19th April 2023

ØU Life Science Investor Konference

Proteins for Life

ExpreS²ion Biotech Holding AB [NASDAQ First North Growth Market: EXPRS2] – a clinical Phase III development stage vaccine company

Bent U. Frandsen, CEO

EXPRES²ION BIOTECHNOLOGIES

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Investment Highlights

We turn complex proteins into tomorrow's vaccines

High-potential pipeline of key focus within infections diseases and oncology, backed up by strong intellectual property rights. Targeting sizeable unmet medical needs and markets

Vaccine development platform with strong track record and partner validation and regulatory approved for late-stage clinical development. +500 proteins produced while posting +90% success rate

Global vaccine market continually growing, from USD 34bn (2017), USD 127bn (2021), to USD 202bn (2022) corresponding to 494% growth (2017-2022)

ExpreS²ion is advancing towards key catalysts during 2023, further de-risking the company's pipeline.

- COVID-19 vaccine clinical Phase III read-out mid-2023. Moving towards commercial launch in 2024.

Unique Technology Platforms

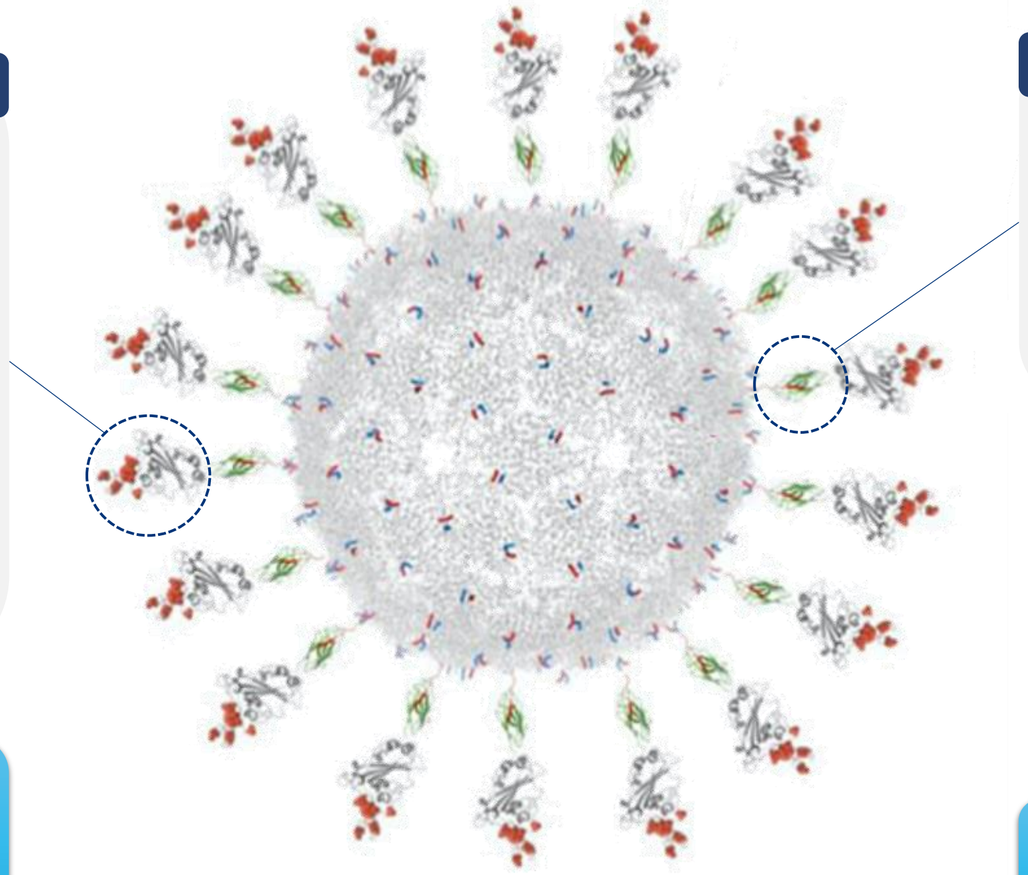
Combines a highly immunogenic antigen with unique presentation technology

ExpreS² platform

- Combines S2 cells with patented expression vectors (add a specific gene into a target cell and command the cell to produce the gene encoded protein), adapted culture agents and reagents (stimulating cell growth)
- Produces the complex surface proteins (antigens), which are critical to immune system recognition and response

100% ownership

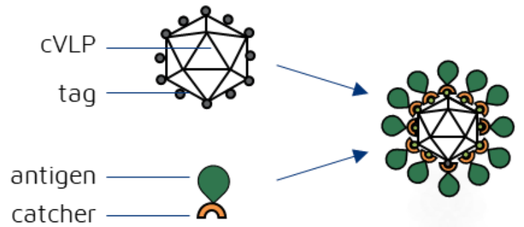
ExpreS2™ technology platform applied to express antigens in all pipeline assets, including therapeutic HER2 vaccine, COVID-19, Influenza, CMV, and Malaria



Particle (VLP) technology

- AdaptVac's proprietary virus-like particles (VLP) technology securely attaches our proteins to the surface of a capsid (outer protein protective shell of a virus), mimicking a virus to elicit an immune response

34% ownership



cVLP: Capsid Virus Like Particle

Same technology platform applied for the therapeutic HER2 vaccine and COVID-19 vaccine ABN-CoV2

[1] Schneider I (1972). "Cell Lines Derived from Late Embryonic Stages of *Drosophila melanogaster*". *J. Embryol. Exp. Morphol.* 27: 363–365.
Note: ExpreS²ion Biotech founders invented an Improved Vector System derived from S2 cells; granted patent until 2032 (US); glyco-engineered S2 cells pending patents until 2040.

Broad Clinical Stage Vaccine Pipeline

[1] 2024 estimate from Evaluate Pharma for top 10 products and other, as of 9 June 2022
[2] Global Data, 2022, for HER2+ breast cancer
[3] Fortune Business Insight, Influenza Vaccine market size 2022-2029, 2022
[4] Market estimate from Moderna, 41st Annual J.P. Morgan Healthcare Conference (Presentation)
[5] Data bridge market research, Global Malaria Vaccines Market – Industry trends and Forecast to 2029, 2022
Note: AdaptVac is a joint venture between ExpreS²ion (34% owned) and NextGen Vaccines (66% owned)

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Breast Cancer - The Most Common Cancer

1 in 8

women will be diagnosed with invasive breast cancer in her lifetime

~25%

are HER2-positive, which is associated with more aggressive tumors and reduced survival.

685,000

deaths worldwide in 2020 due to breast cancer[1]

Global market size expected to growth to **USD 32 billion** by 2026[3]

1. Breast Cancer Research Foundation (https://www.bcrf.org/breast-cancer-statistics-and-resources)
2. Mitri Z et al. The HER2 Receptor in Breast Cancer: Pathophysiology, Clinical Use, and New Advances in Therapy (Chemother Res Pract. 2012; 2012: 743193)
3. Mordor Intelligence, breast cancer therapeutics market, 2021.

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Current Breast Cancer treatments

The ES2B-C001 vaccine can offer significant benefits compared to current treatment options

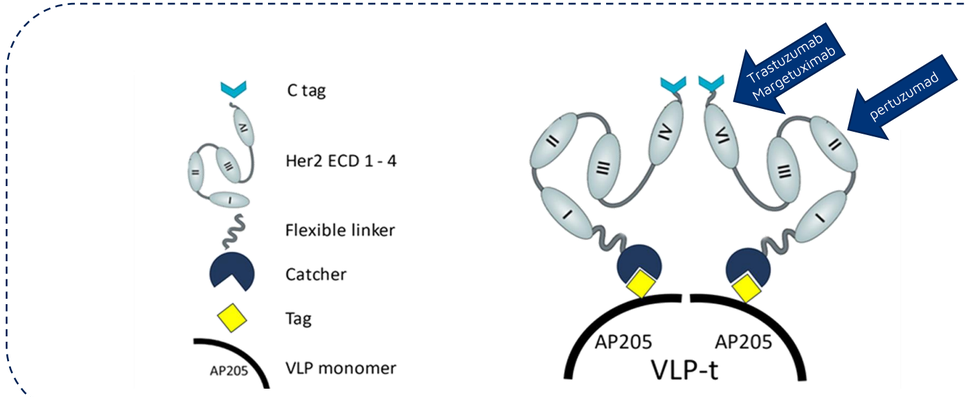
Existing therapies

Monoclonal antibodies are the cornerstone of treatment for HER2+ breast cancer (>USD 11bn sales)[1]

- Target the HER2 receptor on tumor cells to reduce proliferation and induce tumor cell destruction

Herceptin® trastuzumab

PERJETA® pertuzumab



Monoclonal antibodies target one epitope. ES2B-C001 with four subdomains generates a broad polyclonal antibody response

Significant drawbacks exist with existing therapies[2]

- **Resistance** to monoclonal antibodies may develop
- **Potential for cardiac toxicity**
- **Repeated administration required**: 28-day half-life requires administration every 3rd week until remission or resistance develops, costs USD 30-50k

ExpreS²ion's HER2-targeted vaccine approach offers potential to overcome some of the drawbacks through *internal polyclonal antibody production*

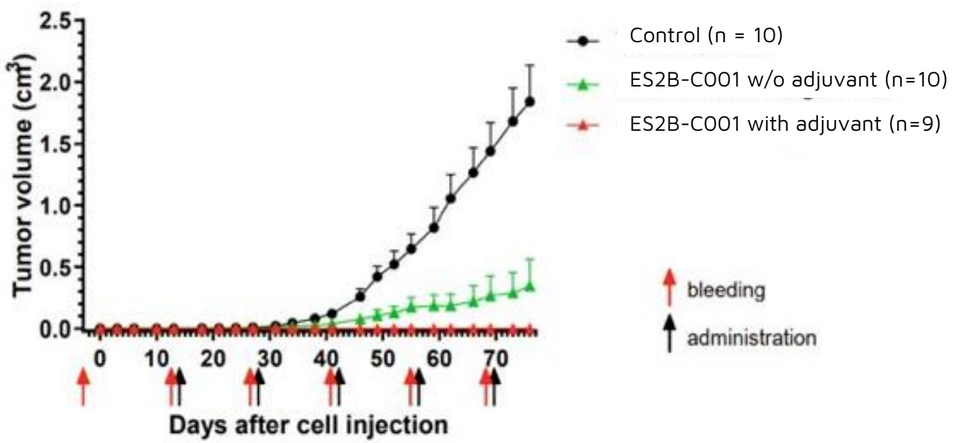
[1]GlobalData, 2022
[2]Pallerla et al. 2021. Cancer Vaccines, Treatment of the Future: With Emphasis onHER2-Positive Breast Cancer, International Journal of Molecular Sciences.;
[3]Krasniqi et al. 2019. Immunotherapy in HER2-positive breastcancer: state of the art and future perspectives, Journal of Hematology & Oncology.
ECD - extracellular domain
VLP - virus like particle

ES2B-C001 Preclinical Proof-of-Concept

ES2B-C001 has demonstrated animal proof-of-concept

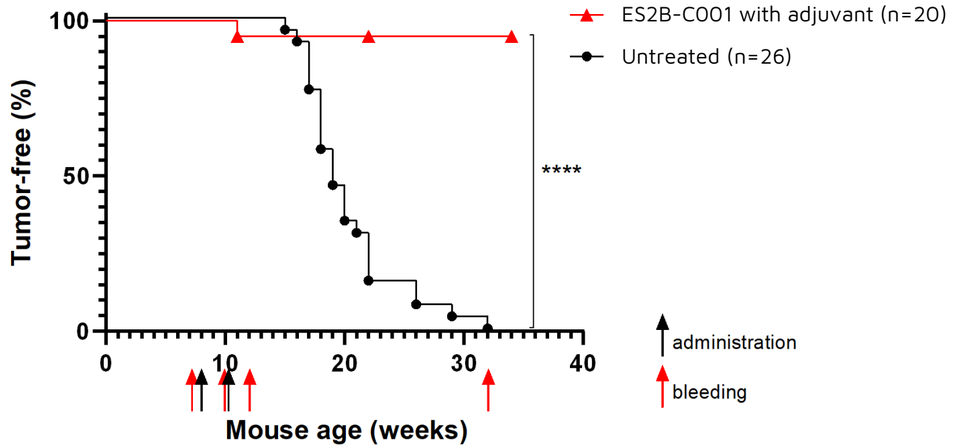
Effectively inhibited tumor development

Tumor growth in FVB mice
(HER2-intolerant)



Prevented tumor development with 95% efficiency

Kaplan-Meier survival curves
****p<0.0001 by the log-rank test



- Two weeks after the inoculation of tumor cells, the first vaccine administration was given. Repeated every 2nd week during the study
- **ES2B-C001 formulated in an adjuvant totally blocks tumor development. ES2B-C001 without adjuvant partly blocks tumor development** and if tumors develop, growth is significantly inhibited

- At mouse age 6-8 weeks, 2 vaccinations with 2 weeks interval were administered to Delta16 mice
- **Two vaccinations prevented tumor development with 95% efficiency** as compared to a control group, where all mice spontaneously developed tumors

Note: FVB mice are mice being challenged with tumors, while Delta16 mice spontaneously develop tumors and have been inoculated with tumor cells to accelerate tumor development

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Publication Supports ES2B-C001

Pre-clinical proof of concept

- Vaccines are a promising therapeutic alternative to monoclonal antibodies against HER-2+ breast cancer.
- Polyclonal antibodies generated after vaccination with ES2B-C001 inhibited growth of human HER-2+ trastuzumab-resistant breast cancer cells.
- Vaccination with ES2B-C001 prevented tumor development in mice models for >1 year.
- The ES2B-C001 vaccine completely inhibited lung metastases in mice challenged intravenously.
- **ES2B-C001 is a promising candidate vaccine for the therapy of tumors expressing HER-2. Preclinical results warrant further development towards human clinical studies.**

biomedicines

Article

MDPI

Prevention and Therapy of Metastatic HER-2⁺ Mammary Carcinoma with a Human Candidate HER-2 Virus-like Particle Vaccine

Francesca Ruzzi [1,†], Arianna Palladini [1,2,†], Stine Clemmensen [3], Anette Strøbæk [3], Nicolaas Buijs [3], Tanja Domeyer [3], Jerzy Dorosz [3], Vladislav Soroka [3], Dagmara Grzadziela [3], Christina Jo Rasmussen [3], Ida Busch Nielsen [3], Max Soegaard [3], Maria Sofia Semprini [1], Laura Scalambra [1], Stefania Angelicola [1], Lorena Landuzzi [4], Pier-Luigi Lollini [1,*,‡] and Mette Thorn [3,‡]

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† These authors contributed equally to this work.
‡ Pier-Luigi Lollini and Mette Thorn jointly supervised this work.

Abstract: Vaccines are a promising therapeutic alternative to monoclonal antibodies against HER-2⁺ breast cancer. We present the preclinical activity of an ES2B-C001, a VLP-based vaccine being developed for human breast cancer therapy. FVB mice challenged with HER-2⁺ mammary carcinoma cells QD developed progressive tumors, whereas all mice vaccinated with ES2B-C001+Montanide ISA 51, and 70% of mice vaccinated without adjuvant, remained tumor-free. ES2B-C001 completely inhibited lung metastases in mice challenged intravenously. HER-2 transgenic Delta16 mice developed mammary carcinomas by 4–8 months of age; two administrations of ES2B-C001+Montanide prevented tumor onset for >1 year. Young Delta16 mice challenged intravenously with QD cells developed a mean of 68 lung nodules in 13 weeks, whereas all mice vaccinated with ES2B-C001+Montanide, and 73% of mice vaccinated without adjuvant, remained metastasis-free. ES2B-C001 in adjuvant elicited strong anti-HER-2 antibody responses comprising all Ig isotypes; titers ranging from 1–10 mg/mL persisted for many months. Antibodies inhibited the 3D growth of human HER-2⁺ trastuzumab-sensitive and -resistant breast cancer cells. Vaccination did not induce cytokine storms; however, it increased the ELISpot frequency of IFN-γ secreting HER-2-specific splenocytes. ES2B-C001 is a promising candidate vaccine for the therapy of tumors expressing HER-2. Preclinical results warrant further development towards human clinical studies.

Keywords: breast cancer; vaccine; virus-like particles (cVLP); HER-2; tyrosine kinase receptor; target therapies; cancer immunotherapy; metastasis

Citation: Ruzzi, F.; Palladini, A.; Clemmensen, S.; Strøbæk, A.; Buijs, N.; Domeyer, T.; Dorosz, J.; Soroka, V.; Grzadziela, D.; Rasmussen, C.J.; et al. Prevention and Therapy of Metastatic Her-2⁺ Mammary Carcinoma with a Human Candidate Her-2 Virus-like Particle Vaccine. *Biomedicines* **2022**, *10*, 2654. https://doi.org/10.3390/biomedicines10102654

Academic Editor: Satoshi Wada

Received: 31 August 2022
Accepted: 17 October 2022
Published: 20 October 2022

Published

October 20, 2022

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Progression as Planned

Important steps as ES2B-C001 is moving closer to the planned clinical Phase I trial in 2024

GMP Manufacturing

- ✓ GMP (Good Manufacturing Practice) Manufacturers selected and Work Order Statements executed
- ✓ ExpreS²ion's processes for manufacturing of material for HER2 antigen and VLP are transferred to the contract manufacturers
- Development of GMP manufacturing processes are progressing as planned

Good manufacturing practices (GMP)

- Risk management
- Suitable facilities & qualified personnel
- Quality management
- Complaints & Recall
- Personnel training & Competence

Preclinical Safety

- ✓ GLP (Good Laboratory Practice) CRO (Contract Research Organisation) selected, and Master Service Agreement executed
- In accordance with feedback from DKMA (Danish Medicines Agency) nonclinical toxicological studies have been planned in two species (preliminary testing in a rodent and non-human primates, NHP) and toxicological GLP study in NHP
- Both preliminary studies are well underway
- GLP tox-study in NHP on track to start in Q1 2023

Therapeutic breast cancer vaccine project planning to file clinical trial application for clinical Phase I in the beginning of 2024 -> first dose in human in 2024

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Oncology Scientific Advisory Board

Key Opinion Leaders (KOLs) providing clinical advice on our oncology development programme

Dr. Giuseppe Curigliano, MD, PhD

Associate Professor of Medical Oncology at the University of Milano and the Head of the Division of Early Drug Development at the European Institute of Oncology, Italy (IRCCS). Dr. Curigliano is recognized among the leading experts in the world within the field of HER2 expressing breast cancer and has authored or co-authored more than 650 peer-reviewed scientific papers.

Dr. Ulrik Lassen, MD, PhD

Professor at University of Copenhagen, Department of Clinical Medicine. In 2017, he was appointed Head of the Department of Oncology at Copenhagen University Hospital, Rigshospitalet, Denmark. As a Clinical Oncologist he has been working with Phase 1 Oncology trials since 2005 and is ESMO board certified in Medical Oncology. Dr. Lassen has (co-)authored ~300 peer reviewed publications.

Dr. Daniel Lenihan, MD, FACC, FESC, FIC-OS

Dr. Lenihan has been active in cardio-oncology, for over 25 years. He has previously held positions at MD Anderson Cancer Center in Houston, Texas, Vanderbilt University in Nashville, Tennessee, and Washington University in St Louis, Missouri. His current research projects include early phase clinical trials in cardio-oncology, heart failure and amyloidosis. Dr. Lenihan serves as editor on several scientific journals and has authored or co-authored more than 210 peer-reviewed scientific papers.

Dr. Michael Andersson, MD, DMSci

Dr. Andersson is a Clinical Oncologist working as consultant at the Breast Oncology Unit in the Copenhagen University Hospital, Rigshospitalet, Denmark since 1998. He has special interest in HER2-positive breast cancer and has published on and been Principal Investigator in several national and international studies of HER2-positive early and metastatic breast cancer. Dr. Andersson has authored or co-authored more than 140 peer reviewed publications.

Dr. Javier Cortes, MD, PhD

Doctor in Medical Oncology, and Head of the International Breast Cancer Centre (IBCC) in Barcelona. Dr. Cortes He is an active member of the Spanish, European, and American Societies of Medical Oncology (SEOM, ESMO, ASCO), and is a member of expert panels that develop the treatment guidelines for metastatic breast cancer. He is the author of more than 380 publications.

Dr. Rupert Bartsch, MD

Associate Professor of medicine at the Medical University of Vienna in Austria and serves as the director of the Breast Cancer Programme at the Department of Oncology. Dr. Bartsch has a longstanding clinical and scientific focus on breast cancer and brain metastases. Together with his colleagues, he has published over 150 articles in peer-reviewed journals.

COVID-19

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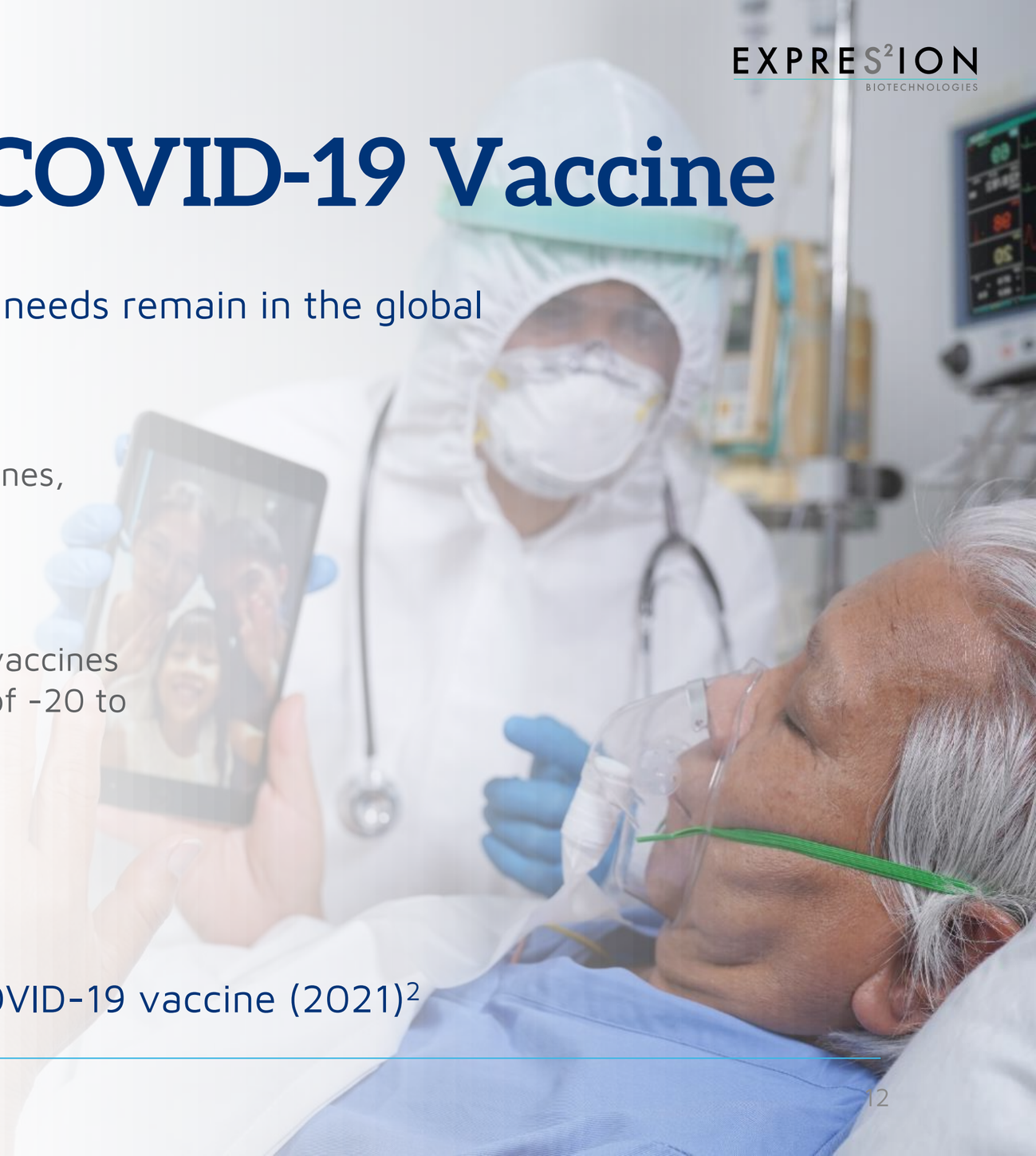
The 2nd Generation COVID-19 Vaccine

With ~**7 million deaths worldwide**[1], significant needs remain in the global long-term fight against the SARS-CoV-2 virus:

- Uncertain duration of effect with current vaccines, expected to need repeated boosters
- Storage and handling requirements for many vaccines create logistical constraints (requires storage of -20 to -80 degrees Celsius)
- Potential mutated variants may require rapid development of new vaccines



Global market size of **USD 137 billion** for the COVID-19 vaccine (2021)[2]

[1] WHO Coronavirus (COVID-19) Dashboard
[2] Meticulous Market Research, 2021

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Publication Supports ABNCoV2 Vaccine

Phase I clinical trial findings

- 45 participants (six to nine per group) were enrolled between March 15 and July 15, 2021. Participants had a total of 249 at least possibly related solicited adverse events (185 grade 1, 63 grade 2, and one grade 3) within a week after vaccination. Two serious adverse events occurred; one was classified as a possible adverse reaction. Antibody titres were dose-dependent with levels plateauing at a vaccination dose of 25–70 µg ABNCoV2. After second vaccination, live virus neutralisation activity against major SARS-CoV-2 variants was high but was lower with an omicron (BA.1) variant. Vaccine-specific IFNγ+ CD4+ T cells were induced.

Phase I clinical trial interpretation

- **Immunisation with ABNCoV2 was well tolerated, safe, and resulted in a functional immune response.**
- **The data support the need for additional clinical development of ABNCoV2 as a second-generation SARS-CoV-2 vaccine.**
- **The modular cVLP platform will accelerate vaccine development, beyond SARS-CoV-2.**

Published

January 18, 2023

Articles

First-in-human use of a modular capsid virus-like vaccine platform: an open-label, non-randomised, phase 1 clinical trial of the SARS-CoV-2 vaccine ABNCoV2

Lancet Microbe 2023

Published Online January 18, 2023 https://doi.org/10.1016/S2666-5247(22)00337-8

Summary

Background Capsid virus-like particles (cVLP) have proven safe and immunogenic and can be a versatile platform to counter pandemics. We aimed to clinically test a modular cVLP COVID-19 vaccine in individuals who were naive to SARS-CoV-2.

Methods In this phase 1, single-centre, dose-escalation, adjuvant-selection, open-label clinical trial, we recruited participants at the Radboud University Medical Center in Nijmegen, Netherlands, and sequentially assigned them to seven groups. Eligible participants were healthy, aged 18–55 years, and tested negative for SARS-CoV-2 and anti-SARS-CoV-2 antibodies. Participants were vaccinated intramuscularly on days 0 and 28 with 6 µg, 12 µg, 25 µg, 50 µg, or 70 µg of the cVLP-based COVID-19 vaccine (ABNCoV2). A subgroup received MF59-adjuvanted ABNCoV2. Follow-up was for 24 weeks after second vaccination. The primary objectives were to assess the safety and tolerability of ABNCoV2 and to identify a dose that optimises the tolerability–immunogenicity ratio 14 days after the first vaccination. The primary safety endpoint was the number of related grade 3 adverse events and serious adverse events in the intention-to-treat population. The primary immunogenicity endpoint was the concentration of ABNCoV2-specific antibodies. The trial is registered with ClinicalTrials.gov, NCT04839146.

Findings 45 participants (six to nine per group) were enrolled between March 15 and July 15, 2021. Participants had a total of 249 at least possibly related solicited adverse events (185 grade 1, 63 grade 2, and one grade 3) within a week after vaccination. Two serious adverse events occurred; one was classified as a possible adverse reaction. Antibody titres were dose-dependent with levels plateauing at a vaccination dose of 25–70 µg ABNCoV2. After second vaccination, live virus neutralisation activity against major SARS-CoV-2 variants was high but was lower with an omicron (BA.1) variant. Vaccine-specific IFNγ+ CD4+ T cells were induced.

Interpretation Immunisation with ABNCoV2 was well tolerated, safe, and resulted in a functional immune response. The data support the need for additional clinical development of ABNCoV2 as a second-generation SARS-CoV-2 vaccine. The modular cVLP platform will accelerate vaccine development, beyond SARS-CoV-2.

Funding EU, Carlsberg Foundation, and the Novo Nordisk Foundation.

Introduction

As of July 9, 2022, there have been over 550 million cases of COVID-19 worldwide, with more than 6 million deaths.[1] Vaccines against SARS-CoV-2, the causative virus, have been instrumental in controlling the pandemic. Vaccination has been implemented globally at unprecedented pace to protect susceptible populations, reduce spread, safeguard health-care systems, and diminish the global social and economic impact of non-pharmaceutical interventions to reduce COVID-19 transmission.[2] However, reduced vaccine effectiveness against new SARS-CoV-2 variants, ongoing transmission, and the absence of universal access are major challenges. Heterologous vaccination with different existing COVID-19 vaccines is an approach to broaden protection; however, so far, it has provided little benefit over homologous boosters.[3] Second-generation COVID-19 vaccines should ideally induce durable cross-protective and transmission-blocking immune responses, while being compatible with globally equitable use.

We developed a novel modular vaccine platform based on capsid virus-like particles (cVLP) that are used as scaffolds for antigen display.[4] This cVLP platform uses a split-protein Tag–Catcher conjugation system (similar to the SpyTag–SpyCatcher technology)[5] to allow for directional, high-density, covalent attachment of protein antigens on the cVLP surface. This cVLP platform was

www.thelancet.com/microbe Published online January 18, 2023 https://doi.org/10.1016/S2666-5247(22)00337-8

COVID-19

ABNCoV2 COVID-19 Vaccine[1]

Successful completion of Phase II study, and on-going Phase III study since Q3 2022

Phase II: Safe & highly efficacious against SARS-CoV-2

- **Favorable safety profile: Vaccine was generally well-tolerated, with no related serious adverse events reported**
  - No relevant difference in the safety profile between subjects receiving the low (50 µg) or high dose (100 µg) of ABNCoV2
- **Strong boosting effect across all variants of concern** (Wuhan, α, β, δ, ο)
- **Strong booster response for both 50µg and 100µg doses**
- **Seronegative antibody titers >90% efficacy, confirms Phase I results**
  - Phase I data documented up to 12 times higher compared to the levels achieved after COVID-19 infection - significantly higher than the virus neutralization levels reported for leading mRNA COVID-19 vaccines[2]
- **Phase II six-month follow up data in Q4 2022 in 41 out of 103 subjects demonstrated durable antibody levels across variants of concern**

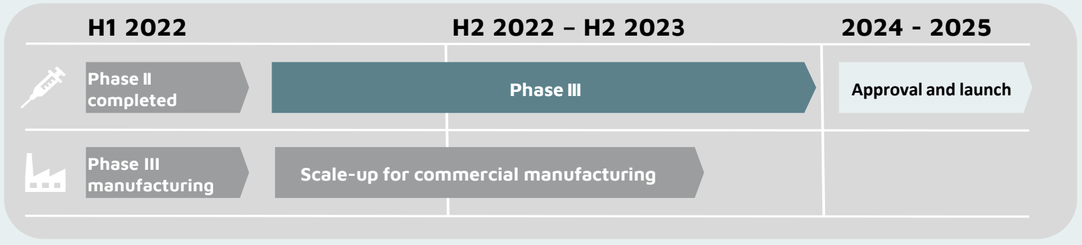
Phase III: Initiation of pivotal study in Q3 2022

- **Bavarian Nordic plan Phase III study initiation Q3 2022, granted DKK 800m funding from the Danish state**
- Approx. 4,000 seropositive subjects in USA and Europe, aiming to demonstrate non-inferiority of ABNCoV2 to a licensed mRNA vaccine
  - U.S. arm with 3,000 subjects, that evaluates the safety and tolerability of the vaccine in subjects receiving a single 100 µg dose of ABNCoV2
  - EU arm in Denmark and Belgium with 1,000 subjects, who receives either a single 100 µg dose of ABNCoV2 or a single 30 µg adult booster dose of COMIRNATY™
- Manufacturing of vaccine bulk for the trial has been completed, filling now ongoing at BN's own manufacturing line
- **Topline Phase III results anticipated around mid 2023**
- **Bavarian Nordic expects rolling submission initiation in H2 2023**

Phase II

Seropositive *Previously infected or fully vaccinated*	**N = 103**	**100 µg**	*Single-shot booster vaccination*
	N = 66	**50 µg**	*Single-shot booster vaccination*
Seronegative *No existing immunity*	**N = 28**	**100 µg**	*Prime-boost vaccination (days 0, 28)*

Phase III



1) Vaccine design described in Fougeroux, *et al.* Nature communications (2021)

2) P. B. Gilbert *et al.*, Science 10.1126/science.abm3425 (2021)

Partnership with Bavarian Nordic

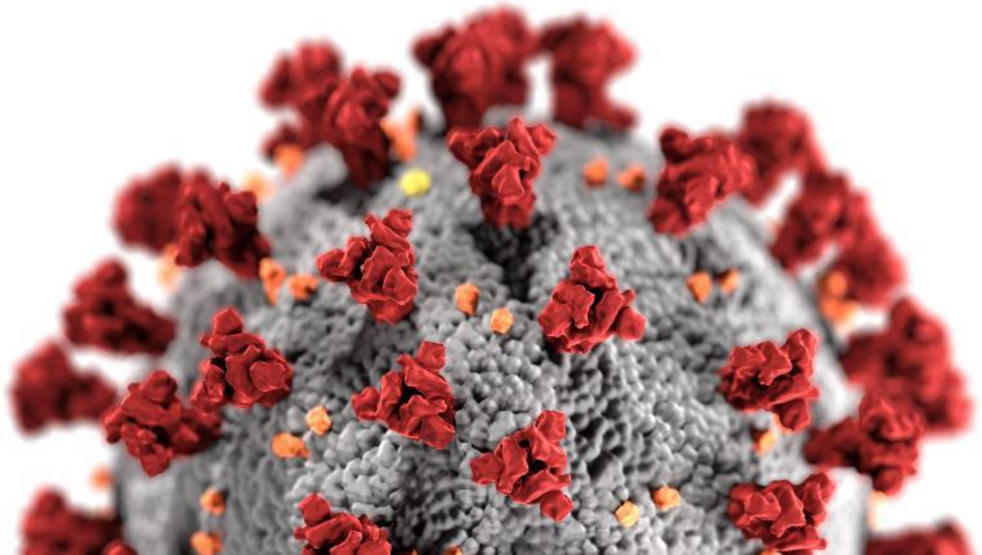
ABNCoV2 is out-licensed with near-term revenue streams supporting ExpreS²ion

AdaptVac receives from Bavarian Nordic

- EUR 4 million upfront (paid in July 2020)
- Up to EUR 136 million in development and sales milestones
- Single- to double-digit-% royalties of Bavarian revenues

ExpreS²ion receives from AdaptVac

- 34% ownership of AdaptVac
- Up to EUR 2 million in commercial milestone payments
- Lower double-digit percentage of AdaptVac royalties



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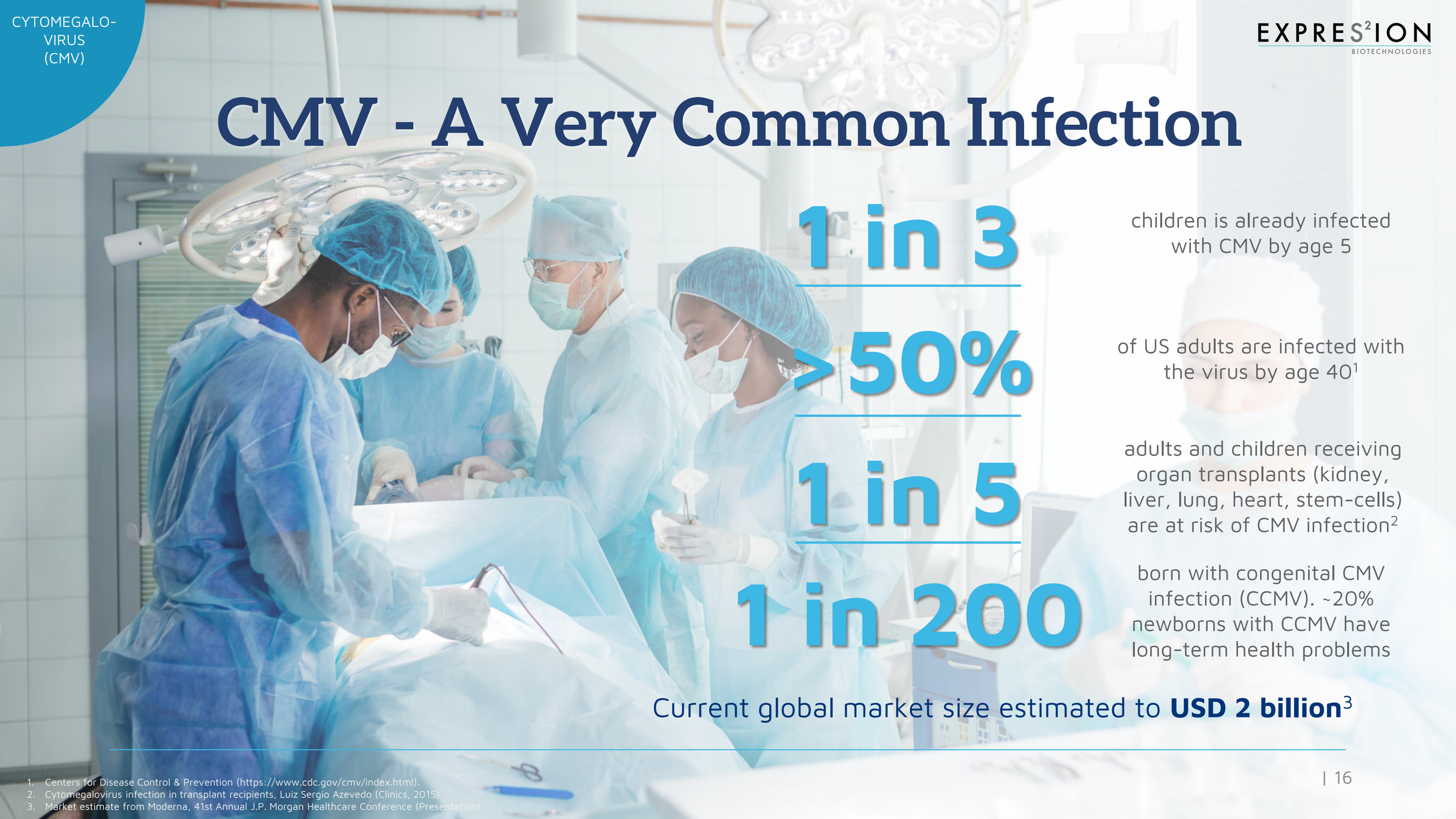
CMV - A Very Common Infection



1 in 3 children is already infected with CMV by age 5

>50% of US adults are infected with the virus by age 40[1]

1 in 5 adults and children receiving organ transplants (kidney, liver, lung, heart, stem-cells) are at risk of CMV infection[2]

1 in 200 born with congenital CMV infection (CCMV). ~20% newborns with CCMV have long-term health problems

Current global market size estimated to **USD 2 billion**[3]

1. Centers for Disease Control & Prevention (https://www.cdc.gov/cmv/index.html).
2. Cytomegalovirus infection in transplant recipients, Luiz Sergio Azevedo (Clinics, 2015)
3. Market estimate from Moderna, 41st Annual J.P. Morgan Healthcare Conference (Presentation)

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EVAXION

Uniting Forces in CMV Vaccine Research

ExpreS²ion and Evaxion Biotech new vaccine research partnership since December 2022

- **Vaccine Discovery Collaboration Agreement** announced Dec. 6th, 2022
- Research partnership with focus on discovery and development of a **novel CMV Vaccine**
- Joint research efforts in discovery phase for ~2 years
  - EVX: AI Platform, including RAVEN™
  - ES2B: ExpreS2™ platform and know how in vaccine production and development
  - EVX: Early establishment of Immunogenicity, e.g., induction of neutralizing Abs in preclinical models
  - POC protection studies in Guinea pig model of congenital infection, TBD
- 50:50 cost sharing during discovery phase
- **Selection of vaccine candidate**, expected in 2025
  - ES2B first option to in-license CMV vaccine asset
  - ES2B sponsors development onwards thereafter

AI = Artificial Intelligence - Using AI, Evaxion (EVX) simulates the human immune system and generate predictive models to identify and develop next-generation medicines

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New Scientific Advisory Board

KOLs providing scientific advice on our infectious diseases' development programmes

Dr. Stanley Plotkin, MD, PhD, DMSci

Dr. Stanley Plotkin serves as a consultant to the vaccine industry and is an emeritus professor at both the Wistar Institute and University of Pennsylvania, USA. He has more than 50 years of vaccine development experience. He developed the rubella vaccine, which is now used worldwide, and has played a pivotal role in both the development and application of various other vaccines including polio, rabies, varicella, rotavirus and cytomegalovirus. He is the author of more than 800 research papers.

Dr. Lone Graff Stensballe, MD, PhD, DMSci

Professor, paediatrician, expert in paediatric infectious disease, DMSc, PhD, MPG. Professor at University of Copenhagen, Department of Clinical Medicine. Consultant in pediatrics at Department of Children and Adolescents at Copenhagen University Hospital, Rigshospitalet, Denmark. 10 years of sponsor experience with phase 3 and 4 large randomized vaccine trials in children recruiting 11,000 Danish infants. Dr. Stensballe has (co-)authored 78 peer reviewed scientific papers.

Dr. Allan Randrup Thomsen, MD, DMSci

Professor Allan Randrup Thomsen is an expert in the immune defence against viral infections and the impact of the immune response on the course of viral infections. Has +40 year in the field and is a renowned advisor at many levels. He heads a research group in Experimental Virology at the Faculty of Health and Medical Sciences that studies how the immune system controls viral infections. Additionally, the researchers investigate how the individual maintains his/her ability to resist a re-infection.

Dr. Mark Schleiss, MD

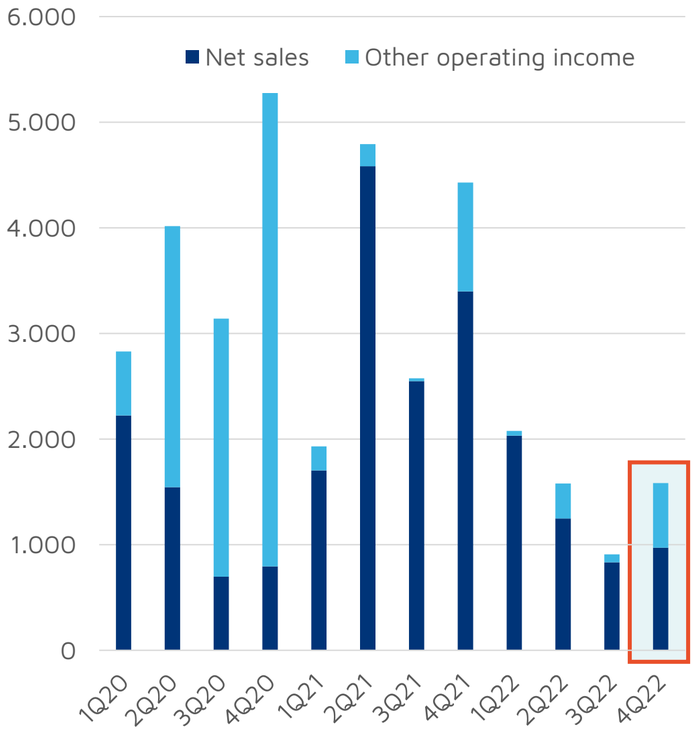
Mark R. Schleiss, MD, is a Professor of Pediatrics in the University of Minnesota Medical School. Received his MD degree from the Oregon Health and Sciences University. Residency at Doernbecher Children's Hospital, Oregon Health and Sciences University, and his Pediatric Infectious Diseases fellowship at Seattle Children's Hospital/Medical Center. Fellowship in Molecular Medicine studying cytomegalovirus (CMV) molecular genetics at the Fred Hutchinson Cancer Research Center. His work in basic, translational and clinical research related to CMV is described at cmv.umn.edu.

Financials and Outlook

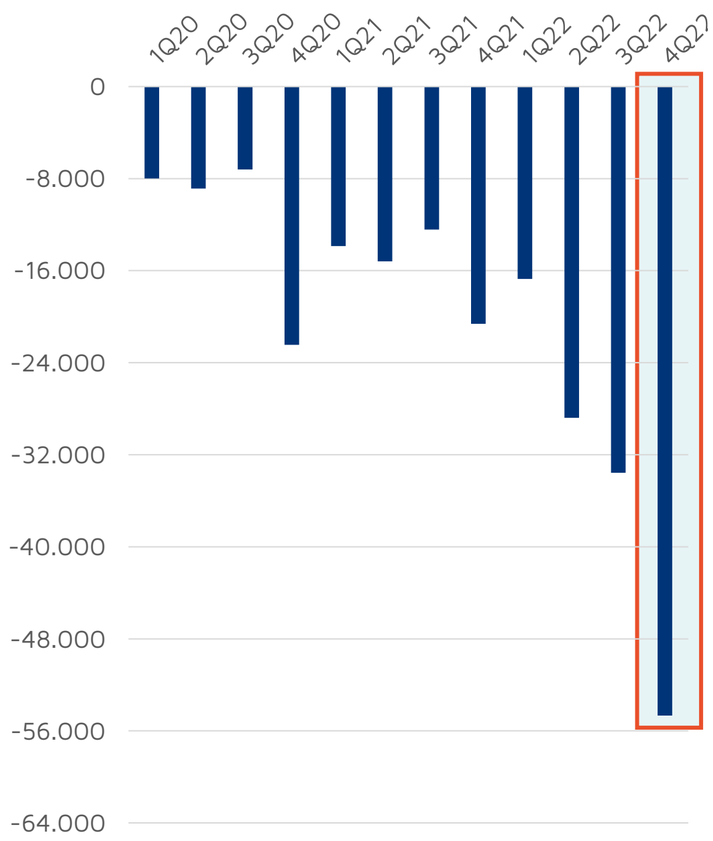
Financials – Fitting the Pipeline Strategy

Q1-Q2 2023 rights issue flows in approximately 54 MSEK in gross proceeds

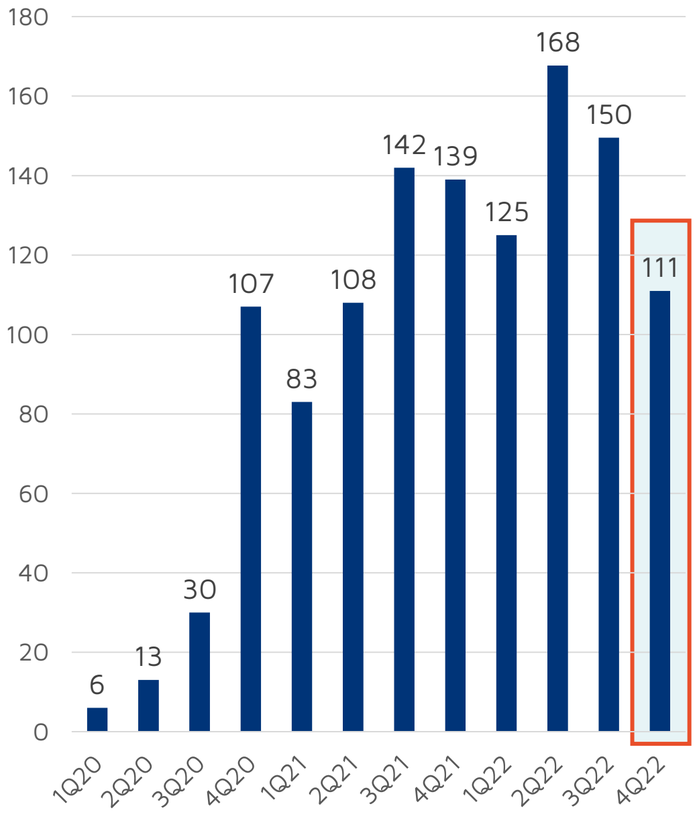
Revenues, SEK `000s



Operating profit/loss, SEK `000s



Cash balance, SEK million



Advancing Towards Key Catalysts

	2022	2023	2024	2025
COVID-19 (ABNCoV2)	✓ BN Phase II study readout H1 2022 ✓ **BN Phase III study initiation Q3 2022**	BN Phase III initial readout BN initiating rolling submission	BN ready for market launch (subject to regulatory approval)	Royalties from sales?
BREAST CANCER (ES2B-C001)	✓ Preclinical animal proof-of-concept results H1 2022 ✓ Preliminary preclinical safety studies initiated	✓ GMP manufacturing processing GLP nonclinical tox-study in NHP ✓ **Initial readout from preliminary nonclinical tox-studies**	Filing of clinical study application Initiation of first in human clinical study 2024	Out-licensing window opens pending human data
INFLUENZA (INDIGO/MUCOVAX)	✓ Advance/support further development in INDIGO of one or more candidates in 2022	✓ **Grant award for the MUCOVAX project for intranasal vaccine** cGMP/Preclinical safety studies initiation on INDIGO (subject to new grant funding)	Progression towards lead influenza vaccine candidate for the MUCOVAX project	
CYTOMEGALOVIRUS (ES2B-I002)	✓ **Establish 50/50% partnership on cytomegalovirus vaccine with Evaxion**	Early research on CMV vaccine target, applying AI	Preclinical testing of immunogenicity of CMV vaccine target	Selection of lead CMV vaccine candidate
MALARIA	✓ RH5 Additional phase I study in a malaria endemic region in Africa launched during 2021, with alternative adjuvant	Pfs 48/45 phase I study initiation 2023 (pending University of Oxford) RH5-VLP phase I initiation 2023 (pending University of Oxford) RH5 phase I study readout H2 2023		

Note: Timeline for ABNCoV2 is based on Bavarian Nordic's communicated timeline, and is subject to potential revision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