

# ASCELIA PHARMA

Advancing Orphan Oncology

# ANNUAL REPORT 2021

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### **Financial Calendar**

5 MAY 2022	Annual General Meeting 2022
11 MAY 2022	Interim Report January-March 2022 (Q1)
18 AUGUST 2022	Half-year Report January-June 2022 (H1)
4 NOVEMBER 2022	Interim Report January-September 2022 (Q3)
10 FEBRUARY 2023	Full-year Report January-December 2022

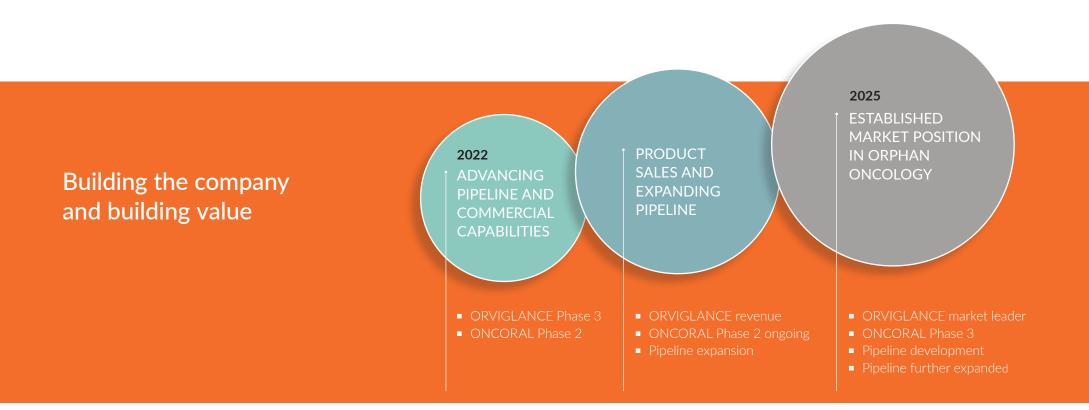
# ADVANCING ORPHAN ONCOLOGY

### **OUR VISION**

To be a leader in identifying, developing and commercializing novel drugs that address unmet needs of people with rare cancers.

### **OUR BASE**

Our headquarter is in Malmö, Sweden, and our US base is in New Jersey. The shares in the company are listed on NASDAQ Stockholm (ticker: ACE).



# OUR PIPELINE

### **ORVIGLANCE** (Mangoral)

#### Diagnostic drug for liver MRI in ongoing Phase 3

Orviglance is our novel <u>non</u>-gadolinium diagnostic drug (contrast agent) to be used in MRI-scans of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases and primary liver cancer) in patients with impaired kidneys at risk of severe side-effects from the gadolinium contrast agents currently on the market. Orviglance characteristics:

- Manganese-based diagnostic drug with Orphan Drug Designation (FDA)
- The only late-stage gadolinium-free agent
- \$500-600 million annual addressable market

### **ONCORAL**

#### **Tablet chemotherapy ready for Phase 2**

Oncoral is our novel oral chemotherapy tablet developed initialy for the treatment of gastric cancer. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral characteristics:

- Oral daily dosing of irinotecan chemotherapy
- Potential for better efficacy and safety by frequent low dosing
- Phase 2 in gastric cancer; potential to expand into other cancer forms



# CEO COMMENTS



The year 2021 continued to be significantly influenced by the Covid-19 pandemic that affected all societies and not the least healthcare systems. It also impacted clinical study activities and for us it meant a slower patient recruitment pace for the Orviglance pivotal Phase 3 study SPARKLE. We have responded to this by increasing the number of hospitals recruiting patients into the study, supported medical staff by sharing best practices for identifying eligible patients and also amended the study protocol to include patients on hemodialysis and patients with hepatic impairment.

In the beginning of 2022 we witnessed Russia's invasion of Ukraine. The consequences of Russia's invasion of Ukraine are both grave and concerning. Because of the escalating situation, we decided here in March 2022 to suspend all clinical activities in Russia, including patient enrolment.

We continue our efforts to support investigators to enroll patients and our expectation is to complete patient enrolment for the SPARKLE study in 2022.

Despite the external volatile macro environment, we have made significant progress across our clinical portfolio:

- Completed the two supportive studies in the Orviglance clinical program
- Presented strong results for Orviglance in a comparison study to gadolinium
- Entered a clinical collaboration with Taiho Oncology for Oncoral
- Gained approval from the FDA of Oncoral's IND application

**Complimentary studies with Orviglance successfully completed.** An important part of our pivotal clinical program with Orviglance are the two complementary studies – Food Effect Study and Hepatic Impairment Study – that have run in parallel with SPARKLE. The last patient visit for the Food Effect Study was completed in Q4 2021 and in March 2022 the last patient visit was completed for the Hepatic Impairment Study.

Preliminary data indicate that Orviglance was well tolerated in both studies. The results are important and will be part of the regulatory submission and approval of Orviglance.

#### Strong results from Orviglance comparison study to gadolini-

**um.** In Q4, at the world's largest radiology conference, RSNA, in Chicago, we presented results from the study in which Orviglance was compared against a liver-specific gadolinium-based contrast agent in patients with normal kidney function.

The comparison study showed that MRI with Orviglance was as effective as the gadolinium contrast agent gadobenate dimeglumine (Multihance) for visualization of lesions and number of detected lesions in the liver. In fact, 2 out of 3 readers reporting higher scores for Orviglance. We also saw that MRI with Orviglance provides improved efficacy in terms of lesion detection and visualization compared to MRI without contrast agent. The study provides robust evidence of the diagnostic value that Orviglance can offer once available to patients and physicians and it is very encouraging that Orviglance is as effective as a gadolinium contrast agent.

The study has also been accepted as an oral scientific presentation at the ESGAR conference to be held in May 31 – June 3 2022, in Lisbon, Portugal.

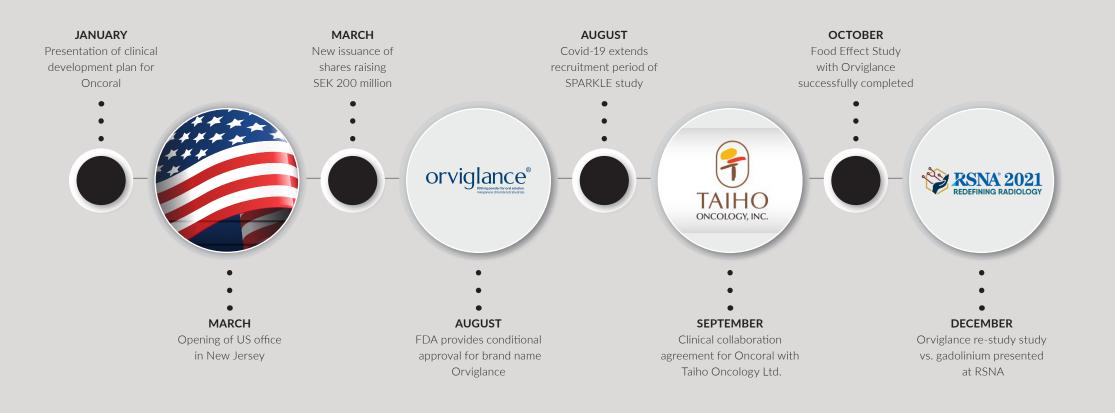
**FDA** acceptance of Oncoral IND application. In December, the FDA approved our Investigational New Drug (IND) application for the upcoming global Phase 2 clinical study in gastric cancer. In the study, our daily oral chemotherapy candidate drug Oncoral will be combined with Taiho Oncology's LONSURF (tri-fluridine and tipiracil) film-coated tablets for oral use.

The clinical collaboration agreement with Taiho Oncology shows the potential for Oncoral to be part of a new treatment regimen for gastric cancer. We believe this investigational alloral tablet combination has the potential to provide a significant treatment benefit to patients suffering from this very aggressive cancer form where there is a massive unmet need.

**Solid financial position.** We have a solid balance sheet and closed the year with 262 MSEK in cash, which will take us into 2023. The liquidity position will be used for the ongoing Phase 3 program for Orviglance and the market launch preparations as well as Oncoral's clinical development program.

**Looking ahead.** Our prime focus in 2022 is to complete the ongoing pivotal study for Orviglance. Alongside we continue our commercial preparations for Orviglance and the preparations for Oncoral's Phase 2 study. We work constantly to create shareholder value, and I look forward to updating you on the progress of Ascelia Pharma.

# KEY EVENTS IN 2021



# STRATEGY

Our vision is to be a leader in identifying, developing and commercializing novel drugs that address unmet needs of people with rare cancers



### IDENTIFY & ACQUIRE STRICT SELECTION CRITERIA

Our criteria for targeted drugs

- Fill a clear unmet medical need within oncology
- Understand mode of action
- Have a de-risked development path
- Potential for orphan drug designation
- Aspire for global leadership



### DEVELOP VALUE CREATION Resources and Assets

#### Strong pipeline and drug development expertise

We leverage our unique portfolio of drugs through our extensive drug development experience supplemented by our strong network of Key Opinion Leaders (KOLs).

#### Intellectual Property Rights

- US Orphan Drug Designation for Orviglance
- Second generation Orviglance patent to 2040
- Oncoral protected by patent to 2035

#### Solid financial position

Well-financed with SEK 262 million in cash balance.



### MONETIZE CRYSTALLIZE VALUE

Create value for patients and hospitals as well as shareholders through bringing our drug candidates to the market by ourselves and/or together with partners.

# ORVIGLANCE®\*

Phase 3 liver MRI contrast agent

- Manganese-based diagnostic drug
- ► The only late stage gadolinium-free agent
- Ongoing global Phase 3 study
- Orphan Drug Designation by FDA
- ► \$500-600 million addressable market

#### Mangoral becomes Orviglance

In August 2021, the U.S. Food and Drug Administration (FDA) conditionally accepted Orviglance as the proposed brand name for manganese chloride tetrahydrate (Mangoral).

Mangoral



\*Orviglance is registered trademark in the US, Europe and several other countries.

# PROBLEM - LIVER METASTASES AND LIVER CANCER

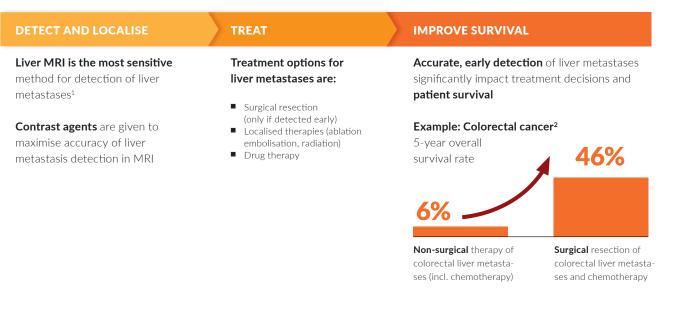
One of the reasons that cancer is a serious disease is its ability to spread to other parts of the body than the location of the primary tumour (i.e. where the first tumour formed). When cancer cells spread to distant lymph nodes, tissues or organs, it is called metastatic cancer. Cancer can spread to 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. For this 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 make 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.



# 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 severely impaired renal function, i.e. impaired kidney function, are at risk from using the currently available contrast agents on the market. 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 carry black box warnings for patients with severely impaired kidneys. 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 (kidney) function.

**Orviglance - free from gadolinium.** Orviglance is expected to be the first gadolinium-free contrast agent for the liver. For patients with severely reduced kidney function, the preferred imaging choice today is an MRI-scan without a contrast agent. This reduces the ability to find and treat liver metastases and consequently patients' chances of survival. Our goal is to establish Orviglance as the standard of care contrast agent for patients with severely impaired kidneys.

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 are 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 **Orviglance aims** to be the standard liver MRI contrast agent in patients with impaired kidney function

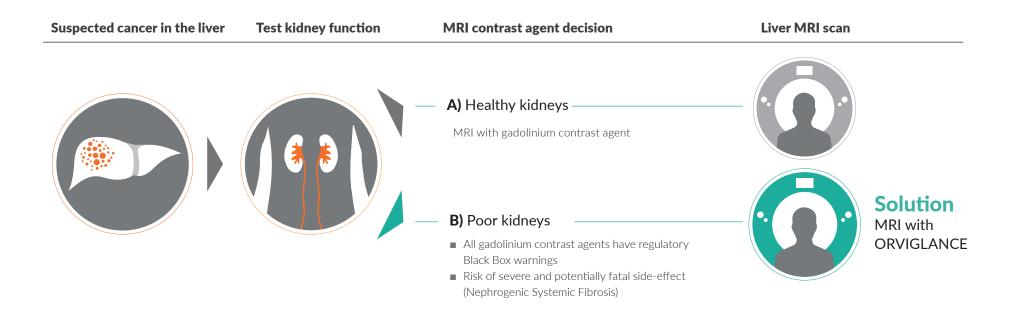


WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF) See full prescribing information for complete boxed warning. Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is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

# SOLUTION - FILLING AN UNMET NEED IN LIVER MRI

ORVIGLANCE aims to be the standard of care liver MRI contrast agent for patients also suffering from poor kidneys. These patients are at risk of severe side-effects from using the current gadolinium-based contrast agents. Orviglance aims to fill this unmet medical need and become standard of care for this patient group.



# HOW ORVIGLANCE WORKS

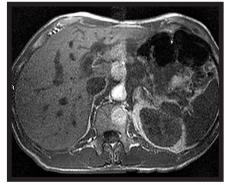
Orviglance is an orally administrated contrast agent used in MRI of the liver. It is based on the chemical element manganese, which is a natural trace element in the body. Orviglance also contains L-Alanine and Vitamin D3 to increase the absorption of manganese from the small intestine into the portal 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 Orviglance, liver metastases are consequently easier to identify due to this contrast effect.

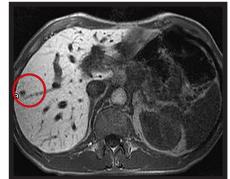
When administered orally, manganese is absorbed from the gastro-intestinal tract, taken up in the liver and excreted via the bile. Due to the high pre-systemic first pass effect only minimal amounts reach the blood stream, so the systemic exposure is very low. The mean manganese blood concentration values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

### Patient example from our Phase 2 study\*

**Unenhanced liver MRI** (i.e. without contrast agent) **Orviglance enhanced liver MRI** 



No metastasis visible



Metastasis becomes visible

# SEVERAL BENEFITS WITH ORVIGLANCE

### Key advantages of Orviglance®



**Strong enhancement** of liver on MRI – metastases do not take up manganese and appear darker on the MRI

Limited systemic exposure and good safety profile

**Provides ease of use** for patients and clinicians alike with oral administration and a flexible 2-6 hour MRI procedure window from ingestion

**FDA Orphan Drug Designation** 

The strong contrast effect with Orviglance 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. Orviglance offers a significantly better alternative than unenhanced MRI (i.e. MRI with no medical contrast agent). Orviglance'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 there is no safe alternative for renally impaired patients that require an MRI scan of the liver. Orviglance 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.

# STRONG CLINICAL RESULTS

**6** phase **1** and **2** clinical studies completed. To date, the clinical development of Orviglance comprises a total number of six completed clinical phase 1 and 2 studies in healthy volunteers and patients with known liver metastases or suspected liver lesions. In total, 127 persons have participated in the completed Phase 1 and Phase 2 clinical studies.

#### Consistent strong efficacy readout and safety profile. The

results of the safety assessments from the six clinical studies show that Orviglance 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 Orviglance and provide strong support that Orviglance 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 3 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 Orviglance significantly improves MRI performance. Compared to unenhanced MRI, 33% more lesions were detected after Orviglance enhanced MRI. Orviglance 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 Orviglance enhanced MRI compared to unenhanced MRI



### **ORVIGLANCE** clinical results

### Phase 1 and 2 (completed)

- Strong efficacy readout
- Safe and well tolerated

### Phase 3 clinical program

#### Food Effect study

Completed. Results expected Q2-2022

#### Hepatic study

Completed. Results expected mid 2022

**Pivotal study (SPARKLE)** Ongoing.

# STUDY VS. GADOLINIUM CONTRAST AGENT

In 2021, strong results were presented from the re-study where Orviglance was compared against a gadolinium contrast agent (Multihance). The results were presented at the Radiological Society of North America (RSNA) in 2021 and will also be shared at an oral presentation at the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) in May/June 2022.



# ONGOING PHASE 3 STUDY (SPARKLE)

The ongoing pivotal Phase 3 study SPARKLE is a global multicentre study in up to 200 patients. The strong results in the Phase 1 and Phase 2, both in terms of safety and efficacy, studies provide a solid foundation for the ongoing Phase 3 program. This is underpinned by the high degree of similarity between the primary endpoints in Phase 2 and Phase 3, and since the Phase 3 study comparator for Orviglance is MRI with no contrast agent. In addition, the follow-up time is less than a week, compared to months or years for the typical Phase 3 oncology study.

### Orviglance's clinical Phase 3 study (based on Phase 3 protocol meeting with FDA and EMA)

NUMBER OF PATIENTS	Global ongoing study in up to 200 patients	
ENDPOINT	<ul> <li>Lesion visualisation</li> <li>Lesions border delineation (border sharpness of lesions)</li> <li>Conspicuity (lesion contrast compared to liver background)</li> </ul>	
COMPARATOR	Unenhanced MRI + Orviglance MRI vs. Unenhanced MRI	
EVALUATION	Centralised evaluation by 3 radiologists	
RANDOMISATION	No – each patient at his/her own control	
FOLLOW-UP	Less than a week	

## Strong support to Phase 3 endpoints from completed studies

The completed Phase 1 and Phase 2 studies have shown strong efficacy results regarding the endpoints that will be evaluated in the Phase 3 study. The completed studies, involving 178 persons in total<sup>1</sup>, have showed a highly significant improvement compared to unenhanced MRI in:

- Delineation: p-value <0.0001
- Conspicuity: p-value <0.0001</li>

Results from both variables underpin that Orviglance significantly improves MRI performance.

<sup>1</sup> The above mentioned results stem from of a blinded-read study, which comprised all imaging data including Phase 1 and Phase 2 data. The blinded-read results have been presented at major radiology conferences

# ADDRESSABLE MARKET OF \$500-600 MILLION

#### \$500-600M annual addresable market in US, EU and Japan

#### Market estimate based on:

#### Upsides

Other markets, e.g., China

Annual growth of 4-5%

- Patients with primary liver cancer or liver metastases and severe kidney impairment (~4%)
- Actual imaging procedures (real-world data)<sup>1</sup>
- Payer and expert input (+75 stakeholders)<sup>2</sup>

#### Value maximizing go-to-market



#### Strong footprint in the US

- 1 SPARKLE Phase 3 Study at leading US sites
- 2 Hepatic Impairment Study 5 at Texas liver institute
- **Ascelia Pharma Inc.** Office in New Jersey

### 4 Manufacturing at Cambrex (partner), NJ

Imaging experts RadMD, NY

#### US team Around 40 FTEs at launch

Clinics/

Hospitals

**Building an Ascelia Pharma US team** 

Around 400 clinics and hospitals serve 75% of the target patient population<sup>1</sup>

Sources:

1: Ascelia Pharma market research with Decision Resources Group, 2020

2: Ascelia Pharma market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

# PREPARING FOR COMMERCIALIZATION

### 2022

### **PREPARE PRODUCT & MARKET**

- Engage with selected stakeholders
- Key opinion leaders and advisors
- Patient advocacy organizations
- Continue preparations for US access and pricing
- Advance pre-launch plans and in-market preparations
- Advance European partnering strategy



### 2023-2024

### **PREPARE MARKET & DRIVE LAUNCH**

- Build US commercial capability
- Prepare EU partner relationship
- Develop commercial supply and logistics operations
- Reach timely market authorization
- Prepare and execute cross-functional launch
  - Payer value and pricing
- Medical advocacy acceptance
- Early adoption and preference





# STRONG RESULTS FROM MARKET RESEARCH

New market research says 84% US healthcare professionals likely to use Orviglance imaging agent in target population. Chief Commercial Officer, Julie Waras Brogren, answers questions about the research.

#### Why is this market research important for Ascelia Pharma?

When preparing for launch, it is important to understand how decision makers see the value proposition of Orviglance – What influences their decisions? How do they perceive the unmet need and value proposition of Orviglance? These insights are key to launch preparations because they help us engage with the right influencers, with the right arguments at the right time.

#### What did the research teach you and the team?

The independent research was conducted with more than 250 health care professionals (radiologists, nephrologists and oncologists). The results confirm the strong need for an effective and safe alternative to gadolinium-based contrast agents (GBCAs) in liver imaging for patients with reduced kidney function. Firstly,

safety is a key decision driver of using an MRI contrast agent.

The most concerning side-effect overall when using GBCAs is Nephrogenic Systemic Fibrosis (NSF), followed by allergies and gadolinium toxicity. More than 15% of the 254 respondents have experienced a case of NSF – and more than half of these health care professionals have practiced medicine less than 15 years, i.e. they were not in clinical practice before the FDA black-box warning was issued in 2007.

In line with their concerns, key decision makers say that they prefer to use MRI without contrast agent for patients with severe kidney impairment (eGFR below 30) or acute kidney injury (AKI). Around 80% of the time, they use either MRI without a contrast agent or reduced dose MRI for these vulnerable patients.

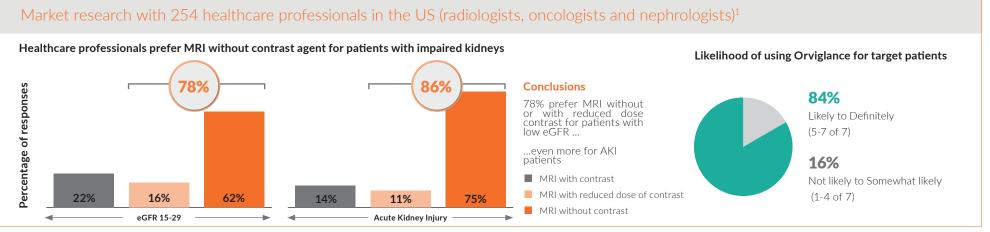
Respondents also say that patients are generally aware of the

risks associated with GBCA, particularly patients with poor kidney function, regardless of whether they have had an MRI before.

When presented the product profile of Orviglance, 84% of respondents say they are likely to or definitely will use Orviglance for the target patient population. These results are consistent with findings from quantitative research completed in 2018.

#### How can you use this market research?

The positive reactions to Orviglance from the research participants are incredibly encouraging. This gives us confidence that, once available, Orviglance can improve the outcomes for patients whose current diagnostic options are sub-optimal. We will also use the valuable insights from the survey when engaging with key stakeholders as we prepare for launch.



<sup>1</sup>As part of the preparations for Orviglance® launch, Ascelia Pharma conducted primary market research in the US. The research covered 16 interviews and a survey among 254 HCPs, including 154 radiologists, 50 nephrologists and 50 oncologists. The research was conducted end 2021/early 2022.

# ONCORAL

Daily oral chemotherapy ready for Phase 2

- Patented tablet chemotherapy formulation
- Potential for better efficacy and safety
- Phase 2 in gastric cancer; potential to expand into other solid cancer forms

# 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, a cancer that begins in glandular tissue. 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 a serious disease.** Gastric cancer is the third most frequent cause of cancer mortality. The five-year survival rate in the US and Europe is only 20%. In this region 80-90 % of the gastric cancer patients in these countries are diagnosed at an advanced stage and/or have disease relapse within five years. When diagnosed at a late stage, gastric cancer is typically un-resectable and/or metastatic. The incidence rate is higher in Asia, as exemplified by Japan where the incidence rate is five times that of the US and Europe.

**Market of USD 3+ billion.** The gastric cancer drug market is growing rapidly and is expected to reach USD 4 billion by 2029 according to GlobalData. This growth is fueled by several factors, including an increase in the overall incidence as well as increase in treatment rates and extended treatment duration.

**Irinotecan is an established and effective chemotherapy.** The current first-line treatment of recurrent or advanced gastric can¬cer includes chemotherapy, generally as a combination of two or three drugs. Chemotherapeutic drugs (cytotoxics) stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.

There are several chemotherapeutic drugs on the market, and one well-established and effective molecule is irinotecan. It has a proven anti-tumor effect and is approved for combination use in several solid cancer indications.

In the US and Europe, irinotecan is currently mainly used for treating metastasized colorectal and pancreatic cancer. Although irinotecan is currently not approved for treating gas¬tric cancer in the US and in the EU, there is off-label clinical use. It is also recognized in clinical guidelines (ESMO, ASCO, NCCN) in mono-therapeutic or combination treatment regimens for ad-vanced gastric cancer. In Japan, irinotecan is approved for the treatment of metastatic gastric cancer.

**Untapped market for oral formulations of irinotecan. T**oday, irinotecan is only available as high-dose intravenous infusion. Ascelia Pharma sees a significant and unmet medical need for new patient-friendly treatments that improve the life expectan-cy and quality of life for patients with gastric cancer.

**Oncoral - an oral chemotherapy.** Oncoral is a daily irinotecan tablet with the potential to offer better efficacy with improved safety following the daily dosing at home compared to intrave¬nous high-dose infusions at the hospital.

### Large unmet need to develop novel therapies

- 1 million new cases every year
- 3rd most common cause of cancer death
- Median survival less than one year
- Need for better and more optimal treatment options for late stage therapy



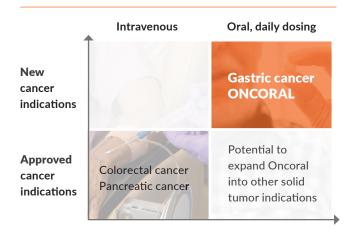
# SOLUTION - CHEMOTHERAPY AS TABLET

Oncoral is a novel daily irinotecan chemotherapy in development. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily irinotecan tablet with the potential to offer better efficacy with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital.

**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 so-called antineoplastic agent that after metabolic activation inhibits the enzyme topoisomerase 1, thereby inducing cancer cell death via the prevention of their DNA replication. Irinotecan is converted by carboxylesterases, primarily in the liver, to the active metabolite SN-38 which is 100–1,000 more potent than irinotecan in killing tumor cells. **Potential to be the first oral version of irinotecan.** Oncoral is a new patented oral tablet formulation 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-tumor activity.

**All-oral chemo combination.** Oncoral has the potential to be combined with other chemotherapies and targeted cancer drugs and enable an all oral combination chemotherapy option with improved clinical outcomes.

### Oncoral - a novel formulation of irinotecan



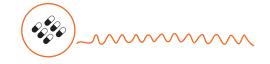
#### **TODAY** – Intravenous bolus infusions



#### Infrequent high-dose IV irinotecan

- Gastrointestinal and haematological side effects
- Side-effects: 30% severe or life-threatening (grade 3 or 4)

#### **TOMORROW** - Oncoral oral daily dosing

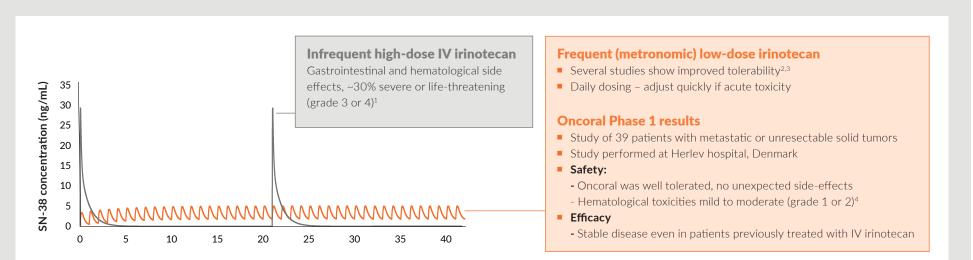


#### Potential - Frequent low-dose irinotecan

- Improved efficacy driven by pharmacokinetic/ dynamic profile
- Improved tolerability due to lower peak exposure with less severe side effects and manageable toxicity with flexible dosing

## ONCORAL PHASE 1: ENCOURAGING RESULTS

**Oncoral – potential to improve both Efficacy and Safety.** Intravenous chemotherapy is often a trade-off between desired treatment effect and tolerability for the patient. With Oncoral as a daily irinotecan tablet there is a potential to improve both efficacy and tolerability compared to intravenous (IV) administration. In addition, it may offer convenience for the patient and at the same time reduce hospital costs with home administration. **Efficacy.** The potential to improve efficacy is based on a fivefold higher conversion rate of irinotecan to the cytotoxic active metabolite SN-38 when dosed orally compared to an IV infusion. In addition, the principle of frequent, low daily dosing, also called metronomic dosing, may optimize the exposure of SN-38 and maximize the anti-tumor effect. Several studies provide proof of concept for metronomic dosing, including improved patient outcomes. **Safety.** Conventional IV bolus administration of irinotecan is associated with toxicity. Most patients experience gastrointestinal and hematological side effects, of which approximately 30% are severe or life-threatening (grade 3 or 4, ref: Camptosar<sup>®</sup> prescribing information). Frequent low dosing, avoiding high peak plasma levels, may reduce toxicity and complications compared to high-dose IV infusions. Oral daily administration also brings the opportunity to adjust dosing quickly in case of acute toxicity.



#### Plasma levels of irinotecan

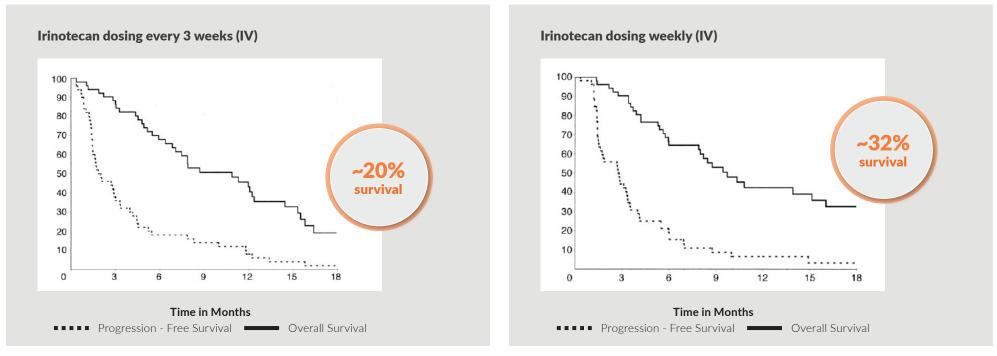
Source: Simulation of Oncoral vs. IV Camptosar

Refs: 1) Camptosar prescribing information 2) Furman et al 1999 3) Perez et al 2004 4) Kumler et al 2018

# IMPROVING EFFICACY BY FREQUENT LOW DOSING

There are a number non-clinical and clinical studies that provide provide proof-of-concept for metronomic/frequent low dosing of irinotecan, including improved patient outcomes. The study below in patients with metastatic refractory breast cancer illustrates improvement in overall survival by frequent low dosing. Overall survival improved from 20% with dosing every third week with high dose to 32% with weekly dosing with a slightly lower dose<sup>1</sup>. With Oncoral as a tablet, it will be possible with daily dosing.

### **OVERALL SURIVAL: STUDY IN PATIENTS WITH METASTATIC REFRACTORY BREAST CANCER, N=103**



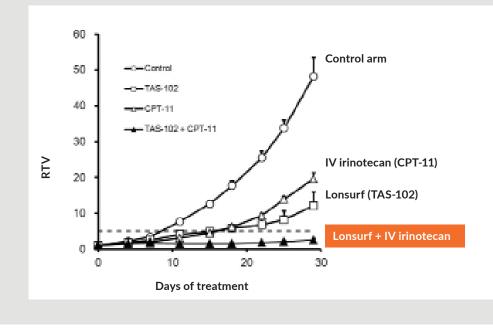
<sup>1)</sup> Perez et al. J Clin Oncol 2004: Randomized Phase II Study of Two Irinotecan Schedules for Patients With Metastatic Breast Cancer Refractory to an Anthracycline, a Taxane, or Both

# POTENTIAL FOR SYNERGISTIC EFFECT

The planned Phase 2 study will address metastatic gastric cancer. In the study, Oncoral will be combined with Taiho Oncology's oral drug Lonsurf that is used today for treating metastatic gastric cancer. The combination of irinotecan (the active substance in Oncoral) and Lonsurf has been tested in animal models, which showed that the combination almost stopped the tumour from growing and gave better results than administering them as monotherapies.

#### Efficacy study in an animal model of gastric cancer<sup>1</sup>

(Relative Tumor Volume, RTV)



#### Strong rationale for gastric cancer

- Large unmet medical need
- Clinical guidelines support efficacy of irinotecan
- Potential for Orphan Drug Designation
- Potential for synergistic effect between Lonsurf and irinotecan

1: Nukatsuka et al: Combination Chemotherapy Using TAS-102 and Irinotecan Hydrochloride, ANTICANCER RESEARCH 35: 1437-1446 (2015)

# PHASE 2 STUDY DESIGN AND COLLABORATION

Clinical collaboration with Taiho Oncology

### Phase 2 study design

PATIENTS	<ul> <li>Around 100 patients</li> <li>Metastatic gastric cancer</li> <li>Randomized controlled, multicenter/multinational</li> </ul>	<ul> <li>Clinical Phase 2 collaboration with Taiho Oncology Inc. (part of Otsuka Group)</li> <li>Taiho Oncology Inc. will supply Lonsurf and provide scientific expertise</li> <li>The collaboration may be extended for further development</li> <li>Ascelia Pharma retains full development and commercialization rights</li> </ul>
COMPARATOR	Oncoral + Lonsurf vs. Lonsurf	EONSURF is approved for treatment of metastatic gastric cancer and metastatic
ENDPOINTS	<b>Primary:</b> Progression Free Survival <b>Secondary:</b> Response rate, PK, Safety and Overall Survival data in a follow up analysis	colorectal cancer
STUDY PERIOD	2022 - 2024	

# ONCORAL SCIENTIFIC ADVISORY BOARD

The development of Oncoral is supported by a high profile Advisory Board of world-leading gastrointentional oncologists. Their joint view is that Oncoral would be an important treatment option for cancer patients, especially in later disease stages.



#### Prof Josep Tabernero, MD, PhD

Head of the Medical Oncology Department at the Vall d'Hebron Barcelona Hospital Campus, Director of the Vall d'Hebron Institute of Oncology (VHIO), and Professor of Medicine

President (2018 – 2019) of ESMO and an Executive Board and Council Member



#### Prof Eric Van Cutsem, MD, PhD

Professor and Division Head of Digestive Oncology at University of Leuven (KUL) and University Hospitals Gasthuisberg, Leuven, Belgium

Co-founded ESMO GI/World Congress on GI Cancer. Serves/served on the board/ committee of ESMO, ASCO, ENET, EORTC, ECCO, ESDO



#### Prof Jaffer A Ajani, MD

Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, USA

Chairs the NCCN committee for gastroesophageal cancers



#### Prof Jeff Evans, MD

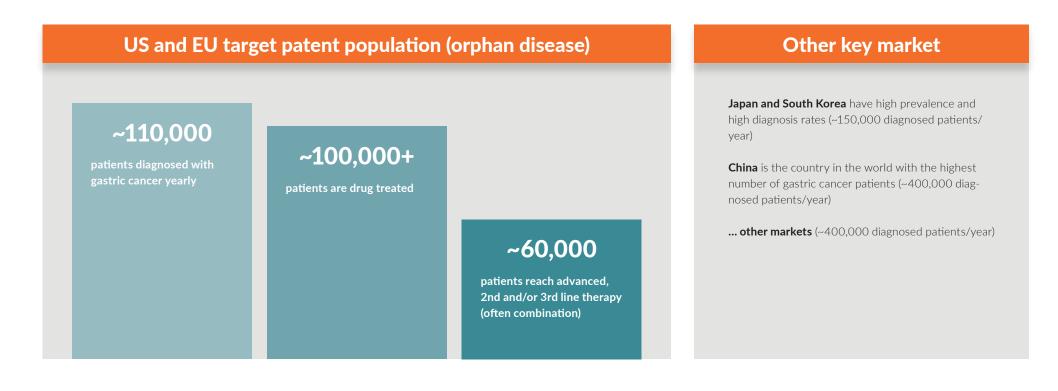
Professor of Translational Cancer Research and Clinical Lead of the Institute of Cancer Sciences, University of Glasgow

Member of the NCRN Upper GI Cancer Pancreatic Cancer and Gastro-Oesophageal Cancer sub-groups

Joint view that Oncoral would be an important treatment option for cancer patients, especially in later disease stages

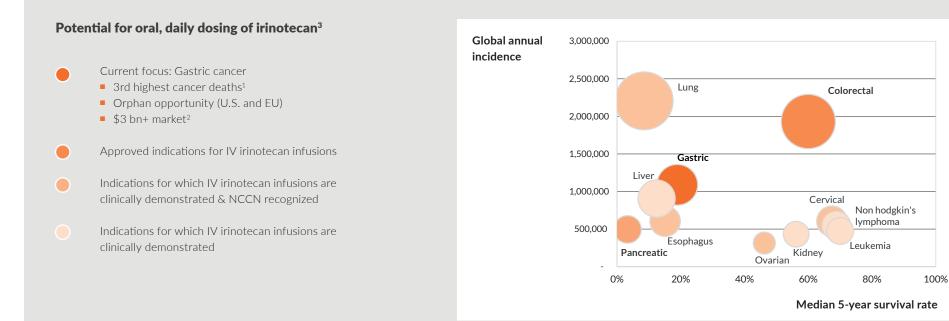
# GASTRIC CANCER - A \$3 BN+ MARKET OPPORTUNITY

There continues to be a massive unmet medical need for better treatment options within gastric cancer. This translates into a commercial opportunity for treatment gastric cancer in excess of \$3 billion on an annual basis. Many patients are diagnosed with gastric cancer every year, but the geographical spread is uneven. In United States and in Europe it is a rare cancer type that allows for an Orphan Drug Designation. In Asia, it is unfortunate a highly prevalent disease in comparison.



# HIGH VALUE OPPORTUNITY IN OTHER CANCER FORMS

Beyond gastric cancer there is potential for subsequent label expansion into other solid tumour indications. Within colorectal and pancreatic cancer, irinitecan for intravenous administration is already approved for use in Europe and the US. Apart from these indications, there are also other cancer forms where irinotecan has been clinically demontrated and recognized



1) International Agency for Research on Cancer (IARC, 2021)

2) GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma - Global Drug Forecast and Market Analysis to 2024

3) Globocan 2020, WHO, Cancer Research UK

# SHAREHOLDER INFORMATION

Ascelia Pharma AB (publ) is listed on Nasdaq Stockholm under the ticker ACE. At 31 December 2021, the company had 33,668,262 registered common shares and 908,186 C-shares with 1/10 voting rights (C-shares are held by Ascelia Pharma AB).

#### Share performance and market cap

In 2021, Ascelia Pharma's share price declined by 47%. The decline followed the trend of other biotech companies during 2021. The market value of Ascelia Pharma at 31 December 2021 was SEK 1.0 billion.

The trading liquidity in the share increased by 67% in 2021 compared to 2020 and the median number of traded shares per day was 51,000 in 2021.

#### **Ownership structure**

The five largest shareholders as of 31 December 2021 had a total of 35% of the capital and 36% of the votes. Around 5% of shares are held directly or indirectly by Management and Board members.

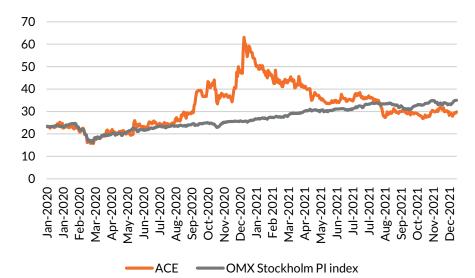
#### **Financial information**

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.

#### **2022 Annual General Meeting**

The AGM of Ascelia Pharma AB (publ) will be held on 5th of May 2022.

Share price development (OMX Stockholm indexed to ACE)





### **Equity analysts:**

Ascelia Pharma is covered by Danske Bank, Erik Penser Bank, Redeye and Analysguiden.

10 LARGEST SHAREHOLDERS PER 31 DEC 2021	No. of shares	% of capital	% of votes
Sunstone Life Science Ventures Fund II	4,778,129	13.8%	14.2%
Fourth Swedish National Pension Fund (AP4)	2,709,266	7.8%	8.0%
Øresund-Healthcare	1,844,165	5.3%	5.5%
Futur Pension	1,514,412	4.4%	4.5%
Avanza Pension	1,277,021	3.7%	3.8%
ÖstVäst Capital Management	1,200,000	3.5%	3.6%
Spogárd Holding A/S	1,010,203	2.9%	3.0%
Unionen	1,000,000	2.9%	3.0%
Nordnet Pensionsförsäkring	850,344	2.5%	0.3%
Eiffel Investment Group	754,432	2.2%	2.5%
Other holders of common shares	16,730,290	48.4%	49.6%
Total common shares	33,668,262	97.4%	99.7%
C-shares (held by Ascelia Pharma), 1/10 voting rights	908,186	2.6%	0.3%
TOTAL ALL SHARES	34,576,448	100%	100%

# 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 2021-01-01 – 2021-12-31 for the Group and the Parent company.

#### **Ownership structure**

Ascelia Pharma AB (publ) is listed on Nasdaq Stockholm. The largest shareholders per 31 December 2021 were Sunstone Life Science Ventures Fund II K/S with 4,778,129 shares (13.8% of total shares) followed by Fourth Swedish National Pension Fund (AP4) with 2,709,266 shares (7.8%) and Øresund Healthcare Capital K/S with 1,770,490 shares (5,3%).

#### ASCELIA PHARMA'S BUSINESS

Ascelia Pharma is a biotech company focused on orphan oncology treatments. We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway. The company has two drug candidates in clinical development:

**Orviglance** (manganese chloride tetrahydrate) is a novel oral contrast agent for MR-imaging developed to improve the detection and visualization of focal liver lesions (including liver metastases and primary tumors) in patients with reduced kidney function. Orviglance, which has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA), is currently in Phase 3 development, including the global multi-center SPARKLE study.

**Oncoral** is a novel irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily tablet with the potential to offer better patient outcomes with improved safety following the daily dosing at home compared to intravenous high-dose infusions at the hospital. Following successful Phase 1 results, Oncoral is now prepared for Phase 2 clinical development.

#### The year in brief

The year 2021 continued to be significantly influenced by the Covid-19 pandemic that affected all societies and not the least healthcare systems. It also impacted clinical study activities and for us it meant a slower patient recruitment pace for the Orviglance pivotal Phase 3 study SPARKLE. We have responded to this by increasing the number of hospitals recruiting patients into the study, supported medical staff by sharing best practices for identifying eligible patients and also amended the study protocol to include patients on hemodialysis and patients with hepatic impairment. Despite the situation with Covid-19, we made significant progress across our clinical portfolio:

- Completed the Food Effect Study in the Orviglance clinical program
- Presented strong results for Orviglance in a comparison study to gadolinium
- Entered a clinical collaboration with Taiho Oncology for Oncoral
- Gained approval from the FDA of Oncoral's IND application

With respect to financing, Ascelia Pharma strengthened the balance sheet through a directed share issue in March 2021 raising SEK 200 million.

#### Multi-year overview, Group

Financials key ratios for the Group				
SEK thousands	2021	2020	2019	
Net sales	-	-	-	
Operating results	-137,948	-93,428	-63,023	
Net results	-125,903	-98,697	-66,036	
Earnings per share (SEK)	-3.82	-3.76	-3.02	
R&D costs/operating costs (%)	78%	69%	69%	
Cash flow from operations	-116,559	-85,527	-54,300	
Equity	307,834	236,056	237,062	
Liquid assets incl. marketable securities	261,599	184,686	184,227	

### **FINANCIAL OVERVIEW 2021**

### EARNINGS AND PROFITABILITY

#### Net sales and other operating income

The Group's net sales in FY-2021 (Jan-Dec) amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognize revenue before products have been launched on the market. Other operating income totaled SEK 317 thousand (SEK 756 thousand).

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

R&D costs for the Group in FY-2021 were SEK 107.6 million (SEK 64.8 million). The cost increase of SEK 42.8 million underlines an overall higher activity level in Ascelia Pharma in the current period vis-à-vis corresponding period last year. This was driven by costs related to Orviglance Phase 3 clinical study and manufacturing preparations as well as increased costs for Oncoral Phase 2 preparations.

#### **Commercial preparation costs**

In FY-2021, costs related to commercial preparations of amounted to SEK 13.2 million (SEK 10.2 million). The costs increase compared with 2020 reflects commercial preparations towards launching of Orviglance to the market.

#### **Administration costs**

Administration costs for the Group in FY-2021 amounted to SEK 17.1 million (SEK 18.3 million). The cost decrease is partially explained by high recruitment costs in Q1-2020.

#### **Operating results (EBIT)**

The operating result in FY-2021 amounted to SEK -137.9 million (SEK -93.4 million). The increased loss reflects the overall higher level of R&D activities and manufacturing preparations in 2021.

#### Net Profit/Loss for the period

The Group's net loss in FY-2021 amounted to SEK -125.9 million (SEK -98.7 million). In FY-2021, net financial income of SEK 8.4 million was recognized due to strengthening of USD, which translated into an increase in the value of bank deposits (a significant part of bank deposit is held in USD to match upcoming cash outflow in these currencies). The net loss corresponds to a loss per share, before and after dilution, of SEK -3.82 (SEK -3.76).

### CASH FLOW

Cash flow from operating activities before changes in working capital in FY-2021 amounted to SEK -130.0 million (SEK -84.8 million). The increased outflow y/y primarily reflects the higher level of R&D activities and manufacturing preparations in the current period. Changes in working capital in the current period totaled an inflow of SEK 13.5 million (outflow of SEK 0.7 million). The inflow in the current period primarily reflects increase in accrued expenses and accounts payable as well as decrease in advance payments to major suppliers.

Cash flow from investing activities in FY-2021 totaled SEK -38 thousand (inflow of SEK 76.0 million). Cash flow from financing activities amounted to an inflow of SEK 184.9 million (inflow of SEK 92.7 million), which reflects net proceeds from the share issuance in the spring 2021.

#### FINANCIAL POSITION

On the closing date, equity amounted to SEK 307.8 million, compared with SEK 236.1 million per 31 December 2020. The increase since 31 December 2020 reflects the issuance of new shares in the spring 2021, which outweighed the net losses incurred in 2021.

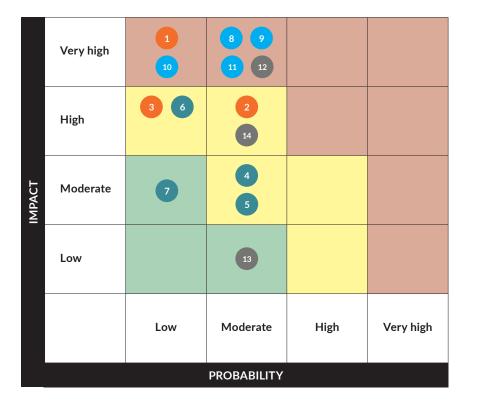
Liquid assets on the closing date amounted to SEK 261.6 million, compared to SEK 184.7 million per 31 December 2020, which also is an effect of the share issuance in the spring 2021 n

#### **RISK AND RISK MANAGEMENT**

In order to grow and sustain the value of Ascelia Pharma and our products, business and organization, we must anticipate and adapt to our surrounding environment and stakeholders. Changes in our environment can have a negative impact – pose a risk – on our image, results and value. Managing risks regularly and systematically is key to creating and protecting value over time. We do this by anticipating and mitigating risks – to the extent possible and reasonable – to limit the likelihood of events occurring and limit the undesirable impact on Ascelia Pharma. Ascelia Pharma categorizes its risks in four broad categories and the associated time frame of 2 years:

- Strategic risks
- Operational and compliance risks
- Commercialization risks
- Financial and macroenvironment risks

The individual risk factors in these categories are summarized in the risk map below. The following pages 35-36 provides a description of the risk factors of how the Group manages these risks.



	TYPE OF RISK	Probability	Impact
	STRATEGIC RISKS		
1	Failure to reach clinical trial endpoints or regulatory approval	Low	Very high
2	Significant delay of key clinical programs	Moderate	High
3	Significant additional post approval regulatory requirements	Low	High
	OPERATIONAL AND COMPLIANCE RISKS		
4	Unable to attract or keep key personnel	Moderate	Moderate
5	Disruption or quality failure of supply and manufacturing	Moderate	Moderate
6	Critical breach of legislation, industry codes and standards	Low	High
7	Significant loss of data (IT) or cyber security breach	Low	Moderate
	COMMERCIALIZATION RISKS		
8	Inability to timely reach targeted pricing & access	Moderate	Very high
9	Unfavorable changes in regulatory or clinical guidelines	Moderate	Very high
10	New competitor entry	Low	Very high
11	Inability to reach desired partnering agreements (out-license)	Moderate	Very high
	FINANCIAL AND MACRO ENVIRONMENT RISKS		
12	Inability to timely raise funds to meet goals	Moderate	Very high
13	Significant unfavorable currency development	Moderate	Low
14	Significant macro events (pandemic, geopolitical) etc.	Moderate	High

### **DIRECTORS' REPORT**

	RISK AREA	DESCRIPTION OF RISK	OPPOSITION FACTORS AND MITIGATING ACTIONS	Probability	Impact
	STRATEGIC RISI	KS			
1	Failure to reach clinical trial end- points or regulatory approval	There is always a risk that the critical medical hypothesis cannot be supported by data from the development activities; this may force the company to re-start research to identify new opportunities or in worst case complete closing of the development for that specific asset. A related risk is that regulatory authorities will not approve the drug, without additional clinical data.	<ul> <li>Both Orviglance and Oncoral are based on established proof-of-principle and known mode- of-action for the API, which reduce the risk of failing on primary endpoints</li> </ul>	Low	Very high
2	Significant delay of key clinical programs	A common cause for delays is difficulties to recruit patients to clinical trials. Ascelia Pharma is working within in rare (orphan) conditions where there by definition are few patients, which may add to this risk.	<ul> <li>Ascelia Pharma conducts feasibility studies to understand the patient pools</li> <li>The clinical trails are run by established international Contract Research Organizations (CROs)</li> <li>Measures to boost patient recruitment for the SPARKLE trial have in 2021 included e.g. addition of clinical sites and protocol amendments</li> </ul>	Moderate	High
3	Significant additional post approval regulatory requirements	Post-approval commitments, i.e., new studies to address (mostly safety) concerns are common and expected pre-requisites for getting a new drug approved.	<ul> <li>Dialogue with the regulatory authorities including the FDA and EMA.</li> </ul>	Low	High
	OPERATIONAL	AND COMPLIANCE RISKS			
4	Unable to attract or keep key personnel	Employees are a critical asset, especially for a small biotech com- pany with dependence key personnel. Inability to retain and attract skilled personnel can lead to loss of knowledge and efficiency.	<ul> <li>Individual development plans, incentive programs, flexible working hours</li> <li>Promotion of good working conditions and collaboration</li> <li>Back-up persons on critical tasks</li> </ul>	Moderate	Moderate
5	Disruption or qual- ity failure of supply and manufacturing	Ascelia Pharma has outsourced a significant part of its clinical de- velopment activities to CROs and all manufacturing is external. Risk that third-party suppliers fail to comply with laws, regulation, guide- lines and practises or is unable to deliver according to expectations that can cause undesirable delays in the development process. Additionally, it may be difficult to find back-up suppliers, for a small company, with small manufacturing volumes.	<ul> <li>Structured vendor selection processes have been implemented to limit the risk of vendor disruption or underperformance, incl. back-up vendors when possible</li> <li>Ongoing monitoring of vendors to ensure Good Pharmaceutical Practice (GxP)</li> </ul>	Moderate	Moderate
6	Critical breach of legislation, industry codes and standards	The pharmaceutical industry legislations and regulations are rigorous and complicated, e.g., in relation to business ethics and requirements for transparency on interactions with health care professionals, and handling of personal data (GDPR). Non-compliance with applicable legislation, codes and standards may be costly and/or can severely impact reputation.	<ul> <li>Data processing agreements on all important contracts involving personal data</li> <li>GDPR policies in place</li> <li>Timely development of processes and procedures to manage the requirements</li> </ul>	Low	High
7	Significant loss of data (IT) or failure or cyber security breach	Ascelia Pharma is dependent on a secure and well-functioning IT environment and intrusion into the systems can be costly	<ul> <li>IT processes and security are classified as a business critical activity and more resources have been assigned to IT</li> <li>Cyber risk insurance is in place</li> </ul>	Low	Moderate

### **DIRECTORS' REPORT**

	RISK AREA	DESCRIPTION OF RISK	OPPOSITION FACTORS AND MITIGATING ACTIONS	Probability	Impact
	COMMERCIALI	ZATION RISKS			
8	Inability to timely reach targeted pricing & access	Ascelia Pharma develops products for indications with high unmet medical need with the expectation of obtaining access and premium pricing. Market approval does not guarantee that the expected premium pricing can be achieved or that reimbursement will be obtained. A significant price reduction or delay of reimbursement/ access will impact market potential.	<ul> <li>Ascelia Pharma applies a value-based pricing strategy for its products and plans to prepare solid value evidence</li> <li>Payer research has been conducted to confirm pricing and access assumptions</li> <li>Pre-launch market access plans and activities implemented to drive early adoption at pricing strategy</li> </ul>	Moderate	High
9	Unfavorable chang- es in regulatory or clinical guidelines	The use of Ascelia Pharma's drugs can be affected by changes in regulatory guidelines, clinical guidelines and recommendations as well as market acceptance among physicians and providers	<ul> <li>Orviglance Phase 3 study is conducted on leading hospitals with influential KOLs</li> <li>External market research has been conducted confirming the unmet medical need</li> <li>Advisory board for Oncoral composed of world-class influential oncology KOLs</li> </ul>	Unlikely	Low
10	New competitor entry	Ascelia Pharma is a small biotech company that may face competi- tion from companies with considerably larger resources.	<ul> <li>Ascelia Pharma focuses on underserved oncology niches where the competitive landscape is less fierce</li> <li>Continuous market monitoring, incl. guidelines, clinical practice and competitors</li> <li>Patents and patent applications are handled by experienced patent attorneys</li> <li>Explore new patents for current products</li> <li>Maximize regulatory exclusivity, e.g., through Orphan Drug Designation and data exclusivity</li> </ul>	Low	High
11	Inability to reach desired partnering agreements (out-li- cense)	On selected markets, Ascelia Pharma aims to out-license its drugs. There is a risk that suitable partners cannot be found or that the terms or collaboration will not be satisfactory.	<ul> <li>In-house Business Development function to drive partnering and out-licensing activities.</li> </ul>	Moderate	High
	FINANCIAL AN	D MACROECONOMIC RISKS			
12	Inability to timely raise funds	Ascelia Pharma is still in development phase with no revenue and dependent on financing from the equity capital markets	<ul> <li>Proactively addressing cash position to ensure runway until revenue generation stage</li> <li>Strong track record for obtaining financing with SEK 500 million raised in 2019-2021</li> </ul>	Moderate	Very high
13	Significant unfa- vorable currency development	Ascelia Pharma has substantial development costs in primarily USD and EUR (with no offsetting revenue in these currencies). Conse- quently, an appreciation of these currencies towards SEK would mean increased costs to the Group	<ul> <li>In accordance with the financial policy, Ascelia Pharma handles the currency exposure by exchanging SEK to USD, EUR and DKK to match upcoming cash outflow</li> </ul>	Likely	Low
14	Significant macro events such as pandemic out- breaks, geopolitical instability etc.	Significant change in the macroeconomic situation can impact the ability conduct business and clinical studies. In 2021, the Covid-19 pandemic caused disruptions to the healthcare industry incl. delays in the enrollment of patients at clinical sites	<ul> <li>Covid-19 safety precautions for employees and stakeholders implemented to minimize risks</li> <li>The Phase 3 study SPARKLE is conducted in different continents and countries, which might mitigate the effect from macro events</li> </ul>	Moderate	High

# OTHER INFORMATION

### **Employees**

Ascelia Pharma 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 31 December 2021 amounted to 21 (11) for both the Group and the Parent company (average 18 employees in 2021 and 11 in 2020). In addition to the employees, Ascelia Pharma utilizes consultants and experts for clinical trials, regulatory affairs, manufacturing, IP rights as well as support functions.

### Significant events after the end of the financial year

Refer to note 28 in this Annual Report for significant events after the reporting period. Special attention shall be directed to the consequences of Russia's invasion of Ukraine, which meant that Ascelia Pharma in March 2022 discontinued all clinical activities in the country. As a result, expected recruitment completion to the SPARKLE study was extended to 2022 (previously H1 2022).

## PARENT COMPANY

Ascelia Pharma AB (publ) fully owns all the companies in the Group. The equity/assets ratio on the closing date was 93% (93%). Equity amounted to SEK 333M (SEK 245M). Liquid assets amounted to SEK 246M (SEK 182M). The company had 21 employees on the closing date.

### Total number of shares

The total number of outstanding common shares as of 31 December 2021 was 33,668,262 and number of C-shares was 908,186 as of 31 December 2021. All shares in Ascelia Pharma are fully paid and have a quota value of SEK 1. There are no restrictions on the right to freely transfer the company's shares.

### **Corporate Social Responsibility**

Ascelia Pharma works to evolve as a sustainable company and has developed a Corporate Social Responsibility policy. The company has, however, not yet reached a state with revenue generation and consequently the company's products have a very limited 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.

Our employees are the cornerstone of our success. Highly qualified, committed and motivated employees are a prerequisite for achieving Ascelia Pharma's business goals. We have individual development plans for each employee that both contribute to the employees' development and motivation and ensure that their goals coincide with the company's business goals. In order to contribute to a good working environment, we have established policies and procedures for sys-

tematic business environment work. Our employees act with high integrity, which is also regulated in our Code of Conduct. Given the current size of the company, no sustainability report for 2021 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 organization 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 12 minuted meetings during 2021. From its membership, the Board has appointed an audit committee, a remuneration committee and a commercialization committee. During the year, the audit committee held five meetings, the remuneration committee held five meetings and commercialization committee held four meetings.

### **Guidelines for remuneration**

The guidelines for remuneration to senior management is described in the Corporate Governance section and in note 7 in this Annual Report.

## Proposed appropriation of the company's result:

The following amounts (SEK) in the Parent Company are at the disposal of the AGM:

SEK
678,831,038
-271,295,591
-109,288,176
298,247,271

Board of Directors proposes that SEK 298,247,271 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 longterm 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 2021**

At the Annual General Meeting held on 5 May 2021, Peter Benson was re-elected as Chairman of the Board and Niels Mengel, Bo Jesper Hansen, René Spogárd, Helena Wennerström, Lauren Barnes and Hans Maier were re-elected as board members. Furthermore, Öhrlings Pricewater-houseCoopers 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. The Annual General Meeting further approved the instructions and rules of procedure for the nomination committee. The Annual General Meeting finally also resolved on an authorization for the board of directors to issue shares and on a share-based incentive program for employees.

#### **Extraordinary General Meeting 2021**

An extraordinary general meeting of Ascelia Pharma AB (publ) was held on April 13, 2021, which resolved on approval of the board of directors' resolution on directed issue of shares.

#### Annual General Meeting 2022

The Annual General Meeting (AGM) of Ascelia Pharma AB (publ) will be held on 5 May 2022. Due to the Covid-19 pandemic and in order to reduce the risk of infection spreading, the AGM, with the support of temporary statutory rules, will be conducted only by postal voting.

#### Shareholders

On 31 December 2021, the five largest shareholders controlled around 35% of capital 36% of the votes. The largest shareholder controlling more than 10% of the capital and votes were Sunstone Life Science Ventures Fund II K/S (13.8% of capital 14.2% of votes). On 31 December 2021, the number of common shares was 33,668,262 and the number C-shares, that has one-tenth of a vote per share, amounted to 908,186. Each common 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.

According to the instructions and rules of procedure for the Nomination Committee, the Nomination Committee shall consist of four members representing the three largest shareholders per the end of September, 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 2021 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;
- Marianne Flink, appointed by the Fourth Swedish National Pension Fund (AP4);
- Håkan Nelson, appointed by Øresund Healthcare; 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 organization 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 seven ordinary board members elected by the general meeting, who are presented in the section Board of directors on pages 45-47 in this Annual Report.

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 2021

The board of director's had 12 meetings in 2021. In addition to decisions concerning external financial reporting, budget and financial forecasts, the board's work during 2021 have primarily comprised matters related to the Phase 3 trial for Orviglance, planning for Oncoral Phase 2 trial and financing activities. The board has evaluated its work to improve the work procedures and enhance efficiency. Conclusions of the work are presented to the nomination committee.

### Reporting period 1 January 2021 - 31 December 2021

		Independent in	relation to		Remur	eration, SEK thousan	nd		Attendar	nce (attendance i	n relation to to	al meetings)
Board member Function	The company and its management	Major shareholders	Board fees	Audit Committee	Remuneration Co Committee	ommercialization Committee	Total	Board of Directors	Audit I Committee	Remuneration Committee	Commercialization Committee	
Peter Benson	Chairman	Yes	Yes	465	-	-	25	490	12/12	-	5/5	4/4
Lauren Barnes	Board member	Yes	Yes	233	-	-	100	333	12/12	-	-	4/4
Bo Jesper Hansen	Board member	Yes	Yes	233	-	-	51	238	10/12	-	5/5	-
Hans Maier	Board member	Yes	Yes	233	-	-	25	258	12/12	-	-	3/4
Niels Mengel	Board member	Yes	Yes	233	25	-	-	258	12/12	5/5	-	-
René Spogárd	Board member	Yes	Yes	233	-	-	-	233	12/12	-	3/5	-
Helena Wennerström	Board member	Yes	Yes	233	100	-	-	333	12/12	5/5	-	-
Total				1,861	125	-	155	2,142				

1) Bo Jesper Hansen resigned from the Commercialization Committee in Q2-2021.

#### **Board committees**

The board of directors has set up three committees: the Audit Committee, the Remuneration Committee and the Commercialization Committee. The board of directors has adopted rules of procedure for all committees.

#### Audit Committee

The Audit Committee is comprised of Helena Wennerström (chairman) 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 five meetings in 2021.

#### Remuneration Committee

The Remuneration Committee is comprised of Bo Jesper Hansen (chairman), Peter Benson and René Spogárd. 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 five meetings in 2021.

#### Commercialization Committee

The Commercialization Committee is comprised of Lauren Barnes (chairman), Peter Benson and Hans Maier. The Commercialization Committee's role is primarily to prepare resolutions to be adopted by the Board pertaining to matters regarding overall commercialization plans and key commercialization decisions of products within Ascelia Pharma. The committee also oversees launch readiness and oversee that commercialization capabilities are available timely and adequately according to agreed plans. The Commercialization Committee had four meetings in 2021.

#### 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 four people which in addition to the CEO is comprised of the Chief Financial Officer, the Chief Medical Officer and the Chief Commercial Officer. The CEO and the senior executives are presented in the section Executive Management on pages 47-48 in this Annual Report.

#### 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 5 May 2021, it was resolved in accordance with the proposal from the Nomination Committee that board remuneration for the period until the annual general meeting in May 2022 shall be paid with SEK 500,000 to the chairman of the board and with SEK 250,000 to each of the other board members who are not employed by the company. The meeting further resolved in accordance with the proposal from the Nomination Committee that remuneration for committee work shall be paid with SEK 100,000 to the chairman of the Audit Committee and same amount for the chairman of the Commercialization Committee, and with SEK 25,000 to each of the other members of these two committees. No separate remuneration shall be paid for work in the Remuneration Committee.

#### Guidelines for remuneration to senior executives

#### Scope and applicability of the guidelines

These guidelines comprise the persons who are part of Ascelia Pharma AB's group management, currently the CEO, CFO, CMO and CCO. The guidelines also encompass any remuneration to members of the board of directors, in addition to board remuneration.

These guidelines are applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the guidelines by the annual general meeting 2020. These guidelines do not apply to any remuneration resolved by the general meeting, such as e.g. board remuneration and share-based incentive programs.

#### The guidelines' promotion of the company's business strategy, long-term interests and sustainability

A successful implementation of Ascelia Pharma's business strategy and safeguarding of Ascelia Pharma's long-term interests, including its sustainability, require that the company is able to recruit and retain highly competent senior executives with a capacity to achieve set goals. In order to achieve this, Ascelia Pharma must offer a competitive total remuneration on market terms, which these guidelines enable.

Long-term share-based incentive programs have been implemented in Ascelia Pharma. For further information about these programs, see note 6 in this Annual Report. The share-based incentive programs have been approved by the general meeting and are therefore not covered by these guidelines.

#### Types of remuneration, etc.

The remuneration shall be on market terms and be competitive, and may consist of the following components: fixed salary, variable cash remuneration, pension benefits and other benefits. For the

individual senior executive, the level of remuneration shall be based on factors such as competence, area of responsibility and performance. Additionally, the general meeting may – irrespective of these guidelines – resolve on, e.g. share and share price-related remuneration.

For employments governed by rules other than Swedish, pension benefits and other benefits may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of these guidelines.

#### Fixed salary

The CEO and other senior executives shall be offered a fixed annual cash salary. The fixed salary shall as a starting point be determined per calendar year with salary revision on an annual basis.

#### Variable cash remuneration

In addition to fixed salary, the CEO and other senior executives may, according to separate agreements, receive variable cash remuneration. Variable cash remuneration covered by these guidelines is intended to promote Ascelia Pharma's business strategy and long-term interests, including its sustainability.

The satisfaction of criteria for awarding variable cash remuneration shall be measured over a period of one or several years. Variable cash remuneration may, for the CEO, amount to a maximum of 40 percent of the fixed annual salary, and for other senior executives, and a maximum of 20 percent of the fixed annual salary. Variable cash remuneration shall not qualify for pension benefits, save as required by mandatory collective bargaining agreements.

The variable cash remuneration shall be linked to one or several predetermined and measurable criteria, which can be financial, such as revenue targets, EBITDA/EBIT targets and budget adherence, or non-financial, such as clinical trial milestones and manufacturing milestones. By linking the goals in a clear and measurable way to the remuneration of the senior executives to Ascelia Pharma's financial and operational development, they contribute to the implementation of the company's business strategy, long-term interests and sustainability.

To which extent the criteria for awarding variable cash remuneration has been satisfied shall be evaluated and determined when the measurement period has ended. The Remuneration Committee is responsible for the evaluation. For financial objectives, the evaluation shall be based on the latest financial information made public by the company.

The board of directors shall have the possibility to, in whole or in part, reclaim variable cash remuneration paid on incorrect grounds.

Additional variable cash remuneration may be awarded in extraordinary circumstances, provided that such extraordinary arrangements are only made on an individual basis, either for the purpose of recruiting or retaining senior executives, or as remuneration for extraordinary performance beyond the individual's ordinary tasks. Such remuneration may not exceed an amount corresponding to 30 percent of the fixed annual salary and may not be paid more than once each year per individual. Any resolution on such remuneration shall be made by the board of directors based on a proposal from the Remuneration Committee.

#### Pension benefits

Pension benefits, including health insurance, shall be defined contribution, insofar as the senior executive is not covered by defined benefit pension under mandatory collective bar-gaining agreements. Pension premiums for defined contribution pensions may amount to a maximum of 30 percent of the fixed annual salary.

#### Other benefits

Other benefits may include life insurance, medical insurance and a company car. Premiums and other costs relating to such benefits may amount to a total of not more than 20 percent of the fixed annual salary.

#### Termination of employment and severance payment

Senior executives shall be employed until further notice or for a specified period of time. Upon termination of an employment by Ascelia Pharma, the notice period may not exceed 12 months. Fixed salary and other remuneration during the notice period and severance pay may not together exceed an amount corresponding to the fixed annual salary for 18 months. Upon termination by the senior executive, the notice period may not exceed six months, without any right to severance pay.

In addition to fixed salary during the period of notice and severance pay, additional remuneration may be paid for non-compete undertakings. Such remuneration shall compensate for loss of income and shall only be paid in so far as the previously employed senior executive is not entitled to severance pay for the period for which the non-compete undertaking applies. The remuneration shall be based on the fixed annual salary at the time of termination of employment and amount to not more than 60 percent of the fixed annual salary at the time of termination of employment, save as otherwise provided by mandatory collective bargaining agreements, and shall be paid during the time as the non-compete under-taking applies, however not for more than 12 months following termination of employment.

#### Salary and employment conditions for employees

In the preparation of the board of directors' proposal for these remuneration guidelines, salary and employment conditions for employees of Ascelia Pharma have been taken into consideration by including information on the employees' total income, the components of the remuneration and increase and growth rate over time, in the Remuneration Committee's and the board of directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable.

#### Consultancy fees to the members of the board of directors

To the extent a member of the board of directors renders services for the company, in addition

to his or her assignment as a member of the board of directors, an additional consultancy fee on market terms may be paid to the member of the board of directors, or to a company controlled by such member of the board of directors, provided that such services contribute to the implementation of Ascelia Pharma's business strategy and the safeguarding of Ascelia Pharma's long-term interests, including its sustainability.

#### Preparation and decision-making progress

The board of directors has established a Remuneration Committee. The Remuneration Committee's duties include i.a. preparing the board of directors' resolution to propose guidelines for remuneration to senior executives. The board of directors shall prepare a proposal for new guidelines at least every fourth year and submit it to the general meeting. The guidelines shall be in force until new guidelines have been adopted by the general meeting. The Remuneration Committee shall also monitor and evaluate programs for variable remuneration for the senior executives as well as the current remuneration structures and compensation levels in the company. The members of the Remuneration Committee are independent in relation to the company and its senior management. The CEO and other members of the senior management do not participate in the board of directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

#### Deviation from these guidelines

The board of directors may temporarily resolve to deviate from these guidelines, in whole or in part, if in a specific case there is special cause for the deviation and a deviation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. As set out above, the Remuneration Committee's tasks include preparing the board of directors' resolutions in remuneration-related matters, which include any resolutions to deviate from these guidelines.

#### Information regarding resolved remunerations that have not yet fallen due

Apart from the commitments to pay ongoing remuneration such as salary, pension and other benefits, there are no previously resolved remuneration to any senior executives that have not yet fallen due. For further information on remuneration to senior executives including share-based incentive programs, please see note 4 in this annual report.

#### Authorization to the board of directors regarding new share issues

At the annual general meeting held on 5 May 2021, it was resolved to authorize 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 shall be permitted is to enable Ascelia Pharma to raise working capital, to execute acquisitions of companies or operating assets as well as to enable new share issues to industrial partners within the framework of partnerships and alliances. The total number of shares that can be issued could not exceed 8,471,066, which corresponds to a dilution of approximately 20 percent calculated on the current number of outstanding shares in Ascelia Pharma.

### **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.

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 analyzing 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 5 May 2021, 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 8.

# BOARD OF DIRECTORS



#### Peter Benson

Born 1955. Chairman of the board of directors since 2017. Member of Commercialization Committee and Remuneration Committee

**Professional background** Peter Benson led the formation of

Sunstone Life Science Ventures and served as its Managing Partner from 2007-2019. In addition, Peter Benson has extensive experience from the Global Life Science industry as an investor, founder, board member and senior executive, including 10 listed companies. Previous positions include Head of Life Science Ventures at Vækstfonden (the Danish Growth Fund), President of Hospital Care and Senior Vice President at Pharmacia AB 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, Diploma from IMD, Switzerland.

#### Other ongoing assignments

Chairman of Ascelia Incentive AB and Sunstone Life Science Ventures ApS. Board member PainDrainer AB.

Holdings in Ascelia Pharma (per 30 March 2022) 15,000 shares in Ascelia Pharma.

### Independence

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



#### Lauren Barnes

Born 1974. Member of the board of directors since 2020. Member of Commercialization Committee

**Professional background** Lauren Barnes is Senior Vice

President, Market Access for Blueprint Medicines (listed on Nasdaq), a commercial stage Boston based precision medicine company. Lauren Barnes has extensive expertise and experience in pricing, market access, pre-commercialization and managed markets in particular for the US market. She has been involved in launch planning of more than 50 drugs, devices and diagnostics during her career. Prior to her current role Lauren was Vice President at Vertex Pharmaceuticals, SVP Avalere Health and has also held various roles at Amgen and the agency that runs the United States Medicare Program, the Centers for Medicare and Medicaid Services.

#### Education

MHS in Public Health from the Johns Hopkins School of Public Health and BA in Public Health from the Johns Hopkins University.

Other ongoing assignments Chair of the National Board of the Cancer Support Community.

Holdings in Ascelia Pharma (per 30 March 2022)

#### Independence

Independent in relation to the Company and its management and in relation to major shareholders.



#### **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 Laborie Inc., Innoventa Medica ApS and vice-chairman of Orphazyme ApS and board member of Reapplix A/S.

Holdings in Ascelia Pharma (per 30 March 2022) 350,019 shares in Ascelia Pharma

#### Independence

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

# **BOARD OF DIRECTORS**



#### Hans Maier

Born 1955. Member of the board of directors since 2017. Member of Commercialization Committee

Professional background Hans Maier is Managing Partner

and co-founder of the Healthcare and Life Science Strategy and Transaction Advisor BGM Associates GmbH, Berlin Germany. In his career as a biopharma executive, Hans Maier has held executive positions within Schering AG and Bayer AG, inter alia as Managing Director of Schering's subsidiaries in Japan and Korea, Managing Director of Schering Dermatology, Head of Corporate Strategy and Business Development of Schering AG and President of the Global Business Unit Diagnostic Imaging in both Schering AG and Bayer AG. He also served on the Executive Committee of Bayer-Schering Pharma AG.

#### Education

Ph.D.in Economics and Diploma in Political Science from Freie Universität Berlin, Germany.

#### Other ongoing assignments

President of the Board of Trustees of the German Heart Center Berlin, Chairman of the Advisory Board of the Fraunhofer Mevis Institute for Digital Medicine, Professor of International Strategic Management at Berlin School of Economics and Law.

#### Holdings in Ascelia Pharma (per 30 March 2022)

20.000 shares in Ascelia Pharma AB.

#### Independence

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



**Niels Mengel** 

board of directors since 2000. Member of Audit Committee

Born 1948. Member of the

#### 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 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 (per 30 March 2022)

271,267 shares in Ascelia Pharma AB directly or through company. Niels Mengel has also, directly and indirectly, invested in Øresund-Healthcare that holds 1,770,490 shares in Ascelia Pharma AB. Through the agreements governing Niels Mengel's investments in Øresund-Healthcare, Niels Mengel has a financial interest corresponding to approximately 50 per cent of the shares in Ascelia Pharma AB held by Øresund-Healthcare.

#### Independence

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

### René Spogárd

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

#### Professional background

René Spogárd is chairman and in-

vestor in a number of companies incl. JEKA Fish A/S. Bollerup Jensen A/S and Flex Funding A/S. René Spogárd has extensive experience from investing in the healthcare sector and board positions in a public environment. René Spogárd 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, Deltag Portefølje Holding 104 ApS, Deltag 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 Spogárds familieanpartsselskab, Spogárd Holding ApS, Spogárd Invest ApS and Spogárd Invest 3 ApS.

#### Holdings in Ascelia Pharma (per 30 March 2022)

1.010,203 shares in Ascelia Pharma AB indirectly through company.

#### Independence

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

# BOARD OF DIRECTORS cont.



#### Helena Wennerström

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

#### Professional background

Helena Wennerström is Chief Financial Officer at ViaCon Group. Previously she was Executive Vice President and Chief Financial

Officer of Bulten AB (publ) listed on Nasdaq Stockholm. Earlier she was Senior Vice President and CFO at Finnveden Bulten AB and also had finance roles at Digitalfabriken AB and Topcon Sweden AB.

#### Education

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

#### Other ongoing assignments

Deputy board member in TVM Consulting i Göteborg AB, deputy board member in ViaCon Group AB (publ) and Director or member of the Board of Directors of a large number of entities within the ViaCon Group.

#### Holdings in Ascelia Pharma (per 30 March 2022)

18,000 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 operation-

al activities or investment responsibilities 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 Pharma Inc. and Ascelia Inventive AB. CEO of Oncoral Pharma ApS.

#### Holdings in Ascelia Pharma (per 30 March 2022)

252,645 shares and 458,856 employee stock options in Ascelia Pharma AB.



#### **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

Board member of iCoat Medical

#### Holdings in Ascelia Pharma (per 30 March 2022)

59,000 shares and 153,059 employee stock options in Ascelia Pharma AB.

# MANAGEMENT



**Kristian Borbos** 

Born 1978. Chief Financial Officer since 2017.

#### Professional background

Kristian Borbos has extensive banking and finance experience from large listed companies including 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/Ørsted and senior analyst at Danske Bank and Danske Markets.

#### Education

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

#### Other ongoing assignments

Board member of Ascelia Pharma Inc. and deputy board member of Ascelia Incentive AB.

#### Holdings in Ascelia Pharma (per 30 March 2022)

18,630 shares and 153,059 employee stock options in Ascelia Pharma AB.



#### **Julie Waras Brogren**

Born 1972. Chief Commercial Officer since 2020.

#### Professional background

Julie Waras Brogren has extensive experience from life science leadership and commercialization, including cross-functional drug launches and medical devices. Julie Waras

Brogren was previously President of BresoTEC, Canada and has held various leadership positions at Novo Nordisk in Denmark and Brazil, including as Senior Director of the Launch Office for the Victoza® GLP-a and Degludec® insulin launches. Julie Waras Brogren also has board experience from life science companies. Julie Waras Brogren started her career at Accenture.

#### Education

M.Sc. in International Business from Copenhagen Business School and Diplome ESC, EM Lyon France, including studies at Chinese University of Hong Kong.

#### Other ongoing assignments

Board member of Ascelia Pharma Inc. and board member of Particle3D.

Holdings in Ascelia Pharma (per 30 March 2022) 26,700 shares in Ascelia Pharma AB.

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# **Consolidated Income Statement**

SEK in thousands (unless otherwise stated)*	Note	Jan-Dec 2021	Jan-Dec 2020
Net sales		-	_
Gross profit/loss		-	-
Other operating income	10	317	756
Administrative costs	6	-17,122	-18,295
Research and development costs	6	-107,574	-64,764
Commercial preparation costs	6	-13,201	-10,228
Other operating costs	10	-368	-897
Operating result	7, 8, 9	-137,948	-93,428
Financial income	11	10,439	11,800
Financial costs	11	-2,014	-18,119
Net financial items		8,425	-6,319
Loss before tax		-129,523	-99,747
Tax	12	3,620	1,050
Loss for the period		-125,903	-98,697
Attributable to:			
Owners of the Parent Company		-125,903	-98,697
Non-controlling interest		-	_
Earnings per share	13		
Before and after dilution (SEK)		-3.82	-3.76

# **Consolidated Statement of Comprehensive Income**

SEK in thousands (unless otherwise stated)*	Note	Jan-Dec 2021	Jan-Dec 2020
Loss for the period		-125,903	-98,697
Other comprehensive income			
Currency translation of subsidiaries**	3, 23	135	-5
Other comprehensive income for the period		135	-5
Total comprehensive income for the period		-125,768	-98,702

\* 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 thousands*	Note	31 Dec 2021	31 Dec 2020
ASSETS			
Intangible assets	14	57,063	57,061
Tangible assets			
Equipment	15	238	301
Right-of-use assets	16	1,581	1,688
Total fixed assets		58,882	59,050
Current assets			
Advance payments to suppliers	19	6,175	8,279
Current receivables			
Income tax receivables	12	4,395	1,748
Other receivables	20, 22	1,165	857
Prepaid expenses and accrued income	21	1,277	754
Cash and bank balances	22, 26	261,599	184,686
Total current assets		274,611	196,324
Total assets		333,493	255,374
EQUITY	23		
Share capital		34,576	28,697
Other contributed capital		678,831	493,731
Reserve of exchange differences on translation		254	119
Loss brought forward (incl. net profit/loss for the period)		-405,827	-286,491
Equity attributable to Parent Company shareholders		307,834	236,056
Total equity		307,834	236,056
LIABILITIES			
Long-term liabilities			
Leasing	16	553	956
Total long-term liabilities		553	956
Current liabilities			
Accounts payable	22	6,147	3,884
Tax payable	12	5	-
Other liabilities		1,509	672
Current lease liabilities	16	1,102	822
Accrued expenses and deferred income	24	16,343	12,984
Total current liabilities		25,106	18,362
Total liabilities		25,659	19,318
Total equity and liabilities		333,493	255,374

# **Consolidated Statements of Changes in Equity**

			Attributable	to parent company sl	nareholders			
		Share capital	Other contributed	Translation reserv	Retained earnings	Total No	n-controlling	Total equity
SEK in thousands*	Note		capital				interests	
Opening balance as of 1 Jan 2020		23,489	405,061	124	-191,612	237,062	-	237,062
Comprehensive income								
Profit/loss for the period		-	-	-	-98,697	-98,697	-	-98,697
Other comprehensive income								
Exchange differences	23	-	-	-5	-	-5	-	-5
Total comprehensive income		-	-	-5	-98,697	-98,702	-	-98,702
Transactions with shareholders								
New issue of C-shares	23	511	-	_	_	511	-	511
Repurchase of own shares C-shares	23	-	-	-	-511	-511	-	-511
New issue of common shares	23	4,697	93,956	-	-	98,653	-	98,653
Issuance expenses	23	-	-5,286	-	-	-5,286	-	-5,286
Share-based remuneration to employees	7	-	-	-	4,329	4,329	-	4,329
Total transactions with shareholders		5,208	88,670	-	3,818	97,696	-	97,696
Closing balance as of 31 Dec 2020		28,697	493,731	119	-286,491	236,056	-	236,056
Comprehensive income								
Profit/loss for the period		-	-	-	-125,903	-125,903	-	-125,903
Other comprehensive income								
Exchange differences		-	-	135	-	135	-	135
Total comprehensive income		-	-	135	-125,903	-125,768	-	-125,768
Transactions with shareholders								
New issue of C-shares	23	397	-	-	-	397	-	397
Repurchase of own shares C-shares	23	-	-	-	-397	-397	-	-397
New issue of common shares	23	5,000	195,000	-	-	200,000	-	200,000
Issuance expenses	23	-	-13,271	-	-	-13,271	-	-13,271
Redemption of warrants	23	482	3,371	-	-	3,853	-	3,853
Share-based remuneration to employees	7	-	-	-	6,964	6,964	-	6,964
Total transactions with shareholders		5,879	185,100	-	6,567	197,546	-	197,546
Closing balance as of 31 Dec 2021		34,576	678,831	254	-405,827	307,834	-	307,834
								· · ·

# **Consolidated Cash Flow Statement**

SEK in thousands*	Note	Jan-Dec 2021	Jan-Dec 2020
Operating activities			
Operating result		-137,948	-93,428
Expensed share based remuneration	7, 26	5,919	7,873
Adjustment for items not included in cash flow	9, 16, 26	1,045	870
Interest received		10	27
Interest paid		-77	-87
Income tax paid/received		1,020	-89
Cash flow from operating activities before changes in working capital		-130,031	-84,834
Cash flow from changes in working capital			
Increase (-)/Decrease (+) of advance payments		2,110	-4,263
Increase (-)/Decrease (+) of operating receivables		-900	1,696
Increase (+)/Decrease (-) of accounts payable		2,258	-1,220
Increase (+)/Decrease (-) of other liabilities		10,004	3,094
Change in working capital		13,472	-693
Cash flow used in operating activities		-116,559	-85,527
Investing activities			
Investment in equipment		-38	-397
Marketable securities/Other investments, net		-	76,388
Cash flow from investing activities		-38	75,991
Financing activities			
Issuance proceeds	23	200,000	98,653
Issuance costs	23	-13,271	-5,285
Redemption of warrants	23	-914	-
Amortisation of loan (leasing)		-944	-643
Cash flow from financing activities		184,871	92,725
Cash flow for the period		68,274	83,189
Cash flow for the period		68,274	83,189
Cash and cash equivalents at start of period	26	184,686	108,516
Exchange rate differences in cash and cash equivalents		8,639	-7,019
Cash and cash equivalents at end of period	26	261,599	184,686

# Parent Company – Income Statement

SEK in thousands*	Note	Jan-Dec 2021	Jan-Dec 2020
Net sales	5	5,495	768
Gross profit/loss		5,495	768
Other operating income	10	241	753
Administrative costs	6	-16,901	-17,882
Research and development costs	6	-94,306	-60,573
Commercial preparation costs	6	-13,223	-10,220
Other operating costs	10	-344	-830
Operating result	7, 8, 9	-119,038	-87,984
Net financial items			
Finance income	11	9,830	11,800
Finance costs	11	-1,940	-18,043
Result from other long-term receivables	11	1,860	157
Net financial costs		9,750	-6,086
Loss before tax		-109,288	-94,070
Тах	12	-	-
Loss for the period		-109,288	-94,070

# Parent Company – Statement of Comprehensive Income

SEK in thousands* Note	Jan-Dec 2021	Jan-Dec 2020
Loss for the period	-109,288	-94,070
Other comprehensive income	-	_
Other comprehensive income for the period	-	-
Total comprehensive income for the period	-109,288	-94,070

# Parent Company – Balance Sheet

SEK in thousand*	Note	31 Dec 2021	31 Dec 2020
ASSETS			
Tangible assets			
Equipment	15	238	301
Right-of-use assets	16	-	-
Financial assets			
Shares in group companies	2, 17	58,068	58,068
Long-term receivables from group companies	18	36,620	9,449
Total fixed assets		94,926	67,818
Current assets			
Advance payments to suppliers	19	5,323	8,279
Current receivables			
Receivables from group companies		6,971	1,346
Income tax receivables	12	739	623
Other receivables	20, 22	656	616
Prepaid expenses and accrued income	21	1,183	706
Cash and bank balances	22, 26	246,311	182,498
Total current assets		261,183	194,068
Total assets		356,109	261,886
EQUITY	23		
Restricted equity			
Share capital		34,576	28,697
Non-restricted equity			
Share premium reserve		678,831	493,731
Loss brought forward		-271,295	-183,792
Loss for the period		-109,288	-94,070
Total equity		332,824	244,566
LIABILITIES			
Long-term liabilities			
Leasing	16	-	-
Total long-term liabilities		-	-
Current liabilities			
Accounts payable	22	5,700	3,733
Other liabilities		1,509	673
Accrued expenses and deferred income	24	16,076	12,914
Total current liabilities		23,285	17,320
Total liabilities		23,285	17,320
Total equity and liabilities		356,109	261,886

# Parent Company – Statements of Changes in Equity

		Restricted equity	Unrestricted	equity	
SEK in thousands*	Note	Share capital	Premium reserv	Retained earnings	Total equity
Opening balance as of 1 Jan 2020		23,489	405,061	-187,610	240,940
Comprehensive income					
Profit/loss for the period		-	-	-94,070	-94,070
Total comprehensive income		-	-	-94,070	-94,070
Transactions with shareholders					
New issue of C-shares	22	511	-	-	511
Repurchase of own shares C-shares	22	-	-	-511	-511
New issue of common shares	22	4,697	93,956	-	98,653
Issuance expenses	22	-	-5,286	-	-5,286
Share-based remuneration to employees	6	-	-	4,329	4,329
Total transactions with shareholders		5,208	88,670	3,818	97,696
Closing balance as of 31 Dec 2020		28,697	493,731	-277,862	244,566
Comprehensive income					
Profit/loss for the period		-	-	-109,288	-109,288
Total comprehensive income		-	-	-109,288	-109,288
Transactions with shareholders					
New issue of C-shares	22	397	-	-	397
Repurchase of own shares C-shares	22	-	-	-397	-397
New issue of common shares	22	5,000	195,000	-	200,000
Issuance expenses	22	-	-13,271	-	-13,271
Redemption of warrants	22	482	3,371	-	3,853
Share-based remuneration to employees	6	-	-	6,964	6,964
Total transactions with shareholders		5,879	185,100	6,567	197,546
Closing balance as of 31 Dec 2021		34,576	678,831	-380,583	332,824

# Parent Company – Cash Flow Statement

SEK in thousands*	Note	Jan-Dec 2021	Jan-Dec 2020
Operating activities			
Operating result		-119,038	-87,984
Expensed share based remuneration	7, 26	5,919	7,873
Adjustment for items not included in cash flow	9, 16, 26	102	203
Interest received		10	27
Interest paid		-3	-12
Income tax paid/received		-116	-507
Cash flow from operating activities before changes in working capital		-113,126	-80,400
Cash flow from changes in working capital			
Increase (-)/Decrease (+) of advance payments		2,956	-4,262
Increase (-)/Decrease (+) of operating receivables		-3,992	1,875
Increase (+)/Decrease (-) of accounts payable		1,968	-1,245
Increase (+)/Decrease (-) of other liabilities		7,658	2,365
Change in working capital		8,590	-1,267
Cash flow used in operating activities		-104,536	-81,667
Investing activities			
Investment in equipment		-38	-397
Marketable securities/Other investments, net		-	76,388
Cash flow from investing activities		-38	75,991
Financing activities			
Issuance proceeds	23	200,000	98,653
Issuance costs	23	-13,271	-5,285
Loan to affiliated company	18	-25,310	-5,582
Redemption of warrants	23	-914	-
Amortisation of loan (leasing)		-	-111
Cash flow from financing activities		160,505	87,675
Cash flow for the period		55,931	81,999
Cash flow for the period		55,931	81,999
Cash and cash equivalents at start of period	26	182,498	107,434
Exchange rate differences in cash and cash equivalents		7,882	-6,935
Cash and cash equivalents at the end of the period	26	246,311	182,498

# 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 Hyllie Boulevard 34, SE-215 32 Malmö, Sweden. 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 30 March 2022 and will be presented to the Annual General Meeting of shareholders on 5 May 2022.

# NOTE 2 SPECIFICATION OF THE GROUP'S HOLDING OF PARTICIPATIONS IN GROUP COMPANIES

Holdings in the subsidiary

			Carrying amount			
	Number of	Participating	SEK			
Subsidiary/Corporate identity number/Registered office	participation rights	interest in %	31 Dec 2021	31 Dec 2020		
Oncoral Pharma ApS, CVR No. 35 48 12 14 Ballerup, Denmark	145,919	100	58,018,000	58,018,000		
Ascelia Incentive AB, Reg. No. 559129-4615 Malmö, Sweden	50,000	100	50,000	50,000		
Ascelia Pharma Inc., FEIN. No. 38 4179470 New Jersey, USA	1,000	100	8			
Total carrying amount of year-end			58,068,008	58,068,000		

The share of capital in all of the above holdings is equivalent to voting rights.

# NOTE 3 SUMMARY OF IMPORTANT ACCOUNTING POLICIES AND DISCLOSURES

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*.

In addition to these standards, both the Swedish Companies Act and the Swedish Annual Accounts Act require certain supplementary disclosure to be made.

The accounting policies applied in the preparation of the consolidated financial statements are disclosed in the respective notes in order to provide a better understanding of the respective accounting field. See the table below for reference to the note in which each significant accounting policy is used and the applicable IFRS standard that is deemed to have significant influence.

ACCOUNTING POLICY	NOTE		IFRS STANDARD
Company acquisitions	3	Consolidated financial statements	IFRS 3
Segment	3	Segment reporting	IFRS 8
Operating expenses	6	Operating expenses	IAS 1
Share-based remuneration	7	Employees, employee benefit expenses and remuneration to the Board	IFRS 2
Financial income and expenses	11	Financial income and expenses	IFRS 9
Income tax	12	Тах	IAS 12
Earnings per share	13	Earnings per share	IAS 33
Intangible assets	14	Intangible assets	IAS 36, IAS 38
Property, plant and equipment	15	Property, plant and equipment	IAS 16, IAS 36
Right-of-use assets	16	Leasing	IFRS 16
Accounts payable	22	Financial instruments by category	IAS 32, IFRS 9
Cash flow statement	26	Cash flow	IAS 7
Transactions with related parties	27	Transactions with related parties	IAS 24

(b) Important estimates and assessments for accounting purposes Preparing the financial statements in accordance with IFRS requires that the management team make important accounting estimates 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 assumptions. 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.

The areas subject to a high degree of assessment or complexity, or areas in which assumptions and estimates are of considerable importance to the consolidated financial statements, are indicated in the following table. The estimates and assumptions are regularly reviewed, and the effect on the carrying amounts is recognized in the income statement.

#### ESTIMATES AND

ASSESSMENTS	NOTE	
Capitalisation of develop- ment expenses	6	Operating expenses by type of cost
Share-based incentive programs	7	Employees, employee benefit expenses and remuneration to the Board
Assessemnt of tax deficit	12	Тах
Asset acquisitios	14	Intangible assets
Impairment of intangible assets	14	Intangible assets
Capitalisation Leases	16	Right-of-use assets

Estimates and assessments are evaluated continuously and based on historical experience and other factors, including expectations of future events considered reasonable under the prevailing conditions.

The Group makes estimates and assumptions about the future. The estimates for accounting purposes that result from these assumptions, by definition, seldom equal the related actual results.

#### (c) Consolidated financial statements 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.

The acquisition method is used for recognizing the Group's acquisition of subsidiaries. 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.

#### 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.

#### Elimination of transactions between Group companies

Intra-group transactions and balance sheet items, as well as unrealized gains or losses that arise from intra-group transactions between companies within the Group are eliminated 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.

#### Translation of foreign currencies

Items in the financial statements for the various Group units are measured in the currency used in the economic environment where each company primarily operates (the functional currency). In the consolidated financial statements, the Swedish krona (SEK) is used, which is the Parent Company's functional and reporting currency.

Transactions in foreign currencies are translated into the functional currency at the exchange rate prevailing at the date of the transaction. Exchange gains and losses arising from the settlement of such transactions and the recalculation of monetary assets and liabilities in foreign currencies at the rate on the balance sheet date are recognized in the income statement. Exchange gains and losses attributable to loans and cash and cash equivalents are recognized as financial income and expenses respectively. All other exchange gains and losses are recognized as Other operating income or Other operating expenses. 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.

The profit and financial position of all Group companies are translated into the Group's reporting currency. Assets and liabilities are translated at the rate on the balance sheet date, income and expenses are translated at the average rate and any resulting exchange rate differences are recognized as a separate portion of equity. Fair value adjustments and goodwill arising from the acquisition of a foreign operation are recognized as assets and liabilities in that operation and translated at the rate on the balance sheet 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.

#### (d) Classification

Fixed 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. Long-term 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 recognized as a current liability.

#### (e) Operating segment recognition

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. The Group consists of only one reportable segment, Ascelia Pharma, as it is at this level that the Group's management team has responsibility for the allocation of resources and assesses the business' results. The Group has operations in Sweden (where the parent company has its registered office) and in Denmark. Operating segments are reported in a way that is consistent with the internal reporting submitted to the highest executive decision maker. The highest executive decision maker is the role with responsibility for allocating resources and making assessments of the results of the operating segments. The executive management team of the Group has been identified as having this role.

#### (f) New or amended accounting standards applied in 2021

The following amended accounting standards were applicable from January 1, 2021: IFRS 4 Insurance Contracts – deferral of IFRS 9 (endorsed by the EU December 15, 2020); and IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 through the Interest Rate Benchmark Reform – Phase 2 (endorsed by the EU on January 13, 2021).

The amended standards did not have any material impact on Ascelia Pharma's financial statements.

# (g) New standards and interpretations not yet applied by the Group

None of the IFRS and IFRIC interpretations yet to enter into force are expected to have a significant impact on the Group.

## PARENT COMPANY'S ACCOUNTING PRINCIPLES

The parent company has prepared the historical financial informa-tion 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 recom-mendation 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 4 FINANCIAL INSTRUMENTS AND FINANCIAL RISKS

In its operations, the Group is exposed to various financial risks. Examples of these are liquidity and financing risks, as well as currency risks. The Board determines risk management policies. Financial activities in the form of risk management, liquidity management and financing are managed for the Group as a whole by the Parent Company. The Group's overall risk management focuses on the unpredictability of financial markets and strives to limit undesirable impact on its result and financial position, to the extent it is possible.

#### 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 fulfil its contractual obligations or that this can only be done at a significantly increased cost.

The available funds at 31 December 2021 provides Ascelia Pharma with liquidity beyond 12 months and is expected to be sufficient to complete the Phase 3 program for Orviglance, continue commercial preparations for Orviglance and prepare for Phase 2 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.

	Purchases in ea	ch currency	Cost increase with 10% depreciation of SEK			
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020		
DKK	6,626	6,874	663	687		
EUR	9,799	12,937	980	1,294		
USD	58,029	34,789	5,803	3,479		
JPY	782	1,033	78	103		
GBP	1,361	-	136	-		
Total	76,597	54,600	7,660	5,460		

#### Currency risks

#### Transaction exposure

Ascelia Pharma purchases services related to drug develoment 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 USD and DKK. A weakening of SEK of 10% against USD och DKK would result in an increased loan receivable for the parent company of around SEK 3.7 million.

#### Credit risk

The Group's credit risk is primarily attributable to bank deposits and prepayment to suppliers. The credit risk is mitigated by placement of liquidity only with banks with high credit ratings. The Group aims to mitigate the credit risk towards suppliers by assessing their creditworthiness and limit the amount of prepayments, to the extent possible. 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 5 NET SALES

# NOTE 6 OPERATING EXPENSES BY TYPE OF COST

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

	Parent co	ompany
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
Intra-Group services	5,495	768
Total net sales	5,495	768

Intra-Group services from the parent company to the subsidiaries mainly include work related to clinical research and development of drugs, as well as administrative support. Pricing of intra-group services has taken place on market terms.

	Gro	oup	Parent company			
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020		
Research and Development costs						
Drug development costs	75,075	43,607	65,503	40,784		
Cost of remuneration to employees*	23,776	17,425	23,785	17,425		
Manufacturing costs	8,723	3,732	5,018	2,364		
Total	107,574	64,764	94,306	60,573		
Administration costs						
Costs of remuneration to employees and board*	8,315	9,409	8,315	9,409		
Other administration costs	8,807	8,886	8,586	8,473		
Total	17,122	18,295	16,901	17,882		
Commercial preparation costs						
Cost of remuneration to employees*	7,444	3,235	7,460	3,227		
Commercial preparation	5,757	6,993	5,763	6,993		
Total	13,201	10,228	13,223	10,220		
Other operating expenses						
Currency differences related to operations	368	897	344	830		
Total	368	897	344	830		

\*Cost of remuneration to employees encompass all types of remuneration including base salary, variable pay, pension, insurance, other benefits, social security costs as well as recognised costs for long-term incentive programs.

## ACCOUNTING POLICIES

The income statement is structured according to function. The functions are as follows:

"Research and development costs" refers to costs for clinical research and development of drugs, raw material and manufacturing costs, salaries and services acquired and costs of premises.

"Administrative costs" refers to costs for salaries, board remuneration, corporate costs including office and equipment, investor relation activites and administrative costs.

"Commercial preparation costs" refers to costs for the Group's commercial organization, including salaries and external consultancy services.

# IMPORTANT ESTIMATES AND ASSESSMENTS FOR ACCOUNTING PURPOSES

#### Capitalisation of development expenses

For the period Jan-Dec 2021, 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.

# NOTE 7 EMPLOYEES, EMPLOYEE BENEFIT EXPENSES AND REMUNERATION TO THE BOARD OF DIRECTORS

## Average number of employees

	Number o	ofpeople	Of whom men, %		
	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020	
Parent company					
Sweden	19.4	11	38%	43%	
Total for parent company	19.4	11	38%	43%	
Subsidiaries					
Denmark	-	-	-	-	
Sweden	-	_	-	-	
Total for subsidiaries	-	-	-	-	
Group total	19.4	11	38%	43%	

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

### Gender division on the board and in executive management

	Number o	f people	Of whom women, %		
	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020	
Board of directors	7	7	29%	29%	
Executive management	4	4	25%	25%	

### Salary, other remuneration and social security expenses

	Salaries and othe	er remuneration	Social secutiry expenses		
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020	
Parent Company	20,466	13,594	9,271	6,485	
(of which pension costs)	-	_	4,241	3,138	
Subsidiaries	-	-	-	-	
(of which pension costs)	-	-	-	-	
Total salaries, other remuneration and social security expenses	20,466	13,594	9,271	6,485	
(of which pension costs)	-	_	4,241	3,138	

#### Remuneration to the board and senior executives

	Jan-Dec 2021					Jan-Dec 2020				
SEK in thousands	Remunera- tion <sup>1)</sup> /Base salary (incl. holiday pay)	Other benefits	Variable remuneration	Share-based remunera- tion <sup>2)</sup>	Pension expenses <sup>3)</sup>	Remunera- tion <sup>1)</sup> /Base salary (incl. holiday pay)	Other benefits	Variable remuneration	Share-based remunera- tion <sup>2)</sup>	Pension expenses <sup>3)</sup>
The Group										
The Board										
Peter Benson	490	-	-	-	-	425	-	-	-	-
Lauren Barnes (elected May 2020)	333	-	-	-	-	150	-	-	-	-
Bo Jesper Hansen	238	-	-	-	-	200	-	-	-	-
Hans Maier	258	-	-	-	-	213	-	-	-	-
Niels Mengel	258	-	-	-	-	225	-	-	-	-
René Spogárd	233	-	-	-	-	200	-	-	-	-
Helena Wennerström	333	-	-	-	-	300	-	-	_	-
Senior executives employed by the company										
Group (incl. subsidiaries)										
Magnus Corfitzen, CEO	1,896	131	576	11,719	553	1,826	77	1,0084)	1,265	552
Other senior executives, 3(3)	4,114	165	613	3,235	1,332	3,994	95	1,0394)	2,080	1,315
Parent Company										
Magnus Corfitzen, CEO	1,896	131	576	11,719	553	1,826	77	1,0084)	1,265	552
Other senior executives, 3(3)	4,114	165	613	3,235	1,332	3,994	95	1,0394)	2,080	1,315

1) Refers to remuneration to the Board and committees.

2) Refers to both recognized costs but not paid-out remuneration for active incentive programs as well as value of exercised options on 17

March 2021 when the options were exercised.

3) 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 2021, two employees opted to receive salary instead of pension (2 persons in the financial year 2020).

4) Refer to bonus for 18-months period (Jul 2019 - Dec 2020).

#### Employee option program

Group					Parent company							
	Option pro	ogram 1	Option pro	ogram 2	Total		Option pro	Option program 1		ogram 2	Total	
		Other		Other		Other		Other		Other		Other
		senior		senior		senior		senior		senior		senior
Number of alloted options	CEO	executives*	CEO e	executives*	CEO	executives*	CEO	executives*	CEO (	executives*	CEO e	executives*
Opening balance as of 1 Jan 2020	275,185	206,388	183,671	321,424	458,856	527,812	275,185	206,388	183,671	321,424	458,856	527,812
Share options alloted	-	-	-	-	-	-	-	-	-	-	-	-
Closing balance as of 31 Dec 2020	275,185	206,388	183,671	321,424	458,856	527,812	275,185	206,388	183,671	321,424	458,856	527,812
Share options alloted	-	-	-	-	-	-	-	-	-	-	-	-
Share options redeemed	-275,185	-206,388	-	-	-275,185	-206,388	-275,185	-206,388	-	-	-275,185	-206,388
Closing balance as of 31 Dec 2021	-	-	183,671	321,424	183,671	321,424	-	-	183,671	321,424	183,671	321,424

\* All alloted options (to both current and former senior executives employed by the company)

The total value of the exercised options in option program 1 amounted to SEK 17.1 million at exercised date in 2021 (excluding social security expenses).

The total recognized costs for both option programs in 2021 including social security expenses amounted to SEK 2.7 million (SEK 2.4 million for the period Jan-Dec 2020).

### Share saving program

	Group			Parent company				
Number of saving shares	Share saving program 1	Share saving program 2	Share saving program 3	Total	Share saving program 1	Share saving program 2	Share saving program 3	Total
Opening balance as of 1 Jan 2020	67,030	-	-	67,030	67,030	-	-	67,030
Saving shares acquired	-	54,145	-	54,145	-	54,145	-	54,145
Of which								
CEO		11,000				11,000		
Other senior executives		24,600				24,600		
Closing balance as of 31 Dec 2020	67,030	54,145	-	121,175	67,030	54,145	-	121,175
Saving shares acquired	-	-	40,870	40,870	-	-	40,870	40,870
Of which								
CEO			10,000				10,000	
Other senior executives			15,500				15,500	
Closing balance as of 31 Dec 2020	67,030	54,145	40,870	162,045	67,030	54,145	40,870	162,045
Of which								
CEO	24,500	11,000	10,000	45,500	24,500	11,000	10,000	45,500
Other senior executives	30,530	24,600	15,500	70,630	30,530	24,600	15,500	70,630

The total recognized costs for the share saving programs in 2021 including social security expenses amounted to SEK 5.4 million (SEK 5.4 million for the period Jan-Dec 2020).

#### Guidelines for remuneration to CEO and other senior executives

#### Introduction to guidelines

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 guidelines shall apply to employment agreements entered into after the adoption of these guidelines by the shareholders' meeting or amendments to existing agreements made after the adoption of the guidelines.

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. Senior executives refer to the CEO and the other persons forming part of Ascelia Pharma's management team.

Remuneration and other employment terms for the CEO and other senior executives are prepared by the Remuneration Committee and resolved by the board of directors.

#### Fixed salary guidelines

The fixed salary shall take into consideration the individual's competence, area of responsibility and performance. A review should generally be made annually.

#### Variable remuneration guidelines

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 per cent of the fixed annual salary for the CEO and 20 per cent 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.

#### Pension guidelines

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 Ascelia Pharma is unchanged over time.

#### Share-based incentive programs guidelines

Share-based incentive programs shall, where applicable, be resolved by the shareholders' meeting.

Other benefits guidelines

The senior executives may be awarded other customary benefits, such as a company car, occupational health services, etc.

#### Severance pay etc. guidelines

In case of termination of the CEO's employment by the company, the notice period should not exceed 6 months. In case the company terminates the CEO's employment, the CEO shall, in addition to salary during the notice period, be entitled to severance payment corresponding to 6 months' base salary. The notice period for other senior executives shall not exceed 6 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.

#### Other information

In addition to the severance pay for the CEO, 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 company's Head of IR & Communications acts as a consultant and the consultancy agreement runs for an indefinate term with a mutual notice period of three months.

#### Share-based incentive programs

Ascelia Pharma has two active employee options programs that include members of the management team and a share-saving program for employees. If the terms of the option programs are met at the time for utilisation, these employees have the right to purchase shares at a pre-determined price. For the share-saving program, employees are entitled to receive matching and performance shares according to terms of the programme. 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 vesting period. Social security costs are revalued at fair value.

In case all outstanding incentive programs are exercised in full, 2.0 million shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate dilution of approximately 5.5% of Ascelia Pharma's share capital after full dilution (calculated on the number of shares that will be added upon full exercise of all incentive programs).

#### Employee option program 1 ("Program 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 former 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 was 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.

In March 2021 during the exercise period, all outstanding options were exercised and consequently 481,573 new shares were issued.

#### Employee option program 2 ("Program 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, the Chief Financial Officer, the Chief Medical Officer and the former Chief Operating 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 can be utilised during the ordinary time for utilisation, 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.

#### Share Saving Program 1

At the Annual General Meeting on 14 November 2019, a resolution was passed to implement a long-term incentive program for employees in the form of a performance-based share saving program. In the program, participants have invested in ordinary shares in Ascelia Pharma ("Saving Shares"). The total amount of Saving Shares invested in this program amounted to 67,030.

For each Saving Share, the participants is entitled to receive 1 Matching Share. In addition, for each Saving Share, the participant shall have the possibility to receive up to 5 Performance Shares for each Saving Share. Receipt of both Matching Shares and Performance Shares are conditional upon the fulfilment of the following conditions: (a) that the participant has retained all Saving Shares during the period from the expiration of the Investment Period to 31 December 2022 (the "Saving Period"); and (b) that the participant has continued to be employed by the company (or another company in its group) throughout the Saving Period.

Receipt of Performance Shares is further conditional upon that the requirement related to the development of the company's share price from the date of the annual general meeting on 14 November 2019 to and including 31 December 2022 (the "Performance Target") is fulfilled. The Performance Target will be measured based on the volume weighted average share price 30 trading days immediately following the annual general meeting on 14 November 2019 and 30 trading days immediately preceding 31 December 2022. An increase in the share price with less than 20 per cent does not entitle to any vesting of any of the Performance Shares, an increase in the share price with 20 per cent entitles to vesting of 1 Performance Share per Saving Share and an increase in the share price with 80 per cent or more entitles to vesting of all the 5 Performance Shares per Saving Share. In the event of an increase in the share price of between 20 and 80 per cent, vesting of the Performance Shares will occur linearly between 1 and 5.

#### Share Saving Program 2

At the Annual General Meeting on 6 May 2020, a resolution was passed to implement a long-term incentive program for employees in the form of a performance-based share saving program. The mechanisms in Share Saving Program 2 are the same as in Share Saving Programe 1. The total amount of Saving Shares invested in Program 2 amounted to 54,145.

Saving Period in Program 2 is 1 October 2020 up to and including 30 September 2023. The Performance Target in Program 2 will be measured based on the volume weighted average share price 30 trading days immediately following the annual general meeting on 6 May 2020 and 30 trading days immediately preceding 30 September 2023.

#### Share Saving Program 3

At the Annual General Meeting on 5 May 2021, a resolution was passed to implement a long-term incentive program for employees in the form of a performance-based share saving program. The mechanisms in Share Saving Program 3 are the same as in Share Saving Programe 1. The total amount of Saving Shares invested in Program 3 amounted to 40,870. Saving Period in Program 3 is 1 October 2021 up to and including 30 September 2024. The Performance Target in Program 3 will be measured based on the volume weighted average share price 30 trading days immediately following the annual general meeting on 5 May 2021 and 30 trading days immediately preceding 30 September 2024.

Cost recognition of share-based incentive programs The total value of the exercised options in option program 1 amounted to SEK 17.1 million at the exercise date in 2021 (excluding social security expenses). The total recognized costs for the option programs and the share saving programs in 2021 including social charges were SEK 2.7 million and SEK 5.4 million, respectively (SEK 2.4 million and SEK 5.4 million, respectively, in 2020).

### **ACCOUNTING POLICIES**

#### Remuneration to employees

Current remuneration

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

#### 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.

#### Share based remuneration

Ascelia Pharma's employees are invited to participate in sharebased incentive 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 employee option prorams) and receive matching and performance shares (share saving programs). 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 programs are utlised. This means that a new market valuation of the incentive programs is made at each balance sheet date, which is the basis for the calculation of the liability for social security charges.

## IMPORTANT ESTIMATES AND ASSESSMENTS FOR ACCOUNTING PURPOSES

#### Share-based incentive programs

#### Employee option programs

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 transaction 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.

#### Share saving programs

The parameter, which have the largest impact on the value of the program, is the publicly traded share price. The fair value of the share saving program is estimated on the issue date using a generally accepted modelling technique, Monte Carlo simulation, to simulate the future share price development. Assumptions have also been made regarding the number of employees to remain in the company once the programmes are fully completed.

The volatility in the company's share price used in the simulation is estimated to 55% based on comparable companies in the same sector.

# NOTE 8 AUDITOR FEES AND REIMBURSEMENTS

SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
Group		
Group		
PwC		
Audit engagements (current year)	585	340
Other audit activities	-	-
Tax advice	50	-
Other services	44	-
Total	679	340
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
	Jan-Dec 2021	Jan-Dec 2020
SEK in thousands Parent company PwC	Jan-Dec 2021	Jan-Dec 2020
Parent company	Jan-Dec 2021 516	Jan-Dec 2020 300
Parent company PwC		
<b>Parent company</b> PwC Audit engagements (current year)		
Parent company PwC Audit engagements (current year) Other audit activities	516	

Audit engagements refer to statutory auditing of the annual and consolidated financial statements and acccounting records 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 as a result of observations during the reviews or the performance of such other duties referred to.

# **NOTE 9 DEPRECIATION OF INTANGIBLE, TANGIBLE AND RIGHT-OF-USE ASSETS**

Depreciation according to plan	Group		Parent company	
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
<b>Tangible assets</b> - Equipment	-102	-95	-102	-95
Right-of-use assets				
- Office	-655	-601	-	-
- Car	-273	-129	-	-108
Total depreciation/amortization	-1,030	-825	-102	-203

# **NOTE 10 OTHER OPERATING INCOME AND COSTS**

Other operating income	Group		Parent company	
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Exchange gains on receivables/liabilities relating to operations	317	716	241	713
Insurance compensation	-	10	-	10
Other operating income	-	30	-	30
Total other operating income	317	756	241	753

#### **ACCOUNTING POLICIES**

Other operating income and costs relate to secondary activities, such as income from e.g. exchange rate differences for items relating to operations, gains on divestitures and the disposal of fixed assets, institutional grants and insurance compensation.

Other Operating costs	Group		Parent company	
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Exchange loss on receivables/liabilities relating to operations	-368	-897	-344	-830
Total other operating costs	-368	-897	-344	-830

# NOTE 11 FINANCIAL INCOME AND COSTS

#### Group

Financial income		
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
Interest income	10	27
Exchange rate differences	10,429	11,096
Unrealized gains on marketable securities	-	-
Capital gains from divestment of marketable securities	-	677
Total	10,439	11,800

#### **Financial costs**

SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
		10
Interest expense	-77	-13
Exchange rate differences	-1,937	-18,106
Total	-2,014	-18,119

#### Parent company

Financial income		
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
Interest income	10	27
Exchange rate differences	9,820	11,096
Unrealized gains on marketable securities	-	_
Capital gains from divestment of marketable securities	-	677
Total	9,830	11,800
Of which group companies	-	-

#### Financial costs

SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
Interest expense	-3	-12
Exchange rate differences	-1,937	-18,031
Total	-1,940	-18,043

#### Result from other long-term

receivables		
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
Interest income from other long-term receivables	1,521	487
Exchange rate differences	339	-330
Total	1,860	157

### ACCOUNTING POLICIES

Financial income and expenses comprise interest income from bank, invested funds and other long-term receivables, interest expense for operating liabilities, dividend income and exchange rate differences.

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. The interest component of financial lease payments is entered in the income statement in accordance with the effective interest method, whereby interest is divided so that each accounting period is charged with an amount based on the liability recognized during the period in question.

# NOTE 12 TAX

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

	Group		Parent company	
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Current tax expense (-)/tax income (+)				
Tax expense/income for the year	3,621	1,050	-	-
Total current tax	3,621	1,050	-	-

#### Reconciliation of effective tax

		Gro	ир	Parent co	ompany
SEK in thousands		Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Loss before tax		-129,523	-99,747	-109,288	-94,070
Tax rate for the Parent Company	20.6%	26,682	21,346	22,513	20,131
Effect of other tax rates for foreign subsidiaries	0.1%	201	-	-	-
Non-deductible expenses	0.0%	-25	-173	-25	-8
Non-taxable income	0.0%	2	-	2	-
Increase of losses carried forward without equivalent capitalisation	-17.9%	-23,239	-20,123	-22,491	-20,123
Utilisation of previously non-capitalised tax deductions	0.0%	-	_	-	_
Recognised effective tax	2.8%	3,621	1,050	-	-

#### Unrecognized deferred tax assets

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

Accumulated tax loss	Group		Parent company	
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Deductible temporary differences	-	-	-	-
Losses related to issurance costs	46,407	33,137	46,407	33,137
Tax losses	421,950	305,667	414,845	305,667
Total	468,357	338,804	461,252	338,804

### ACCOUNTING POLICIES

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 directly 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.

Deductible 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 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.

## IMPORTANT ESTIMATES AND ASSESSMENTS FOR ACCOUNTING PURPOSE

The accounting policies describe the conditions for recognizing deferred tax assets as temporary differences. In this context it is important that the executive management considers whether the business will recognize the tax surplus in a near enough time frame for the asset to be balanceable.

Recognition of deferred tax relating to loss carry-forwards or other future tax deductions may only be reported to the extent that it is probable that the deductions can be offset against surpluses in future taxation. In order for recognition to take place, it must be possible to demonstrate that it is probable that the market approval will entail taxable income that can be used for the tax loss carry-forwards.

At the beginning of the financial year, Ascelia Pharma AB had approximately SEK 339 million in tax deficits. The tax loss for the year 2021 is estimated to amount to approximately SEK 122 million, including transaction costs booked against equity. Consequently, a total tax deficit of SEK 461 million per 31 December 2021. No tax assets have been recognized on the balance sheet.

## **NOTE 13 EARNINGS PER SHARE**

	Gro	ир	Parent company		
	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020	
Result for the year attributable to shareholders of Ascelia Pharma (publ), TSEK	-125,903	-98,697	-109,288	-94,070	
Weighted average number of shares (before and after dilution)	32,959,110	26,270,854	32,959,110	26,270,854	
Result per share (before and after dilution), SEK	-3.82	-3.76	-3.32	-3.58	

## ACCOUNTING POLICIES

The calculation of 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.

Earnings per share before dilution are calculated by dividing profit for the period attributable to the Parent Company's shareholders by the Parent Company's weighted average number of shares outstanding for the financial year. Earnings per share after dilution are calculated by dividing the profit for the period attributable to the Parent Company's shareholders by the Parent Company's weighted average number of shares outstanding after dilution.

## **NOTE 14 INTANGIBLE ASSETS**

## Group

SEK in thousands	31 Dec 2021	31 Dec 2020
Accumulated cost of acquisition		
Opening balance	57,061	57,065
Acquisitions during the year	-	-
Exchange differences during the year	2	-4
Closing balance	57,063	57,061
Accumulated depreciation and impairment		
Opening balance	-	-
Depreciation according to plan	-	-
Impairment for the year	-	-
Closing balance	-	-
Recognized value at year-end	57,063	57,061

## Impairment requirement testing for intangible assets

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 1) at Herlev hospital in Denmark with promising results. Preparations are now being made for Phase 2. 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 the year 2021, 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 14, cont.

## ACCOUNTING POLICIES

#### Intangible assests

#### Expenditure on 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. 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 above.

#### Other intangible assets

Other intangible assets acquired by the Group are recognized at cost of acquisition less accumulated amortization and impairment. Expenditures for internally generated goodwill and trademarks are recognized in the income statement as an expense as it is incurred. The Group's other intangible assets include acquired formulation technology for the purpose of developing tablet-based treatment of cancer, which are set up as assets on the basis of expenditure arising when the technology in question was acquired. The expenditure is capitalized to the extent that the probable economic benefits exceed the expenditures.

#### Depreciation/amortization

Depreciation/amortization according to plan is based on the original cost of acquisition less any residual value. Depreciation/amortization is applied on a straight-line basis over the expected economic life and is recognized as an expense in the income statement. For patents, this does not however exceed the remaining period of patent protection. Depreciation/amortization of acquired research and development takes place as of the accounting period in which the asset becomes available for use.

## IMPORTANT ESTIMATES AND ASSESSMENTS FOR ACCOUNTING PURPOSES

Asset acquisitions versus business combinations

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.

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.

#### 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. To determine 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. In assessing the value of intangible assets as of the end of 2021 and 2020, no impairment requirement was identified.

#### 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.

## **NOTE 15 TANGIBLE ASSETS - EQUIPMENT**

	Gro	up	Parent company		
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020	
Accumulated cost of acquisition					
Opening balance	560	167	471	75	
Acquisitions during the year	39	396	39	396	
Exchange differences during the year	-	-3	-	-	
Closing balance	599	560	510	471	
Accumulated depreciation according to plan					
Opening balance	-259	-167	-170	-75	
Depreciation according to plan	-102	-95	-102	-95	
Exchange differences during the year	-	3	-	-	
Closing balance	-361	-259	-272	-170	
Recognized value					
At the start of the period	301	-	301	-	
At the end of the period	238	301	238	301	

## ACCOUNTING POLICIES

Tangible fixed assets are recognized as assets in the balance sheet when, on the basis of available information, it is likely that the future economic benefit associated with their possession will pass to the Group, and the asset's cost of acquisition can be reliably calculated. Tangible assets are recognized 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.

#### Principles for depreciating tangible assets

Depreciation according to plan is based on the original acquisition value less the estimated residual value. Depreciation is carried out on a straight-line basis over the estimated useful life of the asset. Depreciation period is applied: Equipment 3-5 years.

#### Impairment

Assets with indefinite useful lives are not depreciated/amortized but are tested annually for any impairment requirement. Assets that are depreciated/amortized are assessed for a reduction in value when events or changes in conditions indicate that the carrying amount may not be recoverable. A write-down is carried out for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less selling costs and value in use. When assessing impairment requirements, assets are grouped at the lowest levels where there are separate identifiable cash flows (cash-generating units).

## **NOTE 16 RIGHT-OF-USE ASSETS**

			Gro	up			Parent company					
	31	Dec 202	21	31	Dec 202	20	31	Dec 202	21	31	Dec 202	20
SEK in thousands	Office	Car	Total	Office	Car	Total	Office	Car	Total	Office	Car	Total
Accumulated cost of acquisition												
Opening balance	1,966	520	2,486	-	280	280	-	-	-	-	280	280
Acquisitions during the year	-	818	818	1,966	240	2,206	-	-	-	-	-	-
Reclassifications during the year	-	18	18	-	-	-	-	-	-	-	-280	-280
Closing balance	1,966	1,356	3,322	1,966	520	2,486	-	-	-	-	-	-
Accumulated depreciation according to plan												
Opening balance	-601	-197	-798	-	-68	-68	-	-	-	-	-68	-68
Reclassifications during the year	-	-15	-15	-	-	-	-	-	-	-	184	184
Depreciation according to plan	-655	-273	-928	-601	-129	-730	-	-	-	-	-116	-116
Closing balance	-1,256	-485	-1,741	-601	-197	-798	-	-	-	-	-	-
Recognized value												
At the start of the period	1,365	323	1,688	-	212	212	-	-	-	-	212	212
At the end of the period	710	871	1,581	1,365	323	1,688	-	-	-	-	-	-

## Lease liabilities

	Gro	ир	Parent company			
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020		
Long-term interest-bearing lease liabilities	553	956	-	_		
Current interest-bearing lease liabilities	1,102	822	-	-		
Total interest-bearing lease liabilities	1,655	1,778	-	-		

## ACCOUNTING POLICIES

#### The Group as lessee

The Group's leases primarily comprise right-of-use assets regarding premises rent and car. The leases are recognized as right-of-use assets equating to a lease liability on the day the leased asset becomes available for use by the Group. Short-term leases and leases for which the underlying asset is of low value are excepted.

Each lease payment is distributed between repayment of lease liability and financial expense. The financial expense shall be distributed over the term of the lease so that each accounting period is charged with an amount corresponding to a fixed rate of interest for the liability recognized in the respective period.

The lease period is established as the non-terminable period together with both periods covered by an opportunity to extend the lease if the lessee is reasonably certain to utilize that option, and periods covered by an opportunity to terminate the lease if the lessee is reasonably certain not to utilize that option.

The Group's lease liabilities are entered at the present value of the Group's fixed fees. The lease payments are discounted by the lease's imputed rate of interest, which amounted to 4%. The Group is exposed to any future increases in lease payments based on an index or interest rate that are not part of the lease liability until they come into effect. When adjustments to lease payments based on an index or interest rate come into effect, the lease liability is revalued and adjusted against the right-of-use asset.

The Group's right-of-use assets are recognized at cost of acquisition and initially include the present value of the lease liability, adjusted for lease fees paid on or before the start date, as well as initial direct costs.

#### Principles for depreciating right-of-use assets

Right-of-use assets are depreciated on a straight-line basis over the shorter of the asset's useful life and the length of the lease. Depreciation according to plan is based on the original acquisition value less the estimated residual value.

Depreciation period is applied: Office and car - 3 years.

Note 16, cont.

#### Parent Company

The parent company does not apply IFRS 16 but reports lease fees according to leasing agreements as an expense on a straight-line basis over the leasing period, unless another systematic way can reflect the company's financial benefit better over time.

## IMPORTANT ESTIMATES AND ASSESSMENTS FOR ACCOUNTING PURPOSES

Options to extend and terminate agreements are included in the Group's leases for office and car. The great majority of the options to extend and terminate agreements can only be utilized by the Group and not by the lessors. Once the length of the lease has been determined, the management team considers all the available information that provides an economic incentive to utilize an option to extend, or not to utilize an option to terminate an agreement. Opportunities to extend an agreement are only included in the length of the lease if it is reasonably certain that the agreement will be extended (or not be terminated).

The lease payments are discounted by the lease's implicit discount rate, which is estimated to 4%.

## **NOTE 17 SHARES IN GROUP COMPANIES**

	Parent company			
SEK	31 Dec 2021	31 Dec 2020		
Opening balance	58,068,000	58,068,000		
Formation of Ascelia Pharma Inc.	8			
Carrying amount at year-end	58,068,008	58,068,000		

## Specification of parent company's shares in group companies

			Recognized value 2021	Recognized value 2020
Subsidiaries	Capital share	Voting share	SEK	SEK
Oncoral Pharma ApS	100%	100%	58,018,000	58,018,000
Ascelia Incentive AB	100%	100%	50,000	50,000
Ascelia Pharma Inc.	100%	100%	8	
Total carrying amount of year-end			58,068,008	58,068,000

## **NOTE 18 LONG-TERM RECEIVABLES FROM GROUP COMPANIES**

Accumulated cost	Gro	up	Parent company		
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020	
Opening balance	_	_	9,449	3,710	
Additional receivables (Intra-company loans)*	-	-	25,310	5,582	
Interest income on loans	-	_	1,521	487	
Translation differences	-	-	340	-330	
Carrying amount at year-end	-	-	36,620	9,449	

\*The increase in intra-company loans reflects loans from Ascelia Pharma AB to Oncoral Pharma ApS. The loans are denominated in DKK or USD with a fixed interest rate.

## **NOTE 19 ADVANCE PAYMENTS TO SUPPLIERS**

	Group		Parent company	
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Advance payments to suppliers	6,175	8,279	5,323	8,279
Total	6,175	8,279	5,323	8,279

## ACCOUNTING POLICIES

Partial payments for services are issued to major suppliers before the services are received by the Group in good order or rendered satisfactorily. Advance payments in foreign currencies are measured at their historical cost. Expenses are recognized in Income statement at the time the performance of services takes place and the request is submitted, and thus are reported as expenses for that period.

## **NOTE 20 OTHER RECEIVABLES**

	Group		Parent company	
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Receivables attributable to VAT	1,053	682	544	441
Other receivables	112	175	112	175
Total other receivables	1,165	857	656	616

## NOTE 21 PREPAID EXPENSES AND ACCRUED INCOME

	Grou	qu	Parent company	
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Prepaid rent	232	179	232	179
Prepaid insurance	731	347	637	347
Other items	314	228	314	180
Total	1,277	754	1,183	706

## **NOTE 22 FINANCIAL INSTRUMENTS BY CATEGORY**

	Gro	up	Parent company	
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Financial assets				
Financial assets at fair value through profit/loss				
Fixed income fund	-	-	-	-
Financial assets at amortized cost				
Other receivables	1,165	857	656	616
Cash and bank balances	261,599	184,686	246,311	182,498
Total financial assets	262,764	185,543	246,967	183,114
Financial liabilities				
Financial liabilities at amortized cost				
Accounts payable	6,147	3,884	5,700	3,733
Total financial liabilities	6,147	3,884	5,700	3,733

## The Group reclassifies financial assets when and only when its business model for managing those assets changes.

#### Derecognition

Financial assets, or a portion thereof, are derecognized when the contractual rights to receive the cash flows from the assets have expired, or when they have been transferred and either (i) the Group transfers substantially all the risks and rewards of ownership, or (ii) the Group neither transfers nor retains substantially all the risks and rewards of ownership and the Group has not retained control of the asset.

#### Impairment of financial assets

Upon every reporting occasion, the Group 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.

## Financial liabilities

Classification and subsequent measurement All of the Groups financial liabilities, excluding derivatives, are classified as subsequently measured at amortized cost.

## Interest-bearing liabilities

The accounting policies for interest-bearing lease liabilities are presented in Note 16, Right-of-use assets. The Group had no other interest-bearing liabilities at the end of 2021 and 2020.

## Accounts payable

Accounts payable are obligations to pay for goods or services acquired from suppliers in the ordinary course of business. Accounts payable are classified as current liabilities if they fall due within one year or earlier. If not, they are recognized as long-term liabilities.

Derivative instruments and hedging instruments At the end of 2021 and 2020 the Group had no derivative contracts.

## Derecognition

Financial liabilities are derecognized when they are extinguished, i.e. when the obligation specified in the contract is discharged, cancelled or expires.

## ACCOUNTING POLICIES

## **Financial instruments**

## Initial recognition and measurement

Financial assets and financial liabilities are recognized when the Group becomes party to the contractual provisions of the instrument. Regular way purchases and sales of financial assets are recognized on trade date, the date on which the Group commits to purchase or sell the asset.

At initial recognition, the Group measures a financial asset or financial liability at its fair value plus or minus, in the case of a financial asset or financial liability not at fair value through profit or loss, transaction costs that are incremental and directly attributable to the acquisition or issue of the financial asset or financial liability, such as fees and commissions. Transaction costs of financial assets and financial liabilities carried at fair value through profit or loss are expensed in profit or loss.

## **Financial assets**

Classification and subsequent measurement

The Group classifies its financial instruments in the following categories according to IFRS 9: financial assets valued at fair value either via the income statement or other comprehensive income or

financial asset orthese financial assets is recognized using the effective interestin the case of amethod and included in financial income. The Group's financialalue through profit orassets that are valued at the amortized cost are made up of theitems other receivables, and cash and cash equivalents.

the cash flow of the assets.

Fair value through profit or loss: Assets that do not meet the criteria for amortized cost are measured at fair value through profit and loss. A gain or loss on a financial debt investment that is subsequently measured at fair value through profit or loss and is not part of a hedging relationship is recognized in the financial net in the period in which it arises. Interest income from these financial assets is included in the financial net using the effective interest rate method. 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.

financial assets valued at the amortized cost. The classification of

investments in debt instruments depends on the Group's business

model for handling financial assets and the contractual terms for

collecting contractual cash flows, and where the cash flows only

constitute capital amounts and interest are valued at the amortized

cost. They are included under current assets, with the exception of

items maturing more than 12 months after the balance sheet date.

which are classified as non-current assets. Interest income from

Amortized cost: Assets that are held for the purposes of

## **NOTE 23 EQUITY**

Share capital	Number of shares		
	Jan-Dec 2021 Jan-Dec 20		
At beginning of year			
Ordinary shares	28,186,689	23,488,908	
C-shares	510,545	-	
Number of shares outstanding	28,697,234	23,488,908	
New issue of ordinary shares	5,481,573	4,697,781	
New issue of C-shares	397,641	510,545	
At year-end			
Ordinary shares	33,668,262	28,186,689	
C-shares	908,186	510,545	
Number of shares outstanding	34,576,448	28,697,234	

Translation reserve	Group		
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	
Opening balance	119	124	
Exchange differences	135	-5	
Closing balance	254	119	

## ACCOUNTING POLICIES

Equity is divided between capital attributable to Parent Company shareholders and non-controlling interests. Value transfers in the form of e.g. dividends from the Parent Company and the Group shall be based upon the Board's established statement on the proposed dividend. This statement has to take into account the legal precautionary rules to avoid dividends greater than what financial coverage exists for.

#### Share capital

Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new shares or options are recognized net after tax in equity as a deduction from the issue settlement.

As per December 31 2021 the share capital consisted of 33,668,262 ordinary shares and 908,186 Class-C shares with a quota value of SEK 1 per share. All shares are fully paid. One ordinary share entitles the holder to one vote and one C-share to one-tenth of a vote. All shares entitle the holder to the same proportion of assets and earnings, and carry equal rights in terms of dividends that is determined in due course.

## **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 24 ACCRUED EXPENSES AND PREPAID INCOME

	Gro	ир	Parent co	ompany
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Accrued salaries, including bonus	2,583	1,765	2,583	1,765
Accrued vacation pay	2,384	1,648	2,384	1,648
Accrued social security costs	1,850	1,233	1,850	1,233
Accrued social security costs for share based program	2,335	5,996	2,335	5,996
Other accrued expenses	7,191	2,342	6,924	2,272
Total	16,343	12,984	16,076	12,914

## **NOTE 25 CONTINGENT LIABILITIES**

	Gro	up	Parent co	mpany
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Committments*	11,375	11,349	11,375	11,349
Total contingent liabilities	11,375	11,349	11,375	11,349

\*The committments refer to potential bonus payment of SEK 10 million to Solural Pharma ApS (refer to Note 27, Transactions with related parties) and potential payment to Herlev hospital of DKK 1 million in case of potential outlicensing of Oncoral or a sale of Oncoral.

## NOTE 26 SPECIFICATION FOR NON-CASH ITEMS

	Gro	up	Parent co	ompany
SEK in thousands	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Expensed share based remuneration				
Expensed remuneration	6,964	4,328	6,964	4,328
Expensed social security costs	-1,045	3,545	-1,045	3,545
Adjustments for items not included in cash flow				
Depreciation of equipment	102	95	102	95
Depreciation of right-of-use assets	928	730	-	108
Exchange differences	15	45	-	-
Total adjustments	6,964	8,743	6,021	8,076

## ACCOUNTING POLICIES

#### Cash flow statement

The cash flow statement has been prepared in accordance with the indirect method. The recognized cash flow covers only transactions resulting in receipts or disbursements.

In addition to cash and bank balances, cash and cash equivalents also include short-term financial investments that are subject to only a negligible risk of value fluctuation and which can be traded on an open market in known amounts or which have a remaining term of less than three months from the acquisition date.

Cash and cash equivalents	Gro	up	Parent co	ompany
SEK in thousands	31 Dec 2021	31 Dec 2020	31 Dec 2021	31 Dec 2020
Cash and bank accounts	261,599	184,686	246,311	182,498
Total cash and bank accounts	261,599	184,686	246,311	182,498

"Cash and cash equivalents" in the balance sheet and cash flow statement refers solely to cash and bank accounts. No outstanding fixed income funds are placed during 2021.

NOTE 27 TRANSACTIONS WITH RELATED PARTIES

## Related parties with subsidiaries and senior executives The parent company has a close relationship with its subsidiary, see Note 17, Shares in group companies. Information about remuneration to senior executives is provided in Note 7, Employees, employee benefit expenses and remuneration to the Board.

#### 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 in 2017, shareholders in Ascelia Pharma AB. Per 31 December 2021, the owners of Solural ApS collectively own 2.0% of the shares in Ascelia Pharma ApS has the right to receive a bonus of maximum SEK 10 million if commercialisation occurs through a sale or an outlicensing and SEK 12 million if commercialisation 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 2021, services for a value of around SEK 3.7 million were acquired from Solural Pharma ApS.

## **ACCOUNTING POLICIES**

Transactions with related parties

Transactions have been made with related parties on terms equivalent to those that prevail in commercial transactions.

The internal prices of provided services between Group companies are based on the arm's-length principle (i.e. between parties that are independent of each other and well informed and that have an interest in the transactions).

## NOTE 28 EVENTS AFTER THE BALANCE SHEET DATE

On 15 February 2022, Ascelia Pharma announced that the study where Orviglance was compared against a gadolinium-based contrast agent has been accepted as an oral scientific presentation at the ESGAR conference to be held in May 31 – June 3 in Lisbon, Portugal.

On 2 March 2022, pursuant to the authorization granted by the annual general meeting on 5 May 2021, the board of directors of Ascelia Pharma AB has resolved to issue and immediately thereafter repurchase 294,729 series C-shares. The shares are issued and repurchased in accordance with the share saving program LTI 2021, which was adopted by the annual general meeting on 5 May 2021.

On 7 March 2022, Ascelia Pharma announced that due to the Russian invasion of Ukraine, all clinical activities in Russia in the ongoing Phase 3 study SPARKLE are being suspended. As a consequence, the expected recruitment completion for the SPARKLE study is extended to 2022 (previously H1 2022).

On 11 March 2022, Ascelia Pharma announced that the last patient visit has been completed in the clinical study to evaluate the effect of liver impairment on the safety, pharmacokinetics and pharmacodynamics of the company's lead drug candidate Orviglance.

On 1 April 2022, Ascelia Pharma announced that CFO Kristian Borbos will leave the company to take up a similar position at the Danish biotech company Gubra.

## NOTE 29 APPROPRIATION OF THE COMPANY'S LOSS

## The following amounts in SEK are at the disposal shareholders' AGM

## **Parent company**

Total	298,247,271
Loss for the period	-109,288,176
Loss brought forward	-271,295,591
Share premium reserve	678,831,038

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

To be carried forward	298,247,271
of which to share premium reserve	678,831,038

# 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 soperations, position and profit, and describes significant risks and uncertainty factors that the Parent Company and Group companies face.

Malmö, 30 March 2022

Peter Benson Chairman of the Board Lauren Barnes Director of the Board **Bo Jesper Hansen** Director of the Board

Hans Maier Director of the Board **Niels Mengel** Director of the Board **René Spogárd** Director of the Board

Helena Wennerström Director of the Board Magnus Corfitzen Chief Executive Officer

Our auditors' report was submitted on 8 April 2022, 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 year 2021 except for the corporate governance statement on pages 38-44. The annual accounts and consolidated accounts of the company are included on pages 32-84 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 and the group as of 31 December 2021 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 2021 and their financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2021 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. 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 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 as set out in the table below. 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 December 31, 2021, 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 14. Note 14 contains further description of the impairment test for the year, including significant assumptions. 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.

## 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 1-31 and 88-89. 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 intend 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. 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 Director's and the Managing Director of Ascelia Pharma AB (publ) for the year 2021 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 Director's 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' 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. This description is part of the auditor's report.

## THE AUDITOR'S EXAMINATION OF THE ESEF REPORT

## Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Ascelia Pharma AB (publ) for the financial year 2021.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report #[checksum] has been prepared in a format that, in all material respects, enables uniform electronic reporting.

## Basis for Opinions

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Ascelia Pharma AB (publ) 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 evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

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

The Board of Directors and the Managing Director are responsible for ensuring that the Esef report

has been prepared in accordance with the Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

## Auditor's responsibility

Our responsibility is to form an opinion with reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 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 aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the ESEF report.

The audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The reasonable assurance engagement involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The reasonable assurance engagement also includes an evaluation of the appropriateness and reasonableness of assumptions made by the Board of Director.

The procedures mainly include a technical validation of the Esef report, i.e. if the file containing the Esef report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the Esef report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, statement of financial position, statement of changes in equity and the statement of cash flow.

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

The Board of Directors is responsible for that the corporate governance statement on pages 38-44 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 RevR 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/ the Annual Accounts Act for Credit Institutions and Securities Companies/ the Annual Accounts Act for Insurance Companies.

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 5 May 2021 and has been the company's auditor since the introduction on Nasdaq Stockholm, 13 March 2019.

Malmö, 8 April 2022 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)

 $\label{eq:constraint} European \ \mbox{agency responsible for evaluation of medicinal products}.$ 

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

Alternative performance measures	Definition	Aim
Operating results (TSEK)	Profit before financial items and tax.	The performance measure shows the company's operational performance.
Research and development costs/operating costs (%)	The research and development costs in relation to total operating costs (consisting of the sum of administrative costs, R&D, commercial preparation costs and other operating costs).	The performance measure is useful in order to understand how much of the operating costs that are related to research- and development expenses.

## Definition of alternative financial performance measures

## Reconciliation table for alternative performance measures for the Group

SEK in thousands	Jan-Dec 2021	Jan-Dec 2020
R&D costs	-107,574	-64,764
Administration costs	-17,122	-18,295
Commercial preparation costs	-13,201	-10,228
Other operating costs	-368	-897
Total operating costs	-138,265	-94,184
R&D costs/Operating costs (%)	78%	69%

## Financial calendar

Annual General Meeting 2022: Interim report Q1 2022 (Jan-Mar): Half-year report H1 2022 (Jan-Jun): Interim report 9M 2022 (Jan-Sep): Full-year report 2022 (Jan-Dec): 5 May 2022 11 May 2022 18 August 2022 1 November 2022 10 February 2023

## Contact

Magnus Corfitzen, CEO moc@ascelia.com | +46 735 179 118

Kristian Borbos, CFO kb@ascelia.com | +46 735 179 113

Mikael Widell, IR & Communications mw@ascelia.com | +46 703 119 960



ASCELIA PHARMA AB (publ) Hyllie Boulevard 34 SE-215 32 Malmö, Sweden

ascelia.com