Presentation of Q3 2023 Results

# Innovative vaccines for a healthier world

16 November 2023







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### Management Discussion and Analysis

### ABNCoV2 COVID-19 Booster Vaccine

A unique vaccine based on ExpreS2™-made antigen and AdaptVac's VLP technology

- Phase I, started 2020, completed 2021, conducted under PREVENTnCoV consortia (biotech and academia partners)
- Phase II, started 2021, completed 2022, sponsored by Bavarian Nordic
  - June 2023: 12 months' durability data
  - Clinical proof of concept THE ONLY NON-ADJUVANTED VLP WITH LONG-TERM PROTECTION
- Phase III, started 2022, data in 2023, sponsored by Bavarian Nordic
  - June 2023: Meeting primary end-point
  - DEMONSTRATING NON-INFERIORITY AGAINST A COMMERCIAL mRNA COVID-19 VACCINE (COMIRNATY®)
- Same clinically Phase III-validated technology platforms applied in our therapeutic breast cancer vaccine ES2B-COO1

### Q3 update on ABNCoV2 Phase III

- Bavarian Nordic (BN) reported the secondary endpoint results for their Phase III clinical trial
- Did not successfully meet secondary endpoint: to demonstrate protection against the XBB.1.5 variant
- BN concludes, "No commercial opportunity for the vaccine"

Update on COVID-19 booster vaccine program



- Reduced options for raising capital
- Assumptions for TO8 warrant subscription proceeds changed:
  - SEK 54.5M prospects at April 2023 rights issue, became SEK 3.4M raised
- Proceeds planned for the development of ES2B-CO01/breast cancer vaccine
- Consequently, ExpreS<sup>2</sup>ion initiated a strategic review

Impact on ExpreS<sup>2</sup>ion







# Promising preclinical data package

- We have developed ES2B-C001, a HER2 VLP vaccine candidate to be tested in HER2+ breast cancer patients
- ES2B-C001 completely prevents tumor development after only 2 vaccinations in mice
- The vaccine induces strong and persistent antibody responses as well as T cell responses in mice
- E2B-C001 inhibits the onset, growth, and metastatic spread of HER2+ mammary carcinomas in mice
- The generated antibodies inhibit human HER2+ breast cancer and gastric cancer cells in vitro
- Tox studies completed in rats, and GLP tox studies are in progress in NHP, to be completed by end of 2023
- Regulatory interactions conducted to ensure alignment across CMC, nonclinical and clinical Phase I study
- Clinical CRO selected and qualified
- Fully outsourced setup "ready-to-go" to prepare and execute first-in human (FIH) study
- CTA package and launch study could proceed in 2024 pending securing funds and/or partnership
- Huge potential for HER2-low breast cancer, gastric cancer and other HER2 expressing cancers



### Strategic review

Announced in August 2023

- Strategic evaluation of ES2B-C001
  - Certain activities to advance towards CTA readiness to continue, including the ongoing GLP preclinical safety toxicology study
  - Investigating strategic options
- Initiating a cost reduction program
  - Near-term cash position enables us to maintain the current activity level into 2024
  - Aim to materially extend the runway beyond that in a tight funding market
- Identify how to best create value with our unique technology platform, expertise and exploratory pipeline projects
  - Develop innovative vaccines with a faster and less costly path to value creation



### Leadership

Greater than 200 years deep professional experience to support a pipeline-driven business

### Management Team



#### Bent U. Frandsen, CEO

- MSc in Finance/Strategic Management, Copenhagen Business School,
- >25 years industry finance, business dev. and management experience













#### Keith Alexander, CFO

- MBA, The Wharton School and the University of Pennsylvania, USA
- >20 years of equity research, corporate strategy, asset management and consulting experience





J.P.Morgan

accenture



#### Dr. Farshad Guirakhoo, CSO

- PhD in Virology from the Medical University of Vienna, Austria, and an MSc in Genetics from the International Institute for Biophysics and Biochemistry at the University of Tehran
- >35 years of broad translational research experience in the vaccine development field









#### **Dr. Max Soegaard**, SVP of R&D and Technology

- PhD in Biochem., UCL, UK, and MSc in Molecular Biology; AU, Denmark
- >20 years academic and industrial research experience



**MOLECULAR BIOPHYSICS SUITE DEPARTMENT OF BIOCHEMISTRY** 

### **Board of Directors**



#### Dr. Martin Roland Jensen, Chairman

- PhD. in Molecular and Cell Biology, Univ. of Copenhagen, Denmark >35 years biotech industry management and co-founder experience,
- incl. scientific work in immunology and cancer vaccine development











#### Jakob Knudsen, Board Member

- Law Degree from Univ. of Copenhagen, and MBA, Imperial College, UK
- >25 years commercial experience from international biotech industry









#### Dr. Karin Garre, Board Member

- MD, from University of Copenhagen, Denmark
- >30 years bio-industry management and drug development experience from early to late-stage phases and registration















#### Sara Sande, Board Member

- MSc in Economics, from University of Copenhagen , Denmark >20 years leadership experience in high-tech B2B companies,
- incl. sales excellence, strategy and commercial development









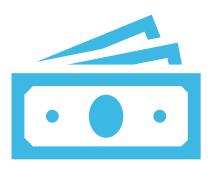


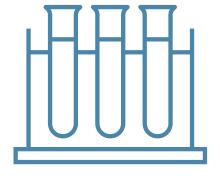


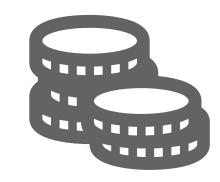


# Outcome of strategic review (I)

Cost reductions







Cut over SEK 50 million in costs

Reductions primarily in R&D, personnel and facilities

Cash runway into 2025



# Outcome of strategic review (II)

ES2B-C001 breast cancer vaccine candidate

Halted plan for <u>CRO-driven</u> Phase I clinical trial



Continuing preparations for advancing into clinical development

Preclinical safety studies

GMP manufacturing

Regulatory alignment



Evaluating other development options

<u>Investigator-driven</u> Phase I clinical trial

Asset sale

Partnership

Out-licensing



# Outcome of strategic review (III)

Other activities, including other pipeline assets and platform development



Enhancing focus on certain exploratory pipeline projects



### Qualification of various factors driving prioritization

Timeline leading to value inflection points

Project funding status – nondilutive (i.e. grant) funding a significant advantage

Cost/benefit analysis



### Saying "no" to lower priority activities

CRO projects must meet more stringent requirements

Exploratory activities must be grant funded or when resources permit





### Other Q3 updates

Updates to Malaria pipeline

Candidate in Phase II clinical trial

- Candidates in Phase I clinical trials
- New clinical trials expected to be initiated over the next year
- Discontinuing updates on two programs



### Pipeline

# Status at last update Progress since last update No further update to be provided

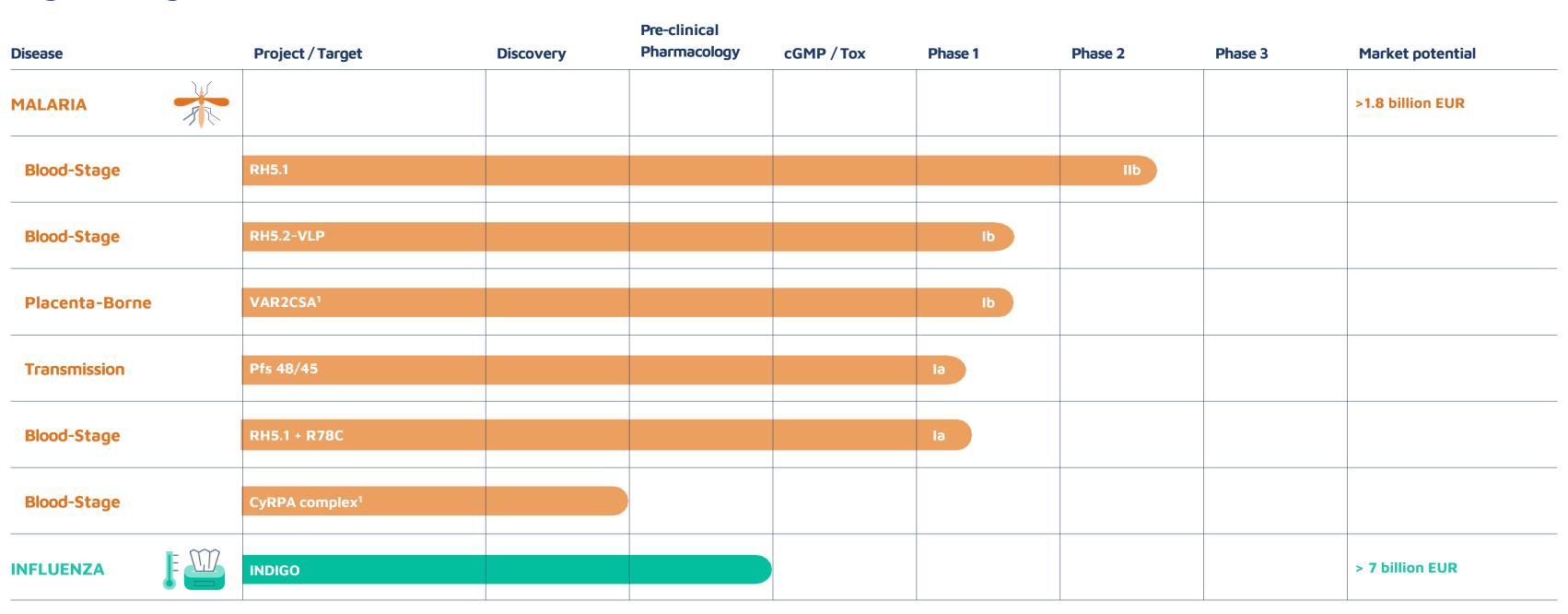
### Updates to legacy programs

Disease	Project / Target	Discovery	Pre-clinical Pharmacology	cGMP / Tox	Phase 1	Phase 2	Phase 3	Market potential
MALARIA								>1.8 billion EUR
Blood-Stage	RH5.1					llb		
Blood-Stage	RH5.2-VLP				Ib			
Placenta-Borne	VAR2CSA				ь			
Transmission	Pfs 48/45				la			
Blood-Stage	RH5.1 + R78C				la			
Blood-Stage	CyRPA complex							
INFLUENZA	INDIGO							> 7 billion EUR



### Pipeline

### Legacy programs



Note: Legacy programs were set up prior to the Company's transition into a pipeline-driven biotech company in 2020 and are driven primarily by academic consortia.

Malaria: Data bridge market research, Global Malaria Vaccines Market – Industry trends and Forecast to 2029, 2022 · Influenza: Fortune Business Insight, Influenza Vaccine market size 2022-2029, 2022



### Pipeline

### Focus programs

Disease		Project / Target	Discovery	Pre-clinical Pharmacology	cGMP / Tox	Phase 1	Phase 2	Phase 3	Market potential
COVID-19 <sup>1</sup>	*	ABNCoV2/SARS-CoV-2 cVLP							> 10 billion EUR
BREAST CANCER		ES2B-C001/Her2 cVLP							> 10 billion EUR
INFLUENZA <sup>2</sup>	F	MucoVax							> 7 billion EUR
CMV <sup>3</sup>		ES2B-I002							> 2 billion EUR
Exploratory		Undisclosed							

<sup>&</sup>lt;sup>1</sup> Developed in collaboration with AdaptVac ApS and other partners and out-licensed to Bavarian Nordic. <sup>2</sup> A joint discovery with the University of Copenhagen. <sup>3</sup> A joint discovery project with Evaxion Biotech A/S COVID-19: ExpreS<sup>2</sup>ion 2024 estimate based on 2023 market size and CAGR through 2028 from Statista, as of 31 July 2023 · Breast Cancer: Global Data, 2022, for HER2+ breast cancer Influenza: Fortune Business Insight, Influenza Vaccine market size 2022-2029, 2022 · CMV: Market estimate from Moderna, 41st Annual J.P. Morgan Healthcare Conference (Presentation)



### Advancing focus pipeline towards key catalysts

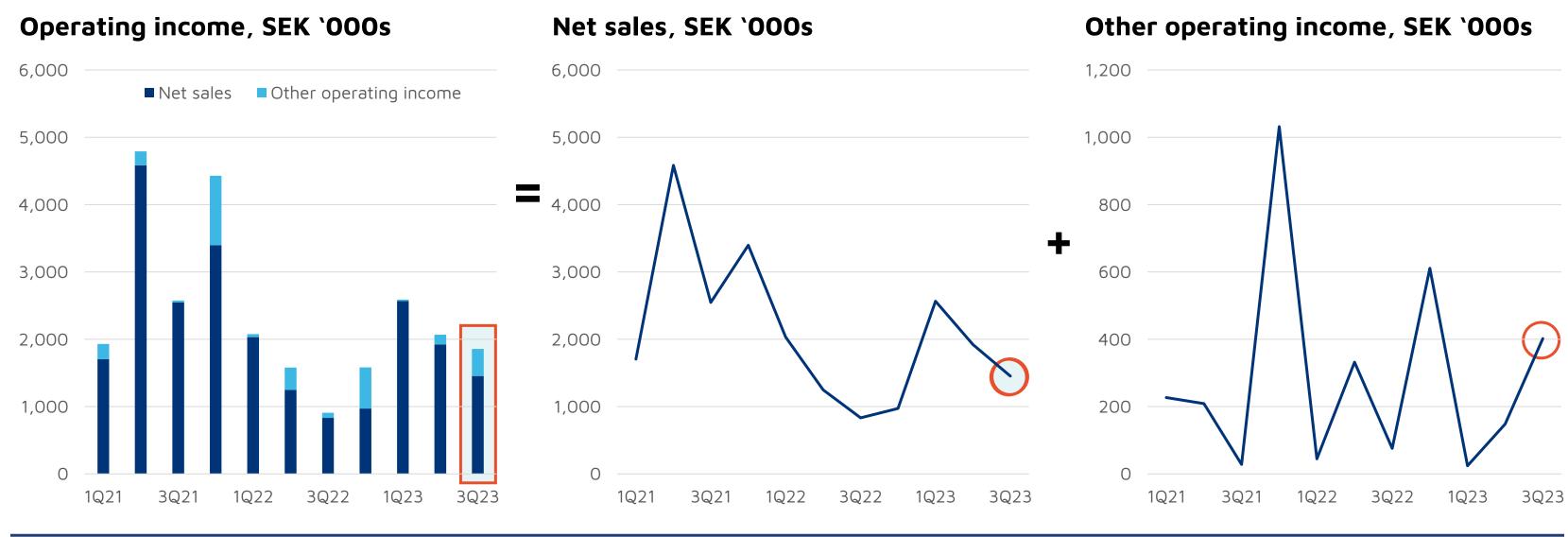
	2022	2023	2024	2025+
COVID-19 ABNCoV2	BN Phase II trial BN Phase III trial readout H1 initiation Q3	✓ BN Phase II 12-month durability data BN  ✓ Phase III initial readout  ✓ Phase III secondary readout  X Bavarian Nordic: "sees no co opportunity"	Phase III milestone related income mmercial	
BREAST CANCER ES2B-C001		Oring  GLP nonclinical tox study in NHP  out from preliminary tox studies	Potential filing of clinical trial application  Potential initiation of first human study	n clinical
INFLUENZA MUCOVAX	MU	√ Initiation of COVAX project for MUCOVAX project anasal vaccine	Completion of design and production of mucosal delivery platform	Validation of influenza vaccine candidate  Optimization of vaccine to maximize efficacy in preventing severe disease and/or infection
CYTOMEGALO- VIRUS ES2B-I002	√ Establish 50/50% partnership on cytomegalovirus vaccine with Evaxion	Early research on CMV vaccine target, applying Al	Preclinical testing of immunogenicity of CMV vaccine target	Selection of lead CMV vaccine candidate



### Financial Results



# Operating income

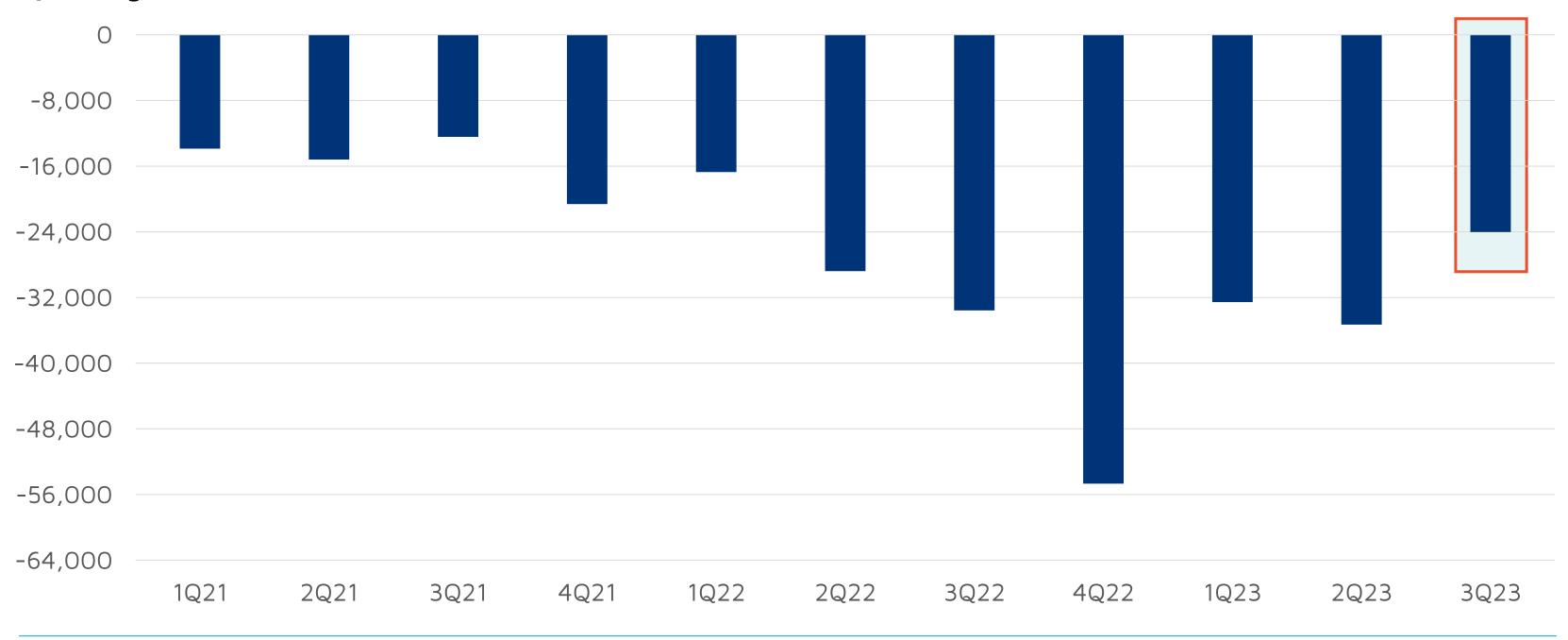


Operating Income, SEK '000s	2023	2022	Growth
3Q	1,856	909	+104%
YTD	6,515	4,567	+43%



# Operating costs

### Operating costs, SEK '000s



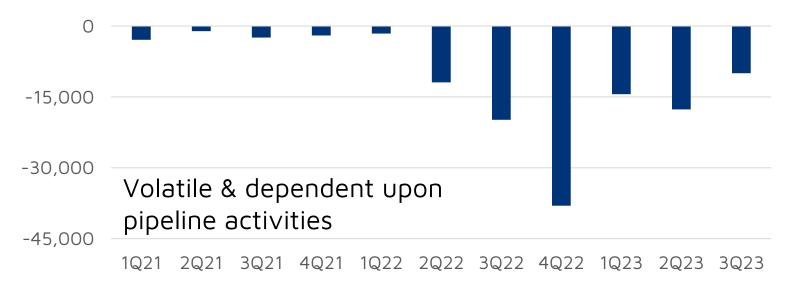
Innovative vaccines for a healthier world



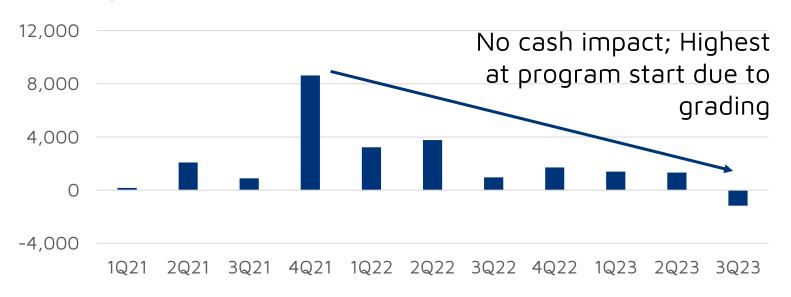
### Operating costs composition

SEK '000s

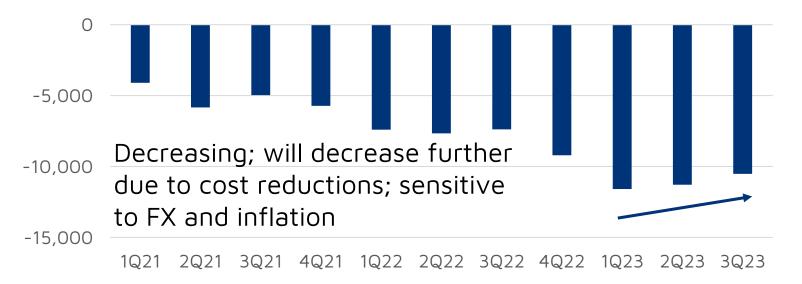
#### **R&D** costs (external)



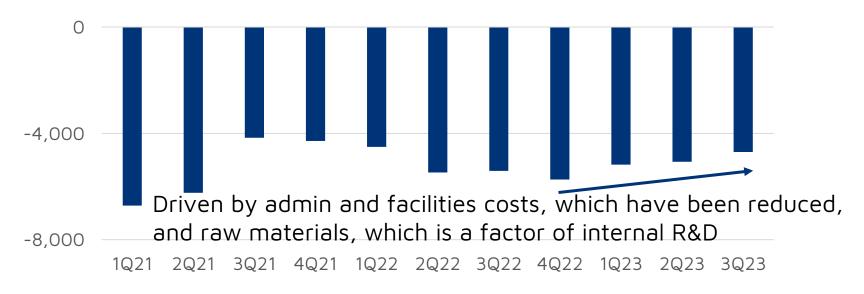
#### Vesting of share-based compensation (non-cash)



#### Personnel costs excl. vesting of share-based compensation



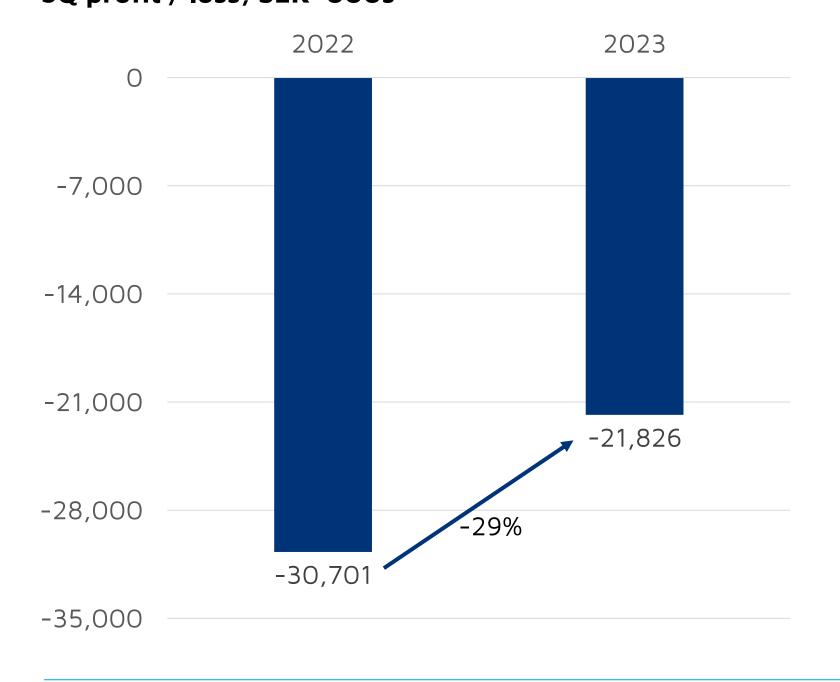
#### Other (adjusted)<sup>1</sup>



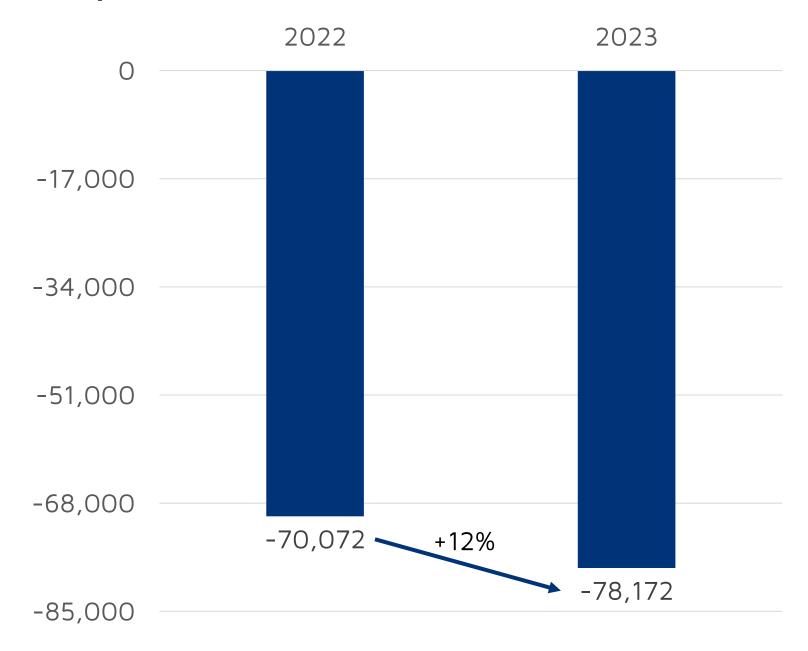


### Profit / loss for the period

### 3Q profit / loss, SEK '000s



### YTD profit / loss, SEK '000s

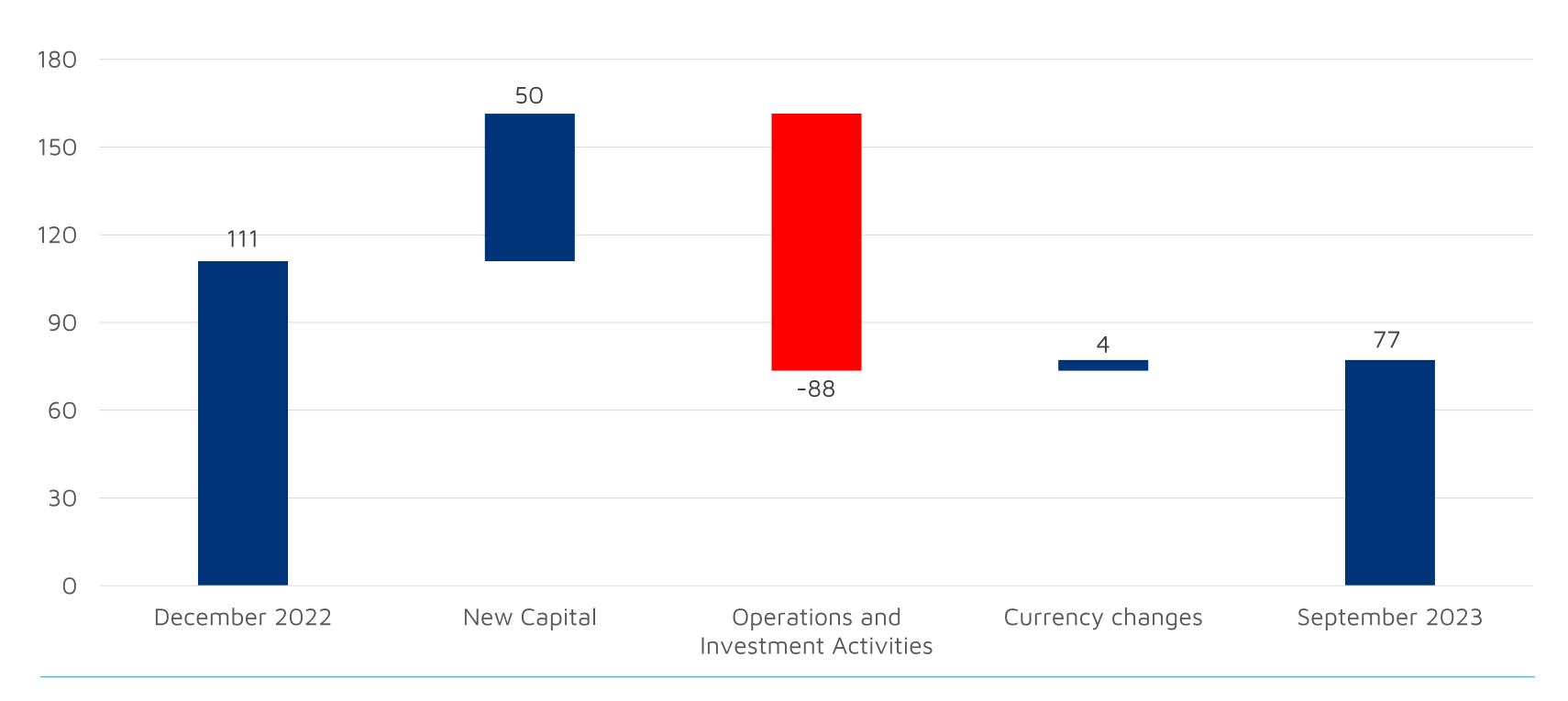


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### Cash development year-to-date

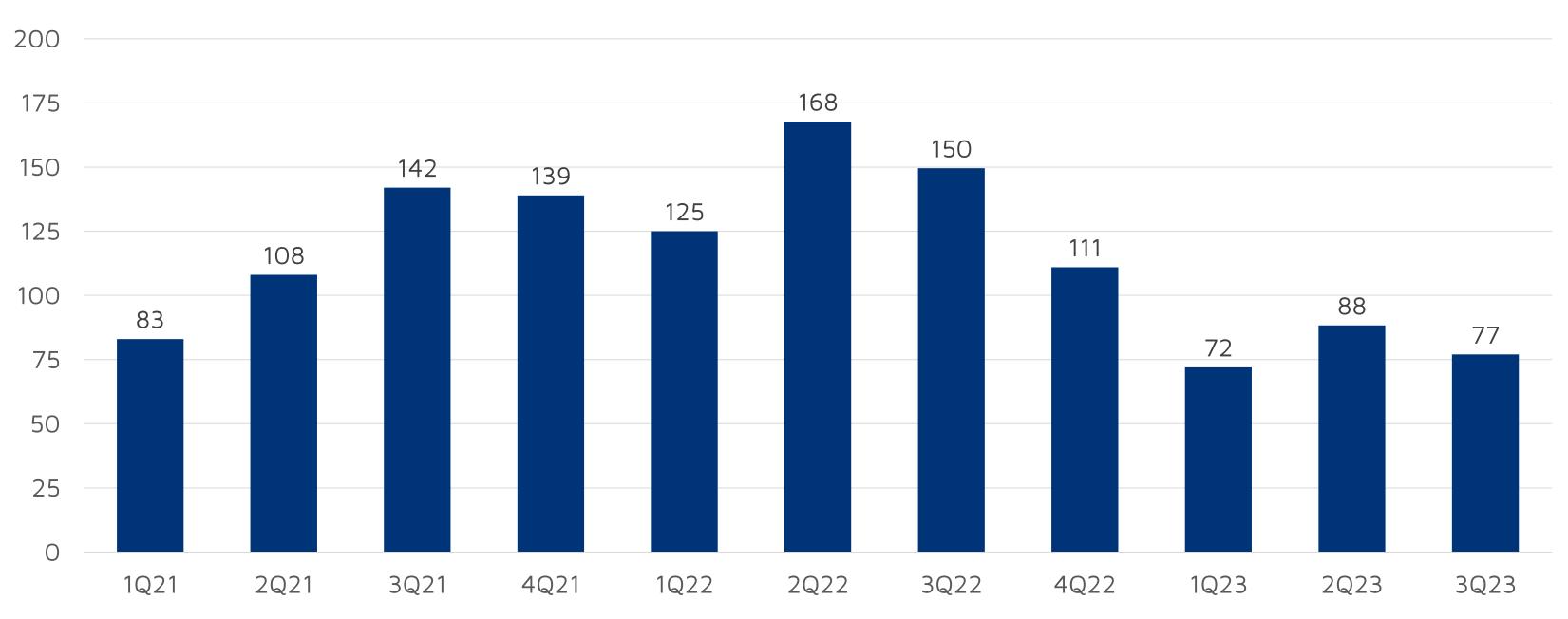
SEK millions





# Cash balance, 1Q21 - 3Q23 quarterly

#### **SEK millions**





### Thank you

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