



Half-Year Report 2025

January – June 2025

Orviglance® NDA Submission Approaching

KEY EVENTS IN Q2 2025

- Study on Orviglance® target patients accepted for presentation at the ISPOR 2025 conference
- Publication of scientific article on Orviglance 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

KEY EVENTS AFTER THE PERIOD

- Updated timeline for submission of the Orviglance NDA to take place early September 2025

“The NDA is essentially complete. The final electronic configuration of the file for the FDA is currently ongoing. This will be completed in two to three weeks after which the NDA will be submitted.”

KEY RATIOS GROUP

Q2 (Apr-Jun)		H1 (Jan-Jun)	
2025	2024	2025	2024
OPERATING RESULT (SEKm)			
-23.0	-11.3	-43.3	-28.0
EARNINGS PER SHARE (SEK)			
-0.20	-0.39	-0.43	-0.89
CASH FLOW FROM OPERATIONS (SEKm)			
-18.0	-12.0	-34.9	-27.0
LIQUID ASSETS (SEKm)			
60.4	29.8	60.4	29.8

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.

Our current focus is on bringing our lead asset, Orvigance through the regulatory approval process in the US. The New Drug Application (NDA) for Orvigance is essentially complete. The final electronic configuration of the file, required to meet US Food and Drug Administration (FDA) standards ("publishing"), is currently ongoing. This will be completed in two to three weeks and the NDA will be submitted by early September. The NDA incorporates guidance received from the FDA at our planned meeting earlier this year. Clinical development for 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).

It's encouraging to see the medical community welcoming Orvigance data for presentation in four oral presentations and five 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.

In April 2025, the successful exercise of warrants series TO 1 provided SEK 43 million additional financing before costs with a subscription rate of 96 percent. We now have a cash runway to at least end 2025, beyond the NDA submission. The runway includes reserved cash for a potential repayment of the SEK 7.5 million convertibles to Fenja end of 2025, but excludes financing from partnering.

We are excited about our continued progress with Orvigance and the NDA filing. Partnership discussions for the commercialization of Orvigance continue and we 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 early September 2025.

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.

"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".

We are also pleased to see the successful acceptances of Orvigance data for presentation at major scientific conferences. SPARKLE have been presented as Cutting-Edge Research at the Radiological Society of North America conference (RSNA) in November 2024. 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 five 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. Orvigance 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 Orvigance 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 April 2025, our TO1 warrants series was exercised with a subscription rate of 96 percent, providing SEK 43 million additional financing before costs. Following the warrant exercise and repayment of the SEK 20 million loan to Fenja, we have a sufficient cash runway to fund operations through at least the end of 2025. The liquidity forecast includes a potential repayment of Fenja's convertible loan of SEK 7.5 million but excludes financing from a potential partner.

Opportunities ahead in 2025 and beyond. With the successfully completed clinical development of Orvigance, we are pleased to advance Orvigance to the registration phase with the upcoming NDA submission. 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.

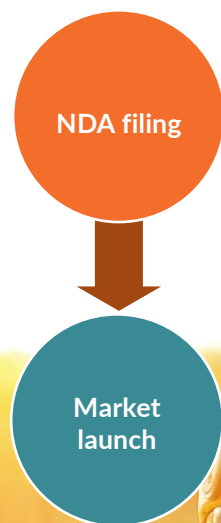
- First-in-class manganese-based diagnostic drug with FDA Orphan Drug Designation
- USD 800 million global annual addressable market
- Clinical development completed, incl. pivotal Phase 3, with consistent positive efficacy and safety data from nine clinical studies with 286 patients and healthy volunteers

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

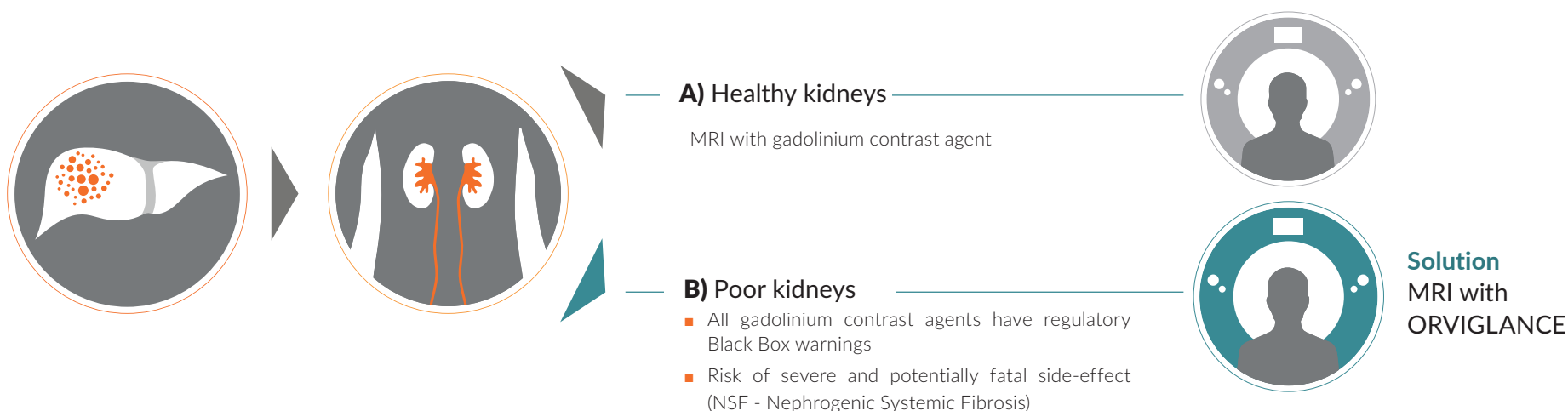
Orviglance is a contrast agent used in MRIs to improve the detection and visualization of focal liver lesions (liver metastases and primary tumors). The liver is the second most common organ for metastasis after the lymph nodes. Detecting liver metastases at an early stage is crucial for determining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

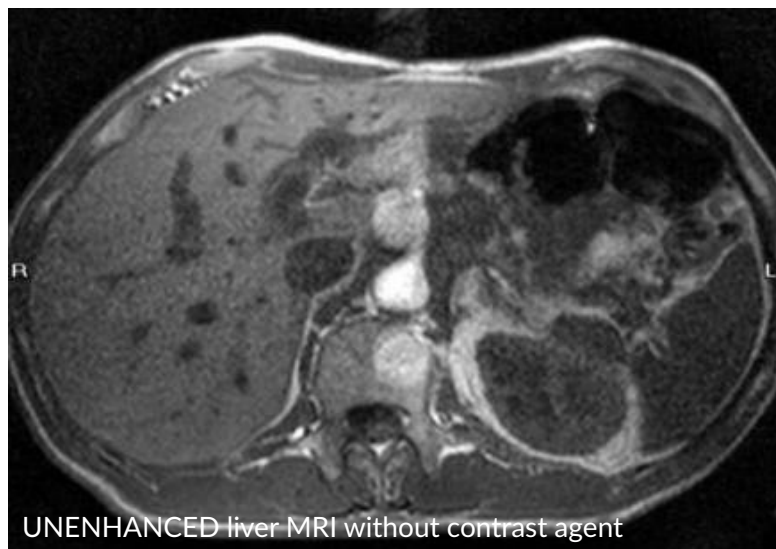
Orviglance is an orally administrated contrast agent developed for use with MRI of the liver. It is based on the chemical element manganese, which is a natural trace element in the body. Orviglance also contains L-alanine and vitamin D3 to enhance the function of manganese as a contrast agent. After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

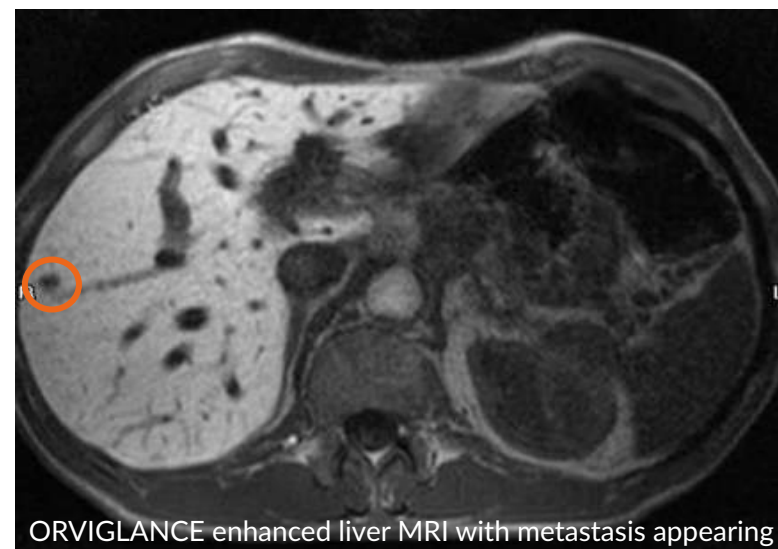
Clinical development of Orviglance has been completed with consistent positive efficacy and safety data from nine studies with 286 patients and healthy volunteers. The pivotal Phase 3 study for Orviglance, SPARKLE successfully met the primary endpoint and demonstrated that Orviglance significantly improved 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. The NDA file is essentially complete and the final electronic configuration for the FDA ("publishing") is currently ongoing. We expect to submit the NDA by early September 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

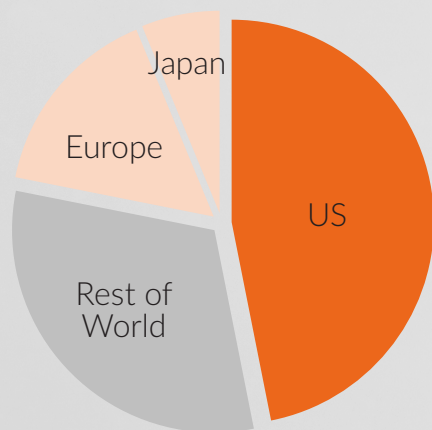
NUMBER OF PATIENTS	Global study with 85 patients	Strong positive Phase 3 results <ul style="list-style-type: none"> ■ For unenhanced images, the median BD and LC scores ranged from 2.1 to 3.0 across readers ■ For Orviglance-enhanced images, the median BD and LC scores increased to 3.0 and 4.0 across readers ■ Increases were statistically significant (p<0.001) for all three readers <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	Lesion visualization scoring using scales from 1 ('poor') to 4 ('excellent') for all lesions for each patient <ul style="list-style-type: none"> ■ Border delineation (BD, border sharpness of lesions) ■ Lesion contrast (LC, conspicuity compared to liver background) 	
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)¹
- Payer and expert input (+75 stakeholders)²



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 NSF³.

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 2025 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.

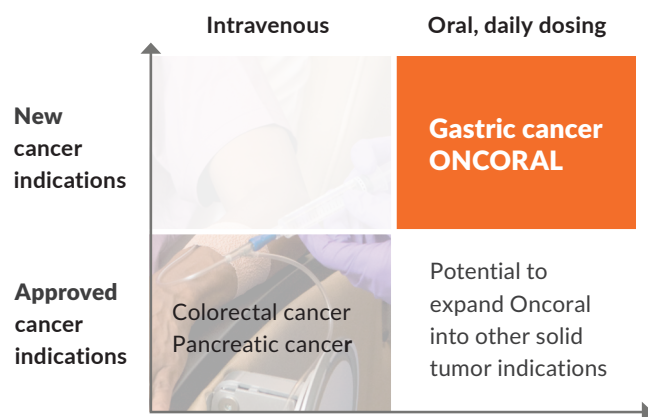
Potential to be the first oral version of irinotecan

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



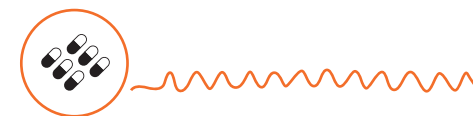
TODAY – Intravenous bolus infusions



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">■ Around 100 patients■ Metastatic gastric cancer
COMPARATOR	Oncoral + Lonsurf vs. Lonsurf
ENDPOINTS	Primary: Progression Free Survival Secondary: 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 Q2 (APR-JUN 2025)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q2 (Apr-Jun 2025) amounted to SEK 0 (SEK 0). Other operating income totalled SEK 0.1 million (SEK 10 thousand). The income refers to exchange rate differences.

Research and development costs (R&D)

R&D costs for the Group in Q2 2025, amounted to SEK 18.7 million (SEK 7.5 million). The cost increase compared to the same quarter last year is related to NDA submission preparations.

Administrative costs

Administrative costs for the Group in Q2 2025, amounted to SEK 4.4 million (SEK 4.5 million).

Commercial preparation costs

No costs for commercial preparations were reported in Q2 2025.

Operating results (EBIT)

The operating result in Q2 2025, amounted to SEK -23.0 million (SEK -11.3 million). The increased loss reflects the higher level of NDA preparations.

Net Profit/Loss for the period

The Group's net loss in Q2 2025 amounted to SEK -23.0 million (SEK -13.3 million). During Q2, net financial costs of SEK -0.2 million was recognized. Interest expenses have been lower in Q2 following the repayment of the loan of SEK 20 million to Fenja. During Q2, there has also been a recognized income of SEK 1.5 million related to the valuation of warrants. This income does not affect liquidity. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.20 (SEK -0.39).

CASH FLOW AND FINANCIAL POSITION

Cash flow from operating activities before changes in working capital in Q2 2025, amounted to SEK -21.8 million (SEK -14.6 million). Changes in working capital for the quarter totalled a positive impact of SEK 3.8 million (SEK 2.6 million). The changes in working capital mainly reflect an increase in other liabilities. Cash flow from investing activities in Q2 amounted to an outflow of SEK -57 thousand (SEK 0). Cash flow from financing activities amounted to an inflow of SEK 21.3 million (inflow of SEK 15.1 million). During Q2, the warrants series TO 1 generated net proceeds of SEK 41.5 million. During the quarter, the loan of SEK 20 million was repaid to Fenja.

On the closing date, equity amounted to SEK 93.7 million, compared with SEK 78.9 million per 31 December 2024 and SEK 47.7 million per 30 June 2024. The increase since 31 December 2024 and 30 June 2024 reflects the new share issue related to the warrants TO 1. With the net proceeds from the issuance, including the repayment of the SEK 20 million loan to Fenja, liquid assets amounted to SEK 60.4 million on the closing date, compared to SEK 75.3 million per 31 December 2024 and SEK 29.8 million per 30 June 2024.

Financial key ratios for the Group	Q2 (April-June)	
	2025	2024
Operating result (SEK 000')	-23,010	-11,328
Net result (SEK 000')	-22,983	-13,271
Earnings per share (SEK)	-0.20	-0.39
Weighted avg. number of shares	112,960,988	33,757,746
R&D costs/operating costs (%)	81%	66%
Cash flow used in operating activities (SEK 000')	-17,987	-11,966
Equity (SEK 000')	93,710	47,687
Liquid assets incl. marketable securities (SEK 000')	60,443	29,775

FINANCIAL OVERVIEW H1 (JAN-JUN 2025)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales during H1 2025 (Jan-Jun) amounted to SEK 0 (SEK 0). Other operating income totalled SEK 0.1 million (SEK 0.4 million). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group during H1 2025 amounted to SEK 34.3 million (SEK 18.3 million). The cost increase of SEK 16.0 million mainly reflects the costs for NDA submission preparations.

Administrative costs

Administrative costs for the Group in the period amounted to SEK 8.9 million (SEK 10.8 million). The cost decrease compared to the same quarter last year, is mainly driven by lower recognized costs for employee incentive programs.

Commercial preparation costs

No costs for commercial preparations were reported in H1 2025.

Operating results (EBIT)

The operating result for the Group in H1 2025 amounted to SEK -43.3 million (SEK -28.0 million). The increased loss mainly reflects the costs for NDA submission preparations.

Net Profit/Loss for the period

The Group's net loss in H1 2025 amounted to SEK -44.7 million (SEK -30.0 million). A net financial loss of SEK -1.7 million was recognized, which mainly reflects interest and arrangement fee expenses related to loans. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.43 (SEK -0.89).

CASH FLOW

Cash flow from operating activities before changes in working capital in H1 2025 amounted to SEK -42.4 million (SEK -26.0 million). Changes in working capital for the period totalled a positive impact of SEK 7.5 million (outflow of SEK -1.0 million). The changes in working capital mainly reflect an increase in other liabilities as well as repayment of advances from suppliers. Cash flow from investing activities amounted to an outflow of SEK -57 thousand (SEK 0). Cash flow from financing activities totalled an

inflow of SEK 21.1 million (inflow of SEK 34.0 million). The inflow during the period is attributable to the net proceeds from the warrants series TO 1 as well as the repayment of the loan of SEK 20 million to Fenja.

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. Remaining loans at Fenja consisting of convertibles, amounted to SEK 7.5 million on 30 Jun 2025.

On the balance sheet date, liquid assets amounted to SEK 60.4 million. We now have a cash runway to late 2025, beyond the NDA submission. This runway includes reserved cash for a potential repayment of the SEK 7.5 million convertibles end of 2025, but excludes financing from partnering.

Financial key ratios for the Group	H1 (January-June)	
	2025	2024
Operating result (SEK 000')	-43,343	-28,047
Net result (SEK 000')	-44,715	-29,965
Earnings per share (SEK)	-0.43	-0.89
Weighted avg. number of shares	104,005,455	33,757,746
R&D costs/operating costs (%)	79%	64%
Cash flow used in operating activities (SEK 000')	-34,902	-27,017
Equity (SEK 000')	93,710	47,687
Liquid assets incl. marketable securities (SEK 000')	60,443	29,775

OTHER INFORMATION

Incentive programs

Ascelia Pharma has one outstanding employee option program as well as three share saving programs. If the terms of the option program are met at the time for utilization, the employees has the right to purchase shares at a pre-determined price. For the share-saving 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 30 June 2025 are exercised in full, a total of 8.1 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 6.5 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

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. In April 2025, when the warrants were exercised, the value of the warrants reached SEK 16.1 million, which generated a total financial income of SEK 2.1 million in H1 2025. This income 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 15 August, Ascelia Pharma updated the timeline for the submission of the NDA to take place early September 2025.

Auditor's review

This interim report has 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.

The Board and the CEO declare that this Interim report provides a true and fair overview of the company and the Group's operations, positions and earnings and describes the material risks and uncertainty factors faced by the Parent company and the companies within the Group.

Malmö, 20 August 2025
Ascelia Pharma AB (publ)

Peter Benson
Chairman

Marianne Kock
Member of the board

Helena Wennerström
Member of the board

Lauren Barnes
Member of the board

Hans Maier
Member of the board

Magnus Corfitzen
CEO

This is a translation of the Swedish language original. In the event of any differences between this translation and the Swedish language original, the latter shall prevail.

AUDITOR'S REPORT

Ascelia Pharma AB (publ), corporate identity number 556571-8797. To the Board of Directors of Ascelia Pharma AB (publ).

Introduction

We have reviewed the condensed interim financial information (interim report) of Ascelia Pharma AB (publ) as of 30 June 2025 and the six-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Material uncertainty regarding the going concern assumption

We would like to draw attention to page 3 of the quarterly report, which shows that the company has a forecasted liquidity that extends to at least the end of 2025. This situation indicates that there is a material uncertainty that may lead to significant doubt about the company's ability to continue operations. We have not modified our statements.

Malmö, 20 August 2025
Öhrlings PricewaterhouseCoopers AB

Mikael Nilsson
Authorized Public Accountant

Consolidated Income Statement

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
SEK in thousands (unless otherwise stated)*	2025	2024	2025	2024
Net sales	-	-	-	-
Gross profit/loss	-	-	-	-
Administrative costs	-4,445	-4,536	-8,890	-10,763
Research and development costs	-18,657	-7,487	-34,319	-18,297
Commercial preparation costs	-	714	-	700
Other operating income	124	10	124	370
Other operating costs	-31	-30	-259	-57
Operating result	-23,010	-11,328	-43,343	-28,047
Finance income	1,839	330	2,547	993
Finance costs	-2,029	-2,275	-4,270	-2,941
Net financial items	-191	-1,945	-1,723	-1,948
Loss before tax	-23,201	-13,273	-45,066	-29,994
Tax	218	2	351	29
Loss for the period	-22,983	-13,271	-44,715	-29,965
Attributable to:				
Owners of the Parent Company	-22,983	-13,271	-44,715	-29,965
Non-controlling interest	-	-	-	-
Earnings per share				
Before and after dilution (SEK)	-0.20	-0.39	-0.43	-0.89

Consolidated Statement of Comprehensive Income

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
SEK in thousands (unless otherwise stated)*	2025	2024	2025	2024
Profit/loss for the period	-22,983	-13,271	-44,715	-29,965
Other comprehensive income				
Currency translation of subsidiaries**	-31	10	93	-52
Other comprehensive income for the period	-31	10	93	-52
Total comprehensive income for the period	-23,014	-13,261	-44,622	-30,017

* 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

	30 Jun	30 Jun	31 Dec
SEK in thousands*	2025	2024	2024
ASSETS			
Non-current assets			
Intangible assets	57,074	57,077	57,078
Tangible assets - Equipment	61	52	15
Right-of-use assets	1,200	541	109
Total non-current assets	58,335	57,670	57,202
Current assets			
Advance payments to suppliers	1,755	3,551	1,755
Current receivables			
Income tax receivables	1,402	1,517	632
Other receivables	2,446	578	5,054
Prepaid expenses and accrued income	949	1,866	1,022
Cash and bank balances	60,443	29,775	75,256
Total current assets	66,994	37,287	83,718
Total assets	125,329	94,957	140,920
EQUITY			
Share capital	117,113	34,871	97,193
Other paid-in capital	744,657	678,747	721,750
Reserve of exchange differences on translation	1,067	619	974
Loss brought forward (incl. net profit/loss for the period)	-769,127	-666,550	-740,973
Equity attributable to Parent Company shareholders	93,710	47,687	78,944
Total equity	93,710	47,687	78,944
LIABILITIES			
Long-term liabilities			
Long-term interest bearing liabilities	-	33,443	-
Lease liabilities	490	22	-
Total long-term liabilities	490	33,465	-
Current liabilities			
Accounts payable	4,312	2,668	4,733
Tax payable	-	1	-
Other liabilities	901	907	19,113
Interest bearing liabilities	6,961	-	25,225
Current lease liabilities	756	604	172
Accrued expenses and deferred income	18,201	9,624	12,733
Total current liabilities	31,129	13,804	61,976
Total liabilities	31,619	47,269	61,976
Total equity and liabilities	125,329	94,957	140,920

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

Consolidated Statements of Changes in Equity

	H1 (Jan-Jun)		Full Year (Jan-Dec)
SEK in thousands*	2025	2024	2024
Equity at start of the period	78,944	74,328	74,328
Comprehensive income			
Profit/loss for the period	-44,715	-29,965	-80,029
Other comprehensive income	93	-52	303
Total comprehensive income	-44,622	-30,017	-79,726
Transactions with shareholders			
New issue of common shares	42,827	-	105,324
Settlement of debt for warrants	16,100	-	-12,385
New issue of C-shares	-	-	-
Common shares: Conversion from C-shares	-	-	-26
C-shares: Resolution of C-shares	-	-	26
Issuance expenses	-1,323	-429	-15,207
Call option premium in relation to loan facility	-	1,433	2,165
Share based remuneration to employees	1,785	2,373	4,446
Total transactions with shareholders	59,388	3,377	84,343
Equity at end of the period	93,710	47,687	78,944

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

Consolidated Cash Flow Statement

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
SEK in thousands*	2025	2024	2025	2024
Operating activities				
Operating result	-23,010	-11,328	-43,343	-28,047
Expensed share based remuneration	1,581	-1,547	2,102	3,477
Adjustment for items not included in cash flow	163	232	436	469
Interest received	210	21	333	35
Interest paid	-542	-1,825	-1,492	-2,432
Income tax paid/received	-202	-148	-417	500
Cash flow from operating activities before changes in working capital	-21,799	-14,594	-42,382	-25,997
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	-	-297	-	-119
Increase (-)/Decrease (+) of operating receivables	1,042	378	2,820	-1,310
Increase (+)/Decrease (-) of accounts payable	-685	1,575	-436	1,142
Increase (+)/Decrease (-) of other liabilities	3,455	972	5,096	-734
Change in working capital	3,813	2,628	7,480	-1,020
Cash flow used in operating activities	-17,987	-11,966	-34,902	-27,017
Investing activities				
Investment in equipment	-57	-	-57	-
Divestment of right-of-use assets	-	-	-	-
Cash flow from investing activities	-57	-	-57	-
Financing activities				
New share issue	42,827	-	42,827	-
Transaction costs for issuance	-1,323	-172	-1,323	-429
Conversion from C-shares	-	-	-	-
Resolution of C-shares	-	-	-	-
Convertible bond issue	-	-	-	1,433
New loans	-	15,485	-	33,443
Amortisation of loan	-20,000	-	-20,000	-
Amortisation of lease liabilities	-173	-219	-402	-433
Cash flow from financing activities	21,331	15,094	21,102	34,014
Cash flow for the period	3,287	3,128	-13,857	6,997
Cash and cash equivalents at start of period	57,300	26,542	75,256	21,855
Exchange rate differences in cash and cash equivalents	-144	104	-955	923
Cash and cash equivalents at end of period	60,443	29,775	60,443	29,775

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

Parent Company – Income Statement

	Q2 (Apr-Jun)		H1 (Jan-Jun)	
SEK in thousands*	2025	2024	2025	2024
Net sales	70	44	137	138
Gross profit/loss	70	44	137	138
Administrative costs	-4,428	-4,496	-8,814	-10,661
Research and development costs	-17,730	-7,488	-32,807	-18,213
Commercial preparation costs	-	714	-	700
Other operating income	63	3	63	3
Other operating costs	-	-1	-53	-29
Operating result	-22,025	-11,224	-41,474	-28,061
Finance income	2,750	327	4,322	870
Finance costs	-1,982	-2,256	-4,210	-2,898
Result from other long-term receivables	-870	1,050	-4,595	1,797
Net financial costs	-102	-879	-4,483	-230
Loss before tax	-22,127	-12,103	-45,957	-28,292
Tax	-	-	-	-
Loss for the period	-22,127	-12,103	-45,957	-28,292

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

Parent Company – Balance Sheet

	30 Jun	30 Jun	31 Dec
SEK in thousands*	2025	2024	2024
ASSETS			
Non-current assets			
Tangible assets			
Equipment	61	52	15
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	36,436	37,303	39,255
Total non-current assets	94,566	95,423	97,338
Current assets			
Advance payments to suppliers	1,755	3,551	1,755
Current receivables			
Receivables from group companies	2,853	2,234	2,560
Income tax receivables	947	1,164	534
Other receivables	2,019	546	5,011
Prepaid expenses and accrued income	949	1,844	1,004
Cash and bank balances	60,164	29,303	74,440
Total current assets	68,686	38,642	85,303
Total assets	163,251	134,065	182,641
EQUITY			
Restricted equity			
Share capital	117,113	34,871	97,193
Non-restricted equity			
Other paid-in capital	744,657	678,747	721,750
Loss brought forward	-681,393	-597,764	-622,123
Loss for the period	-45,957	-28,292	-75,831
Total equity	134,420	87,563	120,989
LIABILITIES			
Long-term liabilities			
Long-term interest bearing liabilities	-	33,443	-
Total long-term liabilities	-	33,443	-
Current liabilities			
Accounts payable	2,795	2,609	4,632
Other liabilities	901	907	19,113
Interest bearing liabilities	6,961	-	25,225
Accrued expenses and deferred income	18,176	9,544	12,683
Total current liabilities	28,832	13,060	61,652
Total equity and liabilities	163,251	134,065	182,641

* 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 H1 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 H1 2025 including social security charges were SEK 1.3 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 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 H1 2025 were SEK 0.8 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

SEK in thousands*	Q2 (April-June)		H1 (January-June)	
	2025	2024	2025	2024
R&D costs	-18,657	-7,487	-34,319	-18,297
Administration costs	-4,445	-4,536	-8,890	-10,763
Commercial preparation costs	-	714	-	700
Other operating costs	-31	-30	-259	-57
Total operating costs	-23,133	-11,339	-43,468	-28,417
R&D costs/Operating costs (%)	81%	66%	79%	64%

Financial calendar

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

5 November 2025
5 February 2026

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