

# Q3

## Alligator Bioscience AB (publ) Interim report January - September 2023 Financial Results and Business Update



*"This quarter we achieved another milestone in the clinical and commercial development of our lead asset mitazalimab with the addition of orphan designation by the European regulators. We now have market exclusivity secured upon approval in our two key markets, the US and the EU. We showcased mitazalimab data at several high-profile industry events and we are continuing to build momentum around our efforts to commercialize mitazalimab, with the full Phase 2 readout from OPTIMIZE-1 due at the start of next year."*

**Søren Bregenholt**

CEO Alligator Bioscience AB (publ)

### Significant events: July – September 2023

#### Mitazalimab granted Orphan Designation by the European Medicines Agency for pancreatic cancer

This designation confers significant financial and regulatory benefits, including 10 years of marketing exclusivity in the EU after product approval. Mitazalimab has now received orphan drug designation in both the EU and the US, providing stronger commercial protection for mitazalimab in these two key markets.

#### Data demonstrating mitazalimab's durable response and encouraging anti-tumor activity presented at industry conferences

- 3rd Annual Myeloid-Directed Therapies Summit: the presentation highlighted the very promising interim efficacy results announced in June 2023 from the OPTIMIZE-1 Phase 2

study and also featured preclinical data on the tumor-directed bispecific conditional CD40 agonist ATOR-4066.

- International Cancer Immunotherapy Conference (CICON) 2023: a poster presentation detailed how mitazalimab combined with FOLFIRINOX induces synergistic anti-tumor effects and long-term survival in a preclinical tumor model.
- AACR Special Conference on Pancreatic Cancer 2023: two presentations were given at the conference, the first highlighted interim efficacy results from OPTIMIZE-1 and the second analyzed interim pharmacodynamic data which validated mitazalimab's mechanism of action.

#### Scientific article highlighting pharmacodynamic data from mitazalimab Phase 1 study published in "Cells"

Publication highlighted how analysis of RNA sequencing on patients from a Phase 1 dose-escalation study revealed that at the current OPTIMIZE-1 Phase 2 dose of 900 µg/kg, mitazalimab induced peripheral transcriptomic alterations consistent with immune activation expected from a strong CD40 agonist.

#### Milestone achieved in the Immuno-Oncology Research Collaboration and License Agreement with Orion Corporation

Technical Feasibility has been achieved in Alligator's second collaboration program with Orion, triggering a new milestone payment to Alligator.

#### SEK 13.8 million received through the exercise of warrants of series TO 6

The warrant exercise generated a utilization rate of approximately 68 percent and followed Alligator's successful preferential rights issue in May 2023, which raised SEK 181 million.

### Significant post-period events

#### Scientific article highlighting ATOR-1017 preclinical data published in "Cancer Immunology, Immunotherapy"

Publication demonstrated how the design, detailed binding epitope and molecular properties of ATOR-1017 translate into very potent activity both *in vitro* and *in vivo*, as monotherapy and in combination with PD-1 inhibitors, while being well tolerated in preclinical models.

#### New Composition of Matter patent granted for mitazalimab in Europe

The new patent expands protection for mitazalimab in Europe, protecting its composition of matter until 2038, including a potential supplementary term.

### Financial summary

#### July-September 2023

- Net sales, SEK 19.4 million (5.1)
- Operating profit/loss, SEK -52.7 million (-51.2)
- Profit/loss for the period, SEK -52.5 million (-51.4)
- Earnings per share before and after dilution, SEK -0.08 (-0.23)
- Cash flow for the period, SEK -86.5 million (-45.6)
- Cash and cash equivalents, including short-term financial assets SEK 123.9 million (97.3)

#### January-September 2023

- Net sales, SEK 46.4 million (15.6)
- Operating profit/loss, SEK -178.6 million (-140.1)
- Profit/loss for the period, SEK -178.8 million (-140.2)
- Earnings per share before and after dilution, SEK -0.45 (-0.64)
- Cash flow for the period, SEK -23.1 million (-131.0)
- Cash and cash equivalents, including short-term financial assets SEK 123.9 million (97.3)

# CEO Comments

I am very pleased to report on another busy and productive quarter for Alligator. With our lead asset mitazalimab continuing to make encouraging progress on its journey through clinical development towards commercialization, the achievement of another milestone in our key collaboration agreement with Orion, and a successful warrant exercise to sustain our financial foundations, we are in a strong position as we enter the final part of the year.

We remain on track to report full top-line data from the OPTIMIZE-1 Phase 2 study evaluating mitazalimab in combination with mFOLFIRINOX in first-line metastatic pancreatic cancer in early Q1 2024. As we see more patients staying longer on the study, and we continue to invest in phase 3 enabling activities for mitazalimab, our burn rate remains relatively high. While we continue to invest in our lead asset, we remain financially diligent across our operations.

This quarter saw mitazalimab receive a second orphan drug designation (ODD) for the treatment of pancreatic cancer, this time from the European Medicines Agency (EMA). This designation confers significant regulatory and financial benefits, including 10 years of marketing exclusivity in European Union countries after product approval. The EMA award follows the decision by the US Food and Drug Administration (FDA) in May this year to grant mitazalimab an Orphan Drug Designation in pancreatic cancer in the US and means we have now secured stronger commercial protection for mitazalimab in our two key markets.

Building on that protection, we have also been granted a new patent by the European Patent Office covering mitazalimab's composition of matter until 2038. This is a significant addition to our overall patent portfolio and provides vital further protection for our lead clinical asset in Europe. Protecting our intellectual property is one of the key pillars of our business strategy and provides a strong foundation for our drug development program.

We continued to release more data this quarter highlighting mitazalimab's ability to activate the immune system and enhance anti-tumor responses to chemotherapy. Data from the OPTIMIZE-1

study featured in presentations at the Annual Tumor Myeloid-Directed Therapies Summit and the AACR Special Conference on Pancreatic Cancer, both of which were held in Boston. It was a great chance to showcase to oncologists and myeloid experts from around the world the OPTIMIZE-1 second interim results we reported in June, in which we demonstrated a deepening of tumor responses and an increase in the Objective Response Rate to 57 percent from 52 percent.

We also presented additional mitazalimab data in a poster at this year's International Cancer Immunotherapy Conference (CICON) in Milan and in a publication in the scientific journal *Cells*. The data highlighted in all these cases add to the growing clinical evidence demonstrating that mitazalimab induces relevant activation of the immune system which leads to enhanced anti-tumor responses to chemotherapy and provides durable benefits to patients with metastatic pancreatic cancer. These data also reinforce mitazalimab's mode of action and further underline the importance of the CD40 research being carried out by our dedicated scientific team.

Our research collaboration and license agreement with Orion Corporation, which aims to discover and develop new bispecific antibody cancer therapeutics, continues to go from strength to strength. We have now attained Technical Feasibility in our second collaboration program. This is an important achievement which not only triggers another milestone payment to Alligator but also highlights the robust discovery and development capability of our proprietary technology platforms, including our proprietary RUBY™ format. Both the first and second programs in our Orion



collaboration are progressing as planned.

Finally this quarter, we raised SEK 13.8 million through the conducted warrant exercise which came in addition to our preferential rights issue in May this year, which raised SEK 181 million. We would like to offer our sincerest thanks to all our investors for your continued support in Alligator's endeavors to develop meaningful therapies for patients with hard-to-treat cancers. We have a busy period coming up to take us to the end of the year, in particular the final leg of our Phase 2 evaluation of mitazalimab in pancreatic cancer leading up to the announcement of the top-line results in Q1 2024, which we are keenly looking forward to.

**Søren Bregenholt**

CEO Alligator Bioscience AB (publ)

# Performance measures Group

	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
<b>Result (KSEK)</b>						
Net sales	5	19,414	5,108	46,369	15,634	35,696
Operating profit/loss		-52,720	-51,233	-178,596	-140,144	-192,789
Profit/loss for the period		-52,501	-51,365	-178,756	-140,152	-193,403
R&D costs		-62,952	-43,958	-193,477	-121,311	-186,945
R&D costs as a percentage of operating costs, %		87%	78%	85%	78%	81%

<b>Capital (KSEK)</b>						
Cash and cash equivalents at end of period		73,919	147,411	123,919	147,411	97,305
Cash and cash equivalents including short-term financial assets at end of period		123,919	147,411	123,919	147,411	97,305
Cash flow from operating activities		-46,537	-42,743	-134,755	-125,290	-172,607
Cash flow for the period		-86,495	-45,556	-23,098	-131,039	-180,875
Equity at the end of the period		81,897	142,256	81,897	142,256	89,051
Equity ratio at the end of the period, %		44%	69%	44%	69%	53%

<b>Info per share (SEK)</b>						
Average number of shares		632,567,111	220,584,878	399,466,214	220,584,878	220,584,878
Earnings per share after dilution*		-0,08	-0,23	-0,45	-0,64	-0,88
Equity per share after dilution*		0,12	0,64	0,12	0,64	0,41

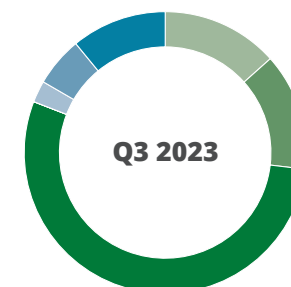
<b>Personnel</b>						
Number of employees at end of period		59	55	59	55	53
Average number of employees		60	52	56	51	50
Average number of employees employed within R&D		52	43	48	42	41

\* Effect from dilution is not considered when result is negative and options where call rate is higher than closing rate is not considered.

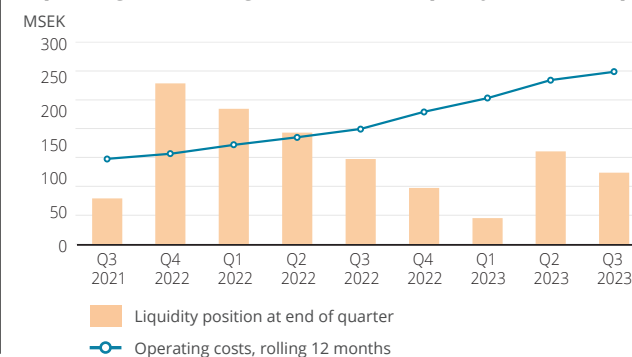
For definitions and calculations, see the sections later in this report.

Operating costs distributed by function, Parent Company

- Business Operations, including IP costs ~13%
- R&D Discovery ~13%
- R&D mitazalimab ~55%
- R&D ATOR-1017 ~2%
- R&D ATOR-4066 ~6%
- R&D Collaborations ~11%



Operating costs, rolling 12 months and Liquidity (MSEK), Group



# Operations

Alligator Bioscience is a clinical-stage biotech company dedicated to developing tumor-directed best-in-class antibodies for hard-to-treat cancers. Our drug candidates have the potential to meet key needs in immuno-oncology by increasing the quantity and quality of tumor-specific T cells within the tumor and, at the same time, remodeling the tumor microenvironment to provide the immune system better access to the tumor. Alligator's highest standards on the safety and efficacy of its drug candidates increase their potential to be combined with current standard therapies, which is key to improving clinical benefits in oncology today.

During 2023, the Company reported significant advancements with its fully-owned and partnered drug candidates. Our technology platforms and pharmaceutical research continue to build long-term value and attract interest from potential partners. To drive competitive and time-efficient development, some specific parts of Alligator's programs are conducted in collaboration with other biotechnology companies, contract laboratories, and leading international research institutions. In addition, our clinical trials are carried out in collaboration with leading specialist physicians and CROs with expertise in oncology clinical development. In summary, the Company has all the necessary expertise and partners to pursue successful projects from concept to clinical development. This has been demonstrated by the OPTIMIZE-1 Phase 2 study interim safety and efficacy results showing the great potential of our lead drug candidate mitazalimab in pancreatic cancer.

## Alligator's Organization

Alligator's research and development organization is divided into five units: Discovery, Chemistry, Manufacturing & Control (CMC), Non-Clinical Development, Medical Science and Clinical Operations. Members of all these functions collaborate cross-functionally in project teams. The Discovery unit is responsible for early-stage research projects up until a drug candidate has been identified. This normally includes the development and evaluation of treatment concepts, the evaluation of potential drug candidates and early-stage confirmation of efficacy. The CMC unit

develops manufacturing processes and is responsible for clinical trial material manufacturing. The Non-Clinical Development unit is responsible for pre-clinical evaluation of safety and efficacy of our molecules, including preparation of the data packages required for clinical trial applications. The Medical Science unit, led by our Chief Medical Officer, is responsible for designing all the clinical and regulatory development plans required to show that Alligator's products are safe and effective. The Clinical Operations unit is responsible for timely and excellent implementation of the clinical trials. Alligator will continue to build and shape the organization to match and support its strategy and objectives.

## Several Proprietary Technologies

Alligator's technology platforms—FIND® (protein optimization technology), ALLIGATOR-FAB™, and ALLIGATOR-GOLD® (antibody libraries)—are used for the discovery and development of novel drug candidates. These platforms enable efficient generation of novel drug candidates with high therapeutic potential.

In addition, the Company has bispecific antibody formats for the development of new dual-action antibodies. With the most recent antibody format, RUBY™, Alligator can generate bispecific molecules from any two antibodies, with excellent properties in terms of stability and manufacturing yield. The format eliminates the need for further optimization, enabling Alligator to quickly move drug candidates from preclinical research to clinical development.



Our 3rd generation proprietary platform technology aims at a more personalized immunotherapy, using CD40-antibodies that instruct the immune system to recognize and attack cancer cells, based on the tumor mutations unique to the individual patient. These antibodies contain one part that binds to tumors and tumor particles and another part that binds to dendritic cells through the CD40 molecule. This interaction between tumor particles and dendritic cells eventually results in a very efficient education and activation of tumor-specific T cells, that subsequently can recognize and destroy the tumor cells.

## Business Model that Creates Value Across the Development Chain

The Company's business model is based on the combination of proprietary drug development and partnerships. To maximize the value of the portfolio, the Company intends to bring its lead molecules from drug discovery and preclinical studies to Proof-of-Concept in human clinical Phase 2 studies and beyond. To generate income, limit portfolio risk, and maximize long-term value, the Company also seeks strategic global and regional partnerships for certain programs and technologies.



# Immuno Oncology Market Overview

Cancer touches many lives, either directly or through its effect on family and loved ones. With the continued rise of cancer diagnoses around the world, the need for more effective treatments also grows. Alligator's drug candidates are designed with an optimal efficacy-tolerability balance to meet the need for therapies that can safely be combined with current standard cancer treatments, to treat, or possibly even cure, hard-to-treat cancers.

## Oncology Market Trends

In 2020, 19.3 million new cancer cases were diagnosed globally, with the number expected to rise to 30.2 million by 2040,<sup>1</sup> and the oncology drug market is expected to account for approximately 40% of the total drug market by 2028.<sup>2</sup> A surge of new and innovative treatment methods is expected to emerge in the marketplace, and immunotherapies will play an important role in these treatment options for cancer.

Alligator believes that the demand for novel immunotherapy drugs will increase along with the global demand for new and more effective oncology therapies, and is well positioned to deliver state-of-the-art antibodies for cancer treatment.

## Immuno-oncology

Most tumors contain immune cells with the potential to attack and destroy cancer cells, and possibly eradicate the entire tumor itself. Cancer cells often activate immunosuppressive strategies to inhibit these types of attacks. Immunotherapies provide several different opportunities to help the immune system defend the body against the cancer. Such strategies help educate

the immune system to better identify tumor cells or enhance the capabilities of the patient's own immune system to attack the tumor with full force

Alligator's innovative assets and technologies target key immuno-oncology molecules to educate and activate the immune system to selectively attack tumors without affecting the rest of the body, a core concept that separates us from other competitors in the industry. The main benefit of tumor-directed treatment is the ability to effectively attack the tumor while minimizing the adverse effects caused by stimulating the whole immune system. This allows our candidates to work synergistically with current chemotherapy regimens and other immunotherapeutic drugs in hard-to-treat, metastatic solid tumors.

Our lead asset mitazalimab is in a clinical Phase 2 study for the treatment of metastatic pancreatic tumors, a tumor type that is one of the hardest cancers to treat and has one of the lowest five-year survival rates.

Approximately 300,000 people in the 16 major markets\* are

diagnosed with pancreatic cancer each year. Although surgery is the best treatment, only 15-20% of those diagnosed can be treated by surgery, while the remaining 85% are left with very few treatment options available to them, with chemotherapy regimens being the standard of care but providing limited clinical benefit.<sup>2</sup>

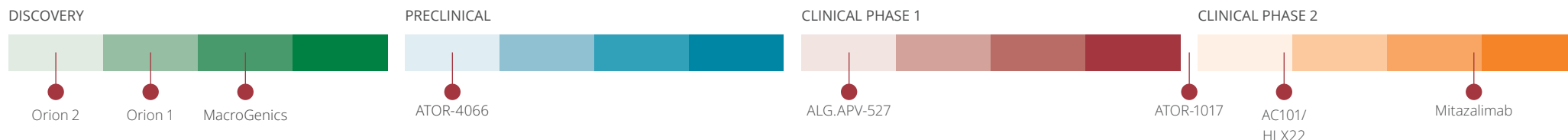
We develop our pipeline programs, from Discovery Phase through clinical Phase 2, with an excellent efficacy-tolerability balance in mind, either alone or in collaboration with partners. These collaborations provide an opportunity of income, and an external validation of our platform, building on our confidence that our candidates will provide meaningful treatment options for people with hard-to-treat cancer, as stand-alone or combination therapies.

<sup>1</sup> International Agency for Research on Cancer (IARC), Data version: 2020, April 2023.

<sup>2</sup> Database GlobalData (Pharma Intelligence Center – Drug Sales), February 2023.

\*) 16 main markets include: Australia, Brazil, Canada, France, Germany, India, Italy, Japan, Mexico, Russia, South Africa, South Korea, Spain, UK, US, Urban China.

## PIPELINE PROJECTS



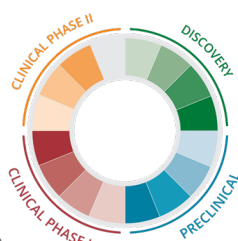
# Pipeline Projects – Internal Programs

Alligator's competitive project portfolio consists of the two clinical-stage assets, mitazalimab and ATOR-1017, and ATOR-4066, a pre-clinical program developed using Alligator's proprietary technology platform Neo-X-Prime™ – as well as several programs developed in collaboration with partners.

## Mitazalimab

Alligator's most advanced drug candidate mitazalimab, a potential game changer in the treatment of solid tumors, is currently in a Phase 2 clinical trial in first line pancreatic cancer called OPTIMIZE-1, with the first and last patients dosed in Q3 2021 and Q2 2023, respectively. This clinical trial is designed to evaluate the safety and efficacy of mitazalimab in combination with mFOLFIRINOX, the most efficacious standard of care chemotherapy for the treatment of advanced pancreatic cancer.

The clinical trial has been designed on the principal that mFOLFIRINOX efficiently kills tumor cells, leading to an increased release of tumor antigens which, when mFOLFIRINOX is used as standalone therapy, only triggers minimal immune response, leading to limited overall efficacy. The use of mitazalimab in combination with mFOLFIRINOX allows for activation of CD40, a receptor on dendritic cells, leading to significantly improved tumor antigen-presentation and subsequent activation of tumor-specific T cells that attack the cancer. The combination of mitazalimab with mFOLFIRINOX is therefore expected to significantly boost the immune response secondary to the release of tumor antigens, hence triggering a powerful attack on solid tumors and significant clinical benefit. The mechanism of action was further validated by two separate pharmacodynamic analyses, both of which demonstrated the desired activation of the immune system after mitazalimab exposure was achieved. This activation of the immune system supports the potential of mitazalimab to activate myeloid cells and overcome the immune



suppressive mechanisms in the tumor microenvironment, which can induce anti-tumor responses and make the tumor more sensitive to other therapies, such as mFOLFIRINOX, in pancreatic cancer patients.

Two Phase 1 clinical trials with mitazalimab were successfully completed, one conducted by Alligator, and the other conducted by Janssen Biotech Inc., both of which showed strong evidence of efficacy and proof-of-mechanism, as well as a manageable safety profile.

In Q1 2022, Alligator announced that mitazalimab was safe and tolerable in combination with mFOLFIRINOX and that 900 µg/kg was selected as the Recommended Phase 2 Dose (RP2D), with the Phase 2 enrolment subsequently initiated at sites in Europe. As a consequence of the accelerated recruitment during 2022, the company announced that the full Phase 2 data would become available in Q1 2024, 9 months earlier than initially expected. The full enrolment of OPTIMIZE-1 was announced on April 12, reconfirming that full topline data are expected in the beginning of Q1 2024.

In early January 2023, the interim efficacy readout for OPTIMIZE-1 was published, showing an Objective Response Rate (ORR) exceeding 50% in the first 23 evaluable patients, and a disease control rate of more than 90%. These results were further put into context with current treatment options in a webinar hosted by Alligator, featuring CMO Sumeet Ambarkhane and Principal Investigator of OPTIMIZE-1, Prof. Jean-Luc van Laethem. Comprehensive data from the January interim readout were presented on June 5, at the ASCO Annual Meeting 2023.

On April 3, Alligator announced that the FDA had cleared the IND for OPTIMIZE-2, a Phase 2 study assessing the safety and efficacy of an immunotherapeutic combination of mitazalimab (CD40 mAb) and a PD-1 inhibitor, in adult patients with histologically confirmed urothelial carcinoma, and who have progressed following prior treatment with PD-(L)1 therapy. Alligator expects to initiate OPTIMIZE-2, during H1 2024 or earlier if operationally feasible.

On May 15, Alligator received an FDA Orphan Drug Designation for mitazalimab in pancreatic cancer, a designation that confers significant benefits in the form of cost savings during development and marketing exclusivity following approval, further reducing the operational risk in the mitazalimab development program. On August 21, Alligator received Orphan Designation from the European Medicines Agency for mitazalimab in pancreatic cancer, which grants similar benefits in the European Union, including 10 years of marketing exclusivity. Receiving Orphan Designation in both the US and the EU gives mitazalimab stronger commercial protection in these two key markets.

On June 26, Alligator announced positive second interim results from OPTIMIZE-1. Maturing data from the initial 23 patients included in the initial interim analysis reported in January 2023 demonstrated tumor responses deepened with the ORR increasing from 52% to 57%, suggesting a durable benefit for patients. Interim analysis conducted on all 57 evaluable patients demonstrated 25 patients responded to treatment resulting in an interim ORR of 44%. Median Duration of Response was 8.7 months compared to 5.9 reported for FOLFIRINOX alone in other studies. Together with several deep tumor responses reported this indicates an immunostimulatory effect of mitazalimab and potential Progression Free Survival (PFS) and survival benefits. We expect the response rate and outcome-related data like Progression Free Survival to improve, as patients stay longer on treatment.

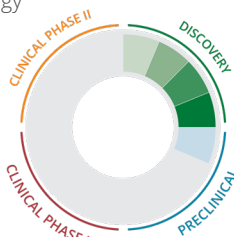
We are extremely encouraged by the interim data and have intensified our business development efforts to identify the right partner to bring mitazalimab to patients as fast as possible in pancreatic cancer and additional indications, thus leveraging its full commercial potential. We believe that the most likely time frame for a partnership deal is during 2024 once data from the OPTIMIZE-1 study become available

# ATOR-4066

Developed using Alligator's technology platform Neo-X-Prime™, ATOR-4066 is a bispecific antibody created to elicit powerful, tumor-specific immune effects. In Neo-X-Prime, we combine Alligator's expertise in immuno-oncology and CD40-targeted therapies with our state-of-the-art technology platform and our bispecific antibody format RUBY™. The concept builds on bispecific antibodies simultaneously binding to CD40 and to molecules preferentially expressed on tumor cells. In addition to a tumor directed activation of dendritic cells, this will also promote physical linkage of circulating tumor material to dendritic cells. Such linking of tumor material with the dendritic cells results in education and activation of tumor neoantigen-specific T cells and induces superior anti-tumor activity.

In addition to CD40, ATOR-4066 binds to carcinoembryonic antigen (CEACAM5), a tumor-associated antigen that is preferentially expressed in certain cancer types such as colorectal, gastric and pancreatic cancer. During 2022, the preclinical data package supporting the mode of action of ATOR-4066 and its potent anti-tumor effect in in vivo models was presented at several scientific meetings and in November 2022 a scientific article was published in the *Journal for Immunotherapy of Cancer*, highlighting the potential of ATOR-4066 and the Neo-X-Prime platform. In April 2023, Alligator presented a poster at the 2023 AACR Annual Meeting. Preclinical *in vivo* and *in vitro* data was also presented at the Annual Tumor Myeloid-Directed Therapies Summit in July 2023. Taken together, the presented data show the ability of ATOR-4066 to remodel the immune microenvironment and activate tumor-infiltrating immune cells in primary human tumors expressing CEA, demonstrating the promise of this new drug candidate and strongly supporting further development towards the clinic.

Efforts to further strengthen the preclinical data package supporting ATOR-4066 and preparations for clinical development are ongoing.

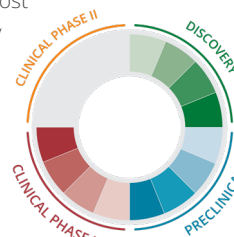


# ATOR-1017

ATOR-1017 is Alligator's second most advanced program and successfully completed Phase 1 dose-escalation study in September 2022. The study was designed to assess the safety and tolerability of ATOR-1017 in patients with advanced solid cancers, and to establish a recommended Phase 2 dose for future studies.

ATOR-1017 is a 4-1BB agonist with a unique profile, most importantly through its ability to enhance the immune activating effect in tumors. This creates opportunities for a powerful, tumor-directed immune activation, which can increase the therapeutic effect and reduce adverse side effects for patients.

Alligator presented a poster at the SITC Annual Meeting in November 2022, highlighting new results from the Phase 1 first-in-human study of ATOR-1017, showing it to be safe and well tolerated at doses up to 900 mg, with an excellent clinical profile as a potential best-in-class asset. Data published in the journal *Cancer Immunology, Immunotherapy* in October 2023 demonstrated how the design, detailed binding epitope (binding site) on 4-1BB and molecular properties of ATOR-1017 translate into very potent activity both in vitro and in vivo, as monotherapy and in combination with anti-PD-1 treatment, while being very well tolerated in preclinical models. These data warrant further development of ATOR-1017 in combination with other therapeutic approaches in solid tumors and Alligator is now seeking a partner to support this.

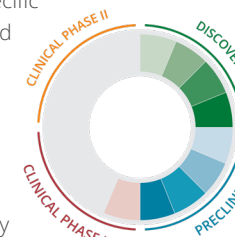


# ALG-APV-527

ALG-APV-527 is a bispecific antibody targeting 4-1BB and 5T4, designed for the treatment of metastatic solid tumors. In 2017, Aptevo Therapeutics and Alligator Bioscience AB signed a co-development agreement under which both companies will equally own and finance the development of the asset.

The original molecules involved in the tumor-binding function and the immunomodulatory function of ALG-APV-527 were developed using Alligator's patented ALLIGATOR-GOLD® antibody library. The bispecific molecule was further developed and improved with Aptevo's technology platform ADAPTIR™. By combining a tumor-binding function with an immunomodulatory function in the same molecule, the drug candidate selectively targets the tumor and stimulates the antitumor-specific immune cells that are present in the tumor.

A publication in a peer-reviewed journal *Molecular Cancer Therapeutics* highlighting ALG-APV-527 preclinical data was published in November 2022. The data demonstrates a favorable preclinical efficacy and safety profile of ALG-APV-527 compared to a first generation 4-1BB antibody. In September 2022, the companies Investigational New Drug (IND) application received a "may proceed" notification from the US Food and Drug Administration (FDA), and in February 2023 the first patient was dosed in the Phase 1 clinical study to evaluate ALG-APV-527 in the treatment of solid tumors expressing the tumor-associated antigen 5T4. The study is being conducted in the US.



# Collaborations and Out-Licensing Agreements

## Orion Corporation

In 2021, Alligator entered a research collaboration and license agreement with Orion Corporation, a global pharmaceutical company based in Finland. The aim of the collaboration is to discover new bispecific antibody cancer therapeutics against immuno-oncology targets. The agreement covers an option to develop three bispecific antibodies. In January 2023 we announced that Orion had exercised its option to initiate a second program within the agreement.

Under the agreement, Alligator will employ its proprietary phage display libraries and its RUBY™ bispecific platform. During the initial research period of the collaboration, Alligator will receive an upfront payment and reimbursement of research costs and other fees.

As part of the agreement, Alligator is eligible for development, approval, and sales milestone payments of up to EUR 313 million. Should Orion exercise its option to continue development and commercialization of the resulting product candidates, Alligator will be eligible to receive additional royalty payments.

On May 11, 2023, Alligator announced that Orion had selected bispecific lead antibodies and subsequently exercised its first development option to these molecules under the agreement. On July 31, 2023, Alligator announced that Technical Feasibility had been achieved in the second collaboration project, triggering a new milestone payment to Alligator.

## MacroGenics, Inc.

In 2021, Alligator entered a joint research collaboration with US-based MacroGenics, Inc., a Nasdaq-listed biopharmaceutical company focused on developing and commercializing innovative monoclonal antibody-based therapeutics for the treatment of cancer. The research collaboration utilizes Alligator's proprietary myeloid engaging Neo-X-Prime™ platform to develop bispecific antibodies against two undisclosed targets.

Under the joint research collaboration agreement, which covers activities from candidate drug generation up until IND-enabling studies, each company will be responsible for its own costs. The parties may continue further development of the resulting bispecific molecule under a separate co-development collaboration and licensing agreement.

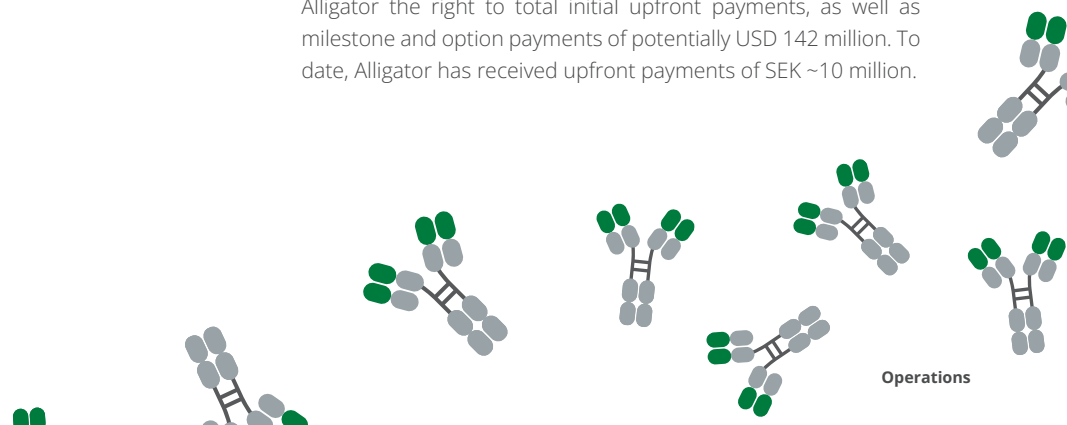
## AC101/HLX22

Through its subsidiary Atlas Therapeutics AB, Alligator holds a participating interest in the clinical Biosynergy (AC101/HLX22) project, run by the listed Korean company AbClon. The drug candidate is now being further developed by the Chinese company Shanghai Henlius, which increased its rights to encompass a global license for development and commercialization in 2018. The phase 2 study had the first patient dosed in Q3 2021, and the estimated primary completion date for the study is April 2023, will full completion expected Q3 2024. In 2022, an IND application has been approved for a second Phase 2 trial in China with AC101/HLX22 in gastric cancer.

Alligator incurs no cost for this project and is entitled to 35% of AbClon's revenue from out-licensing to Shanghai Henlius. In previous financial years, Alligator received two milestone payments totaling USD 3 million in conjunction with regional and global out-licensing.

## Biotheus

In 2019, an agreement was concluded with Chinese company Biotheus, where Biotheus obtained the Chinese rights (Greater China, Hong Kong, Taiwan and Macao) to an antibody from the ALLIGATOR-GOLD® antibody library. The agreement gives Alligator the right to total initial upfront payments, as well as milestone and option payments of potentially USD 142 million. To date, Alligator has received upfront payments of SEK ~10 million.





# The Alligator Share

## Number of shares, stock option program and share saving program

The Extraordinary General Meeting on 24 April 2023 resolved to carry out the rights issue and to reduce the share capital within the aggregate SEK 74,435,668.608 from SEK 88,613,891.20 to SEK 14,178,222.592. This reduction means that the quota value per share is reduced from SEK 0.40 to SEK 0.064. The Rights Issue comprised a maximum of 441,169,756 units. Each unit consists of one ordinary share and one warrant (TO 6). Eight warrants entitle the holder to subscribe for one new ordinary share in the company at a subscription price of SEK 0.40 per share. A total of 275,027,774 warrants were exercised, corresponding to approximately 68 percent of all warrants of series TO 6, for the subscription of a total of 34,378,471 ordinary shares.

As a result of the rights issue and through the warrant exercise, the share capital increased by SEK 27,991,642.368 to SEK 42,169,864, resulting in that the total number of shares outstanding in the company increase from 221,534,728 to 658,904,140 whereof 657,954,290 are ordinary shares and 949,850 are series C shares. The total number of votes in the company after the exercise of the warrants amounts to 658,049,275. As a result of the rights issue and through the warrant exercise, the share capital increased to SEK 42,169,864.

## Share saving program LTI 2021

At the annual general meeting 2021 it was resolved to implement a long-term incentive program by way of a performance-based share saving program for employees in the company ("LTI 2021"). For each ordinary share acquired by the participant on Nasdaq Stockholm, so called saving shares, the participant has a right to receive so called matching shares. In addition, given that a requirement related to the development of the company's share price from the day of the annual general meeting 2021 up until 30 September 2024 has been achieved, the participant has a right to receive further shares in the company free of charge, so called performance shares. After the recalculation due to rights issue the maximum number of ordinary shares that can be issued in relation to LTI 2021 amount to 1,419,206 whereby 1,079,901 for the deliverance of matching

shares and performance shares to participants and 339,305 to hedge payments of future social security contributions, which corresponds to a dilution of approximately 0.22 per cent of the company's share capital and votes.

## Warrant programs, LTI 2022 I/II

At the annual general meeting 2022 it was resolved to implement a long-term incentive program by way of a warrant program for employees in the company and for certain board members ("LTI 2022-I", respectively "LTI 2022-II"). Each warrant in LTI 2022-I/II entitle to subscription of one ordinary share in the company. Subscription of shares by virtue of the warrants may be effected as from 1 June 2025 up to and including 30 June 2025. Due to the rights issue the subscription price per share for above warrant programs, was recalculated to SEK 2.57. In case all warrants issued within the Warrant program LTI 2022I/II program are utilized for subscription of new ordinary shares, a total of 4,115,132 new ordinary shares will be issued, which corresponds to a dilution of approximately 0.62 per cent of the company's ordinary shares after full dilution. Each option entitles to 1.32 shares. All warrants have been transferred to the participants at fair market value.

## Warrant programs 2023/2023-II

At the annual general meeting 2023 it was resolved to implement another long-term incentive program by way of a warrant program for employees in the company and for certain board members ("Warrant program 2023", respectively "Warrant program 2023-II"). In case all warrants issued within the Warrant program 2023/2023-II program are utilized for subscription of new ordinary shares, a total of 10,395,000 new ordinary shares will be issued, which corresponds to a dilution of approximately 1.56 per cent of the company's ordinary shares after full dilution.

In case both the existing incentive programs as well as the warrant programs proposed for the annual general meeting are exercised in full, a total of 15,929,338 ordinary shares will be issued, which corresponds to a total dilution of approximately 2.36 per cent of the company's ordinary shares.

## The Alligator share in brief September 30, 2023

Listed on:	Nasdaq Stockholm Small Cap
Number of shares:	658,904,140 (657,954,290 ordinary shares och 949,850 C shares)
Average turnover per day:	Approximately 1,700,000 (preceding quarter: approx. 2,720,000)
Number of shareholders:	10,415 (preceding quarter: approx. 10,540)
Market capitalization:	SEK 265 million (preceding quarter: approx. SEK 297 million)
Ticker:	ATORX
ISIN:	SE0000767188

## Swedish and foreign ownership



Largest Shareholders, September 30, 2023	No of Shares	%
Koncentra Holding AB (Part of Allegro Investment Fund)	205,840,049	31.2
Roxette Photo NV	53,446,475	8.1
Magnus Petersson*	19,124,338	3.1
Avanza Pension	20,164,481	3.1
Nordnet Pensionförsäkring	17,431,777	2.7
Johan Zetterstedt	10,945,303	1.7
Lars Spånberg	9,641,572	1.5
Jonas Sjögren	6,753,098	1.0
Öhman Fonder	6,271,529	1.0
Pearla Gem Ltd	4,136,681	0.6
Other shareholders	304,198,987	46.5
<b>Total number of shares</b>	<b>657,954,290</b>	<b>100.0</b>

\*Holding verified as per June 30, 2023.

The Company's owner structure is updated regularly on the Company's website: [www.alligatorbioscience.com](http://www.alligatorbioscience.com)

Source: Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

# Other information

## Review

This report has been reviewed by the Company's auditor.

## Employees

The number of employees in the Group at the end of the quarter was 59 (53). Of these, 17 (16) were men and 42 (37) were women. Of the total number of employees at the end of the quarter 51 (44) were employed within research and development.

## Future report dates

Alligator intends to publish its financial reports according to the following:

- Year-end Report 2023: 15 February, 2024
- Annual Report 2023: March, 2024
- January - March 2024 Interim Report: 25 April, 2024

## Risks and uncertainties

During the course of its business operations, the Group is exposed to various financial risks, such as market risk (comprising foreign exchange risk, interest-rate risk and price risk), credit risk and liquidity risk. The aim of the Group's overall risk management is to achieve minimal adverse effects in terms of earnings and financial position.

The Group has transaction exposure from contracted payment flows in foreign currency. Most of the Group's transaction exposure is in USD, GBP and EUR. A 5 % stronger/weaker SEK against the USD would have a positive/negative effect on post-tax profits and equity of approx. +/- SEK 2,332 thousand during the first 9 months of 2023. A 5 % stronger/weaker SEK against the EUR would have a positive/negative effect on post-tax profits and equity of approx. +/- SEK 2,072 thousand. A 5 % stronger/weaker SEK against the GBP would have a positive/negative effect on post-tax profits and equity of approx. +/- SEK 1,263 thousand during the first 9 months of 2023.

The Group's business risks, risk management and financial risks are described in detail in the Annual Report for 2022.

## The impact of the war in Ukraine on the Group's risks

The situation in Ukraine is foremost a humanitarian tragedy that

is causing great human suffering. The Russian invasion of Ukraine has worsened the political security situation in the rest of the world and created great uncertainty in the financial markets, which may affect the company's ability to finance clinical trials in the future. The company has no direct business in, nor does it conduct any clinical studies in Ukraine or Russia, but see a risk that the company eventually will suffer from increased raw material and energy prices, which will translate into increased prices for goods and services.

## Cyber security

Cyber attacks have become a significant threat in society and for Alligator Bioscience, which is dependent on IT support in its daily operations. The company has ongoing work to ensure that the company is well prepared to counter cyber-attacks and other types of intrusion.

## Statement of financial position

The Company works continuously to secure the financing of the operation. This include both business development for new partnering agreements, with an upfront payment upon signing, as well as other options. During the period May-August 2023 the Company carried out a rights issue of approximately SEK 184 million after transaction costs. As the company within the next 12 months has additional financing needs that have not yet been secured, the Board is continuously working on evaluating various financing options to ensure continued operation. It is the Board's assessment that the company has good prospects of securing future financing, for example, through a new share issue, however, the absence of assurance at the same time of submission of this report means that there is a significant uncertainty factor regarding the company's ability to continue operation.

## Forward-looking information

Even though the board and management believe the expectations in this report are justified, no guarantees can be given that they will turn out to be correct. Accordingly, the actual outcome may differ significantly from the assumptions stated in the forward-looking information depending on, among other factors, changes in the economy or market, changes in legal or regulatory demands, political decisions and changes in exchange rates.

## Parent Company

Both Group management functions and all operating activities are carried out in the Parent Company. For additional details, refer to the information provided for the Group since the subsidiaries do not conduct their own operations.

## Notes to the reader

Figures in brackets refer to the outcome for the corresponding period in the preceding year for figures related to the income statement and cash flow. For figures related to the financial position and personnel, figures in brackets refer to December 31, 2022. Unless otherwise stated, all amounts stated are rounded correctly, which may mean that some totals do not tally exactly. "Dollar" means US dollars unless otherwise stated.

## Registered trademarks

FIND® and ALLIGATOR-GOLD® are Alligator Bioscience AB proprietary trademarks which are registered in Sweden and other countries.

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# Financial statements

Unless otherwise stated in this interim report, numbers refer to the Group. Due to the nature of the business, there can be large fluctuations in revenue which are not seasonal or regular but are mainly linked to when milestones generating a payment are reached in out-licensed research projects. Like revenue, expenses can also fluctuate between periods. Among other factors, this fluctuation in expenses is influenced by the current phase of the various projects since certain phases generate higher costs. Figures in brackets refer to the outcome for the corresponding period in the preceding year for figures related to the income statement and cash flow. For figures related to the financial position and personnel, figures in brackets refer to December 31, 2022. Unless stated otherwise, all amounts are in SEK thousand (KSEK). All amounts stated are rounded, which may mean that some totals do not tally exactly.

## Consolidated Income Statement

### Net Sales

Sales for the period pertain primarily to the collaboration and licence agreement with Orion Corporation. In December 2022, Alligator Bioscience and Orion Corporation announced the initiation of the second program of their Immuno-oncology Research Collaboration and License Agreement. In the same period prior year sales referred primarily to the first program within the collaboration and licence agreement with Orion Corporation.

### Other operating income

Other operating income for the quarter comprises primarily of exchange gains in the company's operations.

### Operating costs

The company's costs are higher compared to the same period previous year and pertain mainly to costs related to mitazalimab's Optimize-1 study and ALG.APV 527. External costs for mitazalimab amounted to SEK 33,016 thousand (18,478) during the third quarter of the year. These costs are driven by Phase 3 enabling toxicity studies, drug production and a high number of patients that stay on longer in Optimize-1 compared to the previous year. The first patient in ALG.APV 527 was dosed in February 2023 and the study is currently ongoing. The personnel costs in the third quarter are higher than last year due to an increased number of employees.

### Net financial items

Pertains to returns on liquidity and financial assets as well as unrealized exchange gains and losses as a result of liquidity positions in USD, EUR and GBP.

All amounts KSEK unless specified	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
<b>Operating income</b>						
Net sales	5	19,414	5,108	46,369	15,634	35,696
Other operating income	5	488	130	2,626	597	1,439
<b>Total operating income</b>		<b>19,902</b>	<b>5,238</b>	<b>48,995</b>	<b>16,231</b>	<b>37,135</b>
<b>Operating costs</b>						
Other external costs		-52,471	-36,340	-160,394	-97,242	-147,725
Personnel costs		-16,454	-15,416	-57,219	-49,661	-68,836
Depreciation of tangible assets and intangible assets		-2,684	-4,204	-7,817	-8,294	-11,767
Other operatings expenses		-1,014	-511	-2,162	-1,178	-1,597
<b>Total operating costs</b>		<b>-72,622</b>	<b>-56,471</b>	<b>-227,592</b>	<b>-156,374</b>	<b>-229,925</b>
<b>Operating profit/loss</b>		<b>-52,720</b>	<b>-51,233</b>	<b>-178,596</b>	<b>-140,144</b>	<b>-192,789</b>
<b>Financial items</b>						
Other interest income and similar income statement items		370	26	447	151	32
Interest expense and similar income statement items		-151	-159	-607	-159	-646
<b>Net financial items</b>		<b>219</b>	<b>-132</b>	<b>-160</b>	<b>-8</b>	<b>-614</b>
<b>Profit/loss before tax</b>		<b>-52,501</b>	<b>-51,365</b>	<b>-178,756</b>	<b>-140,152</b>	<b>-193,403</b>
Tax on profit for the period		-	-	-	-	-
<b>Profit for the period attributable to Parent Company share-holders</b>		<b>-52,501</b>	<b>-51,365</b>	<b>-178,756</b>	<b>-140,152</b>	<b>-193,403</b>
<b>Earnings per share</b>						
<b>Earnings per share before and after dilution, SEK</b>		<b>-0.08</b>	<b>-0.23</b>	<b>-0.45</b>	<b>-0.64</b>	<b>-0.88</b>

## Consolidated Statement of Comprehensive Income

All amounts KSEK	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Profit/loss for the period		-52 501	-51 365	-178 756	-140 152	-193 403
Other comprehensive income		-	-	-	-	-
<b>Comprehensive income for the period</b>		<b>-52 501</b>	<b>-51 365</b>	<b>-178 756</b>	<b>-140 152</b>	<b>-193 403</b>

# Consolidated Statement of Financial Position

## ASSETS

### Participations in development projects

The Group's participations in development projects refers to cooperation with the South Korean company AbClon Inc. for the Biosynergy project. Biosynergy is outlicensed to the Chinese company Shanghai Henlius, which is now further developing the drug candidate. At the end of the period, participations in development projects amounted to SEK 17,949 thousand (17,949).

### Right of use assets

At the end of the period, right of use assets amounted to SEK 19,987 thousand (25,550). Right of use assets pertain to leases for offices and laboratories, machines and vehicles.

In June 2022 Alligator entered into a lease agreement with Medicon Village for office premises valid from October 2024 with an agreement period of 5 years. The new agreement is estimated to increase the right of use assets by SEK 42,281 thousand, based on the use of the agreement period without extension and will be reported as a right of use asset only from the time we access the premises. This agreement replaces the current agreement with Medicon Village regarding office premises.

### Cash and cash equivalents

Consolidated cash and cash equivalents, which consist of bank balances, totaled SEK 73,919 thousand (97,305). The Group invested a portion of its liquidity in the fixed interest deposit with 3 months maturity and divestment in October 2023. The value of this deposit amounts to SEK 50 000 thousand (-).

The Group plans to use its liquidity for operating activities. A portion of the Group's liquidity is invested in USD, EUR and GBP foreign currency accounts. In accordance with the Group's Financial Policy, inflows of foreign currencies exceeding the expected requirements for the coming 18 months are to be converted to SEK at the time of payment. Besides this, no further hedging has taken place.

All amounts in KSEK	Note	2023-09-30	2022-09-30	2022-12-31
<b>ASSETS</b>				
<b>Fixed assets</b>				
<b>Intangible assets</b>				
Participations in development projects	3	17,949	17,949	17,949
Softwares		21	103	70
<b>Tangible assets</b>				
Improvements in leased premises		-	152	-
Right of use assets		19,987	19,801	25,550
Equipment, machinery and computers		2,991	1,831	1,386
<b>Financial assets</b>				
Other long term financial fixed assets	6	2,057	-	1,815
<b>Total fixed assets</b>		<b>43,005</b>	<b>39,835</b>	<b>46,770</b>
<b>Current assets</b>				
<b>Current receivables</b>				
Accounts receivable	6	5,660	6,639	13,930
Other receivables	6	5,183	4,678	3,636
Prepayments and accrued income		6,333	6,492	7,942
Other short-term financial assets	6	50,000	-	-
Cash and cash equivalents	6	73,919	147,411	97,305
<b>Total current assets</b>		<b>141,095</b>	<b>165,219</b>	<b>122,814</b>
<b>TOTAL ASSETS</b>		<b>184,100</b>	<b>205,054</b>	<b>169,584</b>



# Consolidated Statement of Financial Position

## EQUITY AND LIABILITIES

### Equity

Equity at the end of the period amounted to SEK 81,897 thousand (89,051), corresponding to an equity ratio of 44 (53) %. The Extraordinary General Meeting on 24 April 2023 resolved to carry out the rights issue and to reduce the share capital within the aggregate SEK 74,435,668.608 from SEK 88,613,891.20 to SEK 14,178,222.592. This reduction means that the quota value per share was reduced from SEK 0.40 to SEK 0.064. The Rights Issue comprised a maximum of 441,169,756 units. Each unit consists of one ordinary share and one warrant (TO 6). Eight warrants entitle the holder to subscribe for one new ordinary share in the company at a subscription price of SEK 0.40 per share. A total of 275,027,774 warrants were exercised, corresponding to approximately 68 percent of all warrants of series TO 6, for the subscription of a total of 34,378,471 ordinary shares.

As a result of the rights issue in June 2023 and through the warrant exercise, the share capital increased by SEK 27,991,642.368 to SEK 42,169,864, resulting in that the total number of shares outstanding in the company increase from 221,534,728 to 658,904,140 whereof 657,954,290 are ordinary shares and 949,850 are series C shares. The total number of votes in the company after the exercise of the warrants amounts to 658,049,275.

### Equity per share before and after dilution

At the end of the period, equity per outstanding share amounted to SEK 0.12 (0.41), before and after dilution. Since the subscription price for issued options has not been reached, these are not taken into account (not "in-the-money"). C shares are not taken into account either.

### Lease liabilities and loans

Lease liabilities pertain to leases for offices and laboratories, machines and vehicles. At the end of the period long- and short-term lease liabilities amounted to SEK 18,450 thousand (24,502). In June 2022 Alligator entered into a lease agreement with Medicon Village for office premises valid from October 2024 with an agreement period of 5 years. The new agreement is estimated to increase the lease liabilities by SEK 42,281 thousand, based on the use of the agreement period without extension, and will be reported as

a lease liability only from the time we access the premises. This agreement replaces the current agreement with Medicon Village regarding office premises.

### Accrued expenses and deferred income

At the end of the period, accrued expenses and deferred income amounted to SEK 69,979 thousand (39,655). Expenses pertain to accrued expenses for clinical activities, personnel and other expenses. Accrued costs are higher compared to the same period last year and are primarily related to accrued patient costs for mitazalimab's Optimize-1 study and costs related to Phase 1 studie for ALG.APV 527, patient costs for mitazalimab's OPTIMIZE-1 study and costs related to the initiation of clinical studies for ALG.APV-527.

All amounts in KSEK	Note	2023-09-30	2022-09-30	2022-12-31
<b>EQUITY AND LIABILITIES</b>				
<b>Equity</b>				
Share capital		42,170	88,614	88,614
Other capital contributions		1,055,459	911,914	911,901
Retained earnings and profit/loss for the period		-1,015,731	-858,271	-911,463
<b>Equity attributable to Parent Company shareholders</b>		<b>81,897</b>	<b>142,257</b>	<b>89,051</b>
<b>Non-current provisions and liabilities</b>				
Lease liabilities	6	9,640	11,877	16,003
<b>Total non-current provisions and liabilities</b>		<b>9,640</b>	<b>11,877</b>	<b>16,003</b>
<b>Current liabilities</b>				
Accounts payable	6	11,966	4,362	13,343
Other liabilities		1,808	1,167	3,032
Lease liabilities	6	8,810	7,068	8,499
Accrued expenses and deferred income	6	69,979	38,323	39,655
<b>Total current liabilities</b>		<b>92,563</b>	<b>50,920</b>	<b>64,529</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>184,100</b>	<b>205,054</b>	<b>169,584</b>

## Consolidated Statement of Changes in Equity, in summary

All amounts in KSEK		2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
<b>Opening balance</b>		<b>121,835</b>	<b>193,224</b>	<b>89,051</b>	<b>282,273</b>	<b>282,273</b>
New capital issue		13,751	-	195,097	380	380
Transaction costs		-1,196	370	-23,979	-343	-343
Treasury shares		-	-	-	-380	-380
Warrants		-	-	440	426	426
Effect of share-based payments personnel		8	27	52	52	99
Repurchase of warrants		-	-	-9	-	-
Profit/loss for the period		-52,501	-51,365	-178,756	-140,152	-193,403
<b>Closing balance</b>		<b>81,897</b>	<b>142,256</b>	<b>81,897</b>	<b>142,256</b>	<b>89,051</b>

# Consolidated Statement of Cash Flows

## Investments

Investments during the quarter consisted of laboratory equipment SEK 39 (-) thousand. Investments during the year amounts to SEK 2,459 thousand.

## Cash flow for the period

Cash flow for the quarter totaled SEK -86,495 thousand (-45,556). In July 2023 the company invested a portion of its liquidity in the fixed interest deposit with 3 months maturity and divestment in October 2023. The value of this deposit amounts to SEK 50 000 (-) thousand.

In June 2023, the company carried out a rights issue SEK 181,346 thousand and in August 2023 the company received SEK 13,751 thousand through the exercise of warrants of series TO 6 which had positive effect on the cash flow. Transaction cost amounted to SEK 23,979 thousand.

All amounts in KSEK	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
<b>Operating activities</b>					
Operating profit/loss	-52,720	-51,233	-178,596	-140,144	-192,789
Adjustments for items not generating cash flow					
Depreciation and impairments	2,684	1,102	7,817	5,218	11,767
Effect from warrant program	8	26	52	53	99
Other items, no impact on cash flow	-	3	-	177	-19
Interest received	473	-	510	-	-
Interest paid	-115	-3	-381	-126	-646
Tax paid	-	-	-	-	-
<b>Cash flow from operating activities before changes in working capital</b>	<b>-49,671</b>	<b>-50,105</b>	<b>-170,598</b>	<b>-134,821</b>	<b>-181,588</b>
<b>Changes in working capital</b>					
Change in operating receivables	572	-1,862	8,090	567	-5,859
Change in operating liabilities	2,532	9,225	27,723	8,965	14,840
<b>Cash flow from operating activities</b>	<b>-46,567</b>	<b>-42,743</b>	<b>-134,785</b>	<b>-125,290</b>	<b>-172,607</b>
<b>Investing activities</b>					
Acquisition of tangible assets	-39	-	-2,459	-293	-440
<b>Cash flow from investing activities</b>	<b>-39</b>	<b>-</b>	<b>-2,459</b>	<b>-293</b>	<b>-440</b>
<b>Financing activities</b>					
Amortization of leasing liabilities	-2,445	-3,183	-7,404	-5,435	-7,806
Amortization of installment purchase	-	-	-	-104	-104
New share issue	13,751	380	195,097	380	380
Transaction costs	-1,196	-10	-23,979	-343	-343
Warrants	-	-	440	426	426
Repurchase of warants	-	-	-9	-	-
Purchase of treasury shares	-	-	-	-380	-380
Acquisition of other short term investments	-50,000	-	-50,000	-	-
<b>Cash flow from financing activities</b>	<b>-39,920</b>	<b>-2,813</b>	<b>114,116</b>	<b>-5,456</b>	<b>-7,827</b>
<b>Cash flow for the period</b>	<b>-86,495</b>	<b>-45,556</b>	<b>-23,098</b>	<b>-131,039</b>	<b>-180,874</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>160,552</b>	<b>192,913</b>	<b>97,305</b>	<b>278,148</b>	<b>278,148</b>
Exchange rate differences in cash and cash equivalents	-137	53	-288	301	32
<b>Cash and cash equivalents at end of period</b>	<b>73,919</b>	<b>147,411</b>	<b>73,919</b>	<b>147,411</b>	<b>97,305</b>

## Parent Company Income Statement

All amounts in KSEK	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
<b>Operating income</b>						
Net sales	5	19,414	5,108	46,369	15,634	35,696
Other operating income	5	488	130	2,626	597	1,439
<b>Total operating income</b>		<b>19,902</b>	<b>5,238</b>	<b>48,995</b>	<b>16,231</b>	<b>37,135</b>
<b>Operating costs</b>						
Other external costs		-54,977	-39,660	-167,695	-102,450	-155,785
Personnel costs		-16,454	-15,416	-57,219	-49,661	-68,836
Depreciation and impairment of tangible assets and intangible assets		-309	-1,083	-903	-3,389	-4,165
Other operating expenses		-1,014	-511	-2,162	-1,178	-1,597
<b>Total operating costs</b>		<b>-72,754</b>	<b>-56,671</b>	<b>-227,979</b>	<b>-156,678</b>	<b>-230,383</b>
<b>Operating profit/loss</b>		<b>-52,851</b>	<b>-51,432</b>	<b>-178,983</b>	<b>-140,447</b>	<b>-193,248</b>
<b>Results from financial items</b>						
Other interest income and similar income statement items		370	26	447	151	35
Interest expense and similar income statement items		-36	27	-226	146	-4
<b>Net financial items</b>		<b>334</b>	<b>53</b>	<b>221</b>	<b>297</b>	<b>31</b>
<b>Profit/loss after financial items</b>		<b>-52,517</b>	<b>-51,379</b>	<b>-178,762</b>	<b>-140,150</b>	<b>-193,217</b>
<b>Appropriations</b>						
Group contribution received		-	-	-	-	407
<b>Total appropriations</b>		<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>407</b>
<b>Result before tax</b>		<b>-52,517</b>	<b>-51,379</b>	<b>-178,762</b>	<b>-140,150</b>	<b>-192,810</b>
Tax on profit for the year		-	-	-	-	-
<b>Profit/loss for the period</b>		<b>-52,517</b>	<b>-51,379</b>	<b>-178,762</b>	<b>-140,150</b>	<b>-192,810</b>

## Parent Company Statement of Comprehensive Income

All amounts in KSEK	Note	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Profit/loss for the period		-52,517	-51,379	-178,762	-140,150	-192,810
Other comprehensive income		-	-	-	-	-
<b>Profit/loss for the year</b>		<b>-52,517</b>	<b>-51,379</b>	<b>-178,762</b>	<b>-140,150</b>	<b>-192,810</b>

# Parent Company

## Balance Sheet

All amounts in KSEK	Note	2023-09-30	2022-09-30	2022-12-31
<b>ASSETS</b>				
<b>Fixed assets</b>				
<b>Intangible assets</b>				
Software		21	103	70
<b>Total intangible assets</b>		<b>21</b>	<b>103</b>	<b>70</b>
<b>Tangible assets</b>				
Improvements in leased premises		-	152	-
Equipment, machinery and computers		2,991	1,831	1,386
<b>Total tangible assets</b>		<b>2,991</b>	<b>1,983</b>	<b>1,386</b>
<b>Financial assets</b>				
Participations in Group companies	3	20,294	20,294	20,294
Other long term financial fixed assets		2,057	-	1,815
<b>Total financial assets</b>		<b>22,351</b>	<b>20,294</b>	<b>22,109</b>
<b>Total fixed assets</b>		<b>25,363</b>	<b>22,379</b>	<b>23,565</b>
<b>Current assets</b>				
<b>Current receivables</b>				
Accounts receivables		5,660	6,639	13,930
Receivables from Group companies		845	438	845
Other receivables		5,183	4,677	3,636
Prepayments and accrued income		8,746	8,313	10,037
<b>Total current receivables</b>		<b>20,434</b>	<b>20,067</b>	<b>28,447</b>
Other short-term investments		50,000	-	-
Cash and bank deposits		72,233	146,130	96,046
<b>Total current assets</b>		<b>142,667</b>	<b>166,196</b>	<b>124,494</b>
<b>TOTAL ASSETS</b>		<b>168,029</b>	<b>188,576</b>	<b>148,059</b>



# Parent Company

## Balance Sheet

All amounts in KSEK	Note	2023-09-30	2022-09-30	2022-12-31
<b>EQUITY AND LIABILITIES</b>				
<b>Equity</b>				
<b>Restricted equity</b>				
Share capital		42,170	88,614	88,614
<b>Total restricted equity</b>		<b>42,170</b>	<b>88,614</b>	<b>88,614</b>
<b>Non-restricted equity</b>				
Share premium reserve		1,054,614	911,488	911,488
Retained earnings		-834,245	-715,941	-715,923
Profit/loss for the period		-178,762	-140,150	-192,810
<b>Total non-restricted equity</b>		<b>41,607</b>	<b>55,397</b>	<b>2,755</b>
<b>Total equity</b>		<b>83,777</b>	<b>144,011</b>	<b>91,369</b>
<b>Current liabilities</b>				
Accounts payable		11,966	4,362	13,343
Other liabilities		1,808	1,167	3,032
Accrued expenses and deferred income		70,478	39,036	40,314
<b>Total current liabilities</b>		<b>84,252</b>	<b>44,565</b>	<b>56,690</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>168,029</b>	<b>188,576</b>	<b>148,059</b>

# Notes

## Note 1 General information

This Interim report covers the Swedish Parent Company Alligator Bioscience AB (publ), corporate registration number 556597-8201, and its subsidiaries Atlas Therapeutics AB, corporate registration number 556815-2424, and A Bioscience Incentive AB, corporate registration number 559056-3663. Group's business operations are mainly carried out in the Parent Company.

The Parent Company is a Swedish public limited liability company registered and domiciled in the Municipality of Lund. The office is located at Medicon Village, SE-223 81 Lund.

## Note 2 Accounting policies

This Interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable regulations in the Swedish Annual Accounts Act (ÅRL). The interim report for the Parent Company has been prepared in accordance with the Swedish Annual Accounts Act (ÅRL) and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities.

The accounting policies and calculation methods used in this report are the same as those described in the Annual report for 2022.

## Note 3 Effects of changed estimates and judgments

Significant estimates and judgments are described in Note 3 and Note 18 of the Annual report for 2022. There have been no changes to the company's estimates and judgments since the Annual report for 2022 was prepared.

## Note 4 Segment reporting

The company conducts only one business activity, namely research and development in the field of immunotherapy, and the chief operating decision-maker is thus only responsible for regularly making decisions on and allocating resources to one entity. Accordingly, the company comprises only one operating segment, which corresponds to the Group as a whole, and no separate segment reporting is provided.

## Note 5 Consolidated Income

A breakdown of the Group's revenue regarding license revenue as follows:

All amounts in KSEK	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Licensing income	5,906	-	11,500	-	-
Reimbursement for development work	13,508	5,108	34,869	15,635	35,696
<b>Total</b>	<b>19,414</b>	<b>5,108</b>	<b>46,369</b>	<b>15,635</b>	<b>35,696</b>

A breakdown of the Group's other operating income is as follows:

All amounts in KSEK	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Swedish government grants received	262	-	989	179	305
Insurance compensation	-	-	-	6	6
Operational exchange rate gains	227	121	1,620	403	1,103
Other	-	9	18	9	25
<b>Total</b>	<b>488</b>	<b>130</b>	<b>2,626</b>	<b>596</b>	<b>1,439</b>

#### Note 6 Financial instruments

Cash and cash equivalents for the Group at September 30, 2023 consisted of bank balances amounting to SEK 73,919 thousand (97,305). Other short-term investments refer to fixed interest deposit with divestment in October 2023. For financial assets and liabilities, the reported value as below is considered a reasonable approximation of fair value.

All amounts in KSEK	2023-09-30	2022-09-30	2022-12-31
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##### Financial assets valued at amortized cost

Other long term financial fixed assets	2,057	-	1,815
Other short-term investments	50,000	-	-
Accounts receivable	5,660	6,639	13,930
Other receivables	6	-	-
Liquid assets - bank accounts	73,919	147,411	97,305
<b>Total financial assets</b>	<b>131,642</b>	<b>154,050</b>	<b>113,050</b>

##### Financial liabilities valued at amortized cost

Long-term lease liabilities	9,640	11,877	16,003
Accounts payable	11,966	4,362	13,343
Short-term lease liabilities	8,810	7,068	8,499
Accrued expenses	64,887	33,238	36,072
<b>Total financial liabilities</b>	<b>95,302</b>	<b>56,545</b>	<b>73,917</b>

#### Note 7 Related party transactions

In connection with the rights Issue, Alligator has in March 2023 entered into an agreement on a top guarantee of MSEK 10 with the Company's largest shareholder Koncentra, in which company board member Staffan Enkrantz is chairman of the board of directors. Furthermore, Alligator has in March 2023 entered into an agreement of a top guarantee of MSEK 0.5 and a bottom guarantee of MSEK 0.5 with board member Hans-Peter Ostler. For the guarantee commitments, cash compensation of 11% of the guaranteed amounts is paid for the bottom guarantee, and of 13% of the guaranteed amount for the top guarantees. The guarantee compensation was paid in June 2023 after the Swedish Companies Registration Office has registered the rights Issue.

In addition to the above, the Company has not carried out any other related party transactions during the third quarter 2023 or during the previous year.

# Financial definitions

## **Equity per share after dilution**

Equity divided by the total number of shares at the end of the period and any outstanding options where the Company's share price on the reporting date is at least equal to the conversion price of the option.

## **Equity per share before dilution**

Equity divided by the number of shares at the end of the period.

## **R&D costs**

The Company's direct costs for research and development. Refers to costs for personnel, materials and external services.

## **R&D costs as a percentage of operating costs excluding impairments**

R&D costs as a percentage of operating costs excluding impairments.

## **Average number of shares before and after dilution**

Average number of outstanding shares during the period. The number of shares after dilution also takes account of outstanding options where the Company's share price on the reporting date is at least equal to the conversion price of the option.

## **Average number of employees**

Average number of employees at the beginning and end of the period.

## **Average number of employees within R&D**

Average number of employees within the Company's R&D departments at the beginning and end of the period.

## **Cash flow from operating activities**

Cash flow before investing and financing activities.

## **Cash and cash equivalents, including securities**

Cash and cash equivalents consists of bank balances, interest funds and publicly traded corporate bonds.

## **Cash flow for the period**

Net change in cash and cash equivalents excluding the impact of unrealized foreign exchange gains and losses.

## **Earnings per share before and after dilution**

Earnings divided by the weighted average number of shares during the period before and after dilution respectively. If the result is negative, the number of shares before dilution is also used for the calculation after dilution.

## **Operating costs excluding impairments**

Other external costs, personnel costs and depreciation (excluding impairments of tangible and intangible assets).

## **Operating profit/loss**

Profit/loss before financial items and taxes.

## **Equity ratio**

Equity as a percentage of total assets.

## **Total assets**

Total of the Company's assets.

# Calculation of Performance Measures

Alligator presents certain financial performance measures in this report, including measures that are not defined under IFRS. The Company believes that these performance measures are an important complement because they allow for a better evaluation of the Company's economic trends. These financial performance measures should not be viewed in isolation or be considered to replace the performance indicators that have been prepared in accordance with IFRS. In addition, such performance measures as Alligator has defined them should not be compared with other performance measures with similar names used by other companies. This is because the above-mentioned performance measures are not always defined in the same manner, and other companies may calculate them differently to Alligator.

To the right is shown the calculation of key figures, for the mandatory earnings per share according to IFRS and also for performance measures that are not defined under IFRS or where the calculation is not shown in another table in this report.

The Company's business operation is to conduct research and development which is why "R&D costs/Operating costs excluding impairment in percent" is an essential indicator as a measure of efficiency, and how much of the Company's costs relate to R&D.

The Company does not have a steady flow of income, with income generated irregularly in connection with the signing of license agreements and achievement of milestones. Therefore, the Company monitors performance indicators such as equity ratio and equity per share in order to assess the Company's solvency and financial stability. These are monitored along with the cash position and the various measures of cash flows shown in the consolidated statement of cash flow.

All amounts KSEK unless specified	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Profit/loss for the period	-52,501	-51,365	-178,756	-140,152	-193,403
Average number of shares before dilution	632,567,111	220,584,878	399,466,214	220,584,878	220,584,878
<b>Earnings per share before dilution, SEK</b>	<b>-0.08</b>	<b>-0.23</b>	<b>-0.45</b>	<b>-0.64</b>	<b>-0.88</b>
Average number of shares after dilution	632,567,111	220,584,878	399,466,214	220,584,878	220,584,878
<b>Earnings per share after dilution, SEK</b>	<b>-0.08</b>	<b>-0.23</b>	<b>-0.45</b>	<b>-0.64</b>	<b>-0.88</b>

Operating costs	-72,622	-56,471	-227,592	-156,374	-229,925
<b>Operating costs excluding impairments</b>	<b>-72,622</b>	<b>-56,471</b>	<b>-227,592</b>	<b>-156,374</b>	<b>-229,925</b>
Reduce of administrative expenses	6,987	8,309	26,297	26,770	31,213
Reduce of depreciation	2,684	4,204	7,817	8,294	11,767
<b>Research and development costs</b>	<b>-62,952</b>	<b>-43,958</b>	<b>-193,477</b>	<b>-121,311</b>	<b>-186,945</b>
<b>R&amp;D costs / Operating costs excluding impairments %</b>	<b>87%</b>	<b>78%</b>	<b>85%</b>	<b>78%</b>	<b>81%</b>

Equity	81,897	142,256	81,897	142,256	89,051
Number of shares before dilution	657,954,290	220,584,878	657,954,290	220,584,878	220,584,878
<b>Equity per share before dilution, SEK</b>	<b>0.12</b>	<b>0.64</b>	<b>0.12</b>	<b>0.64</b>	<b>0.40</b>
Number of shares after dilution	657,954,290	220,584,878	657,954,290	220,584,878	220,584,878
<b>Equity per share after dilution, SEK</b>	<b>0.12</b>	<b>0.64</b>	<b>0.12</b>	<b>0.64</b>	<b>0.40</b>

Equity	81,897	142,256	81,897	142,256	89,051
Total assets	184,100	205,054	184,100	205,054	169,584
<b>Equity ratio, %</b>	<b>44%</b>	<b>69%</b>	<b>44%</b>	<b>69%</b>	<b>53%</b>

<b>Cash and cash equivalents at end of period</b>	<b>123,919</b>	<b>147,411</b>	<b>123,919</b>	<b>147,411</b>	<b>97,305</b>
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For definitions, see the section "Financial definitions" on page 22.



# The declaration of the Board of Directors and the CEO



*Anders Ekblom*



*Hans-Peter Ostler*



*Eva Sjökvist Saers*



*Graham Dixon*



*Veronica Wallin*



*Staffan Encrantz*



*Denise Goode*



*Anette Sundstedt*



*Søren Bregenholt*

The Board and the CEO declare that this Interim report provides a true and fair overview of the Company and the Group's operations, positions and earnings and describes the material risks and uncertainty factors faced by the Parent Company and the companies within the Group.

Lund, October 26, 2023

**Anders Ekblom**  
Chairman of the Board

**Hans-Peter Ostler**  
Vice chairman of the Board

**Eva Sjökvist Saers**  
Board member

**Graham Dixon**  
Board member

**Veronica Wallin**  
Board member

**Staffan Encrantz**  
Board member

**Denise Goode**  
Board member

**Anette Sundstedt**  
Board member  
*Employee representative*

**Søren Bregenholt**  
CEO

# Review report

**Alligator Bioscience AB (publ), corporate identity number  
556597-8201**

**To the Board of Directors of Alligator Bioscience AB (publ)**

## Introduction

We have reviewed the condensed interim report for Alligator Bioscience AB (publ) as at September 30, 2023 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

## Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

## Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material aspects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

## Material Uncertainty Related to Going Concern

We would like to draw attention to the section "Statement of financial position" on page 10 in the interim report where it is described that there is ongoing work related to the continued financing of the operations. The ongoing work means that the company does not, at the time of issuing our review report report, have secured funding. This condition indicates that there is a material uncertainty that may cast significant doubt on the company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Malmö, 26 October 2023  
Öhrlings PricewaterhouseCoopers AB

***Ola Bjärehäll***

Authorized Public Accountant

# Glossary

**Agonist.** A compound which binds to a receptor and stimulates its activity.

**Antigen.** Substance which triggers a reaction in the immune system, such as a bacteria or virus.

**Antibody.** Proteins used by the body's immune defenses to detect and identify xenobiotic material.

**Bispecific antibodies.** Antibody-based products which bind to two different targets and thus have dual functions.

**Cancer.** A disease in which cells divide in an uncontrolled manner and invade neighboring tissue. Cancer can also spread (metastasize) to other parts of the body through the blood and the lymphatic system.

**Checkpoint inhibitor.** An antibody with the ability to break the immune system's tolerance to something dangerous, for example a cancer tumor. Immune-inhibiting signals can be blocked through binding to a specific receptor such as CTLA-4 or PD-1.

**Clinical study.** The examination of healthy volunteers or patients to study the safety and efficacy of a potential drug or treatment method.

**CRO (Clinical Research Organization).** Company specialized in performing contract research and clinical studies on behalf of other pharma or biotech companies.

**CTA (Clinical Trial Authorization).** Application to start clinical trials in humans which is submitted to a regulatory authority.

**CTLA-4 (Cytotoxic T-lymphocyte-Associated protein-4).** An immune-inhibiting molecule expressed in and on the surface of T cells, primarily regulatory T cells.

**Dendritic cell.** A type of cell which detects xenobiotic substances. A key role of dendritic cells is their ability to stimulate T cells in the immune system.

**Discovery.** This research phase usually encompasses the development and evaluation of treatment concepts, the evaluation of potential drug candidates, and early efficacy studies.

**Disease control rate (DCR).** Proportion of patients with objective response or stabilization of disease.

**Drug candidate.** A specific compound usually designated before or during the preclinical phase. The drug candidate is the compound that is then studied in humans in clinical studies.

**EMA.** The European Medicines Agency.

**Experimental model.** A model of a disease or other injury to resemble a similar condition in humans.

**FDA.** The US Food and Drug Administration.

**GMP (Good Manufacturing Practice).** Quality assurance methodology designed to ensure that products are manufactured in a standardized manner, such that quality requirements are satisfied.

**Immuno-oncology.** Field of oncology in which cancer is treated by activating the immune system.

**INN (International Nonproprietary Name).** Generic name on a drug substance. The INN is selected by the World Health Organization (WHO) since 1953.

**Lead.** A potential drug candidate which binds to the actual target molecule/s.

**Ligand.** Binds to a receptor. Could be a drug, hormone or a transmitter substance.

**Lymphocyte.** A type of white blood cells.

**Macrophages.** A type of white blood cell of the immune system that engulfs and digests cellular debris and foreign materia such as bacteria.

**Milestone payment.** Financial consideration received in the course of a project/program when a specified objective is reached.

**Mitazalimab.** Generic name (INN) for ADC-1013.

**Monospecific antibodies.** Antibody-based product which bind only to one target, such as a receptor.

**NK cells.** NK cells (Natural Killer) are lymphocytes with the ability to activate several different cells in the immune system, such as macrophages.

**Oncology.** Term for the field of medicine concerned with the diagnosis, prevention and treatment of tumor diseases.

**Objective Response Rate (ORR)** Assessment of the tumor burden after a given treatment in patients with solid tumors. Important parameter to demonstrate the efficacy of a treatment and serves as a primary or secondary end-point in clinical trials.

**Patent.** Exclusive rights to a discovery or invention.

**PD-1 (Programmed Death-1).** Immune-inhibiting receptor on the surface of certain cells, for example tumor cells.

**PD-L1 (Programmed Death-Ligand-1).** The ligand that binds to PD-1, helping the cancer evade the body's immune defense.

**Phase 1,2 and 3.** The various stages of studies on the efficacy of a pharmaceutical in humans. See also "clinical study." Phase 1 examines the safety

on healthy human subjects, Phase 2 examines efficacy in patients with the relevant disease and Phase 3 is a large-scale study that verifies previously achieved results. In the development of new pharmaceuticals, different doses are trialed and safety is evaluated in patients with relevant disease. Phase 2 is often divided into Phase 2a and Phase 2b. In Phase 2a, which is open, different doses of the pharmaceutical are tested without comparison against placebo and focusing on safety and the pharmaceutical's metabolism in the body. Phase 2b is 'blind', and tests the efficacy of selected dose(es) against placebo.

**Pharmacokinetics.** The study of the turnover of substances in the body, for example how the amount of the substance is changed by absorption, distribution, metabolism and excretion.

**Pharmacology.** The study of how substances interact with living organisms to bring about a functional change.

**Preclinical.** The stage of drug development before the drug candidate is tested in humans. It includes the final optimization of the drug candidate, the production of materials for future clinical studies and the compilation of a data package for an application to start clinical studies.

**Proof of concept studies.** Studies carried out to provide support for dosages and administration paths in subsequent clinical studies.

**R&D.** Research & Development

**Receptor.** A receptor on a cell which picks up chemical signals.

**RECIST.** Response Evaluation Criteria in Solid Tumors - simple and pragmatic methodology to evaluate the activity and efficacy of new cancer therapeutics in solid tumors, using validated and consistent criteria to assess changes in tumor burden.

**Sponsor.** The person, company, institution or organization responsible for initiating, organizing or financing a clinical study.

**T cell.** A type of white blood cell which is important to the specific immune defense.

**Tumor-associated antigen (TAA).** A protein expressed to a much higher degree on the surface of tumor cells than healthy cells.

**Tumor cell.** A cell that divides relentlessly.

**Tumor necrotic factor receptor superfamily (TNFR-SF).** A group of immune-modulating target proteins related to the tumor necrosis factor protein. The name 'tumor necrosis factor' was derived from the fact that the first function detected for the protein was its ability to kill some types of tumor cells, though it was later discovered to have an immune-regulatory function.

