nykode therapeutics

# Q2 2023 Results Presentation

**August 23, 2023**

# 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

Takeda

NYCOMED

PPD

KLIFO

**AGNETE FREDRIKSEN**

Chief Business Officer & Co-founder

Affitech

Medinnova

**HARALD GURVIN**

Chief Financial Officer

SFL

FLEX LNG

# Q2 2023 highlights

- Positive final results from Phase 2 trial of VB10.16 in advanced cervical cancer
- Expansion of the clinical collaboration with Roche combining VB10.16 with atezolizumab in the potentially registrational trial, C-04, in advanced cervical cancer
- Well-capitalized with a cash position of $174m at June 30, 2023

**Post period update**:

- Approval from competent authorities in all eight European countries for the VB-C-03 trial with VB10.16 in combination with KEYTRUDA®[1] (pembrolizumab) in PD-L1 positive 1st line head and neck cancer
- Safety clearance of the 9 mg dose of VB10.NEO in the VB-N-02 trial, with no safety concerns and no dose-limiting toxicities observed
- Henrik Søndergaard hired to lead the dedicated Autoimmune research group

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

# 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] | | | | | Initiate trial (Q4 2023) |
| | | HPV16+ head and neck cancer | nykode [2] | | | | | FPFD (Q3 2023) |
| | Regeneron programs | Undisclosed | nykode REGENERON [3] | | | | | |
| | Internal | Undisclosed | nykode | | | | | Update (Q4 2023) |
| Individua-lized | VB10.NEO | Melanoma, lung, bladder, renal, head and neck cancer; locally advanced and metastatic tumors | nykode Genentech [4] | | | | | |
| | | Locally advanced and metastatic tumors | nykode Genentech [4] | | | | | |
| **Infectious Disease** | | | | | | | | |
| Regeneron programs | | Undisclosed | nykode REGENERON [3] | | | | | |
| Internal | | Undisclosed | nykode | | | | | |
| **Autoimmune** | | | | | | | | |
| Internal | | Undisclosed | nykode | | | | | Update (Q3 2023) |

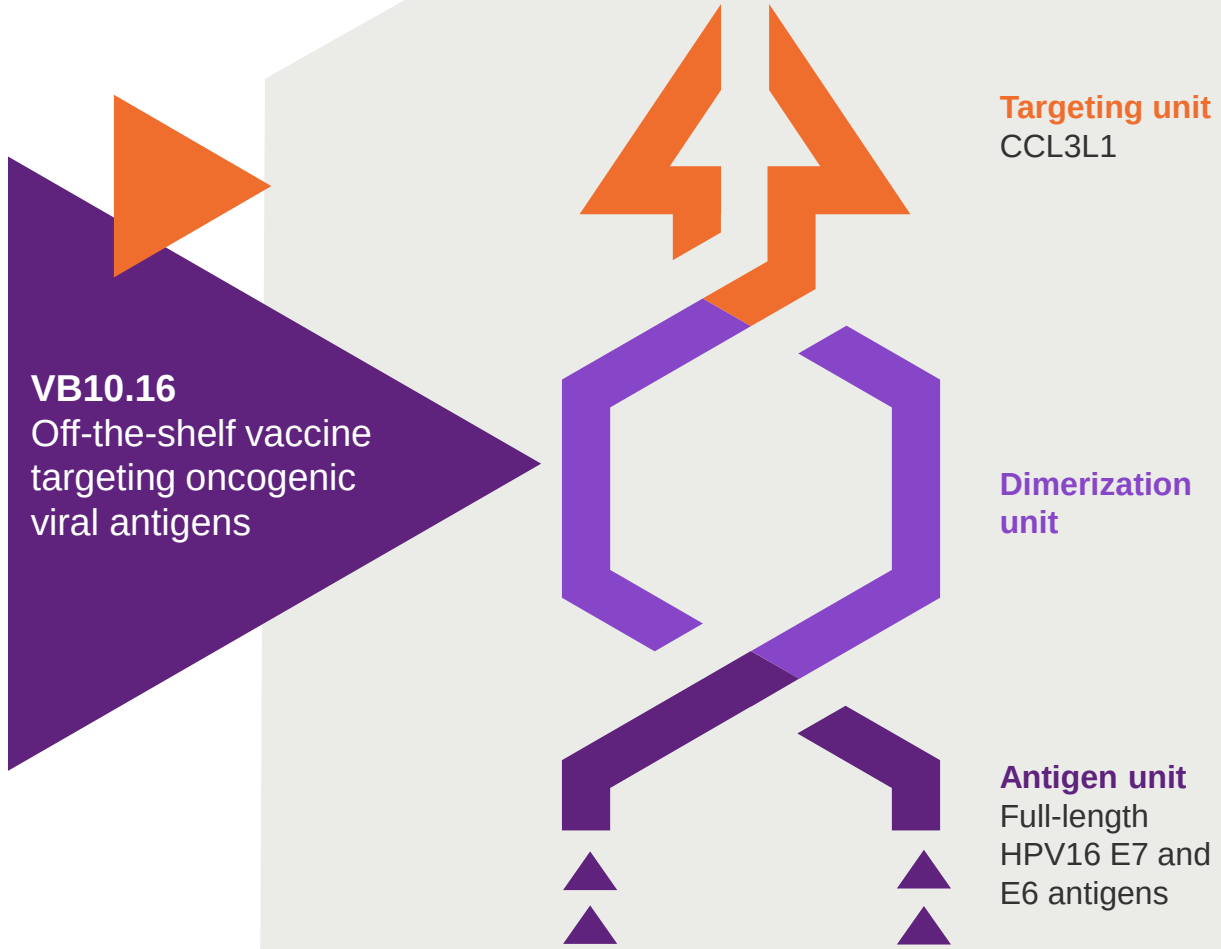
1. Wholly-owned by Nykode. Potentially registrational. Roche supplies atezolizumab; 2. Wholly-owned by Nykode. Merck (MSD) supplies pembrolizumab; 3. Collaboration with Regeneron; 4. Genentech has an exclusive license to VB10.NEO.

# R&D update

# VB10.16: 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
- Wholly-owned by Nykode



# VB10.16 highlights
## Targeted vaccines for HPV16+ cancers

| | C-02 | C-03 | C-04 |
|---|---|---|---|
| Indication | Advanced Cervical Cancer | Unresectable recurrent or metastatic head and neck cancer (HNSCC) and PD-L1+ | Cervical Cancer |
| Dose | 3 mg in combination with atezolizumab (Tecentriq®) | Up to 9 mg in combination with pembrolizumab (Keytruda®[1]) | In combination with atezolizumab |
| Phase | 2a | 1/2a | 2 |
| Status | Fully enrolled | Enrolment to start | Enrolment to start |
| Next catalyst | Updated survival data Q1 2024 | FPFD Q3 2023 | Initiate potentially registrational trial (U.S.) Q4 2023 |

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

# Data from the VB10.16 Ph2 trial compared with relevant current and future SoC as evaluated in third-party trials

| Endpoint | VB10.16 plus atezolizumab in PD-L1+ (n = 24) | Pembrolizumab in PD-L1+ (Keynote-158, n = 82)** | Cemiplimab in PD-L1+ (Empower-Cervical 1, n = 82, cemiplimab arm) †† | Tisotumab vedotin (PD-L1 agnostic) (InnovaTV 204, n = 101) ‡‡ |
|---|---|---|---|---|
| **ORR** | **29%*** | 17% | 18% | 24% |
| **mPFS** | **6.3 mo‡** | 2.1 mo | 3.0 mo | 4.2 mo |
| **mOS** | **Not reached (25.0+ mo)** | 11.0 mo | 13.9 mo | 12.1 mo |

Median OS has not yet been reached

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
NA = not available in publication / presentation / abstract

* 40% (6/15) in PD-L1+ with **1 prior line** of systemic anticancer therapy (SACT)

† 80% (12/15) in PD-L1+ with **1 prior line** of SACT

‡ 16.9 mo in PD-L1+ with **1 prior line** of SACT (n = 15)

** 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

‡‡ Coleman et al. Efficacy and safety of tisotumab vedotin in previously treated recurrent or metastatic cervical cancer (innovaTV 204/GOG-3023/ENGOT-cx6): A multicentre, open-label, single-arm, phase 2 study. Lancet Oncol 2021

(Tabernero et al. Phase II multicohort study of atezolizumab monotherapy in multiple advanced solid cancers. ESMO Open. 2022 did not report PD-L1+ patient data).

# C-02 data supports patient population selection for future trials

- Clinical activity observed across all endpoints in PD-L1+ patients
- Strongest results in PD-L1+ patients with 1 prior line of systemic therapy, support potential in patient populations selected for future trials

| Endpoint | PD-L1+ | PD-L1+ and 1 prior line of SACT |
|---|---|---|
| **ORR** | 29% | 40% |
| **CR** | 8% | 13% |
| **DCR** | 75% | 80% |
| **mDOR, months** | 17.1 | 17.1 |
| **mPFS, months** | 6.3 | 16.9 |
| **mOS, months** | >25 N.R | >25 N.R. |

# **VB10.NEO:** leading technology for individualized cancer neoantigen immunotherapy

### Strong in-house bioinformatic competences and proprietary neoantigen selection method

- Trained on Nykode's data and unique broad CD8 dominated immune response
- Focus on clonal and clinically relevant epitopes
- High quality immunogenic neoepitopes shown to correlate with clinical responses

### Optimal manufacturing for individualized

- DNA plasmid manufacturing is an intermediate in mRNA and viral vector productions and thus will be more rapid, cost-effective and robust
- 100% manufacturing success rate to date

### Safe and well tolerated platform

# VB10.NEO highlights

## Safety clearance of 9 mg dose with no safety concerns and no dose limiting toxicities observed

| | N-01 | N-02 |
|---|---|---|
| Indication | Melanoma, non-small cell lung cancer (NSCLC), clear renal cell carcinoma, urothelial cancer or squamous cell carcinoma of the head and neck (SCCHN) | Locally advanced and metastatic tumors covering more than ten indications |
| Dose | 3 mg dose in combination with a CPI | 3-9 mg dose escalation, in combination with atezolizumab |
| Phase | 1/2a | 1b |
| Status | Fully enrolled | Enrolling |
| Partnered | Genentech<br>A Member of the Roche Group | |

Note: Genentech has an exclusive license to VB10.NEO. Collaboration and license to 5 programs with Regeneron. Collaboration and license with Adaptive Biotechnologies on SARS-CoV-2 T cell vaccine. Roche supplies atezolizumab; . Merck (MSD) supplies pembrolizumab

# Other R&D highlights

## Oncology:

Progressing internal programs to select new development candidate in Q4 2023.

## Autoimmune disorders:

Established dedicated Autoimmune research group, effective from September 1, 2023.

Appointment of Henrik Søndergaard as Head of Tolerance.

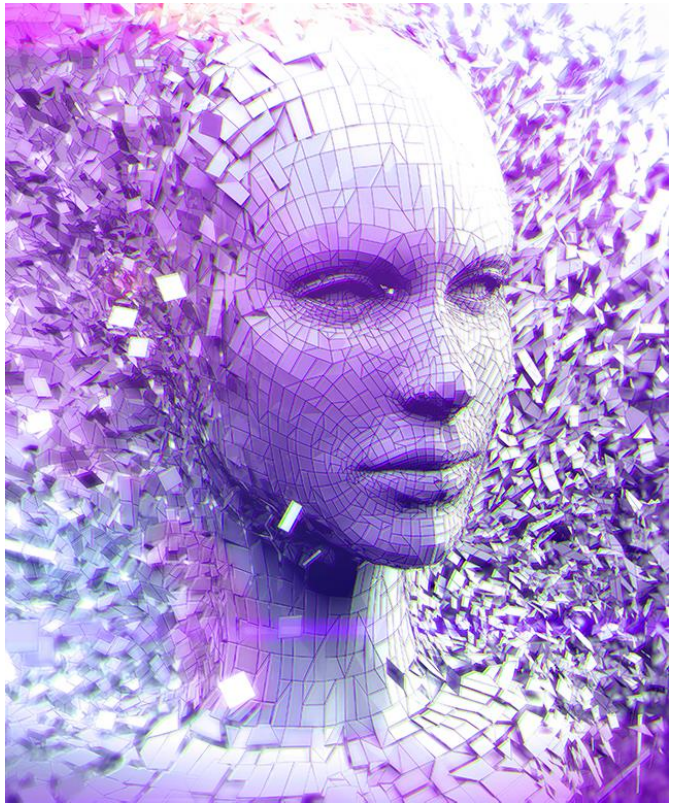
**Henrik Søndergaard**
Head of Tolerance

- 15+ years of drug development experience
- Prior leadership and operational roles at Novo Nordisk and Roche's RNA molecule research unit at Roche Innovation Center Copenhagen

# Q2 2023
# Financial Results

# Strong financial foundation for achieving our vision

## Cash position of $174m end Q2 2023



- Financially well positioned to execute the Company's strategy over the next years
- Nykode continues to explore a potential listing on the Nasdaq Global Market in the United States

# Income Statement

| Amounts in USD '000 | Q2 2023 | Q2 2022 | YTD 2023 | YTD 2022 |
|---|---|---|---|---|
| Revenue from contracts with customers | 5,000 | 3,114 | 8,126 | 3,830 |
| Other income | 100 | 309 | 281 | 617 |
| **Total revenue and other income** | **5,100** | **3,423** | **8,406** | **4,447** |
| Employee benefit expenses | 5,143 | 3,435 | 11,800 | 4,723 |
| Other operating expenses | 11,354 | 9,775 | 22,222 | 17,679 |
| Depreciation | 542 | 460 | 1,007 | 914 |
| **Operating profit (loss)** | **(11,939)** | **(10,246)** | **(26,622)** | **(18,869)** |
| Finance income | 2,537 | 1,695 | 5,845 | 2,358 |
| Finance costs | 821 | 2,372 | 1,439 | 2,969 |
| **Profit (loss) before tax** | **(10,223)** | **(10,923)** | **(22,216)** | **(19,480)** |
| Income tax expense | (1,012) | (2,174) | (2,643) | (3,833) |
| **Profit (loss) for the period** | **(9,211)** | **(8,749)** | **(19,572)** | **(15,647)** |

**Revenue from contracts with customers**

- R&D activities under Genentech and Regeneron agreements
- $4.9m (Q2 2023) and $7.4m (1H 2023) under Genentech agreement
- $0.1m (Q2 2023) and $0.7m (1H 2023) under Regeneron agreement

**Other income**

- Government grants from SkatteFUNN and Research Council of Norway

**Employee benefit expenses**

- Increase due to growth in organization
- 1H 2022 includes $6.6m reduction in social security cost accrual for share based payments

**Other operating expenses**

- Increase in 2023 mainly due to increased R&D activities

**Finance income**

- Increase in 2023 mainly due to increased interest income

# Balance Sheet

| Amounts in USD '000 | 30/06/2023 | 31/12/2022 |
|---|---|---|
| **ASSETS** | | |
| **Non-current assets** | | |
| Property, plant and equipment | 3,981 | 3,517 |
| Right-of-use assets | 6,920 | 6,009 |
| Intangible assets | 68 | 32 |
| Other long-term receivables | 47 | 46 |
| **Total non-current assets** | **11,017** | **9,604** |
| | | |
| **Current assets** | | |
| Trade receivables | 11 | 2,544 |
| Other receivables | 4,228 | 2,943 |
| Cash and cash equivalents | 173,583 | 206,386 |
| **Total current assets** | **177,822** | **211,873** |
| **TOTAL ASSETS** | **188,839** | **221,477** |

**Cash and cash equivalents**

- Strong cash position of $174m at June 30, 2023

**Trade receivables**

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

# Balance Sheet - contd.

| Amounts in USD ’000 | 30/06/2023 | 31/12/2022 |
|---|---|---|
| **EQUITY AND LIABILITIES** | | |
| Equity | | |
| Share capital | 339 | 338 |
| Share premium | 84,145 | 83,318 |
| Other capital reserves | 13,115 | 11,694 |
| Other components of equity | (3,037) | (3,044) |
| Retained earnings | 45,140 | 64,713 |
| **Total equity** | **139,703** | **157,018** |
| | | |
| **Non-current liabilities** | | |
| Non-current lease liabilities | 4,683 | 4,365 |
| Non-current provisions | 11 | 30 |
| Deferred tax liabilities | 18,436 | 21,079 |
| **Total non-current liabilities** | **23,130** | **25,474** |
| | | |
| **Current liabilities** | | |
| Government grants | 2 | 133 |
| Current lease liabilities | 1,395 | 1,147 |
| Trade and other payables | 7,046 | 10,175 |
| Current provisions | 5,161 | 7,714 |
| Current contract liabilities | 12,322 | 19,736 |
| Income tax payable | 81 | 80 |
| **Total current liabilities** | **26,006** | **38,985** |
| **Total liabilities** | **49,136** | **64,459** |
| | | |
| **TOTAL EQUITY AND LIABILITIES** | **188,839** | **221,477** |

**Equity**

- Total equity of $140m as per June 30, 2023
- Equity ratio of 74%

**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 $12.3m per June 30, 2023, down from $19.7m per December 31, 2022, in line with revenues recognized

# Rich calendar of milestones expected in the next 12 months

| | | | |
|---|---|---|---|
| Oncology | 1H 2023 | **VB10.16 Cervical Cancer** | Final results from VB-C-02 Phase 2 study; 12 month treatment follow-up ✓ |
| | 2H 2023 | **VB10.16 Head and Neck Cancer** | First patient dosed in C-03 trial with KEYTRUDA®[1] in patients with PD-L1 positive 1st line unresectable recurrent or metastatic disease |
| | Q4 2023 | **VB10.16 Cervical Cancer** | Initiate potentially registrational C-04 trial in the U.S. in patients with recurrent/metastatic disease and PD-L1 positive tumors |
| | Q4 2023 | **Undisclosed Oncology** | Nomination of an additional oncology development candidate for a new internal oncology program |
| | Q1 2024 | **VB10.16 Cervical Cancer** | Updated survival data from C-02 trial |
| Autoimmune | Q3 2023 | **Autoimmunity and Allergy** | Update on Nykode's Ag-specific immune tolerance platform |

Note: The news flow from the collaboration with Genentech and Regeneron is at their discretion, respectively
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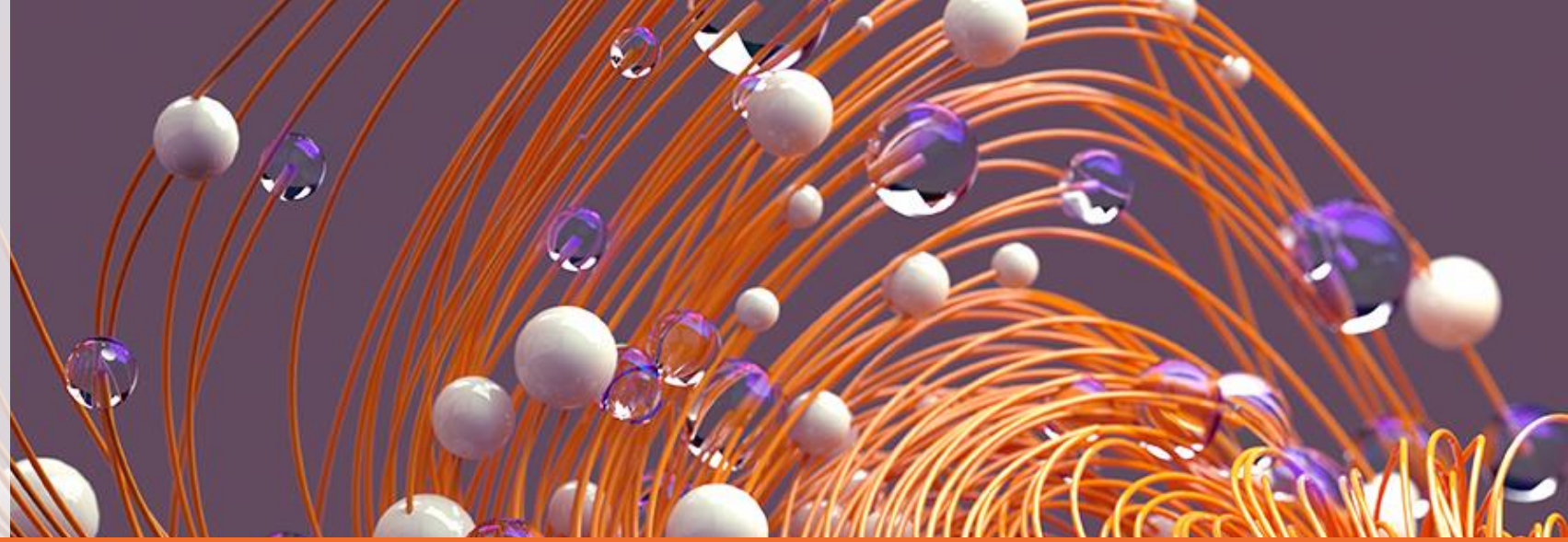
# SAVE THE DATE!



Nykode to a host a **Capital Markets Days in NYC and Oslo**.
Members of the Management Team and a Key Opinion Leader will present latest updates on the Vaccibody platform and its clinical programs:

- **NYC - September 20, 2023**
- **Oslo - September 27, 2023**

Stay tuned!

# UNLOCKING THE FUTURE OF MEDICINE

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