nykode therapeutics

Q1 2024 Results Presentation

May 14, 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 Scientific Officer & Business Development

HARALD GURVIN

Chief Financial Officer

KLAUS EDVARDSEN

Chief Research & Development Officer

Q1 2024 Highlights

- Presented top line conclusions from the updated analysis from the Phase 2 VB-C-02 trial in advanced cervical cancer, affirming prolonged benefits and indicating a synergistic treatment effect of VB10.16 and atezolizumab (Tecentriq®).

- Announced advances in the inverse vaccine platform, showing promising results in treating autoimmune diseases and underscoring the platform's potential.

- Presented additional preclinical data on the inverse vaccine platform, demonstrating long-term protection against diabetes following treatment withdrawal.

Post-period end Highlights

- Initiated Phase 2 VB-C-04 trial in second line HPV16-positive cervical cancer in patients with HPV16-positive, PD-L1-positive, recurrent, or metastatic cervical cancer.
- Concluded enrollment of the 6 mg cohort in the VB-C-03 (VB10.16) trial in first-line head and neck cancer patients.
- Presented new preclinical data from our collaboration with Genentech, focusing on the differentiation of our proprietary vaccine technology.
- Announced clinical collaboration with MSD to evaluate VB10.16 in combination with KEYTRUDA® (pembrolizumab) in patients with HPV16-positive high-risk locally advanced cervical cancer

Broad pipeline targeting early to late-stage cancer treatment

	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	Finalize enrolment Pt 1 (Q4 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	
		Incurable 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

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+ *(analysis from April 2023*)*	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

**Updated analysis (March 2024) closely mirrors previously reported positive outcome.*

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.

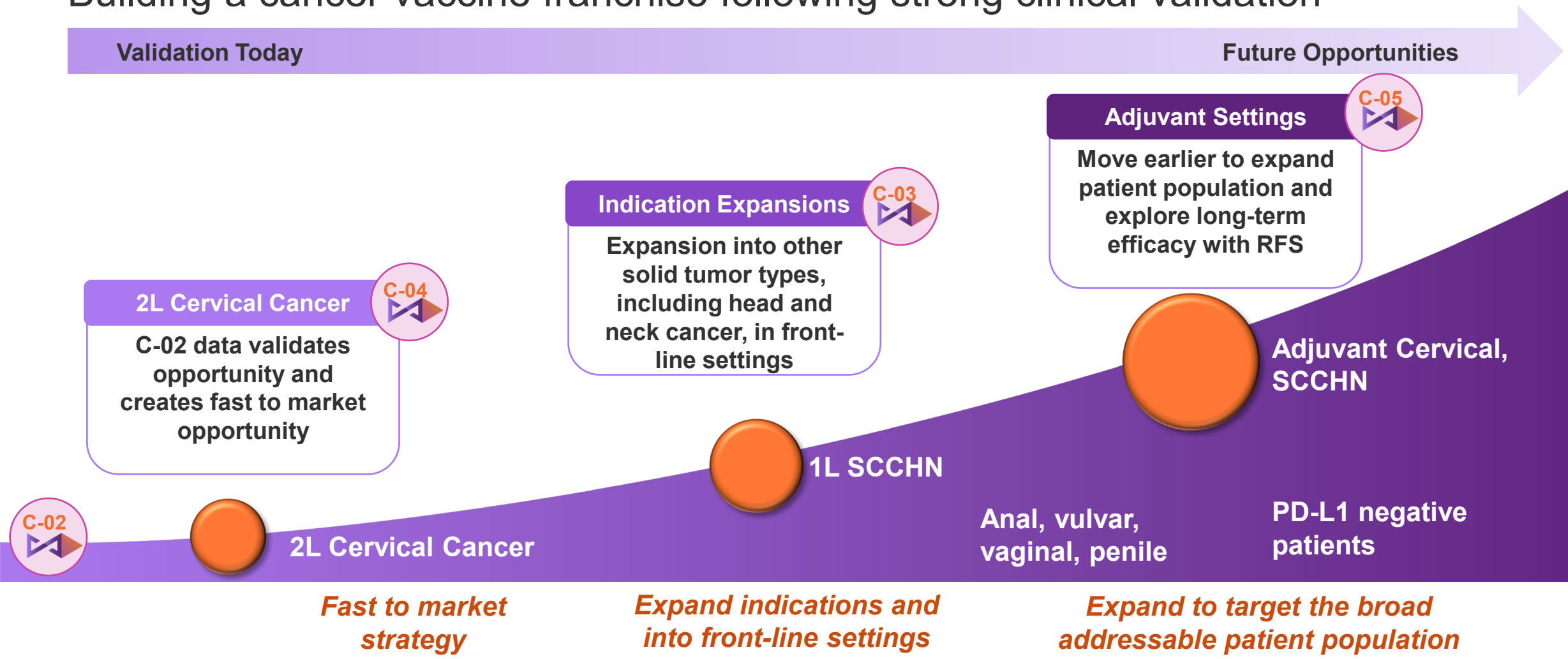
** Chung et al. Efficacy and safety of pembrolizumab in previously treated advanced cervical cancer: Results from the phase II KEYNOTE-158 study. J Clin Oncol 2019

†† 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



VB10.NEO Individualized cancer immunotherapy

VB10.NEO Key Differentiators

Solid manufacturing chain

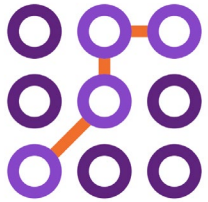
- ✓ 100% successful vaccine production
- ✓ Robust supply chain

Safety

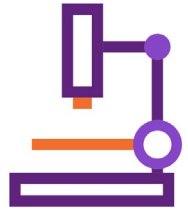
- ✓ Safety profile similar to checkpoint inhibitor monotherapy
- ✓ No increase in immune-related adverse events

NeoSELECT

- ✓ High fraction of immunogenic neoantigens
- ✓ Strong ability to select neoantigens across different tumor entities



Immune response



- ✓ Induces broad and strong T cell responses
- ✓ Long-lived and persistent immune responses

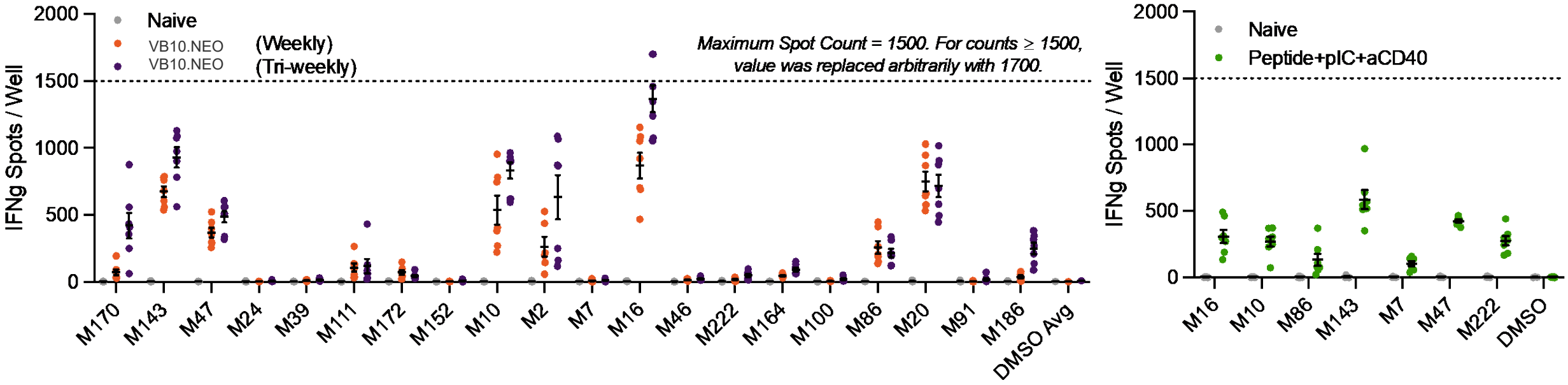
Strong partnership

- ✓ Validated technology
- ✓ Unique targeting module

Competitive player

- ✓ Well-tolerated across trials and in different combinations
- ✓ Within the validated field of personalized vaccines

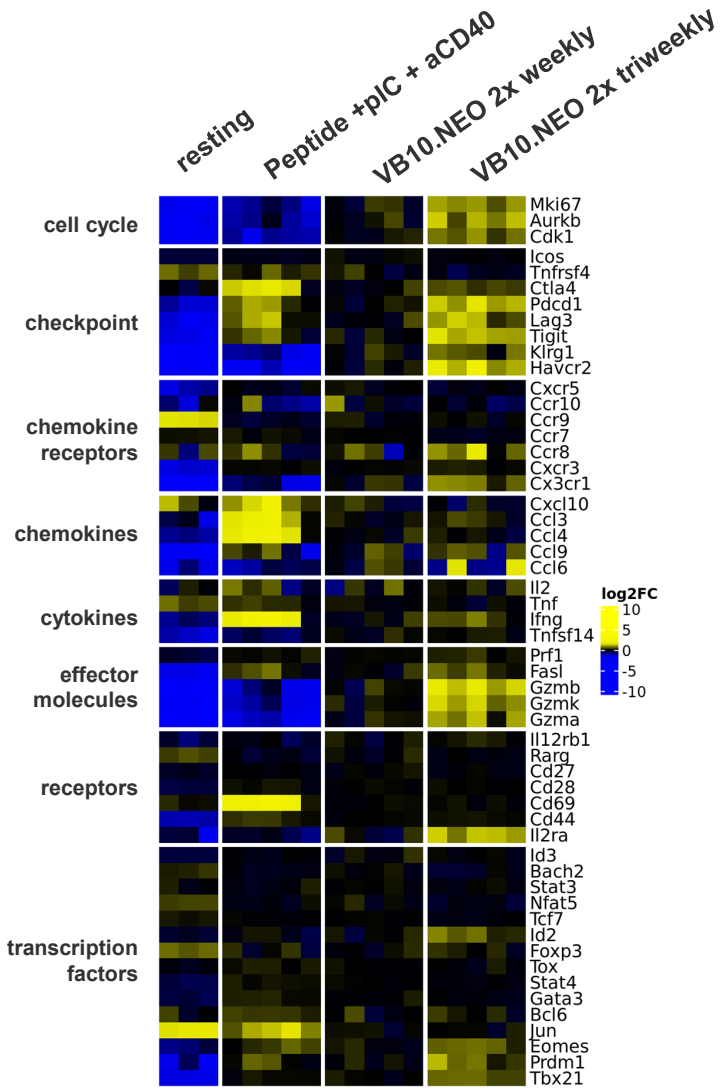
APC-targeted DNA vaccine induces a broader and stronger T cell response than peptide vaccines



The magnitude of the T cell responses are optimal with triweekly vaccination interval

Genentech
A Member of the Roche Group

APC targeted vaccine induce potentiated CD8 T cell phenotypes



- Prominent increased expression of cell cycle, checkpoint and effector genes with VB10.NEO compared to peptide + adjuvant vaccines
- CD8 T cell transcription factor profile consistent with higher differentiation towards effector/effector memory phenotypes
- Tri-weekly dosing regimen is optimal inducing increased expression of activation and effector genes
- Pathway enrichment suggest that tri-weekly regimen potentially enhances immune responses, cell differentiation, proliferation, cell signaling and metabolic processes, promoting a stronger and more effective immune response

Genentech
A Member of the Roche Group

Nykode's platform potential further supported by recent experience with VB10.NEO

- VB10.NEO is able to induce a broad and CD8 dominating T cell response both as pDNA and mRNA vaccines
- VB10.NEO induces a T cell profile consistent with higher differentiation towards effector/effector memory phenotypes
- Dosing regiment (tri-weekly versus weekly) dosing is important for obtaining the strongest and most effective immune response

Autoimmunity platform update

Why Tolerance

Competition

- ✓ Limited competition within antigen specific tolerance

Opportunities

- ✓ Autoimmune disease
- ✓ Allergies
- ✓ Organ transplantation

Partnership opportunities

- ✓ New platform allows product specific collaborations
- ✓ Early interest from potential Pharma partners

Tolerance Highlights

Medical Need

- ✓ High unmet medical need areas
- ✓ Existing therapies are broadly immune suppressive

Preclinical data

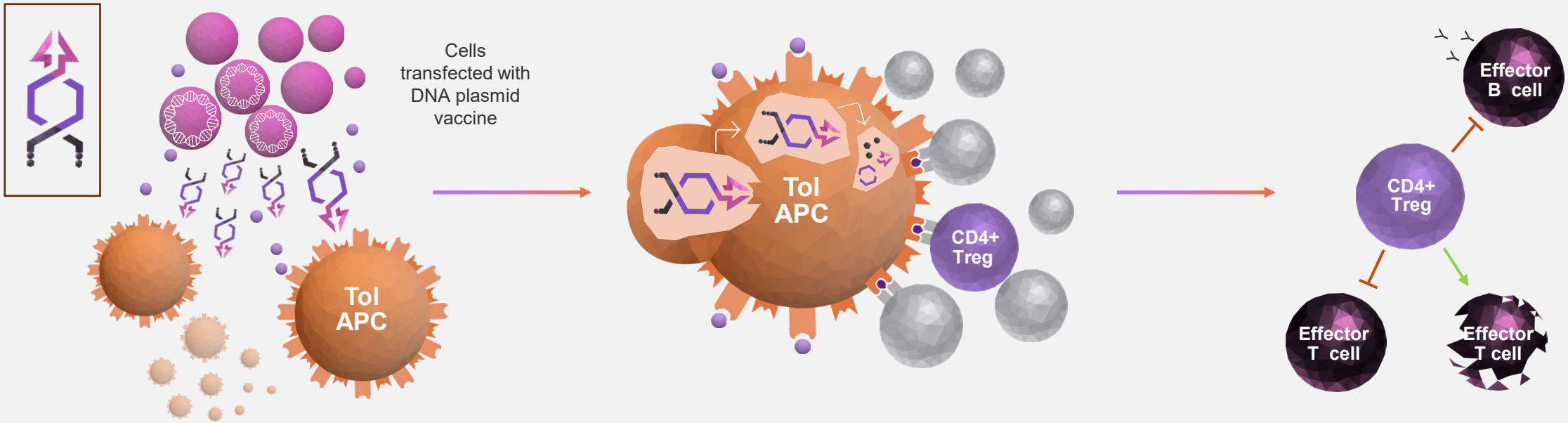
- ✓ Multiple exploratory vaccines designed successfully
- ✓ Positive data in autoimmune disease models of multiple sclerosis and type 1 diabetes

Platform fit

- ✓ Nykode APC targeted platform uniquely positioned to target antigens to tolerizing DCs
- ✓ Addition of immune-inhibitory cytokines (4th module)

Induction of antigen specific tolerance can be achieved by targeting disease causing epitopes to tolerogenic APCs

MECHANISM OF ACTION – TOLERANCE INDUCTION (INVERSE VACCINATION)

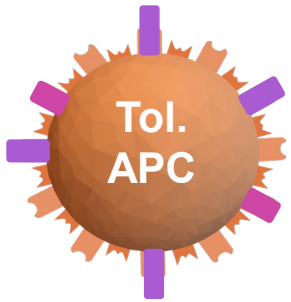


1 Cells encode and secrete Tol APC-targeted Vaccibody proteins together with immunosuppressive molecules/modulators to enhance tolerogenic APC function.

2 The Tol APCs present vaccine antigens in a tolerogenic milieu supported by the vaccine co-encoded suppressive molecules, and prime regulatory T cell (Treg) activation and expansion.

3 The Tregs inhibit or delete disease-specific effector T cells and inhibit effector B cells

APC targeting is required for effective disease protection



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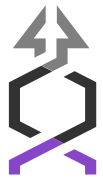

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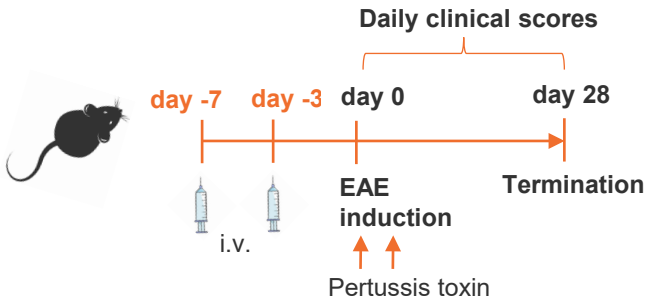
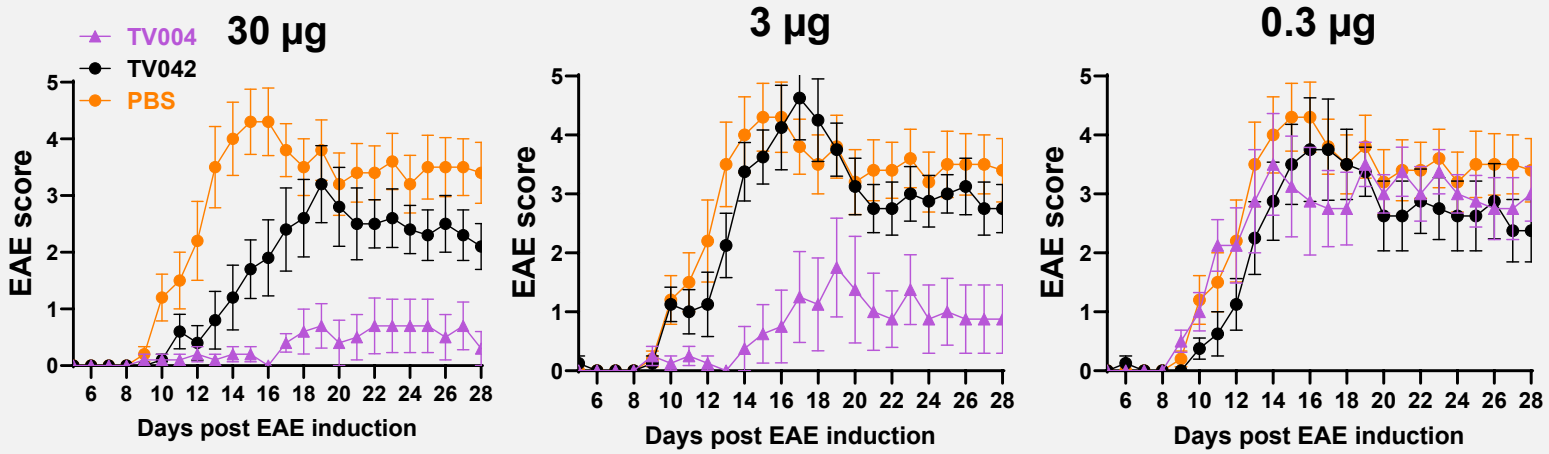
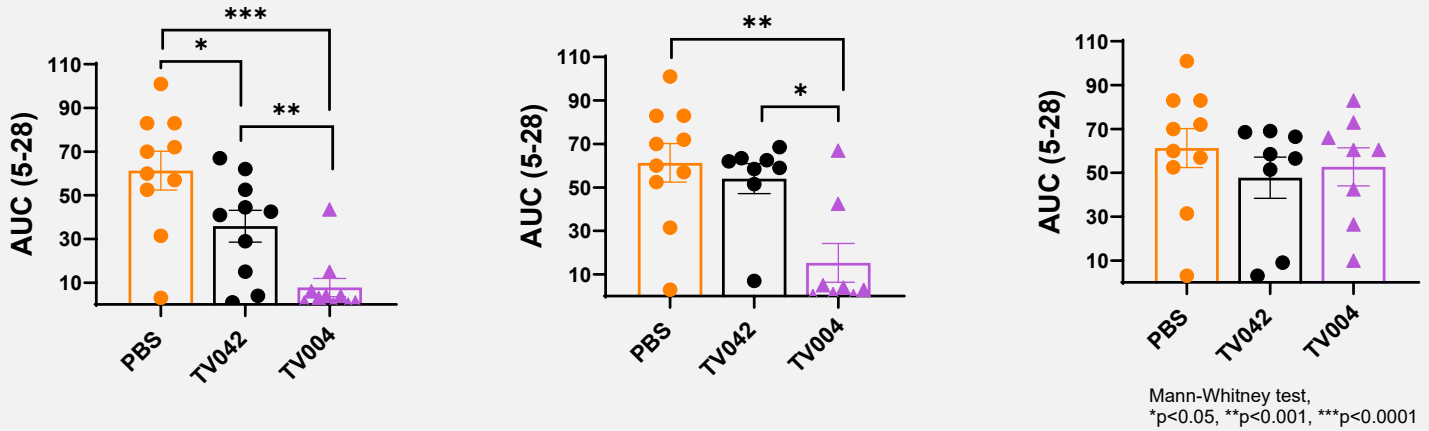
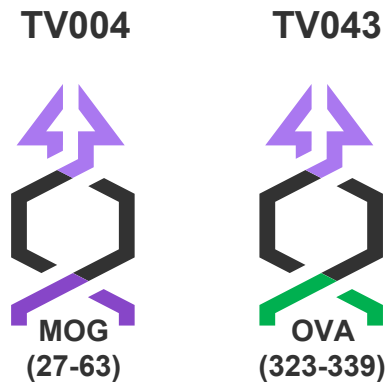


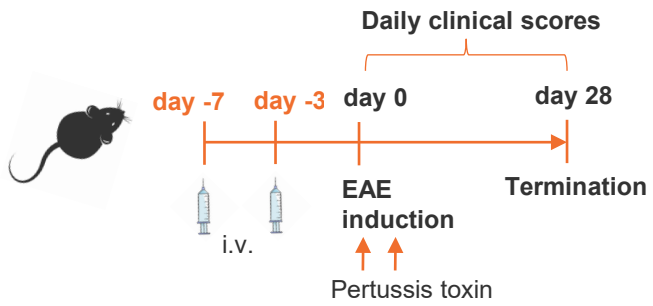
EAE MODEL



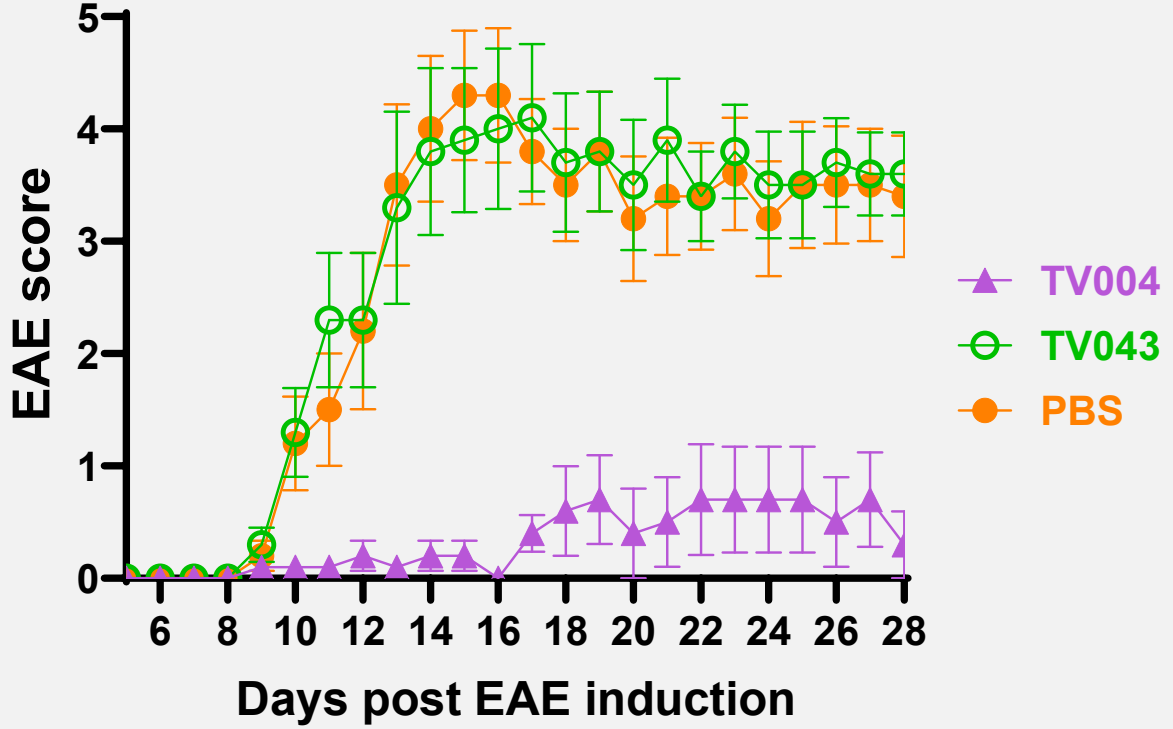


Vaccibody delivers Ag-specific suppression of EAE

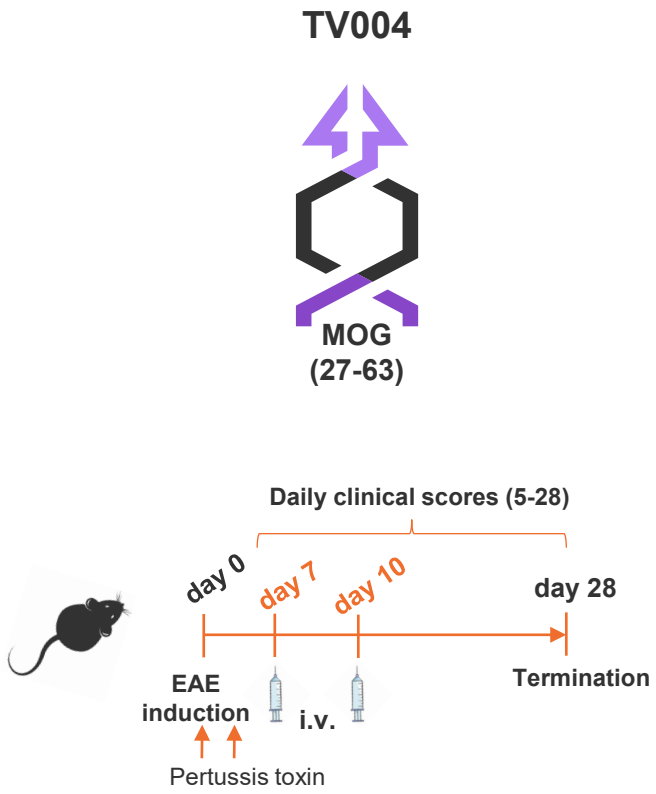




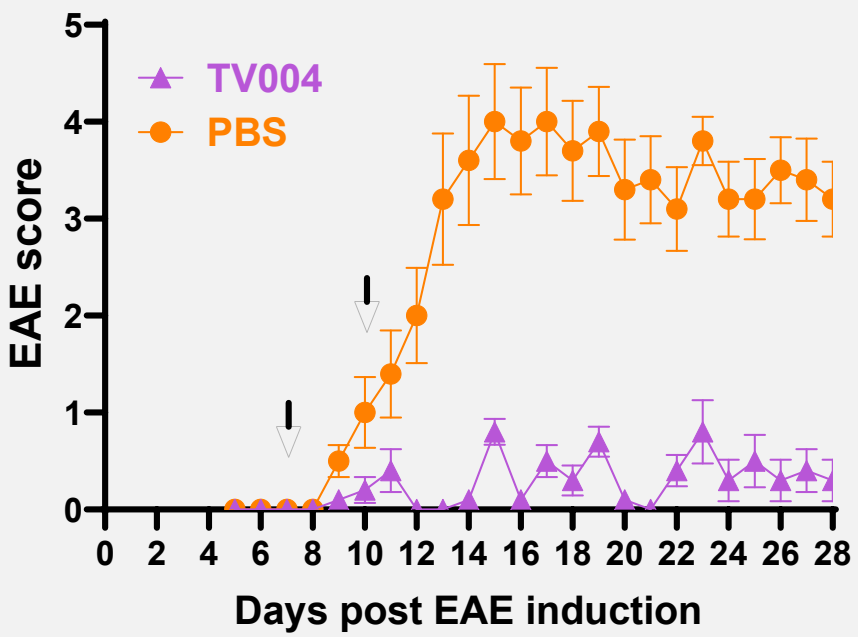
EAE MODEL – OVA CONTROL

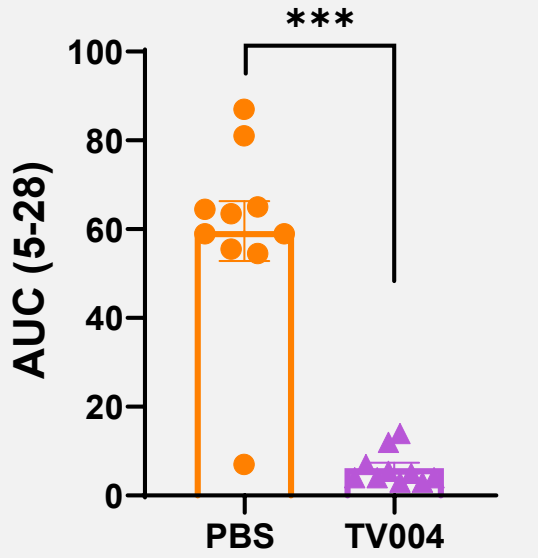


Vaccibody vaccine prevents EAE disease in an early therapeutic setting



EAE MODEL – EARLY THERAPEUTIC DELIVERY



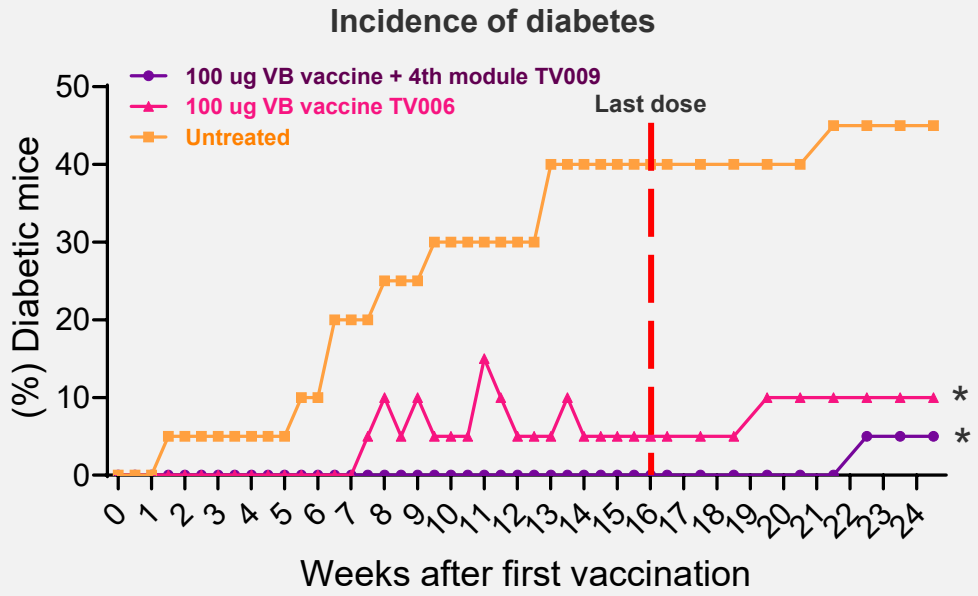


Mann-Whitney test, ***p<0.0001

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

Recent Autoimmunity Results Supports the Potency in Nykode's APC-targeted platform

DIABETES MODEL:

- DNA vaccination with Vaccibody targeting tolerizing APCs show potent prevention of diabetes in NOD mice
- Co-expression of selected immune-modulatory cytokines protects all mice from diabetes with durable response post treatment withdrawal

EAE MODEL:

- Recombinant Vaccibody vaccines deliver potent EAE disease amelioration in a preventive and early therapeutic setting
- The Vaccibody vaccine effects were dose-dependent, antigen-specific,
  driven by selective APC receptor targeting and reproducable with different targeting units.

These data demonstrate the flexibility of Nykode's APC targeted platform and its ability to deliver potent tolerizing responses in different models of autoimmune disease

Q1 2024
Financial Results

Income Statement

Amounts in USD '000	Q1 2024	Q1 2023	FY 2023
Revenue from contracts with customers	827	3,126	12,902
Other income	189	181	421
Total revenue and other income	**1,016**	**3,307**	**13,323**
Employee benefit expenses	8,822	6,657	27,482
Other operating expenses	7,228	10,867	41,801
Depreciation	570	465	2,122
Operating profit (loss)	**(15,604)**	**(14,682)**	**(58,082)**
Finance income	2,245	3,308	18,674
Finance costs	3,089	618	4,678
Profit (loss) before tax	**(16,448)**	**(11,992)**	**(44,086)**
Income tax expense	(1,504)	(1,631)	(8,932)
Profit (loss) for the period	**(14,944)**	**(10,361)**	**(35,154)**

Revenue from contracts with customers

- R&D activities under Genentech and Regeneron agreements
- $0.7m (Q1 2024) and $2.5m (Q1 2023) under Genentech agreement
- $0.1m (Q1 2024) and $0.6m (Q1 2023) under Regeneron agreement

Other income

- Government grants from SkatteFUNN and Research Council of Norway

Employee benefit expenses

- Increase due to growth in organization

Finance income/costs

- Mainly interest income and unrealized currency loss

Balance Sheet

Amounts in USD '000	31/03/2024	31/12/2023
ASSETS		
Non-current assets		
Property, plant and equipment	4,242	4,413
Right-of-use assets	5,686	6,104
Intangible assets	68	70
Other non-current receivables	30,063	31,923
Total non-current assets	**40,059**	**42,510**
Current assets		
Trade receivables	220	-
Other receivables	4,316	3,073
Cash and cash equivalents	147,296	162,602
Total current assets	**151,832**	**165,675**
TOTAL ASSETS	**191,891**	**208,185**

Cash and cash equivalents

- Strong cash position of $147.3m at March 31, 2024

Other non-current receivables

- Mainly reflects the NOK 325 million payment to the Norwegian Tax Authorities (NTA) in the fourth quarter of 2023 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 to the Norwegian Tax Administration (Norw: Skatteklagenemda)
- Receivable is in NOK and USD equivalent will fluctuate with exchange rate movements

Balance Sheet - contd.

Amounts in USD ’000	31/03/2024	31/12/2023
EQUITY AND LIABILITIES		
Equity		
Share capital	367	367
Share premium	128,986	128,986
Other capital reserves	17,298	15,395
Other components of equity	(3,046)	(3,048)
Retained earnings	15,115	29,559
Total equity	**158,720**	**171,259**
Non-current liabilities		
Non-current lease liabilities	3,744	4,269
Non-current provisions	1	2
Other non-current liabilities	864	-
Deferred tax liabilities	10,543	12,047
Total non-current liabilities	**15,152**	**16,318**
Current liabilities		
Government grants	98	104
Current lease liabilities	1,387	1,457
Trade and other payables	3,993	7,064
Current provisions	4,794	3,750
Current contract liabilities	7,747	8,233
Income tax payable	-	-
Total current liabilities	**18,019**	**20,608**
Total liabilities	**33,171**	**36,926**
TOTAL EQUITY AND LIABILITIES	**191,891**	**208,185**

Equity

- Total equity of $158.7m as per March 31, 2024
- Equity ratio of 83%

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 $7.7m per March 31, 2024, down from $8.2m per December 31, 2023, in line with revenues recognized

Upcoming milestones

Oncology	Q1 '24		**VB10.16 Cervical Cancer**	Updated survival data from VB-C-02 Phase 2 trial
Oncology	Q2 '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	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

UNLOCKING THE FUTURE OF MEDICINE

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