nykode therapeutics

Q4 2023 Results Presentation

February 28, 2024

Forward-looking statement

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

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

Today’s presenters from Nykode management

International management team with solid drug development experience

MICHAEL ENGSIG

Chief Executive Officer

AGNETE FREDRIKSEN

Chief Business Officer & Co-founder

HARALD GURVIN

Chief Financial Officer

KLAUS EDVARDSEN

Chief Development Officer

Q4 2023 Highlights

- Expanded oncology pipeline with the addition of NYK011 aimed at preventing and treating colorectal cancer including Nykode's proprietary next generation technology
- Presented preclinical data demonstrating Nykode’s APC targeted technology yields superior immune response, whether delivered as DNA or mRNA
- Successful private placement of $45m
- Well-capitalized with a cash position of $162.6m at December 31, 2023

Post-period end:

- Presented additional preclinical data on the inverse vaccine platform, demonstrating long-term protection against diabetes following treatment withdrawal
- Opened enrollment for the next dose level of 6 mg in the VB-C-03 (VB10.16) following the successful safety run-in of the first dose level cohort

Private placement highlights

- Raised NOK 505 million ($45m)
- Offering significantly oversubscribed, demonstrating robust interest from international life-science specialist investors
- Use of Proceeds:
  - Advance VB10.16 clinical studies, including VB-C-05 in locally advanced cervical cancer
  - Expand the pipeline and accelerate R&D to enhance Nykode's platform and broaden into autoimmune diseases
  - Progress CMC (Chemistry, Manufacturing, and Controls) operations

Rich and diversified pipeline

	Asset	Indication	Rights	Preclinical	Phase 1	Phase 2	Phase 3	Upcoming Catalyst
Oncology								
Off-the-shelf	VB10.16	HPV16+ cervical cancer	nykode [1]				C-02, C-04	Initiate trial (Q1 2024)
		HPV16+ head and neck cancer	nykode [2]			C-03		Dose level recommendation (H2 2024)
		HPV16+ locally advanced cervical cancer	nykode [2]				C-05	Protocol in development
	Regeneron programs	Undisclosed	nykode REGENERON [3]					Selection of lead candidate
	NYK011	Colorectal: pre-cancerous polyps to cancer	nykode					Update (H2 2024)
Individua-lized	VB10.NEO	Melanoma, lung, bladder, renal, head and neck cancer; locally advanced and metastatic tumors	nykode Genentech [4]				N-01	
		Locally advanced and metastatic tumors	nykode Genentech [4]			N-02		
Infectious Disease								
Regeneron programs		Undisclosed	nykode REGENERON					
Autoimmune								
Internal		Undisclosed	nykode					Update (H1 2024)

1. Wholly-owned by Nykode. Potentially registrational. Roche supplies atezolizumab; 2. Wholly-owned by Nykode. Merck (MSD) supplies pembrolizumab; 3. Collaboration with Regeneron; 4. Genentech has an exclusive license to VB10.NEO.

R&D update

Nykode's proprietary technology platform allows APC-targeting to direct immune responses

DNA plasmid encoding Nykode vaccine

Targeting unit to attract and bind APCs

Ability to tailor the targeting unit enables induction of different immune response profiles to specific diseases[1]

Dimerization unit for crosslinking targeted receptors on the surface of the APC

To facilitate strong bivalent binding

Antigenic unit presents globular antigens or set of T cell epitopes

Antigens of choice from cancer, viruses, bacteria, parasites or autoimmune disease

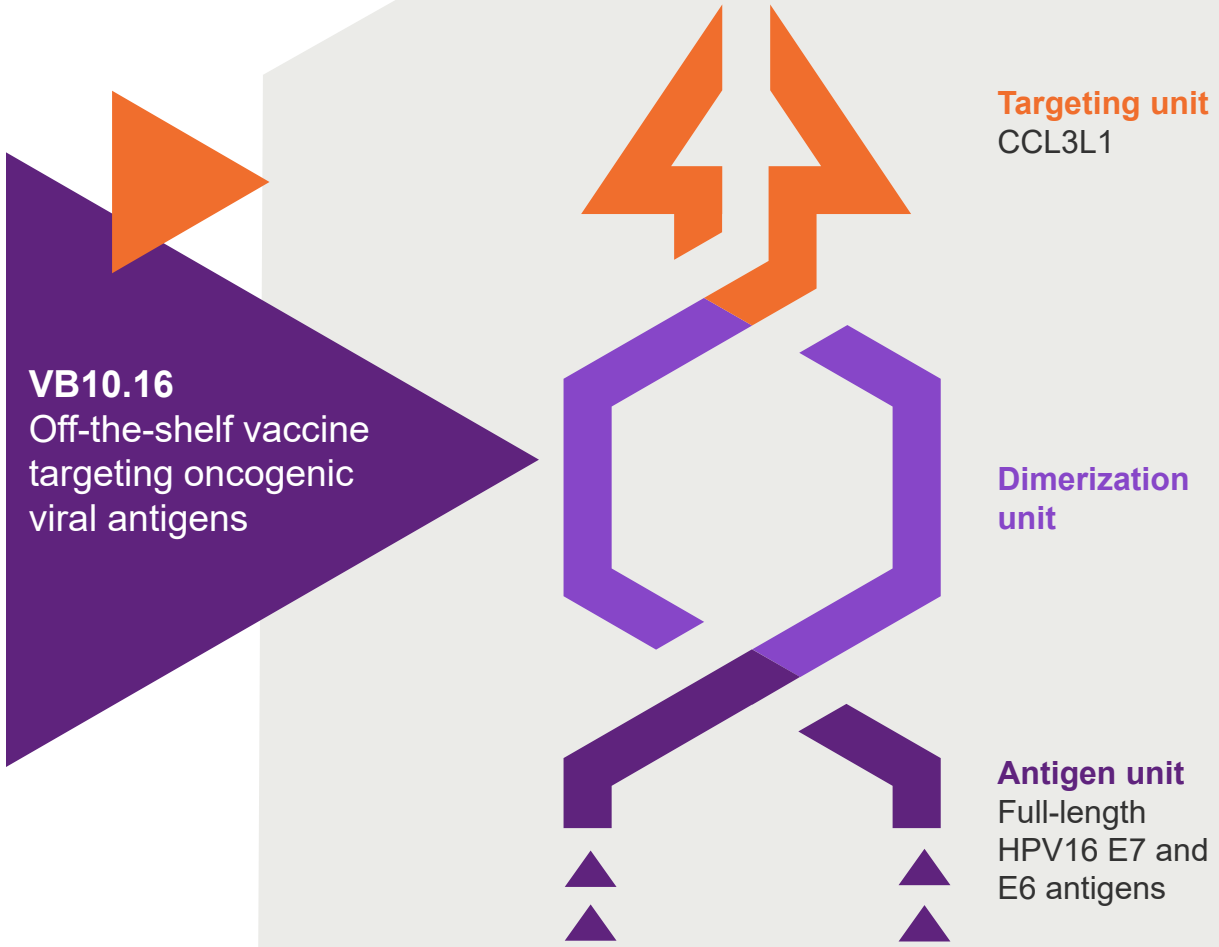
Nykode's immunotherapy candidates may be delivered through DNA, mRNA, viral vectors or as recombinant proteins

Note: [1] Targeting unit can consist of natural ligands, including cytokines/chemokines; bacterial proteins; antibody fragments

VB10.16: Therapeutic vaccine candidate for HPV16+ cancers

Off-the-shelf therapeutic cancer DNA vaccine against HPV16 induced malignancies

- HPV16 is the most prevalent oncogenic HPV strain
- Targeting the cancer-specific full-length HPV16 E7 and E6 antigens
- Promising Phase 2a data demonstrating strongly competitive efficacy vs. existing standards of care
- Wholly-owned by Nykode



VB10.16 C-02 data compare strongly to CPI monotherapy as well as expected SoC in ≥2L r/m cervical cancer

	VB10.16 plus atezolizumab in PD-L1+	CPI Monotherapy in r/m CC			
		Atezolizumab in PD-L1+†††	Pembrolizumab in PD-L1+**	Cemiplimab in PD-L1+ ††	Tisotumab vedotin (PD-L1 agnostic) ‡‡
Trial name	**C-02**	Skyscraper-04, atezolizumab arm	Keynote-158	Empower-Cervical 1, cemiplimab arm	InnovaTV 301, tisotumab vedotin arm
ORR	**29%**	16%	17%	18%	18%
mPFS	**6.3 mo**	1.9 mo	2.1 mo	3.0 mo	4.2 mo
mOS	**Not reached (25.0+ mo)**	10.6 mo	11.0 mo	13.9 mo	11.5 mo

Median OS not yet reached (last update August ‘23)

Notes: The data shown on this slide represents third-party clinical trials involving different trial designs and patient populations. These trials are not head-to-head evaluations of VB10.16 against standard of care

††† Salani et al. Efficacy and safety results from Skyscraper-04: An open-label randomized phase 2 trial of tiragolumab plus atezolizumab for PD-L1-positive recurrent cervical cancer. IGCS 2023.

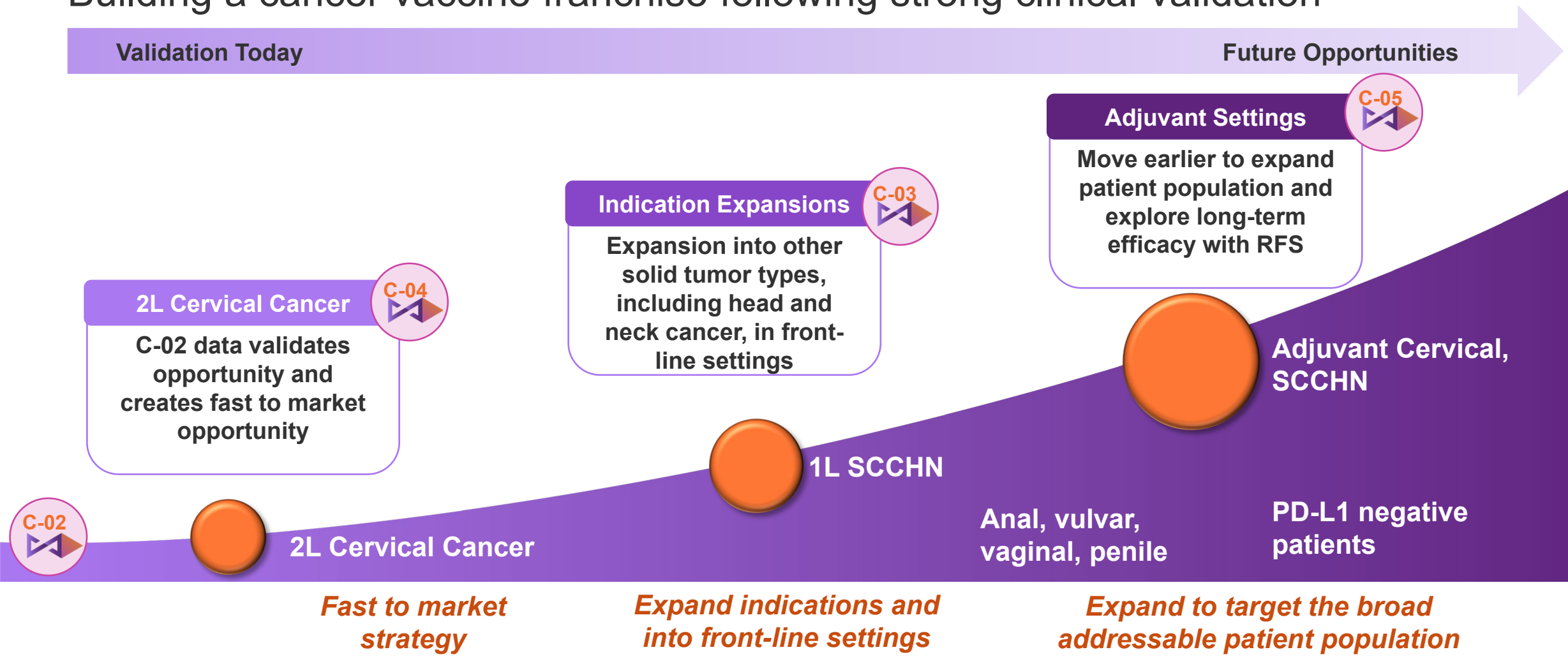
** Chung et al. Efficacy and safety of pembrolizumab in previously treated advanced cervical cancer: Results from the phase II KEYNOTE-158 study. J Clin Oncol 2019

†† Tewari et al. Survival with cemiplimab in recurrent cervical cancer. N Engl J Med 2022

‡‡ Confirmatory phase 3 RCT evaluating tisotumab vedotin vs. investigator’s choice chemotherapy (topotecane, vinorelbine, gemcitabine, irinotecan, or pemetrexed). Ignace Vergote: innovaTV 301/ENGOT-cx12/GOG-3057: A Global, Randomized, Open-Label, Phase 3 Study of Tisotumab Vedotin vs Investigator’s Choice of Chemotherapy in 2L or 3L Recurrent or Metastatic Cervical Cancer. ESMO 2023.

Maximizing addressable patient populations by diversifying offerings and broadening therapeutic scope

Building a cancer vaccine franchise following strong clinical validation



Creating a portfolio of targeted vaccines for HPV16+ cancers
VB10.16 portfolio

	C-02	C-03	C-04	C-05
Indication	r/m Cervical Cancer, ≥2L	r/m head and neck cancer (HNSCC), PD-L1+, 1L	r/m Cervical Cancer, PD-L1+, 2L	Locally Advanced Cervical Cancer (LACC)
Dose	3 mg in combination with atezolizumab (Tecentriq®)	Up to 9 mg in combination with pembrolizumab (Keytruda®[1])	9 mg in combination with atezolizumab (Tecentriq®)	TBD
Phase	2a	1/2a	2	2
Status	Finalized	Enrolling second dose level (6 mg); 11 out estimated 22 sites activated in 8 countries	Enrolment to start. Currently 36 US sites in process of activation	Protocol in development
Next catalyst(s)	Updated survival data Q1 2024	Recommended Ph2 dose for Part 2 in H2 2024	Initiate potentially registrational trial (U.S.) Q1 2024; finalize enrolment of Part 1 in Q4 2024	

VB10.16 is wholly owned by Nykode

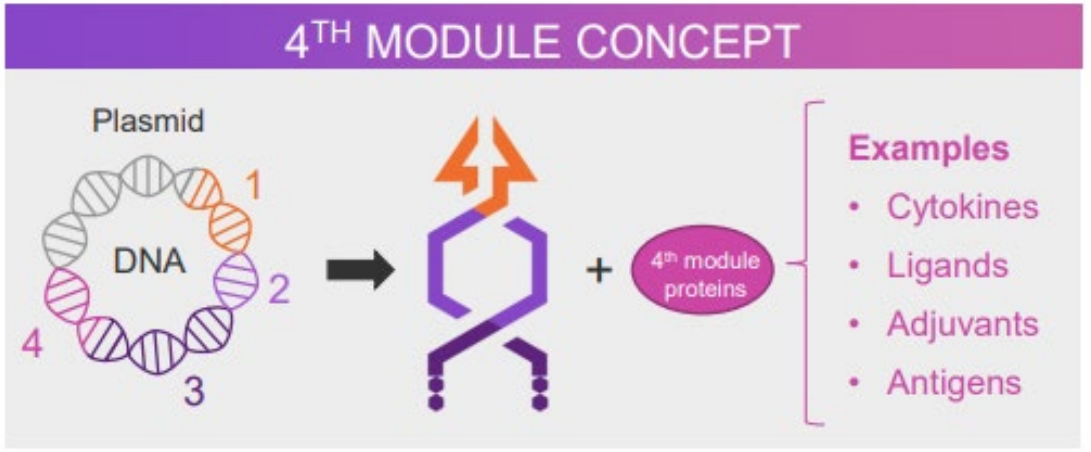
1. Note: KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

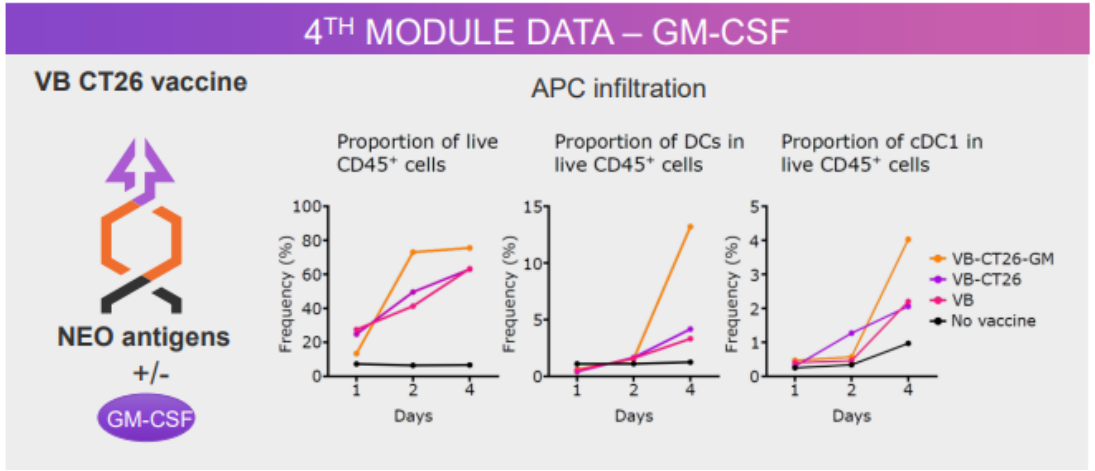
NYK011 aims at addressing patients ranging from high-risk pre-cancerous polyps to colorectal cancer

- Colorectal cancer develops from premalignant polyps on the colon or rectum's mucosal surface
- Disease development and screening programs represent an opportunity to identify and treat high-risk patients
- Nykode's latest pipeline expansion introduces a preclinical program aimed at targeting patient populations ranging from high-risk pre-cancerous colonic polyps to colorectal cancer
- In line with Company's strategic vision of a comprehensive cancer vaccine portfolio addressing all cancer stages

Potential first-in-class program including Nykode's 4th module 2nd generation technology

- NYK011 is a potential first-in-class oncology vaccine program based on careful selection and novel combination of tumor-associated antigens (TAA)
- Leverages Nykode's expertise to elicit strong and broad CD8 T cell responses by targeting antigens to APC, capable of breaking tolerance against TAA's
- Incorporates Nykode's 4th module 2nd generation technology to further improve and customize the immune responses





Note: GM-CSF data illustrative; does not reflect construct of NYK011

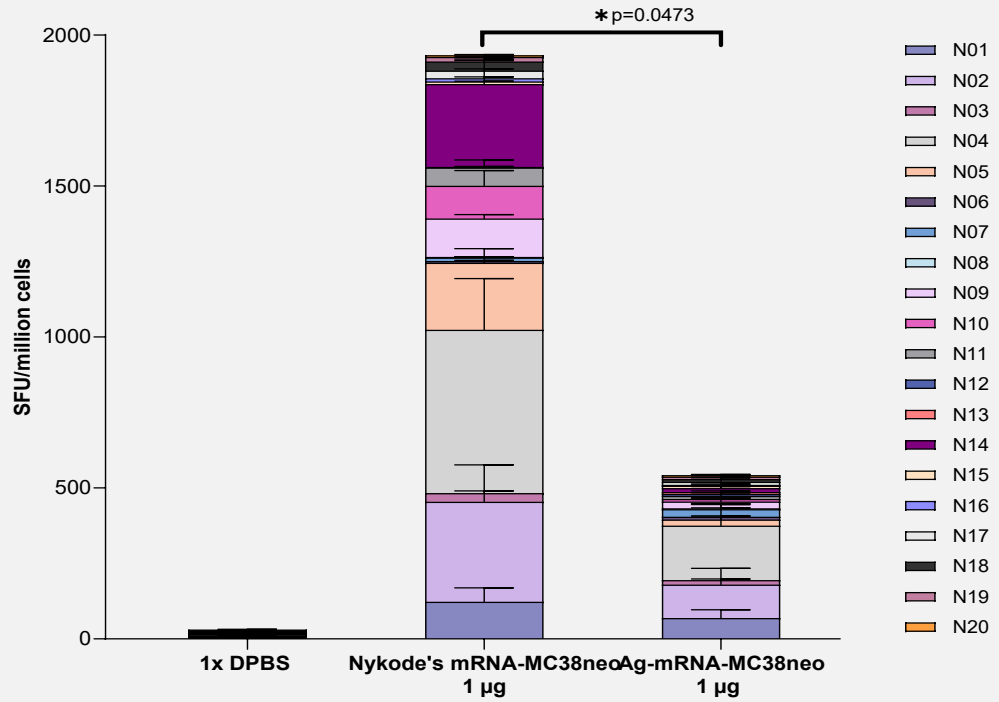
Nykode's APC targeting technology can leverage mRNA vaccines and presents opportunity for platform expansion

- Targeted delivery via APCs using Nykode's technology has been shown to induce broader and stronger CD8+ immune responses vs. existing 'antigen-alone' approaches.
- Preclinical studies have demonstrated that Nykode's APC-targeted vaccines delivered as mRNA improves the number of immunogenic antigens vs. 'antigen-alone' approaches
- The potential to leverage Nykode's APC targeted approach across vectors and formulations into an expanding range of indications presents a significant growth opportunity for Nykode's broad oncology platform

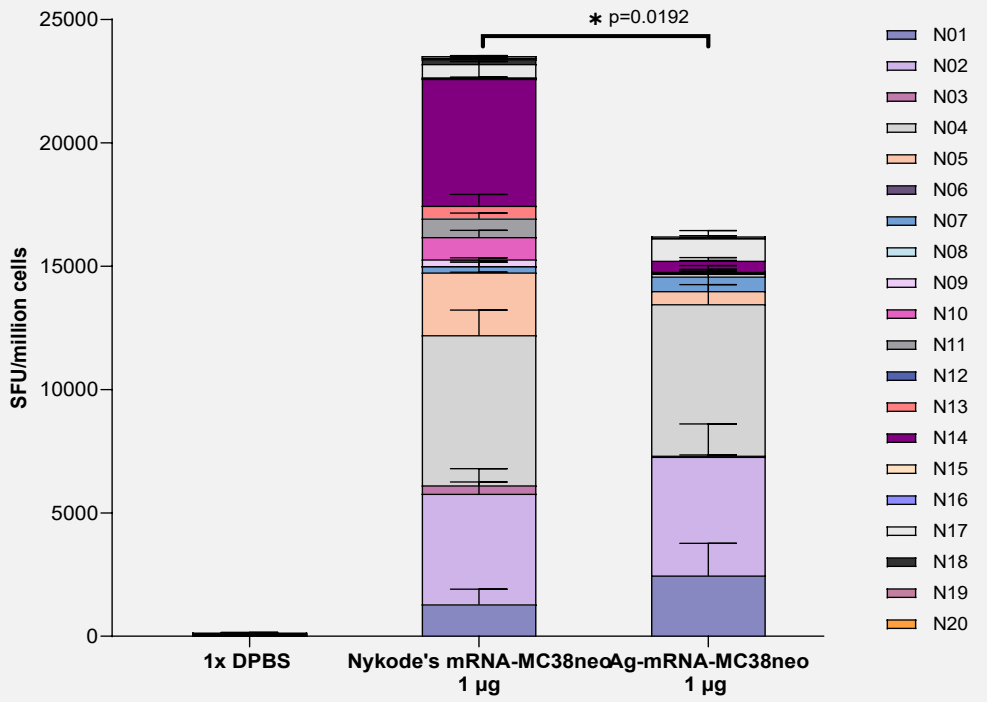
Superior immunogenicity using Nykode's APC-targeted mRNA-LNP vaccines

Stronger T cell responses to a wider variety of T cell epitopes

Prime vaccination only (D14)



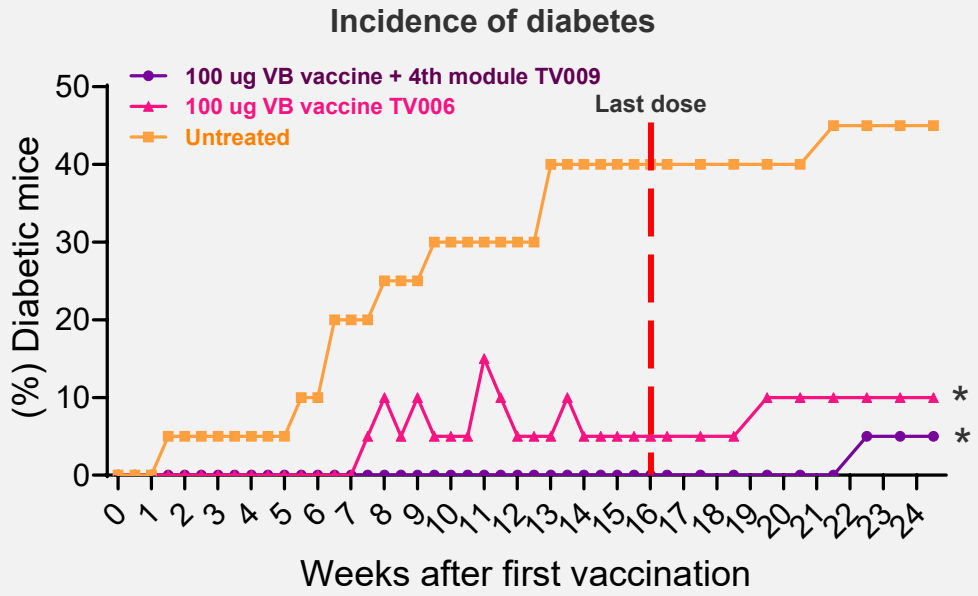
Prime + boost vaccination (D28)



DNA vaccination with Vaccibody induces long-lasting efficacy post treatment in a diabetes model

NOD DIABETES MODEL (ONGOING STUDY)

Diabetes antigen: PPI



PPI antigen alone is not protective in this model. Grönholm J et al.,2017, Pagni PP et al (2022), Pham MN et al, 2016, Daniel C et al. 2011

Q4 2023
Financial Results

Income Statement

Amounts in USD '000	Q4 2023	Q4 2022	FY 2023	FY 2022
Revenue from contracts with customers	2,191	2,690	12,902	7,168
Other income	89	610	421	1,861
Total revenue and other income	**2,280**	**3,300**	**13,323**	**9,029**
Employee benefit expenses	8,892	7,427	27,482	18,047
Other operating expenses	9,970	9,815	41,801	42,325
Depreciation	568	441	2,122	1,813
Operating profit (loss)	**(17,150)**	**(14,382)**	**(58,082)**	**(53,156)**
Finance income	9,272	3,146	18,674	8,637
Finance costs	1,580	1,070	4,678	6,464
Profit (loss) before tax	**(9,458)**	**(12,307)**	**(44,086)**	**(50,983)**
Income tax expense	(4,120)	(101)	(8,932)	(8,240)
Profit (loss) for the period	**(5,338)**	**(12,206)**	**(35,154)**	**(42,743)**

Revenue from contracts with customers

- R&D activities under Genentech and Regeneron agreements
- $2.0m (Q4 2023) and $12.0m (FY 2023) under Genentech agreement
- $0.2m (Q4 2023) and $0.9m (FY 2023) under Regeneron agreement

Other income

- Government grants from SkatteFUNN and Research Council of Norway

Employee benefit expenses

- Increase due to growth in organization
- FY 2022 includes $8.0m reduction in social security cost accrual for share based payments

Other operating expenses

- Decrease for FY 2023 mainly due to recognition of a non-recurring cost of $6.3m in 2022

Finance income

- Increase in 2023 mainly due to increased interest income and USD/NOK exchange rate movements

Balance Sheet

Amounts in USD '000	31/12/2023	31/12/2022
ASSETS		
Non-current assets		
Property, plant and equipment	4,413	3,517
Right-of-use assets	6,104	6,009
Intangible assets	70	32
Other non-current receivables	31,923	46
Total non-current assets	**42,510**	**9,604**
Current assets		
Trade receivables	-	2,544
Other receivables	3,073	2,943
Cash and cash equivalents	162,602	206,386
Total current assets	**165,675**	**211,873**
TOTAL ASSETS	**208,185**	**221,477**

Cash and cash equivalents

- Strong cash position of $162.6m at December 31, 2023

Other non-current receivables

- Increase due to payment to Norwegian Tax Authorities (NTA) in the fourth quarter following the decision by the NTA on the tax treatment of upfront payments received under a license agreement entered into in 2020
- Nykode has appealed the decision

Trade receivables

- Reduction due to receipt of $2.5m milestone under Genentech agreement in Q1 2023

Balance Sheet - contd.

Amounts in USD ’000	31/12/2023	31/12/2022
EQUITY AND LIABILITIES		
Equity		
Share capital	367	338
Share premium	128,986	83,318
Other capital reserves	15,395	11,694
Other components of equity	(3,048)	(3,044)
Retained earnings	29,559	64,713
Total equity	**171,259**	**157,018**
Non-current liabilities		
Non-current lease liabilities	4,269	4,365
Non-current provisions	2	30
Deferred tax liabilities	12,047	21,079
Total non-current liabilities	**16,318**	**25,474**
Current liabilities		
Government grants	104	133
Current lease liabilities	1,457	1,147
Trade and other payables	7,064	10,175
Current provisions	3,750	7,714
Current contract liabilities	8,233	19,736
Income tax payable	-	80
Total current liabilities	**20,608**	**38,985**
Total liabilities	**36,926**	**64,459**
TOTAL EQUITY AND LIABILITIES	**208,185**	**221,477**

Equity

- Total equity of $171m as per December 31, 2023
- Equity ratio of 82%

Contract liabilities

- Payments received/due for services not rendered under the Genentech agreement
- Invoicing follows milestone payments
- Revenues recognized as services are delivered
- Contract liability of $8.2m per December 31, 2023, down from $19.7m per December 31, 2022, in line with revenues recognized

Upcoming milestones

Oncology	Q1 '24	**VB10.16 Cervical Cancer**	Initiate potentially registrational VB-C-04 trial in the U.S. in patients with recurrent/metastatic disease and PD-L1 positive tumors
Oncology	Q1 '24	**VB10.16 Cervical Cancer**	Updated survival data from VB-C-02 Phase 2 trial
Oncology	H2 '24	**VB10.16 Head and Neck Cancer**	Recommended Phase 2 dose for Part 2 of the VB-C-03 trial in PD-L1+ patients with 1st line recurrent/metastatic advanced head and neck cancer
Oncology	Q4 '24	**VB10.16 Cervical Cancer**	Finalized enrollment for Part 1 of the VB-C-04 trial
Oncology	H2 '24	**NYK011 CRC**	Update on preclinical oncology vaccine program
Auto-immune	H1 '24	**Autoimmunity and Allergy**	Update on Nykode's inverse vaccine technology platform
Other	H1 '24	**Platform**	Update on Nykode's APC targeted vaccine technology delivered by mRNA

Note: The news flow from the collaboration with Genentech and Regeneron is at their discretion, respectively

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