



**ASCELIA  
PHARMA**

# **ANNUAL REPORT 2018/2019**

1 July 2018 – 30 June 2019

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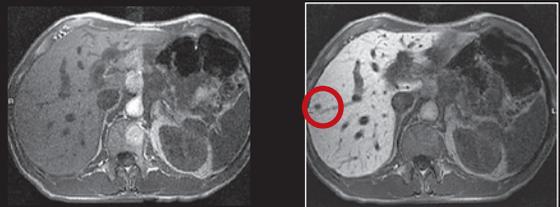
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**CEO Mangoral Phase III starting**  
in H2-19

**p.4**



**Mangoral improves visualisation**



**p.15**

Improves the chances to find **liver metastases**

**Oncoral (chemo tablet) Promising Phase I results**

**p.19**

**IPO on Nasdaq Stockholm raised SEK 200 million**



**p.24**

**Solid financial position**  
with a fully financed Phase III program for Mangoral

**p.27**

**Financial Calendar**

<b>8 NOV 2019</b>	Interim Report July-September 2019 (three months)
<b>14 NOV 2019</b>	Annual General Meeting
<b>14 FEB 2020</b>	Half-year Report July-December 2019 (six months)
<b>12 MAY 2020</b>	Interim Report July 2019-March 2020 (nine months)
<b>20 AUG 2020</b>	Full-year Report July 2019-June 2020 (FY)

# ABOUT ASCELIA PHARMA

- ▶ Ascelia Pharma is an oncology-dedicated orphan drug development company located in Malmö, Sweden.
- ▶ We develop drugs which target unmet medical needs, have an established mode of action and a relatively low development risk
- ▶ Ascelia Pharma has two drug candidates – Mangoral® and Oncoral – currently under development
- ▶ Ascelia Pharma’s shares are listed on Nasdaq Stockholm under the ticker ACE

## MANGORAL (Phase III ready liver oral contrast agent)

Mangoral is our novel non-gadolinium contrast agent used in MRI-scans of the liver. Mangoral is developed to improve the visualisation of focal liver lesions (liver metastases) in patients with impaired kidneys that are at risk of severe side-effects from the gadolinium contrast agents currently on the market. Mangoral characteristics:

- USD 350-500 million annual addressable market
- Non-gadolinium agent and no competing drugs
- De-risked Phase III program starting in H2-19
- Phase III final results expected end 2020 / early 2021
- Orphan Drug Designation

## ONCORAL (Phase II ready tablet chemotherapy)

Oncoral is our novel oral chemotherapy tablet ready for Phase II clinical studies for the treatment of gastric cancer. Oncoral characteristics:

- Significant patient and hospital benefits with oral chemotherapy
- Oncoral is based on irinotecan, which is an effective molecule for killing cancer
- Oncoral has completed phase I clinical studies with promising results



# CEO COMMENTS



**This fiscal year has so far been most transformative period of Ascelia Pharma's history.** Not only did we successfully continue the development of our innovative and proprietary products Mangoral and Oncoral to address significant unmet medical needs and help patients with selected types of cancer, we also made a successful and substantially oversubscribed listing on Nasdaq Stockholm.

The IPO provided us with approximately SEK 222 million in gross proceeds as a result of the offering and the over-allotment option, and added about 6,000 new shareholders, both

institutional and private investors. In the process, we received a lot of positive attention in the investor community for Ascelia Pharma and our projects. I am very pleased and proud of the interest that many reputable investors have shown in our company, including Alto Invest, Handelsbanken Fonder and the Fourth Swedish National Pension Fund (AP4), as well as a number of existing shareholders, including Sunstone Capital and Øresund-Healthcare Capital.

**Fully financed Phase III for Mangoral.** Most importantly for Ascelia Pharma, the IPO secured full financing for the upcoming Phase III study of our lead candidate Mangoral. Later this year, we aim to enrol the first patient to this pivotal study later as well as advancing our commercialisation plans.

**Phase III study expected to start in second half of 2019.** The start of this study is the most important near-term milestone for us. Mangoral will enable patients with a severely impaired kidney function to undergo a liver MRI scan with a contrast agent. With Mangoral, the likelihood of finding liver metastases increases significantly. This is crucial for determining the right treatment method and subsequently the patient's chance of survival.

The addressable market for Mangoral is estimated to be USD 350-500 million yearly. Within this patient segment Mangoral is expected to be the only product on the market.

**I believe we are already well prepared to start this pivotal study of Mangoral** which could enable approval of the only non-gadolinium liver MRI drug for use in patients who are at risk of serious side effects from the gadolinium-based contrast media available on the market today. We have successfully concluded

» **Proceeds from the IPO provided us with full financing for Mangoral Phase III**

discussions with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) regarding the study design and will now complete the preparatory work to start the trial. We are confident that we have a robust trial design with the potential to confirm the excellent data observed in our Phase II studies and support approval.

**Final Phase results end of 2020 / beginning of 2021.** We expect to have enrolled the last patient in the study in the second half of 2020. Final study results are expected at the end of 2020 or beginning of 2021. This means that this study is fairly short, compared to most other Phase III trials.

**New patent application.** At the same time, we have to look beyond these important milestones. In early June, we filed a patent application for an improved next generation formulation of Mangoral, which among other benefits will be even more patient friendly and convenient than today's formulation. Upon grant, the new patent would further improve the unique value proposition of Mangoral and extend the intellectual property protection rights until year 2040. This demonstrates our long-term commitment to provide better imaging solutions for a patient population with poor alternatives today, i.e. patients in need of liver MRI procedure which cannot tolerate current contrast agents on the market due to impaired kidney function.

The potential to extend the exclusivity rights of our Mangoral franchise until year 2040 will add significant value and is a result of our successful Life Cycle Management work and our focus on developing novel and better medicinal products for patients in need.

**Promising Phase I results for Oncoral.** The Phase I results for Oncoral support our preparations for a Phase II clinical study. Oncoral is our novel oral chemotherapy tablet of irinotecan for the treatment of gastric cancer. In 2018, we presented encouraging results for Oncoral phase I study at the annual European Society for Medical Oncology (ESMO) congress in Germany. The data demonstrated that Oncoral was well tolerated; side effects were generally mild to moderate, manageable and similar in type to those observed with intravenous irinotecan. The results were published in *Cancer Chemotherapy and Pharmacology*, a peer reviewed medical journal covering oncological pharmacotherapy.

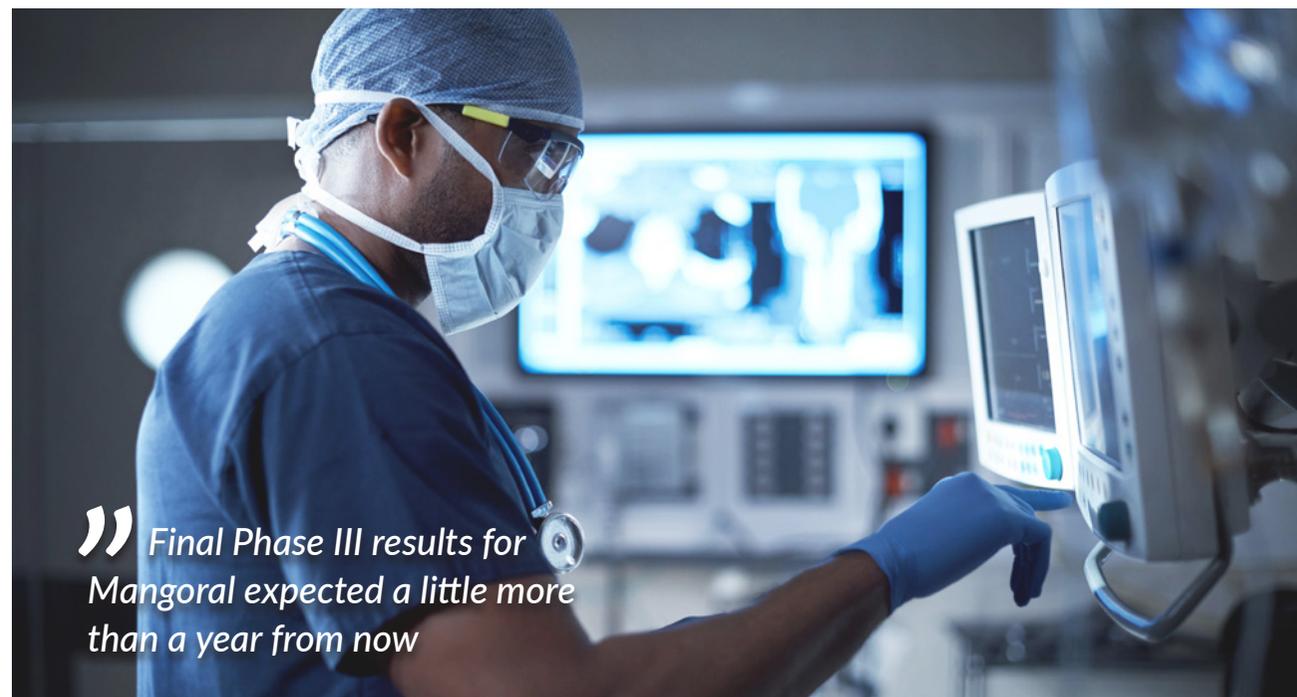
**More encouraging Oncoral data.** The results from the Phase I extension study presented in early April this year demonstrated reassuring tolerability of Oncoral administered in combination with oral capecitabine. Cancer therapy is very often given as a combination of several drugs in parallel. Oncoral in combination with oral capecitabine could become a more convenient and patient friendly treatment option compared to the intravenous formulations of these compounds. This could enable an attractive all-oral chemo combination. The encouraging tolerability profile justifies further clinical studies to assess the efficacy of this treatment regimen. These results were published in the medical journal *Cancer Chemotherapy and Pharmacology*.

**The next step for Oncoral** will be to start preparing for the Phase II study. We have great faith in this very interesting product candidate, which will be of so much value to both patients and the society. Oral chemotherapeutic drugs potentially offer a wide number of advantages, including greater convenience, fewer hospital/doctor's office visits, less pain, better safety profile and the avoidance of problems related to venous access. It also, importantly, saves hospital bills with fewer patient visits.

**Exciting times ahead. I believe you agree with me when I say that we have exciting and hopefully rewarding times ahead of us.** I look forward to updating you about our progress with Mangoral and Oncoral, as they make their way through the clinical development process, and ultimately reach those patients who need support taking on their cancer.

**Magnus Corfitzen**

CEO Ascelia Pharma AB (publ)



“ *Final Phase III results for Mangoral expected a little more than a year from now* ”

# THE YEAR IN BRIEF

Q1

## **JULY-SEP 2018**

- Oncoral Phase I study results accepted as a poster presentation for European Society for Medical Oncology (ESMO) Congress in Oct 2018
- Carl Bjartmar appointed as new Chief Medical Officer

Q2

## **OCT-DEC 2018**

- Successfully concluded discussions with the FDA regarding Mangoral's study design for the single pivotal Phase III trial
- Encouraging results from Oncoral's Phase I study presented at ESMO Congress

Q3

## **JAN-MAR 2019**

- Significantly oversubscribed IPO raising SEK 200 million
- More than 6,000 new shareholders in the IPO – both institutional and private
- Fully financed Phase III program for Mangoral
- Publication of the results from Oncoral's Phase I study

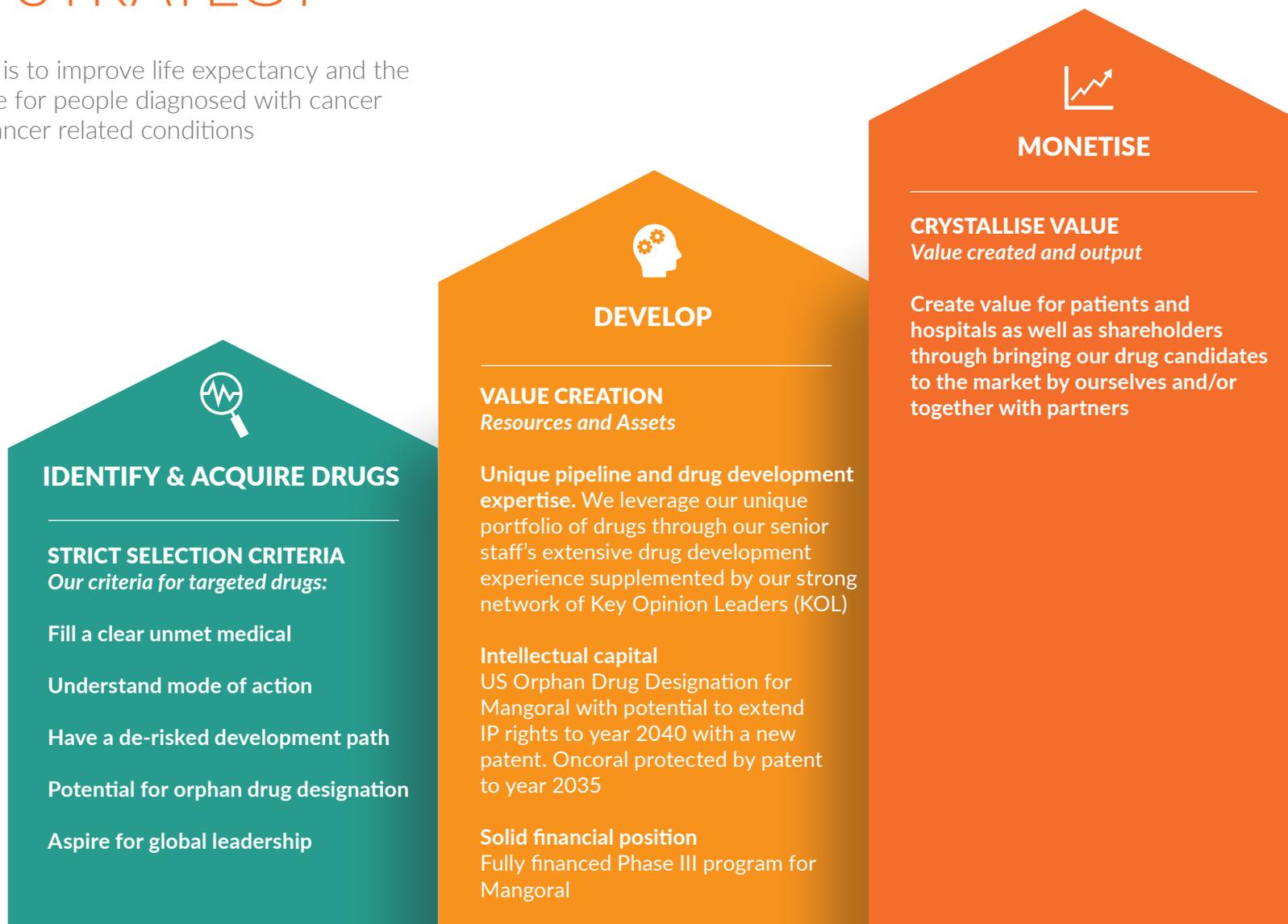
Q4

## **APR-JUN 2019**

- Supportive feedback from EMA on the Phase III program for Mangoral
- Publication of the promising results from Oncoral's Phase I combination study with oral capecitabine
- IPO overallotment utilised raising SEK 22 million
- New patent filed for Mangoral with potential to extend IP rights to year 2040

# OUR STRATEGY

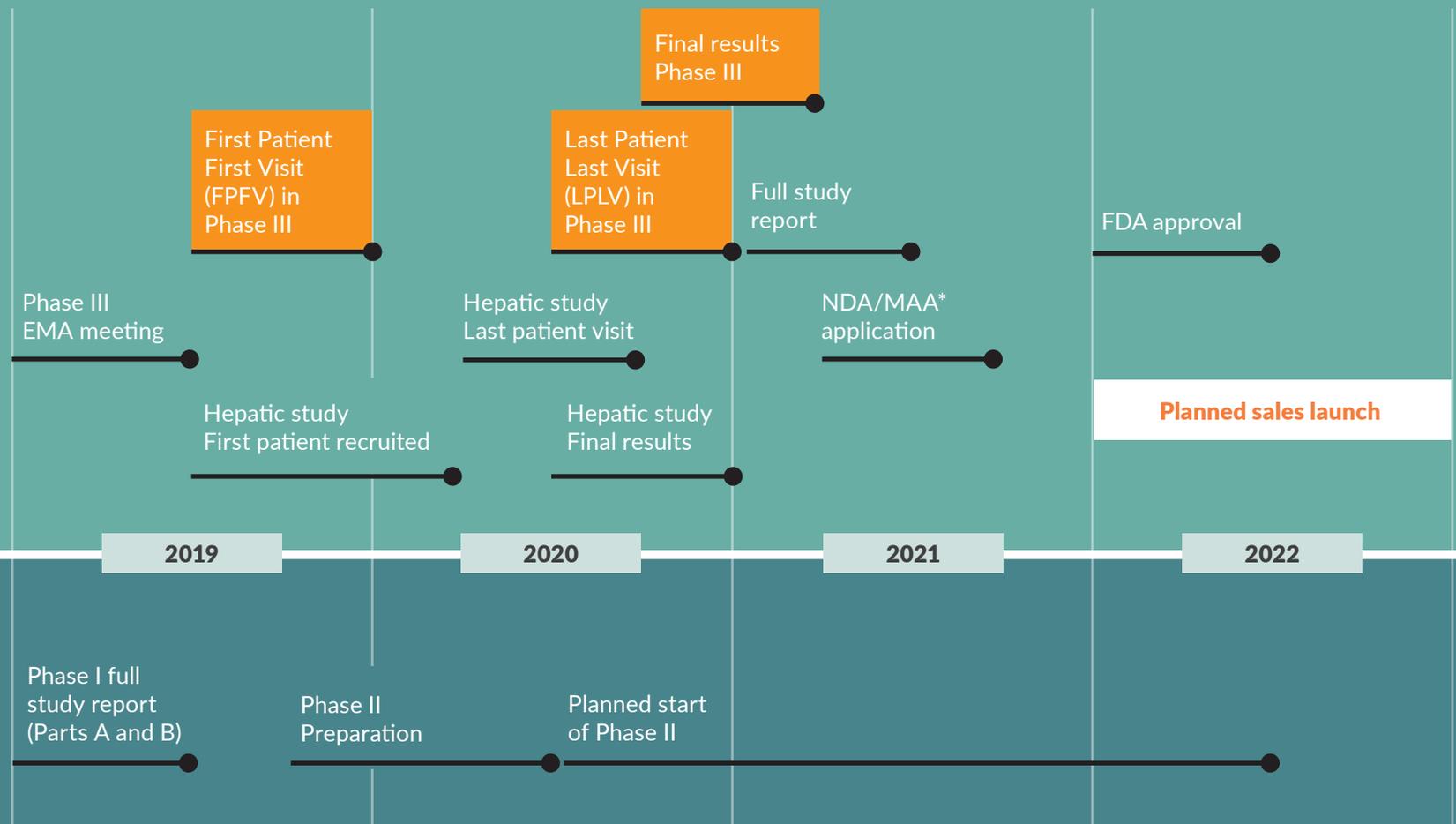
Our mission is to improve life expectancy and the quality of life for people diagnosed with cancer and other cancer related conditions



# SIGNIFICANT VALUE DRIVERS AHEAD

## Development timeline

### MANGORAL



\* NDA: New Drug Application (US)

\* MAA: Market Authorisation Application (EU)

# MANGORAL

Phase III ready liver contrast agent

- ▶ USD 350-500 million annual addressable market
- ▶ Non-gadolinium agent and no competing drugs
- ▶ De-risked Phase III program
- ▶ Final Phase III results end 2020 / early 2021
- ▶ Orphan Drug Designation

# PROBLEM – LIVER METASTASES

One of the reasons that cancer is a serious disease is its ability to spread to other parts of the body than the location of the primary tumour (i.e. where the first tumour formed). When cancer cells spread to distant lymph nodes, tissues or organs, it is called metastatic cancer. Cancer can spread to any part of the body, but certain areas such as the liver are more prone to metastases than others

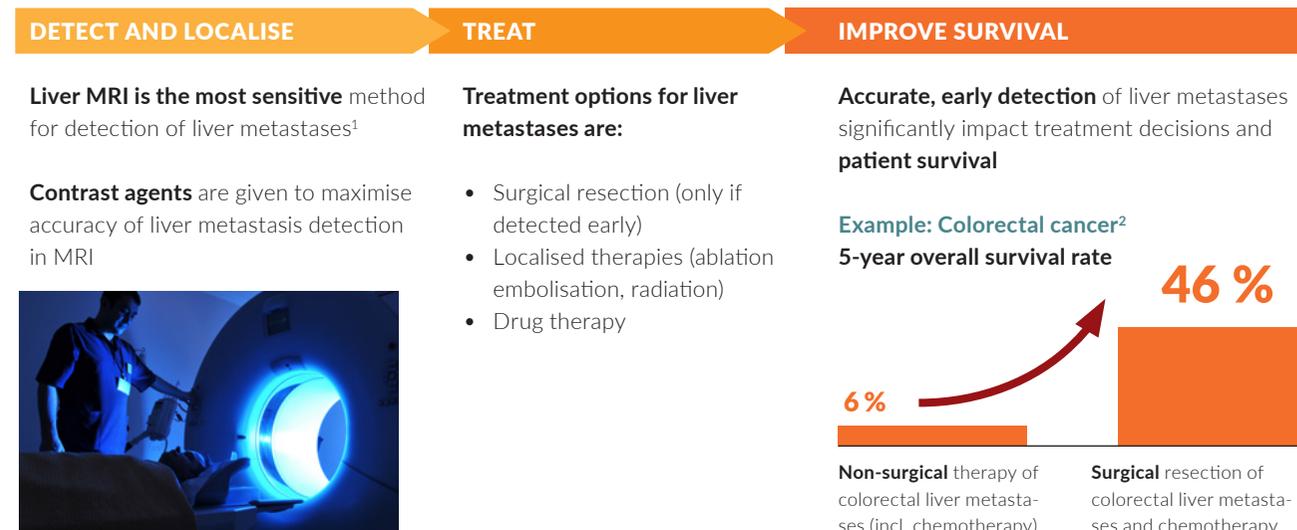
**The liver is the second most common organ for metastasis** after the lymph nodes. Up to 50-70 percent of patients with colorectal cancer develop liver metastases, and liver metastases seem to play a significant role in the cause of death of patients who die with breast or colorectal cancer.

**Correct diagnosis is critical for management of patients** with liver metastases, and imaging plays an essential role in both initial staging, pre-operative planning, monitoring of treatment effect and surveillance for recurrence of disease. If liver metastases are correctly detected and deemed eligible for surgical removal, the survival rate can be significantly improved, and sometimes full recovery is possible. The five-year overall survival rate for patients undergoing resection for colorectal liver metastases has been reported to be 46 percent compared to only 6 percent for patients who were not subjected to surgical treatment of their liver metastases

**Magnetic Resonance Imaging (MRI) is considered the preferred imaging modality** for both initial cancer disease staging and monitoring of liver metastases. MRI is an imaging method that uses non-ionizing radiation to create useful diagnostic images. MRI scans use radio waves and strong magnets, and unlike CT and PET-CT, MRI gives no radiation to the patient. An MRI scanner consists of a large, powerful

magnet in which the patient lies. Signals are sent to the body by a radio wave antenna, which in turn receives signals back. The returning signal patterns are converted by a computer into very detailed images of parts of the body. To enhance the quality of the MRI, patients are given contrast agents prior to the procedure.

**Contrast agents improve the MRI-scans.** A contrast agent is a substance that makes abnormalities, such as metastases, appear clearer due to the special magnetic properties of the elements in the contrast agent and thereby increase the sensitivity and/or specificity of the image.



1) Albiin N et al. Manganese chloride tetrahydrate (CMC-001) enhanced liver MRI: evaluation of efficacy and safety in healthy volunteers. MAGMA. 2012 Mar 8

2) Clinical Colorectal Cancer, Vol. 15, No. 4, Dec 2016, e183-192

# PROBLEM – CURRENT AGENTS NOT FOR EVERYONE

The contrast agent assists in diagnosis and staging and helps to guide treatment decisions and planning. MRI with contrast is a very sensitive and useful imaging method to assess and select patients eligible for metastatic resection or locally directed non-surgical treatment. MRI with contrast is also used to determine if a given treatment has been effective, and/or for surveillance of possible recurrence of disease.

**Current contrast agents on the market are not for everyone.**

Patients with impaired renal function, i.e. impaired kidney function, cannot tolerate the currently available contrast agents on the market. All contrast agents today are based on the heavy metal Gadolinium and for patients with impaired renal function these contrast agents increase the risk of Nephrogenic Systemic Fibrosis (NSF). NSF is a rare, but serious and life-threatening condition causing extensive waxy thickening and hardening of the skin. The skin can become hyperpigmented and take on a “wooden texture”. It can lead to joint contractures, as well as muscle and fascial fibrosis, which may lead to severe immobility. Fibrosis can also develop in the diaphragm, muscles in the thigh and lower abdomen, and the lung vessels. NSF worsens over time and can cause death, as a result from multi-system failure due to sclerotic transformation of organ systems.

**Black-box warnings.** Current contrast agents are contraindicated for patients with severely impaired kidneys and carry black box warnings. Regulatory agencies such as FDA and EMA has published guidelines for the use of Gadolinium-Based-Contrast Agents (GBCAs) in MRI with restrictions on the use of GBCAs on patients with severely reduced renal function.

**Mangoral is the only available solution.** The only MR-scan patient with severely impaired kidneys can have today is an MR-

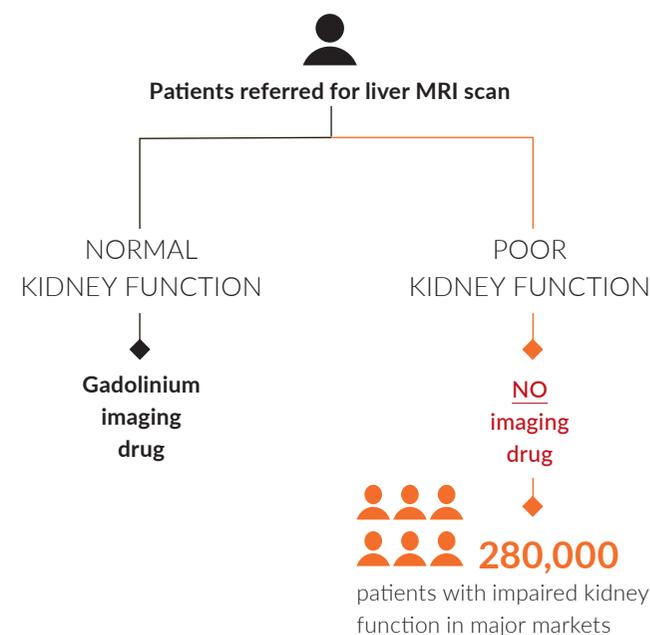
scan without a contrast agent, which reduce the ability to find and treat liver metastases and consequently patients chances of survival. Mangoral will be the only solution available for patients with severely impaired kidneys.

**Recent Gadolinium concerns also for patient with normal kidney function.** In addition to the association with NSF, there have been recent reports of accumulation of Gadolinium in the brain. Although the side-effects of brain accumulation of Gadolinium is yet to be determined, the European Regulatory Authority EMA suspended three Gadolinium-based products in November 2017. In December 2017, the FDA warned that Gadolinium based contrast agents are retained in the body and required new class warnings.



**WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)**  
 See full prescribing information for complete boxed warning. Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities.

- The risk of NSF appears to highest among patients with:
  - Chronic, severe kidney disease (GFR < 30 mL/min/1.73m2), or
  - Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function.
- For patients at risk for chronically reduced renal function (for example, age > 60 years, hypertension, or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing (5.1)



**Mangoral aims to be the new gold standard liver MRI imaging drug for patients with impaired kidney function**

# INTERVIEW WITH RADIOLOGY PROFESSOR RENDON C. NELSON

## **Why is contrast enhanced magnetic resonance imaging (MRI) better than other existing procedures or modalities for detecting liver metastases?**

There are a variety of available diagnostic imaging techniques for cancer detection, including MRI, computed tomography (CT) and Positron emission tomography-computed tomography (PET-CT), and ultrasound. For examination of soft tissue, including the liver, MRI is often the preferred medical imaging technique due to the superior depiction of tissue characteristics. If used with a contrast agent, it is a sensitive method for detecting liver metastases, and unlike CT and PET-CT, MRI does not expose the patient to radiation.

## **Why is it so important to use a contrast agent when you do a liver MRI?**

Contrast agents make abnormalities, such as metastases, appear clearer due to the special paramagnetic properties of the elements in the agent. Thereby, it increases the diagnostic value of the image by helping to detect more lesions with higher confidence. The liver is one of the most frequent – and often the first – site where metastasis occurs.

The contrast agent assists in diagnosis and staging a tumour, and it helps to guide treat-

ment decisions and planning. MRI with a contrast agent is known to be a superior imaging method compared to unenhanced imaging without a contrast agent. It is one of the keys to assessing and selecting patients eligible for metastatic resection or locally directed non-surgical treatment. MRI with a contrast agent is also used to determine if a given treatment has been effective, and/or for surveillance of possible recurrence of disease.

## **Why patients with a poor kidney function cannot use existing contrast agents?**

Patients with severely impaired renal function (i.e. insufficient function of the kidneys) have reduced capacity to excrete the currently used contrast agents, which are all based on the heavy metal gadolinium. This inability may lead to accumulation of gadolinium in certain tissue, and in exceptional cases cause a very serious and potentially life-threatening condition called nephrogenic systemic fibrosis (NSF).

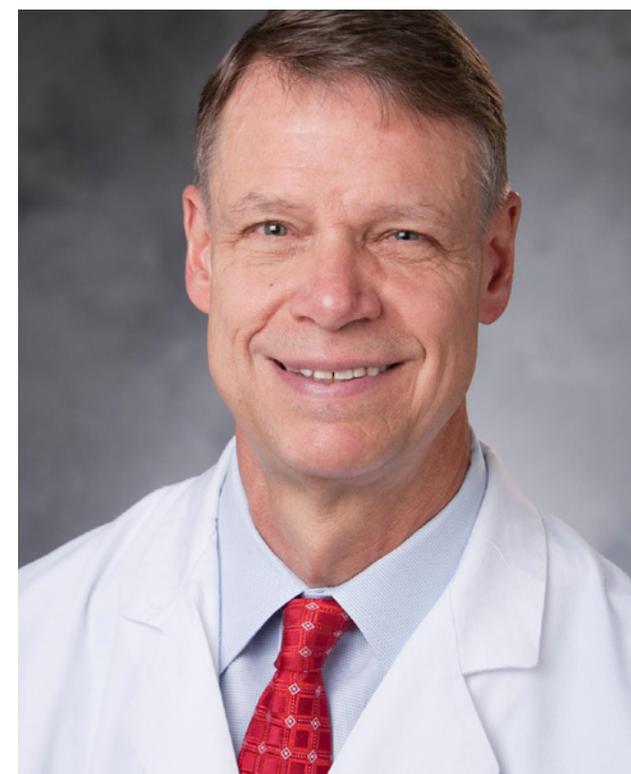
## **How do you identify patients that should avoid currently available contrast agents?**

It is a well-established medical practice, as well as a requirement per regulatory guidelines, to screen high risk patients, i.e. patients with higher likelihood of impaired renal function.

Normally they are over 60 years of age and/or suffer from diabetes and/or hypertension. The kidney function is assessed through a simple blood test.

## **Can Mangoral potentially be used for all MRIs?**

Mangoral specifically targets a patient population that have severely impaired renal function and therefore cannot use currently available contrast agents. Mangoral is the first contrast agent in the world to obtain Orphan Drug Designation by the FDA for use in liver MRI in patients where use of gadolinium-based contrast agents may be medically inadvisable, or where gadolinium-based contrast agents cannot be administered. Theoretically, it can be used on all patients undergoing an MRI to detect metastasis in the liver, regardless of renal function, but the target indication is on this smaller population of patients where the unmet need is high.



**Professor Rendon C. Nelson, MD, FACR,** abdominal imaging specialist, radiologist, at Duke University School of Medicine.

# SOLUTION – MANGORAL IMPROVES LIVER VISUALISATION

Mangoral is an orally administered contrast agent used in MRI of the liver. It is based on the chemical element manganese, which is a natural trace element in the body. Mangoral also contains L-Alanine and Vitamin D3 to increase the absorption of manganese from the small intestine into the portal liver vein. From there the manganese is transported to the liver where it is taken up by and retained in the normal liver cells, also known as the hepatocytes.

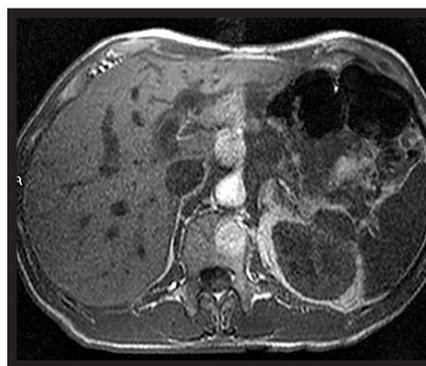
The high manganese uptake causes the liver parenchyma to appear bright on MR images. As liver metastases are not liver cells, they do not take up manganese and consequently metastases appear dark on MR images. With Mangoral, liver metastases are consequently easier to identify due to this contrast effect.

When administered orally, manganese is absorbed from the gastro-intestinal tract, taken up in the liver and excreted via the bile. Due to the high pre-systemic first pass effect only minimal amounts reach the blood stream, so the systemic exposure is very low. The mean manganese blood concentration values were within the normal range at all dose levels tested in the performed clinical studies on Mangoral.

## Patient example from our Phase II study\*

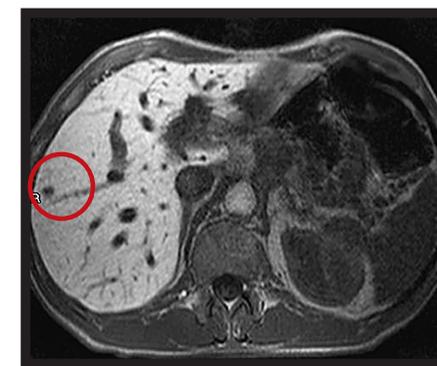
### Unenhanced liver MRI

*(standard of care today in target patient population)*



**No metastasis visible**

### Mangoral enhanced liver MRI



**Metastasis becomes visible**

# SOLUTION – SEVERAL BENEFITS WITH MANGORAL

**The strong contrast effect with Mangoral** makes it an appropriate liver contrast agent for patients where the use of Gadolinium-Based Contrast Agents may be medically inadvisable or cannot be administered. Mangoral offers a significantly better alternative than unenhanced MRI (i.e. MRI with no medical contrast agent), which is the current gold standard for these patients. Mangoral's patient segment comprises mainly patients with severe renal insufficiency who have an estimated eGFR below 30, i.e. patients with chronic kidney disease stages 4 and 5 as well as patients with Acute Kidney Injury (AKI).

**In summary**, there is a large medical need since the current gold standard diagnostic modality for this patient population is an MRI scan without any contrast agent. Mangoral enhanced MRI will lead to earlier detection of metastases and detection of smaller metastases. This will improve the possibilities of optimal management of the liver metastases and ultimately positively impact quality of life of the patients and lead to higher survival rates.

## Key advantages of Mangoral®

- ▶ Potential to be the first and only non-Gadolinium contrast agent for liver MRI
- ▶ Mangoral is based on manganese – a natural trace element in the body – with no risk of NSF
- ▶ Strong enhancement of liver on MRI – metastases do not take up manganese and appear darker on the MRI
- ▶ No competing drugs
- ▶ Limited systemic exposure and good safety profile
- ▶ Large and flexible time window for MRI since patients can be scanned 2-6 hours after ingestion – reduced scanner occupancy time at the clinics
- ▶ Provides ease of use for patients and clinicians alike (oral administration)
- ▶ FDA Orphan Drug Designation

# CLINICAL RESULTS – STRONG RESULTS

**6 phase I and II clinical studies completed.** To date, the clinical development of Mangoral comprises a total number of six completed clinical phase I and II studies in healthy volunteers and patients with known liver metastases or suspected liver lesions. In total, 127 persons have participated in the completed Phase I and Phase II clinical studies.

**Consistent strong efficacy readout and safety profile.** The results of the safety assessments from the six clinical studies show that Mangoral is safe and well tolerated with observed adverse events being mostly mild and transient (diarrhea and nausea were most frequently reported). Overall, the results from the efficacy analyses show that diagnostic quality scores improved after use of Mangoral and provide strong support that Mangoral is an effective liver specific non-gadolinium liver MRI contrast agent.

**Blind read study of all imaging data confirming the strong efficacy data.** In order to further validate the results of the individual clinical studies and also provide guidance for the design of the Phase III program, Ascelia Pharma has performed a re-evaluation of all the available imaging data, in a so-called “blinded read” study. The results of this blinded read study have been presented at large radiology conferences.

The blinded study with 178 persons underlined that Mangoral significantly improves MRI performance. Compared to unenhanced MRI, 33% more lesions were detected after Mangoral enhanced MRI. Mangoral also improved MRI performance in terms of lesion visualisation (conspicuity; p-value <0.0001) and delineation (p-value <0.0001), and quantitative parameters like lesion to liver contrast ratio was significantly improved on Mangoral enhanced MRI compared to unenhanced MRI

## Study results in summary

### CLINICAL EFFICACY

Mangoral® improved the performance of liver MRI compared to MRI without the use of a contrast agent

### SAFETY

The completed studies did not identify any safety concerns and Mangoral was regarded as safe

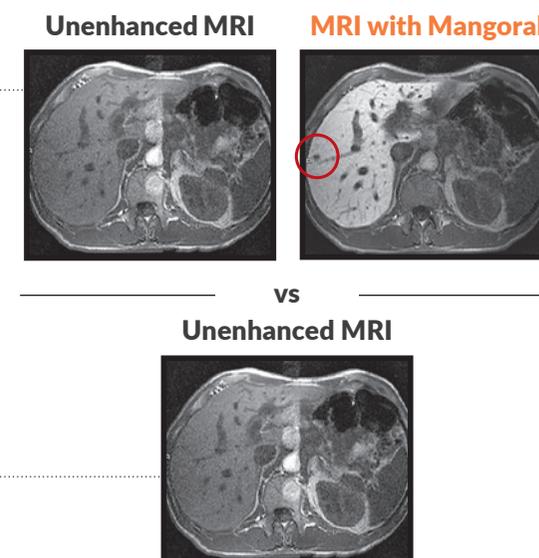
# DEVELOPMENT PLAN – DERISKED PHASE III

The Phase III study will be a multicentre study in up to 200 patients. The study is expected to start in H2-2019 with final results to be presented at the end of 2020 or beginning of 2021. The strong results in the Phase I and Phase II studies support our belief that the likelihood of success in Phase III is significantly larger than the average oncology drug in Phase III. This is due

to the known mode of action of Mangoral and a high degree of similarity between Phase II and Phase III primary endpoints for Mangoral and since the planned Phase III study comparator for Mangoral is MRI with no contrast agent. In addition, the follow-up time is only a few days, compared to months or years for the typical Phase III oncology study.

Mangoral clinical phase III study design – based on Phase III protocol meeting with FDA and EMA

<b>NUMBER OF PATIENTS</b>	<b>Up to 200 patients</b>
<b>ENDPOINT</b>	<b>Lesion visualisation</b> <ul style="list-style-type: none"> <li>No. of lesions visualised</li> <li>Semi-quantitative and Semi-qualitative parameters</li> </ul>
<b>COMPARATOR</b>	<b>Unenhanced MRI + Mangoral MRI vs. Unenhanced MRI</b>
<b>EVALUATION</b>	<b>Centralised evaluation by 3 radiologists</b>
<b>RANDOMISATION</b>	<b>No – each patient will be in both study arms</b>
<b>FOLLOW-UP</b>	<b>72 hours</b>



# MARKET – NO COMPETING PRODUCTS

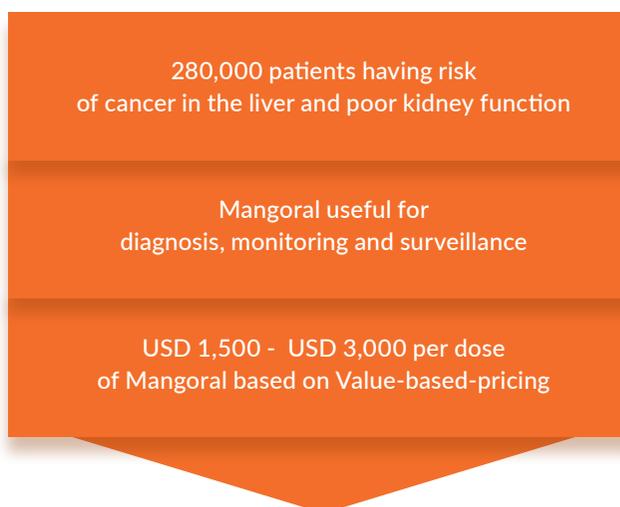
As there are no MRI liver contrast agents serving Mangoral's patient population, there is no published data available on the market size. Ascelia Pharma has estimated the addressable market size based on thorough analyses, which has been supported by third party market research.

The addressable patient population is based on detailed epidemiology analysis by geography, age groups and primary disease and therein the estimated prevalence of CKD and projected incidence and prevalence of relevant solid cancers. Ascelia Pharma estimates the addressable population to around 280,000 patients in major markets.

The pricing of Mangoral will be value based, and Ascelia Pharma has conducted more than 25 interviews with healthcare payer representatives to assess the accessibility to reimbursement, separate reimbursement coding and pricing. The feedback from the payer interviews have been used in the price assessment. Pricing of other relevant high value diagnostics has also been reviewed as part of the price assessment. Based on this and the potential for Mangoral to provide overall cost savings to the health care system, the estimated cost per dose of Mangoral is USD 1,500 – 3,000.

Combining the patient population, number of scans and pricing, Ascelia Pharma estimates an addressable annual market size for Mangoral to be USD 350–500 million.

## Overview of Mangoral's addressable market



**USD 350-500 million**  
annual addressable market for Mangoral

# COMMERCIAL STRATEGY FOR A 2022 SALES LAUNCH

- ▶ Ascelia Pharma's sales activities will target major hospitals with nephrology units
- ▶ 10-20 sales reps in the US sufficient for significant penetration
- ▶ Reimbursement expected shortly after sales launch
- ▶ Chief Commercial Officer will be recruited during the Phase III clinical study to finalise commercial strategy and prepare launch
- ▶ No recent innovation in the MRI space has enabled Mangoral to attract major attention. This will be utilised in the pre marketing phase
- ▶ Go-to-market in Europe is being evaluated
- ▶ Find commercial partners in Japan, South Korea and Rest of World

**10-20 Sales Reps**  
sufficient for penetration  
in concentrated US regions

# ONCORAL

Phase II ready tablet chemotherapy  
for gastric cancer

- ▶ Novel tablet formulation with significant patient and hospital benefits
- ▶ Effective molecule for killing cancer
- ▶ Promising Phase I results



# PROBLEM – GASTRIC CANCER

Gastric cancer is a disease in which cancer cells form in the lining of the stomach. Almost all gastric cancers are adenocarcinomas (i.e. a cancer that begins in glandular tissue) and some gastric cancers over-express the molecule HER2. Gastric cancer is often in an advanced stage when it is diagnosed. At this stage it can often be treated, but rarely cured

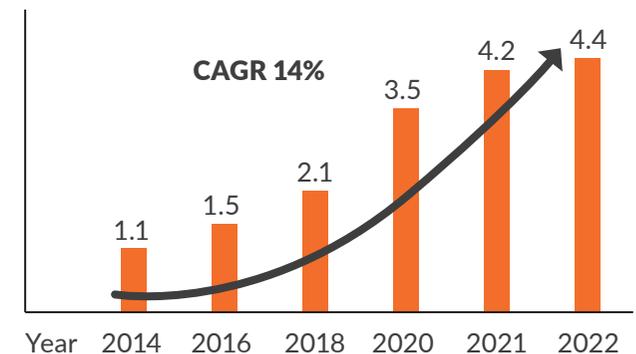
**Gastric cancer is serious disease.** In fact, is the third most deadly cancer form and the five-year survival rate is only 20%. While gastric cancer is considered an orphan indication by the FDA and EMA, it has an addressable global market of USD 2 billion which is expected to surpass USD 4 billion in 2022.

**Chemotherapy is the backbone treatment.** The current backbone of first-line treatment of advanced gastric cancer is chemotherapy, either as double or triple combinations. Chemotherapeutic drugs (cytotoxics) stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.

**Irinotecan is an established and effective chemotherapy.** There are a number of chemotherapeutic drugs on the market and one well-established and effective molecule is irinotecan. Irinotecan has a proven anti-tumour effect and is approved for combination use in a number of solid cancer indications. In the United States and Europe, irinotecan is currently mainly used for treating metastasised colorectal cancer. Although irinotecan is currently not approved for treating gastric cancer in the United States and in the EU, there is off-label use and included in recognised clinical guidelines (ESMO, ASCO, NCCN) in monotherapeutic or combination treatment regimens for advanced gastric cancer.

**Untapped market for oral formulations of irinotecan.** Today, irinotecan is only available intravenously and still not for gastric cancer in Europe and the US. Ascelia Pharma consequently sees a significant unmet medical need for new treatments that improve the life expectancy and quality of life for patients with advanced gastric cancer. In particular, HER2-negative advanced gastric cancer patients. This is exactly the role that Oncoral attempts to fill.

Global gastric cancer market (USDbn)



(Source GlobalData)

# SOLUTION - A PATIENT FRIENDLY TABLET CHEMO

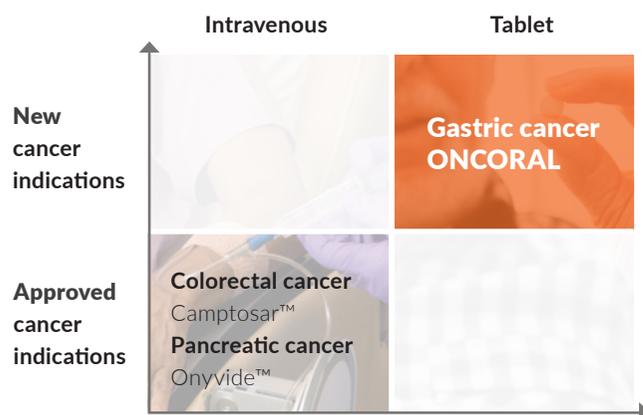
Oncoral is an oral tablet formulation of irinotecan intended for combination use as a chemotherapeutic treatment of unresectable and metastatic gastric cancer. Irinotecan has already demonstrated safety and efficacy and is currently used intravenously for the treatment of colorectal and pancreatic cancer. Having an oral tablet formulation of irinotecan, Oncoral will provide gastric cancer patients with the opportunity to take part of their chemotherapy at home and at the same time it will save hospital bills

**Anti-cancer effect is proven.** The active pharmaceutical ingredient (API) in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is an antineoplastic agent that after metabolic activation inhibits Topoisomerase 1 and exerts its cytotoxic effect via prevention of DNA replication. Irinotecan is converted by carboxylesterases primarily in the liver to the active metabolite SN-38 which is approximately 100–1,000 more cytotoxic than irinotecan in human and rodent tumour cell lines.

**Oncoral can be first oral version of irinotecan.** Oncoral is a new proprietary and patented oral gastro-resistant tablet of irinotecan. Oncoral enables a secure and efficient release and absorption of irinotecan from the gastro-intestinal tract after peroral administration with a high conversion rate of irinotecan to the active metabolite SN-38 which has a high anti-tumour activity.

**All-oral chemo combination.** Oncoral has the potential to be combined with other chemotherapies and targeted cancer drugs and Oncoral enables an all oral combination chemotherapy option with health-economic benefits.

## Oncoral - a novel formulation of irinotecan



## Advantages of oral tablet chemotherapy vs. intravenous

### Patients

- Tablets can be swallowed at home instead of intravenous administration at the hospital
- Sense of control over treatment and less interference with daily activities
- No risk of medical complications and pain from medical intravenous lines
- Less travel to hospital/clinic
- Enables fine tuning of individual dosing

### Clinicians

- Better utilisation of hospital stay for patient-centered care
- Intravenous facilities can be prioritised for targeted therapies instead
- Less risk of adverse effects from intravenous chemotherapy (e.g. hospital-acquired infection or leakage of infused cytostatic from vasculature to surrounding tissue)

### Payers

- All-oral chemotherapeutic regimens reduce the need to spend hospital resources on more expensive intravenous administration
- Less risk of hospital-acquired infections (which leads to a need for additional treatment), leading to reduced costs
- Less need for handling of side effects mainly associated with intravenous administration of chemotherapy, leading to overall reduced costs

# CLINICAL RESULTS – PROMISING PHASE I RESULTS

Oncoral has completed an investigator sponsored Phase I trial at Herlev Hospital, Denmark. The objectives of the study were to determine safety, tolerability and maximum tolerated dose of Oncoral given as single agent and when administered in combination with the oral chemotherapeutic drug capecitabine. Additional objectives were to describe the pharmacokinetics of Oncoral given as single agent, and to determine any objective tumour response or stable disease. Twenty-five patients were enrolled in the part of the study with Oncoral given as single agent and 12 additional patient were enrolled in the second part of the study where Oncoral was given in combination with capecitabine

## Results from Phase 1 single agent study (published in Jan 2019)

- ▶ Results showed that Oncoral was well tolerated; side effects were generally mild to moderate, manageable and similar in type to those observed with intravenous irinotecan
- ▶ Hematological toxicities were few and all were mild to moderate
- ▶ Pharmacokinetic (PK) data showed consistent daily exposures during treatment at days 1 and 14 with no drug accumulation
- ▶ The active metabolite, SN-38, interpatient variability was in the same range as after infusion of irinotecan
- ▶ In this heavily pre-treated patient population, Oncoral indicated activity even among patients previously treated with irinotecan infusion
- ▶ The study was presented at ESMO congress in October 2018

## Result from Phase 1 combination study (published in April 2019)

- ▶ The combination of Oncoral with another oral chemotherapy, capecitabine, was encouraging which could enable an all-oral chemotherapy combination
- ▶ The study data demonstrated reassuring tolerability of Oncoral together with capecitabine
- ▶ The combination with capecitabine could become a more convenient and patient friendly treatment option compared to the intravenous formulations of these compounds
- ▶ The encouraging tolerability profile justifies further clinical studies to assess the efficacy of this treatment regimen

## DEVELOPMENT PLAN

With promising Phase I results, we are now planning for Oncoral's Phase II program. The clinical development strategy for Oncoral is to obtain Phase II data and then to partner for the further development to market. The plan is to design and conduct a Phase II study on Oncoral in combination with capecitabine and a selected targeted anti-cancer agent, in irinotecan naive, HER2 negative patients with unresectable or metastatic gastric cancer. Preliminary plans for the Phase II study involve a dose-escalation part with Oncoral, capecitabine and the selected targeted agent in order to determine safety and tolerability and define doses for the extension part of the Phase II study. The extension part of the study aims at establishing proof of clinical concept based on relevant safety and efficacy parameters.

Planning for Phase II is ongoing with the preparatory work in 2019 including study design and protocol. Recruitment of patients is expected to start in 2020 (completion of Oncoral's Phase II study will require additional financing).

### KEY ADVANTAGES WITH ONCORAL

- ▶ Formulated as a tablet for convenient dosing and health-economic benefits
- ▶ Irinotecan shown to be effective in killing cancer cells
- ▶ Promising safety profile of oral administration demonstrated in Phase I clinical study
- ▶ Potential for all-tablet chemo- combination
- ▶ Expected to be efficacious and safe in combination with other well-recognised anti-cancer drug

# SHAREHOLDER INFORMATION

Ascelia Pharma was listed on Nasdaq Stockholm Small-cap on 13 March 2019, under the ticker ACE. Through the IPO, Ascelia Pharma raised gross proceeds of SEK 200 million plus SEK 22 million through the overallotment option. In total, 8,882,017 shares were issued in the IPO and we welcomed around 6,000 new shareholders to the company.

At 30 June 2019, Ascelia Pharma had 23,488,908 registered ordinary shares, corresponding to 23,488,908 votes. Each share in Ascelia Pharma provides an equal participation in the company's capital and earnings.

## **IPO provided Ascelia Pharma with a fully financed Phase III program**

The IPO in 2019 provided Ascelia Pharma with a fully financed Phase III program for the lead drug candidate Mangoral. Proceeds from the IPO will also be used for commercial planning for Mangoral and preparations for Oncoral's Phase II study.

## **Share performance**

From 13 March 2019 until 30 of June 2019, Nasdaq Stockholm increased by 4.3%. Ascelia Pharma's share price declined in the corresponding period by 20.8% from a price of SEK 25 in the IPO to SEK 19.8 at 30 June 2019. The highest closing price in this period, SEK 29.3, was on 14 March 2019, while lowest price, SEK 19.2, was noted on 25 April 2019. The market value of Ascelia Pharma at 30 June 2019 was SEK 465 million.

## **Ownership structure**

As of 30 June 2019, the five largest shareholders as of 30 June 2019 had a total of 50% of the capital and votes.

## **Financial information**

Ascelia Pharma publishes four interim reports and an annual report. The reports are available to read and download from the website of Ascelia Pharma, [www.ascelia.com](http://www.ascelia.com).





### 2019 Annual General Meeting

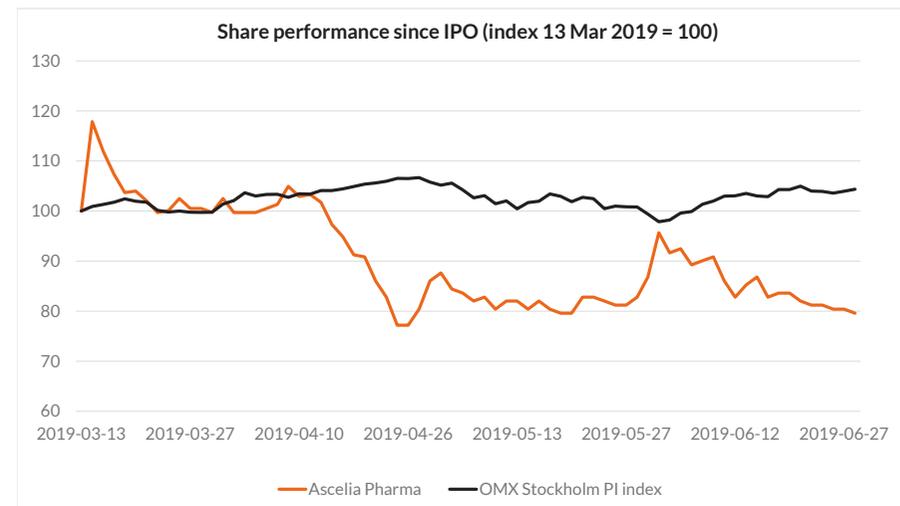
The Annual General Meeting of Ascelia Pharma AB (publ) will be held on 14 of November 2019 at Setterwalls Advokatbyrå AB in Malmö with address Stortorget 23, 211 34 Malmö, Sweden.

#### 10 LARGEST SHAREHOLDERS

	No. of shares	% of capital	% of votes
Sunstone Life Science Ventures Fund II K/S	4,497,699	19.1%	19.1%
CMC SPV of 3 April 2017	2,937,606	12.5%	12.5%
Öresund-Healthcare Capital K/S	2,020,490	8.6%	8.6%
Alto invest	1,175,184	5.0%	5.0%
Handelsbanken Småbolagsfond	1,109,999	4.8%	4.8%
Fourth Swedish National Pension Fund (AP4)	920,000	3.9%	3.9%
Styrelsen for Institutioner og Uddannelsesstøtte (SIU)	512,014	2.2%	2.2%
Spogard Holding ApS	454,388	1.9%	1.9%
Helida Invest APS	384,501	1.6%	1.6%
Alvina Invest ApS	288,377	1.2%	1.2%
Other shareholders	9,178,619	39.1%	39.1%
<b>TOTAL</b>	<b>23,488,908</b>	<b>100%</b>	<b>100%</b>

### Equity analysts:

Ascelia Pharma is covered by Analysguiden, Redeye and Vator Securities



# DIRECTORS' REPORT

The board and the CEO of Ascelia Pharma AB (publ), (Ascelia Pharma), based in Malmö, Sweden corporate ID no. 556571-8797 hereby submit the annual report and consolidated financial statements for the fiscal year 2018-07-01 – 2019-06-30 (2018/2019) for the Group and the Parent company.

## Ownership structure

Ascelia Pharma (publ) is listed on Nasdaq Stockholm. The largest shareholders per 30 June 2019 were Sunstone Life Science Ventures Fund II K/S with 4,497,699 shares (19.1% of total) followed by CMC SPV of 3 April 2017 AB with 2,937,606 shares (12.5% of total) and Øresund Healthcare Capital K/S with 2,020,490 shares (8.6% of total). Sunstone Life Science Ventures Fund II K/S and Øresund Healthcare Capital K/S also own 13% and 5% respectively, of the shares in CMC SPV of 3 April 2017 AB.

## ASCELIA PHARMA'S BUSINESS

Ascelia Pharma is an oncology-dedicated orphan drug development company located in Malmö, Sweden, focused on the development of novel drugs with an established mode of action. Ascelia Pharma's strategy is to develop and make available to patients a portfolio of differentiated and de-risked drug candidates addressing unmet medical needs with potential for orphan drug designation in cancer and cancer-related diseases.

Ascelia Pharma currently has two clinical stage drug candidates under development. Ascelia Pharma's lead candidate, Mangoral, is Phase III-ready, and is a contrast agent to facilitate the visualisation of focal liver lesions in patients with known or suspected focal liver lesions and severe renal insufficiency (impaired kidney function). The second candidate, Oncoral, is a Phase II-ready novel tablet formulation of the well-known chemotherapeutic agent irinotecan. Mangoral has received orphan drug designation by the FDA and Oncoral targets gastric cancer which is considered an orphan drug indication by the FDA and EMA.

## Significant events during the year

- 2018-09-14** Carl Bjartmar appointed as new Chief Medical Officer
- 2018-10-23** Phase I study results for Oncoral presented as poster presentation for European Society for Medical Oncology (ESMO) Annual Congress
- 2018-11-13** Encouraging results from clinical Phase I study of Oncoral presented in a new publication
- 2018-11-19** Positive feedback from FDA on design of the pivotal Phase III study with Mangoral
- 2019-03-13** IPO on Nasdaq Stockholm with total issuance of SEK 200 million
- 2019-04-08** Encouraging results from Oncoral's Phase I combination study with oral capecitabine
- 2019-04-12** IPO overallotment optioned exercised raising SEK 22 million
- 2019-05-07** Supportive feedback from EMA on the phase III program for Mangoral
- 2019-06-10** Strengthening of the Mangoral franchise by filing of a patent application for next generation Mangoral product

## Multi-year overview, Group

Financials key ratios for the Group	FY (Jul-Jun)		
	2018/2019	2017/2018	2016/2017*
SEK thousands			
Net sales	-	-	n/a
Operating results	-37,392	-24,713	n/a
Net results	-37,134	-24,392	n/a
Earnings per share (SEK)	-2.16	-2.12	n/a
R&D costs/operating costs (%)	61%	36%	n/a
Cash flow from operations	-30,333	-20,958	n/a
Equity	276,075	111,730	77,601
Liquid assets incl. marketable securities	225,048	55,063	1,627

\* Ascelia Pharma Group was formed on 30 June 2017 through the acquisition of Oncoral Pharma ApS. As 30 June is the fiscal-year end date, the result and cash flow figures for 2016/2017 only includes one day. No business activities took place after acquisition on that particular day 30 June 2017.

## Financial overview

### Net sales and other operating income

The Group's net sales for full-year amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognise revenue before products have been launched on the market. Other operating income totalled SEK 203 thousand (SEK 1,062 thousand). The decline in other operating income of SEK 859 thousand is explained by last year benefitting from investment grants from innovation agencies for Oncoral's phase I study.

### Research and development costs (R&D)

R&D costs for the Group for the full-year were SEK 22.9 million (SEK 9.4 million). The cost increase of SEK 13.6 million underlines an overall higher activity level in Ascelia Pharma in the current year vis-à-vis corresponding last year. This was especially pertinent for Mangoral where detailed preparations have been made for the phase III clinical study including establishing the clinical study protocol, work to select clinical study sites and manufacturing preparations.

### Administration costs

Administration costs for the Group in the full-year amounted to SEK 14.4 million (SEK 16.4 million) illustrating a cost decrease of SEK 2.0 million compared with last year.

### Operating results (EBIT)

Full-year operating results amounted to SEK -37.4 million (SEK -24.7 million). The cost increase mainly reflects the overall higher level of R&D activities in the current period.

### Net Profit/Loss for the period

The Group's full-year net loss amounted to SEK -37.1 million (SEK -24.4 million). The increased net loss mirrors the development in EBIT and corresponds to a loss per share, before and after dilution, of SEK 2.16 (SEK 2.12).

### Cash flow

Cash flow from operating activities before changes in working capital amounted to SEK -36.0 million (SEK -19.6 million). The increased outflow reflects the overall higher level of R&D costs in the current year. Changes in working capital in the current year totalled an inflow of SEK 5.7 million (outflow of SEK 1.4 million). The positive working capital development in the current year primarily reflects an increase in trade payables as well as an increase in other liabilities. In total, cash flow from operating activities after changes in working capital amounted to SEK -30.3 million (SEK -21.0 million).

Cash flow from investing activities amounted to SEK -75.0 million (SEK 0) and represents investment of bank balances into a fixed income fund (highly liquid fund with the lowest risk classification).

Cash flow from financing activities totalled SEK 200.2 million (SEK 74.4), which reflects the proceeds raised in the IPO (net of issuance expenses).

### Financial position

On the closing date, equity stood at SEK 276.1 million, compared with SEK 111.7 million per 30 June 2018. The increase since 30 June 2018 reflects the issuance of new shares in connection with the IPO in spring 2019. In total, 8.9 million shares were raised, including utilisation of the over-allotment option, taking the total amount of shares per 30 June 2019 to 23.5 million. Liquid assets including marketable securities on the closing date amounted to SEK 225.0 million compared with SEK 55.1 million as of 30 June 2018. The increase since 30 June 2018 reflects the issuance of new shares in the IPO.

## RISK AND RISK MANAGEMENT

Ascelia Pharma's activities and markets are exposed to a number of risks and uncertainties which impact, or could impact, the company's business, financial position and result. The risks and uncertainties, which Ascelia Pharma considers to have the largest impact on its results are:

- Clinical drug development risks
- Regulatory risks
- Commercialisation and licensing risks
- Intellectual property rights and other forms of protection
- Financing risk
- Currency risks

These factors are described in more detail below. The Group's overall strategy for risk management is to limit undesirable impact on its result and financial position, to the extent it is possible.

### Clinical drug development risks

Ascelia Pharma is solely focused on development of clinical stage drugs that satisfy medical needs within oncology. The company's ability to successfully develop clinical stage drugs as well as the ability to identify new drug candidates is of great importance for the long term results and ability to generate a return for the shareholders.

Ascelia Pharma's drug candidate Mangoral® is being prepared for phase III studies and Oncoral has completed its phase I studies. The continued development of both Mangoral® and Oncoral will entail significant costs for Ascelia Pharma also in the future and are subject to several risks including development delays, cost overruns and non satisfactory results from clinical studies. The Group's research and development expenses are related to the development of its product candidates. Ascelia Pharma's research and development expenses for the financial year 2018/2019 amounted to SEK 22.9 million, which corresponds to 61% of the operating costs.

The total costs for completing the development programs of Mangoral and Oncoral is dependent on several factors, including Ascelia Pharma's ability to operate the development program forward according to plan and to obtain necessary approvals from relevant medical authorities. The actual costs can be unevenly distributed over its lifetime and could exceed the estimated costs. It is common that a development program for drugs is affected by delays and cost overruns. Consequently, the inherent risk should be considered high.

### Regulatory risks

Ascelia Pharma operates in the pharmaceutical industry, which is subject to strict laws, rules and regulations. The regulatory framework entails high requirements with respect to e.g. clinical studies, sales permits, production, marketing, distribution, packaging, labelling, security, efficacy and quality. Ascelia Pharma believes that it will incur significant costs for regulatory compliance, e.g. through consultancy services within relevant areas and increased administrative expenses due to the planned expansion of the organisation with regards to i.a. clinical and regulatory affairs, in the future. If Ascelia Pharma does not meet the legal and regulatory obligations it could have a materially negative affect on future revenue and earnings.

### Commercialisation and licensing risks

Ascelia Pharma plans to strengthen its operations through recruitments, i.a. for developing a commercialisation organisation. The company considers this strategy necessary both for the commercialisation of Mangoral® and Oncoral as well as from a negotiation point of view, where a clear strategy for the commercialisation is considered to be an advantage in a negotiation with potential business partners. There is no guarantee that Ascelia Pharma will find suitable business partners for commercialisation or that the terms for cooperation will be satisfying. If the company chooses to establish an own sales and market division, there is a risk that this division will not be satisfactory or that the work to establish such an operation is more costly and time consuming than estimated.

### Risks associated with intellectual property rights and other forms of protection

Ascelia Pharma's operations are dependent on its ability to protect its products and innovations. Thus, it is crucial for the company to maintain patents and other intellectual property rights. Monitoring and maintaining of intellectual property is costly and time consuming and Ascelia

Pharma expects such costs to increase in the future if it expands its intellectual property portfolio, e.g. through additional patents or trademarks. If Mangoral obtains market approval, the product candidate could be covered by data protection and market exclusivity in the United States for 7 years, in Japan for 10 years (if orphan drug designation is obtained) and in the EU for 8+2 years alternatively 10+2 years if orphan drug designation is obtained in the region. Ascelia Pharma has also obtained orphan drug designation for Mangoral in the United States, which could mean market exclusivity in the United States if market approval is received.

Oncoral has obtained patent protection in the US and Europe and Ascelia Pharma believes that the product candidate has potential to obtain both orphan drug designation and data exclusivity in relevant markets. Efforts with regards to applications and managing orphan drug designation and other interactions with medical authorities are costly and time consuming and are expected to continue in the future.

### Financing risk

Drug development is in general costly and since Ascelia Pharma has still not reached a stage where revenue is generated, the business is dependent on equity financing. There is a risk that future financing cannot be obtained or only at unattractive terms. Ascelia Pharma is proactively working to ensure sufficient funds for its drug development programs. This was underlined by the completed IPO in spring 2019 where gross proceeds of SEK 222 million were raised. The financing through the IPO ensured a fully financed clinical development program for Mangoral. Further clinical development of Oncoral would, however, require additional financing.

### Currency risks

Ascelia Pharma is headquartered in Sweden and the presentation currency in the company's accounting is Swedish crowns (SEK). The company has costs related to its operations in foreign currencies, mainly in EUR, and USD. Fluctuations in these currencies against SEK can affect the company's financial position and result negatively. With the current non-revenue state of the company with no matching incoming funds in EUR and USD, an appreciation of these costs towards SEK would mean increased costs to the Group. Currency risks is described further in the Notes of this Annual Report. The Group is through the acquisition of Oncoral Pharma ApS exposed to the conversion risk that emerges from the translation of the subsidiary's income statement and balance sheet from DKK to SEK. Ascelia Pharma has not used financial derivatives in order to hedge currency risk.

## OTHER INFORMATION

### Employees

Ascelia Pharma AB is reliant on key individuals in its operational and development activities. The ability to recruit and retain qualified co-workers is of material importance to ensure the level of expertise in the company. The number of full-time employees as of 30 June 2019, incl. Head of IR employed as consultant, amounted to six (five) for both the Group and the Parent company (average five employees for 2018/2019 and four employees for 2017/2018). Furthermore, in addition to the employees, Ascelia Pharma utilises consultants and experts for clinical trials, regulatory affairs, manufacturing, IP rights as well as support functions.

### PARENT COMPANY

Ascelia Pharma AB (publ) fully owns all the companies in the Group. The equity/assets ratio on the closing date was 96% (96%). Equity amounted to SEK 279.2 million (112.8) million. Liquid assets including marketable securities amounted to SEK 223.8 million (53.8) million. The company had six employees on the closing date, including Head of IR and communications (through consultancy agreement).

### Total number of shares

The total number of outstanding shares as of 30 June 2019 was 23,488,908.

### Environment:

Ascelia Pharma works to evolve as a sustainable company. The company has not yet reached a state with revenue generation and consequently the company's products have no impact on the environment. The environmental impact stems from purchasing of products and services, energy consumption and travel. Ascelia Pharma has the ambition to contribute to a sustainable development and improve its environmental impact as far as it is economically viable. Given the current size of the company, no sustainability report for 2018/2019 has been established.

### Board activities

The Board has adopted a set of working procedures, instructions and a number of policies that define the allocation of responsibilities between the Board, the President and CEO, committees appointed by the Board and Group management. The Board has ultimate responsibility for the Group's operations and organisation and ensures that the duties of the President and CEO as well as financial operations are carried out in compliance with established principles. The Board held

15 minuted meetings during the year (of which seven meetings were per capsulam). From its membership, the Board has appointed an audit committee and a remuneration committee. During the year, the audit committee held four meetings and the remuneration committee held four meetings.

### Guidelines for remuneration

The Board proposes essentially unchanged guidelines for remuneration to senior management. For information about the guidelines applicable up until the 2019 Annual General Meeting, refer to the Corporate Governance Report in this Annual Report.

### Proposed appropriation of the company's loss:

The following amounts (SEK) in the Parent Company are at the disposal of the Annual General Meeting:

	SEK
Share premium reserve	405,060,843
Retained earnings	-114,310,518
Net income (loss) for the period	-35,060,147
<b>Total</b>	<b>255,690,178</b>

Board of Directors proposes that SEK 255,690,178 is carried forward.

### Dividend policy

Up to now, Ascelia Pharma has not paid any dividends and Ascelia Pharma's intention is to continue to focus on further development and expansion of the company's project portfolio. In accordance with the dividend policy adopted by the Board of Directors, available financial resources and any reported results shall therefore be reinvested in the business to finance the company's long-term strategy. Hence, the Board of Directors' intention is not to propose a dividend to shareholders before the company is able to generate a long-term sustainable profitability and a long-term sustainable positive cash flow. Any future dividends and the size thereof will be determined on the basis of the company's long-term growth, earnings trend and capital requirements, taking into account, at all times applicable, objectives and strategies. Dividends shall, in so far as dividends are proposed, be well-balanced with respect to the company's objectives, scope and risk.

# CORPORATE GOVERNANCE REPORT

## Corporate Governance in Ascelia Pharma

Ascelia Pharma is a Swedish public limited liability company with its registered office in Malmö, Sweden. The company's corporate governance is based on Swedish law and internal rules and instructions. Ascelia Pharma also follows Nasdaq Stockholm's Rule Book for Issuers and apply the Swedish Corporate Governance Code (the "Code"). The Code applies to all Swedish companies with shares listed on a regulated market in Sweden. The Code is based on the so-called "comply or explain" principle. This means that a company that applies the Code may choose to deviate from certain rules of the Code, but must then describe its alternative solution and explain the reason for the deviation in its annual corporate governance report. This corporate governance report has been drawn up in accordance with the rules in the Annual Accounts Act and in the Code.

## Annual General Meeting

According to the Swedish Companies Act (2005:551), the general meeting is the company's highest decision-making body. At the general meeting, the shareholders exercise their voting rights in key issues, such as changes to the articles of association, the election of the board of directors and auditors, adoption of the income statement and balance sheet, discharge from liability of the board of directors and the CEO, the appropriation of profit or loss and the principles for the appointment of the nomination committee. The Annual General Meeting (AGM) must be held within six months from the end of the financial year.

In addition to the annual general meeting, extraordinary general meetings may be convened. According to the articles of association, notices convening the general meetings are to be published in the Swedish National Gazette (Sw. Post- och Inrikes Tidningar) and by making the notice available on the company's website. Information regarding the notice shall at the same time be advertised in Svenska Dagbladet. General meetings in Ascelia Pharma are held in Malmö.

## Right to attend AGMs

To attend and vote at the general meeting, either in person or through a proxy, shareholders must be registered in the share register kept by Euroclear Sweden AB five business days prior to the

meeting and also register their participation to the company no later than on the date specified in the notice convening the meeting. This date cannot be a Sunday, other public holiday, Saturday, Midsummer Eve, Christmas Eve or New Year's Eve and not fall earlier than the fifth business day prior to the meeting. Shareholders who wish to have a specified matter brought before the general meeting must submit a written request to the company's board of directors. Such request must normally have been received by the board of directors no later than seven weeks before the general meeting.

## Annual General Meeting 2018

At the Annual General Meeting held on 23 November 2018, Peter Benson was re-elected as Chairman of the Board and Niels Mengel, Bo Jesper Hansen, René Spogård, Helena Wennerström and Hans Maier were re-elected as board members. Furthermore, Öhrlings PricewaterhouseCoopers AB was re-elected as auditor.

The Annual General Meeting resolved on fees to the board of directors and guidelines for remuneration to the CEO and other senior executives as described under "Remuneration" below. The Annual General Meeting further approved the instructions and rules of procedure for the nomination committee as described under Nomination committee below. The Annual General Meeting finally also resolved on an authorization for the board of directors to issue shares as described under "Authorization to the board of directors regarding new share issues" and on an employee option program for senior executives.

## Annual General Meeting 2019

The Annual General Meeting (AGM) of Ascelia Pharma AB (publ) will be held on 14 November 2019 in Malmö, Sweden. The AGM will be held at Setterwalls Advokatbyrå AB in Malmö with address Stortorget 23, 211 34 Malmö, Sweden.

## Shareholders

At 30 June 2019, the five largest shareholders controlled around 50% of capital and votes. The lar-

gest shareholders controlling more than 10% of the capital and votes were Sunstone Life Science Ventures Fund II K/S (19.1%) and CMC SPV of 3 April 2017 AB (12.5%). At 30 June 2019, the number of shares was 23,488,908. There is only one class of share and all shares have equal rights to the company's assets and profits. Each share entitles the holder to one vote and there are no limitations as to the number of votes each shareholder can cast at a general meeting.

### Nomination Committee

The duties of the nomination committee include the preparation and drafting of proposals regarding the election of members of the board of directors, the chairman of the board of directors, the chairman of the general meeting and auditors. The nomination committee shall also propose fees for board members and the auditor. The composition of the nomination committee is publicly announced at least six months ahead of the AGM.

At the annual general meeting held on 23 November 2018, it was resolved to adopt instructions and rules of procedure for the nomination committee according to which the nomination committee shall consist of four members representing the three largest shareholders per the end of March, together with the chairman of the board of directors. The three largest shareholders are considered to be the three largest shareholders as registered with Euroclear Sweden AB.

In accordance with the adopted instructions, the nomination committee in front of the 2019 Annual General meeting is comprised of the following persons:

- Jørgen Thorball, chairman of the Nomination Committee, appointed by Sunstone Life Science Ventures II K/S;
- Nils Lorentzen, appointed by CMC SPV of 3 April 2017 AB;
- Håkan Nelson, appointed by Øresund Healthcare Capital K/S; and
- Peter Benson, chairman of the board of directors.

### The Board of Directors

After the general meeting, the board of directors is the highest decision-making body. According to the Swedish Companies Act, the board of directors is responsible for the organisation and management of the company's affairs, which means that the board of directors is responsible for, among other things, establishing targets and strategies, securing procedures and systems for monitoring of set targets, continuously assessing the company's financial position and evaluating the operational management. Furthermore, the board of directors is responsible for ensuring that proper information is given to the company's shareholders, that the company complies with laws and regulations and that the company develops and implements internal policies and ethical guidelines. Moreover, the board of directors is responsible for ensuring that annual reports and interim reports are prepared in a timely matter. The board of directors also appoints the company's CEO.

The members of the board of directors are elected annually at the annual general meeting for the period until the end of the next annual general meeting. According to the Ascelia Pharma's articles of association, the board of directors shall consist of no less than three and no more than eight board members without any deputy board members. The articles of association do not include any separate provisions regarding appointment or dismissal of board members. Currently, the board of directors consists of six ordinary board members elected by the general meeting, who are presented in the section Board of directors, and Executive Management.

According to the Code, the chairman of the board of directors is to be elected by the general meeting. The role of the chairman is to lead the board of directors' work and to ensure that the work is carried out efficiently, and that the board of directors fulfils its obligations.

### Board's procedures

The board of directors adheres to written rules of procedure which are revised annually and adopted at the constituent board meeting. The rules of procedure regulate, among other things, the practice of the board of directors, tasks, decision-making within the company, the board of directors' meeting agenda, the chairman's duties and allocation of responsibilities between the board of directors and the CEO. Instruction for financial reporting and instructions for the CEO are also adopted in connection with the constituent board meeting. The board of directors' work is also carried out based on an annual briefing plan which fulfils the board of directors' need for information. The chairman and the CEO maintain, alongside the board meetings, an ongoing dialogue on the management of the company.

The board of directors meets according to a pre-determined annual schedule and in addition to the constituent board meeting, at least six ordinary board meetings shall be held between each annual general meeting. In addition to these meetings, extra meetings can be arranged for processing matters which cannot be referred to any of the ordinary meetings.

### Board of Directors' work and meetings in fiscal year 2018/2019

The board of directors had 15 meetings in the fiscal year 2018/2019, of which seven meetings were held by circulation. In addition to decisions concerning external financial reporting, budget and financial forecasts, the board's work during 2018/2019 have primarily comprised matters related to the preparation of the Phase III trial for Mangoral, Oncoral's Phase I completion and planning for Phase II as well IPO preparations and decisions thereto. The board has evaluated its work to prove the work procedures and enhance efficiency. Conclusions of the work are presented to the nomination committee.

## Reporting period 1 July 2018 - 30 June 2019

Board member	Function	Independent in relation to		Remuneration, SEK thousand <sup>3</sup>				Attendance 1)		
		The company and its management	Major shareholders	Board fees	Audit Committee	Remuneration Committee	Total	Board of Directors 2)	Audit Committee	Remuneration Committee 2)
Peter Benson	Chairman	Yes	No	233	15	-	248	8/8	4/4	-
Bo Jesper Hansen	Board member	Yes	Yes	117	-	-	117	3/8	-	4/4
Hans Maier	Board member	No	No	200	-	-	200	6/8	-	4/4
Niels Mengel	Board member	Yes	No	117	15	-	131	8/8	4/4	-
René Spogård	Board member	Yes	No	117	-	-	117	8/8	-	4/4
Helena Wennerström	Board member	Yes	Yes	200	50	-	250	8/8	4/4	-
<b>Total</b>				<b>984</b>	<b>70</b>	<b>-</b>	<b>1,063</b>			

1) Figures in table show the total number of meetings attended/total number of meetings

2) Excluding per capsulam meetings

3) Peter Benson, Bo Jesper Hansen, Niels Mengel and René Spogård chose not obtain any remuneration up until AGM on 23 November 2018.

### Board committees

The board of directors has set up two committees: the audit committee and the remuneration committee. The board of directors has adopted rules of procedure for both committees.

#### Audit Committee

The audit committee is comprised of Helena Wennerström (chairman), Peter Benson and Niels Mengel. The audit committee's role is mainly to monitor the company's financial position, to monitor the effectiveness of the company's internal control and risk management, to be informed about the audit of the annual report and consolidated financial statements, and to review and monitor the auditor's impartiality and independence. The audit committee shall also assist the nomination committee in proposals for decisions on the election and remuneration of the auditor. The audit committee had four meetings in the fiscal year 2018/2019 (no meetings by circulation).

#### Remuneration Committee

The remuneration committee is comprised of Bo Jesper Hansen (chairman) and René Spogård. Hans Maier resigned from the Remuneration Committee in connection with Ascelia Pharma entering into a consultancy agreement with BGM Associates GmbH, in which company Hans Maier is Managing Director and a major shareholder. The remuneration committee's role is primarily to prepare matters regarding remuneration and other terms of employment for the CEO and other senior executives. The remuneration committee shall also monitor and evaluate ongoing and completed programs for variable remuneration to the company's management and to monitor and evaluate the implementation of the guidelines for remuneration to senior executives which the annual general meeting has adopted. The remuneration committee had four meetings in the fiscal year

2018/2019 (no meetings by circulation). All board members as well as the executive management members are presented in more detail on pages 36-39.

### The CEO and other senior executives

The role of the CEO is subordinate to the board of directors and the CEO's main task is to carry out the company's ongoing management and the daily activities of the company. The rules of procedure of the board of directors and the instructions for the CEO stipulate which matters the board of directors shall resolve upon, and which matters that fall within the CEO's area of responsibility. Furthermore, the CEO is responsible for preparing reports and necessary information for decision-making prior to board meetings and presents the material at board meetings.

Ascelia Pharma has a management team consisting of five people which in addition to the CEO is comprised of the CFO, the Chief Medical Officer, the Chief Operating Officer and the Head of IR & Communications. The CEO and the senior executives are presented in the section Board of directors, and Executive Management.

### Remuneration

#### Remuneration to the Board

Fees to board members elected by the general meeting are resolved by the annual general meeting. At the annual general meeting held on 23 November 2018, it was resolved that fees of SEK 400,000 were to be paid to the chairman and that fees of SEK 200,000 was to be paid to each of the other board members who are not employed by the company. In addition, it was resolved that

fees of SEK 50,000 should be paid to the chairman of the audit committee and that fees of SEK 25,000 should be paid to each other member of the audit committee.

#### **Remuneration to the CEO and other senior executives**

Remuneration to senior executives consists of basic salary, variable remuneration, pension benefits, share related incentive programs and other benefits.

At the annual general meeting held on 23 November 2018, guidelines were adopted with the following main content. Ascelia Pharma shall offer remuneration levels and employment terms at market terms, aimed at facilitating the recruitment and retention of senior executives with high competence and capacity, in order to achieve established targets. The remuneration to the CEO and other senior executives can be comprised of fixed salary, variable remuneration, pension benefits, share-based incentive programs resolved by the shareholders' meeting and other benefits.

The fixed salary shall take into consideration the individual's competence, area of responsibility and performance. The variable remuneration is to be based on the outcome of predetermined well defined objectives. The variable consideration is to be limited and may not exceed 40 percent of the fixed annual salary for the CEO and 20 percent of the fixed annual salary for other senior executives, whereby the individual highest level should be based on factors such as the position held by the specific individual.

In addition to what follows from law or collective bargain agreements or other agreements, the CEO and other senior executives may be entitled to arrange individual pension schemes. Refrained salaries and variable remuneration can be used for increased pension contributions, provided that the total cost for the company is unchanged over time. Share-based incentive programs shall, where applicable, be resolved by the shareholders' meeting.

In case of termination of the CEO's employment by the company, the notice period should not exceed six months. In case the company terminates the CEO's employment, in addition to salary during the notice period, severance payment corresponding to up to six months base salary shall be permitted. The notice period for other senior executives shall not exceed six months. The employment agreements with senior executives may also include provisions regarding right for the senior executive to receive customary compensation for non-compete undertakings following the termination of the employment.

The board of directors shall be entitled to deviate from these guidelines in individual cases if there are special reasons for doing so.

#### *Share based incentive programs*

Ascelia Pharma has two active employee options programs that include members of the management team. If the terms of the programs are met at the time for utilisation, these employees have the right to purchase shares at a pre-determined price. In case all warrants issued in relation to the employee option programs are utilised for subscription of new shares, a total of 1,296,680 new shares will be issued (including hedge for social security charges). This corresponds to a total dilution effect of approximately 5.5% in relation to the total number of outstanding shares.

For additional information about the share-based incentive programs is found in note 4 in this Annual Report.

#### **Authorisation to the board of directors regarding new share issues**

At the annual general meeting held on 23 November 2018, it was resolved to authorise the board of directors to, at one or several occasions, during the time up until the next annual general meeting, with or without deviation from the shareholders' preferential rights, and with or without provisions regarding payment in kind or through set-off or other provisions, resolve to issue shares. The reason for that deviation from the shareholders' preferential rights should be permitted was to enable the company to raise working capital, to execute acquisitions of companies or operating assets, as well as to enable issues to institutional investors and the public in connection with a listing of the company. The total number of shares that can be issued could not exceed 18,000,000. The board of directors has utilised the authorisation for two new issues in which in the aggregate 8,882,017 shares were issued in connection with Ascelia Pharma's listing on Nasdaq Stockholm.

## **Internal Control**

### **Overview**

The overall purpose of the internal control is to ensure that the Ascelia Pharma's strategies and objectives can be implemented within the business and to ensure that the financial reporting has been prepared in accordance with applicable laws, accounting standards and other requirements imposed on listed companies. The board of directors' responsibility for the internal control is governed by the Swedish Companies Act, the Swedish Annual Reports' Act and the Code.

In the rules of procedure for the board of directors, the instructions for the CEO and the instructions for financial reporting, all of which have been adopted by the board of directors, the allocation of the roles and responsibilities have been stated to contribute to an effective management of the company's risks.

The board of directors has also established an audit committee whose tasks mainly include to monitor the effectiveness of the company's internal control, internal audit and risk management, to be informed about the audit of the annual report and consolidated financial statements, and to review and monitor the auditor's impartiality and independence. In addition to the abovementioned controls, the Ascelia Pharma has standard operating procedures that govern the control and quality of its drug development (including requirement to its partners participating in drug development).

With regards to risk assessments, these are carried out in connection with strategic planning and forecasting work and specific risk sessions are held to identify and quantify as well as evaluate and decide how the identified risks can be managed and, if possible, be eliminated. The presentation of the identified risks shall, as a minimum, be submitted to the board of directors once per year. Ascelia Pharma's most recent risk assessment session was held in June 2019. Within the board of directors, the Audit Committee is responsible for continuously assessing the company's risks.

#### **Control environment**

The board of directors bears the overall responsibility for internal control over financial reporting. To create and maintain a functioning control environment, the board of directors has adopted a number of policies governing financial reporting. These mainly comprise the rules of procedure for the board of directors, the instructions for the CEO and the instructions for financial reporting. The board of directors has also adopted a special set of signatory rules and a financial policy. Ascelia Pharma also has a manual containing principles, guidelines and process specifications for accounting and financial reporting.

The audit committee within the board of directors ensures that the approved principles for financial reporting and internal control are complied with and that regular contact with the company's auditor is maintained. The responsibility for maintaining an effective control environment and for the day-to-day work on internal control over financial reporting rests with the CEO with assistance from the CFO. The CEO and CFO reports to the board of directors on a regular basis in accordance with the instruction to the CEO and the terms of reference for financial reporting. The board of directors also receives reports from the company's auditor. Based on Ascelia Pharma's current size and operations, the board of directors has decided not to set up a separate internal audit function.

#### **Risk assessment**

Ascelia Pharma's management has regular discussions to identify and evaluate the risks arising in the company's operations and to assess how these risks can be managed. Once a year, these risks are presented to the board of directors in a risk session accompanied by a risk assessment memo, which include a heat map quantifying the impact and likelihood of identified risks. The risk assessment work also includes identification of risks that may impact the basic requirements for

the financial reporting of the company. The risk assessment results in a number of control targets supporting the basic requirements for financial reporting. These control targets aim to ensure that Ascelia Pharma meets its objectives for financial reporting. The financial reporting shall be correct and complete, and meet all applicable laws, rules and recommendations, provide a fair description of the company's business and support a rational and informed valuation of the business. In addition to these three objectives, internal financial reporting shall support proper business decision-making at all levels.

#### **Control activities**

Control activities limit the identified risks and ensure correct and reliable financial reporting. The CFO plays a key role in analysing and following up the Group's financial reporting and results. There are functions for the analysis and follow-up of the financial reporting of the Group and subsidiaries. Control activities also comprise a review and follow-up of Ascelia Pharma's governing documents relating to risk management and analysing complex transactions or valuation of assets or liabilities encompassing a significant element of judgement.

The board of directors is responsible for internal control and monitoring of the company's management. This is done primarily by examining the company's steering documents and identified risk factors.

#### **Information and communication**

Ascelia Pharma has information and communication channels intended to promote the accuracy of financial reporting and to facilitate reporting and feedback from operations to the board of directors and the management, for example by making corporate governance documents such as internal policies, guidelines and instructions regarding the financial reporting available and known for employees. The board of directors has also adopted an information policy that governs Ascelia Pharma's provision of information.

#### **Monitoring**

The compliance and effectiveness of internal controls are monitored regularly. The CEO ensures that the board of directors receives continuous reports on the development of Ascelia Pharma's activities, including the development of Ascelia Pharma's results and financial position, and information about important events, such as operational events of the drug development and major agreements and contracts. The CEO also reports on these issues at each board meeting. The audit committee supports the board of directors by preparing activities that assure the quality of the company's financial reporting. This is partly achieved by the audit committee checking the financial information and the Ascelia Pharma's financial controls. The Board considers that the internal controls are effective in all material respects and, on back of this, has deemed that there is no need

to establish a special internal audit function.

### **External auditor**

Ascelia Pharma's auditor is appointed by the annual general meeting for the period until the end of the next annual general meeting. The auditor examines the annual report and accounts as well as the management performed by the board of directors and the CEO. Following each financial year, the auditor shall submit an audit report to the annual general meeting. The company's auditor reports its observations from the audit and its assessment of the company's internal control to the board of directors.

At the Annual General Meeting held on 23 November 2018, Öhrlings PricewaterhouseCoopers AB (PwC) was re-elected as the company's auditor with Carl Fogelberg being the certified public accountant in charge of the audit. PwC audits Ascelia Pharma AB (publ) and all subsidiaries.

At the annual general meeting, it was also resolved that the fees to the auditor should be paid in accordance with normal charging standards and approved invoice. Further information about fees to the auditor can be found in note 6.

# BOARD OF DIRECTORS



## **Peter Benson**

*Born 1955. Chairman of the board of directors since 2017. Member of Audit Committee*

### **Professional background**

Peter Benson is Chairman and General Partner of Sunstone

Capital Life Science Ventures and chairman of Alligator Bioscience AB, which is listed on Nasdaq Stockholm. Peter Benson has extensive experience from the Life Science sector as an investor, board member and executive positions, including several listed companies. Peter Benson was vice chairman of Zealand Pharma during its IPO and has previously inter alia been Head of Life Science Ventures at Vækstfonden (the Danish Growth Fund), President of Hospital Care and Senior Vice President at Pharmacia as well as Executive Vice President Marketing & Sales at Kabi Pharmacia Parenterals.

### **Education**

Graduate in business administration from Lund University, Sweden. MA in Economics from the University of California, US.

### **Other ongoing assignments**

Chairman of Alligator Bioscience AB (publ), Ascelia Incentive AB, Good Partners Media Group AB and Sunstone LSV Partners Holding ApS. Board member Arcoma Aktiebolag, CMC SPV of 3 April 2017 AB, Jollingham AB, Montela Aktiebolag, and Sunstone Capital A/S (and subsidiaries within the Sunstone Capital A/S sphere). Deputy board member of JellyBean Aktiebolag.

### **Holdings in Ascelia Pharma**

-

### **Independence**

Independent in relation to the company and its management, but not in relation to major shareholders. Managing Partner of Sunstone Life Science Venture A/S and board member of CMC SPV of 3 April 2017 AB



## **Bo Jesper Hansen**

*Born 1958. Member of the board of directors since 2010. Chairman of Remuneration Committee*

### **Professional background**

Bo Jesper Hansen has extensive experience from orphan drug research

and development, international marketing and business development. Bo Jesper Hansen is and has previously been chairman and member of the board of directors in a number of biotech and pharma companies, including executive chairman of Swedish Orphan Biovitrum AB (publ), Topotarget A/S (publ) and Karolinska Development AB (publ) and chairman of Ablynx nv (publ).

### **Education**

M.D. and Ph.D. from University of Copenhagen, Denmark.

### **Other ongoing assignments**

Chairman of Karo Pharma AB, Innoventa Medica ApS, Karo Pharma and Laborie Inc. Board member of Azanta A/S and vice-chairman of Orphazyme ApS.

### **Holdings in Ascelia Pharma**

250,164 shares in Ascelia Pharma AB. Bo Jesper Hansen also holds approximately 4 per cent of the shares in CMC SPV of 3 April 2017 AB that holds 2,937,606 shares in Ascelia Pharma AB.

### **Independence**

Independent in relation to the company and its management, and in relation to major shareholders. Shareholder in CMC SPV of 3 April 2017 AB.



## **Hans Maier**

*Born 1955. Member of the board of directors since 2017.*

### **Professional background**

Hans Maier has held senior positions within Schering AG and Bayer

AG in Europe and Asia, inter alia as Managing Director in Korea and in Japan, Head of Corporate Strategy and Business Development of Schering AG and Head of the Global Business Unit Diagnostic Imaging in both Schering AG and Bayer AG. Hans Maier is a member of several supervisory and advisory boards, including the German Heart Center Berlin (President of the Board of Trustees) and the Fraunhofer MEVIS Institute for Digital Medicine (Chairman of the Advisory Board).

### **Education**

Ph.D. in Economics and Social Sciences and Degree in Political Science from Freie Universität Berlin, Germany.

### **Other ongoing assignments**

Board member of Deutsches Herzzentrum Berlin and Fraunhofer Institute for Medical Image Computing MEVIS. Co-Founder and Managing Partner of BGM Associates GmbH.

### **Holdings in Ascelia Pharma**

20,000 shares in Ascelia Pharma AB.

### **Independence**

Not independent in relation to the company and its management, but independent in relation to major shareholders.

# BOARD OF DIRECTORS



## Niels Mengel

Born 1948. Member of the board of directors since 2000. Member of Audit Committee

### Professional background

Niels Mengel is Founding Partner, board member and CEO of Øresund-Healthcare Capital. Niels

Mengel has extensive experience from the healthcare industry as an investor. Niels Mengel has previously inter alia been Executive Vice President at ISS World Services A/S and Director at PA Consulting Group.

### Education

M.B.A. from London Business School, England. M.Sc. in Macro Economy and Finance from University of Copenhagen, Denmark.

### Other ongoing assignments

Board member of Dansk Aktionærforening. Board member of Better Finance (The European Federation of Investors and Financial Services Users), Black Swan Strategy A/S and Upstream Invest A/S. Board member and managing partner of Øresund-Healthcare Management A/S. Limited partner of Øresund-Healthcare Capital K/S. Partner of ØHM Exit I I/S and ØHM Exit II I/S. Member of management (executive) in Kibegeon ApS.

### Holdings in Ascelia Pharma

15,300 shares in Ascelia Pharma AB. Niels Mengel, has also directly and indirectly, invested in Øresund-Healthcare Capital K/S that holds (i) 2,020,490 shares in Ascelia Pharma AB and (ii) approximately 5 per cent of the shares in CMC SPV of 3 April 2017 AB that holds 2,937,606 shares in Ascelia Pharma AB. Through the agreements governing Niels Mengel's investments in Øresund-Healthcare Capital K/S, Niels Mengel has a financial interest corresponding to (a) approximately 50 per cent of the shares in Ascelia Pharma AB held by Øresund-Healthcare Capital K/S and (b) 100 per cent of the shares in CMC SPV of 3 April 2017 AB held by Øresund-Healthcare Capital K/S.

### Independence

Independent in relation to the company and management, but not in relation to major shareholders. Founding partner of Øresund-Healthcare Capital K/S.



## René Spogård

Born 1954. Member of the board of directors since 2017. Member of Remuneration Committee

### Professional background

René Spogård is chairman and investor in a number of companies incl. JEKA Fish A/S, Bollerup Jensen A/S

and Flex Funding A/S. René Spogård has extensive experience from investing in the healthcare sector and board positions in a public environment. René Spogård has previously inter alia been owner and Managing Director at TNS Gallup A/S and Director at TNS plc (listed on London Stock Exchange).

### Education

H.D. in Marketing from Copenhagen Business School, Denmark.

### Other ongoing assignments

Chairman of Ambrox Property Invest III A/S, Bollerup Jensen A/S, Bollerup Jensen Adhesives ApS, Bollerup Jensen Water Holding ApS, CMC SPV of 3 April 2017 AB, Cimbric A/S, Deltaq Portefølje Holding 104 ApS, Deltaq Portefølje Holding II ApS, Deltaq Portefølje Holding IV ApS, Deltaq Portefølje Holding VI ApS, Flex Funding A/S, Jeka Fish A/S, Jeka Fish Holding ApS, Jeka Fish Holding 2 ApS, Jysk Industri Holding A/S and Preservation Technologies I/S. Deputy chairman of Nordisk Krabbe Kompagni A/S. Board member of Ambrox Capital A/S, Ambrox Korsør A/S, Bollerup Jensen Adhesives Holding ApS, Bollerup Jensen Water ApS, Bollerup Jensen Wood ApS and Flex Funding Fintech ApS. Member of management (executive) and partner of Dadephi ApS, René Spogårds amilleanpartsselskab, Spogård Holding ApS, Spogård Invest ApS and Spogård Invest 3 ApS.

### Holdings in Ascelia Pharma

454,418 shares in Ascelia Pharma AB indirectly through company. René Spogård also indirectly holds approximately 24 per cent of the shares in CMC SPV of 3 April 2017 AB that holds 2,937,606 shares in Ascelia Pharma AB.

### Independence

Independent in relation to the company and its management, but not in relation to major shareholders. Shareholder in and chairman of the board of directors of CMC SPV of 3 April 2017 AB.



## Helena Wennerström

Born 1965. Member of the board of directors since 2017. Chairman of Audit Committee

### Professional background

Helena Wennerström has been Executive Vice President of Bulten AB (publ) since 2014 and has been

its Chief Financial Officer since 2006. Helena Wennerström's work within Bulten AB also includes the Investor Relations and Communications activities and IT. Helena Wennerström has earlier served finance roles at Digitalfabriken and Topcon.

### Education

Master of Science in Business Administration and Economics from Örebro University.

### Other ongoing assignments

Chairman of Bulten Fasteners AB. Board member of Bulten Fasteners Tianjin Co. LTD, Bulten Hallstahammar AB, Bulten North America LLC, Bulten Polska S.A., Bulten Sweden AB, Bulten Fasteners (China) Co Ltd., and BBB Services Ltd. Deputy board member of Bulten Industrifastighet AB, Finnveden Micro Fasteners AB and Finnveden Trading Aktiebolag. Deputy Managing Director of Bulten AB.

### Holdings in Ascelia Pharma

8,000 shares in Ascelia Pharma AB.

### Independence

Independent in relation to the company and its management, and in relation to major shareholders.

# MANAGEMENT



## **Magnus Corfitzen**

*Born 1975. Chief Executive Officer since 2014.*

### **Professional background**

Magnus Corfitzen has extensive experience from investing, building and growing Life Science companies in various roles including operational activities or investment respon-

sibilities for public and private biotech and medtech companies. Magnus Corfitzen also has board experience from a number of Life Science companies. Magnus Corfitzen has previously inter alia been Investment Director at Sunstone Capital A/S and Investment Director at Vækstfonden (the Danish Growth Fund). Prior to entering the healthcare venture capital field he was a Portfolio Manager at Danske Capital with responsibility for investments into listed biotech and medtech companies and he started his career at McKinsey & Company.

### **Education**

M.Sc. in Mathematical Economics from the University of Aarhus, Denmark, which included studies at Harvard University, US.

### **Other ongoing assignments**

Board member of Ascelia Incentive AB. CEO of Oncoral Pharma ApS.

### **Holdings in Ascelia**

27,180 shares and 458,856 employee stock options in Ascelia Pharma AB. Magnus Corfitzen also holds approximately 2 per cent of the shares in CMC SPV of 3 April 2017 AB that holds 2,937,606 shares in Ascelia Pharma A



## **Carl Bjartmar**

*Born 1963. Chief Medical Officer since 2018.*

### **Professional background**

Carl Bjartmar has a long and solid track record in late-stage orphan drug development. He has previously served in senior roles at large international pharma companies such

as Lundbeck, Sanofi and Genzyme, where he gained extensive experience in clinical development, in particular the development of novel therapies for rare diseases. Carl was most recently before joining Ascelia, Chief Medical Officer for the Swedish biotech company Wilson Therapeutics.

### **Education**

M.D. and Ph.D. from the University of Linköping.

### **Other ongoing assignments**

-

### **Holdings in Ascelia**

17,000 shares and 153,059 employee stock options in Ascelia Pharma A



## **Kristian Borbos**

*Born 1978. Chief Financial Officer since 2017.*

### **Professional background**

Kristian Borbos has extensive banking and finance experience from large listed companies as Sell-side Analyst and other advisory roles in banking to various financial positions

in large corporates including treasury, financial reporting and planning and IR activities. Kristian Borbos has previously inter alia been Business Finance Manager at Novozymes, Lead Investor Relations Manager at DONG Energy and senior analyst at Danske Bank and Danske Markets.

### **Education**

M.Sc. in Business Administration from Lund University, Sweden.

### **Other ongoing assignments**

Deputy board member of Ascelia Incentive AB.

### **Holdings in Ascelia**

3,400 shares and 153,059 employee stock options in Ascelia Pharma AB

# MANAGEMENT



**Dorthe da Graça Thrige**  
*Born 1967. Chief Operating Officer since 2014.*

#### **Professional background**

Dorthe da Graça Thrige has extensive experience in R&D and executive management at leading Swedish and Danish biotech and pharma companies such as Pharmacia,

AstraZeneca and Active Biotech. Dorthe da Graça Thrige has previous experience from inter alia various positions at Active Biotech AB, including Director of Development, Head of Project Management and Head of Drug Discovery and Research Scientist at AstraZeneca.

#### **Education**

M.Sc. in Pharmaceutical Sciences and Ph.D. in Structural Medicinal Chemistry from University of Copenhagen, Denmark.

#### **Other ongoing assignments**

-

#### **Holdings in Ascelia Pharma**

15,530 shares and 152,898 employee stock options in Ascelia Pharma AB. Dorthe da Graça Thrige also holds approximately 1 per cent of the shares in CMC SPV of 3 April 2017 AB that holds 2,937,606 shares in Ascelia.



**Mikael Widell**  
*Born 1958. Head of IR & Communication since 2018.*

#### **Professional background**

Mikael Widell has more than 30 years' experience within communications, including journalism with 14 years within financial media, e.g. Dagens Industri, and has had different positions within in-house corporate communications, e.g. AstraZeneca,

Biovitrum (Sobi) and Nordic Capital as well as strategic work as a communications advisor within financial PR and IR. Mikael is a partner and co-founder of the IR/PR firm Cord Communications and is Head of Communication & IR at the main market listed company Calliditas Therapeutics.

#### **Education**

M.A. in English from Lund University and studies in Economics at Lund University.

#### **Other ongoing assignments**

Board member of CordCom Consultants AB. General partner of WZ Kommunikation Kommanditbolag.

#### **Holdings in Ascelia Pharma**

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# Consolidated Income Statement

SEK in thousand (unless otherwise stated)*	Note	FY	
		2018/2019	2017/2018
Net sales		-	-
<b>Gross profit/loss</b>		-	-
Other operating income		203	1,062
Administrative costs	4-6	-14,406	-16,366
Research and development costs	4-5	-22,923	-9,367
Other operating costs	5	-265	-42
<b>Operating result</b>		<b>-37,392</b>	<b>-24,713</b>
Financial income	7	76	10
Financial costs	7	-236	-39
<b>Net financial items</b>		<b>-160</b>	<b>-30</b>
<b>Loss before tax</b>		<b>-37,552</b>	<b>-24,743</b>
Tax	8	417	351
<b>Loss for the period</b>		<b>-37,134</b>	<b>-24,392</b>
Attributable to:			
Owners of the Parent Company		-37,134	-24,392
Non-controlling interest		-	-
Earnings per share	9		
Before and after dilution (SEK)		-2.16	-2.12

# Consolidated Statement of Comprehensive Income

SEK in thousand*	Note	FY	
		2018/2019	2017/2018
<b>Loss for the period</b>		<b>-37,134</b>	<b>-24,392</b>
<b>Other comprehensive income</b>			
Currency translation of subsidiaries**		15	54
<b>Other comprehensive income for the period</b>		<b>15</b>	<b>54</b>
<b>Total comprehensive income for the period</b>		<b>-37,119</b>	<b>-24,338</b>

\* Some figures are rounded, so amounts might not always appear to match when added up.

\*\* Will be classified to profit and loss when specific conditions are met

# Consolidated Balance Sheet

SEK in thousand*	Note	30 Jun 2019	30 Jun 2018
<b>ASSETS</b>			
Intangible assets	10	57,067	57,066
Tangible assets	11	275	-
Financial investments		-	1
<b>Total non-current assets</b>		<b>57,342</b>	<b>57,067</b>
Income tax receivables		765	507
Prepaid expenses and accrued income	13	3,358	2,955
Other receivables	12	906	557
Marketable securities	15	75,076	-
Cash and cash equivalents	14	149,972	55,063
<b>Total current assets</b>		<b>230,078</b>	<b>59,082</b>
<b>Total assets</b>		<b>287,420</b>	<b>116,149</b>
<b>EQUITY</b>			
Share capital	16	23,489	14,607
Other paid-in capital		405,061	213,700
Loss brought forward		-152,475	-116,577
<b>Equity attributable to Parent Company shareholders</b>		<b>276,075</b>	<b>111,730</b>
<b>Total equity</b>		<b>276,075</b>	<b>111,730</b>
<b>LIABILITIES</b>			
Leasing	20	146	-
<b>Total long-term liabilities</b>		<b>146</b>	<b>-</b>
Trade payables		4,267	634
Other liabilities	17	2,140	880
Accrued expenses and deferred income	18	4,793	2,905
<b>Total current liabilities</b>		<b>11,199</b>	<b>4,419</b>
<b>Total liabilities</b>		<b>11,345</b>	<b>4,419</b>
<b>Total equity and liabilities</b>		<b>287,420</b>	<b>116,149</b>

\* Some figures are rounded, so amounts might not always appear to match when added up.

# Consolidated Statements of Changes in Equity

SEK in thousand*	Note	FY (Jul-Jun)	
		2018/2019	2017/2018
<b>Equity at start of the period</b>		<b>111,730</b>	<b>77,601</b>
<b>Comprehensive income</b>			
Profit/loss for the period		-37,134	-24,240
Other comprehensive income		15	54
<b>Total comprehensive income</b>		<b>-37,119</b>	<b>-24,186</b>
<b>Transactions with shareholders</b>			
New share issue with cash contribution	16	222,050	60,436
Issuance expenses	16	-21,807	-6,044
Share based remuneration to employees	4	1,221	3,922
<b>Total transactions with shareholders</b>		<b>201,464</b>	<b>58,314</b>
<b>Equity at end of the period</b>		<b>276,075</b>	<b>111,730</b>

\* Some figures are rounded, so amounts might not always appear to match when added up.

# Consolidated Cash Flow Statement

SEK in thousand*	Note	FY	
		2018/2019	2017/2018
		<b>Jul-Jun</b>	
<b>Operating activities</b>			
Loss before tax		-37,552	-24,743
Expensed share based remuneration	4	2,258	4,454
Adjustment for items not included in cash flow		-710	692
Income tax paid		-	-
<b>Cash flow from operating activities before changes in working capital</b>		<b>-36,003</b>	<b>-19,597</b>
<b>Cash flow from changes in working capital</b>			
Increase (-)/Decrease (+) of operating receivables		-2,205	-1,225
Increase (+)/Decrease (-) of trade payables		3,813	-46
Increase (+)/Decrease (-) of other liabilities		4,062	-90
Change in working capital		5,670	-1,360
<b>Cash flow used in operating activities</b>		<b>-30,333</b>	<b>-20,958</b>
<b>Investing activities</b>			
Investment in marketable securities	15	-75,000	-
<b>Cash flow from investing activities</b>		<b>-75,000</b>	<b>-</b>
<b>Financing activities</b>			
Issuance proceeds	16	222,050	80,436
Issuance costs	16	-21,807	-6,044
<b>Cash flow from financing activities</b>		<b>200,243</b>	<b>74,393</b>
<b>Cash flow for the period</b>		<b>94,909</b>	<b>53,435</b>
Cash flow for the period		94,909	53,435
Cash and cash equivalents at start of period		55,063	1,627
<b>Cash and cash equivalents at end of period</b>	14	<b>149,972</b>	<b>55,063</b>

\* Some figures are rounded, so amounts might not always appear to match when added up.

## Parent Company – Income Statement

	Note	FY	
		2018/2019	2017/2018
SEK in thousand*			
Net sales		194	-
<b>Gross profit/loss</b>		<b>194</b>	<b>-</b>
Administrative costs	4-6	-14,162	-16,311
Research and development costs	4-5	-21,045	-7,448
Other operating income		203	640
Other operating costs	5	-265	-42
<b>Operating result</b>		<b>-35,076</b>	<b>-23,162</b>
<b>Net financial items</b>			
Other interest income and similar profit	7	377	60
Interest costs and similar Profit/loss items	7	-311	-39
<b>Loss after financial items</b>		<b>-35,010</b>	<b>-23,140</b>
Group contribution		-50	-
Tax	8	-	-
<b>Loss for the period</b>		<b>-35,060</b>	<b>-23,140</b>

## Parent Company – Statement of Comprehensive Income

	Note	FY	
		2018/2019	2017/2018
SEK in thousand*			
<b>Loss for the period</b>		<b>-35,060</b>	<b>-23,140</b>
Other comprehensive income		-	-
<b>Other comprehensive income for the period</b>		<b>-</b>	<b>-</b>
<b>Total comprehensive income for the period</b>		<b>-35,060</b>	<b>-23,140</b>

\* Some figures are rounded, so amounts might not always appear to match when added up.

# Parent Company – Balance Sheet

SEK in thousand*	Note	30 Jun 2019	30 Jun 2018
<b>ASSETS</b>			
<b>Non-current assets</b>			
Tangible assets	11	275	-
Financial assets			
Participations in Group companies	10	58,068	58,068
Other securities held as non-current assets		-	1
Other long-term receivables	12	3,395	1,958
<b>Total non-current assets</b>		<b>61,738</b>	<b>60,027</b>
<b>Current assets</b>			
Other receivables	12	1,211	237
Prepaid expenses and accrued income	13	3,358	2,985
<b>Total current receivables</b>		<b>4,569</b>	<b>3,222</b>
Marketable securities	15	75,076	-
Cash and bank balances	14	148,743	53,792
<b>Total current assets</b>		<b>228,389</b>	<b>57,014</b>
<b>Total assets</b>		<b>290,126</b>	<b>117,040</b>
<b>EQUITY</b>			
Restricted equity	16		
Share capital		23,489	14,607
Non-restricted equity			
Share premium reserve		405,061	213,700
Loss brought forward		-114,311	-92,391
Loss for the period		-35,060	-23,140
<b>Total equity</b>		<b>279,179</b>	<b>112,775</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Leasing	20	146	-
<b>Total non-current liabilities</b>		<b>146</b>	<b>-</b>
<b>Current liabilities</b>			
Trade payables		3,847	486
Other liabilities	17	2,140	880
Accrued expenses and deferred income	18	4,814	2,899
<b>Total current liabilities</b>		<b>10,801</b>	<b>4,265</b>
<b>Total equity and liabilities</b>		<b>290,126</b>	<b>117,040</b>

\* Some figures are rounded, so amounts might not always appear to match when added up.

## Parent Company – Statements of Changes in Equity

SEK in thousand*	Note	FY (Jul-Jun)	
		30 Jun 2019	30 Jun 2018
<b>TSEK</b>			
<b>Equity at start of the period</b>		<b>112,775</b>	<b>77,601</b>
<b>Comprehensive income</b>			
Profit/loss for the period		-35,060	-23,140
Other comprehensive income		-	-
<b>Total comprehensive income</b>		<b>-35,060</b>	<b>-23,140</b>
<b>Transactions with shareholders</b>			
New share issue with cash contribution	16	222,050	60,436
Issuance costs	16	-21,807	-6,044
Share based remuneration to employees	4	1,221	3,922
<b>Total transactions with shareholders</b>		<b>201,464</b>	<b>58,314</b>
<b>Equity at end of the period</b>		<b>279,179</b>	<b>112,775</b>

\* Some figures are rounded, so amounts might not always appear to match when added up.

# Parent Company – Cash Flow Statement

SEK in thousand*	Note	FY 2018/2019	FY 2017/2018
<b>Operating activities</b>			
Loss before tax		-35,010	-23,140
Expensed share based remuneration	4	-	4,454
Adjustment for items not included in cash flow		1,277	674
Income tax paid		-	-
<b>Cash flow before changes in working capital</b>		<b>-33,733</b>	<b>-18,012</b>
<b>Cash flow from changes in working capital</b>			
Increase (-)/Decrease (+) of operating receivables		-2,511	-1,287
Increase (+)/Decrease (-) of trade payables		3,361	-54
Increase (+)/Decrease (-) of other liabilities		3,997	65
<b>Cash flow used in operating activities</b>		<b>-28,886</b>	<b>-19,288</b>
<b>Investing activities</b>			
Acquisition of subsidiary		-	-50
Intercompany loans	12	-1,405	-1,958
Investment in financial assets	15	-75,000	-
<b>Cash flow from investing activities</b>		<b>-76,405</b>	<b>-2,008</b>
<b>Financing activities</b>			
Issuance proceeds	16	222,050	80,436
Issuance costs	16	-21,807	-6,004
<b>Cash flow from financing activities</b>		<b>200,243</b>	<b>74,393</b>
Cash flow for the period		94,952	53,097
Cash and cash equivalents at the beginning of the period		53,792	695
<b>Cash and cash equivalents at the end of the period</b>	14	<b>148,743</b>	<b>53,792</b>

\* Some figures are rounded, so amounts might not always appear to match when added up.

# NOTES

## NOTE 1 GENERAL INFORMATION

Ascelia Pharma AB (publ) with corporate identity number 556571-8797 and its subsidiaries (jointly the Group) develop drugs within oncology. The Parent Company conducts operations in the legal form of a limited liability company, with its registered office in Malmö, Sweden. The company's postal address is Per Albin Hanssons väg 41, SE-205 12 Malmö, Sweden. The Group's financial year runs from 1 July to 30 June. The company's shares are since 13 March 2019 listed on Nasdaq Stockholm.

This annual report and the consolidated financial statements were approved for publication by the Board on 10 October 2019 and will be presented to the Annual General Meeting of shareholders on 14 November 2019.

## NOTE 2 SIGNIFICANT ACCOUNTING PRINCIPLES

The most important accounting policies for the preparation of this year's consolidated financial statements are found below.

### (a) Statement of compliance with legislation and accounting standards

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) adopted by the EU. In addition, the recommendation RFR 1 Supplementary Accounting Rules for Groups, issued by the Swedish Financial Reporting Board, has been applied. The parent company has applied the same accounting policies as those applied in the consolidated financial statements except as set out below in the section *Parent company's accounting principles*.

### (b) Valuation criteria applied in preparation of financial statements

Assets and liabilities are measured at their historical cost.

### (c) Functional currency and presentation currency

The parent company's functional currency is Swedish kronor (SEK), which is also the presentation currency of the parent company and the Group. Accordingly, the financial statements are presented in SEK. All amounts, unless otherwise stated, are rounded up to the nearest thousand.

### (d) Accounting estimates and judgements in the financial statements

Preparing the financial statements in accordance with IFRS requires that the management team make accounting estimates and judgements as well as assumptions that influence the application of the accounting principles and the carrying amounts of assets, liabilities, revenue, and expenses. Actual outcomes may differ from these estimates and judgements. The estimates and judgements are regularly reviewed. Changes in estimates are reported in the period in which the change is made if the change affects only that period, or in the period in which the change is made and future periods if the change affects both the current and future periods. Judgements made by the management team in the application of IFRS Standards that have a significant impact on the financial statements and estimates may also entail significant adjustments in the financial statements of subsequent years. These are described in further detail in note 25.

### (e) New IFRS standards implemented in fiscal year 2018/2019

*IFRS 9 Financial Instruments* has replaced *IAS 39 Financial instruments: Recognition and Measurement* as of January 1, 2018. Ascelia Pharma has applied IFRS 9 in this financial year starting on 1 July 2018. IFRS 9 involves changes in how financial assets are classified and measured and introduces an impairment model based on expected credit losses instead of actual losses and changes in principles for hedge accounting for the purpose, among other things, of simplifying and increasing concordance with a company's internal risk management strategies. Ascelia Pharma does not consider IFRS 9 to have any significant effect on the consolidated financial statements given the Group's current very limited exposure to credit risk as well as absence of financial derivatives.

As of January 1, 2018, IFRS 15 *Revenue from Contracts with Customers* has replaced previous IFRS related to revenue recognitions, such as IAS 18 *Revenue*, IAS 11 *Construction Contracts* and IFRIC 13 *Customer Loyalty Programs*. Ascelia Pharma has applied IFRS 15 in this financial year starting on 1 July 2018. As the Group currently does not have revenue from contracts with customers, the standard does not presently impact the Group.

As of January 1, 2019, IFRS 16 *Leases* has replaced previous IFRS standards related to leases, such as IAS 17 *Leases* and IFRIC 4 *Determining Whether an Arrangement Contains a Lease*. Ascelia Pharma has decided to early implement IFRS 16 rules on leases in this financial year starting on 1 July 2018. IFRS 16 mainly affects leases, and the principal effect is that all leases recognised as operating leases are recognised in a manner that resembles the way finance leases are recognised. This means that assets and liabilities are recognised for operating leases with the relevant reporting of depreciation and interest costs. The financial impact on Ascelia Pharma is relatively limited as the operating leasing contracts are few and short at limited amount (only car leasing).

### (f) Classification

Non-current assets comprise amounts that are expected to be recovered or paid more than 12 months after the balance sheet date, whereas current assets comprise amounts expected to be recovered or paid within 12 months from the balance sheet date. Non-current liabilities comprise amounts that Ascelia Pharma, as per the end of the reporting period, has an unconditional right to decide to pay later than 12 months after the end of the reporting period. If there is no such right at the end of the reporting period or if there is a liability for trading or if a liability is expected to be settled within the normal business cycle – the liability amount is recognised as a current liability.

### (g) Operating segment reporting

An operating segment is a part of the Group that conducts business operations from which it generates revenue and incurs expenses and for which independent financial information is available. Furthermore, the Company's chief operating decision maker monitors the earnings of an operating segment in order to evaluate performance and allocate resources to the operating segment. Ascelia Pharma has identified one operating segment, which is the Group in its entirety. This assessment is based on that the Group's chief decision maker, who is the CEO, monitors the Group in its entirety. The financial statements are based on a Group-wide functional organisational and management structure.

Note 2, cont.

#### **(h) Basis of consolidation and business combination**

##### **(i) Subsidiaries**

Subsidiaries are entities over which Ascelia Pharma AB has a controlling influence. Controlling influence exists if Ascelia Pharma AB has power over the investee, is exposed to or is entitled to variable return from its involvement and can, through its influence over the investment, affect returns. When assessing whether controlling influences exist, potential voting rights are considered as well as whether there is de facto control.

Subsidiaries are reported in accordance with the acquisition method. Under this method, an acquisition of a subsidiary is treated as a transaction in which the Group indirectly acquires the assets and assumes the liabilities. The purchase price allocation determines the fair value of the acquired identifiable assets and assumed liabilities, as well as any non-controlling interests, on the acquisition date. Transaction fees that arise, with the exception of transaction fees attributable to equity instruments on issue or debt instruments, are recognized directly through the Income Statement. In the event of an acquisition of a subsidiary in which the transferred payment comprises own share, the payment's value in the purchase price allocation is based on the actual share value at the time of the acquisition.

##### **(ii) Asset purchases**

When acquisitions of subsidiaries involve the acquisition of net assets that do not comprise operations, the acquisition cost of each identifiable asset and liability is allocated up based on its fair value at the time of acquisition. Transaction costs are added to the purchase price of the acquired net assets. When the consideration is paid by own shares the acquired assets and liabilities are measured at fair value based on the acquired assets and liabilities at the time of the acquisition, provided that the fair value of the acquired assets and liabilities (in rare cases) cannot be reliably estimated. In the latter case the acquired net assets are measured based on the fair value of the own shares.

##### **(iii) Transactions that are eliminated upon consolidation**

Intra-group receivables and liabilities, income or expenses, and unrealized profits or losses that arise from intra-group transactions between companies within the Group are eliminated entirely when preparing the consolidated accounts. Unrealized losses are eliminated in the same way as unrealized profits but only to the extent that there is no impairment requirement.

#### **(i) Foreign currency**

##### **(i) Foreign currency transactions**

Transactions in foreign currencies are translated into the functional currency at the exchange rate prevailing at the date of the transaction. The functional currency is the currency of the primary economic environment in which the Company operates. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are translated to the functional currency at the exchange rate prevailing at the balance sheet date. Foreign exchange differences arising on translation are recognized in the Income Statement. Non-monetary assets and liabilities measured in terms of historical cost in a foreign currency are translated using the exchange rate prevailing at the date of the transaction. Non-monetary assets and liabilities that are measured at fair value are retranslated to the functional currency at the exchange rate prevailing at the date that the fair value was determined.

##### **(ii) Financial statements of foreign operations**

The assets and liabilities of foreign operations, including goodwill and other consolidated surplus and deficit values, are translated from the foreign operation's functional currency to the Group's presentation currency, SEK, at the existing exchange rate at the balance sheet date. Income and expenses of foreign operations are translated to SEK using an average rate that is an approximation of the exchange rate prevailing at each individual transaction date.

Translation differences that arise in currency translations of foreign operations are recognized in other comprehensive income and accrued in a separate component in equity – the translation reserve. When control of a foreign operation ceases, the accumulated translation differences attributable to the operation are realized, at which point they are reclassified in equity to profit/loss for the year. In the case of a sale where the controlling interest still exists, a proportional share of the cumulative translation differences is transferred from the translation reserve to non-controlling interests.

##### **(j) Leasing**

As a lessee, the Group has only operating lease contracts. Costs pertaining to operating lease contracts are recognized in the Income Statement on a straight-line basis over the period of the lease. Benefits obtained in connection with the signing of a lease are recognized in the Income Statement as a reduction in the leasing fees on a straight-line basis over the term of the lease. Variable

charges are recognized as an expense in the period that they are incurred.

##### **(k) Financial income and expense**

Financial income consists of interest income on invested funds as well as exchange differences for monetary items. Interest revenues from financial instruments are recognized according to the effective interest method (see below). Dividend income is recognized when the right to receive dividends is established at an annual meeting of shareholders. The profit/loss from the disposal of a financial instrument is recognized once the risks and rewards that are linked to owning the instrument are transferred to the buyer and the Group no longer has control of the instrument. Financial expense consists of interest expense for operating liabilities as well as exchange differences. Exchange gains and exchange losses are offset, and the net amount is recognized. Effective interest is the rate that discounts the estimated future receipts and payments during a financial instrument's expected duration at the financial asset's or liability's recognized net value. The calculation includes all fees that are paid or received by the parties to the contract that are part of the effective interest, transaction expenses, and all premiums and discounts.

##### **(l) Taxes**

Income tax consists of current tax and deferred tax. Income tax is reported in the Income Statement except for when underlying transactions are recognized in other comprehensive income or in equity, in which case the associated tax effect is reported in other comprehensive income or in equity. Current tax is tax that must be paid or received for the current year in application of the tax rates that are enacted or substantially enacted as at the balance sheet date. Current tax also includes adjustment of the current tax attributable to previous periods.

Deferred tax is calculated according to the balance sheet method based on temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Temporary differences do not take into account Group-related goodwill or the difference that arose at initial recognition of assets and liabilities that is not a business combination, which at the time of the transaction do not affect the reported or taxable results, such as in connection with asset purchases. In addition, temporary differences attributable to participations in subsidiaries that are not expected to be reversed within the foreseeable future are also

Note 2, cont.

not taken into account. The valuation of deferred tax is based on how underlying assets and liabilities are expected to be recovered or settled. Deferred tax is calculated by applying the tax rates and tax rules enacted or substantially enacted as at the balance sheet date. Deferred tax receivable relating to deductible temporary differences and loss carry-forwards are recognized only to the extent that it is probable that they will be utilized. The value of the deferred tax receivable is reduced when it is no longer probable that it can be used. When participating interests in subsidiaries are acquired – asset purchases – no separate deferred tax is recognized at the time of acquisition; instead the asset is recognized at cost, which corresponds to the fair value of the asset. After the date of the acquisition, deferred tax is recognized only for the change in carrying amount and changes in the amount used for taxation purposes that rise after the time of acquisition.

#### **(m) Financial instruments**

Financial instruments recognized on the assets side of the balance sheet include cash and cash equivalents, receivables, and other receivables. On the liabilities side, there are trade payables and other liabilities.

#### *Recognition and derecognition*

A financial asset or a financial liability is recognised in the balance sheet when the company becomes party to the contractual provisions of the instrument. A receivable is recognised when the company has performed and the counterparty has a contractual obligation to pay, even if an invoice has not yet been sent. Accounts receivable are recognised when the invoice has been sent. A liability is included when the counterparty has performed and there is a contractual obligation to pay, even if an invoice has not yet been received.

Accounts payable are recognized when an invoice has been received. A financial asset is derecognised when the rights in the contract are realized or expired, or when control of the contractual rights is lost. The same applies to a portion of a financial asset. A financial liability is derecognized when the obligation in the contract is fulfilled or in some other way expires. The same applies to part of a financial liability.

#### *Classification and measurement*

IFRS 9 involves how financial assets are classified and measured and introduces an impairment model based on expected credit losses instead of actual losses and changes in principles for hedge accounting for the purpose, among other things, of simplifying and

increasing concordance with a company's internal risk management strategies. Similar to IAS39, financial assets are classified in different categories. Some are being measured at amortised costs and others at fair value. Regarding the Group's financial liabilities, IFRS 9 is not materially different to IAS39. The impairment model for hedge accounting could lead to more financial hedging strategies being eligible for hedge accounting under IFRS 9 than IAS39.

#### **(n) Tangible assets**

Tangible assets are recognized in the Group at acquisition cost less accumulated depreciation and any impairments. The acquisition cost consists of the purchase price as well as costs directly related to bringing the asset to the necessary place and condition for its use in accordance with the purpose of the acquisition.

The carrying value of a tangible asset is derecognized when the asset is sold or disposed of, or when no further financial rewards are expected to be received from the use or disposal/sale of the asset. Gains or losses arising from the sale or disposal of an asset are calculated as the difference between the sale price and the asset's carrying value, less expenses directly related to the sale. Gains and losses are reported under other income/expenses. Tangible assets are depreciated on a straight-line basis over the estimated useful life of the asset.

Estimated useful life of the asset:

Equipment 3–5 years

#### **(o) Intangible assets**

##### *Research and development*

Expenditure on research activities related to the obtaining of new scientific or technical knowledge is expensed as incurred, except for when the research activities are acquired in a business combination; see below. Expenditure on development activities, whereby the research results or other knowledge is applied to accomplish new or improved products or processes, is recognized as an asset in the balance sheet, provided that the product or process is technically and commercially feasible and Ascelia Pharma has sufficient resources to complete development, and is subsequently able to use or sell the intangible asset.

Other development expenses are expensed as incurred with the exception of acquired development. Research and development acquired through a business combination are stated at the fair

value at the date of the acquisition. After the acquisition date, acquired research and development are stated on a historical cost basis and are tested for impairment as described below. Amortization of acquired research and development is recognized first when the project is considered complete. Amortization is then undertaken on a straight-line basis over the expected economic life; for patents, this does not however exceed the remaining period of patent protection.

#### **(p) Impairments**

The Group's recognised assets are assessed at the end of every reporting period to determine if there is any indication that impairment is required. IAS 36 is applied to the impairment of assets other than financial assets, which are reported in accordance with IFRS 9 (IAS 39 was applied to financial assets in the fiscal year 2017/2018).

##### *Impairment of intangible assets*

For intangible assets not yet subject to amortisation, the recoverable amount is calculated annually. The recoverable amount is the higher value of the fair value minus the cost of sale and the value in use. When calculating the value in use, the future cash flow is discounted by a discount factor, which takes into account risk-free interest and the risk associated with the specific asset.

##### *Impairment of financial assets*

Upon every reporting occasion, the Company examines whether there is objective evidence that a financial asset or group of assets requires impairment. Objective evidence consists of observable conditions that have occurred and have a negative impact on the possibility to recover the acquisition value.

##### *Reversal of impairments*

An impairment of assets, as included in the application of IAS 36, is reversed if there is both an indication that there is no longer an impairment requirement and that a change has been made in the assumptions that formed the basis of the calculation of the recoverable amount. However, impairment of goodwill is never reversed. A reversal is made only to the extent that the asset's carrying value after the reversal does not exceed the carrying value that would have been recognized, with a deduction for depreciation if applicable, had no impairment been made. Impairment of loans and receivables that are recognized at amortised cost are reversed if the previous reasons for impairment no longer exist and full payment can be expected to be obtained from the customer.

Note 2, cont.

**(q) Earnings per share**

The calculation of basic earnings per share is based on the profit or loss attributable to ordinary equity holders of the parent company and the weighted average number of common shares outstanding during the year. When calculating diluted earnings per share, the weighted average number of shares outstanding is adjusted for the effects of all dilutive potential common shares. Potential common shares are considered diluted only during periods when it leads to lower profit or bigger loss per share.

**(r) Remuneration to employees**

**(i) Current remuneration**

Current benefits to employees are calculated without discounting and recognised as costs when the related services are received.

**(ii) Pensions**

The Group has only defined-contribution pension plans. Pension plans classified as defined-contribution plans are those where the company's obligation is limited to the contributions the company has undertaken to pay. In such cases, the size of the employee's pension is dependent on the contributions paid by the company to the plan or to an insurance company and the return on capital yielded by the contributions. Consequently, it is the employee who bears the actuarial risk (that the pension payment will be lower than expected) and the investment risk (that the invested assets will be insufficient to provide the expected payments). The company's obligations with regard to payments to defined-contribution plans are recognised in the Income Statement as they are earned by the employee's performance of services for the company during a period.

**(iii) Share based remuneration**

Ascelia Pharma's key employees are invited to participate in employee option programs. If the terms of the programs are met at the time for utilisation, these employees have the right to purchase shares at a pre-determined price. The Group recognises share-based remuneration, which is personnel may receive. A personnel cost is recognized, together with a corresponding

increase in equity, distributed over the period in which the vesting conditions are met, which is the date on which the relevant employees become fully entitled to the compensation.

Social security costs attributable to share-based remuneration are expensed in the periods in which the programs are provided. The liability for social security costs arising is re-evaluated at each reporting date based on a new calculation of the fees expected to be paid when the options are exercised. This means that a new market valuation of the options is made at each balance sheet date, which is the basis for the calculation of the liability for social security charges.

Refer to note 4 for further details of share based remuneration.

**(s) Contingent liabilities**

Information on a contingent liability is provided when there is a possible obligation originating from past events and whose occurrence is confirmed only by one or more uncertain future events outside the Group's control or when there is an obligation that is not reported as a liability or provision because it is unlikely that an outflow of resources will be needed or it cannot be calculated with sufficient reliability.

**PARENT COMPANY'S ACCOUNTING PRINCIPLES**

The parent company has prepared the historical financial information according to the Annual Accounts Act (1995:1554) and the Swedish Financial Reporting Board's recommendation RFR 2 *Accounting for Legal Entities*. In addition, the Swedish Financial Reporting Board's issued statements applicable to listed companies are applied. The application of RFR 2 means that the parent company in the historical financial information for the legal entity shall apply all of the IFRS Standards and statements adopted by the EU to the extent allowed according to the Swedish Annual Accounts Act, the Act on Safeguarding of Pension Commitments, and with respect to the link between accounting and taxation. The recommendation states exceptions from and additions to IFRS Standards that shall be made.

**Differences between the Group's and the parent company's accounting principles**

The accounting principles of the parent company are consistent in all material respects with the accounting principles of the Group. The differences between the Group's and the parent company's accounting principles are described below. The accounting

principles given below for the parent company have been consistently applied for all periods as presented in the parent company's financial statements.

*Classification and presentation*

The parent company's income statement and balance sheet are prepared in accordance with the model detailed in the Annual Accounts Act, while the statement of profit or loss and other comprehensive income, the statement of changes in equity, and the statement of cash flows are based on IAS 1 *Presentation of Financial Statements* and IAS 7 *Statement of Cash Flows* respectively. The differences in the income statement and balance sheet of the parent company compared with the consolidated accounts mainly involve the reporting of financial income and expenses, assets, and equity.

*Subsidiaries*

Participations in subsidiaries are recognized in the parent company in accordance with the cost method. Thus, transaction expenses are included in the carrying amount of holdings in subsidiaries. In the consolidated accounts, transaction expenses attributable to subsidiaries are directly recognized in the profit/loss when they are incurred.

*Financial instruments and hedge accounting*

Due to the link between accounting and taxation, the regulations pertaining to the financial instruments in IFRS 9 are not applied to the parent company as a legal entity. Within the parent company, financial assets are measured at their acquisition values less any impairment and financial current assets according to the lower of cost and net realizable value.

### NOTE 3 OPERATING SEGMENTS

The Ascelia Pharma Group's operations consist of research and development for the development of pharmaceuticals. As follow-ups are conducted and resources are distributed in a joint manner for all research and development projects, the Group's operations are considered to comprise one operating segment. The Group has operations in Sweden (where the parent company has its registered office) and in Denmark. The tangible assets in Sweden and in Denmark are fully depreciated. The consolidated intangible assets are in their entirety related to Denmark and the acquisition of Oncoral Pharma ApS (see note 8).

### NOTE 4 EMPLOYEES, STAFF COSTS, AND REMUNERATION TO SENIOR EXECUTIVES

#### Average no. of employees

	2018-07-01- 2019-06-30	of which are men	2017-07-01- 2018-06-30	of which are men
<b>Group</b>				
Sweden	5	80%	4	75%
<b>Group total at the balance sheet date</b>	<b>5</b>	<b>80%</b>	<b>4</b>	<b>75%</b>
<b>Parent company</b>				
Sweden	5	80%	4	75%
<b>Total at the balance sheet date</b>	<b>5</b>	<b>80%</b>	<b>4</b>	<b>75%</b>

Figures above include Head of IR and Communications (employed through consultancy agreement). There are no employees in the subsidiaries.

#### Gender division in Company management

	30 June 2019 Percentage of women	30 June 2018 Percentage of women
<b>Group</b>		
Board of Directors	17%	17%
Other senior executives	20%	25%
<b>Parent company</b>		
Board of Directors	17%	17%
Other senior executives	20%	25%

#### Salary and remuneration to senior executives

Group	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
<b>SEK in thousands</b>		
<i>Chief Executive Officer (Magnus Corfitzen)</i>		
Base salary	1,410	1,260
Pension**	17	101
Variable remuneration	451	504
Share based remuneration	529	1,961
Other benefits	172	155
<b>Total</b>	<b>2,579</b>	<b>3,981</b>

	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
<b>SEK in thousands</b>		
<i>Other senior executives*</i>		
Base salary	3,267	2,893
Pension**	693	147
Variable remuneration	565	-
Share based remuneration	692	1,961
Other benefits	135	58
<b>Total</b>	<b>5,352</b>	<b>5,059</b>

#### Parent company

SEK in thousands	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
<i>Chief Executive Officer (Magnus Corfitzen)</i>		
Base salary	1,410	1,260
Pension**	17	101
Variable remuneration	451	504
Share based remuneration	529	1,961
Other benefits	172	155
<b>Total</b>	<b>2,579</b>	<b>3,981</b>

SEK in thousands	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
<i>Other senior executives*</i>		
Base salary	3,267	2,893
Pension**	693	147
Variable remuneration	565	-
Share based remuneration	692	1,961
Other benefits	135	58
<b>Total</b>	<b>5,352</b>	<b>5,059</b>

\* Senior executives constituted four persons in 2018/2019 plus Head of IR and Communications employed through consultancy agreement (four persons in 2017/2018).

\*\* The Parent company has a defined-contribution pension plan. Under the plan, some employees can decide whether the company should, instead of making pension contributions, pay the equivalent amount out as salary. In 2018/2019, two employees opted to receive salary instead of pension (3 persons in 2017/2018).

Total employee costs (all employees) for the Group and the Parent company including costs for share based remuneration, but excluding social charges, amounted to SEK 8.4 million in 2018/2019 (SEK 9.3 million). Social charges and insurances (all employees) for the Group and the Parent company amounted to SEK 2.9 million in 2018/2019 (SEK 2.0 million). Information about remuneration paid to the Board of Directors is found in the Corporate Governance section.

Note 4, cont.

#### **Employment agreements for the Chief Executive Officer and other senior executives**

Remuneration to the Chief Executive Officer other senior executives constitutes a base salary, variable remuneration, pension, share-related incentive programs and other benefits including company car. Other senior executives refer to the three persons, which together with the Chief Executive Officer, constitutes the management team of Ascelia Pharma. Variable remuneration refers to bonus, which can be realized if predetermined targets are reached. The notice period for the CEO is mutually six months. Should the company terminate the employment, the CEO is also entitled to severance pay equal to four times his fixed monthly base salary. As of June 30 2019, the CEO had, 458,856 employee options. Each option entitles a right to acquire one new share in Ascelia Pharma AB. As of the same date, the total number of employee options was 459,016 for the other senior executives. In addition to the severance, in case the company would be subject to a change of control resulting in that more than 50 percent of the shares are held by one shareholder and provided that neither the company nor the CEO has given notice of termination or has otherwise brought the agreement to terminate within a period of six months after the change of control, the CEO is entitled to a retention bonus of six times the monthly gross salary.

The employment agreements for the other senior executives stipulate mutual notice periods of between three to six months. In addition to fixed base salary, senior executives are entitled to a yearly bonus of maximum 20 percent of the annual base salary. The bonus is linked to the achievement of target goals that resolved annually based on agreements between the Company and the senior executives. All senior executives are also entitled to individual pension contributions.

The company's Head of IR & Communications acts as a consultant and the consultancy agreement has a fixed term of 12 months from the date of listing on Nasdaq Stockholm and runs thereafter for an indefinite term with a mutual notice period of three months. However, the company has the right to terminate the contract in advance with a notice period of three months.

#### **Employee stock option programs**

Ascelia Pharma has two active employee options programs that include members of the management team. If the terms of the programs are met at the time for utilisation, these employees have the right to purchase shares at a pre-determined price. The Group recognises share-based remuneration, which personnel may

receive. A personnel cost is recognised, together with a corresponding increase in equity, distributed over the period in which the vesting conditions are met, which is the date on which the relevant employees become fully entitled to the compensation.

At the beginning of the fiscal year 2018/2019, the number of allotted employee options amounted to 505,369. During the year, 68,796 employee options were reduced due to resignation of the former Chief Medical Officer. During the year, 505,095 employee options was allotted in connection with the AGM on 23 November 2018. Total number of employee options at the end of the fiscal year 2018/2019 consequently amounted to 986,668.

In case all employee options issued in relation to the employee option programs are utilised for subscription of new shares (including hedge for social security charges), a total of 1,296,680 new shares will be issued. This corresponds to a total dilution effect of approximately 5.5% in relation to the total number of outstanding shares per 30 June 2019.

#### **Employee option programme 1 ("Programme 1")**

At the Extraordinary General Meeting held on 26 April 2018, it was resolved to implement an employee option program comprised by a maximum of 550,369 employee options. The employee options have been allotted free of charge to the Chief Executive Officer, the former Chief Medical Officer and the Chief Operating Officer. The allotted employee options vest with 50 percent on the allotment and the remaining employee options will vest with 25 percent on 31 October 2018 and with 25 percent on 31 October 2019.

Vesting is conditional upon that the participant is still employed by the company and that the employee has not terminated the employment as of the date when the respective vesting occurs. If the participant ceases to be employed or terminates the employment before a vesting date, the already vested employee options can be utilized during the ordinary time for utilization in accordance with the below, but further vesting will not take place.

The company's former Chief Medical Officer left the company in the summer of 2018, after which the maximum number of employee options that can be vested was reduced to 481,573. Each vested employee option entitles a right to acquire one new share in the company against cash consideration at a subscription price of SEK 8 per share.

Vested employee options can be utilised during month 24 – 27 after the listing (i.e. 13 March 2021 to 13 June 2021) and in connection with a trade sale. Vested employee options can be utilised immediately in connection with the trade sale. Vested

employee options that are not exercised in the relevant exercise windows will automatically lapse.

Trade sale is defined as:

- firm offer from a third party to acquire at least 90 percent of the shares in the company and provided that shareholders representing more than 50 percent of the shares accepts such offer (or is obliged to accept the offer in accordance with a shareholders' agreement);
- the sale of all or substantially all of the company's activities, including a sale of all or a material part of the company's intellectual properties (irrespective of whether such transaction is carried out through a sale of a subsidiary of the company or through a sale of the activities in a subsidiary of the company); or
- other similar event which the Board considers shall be treated as a trade sale.

#### **Employee option program programme 2 ("Programme 2")**

At the annual general meeting held on 23 November 2018, it was resolved to implement an additional employee option program comprised by a maximum of 505,095 employee options. The employee options have been allotted free of charge to the Chief Executive Officer, Chief Financial Officer, Chief Operating Officer and Chief Medical Officer. The allotted employee options will vest with 25 percent on each of 31 October 2019, 31 October 2020, 31 October 2021 and 31 October 2022.

Vesting is conditional upon that the participant is still employed by the company and that the employee has not terminated the employment as of the date when the respective vesting occurs. If the participant ceases to be employed or terminates the employment before a vesting date, the already vested employee options can be utilized during the ordinary time for utilization in accordance with the below, but further vesting will not take place.

Each vested employee option entitles a right to acquire one new share in the company against cash consideration at a subscription price of SEK 22.50 per share. Vested employee options can be utilised during the period 1 November 2022 – 31 January 2023 and in connection with a trade sale. Vested employee options can be utilised immediately in connection with the trade sale. Vested employee options that are not exercised in the relevant exercise windows will automatically lapse.

Note 4, cont.

#### Value of allotted options

The calculated value of the options at the time of allotment for the first program was approximately SEK 10 per option and SEK 10 per option for the second program. The value of the options was calculated with an adjusted Black-Scholes model, which takes into consideration the exercise price, the term of the options, share price on the allotment date and expected volatility in the share price, and risk-free interest for the term of the options. In the calculation of the option value at allotment, assumptions were also made for the likelihood that an IPO or a trade sale to occur prior to the last day for exercise of the options. Assumptions were also made regarding the number of employees to remain in the company once the programmes are fully completed.

Since no listed prices were available prior to the IPO in March 2019, the share prices on allotment dates have been based on previous share transactions including the acquisition of Oncoral Pharma ApS (acquired with own shares) and new share issues with cash contribution. All transactions have time-wise been conducted in close proximity to the introduction of each option program. The value of the options are furthermore based on the following data:

- Risk-free interest rate: 0%
- Estimated volatility in the company's share price: 55%

The estimated volatility in the share price is based on comparable companies in the same sector.

Refer to note 25 for a description of important estimations and judgements.

#### Change in holdings of employee options for CEO and other senior executives

	No. of allotted options per 1 July 2018	Change*	No. of allotted options per 30 June 2019
CEO	275,185	183,671	458,856
Other senior executives	275,184	252,628	527,812
<b>Total</b>	<b>550,369</b>	<b>436,573</b>	<b>986,668</b>

\* During the year, 505,095 employee options have been allotted, of which 183,671 to the CEO, while 68,769 employee options have been terminated following resignation of the former Chief Medical Officer.

**NOTE 5 OPERATING EXPENSES BY TYPE OF COST**

The Group reports its income statement based on functions. The key cost items are presented below.

SEK in thousands	Group		Parent company	
	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
<b>Research and Development costs</b>				
Drug development costs	15,574	3,233	13,695	1,314
Cost of remuneration to employees	4,844	5,239	4,844	5,239
Manufacturing costs	2,506	895	2,506	895
<b>Total</b>	<b>22,923</b>	<b>9,367</b>	<b>21,045</b>	<b>7,488</b>
<b>Administration costs</b>				
Costs for remuneration to employees and board	7,818	6,081	7,818	6,081
Other administration costs	6,588	10,285	6,344	10,230
<b>Total</b>	<b>14,406</b>	<b>16,366</b>	<b>14,162</b>	<b>16,311</b>
<b>Other operating expenses</b>				
Currency differences related to operations	265	42	265	42
<b>Total</b>	<b>265</b>	<b>42</b>	<b>265</b>	<b>42</b>

**NOTE 6 AUDITOR FEES AND REIMBURSEMENTS**

SEK in thousands	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
<b>Group</b>		
<i>PwC</i>		
Audit engagements (current year)	512	140
Other audit activities	475	-
Tax advice	-	-
Other services	405	-
<b>Total</b>	<b>1,392</b>	<b>140</b>
<i>KPMG</i>		
Audit engagements (current year)	-	-
Other audit activities	-	2,405
Tax advice	-	131
Other services	-	1,172
<b>Total</b>	<b>-</b>	<b>3,708</b>
<b>SEK in thousands</b>	<b>2018-07-01- 2019-06-30</b>	<b>2017-07-01- 2018-06-30</b>
<b>Parent company</b>		
<i>PwC</i>		
Audit engagements (current year)	444	100
Other audit activities	475	-
Tax advice	-	-
Other services	405	-
<b>Total</b>	<b>1,324</b>	<b>100</b>
<i>KPMG</i>		
Audit engagements (current year)	-	-
Other audit activities	-	2,405
Tax advice	-	131
Other services	-	1,172
<b>Total</b>	<b>-</b>	<b>3,708</b>

Audit engagements refer to statutory auditing of annual and consolidated financial statements as well as the Board's and CEO's administration of the company, along with audits and other reviews performed as agreed upon or contracted. This includes other tasks that are incumbent on the company's auditor to perform as well as consultancy or other assistance occasioned by observations during such reviews or the performance of such other tasks.

**NOTE 7 NET FINANCIAL ITEMS**

Group	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
<b>SEK in thousands</b>		
<b>Interest income and similar profit/loss items</b>		
Interest income and currency adjustment	76	10
<b>Total</b>	<b>76</b>	<b>10</b>
Of which group companies	-	-
<b>Interest expense and similar profit/loss items</b>		
Interest expense	-33	-18
Net exchange rate differences	-203	-21
<b>Total</b>	<b>-236</b>	<b>-39</b>
<b>Parent company</b>		
<b>SEK in thousands</b>		
<b>Interest income and similar profit/loss items</b>		
Interest income and currency adjustment	377	60
<b>Total</b>	<b>377</b>	<b>60</b>
Of which group companies	226	30
<b>Interest expense and similar profit/loss items</b>		
Interest expense	-29	-18
Net exchange rate differences	-282	-21
<b>Total</b>	<b>-311</b>	<b>-39</b>

**NOTE 8 TAXES**

Recognised in the statement of profit or loss and other comprehensive income/income statement

SEK in thousands	Group		Parent company	
	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
<b>Current tax expense (-)/tax income (+)</b>				
Tax expense/income for the year	417	351	-	-
<b>Total recognized tax expense/income for the year</b>	<b>417</b>	<b>351</b>	<b>-</b>	<b>-</b>

**Tax reconciliation**

SEK in thousands	Group		Parent company	
	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30	2017-07-01- 2018-06-30	2017-07-01- 2018-06-30
<b>Loss before tax</b>	-37,552	-24,743	-35,060	-23,140
Tax rate for the parent company	22.0%	8,261	5,443	7,713
Effect of other tax rates for foreign subsidiaries	-0.3%	-131	5	-
Non-deductible expenses	-0.1%	-30	-6	-30
Increase of losses carried forward without equivalent capitalization	-20.5%	-7,683	-5,091	-7,683
Utilization of previously non-capitalized tax deductions	-1.1%	-417	351	-
<b>Recognized effective tax</b>	<b>0.0%</b>	<b>-</b>	<b>-</b>	<b>-</b>

**Unrecognized deferred tax assets**

Deductible temporary differences and tax losses for which deferred tax assets have not been recognized in the balance sheet (unrecognized deferred tax assets have no expiration date):

SEK in thousands	Group		Parent company	
	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30	2017-07-01- 2018-06-30	2017-07-01- 2018-06-30
Deductible temporary differences	-	-	-	-
Losses related to emission costs	21,807	-	21,807	-
Tax losses	145,372	137,699	145,372	137,693
<b>Total</b>	<b>167,179</b>	<b>137,699</b>	<b>167,179</b>	<b>137,693</b>

**NOTE 9 EARNINGS PER SHARE**

Group	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
Result per share	-2.16	-2,12
Average number of shares	17,171,703	11,518,832
<b>Parent company</b>		
	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
Result per share	-2.04	-2,01
Average number of shares	17,171,703	11,518,832

**NOTE 10 INTANGIBLE ASSETS**

Group	2019-06-30	2018-06-30
<b>SEK in thousands</b>		
<b>Accumulated cost of acquisition</b>		
Opening balance	57,066	57,057
Acquisitions	-	-
Currency adjustment	1	9
<b>Closing balance</b>	<b>57,067</b>	<b>57,066</b>
<b>Accumulated amortization and impairment losses</b>		
Opening balance	-	-
Impairment charge, current year	-	-
Amortization, current year	-	-
<b>Closing balance</b>	<b>-</b>	<b>-</b>
<b>Carrying amount</b>	<b>57,067</b>	<b>57,066</b>

Each year, the Group tests whether there is an impairment requirement with regards to intangible assets. For Ascelia Pharma, the recognized intangible assets refer to the R&D project in progress (Oncoral), which was acquired through the subsidiary Oncoral Pharma ApS.

The consideration consisted of a new share issue in Ascelia Pharma. The project has completed the first development phase (Phase I) at Herlev hospital in Denmark. The product candidate is a tablet formulation of irinotecan, which is a widely used chemotherapeutic agent with documented effects on selected solid tumors. The project is initially measured at fair value based on the discounted future net cash flow the project is deemed to generate and also considering the fair value of the consideration paid in a separate parallel transaction comprising a new share issue for cash in Ascelia Pharma at the same point in time.

The impairment test Oncoral is based on estimated risk adjusted future cash. Significant assumptions in the financial plans include projected revenue and operating margins. The forecasted risk adjusted cash flow has been calculated at present value using a discount rate of 12.0% before tax. The discount factor has been determined by considering the risk-free interest rate and the risk associated with the specific asset.

In 2018/2019, the estimated recoverable amount for Ascelia Pharma exceeded the book value, which is why no impairment requirement has been identified. Alternative calculations have been made by changing the assumptions concerning the discount rate. An increase of the discount rate by two percentage points would not result in any impairment requirement for intangible assets related to Ascelia Pharma.

## NOTE 11 TANGIBLE ASSETS

SEK in thousands	Group		Parent company	
	2019-06-30	2018-06-30	2019-06-30	2018-06-30
<i>Opening balance</i>				
Inventory	167	161	75	75
Other	-	-	-	-
<b>Total</b>	<b>167</b>	<b>161</b>	<b>75</b>	<b>75</b>
<i>Closing balance</i>				
Inventory	167	161	75	75
Currency adjustment	1	6	-	-
Other (car leasing)	280	-	280	-
<b>Total</b>	<b>448</b>	<b>167</b>	<b>355</b>	<b>75</b>
<b>Depreciation</b>				
<i>Opening balance</i>				
Inventory	-167	-161	-75	-75
Other	-	-	-	-
<b>Total</b>	<b>-167</b>	<b>-161</b>	<b>-75</b>	<b>-75</b>
Current year's depreciation inventory	-	-	-	-
Current year's depreciation other	-5	-	-5	-
<b>Total current year's depreciation</b>	<b>-5</b>	<b>-</b>	<b>-5</b>	<b>-</b>
<i>Closing balance</i>				
Inventory	-167	-161	-75	-75
Currency adjustment	-1	-6	-	-
Other	-5	-	-5	-
<b>Total</b>	<b>-173</b>	<b>-167</b>	<b>-80</b>	<b>-75</b>
<b>Carrying amount</b>				
<i>Opening balance</i>				
Inventory	-	-	-	-
Other	-	-	-	-
<b>Total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<i>Closing balance</i>				
Inventory	-	-	-	-
Leasing	275	-	275	-
<b>Total</b>	<b>275</b>	<b>-</b>	<b>275</b>	<b>-</b>

## NOTE 12 NON-CURRENT RECEIVABLES AND OTHER RECEIVABLES

SEK in thousands	Group	
	2019-06-30	2018-06-30
<b>Non-current receivables classified as non-current assets</b>		
Intra-company loans	-	-
<b>Total</b>	<b>-</b>	<b>-</b>
<b>Other receivables classified as current assets</b>		
Recoverable VAT	859	510
Other items	47	47
<b>Total</b>	<b>906</b>	<b>557</b>

SEK in thousands	Parent company	
	2019-06-30	2018-06-30
<b>Non-current receivables classified as non-current assets</b>		
Intra-company loans*	3,395	1,958
<b>Total</b>	<b>3,395</b>	<b>1,958</b>
<b>Other receivables classified as current assets</b>		
Recoverable VAT	620	190
Other items	591	47
<b>Total</b>	<b>1,211</b>	<b>237</b>

\*The increase in intra-company loans reflects loans from Ascelia Pharma AB to Oncoral Pharma ApS. The loans are denominated in DKK with a fixed interest rate. A change in DKK against SEK of 10% would result in an increased loan receivable for the parent company of around SEK 340 thousand.

### NOTE 13 PREPAID EXPENSES AND ACCRUED INCOME

Group		
SEK in thousands	2019-06-30	2018-06-30
Prepaid trade payables	1,058	1,424
Prepaid issuance costs	-	1,500
Prepaid rent	44	32
Other items	2,256	-
<b>Total</b>	<b>3,358</b>	<b>2,955</b>

#### Parent company

SEK in thousands	2019-06-30	2018-06-30
Prepaid trade payables	1,058	1,424
Prepaid issuance costs	-	1,500
Prepaid rent	44	32
Other items	2,256	30
<b>Total</b>	<b>3,358</b>	<b>2,985</b>

### NOTE 14 CASH AND CASH EQUIVALENTS

Group		
SEK in thousands	2019-06-30	2018-06-30
<i>The following items are included in cash and cash equivalents</i>		
Bank balances	149,972	55,063
<b>Total according to the statement of financial position</b>	<b>149,972</b>	<b>55,063</b>

#### Parent company

SEK in thousands	2019-06-30	2018-06-30
<i>The following items are included in cash and cash equivalents</i>		
Bank balances	148,743	53,792
<b>Total according to the statement of financial position</b>	<b>148,743</b>	<b>53,792</b>

### NOTE 15 MARKETABLE SECURITIES

Group		
SEK in thousands	2019-06-30	2018-06-30
Fixed income fund	75,076	-
<b>Total according to the statement of financial position</b>	<b>75,076</b>	<b>-</b>

#### Parent company

SEK in thousands	2019-06-30	2018-06-30
Fixed income fund	75,076	-
<b>Total according to the statement of financial position</b>	<b>75,076</b>	<b>-</b>

IFRS 9 includes a valuation approach with three categories for valuation of financial assets: amortised costs, fair value via other comprehensive income or via the Income Statement. The fixed income fund has been valued and classified according to fair value via the Income Statement with level 1 in the valuation hierarchy based on listed prices on a traded market.

Within EU's classification system, the fixed income fund has the lowest risk category on a scale from 1-7.

The investment of SEK 75 million into the fund was made in Q4 2018/2019 (Apr-Jun 2019)

## NOTE 16 EQUITY

### Share capital

Number of shares	2019-06-30	2018-06-30
Issued per 1 July	14,606,891	11,249,314
New cash share issue	8,882,017	3,357,577
<b>Issued per 30 June</b>	<b>23,488,908</b>	<b>14,606,891</b>

There is only one share class in Ascelia Pharma (common share). Holders of common share are entitled to a dividend that is determined in due course, and each share entitles the holder to one vote at the annual meeting of shareholders.

During fiscal year 2018/2019, a total number of 8,882,017 shares were issued in connection with the IPO on Nasdaq Stockholm (of which 882,017 shares were issued through the overallotment option in the IPO).

Total gross proceeds raised in the IPO was SEK 222.1 million. Net of issuance expenses, the amount raised was SEK 200.2 million.

#### *Translation reserve*

The translation reserve covers all exchange rate differences that arise in translating the financial statements of foreign entities whose financial statements were prepared in currencies other than the Group's presentation currency. The parent company and the Group present their financial statements in SEK. When control of a foreign operation ceases, the accumulated translation differences attributable to the operation are realised, at which point they are reclassified in equity to profit/loss for the year. In the case of a sale where the controlling interest still exists, a proportional share of the cumulative translation differences is transferred from the translation reserve to non-controlling interests.

#### *Parent company*

##### *Restricted reserves*

Restricted reserves cannot be reduced through distribution of profits.

##### *Non-restricted equity*

Together with profit/loss for the year, the following funds make up non-restricted equity – that is, the amount available for dividends to the shareholders:

##### *Share premium reserve*

When shares are issued at a premium – that is, when the amount paid for shares exceeds their nominal price – an amount equivalent to the amount received in excess of the share's nominal value is transferred to the share premium reserve.

##### *Profit/loss brought forward*

Profit/loss brought forward consists of the previous year's profit/loss brought forward and profit after being reduced by paid-out dividends.

**NOTE 17 OTHER LIABILITIES**

<b>Group</b>		
<b>SEK in thousands</b>	<b>2019-06-30</b>	<b>2018-06-30</b>
<b>Other current liabilities</b>		
Liabilities to employees incl. bonus provisions and social charges	1,432	667
Other liabilities	708	213
<b>Total</b>	<b>2,140</b>	<b>880</b>
<b>Parent company</b>		
<b>SEK in thousands</b>	<b>2019-06-30</b>	<b>2018-06-30</b>
<b>Other current liabilities</b>		
Liabilities to employees incl. bonus provisions and social charges	1,432	667
Other liabilities	708	213
<b>Total</b>	<b>2,140</b>	<b>880</b>

**NOTE 18 ACCRUED EXPENSES AND DEFERRED INCOME**

<b>Group</b>		
<b>SEK in thousands</b>	<b>2019-06-30</b>	<b>2018-06-30</b>
Vacation pay	894	750
Social charges	234	194
Other items	3,665	1,962
<b>Total</b>	<b>4,793</b>	<b>2,905</b>
<b>Parent company</b>		
<b>SEK in thousands</b>	<b>2019-06-30</b>	<b>2018-06-30</b>
Vacation pay	894	750
Social charges	234	194
Other items	3,686	1,955
<b>Total</b>	<b>4,814</b>	<b>2,899</b>

**NOTE 19 FINANCIAL INSTRUMENTS AND FINANCIAL RISKS**

The Group's operations expose it to a variety of financial risks. Ascelia Pharma is mainly exposed to liquidity risks and financing risks as well as currency risks.

**Liquidity risks and financing risks**

Liquidity risks and financing risks are the risks that the Group will not have access to financing in order to fulfill its contractual obligations or that this can only be done at a significantly increased cost.

In March 2019, Ascelia Pharma completed an IPO on Nasdaq Stockholm. Net of issuance expenses and including the overallotment option, the IPO provided Ascelia Pharma with SEK 200.2 million in cash. The funds raised through the IPO together with already existing bank balances provided Ascelia Pharma with liquidity beyond 12 months. The available funds at 30 June 2019 will allow Ascelia Pharma to complete the Phase III program for Mangoral, initiate commercial preparations for Mangoral and prepare for Phase II studies for Oncoral.

In accordance with Ascelia Pharma's financial policy, liquid funds are only to be placed in bank balances or highly liquid fixed income funds or interest-bearing securities with low credit risk. The financial policy also stipulates that bank deposit shall only be with banks with a long-term credit rating of least BBB+ from Standard & Poor's or equivalent from Moody's and/or Fitch.

The Group has no interest-bearing or long-term liabilities. All trade payables and accrued expenses fall due within 12 months.

Note 19, cont.

SEK in thousands	Purchases in each currency		Cost increase with 10% depreciation of SEK	
	2018/2019	2017/2018	2018/2019	2017/2018
DKK	3,663	521	366	52
EUR	5,783	142	578	14
USD	8,890	1,300	889	130
<b>Total</b>	<b>18,336</b>	<b>1,963</b>	<b>1,834</b>	<b>196</b>

#### Currency risks

##### Transaction exposure

Ascelia Pharma purchases services related to drug development particularly in USD, EUR and DKK. The effect of a weakening of Swedish crown by 10% on each currency are described in the table above.

The currency risk management in Ascelia Pharma focuses on transaction risk. Managing translation currency exposure in equity is not deemed relevant to safeguard operations (changes in equity from currency movement is not foreseen to expose Ascelia to significant risks). According to Ascelia Pharma's financial policy, management of currency exposures shall be based on contracted orders/purchases and be highly probable forecasted cash flows. Transaction exposure is handled by exchanging bank balances in SEK into foreign currencies (mainly USD, EUR and DKK) to match upcoming cash outflow. Financial hedging instruments such as futures, forwards and options are not used.

Currency risk is also present in the parent company through intra-company loans from Ascelia Pharma AB to Oncoral Pharma ApS denominated in DKK. A weakening of SEK of 10% against DKK would result in an increased loan receivable for the parent company of around SEK 340 thousand.

#### Credit risk

The Group's credit risk is primarily attributable to bank deposits. This risk is considered to be low because the cash in bank accounts are in large Swedish and Danish banks with high credit ratings. Counterparty risk associated with customers or business partners is currently not applicable given the pre-revenue state of the company

#### Carrying amount of financial assets and financial liabilities per valuation category

The carrying value of financial assets and financial liabilities are due to its short-term maturity considered to be reasonable estimates of the fair value for each class of financial assets and financial liabilities.

## NOTE 20 OPERATING LEASES

#### Leases with the Company as lessee

Non-cancellable leasing payments amount to:

#### Group

SEK in thousands	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
Within one year	131	91
Between one and five years	163	80
Beyond five years	-	-
<b>Total</b>	<b>294</b>	<b>171</b>

#### Parent company

SEK in thousands	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
Within one year	131	91
Between one and five years	163	80
Beyond five years	-	-
<b>Total</b>	<b>294</b>	<b>171</b>

The operating leases comprise lease of two company cars. These leases expire in October 2020 and June 2022, respectively. The present value of the operating leases amount to SEK 280 thousand (discount rate of 4% has been used).

Note 20, cont.

**Expensed operating lease fees amount to**

Group	2018-07-01- 2019-06-30	2018-06-30- 2019-06-30
SEK in thousands		
Minimum lease payments	199	315
<b>Total leasing costs</b>	<b>199</b>	<b>315</b>

Parent company	2018-07-01- 2019-06-30	2017-07-01- 2018-06-30
SEK in thousands		
Minimum lease payments	199	315
<b>Total leasing costs</b>	<b>199</b>	<b>315</b>

**NOTE 21 PLEDGED ASSETS, CONTINGENT LIABILITIES, AND CONTINGENT ASSETS**

**Group**

SEK in thousands	2019-06-30	2018-06-30
Commitments*	11,410	11,818
<b>Total</b>	<b>11,410</b>	<b>11,818</b>

**Parent company**

SEK in thousands	2019-06-30	2018-06-30
Commitments*	11,414	11,818
<b>Total</b>	<b>11,414</b>	<b>11,818</b>

\*The commitments refer to potential bonus payment of SEK 10 million to Solural Pharma ApS (refer to note 23) and potential payment to Herlev hospital of DKK 1 million in case of potential outlicensing of Oncoral or a sale of Oncoral.

**NOTE 22 APPROPRIATION OF THE COMPANY'S LOSS**

The following amounts in SEK are at the disposal of the annual meeting of shareholders:

**Parent company**

Share premium reserve	405,060,843
Loss brought forward	-114,310,518
Loss for the period	-35,060,147
<b>Total</b>	<b>255,690,178</b>

The Board proposes the following appropriation of funds and non-restricted reserves:

Carried forward	255,690,178
of which to share premium reserve	405,060,843

**NOTE 23 RELATED PARTIES**

*Related parties with subsidiaries and senior executives*

The parent company has a close relationship with its subsidiary; see note 24. For remuneration to senior executives, see note 4.

*Purchasing of services from related parties*

Oncoral Pharma ApS has an agreement with Solural Pharma ApS according to which, Solural Pharma ApS provides development and manufacturing of clinical study material. The owners of Solural Pharma ApS are the founders of Oncoral Pharma ApS and are, after the sale of Oncoral Pharma ApS to Ascelia Pharma AB, shareholders in Ascelia Pharma AB. The owners of Solural ApS collectively own 4.1% of the shares in Ascelia Pharma AB. In addition to payment for services performed, Solural Pharma ApS has the right to receive a bonus of maximum SEK 10 million if commercialization occurs through a sale or a outlicensing and SEK 12 million and if commercialization is carried out by Oncoral Pharma ApS or Ascelia Pharma AB itself. Regardless the commercialisation method, Oncoral Pharma ApS has the right to, at any time, finally settle Solural Pharma ApS right for remuneration by payment of SEK 10 million. In 2018/2019, services for a value of DKK 1.4 million were acquired from Solural Pharma ApS.

Oncoral Pharma ApS has purchased accounting services from Capnova A/S. Capnova A/S was previously a shareholder in Oncoral Pharma ApS. After the sale of the company to Ascelia Pharma AB, Capnova A/S holds shares in Ascelia Pharma AB amounting to less than 1% of the total shares. In 2018/2019, services for a value of DKK 14,500 were acquired from Capnova A/S.

In 2018/2019, consulting services for a total value of EUR 25 thousand was acquired from BGM Associates where Ascelia Pharma's board member Hans Maier is Managing Director.

**NOTE 24 GROUP COMPANIES***Holdings in the subsidiary*

Subsidiary/Corporate identity number/ Registered office	Number of participation rights	Participating interest in %	Carrying amount	
			2019-06-30	2018-06-30
Oncoral Pharma Aps, CVR number 35 48 12 14 Ballerup, Denmark	145,919	100	58,018	58,018
Ascelia Incentive AB, Reg. No. 559129-4615 Malmö Sweden	50,000	100	50	50
<b>Parent company</b>				
Accumulated acquisition value				
Opening balance			58,068	58,018
Purchases			-	50
Closing balance			58,068	58,068
<b>Carrying amount on 30 June</b>			<b>58,068</b>	<b>58,068</b>

**NOTE 25 IMPORTANT ESTIMATIONS AND JUDGEMENTS**

**Asset acquisitions versus business combinations and deferred tax**  
Acquisition of companies can be classified as business combinations or asset acquisitions in accordance to IFRS 3. Each individual acquisition is assessed individually. In the cases where the company acquisition only consists of a development project and does not include important processes, the acquisition is classified as an asset acquisition. If the acquisition contains strategic processes that are associated with operations, it is classified as a business combination. The acquisition of Oncoral in 2017 was considered to be an asset acquisition.

**Valuation of intangible assets**

The recognised research and development project in progress is subject for management's impairment test. The most critical assumption, subject to evaluation by management, is whether the recognised intangible asset will generate future economic benefits that at a minimum correspond to the intangible asset's carrying amount. Management's assessment is that the expected future cash flows will be sufficient to cover the intangible asset's carrying amount and accordingly no impairment loss has been recognised.

**Capitalisation of development expenses**

For full-year 2018/2019, the criteria for classifying R&D costs as an asset according to IAS 38 has not been met (capitalisation of development expenses is normally done in connection with final regulatory approval). Hence, all R&D costs related to the development of the product candidates have been expensed.

**New accounting standards**

The new standards IFRS 15 on Revenue and IFRS 9 Financial instruments has been implemented in this financial year starting on 1 July 2018. As the Group currently does not have revenue from contracts with customers, IFRS 15 does not presently impact the Group. Furthermore, IFRS 9 does not have any significant effect on the financial statements given the Group's current very limited exposure to credit risk as well as the absence of financial derivatives. Ascelia Pharma has chosen to early implement the new IFRS 16 rules on leases for the fiscal year 2018/2019. The net present value of the leases amounted to SEK 0.3 million per 30 June 2019 (only car leases).

**Employee option programme**

Ascelia Pharma has implemented two employee option programs with individual terms and conditions. The parameters, which have the largest impact on the value of the options are likelihood for an IPO or sale of the company and the value of the company. Given the completed IPO in March 2019, the Management in Ascelia Pharma has adjusted the likelihood for completion of IPO to 100% and valued the shares according to the publicly traded share price. The total recognised costs for the option programs were SEK 2.3 million in FY 2018/2019 (see note 4 for further information).

**NOTE 26 SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD**

No significant events have occurred after the reporting period.

# DECLARATION AND SIGNATURES

Ascelia Pharma AB, 556571-8797

The Board of Directors and the CEO confirm that the annual accounts have been prepared in accordance with accepted accounting standards in Sweden, and that the consolidated accounts have been prepared in accordance with the international accounting standards, IFRS, as adopted by EU. The annual accounts and the consolidated accounts give a true and fair view of the Group's and Parent Company's financial position and profit. The Board of Directors' Report for the Group and the Parent Company gives a true and fair view of the Group's and the Parent Company's operations, position and profit, and describes significant risks and uncertainty factors that the Parent Company and Group companies face.

Malmö, 10 October 2019

**Peter Benson**  
Chairman of the Board

**Bo Jesper Hansen**  
Director of the Board

**Hans Maier**  
Director of the Board

**Niels Mengel**  
Director of the Board

**René Spogård**  
Director of the Board

**Helena Wennerström**  
Director of the Board

**Magnus Corfitzen**  
Chief Executive Officer

Our auditors' report was submitted on  
14 October 2019, Öhrlings PricewaterhouseCoopers AB

**Carl Fogelberg**  
Authorised Public Accountant

# AUDITOR'S REPORT

To the Board of Directors of Ascelia Pharma AB (publ), corporate identity number 556571-8797

## REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

### Opinions

We have audited the annual accounts and consolidated accounts of Ascelia Pharma AB (publ) for the financial year 1 July 2018 -30 June 2019 except for the corporate governance statement pages 30-35. The annual accounts and consolidated accounts of the company are included on pages 36-66 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company as of 30 June 2018 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2018 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 30-35. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts. We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

### Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Our audit approach

#### Audit scope

We designed our audit by determining materiality and assessing the risks of material misstatement in the consolidated financial statements. In particular, we considered where management made subjective judgements; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits, we also addressed the risk of management override of internal controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud.

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the consolidated financial statements as a whole, taking into account the structure of the Group, the accounting processes and controls, and the industry in which the group operates.

#### Materiality

The scope of our audit was influenced by our application of materiality. An audit is designed to obtain reasonable assurance whether the financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the consolidated financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall group materiality for the consolidated financial statements as a whole. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

### Key audit matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

## Key audit matter

## How our audit addressed the Key audit matter

### Acquired development projects and shares in subsidiaries

In June 2017, Ascelia acquired Pharma Oncoral Aps, which conducted research and the development project Oncoral. The research projects are not yet completed and depreciation has not begun.

As of June 30, 2019, the value of acquired development projects amounts to a total of SEK 57 million in the statement of financial position for the Group and the value of shares in subsidiaries in the parent company amounts to SEK 58 million in the balance sheet for the parent company. According to IFRS, non-amortized fixed assets must be tested for impairment at least annually. The test means that the management needs to apply estimates and estimates of the future to ensure the book value.

The company conducts an annual impairment test for the acquired development expenses. In view of the size of the amounts and the impact of the management's assumptions on the result of this impairment test, we have determined that this is an important area.

A description of the company's impairment testing process can be found in the section "Important estimates and judgments" in Note 25. Note 10 contains further description of the impairment test

In our audit, we have the task of evaluating and reviewing the Company's application of the accounting principles and evaluating the basis on which the impairment test is based. Our review has included, but is not limited to,

- Review of the mathematical model used in the impairment test with regard to its theoretical and mathematical accuracy

- Challenged management in the assumptions made regarding, among other things, future sales levels and discount rates and probability weights

- Compared management's assumption against comparable external data

We have also sought out the executive management's comments on the development of the research projects and the results presented through the company's press releases.

Our review has not resulted in any adjustments and we have not reported any material observations regarding the valuation of intangible fixed assets to the Audit Committee.

## Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-35 and 71-73. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

## Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

## Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

A further description of our responsibility for the audit of the annual accounts and consolidated accounts is available on Revisorsinspektionen's website [www.revisorsinspektionen.se/revisornsansvar](http://www.revisorsinspektionen.se/revisornsansvar). This description is part of the auditor's report.

## REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

### Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Ascelia Pharma AB (publ) for the financial year 1 July 2018 -30 June 2019 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

A further description of our responsibility for the audit of the administration is available on Revisorsinspektionen's website: [www.revisorsinspektionen.se/revisornsansvar](http://www.revisorsinspektionen.se/revisornsansvar). This description is part of the auditor's report.

### The auditor's examination of the corporate governance statement

The Board of Directors is responsible for that the corporate governance statement on pages 30-35 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevU 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

Öhrlings PricewaterhouseCoopers AB, box 4009, 203 11 Malmö, was re-appointed auditor of Ascelia Pharma AB (publ) by the general meeting of the shareholders on the 23 November 2018 and has been the company's auditor since the introduction on Nasdaq Stockholm, 13 March 2019.

Malmö 14 October 2019

Öhrlings PricewaterhouseCoopers AB

**Carl Fogelberg**

Authorized Public Accountant

# GLOSSARY

## **Abbreviated New Drug Application (ANDA)**

An application submitted to the FDA for the review and potential approval of a generic drug product.

## **Ablation**

Destruction of a body part or tissue or its function. Ablation may be performed by surgery, hormones, drugs, radiofrequency, heat, or other methods.

## **Active pharmaceutical ingredient (API)**

The ingredient in a pharmaceutical drug that is biologically active used similar to "Active substance/ingredient" below.

## **Active substance/ingredient**

The ingredient in a pharmaceutical drug that is biologically active.

## **Acute kidney injury (AKI)**

An abrupt loss of kidney function.

## **Advanced cancer**

Cancer that has grown outside the organ it started in.

## **Bioequivalence studies**

Studies to prove that a product is bioequivalent, i.e. pharmaceutically equivalent, to another drug. Bioequivalence studies are required in an ANDA.

## **Blinded study**

A study in which information about the test is masked to reduce or eliminate bias.

## **Chemotherapy**

A type of cancer treatment that uses one or more anti-cancer drugs.

## **Chronic kidney disease (CKD)**

A progressive loss in kidney function over a prolonged time period.

## **Clinical studies**

Studies on healthy or non-healthy individuals to study the effects of a drug or a treatment method.

## **Colorectal cancer**

Refers to cancer developing in the large intestine, usually in the rectum or colon.

## **Computed tomography scan (CT Scan)**

A type of scanning method, in which many two-dimensional pictures are computer-processed to create a three-dimensional picture.

## **Contrast agent/imaging drug**

A substance used to enhance the contrast in medical imaging.

## **Cytotoxic drug**

A type of drug used within chemotherapy.

## **Data exclusivity**

In this context a term to describe the time-period in which no ANDA can be approved based on the exclusive data for the drug.

## **Embolisation**

A procedure using particles, such as tiny gelatin sponges or beads, to block a blood vessel. Embolisation may be used to stop bleeding or to block the flow of blood to a tumor or abnormal area of tissue.

## **European Medicines Agency (EMA)**

European agency responsible for evaluation of medicinal products.

## **Focal liver lesion**

Localized changes in liver tissue.

## **Food and Drug Administration (FDA)**

US federal agency responsible for evaluation of medicinal products.

## **Food effect bioavailability study**

A study with the objective to evaluate the effect of food on the bioavailability of a drug.

## **Gadolinium**

A heavy metal used as a contrast enhancer, see "Gadolinium-based contrast agent (GBCA)" below.

## **Gadolinium-based contrast agent (GBCA)**

A contrast agent based with gadolinium as a contrast enhancer.

## **Generic Drug**

A pharmaceutical that is equivalent to a brand-name product in dosage, strength, route of administration, quality, performance and intended use.

## **Good Clinical Practice (GCP)**

An international quality standard for the performance of clinical studies.

## **Good Manufacturing Practice (GMP)**

A set of manufacturing guidelines set up by the authorization agency for medicinal products. GMP can differ depending on the authority.

## **HER2**

A gene that can play a role in the development of certain cancer forms.

## **Incidence**

A measure of the probability of occurrence of a medical condition in a population.

## **Infusion**

A continuous injection of a substance into the body.

## **In vitro studies**

Studies performed outside of the normal biological context. Often used to refer to studies outside of the body.

## **In vivo studies**

Studies performed in a living organism, for example in humans.

## **Listed drug**

A new drug approved for sale (distinguished from generic drugs).

## **Magnetic resonance imaging (MRI)**

A medical imaging technique used in radiology.

## **Market exclusivity**

In this context, the period following regulatory approval of an orphan drug in which no marketing authorization will be accepted for the same therapeutic indication.

## **Metastases**

The spread of a cancer to a different part of the body.

## **Nephrogenic systemic fibrosis (NSF)**

A serious condition involving fibrosis of skin, joints, eyes, and internal organs.

## **Orphan Drug**

A pharmaceutical agent that has been developed specifically to treat a rare medical condition.

## **Positron emission tomography (PET)**

An imaging technique used to observe metabolic processes in the body.

## **Pre-clinical research**

The research phase before clinical studies where initial drug safety data are collected.

## **Prevalence**

The proportion of a population suffering from a certain disease.

## **Primary tumor**

The first cancer tumor formed.

## **Special populations study**

Studies within a certain population, such as the elderly, populations with certain impairments or diseases, etc.

## **Targeted agent**

Agents interfering with specific molecules that are part of the cancer growth.

# ALTERNATIVE PERFORMANCE MEASURES

## Definition of alternative financial performance measures

### Alternative performance measures

#### Operating results (TSEK)

#### Definition

Profit before financial items and tax.

#### Aim

The performance measure shows the company's operational performance.

#### Research and development costs/operating costs (%)

The research and development expenses in relation to total operating costs (consisting of the sum of administrative expenses, research and development as well as other operating expenses).

The performance measure is useful in order to understand how much of the operating costs that are related to research- and development expenses.

## Reconciliation table for alternative performance measures for the Group

	FY (Jun-Jul)	
	2018/2019	2017/2018
R&D costs (SEK 000')	-22,923	-9,367
Administration costs (SEK 000')	-14,406	-16,366
Other operating costs (SEK 000')	-265	-42
<b>Total operating costs (SEK 000')</b>	<b>-37,595</b>	<b>-25,775</b>
<b>R&amp;D costs/Operating costs (%)</b>	<b>61%</b>	<b>36%</b>

## Financial calendar

Interim report three months 2019/2020:	8 November 2019
Annual General Meeting:	14 November 2019
Interim report six months 2019/2020:	14 February 2020
Interim report nine months 2019/2020:	13 May 2020
Full-year report 2019/2020:	20 August 2020

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