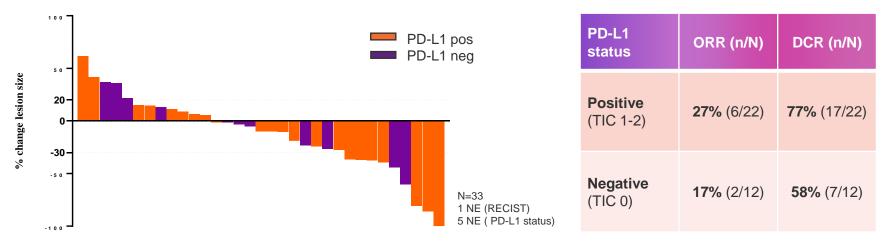
- Durable responses in the DCR population
- 6 out of 8 ORR patients have an ongoing response

N=38 1=NE; not evaluable Treatment period week 0-48

- Subjects with ongoing study treatment at cut off date (n=12)
- 3 responders who completed study treatment showed ongoing response on last available scan (Week 51)

## Anti-tumor activity was observed both in patients with positive and negative baseline PD-L1 status

Tumor regression in PD-L1 +/-



These findings support that VB10.16 in combination with atezolizumab may enhance clinical responses also in PD-L1 negative patients where CPI monotherapy is not approved

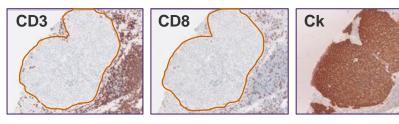
Nykode Therapeutics | Webcast | Non-confidential

PD-L1 was scored by TIC (Tumor and immune cell) scoring using Ventana SP263 platform (Roche Diagnostics)

PD-L1 status at baseline was available in 34 patients, 1 PD-L1 negative patient was NE according to RECIST

## Disease control achieved in patients with non-inflamed tumors at baseline

#### T cell excluded tumor



#### **Immune Desert**



10 of 14 patients with non-inflamed tumor immune status at baseline achieved disease control on combination treatment

DCR

Non-inflamed tumors	10 of 14 (71%)	
T cell excluded	5 (36%)	
Immune desert	5 (36%)	

Patients with non-inflamed tumor at baseline, generally unresponsive to CPI monotherapy, show disease control on the combination treatment

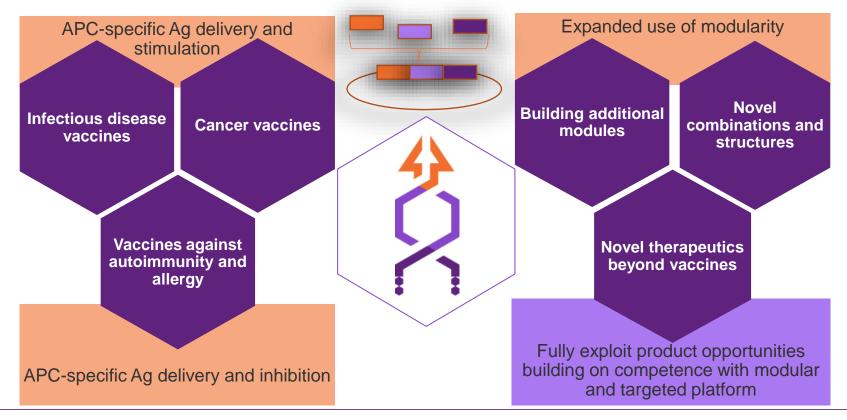
### VB C-02: Positive interim results from VB C-02 May 2022 Conclusions

- VB10.16 in combination with atezolizumab showed durable responses with a very high disease control rate (DCR) of 64% in heavily pre-treated advanced cervical cancer patients
- Anti-tumor efficacy was observed in both PD-L1 positive and negative patients, with 27% overall response rate (ORR) and 77% DCR in PD-L1 positive patients and 17% ORR and DCR 58% in PD-L1 negative patients
- DCR of 71% was observed in patients with non-inflamed tumors, including both immune desert and T cell excluded tumors
- HPV16-specific IFN-γ T cell responses were associated with clinical efficacy
- Complete clearance of HPV16 ctDNA was significantly correlated with clinical outcomes
- VB10.16 in combination with atezolizumab is well-tolerated and has a safety profile comparable to CPI monotherapy

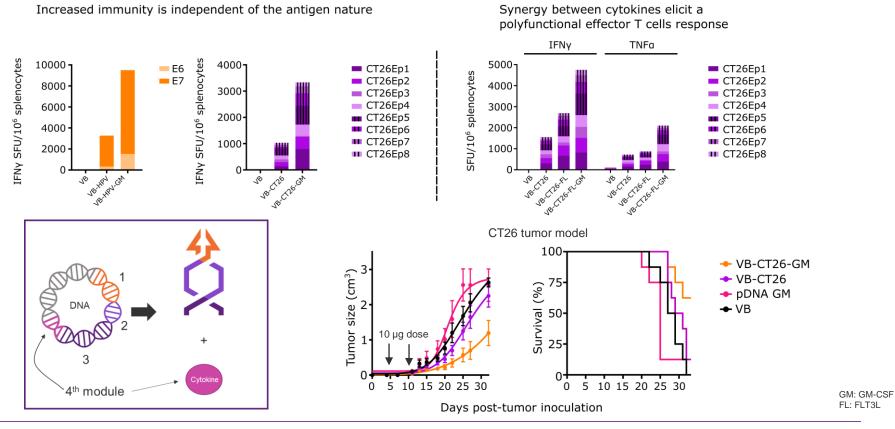
### The anti-tumor activity seen in the PD-L1 negative population may potentially open up for treatment of a new subset of patients

# Further platform potential

## Nykode's modular platform enables generation of multiple specific and innovative products

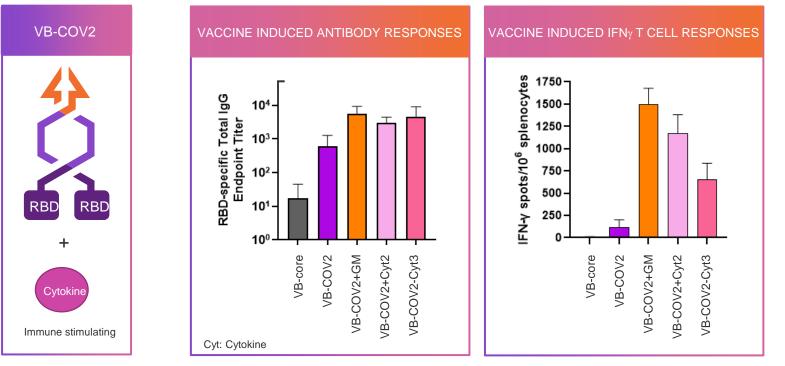


### Further platform improvement by adding a 4<sup>th</sup> module Adding gas pedal, brake and/or steering wheel



## 4<sup>th</sup> module also applicable for infectious diseases

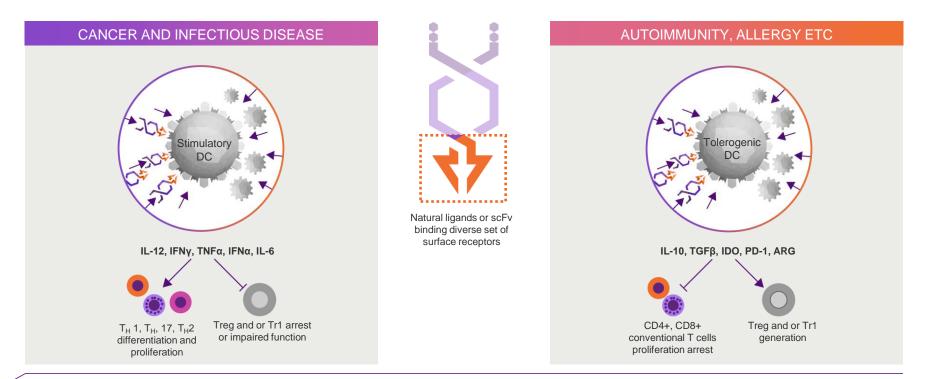
Different 4<sup>th</sup> modules boost both antibody and T cell responses



· Antibody responses were evaluated using end-point titer ELISA assay

T cell responses were evaluated using in ex vivo ELISpot detecting RBD specific peptides

## Targeting unit offers unique ability to explore Ag-specific immune tolerance



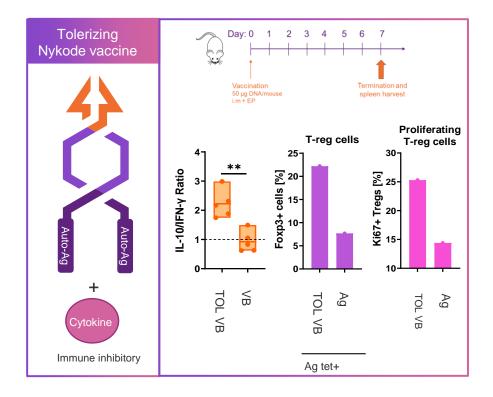
## APC-targeted technology and 4<sup>th</sup> module offers unique ability to induce Ag-specific immune tolerance

### **Tolerizing vaccine design**

- Targeting specific receptor on tolerizing antigen presenting cells
- 4<sup>th</sup> module immune inhibitory cytokine

### **Key results**

- Increase in the IL10 and IFN<sub>γ</sub> ratio compared to standard vaccibody
- Increase in Ag specific T regulatory cells
- Increase in T regulatory cell proliferation



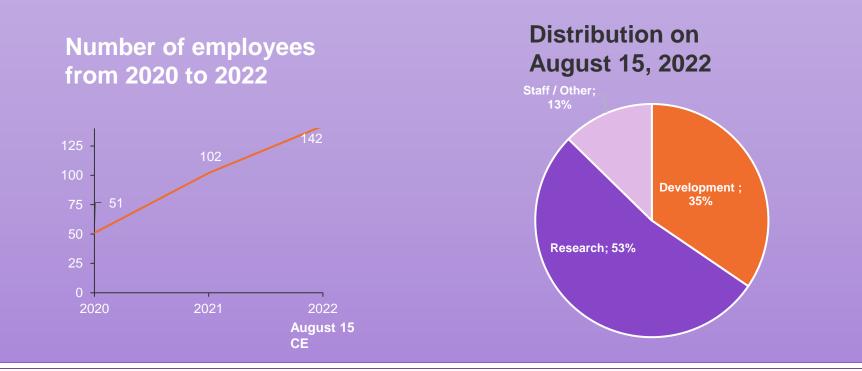
## Nykode is focusing on three strategic priorities

Rapidly advance existing assets through the clinic	<ul> <li>Clinical pipeline in multiple disease areas incl products with broad potential</li> <li>Promising clinical data from VB C-01, VB C-02 and VB N-01</li> <li>Favorable safety profile, correlation of immune responses and clinical efficacy</li> </ul>	
	<ul> <li>Modular Vaccibody technology for APC-targeted Ag delivery</li> </ul>	
Further leverage the technology platform to expand the pipeline	<ul> <li>•CCL3L1-targeted vaccines proven to induce broader CD8 T cell responses</li> <li>•Expansion of APC-targeted technology for antigen-specific immune tolerance</li> <li>•Next generation vaccine improvements further enhance and control responses</li> </ul>	
Seek strategic partnerships to compliment our strengths	<ul> <li>Out-licensing deals with potentially &gt; \$1.64B in payments + additional royalties</li> <li>Selected partnerships to access complimentary technologies</li> <li>In-licensing of antigen access and delivery devices, CPI supply etc</li> </ul>	

Well-positioned to drive future value creation through innovation and execution of the broad pipeline supported by a solid balance sheet and international partners

## Organization

## **Continued strong growth across the organization (current employees)**



## Strengthening the Nykode leadership team

 International experience from biotech and Big Pharma with extensive early and late stage drug development expertise

### **KLAUS EDVARDSEN**

### CHIEF DEVELOPMENT OFFICER

Extensive experience from leading drug development programs within oncology, hematology and infectious diseases in both biotech and pharma companies:

- CureVac (as CDO)
- Merck KGaA
- AstraZeneca



### LOUISE STUBBE

### CHIEF LEGAL OFFICER

More than a decade of life sciences industry experience from both private and listed companies. Experience from building and managing global legal departments.:

- KemPharm
- Orphazyme
- LEO Pharma



## Continuing the internationalization with two new industry experienced members

- International executive level
- Drug development and commercialization experience
- Extensive Biotech and Big Pharma experience

#### Elaine Sullivan

Currently, serves as:

- CEO of Keltic Pharma Therapeutics Ltd
- Various Non-executive directorships including Active Biotech AB, Open Orphan PLC and IP Group plc amongst others
- Former positions includes:
- CEO of Carrick Therapeutics, Ltd
- Eli Lilly and Company VP, Global External Research and Development
- AstraZeneca Plc VP and Head of New Opportunities Therapy Area; VP, Science and Technology





Currently serves as:

- Chairman of Aerami Therapeutics, Inc.
- Various other Non-executive directorships Former positions includes:
- Various CEO and Chairman positions
- Senior Vice PresidentSanofi President, Region Head for North America, Pharmaceuticals & Consumer Health
- GlaxoSmithKline –Senior Vice President and Business Unit Head, Cardiovascular, Metabolic and Urology; Senior Vice President, Global Leadership and Organization Development



## **Financials**

## Highlights



- Financially well positioned to grow and execute the Company's strategy over the next years
- Strong balance sheet with total liquidity<sup>1</sup> of \$223 mill at June 30, 2022

- Successful listing on the main list of Oslo Stock Exchange
  - First day of trading June 16, 2022
  - To facilitate greater liquidity in the shares and attract new potential shareholders in order to build a more diversified shareholder base
- Nykode continues to explore a potential listing on the Nasdaq Global Market in the United States

## **Income Statement**

Amounts in USD '000	Q2 2022	Q2 2021	YTD 2022	YTD 2021
Revenue from contracts with customers	3,114	1,607	3,830	2,054
Other income	309	291	617	625
Total revenue and other income	3,423	1,898	4,447	2,678
Employee benefit expenses	3,435	2,714	4,723	6,576
Other operating expenses	9,775	6,765	17,679	11,054
Depreciation	460	103	914	205
Operating profit (loss)	(10,246)	(7,684)	(18,869)	(15,156)
Finance income	1,695	379	2,358	595
Finance costs	2,372	272	2,969	1,242
Profit (loss) before tax	(10,923)	(7,577)	(19,480)	(15,803)
Income tax expense	(2,174)	(1,330)	(3,833)	(3,048)
Profit (loss) for the period	(8,749)	(6,246)	(15,647)	(12,754)

#### Revenue from contracts with customers

- R&D activities under Genentech and Regeneron agreements
- \$2.9m (2Q 2022) and \$3.4m (1H 2022) under Genentech agreement
- \$0.2m (2Q 2022) and \$0.4m (1H 2022) under Regeneron agreement

#### Other income

 Government grants from SkatteFUNN and Research Council of Norway

#### Employee benefit expenses

- · Continued increase in number of employees
- Decrease in 1H 2022 mainly due to decrease in social security costs on share-based payments

#### Other operating expenses

Increase in 2022 mainly due to increase in R&D activities

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

Mainly related to movements in foreign currency exchange rates

### **Balance Sheet**

Amounts in USD '000	30/06/2022	31/12/2021
ASSETS		
Non-current assets		
Property, plant and equipment	2,771	1,884
Right-of-use assets	6,698	7,281
Intangible assets	32	32
Other long-term receivables	456	501
Total non-current assets	9,957	9,698
Current assets		
Trade receivables	2,689	23,750
Other receivables	2,872	3,708
Other current financial assets	10,035	12,169
Cash and cash equivalents	213,279	216,231
Total current assets	228,875	255,858
TOTAL ASSETS	238,832	265,556

#### Cash and cash equivalents

Strong cash position of \$213.3m as per June 30, 2022

#### Other current financial assets

Liquid money market funds of \$10.0m as per June 30, 2022

#### Trade receivables

- Amounts invoiced under Genentech and Regeneron agreements
- \$20m milestone payment from Genentech invoiced 4Q 2021, received 1Q 2022.

### **Balance Sheet - contd.**

Amounts in USD '000	30/06/2022	31/12/2021
EQUITY AND LIABILITIES		
Equity		
Share capital	334	333
Share premium	82,314	81,526
Other capital reserves	9,682	7,863
Other components of equity	(3,056)	(3,122)
Retained earnings	91,808	107,455
Total equity	181,082	194,055
Non-current liabilities		
Non-current lease liabilities	4,798	5,819
Non-current provisions	360	4,915
Deferred tax liabilities	25,566	29,400
Total non-current liabilities	30,724	40,134
Current liabilities		
Government grants	168	219
Current lease liabilities	1,195	1,350
Trade and other payables	5,394	8,494
Current provisions	2,659	5,234
Current contract liabilities	17.611	16.044
Income tax payable	17,011	26
Total current liabilities	27,026	31,367
Total liabilities	57,750	71,501
	51,150	71,301
TOTAL EQUITY AND LIABILITIES	238,832	265,556

#### Equity

- Total equity of \$181.1m as per June 30, 2022
- Equity ratio of 76%

## **Upcoming Catalysts**

	2022 Key Priorities	Program	Indication	Partnerships	Milestones
Wholly-Owned Candidat	es				
Oncology	<ul> <li>Advance internal oncology programs including cervical cancer program</li> <li>Expand into additional indications for VB10.16, including head and neck cancer</li> </ul>	VB10.16 (off-the-shelf)	HPV16+ cervical cancer		<ul> <li>Present updated Phase 2 data (1H 2023)</li> <li>Provide updated development strategy</li> <li>Initiate Phase Ib trial in HNSCC</li> </ul>
		Internal programs	Undisclosed		
Infectious Disease	<ul> <li>Advance COVID-19 vaccines</li> <li>Expand into additional high- priority disease areas</li> </ul>	VB10.COV2	SARS-CoV-2	Adaptive	<ul> <li>Present Phase 1 key results measuring immune responses in previously vaccinated subjects (2H 2022)</li> </ul>
		Internal programs	Undisclosed		
Technology	Leverage technology platform				<ul> <li>Announce further preclinical data from Ag-specific immune tolerance platform</li> </ul>
Manufacturing	<ul> <li>Enhance control of manufacturing capacity and capability</li> </ul>				Provide update on manufacturing strategy

## UNLOCKING THE FUTURE OF MEDICINE

Contact: Agnete Fredriksen Chief Business Officer IR@vaccibody.com

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