



# Interim Report Q1

January – March 2025

## Positive Outcome of Orvigance® FDA Meeting in Advance of the NDA Submission

### KEY EVENTS IN Q1 2025

- Three scientific abstracts with SPARKLE Phase 3 data accepted for presentation at the ESGAR congress 2025
- Extraordinary General Meeting on 25 February 2025 to adopt an employee stock option proposal
- Nomination Committee appointed for AGM 2025 in Ascelia Pharma AB
- Announcement of positive outcome of FDA Meeting and confirmed plan to submit the NDA for Orvigance mid-2025
- Subscription price for warrants series TO 1 determined to SEK 2.15 and exercise period initiated on 1 April 2025

### KEY EVENTS AFTER THE PERIOD

- Study on Orvigance target patients accepted for presentation at the ISPOR 2025 conference
- Publication of scientific article on Orvigance in Investigative Radiology
- Ascelia Pharma receives gross proceeds of SEK 43 million from exercise of warrants series TO 1
- Bulletin from the Annual General Meeting in Ascelia Pharma AB on 7 May 2025

*“We are very pleased with the outcome of our meeting with the FDA and look forward to advancing the NDA submission for Orvigance as planned.”*

### KEY RATIOS GROUP

	Q1 (Jan-Mar)	
	2025	2024
OPERATING RESULT (SEKm)		
	-20.3	-16.7
EARNINGS PER SHARE (SEK)		
	-0.23	-0.49
CASH FLOW FROM OPERATIONS (SEKm)		
	-16.9	-15.0
LIQUID ASSETS (SEKm)		
	57.3	26.5

# CEO STATEMENT



**Positive Orvigance Phase 3 results.** As announced in 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 positive results had both an acceptable level of variability and high statistical significance (P values <0.001) for all three readers. In the Full Study Report from SPARKLE, the results of secondary endpoints further reinforce the successful study outcomes.

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

Clinical development for our lead asset, Orvigance, is successfully completed with consistent positive efficacy and safety results from nine clinical studies with a total of 286 patients and healthy volunteers. In our Phase 3 study, SPARKLE, Orvigance significantly improved visualization of focal liver lesions in patients with impaired kidney function, meeting the primary endpoint with statistical significance for all three readers (<0.001). We are now focusing on bringing Orvigance through the regulatory approval process.

In March 2025, we announced the outcomes from our planned meeting with the US Food and Drug Administration (FDA). The meeting provided clear and concrete guidance for the Orvigance NDA. Incorporating the detailed FDA feedback from this meeting into the NDA is progressing well and we continue to expect submission by mid-year 2025, most likely during the first half of August.

It's encouraging to see the medical community welcoming Orvigance data for presentation in four oral presentations and four abstracts at key scientific conferences thus far. In April 2025, a new scientific publication in Investigative Radiology was published featuring Orvigance in a comparison study to unenhanced MRI and to gadolinium.

We were pleased to see the successful outcome of the TO 1 warrants exercise, which provided SEK 43 million additional financing before costs with a subscription rate of 96 percent in April 2025. This strengthens our financial flexibility. We now have a cash runway to at least end 2025, well beyond the NDA submission and repayment of the SEK 20 million loan to Fenja with reserved cash for a potential repayment of the SEK 7.5 million convertibles end of 2025. This runway excludes financing from partnering.

We are excited about our continued progress with Orvigance and are in a strong position to submit the NDA according to plan. We are also progressing our partnership discussions for the commercialization of Orvigance and look forward realizing the potential of Orvigance and provide better access to diagnosis and care for cancer patients with impaired kidney function.

**Completion of Orvigance clinical development.** With the positive results and Full Study Report 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. 85 patients with known or suspected focal liver lesions and severely impaired kidney function were included in the global multi-center Phase 3 SPARKLE study.

The strong results reinforce our confidence in the market potential and path to market for Orvigance. We are now focusing 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 continue to advance the dialogues with potential commercialization partners to make Orvigance available to patients who need high-quality liver imaging without the safety risks associated with gadolinium.

**Recognition in the scientific community.** In April 2025, a new scientific publication in Investigative Radiology was published featuring Orvigance in a Phase II comparison study to unenhanced MRI and to gadolinium. The original study was conducted at Karolinska Institute. The publication presents data from a re-evaluation of the images utilizing the same independent reader methodology and approach as SPARKLE.

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*"We are pleased to see the strong interest in Orviglance within the scientific community with the continued acceptance of our SPARKLE Phase 3 data for presentation at major conferences".*

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We are also pleased to see the successful acceptances of Orviglance data for presentation at major scientific conferences. **SPARKLE** have been presented as Cutting-Edge Research at the Radiological Society of North America conference (RSNA). Other key conferences have also welcomed SPARKLE data, such as the American Society of Nephrology Kidney Week, Society of Abdominal Radiology (SAR), and European Society of Gastrointestinal and Abdominal Radiology (ESGAR). In addition, the abstract 'Burden of Illness in US Patients with Liver Cancer and Kidney Disease – A Real-World Claims Analysis' was accepted for presentation at the Professional Society for Health Economics and Outcomes Research (ISPOR) Conference.

In total four oral presentations and four abstract presentations have been accepted at major conferences thus far, underscoring the interest in the medical and scientific community for an alternative to gadolinium-based contrast agents for patients with reduced kidney function.

**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 commercialization strategy is to launch Orviglance 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 current focus is to create value by progressing the dialogue with potential partners and by ensuring launch readiness for a partners at approval.

**Strengthened financial position.** In September 2024, we completed a fully subscribed Rights Issue of ordinary shares and warrants, reaching SEK 105 million before costs. In April 2025, warrants TO 1 from this Rights Issue were exercised with a subscription rate of 96 percent, providing SEK 43 million additional financing before costs. This strengthens our financial flexibility. We now have a cash runway to at least end 2025, well beyond the NDA submission and repayment of the SEK 20 million loan to Fenja with reserved cash for a potential repayment of the SEK 7.5 million convertibles end of 2025. This runway excludes financing from partnering.

**Opportunities ahead in 2025 and beyond.** With positive results from SPARKLE and the successful warrants financing, we are excited to advance Orviglance to the registration phase and make it available for patients in need. We are on an exciting journey with opportunities for growing Ascelia Pharma in 2025 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.

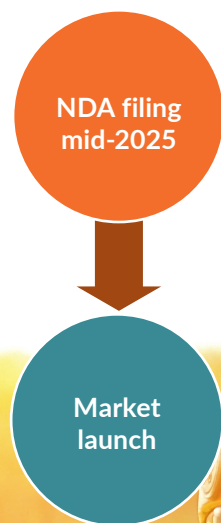
- First-in-class manganese-based diagnostic drug with FDA Orphan Drug Designation
- USD 800 million global annual addressable market
- Clinical development completed, incl. pivotal Phase 3, with consistent positive efficacy and safety data from nine clinical studies with 286 patients and healthy volunteers

## 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 NEED 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.

## USD 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 gadolinium based contrast agents. These contrast agents, carry black box warnings for patients with severely reduced kidney function.

The completed clinical studies show that Orviglance improves 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 for these patients.

The immediate addressable market for Orviglance is estimated at USD 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 regulatory approval.

## Early detection of liver metastases is key

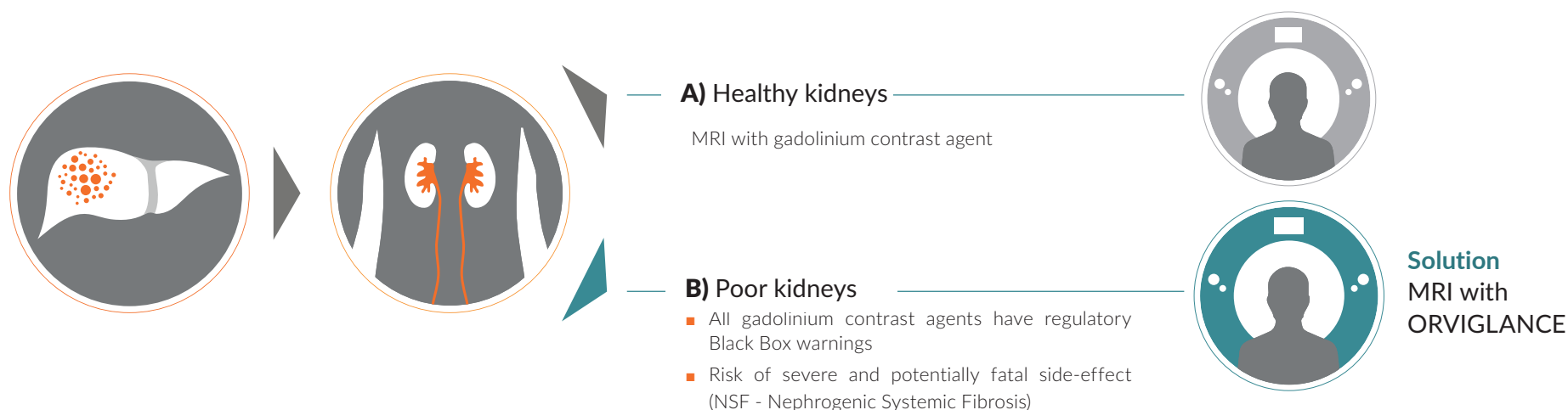
Orviglance is a contrast agent used in MRIs to improve the detection and visualization of focal liver lesions (liver metastases and primary tumors). The liver is the second most common organ for metastasis after the lymph nodes. Detecting liver metastases at an early stage is crucial for determining the right treatment method and for 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.

### Suspected cancer in the liver

### Test kidney function

### MRI contrast agent decision

### Liver MRI scan



# ORVIGLANCE CLINICAL DEVELOPMENT COMPLETED

Orphan liver MRI contrast agent in registration phase

## How Orviglance works

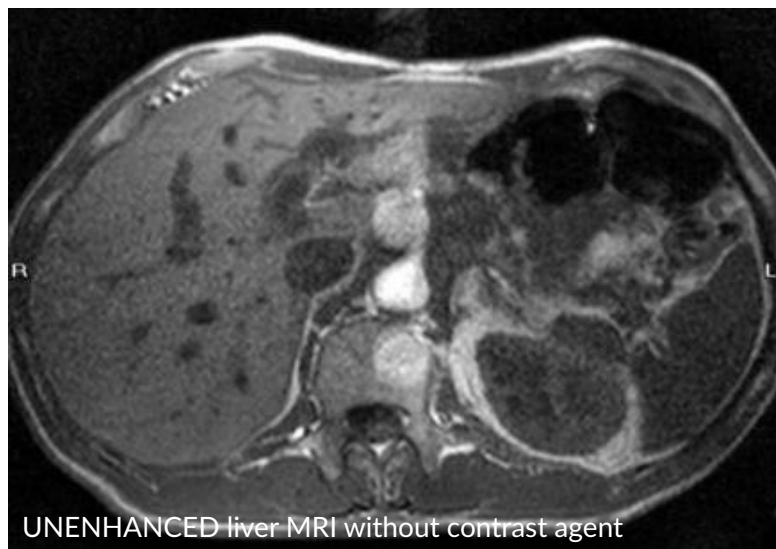
Orviglance is an orally administrated contrast agent developed for use with MRI of the liver. It is based on the chemical element manganese, which is a natural trace element in the body. Orviglance also contains L-alanine and vitamin D3 to enhance the function of manganese as a contrast agent. After 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. Liver metastases are easier to identify due to this contrast effect by Orviglance.

## Successful clinical development

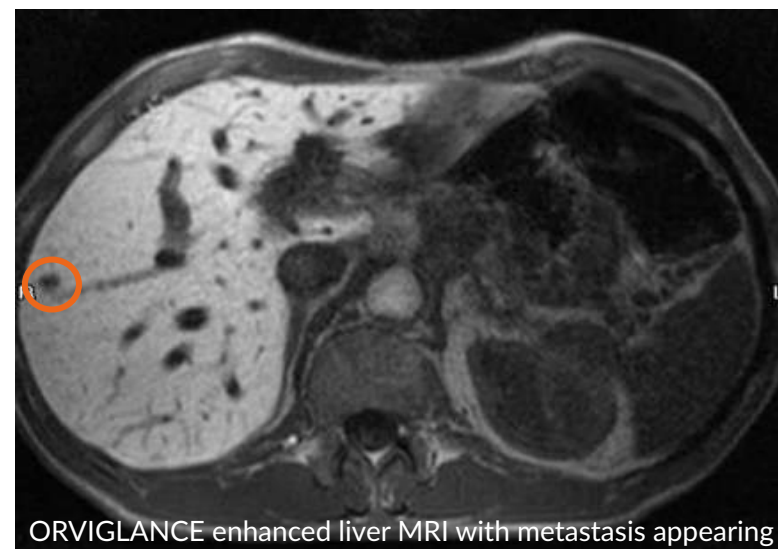
Clinical development of Orviglance has been completed with consistent positive efficacy and safety data from nine studies with 286 patients and healthy volunteers. The pivotal Phase 3 study for Orviglance, SPARKLE successfully met the primary endpoint and demonstrated that Orviglance significantly improved visualization of focal liver lesions compared to unenhanced MRI. The positive results were strong and conclusive and had both an acceptable level of variability and high statistical significance (P values <0.001) for all three readers. 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

The NDA submission for subsequent regulatory review and approval is now in finalization. This includes the Full Clinical Study Report completed in Q4 2024 and conclusions from a meeting with the FDA in advance of NDA submission. This meeting was held in Q1 2025 as planned with clear and concrete guidance from the FDA. The meeting discussion and final minutes support the finalization of the NDA submission as planned. Incorporating the detailed FDA feedback from the meeting into the NDA is progressing well and we continue to expect to submit the NDA by mid-year 2025.



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



# 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 MRI without contrast, 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 was completed with 85 enrolled patients with suspected or known focal liver lesions and severely impaired kidney function.

The evaluation of the primary endpoint was carried out by three blinded, independent radiologists (readers), in accordance with regulatory guidance to the industry. The readers assessed the changes in visualization of liver lesions with and without Orviglance, as well as other secondary efficacy endpoints.

Following an unacceptably high intra-reader variability in the first image scoring by readers mid-2023, a new evaluation of the images with new readers was successfully completed with the announced positive headline results and acceptable variability in May 2024, in line with the planned timeline.

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

## Orviglance clinical Phase 3 study

NUMBER OF PATIENTS	Global study with 85 patients	<b>Strong positive Phase 3 results</b> <ul style="list-style-type: none"> <li>■ For unenhanced images, the median BD and LC scores ranged from 2.1 to 3.0 across readers</li> <li>■ For Orviglance-enhanced images, the median BD and LC scores increased to 3.0 and 4.0 across readers</li> <li>■ Increases were statistically significant (p&lt;0.001) for all three readers</li> </ul> <p>The results of secondary endpoints generally support the superiority of Orviglance compared to unenhanced MRI, e.g. with at least one additional lesion detected in 40-52% of patients with Orviglance across readers.</p> <p>No analysis favours unenhanced MRI, including in patient sub-group analysis.</p> <p>Orviglance superiority vs. unenhanced was demonstrated regardless of whether unenhanced was compared to images with Orviglance combined with unenhanced or images with Orviglance alone.</p>
PRIMARY ENDPOINT	<b>Lesion visualization scoring using scales from 1 ('poor') to 4 ('excellent') for all lesions for each patient</b> <ul style="list-style-type: none"> <li>■ Border delineation (BD, border sharpness of lesions)</li> <li>■ Lesion contrast (LC, conspicuity compared to liver background)</li> </ul>	
COMPARATOR	Unenhanced MRI + Orviglance MRI vs. Unenhanced MRI	
EVALUATION	Centralized evaluation by 3 radiologists (blinded readers)	
RANDOMIZATION	None – each patient their own control	
FOLLOW-UP	Less than a week	

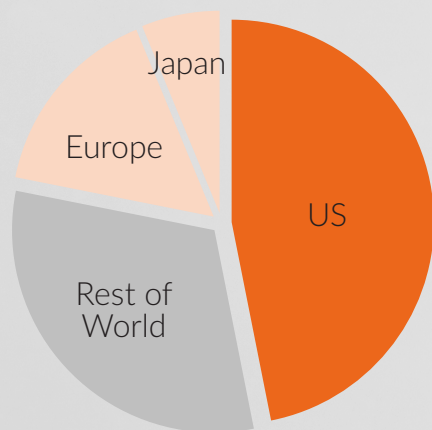


# ANNUAL ADDRESSABLE MARKET OF USD 800 MILLION

## 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 USD 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.

“

*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*

## 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

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).

# ONCORAL POTENTIAL WITH 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.

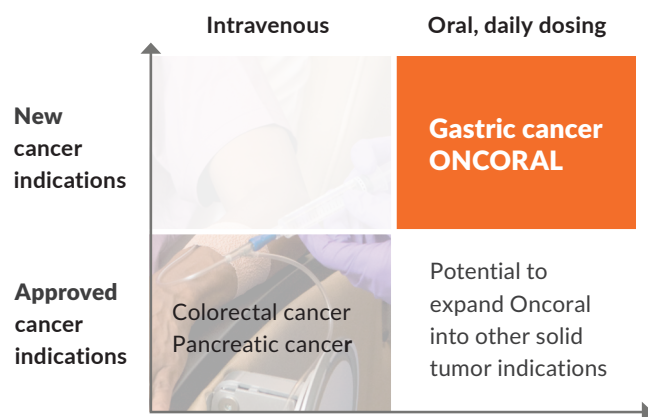
## Potential to be the first oral version of irinotecan

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



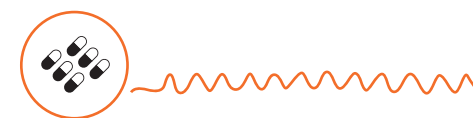
## TODAY – Intravenous bolus infusions



### 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

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



**TAIHO ONCOLOGY**

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

# FINANCIAL OVERVIEW Q1 (JAN-MAR 2025)

## EARNINGS AND PROFITABILITY

### Net sales and other operating income

The Group's net sales in Q1 (Jan-Mar 2025) amounted to SEK 0 (SEK 0). Other operating income totalled SEK 0 (SEK 360 thousand).

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

R&D costs for the Group in Q1 2025, amounted to SEK 15.7 million (SEK 10.8 million). The cost increase compared to the same quarter last year is related to ramp-up of NDA submission preparations.

### Administration costs

Administration costs for the Group in Q1 2025, amounted to SEK 4.4 million (SEK 6.2 million). The decrease in costs primarily reflects a reduction in recognized costs for employee incentive programs compared to the same quarter last year.

### Commercial preparation costs

During Q1 2025, the costs related to commercial preparations amounted to SEK 0 (SEK 14 thousand).

### Operating results (EBIT)

The operating result in Q1 2025, amounted to SEK -20.3 million (SEK -16.7 million). The increased loss reflects the higher level of NDA preparations.

### Net Profit/Loss for the period

The Group's net loss in Q1 amounted to SEK -21.7 million (SEK -16.7 million). During Q1 2025, net financial costs of SEK -1.5 million was recognized which mainly reflects a currency loss on bank deposits in USD and interest expenses related to loans. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.23 (SEK -0.49).

## CASH FLOW AND FINANCIAL POSITION

Cash flow from operating activities before changes in working capital in Q1 2025, amounted to SEK -20.6 million (SEK -11.4 million). Changes in working capital for the quarter totalled a positive impact of SEK 3.7 million (outflow of SEK -3.6 million). The changes in working capital reflect an increase in other liabilities as well as repayment of advances from suppliers. Cash flow from investing activities in Q1 amounted to SEK 0 (SEK 0). Cash flow from financing activities amounted to an outflow of SEK -0.2 million (inflow of SEK 18.9 million), which reflects amortization of lease liabilities.

On the closing date, equity amounted to SEK 57.8 million, compared with SEK 78.9 million per 31 December 2024 and SEK 62.9 million per 31 March 2024. The decrease since 31 December 2024 reflects the net loss incurred. Liquid assets amounted to SEK 57.3 million on the closing date, compared to SEK 75.3 million per 31 December 2024 and SEK 26.5 million per 31 March 2024. The decrease in liquid assets compared to 31 December 2024, reflects the net loss incurred.

The exercise period for warrants series TO 1 in Ascelia Pharma AB ended on 15 April 2025. The outcome shows that a total of 19,919,494 TO 1 were exercised for subscription of 19,919,494 new ordinary shares, corresponding to a subscription rate of approximately 96 percent. Ascelia Pharma thus receives proceeds of approximately SEK 43 million before issue costs. This strengthens our financial flexibility with a cash runway to at least end 2025, well beyond the NDA submission and repayment of the SEK 20 million loan to Fenja with reserved cash for a potential repayment of the SEK 7.5 million convertibles end of 2025. Runway excludes financing from partnering.

Financial key ratios for the Group	Q1 (Jan-Mar)	
	2025	2024
Operating result (SEK 000')	-20,333	-16,719
Net result (SEK 000')	-21,732	-16,694
Earnings per share (SEK)	-0.23	-0.49
Weighted avg. number of shares	96,106,032	33,757,746
R&D costs/operating costs (%)	77%	63%
Cash flow used in operating activities (SEK 000')	-16,915	-15,051
Equity (SEK 000')	57,820	62,881
Liquid assets incl. marketable securities (SEK 000')	57,300	26,542

# 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 have the right to purchase shares at a pre-determined price. For the share-saving programs, 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 2024 on pages 67-69.

In case all outstanding incentive programs per 31 March 2025 are exercised in full, a total of 5.9 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 5.8 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).

## Warrants TO 1

The warrants are valued at fair value based on the necessary variables using a Monte Carlo simulation. A first valuation was made after the Rights Issue in September 2024, which yielded a value of SEK 12.4 million. This value is recognized as a liability on the balance sheet. A new fair value is calculated at each quarterly period. On March 31, 2025, the value of the warrants was SEK 17.6 million, which generates a financial income of SEK 0.6 million in 2025. The cost has no cash impact.

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

Ascelia Pharma continuously needs to secure financing to ensure continued development and growth. Market dynamics and financing needs create uncertainties regarding ongoing and future operations. To strengthen the balance sheet and ensure continued operations, the Company carried out a fully subscribed Rights Issue in September 2024 with warrants exercised in April 2025.

From an operational perspective, the Company is exposed to a number of risks and uncertainties which impact, or could impact, its business, operations, financial position, and results. The risks and uncertainties considered to have the highest impact on results are within 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.

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 2024 on pages 35-37.

## Significant events after the end of the reporting period

On 4 April, Ascelia Pharma announced the acceptance of a study on Burden of Illness Real-World Data of Orviglance target patients for presentation at the ISPOR 2025 conference.

On 8 April, Ascelia Pharma announced the publication of a scientific article on Orviglance in the journal Investigative Radiology.

On 16 April, Ascelia Pharma announced the outcome from the exercise of warrants series TO 1 with gross proceeds of SEK 43 million.

## 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 2025  
Ascelia Pharma AB (publ)

**Magnus Corfitzen**  
CEO



## Consolidated Income Statement

	Q1 (Jan-Mar)	
SEK in thousands (unless otherwise stated)*	2025	2024
Net sales	-	-
<b>Gross profit/loss</b>	-	-
Administrative costs	-4,445	-6,227
Research and development costs	-15,661	-10,810
Commercial preparation costs	-	-14
Other operating income	-	360
Other operating costs	-227	-28
<b>Operating result</b>	<b>-20,333</b>	<b>-16,719</b>
Finance income	708	663
Finance costs	-2,240	-666
<b>Net financial items</b>	<b>-1,532</b>	<b>-3</b>
<b>Loss before tax</b>	<b>-21,865</b>	<b>-16,722</b>
Tax	133	28
<b>Loss for the period</b>	<b>-21,732</b>	<b>-16,694</b>
Attributable to:		
Owners of the Parent Company	-21,732	-16,694
Non-controlling interest	-	-
Earnings per share		
Before and after dilution (SEK)	-0.23	-0.49

## Consolidated Statement of Comprehensive Income

	Q1 (Jan-Mar)	
SEK in thousands (unless otherwise stated)*	2025	2024
<b>Profit/loss for the period</b>	<b>-21,732</b>	<b>-16,694</b>
<b>Other comprehensive income</b>		
Currency translation of subsidiaries**	124	-62
<b>Other comprehensive income for the period</b>	<b>124</b>	<b>-62</b>
<b>Total comprehensive income for the period</b>	<b>-21,609</b>	<b>-16,756</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*	2025	2024	2024
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	57,070	57,078	57,078
Tangible assets - Equipment	8	71	15
Right-of-use assets	1,411	757	109
<b>Total non-current assets</b>	<b>58,490</b>	<b>57,906</b>	<b>57,202</b>
<b>Current assets</b>			
Advance payments to suppliers	1,755	3,255	1,755
<b>Current receivables</b>			
Income tax receivables	975	1,373	632
Other receivables	2,934	535	5,054
Prepaid expenses and accrued income	1,522	2,516	1,022
Cash and bank balances	57,300	26,542	75,256
<b>Total current assets</b>	<b>64,486</b>	<b>34,220</b>	<b>83,718</b>
<b>Total assets</b>	<b>122,975</b>	<b>92,126</b>	<b>140,920</b>
<b>EQUITY</b>			
Share capital	97,193	34,871	97,193
Other paid-in capital	721,750	678,747	721,750
Reserve of exchange differences on translation	1,097	609	974
Loss brought forward (incl. net profit/loss for the period)	-762,220	-651,347	-740,973
<b>Equity attributable to Parent Company shareholders</b>	<b>57,820</b>	<b>62,881</b>	<b>78,944</b>
<b>Total equity</b>	<b>57,820</b>	<b>62,881</b>	<b>78,944</b>
<b>LIABILITIES</b>			
<b>Long-term liabilities</b>			
Long-term interest bearing liabilities	-	17,958	-
Lease liabilities	689	73	-
<b>Total long-term liabilities</b>	<b>689</b>	<b>18,031</b>	<b>-</b>
<b>Current liabilities</b>			
Accounts payable	4,977	1,094	4,733
Tax payable	-	-	-
Other liabilities	18,557	1,170	19,113
Interest bearing liabilities	25,781	-	25,225
Current lease liabilities	770	772	172
Accrued expenses and deferred income	14,381	8,177	12,733
<b>Total current liabilities</b>	<b>64,466</b>	<b>11,214</b>	<b>61,976</b>
<b>Total liabilities</b>	<b>65,155</b>	<b>29,245</b>	<b>61,976</b>
<b>Total equity and liabilities</b>	<b>122,975</b>	<b>92,126</b>	<b>140,920</b>

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

# Consolidated Statements of Changes in Equity

	Q1 (Jan-Mar)		Full Year (Jan-Dec)
SEK in thousands*	2025	2024	2024
<b>Equity at start of the period</b>	<b>78,944</b>	<b>74,328</b>	<b>74,328</b>
<b>Comprehensive income</b>			
Profit/loss for the period	-21,732	-16,694	-80,029
Other comprehensive income	124	-62	303
<b>Total comprehensive income</b>	<b>-21,609</b>	<b>-16,756</b>	<b>-79,726</b>
<b>Transactions with shareholders</b>			
New issue of common shares	-	-	105,324
Warrants	-	-	-12,385
New issue of C-shares	-	-	-
Common shares: Conversion from C-shares	-	-	-26
C-shares: Resolution of C-shares	-	-	26
Issuance expenses	-	-257	-15,207
Call option premium in relation to loan facility	-	1,433	2,165
Share based remuneration to employees	485	4,134	4,446
<b>Total transactions with shareholders</b>	<b>485</b>	<b>5,309</b>	<b>84,343</b>
<b>Equity at end of the period</b>	<b>57,820</b>	<b>62,881</b>	<b>78,944</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)	
	2025	2024
<b>Operating activities</b>		
Operating result	-20,333	-16,719
Expensed share based remuneration	521	5,024
Adjustment for items not included in cash flow	273	237
Interest received	123	14
Interest paid	-950	-607
Income tax paid/received	-215	649
<b>Cash flow from operating activities before changes in working capital</b>	<b>-20,582</b>	<b>-11,402</b>
<b>Cash flow from changes in working capital</b>		
Increase (-)/Decrease (+) of advance payments	-	178
Increase (-)/Decrease (+) of operating receivables	1,777	-1,688
Increase (+)/Decrease (-) of accounts payable	249	-433
Increase (+)/Decrease (-) of other liabilities	1,640	-1,706
Change in working capital	3,667	-3,649
<b>Cash flow used in operating activities</b>	<b>-16,915</b>	<b>-15,051</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>		
New share issue	-	-
Transaction costs for issuance	-	-257
Conversion from C-shares	-	-
Resolution of C-shares	-	-
Convertible bond issue	-	1,433
New loans	-	17,958
Amortisation of loan	-	-
Amortisation of lease liabilities	-229	-214
<b>Cash flow from financing activities</b>	<b>-229</b>	<b>18,919</b>
<b>Cash flow for the period</b>	<b>-17,144</b>	<b>3,868</b>
Cash and cash equivalents at start of period	75,256	21,855
Exchange rate differences in cash and cash equivalents	-811	819
<b>Cash and cash equivalents at end of period</b>	<b>57,300</b>	<b>26,542</b>

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

## Parent Company – Income Statement

	Q1 (Jan-Mar)	
SEK in thousands*	2025	2024
Net sales	68	95
<b>Gross profit/loss</b>	<b>68</b>	<b>95</b>
Administrative costs	-4,387	-6,165
Research and development costs	-15,077	-10,725
Commercial preparation costs	-	-14
Other operating income	-	-
Other operating costs	-53	-28
<b>Operating result</b>	<b>-19,449</b>	<b>-16,837</b>
Finance income	1,572	544
Finance costs	-2,228	-643
Result from other long-term receivables	-3,725	747
<b>Net financial costs</b>	<b>-4,382</b>	<b>649</b>
Loss before tax	-23,831	-16,189
Group contribution	-	-
Tax	-	-
<b>Loss for the period</b>	<b>-23,831</b>	<b>-16,189</b>

## Parent Company – Statement of Comprehensive Income

	Q1 (Jan-Mar)	
SEK in thousands*	2025	2024
<b>Loss for the period</b>	<b>-23,831</b>	<b>-16,189</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>-23,831</b>	<b>-16,189</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*	2025	2024	2024
<b>ASSETS</b>			
<b>Non-current assets</b>			
Tangible assets			
Equipment	8	71	15
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	36,394	36,621	39,255
<b>Total non-current assets</b>	<b>94,470</b>	<b>94,760</b>	<b>97,338</b>
<b>Current assets</b>			
Advance payments to suppliers	1,755	3,255	1,755
<b>Current receivables</b>			
Receivables from group companies	2,708	1,766	2,560
Income tax receivables	749	1,019	534
Other receivables	2,910	514	5,011
Prepaid expenses and accrued income	1,522	2,487	1,004
Cash and bank balances	56,646	26,051	74,440
<b>Total current assets</b>	<b>66,289</b>	<b>35,092</b>	<b>85,303</b>
<b>Total assets</b>	<b>160,759</b>	<b>129,852</b>	<b>182,641</b>
<b>EQUITY</b>			
Restricted equity			
Share capital	97,193	34,871	97,193
Non-restricted equity			
Other paid-in capital	721,750	678,747	721,750
Loss brought forward	-697,469	-595,833	-622,123
Loss for the period	-23,831	-16,189	-75,831
<b>Total equity</b>	<b>97,643</b>	<b>101,597</b>	<b>120,989</b>
<b>LIABILITIES</b>			
<b>Long-term liabilities</b>			
Long-term interest bearing liabilities	-	17,958	-
<b>Total long-term liabilities</b>	<b>-</b>	<b>17,958</b>	<b>-</b>
<b>Current liabilities</b>			
Accounts payable	4,938	1,064	4,632
Other liabilities	25,781	1,171	19,113
Interest bearing liabilities	18,557	-	25,225
Accrued expenses and deferred income	13,840	8,062	12,683
<b>Total current liabilities</b>	<b>63,116</b>	<b>10,297</b>	<b>61,652</b>
<b>Total equity and liabilities</b>	<b>160,759</b>	<b>129,852</b>	<b>182,641</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. 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 2025, 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 one ongoing employee option program which was implemented in February 2025. The parameter, which have

the largest impact on the value of the options, is the publicly traded share price. In December 2024, the third option program was expired and no options were exercised.

The total recognized costs for the option program in Q1 2025 including social security charges were SEK 0.2 million.

### Share saving programs

Ascelia Pharma has three active long-term incentive programs for employees in the form of performance-based share saving programs. 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 2025 were SEK 0.3 million.

# Notes

## Definitions of 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

	Q1 (Jan-Mar)	
SEK in thousands*	2025	2024
R&D costs	-15,661	-10,810
Administration costs	-4,445	-6,227
Commercial preparation costs	-	-14
Other operating costs	-227	-28
<b>Total operating costs</b>	<b>-20,333</b>	<b>-17,079</b>
<b>R&amp;D costs/Operating costs (%)</b>	<b>77%</b>	<b>63%</b>

## Financial calendar

Half-year report 2025 (Jan-Jun):  
Interim report 9M 2025 (Jan-Sep):  
Full-year report 2025 (Jan-Dec):

21 August 2025  
5 November 2025  
5 February 2026

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