



### Forward-looking statements and disclaimer

This report contains forward-looking statements. The words "believe". "expect". "anticipate", "intend" and "plan" and similar expressions identify forward-looking statements. All statements other than statements of historical facts included in this report, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward-looking statements. Such forward-looking statements involve known and unknown risks uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such forwardlooking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future. The important factors that could cause our actual results, performance or achievements to differ materially from those in the forward-looking statements include, among others, risks associated with product discovery and development, uncertainties related to the outcome of clinical trials. slower than expected rates of patient recruitment, unforeseen safety issues resulting from the administration of our products in patients, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive

environment in relation to our business area. and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors. Further, certain forward-looking statements are based upon assumptions of future events which may not prove to be accurate. The forward-looking statements in this document speak only as at the date of this report. ExpreS<sup>2</sup>ion Biotech does not undertake any obligation to update or revise forward-looking statements in this report nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.

#### **Definitions**

"ExpreS<sup>2</sup>ion Biotech Holding AB" refers to ExpreS<sup>2</sup>ion Biotech Holding AB with corporate identity number 559033-3729. "The Company" or "ExpreS<sup>2</sup>ion" refers to the group, i.e. ExpreS<sup>2</sup>ion Biotech Holding AB and its fully owned operational subsidiary ExpreS<sup>2</sup>ion Biotechnologies ApS, Denmark.



# A word from our CEO

"The vaccination of the first subject in the COVID-19 Phase III clinical trial for ABNCoV2 as a booster vaccine is a historic milestone for ExpreS<sup>2</sup>ion as a company, as this is the first time our ExpreS2 platform is being evaluated in a clinical Phase III trial."

The third quarter of the year turned out to be another busy and successful period for our company, with continued strong progress for our pipeline-driven strategy.

The most important milestone reached during the quarter was the vaccination of the first subject in the COVID-19 Phase III clinical trial for ABNCoV2 as a booster vaccine, which we announced in September. In this trial, initiated by the licensee Bavarian Nordic, the ABNCoV2 vaccine is being compared to the licensed mRNA vaccine Comirnaty®, with initial results expected towards the end of 2022. This large doubleblind, controlled Phase III clinical trial will include approximately 4,000 adult subjects who either previously completed primary vaccination or have already received one booster dose of a licensed COVID-19 vaccine.

The start of this Phase III trial is an important milestone for this high-profile Nordic COVID-19 vaccine project, and it was followed by the initiation of the Danish part of the trial at hospitals on Zealand, Jutland and Funen during October. It is also a historic milestone for ExpreS<sup>2</sup>ion as a company, as this is the first time our ExpreS2 platform is being evaluated in a clinical Phase III trial. This progress is therefore positive for all parts of our business, and of course even more so if the trial turns out to be successful.

We are also seeing continued progress according to plan in our fully owned HER2-breast cancer vaccine project. The ES2B-CO01 candidate is currently undergoing preclinical safety studies, which are expected to be completed next year. At the same time, we continue to scale up the

manufacturing process for the HER2 antigen and VLP parts of the candidate together with contract manufacturers. These processes and the manufacturing of GMP material are also expected to be completed during 2023, followed by the first clinical trial in 2024.

The progress in our activities in the quarter was both satisfying and expected, including the ongoing Phase III validation of our ExpreS2 platform for the first time. I speak for the whole ExpreS2ion team when I say we have great confidence in our abilities directed towards the creation of powerful vaccines for COVID-19, breast cancer, influenza and malaria, in collaboration with valued partners around the world.

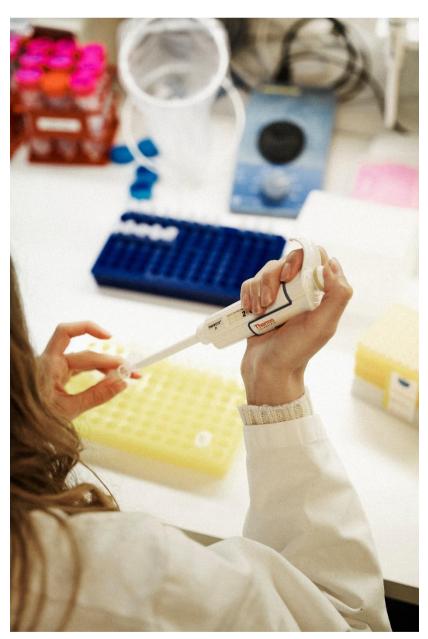
Looking ahead, the near future will surely be very interesting as we are approaching the presentation of the initial results from the COVID-19 Phase III clinical trial for ABNCoV2, which are expected in early 2023. If the outcome is positive, rolling submissions will then be provided to regulatory authorities with the aim of obtaining approval in 2023. I really do hope that this becomes a reality, so that the global community gets access to an important new tool in the continued fight

against COVID-19. This is needed if we are to be able to wind down social safety measures in all parts of the world. As a Danish citizen, I will be especially proud if a day comes in the not too distant future when ExpreS²ion's hard work over the years can finally be converted into a valuable treatment for the Danish healthcare system. Not just of myself, but of all my colleagues, our partners and our investors who will then have made it possible for us to succeed with such an extraordinary and at the same time very tangible achievement.

#### Bent U. Frandsen

CEO, ExpreS<sup>2</sup>ion Biotech Holding AB





# About ExpreS<sup>2</sup>ion

ExpreS<sup>2</sup>ion Biotechnologies ApS was founded in 2010 on the realisation that to produce the complex proteins needed for biological drugs and vaccines of the future, in a safer and more efficient manner, a new protein expression system would be needed.

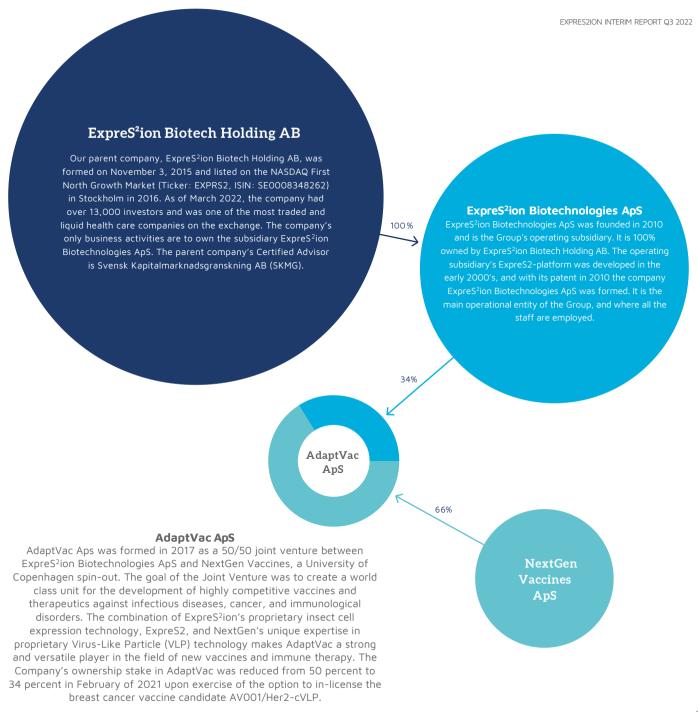
The Company developed the ExpreS2 recombinant protein expression platform supporting all phases of drug discovery and R&D as well as GMP manufacturing for clinical studies. With the ExpreS2 platform, the Company enables high-quality production of complex proteins using *Drosophila melanogaster* (fruit fly) S2 cell lines. ExpreS²ion has emerged as a company capable of solving difficult protein challenges and intends to be at the forefront of vaccine development platforms. Since 2019, ExpreS²ion's offering to the biopharmaceutical industry also includes glycol-engineered S2 cell lines under the GlycoX-S2™ brand. This allows for functional modification, e.g., by enhancing immunogenicity or improving pharmacokinetics. The Company sells licenses to use the ExpreS2 platform as a whole or in part to both pharmaceutical companies and research institutions. All ExpreS²ion's pipeline assets incorporate the ExpreS2 technology.

#### The Company believes that the strengths of the platform include:

- Significantly less costly and timeconsuming than alternative methods, which is an important competitive advantage, considering time-to-market and patent expiry. It also makes the platform particularly valuable for the development of diagnostics and vaccines in epidemic or pandemic situations where speed is of the essence.
- 2. Generates higher yields, i.e. amount of protein per manufacturing batch, compared to competing systems.
- 3. Provides homogeneous manufacturing batches, a requirement in pharmaceutical development. The platform includes the Company's patented expression vectors which were developed, among other things, to make it possible for the cells to generate higher yields.
- 4. Since 2019 the Company's offering to the biopharma sector includes glycoengineered S2 cell lines under the GlycoX-S2™ brand. This allows for functional modification, e.g. by enhancing immunogenicity or improving pharmacokinetics.

# **Company structure**

ExpreS<sup>2</sup>ion has a streamlined company structure. ExpreS<sup>2</sup>ion Biotech Holding AB is the Swedish entity listed on Nasdaq First North Growth Market since 2016. ExpreS<sup>2</sup>ion Biotechnologies ApS is the operational entity, with offices and labs in the Scion DTU Science park 20 km north of Copenhagen, Denmark, and was established in 2010. AdaptVac ApS is a joint venture established in 2017 together with a group of scientists from the Institute of Immunology and Microbiology at the University of Copenhagen. The scientists own their part of AdaptVac through a joint holding company named NextGen Vaccines ApS.



# **Business** model

#### Vision and mission of the Company

ExpreS<sup>2</sup>ion is a biotechnology company that turns complex proteins into tomorrow's vaccines and aims to become a leading player within infectious diseases and cancer. The Company strives to deliver new preventive and therapeutic products that meet some of the gravest global medical needs. The Company aims to achieve this through scientific excellence, a continued focus on academic and industrial collaborations and a profound loyalty to the Company's core skills in protein expression and vaccine development.

#### **Business model**

The Company's business model is first and foremost to develop a unique pipeline of preventive and therapeutic vaccine products. In parallel herewith, the Company generates revenue by providing fee-for-service contract research and products within recombinant protein expression, as well as outlicensing the ExpreS2 platform to research institutes and pharmaceutical companies which develop biopharmaceutical drugs and vaccines

on their own, or in cooperation with the Company. The Company also sells ExpreS2 test kits and reagents for application as research tools or diagnostics. This model generates short term revenue from the contract research organization (CRO) business, while the pharmaceutical products developed using the Company's tech nology carry potential future royalties, license fees, and milestone payments.

The Company is building its own pipeline of preclinical and later-stage clinical biopharmaceutical drug and vaccine candidates. ExpreS<sup>2</sup>ion will carry out its own initial research, preclinical and early clinical development work (proofof-concept) prior to out-licensing. The agreement with Bavarian Nordic in 2020, under which Bavarian Nordic assumes all future development costs for the COVID-19 vaccine program and pay certain milestones and royalties, subject to external funding, is according to the Company the first example of validated ability to develop new preventive and therapeutic products that meet some of the gravest medical needs.

The Company believes that the combination of an inhouse pipeline of biopharmaceutical drug and vaccine candidates, while maintaining a revenue generating CRO business, puts the Company in a good position to balance risk and return and create value for its shareholders.

#### Strategy and growth

ExpreS<sup>2</sup>ion aims to develop the pipeline further by adding additional projects while continuing preclinical and early clinical development work on existing projects. The Company targets human Proof-of-Concept in order to maximize high-value partnerships for further development, but acknowledge that earlier partnering is also an option for progressing pipeline projects. The Company also aims to improve the technology platform further to ensure competitiveness. This is done by improving the ExpreS2 system, potentially adding relevant compatible technologies, and continuing to sell licenses for the use of the ExpreS2 platform.

#### ExpreS2 Platform for Protein Expression:

+500 different proteins have been produced with the ExpreS2 platform, while posting a success rate exceeding 90% across +100 clients and partners.





### Novel Pipeline Development





#### Independent

Fully-owned development of novel protein therapeutics and vaccines

After human PoC, targeting partner externally for further development

#### Collaboration

Partner with leading research organizations to source and develop novel programs

Potential to fully acquire programs for independent development

#### **Services**

Early-stage R&D for leading academic, research, and biotech organizations

Protein feasibility, delivery, and transfer to GMP production

#### Licensing & Kit Sales

Fully out-license rights to ExpreS2 technology

Sell test kits and reagents for research or diagnostic applications

Significant upside potential: Intermediate/long-term Revenue-generating business: Current and long-term payments

# **Partners**

#### **Broad Customer and Collaborator Base**

With over 100 currently active or former academic and industrial service and license contracts, the Company has built a large network in the international research community since its inception in 2010. Furthermore, the Company is currently a part of an inter- national research consortia which together has been granted more than an estimated EUR 40 million of non-dilutive public funding. The Company also sells licenses to use the ExpreS2 platform as a whole or in part, thus allowing its clients to participate in or be entirely responsible for the development of the required proteins. The Company sells ExpreS2 test kits and reagents for application as research tools or diagnostics. The Company may also enter into agreements in which the client accepts a quotation and is charged for the development, production and delivery of research grade proteins, using the ExpreS2 platform.

The Company services both pharmaceutical companies and research institutions. The ExpreS2 platform is equally suited for academic research, analytics and commercial drug development, both in vaccines and other biopharma fields. The Company's clients are not limited to any geographic area and are located all over the world. Since its foundation in 2010. the Company has worked with more than 100 clients and partners. The agreements with these clients, which in many cases are world-leading universities, research institutions and pharmaceutical companies, have generated significant revenues for the Company over the years. It currently has more than ten major clients. For instance, the Company has out-licensed the ExpreS2 platform for research to Hoffman-La Roche, Imperial College London and Francis Crick Institute among others, and outlicensed the platform for clinical development to the University of Copenhagen and the Jenner Institute of the University of Oxford, among others.



+100

Since its foundation in 2010, the Company has worked with more than 100 clients and partners



#### **Academics**

- Boston Children's Hospital
- Cancer Research, UK
- Harvard Medical School
- Imperial College London
- The Jenner Institute
- Sir William Dunn School of Pathology
- Statens Serum Institute
- Technical University of Denmark (DTU)
- University of Copenhagen
- Department of Biochemistry, University of Oxford



#### Bio Pharma

- Fli I illy
- Janssen, Pharmaceutical companies of Johnson & Johnson
- Novartis
- Roche
- Servier



Small and medium-sized enterprises, contract manufacturing organizations, diagnostics and retailers

- AGC Biologics
- Genlbet Biopharmaceuticals
- Idorsia
- Integrated biotherapeutics
- Intravacc
- Virion\Serion; SERION Diagnostics

# **Pipeline**

DISEASE		Project / Target	Discovery	Pre-clinical Pharmacology	cGMP / Tox	Phase 1	Phase 2	Phase 3	Market potential
Corona virus	30.75	ABNCoV2/SARS-CoV-2 cVLP							> 100 billion EUR
Breast cancer	The state of the s	ES2B-C001/Her2 cVLP							> 15 billion EUR
Influenza		Hemagglutinin							> 4 billion EUR
Malaria	**								> 0.6 billion EUR
I: Blood		RH5							
II: Blood		RH5-VLP							
III: Transmission	1	Pfs 48/45							
IV: Placental		VAR2CSA							
V: Blood		CYRPA complex							

As of October 2022

# Pipeline



#### **CORONAVIRUS/COVID-19**

ExpreS<sup>2</sup>ion and its associated company AdaptVac have been engaged in the development of a unique capsid virus-like particle (cVLP) COVID-19 vaccine, partly sponsored through a Horizon 2020 EU grant award to the PREVENT-nCoV consortium to rapidly advance the vaccine candidate against COVID-19 into the clinical stage. The candidate vaccine is a cVLP applying ExpreS2-produced SARS-CoV-2 antigens, thereby creating a powerful immunogenic vaccine. In July 2020, AdaptVac and Bavarian Nordic, a fully integrated biotechnology company focused on the development, manufacture and commercialization of life-saving vaccines, entered into a license agreement providing Bayarian Nordic the global commercialization rights to the proprietary capsid virus like particle based SARS-CoV-2 subunit vaccine, designated ABNCoV2. For application of our proprietary protein production system ExpreS2, ExpreS<sup>2</sup>ion and AdaptVac have also entered into a license agreement for this project.

In addition to ExpreS2ion and AdaptVac. the PREVENT-nCoV consortium members are Leiden University Medical Center (LUMC), Institute for Tropical Medicine (ITM) at University of Tübingen. The Department of Immunology and Microbiology (ISIM) at University of Copenhagen, the Laboratory of Virology at Wageningen University, and Radboud University Medical Center. We announced the first headline results of the clinical Phase I/IIa in August 2021 and demonstrated positive safety and efficacy outcomes. Bavarian Nordic is currently running a Phase II study to determine the vaccine's potential as a universal booster. Preliminary results in December 2021 demonstrated a strong boosting effect for all variants tested and confirmed the vaccine's excellent profile as a nonadjuvanted universal COVID-19 booster vaccine.

Additional positive Phase II results were presented in February 2022. The full study data confirms that existing levels of SARS-CoV-2 neutralizing antibodies increased by 2-40-fold, depending on the initial levels of antibodies, with no serious adverse events reported. Based on this excellent outcome, Bavarian Nordic initiated a Phase III study in the third quarter of 2022. In October 2022, Bavarian Nordic announced that ABNCoV2 demonstrated durable antibody response six months after vaccination, reflecting a less sharp decline

in peak neutralizing titers compared to data published for mRNA vaccines, indicating a potentially longer duration of protection across variants of concern.



#### **BREAST CANCER**

Breast cancer is a widespread oncology indication affecting more than 1.3 million people worldwide annually, resulting in more than 450,000 deaths (Tao, 2015: www.ncbi.nlm.nih.gov/pubmed/2554 3329). The most common treatment today is based on monoclonal antibodies, where the dominating therapies Herceptin (trastuzumab) and Perjeta (pertuzumab) generate annual global sales of USD 7 billion.

The target product profile of our lead breast cancer project, ES2B-C001 (HER2-cVLP), is tailored to be highly competitive both in terms of cost and efficacy, thus aiming at a significant market share.

In February 2021, ExpreS<sup>2</sup>ion signed a final patent license agreement with AdaptVac whereby ExpreS<sup>2</sup>ion exclusively licensed in AVOO1 (renamed FS2B-CO01). This gives ExpreS2ion full control over and responsibility for driving this valuable asset forward, hereby realising the very significant value of this project. At the end of 2021. ExpreS2ion's candidate demonstrated strong tumor-growth inhibiting effect in a mice models, thus reaching an important pre-clinical milestone ahead of schedule. Additionally, anti-HER2 antibodies from these studies were found to effectively inhibit tumor growth in human cancer cells. The candidate also demonstrated proof-ofconcept in HER2-transgenic preventive as well as therapeutic tumor mice models, thus reaching a further important preclinical milestone.

Based on feedback from the Danish Medicines Agency (DKMA), ExpreS<sup>2</sup>ion will conduct additional preclinical safety studying, which will increase the robustness of the project's preclinical data. Consequently, the Company is now aiming to file the clinical trial application for the Phase I trial towards the end of 2023, with the aim of dosing first in human in the first half of 2024.

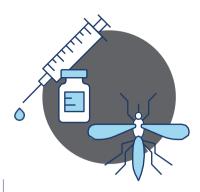


#### **INFLUENZA**

The international next-generation influenza vaccine consortium INDIGO, led by the University of Amsterdam with ExpreS²ion as a participating member, is developing a next-generation influenza vaccine in a large collaboration between public and private R&D organisations from the EU, India, and the United States. The project has been awarded a 10 MEUR Horizon 2020 grant from the EU, of which ExpreS²ion's participation was directly awarded 0.6 MEUR.

The INDIGO consortium plans to carry out the preclinical and clinical development of the project, which contains two novel influenza vaccine concepts, including the application of a novel potent adjuvant by LiteVax BV, the Netherlands, as well as the use of the ExpreS2 platform for antigen production by ExpreS2ion. The aim is to create an influenza vaccine that meets the requirements of global vaccination, i.e. to achieve <10% instead of 60% non-responders, combined with a lower

manufacturing cost and better accessibility.



#### **MALARIA PROJECTS**

#### Malaria I

#### Blood stage (RH5-1)

Jenner Institute of the University of Oxford is developing the blood-stage Plasmodium falciparum malaria antigen RH5.1 with ExpreS<sup>2</sup>ion as a collaboration partner. The RH5.1 antigen is produced in ExpreS<sup>2</sup>ion's ExpreS2 platform.

#### Malaria II

#### Blood stage (RH5-2)

With the aim to further improve efficacy, the Jenner Institute of the University of Oxford is developing a second-generation RH5 vaccine, RH5.2, in the ExpreS2 platform. RH5.2 has been engineered to retain regions important for red blood cell recognition, which are targeted by neutralising antibodies. Additionally, the RH5.2 protein will be

displayed on the surface of a hepatitis B derived virus-like particle (VLP) in order to maximise the induction of high titre antibodies. The project is funded by the Wellcome Trust.

#### Malaria III

#### Transmission (Pfs48/45)

The goal for a transmission-blocking vaccine is to prevent the transfer to mosquitos feeding on persons infected with malaria, thus effectively hindering further spread of the disease. Thereby a transmission-blocking vaccine does not give direct protection from the disease, but it stops the disease from spreading and could therefore lead to eradication of malaria. During the last decade, the inability to produce the full-length Pfs48/45 antigen has been a major roadblock for researchers aiming to create a transmission-blocking malaria vaccine. However, this challenge was overcome by ExpreS<sup>2</sup>ion and Jenner Institute at the University of Oxford.

This vaccine is developed by the Horizon 2020-funded OptiMalVax grant consortium, led by Jenner Institute at the University of Oxford with ExpreS²ion as a member. The objective of the consortium is to create a combination malaria vaccine, and its clinical program will include trials to assess the preerythrocytic, blood-stage and mosquito-stage components of the combination vaccine, including this transmission vaccine.

#### Malaria IV

#### Placental (VAR2CSA)

ExpreS<sup>2</sup>ion is a part of the PlacMalVac project that started in 2013 as an international consortium project with the aim to develop a vaccine against placental malaria. The project is based on the antigen VAR2CSA, which enable parasite accumulation in the placenta and was discovered by Professor Ali Salanti and others at the University of Copenhagen.

#### Malaria V

#### Blood-stage (PfRipr complex)

An international research team, including scientists from ExpreS<sup>2</sup>ion and led by the Walter and Eliza Hall Institute of Medical Research (WEHI), is developing a next generation malaria vaccine that is targeting a recently discovered molecular 'key' that the deadly malaria parasite uses to enter human blood cells. The malaria 'kev' was first described in a Nature article, published December 2018 from the group. It is a complex of three parasite proteins called Rh5, CyRPA and Ripr, where the three proteins work together to unlock and enter the cell. This central role in the infection of human blood cells makes the complex a new and promising target for vaccine development. The vaccine is based on a patent co-owned by WEHI and ExpreS<sup>2</sup>ion.

### Significant events

#### Third quarter of 2022

On July 11, ExpreS<sup>2</sup>ion Biotech Holding AB announced that 167,394 warrants held by employees under the 2019 Warrant Program ("TO2") have been fully exercised, providing ExpreS<sup>2</sup>ion SEK 805,165. The exercise has increased the number of shares by 167,394 from 36,994,712 to 37,162,106.

On August 10, ExpreS<sup>2</sup>ion announced that 136,422 warrants held by employees under the 2019 Warrant Program ("TO2") have been fully exercised, providing ExpreS<sup>2</sup>ion SEK 656,190. The exercise has increased the number of shares by 136,422 from 37,162,106 to 37,298,528.

On August 18, ExpreS<sup>2</sup>ion Biotech Holding AB announced its second quarter financial results for 2022.

On September 2, ExpreS<sup>2</sup>ion announced that a Phase III clinical trial to evaluate the ABNCoV2 capsid virus-like particle (cVLP) based COVID-19 vaccine had been initiated by Bavarian Nordic, including the vaccination of the first subject. The trial aims to demonstrate non-inferiority of ABNCoV2 as a booster vaccine for individuals with previous COVID-19 disease or vaccination compared to the licensed mRNA vaccine Comirnaty®. Initial trial results are expected towards the end of 2022.

On September 7, ExpreS<sup>2</sup>ion Biotech Holding AB announced that 308,268 warrants held by employees under the 2019 Warrant Program ("TO2") have been fully exercised, providing ExpreS<sup>2</sup>ion SEK 1,482,769. The exercise has increased the number of shares by 308,268 from 37,298,528 to 37,606,796. All 612,084 TO2 warrants have now been exercised, providing ExpreS<sup>2</sup>ion in total SEK 2,944,124.

#### **Subsequent events**

On October 6, ExpreS<sup>2</sup>ion Biotech Holding AB announced that Allan Rosetzsky, with immediate effect, had decided to resign from ExpreS<sup>2</sup>ion's board of directors. Hereafter the board of directors will consist of Martin Roland Jensen (Chair), Jakob Knudsen, Karin Garre, and Sara Sande.

On October 17, ExpreS<sup>2</sup>ion announced that follow-up results from Bavarian Nordic's Phase II clinical trial for the ABNCoV2 capsid virus-like particle (cVLP) based COVID-19 booster vaccine show that antibody titers remained high at levels associated with greater than 90% efficacy six months after vaccination for both the Wuhan and the Omicron variant.

On October 24, ExpreS<sup>2</sup>ion announced that the journal Biomedicines published an article about the breast cancer vaccine candidate ES2B-C001 titled "Prevention and therapy of metastatic HER-2+ mammary carcinoma with a human candidate HER-2 virus-like particle vaccine".

On November 3, ExpreS²ion announced the establishment of an Oncology Scientific Advisory Board (OSAB). The six initial members of the ExpreS²ion OSAB bring a depth of knowledge in oncology, breast cancer, clinical trials and therapeutic HER2 vaccines, and will contribute to the development of ExpreS²ion's proprietary HER2-cVLP breast cancer vaccine, ES2B-CO01. The OSAB will serve as advisors, potential contributors to the planned clinical studies and participants in Key Opinion Leader events for the scientific community and investors.

# Advancing towards key catalysts

2023 2024+ 2022 BN Phase III initial readout in early 2023 BN Phase III **BN Phase II** trial readout trial initiation BN initiating CORONAVIRUS/ Q3 rolling submission COVID-19 BN ready for market launch ABNCoV2 (subject to regulatory approval) Outlicensing Preclinical animal GMP Preclinical safety Filing of clinical Initiation of first window opens proof-of-concept manufacturing studies readout human clinical trial application pendina study 2024 results H1 processing **BREAST CANCER** human data ES2B-C001 Advance/support further cGMP/Preclinical safety studies development of one or more initiation (subject to new grant candidates funding) INFLUENZA Pfs 48/45 phase I RH5-VLP phase I RH5 phase I trial trial initiation readout H2 initiation MAI ARIA

# Summary of Q3 interim results



#### Third Quarter (July - September 2022)

- Operating income amounted to 909 (2,576) KSEK.
- Profit/loss after financial items amounted to -31,810 (-10,308) KSEK.
- Profit/loss for the period amounted to -30,701 (-9,382) KSEK.
- Net income per share\* amounted to -0.82 (-0.32) SEK.

#### Year-to-date (January - September 2022)

- Operating income amounted to 4,567 (9,300) KSEK.
- Profit/loss after financial items amounted to -73,294 (-32,572) KSEK.
- Profit/loss for the period amounted to -70,072 (-29,605) KSEK.
- Net income per share\* amounted to -2.05 (-1.04) SEK.

#### **Key financials**

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Operating income
Profit/loss after financial items
Profit/loss for the period
Earnings per share\*
Cash balance, end of period
Cash balance including SKAT
balance, end of period\*\*
Total assets
Equity/asset ratio (%)\*\*\*

Q3 2022	Q3 2021	% Change
909	2,576	-65%
-31,810	-10,308	209%
-30,701	-9,382	227%
-0.82	-0.32	158%
149,561	141,998	5%
149,561	141,998	5%
170,498	159,428	7%
87%	92%	-4%

YTD 2022	YTD 2021	% Change	FY 2021
4,567	9,300	-51%	13,730
-73,294	-32,572	125%	-47,516
-70,072	-29,605	137%	-43,925
-2.05	-1.04	98%	-1.50
149,561	141,998	5%	37,111
149,561	141,998	5%	138,880
170,498	159,428	7%	151,956
87%	92%	-4%	92%

Figures in parenthesis are the numbers from the same period in 2021.

<sup>\*</sup>The Group's net income per share: The net income for the period divided with the average number of shares for the period. For the period January to September 2022, the average number of shares amounted to 34,250,095. As of 30/09/2022, the total number of shares in ExpreS<sup>2</sup>ion Biotech Holding AB was 37,606,796.

<sup>\*\*</sup>In Q4 2021 the Company decided to store cash in its account with the Danish tax authority (SKAT), where no interest is charged. See callout on next page for more information.

<sup>\*\*\*</sup>Equity ratio: Shareholder's equity divided by total capital.

#### Financial overview

#### Development in figures for Q3 2022

#### Operating income

Total operating income during the third quarter of 2022 amounted to KSEK 909 (2,576), which was 65% lower compared to the same period last year. Revenue continued to decline in the third quarter as the company shifted its focus from its legacy CRO business to its development pipeline. Net sales from client projects, licenses and web store purchases fell 67% compared to Q3 2021, while other operating income, which primarily reflects grants, increased minimally year-over-year on an absolute hasis

#### Profit/loss for the period

The net loss for the third quarter of 2022 amounted to KSEK -30,701 (-9,382). The lower result is primarily driven by a SEK 17.4 million increase in R&D costs, primarily related to preclinical development and chemistry, manufacturing and controls (CMC) of the breast cancer vaccine candidate ES2B-C001. Other significant drivers include higher personnel costs (-SEK 2.5 million) due to a higher headcount and lower operating income (-SEK 1.7 million) mentioned above. Other external costs increased SEK 6.8 million and other operating expenses decreased SEK 7.0 million, reflecting the reversal of grant income disclosed in the Q3 2021 report. Excluding that reversal, those two lines did not materially change year-over-year.

#### Cash and cash equivalents

As of September 30, 2022, ExpreS<sup>2</sup>ion's cash and bank amounted to KSEK 149,561 (141,998). During the quarter, cash decreased by SEK 21 million driven by negative cash flow from operations of SEK 23 million, driven by the factors mentioned in the paragraphs above, partially offset by the positive impact of the TO2 warrant program exercise which raised SEK 3 million. During the third quarter, it was announced that Company's cash in its DKK account will no longer incur negative interest.

#### Development in figures year-to-date 2022

#### Operating income

Total operating income in the first nine months of 2022 amounted to KSEK 4,567 (9,300), which was 51% lower compared to the same period last year. Net sales from client projects, licenses and purchases from our web store of SEK 4.1 million reflects a decrease of 53% year-over-year, whereas grant income of SEK 0.5 million reflects a year-over-year decrease of 2%.

#### Profit/loss for the period

The net loss in the first nine months of 2022 amounted to KSEK -70,072 (-29,605). The lower result is primarily driven by a SEK 25.5 million increase in R&D costs, which related to the preclinical development and CMC of the breast cancer vaccine candidate ES2B-C001. Other significant drivers include higher personnel costs (-SEK 12.4 million) due to a higher headcount and non-cash incentive compensation charges that are reversed in the cash flow statement, and the lower operating income (-SEK 4.7 million) mentioned above. Partially offsetting is a reduction in costs attributed to raw materials (+SEK 2.5 million). The year-to-date figures are similarly impacted by the 3Q 2021 grant income reversal mentioned in the 3Q 2022 commentary to the left. After adjusting for the reversal, other external costs increased by approximately SEK 2.9 million, reflecting an increase in premises, insurance and other costs partially offset by income from financial investments and an increase in the accrued R&D tax credit.

### Income statement - group

KSEK	Q3 2022	Q3 2021	% change	YTD 2022	YTD 2021	% change	FY 2021
Operating income							
Net sales	833	2,548	-67%	4,114	8,836	-53%	12,234
Other operating income	76	28	171%	453	464	-2%	1,496
Total operating income	909	2,576	-65%	4,567	9,300	-51%	13,730
Operating costs							
Raw materials & consumables	-1,653	-68	2331%	-3,751	-6,341	-41%	-7,513
Research & development costs	-19,828	-2,420	719%	-33,310	-7,830	325%	-9,815
Other external costs	-3,441	3,326	-203%	-10,690	-720	1384%	-3,516
Personnel costs	-8,338	-5,851	43%	-30,395	-18,023	69%	-32,374
Depreciation of tangible & intangible fixed assets	-317	-316	0%	-945	-1,490	-37%	-1,809
Other operating expenses	0	-7,104	-100%	0	-7,104	-100%	-7,099
Total operating costs	-33,577	-12,433	170%	-79,091	-41,508	91%	-62,126
Operating profit/loss	-32,668	-9,857	231%	-74,524	-32,208	131%	-48,396
Result from financial investments							
Result in associated companies	0	1	-100%	0	671	-100%	671
Other interest income & similar items	1,217	34	3523%	2,017	0	n/a	0
Interest expense & similar items	-359	-485	-26%	-787	-1,035	-24%	209
Total result from financial investments	858	-451	-290%	1,230	-364	-438%	880
Profit/loss after financial items	-31,810	-10,308	209%	-73,294	-32,572	125%	-47,516
Income tax on the result for the period	1,109	926	20%	3,222	2,967	9%	3,591
Profit/loss for the period	-30,701	-9,382	227%	-70,072	-29,605	137%	-43,925

### Balance sheet - group

KSEK	Q3 2022	YE 2021	% change	Q3 2021
Assets				
Assets				
Concessions, patents, licenses, trademarkets and similar intellectual rights	2 011	2 141	-4%	2 240
Total non-current intangible assets	3,011 <b>3,011</b>	3,141 <b>3,141</b>	-4% - <b>4%</b>	3,240 3,240
Total Holl-corrent intelligible assets	3,011	3,141	-470	3,240
Plants and machinery	850	1,209	-30%	1,420
Total non-current tangible assets	850	1,209	-30%	1,420
Interest in associated companies	25	23	9%	23
Other long-term receivables	1,503	1,119	34%	1,117
Total non-current financial assets	1,528	1,142	34%	1,140
Total non-current assets	5,389	5,492	-2%	5,800
Accounts receivable	1,050	1,623	-35%	4,438
Tax receivables	6,950	3,470	100%	5,680
Other receivables	1,299	2,012	-35%	929
Prepaid expenses and accrued income	6,249	479	1205%	583
Total receivables	15,548	7,584	105%	11,630
Other short-term investments	0	101,769	-100%	0
Total short-term investments	0	101,769	-100%	0
Cash and bank	149,561	37,111	303%	141,998
COST ON OUT IN	143,501	37,111	30370	סככ,ודו
Total current assets	165,109	146,464	13%	153,628
TOTAL ASSETS	170,498	151,956	12%	159,428

KSEK	Q3 2022	YE 2021	% change	Q3 2021
Equity and liabilities				
Share capital	4,179	3,461	21%	3,461
Other capital contributions	302,398	266,243	14%	257,438
Other equity including net loss for the period	-157,703	-129,358	22%	-114,911
Total equity	148,874	140,347	6%	145,988
Provision for taxes	621	671	-7%	691
Total provisions	621	671	-7%	691
Other long-term liabilities	2,348	3,477	-32%	3,920
Total long-term liabilities	2,348	3,477	-32%	3,920
Liabilities to credit institutions	1,810	1,918	-6%	1,960
Accounts payable	12,984	1,685	671%	1,761
Other liabilities	3,861	3,858	0%	5,108
Total short-term liabilities	18,655	7,461	150%	8,829
TOTAL EQUITY AND LIABILITIES	170,498	151,956	12%	159,428

#### Note: Cash and bank

On June 15, 2022, SKAT lowered the payout limit to DKK 200,000, resulting in a transfer of the Company's assets in its SKAT account back to the Company's bank account. Consequently, at the end of Q2 2022 the Company no longer stored cash in its SKAT account, shown in other short-term investments. For more information, please see the full-year 2021 and Q1 2022 financial reports.

## Changes in equity - group

#### FY 2021

	Other equity including net profit for the			
KSEK	Share capital	Other capital contributions	period	Total equity
Opening balance as of January 1st, 2021	3,067	178,042	-86,561	94,548
Issuance of new shares	394	82,910		83,304
Issuing expenses		-6,778		-6,778
Vesting of share-based compensation		11,756		11,756
Exchange difference for the period			1,442	1,442
Profit-loss for the period			-43,925	-43,925
Total equity as of December 31st, 2021	3,461	265,931	-129,045	140,347

#### YTD 2022

		Other capital	Other equity including net profit for the	
KSEK	Share capital	contributions	period	Total equity
Opening balance as of January 1st, 2022	3,461	265,931	-129,045	140,347
Issuance of new shares	718	75,242		75,960
Issuing expenses		-12,185		-12,185
Vesting of share-based compensation		7,953		7,953
Exchange difference for the period			6,871	6,871
Profit-loss for the period			-70,072	-70,072
Total equity as of September 30, 2022	4,179	336,941	-192,246	148,874

### Cash flow statement - group

KSEK	Q3 2022	Q3 2021	% change	YTD 2022	YTD 2021	% change	FY 2021
Operating profit/loss	-32,668	-9,857	231%	-74,524	-32,208	131%	-48,396
Adjustments for items not included in the cash flow	1,270	1,199	6%	8,833	4,612	92%	13,486
Received interest	1,217	34	3481%	2,017	0	n/a	0
				,	_		
Interest paid	-1,553	-276	463%	-2,711	-871	211%	-1,194
Cash flow from operating activities before changes in	- <b>31,734</b>	-7 <b>-8,907</b>	-100% <b>256%</b>	- <b>66,380</b>	-12 <b>-28,479</b>	-141% <b>133%</b>	2,795 <b>-33,309</b>
working capital	-31,734	-6,507	230%	-00,300	-20,479	13370	-33,309
Decrease(+)/increase(-) of current receivables	1,116	3,544	-69%	-4,366	-3,187	37%	-1,350
Decrease(+)/increase(-) of current liabilities	7,281	-1,595	-556%	10,564	-9,670	-209%	-10,988
Cash flow from operating activities	-23,337	-6,958	235%	-60,182	-41,336	46%	-45,646
Investments in associated companies	0	0	n/a	0	682	-100%	682
Investments in intangible non-current assets	0	45	-100%	0	45	-100%	45
Investments in tangible non-current assets	-90	-202	-55%	-190	-715	-73%	-715
Other investing activities	493	0	n/a	104,675	0	n/a	-100,933
Cash flow from investing activities	403	-157	-357%	104,485	12	n/a	-100,921
Leasing agreement	-95	-157	-39%	-430	-465	-8%	-621
Loans	-448	-344	30%	-1,331	-1,014	31%	-1,361
Issuance of new shares	2,944	44,257	-93%	75,960	83,304	-9%	83,304
Costs of issuing shares	-55	-3,431	-98%	-12,185	-6,778	80%	-6,778
Cash flow from financing activities	2,346	40,325	-94%	62,014	75,048	-17%	74,545
Cash flow for the period	-20,588	33,210	-162%	106,317	33,723	215%	-72,023
Cash and cash equivalents at the beginning of the period	167,719	108,289	55%	37,111	106,832	-65%	106,832
Exchange difference cash and cash equivalents	2,430	499	387%	6,133	1,443	325%	2,302
Cash and cash equivalents at the end of the period	149,561	141,998	5%	149,561	141,998	5%	37,111

cash equivalents at the end of the period At the end of Q2 2022, the Company no longer stored any cash in its SKAT account. The transfers from SKAT are presented in

Note: Cash and

See callout on page 18 for more information.

"Other investing activities."

## Income statement - parent

KSEK	Q3 2022	Q3 2021	% change	YTD 2022	YTD 2021	% change	FY 2021
Operating income							
Net sales	0	0	n/a	201	167	20%	368
Total operating income	О	0	n/a	201	167	20%	368
Operating costs							
Other external costs	-592	-482	23%	-3,165	-3,030	4%	-4,501
Personnel costs	-354	-314	13%	-1,759	-1,007	75%	-2,670
Total operating costs	-946	-796	19%	-4,924	-4,037	22%	-7,171
Operating profit/loss	-946	-796	19%	-4,723	-3,870	22%	-6,803
Result from financial investments							
Other interest income & similar items	627	0	n/a	938	0	n/a	1,015
Interest expense & similar items	0	319	-100%	-36	148	-124%	-181
Total result from financial investments	627	319	97%	902	148	509%	834
Profit/loss after financial items	-319	-477	-33%	-3,821	-3,722	3%	-5,969
Income tax on the result for the period	0	0	n/a	0	0	n/a	0
Profit/loss for the period	-319	-477	-33%	-3,821	-3,722	3%	-5,969

## Balance sheet - parent

KSEK	Q3 2022	YE 2021	% change	Q3 2021
Assets				
Shares in group companies	254,095	247,563	3%	168,307
Receivables from group companies	57,327	0	n/a	27,893
Total financial non-current assets	311,422	247,563	26%	196,200
Total non-current assets	311,422	247,563	26%	196,200
	,	·		·
Tax receivables	17	18	-6%	45
Other receivables	66	179	-63%	116
Prepaid expenses and accrued income	180	86	109%	60
Total receivables	263	283	-7%	221
Cash and bank	8,758	5,220	68%	49,620
Total current assets	9,021	5,503	64%	49,841
TOTAL ASSETS	320,443	253,066	27%	246,041

KSEK	Q3 2022	YE 2021	% change	Q3 2021
Equity and liabilities				
Share capital	4,179	3,461	21%	3,461
Restricted equity	4,179	3,461	21%	3,461
Share premium fund and retained earnings	319,221	254,180	26%	245,552
Profit/loss for the period	-3,821	-5,969	-36%	-3,722
Unrestricted equity	315,400	248,211	27%	241,830
Total equity	319,579	251,672	27%	245,291
Payables to group companies	0	790	-100%	0
Other liabilities	864	604	43%	750
Total short-term liabilities	864	1,394	-38%	750
TOTAL EQUITY AND LIABILITIES	320,443	253,066	27%	246,041

## Changes in equity - parent

#### FY 2021

			Other equity	
KSEK	Share capital	Other capital contributions	including net profit for the period	Total equity
			·	
Opening balance as of January 1st, 2021	3,067	171,502	-5,210	169,359
Issuance of new shares	394	82,910		83,304
Issuing expenses		-6,778		-6,778
Vesting of share-based compensation		11,756		11,756
Profit-loss for the period			-5,969	-5,969
Total equity as of December 31st, 2021	3,461	259,390	-11,179	251,672

#### YTD 2022

			Other equity	
		Other capital	including net profit	
KSEK	Share capital	contributions	for the period	Total equity
Opening balance as of January 1st, 2022	3,461	259,390	-11,179	251,672
Issuance of new shares	718	75,242		75,960
Issuing expenses		-12,185		-12,185
Vesting of share-based compensation		7,953		7,953
Profit-loss for the period			-3,821	-3,821
Total equity as of September 30, 2022	4,179	330,400	-15,000	319,579

# Shareholder information

ExpreS<sup>2</sup>ion Biotech Holding AB's share was listed at Nasdaq First North Growth Market on July 29, 2016. The trading name of the share is EXPRS2 and the ISIN-code is SE0008348262. As of September 30, 2022, the number of shares in ExpreS<sup>2</sup>ion Biotech Holding AB amounted to 37,606,796. The average amount of shares in the third quarter of 2022 amounted to 37,294,784. The Company has one class of shares. Each share carries equal rights to share in the Company's assets and earnings.

#### **Certified Advisor**

Svensk Kapitalmarknadsgranskning AB

Email: ca@skmg.se
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#### List of largest shareholders

Name	Number of shares held	Share of votes and capital
Avanza Pension	1,932,077	5.14%
Summary, shareholders over 5%	1,932,077	5.14%
Remaining shareholders under 5%	35,674,719	94.86%
Total September 30, 2022	37,606,796	100.00%

# Warrants

As of September 30<sup>th</sup>, 2022, the Company had one completed and two active series of warrants issued, all of which are part of incentive programs. These series are identified as T02, T06 and T07.

#### TO2 (2019/2022)

On May 23, 2019, the Annual General Meeting resolved to implement an incentive program for all employees and issue a maximum of 680,100 warrants, of which 612,084 were subscribed for and allocated to the employees. The exercise period for the TO2 warrant series was in three months from June 1 through August 31 2022, and was carried out in three tranches during the respective months. As of the date of publication of this report, all 612,084 warrants have been fully exercised, reflecting warrants exercised in the full exercise period.

#### TO6 (2020/2024)

On September 23, 2020, the Extraordinary General Meeting resolved to implement an incentive program for management and key persons and issue a maximum of 1,000,000 warrants. All warrants were subscribed for by the Company's subsidiary ExpreS²ion Biotechnologies ApS. As of the publication of this report 905,333 warrants have been transferred to selected employees.

#### TO7 (2021/2024)

On May 26, 2021, the Annual General Meeting resolved to implement an incentive program for senior executives, employees and other key persons not included in the TO6 program, and issue a maximum of 1,050,000 warrants, of which 797,780 were subscribed for and allocated to the employees as of the publication of this report. All warrants will be subscribed for by the Company's subsidiary ExpreS<sup>2</sup>ion Biotechnologies ApS.



# Other matters

#### **Employees**

As of September 30, 2022, there were a total of 30 employees, corresponding to 26 full-time equivalents (FTE's).

#### Operational risks and uncertainties

The risks and uncertainties that ExpreS²ion's operations are exposed to are summarized in terms of pharmaceutical development, competition, technology development, patents, government requirements, capital requirements, currencies, and interest rates. During the current period, no significant changes regarding risk or uncertainty factors have occurred. For more detailed reporting of risks and uncertainties refer to the Company's annual report for the fiscal year of 2021.

#### Auditor review

This interim report has not been formally reviewed by the Company's auditor.

#### Accounting principles

ExpreS<sup>2</sup>ion Biotech Holding AB applies the Swedish Annual Accounts Act and Swedish Accounting Standards Board's general standard BFNAR 2012:1 (K3) when preparing its financial statements.

#### For more information, please contact

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Keith Alexander, CFO
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#### Financial calendar

February 9, 2023 Full-year report, 2022

# Declaration of The Board of Directors and CEO

The Board of Directors and CEO assure that the interim report presents a true and fair view of ExpreS2ion Biotech Holding AB's business, operations, position and results.

Hørsholm, Denmark November 17, 2022

ExpreS<sup>2</sup>ion Biotech Holding AB c/o Mindpark, Rönnowsgatan 8c, S-252 25 Helsingborg

Board of Directors and CEO



