

**ASCELIA  
PHARMA**

Advancing  
Orphan Oncology

# ANNUAL REPORT 2022



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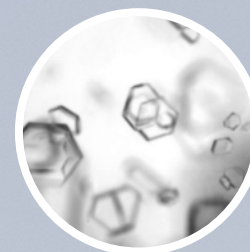
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### CEO STATEMENT

Orviglance Phase 3 study fully enrolled

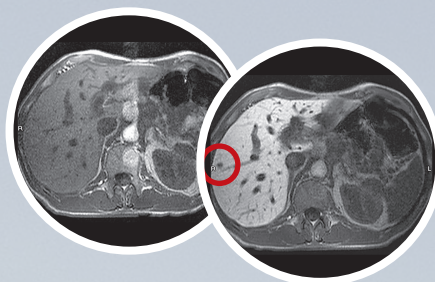
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### ORVIGLANCE®

Strong results for Orviglance vs. gadolinium contrast agent

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### ORVIGLANCE®

Orviglance improves chances to identify liver metastases

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### ONCORAL

Daily oral chemotherapy ready for Phase 2

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## FINANCIAL POSITION

Solid balance sheet with SEK 150 million in cash by the end of 2022.

p.35

## FINANCIAL CALENDAR

4 May 2023	Annual General Meeting 2023
11 May 2023	Interim report Q1 2023 (Jan-Mar)
18 August 2023	Half-year report H1 2023 (Jan-Jun)
8 November 2023	Interim report Q3 2023 (Jan-Sep)
9 February 2024	Full-year report 2023 (Jan-Dec)

# CEO STATEMENT



2022 was a very intense and productive year for Ascelia Pharma, where we had a particular focus on the important Phase 3 program with Orviglance<sup>®</sup>, our contrast agent for MRI and in March 2023 we were pleased to announce that the study had been successfully completed with 85 patients.

**Our progress in 2022 with the phase 3 clinical program with Orviglance puts us on course for a successful 2023.** In December, we presented stronger than anticipated effect of Orviglance which is a key factor when calculating the size of a clinical study. During the autumn, constructive dialogues were held with the US Food and Drug Administration (FDA) regarding the then ongoing phase 3 study SPARKLE and the stronger than expected efficacy of Orviglance. Based on these discussions, we decided to change the patient recruitment target in the study to significantly fewer patients than originally planned and the recruitment target was reduced from 200 to 80 patients.

**In February 2023, we announced that we had reached our patient recruitment target of 80 patients in the SPARKLE study,** in line with our updated timelines. This was a very important milestone in the history of Ascelia Pharma and a major step on our journey to make Orviglance available to patients worldwide. The headline results from this pivotal study are expected in mid-2023.

We are pleased to reach this important milestone, despite the difficult circumstances for SPARKLE and other clinical studies during the last few years. We had to actively try to counter the effects of the global COVID-19 pandemic, as well as Russia's invasion of Ukraine in February. Due to the escalating situation,

we decided back in early March to suspend all clinical activities in Russia, including patient recruitment. This, of course, had an immediate impact on the recruitment rate, although we were able to add additional clinics in other countries during the rest of the year.

In 2022, we also successfully completed two other clinical studies – the hepatic study and the food effect study – which have been ongoing in parallel with SPARKLE. In September, we announced the final results of the hepatic study, which confirms that Orviglance is well tolerated in patients with hepatic impairment. In May, the food effect study successfully showed that the image improvement with Orviglance was not affected by a light meal.

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*“The results from all our clinical studies so far confirm that Orviglance improves the detection and visualization of focal liver lesions in patients with severe kidney impairment”*

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**Orviglance data presented at several scientific conferences.**

Results from the food effect study were presented as an oral presentation at the world's largest radiology conference, RSNA, on November 27 – December 1 in Chicago. At the annual ESGAR conference in Lisbon earlier in the year, we had an oral presentation with the results from a study comparing Orviglance against a gadolinium-based contrast agent, as well as with unenhanced MRI. Importantly, the evaluation was done with the same methodology and parameters used in SPARKLE and has therefore given us a data-driven approach to reducing the size of the SPARKLE study.

The positive reactions to Orviglance in scientific circles are very encouraging and the results from all our clinical studies have so far confirmed that Orviglance provides an improved visualization and detection in magnetic resonance imaging (MRI) of cancer of the liver in patients with impaired renal function.

Performed market researches shows very strong support for Orviglance. In parallel with our development work for Orviglance, our team continues its preparations for the planned market launch of Orviglance. In March, we announced the results of an independent market study that shows the major medical needs that Orviglance addresses. Importantly, it showed that 84 percent of healthcare professionals are likely to use Orviglance for MRI scans in patients with liver cancer and renal impairment.

In the independently conducted market survey, 270 healthcare professionals in the US were asked about their choice of imaging procedure and contrast agents in patients with cancer. The main driver for their choice of contrast agent for liver MRI scans is patient safety, and in particular the need to minimize the risk of nephrogenic systemic fibrosis (NSF), a side effect associated with the use of the currently available gadolinium contrast agents in patients with renal impairment – the target patient population for Orviglance.

**A second US patent increases the value of Oncoral,** further strengthening our intellectual property rights. At the end of May, we announced our second Notice of Allowance for a US patent for our new oral chemotherapy treatment Oncoral, which is under development.

**Expansion of the leadership team.** In the autumn of 2022 the leadership team was increased to include seven members, representing all important line functions within the company. The expansion is an important and logical step in the growth of Ascelia Pharma and in our preparations to becoming a commercial stage company. I am convinced this change will contribute greatly to our growth journey forward.

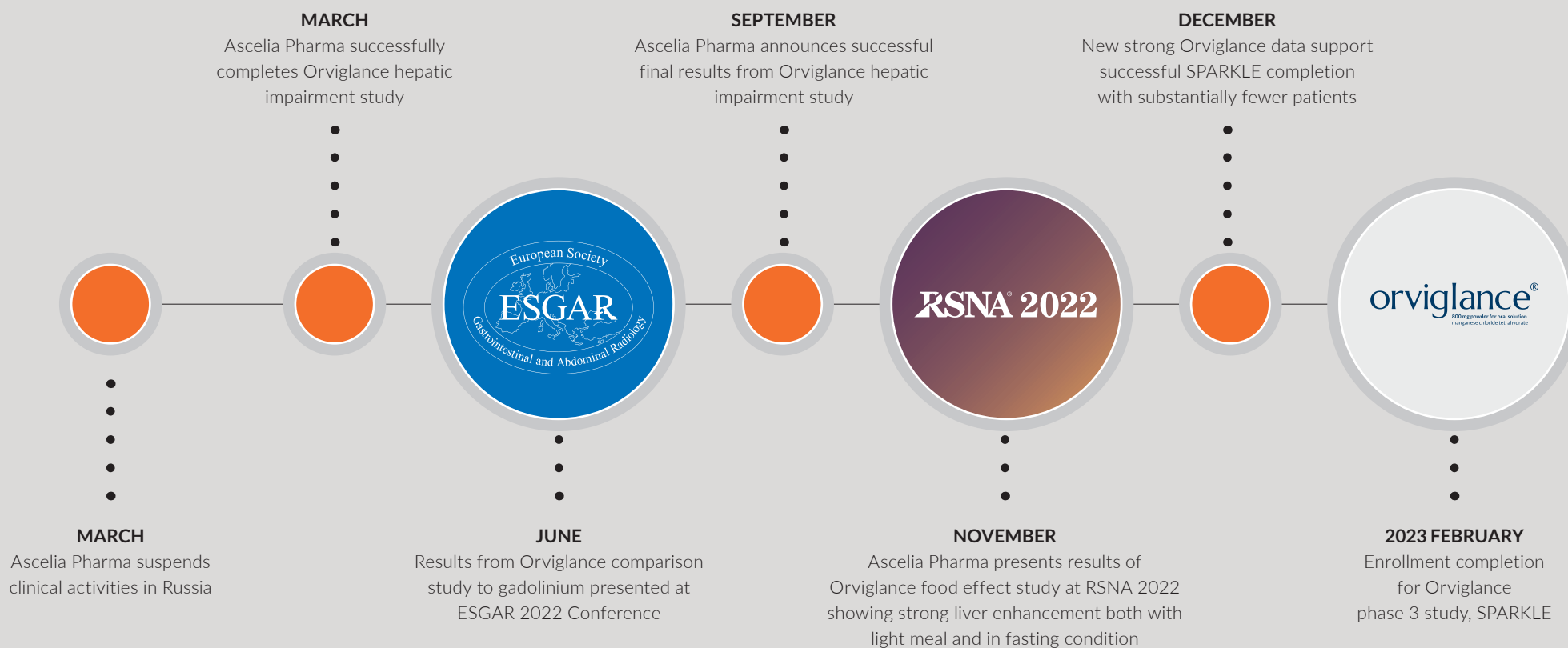
**Financial position.** Our development requires access to liquidity. We have a solid balance sheet and ended the fourth quarter with SEK 149.6 million in cash and cash equivalents, which will

take us into Q4 2023 with our planned activities, but could in an orderly manner be extended to Q2 2024. The cash and cash equivalents will primarily be used to complete the ongoing Phase 3 program and prepare for the New Drug Application (NDA) for Orviglance and activities prior to market launch.

**Outlook.** As we have now successfully completed patient recruitment in our Phase 3 program with Orviglance, we look forward to a successful 2023 with headline results in the middle of the year, as well as preparations for the NDA and launch. I look forward to updating you on our achievements as Ascelia Pharma grows.

**Magnus Corfitzen, CEO**

# KEY EVENTS IN 2022



# 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 Orvigance
- Second generation Orvigance patent to 2040
- Oncoral protected by patent to 2035

#### **Solid financial position**

Well-financed with approx. SEK 150 million in cash balance.



## CAPTURE VALUE

### CRYSTALLIZE VALUE

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

# ADVANCING ORPHAN ONCOLOGY

## OUR VALUES

### FOCUS

We are devoted to improving the lives of patients and creating values for our stakeholders.

### COURAGE

We work tirelessly and follow our convictions even when it means changing status quo.

### INTEGRITY

We build powerful relationship with mutual respect and adhere to the high ethical standards of our industry.

## OUR VISION

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

## 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).

## Building the company and building value

2022

ADVANCING PIPELINE AND COMMERCIAL CAPABILITIES

- ORVIGLANCE Phase 3
- ONCORAL ready for Phase 2

PRODUCT SALES AND EXPANDING PIPELINE

- ORVIGLANCE revenue
- ONCORAL Phase 2
- Pipeline expansion

2025 →

ESTABLISHED MARKET POSITION IN ORPHAN ONCOLOGY

- ORVIGLANCE market leader
- ONCORAL Phase 3
- Pipeline development
- Pipeline further expanded



# OUR PIPELINE

## ORVIGLANCE

### Diagnostic drug for liver magnetic resonance imaging (MRI) in ongoing Phase 3

Orviglance is our novel non-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
- \$800 million annual global addressable market of which \$500-600 million is related to US, EU & Japan

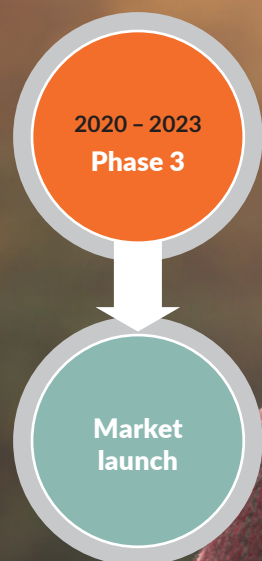
## ONCORAL

### Tablet chemotherapy ready for Phase 2

Oncoral is our novel oral irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan 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
- Ready for Phase 2 in gastric cancer; potential to expand into other cancer forms

## Expected timelines



**Orviglance®**  
Visualization of focal liver lesions  
(liver metastases, primary liver cancer)



**Oncoral**  
Gastric cancer treatment  
and expansion potential to other cancer forms



# ORVIGLANCE<sup>®</sup>

Phase 3 liver MRI contrast agent

- ▶ Manganese-based diagnostic drug
- ▶ The only late stage gadolinium-free agent
- ▶ Phase 3 fully enrolled
- ▶ Headline results mid 2023
- ▶ Orphan Drug Designation by FDA
- ▶ \$800 million global addressable market



# PROBLEM – LIVER METASTASES AND LIVER CANCER

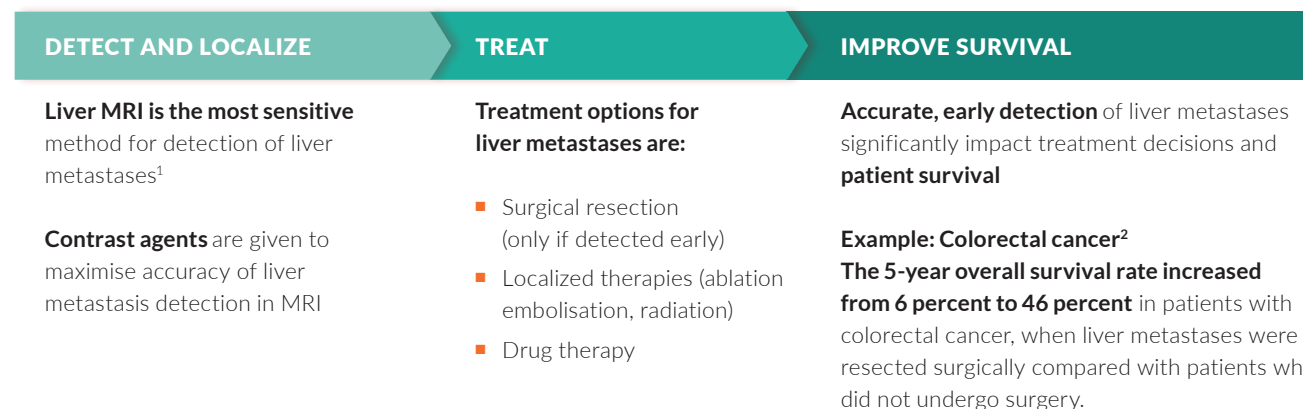
One of the reasons that cancer is a serious disease is its ability to spread to other parts of the body than the location of the primary tumor (i.e. where the first tumor formed). When cancer cells spread to distant lymph nodes, tissues or organs, it is called metastatic cancer. Cancer can spread to 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. For example, 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<sup>2</sup>.

**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. 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 in the image. This occurs thanks to the special magnetic properties of the chemical element in the contrast agent.



# 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 have 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 EMA suspended three gadolinium-based products in November 2017. In December 2017, the FDA warned that gadolinium-based contrast agents (GBCAs) are retained in the body and required new class warnings.

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



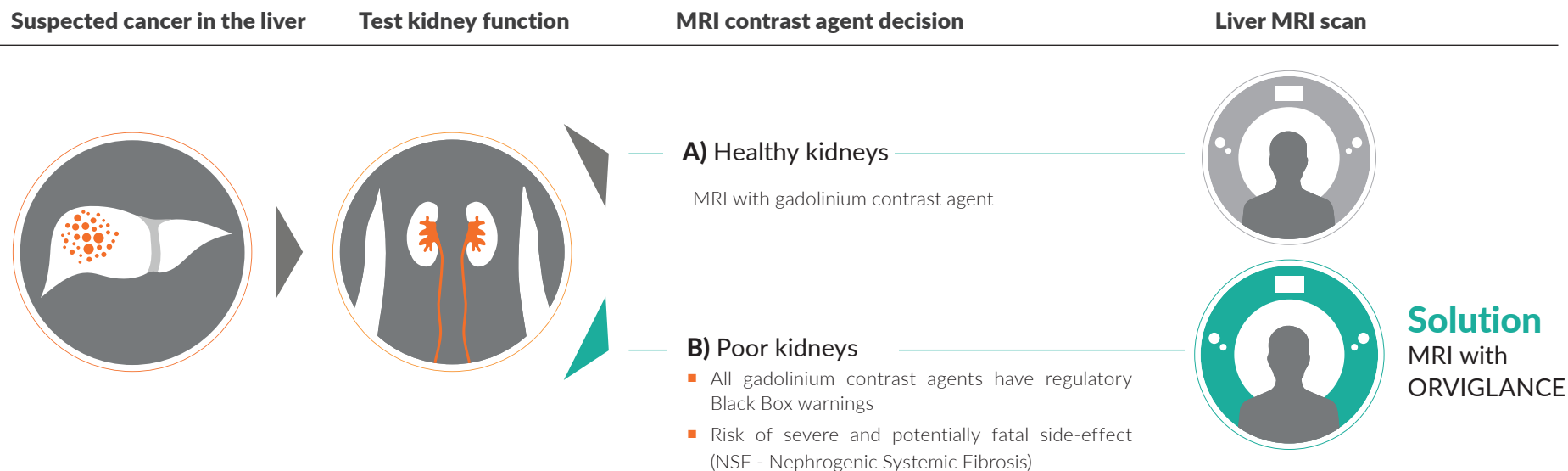
**WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)**  
See full prescribing information for complete boxed warning.  
Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information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

- The risk of NSF appears to highest among patients with:
  - Chronic, severe kidney disease (GFR < 30 mL/min/1.73m<sup>2</sup>), or
  - Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function.
- For patients at risk for chronically reduced renal function (for example, age > 60 years, hypertension, or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing (5.1)



# SOLUTION – ORVIGLANCE THAT FILLS THE UNMET NEED FOR LIVER MR IN PATIENTS WITH RENAL IMPAIRMENT

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 developed for use with 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 enhance the function of manganese as a contrast agent. After having been absorbed from the small intestine, the manganese is transported to the liver where it is taken up by and retained in the normal liver cells.

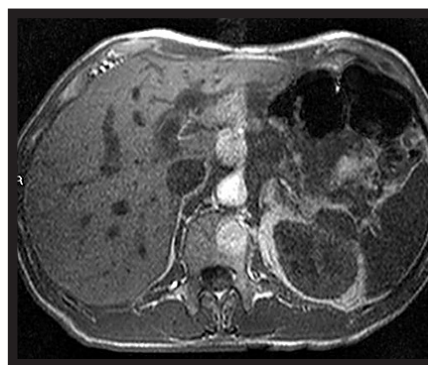
The high manganese uptake causes the normal liver tissue to appear bright on MR images. Metastases and tumor cells do not take up manganese to the same extent as normal liver tissue and therefore appear dark on MR images. With Orviglance, liver metastases are consequently easier to identify due to this 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 clinical studies with Orviglance.

## Patient example from our Phase 2 study\*

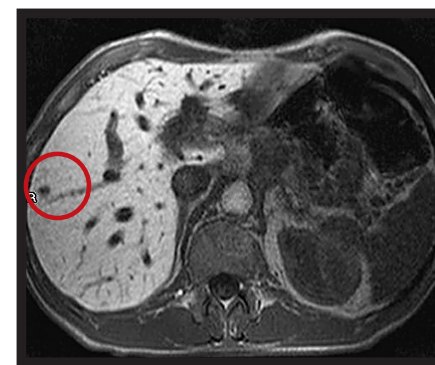
### Unenhanced liver MRI

(i.e. without contrast agent)



No metastasis visible

### Orviglance enhanced liver MRI



Metastasis becomes visible

\*Source: Patient with colorectal cancer. (Study CMC-P002)

# SEVERAL BENEFITS WITH ORVIGLANCE

## Key advantages of Orviglance®



**Potential to be** the first and only non-gadolinium contrast agent for liver MRI

**Based on manganese** – a natural trace element in the body – with no risk of NSF

**Strong evidence for liver MRI enhancement** from phase 1 and 2 studies

**Limited systemic exposure** and good safety profile

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

**The strong contrast effect with Orviglance** observed in the completed phase 1 and 2 studies makes it a good candidate as liver contrast agent for patients where the use of gadolinium-based contrast agents may be medically inadvisable or cannot be administered. Orviglance has the potential to offer a significantly better alternative than unenhanced MRI (i.e. MRI with no medical contrast agent). The patient segment for Orviglance comprises mainly patients with severe renal insufficiency who have an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m<sup>2</sup>, i.e. patients with chronic kidney disease stages 4 and 5 as well as patients with acute kidney injury.

**In summary**, there is a large medical need since there is no safe alternative for renally impaired patients who require an MRI scan of the liver. We believe Orviglance has the potential to become the preferred liver MRI contrast agent for this group of patients.



# STRONG CLINICAL RESULTS

**Eight out of nine clinical studies completed.** The clinical program for Orviglance consists of nine studies – eight phase 1 and 2 studies and one pivotal phase 3 study (SPARKLE). The eight phase 1 and 2 studies, including 201 subjects, have been completed. SPARKLE has completed enrollment with 85 patients and the final analysis is ongoing with an aim to present headline results mid-year and the full study report before year-end 2023. Totally, 286 subjects (healthy volunteers and patients) will contribute to the overall clinical evaluation of Orviglance.

**Consistent strong efficacy readout and safety profile.** Overall, the results from the eight completed clinical studies showed that Orviglance was safe and well tolerated with mostly reports of mild and transient adverse events related to the gastrointestinal tract (diarrhea and nausea). These studies also showed that diagnostic quality scores were improved after use of Orviglance and provided strong support for that Orviglance is an effective non-gadolinium liver MRI contrast agent.<sup>1</sup>

Six of the phase 1 and 2 studies were completed before the initiation of the phase 3 program. During the past year, a study investigating the effect on the MRI contrast performance in connection

with of food intake shortly before administration of Orviglance (food effect study) and another study investigating safety and pharmacokinetics of Orviglance in patients with various degree of liver impairment (hepatic impairment study) were completed. The food effect study demonstrated that the MRI signal enhancement in the liver after a light meal was comparable to fasting conditions. The hepatic impairment study demonstrated that there was no renal excretion of Orviglance. Excretion is primarily occurring via the liver also in this subgroup of patients. No new adverse events were observed in the study.



1) These studies have been published in Thomsen HS et al. Acad Radiol 2004; 11: 630-636, Thomsen HS et al. Eur Radiol 2007; 17: 273-278, Rief M et al. Invest Radiol. 2010; 45: 565-71, Brismar TB et al. Eur Radiol 2012; 22:633-41, Albiin N et al. MAGMA. 2012; 25:361-368, Shamsi, K., Oral presentation at ESGAR 2022: SSG12-2, Lisbon, Portugal., Shamsi, K., Oral presentation at RSNA 2022: W7-SSG15-2, Chicago, IL, United States. Hepatic impairment study P017 has not yet been published.

### Blinded read study of all imaging data confirming the strong efficacy data.

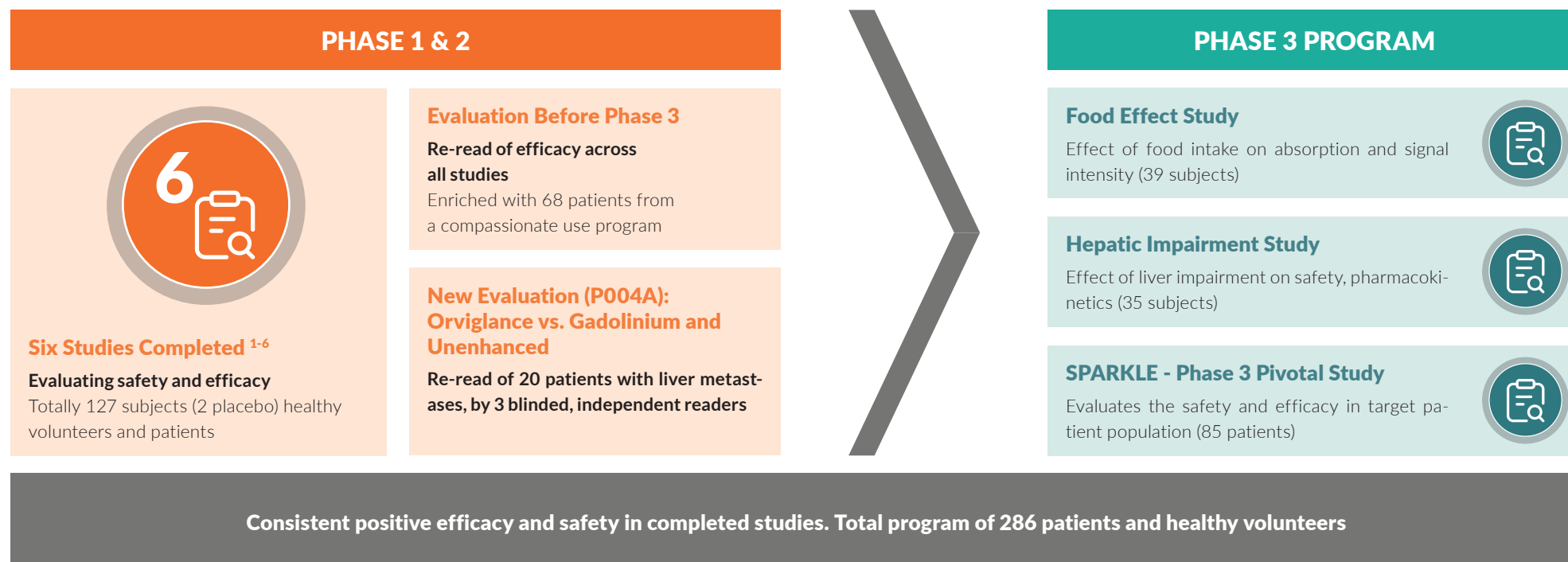
In order to further validate the results of the first six individual clinical studies and also provide guidance for the design of the Phase 3 program, Ascelia Pharma performed a re-evaluation of all the available imaging data, in a so-called “blinded re-read” study. The results of this blinded read study have been presented at large radiology conferences.

The blinded study, which included 178 persons (healthy volunteers and patients) underlined that Orviglance significantly improves MRI performance compared to unenhanced MRI

(without contrast). Importantly, Orviglance improved MRI performance in terms of lesion visualization (also termed contrast or conspicuity; p-value <0.0001) and delineation (p-value <0.0001) which was measured by a similar method as is used in the phase 3 program. Further, compared to unenhanced MRI, 33 percent more lesions were detected with Orviglance-enhanced MRI.

In 2021/2022, a new re-read analysis was performed of a MR images from a study that originally was designed to evaluate the diagnostic performance of Orviglance in comparison with a gadolinium-based contrast agent in 20 patients with known

liver metastasis<sup>1</sup>. This new re-read used the exact same evaluation method for the primary endpoint of lesion visualization as is used in the pivotal phase 3 study: three blinded, independent radiologists scored the border lineation and lesion contrast on unenhanced MR images and with Orviglance. The results of this new analysis confirmed that Orviglance-enhanced liver images were comparable to gadolinium-enhanced images and Orviglance provided superior liver MRI enhancement vs. unenhanced MRI (p-value <0.009).



<sup>1</sup>) The original study was published in Brismar TB et al., Eur Radiol 2012; 22:633-41.

# PHASE 3 STUDY (SPARKLE)

The pivotal Phase 3 study (SPARKLE) is a global multicentre study, which has been completed with 85 enrolled patients with suspected or known focal liver lesions and severely impaired kidney function. The primary objective is to demonstrate an improved visualization of liver lesions compared to MRI without contrast, unenhanced MRI.

The primary endpoint of the SPARKLE study is similar to what was studied in the phase 1 and 2 studies. The strong results in the Phase 1 and Phase 2 studies, both in terms of safety and efficacy, provide a solid foundation for the ongoing Phase 3 program.

## Orviglance clinical Phase 3 study

<b>NUMBER OF PATIENTS</b>	<b>Global study with 85 patients</b>
<b>PRIMARY ENDPOINT</b>	<b>Lesion visualization</b> <ul style="list-style-type: none"> <li>■ Lesions border delineation (border sharpness of lesions)</li> <li>■ Conspicuity (lesion contrast compared to liver background)</li> </ul>
<b>COMPARATOR</b>	<b>Unenhanced MRI + Orviglance MRI vs. Unenhanced MRI</b>
<b>EVALUATION</b>	<b>Centralised evaluation by 3 radiologists</b>
<b>RANDOMIZATION</b>	<b>None – each patient is his/her own control</b>
<b>FOLLOW-UP</b>	<b>Less than a week</b>

### 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



Results from both variables show 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 from six phase 1 and 2 studies completed before start of the phase 3 program. The blinded-read results have been presented at major radiology conferences



# GLOBAL ADDRESSABLE MARKET OF \$800 MILLION (\$500-600 MILLION US, EU & JAPAN)

## \$800 M global annual addressable market

### Market estimate based on:

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

## Go-to-market model



## Strong footprint in the US

- 1 SPARKLE Phase 3 Study**  
at leading US sites
- 2 Hepatic Impairment Study**  
at Texas liver institute
- 3 Ascelia Pharma Inc.**  
Office in New Jersey
- 4 Manufacturing**  
at Cambrex (partner), NJ
- 5 Imaging experts**  
RadMD, NY

## Building an Ascelia Pharma US team

<b>US team</b>	Around 40 FTEs at launch
<b>Clinics/Hospitals</b>	Around 400 clinics and hospitals serve 75 percent 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

# BRINGING ORVIGLANCE TO MARKET

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 →

## 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 percent 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 healthcare 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 percent of the 254 respondents have experienced a case of NSF – and more than half of these healthcare 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 percent 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

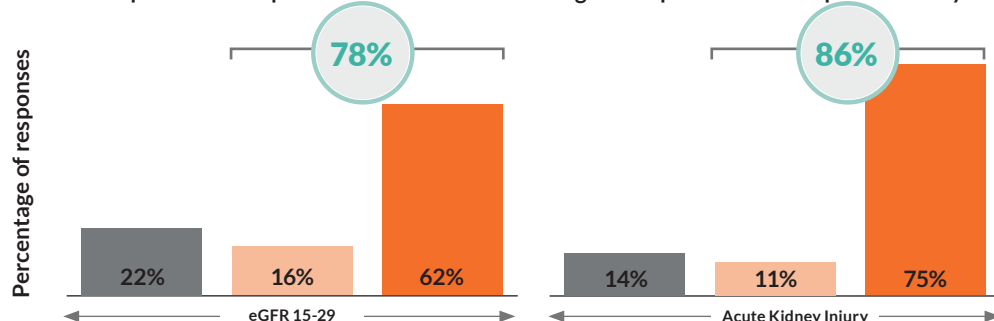
risks associated with GBCA, particularly patients with poor kidney function, regardless of whether they have had an MRI before. When presented the product profile of Orviglance, **84 percent of respondents say they are likely to or definitely will use Orviglance for the target patient population.** These 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.

## Market research with 254 healthcare professionals in the US (radiologists, oncologists and nephrologists)<sup>1</sup>

### Healthcare professionals prefer MRI without contrast agent for patients with impaired kidneys



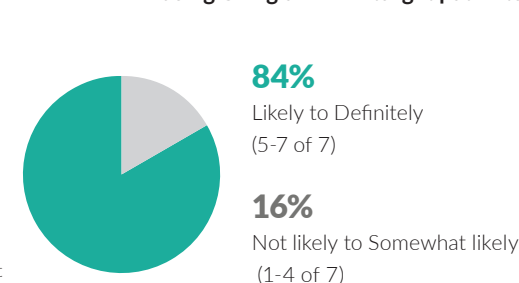
### Conclusions

78 percent prefer MRI without or with reduced dose contrast for patients with low eGFR ...

...even more for AKI patients

- MRI with contrast
- MRI with reduced dose of contrast
- MRI without contrast

### Likelihood of using Orviglance for target patients



<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.



# MOMENTUM FOR AN ALTERNATIVE TO GADOLINIUM

The attention to issues related to gadolinium exposure and the need for safer alternatives is growing.

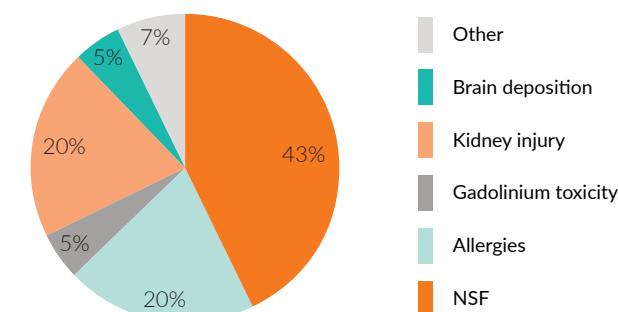
## Risks for kidney patients impact clinical decisions

For patients with impaired kidney function, healthcare professionals, payers and other key decision makers in radiology are well aware of the regulatory black-box warning of the use of gadolinium-based contrast agents (GBCAs). In fact, market research shows that in the US almost 90 percent of hospitals have guidelines for the use of GBCAs<sup>1</sup> and more than 90 percent of healthcare professionals think the risk of nephrogenic system fibrosis (NSF) is a concern when using GBCAs<sup>2</sup>.

Overall, insights and market research tell us that the safety concerns related to the use of gadolinium impact clinical decisions making and that the preferred imaging choice for patients where the use of gadolinium is medically inadvisable is an MRI without contrast, or with a non-liver specific lower-risk GBCA – both reducing the ability of clinicians to find and treat focal liver lesions, ultimately impacting the patient's treatment and chance of survival.

Orviglance aims to address this need for a liver imaging option for cancer patients with poor kidney function, where patients, caretakers and healthcare providers are free from concern or uncertainty of gadolinium-related safety risks.

## NSF and other gadolinium toxicities are the most important concerns of GBCAs<sup>2</sup>



N = 254, oncologist, nephrologist, and radiologist responses.

Q: Which side effects or adverse events are you most concerned about when using contrast agents (shown as percent split of highest concern).

Beyond the safety concerns for patients with kidney disease, there is growing attention to other concerns related to the use of gadolinium.

## Unknown safety impact of gadolinium retention in the brain and other organs

Beyond the risk of NSF in kidney impaired patients, gadolinium is well known to be retained in the brain and other organs in patients, regardless of kidney function. Scrutiny over the possible short- and long-term safety risks of gadolinium retention is a key concern of the scientific and medical communities, as well as regulators such as the FDA. And many questions remain open.

For example, a group of researchers write 'Recently studies have confirmed gadolinium accumulation in human brain following repeated gadolinium-based contrast agent administrations, regardless of an intact BBB (ref: blood-brain barrier) or normal renal function. Linear chelates GBCAs can result in more gadolinium deposition than macrocyclic chelates GBCAs. However, the impact of the retained gadolinium in the brain remains unknown, which needs large prospective studies to clarify in the future. It is recommended to take caution when using macrocyclic chelates GBCAs and keep as low doses as possible for reducing gadolinium accumulation in brain.'<sup>13</sup>



At the end of 2021, members of the American College of Radiology (ACR) recommended a new term for symptoms reported after GBCA exposure –Symptoms Associated with Gadolinium Exposure, or SAGE – in order to help researchers and healthcare providers describe and standardize reporting of these symptoms.<sup>4</sup>

In 2022, the FDA reminds healthcare providers that safety information should be given to patients before receiving GBCA injections. The agency states ‘...we are requiring several actions to alert healthcare professionals and patients about gadolinium retention after an MRI using a GBCA. These include requiring a patient Medication Guide that every patient will be asked to read before receiving a GBCA. We are also requiring manufacturers of GBCAs to conduct human and animal studies to further assess the safety of these agents’<sup>5</sup>. With this in mind, the FDA required gadolinium manufactures to conduct a long-term study to understand the possible effects of GBCA administration on body movement and mental skills when given to patients multiple times over 5 years.<sup>6</sup>

### Increasing environmental scrutiny

It is also well known that gadolinium is excreted via the kidneys in urine. Because it is difficult to remove in our sewage systems, it is discharged into the environment and into our drinking water. Gadolinium concentrations in rivers and drinking water is found to be higher close to larger cities and densely populated areas – and gadolinium is even found in soft drinks.<sup>7</sup>

In short, regulators, researchers and the medical community are acting on the uncertainties and unknown safety risks of the use of gadolinium and there is a growing urgency to find a viable alternative to the growing use of gadolinium – an alternative that is neither associated with the short- and long-term safety concerns of gadolinium for patients, nor with the unknown effects of gadolinium in our environment and drinking water. The industry is responding with innovation focused on safer and smaller dose gadolinium alternatives, as well as non-gadolinium contrast agents.

For Ascelia Pharma, the momentum for an alternative to gadolinium, for Orviglance, is getting better and better. Orviglance is the only late-stage non-gadolinium MRI contrast agent in development and is expected to be first-in-class to lead a gadolinium free future.

1) Market research for Ascelia Pharma by Back Bay in 2019, including surveys with 84 US radiologists,

2) Market research for Ascelia Pharma conducted by Two Labs Pharma Services in Q4 2021/ Q1 2022, including 16 interviews and 254 surveys with US oncologist, nephrologist, and radiologist responses

3) Bang G. Gadolinium Deposition in Brain: Current Scientific Evidence and Future Perspectives. *Mol. Neurosci.*, 20 September 2018.

4) McDonald R, et al Symptoms Associated with Gadolinium Exposure (SAGE): A Suggested Term. *Radiology* 2022 302:2, 270-273.

5) FDA.gov: ‘FDA warns that gadolinium-based contrast agents (GBCAs) are retained in the body; requires new class warnings’, 20 Jan 2022.

6) ODYSSEY Study. <https://clinicaltrials.gov/ct2/show/NCT04373564>

7) For example: Brünjes R. et al. Anthropogenic gadolinium in freshwater and drinking water systems, *Water Research*, Volume 182, 2020. Macke M. et al. Fast and automated monitoring of gadolinium-based contrast agents in surface waters. *Water Res.* 2021 Dec 1;207.



# ONCORAL

Daily oral chemotherapy  
ready for Phase 2

- ▶ Patented daily 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 percent. In this region 80-90 percent 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 unresectable 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 cancer 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 gastric 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 monotherapeutic or combination treatment regimens for advanced gastric cancer. In Japan, irinotecan is approved for the treatment of metastatic gastric cancer.

**Untapped market for oral formulations of irinotecan.** Today, 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 expectancy 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 intravenous 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 – ONCORAL CHEMOTHERAPY AS TABLET

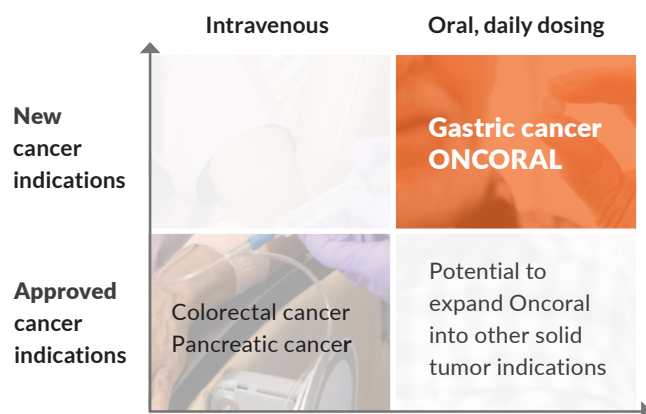
Oncoral is a novel daily irinotecan chemotherapy in development. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily irinotecan tablet with the potential to offer better efficacy with improved safety following the daily dosing at home compared to intravenous high-dose 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 a 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, which enables a reliable release and efficient absorption of irinotecan from the gastro intestinal tract after oral administration. With oral administration, irinotecan can be given with low daily doses. This is very different from the current standard of giving a high intravenous doses every third week.

**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



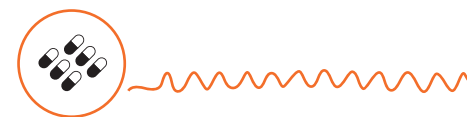
## TODAY – Intravenous bolus infusions



### Infrequent high-dose IV irinotecan

- Gastrointestinal and hematological side effects
- Dose limiting toxicity: 30 percent severe or life-threatening (grade 3 or 4)

## TOMORROW – Oncoral oral daily dosing



### Potential – Frequent low-dose irinotecan

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

# ONCORAL PHASE 1: ENCOURAGING RESULTS

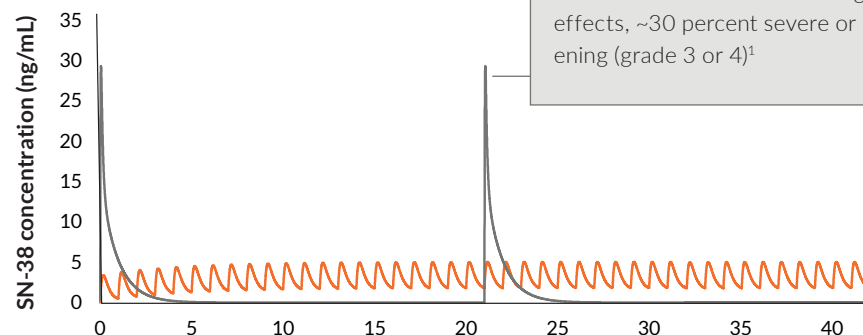
## Oncoral – potential to improve both Efficacy and Safety.

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 percent are severe or life-threatening (grade 3 or 4, ref: Camptosar® 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



### Infrequent high-dose IV irinotecan

Gastrointestinal and hematological side effects, ~30 percent severe or life-threatening (grade 3 or 4)<sup>1</sup>

### Frequent (metronomic) low-dose irinotecan

- Several studies show improved tolerability<sup>2,3</sup>
- Daily dosing – adjust quickly if acute toxicity

### Oncoral Phase 1 results

- Study of 39 patients with metastatic or unresectable solid tumors
- Study performed at Herlev hospital, Denmark
- Safety:**
  - Oncoral was well tolerated, no unexpected side-effects
  - Hematological toxicities mild to moderate (grade 1 or 2)<sup>4</sup>
- Efficacy**
  - Stable disease even in patients previously treated with IV irinotecan

Source: Simulation of Oncoral vs. IV Camptosar

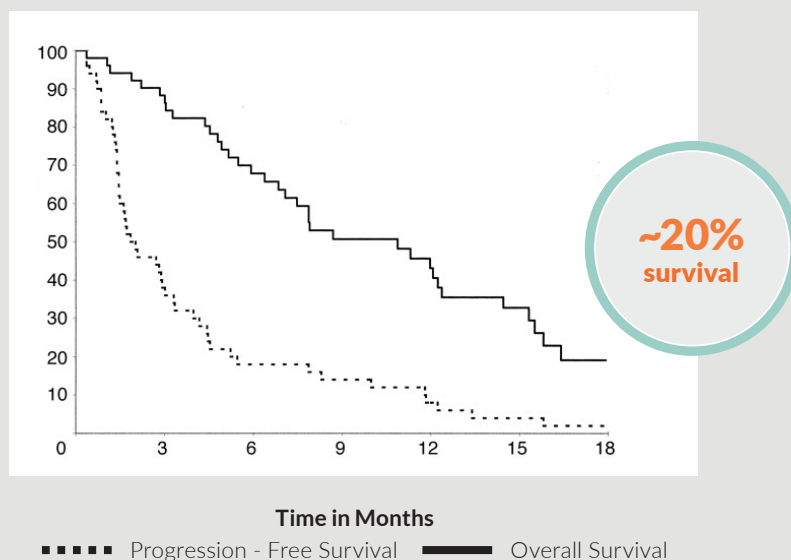
Refs: 1) Camptosar prescribing information 2) Furman et al 1999 3) Perez et al 2004 4) Kumler et al 2018

# IMPROVING EFFICACY BY FREQUENT LOW DOSING

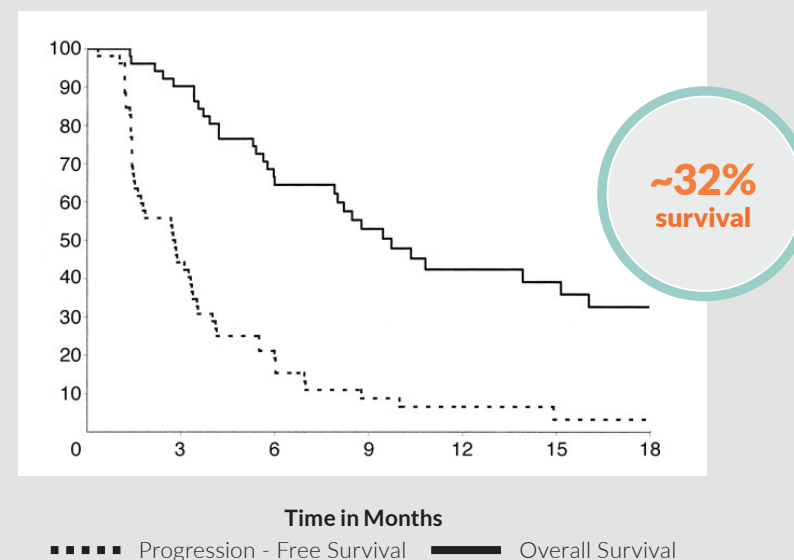
There are a number of non-clinical and clinical studies that provide proof-of-concept for metronomic/frequent low dosing of irinotecan, including improved patient outcomes. The study below in patients with metastatic refractory breast cancer illustrates improvement in overall survival by frequent low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

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

**Irinotecan dosing every 3 weeks (IV)**



**Irinotecan dosing weekly (IV)**



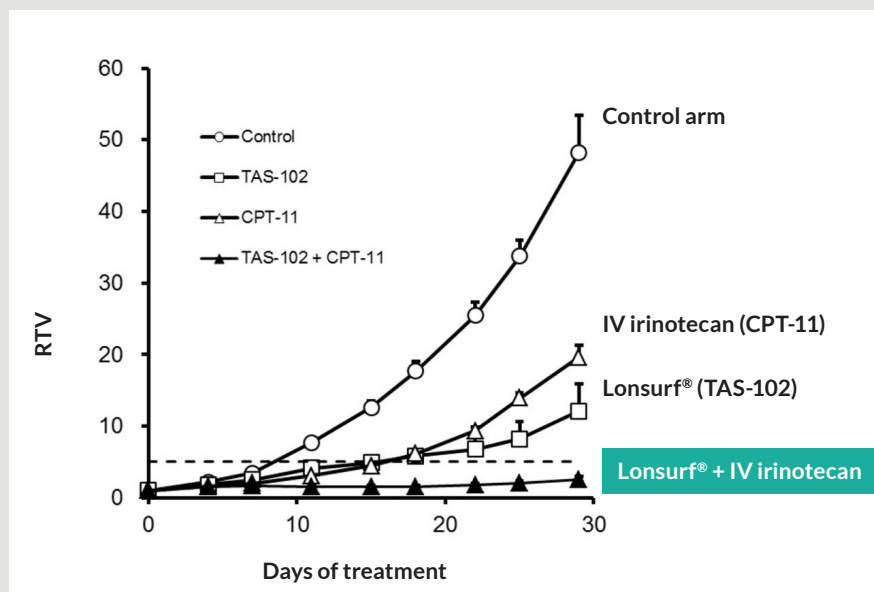
<sup>1</sup>Perez et al. J Clin Oncol 2004: Randomized Phase II Study of Two Irinotecan Schedules for Patients With Metastatic Breast Cancer Refractory to an Anthracycline, a Taxane, or Both

# 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 tumor 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

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



# PHASE 2 STUDY DESIGN AND COLLABORATION

## Phase 2 study design

<b>PATIENTS</b>	<ul style="list-style-type: none"><li>■ Around 100 patients</li><li>■ Metastatic gastric cancer</li></ul>
<b>COMPARATOR</b>	Oncoral + Lonsurf® vs. Lonsurf®
<b>ENDPOINTS</b>	<b>Primary:</b> Progression Free Survival <b>Secondary:</b> Response rate, Pharmacokinetics, Safety and Overall Survival data in a follow up analysis
<b>STUDY PERIOD</b>	2 - 2½ years, study start pending

## Clinical collaboration with Taiho Oncology

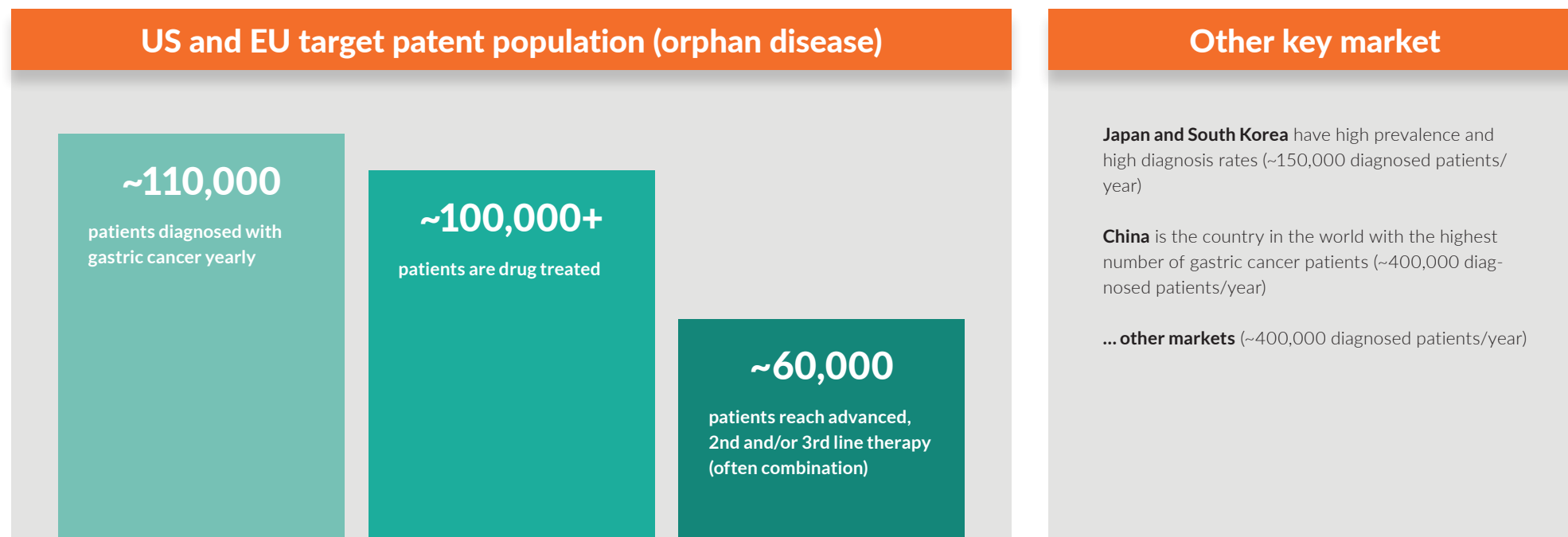
- Clinical Phase 2 collaboration with Taiho Oncology Inc. (part of Otsuka Group)
- Taiho Oncology Inc. will supply Lonsurf® and provide scientific expertise
- The collaboration may be extended for further development
- Ascelia Pharma retains full development and commercialization rights



LONSURF® is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

# 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.



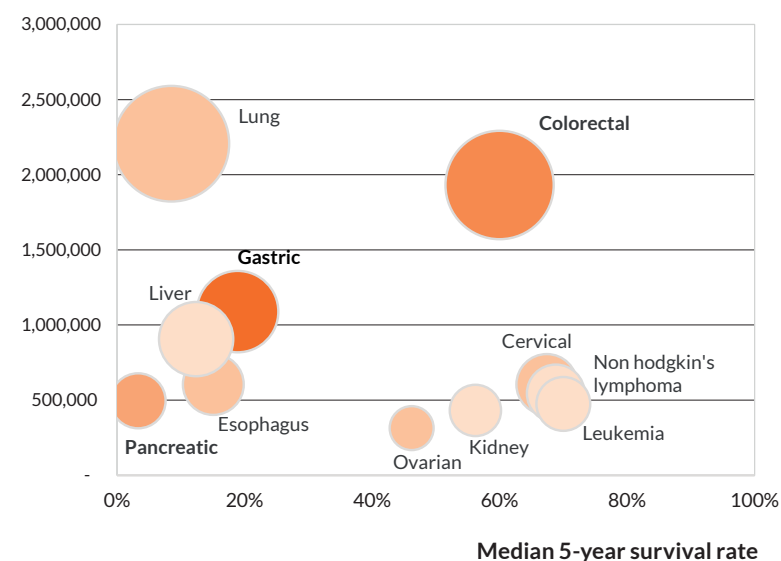
# HIGH VALUE OPPORTUNITY IN OTHER CANCER FORMS

Beyond gastric cancer, there is potential for subsequent label expansion into other solid tumor indications. Within colorectal and pancreatic cancer, irinotecan 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 demonstrated and recognized.

## Potential for oral, daily dosing of irinotecan<sup>3</sup>

- Current focus: Gastric cancer
  - 3rd highest cancer deaths<sup>1</sup>
  - Orphan opportunity (US. and EU)
  - \$3 bn+ market<sup>2</sup>
- Approved indications for IV irinotecan infusions
- Indications for which IV irinotecan infusions are clinically demonstrated & NCCN recognized
- Indications for which IV irinotecan infusions are clinically demonstrated

Global annual incidence



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 2022, the company had 33,668,262 registered common shares and 1,202,915 C-shares with 1/10 voting rights (C-shares are held by Ascelia Pharma AB).

## Share performance and market cap

In 2022, Ascelia Pharma's share price declined by 50 percent. The decline followed the trend of other biotech companies during 2022. The market value of Ascelia Pharma at 31 December 2022 was SEK 0.5 billion.

In 2022, 14.3 million shares were traded on all marketplaces. The average number of shares traded per day in 2022 was 56,900.

## Ownership structure

The five largest shareholders as of 31 December 2022 had a total of 36 percent of the capital and 37 percent of the votes. Around 5 percent of shares are held directly or indirectly by Management and Board members.

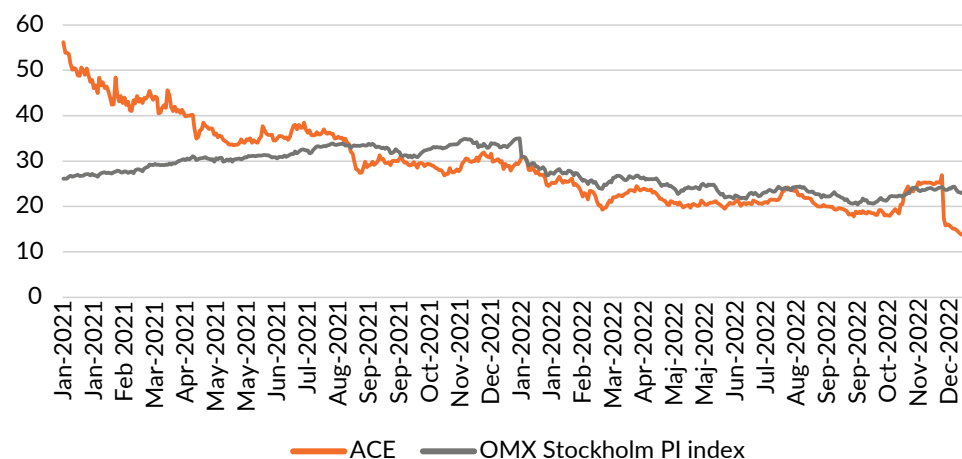
## Financial information

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](http://www.ascelia.com).

## 2023 Annual General Meeting

The AGM of Ascelia Pharma AB (publ) will be held on 4th of May 2023.

## 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 2022	No. of shares	% of capital	% of votes
Sunstone Life Science Ventures Fund II	4,778,129	13.7%	14.1%
Fourth Swedish National Pension Fund (AP4)	2,709,266	7.8%	8.0%
Avanza Pension	1,802,713	5.2%	5.3%
Øresund-Healthcare Management A/S	1,770,490	5.1%	5.2%
Futur Pension	1,367,590	3.9%	4.1%
ÖstVäst Capital Management	1,200,000	3.4%	3.6%
René Spogård	1,070,243	3.1%	3.2%
Nordnet Pensionsförsäkring	1,004,917	2.9%	3.0%
Unionen	902,480	2.6%	2.7%
HealthInvest Partners	750,000	2.2%	2.2%
Other holders of common shares	16,312,434	48.5%	46.8%
Total common shares	33,668,262	96.6%	99.7%
C-shares (held by Ascelia Pharma), 1/10 voting rights	1,202,915	3.4%	0.3%
<b>TOTALT ANTAL AKTIER</b>	<b>34,871,177</b>	<b>100%</b>	<b>100%</b>

# 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 2022-01-01 – 2022-12-31 for the Group and the Parent company.

## Ownership structure

Ascelia Pharma AB (publ) is listed on Nasdaq Stockholm. The largest shareholders per 31 December 2022 were Sunstone Life Science Ventures Fund II K/S with 4,778,129 shares (13.7 percent of total shares) followed by Fourth Swedish National Pension Fund (AP4) with 2,709,266 shares (7.8 percent) and Avanza Pension with 1,802,713 shares (5.2 percent)

## 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.

### About Orviglance (previously referred to as Mangoral)

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. These patients are at risk of serious side effects from the currently available class of gadolinium-based contrast agents. Orviglance has been granted an Orphan Drug Designation by the US Food and Drug Administration (FDA). A clinical program of nine studies, including the global Phase 3 study SPARKLE, have been fully enrolled.

### About Oncoral

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

Due to the Russian invasion of Ukraine, all clinical activities in Russia in the Phase 3 study SPARKLE were suspended in March 2022. Among the 47 clinical sites opened at the time, 13 were located in Russia. The decision to suspend clinical activities in Russia extended the timeline for completing patient recruitment in the study. Moving forward, we do not see any direct impact on the company.

The results of the Food-Effect study that was presented in May 2022 showed that Orviglance image enhancement of the liver is not reduced by light meal. The reporting of the final results for the Food Effect study concludes two of the three studies in Ascelia Pharma's ongoing phase 3 clinical program for registration of Orviglance. During the year, the Hepatic Impairment Study with Orviglance was also successfully completed. In December, new data were available showing that the SPARKLE study could be completed with 80 patients. This led to an earlier expected completed patient recruitment phase with a subsequent top-line readout in mid-2023. At the year end, 65 patients had completed the study.

Our strong belief in Oncoral is unchanged based on the Notice of Allowance for a US patent for our new oral chemotherapy treatment Oncoral, which is under development. The new patent further strengthens the intellectual property rights of Oncoral and provides protection until 2035 in the United States.

In October, it was decided to expand the management team to include all line functions as part of the expected growth. We now have a strong management team to move Ascelia Pharma forward towards becoming a commercial company.

## Multi-year overview, Group

### Financials key ratios for the Group

SEK thousands	2022	2021	2020
Net sales	-	-	-
Operating result	-147,007	-39,160	-93,428
Net result	-131,223	-35,073	-98,697
Earnings per share (SEK)	-3.77	-1.01	-3.76
R&D costs/operating costs ( percent)	80%	71%	69%
Cash flow used in operating activities	-125,263	-32,246	-85,527
Equity	180,859	307,834	236,056
Liquid assets incl. marketable securities	149,555	261,599	184,686

## FINANCIAL OVERVIEW 2022

### EARNINGS AND PROFITABILITY

#### Net sales and other operating income

The Group's net sales in FY-2022 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 totalled SEK 827 thousand (SEK 317 thousand). The income refers to exchange rate gains.

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

R&D costs for the Group in FY-2022 were SEK 118.1 million (SEK 107.6 million). The cost increase of SEK 10.5 million reflects the increased patient recruitment compared to last year.

#### Commercial preparation costs

During FY-2022, costs related to commercial preparations for Orvigance amounted to SEK 14.9 million (SEK 13.2 million). The cost increase compared with FY-2021 reflects a step-up in market launch preparations.

#### Administration costs

Administration costs for the Group in FY-2022 amounted to SEK 14.6 million (SEK 17.1 million). The cost decrease primarily reflects a decrease in recognized costs for employee incentive programs.

#### Operating results (EBIT)

The operating result in FY-2022 amounted to SEK -147.0 million (SEK -137.9 million). The increased loss primarily reflects the higher level of R&D costs related to increased patient recruitment compared to FY-2021.

#### Net profit/loss for the period

The Group's net loss in FY-2022 amounted to SEK -131.2 million (SEK -125.9 million). In the current period, net financial income of SEK 13.3 million was recognized due to primarily strengthening of USD against SEK, 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 this currency). The net loss corresponds to a loss per share, before and after dilution, of SEK -3.77 (SEK -3.82).

### CASH FLOW

Cash flow from operating activities before changes in working capital in FY-2022 amounted to SEK -139.9 million (SEK -130.0 million). The increased outflow y/y primarily reflects the higher level of R&D activity in the current period. Changes in working capital for the period totalled an inflow of SEK 14.7 million (inflow of SEK 13.5 million). The inflow in the current period primarily reflects the increase in accounts payable. Cash flow from investing activities in FY-2022 totalled an outflow of SEK -65 thousand (SEK -38 thousand), which reflects a value loss in divestment of a leasing car. Cash flow from financing activities amounted to an outflow of SEK -1.1 million (inflow of SEK 184.9 million), which mainly reflects amortization of lease liabilities.

### FINANCIAL POSITION

On the closing date, equity amounted to SEK 180.9 million, compared with SEK 307.8 million per 31 December 2021. The decrease since 31 December 2021 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 149.6 million, compared to SEK 261.6 million per 31 December 2021. The decrease since 31 December 2021 reflects the net loss incurred.

# RISK AND RISK MANAGEMENT

## How Ascelia Pharma is adapting to the company's exposure to various risks.

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**

- Delay of development projects
- Disruption or quality failure of supply and manufacturing
- Negative outcome of development projects

### **OPERATIONAL AND COMPLIANCE RISKS**

- Unable to attract or retain key personnel
- Critical breach of legislation, industry codes and standards
- Significant loss of data (it) or failure or cyber security breach

### **COMMERCIALIZATION RISKS**

- Partnering risk
- Reduced payer willingness to support targeted price or access
- New competitor entry
- Unfavorable changes in regulatory or clinical guidelines

### **FINANCIAL AND MACRO ENVIRONMENT RISKS**

- Inability to timely raise funds to meet goals
- Substantial currency impact on financial resources
- Substantial macro events such as pandemic outbreaks, war, geopolitical instability etc.

*These are the most important risks and other risks can apply.*



## Strategic risks

### NEGATIVE OUTCOME OF DEVELOPMENT PROJECTS

Failure to reach approval due to e.g., negative results would negatively impact the possibility for patients to get access to important new products and the company's financial position.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Prioritizing development of drugs with well-established mechanism-of-action
- Regulatory interactions to discuss regulatory pathways
- Analyze existing data including literature to evaluate risk

### DELAY OF DEVELOPMENT PROJECTS

Delay of key development projects, e.g. due to unforeseen events in the preparation of Orviglance NDA or requests for additional data during the NDA approval process, will negatively impact cost and time of development.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Focus resources on key asset (Orviglance) to ensure sufficient quality and timely delivery of activities on critical path
- Regulatory interactions to discuss regulatory strategy and pathways

### DISRUPTION OR QUALITY FAILURE OF SUPPLY AND MANUFACTURING

Failure by third-party contract organizations to provide clinical study or manufacturing services in accordance with current legal, regulatory, and quality standards may increase costs or cause significant delays of development activities or product supply.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Focusing on the selection, management and quality monitoring of key vendors, in order to maintain collaboration, proactive planning and compliance





## Operational and compliance risks

### UNABLE TO ATTRACT OR RETAIN KEY PERSONNEL

Inability to retain and attract competent personnel can lead to loss of knowledge and efficiency.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Ensuring that Ascelia Pharma is a great place to work by creating a strong purpose, living our corporate values and offering opportunities for personal development, market based compensation and attractive working conditions

### CRITICAL BREACH OF LEGISLATION, INDUSTRY CODES AND STANDARDS

Non-compliance with applicable legislation, codes and standards may be costly and/or can severely impact reputation.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Continuous review and improvement of relevant business processes

### SIGNIFICANT LOSS OF DATA (IT) OR FAILURE OR CYBER SECURITY BREACH

Disruption of IT infrastructure, loss of data or data integrity breach can cause limitations in our ability to maintain operations.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Continuous monitoring and development of IT infrastructure, security and related processes
- Continuous review that we are properly cyber-insured



## Business environment and commercialization risks

### PARTNERING RISK

In selected markets, out-licensing or partnering for development or commercialization of assets is part of the strategy of Ascelia Pharma. Not finding suitable, sufficiently attractive partnering opportunities or risk that chosen partner not performing will increase required investments and operational complexity for Ascelia Pharma, or delay progress of asset development.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Partnering and out-licensing activities are continuously evaluated and proactively pursued according to strategy and opportunity
- Thorough due diligence and evaluation of strategic options conducted as part of partnering efforts
- Corresponding risk management

### UNFAVORABLE CHANGES 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, which could negatively impact the addressable market size or adoption

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Engagement with experts to support clinical development, regulatory and commercial strategy development
- External market research and oversight for ongoing monitoring
- Medical advocacy and education support pre-launch and launch

### REDUCED PAYER WILLINGNESS TO SUPPORT TARGETED PRICE OR ACCESS

Market approval does not guarantee that the expected pricing can be achieved or that access will be obtained. A significant price reduction or delay of reimbursement/access will impact market potential.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Applying value-based pricing and value evidence generation
- Conducting payer research on an ongoing basis to inform pricing and access strategies
- Pre-launch market access plans and activities implemented to drive early adoption at pricing strategy

### NEW COMPETITOR ENTRY

Launch of new products by other companies addressing the same unmet need could impact the potential market share of Ascelia Pharma's products.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Portfolio strategy focuses on assets with the potential to address clear unmet needs for a well-defined patient population
- Continuous monitoring market and supports ongoing activity planning
- Strategies and governance are in place to maximize exclusivity and mitigate competitor risks, e.g., with regulatory exclusivity and Orphan Drug Designations, and patent portfolio management with external expert support



## Financial and macro environment risks

### INABILITY TO TIMELY RAISE FUNDS TO MEET GOALS

Ascelia Pharma is still in development phase with no revenue and dependent on securing financing to fund operations from external sources.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- Long- and short term plans to secure capital from various external sources to ensure ability to fund operations
- Diligent budgeting and follow up to ensure available capital is utilized in the best manner

### SUBSTANTIAL CURRENCY IMPACT ON FINANCIAL RESOURCES

Ascelia Pharma has substantial costs in various currencies including USD and EUR. Consequently, an appreciation of these currencies towards SEK would mean increased costs to the Group.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- In accordance with the financial policy, Ascelia Pharma handles the currency exposure by exchanging SEK to USD, EUR and DKK to match expected cash outflow

### SUBSTANTIAL MACRO EVENTS SUCH AS PANDEMIC OUTBREAKS, WAR, GEOPOLITICAL INSTABILITY ETC.

Significant change in the macroeconomic situation, since 2020, can impact the ability conduct business and clinical studies. Since 2020, the COVID-19 pandemic caused disruptions to the healthcare industry incl. delays in the enrollment of patients at clinical sites. Geopolitical effects, inflation and currency exposure has affected the year of 2022.

#### RISK MANAGEMENT & IMPLEMENTED MEASURES

- COVID-19 safety precautions for employees and stakeholders implemented precautions to minimize risks
- The Phase 3 study SPARKLE was conducted in different continents and countries, which might mitigate the effect from macro events





# OTHER INFORMATION

## Employees

The number of full-time employees as of 31 December 2022 amounted to 24 (21) for both the Group and the Parent company (average 23 employees in 2022 and 18 in 2021). In addition to the employees, Ascelia Pharma utilizes consultants and experts for clinical studies regulatory affairs, manufacturing, intellectual property 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.

## PARENT COMPANY

Ascelia Pharma AB (publ) fully owns all the companies in the Group. The equity/assets ratio on the closing date was 85 percent (93 percent). Equity amounted to SEK 215M (SEK 333M). Liquid assets amounted to SEK 138M (SEK 246M). The company had 24 employees on the closing date.

## Total number of shares

The total number of outstanding common shares as of 31 December 2022 was 33,668,262 and number of C-shares was 1,202,915 as of 31 December 2022. 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.

## Sustainability

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 systematic 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 2022 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 2022.

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 three meetings and commercialization committee held four meetings.

## Authorization to the board of directors regarding new issues of securities and repurchases

For authorizations granted by the Annual General Meeting to the Board of Directors, reference is made to p.47 of the Corporate Governance Report.

## 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: Board of Directors proposes that SEK 180,110,584 is carried forward.

	SEK
Share premium reserve	678,747,458
Retained earnings	-377,266,145
Net income (loss) for the period	-121,370,729
<b>Summa</b>	<b>180,110,584</b>

## Dividend policy

Up to now, Ascelia Pharma has not paid any dividends and Ascelia Pharma's intention is to continue to focus on further development and expansion of the company's project portfolio. In accordance with the dividend policy adopted by the Board of Directors, available financial resources and any reported results shall therefore be reinvested in the business to finance the company's long-term strategy. Hence, the Board of Directors' intention is not to propose a dividend to shareholders before the company is able to generate a long-term sustainable profitability and a long-term sustainable positive cash flow. Any future dividends and the size thereof will be determined based on 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 Annual General Meeting is the company's highest decision-making body. At the Annual 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 Annual 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 Annual General Meeting.

## Annual General Meeting 2022

At the Annual General Meeting held on 5 May 2022, Peter Benson was re-elected as Chairman of the Board and Niels Mengel, René Spogård, Helena Wennerström, Lauren Barnes and Hans Maier were re-elected as board members. Bo Jesper Hansen had declined re-election. Furthermore, Öhrlings PricewaterhouseCoopers AB was re-elected as auditor.

The Annual General Meeting resolved on fees to the board of directors and guidelines for remuneration to the CEO and other senior executives. The Annual General Meeting further approved the instructions and rules of procedure for the nomination committee and approved updated guidelines for remuneration to senior executives. The Annual General Meeting finally also resolved on an authorization for the board of directors to issue shares, on a share-based incentive program for employees as well as on an authorization for the board of directors on transfers of own ordinary shares.



## Annual General Meeting 2023

The Annual General Meeting (AGM) of Ascelia Pharma AB (publ) will be held on 4 May 2023.

### Shareholders

On 31 December 2022, the five largest shareholders controlled around 36 percent of capital 37 percent of the votes. The largest shareholder controlling more than 10 percent of the capital and votes were Sunstone Life Science Ventures Fund II K/S (13.7 percent of capital 14.1 percent of votes). On 31 December 2022, 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 1,202,915. 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 2023 Annual General Meeting is comprised of the following persons:

- Jørgen Thorball, chairman of the Nomination Committee, appointed by Sunstone Life Science Ventures Fund 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 five ordinary board members elected by the general meeting, who are presented in the section Board of directors on pages 49-50 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 2022

The board of director's had 12 meetings in 2022. In addition to decisions concerning external financial reporting, budget and financial forecasts, the board's work during 2022 have primarily comprised matters related to the Phase 3 study for Orviglance, planning for Oncoral Phase 2 study 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 2022 - 31 December 2022

Board member	Funktion	Independent in relation to		Remuneration, TSEK					Attendance (attendance in relation to total meetings)			
		The company and its management	Major shareholders	Board fees	Audit Committee	Remuneration Committee	Commercialization Committee	Total	Board of Directors	Audit Committee	Remuneration Committee	Commercialization Committee
Peter Benson	Chairman	Yes	Yes	516	–	16	25	557	12/12	–	3/3	4/4
Lauren Barnes	Board member	Yes	Yes	258	–	–	100	358	11/12	–	–	4/4
Niels Mengel	Board member	Yes	Yes	258	25	–	–	283	12/12	5/5	–	–
Hans Maier	Board member	Yes	Yes	258	–	–	25	283	11/12	–	–	3/4
Helena Wennerström	Board member	Yes	Yes	258	100	–	–	358	12/12	5/5	–	–
René Spogård <sup>1)</sup>	Board member	Yes	Yes	258	–	33	–	291	11/12	–	2/3	–
Bo Jesper Hansen <sup>2)</sup>	Board member	Yes	Yes	86	–	–	–	86	4/4	–	–	–
<b>Total</b>				<b>1,892</b>	<b>125</b>	<b>49</b>	<b>150</b>	<b>2,216</b>				

1) René Spogård passed away in March 2023. Réne was a board member during the entire year 2022.

2) Bo Jesper Hansen resigned as a board member at the annual meeting 2022.

### 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 2022.

#### Remuneration Committee

The Remuneration Committee is comprised of René Spogård (chairman) and Peter Benson. 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 three meetings in 2022.

#### 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 2022.

#### 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 seven people which in addition to the CEO is comprised of the Chief Commercial Officer/Deputy CEO, Chief Financial Officer, Chief Scientific Officer, VP Product Development & Supply and IT, VP Regulatory Affairs & QA and VP Clinical Development. The CEO and the senior executives are presented in the section Management on pages 51-52 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 2022, 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 2023 shall be paid with SEK 525,000 to the chairman of the board and with SEK 262,500 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, 100,000 to the chairman of the Commercialization Committee and 50,000 to the chairman of the Remuneration Committee. To each of the other members of the Audit Committee, the Commercialization Committee and the Remuneration Committee, it was resolved that remuneration of SEK 25,000 would be paid.

### Guidelines for remuneration to senior executives

#### Scope and applicability of the guidelines

These guidelines comprise the persons who are part of the group management, currently the CEO, CFO, CSO, CCO/Deputy CEO, VP Product Development & Supply and IT, VP Regulatory Affairs & QA and VP Clinical Development. 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 2022. These guidelines do not apply to any remuneration resolved by the Annual 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 7 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, considering, 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 study 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 bargaining 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 undertaking 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 7 in this annual report.

**Authorization to the board of directors regarding new issues of securities and repurchases of shares**

At the Annual General Meeting held on 5 May 2022, 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 new ordinary shares, convertibles and/or warrants. 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 8,417,066, which corresponds to a dilution of approximately 20 percent calculated on the current number of outstanding shares in Ascelia Pharma. To the extent an issue is made with deviation from the shareholders' preferential rights, the issue should be made on market terms.

At the Annual General Meeting, it was furthermore, as part of the resolution to implement the incentive program LTI 2022, resolved to authorize the board of directors, for the period up until the next Annual General Meeting, on one or several occasions, to issue a maximum of 973,677 series C shares. The new shares may, with deviation from the shareholders' preferential rights, only be subscribed for by a bank or a securities company at a subscription price which corresponds to the quota value of the shares. The purpose of the authorization and the reason for the deviation from the shareholders' preferential rights in connection with an issue of shares is to secure delivery of shares in LTI 2022 and, in terms of liquidity, to hedge payments of future social security contributions related to LTI 2022. As part of the resolution to implement LTI 2022, the Annual General Meeting also resolved to authorize the board of directors, for the period up until the next annual general meeting, on one or several occasions, to repurchase its own series C shares. Repurchase may only be effected through a public offer directed to all holders of series C shares and shall comprise all outstanding series C shares. Repurchase may also be made of so-called interim shares, by Euroclear Sweden AB designated as a Paid Subscribed Share (Sw. Betald Tecknad Aktie (BTA), regarding a series C share. Repurchase shall be made at a purchase price per share which corresponds to the quota value of the share.

**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 analysing and following up the Group's financial reporting and results. There are functions for the analysis and follow-up of the financial reporting of the Group and subsidiaries. Control activities also comprise a review and follow-up of Ascelia Pharma's governing documents relating to risk management and analysing complex transactions or valuation of assets or liabilities encompassing a significant element of judgement. The board of directors is responsible for internal control and monitoring of the company's management. This is done primarily by examining the company's steering documents and identified risk factors.

### **Information and communication**

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

### **Monitoring**

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

### **External auditor**

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

At the Annual General Meeting held on 5 May 2022, 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 Pharma AB, Ascelia Incentive AB och Good Partners Media Group AB. Board member of Dextech Medical AB, Jollingham AB, Jollingham Group AB och PainDrainer AB. Deputy board member of Jelly Bean AB.

### Holdings in Ascelia Pharma (per 15 March 2023)

45,000 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. Chairman 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 15 March 2023)

-

### Independence

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



## Niels Mengel

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

### Professional background

Niels Mengel is Founding Partner, board member and CEO of Øresund-Healthcare Capital. Niels Mengel has extensive experience from the healthcare industry as an investor. Niels Mengel has previously inter alia been Executive Vice President at ISS World Services A/S and Director at PA Consulting Group.

### Education

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

### Other ongoing assignments

Board member of 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 15 March 2023)

293,758 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.

# 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 15 March 2023)

20,000 shares in Ascelia Pharma AB.

### Independence

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



## Helena Wennerström

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

### Professional background

Helena Wennerström is Vice President, Corporate Finance 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.

### Holdings in Ascelia Pharma (per 15 March 2023)

30,000 shares in Ascelia Pharma AB.

### Independence

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



## René Spogård

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

### Professional background

René Spogård was chairman and investor in a number of companies incl. JEKA Fish A/S, Bollerup Jensen A/S and Flex Funding A/S. René Spogård has extensive experience from investing in the healthcare sector and board positions in a public environment. René Spogård has previously inter alia been owner and Managing Director at TNS Gallup A/S and Director at TNS plc (listed on London Stock Exchange).

## ASCELIA PHARMA MOURNS THE PASSING OF BOARD MEMBER RENÉ SPOGÅRD

Ascelia Pharma AB announced on March 13, 2023, that René Spogård, a member of the company's Board of Directors, has passed away.

Peter Benson, Chairman of Ascelia Pharma stated, "I, along with the other members of the board and the management team, are deeply saddened by René's unexpected passing and our sincere condolences goes to his family. He leaves a legacy of business acumen and creative thinking. René has played an important role in Ascelia Pharma since becoming a director six years ago and we will always be appreciative of his significant contributions and support. He will be greatly missed".

# MANAGEMENT



**Magnus Corfitzen**

Born 1975. Chief Executive Officer since 2014.

## Professional background

Magnus Corfitzen has extensive experience from investing, building and growing Life Science companies in various roles including operational activities or investment responsibilities for public and private biotech and medtech companies. Magnus also has board experience from a number of Life Science companies. Magnus 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 15 March 2023)

309,645 shares in Ascelia Pharma AB.



**Déspina**

**Georgiadou Hedin**

Born 1986. Chief Financial Officer since 2022.

## Professional background

Déspina Georgiadou Hedin has a solid corporate experience particularly within finance in both development and commercial stage companies, HR, and auditing. Déspina has previously been CFO and HR manager at Bioglan AB, and prior to that, she served as Chief Accountant and Senior Financial Specialist at Sol Voltaics AB. Déspina also has a background as auditor from the accounting firm BDO. Déspina joined Ascelia Pharma in 2022.

## Education

M.Sc. in Business and Economics, from Linnaeus University, Växjö/Kalmar, Sweden

## Other ongoing assignments

-

## Holdings in Ascelia Pharma (per 15 March 2023)

-



**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 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-1 and Degludec® insulin launches. Julie also has board experience from life science companies. Julie 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.

## Holdings in Ascelia Pharma (per 15 March 2023)

48,700 shares in Ascelia Pharma AB.



**Andreas Norlin**

Born 1970. Chief Scientific Officer since 2022.

## Professional background

Andreas Norlin has 20+ years experience from research, preclinical- and clinical-stage drug development within e.g., oncology, inflammatory disease and diabetes. During the most recent years before joining Ascelia, Andreas had strategic executive roles in several biotech start-up companies in the Greater Copenhagen area. Before that he served as Project Vice President and held other development project leadership positions at Novo Nordisk, Denmark. Andreas started his career with various positions in preclinical R&D at Camurus AB, Sweden. Andreas joined Ascelia Pharma in 2020 and became a member of the Management Team in 2022.

## Education

M.Sc. in Biology and PhD in Animal Physiology from Lund University, Sweden. In addition, he has training within Drug Development Strategy and Medical Marketing from Copenhagen Business School.

## Other ongoing assignments

Member of the Board of Directors for Apoglyx AB, Sweden. Founder of and Senior advisor at Xkout Bioscience AB.

## Holdings in Ascelia Pharma (per 15 March 2023)

6,425 shares in Ascelia Pharma AB.

# MANAGEMENT



## **Carin Linde**

*Born 1972.*

*VP Pharmaceutical Development & Supply and IT since 2022.*

### **Professional background**

Carin Linde has 25+ years of experience from pharmaceutical and life science in-

dustry from late-stage development and commercial manufacturing. Before joining Ascelia Pharma in 2019, Carin held a position as Director Analytical Development and Site Manager Centre of Excellence at BioGaia. Carin began her career at AstraZeneca and held several senior positions within R&D and Operations within analytical development, process technology and supply chain. Carin joined Ascelia Pharma in 2019 and became a member of the Management Team in 2022.

### **Education**

M.Sc. chemistry, Lund University, Sweden

### **Other ongoing assignments**

Board member: Roslagsautomation AB

### **Holdings in Ascelia Pharma** (per 15 March 2023)

26,776 shares in Ascelia Pharma AB.



## **Marie Källström**

*Born 1966.*

*VP of Regulatory Affairs & QA since 2022.*

### **Professional background**

Marie Källström has more than 25 years of global experience from Regulatory Affairs

positions in late-stage pharmaceutical development in companies such as Pfizer, AstraZeneca and Pharmacia. The last position was Regulatory Specialist at Novo Nordisk with responsibility for coordinating the development of NDA/MAA documentation as well as planning and participation several Authority interactions within the development of pharmaceutical products for treatment of diabetes and obesity. Marie Joined Ascelia Pharma in 2020 and became a member of the Management Team in 2022..

### **Education**

M.Sc. in Biology at Lund University, Sweden

### **Other ongoing assignments**

-

### **Holdings in Ascelia Pharma** (per 15 March 2023)

5,900 shares in Ascelia Pharma AB.



## **Jennie Wilborgsson**

*Born 1984.*

*VP, Clinical Development since 2022.*

### **Professional background**

Jennie Wilborgsson has more than 15 years of experience within clinical drug develop-

ment from both late stage pharmaceutical companies and the consultancy business. Before joining Ascelia Pharma in November 2022, Jennie was heading up the global clinical project management department in KLIFO A/S and has prior to that held various leadership positions within clinical operations in Ferring Pharmaceuticals.

### **Education**

B.Sc Medical Science, Lund University, Sweden

### **Other ongoing assignments**

-

### **Holdings in Ascelia Pharma** (per 15 March 2023)

-



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## Consolidated Income Statement

SEK in thousands (unless otherwise stated)*	Note	Jan-Dec 2022	Jan-Dec 2021
Net sales		-	-
<b>Gross profit/loss</b>		-	-
Other operating income	10	827	317
Administrative costs	6	-14,628	-17,122
Research and development costs	6	-118,113	-107,574
Commercial preparation costs	6	-14,929	-13,201
Other operating costs	10	-163	-368
<b>Operating result</b>	7, 8, 9	<b>-147,007</b>	<b>-137,948</b>
Financial income	11	17,816	10,439
Financial costs	11	-3,965	-2,014
<b>Net financial items</b>		<b>13,851</b>	<b>8,425</b>
<b>Loss before tax</b>		<b>-133,155</b>	<b>-129,523</b>
Tax	12	1,933	3,620
<b>Loss for the period</b>		<b>-131,223</b>	<b>-125,903</b>
Attributable to:			
Owners of the Parent Company		-131,223	-125,903
Non-controlling interest		-	-
Earnings per share	13		
Before and after dilution (SEK)		-3.77	-3.82

## Consolidated Statement of Comprehensive Income

SEK in thousands (unless otherwise stated)*	Note	Jan-Dec 2022	Jan-Dec 2021
<b>Loss for the period</b>		<b>-131,223</b>	<b>-125,903</b>
<b>Other comprehensive income</b>			
Currency translation of subsidiaries**	3, 23	718	135
<b>Other comprehensive income for the period</b>		<b>718</b>	<b>135</b>
<b>Total comprehensive income for the period</b>		<b>-130,504</b>	<b>-125,768</b>

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

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

# Consolidated Balance Sheet

SEK in thousands*	Note	31 Dec 2022	31 Dec 2021
<b>ASSETS</b>			
Intangible assets	14	57,074	57,063
<b>Tangible assets</b>			
Equipment	15	163	238
Right-of-use assets	16	462	1,581
<b>Total fixed assets</b>		<b>57,700</b>	<b>58,882</b>
<b>Current assets</b>			
Advance payments to suppliers	19	5,359	6,175
<b>Current receivables</b>			
Income tax receivables	12	2,785	4,395
Other receivables	20, 22	1,745	1,165
Prepaid expenses and accrued income	21	1,426	1,277
Cash and bank balances	22, 26	149,555	261,599
<b>Total current assets</b>		<b>160,869</b>	<b>274,611</b>
<b>Total assets</b>		<b>218,569</b>	<b>333,493</b>
<b>EQUITY</b>			
Share capital	23	34,871	34,576
Other contributed capital		678,747	678,831
Reserve of exchange differences on translation		718	254
Loss brought forward (incl. net profit/loss for the period)		-533,478	-405,827
<b>Equity attributable to Parent Company shareholders</b>		<b>180,859</b>	<b>307,834</b>
<b>Total equity</b>		<b>180,859</b>	<b>307,834</b>
<b>LIABILITIES</b>			
<b>Long-term liabilities</b>			
Leasing	16	193	553
<b>Total long-term liabilities</b>		<b>193</b>	<b>553</b>
<b>Current liabilities</b>			
Accounts payable	22	15,881	6,147
Tax payable	12	-	5
Other liabilities		1,688	1,509
Current lease liabilities	16	291	1,102
Accrued expenses and deferred income	24	19,657	16,343
<b>Total current liabilities</b>		<b>37,518</b>	<b>25,106</b>
<b>Total liabilities</b>		<b>37,711</b>	<b>25,659</b>
<b>Total equity and liabilities</b>		<b>218,569</b>	<b>333,493</b>

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

# Consolidated Statements of Changes in Equity

SEK in thousands*	Note	Attributable to parent company shareholders				Total Non-controlling interests	Total equity
		Share capital	Other contributed capital	Translation reserv	Retained earnings		
<b>Opening balance as of 1 Jan 2021</b>		<b>28,697</b>	<b>493,731</b>	<b>119</b>	<b>-286,491</b>	<b>236,056</b>	<b>-</b>
<b>Comprehensive income</b>							
Profit/loss for the period		-	-	-	-125,903	-125,903	-
<b>Other comprehensive income</b>							
Exchange differences	23	-	-	135	-	135	-
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>135</b>	<b>-125,903</b>	<b>-125,768</b>	<b>-</b>
<b>Transactions with shareholders</b>							
New issue of C-shares	23	397	-	-	-	397	-
Repurchase of own shares C-shares	23	-	-	-	-397	-397	-
New issue of common shares	23	5,000	195,000	-	-	200,000	-
Issuance expenses	23	-	-13,271	-	-	-13,271	-
Redemption of warrants	23	482	3,371	-	-	3,853	-
Share-based remuneration to employees	7	-	-	-	6,964	6,964	-
<b>Total transactions with shareholders</b>		<b>5,879</b>	<b>185,100</b>	<b>-</b>	<b>6,567</b>	<b>197,546</b>	<b>-</b>
<b>Closing balance as of 31 Dec 2021</b>		<b>34,576</b>	<b>678,831</b>	<b>254</b>	<b>-405,827</b>	<b>307,834</b>	<b>-</b>
<b>Comprehensive income</b>							
Profit/loss for the period		-	-	-	-131,223	-131,223	-
<b>Other comprehensive income</b>							
Exchange differences		-	-	718	-	718	-
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>718</b>	<b>-131,223</b>	<b>-130,504</b>	<b>-</b>
<b>Transactions with shareholders</b>							
New issue of C-shares	23	295	-	-	-	295	-
Repurchase of own shares C-shares	23	-	-	-	-295	-295	-
New issue of common shares	23	-	-	-	-	-	-
Issuance expenses	23	-	-84	-	-	-84	-
Redemption of warrants	23	-	-	-	-	-	-
Share-based remuneration to employees	7	-	-	-	3,612	3,612	-
<b>Total transactions with shareholders</b>		<b>295</b>	<b>-84</b>	<b>-</b>	<b>3,317</b>	<b>3,529</b>	<b>-</b>
<b>Closing balance as of 31 Dec 2022</b>		<b>34,871</b>	<b>678,747</b>	<b>972</b>	<b>-533,732</b>	<b>180,859</b>	<b>-</b>

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

# Consolidated Cash Flow Statement

SEK in thousands*	Note	Jan-Dec 2022	Jan-Dec 2021
<b>Operating activities</b>			
Operating result		-147,007	-137,948
Expensed share based remuneration	7, 26	1,627	5,919
Adjustment for items not included in cash flow	9, 16, 26	1,091	1,045
Interest received		635	10
Interest paid		-48	-77
Income tax paid/received		3,772	1,020
<b>Cash flow from operating activities before changes in working capital</b>		<b>-139,930</b>	<b>-130,031</b>
<b>Cash flow from changes in working capital</b>			
Increase (-)/Decrease (+) of advance payments		850	2,110
Increase (-)/Decrease (+) of operating receivables		-1,362	-900
Increase (+)/Decrease (-) of accounts payable		9,722	2,258
Increase (+)/Decrease (-) of other liabilities		5,456	10,004
Change in working capital		14,667	13,472
<b>Cash flow used in operating activities</b>		<b>-125,263</b>	<b>-116,559</b>
<b>Investing activities</b>			
Investment in equipment		-	-38
Divestment of right-of-use assets		65	-
<b>Cash flow from investing activities</b>		<b>-65</b>	<b>-38</b>
<b>Financing activities</b>			
New issue of C-shares	23	295	397
Repurchase of own shares C-shares	23	-295	-397
Issuance proceeds	23	-	200,000
Issuance costs	23	-84	-13,271
Redemption of warrants	23	-	-914
Amortisation of loan (leasing)		-1,016	-944
<b>Cash flow from financing activities</b>		<b>-1,100</b>	<b>184,871</b>
<b>Cash flow for the period</b>		<b>-126,428</b>	<b>68,274</b>
Cash flow for the period		-126,428	68,274
Cash and cash equivalents at start of period	26	261,599	184,686
Exchange rate differences in cash and cash equivalents		14,384	8,639
<b>Cash and cash equivalents at end of period</b>	26	<b>149,555</b>	<b>261,599</b>

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



## Parent Company – Income Statement

SEK in thousands*	Note	Jan-Dec 2022	Jan-Dec 2021
Net sales	5	1,142	5,495
<b>Gross profit/loss</b>		<b>1,142</b>	<b>5,495</b>
Other operating income	10	124	241
Administrative costs	6	-14,441	-16,901
Research and development costs	6	-108,077	-94,306
Commercial preparation costs	6	-14,963	-13,223
Other operating costs	10	-131	-344
<b>Operating result</b>	7, 8, 9	<b>-136,346</b>	<b>-119,038</b>
<b>Net financial items</b>			
Finance income	11	16,721	9,830
Finance costs	11	-3,384	-1,940
Result from other long-term receivables	11	1,639	1,860
<b>Net financial costs</b>		<b>14,976</b>	<b>9,750</b>
<b>Loss before tax</b>		<b>-121,371</b>	<b>-109,288</b>
Tax	12	-	-
<b>Loss for the period</b>		<b>-121,371</b>	<b>-109,288</b>

## Parent Company – Statement of Comprehensive Income

SEK in thousands*	Note	Jan-Dec 2022	Jan-Dec 2021
<b>Loss for the period</b>		<b>-121,371</b>	<b>-109,288</b>
Other comprehensive income		-	-
<b>Other comprehensive income for the period</b>		<b>-</b>	<b>-</b>
<b>Total comprehensive income for the period</b>		<b>-121,371</b>	<b>-109,288</b>

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

# Parent Company – Balance Sheet

SEK in thousand*	Note	31 Dec 2022	31 Dec 2021
<b>ASSETS</b>			
<b>Tangible assets</b>			
Equipment	15	163	238
Right-of-use assets	16	–	–
<b>Financial assets</b>			
Shares in group companies	2, 17	58,068	58,068
Long-term receivables from group companies	18	38,486	36,620
<b>Total fixed assets</b>		<b>96,717</b>	<b>94,926</b>
<b>Current assets</b>			
Advance payments to suppliers	19	5,359	5,323
<b>Current receivables</b>			
Receivables from group companies		8,395	6,971
Income tax receivables	12	756	739
Other receivables	20, 22	1,627	656
Prepaid expenses and accrued income	21	1,349	1,183
Cash and bank balances	22, 26	137,879	246,311
<b>Total current assets</b>		<b>155,365</b>	<b>261,183</b>
<b>Total assets</b>		<b>252,082</b>	<b>356,109</b>
<b>EQUITY</b>			
Restricted equity	23		
Share capital		34,871	34,576
Non-restricted equity			
Share premium reserve		678,747	678,831
Loss brought forward		-377,266	-271,295
Loss for the period		-121,371	-109,288
<b>Total equity</b>		<b>214,982</b>	<b>332,824</b>
<b>LIABILITIES</b>			
<b>Long-term liabilities</b>			
Leasing	16	–	–
<b>Total long-term liabilities</b>		<b>–</b>	<b>–</b>
<b>Current liabilities</b>			
Accounts payable	22	16,022	5,700
Other liabilities		1,688	1,509
Accrued expenses and deferred income	24	19,390	16,076
<b>Total current liabilities</b>		<b>37,101</b>	<b>23,285</b>
<b>Total liabilities</b>		<b>37,101</b>	<b>23,285</b>
<b>Total equity and liabilities</b>		<b>252,082</b>	<b>356,109</b>

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

# Parent Company – Statements of Changes in Equity

SEK in thousands*	Note	Restricted equity	Unrestricted equity		Total equity
		Share capital	Premium reserv	Retained earnings	
<b>Opening balance as of 1 Jan 2021</b>		<b>28,697</b>	<b>493,731</b>	<b>-277,862</b>	<b>244,566</b>
<b>Comprehensive income</b>					
Profit/loss for the period		–	–	-109,288	-109,288
<b>Total comprehensive income</b>		<b>–</b>	<b>–</b>	<b>-109,288</b>	<b>-109,288</b>
<b>Transactions with shareholders</b>					
New issue of C-shares	23	397	–	–	397
Repurchase of own shares C-shares	23	–	–	-397	-397
New issue of common shares	23	5,000	195,000	–	200,000
Issuance expenses	23	–	-13,271	–	-13,271
Redemption of warrants	23	482	3,371	–	3,853
Share-based remuneration to employees	7	–	–	6,964	6,964
<b>Total transactions with shareholders</b>		<b>5,879</b>	<b>185,100</b>	<b>6,567</b>	<b>197,546</b>
<b>Closing balance as of 31 Dec 2021</b>		<b>34,576</b>	<b>678,831</b>	<b>-380,583</b>	<b>332,824</b>
<b>Comprehensive income</b>					
Profit/loss for the period		–	–	-121,371	-121,371
<b>Total comprehensive income</b>		<b>–</b>	<b>–</b>	<b>-121,371</b>	<b>-121,371</b>
<b>Transactions with shareholders</b>					
New issue of C-shares	23	295	–	–	295
Repurchase of own shares C-shares	23	–	–	-295	-295
New issue of common shares	23	–	–	–	–
Issuance expenses	23	–	-84	–	-84
Redemption of warrants	23	–	–	–	–
Share-based remuneration to employees	7	–	–	3,612	3,612
<b>Total transactions with shareholders</b>		<b>295</b>	<b>-84</b>	<b>3,317</b>	<b>3,529</b>
<b>Closing balance as of 31 Dec 2022</b>		<b>34,871</b>	<b>678,747</b>	<b>-498,637</b>	<b>214,982</b>

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

# Parent Company – Cash Flow Statement

SEK in thousands*	Note	Jan-Dec 2022	Jan-Dec 2021
<b>Operating activities</b>			
Operating result		-136,346	-119,038
Expensed share based remuneration	7, 26	1,627	5,919
Adjustment for items not included in cash flow	9, 16, 26	-142	102
Interest received		608	10
Interest paid		-	-3
Income tax paid/received		-17	-116
<b>Cash flow from operating activities before changes in working capital</b>		<b>-134,271</b>	<b>-113,126</b>
<b>Cash flow from changes in working capital</b>			
Increase (-)/Decrease (+) of advance payments		-35	2,956
Increase (-)/Decrease (+) of operating receivables		-2,561	-3,992
Increase (+)/Decrease (-) of accounts payable		10,322	1,968
Increase (+)/Decrease (-) of other liabilities		5,479	7,658
Change in working capital		13,204	8,590
<b>Cash flow used in operating activities</b>		<b>-121,067</b>	<b>-104,536</b>
<b>Investing activities</b>			
Investment in equipment		-	-38
Marketable securities/Other investments, net		-	-
<b>Cash flow from investing activities</b>		<b>-</b>	<b>-38</b>
<b>Financing activities</b>			
New issue of C-shares	23	295	397
Repurchase of own shares C-shares	23	-295	-397
Issuance proceeds	23	-	200,000
Issuance costs	23	-84	-13,271
Loan to affiliated company	18	-11	-25,310
Redemption of warrants	23	-	-914
Amortisation of loan (leasing)		-	-
<b>Cash flow from financing activities</b>		<b>-94</b>	<b>160,505</b>
<b>Cash flow for the period</b>		<b>-121,161</b>	<b>55,931</b>
Cash flow for the period		-121,161	55,931
Cash and cash equivalents at start of period	26	246,311	182,498
Exchange rate differences in cash and cash equivalents		12,729	7,882
<b>Cash and cash equivalents at the end of the period</b>	26	<b>137,879</b>	<b>246,311</b>

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

# NOTES

## NOTE 1 GENERAL INFORMATION

Ascelia Pharma AB (publ) with corporate identity number 556571-8797 and its subsidiaries (jointly the Group) develop drugs within oncology. The Parent Company conducts operations in the legal form of a limited liability company, with its registered office in Malmö, Sweden. The company's postal address is 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 2023 and will be presented to the Annual General Meeting of shareholders on 4 May 2023.

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

### *Holdings in the subsidiary*

Subsidiary/Corporate identity number/Registered office	Number of participation rights	Participating interest in %	Carrying amount SEK	
			31 Dec 2022	31 Dec 2021
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	8
<b>Total carrying amount of year-end</b>			<b>58,068,008</b>	<b>58,068,008</b>

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	Tax 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

Note 3, cont.

**(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 development expenses	6	Operating expenses by type of cost
Share-based incentive programs	7	Employees, employee benefit expenses and remuneration to the Board
Assessment of tax deficit	12	Tax
Asset acquisitions	14	Intangible assets
Impairment of intangible assets	14	Intangible assets
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 acquisition**

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.

Note 3, cont.

#### **(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 2022**

The following amended accounting standards were applicable from January 1, 2022: IFRS 3, IAS 37, IFRIC 21, IAS 16, IFRS 1, IFRS 9, IFRS 16 and IAS 41.

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

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

The accounting principles of the parent company are consistent in all material respects with the accounting principles of the Group. The differences between the Group's and the parent company's accounting principles are described below. The accounting principles given below for the parent company have been consistently applied for all periods as presented in the parent company's financial statements.

#### **Classification and presentation**

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

#### **Subsidiaries**

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

#### **Financial instruments and hedge accounting**

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

## NOTE 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 2022 provides Ascelia Pharma with liquidity beyond 12 months and is expected to be sufficient to complete the Phase 3 program for Orvigance, continue commercial preparations for Orvigance 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 accounts payable and accrued expenses fall due within 12 months.

SEK in thousands	Purchases in each currency		Cost increase with 10% depreciation of SEK	
	Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
DKK	4,413	6,626	441	663
EUR	13,513	9,799	1,351	980
USD	54,075	58,029	5,408	5,803
JPY	–	782	–	78
GBP	757	1,361	76	136
CAD	920	–	92	–
<b>Total</b>	<b>73,678</b>	<b>76,597</b>	<b>7,368</b>	<b>7,660</b>

### Currency risks

#### Transaction exposure

Ascelia Pharma purchases services related to drug development particularly in USD, EUR and DKK. The effect of a weakening of Swedish crown by 10 percent 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 percent against USD and DKK would result in an increased loan receivable for the parent company of around SEK 3.8 million.

### Credit risk

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

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

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

## NOTE 5 NET SALES

SEK in thousands	Parent company	
	Jan-Dec 2022	Jan-Dec 2021
Intra-Group services	1,142	5,495
<b>Total net sales</b>	<b>1,142</b>	<b>5,495</b>

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.

## NOTE 6 OPERATING EXPENSES BY TYPE OF COST

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

SEK in thousand	Group		Parent company	
	Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
<b>Research and Development costs</b>				
Drug development	88,233	75,075	78,567	65,503
Cost of remuneration to employees*	25,988	23,776	26,039	23,785
Manufacturing	3,892	8,723	3,471	5,018
<b>Total</b>	<b>118,113</b>	<b>107,574</b>	<b>108,077</b>	<b>94,306</b>
<b>Administration costs</b>				
Costs of remuneration to employees and board*	3,900	8,315	3,915	8,315
Other administration costs	10,728	8,807	10,526	8,586
<b>Total</b>	<b>14,628</b>	<b>17,122</b>	<b>14,441</b>	<b>16,901</b>
<b>Commercial preparation costs</b>				
Cost of remuneration to employees*	10,375	7,444	10,408	7,460
Commercial preparation	4,554	5,757	4,554	5,763
<b>Total</b>	<b>14,929</b>	<b>13,201</b>	<b>14,962</b>	<b>13,223</b>
<b>Other operating expenses</b>				
Currency differences related to operations	163	368	131	344
<b>Total</b>	<b>163</b>	<b>368</b>	<b>131</b>	<b>344</b>

\*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 activities 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 2022, 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 of people		Of whom men, %	
	Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
<b>Parent company</b>				
Sweden	22	19.4	27%	38%
<b>Total for parent company</b>	<b>22</b>	<b>19.4</b>	<b>27%</b>	<b>38%</b>
<b>Subsidiaries</b>				
Denmark	-	-	-	-
Sweden	-	-	-	-
<b>Total for subsidiaries</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Group total</b>	<b>22</b>	<b>19.4</b>	<b>27%</b>	<b>38%</b>

There are no employees in the subsidiaries.

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

	Number of people		Of whom women, %	
	Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
Board of Directors	6	7	33%	29%
Executive management	7	4	71%	25%

**Salaries, other remuneration and social security expenses**

<i>SEK in thousands</i>	Salaries and other remuneration		Social security expenses	
	Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
Parent Company	24,625	20,466	10,839	9,271
(of which pension costs)	-	-	5,038	4,241
Subsidiaries	-	-	-	-
(of which pension costs)	-	-	-	-
<b>Total salaries, other remuneration and social security expenses</b>	<b>24,625</b>	<b>20,466</b>	<b>10,839</b>	<b>9,271</b>
(of which pension costs)	-	-	5,038	4,241

Note 7, cont.

## Remuneration to the board and senior executives

SEK in thousands	Jan-Dec 2022					Jan-Dec 2021				
	Remuneration <sup>1</sup> /Base salary (incl. holiday pay)	Other benefits	Variable remuneration	Share-based remuneration <sup>2</sup>	Pension expenses <sup>3</sup>	Remuneration <sup>1</sup> /Base salary (incl. holiday pay)	Other benefits	Variable remuneration	Share-based remuneration <sup>2</sup>	Pension expenses <sup>3</sup>
<b>The Group</b>										
<b>The Board</b>										
Peter Benson	557	-	-	-	-	490	-	-	-	-
Lauren Barnes	358	-	-	-	-	333	-	-	-	-
Bo Jesper Hansen (resigned May 2022)	86	-	-	-	-	238	-	-	-	-
Hans Maier	283	-	-	-	-	258	-	-	-	-
Niels Mengel	283	-	-	-	-	258	-	-	-	-
René Spogård (passed away March 2023)	291	-	-	-	-	233	-	-	-	-
Helena Wennerström	358	-	-	-	-	333	-	-	-	-
<b>Senior executives employed by the company</b>										
<b>Group (incl. subsidiaries)</b>										
Magnus Corfitzen, CEO	2,013	149	576	2,034	625	1,896	131	576	11,719	553
Other senior executives <sup>4</sup> , 7(7)	7,721	161	893	2,735	2,278	4,114	165	613	3,235	1,332
<b>Parent Company</b>										
Magnus Corfitzen, CEO	2,013	149	576	2,034	625	1,896	131	576	11,719	553
Other senior executives <sup>4</sup> , 7(7)	7,721	161	893	2,735	2,278	4,114	165	613	3,235	1,332

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 (SEK 17.1 million) 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 2022, two employees opted to receive salary instead of pension (2 persons in the financial year 2021).

4) At year-end

Note 7, cont.

**Employee option program**

	Group						Parent company					
	Option program 1		Option program 2		Total		Option program 1		Option program 2		Total	
	CEO	Other senior executives*	CEO	Other senior executives*	CEO	Other senior executives*	CEO	Other senior executives*	CEO	Other senior executives*	CEO	Other senior executives*
<i>Number of allotted options</i>												
Opening balance as of 1 Jan 2021	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 allotted	-	-	-	-	-	-	-	-	-	-	-	-
Share options redeemed	-275,185	-206,388	-	-	-275,185	-206,388	-275,185	-206,388	-	-	-275,185	-206,388
<b>Closing balance as of 31 Dec 2021</b>	<b>-</b>	<b>-</b>	<b>183,671</b>	<b>321,424</b>	<b>183,671</b>	<b>321,424</b>	<b>-</b>	<b>-</b>	<b>183,671</b>	<b>321,424</b>	<b>183,671</b>	<b>321,424</b>
Share options allotted												
Share options redeemed												
<b>Closing balance as of 31 Dec 2022</b>	<b>-</b>	<b>-</b>	<b>183,671</b>	<b>321,424</b>	<b>183,671</b>	<b>321,424</b>	<b>-</b>	<b>-</b>	<b>183,671</b>	<b>321,424</b>	<b>183,671</b>	<b>321,424</b>

\* All allotted 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 gain for both option programs in 2022 including social security expenses amounted to SEK 1.0 million (cost for the period Jan-Dec 2021 SEK -2.7 million).

**Share saving program**

	Group					Parent company				
	Share saving program 1	Share saving program 2	Share saving program 3	Share saving program 4	Total	Share saving program 1	Share saving program 2	Share saving program 3	Share saving program 4	Total
<i>Number of saving shares</i>										
Opening balance as of 1 Jan 2021	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		
<b>Closing balance as of 31 Dec 2021</b>	<b>67,030</b>	<b>54,145</b>	<b>40,870</b>	<b>-</b>	<b>162,045</b>	<b>67,030</b>	<b>54,145</b>	<b>40,870</b>	<b>-</b>	<b>162,045</b>
Saving shares acquired	-	-	-	50,194	50,194	-	-	-	50,194	50,194
Divested	-12,530	-14,100	-12,400		-39,030	-12,530	-14,100	-12,400		-39,030
Of which										
CEO				22,500					22,500	
Other senior executives	-12,530	-14,100	-8,500	25,081		-12,530	-14,100	-8,500	25,081	
<b>Closing balance as of 31 Dec 2022</b>	<b>54,500</b>	<b>40,045</b>	<b>28,470</b>	<b>50,194</b>	<b>173,209</b>	<b>54,500</b>	<b>40,045</b>	<b>28,470</b>	<b>50,194</b>	<b>173,209</b>
Of which										
CEO	24,500	11,000	10,000	22,500	68,000	24,500	11,000	10,000	22,500	68,000
Other senior executives	23,000	26,014	11,930	25,081	86,025	23,000	26,014	11,930	25,081	86,025

The total recognized costs for the share saving programs in 2022 including social security expenses amounted to SEK 2.6 million (SEK 5.4 million for the period Jan-Dec 2021).

Note 7, cont.

## 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 30 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 indefinite term with a mutual notice period of three months.

### Share-based incentive programs

Ascelia Pharma has one active employee options programs that include members of the management team and a share-saving program for employees. If the terms of the option program 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, 1.2 million shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate dilution of approximately 3.4 percent 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 is conditional upon that the participant is still employed by the company and that the employee has not terminated the employment as of the date when the respective vesting occurs. If the participant ceases to be employed or terminates the employment before a vesting date, the already vested employee options can be utilized during the ordinary time for utilization in accordance with the below, but further vesting will not take place. The company's former Chief Medical Officer left the company in the summer of 2018, after which the maximum number of employee options that can be vested was reduced to 481,573.

Each vested employee option entitles a right to acquire one new share in the company against cash consideration at a subscription price of SEK 8 per share. Vested employee options can be utilised during month 24 – 27 after the listing (i.e. 13 March 2021 to 13 June 2021) and in connection with a trade sale. Vested employee options can be utilised immediately in connection with the trade sale.

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

Note 7, cont.

#### *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. Total charge based on valuation as of Grant date was SEK 6.0 million.

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 Program 1. The total amount of Saving Shares invested in Program 2 amounted to 54,145. Total charge based on valuation as of Grant date was SEK 8.8 million.

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 Program 1. The total amount of Saving Shares invested in Program 3 amounted to 40,870. Total charge based on valuation as of Grant date was SEK 3.5 million.

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.

#### *Share Saving Program 4*

At the Annual General Meeting on 5 May 2022, 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 4 are the same as in Share Saving Program 1. The total amount of Saving Shares invested in Program 4 amounted to 50,194. Total charge based on valuation as of Grant date was SEK 4.3 million.

Saving Period in Program 4 is 1 October 2022 up to and including 30 September 2025. The Performance Target in Program 4 will be measured based on the volume weighted average share price 30 trading days immediately following the annual general meeting on 5 May 2022 and 30 trading days immediately preceding 30 September 2025.

#### *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 exercised date in 2021 (excluding social security expenses).

For the outstanding option program, a gain of SEK 1.0 million including social security charges was recognized in 2022 (costs of SEK 2.7 million in 2021). The total recognized costs for the share saving programs including social security charges in 2022 were SEK 2.6 million (SEK 5.4 million in 2021).



Note 7, cont.

## 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 share-based 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 programmes) and receive matching and performance shares (share saving programme). 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 programmes are utilised. This means that a new market valuation of the incentive programmes 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 percent
  - Estimated volatility in the company's share price: 55 percent
- 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 percent based on comparable companies in the same sector.

## NOTE 8 AUDITOR FEES AND REIMBURSEMENTS

SEK in thousands	Jan-Dec 2022	Jan-Dec 2021
<b>Group</b>		
PwC		
Audit engagements (current year)	510	585
Other audit activities	–	–
Tax advice	13	50
Other services	30	44
<b>Total</b>	<b>553</b>	<b>679</b>

SEK in thousands	Jan-Dec 2022	Jan-Dec 2021
<b>Parent company</b>		
PwC		
Audit engagements (current year)	500	516
Other audit activities	–	–
Tax advice	12	50
Other services	30	44
<b>Total</b>	<b>542</b>	<b>610</b>

Audit engagements refer to statutory auditing of the annual and consolidated financial statements and accounting 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**

<b>DEPRECIATION ACCORDING TO PLAN</b>		<b>Group</b>		<b>Parent company</b>	
<i>SEK in thousands</i>		<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>	<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>
<b>Tangible assets</b>					
Equipment		-74	-102	-74	-102
<b>Right-of-use assets</b>					
Office		-655	-655	-	-
Car		-317	-273	-	-
<b>Total depreciation/amortization</b>		<b>-1,046</b>	<b>-1,030</b>	<b>-74</b>	<b>-102</b>

**NOTE 10 OTHER OPERATING INCOME AND COSTS**

<b>Other operating income</b>		<b>Group</b>		<b>Parent company</b>	
<i>SEK in thousands</i>		<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>	<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>
Exchange gains on receivables/liabilities relating to operations		827	317	124	241
Insurance compensation		-	-	-	-
Other operating income		-	-	-	-
<b>Total other operating income</b>		<b>827</b>	<b>317</b>	<b>124</b>	<b>241</b>

<b>Other operating costs</b>		<b>Group</b>		<b>Parent company</b>	
<i>TSEK</i>		<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>	<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>
Exchange loss on receivables/liabilities relating to operations		-164	-368	-131	-344
<b>Total other operating costs</b>		<b>-164</b>	<b>-368</b>	<b>-131</b>	<b>-344</b>

**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.

**NOTE 11 FINANCIAL INCOME AND COSTS****Group****Financial income**

<i>SEK in thousands</i>	<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>
Interest income	635	10
Exchange rate differences	17,181	10,429
Unrealized gains on marketable securities	–	–
Capital gains from divestment of marketable securities	–	–
<b>Total</b>	<b>17,816</b>	<b>10,439</b>

**Financial costs**

<i>SEK in thousands</i>	<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>
Interest expense	-48	-77
Exchange rate differences	-3,917	-1,937
<b>Total</b>	<b>-3,965</b>	<b>-2,014</b>

**Parent company****Financial income**

<i>SEK in thousands</i>	<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>
Interest income	608	10
Exchange rate differences	16,113	9,820
Unrealized gains on marketable securities	–	–
Capital gains from divestment of marketable securities	–	–
<b>Total</b>	<b>16,721</b>	<b>9,830</b>
Of which group companies	–	–

**Financial costs**

<i>SEK in thousands</i>	<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>
Interest expense	–	-3
Exchange rate differences	-3,384	-1,937
<b>Total</b>	<b>-3,384</b>	<b>-1,940</b>

**Result from other long-term receivables**

<i>SEK in thousands</i>	<b>Jan-Dec 2022</b>	<b>Jan-Dec 2021</b>
Interest income from other long-term receivables	2,882	1,521
Exchange rate differences	–	339
Impairment of other long-term receivables	-1,244	–
<b>Total</b>	<b>1,638</b>	<b>1,860</b>

**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

SEK in thousands	Group		Parent company	
	Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
<b>Current tax expense (-)/tax income (+)</b>				
Tax expense/income for the year	1,933	3,621	-	-
<b>Total current tax</b>	<b>1,933</b>	<b>3,621</b>	<b>-</b>	<b>-</b>

### Reconciliation of effective tax

SEK in thousands		Group		Parent company	
		Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
Loss before tax		-133,155	-129,523	-121,371	-109,288
Tax rate for the Parent Company	20,60%	27,430	26,682	25,002	22,513
Effect of other tax rates for foreign subsidiaries	0,07%	97	201	-	-
Non-deductible expenses	-0,23%	-308	-25	-308	-25
Non-taxable income	0,00%	-	2	-	2
Increase of losses carried forward without equivalent capitalisation	-18,99%	-25,286	-23,239	-24,694	-22,491
Utilisation of previously non-capitalised tax deductions	0,00%	-	-	-	-
<b>Recognised effective tax</b>	<b>1,45%</b>	<b>1,933</b>	<b>3,621</b>	<b>-</b>	<b>-</b>

### Unrecognised 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):

SEK in thousands	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
<b>Accumulated tax loss</b>				
Deductible temporary differences	-	-	-	-
Losses related to insurance costs	46,491	46,407	46,491	46,407
Tax losses	538,656	421,950	534,721	414,845
<b>Total</b>	<b>585,147</b>	<b>468,357</b>	<b>581,212</b>	<b>461,252</b>

## 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.

Note 12, cont.

## 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 461 million in tax deficits. The tax loss for the year 2021 is estimated to amount to approximately SEK 120 million, including transaction costs booked against equity. Consequently, a total tax deficit of SEK 581 million per 31 December 2022. No tax assets have been recognized on the balance sheet.

## NOTE 13 EARNINGS PER SHARE

	Group		Parent company	
	Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
Result for the year attributable to shareholders of Ascelia Pharma (publ), TSEK	-131,223	-125,903	-121,371	-109,288
Weighted average number of shares (before and after dilution)	34,798,504	32,959,110	34,798,504	32,959,110
<b>Result per share (before and after dilution), SEK</b>	<b>-3.77</b>	<b>-3.82</b>	<b>-3.49</b>	<b>-3.32</b>

## 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

SEK in thousands	Group	
	31 Dec 2022	31 Dec 2021
<b>Accumulated cost of acquisition</b>		
Opening balance	57,063	57,061
Acquisitions during the year	-	-
Exchange differences during the year	11	2
<b>Closing balance</b>	<b>57,074</b>	<b>57,063</b>
<b>Accumulated depreciation and impairment</b>		
Opening balance	-	-
Depreciation according to plan	-	-
Impairment for the year	-	-
<b>Closing balance</b>	<b>-</b>	<b>-</b>
<b>Recognized value at year-end</b>	<b>57,074</b>	<b>57,063</b>

### 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 percent 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 2022, 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 assets

#### *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 2022 and 2021, 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

SEK in thousands	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
<b>Accumulated cost of acquisition</b>				
Opening balance	599	560	510	471
Acquisitions during the year	–	39	–	39
Exchange differences during the year	–	–	–	–
<b>Closing balance</b>	<b>599</b>	<b>599</b>	<b>510</b>	<b>510</b>
<b>Accumulated depreciation according to plan</b>				
Opening balance	-361	-259	-272	-170
Depreciation according to plan	-74	-102	-74	-102
Exchange differences during the year	–	–	–	–
<b>Closing balance</b>	<b>-435</b>	<b>-361</b>	<b>-346</b>	<b>-272</b>
<b>Recognized value</b>				
At the start of the period	238	301	238	301
<b>At the end of the period</b>	<b>163</b>	<b>238</b>	<b>163</b>	<b>238</b>

## 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 AND LEASE LIABILITIES

SEK in thousands	Group						Parent company					
	31 Dec 2022			31 Dec 2021			31 Dec 2022			31 Dec 2021		
	Office	Car	Total	Office	Car	Total	Office	Car	Total	Office	Car	Total
<b>Accumulated cost of acquisition</b>												
Opening balance	1,966	1,356	3,322	1,966	520	2,486	-	-	-	-	-	-
Acquisitions during the year	-	263	263	-	818	818	-	-	-	-	-	-
Reclassifications during the year	-	-	-	-	18	18	-	-	-	-	-	-
Divestments and disposals	-	-855	-855	-	-	-	-	-	-	-	-	-
<b>Closing balance</b>	<b>1,966</b>	<b>764</b>	<b>2,730</b>	<b>1,966</b>	<b>1,356</b>	<b>3,322</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Accumulated depreciation according to plan</b>												
Opening balance	-1,256	-485	-1,741	-601	-197	-798	-	-	-	-	-	-
Reclassifications during the year	-	-	-	-	-15	-15	-	-	-	-	-	-
Divestments and disposals	-	445	445	-	-	-	-	-	-	-	-	-
Depreciation according to plan	-655	-317	-972	-655	-273	-928	-	-	-	-	-	-
<b>Closing balance</b>	<b>-1,911</b>	<b>-357</b>	<b>-2,268</b>	<b>-1,256</b>	<b>-485</b>	<b>-1,741</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Recognized value</b>												
At the start of the period	710	871	1,581	1,365	323	1,688	-	-	-	-	-	-
<b>At the end of the period</b>	<b>55</b>	<b>407</b>	<b>462</b>	<b>710</b>	<b>871</b>	<b>1,581</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>

### Lease liabilities

	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
Long-term interest-bearing lease liabilities	193	553	-	-
Current interest-bearing lease liabilities	291	1,102	-	-
<b>Total interest-bearing lease liabilities</b>	<b>484</b>	<b>1,655</b>	<b>-</b>	<b>-</b>

## 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 for the cars are discounted by the lease's imputed rate of interest, which is estimated to 7 percent. 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.

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 for the cars are discounted by the lease's implicit discount rate, which is estimated to 7 percent.

**Maturity analysis on future lease liabilities**

	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
<b>SEK in thousands</b>				
Within a year	966	922	966	922
Between one year and three years	173	377	173	377
	<b>1,139</b>	<b>1,299</b>	<b>1,139</b>	<b>1,299</b>

Future lease payments in accordance with the above are nominal.

**NOTE 17 SHARES IN GROUP COMPANIES**

SEK	Parent company	
	31 Dec 2022	31 Dec 2021
Opening balance	58,068,008	58,068,000
Formation of Ascelia Pharma Inc.	–	8
<b>Carrying amount at year-end</b>	<b>58,068,008</b>	<b>58,068,008</b>

Specification of parent company's shares in group companies

Subsidiaries	Capital share in %	Voting share in %	Recognized value 2022 in SEK	Recognized value 2021 in 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	8
<b>Total carrying amount of year-end</b>			<b>58,068,008</b>	<b>58,068,008</b>

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

SEK in thousands	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
<b>Accumulated cost</b>				
Opening balance	–	–	36,620	9,449
Additional receivables (Intra-company loans)*	–	–	11	25,310
Interest income on loans	–	–	2,882	1,521
Translation differences	–	–	–	340
Impairment of intra-company receivables	–	–	1,027	–
<b>Carrying amount at year-end</b>	<b>–</b>	<b>–</b>	<b>38,486</b>	<b>36,620</b>

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

**NOTE 19 ADVANCE PAYMENTS TO SUPPLIERS**

<i>SEK in thousands</i>	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
Advance payments to suppliers	5,359	6,175	5,359	5,323
<b>Total</b>	<b>5,359</b>	<b>6,175</b>	<b>5,359</b>	<b>5,323</b>

**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**

<i>SEK in thousands</i>	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
Receivables attributable to VAT	990	1,053	873	544
Other receivables	755	112	754	112
<b>Total other receivables</b>	<b>1,745</b>	<b>1,165</b>	<b>1,627</b>	<b>656</b>

**NOTE 21 PREPAID EXPENSES AND ACCRUED INCOME**

<i>SEK in thousands</i>	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
Prepaid rent	256	232	256	232
Prepaid insurance	537	731	469	637
Other items	633	314	624	314
<b>Total</b>	<b>1,426</b>	<b>1,277</b>	<b>1,349</b>	<b>1,183</b>

## NOTE 22 FINANCIAL INSTRUMENTS BY CATEGORY

SEK in thousands	Group		Parent Company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
<b>Financial assets</b>				
Financial assets at fair value through profit/loss				
Fixed income fund	–	–	–	–
Financial assets at amortized cost				
Other receivables	1,745	1,165	1,627	656
Cash and bank balances	149,555	261,599	137,879	246,311
<b>Total financial assets</b>	<b>151,300</b>	<b>262,764</b>	<b>139,506</b>	<b>246,967</b>
<b>Financial liabilities</b>				
Financial liabilities at amortized cost				
Accounts payable	15,881	6,147	16,022	5,700
<b>Total financial liabilities</b>	<b>15,881</b>	<b>6,147</b>	<b>16,022</b>	<b>5,700</b>

### 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 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 the cash flow of the assets.

**Amortized cost:** Assets that are held for the purposes of 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 these financial assets is recognized using the effective interest method and included in financial income. The Group's financial assets that are valued at the amortized cost are made up of the items other receivables, and cash and cash equivalents.

**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.

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 and Lease liabilities. The Group had no other interest-bearing liabilities at the end of 2022 and 2021.

##### 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 2022 and 2021 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.



## NOTE 23 EQUITY

Share capital	Number of shares	
	Jan-Dec 2022	Jan-Dec 2021
<b>At beginning of year</b>		
Ordinary shares	33,668,262	28,186,689
C-shares	908,186	510,545
<b>Number of shares outstanding</b>	<b>34,576,448</b>	<b>28,697,234</b>
New issue of ordinary shares	–	5,481,573
New issue of C-shares	294,729	397,641
<b>At year-end</b>		
Ordinary shares	33,668,262	33,668,262
C-shares	1,202,915	908,186
<b>Number of shares outstanding</b>	<b>34,871,177</b>	<b>34,576,448</b>

Translation reserve	Group	
	Jan-Dec 2022	Jan-Dec 2021
<i>SEK in thousands</i>		
Opening balance	254	119
Exchange differences	464	135
<b>Closing balance</b>	<b>718</b>	<b>254</b>

## 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 2022 the share capital consisted of 33,668,262 ordinary shares and 1,202,915 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**

SEK in thousands	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
Accrued salaries, including bonus	1,800	2,583	1,800	2,583
Accrued vacation pay	2,602	2,384	2,602	2,384
Accrued social security costs	1,697	1,850	1,697	1,850
Accrued social security costs for share based program	350	2,335	350	2,335
Other accrued expenses	13,208	7,191	12,941	6,924
<b>Total</b>	<b>19,657</b>	<b>16,343</b>	<b>19,390</b>	<b>16,076</b>

**NOTE 25 CONTINGENT LIABILITIES**

SEK in thousands	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
Committments*	11,496	11,375	11,496	11,375
<b>Total contingent liabilities</b>	<b>11,496</b>	<b>11,375</b>	<b>11,496</b>	<b>11,375</b>

\* 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**

<i>SEK in thousands</i>	Group		Parent company	
	Jan-Dec 2022	Jan-Dec 2021	Jan-Dec 2022	Jan-Dec 2021
<b>Expensed share based remuneration</b>				
Expensed remuneration	3,612	6,964	3,612	6,964
Expensed social security costs	-1,985	-1,045	-1,985	-1,045
<b>Adjustments for items not included in cash flow</b>				
Depreciation of equipment	74	102	74	102
Depreciation of right-of-use assets	972	928	-	-
Disposal of right-of-use assets	57	-	-	-
Impairment of receivables	-	-	-217	-
Exchange differences	-12	15	-	-
<b>Total adjustments</b>	<b>2,718</b>	<b>6,964</b>	<b>1,484</b>	<b>6,021</b>

<i>SEK in thousands</i>	Group		Parent company	
	31 Dec 2022	31 Dec 2021	31 Dec 2022	31 Dec 2021
<b>Cash and cash equivalents</b>				
Cash and bank accounts	149,555	261,599	137,879	246,311
<b>Total cash and bank accounts</b>	<b>149,555</b>	<b>261,599</b>	<b>137,879</b>	<b>246,311</b>

"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 2022.

**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.

## NOTE 27 TRANSACTIONS WITH RELATED PARTIES

### *Related parties with subsidiaries and senior executives*

The parent company has a close relationship with its subsidiaries, 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 2022, the owners of Solural ApS collectively own 1.85 percent of the shares in Ascelia Pharma AB. In addition to payment for services performed, Solural Pharma ApS has the right to receive a bonus of maximum SEK 10 million if 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 2022, services for a value of around SEK 0.8 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 27 January 2023 it was announced that 71 patients have completed the SPARKLE study.

On 21 February the board of directors of Ascelia Pharma AB has resolved to convert 54,500 series C shares into ordinary shares for delivery of shares to participants in the long-term incentive program in the form of a performance-based share saving program that was adopted at the annual general meeting held on 14 November 2019 ("LTI 2019").

On 28 February 2023 the successful completion of the patient enrollment in the company's pivotal phase 3 clinical study SPARKLE with the lead candidate drug Orvigance® was announced.

On 3 March it was announced that the last patient's last visit (LPLV) has been completed and 85 patients in total have successfully completed the pivotal phase 3 clinical study SPARKLE with the lead candidate drug Orvigance®.

On March 13, the decision of the U.S. Patent and Trademark Office (USPTO) to allow the issuance of a third patent covering the composition of Oncoral was announced.

## NOTE 29 APPROPRIATION OF THE COMPANY'S LOSS

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

#### Parent company

Share premium reserve	678,747,458
Loss brought forward	377,266,145
Loss for the period	121,370,729
<b>Total</b>	<b>180,110,584</b>

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

To be carried forward	180,110,584
of which to share premium reserve	678,747,458

# DECLARATION AND SIGNATURES

Ascelia Pharma AB, 556571-8797

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

Malmö, 30 March 2023

**Peter Benson**  
Chairman of the Board

**Lauren Barnes**  
Director of the Board

**Hans Maier**  
Director of the Board

**Niels Mengel**  
Director of the Board

**Helena Wennerström**  
Director of the Board

**Magnus Corfitzen**  
Chief Executive Officer

Our auditors' report was submitted on  
13 April 2023, 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 2022 except for the corporate governance statement on pages 42-48. The annual accounts and consolidated accounts of the company are included on pages 32-88 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 2022 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 2022 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, 2022, 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 93-94. The other information also includes the Remuneration Report which we received before the signing date of this Auditor's report. 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](http://www.revisorsinspektionen.se/revisornsansvar). This description is part of the auditor's report.

## REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

### Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Ascelia Pharma AB (publ) for the year 2022 and the proposed appropriations of the company's profit or loss.

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

### Basis for Opinions

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

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

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

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

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

### Auditor's responsibility

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

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

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

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

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

## THE AUDITOR'S EXAMINATION OF THE 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 2022.

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 Directors and the Managing 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 42-48 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 2022 and has been the company's auditor since the introduction on Nasdaq Stockholm, 13 March 2019.

Malmö, 13 April 2023

Öhrlings PricewaterhouseCoopers AB

**Carl Fogelberg**

Authorized Public Accountant

# GLOSSARY

## Abbreviated New Drug Application (ANDA)

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

## Ablation

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

## Active pharmaceutical ingredient (API)

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

## Active substance/ingredient

The ingredient in a pharmaceutical drug that is biologically active.

## Acute kidney injury (AKI)

An abrupt loss of kidney function.

## Advanced cancer

Cancer that has grown outside the organ it started in.

## Bioequivalence studies

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

## Blinded study

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

## Chemotherapy

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

## Chronic kidney disease (CKD)

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

## Clinical studies

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

## Colorectal cancer

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

## Computed tomography scan (CT Scan)

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

## Contrast agent/imaging drug

A substance used to enhance the contrast in medical imaging.

## Cytotoxic drug

A type of drug used within chemotherapy.

## Data exclusivity

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

## Embolisation

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

## European Medicines Agency (EMA)

European agency responsible for evaluation of medicinal products.

## Focal liver lesion

Localized changes in liver tissue.

## Food and Drug Administration (FDA)

US federal agency responsible for evaluation of medicinal products.

## Food effect bioavailability study

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

## Gadolinium

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

## Gadolinium-based contrast agent (GBCA)

A contrast agent based with gadolinium as a contrast enhancer.

## Generic Drug

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

## Good Clinical Practice (GCP)

An international quality standard for the performance of clinical studies.

## Good Manufacturing Practice (GMP)

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

## HER2

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

## Incidence

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

## Infusion

A continuous injection of a substance into the body.

## In vitro studies

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

## In vivo studies

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

## Listed drug

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

## Magnetic resonance imaging (MRI)

A medical imaging technique used in radiology.

## Market exclusivity

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

## Metastases

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

## Nephrogenic systemic fibrosis (NSF)

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

## Orphan Drug

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

## Positron emission tomography (PET)

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

## Pre-clinical research

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

## Prevalence

The proportion of a population suffering from a certain disease.

## Primary tumor

The first cancer tumor formed.

## Special populations study

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

## Targeted agent

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

# ALTERNATIVE PERFORMANCE MEASURES

## Definition of alternative financial performance measures

### Alternative performance measures

#### Operating results (TSEK)

### Definition

Profit before financial items and tax.

### Aim

The performance measure shows the company's operational performance.

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

The research and development 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.

## Reconciliation table for alternative performance measures for the Group

SEK in thousands	Jan-Dec 2022	Jan-Dec 2021
R&D costs	-118,113	-107,574
Administration costs	-14,628	-17,122
Commercial preparation costs	-14,929	-13,201
Other operating costs	-163	-368
<b>Total operating costs</b>	<b>-147,834</b>	<b>-138,265</b>
<b>R&amp;D costs/Operating costs (%)</b>	<b>80%</b>	<b>78%</b>

## Financial calendar

Annual General Meeting 2023:	4 May 2023
Interim report Q1 2023 (Jan-Mar):	11 May 2023
Half-year report H1 2023 (Jan-Jun):	18 August 2023
Interim report Q3 2023 (Jan-Sep):	8 November 2023
Full-year report 2023 (Jan-Dec):	9 February 2024

## Contact

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