



# Full Year and Q4 Report 2025

January – December 2025

## FDA Accepts Orviglance® NDA for Review

### KEY EVENTS IN Q4 2025

- FDA accepts Orviglance NDA for review aiming for a decision by 3 July 2026 as the PDUFA date
- Filing of a new patent application for Orviglance
- Management changes to support future growth
- Conversion of series C shares into ordinary shares for delivery to participants in incentive program
- Nomination Committee appointed for AGM 2026

### KEY EVENTS AFTER THE PERIOD

- Deputy CEO Julie Waras Brogren to leave the company

“ FDA's acceptance of the Orviglance NDA for review represents yet another significant step towards making Orviglance available to patients. We look forward to continuing to work with the FDA throughout the review process.”

### KEY RATIOS GROUP

Q4 (Oct-Dec)		FY (Jan-Dec)	
2025	2024	2025	2024
<b>OPERATING RESULT (SEKm)</b>			
-15.8	-21.9	-74.4	-67.8
<b>EARNINGS PER SHARE (SEK)</b>			
-0.13	-0.29	-0.67	-1.48
<b>CASH FLOW FROM OPERATIONS (SEKm)</b>			
-21.7	-18.8	-72.3	-62.8
<b>LIQUID ASSETS (SEKm)</b>			
49.9	75.3	49.9	75.3

# CEO STATEMENT



**Orviglance NDA submitted.** The NDA for Orviglance was submitted to the FDA early September 2025. Ascelia Pharma seeks marketing approval for Orviglance as liver magnetic resonance imaging (MRI) contrast agent for patients with severe kidney impairment. These patients have the highest risk of developing the serious and potentially fatal condition Nephrogenic Systemic Fibrosis (NSF) after exposure to the gadolinium-based contrast agents normally used today. Regulatory bodies have issued warnings for the use of these agents in this vulnerable patient population and Orviglance has been granted an Orphan Drug Designation by the FDA.

Mid November 2025, the FDA formally accepted the NDA filing in their 'day 74 letter'. The expected date for their decision, i.e. PDUFA date, is 3 July 2026, as a standard 10 months review.

Following the Orviglance New Drug Application (NDA) submission in September 2025, we continued to make solid progress in Q4. In November, we received the US Food and Drug Administration (FDA) Day 74 letter, which formally accepted our NDA for review, aiming for a decision by 3 July 2026 as the PDUFA date. This milestone underscores the quality and completeness of our submission and marks a critical step toward making Orviglance available to patients with severe kidney impairment who need a contrast enhanced liver MRI procedure. We look forward to continuing to work with the FDA throughout the review process.

The NDA submission is based on the successful completion of the development program, which includes nine clinical studies with consistent positive efficacy and safety results. In our Phase 3 study, SPARKLE, Orviglance 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 have a cash runway into Q4 2026, well beyond the expected FDA approval date of Orviglance. This follows a directed share issue in September 2025, raising SEK 30 million before costs, which strengthened our balance sheet based on the inbound interest expressed by investors.

Our partnering process continues to progress, and multiple potential partners demonstrate strong strategic interest. With the regulatory timeline now firmly established, these dialogues have gained additional momentum and clarity, and we remain well positioned to secure a partnering agreement.

**Completion of Orviglance clinical development.** The NDA submission is based on a successfully completed development program, including nine clinical studies with consistent positive efficacy and safety results. The program includes 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 pivotal Phase 3 study, SPARKLE.

In 2024, the SPARKLE study successfully met the primary endpoint, demonstrating that Orviglance significantly improved visualization of focal liver lesions compared to unenhanced MRI. The positive results had an acceptable level of variability and high statistical significance ( $P$  values  $<0.001$ ) for all three independent

readers, who scored study images according to the FDA agreed methodology.

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

Orviglance aims to give patients with impaired kidney function access to safe and effective liver imaging and the strong results from the clinical studies reinforce our confidence in the market potential and path to market for Orviglance. We are now focused on bringing Orviglance successfully through the FDA review process.

*"We have a cash runway into Q4 2026, well beyond the expected FDA approval date of Orviglance 3 July 2026".*

**Recognition in the scientific community.** We are pleased to see the acceptances of Orviglance data for presentation at major scientific conferences. In total four oral presentations and six abstract presentations have been accepted since the announcement of our Phase 3 results, underscoring the interest in the medical and scientific community for an alternative to gadolinium-based contrast agents.

Orviglance data and SPARKLE results have been presented at the Radiological Society of North America conference (RSNA) in November 2024 and 2025. 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, a burden of illness real-world data analysis was presented at the Professional Society for Health Economics and Outcomes Research (ISPOR) Conference. In April 2025, an article in Investigative Radiology was published featuring Orviglance in a Phase 2 comparison study to unenhanced MRI and to gadolinium. The publication presents data utilizing the same independent reader methodology and approach as used in SPARKLE.

**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 annual procedures in the target patient population in the US alone. Our strategy is to launch Orviglance with commercialization partners. This strategy enables us to leverage established commercialization capabilities of a partner with a low investment from Ascelia Pharma required for launch. A focused, ambitious launch plan, built on advanced market insights, is in place.

Orviglance is an attractive commercial opportunity for a partner. We continue to advance the dialogues with potential commercialization partners to make Orviglance available to patients who need high-quality liver imaging without the safety risks associated with gadolinium. With the regulatory timeline now firmly established, these dialogues have gained additional momentum and clarity and we remain well positioned to secure a partnering agreement.

**Sound financial position.** We have a cash runway into Q4 2026, well beyond the expected FDA approval date of Orviglance. This follows our strengthening of the balance sheet earlier in second half 2025. In September 2025, Fenja converted all outstanding convertibles of SEK 7.5 million. Late September, we successfully completed a directed share issue raising SEK 30 million before costs, based on the inbound interest expressed by investors.

**A transformative 2026 for Ascelia Pharma.** With the Orviglance NDA submission, we are excited to advance Orviglance through the FDA review process. With an expected FDA approval and commercial partner driving the first launch of Orviglance in the US, we expect 2026 to be truly transformative for Ascelia Pharma. We look forward to reaching these key milestones in 2026 and to continuing our journey to advance and grow Ascelia Pharma.

**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.

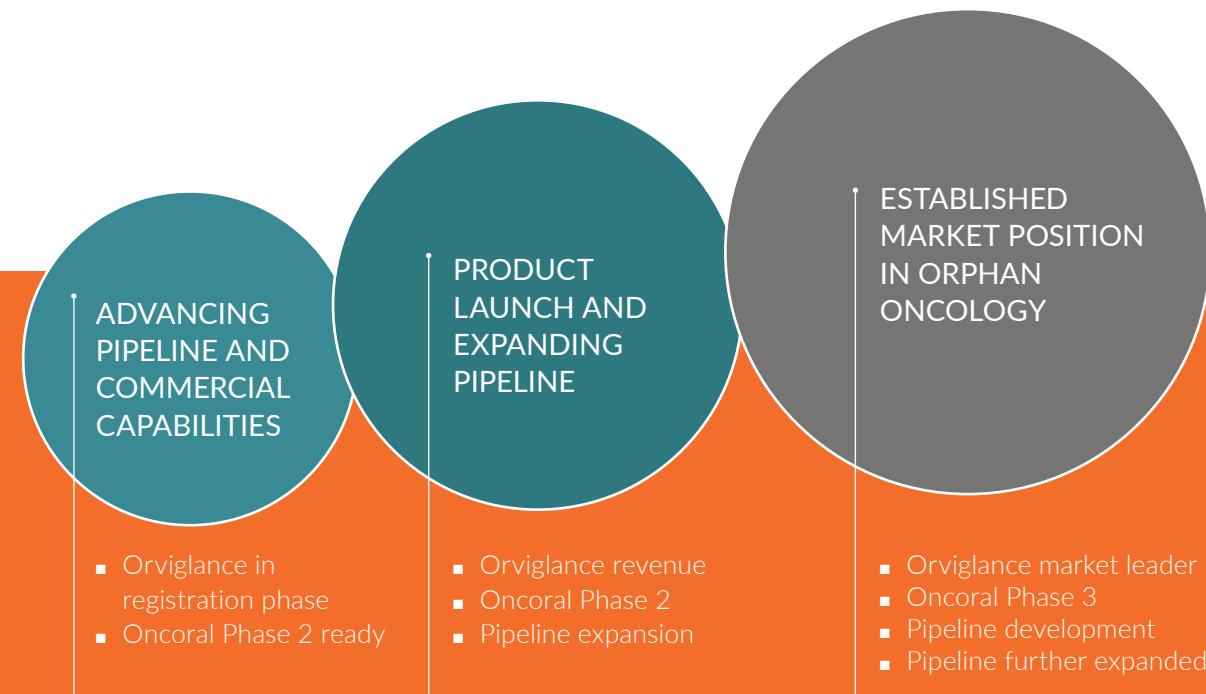
## OUR VISION

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**

# 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
- NDA submitted to the FDA

## 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 ADDRESSES UNMET NEED FOR LIVER MRI IN PATIENTS WITH KIDNEY IMPAIRMENT

Orvigance 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 Orvigance 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 Orvigance improves the diagnostic performance of MRI and offers a significantly better alternative than unenhanced MRI (i.e., MRI without contrast agent). Consequently, Orvigance fills a significant unmet

medical need to improve the diagnosis, and subsequently, the treatment of liver metastases and primary liver cancer for these patients.

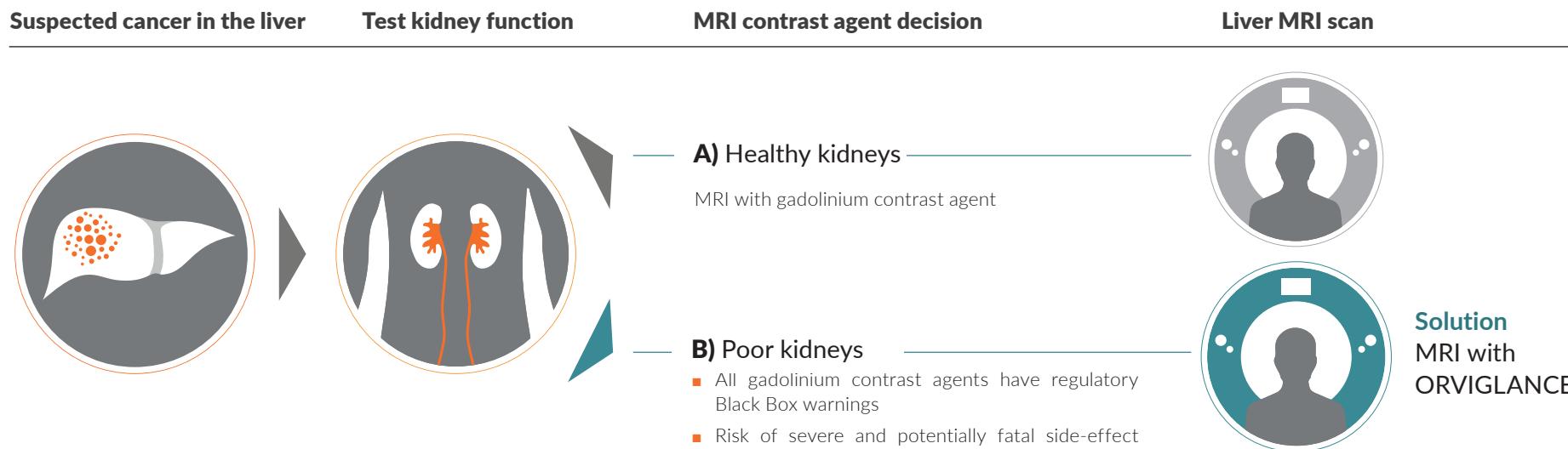
The immediate addressable market for Orvigance is estimated at USD 800 million yearly and Orvigance is expected to be the only gadolinium-free product on the market for this patient segment.

## Orphan Drug Designation

Orvigance 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

Orvigance 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.



# ORVIGLANCE CLINICAL DEVELOPMENT COMPLETED

Orphan liver MRI contrast agent in registration phase

## How Orvigance works

Orvigance 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. Orvigance 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 Orvigance.

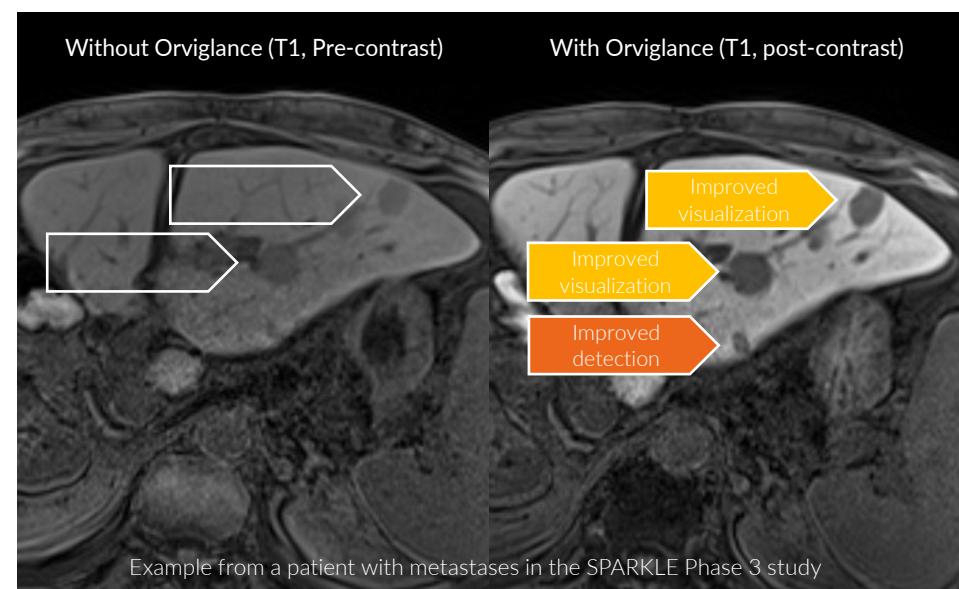
## Successful clinical development

Clinical development of Orvigance 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 Orvigance, SPARKLE successfully met the primary endpoint and demonstrated that Orvigance 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 Orvigance, such as mild- to moderate nausea. No serious adverse drug reactions were observed.

## Advanced to registration phase

The NDA for Orvigance was submitted to the FDA early September 2025. To reach this milestone, the Full Clinical Study Report from SPARKLE Phase 3 was completed in Q4 2024 and a pre-NDA meeting with the FDA was held in Q1 2025. The meeting provided clear and concrete guidance from the FDA for the finalization and submission of the NDA. Mid November 2025, the FDA formally accepted the NDA filing in their 'day 74 letter'. The expected date for their decision, i.e. PDUFA date, is 3 July 2026, in accordance with a standard 10 months review.

## Improved visualization of focal liver lesions with Orvigance



# 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.

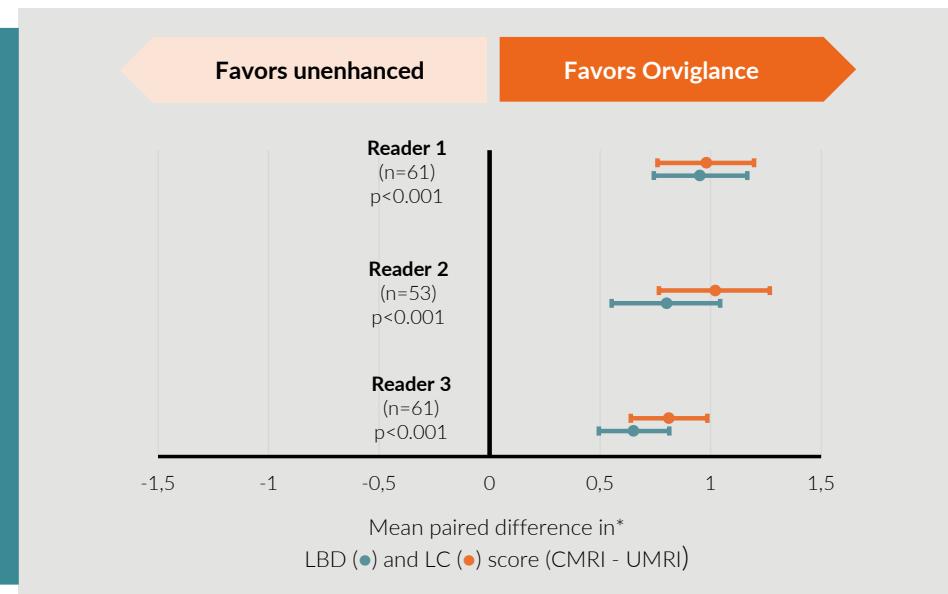
## Strong positive Phase 3 results

- For unenhanced images, the median BD and LC scores ranged from 2.1 to 3.0 across readers
- For Orviglance-enhanced images, the median BD and LC scores increased to 3.0 and 4.0 across readers
- Increases were statistically significant ( $p<0.001$ ) for all three readers

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.

No analysis favours unenhanced MRI, including in patient sub-group analysis.

Superiority vs. unenhanced was demonstrated both when unenhanced was compared to images with Orviglance combined with unenhanced and for images with Orviglance alone.



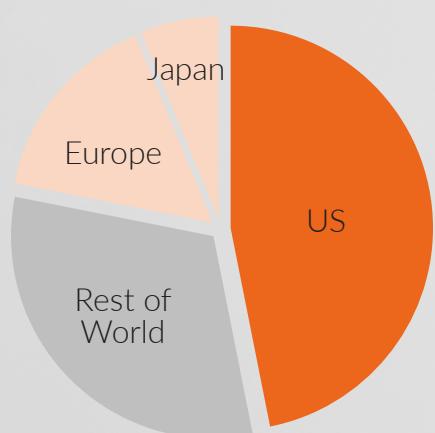
\*Visualization assessed by 3 independent readers as the improvement of Lesion border delineation (LBD) and Lesion contrast (LC) on combined Orviglance-enhanced + unenhanced (CMRI) images compared to unenhanced (UMRI) images for all matched lesions, using a 4-point scale (from 1 ("poor") to 4 ("excellent")). Data presented as mean paired differences for matched lesions per patient for CMRI and UMRI with 95% Confidence Intervals. One-sided paired t-test ( $\alpha=0.025$ ). Total N=85, n=number of patients with matched lesions (per reader).

# 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.

## 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.

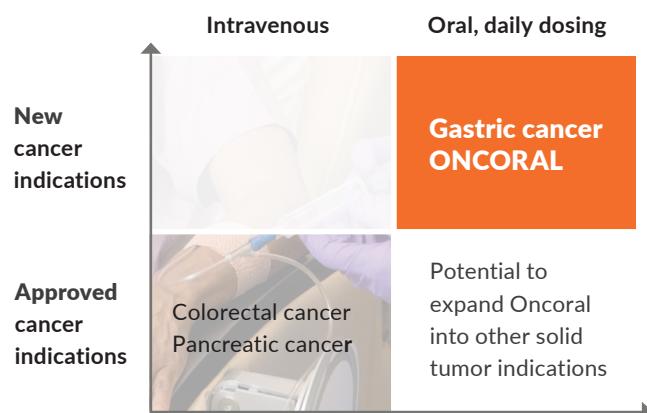
## Potential to be the first oral version of irinotecan

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.

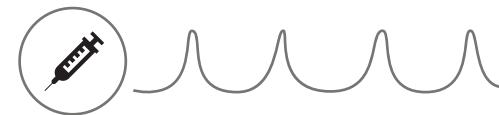
## All-oral chemo combination

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

<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



**TAIHO ONCOLOGY**

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

# FINANCIAL OVERVIEW Q4 (OCT-DEC 2025)

## EARNINGS AND PROFITABILITY

### Net sales and other operating income

The Group's net sales in Q4 (Oct-Dec 2025) amounted to SEK 0 (SEK 0). Other operating income totaled SEK 24 thousand (SEK 83 thousand). The income refers to exchange rate gains.

### Administrative costs

Administrative costs amounted to SEK 4.1 million (SEK 3.7 million). The cost increase compared to the same period last year is mainly driven by higher recognized costs for employee incentive programs.

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

R&D costs amounted to SEK 11.6 million (SEK 18.3 million). The cost decrease compared to the same period last year is related to the finalized NDA submission early September 2025.

### Commercial preparation costs

No costs for commercial preparations were reported in the period.

### Operating results (EBIT)

The operating result amounted to SEK -15.8 million (SEK -21.9 million). The cost decrease is related to the finalized NDA submission early September 2025.

### Net Profit/Loss for the period

The Group's net loss in Q4 2025 amounted to SEK -15.9 million (SEK -28.3 million). A net financial cost of SEK -0.2 million was recognized due to weakening of USD against SEK which translated into a decrease in the value of bank deposit. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.13 (SEK -0.29).

## CASH FLOW AND FINANCIAL POSITION

Cash flow from operating activities before changes in working capital amounted to SEK -13.8 million (SEK -21.3 million). Changes in working capital for the quarter showed an outflow of SEK -7.9 million (SEK 2.5 million) and reflect a large decrease in accounts payables as well as other liabilities. Cash flow from investing activities amounted to SEK 0 (SEK 0). Cash flow from financing activities amounted to an outflow of SEK -0.4 million (outflow of SEK -2.0 million) which relates to issuance expenses and amortization of lease liabilities.

On the closing date, equity amounted to SEK 99.5 million, compared with SEK 78.9 million per 31 December 2024. The increase since 31 December 2024 reflects the new share issue related to the warrants TO 1 in April 2025 and the directed new share issue carried out in September 2025 as well as the net loss incurred. Liquid assets amounted to SEK 49.9 million on the closing date, compared to SEK 75.3 million per 31 December 2024.

Financial key ratios for the Group	Q4 (October-December)	
	2025	2024
Operating result (SEK 000')	-15,779	-21,929
Net result (SEK 000')	-15,865	-28,332
Earnings per share (SEK)	-0.13	-0.29
Weighted avg. number of shares	126,840,387	96,091,733
R&D costs/operating costs (%)	73%	83%
Cash flow used in operating activities (SEK 000')	-21,692	-18,785
Equity (SEK 000')	99,472	78,944
Liquid assets incl. marketable securities (SEK 000')	49,861	75,256

# FINANCIAL OVERVIEW FULL YEAR (JAN-DEC 2025)

## EARNINGS AND PROFITABILITY

### Net sales and other operating income

The Group's net sales for the full year 2025 (Jan-Dec) amounted to SEK 0 (SEK 0). Other operating income totaled SEK 0.1 million (SEK 0.5 million). The income refers to exchange rate gains.

### Administrative costs

Administrative costs in the period amounted to SEK 17.3 million (SEK 18.0 million). The cost decrease compared to the same quarter last year, is mainly driven by lower recognized costs for employee incentive programs.

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

R&D costs amounted to SEK 56.8 million (SEK 50.8 million). The cost increase of SEK 6.0 million mainly reflects the costs for NDA preparations and submission.

### Commercial preparation costs

No costs for commercial preparations were reported in the period.

### Operating results (EBIT)

The operating result for the Group amounted to SEK -74.4 million (SEK -67.8 million). The increased loss mainly reflects the costs for NDA preparation and submission.

### Net Profit/Loss for the period

The Group's net loss in the period amounted to SEK -76.3 million (SEK -80.0 million). A net financial loss of SEK -2.3 million was recognized, which mainly reflects currency loss related to weakening of USD against SEK and arrangement fee expenses related to loans. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.67 (SEK -1.48).

## CASH FLOW

Cash flow from operating activities before changes in working capital amounted to SEK -70.2 million (SEK -66.4 million). Changes in working capital for the period showed an outflow of SEK -2.0 million (SEK 3.5 million) and reflect a decrease in accounts payable and other liabilities as well as a decrease in credits on the tax account.

Cash flow from investing activities amounted to an outflow of SEK -57 thousand (SEK 0). Cash flow from financing activities totaled an inflow of SEK 48.2 million (inflow of SEK 115.2 million). The inflow during the period is attributable to the net effect of proceeds from the warrants series TO 1 and repayment of the loan to Fenja in April 2025, and proceeds from the directed new share issue carried out in September.

## FINANCIAL POSITION

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 received net proceeds of SEK 41.5 million. In connection to the new share issuance a loan of SEK 20 million was repaid to Fenja.

In September 2025, Fenja converted all outstanding convertibles of SEK 7.5 million. Later in the month, we successfully completed a directed share issue, raising SEK 30 million before costs. With this fundraise, we broaden our investor base and strengthen our balance sheet. On the balance sheet date, liquid assets amounted to SEK 49.9 million.

We now have a cash runway into Q4 2026, well beyond the expected FDA approval date of Orviglance.

Financial key ratios for the Group	Full Year (January-December)	
	2025	2024
Operating result (SEK 000) <sup>1</sup>	-74,374	-67,766
Net result (SEK 000)	-76,253	-80,029
Earnings per share (SEK)	-0.67	-1.48
Weighted avg. number of shares	113,439,929	54,001,187
R&D costs/operating costs (%)	76%	74%
Cash flow used in operating activities (SEK 000)	-72,252	-62,844
Equity (SEK 000)	99,472	78,944
Liquid assets incl. marketable securities (SEK 000)	49,861	75,256

# OTHER INFORMATION

## Incentive programs

Ascelia Pharma has one outstanding employee option program and two 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 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 and the liability is recognized on an ongoing basis. 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 December 2025 are exercised in full, a total of 7.4 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 5.5 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

In April 2025 the warrants TO 1 were exercised. The warrants were 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 and a new fair value was calculated at each quarterly period which according to the accounting principles of IFRS 9, resulted in either a financial income or a financial cost. In 2025 a financial income of SEK 2.1 million was recognized related to TO 1. This income has no cash impact.

## Risks and uncertainties

Ascelia Pharma is exposed to a range of operational risks and uncertainties that affect, or could affect, its business, operations, financial position, and results. The risks assessed as having the greatest potential impact relate to clinical drug development, regulatory conditions, commercialization and licensing, intellectual property rights and other protective mechanisms, financing conditions, and broader macroeconomic factors. These include the effects of pandemics, geopolitical developments, inflation, and foreign exchange fluctuations.

The Group's overarching risk management approach is to mitigate and limit undesirable impacts on earnings and financial position. A detailed description of the Group's risks and uncertainties is provided in the Annual Report 2024 on pages 35-37.

Ascelia Pharma's research and development activities require continuous access to capital, and must therefore ensure that sufficient financing is available to support ongoing development and future growth. Revenue streams such as those generated through partnership agreements with pharmaceutical companies arise irregularly, which reinforces the importance of maintaining strong liquidity.

Depending on the timing of when cash flow becomes positive, Ascelia Pharma may require additional capital. There is a risk that such financing may not be available when needed or on favorable terms, which could negatively affect the business and create uncertainty regarding ongoing and future operations.

Ascelia Pharma currently has a cash runway extending into Q4 2026 and the financing of operations for the coming 12 months and beyond is therefore dependent on revenue or other financing sources. The Board of Directors continuously evaluates various financing possibilities and risks as described above and has concluded that the interim report can be prepared on a going concern basis in accordance with IAS 8.

## Significant events after the end of the reporting period

On 21 January, Ascelia Pharma announced that Deputy CEO Julie Waras Brogren will leave the company.

## Auditor's review

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

## Annual General Meeting (AGM) 2026

The AGM of Ascelia Pharma AB (publ) will be held on 4 May, 2026. Shareholders wishing to have a matter discussed at the AGM should send their suggestion by e-mail to: ir@ascelia.com or by mail to: ASCELIA PHARMA AB Hyllie Boulevard 34; SE-215 32 Malmö

## Dividend

In accordance with Ascelia Pharma's dividend policy, no dividend is proposed and available financial resources is reinvested in the business to finance the company's long-term strategy. The Board of Directors' intention is not to propose a dividend to shareholders before the company is able to generate a longterm sustainable profitability and a long-term sustainable positive cash flow.

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, 4 February 2026  
Ascelia Pharma AB (publ)

**Magnus Corfitzen**  
CEO

# Consolidated Income Statement

SEK in thousands (unless otherwise stated)*	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
	2025	2024	2025	2024
Net sales	-	-	-	-
<b>Gross profit/loss</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
Administrative costs	-4,117	-3,682	-17,314	-17,995
Research and development costs	-11,611	-18,328	-56,816	-50,798
Commercial preparation costs	-	-		669
Other operating income	24	83	148	459
Other operating costs	-75	-1	-391	-100
<b>Operating result</b>	<b>-15,779</b>	<b>-21,929</b>	<b>-74,374</b>	<b>-67,766</b>
Finance income	186	423	3,159	1,584
Finance costs	-339	-6,865	-5,507	-13,942
<b>Net financial items</b>	<b>-154</b>	<b>-6,442</b>	<b>-2,348</b>	<b>-12,358</b>
<b>Loss before tax</b>	<b>-15,933</b>	<b>-28,371</b>	<b>-76,721</b>	<b>-80,124</b>
Tax	67	39	468	94
<b>Loss for the period</b>	<b>-15,865</b>	<b>-28,332</b>	<b>-76,253</b>	<b>-80,029</b>
Attributable to:				
Owners of the Parent Company	-15,865	-28,332	-76,253	-80,029
Non-controlling interest	-	-	-	-
Earnings per share				
Before and after dilution (SEK)	-0.13	-0.29	-0.67	-1.48

# Consolidated Statement of Comprehensive Income

SEK in thousands (unless otherwise stated)*	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
	2025	2024	2025	2024
<b>Profit/loss for the period</b>	<b>-15,865</b>	<b>-28,332</b>	<b>-76,253</b>	<b>-80,029</b>
<b>Other comprehensive income</b>				
Currency translation of subsidiaries**	43	323	134	303
<b>Other comprehensive income for the period</b>	<b>43</b>	<b>323</b>	<b>134</b>	<b>303</b>
<b>Total comprehensive income for the period</b>	<b>-15,823</b>	<b>-28,009</b>	<b>-76,119</b>	<b>-79,726</b>

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

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

# Consolidated Balance Sheet

SEK in thousands*	31 Dec	
	2025	2024
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets	57,070	57,078
Tangible assets - Equipment	52	15
Right-of-use assets	885	109
<b>Total non-current assets</b>	<b>58,007</b>	<b>57,202</b>
<b>Current assets</b>		
Advance payments to suppliers	145	1,755
<b>Current receivables</b>		
Income tax receivables	1,014	632
Other receivables	1,756	5,054
Prepaid expenses and accrued income	1,159	1,022
Cash and bank balances	49,861	75,256
<b>Total current assets</b>	<b>53,935</b>	<b>83,718</b>
<b>Total assets</b>	<b>111,941</b>	<b>140,920</b>
<b>EQUITY</b>		
Share capital	127,903	97,193
Other paid-in capital	771,366	721,750
Reserve of exchange differences on translation	1,108	974
Loss brought forward (incl. net profit/loss for the period)	-800,904	-740,973
<b>Equity attributable to Parent Company shareholders</b>	<b>99,472</b>	<b>78,944</b>
<b>Total equity</b>	<b>99,472</b>	<b>78,944</b>
<b>LIABILITIES</b>		
<b>Long-term liabilities</b>		
Long-term interest bearing liabilities	-	-
Lease liabilities	72	-
<b>Total long-term liabilities</b>	<b>72</b>	<b>-</b>
<b>Current liabilities</b>		
Accounts payable	2,042	4,733
Tax payable	-	-
Other liabilities	973	19,113
Interest bearing liabilities	-	25,225
Current lease liabilities	898	172
Accrued expenses and deferred income	8,484	12,733
<b>Total current liabilities</b>	<b>12,397</b>	<b>61,976</b>
<b>Total liabilities</b>	<b>12,469</b>	<b>61,976</b>
<b>Total equity and liabilities</b>	<b>111,941</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

SEK in thousands*	Full Year (Jan-Dec)	
	2025	2024
<b>Equity at start of the period</b>	<b>78,944</b>	<b>74,328</b>
<b>Comprehensive income</b>		
Profit/loss for the period	-76,253	-80,029
Other comprehensive income	134	303
<b>Total comprehensive income</b>	<b>-76,119</b>	<b>-79,726</b>
<b>Transactions with shareholders</b>		
New issue of common shares	80,325	105,324
Settlement of debt for warrants	16,100	-12,385
New issue of C-shares	-	-
Common shares: Conversion from C-shares	-53	-26
C-shares: Resolution of C-shares	53	26
Issuance expenses	-3,808	-15,207
Call option premium in relation to loan facility	-	2,165
Share based remuneration to employees	4,030	4,446
<b>Total transactions with shareholders</b>	<b>96,647</b>	<b>84,343</b>
<b>Equity at end of the period</b>	<b>99,472</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*	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
	2025	2024	2025	2024
<b>Operating activities</b>				
Operating result	-15,779	-21,929	-74,374	-67,766
Expensed share based remuneration not included in cash flow	1,000	51	4,164	4,340
Adjustment for other items not included in cash flow	222	119	852	49
Interest received	186	735	811	773
Interest paid	-36	-1,366	-1,739	-5,224
Income tax paid/received	584	1,100	72	1,453
<b>Cash flow from operating activities before changes in working capital</b>	<b>-13,823</b>	<b>-21,290</b>	<b>-70,213</b>	<b>-66,374</b>
<b>Cash flow from changes in working capital</b>				
Increase (-)/Decrease (+) of advance payments	1,610	1,500	1,610	1,678
Increase (-)/Decrease (+) of operating receivables	-223	-2,867	3,402	-4,988
Increase (+)/Decrease (-) of accounts payable	-5,203	2,136	-2,687	3,206
Increase (+)/Decrease (-) of other liabilities	-4,052	1,736	-4,364	3,634
Change in working capital	-7,868	2,505	-2,039	3,530
<b>Cash flow used in operating activities</b>	<b>-21,692</b>	<b>-18,785</b>	<b>-72,252</b>	<b>-62,844</b>
<b>Investing activities</b>				
Investment in equipment	-	-	-57	-
Divestment of right-of-use assets	-	-	-	-
<b>Cash flow from investing activities</b>	<b>-</b>	<b>-</b>	<b>-57</b>	<b>-</b>
<b>Financing activities</b>				
New share issue	-	-	72,825	105,324
Transaction costs for issuance	-190	-756	-3,808	-15,207
Conversion from C-shares	-53	-26	-53	-26
Resolution of C-shares	53	26	53	26
Convertible bond issue	-	-	-	733
New loans	-	-990	-	32,725
Amortisation of loan	-	-	-20,000	-7,500
Amortisation of lease liabilities	-205	-230	-805	-887
<b>Cash flow from financing activities</b>	<b>-395</b>	<b>-1,975</b>	<b>48,212</b>	<b>115,187</b>
<b>Cash flow for the period</b>	<b>-22,087</b>	<b>-20,760</b>	<b>-24,097</b>	<b>52,343</b>
Cash and cash equivalents at start of period	72,275	95,718	75,256	21,855
Exchange rate differences in cash and cash equivalents	-327	298	-1,298	1,058
<b>Cash and cash equivalents at end of period</b>	<b>49,861</b>	<b>75,256</b>	<b>49,861</b>	<b>75,256</b>

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

# Parent Company – Income Statement

SEK in thousands*	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
	2025	2024	2025	2024
Net sales	250	55	482	214
<b>Gross profit/loss</b>	<b>250</b>	<b>55</b>	<b>482</b>	<b>214</b>
Administrative costs	-4,061	-3,640	-17,135	-17,825
Research and development costs	-11,539	-18,260	-55,112	-50,571
Commercial preparation costs	-	-	-	669
Other operating income	24	-	87	10
Other operating costs	-	-2	-85	-32
<b>Operating result</b>	<b>-15,326</b>	<b>-21,847</b>	<b>-71,762</b>	<b>-67,536</b>
Finance income	1,260	4,141	7,026	5,178
Finance costs	-303	-7,317	-5,369	-14,136
Result from other long-term receivables	-1,124	-1,907	-6,194	663
<b>Net financial costs</b>	<b>-167</b>	<b>-5,083</b>	<b>-4,537</b>	<b>-8,295</b>
Loss before tax	-15,492	-26,930	-76,300	-75,831
Tax	-	-	-	-
<b>Loss for the period</b>	<b>-15,492</b>	<b>-26,930</b>	<b>-76,300</b>	<b>-75,831</b>

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

# Parent Company – Balance Sheet

SEK in thousands*	31 Dec	
	2025	2024
<b>ASSETS</b>		
<b>Non-current assets</b>		
Tangible assets		
Equipment	52	15
Financial assets		
Shares in affiliated companies	58,068	58,068
Other long-term receivables from group companies	39,187	39,255
<b>Total non-current assets</b>	<b>97,307</b>	<b>97,338</b>
<b>Current assets</b>		
Advance payments to suppliers	145	1,755
<b>Current receivables</b>		
Receivables from group companies	3,229	2,560
Income tax receivables	551	534
Other receivables	1,702	5,011
Prepaid expenses and accrued income	1,151	1,004
Cash and bank balances	48,685	74,440
<b>Total current assets</b>	<b>55,462</b>	<b>85,303</b>
<b>Total assets</b>	<b>152,769</b>	<b>182,641</b>
<b>EQUITY</b>		
Restricted equity		
Share capital	127,903	97,193
Non-restricted equity		
Other paid-in capital	771,366	721,750
Loss brought forward	-681,632	-622,123
Loss for the period	-76,300	-75,831
<b>Total equity</b>	<b>141,336</b>	<b>120,989</b>
<b>LIABILITIES</b>		
<b>Long-term liabilities</b>		
Long-term interest bearing liabilities	-	-
<b>Total long-term liabilities</b>	<b>-</b>	<b>-</b>
<b>Current liabilities</b>		
Accounts payable	2,031	4,632
Other liabilities	973	19,113
Interest bearing liabilities	-	25,225
Accrued expenses and deferred income	8,428	12,683
<b>Total current liabilities</b>	<b>11,432</b>	<b>61,652</b>
<b>Total equity and liabilities</b>	<b>152,769</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 to 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 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 has

the largest impact on the value of the options, is the publicly traded share price.

The total recognized costs for the option program in FY 2025 including social security charges were SEK 3.1 million.

### Share saving programs

Ascelia Pharma has two active long-term incentive programs for employees in the form of performance-based share saving programs. The parameter, which has 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 FY 2025 were SEK 1.1 million.

# Notes

## Definitions of alternative performance measures

Alternative performance measures	Definition	Aim
<b>Operating results (TSEK)</b>	Profit before financial items and tax.	The performance measure shows the company's operational performance.
<b>Research and development costs/Operating costs (%)</b>	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*	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
	2025	2024	2025	2024
Administrative costs	-4,117	-3,682	-17,314	-17,995
R&D costs	-11,611	-18,328	-56,816	-50,798
Commercial preparation costs	-	-	-	669
Other operating costs	-75	-1	-391	-100
<b>Total operating costs</b>	<b>-15,803</b>	<b>-22,012</b>	<b>-74,521</b>	<b>-68,225</b>
<b>R&amp;D costs/Operating costs (%)</b>	<b>73%</b>	<b>83%</b>	<b>76%</b>	<b>74%</b>

## Financial calendar

Annual General Meeting 2026:	4 May 2026
Interim report Q1 2026 (Jan-Mar):	12 May 2026
Half-year report 2026 (Jan-Jun):	20 August 2026
Interim report 9M 2026 (Jan-Sep):	5 November 2026
Full-year report 2026 (Jan-Dec):	11 February 2027

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