

A revolution for life.

# Competitive safety data for ADC-1013.

# Significant events April-June

- Janssen presented data from the clinical Phase I study with ADC-1013 indicates good safety and shows initial signs of clinical effect.
- Study design and progress for the ongoing ATOR-1015 Phase I study showcased at ASCO.
- Clinical trial authorization (CTA) application submitted to initiate a ATOR-1017 Phase I study.
- New preclinical data presented at scientific conferences:
- ATOR-1015:s tumor-localizing properties, shown with live-imaging technique, presented at PEGS (The Essential Protein Engineering Summit).
- ALG.APV-527 data, showing a favorable preclinical safety profile, presented at AACR (American Association for Cancer Research).
- ATOR-1144 demonstrates potential to activate both the innate and the adaptive immune system with a direct anti-tumor effect. Data presented at AACR.



Through its subsidiary Atlas
Therapeutics, the Group holds
an ownership interest in the drug
candidate AC101, that the South
Korean company AbClon has outlicensed to Henlius. Alligator incurs
no overheads for this project, but
is entitled to a share of any future

# Financial information

April-lune 2019

- Net sales, SEK 0.0 million (0.4)
- Total operating costs SEK -50.6 million (-39.9)
- Operating result, SEK -50.5 million (-39.1)
- Earnings per share before and after dilution, SEK -0.69 (-0.53)
- Cash flow for the period, SEK -44.9 million (-31.1)
- Cash, cash equivalents, incl securities, SEK 358.2 million (518.4)

#### January-June 2019

- Net sales, SEK 0.1 million (1.2)
- Total operating costs SEK -97.3 million (-84.9)
- Operating result, SEK -96.7 million (-83.1)
- Earnings per share before and after dilution, SEK -1.31 (-1.12)
- Cash flow for the period, SEK -79.2 million (-30.3)

"The results that Janssen presented at ASCO show that ADC-1013 can be administered in considerably higher doses than any of the other CD40 antibodies in clinical development. [...] The study also shows early signs of clinical efficacy"

CFO Per Norlén

# About the report

This information is such information as Alligator Bioscience AB (publ) is obliged to make public pursuant to the Swedish Securities Markets Act. The information was submitted for publication at 8:00 a.m. CEST on July 11, 2019. For contact details, see page 14.

#### 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, 2018. Unless otherwise stated, all amounts stated are rounded correctly, which may mean that some totals do not tally exactly.

#### Registered trademarks

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# Comments from the CEO.



The American Society of Clinical Oncology (ASCO) is a professional organization for oncologists and oncology professionals from all over the world. Since the organization was founded in 1964, the organization's Annual Meeting is one of the premier scientific congresses in the world and this year attracted more than 40,000 visitors. At the ASCO 2019 Annual Meeting, ADC-1013 and ATOR-1015 were presented.

# Janssen presents data for JNJ-7107 (ADC-1013) at ASCO

The Phase I clinical trial for ADC-1013 led by Janssen Biotech, Inc. (Janssen) is now approaching completion. The primary endpoint of the trial is to demonstrate the drug candidate's safety in cancer patients and to define the recommended dose level for the upcoming Phase II trial. The results that Janssen presented at ASCO show that ADC-1013 can be administered in considerably higher doses than any of the other CD40 antibodies in clinical development. The doses used are safe and tolerable, and it was also noted that the maximum tolerated dose has not yet been achieved in the trial which is is highly positive. This is in line with the results from Alligator's first trial with ADC-1013 and, in my opinion, shows that we have succeeded in our ambition to create a CD40 antibody that stimulates the immune system without causing adverse systemic side effects. The study also shows early signs of clinical efficacy; in ten patients, their cancer was stabilized. This means that the disease process has been stopped and that the size of the tumors is no longer growing. In addition, one patient presented a partial response, which means that the size of their cancer tumor has decreased. The results presented at ASCO are promising and strengthen my already major confidence in the CD40 field, and in ADC-1013 in particular.

# ATOR-1015 - Phase I recruitment progressing well

The other Alligator project presented at ASCO was the drug candidate ATOR-1015. Immunostimulation with CTLA-4 has demonstrated impressive clinical efficacy against several cancers, but CTLA-4 stimulation is also associated with severe side effects. Our ambition is that ATOR-1015 will be at least as effective as today's anti-CTLA-4 drug, but considerably better tolerated by patients. ATOR-1015 has the potential to achieve this by seeking out the tumor region and selectively targeting the immune system there.

The Phase I trial was started at the end of 2018 with a dose escalation study in patients with metastatic cancer. The primary endpoint of the trial is to evaluate safety and tolerability. The first patient was dosed in March 2019. Charlotte Russell, Alligator's Chief Medical Officer, presented the study design and progress for ATOR-1015 at ASCO under the Meeting Abstract *Developmental Immunotherapy and Tumor Immunobiology.* Recruitment to the study is progressing well with three dose levels evaluated for initial safety at hospitals in Lund, Stockholm and Uppsala. The Phase I study will comprise up to 50 patients and the results will be presented in the second-half of 2020.

#### ATOR-1017 moves toward clinical trials

On June 18, 2019, we filed a clinical trial authorization (CTA) application to start a clinical study of the ATOR-1017 antibody. The planned Phase I study is a dose escalation study in patients with metastatic cancer. The study will be conducted at three different clinics across Sweden.

We look forward to starting patient enrollment as soon as the application is approved by the authorities. This will be the third of our drug candidates to initiate clinical development, a significant milestone in our efforts to develop the next generation of cancer immunotherapies.

## Per Norlén

CEO Alligator Bioscience

# Performance measures, Group.

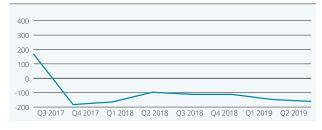
# Net sales, SEK million



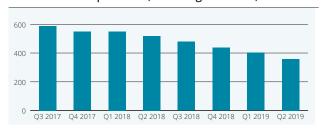
# Operating costs, rolling 12 months, SEK million



# Cash flow, rolling 12 months, SEK million



# Cash and cash equivalents, including securities, SEK million



	2019	2018	2019	2018	2018
Note	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Result (TSEK)					
Net sales 5	30	392	70	1,167	26,959
Operating profit/loss	-50,507	-39,108	-96,745	-83,102	-153,080
Profit/loss for the period	-49,306	-37,611	-93,692	-79,819	-150,043
R&D costs	-38,983	-28,957	-73,863	-64,473	-139,493
R&D costs as a percentage of operating costs excl. impairments	77%	73%	76%	76%	77%
Capital (TSEK)					
Cash and cash equivalents at end of period	284,950	444,575	284,950	444,575	362,878
Cash, cash equivalents and bonds at end of period	358,155	518,393	358,155	518,393	436,391
Cash flow from operating activities	-43,346	-30,003	-74,126	-23,835	-104,115
Cash flow for the period	-44,904	-31,072	-79,168	-30,299	-111,770
Equity at the end of the period	374,812	538,295	374,812	538,295	468,310
Equity ratio at the end of the period, %	89%	95%	89%	95%	92%
Info per share (SEK)					
Earnings per share before dilution	-0.69	-0.53	-1.31	-1.12	-2.10
Earnings per share after dilution*	-0.69	-0.53	-1.31	-1.12	-2.10
Equity per share before dilution	5.25	7.54	5.25	7.54	6.56
Equity per share after dilution*	5.25	7.54	5.25	7.54	6.56
Personnel					
Number of employees at end of period	56	49	56	49	55
Average number of employees	56	49	56	50	51
Average number of employees employed within R&D	48	42	48	43	44

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

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

# Operations.

Alligator Bioscience AB is a public Swedish biotech company specialized in the development of novel immuno-oncology drugs for tumor-directed immunotherapy, with the aim of providing more effective treatment with fewer side effects. The strategy is to develop drug candidates that selectively stimulate the immune system in the tumor region, rather than the whole body. In this area, Alligator is strongly differentiated and there is currently a major unmet medical need for novel and improved therapies.

The drug development process is carried out in Alligator's laboratory by the company's own personnel. All of the expertise required for running successful projects is represented. To make the process as competitive and time-efficient as possible, some of this work is also carried out in collaboration with other biotech companies, contract laboratories and leading international immuno-oncology research institutions.

# Several patented technologies

The development of novel drug candidates is based on Alligator's patented technology platforms FIND® (protein optimization technology) and ALLIGATOR-GOLD® (antibody library). These platforms enable efficient generation of novel drug candidates with high potential. In addition, the company has two unique bispecific antibody formats for the development of novel dual-action antibodies. The latest, RUBY™, allows Alligator to easily generate bispecific molecules from any two antibodies, with excellent stability and manufacturability properties. The format abolishes the need for further optimization and enables Alligator to move drug candidates faster from preclinical to the clinical phase. Together, these technologies provide Alligator with a strong base for the development of bispecific, tumor-directed drug candidates.

# Competitive project portfolio

Alligator's project portfolio includes the clinical and preclinical drug candidates ADC-1013, ATOR-1015, ATOR-1017, ALG. APV-527 and ATOR-1144, plus a number of early-stage research projects. All drug candidates are developed for tumor-directed immunotherapy, are directed against immunostimulatory receptors and can provide long-lasting protection against cancer. Future cancer treatments will probably involve several different drugs in combination. However, although the combination therapies used to date have boosted the clinical effect, they have also led to a higher risk of developing severe immune-related adverse events. Alligator's concept of tumor-directed immunotherapy provides an opportunity to solve this and develop new cancer therapies with higher efficacy without increasing the risk of severe side effects.

# Alligator's business model

		DISCOVERY	PRECLINICAL	CLINICAL PHASE I	CLINICAL PHASE II	CLINICAL PHASE III	MARKET
Costs	•	Research until selection of drug candidate. Patent application.	Preclinical studies. Presentations at scientific conferences.	Phase I clinical studies and out-licensing activities.	Phase II clinical studies and out-licensing activities.		
Revenue	•			Partnering/out-licensing Initial payment.	Partnering/out-licensing Initial payment. Milestone payments.	Partnering/out-licensing Milestone payments.	Partnering/out-licensing Royalties.

# Alligator's organization

Alligator's research organization is divided into three units: Discovery, Preclinical and Clinical. The Discovery Unit is responsible for early-stage research projects through to the identification of a drug candidate. This normally includes the development and evaluation of treatment concepts, the evaluation of potential drug candidates and early-stage efficacy testing. The Preclinical Unit is responsible for manufacturing clinical study materials and for compiling a clinical data package sufficient for clinical study applications. The Clinical Unit assumes responsibility

when the drug candidate enters a Phase I clinical study and for the subsequent clinical development until successful outlicensing.

# Business model that creates value across the development chain

The company's business model is based on proprietary drug development – from early-phase research and preclinical development to Phase II clinical studies, when the treatment is validated in patients. The plan is to subsequently out-license the

drug candidate to a licensee for further development and market launch. This business model provides opportunities for the company to generate revenue even before the drug reaches the market, as revenue when agreements are signed and milestone payments received during the development process. The business model was validated in 2015 when a license agreement was signed with Janssen Biotech, Inc. Under the agreement, Alligator is entitled to up to USD 695 million in milestone payments during the development process as well as royalties from future global sales of the drug.

# Drug development at Alligator - the different phases

## DISCOVERY

In the Discovery phase, Alligator creates mono and bispecific antibodies using its technology platforms ALLIGATOR-GOLD, FIND and two bispecific fusion formats.

The development and evaluation of treatment concepts, evaluation of various potential drug candidates and early-stage efficacy testing.

The antibodies are optimized to achieve the set objectives in terms of function, binding affinity and stability, after which a drug candidate is selected for further development.

## **PRECLINICAL**

In the Preclinical phase, final optimization takes place and the safety and efficacy of the drug candidate is assessed together with its clinical potential. These studies are conducted both internally at Alligator and together with external partners.

Alongside of these preclinical activities, research activities continue to increase understanding of the candidate's biological function. This phase also includes activities for the production of materials for upcoming clinical studies.

# **CLINICAL PHASE I**

The first human studies are conducted in smaller cohorts, normally 20–80 patients with metastatic cancer. The aim of these studies is mainly to show that the compound is safe.

Studies are also carried out to see how the drug is absorbed, distributed and metabolized.

## **CLINICAL PHASE II**

The endpoint of Phase II studies is to show that the substance has the intended medical efficacy and to determine optimal dosage. Normally, 100-300 patients are tested

By the end of Phase II, the drug's efficacy, probable dosage and side-effects profile should have been determined.

## **CLINICAL PHASE III**

The drug is tested on a larger cohort of patients in Phase III, usually between 1,000 and 3,000 patients.

The endpoint of Phase III studies is to demonstrate that the new compound is at least as good or better than previously approved treatments.

When the Phase III program is complete, a statement can be issued about the drug's properties and common side effects and the documentation required to register the drug has been compiled.



# **ADC-1013.** Clinical drug candidate out-licensed to Janssen Biotech, Inc.



ADC-1013 is an immunostimulatory antibody for the treatment of metastatic cancer. The drug candidate is since 2015 out-licensed to Janssen Biotech, Inc. (Janssen), which is running all continued clinical development. To date, ADC-1013 (called JNJ-7107 by Janssen) has generated revenue of almost SEK 400 million for Alligator. The total amount of the predefined milestone payments is potentially USD 695 million.

# Events during the second quarter

Promising safety and tolerability data from a second Phase I clinical study of ADC-1013 (JNJ-7107) in cancer patients were presented at the ASCO 2019 Annual meeting held in Chicago on May 31- June 4. The results showed that side effects were generally mild and transient.

The study is still ongoing and has enrolled a total of 95 patients. The maximum tolerated dose has not yet been reached. Doses up to 1200  $\mu$ g/kg i.v without premedication, and up to 2000  $\mu$ g/kg with premedication have been shown to be safe and tolerable. Early signs of clinical activity in this study included a partial response (PR) in a patient with renal cell cancer and 10 patients with prolonged stable disease (SD)  $\geq$ 6 months.

# Commercial status: out-licensed to Janssen with potential milestone payments of USD 695 million

The license agreement with Janssen comprises predefined milestone payments with a potential total value of about USD 695 million. If the commercialization is successful, Alligator will also be entitled to incremental royalties based on global net sales.

# Project status: Phase I studies

To date, the clinical program has comprised two Phase I studies. The first study was conducted by Alligator, and focused on intratumoral administration. The results from that study showed that ADC-1013 is well-tolerated at clinically relevant doses.

The second Phase I clinical study is currently being conducted by Janssen, see above "Events during the second quarter".

# 2019 objectives

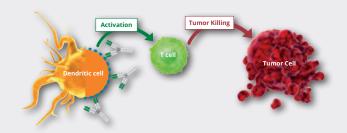
☐ Conclusion of Phase I patient study.

# Mechanism of action

#CD40



- 1. The dendritic cell presents the target molecule CD40 on its surface
- 2. ADC-1013 binds to CD40 and triggers activation of the immune system's beneficial T cells.
- 3. The T cells are activated to kill tumor cells.



ADC-1013 is an agonistic – or stimulatory – antibody that targets CD40, a receptor in the dendritic cells of the immune system, which are the cells that detect enemies such as cancer cells. ADC-1013's activation of CD40 enables dendritic cells to stimulate the immune response's weapons more effectively – in this case, T cells – allowing the immune system to selectively attack the cancer. ADC-1013 has been optimized using Alligator's unique FIND technology, with the aim of improving binding affinity. This makes it possible to achieve efficacy with very low doses. In preclinical experimental models, ADC-1013 has been shown to induce a potent tumor-directed immune response and provide long-lasting tumor immunity. In addition, preclinical data have demonstrated how ADC-1013 can be used against multiple types of cancer.

# **ATOR-1015.** Tumor-localizing bispecific CTLA-4 antibody with dual immunostimulatory function.



ATOR-1015 is a bispecific antibody that targets CTLA-4 and OX40, developed for tumor-directed treatment of metastatic cancer. One part of the antibody blocks CTLA-4 and the other part binds to OX40 and thus activates the immune system. The drug should be used as either a single therapy or in combination with other immunotherapies, such as PD-1 inhibitors. The ATOR-1015 antibody has been assembled and optimized using Alligator's unique ALLIGATOR-GOLD and FIND technologies and a bispecific fusion format.

# Events during the second quarter

ATOR-1015 Phase I study outline was showcased at the ASCO 2019 Annual meeting held in Chicago on May 31- June 4. The study design includes accelerated dose titration with one patient cohorts, followed by a modified 3+3 design with at least three patients per dose level. At the maximum tolerated dose, or at a lower dose level, an expansion cohort is planned with up to 14 patients for additional safety and efficacy evaluation. At ASCO, it was reported that three dose levels were evaluated for initial safety.

ATOR-1015 was in early April also presented at the Essential Protein Engineering Summit (PEGS) in Boston. New preclinical tumor-localization data demonstrates that ATOR-1015 physically localizes to the tumor in an experimental tumor model using a live imaging technique. The new results further reinforce ATOR-1015's concept of selective activation of the immune system in the tumor area.

# Project status: Clinical Phase I

In March 2019, the first patient was dosed in a clinical Phase I dose-escalation study in patients with metastatic cancer. The study is planned to include up to 53 patients. The principal investigator is Dr Jeffrey Yachnin at the Clinical Trials Unit, Department of Oncology at Karolinska University Hospital in Stockholm. The primary aim of the study is to investigate the safety and tolerability of ATOR-1015 and to identify the recommended dose for subsequent Phase II studies. For further information, please refer to:

https://www.clinicaltrials.gov/ct2/show/NCT03782467?ter-m=1015&rank=1

# 2019 objectives

Progress of the clinical Phase I study to enable preliminary data read-out in the second half of 2020.

# Mechanism of action





- 1. ATOR-1015 binds to CTLA-4 and OX40 on the regulatory T cells, the cells which restrain the immune system.
- 2. The macrophages are activated to kill Tregs, removing the inhibitory effect of Tregs on the beneficial T cells.
- 3. The effector T cells (light green) are multiplied in number and are activated to kill the tumor cells.



ATOR-1015 binds to two different immunomodulatory receptors – the CTLA-4 inhibitory receptor, and an OX40 costimulatory receptor. In preclinical studies, the bispecificity has been shown to cause a significant increase in the immunostimulatory effect and is expected be achieved mainly in environments where both of the target molecules are expressed at high levels, such as in a tumor. This means that ATOR-1015 may have potent immunostimulatory effects in the tumor environment, but not in the rest of the body, with the goal of reducing the side effects while maintaining efficacy. ATOR-1015 is primarily designed for combination therapies and the preclinical results presented include data indicating an additive anti-tumor effect in combination therapy with a PD-1 pathway-blocking antibody.

# **ATOR-1017.** Potent killing of tumor cells through stimulation of both T and NK cells.



ATOR-1017 is a monoclonal antibody that activates the costimulatory function of 4-1BB on T and NK cells in the tumor region and has been developed for the treatment of metastatic cancer. 4-1BB has the capacity to stimulate the immune cell populations required for tumor control.

# Events during the second quarter

In the end of June, the company submitted a clinical trial authorization (CTA) application to the relevant regulatory authorities to initiate a Phase I study. The study will be a first-in-human, dose-escalation study in patients with advanced cancer. It will be conducted at 3 sites in Sweden and will enroll up to 50 patients. The primary objective of the study is to assess the safety and tolerability of ATOR-1017 and to determine the recommended dose for the subsequent Phase II studies.

# Project status: Preclinical development

Preclinical data for the drug candidate ATOR-1017 was in early April presented at the Essential Protein Engineering Summit (PEGS) in Boston. The data shows that ATOR-1017, in an experimental model for colon cancer (MC38), displays potent anti-tumor effects. Furthermore, ATOR-1017 induces a dose-dependent effect on tumor growth inhibition and survival.

Extensive preclinical data have been presented showing that ATOR-1017 stimulates both NK and T cells, both of which contribute to an effective immune-mediated killing of tumor cells. As well as leading to amplification of the tumor-directed immune response, the 4-1BB stimulation of T cells also develops an immunological memory of the tumor. NK cells are immune cells that specifically target tumor cells trying to evade the immune system's response. NK cells also strengthen cell-death signaling from the immune system's tumor-specific T cells. Stimula-

tory antibodies against 4-1BB therefore strengthen the ability of both NK and T cells to attack tumor cells.

These preclinical data provide additional support for the positioning of ATOR-1017 as a best-in-class 4-1BB antibody with the potential to reduce side effects, but also to generate a potent and long-lasting immune response.

# 2019 objectives

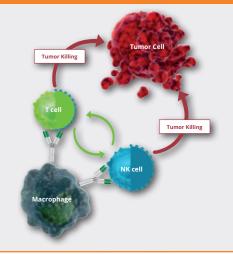
- ✓ Submit CTA application.
- ☐ Start of Phase I clinical study later in the year.

# Mechanism of action

#4-1BB #Fc-gamma receptor



- 1. ATOR-1017 binds to the target molecule 4-1BB on the surface of T cells and NK cells.
- 2. The immunostimulatory function is dependent on binding to Fc-gamma receptor on macrophages.
- 3. The beneficial T cells are activated to kill tumor cells.



ATOR-1017 is distinct from other 4-1BB antibodies, partly because of its unique binding profile, but also because its immunostimulatory function is dependent on crosslinking to Fc-gamma receptors in immune cells. This localizes the immunostimulation to the tumor region where both 4-1BB and Fc gamma receptors are expressed at high levels – totally in line with the treatment strategy for Alligator's drug candidates. The objective is to achieve an effective tumor-directed immune response with minimum side effects.

# **ALG.APV-527.** A tumor-binding and immunomodulatory antibody in the same molecule.



ALG.APV-527 is a bispecific antibody (4-1BB and 5T4) for the treatment of metastatic cancer. The antibody has two functions: to stimulate antitumor-specific T cells via the costimulatory receptor 4-1BB, and to bind to the 5T4 protein on the surface of tumor cells and thereby localize the immunostimulation to the tumor.

# ■ Events during the second quarter

In April, data for ALG.APV-527 was presented at the Annual Meeting of the American Association for Cancer Research (AACR) showing that ALG.APV-527 has a favorable safety profile, which will be important information for the upcoming application for clinical trial authorization.

# Project status: Preclinical development

Preclinical data for ALG.APV-527 has been presented at several scientific conferences. Data shows that ALG.APV-527 has the potential to selectively stimulate and strengthen the T cell

response in the tumor without stimulating the immune system in the rest of the body. The data shows that ALG.APV-527 localizes to 5T4 positive tumors and selectively stimulates and enhances tumor-directed immune cell (T cell and NK cell) responses. Additionally, the data shows that 5T4 antigen is present on a wide range of tumor types. The findings support its overall potential to evoke an effective tumor-directed immune response with fewer adverse events.

A preclinical data package is currently being compiled to support the submission of a clinical trial authorization (CTA) application in the second half of 2019

# Co-development with Aptevo

In July 2017, Aptevo Therapeutics and Alligator Bioscience signed an agreement regarding the co-development of ALG. APV-527. The antibody is based on Alligator's original bispecific drug candidate ATOR-1016. Under the agreement, the companies will equally own and finance the development of the drug candidate through the Phase II clinical study.

The original molecules involved in the tumor-binding function and immunomodulatory function of ALG.APV-527 were developed using Alligator's patented antibody library, ALLIGATOR-GOLD. The bispecific molecule was then further developed and improved jointly with Aptevo, using their technology platform ADAPTIR™. A drug candidate was created by combining a tumor-binding function with an immunomodulatory function in the same molecule, that can selectively target the tumor and stimulate the antitumor-specific immune cells that are found there.

# 2019 objectives

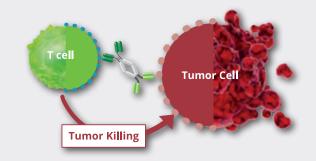
☐ Submit CTA application.

# Mechanism of action

#4-1BB #5T4



- ALG.APV-527 seeks out the tumor region and binds to the 5T4 target molecule on the surface of tumor cells.
- 2. In the tumor region, ALG.APV-527 simultaneously binds to 4-1BB on the surface of T cells.
- 3. The beneficial T cells are activated to kill tumor cells.



4-1BB has the ability to stimulate the immune cells (antitumor-specific T cells) involved in tumor control, making 4-1BB a particularly compelling target for cancer immunotherapy. The tumor-binding function of ALG.APV-527 targets the 5T4 tumor-associated antigen. 5T4 is a protein expressed on multiple tumor types as well as certain types of aggressive tumor cells (tumor-initiating cells), but at low levels or not at all in normal tissue, making 5T4 a compelling target molecule for cancer therapy.

# **ATOR-1144.** Tumor-localizing bispecific CTLA-4 x GITR antibody with broadened capacity to activate the immune system.



The drug candidate ATOR-1144 is a tumor-localizing bispecific CTLA-4 x GITR antibody with the potential to activate both the innate and the adaptive immune system with a direct anti-tumor effect. The innate immune system is our first line of defense against invading organisms while the adaptive immune system acts as a second line of defense and also affords protection against re-exposure to the same pathogen.

# Events during the second quarter

In April, new preclinical data was presented at the Annual Meeting of the American Association for Cancer Research (AACR) demonstrating that ATOR-1144 works through several pathways: activation of effector T cells (immune activating), depletion of regulatory T cells (immune suppressive) and tumor cells, as well as activation of NK (natural killer) cells, for enhanced tumor cell killing. Furthermore, GITR is shown to be expressed on additional other cells involved in direct tumor cell killing.

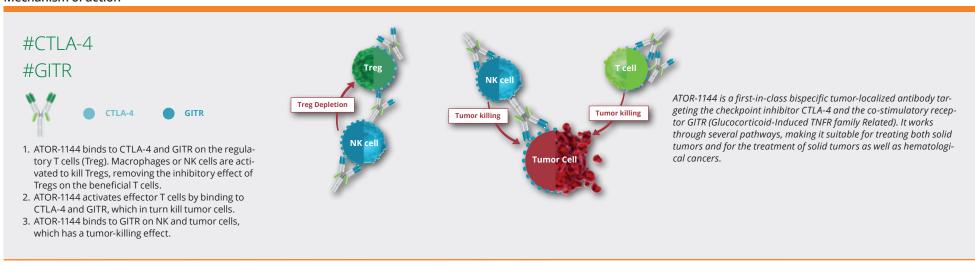
# Project status: Preclinical phase

ATOR-1144 comprises two binding components: a GITR-specific antibody isolated from ALLIGATOR-GOLD and a CTLA-4-specific binding component developed by FIND optimization of CD86, a natural ligand for CTLA-4. ATOR-1144 entered the preclinical development phase shortly before the end of 2018.

# 2019 objectives

☐ Preclinical studies will continue during the year, including experimental studies to demonstrate anti-tumor effects.

# Mechanism of action





# Other projects.

Alligator's early-stage research projects include several projects with components created using ALLIGATOR-GOLD and FIND, and then assembled using Alligator's bispecific fusion format. In January 2019, the company also presented RUBY, a novel concept in bispecific antibody formats.

In January 2019, the company presented RUBY, a novel concept in bispecific antibody formats. The RUBY concept gives Alligator competitive abilities to generate therapeutic antibodies that are both efficient and highly manufacturable. The format abolishes the need for further optimization and enables Alligator to move

drug candidates faster from preclinical to the clinical phase. This positions Alligator with a competitive edge in the field of immuno-oncology to deliver pipeline leads at increased speed for successful out-licensing.

# AC101 agreement with AbClon

Through its subsidiary Atlas Therapeutics AB, the Group holds an ownership interest in the Biosynergy (AC101) preclinical project, run by the South Korean company AbClon. Alligator incurs no overheads for this project, but is entitled to a share of any future returns. During previous financial years, Alligator received two milestone payments totaling SEK 2.1 million in conjunction with a regional out-licensing of one of these products, the HER2 antibody AC101.

In autumn 2018, a third party, Shanghai Henlius Biotech, Inc. ("Henlius"), chose to expand the scope of the AC101 agreement from a regional to a global agreement. The exercising of this option triggered a payment of USD 10 million (approximately SEK 90 million) from Henlius to AbClon Inc. ("AbClon"). Alligator holds an ownership interest in this project through its subsidiary Atlas Therapeutics AB that entitles Alligator to 35 percent of AbClon's revenue from the agreement with Henlius. Alligator received a payment of USD 3.5 million (approximately SEK 25 million) in March 2019.



# There is a huge unmet need for new, effective treatments.

One in five men and one in six women worldwide will at some stage of their lives develop cancer. Every year, about 18 million people are diagnosed with cancer and approximately 10 million people die of cancer (Globocan 2018), which means there is a major unmet need for advanced cancer care. One reason why cancer cases are constantly increasing is our increasing lifespan. Another is that diagnostics have improved. This means that more cancer cases are detected, more often in an early stage, which improves the chances of successful treatment.

# Targeted attack on the cancer tumor

The immune system is the body's protection against attacks by pathogenic micro-organisms (such as viruses and bacteria) and by cancer cells. Growing tumors often contain large numbers of immune cells with an innate ability to attack the cancer

cells. However, the cancer often develops its own protection against the immune system, by producing immunosuppressive agents, for example. Immunotherapy strengthens the body's ability to fight cancer effectively, which blocks or weakens the tumor's defense. The immune cells that destroy the cancer cells can then survive in the body and protect against metastases that may develop after the treatment. This "vaccination effect" is unique to immunotherapy. Through the use of biomolecular engineering and the company's patented technology platforms, Alligator's drug candidates are designed to selectively stimulate the immune system in the area surrounding the tumor rather than the whole body – which is not only expected to have a better effect, but also fewer side effects.

# Growing importance of immunotherapies

Immuno-oncology is one of the fastest growing areas of drug research. The global market for cancer immunotherapies is expected to grow to nearly USD 107 billion in 2023. As an

example, the sales of Merck's drug Keytruda® (PD-1 inhibitor) is expected to exceed USD 11 billion in 2019 (USD 7.1 billion in 2018). Source: Cowen Therapeutics Outlook March 2019.

Immunotherapy has revolutionized cancer therapy in recent years, and is showing positive effects in a large proportion of patients and over a longer period of time compared with previous treatments. Future cancer treatments will probably involve several different drugs in combination. However, although the combination therapies used to date have boosted the clinical effect, they have also led to a higher risk of developing severe immune-related adverse events. Alligator's concept of tumor-directed immunotherapy provides an opportunity to solve this and develop new cancer therapies with higher efficacy without increasing the risk of severe side effects.

# The Alligator share.

# Number of shares and stock option program

The total number of outstanding shares in the company at the end of the quarter was 71,388,615 (71,388,615).

At the AGM held in 2016, a resolution was passed regarding two incentive programs: an employee option program and a warrant program.

Under the employee option program, 900,000 employee stock options were allotted free of charge to participants. The employee options have been vested in installments until May 1, 2019. Of the allotted employee options, 846,664 have been vested and 53,336 have lapsed since the individuals to whom they were allotted have since left the company. To secure delivery under the employee option program, and to cover ancillary costs, primarily social security contributions, a total of 1,182,780 warrants were issued to a subsidiary of which 900,000 were allotted to employees free of charge and 282,780 were issued to cover ancillary costs. As a consequence of the warrants having lapsed, a total of maximum 1,112,686 warrants can be exercised in the program.

A total of 1,000,000 subscription options were issued under the program, of which a total of 857,000 warrants had been transferred to the participants in the program at market value at the end of the quarter. Further transfers will not take place and, as a consequence, a maximum of 857,000 warrants can be exercised in the program.

Each warrant in the two programs entitles the holder to acquire one new share at an exercise price of SEK 75. The warrants can be exercised in the periods from June 1, 2019 until August 31, 2019 and from March 1, 2020 until May 31, 2020.

At the 2018 AGM, it was decided to set up another employee option program whereby 2,275,000 employee options were allotted free of charge to participants. The employee options will be vested in installments until May 1, 2021. Vesting is subject to the participant remaining in the company's employment

and not having resigned on a given qualifying date. Of the allotted employee options, 568,750 have been vested, 1,683,750 may still be vested and 11,250 have lapsed since the individual to whom they were allotted has since left the company. To secure delivery under the employee stock option program, and to cover ancillary costs, primarily social security contributions, a total of 2,989,805 warrants were issued to a subsidiary of which 2,275,000 were allotted to employees free of charge and 714,805 were issued to cover ancillary costs. As a consequence of the warrants having lapsed, a total of maximum 2,975,020 warrants can be exercised in the program.

Each warrant in the program entitles the holder to acquire one new share at an exercise price of SEK 75. The warrants are expected to be available to exercise one month after the publication of the first quarter reports for 2021 and 2022.

Upon full exercise of all warrants issued in respect of the share subscription incentive programs, a total of 4,944,706 shares will be issued, thereby increasing the number of shares to a maximum of 76,333,321, corresponding a to dilution by 6.5%.



# The Alligator share in brief (June 28, 2019)

- Listed on: Nasdag Stockholm Mid Cap
- Number of shares: 71,388,615
- Average turnover per day: Approximately 60,000 (preceding quarter approximately 73,000)
- Number of shareholders: Approximately 5,800 (preceding quarter approximately 5,600)
- Market capitalization: SEK 1,781 million (preceding quarter SEK 1,756 million)
- Ticker: ATORX
- ISIN: SE0000767188



# Largest shareholders, June 28, 2019

Shareholder	No. of shares	%
Banque Internationale à Luxembourg SA	13,318,240	18.7
Johnson & Johnson Innovation	5,762,523	8.1
Sunstone Life Science Ventures Fund II K/S	5,758,485	8.1
Lars Spånberg	3,213,858	4.5
Norron funds	2,303,177	3.2
4AP fund	2,202,183	3.1
Öhman funds	1,956,725	2.7
Catella funds	1,838,772	2.6
Öresund, Investment AB	1,631,117	2.3
Mikael Lönn	1,422,183	2.0
Remaining share holders	31,981,352	44.8

Banque Internationale à Luxembourg SA (BIL) is a group of mainly Swedish investors with their shares managed by BIL.

The company's owner structure is updated monthly on the company's website: www.alligatorbioscience.com.

Source: Shareholder data is based on a report from Euroclear and Monitor (Modular Finance) as of June 28, 2019, where certain foreign accounts have been identified by the company.

# Other information.

#### Review

This report has not been reviewed by the company's auditor.

# **Employees**

The number of employees in the Group at the end of the quarter was 56 (55). Of these, 14 (14) were men and 42 (41) were women.

Of the total number of employees, 48 (47) were employed within Research and Development.

# Future report dates

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

Q3 Interim report on October 24, 2019 Year-end report 2019 on February 12, 2020

# Prospective information

As the company's project portfolio is expected to advance to more cost-intensive phases, Alligator's management has concluded that costs for 2019 are expected to increase within the range of approximately 10-20% compared with 2018.

The company out-licensed the ADC-1013 project to Janssen Biotech, Inc. and receives milestone payments as the various

milestones in the project are achieved. The company does not expect to receive any milestone payments from this project in 2019.

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

#### 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's business risks, risk management and financial risks are described in detail in the Annual Report for 2018. No significant events occurred during the year that impacted or changed these descriptions of the Group's risks and risk management

# Parent Company

Net sales, earnings trend, financial position and liquidity
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.

# For further information, please contact:

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# Financial statements

Unless otherwise stated, this Interim Report refers 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, 2018.

Unless stated otherwise, all amounts are in SEK thousand (TSEK). 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 payments for development work related to the agreement for ADC-1013. In the same period prior year, sales pertained primarily to payments for development work related to the agreement for ADC-1013.

## Other operating income

Other operating income for the year comprises exchange gains in the company's operations. In the same period prior year, revenue comprised exchange gains in the company's operations.

# Operating expenses

The company has expanded its operations compared with the same period prior year and its ongoing projects have progressed. The overall cost level is within the previously communicated cost increase interval of 10-20 percent compared to last year. As the clinical study for ATOR-1015 progresses and the production of materials in certain projects begins, costs are expected to increase relative to the same period prior year. Employee benefit expenses have increased as a result of additional people being employed, mainly within R&D.

#### Total financial items

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

		2019	2018	2019	2018	2018
All amounts TSEK unless specified	Note	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Net sales	5	30	392	70	1,167	26,959
Other operating income	5	90	420	477	625	1555
Total operating income		120	811	547	1,792	28,514
Operating costs						
Other external costs		-30,025	-23,516	-57,958	-54,286	-121,162
Personnel costs		-17,272	-14,420	-32,191	-26,538	-52,144
Depreciation of tangible assets and intangible assets		-2,884	-1,466	-5,792	-2,875	-5,902
Other operatings expenses		-446	-518	-1,352	-1,195	-2,387
Total operating costs		-50,627	-39,920	-97,292	-84,894	-181,594
Operating profit/loss		-50,507	-39,108	-96,745	-83,102	-153,080
Result from other securities and receivables		317	276	627	590	1,160
Other interest income and similar income statement items		998	1,890	2,641	6,270	7,465
Interest expense and similar income statement items		-125	-669	-238	-3,577	-5,587
Net financial items		1,191	1,498	3,030	3,283	3,037
Profit/loss before tax		-49,316	-37,611	-93,715	-79,819	-150,043
Tax on profit for the period		0	0	0	0	0
Deffered tax		11	0	23	0	0
Profit for the period attributable to Parent Company						
shareholders		-49,306	-37,611	-93,692	-79,819	-150,043
Earnings per share before dilution, SEK		-0.69	-0.53	-1.31	-1.12	-2.10
Earnings per share after dilution, SEK		-0.69	-0.53	-1.31	-1.12	-2.10

# Consolidated

# Statement of Comprehensive Income

	2019	2018	2019	2018	2018
All amounts TSEK Note	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Profit/loss for the period	-49,306	-37,611	-93,692	-79,819	-150,043
Other comprehensive income	0	0	0	0	0
Comprehensive income for the period	-49,306	-37,611	-93,692	-79,819	-150,043

# Consolidated

# Statement of Financial Position

## Cash and cash equivalents

Consolidated cash and cash equivalents, which consist of bank balances and short-term, highly liquid investments, totaled SEK 284,950 thousand (362,878). Bank balances amounted to SEK 132,733 thousand (112,024). A portion of the Group's liquidity is invested in short-term interest funds funds, which is recognized as cash and cash equivalents. This investment can easily be converted to cash and is subject to an immaterial risk of changes in value. The investment totals a nominal amount of SEK 150,908 thousand (250,439) and the value at the end of the period was SEK 152,216 thousand (250,854).

# Cash, cash equivalents and other short-term investments, including financial assets

The Group invests a portion of its liquidity in corporate bonds, which are deemed to be easily convertible to cash. The value of these bonds amounts to SEK 73,206 thousand (73,513), of which SEK 20,068 (20,254) is classified as short-term since two of the bonds mature within 12 months. No loans had been raised as of 30 June 2019 and no loans have been raised since that date. The Group has no loans or loan commitments.

The Group plans to use its liquidity for operating activities. According to the Group's Financial Policy, the Group is to have sufficient bank balances to cover its expected liquidity requirements for a minimum of 18 months. Excess liquidity may be invested with a low risk and an average fixed period of not more than 18 months. 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.

#### Equity

Equity at the end of the period amounted to SEK 374,812 thousand (468,310), corresponding to an equity ratio of 89 (92)%.

#### Equity per share before and after dilution

At the end of the period, equity per outstanding share amounted to SEK 5.25 (6.56), 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").

All amounts in TSEK	Note	2019-06-30	2018-06-30	2018-12-31
ASSETS				
Fixed assets				
Intangible assets				
Participations in development projects	3	17,949	17,949	17,949
Patents		429	1,050	702
Softwares		410	0	464
Tangible assets				
Improvements in leased premises		2,130	2,738	2,434
Right of use assets	2	20,675	0	0
Equipment, machinery and computers		14,309	17,453	15,804
Financial assets				
Other investments held as fixed assets	2, 6	53,138	73,819	53,259
Other investments held as fixed assets		23	0	0
Total fixed assets		109,062	113,008	90,612
Current assets				
Current receivables	_	20	200	25 220
Accounts receivable	6	30	390	25,328
Other receivables	6	2,902	3,156	4,564
Prepayments and accrued income	_	3,837	4,023	4,521
Other short-term financial assets	6	20,068	0	20,254
Cash and cash equivalents	6	284,950	444,575	362,878
Total current assets TOTAL ASSETS		311,787	452,143	417,545
TOTAL ASSETS		420,849	565,151	508,156
EQUITY AND LIABILITIES				
Equity				
Share capital		28,555	28,555	28,555
Other capital contributions		662,614	662,614	662,614
Retained earnings and profit/loss for the period		-316,357	-152,875	-222,860
Equity attributable to Parent Company shareholders		374,812	538,295	468,310
				, ,
Non-current provisions and liabilities				
Lease Liabilities	2, 6	13,725	0	0
Total non-current provisions and liabilities		13,725	0	0
Current liabilities				
Current liabilities Accounts payable	6	7,167	10,462	17,702
Other liabilities	0	924	798	1,564
Lease Liabilities	2, 6	5,573	790	1,364
Accrued expenses and deferred income	2, 6	18,648	15,596	20,580
Total current liabilities	6	32,311	26,856	39,847
TOTAL EQUITY AND LIABILITIES		420.849	565,151	508,156
TOTAL EQUIT AND LIABILITIES		420,049	202,131	500,150

# Consolidated

# Statement of Changes in Equity

#### 2019 2018 2019 2018 2018 All amounts in TSEK Apr-Jun Apr-Jun Jan-Jun Jan-Jun lan-Dec Opening balance 424,043 575,916 468,310 617,956 617,956 New capital issue 0 75 Effect of share-based payments -10 194 159 397 Profit/loss for the period -37,611 -93,692 -79,819 -49.306 -150.043 0 0 Other comprehensive income in the period Closing balance 374,812 538,295 374,812 538,295 468,310

# Consolidated

# Statement of Cash Flows

# Investments

Investments for the first quarter amounted to SEK 183 thousand (1,069). These investments comprised laboratory equipment totaling SEK 183 thousand (1,069).

Investments during the first half of 2019 was made in laboratory equipment SEK 816 thousand (5,891). During the period, investments in leased premises amounted to SEK 0 thousand (573).

#### Cash flow for the period

Cash flow for the second quarter totaled SEK -44,904 thousand (-31,072).

Cash flow for the first half of 2018 amounted to SEK -79,168 (-30,299). During the first quarter, a payment was received as a result of Shanghai Henlius Biotech, Inc. exercising an option to acquire the global licensing rights to the Biosynergy project, which was recognized as revenue in the fourth quarter of 2018.

All amonumbs in TCFI/	2019	2018	2019	2018	2018
All amounts in TSEK Operating activities	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Operating activities Operating profit/loss	-50,507	-39,108	-96,745	-83,102	-153,080
Adjustments for items not generating cash flow	-30,307	-39,100	-90,743	-05,102	-133,000
Depreciation and impairments	2,884	1,466	5,792	2,875	5,902
Effect from warrant program	75	-10	194	159	397
Other items, no impact on cash flow	648	249	1,362	648	32
Interest received	483	436	955	984	1,886
Interest paid	-107	430	-220	0	1,000
Tax paid	0	0	-220	0	0
Cash flow from operating activities before changes in working	U	U	U	U	U
capital	-46,524	-36,968	-88,661	-78,437	-144,863
apitai	-40,324	-30,908	-00,001	-/0,43/	-144,603
Changes in working capital					
Change in operating receivables	-151	3,009	27.643	52,823	25,979
Change in operating liabilities	3,329	3,955	-13,108	1,779	14.769
Cash flow from operating activities	-43,346	-30,003	-74,126	-23,835	-104,115
lanca adia a a adiada a					
Investing activities	0	0	0	0	E 41
Acquisition of intangible assets	0	1,000	0	0	-541
Acquisition of tangible assets	-183	-1,069	-816	-6,464	-7,124
Divestment of property, plant and equipment	0	0	0	0	10
Cash flow from investing activities	-183	-1,069	-816	-6,464	-7,655
Financing activities					
Amortization of leasing liabilities	-1,376	0	-4,226	0	0
Cash flow from financing activities	-1,376	0	-4,226	0	0
cash now from maneing accivities	1,570	· ·	1,220	· ·	Ū
Cash flow for the period	-44,904	-31,072	-79,168	-30,299	-111,770
Cash and cash equivalents at beginning of period	329,533	474,684	362,878	472,919	472,919
Exchange rate differences in cash and cash equivalents	329,333	962	1,240	1,955	1,728
Cash and cash equivalents at end of period	284,950	444,575	284,950	444,575	362,878
cash and cash equivalents at end of period	204,950	444,3/3	20 <del>4</del> ,950	444,3/3	302,070

<sup>\*</sup> Bonds, SEK 73 millions, which are being expected to be easy to convert to cash, are not included in cash and cash equivilants.

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# Parent Company

# **Income Statement**

Parent Company **Statement of Comprehensive Income** 

	2019	2018	2019	2018	2018
All amounts in TSEK Note	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Net sales	30	392	70	1,167	1,751
Other operating income	90	420	155	625	1,555
Total operating income	120	811	226	1,792	3,307
Operating costs					
Other external costs	-31,507	-23,516	-60,918	-54,283	-121,159
Personnel costs	-17,272	-14,420	-32,191	-26,538	-52,144
Depreciation and impairment of tangible assets and					
intangible assets	-1,459	-1,466	-2,943	-2,875	-5,902
Other operatings expenses	-446	-518	-1,352	-1,195	-2,121
Total operating costs	-50,685	-39,920	-97,404	-84,892	-181,325
Operating profit/loss	-50,564	-39,108	-97,178	-83,099	-178,019
Results from financial items					
Result from other securities and receivables	317	276	627	590	1,160
Other interest income and similar income statement items	364	1,641	1,658	5,621	7,871
Interest expense and similar income statement items	-19	-669	-19	-3,577	-5,587
Net financial items	662	1,248	2,266	2,635	3,444
Profit/loss after financial items	-49,902	-37,860	-94,912	-80,465	-174,575
Appropriations					
Group contribution received	0	0	0	0	14,677
Total appropriations	0	0	0	0	14,677
Result before tax	-49,902	-37,860	-94,912	-80,465	-159,898
Tax on profit for the year	0	0	0	0	0
Profit/loss for the period	-49,902	-37,860	-94,912	-80,465	-159,898

	2019	2018	2019	2018	2018
All amounts in TSEK Note	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Profit/loss for the period	-49,902	-37,860	-94,912	-80,465	-159,898
Other comprehensive income	0	0	0	0	0
Profit/loss for the year	-49,902	-37,860	-94,912	-80,465	-159,898

# Parent Company **Balance Sheet**

All amounts in TSEK No	te 2019-06-30	2018-06-30	2018-12-31
ASSETS			
Fixed assets			
Intangible assets			
Patents	429	1,050	702
Software	410	0	464
Total intangible assets	839	1,050	1,166
Tangible assets			
Improvements in leased premises	2,130		2,434
Equipment, machinery and computers	14,309	17,453	15,804
Total tangible assets	16,438	20,191	18,238
Financial assets			
Participations in Group companies	<b>3</b> 20,294	20,294	20,294
Other investments held as fixed assets	<b>2</b> 53,138		53,259
Total financial assets	73,432		73,553
Total fixed assets	90,709	115,353	92,957
Cirront scate			
Current assets Current receivables			
Accounts receivables	30	390	387
Receivables from Group companies	0		14,677
Other receivables	2,902		4,563
Prepayments and accrued income	5,319		4,503
Total current receivables	8,251		24,148
Other short-term investments	<b>2</b> 170,976		270,693
Cash and bank deposits	119,391		109,353
Total current assets	298,617		404,195
TOTAL ASSETS	389,326		497,152
TOTALAGETS	303,320	303,330	737,132
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	28,555	28,555	28,555
Total restricted equity	28,555		28,555
Non-restricted equity			
Share premium reserve	662,741	662,741	662,741
Retained earnings	-233,797		-74,094
Profit/loss for the period	-94,912		-159,898
Total non-restricted equity	334,032	507,944	428,750
Total equity	362,588		457,305
Current liabilities			
	7167	10.462	17,702
Accounts payable  Other liabilities	7,167 924		17,702
Other liabilities			
Accrued expenses and deferred income  Total current liabilities	18,648		20,580
	26,738		39,847
TOTAL EQUITY AND LIABILITIES	389,326	563,356	497,152

# 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. All the Group's business operations are 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 head 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 2018 with the following exceptions.

# **IFRS 16 Leases**

The new standard that entered into force on January 1, 2019, IFRS 16 Leases, has been implemented during the financial year and had no material impact on the Group's or the Parent Company's financial statements for the period. This standard replaces IAS 17 Leases. The transition to IFRS 16 has been recognized in accordance with the modified retrospective approach, meaning that the transition has been recognized as an adjustment of the opening balance at the transition date. Comparative figures and previous years have not be restated. For more information on the impact on the consolidated financial statements at the transition date, refer to Note 2 Accounting policies and Note 10 Leasing in the Annual Report for 2018.

The Group determines whether a contract is, or contains, a lease at the start of the contract. The Group recognizes a right-of-use assets and a corresponding lease liability for all leases in which the Group is the lessee, with the exception of leases where the underlying asset is of a low value. For leases that fulfill the criteria for the exemption rules, the Group recognizes lease payments as an operating expense on a straight-line basis over the lease term, provided no other systematic method for allocating the lease payment provides a fairer presentation taking into account how the economic benefits from the underlying asset are consumed by the lessee.

The lease liability is initially measured at the present value of the future lease payments that have not been paid as of the start date for the lease, discounted by the implicit interest rate or, if this cannot easily be determined, by the incremental borrowing rate. The incremental borrowing rate is the interest rate that a lessee would need to pay for financing through loans in a corresponding period, and with corresponding collateral, for the right of use for an asset in a similar economic environment.

The following lease payments are included in the measurement of lease liabilities:

- fixed fees (including essentially fixed fees) less any benefits in connection with signing the lease that are to be received.
- variable lease payments that are dependent on an index or price, initially measured using an index or price on the start date,
- amounts expected to be paid by the lessee according to residual value guarantees,
- the exercise price for an option, if the lessee is reasonably certain that such an option will be exercised, and
- penalty charges paid upon termination of the lease, if the lease term reflects the fact that the lessee will exercise an option to terminate the lease.

Lease liabilities are presented on a separate line in the statement of financial position.

Lease liabilities are recognized in the subsequent period by increasing the liability to reflect the effect of interest and reducing the liability to reflect the effect of lease payments made.

Lease liabilities are remeasured with a corresponding adjustment of the right-of-use asset according to the rules of the standard. No such adjustments have been made during the current period.

The right-of-use asset is initially recognized at the value of the lease liability, plus lease payments made on or prior to the start date for the lease and initial direct expenses. The right-of-use asset is recognized in the subsequent period at cost loss depreciation and impairment.

If the Group undertakes an obligation to dismantle a leased asset, to restore land or to restore and renovate an asset to a condition agreed on in the lease, a provision for such obligations is recognized in accordance with IAS 37. Such provisions are included in the cost of the right-of-use asset, provided they are not linked to the production of inventory.

Right-of-use assets depreciated over their estimated useful life or, if it is shorter, over the agreed lease term. If a lease entails a transfer of ownership right at the end of the lease term, or if the cost includes a probable exercise of a call option, the right-of-use asset is depreciated over its useful life. Depreciation commences on the start date for the lease.

Right-of-use assets are presented on a separate line in the statement of financial position.

The group applies the principles of IAS 36 for impairment of right-of-use assets and recognizes this item in accordance with the accounting policy for tangible assets according to IAS 16.

Variable lease payments that are not dependent on an index or price are not included in the measurement of lease liabilities and right-of-use assets. Such lease payments are recognized as a cost under operating profit in the period in which they arise.

IFRS 16 contains practical exemption rules that entail that the lessee does not need to separate service components from the applicable lease payment by class of asset. The Group has chosen not to apply this exemption rule.

As a result of this new standard, complete updated accounting policies will be presented in the company's Annual Report for 2019.

# Note 3 Effects of changed estimates and judgments

Significant estimates and judgments are described in Note 3 of the Annual Report for 2018. There have been no changes to the company's estimates and judgments since the Annual Report for 2018 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 is as follows:

	2019	2018	2019	2018	2018
All amounts in TSEK	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Licensing income	0	0	0	0	25,207
Reimbursement for development work	30	392	70	1,167	1,751
Milestone revenue	0	0	0	0	0
Royalty	0	0	0	0	0
Total	30	392	70	1,167	26,959

A breakdown of the Group's revenue per project is as follows:

All amounts in TSEK	2019 Apr-Jun	2018 Apr-Jun	2019 Jan-Jun	2018 Jan-Jun	2018 Jan-Dec
ADC-1013	30	390	70	1,136	1,720
Biosynergy	0	0	0	0	25,207
Other	0	1	0	31	32
Total	30	392	70	1,167	26,959

Alligator receives revenues in USD from out-licensed projects.

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

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	2019	2018	2019	2018	2018
All amounts in TSEK	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Swedish government grants received	0	0	0	0	68
EU grants received	0	0	0	0	0
Operational exchange rate gains	90	420	476	625	1,488
Other	0	0	1	0	0
Total	90	420	477	625	1,555

# **Note 6 Financial instruments**

Cash and cash equivalents at June 30, 2019 consisted of bank balances amounting to SEK 132,733 thousand and investments in fixed income funds totaling SEK 152,216 thousand. Other investments held as fixed assets and other short-term investments pertain to investments in corporate bonds. The accounting policies for these are described in Note 2. For other financial assets and liabilities, the reported value as above is considered a reasonable approximation of fair value.

All amounts in TSEK	2019-06-30	2018-06-30	2018-12-31
Financial assets valued at fair value through profit and	loss		
Liquid assets - Interest funds	152,216	276,470	250,854
Financial assets valued at amortized cost			
Other investments held as fixed assets	53,138	73,819	53,259
Other short term investments	20,068	0	20,254
Accounts receivable	30	390	25,328
Other receivables	856	0	843
Liquid assets - Bank accounts	132,733	168,105	112,024
Total financial assets	359,042	518,784	462,562
Financial liabilities valued at amortized cost			
Long term lease liabilities	13,725	0	0
Accounts payable	7,167	10,462	17,702
Short term lease liabilities	5,573	0	0
Accrued expenses	13,772	11,684	15,827
Total financial liabilities	40,237	22,145	33,529

# **Note 7 Related party transactions**

Alligator has a consulting agreement with Carl Borrebaeck through the company Ocean Capital AB pertaining to expert assistance with the evaluation of early-phase research projects and new antibodies. Pricing has been determined on market conditions. These related party transactions corresponded to an expense of SEK 180 thousand (180) for the second quarter and SEK 360 thousand (360) for the year to date.

# 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.

The table below shows 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.

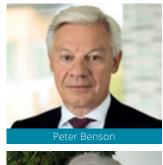
The company's business operation is to conduct research and development which is why "R&D costs/Operating costs excluding impairment in %" is an essential indicator as a measure of efficiency, and how much of the company's costs relate to R&D.

As mentioned earlier in this report, the company does not have a steady flow of revenue, with revenue 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.

For definitions, see the section "Financial definitions" on page 25.

	2040	2040	2010	2040	2040
All and a contact TCFIX and a contact file of	2019	2018	2019	2018	2018
All amounts TSEK unless specified	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Profit/loss for the period	-49,306	-37,611	-93,692	-79,819	-150,043
Average number of shares before dilution	71,388,615	71,388,615	71,388,615	71,388,615	71,388,615
Earnings per share before dilution, SEK	-0.69	-0.53	-1.31	-1.12	-2.10
Average number of shares after dilution	71,388,615	71,388,615	71,388,615	71,388,615	71,388,615
Earnings per share after dilution, SEK	-0.69	-0.53	-1.31	-1.12	-2.10
Operating costs	-50,627	-39,920	-97,292	-84,894	-181,594
Impairment of tangible assets and intangible assets	0	0	0	0	0
Operating costs excluding impairments	-50,627	-39,920	-97,292	-84,894	-181,594
Administrative expenses	-8,761	-9,497	-17,637	-17,547	-36,199
Depreciation	-2,884	-1,466	-5,792	-2,875	-5,902
Research and development costs	-38,983	-28,957	-73,863	-64,473	-139,493
R&D costs / Operating costs excluding impairments %	77%	73%	76%	76%	77%
Equity	374,812	538,295	374,812	538,295	468,310
Average number of shares before dilution	71,388,615	71,388,615	71,388,615	71,388,615	71,388,615
Equity per share before dilution, SEK	5.25	7.54	5.25	7.54	6.56
Average number of shares after dilution	71,388,615	71,388,615	71,388,615	71,388,615	71,388,615
Equity per share after dilution, SEK	5.25	7.54	5.25	7.54	6.56
Equity	374,812	538,295	374,812	538,295	468,310
Total assets	420,849	565,151	420,849	565,151	508,156
Equity ratio, %	89%	95%	89%	95%	92%
4. 3					
Other investments held as fixed assets (publicly traded					
corporate bonds)	53,138	73,819	53,138	73,819	53,259
Other short-term financial assets (publicly traded corporate	22,.30	. 2,213	22,.30	,	22,233
bonds)	20,068	0	20,068	0	20,254
Cash and cash equivalents	284,950	444,575	284,950	444,575	362,878
Cash and cash equivalents at end of period	358,155	518,393	358,155	518,393	436,391
east. and tast. equivalents at end of period	330,133	3.0,333	330,133	3.0,333	130,331

# The declaration of the Board of Directors and the CEO.



















Peter Benson Chairman

Carl Borrebaeck Member of the Board

Ulrika Danielsson Member of the Board Graham Dixon Member of the Board

Kirsten Drejer Member of the Board Anders Ekblom Member of the Board

Kenth Petersson Member of the Board Jonas Sjögren Member of the Board

Laura von Schantz Employee representative Per Norlén CEO





# Financial definitions.

# 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.

# 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.

# 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.

# Cash flow from operating activities

Cash flow before investing and financing activities.

# 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.

# 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 delution

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

# **Equity ratio**

Equity as a percentage of Total assets.

# 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.

#### 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

 $\ensuremath{\mathsf{R\&D}}$  costs as a percentage of operating costs excluding impairments.

## Total assets

Total of the Company's assets.



# 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)

A company specialized in performing clinical studies.

# CTA (Clinical Trial Authorization)

An 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.

# 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.

#### EM/

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.

# Good Manufacturing Practice (GMP)

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.

#### 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.

# 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.

# Patent

Exclusive rights to a discovery or invention.

# Glossary, cont'd.

# 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 I, II and III

The various stages of studies on the efficacy of a pharmaceutical in humans. See also "clinical study." Phase I examines the safety on healthy human subjects, Phase II examines efficacy in patients with the relevant disease and Phase III 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 II is often divided into Phase IIa and Phase IIb. In Phase IIa, 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 IIb 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.

# 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.

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# Important milestones in Alligator's history.



