



# Interim Report Q1

January – March 2024

## Primary Endpoint Met with Strong Headline Results in Orviglance® Phase 3 Study

### KEY EVENTS IN Q1 2024

- Nomination Committee appointed for the Annual General Meeting 2024
- Orviglance review article is published in Investigative Radiology
- Ascelia Pharma secures financing of up to SEK 35 million

### KEY EVENTS AFTER THE PERIOD

- SPARKLE image reading completed with expected headline results first half of May 2024
- Ascelia Pharma draws down SEK 15 million second tranche under existing loan
- Primary endpoint successfully met with strong headline results in Orviglance phase 3 study
- Bulletin from the Annual General Meeting in Ascelia Pharma AB on 6 May 2024
- Ascelia Pharma hosts Investor Update: Bringing Orviglance to Patients

*“We are thrilled to announce these strong and convincing Phase 3 results for Orviglance. This is the most significant milestone achievement for Ascelia Pharma so far”*

### KEY RATIOS GROUP

	Q1 (Jan-Mar)	
	2024	2023
<b>OPERATING RESULT (SEKm)</b>		
	-16.7	-36.7
<b>EARNINGS PER SHARE (SEK)</b>		
	-0.5	-1.1
<b>CASH FLOW FROM OPERATIONS (SEKm)</b>		
	-15.0	-37.5
<b>LIQUID ASSETS (SEKm)</b>		
	26.5	111.4

# CEO STATEMENT



**Positive Orvigance Phase 3 headline results.** As announced on 2 May 2024, the pivotal Phase 3 study for Orvigance, SPARKLE successfully met the primary endpoint and demonstrated that the company's magnetic resonance imaging (MRI) contrast agent, Orvigance significantly improved visualization of focal liver lesions compared to unenhanced MRI. The results had high statistical significance ( $P$  values  $<0.001$ ) for all three readers and the reliability of the data was strong and conclusive for all three readers – this includes an acceptable level of variability.

Common adverse events in this vulnerable patient population were in line with previous studies with Orvigance, such as mild-to moderate nausea. No serious adverse drug reactions were observed.

On 2 May 2024, we announced positive headline results from our Phase 3 study with Orvigance. It was a day the entire team has been eagerly waiting for. The results were strong and showed that Orvigance significantly improved visualization of focal liver lesions, successfully meeting the primary endpoint in the pivotal Phase 3 study, SPARKLE with statistical significance for all three readers ( $<0.001$ ). These strong results mark the completion of clinical development for Orvigance and reinforce our confidence in the regulatory and commercial path ahead for Orvigance.

We will now focus on bringing Orvigance through the regulatory submission and approval process. In parallel, we will continue to advance launch readiness and dialogue with potential commercialization partners to make Orvigance available to patients who need high-quality liver imaging without gadolinium-related safety risk. Submission of the New Drug Application (NDA) to the US Food and Drug Administration (FDA) to obtain regulatory approval is expected by mid-2025.

We look very much forward to executing on the opportunities ahead for Ascelia Pharma in 2024 and beyond.

**Completion of Orvigance clinical development.** With the positive headline results for SPARKLE, clinical development of Orvigance has been successfully completed with consistent positive efficacy and safety data from nine clinical studies with a total of 286 patients and healthy volunteers. In the global multi-center Phase 3 SPARKLE study, 85 patients with known or suspected focal liver lesions and severely impaired kidney function were successfully completed with MRI data.

In the middle of 2023, the images from the study were evaluated by three independent radiologists (readers) in accordance with regulatory guidance to the industry. In this process, a high intra-reader variability in the image scoring by the readers was discovered, preventing us from evaluating the efficacy data from

SPARKLE. A new evaluation of the images with new readers was therefore required. We successfully completed the re-evaluation according to the planned timeline, and on 2 May 2024 we announced positive headline results.

The strong results reinforce our confidence in Orvigance and the path to market. We will now focus on bringing Orvigance through the regulatory submission and approval process. We expect to submit the NDA file to the FDA by mid-2025 to obtain regulatory approval. In parallel, we will continue to advance launch readiness and dialogue with potential commercialization partners to make Orvigance available to patients who need high-quality liver imaging without the safety risks associated with gadolinium.

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*"We have met a major milestone, with the successful headline results from our Orviglance Phase 3 study. We look forward to meeting the next milestones on our journey to making Orviglance available to patients and transforming Ascelia Pharma to a commercial stage company."*

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**Recognition in the scientific community.** We were pleased to see the acceptance for publication of a scientific review article on Orviglance in the journal Investigative Radiology in a special issue "A new era in MR contrast media" published in January 2024. The scientific review article, titled *Oral manganese chloride tetrahydrate, a novel magnetic resonance liver imaging agent for patients with renal impairment: efficacy, safety and clinical implication*, reviews and discusses liver imaging in patients with severely impaired kidney function as well as the development of Orviglance and its potential role in clinical practice.

It's a pleasure to have this publication accepted in one of the leading journals in radiology, showing that the scientific community sees a need for novel contrast agents without gadolinium.

**Strategy to commercialize with partners.** Orviglance addresses a well-defined unmet medical need representing an annual global addressable market of USD 800 million, with 100,000 procedures in the target patient population in the US alone.

Our strategy is to launch with commercialization partners. This approach enables us to leverage established commercialization capabilities with a low investment requirement for launch. A focused, ambitious launch plan, built on advanced market insights, is in place. Our focus in 2024 is to create value by ensuring Orviglance launch readiness when approved.

**Strengthened financial position.** The significant cost saving initiatives implemented from the start of the SPARKLE data re-evaluation in August 2023, led to a substantially lower cost level, also in Q1 2024.

On 4 February 2024, we announced that we have secured additional financing of SEK 35 million. On 18 April, we exercised our right to draw down the last SEK 15 million under the loan facility of the agreement. This strengthened financial position is an important and value-adding step to maintain financial and strategic flexibility. We are also very pleased to secure a financing solution with a maximum dilution of only around 4 percent for our shareholders. With the full financing in place, we have a cash runway into Q2 2025, covering the completion of time critical activities for the NDA. Relevant sources of financing will be explored in due time to support the continued growth longer term, including the submission of the NDA file by mid-2025.

**A transformative 2024 ahead.** With positive headline results from SPARKLE, we are excited to advance Orviglance through the registration process and make it available for patients together with a partner. I look forward to sharing our continued progress and other opportunities for growing Ascelia Pharma in 2024 and beyond.

**Magnus Corfitzen**  
CEO

# 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 Ascelia Pharma and building value

### ADVANCING PIPELINE AND COMMERCIAL CAPABILITIES

- ORVIGLANCE in registration phase
- ONCORAL Phase 2 ready

### PRODUCT LAUNCH AND EXPANDING PIPELINE

- ORVIGLANCE revenue
- ONCORAL Phase 2
- Pipeline expansion

### ESTABLISHED MARKET POSITION IN ORPHAN ONCOLOGY

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

# OUR PIPELINE

## ORVIGLANCE

### Diagnostic drug for liver MRI in registration phase

Orviglance is our first-in-class non-gadolinium diagnostic drug (contrast agent) to be used for magnetic resonance imaging (MRI) of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases and primary liver cancer) in patients with impaired kidney function at risk of severe side-effects from the gadolinium contrast agents currently on the market.

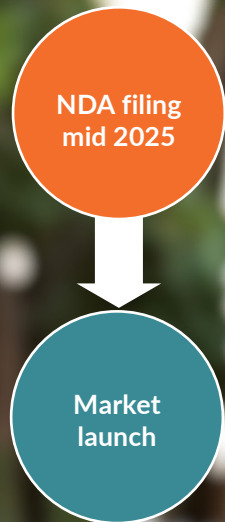
- First-in-class manganese-based diagnostic drug with FDA Orphan Drug Designation
- \$800 million global annual addressable market
- Clinical development completed, incl. pivotal Phase 3, with consistent positive efficacy and safety data from nine clinical studies with 286 patients and healthy volunteers

## ONCORAL

### Daily tablet chemotherapy ready for Phase 2

Oncoral is our novel oral irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. The potential anti-tumor effect of irinotecan is well established.

- 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 cancers



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



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



# ORVIGLANCE ADDRESSES UNMET NEEDS FOR LIVER MRI IN PATIENTS WITH KIDNEY IMPAIRMENT

Orviglance aims to be the standard of care liver MRI contrast agent for patients also suffering from severe kidney impairment. These patients are at risk of severe side-effects from using gadolinium-based contrast agents.

## \$800 million global annual addressable market

The target group for Orviglance is patients who need liver imaging and have severely impaired kidney function. This patient group is at risk of serious, and potentially fatal, side effects from using the currently available contrast agents. These contrast agents, which all are based on the heavy-metal gadolinium, carry Black Box warnings for patients with severely reduced kidney function.

The completed clinical trials show that Orviglance improve the diagnostic performance of MRI and offers a significantly better alternative than unenhanced MRI (i.e., MRI without contrast agent). Consequently, Orviglance fills a significant unmet medical need to

improve the diagnosis, and subsequently, the treatment of liver metastases and primary liver cancer.

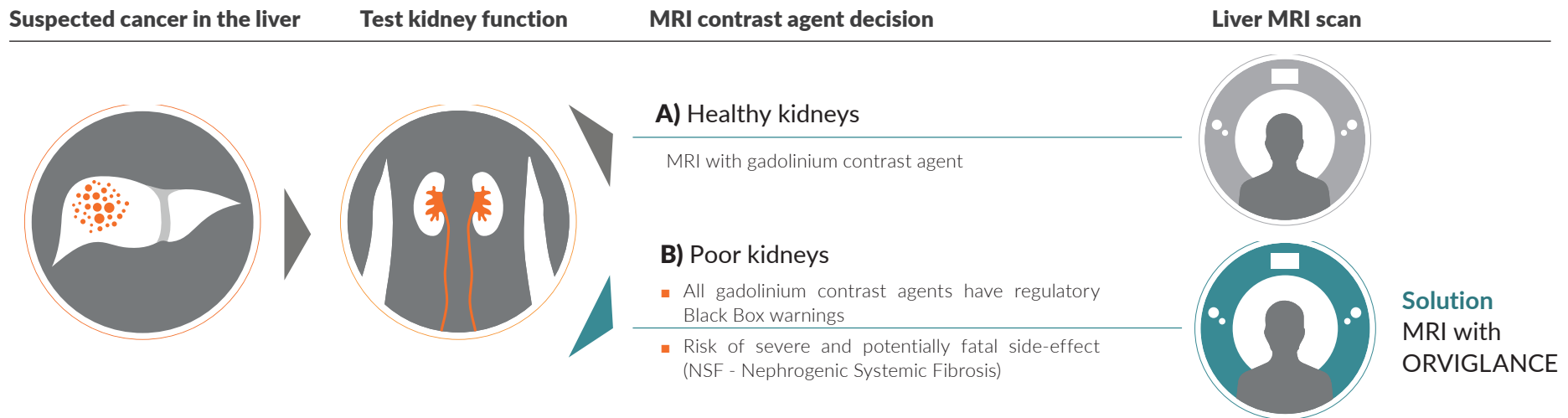
The immediate addressable market for Orviglance is estimated at \$800 million yearly and Orviglance is expected to be the only gadolinium-free product on the market for this patient segment.

## Orphan Drug Designation

Orviglance has received Orphan Drug Designation from the FDA. One major advantage of orphan drug status is, among other things, that orphan drugs can obtain longer market exclusivity after market approval.

## Early detection of liver metastases is key.

Orviglance is a contrast agent used in MRIs to improve the visualization of focal liver lesions (liver metastases and primary tumors). The liver is the second most common organ for metastasis after the lymph nodes. Detecting liver metastases at an early stage is crucial for determining the right treatment method and the patient's chances of survival. Studies show that the five-year survival rate can increase from 6 percent to 46 percent if liver metastases can be removed surgically. An accurate MR scan using contrast agents is therefore critical to evaluate the possibility for surgical resection, but also for monitoring of treatment effect and surveillance for recurrence of the disease.



# ORVIGLANCE CLINICAL DEVELOPMENT COMPLETED

Orphan liver MRI contrast agent in registration phase

## How Orviglance works

Orviglance is an orally administered 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. Liver metastases are easier to identify due to this contrast effect by Orviglance.

## Successful clinical development

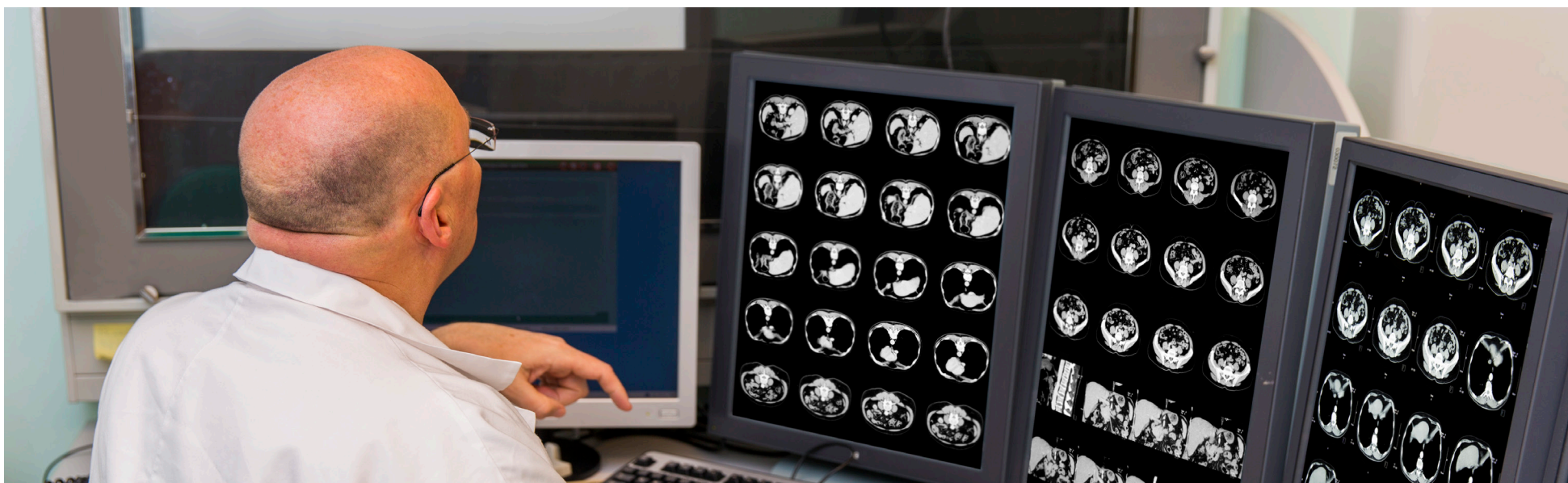
Clinical development of Orviglance has been completed with consistent positive efficacy and safety data from nine studies with 286 patients and healthy volunteers.

The pivotal Phase 3 study for Orviglance, SPARKLE successfully met the primary endpoint and demonstrated that Orviglance significantly improved visualization of focal liver lesions compared to unenhanced MRI. The results had high statistical significance (P values <0.001) for all three readers and the reliability of the data was strong and conclusive for all three readers, including an acceptable level of variability.

Common adverse events in this vulnerable patient population were in line with previous studies with Orviglance, such as mild-to moderate nausea. No serious adverse drug reactions were observed.

## Advanced to registration phase

Submission of the NDA file to the FDA is expected by mid-2025. Key required steps during the NDA preparations include the Full Clinical Study Report early Q4 2024 and conclusions from an FDA pre-submission meeting by Q1 2025.



# PHASE 3 SUCCESSFULLY COMPLETED

## Phase 3 primary endpoint met

The pivotal Phase 3 study, SPARKLE, successfully met the primary endpoint and demonstrated that Orviglance significantly improved the visualization of focal liver lesions compared to unenhanced MRI. The results for all three readers were highly statistically significant (P values <0.001).

Common adverse events in this vulnerable patient population were in line with previous studies with Orviglance, such as mild- to moderate nausea. No serious adverse drug reactions were observed.

## Designed to support regulatory approval

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 was to demonstrate an improved visualization of liver lesions (the primary endpoint) compared to MRI without contrast, unenhanced MRI. The evaluation of the primary endpoint was independently carried out by three blinded, independent radiologists (readers), who assessed changes of visualization of

liver lesions with and without Orviglance, as well as other secondary efficacy endpoints.

The Phase 3 study aims to support a regulatory filing and approval for use of Orviglance for liver imaging in patients where the use of gadolinium is medically inadvisable. It was designed in accordance with industry standards, regulatory guidance for imaging agent development and based on discussions with regulatory agencies.

## 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>■ Border delineation (border sharpness of lesions)</li> <li>■ Lesion contrast (conspicuity compared to liver background)</li> </ul>
<b>COMPARATOR</b>	<b>Unenhanced MRI + Orviglance MRI vs. Unenhanced MRI</b>
<b>EVALUATION</b>	<b>Centralized evaluation by 3 radiologists</b>
<b>RANDOMIZATION</b>	<b>None – each patient their own control</b>
<b>FOLLOW-UP</b>	<b>Less than a week</b>

### Strong positive Phase 3 headline results

Visualization of focal liver lesions with Orviglance (CMRI) vs. unenhanced MRI was strongly superior with statistical significance for all three readers (<0.001)

Results from both variables show that Orviglance significantly improves MRI performance



### Orviglance advances to registration phase

Submission of the NDA file to the FDA is expected by mid-2025

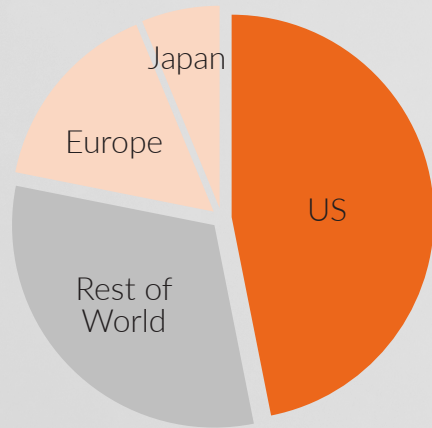


# ANNUAL ADDRESSABLE MARKET OF \$800 MILLION

## Clear and attractive addressable market

Orviglance addresses a well-defined unmet medical need representing an attractive commercial potential with an annual global addressable market of \$800 million. This estimate is 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>



## Unique opportunity to address an unmet need

Orviglance addresses an attractive market opportunity by offering contrast enhanced liver imaging for cancer patients with poor kidney function

- not associated with gadolinium safety risks for patients with poor kidney function
- addressing the increasing demand for alternatives to toxic gadolinium

90 percent of health care professionals are concerned by safety issues related to gadolinium contrast agents including NSF. In fact, according to market research, 16 percent of healthcare providers have experienced gadolinium-induced NSF<sup>3</sup>.

In the US alone real-world data shows that 100,000 abdominal imaging procedures are performed every year in 50,000 patients that fall under the black-box warning for gadolinium contrast agents, which is about 4 percent of the cancer patient population undergoing abdominal imaging.

## Partnering strategy

The go-to-market strategy for Orviglance is to launch with commercialization partners. This approach enables Ascelia Pharma to leverage established commercialization capabilities and maintain a low investment requirement for launch.

The focus of Ascelia Pharma is to create value by ensuring launch readiness and collaboration with a partner by preparing for optimal adoption by key stakeholders at launch.

**UNIQUE OPPORTUNITY**

Give people with cancer in the liver and poor kidney function  
ACCESS TO SAFE AND EFFECTIVE IMAGING  
to live healthier and longer lives

**CLEAR AMBITION**

Be the STANDARD OF CARE liver imaging choice  
for cancer patients with poor kidney function

**FOCUSED, AMBITIOUS STRATEGY**

Ensure OPTIMAL LABEL, timely SUPPLY and launch READINESS  
Drive EARLY ADOPTION AND PREFERENCE by decision  
makers with focused efforts and a strong value proposition

“

*Our commercialization strategy is to launch through partners, supporting our ambition to secure the optimal balance between future revenues and investment required. Our focus in 2024 is therefore to continue the ongoing dialogue with potential partners and to ensure that Orviglance is ready for launch when approved”, says Julie Waras Brogren, Deputy CEO*

1) Ascelia Pharma market research on real-world volumes with DRG (2020)

2) Market access research and analyses with Charles River Associates (2020), Triangle (2022)

and Trinity (2022), incl. 75 stakeholder and expert interactions. Final pricing and access strategy subject to Phase 3 data and payer evidence

3) Ascelia Pharma market research with Two Labs including 254 US HCPs (2022).

# POTENTIAL BENEFITS OF DAILY DOSING

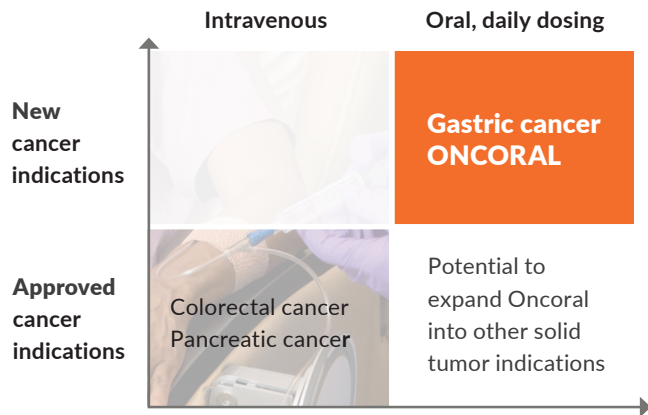
Oncoral is a novel daily irinotecan chemotherapy in development. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a daily irinotecan tablet with the potential to offer better efficacy with improved safety following the daily dosing at home compared to intravenous high-dose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

**Proven anti-cancer effect.** The active substance 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

# 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



# FINANCIAL OVERVIEW Q1 (JAN-MAR 2024)

## EARNINGS AND PROFITABILITY

### Net sales and other operating income

The Group's net sales in Q1 (Jan-Mar 2024) 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 360 thousand (SEK 311 thousand). The income refers to exchange rate gains.

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

R&D costs for the Group in Q1 were SEK 10.8 million (SEK 29.6 million). The cost decrease of SEK 18.8 million reflects completion of SPARKLE patient recruitment activities and previous communicated cost-cutting initiatives.

### Commercial preparation costs

During Q1, the costs related to commercial preparations amounted to SEK 14.0 thousand (SEK 2.9 million). This reflects the decrease in commercial preparations due to cost-cutting initiatives.

### Administration costs

Administration costs for the Group in Q1 amounted to SEK 6.2 million (SEK 4.3 million). The increased costs compared to the same period last year, primarily relates to an increase in recognized costs for employee incentive programs.

### Operating results (EBIT)

The operating result in Q1 amounted to SEK -16.7 million (SEK -36.7 million). The decreased loss reflects completion of SPARKLE patient recruitment activities and implemented cost-cutting initiatives.

### Net Profit/Loss for the period

The Group's net loss in Q1 amounted to SEK -16.7 million (SEK -37.2 million). During the quarter, net financial costs of SEK -3.0 thousand was recognized which reflects a positive currency gain on bank deposits in USD with a corresponding interest expense related to loans. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.49 (SEK -1.07).

## CASH FLOW

Cash flow from operating activities before changes in working capital in Q1 amounted to SEK -11.4 million (SEK -35.7 million). The decreased outflow reflects the completion of SPARKLE patient recruitment as well as initiated cost-cutting initiatives. Changes in working capital for the quarter totalled an outflow of SEK -3.6 million (outflow of SEK -1.9 million). The outflow primarily reflects the decrease in accounts payable and other liabilities. Cash flow from investing activities in Q1 amounted to SEK 0 (SEK 0). Cash flow from financing activities amounted to an inflow of SEK 18.9 million (outflow of SEK -0.2 million), which reflects the new loans during the quarter.

## FINANCIAL POSITION

On the closing date, equity amounted to SEK 62.9 million, compared with SEK 74.3 million per 31 December 2023 and SEK 144.7 million per 31 March 2023. The decrease since 31 December 2023 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 26.5 million, compared to SEK 21.9 million per 31 December 2023 and SEK 111.4 million per 31 March 2023. The decrease in liquid assets reflects the net loss incurred.

On 4 February 2024, additional financing of SEK 35 million was secured, consisting of a SEK 15 million convertible and a SEK 20 million loan, of which SEK 15 million was drawn on 18 April, after the closing of the quarter.

Financial key ratios for the Group	Q1 (January-March)	
	2024	2023
Operating result (SEK 000')	-16,719	-36,707
Net result (SEK 000')	-16,694	-37,219
Earnings per share (SEK)	-0.5	-1.1
Weighted avg. number of shares	33,757,746	33,690,062*
R&D costs/operating costs (%)	63%	80%
Cash flow used in operating activities (SEK 000')	-15,051	-37,530
Equity (SEK 000')	62,881	144,687
Liquid assets incl. marketable securities (SEK 000')	26,542	111,371

\*The amount for 2023 is adjusted for C-shares.

# OTHER INFORMATION

## Incentive programs

Ascelia Pharma has one outstanding employee option program as well as three share saving programs. If the terms of the option program are met at the time for utilization, the employees has 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 the terms of the program.

The Group recognizes share-based remuneration, which personnel may receive. A personnel cost is recognized, together with a corresponding increase in equity, distributed over the vesting period. Social security costs are revalued at fair value. Further information about the incentive programs can be found in the Annual Report 2023 on pages 67-69.

In case all outstanding incentive programs per 31 March 2024 are exercised in full, a total of 3.2 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 8.6 percent of Ascelia Pharma's share capital after full dilution (calculated on the number of common shares that will be added upon full exercise of all incentive programs).

## Information about risks and uncertainties for the Group and the parent company

Ascelia Pharma's activities and markets are exposed to a number of risks and uncertainties which impact, or could impact, the company's business, financial position and result. The risks and uncertainties, which Ascelia Pharma considers to have the largest impact on its results are clinical drug development, regulatory conditions, commercialization and licensing, intellectual property rights and other forms of protection, financing conditions, macroeconomic conditions including impact from pandemics, geopolitical effects, inflation and foreign exchange exposure.

## Other information

The Group's overall strategy for risk management is to limit undesirable impact on its result and financial position, to the extent it is possible. The Group's risks and uncertainties are described in more detail in the Annual Report 2023 on pages 35-37.

## Significant events after the end of the reporting period

On 24 April 2024 Ascelia Pharma announced that the SPARKLE image reading is completed and that headline results are expected first half of May 2024.

On 18 April 2024 Ascelia Pharma announced that the company has exercised its right to draw down the SEK 15 million second tranche.

On 2 May Ascelia Pharma announced that liver imaging drug candidate, Orviglance, significantly improved visualization of focal liver lesions, successfully meeting the primary endpoint in the pivotal Phase 3 study SPARKLE.

On 7 May 2024 Ascelia Pharma welcomed investors, analysts and media to a virtual update and live Q&A.

## Auditor's review

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

This interim report has been prepared in both Swedish and English versions. In the event of any differences between the translations and the Swedish original, the Swedish version shall prevail.

Malmö, 16 May 2024  
Ascelia Pharma AB (publ)

**Magnus Corfitzen**  
CEO



## Consolidated Income Statement

SEK in thousands (unless otherwise stated)*	Q1 (Jan-Mar)	
	2024	2023
Net sales	-	-
<b>Gross profit/loss</b>	-	-
Administrative costs	-6,227	-4,285
Research and development costs	-10,810	-29,620
Commercial preparation costs	-14	-2,896
Other operating income	360	311
Other operating costs	-28	-217
<b>Operating result</b>	<b>-16,719</b>	<b>-36,707</b>
Finance income	663	307
Finance costs	-666	-867
<b>Net financial items</b>	<b>-3</b>	<b>-560</b>
<b>Loss before tax</b>	<b>-16,722</b>	<b>-37,267</b>
Tax	28	49
<b>Loss for the period</b>	<b>-16,694</b>	<b>-37,219</b>
Attributable to:		
Owners of the Parent Company	-16,694	-37,219
Non-controlling interest	-	-
Earnings per share		
Before and after dilution (SEK)	-0.5	-1.1

## Consolidated Statement of Comprehensive Income

SEK in thousands (unless otherwise stated)*	Q1 (Jan-Mar)	
	2024	2023
<b>Profit/loss for the period</b>	<b>-16,694</b>	<b>-37,219</b>
<b>Other comprehensive income</b>		
Currency translation of subsidiaries**	-62	65
<b>Other comprehensive income for the period</b>	<b>-62</b>	<b>65</b>
<b>Total comprehensive income for the period</b>	<b>-16,756</b>	<b>-37,154</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

	31 Mar	31 Mar	31 Dec
SEK in thousands*	2024	2023	2023
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	57,078	57,076	57,074
Tangible assets - Equipment	71	145	89
Right-of-use assets	757	1,769	973
<b>Total non-current assets</b>	<b>57,906</b>	<b>58,990</b>	<b>58,135</b>
<b>Current assets</b>			
Advance payments to suppliers	3,255	3,458	3,433
<b>Current receivables</b>			
Income tax receivables	1,373	3,066	1,981
Other receivables	535	1,728	480
Prepaid expenses and accrued income	2,516	1,669	1,188
Cash and bank balances	26,542	111,371	21,855
<b>Total current assets</b>	<b>34,220</b>	<b>121,291</b>	<b>28,937</b>
<b>Total assets</b>	<b>92,126</b>	<b>180,281</b>	<b>87,072</b>
<b>EQUITY</b>			
Share capital	34,871	34,871	34,871
Other paid-in capital	678,747	678,747	678,747
Reserve of exchange differences on translation	609	65	671
Loss brought forward (incl. net profit/loss for the period)	-651,347	-568,997	-639,962
<b>Equity attributable to Parent Company shareholders</b>	<b>62,881</b>	<b>144,687</b>	<b>74,328</b>
<b>Total equity</b>	<b>62,881</b>	<b>144,687</b>	<b>74,328</b>
<b>LIABILITIES</b>			
<b>Long-term liabilities</b>			
Long-term interest bearing liabilities	17,958	-	-
Lease liabilities	73	855	176
<b>Total long-term liabilities</b>	<b>18,031</b>	<b>855</b>	<b>176</b>
<b>Current liabilities</b>			
Accounts payable	1,094	8,102	1,525
Tax payable	-	-	-
Other liabilities	1,170	1,733	1,640
Current lease liabilities	772	953	884
Accrued expenses and deferred income	8,177	23,950	8,519
<b>Total current liabilities</b>	<b>11,214</b>	<b>34,739</b>	<b>12,568</b>
<b>Total liabilities</b>	<b>29,245</b>	<b>35,594</b>	<b>12,744</b>
<b>Total equity and liabilities</b>	<b>92,126</b>	<b>180,281</b>	<b>87,072</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*	Q1 (Jan-Mar)		FY (Jan-Dec)
	2024	2023	2023
<b>Equity at start of the period</b>	<b>74,328</b>	<b>180,859</b>	<b>180,859</b>
<b>Comprehensive income</b>			
Profit/loss for the period	-16,694	-37,219	-109,288
Other comprehensive income	-62	65	-301
<b>Total comprehensive income</b>	<b>-16,756</b>	<b>-37,154</b>	<b>-109,589</b>
<b>Transactions with shareholders</b>			
New issue of C-shares	-	-	-
Repurchase of own shares C-shares	-	-	-
New issue of common shares	-	-	-
Common shares: Conversion from C-shares	-	-55	-89
C-shares: Resolution of C-shares	-	55	89
Issuance expenses	-257	-	-30
Call option premium in relation to loan facility	1,433	-	-
Share based remuneration to employees	4,134	981	3,088
<b>Total transactions with shareholders</b>	<b>5,309</b>	<b>981</b>	<b>3,058</b>
<b>Equity at end of the period</b>	<b>62,881</b>	<b>144,687</b>	<b>74,328</b>

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

# Consolidated Cash Flow Statement

SEK in thousands*	Q1 (Jan-Mar)	
	2024	2023
<b>Operating activities</b>		
Operating result	-16,719	-36,707
Expensed share based remuneration	5,024	972
Adjustment for items not included in cash flow	237	294
Interest received	14	34
Interest paid	-607	-35
Income tax paid/received	649	-208
<b>Cash flow from operating activities before changes in working capital</b>	<b>-11,402</b>	<b>-35,650</b>
<b>Cash flow from changes in working capital</b>		
Increase (-)/Decrease (+) of advance payments	178	1,901
Increase (-)/Decrease (+) of operating receivables	-1,688	-350
Increase (+)/Decrease (-) of accounts payable	-433	-7,777
Increase (+)/Decrease (-) of other liabilities	-1,706	4,345
Change in working capital	-3,649	-1,880
<b>Cash flow used in operating activities</b>	<b>-15,051</b>	<b>-37,530</b>
<b>Investing activities</b>		
Investment in equipment	-	-
Divestment of right-of-use assets	-	-
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-</b>
<b>Financing activities</b>		
Transaction costs for issuance	-257	-
Conversion from C-shares	-	-55
Resolution of C-shares	-	55
Convertible bond issue	1,433	-
New loans	17,958	-
Amortisation of loan (leasing)	-214	-229
<b>Cash flow from financing activities</b>	<b>18,919</b>	<b>-229</b>
<b>Cash flow for the period</b>	<b>3,868</b>	<b>-37,759</b>
Cash flow for the period	3,868	-37,759
Cash and cash equivalents at start of period	21,855	149,555
Exchange rate differences in cash and cash equivalents	819	-425
<b>Cash and cash equivalents at end of period</b>	<b>26,542</b>	<b>111,371</b>

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

## Parent Company – Income Statement

SEK in thousands*	Q1 (Jan-Mar)	
	2024	2023
Net sales	95	188
<b>Gross profit/loss</b>	<b>95</b>	<b>188</b>
Administrative costs	-6 165	-4 205
Research and development costs	-10 725	-29 471
Commercial preparation costs	-14	-2 902
Other operating income	-	14
Other operating costs	-28	-14
<b>Operating result</b>	<b>-16 837</b>	<b>-36 390</b>
Finance income	544	140
Finance costs	-643	-571
Result from other long-term receivables	747	725
<b>Net financial costs</b>	<b>649</b>	<b>294</b>
Loss before tax	-16 189	-36 096
Group contribution	-	-
Tax	-	-
<b>Loss for the period</b>	<b>-16 189</b>	<b>-36 096</b>

## Parent Company – Statement of Comprehensive Income

SEK in thousands*	Q1 (Jan-Mar)	
	2024	2023
<b>Loss for the period</b>	<b>-16 189</b>	<b>-36 096</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>-16 189</b>	<b>-36 096</b>

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



# Parent Company – Balance Sheet

	31 Mar	31 Mar	31 Dec
SEK in thousands*	2024	2023	2023
<b>ASSETS</b>			
<b>Non-current assets</b>			
Tangible assets			
Equipment	71	145	89
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	36,621	39,211	35,874
<b>Total non-current assets</b>	<b>94,760</b>	<b>97,424</b>	<b>94,032</b>
<b>Current assets</b>			
Advance payments to suppliers	3,255	3,458	3,433
<b>Current receivables</b>			
Receivables from group companies	1,766	8,989	15,114
Income tax receivables	1,019	964	1,668
Other receivables	514	1,707	453
Prepaid expenses and accrued income	2,487	1,592	1,129
Cash and bank balances	26,051	99,580	8,199
<b>Total current assets</b>	<b>35,092</b>	<b>116,290</b>	<b>29,996</b>
<b>Total assets</b>	<b>129,852</b>	<b>213,714</b>	<b>124,027</b>
<b>EQUITY</b>			
Restricted equity			
Share capital	34,871	34,871	34,871
Non-restricted equity			
Other paid-in capital	678,747	678,747	678,747
Loss brought forward	-595,833	-497,656	-495,578
Loss for the period	-16,189	-36,096	-105,563
<b>Total equity</b>	<b>101,597</b>	<b>179,867</b>	<b>112,477</b>
<b>LIABILITIES</b>			
<b>Long-term liabilities</b>			
Long-term interest bearing liabilities	17,958	-	-
<b>Total long-term liabilities</b>	<b>17,958</b>	<b>-</b>	<b>-</b>
<b>Current liabilities</b>			
Accounts payable	1,064	8,434	1,489
Other liabilities	1,171	1,733	1,640
Accrued expenses and deferred income	8,062	23,680	8,422
<b>Total current liabilities</b>	<b>10,297</b>	<b>33,847</b>	<b>11,551</b>
<b>Total equity and liabilities</b>	<b>129,852</b>	<b>213,714</b>	<b>124,027</b>

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

# Notes

## General information

This interim report for the Group has been prepared according to IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act (ÅRL). The interim report for the parent company has been prepared according to the Swedish Annual Accounts Act chapter 9, Interim Reporting. The fair value of the debt component of a convertible bond is calculated using a discount rate which is based on the market rate for a debt with the same terms without the conversion right to shares. The amount is reported as debt at amortized cost until the debt is converted or matures. The conversion right is initially reported as the difference between the fair value of the entire compound financial instrument and the fair value of the debt component. The value of the conversion right is reported in equity. For the Group and the parent company, the same accounting principles and basis for calculations have been applied as in the recent Annual Report.

## Fair value of financial instruments

The recognized value for other receivables, cash and cash equivalents, trade payables and other liabilities constitutes a reasonable approximation of fair value. Interest bearing liabilities are recognized at amortized cost which is considered an approximation of the fair value.

## Purchases from related parties

No significant transactions with related parties have occurred during the period.

## Use of non-international financial reporting standards (IFRS) performance measures

Reference is made in this interim report to alternative performance measures that are not defined according to IFRS. Ascelia Pharma considers these performance measures to be an important complement since

they enable a better evaluation of the company's economic trends. The company believes that these alternative performance measures give a better understanding of the company's financial development and that such key performance measures contain additional information to the investors to those performance measures already defined by IFRS. Furthermore, the key performance measures are widely used by the management in order to assess the financial development of the company. These financial key performance measures should not be viewed in isolation or be considered to substitute the key performance measures prepared by IFRS.

Furthermore, such key performance measures should not be compared to other key performance measures with similar names used by other companies. This is due to the fact that the above-mentioned key performance measures are not always defined identically by other companies. These alternative performance measures are described below.

## Important estimations and judgements

### Valuation of intangible assets

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

## Capitalization of development expenses

In Q1 2024, the criteria for classifying R&D costs as an asset according to IAS 38 has not been met (capitalization 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.

## Share-based incentive programs

### Employee option programs

Ascelia Pharma has in total implemented three employee option programs with individual terms and conditions of which one program is active. The parameter, which have the largest impact on the value of the options, is the publicly traded share price.

In January 2023, the second option program was expired and the options were not exercised. In November 2023 a new option program was implemented.

The total recognized costs for the option programs including social security charges in Q1 2024 were SEK 4.4 million.

### Share saving programs

Ascelia Pharma has implemented five long-term incentive programs for employees in the form of performance-based share saving programs of which three are active. The parameter, which have the largest impact on the value of the programs, is the publicly traded share price.

The total recognized costs for the share saving programs including social security charges in Q1 2024 were SEK 0.7 million.

# Notes

## Definitions of alternative performance measures

### Alternative performance measures

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

## Reconciliation table for alternative performance measures for the Group

SEK in thousands*	Q1 (Jan-Mar)	
	2024	2023
R&D costs	-10,810	-29,620
Administration costs	-6,227	-4,285
Commercial preparation costs	-14	-2,896
Other operating costs	-28	-217
<b>Total operating costs</b>	<b>-17,079</b>	<b>-37,018</b>
<b>R&amp;D costs/Operating costs (%)</b>	<b>63%</b>	<b>80%</b>

## Financial calendar

Half-year report H1 2024 (Jan-Jun):	15 August 2024
Interim report 9M 2024 (Jan-Sep):	7 November 2024
Full-year report 2024 (Jan-Dec):	7 February 2025

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