ASCELIA PHARMA
Advancing Orphan Oncology

Interim Report 9M 2024

January – September 2024

Successful Outcome from Rights Issue with SEK 105 Million Extends Runway Until Late 2025

KEY EVENTS IN Q3 2024

- Ascelia Pharma carries out a Rights Issue of units of approximately SEK 105 million
- Notice of and bulletin from Extraordinary General Meeting on 14 August
- Announcement of outcome in fully subscribed SEK 105 million Rights Issue with runway extended to late 2025
- Ascelia Pharma resolves on a directed issue of convertibles of SEK 7.5 million
- Change in number of votes and shares in Ascelia Pharma AB

KEY EVENTS AFTER THE PERIOD

- Orviglance SPARKLE study primary results accepted as cutting-edge oral presentation at RSNA 2024
- Proposal for election of Marianne Kock as new member of the Board of Directors
- Notice of and bulletin from Extraordinary General Meeting on 30 October
- Orviglance SPARKLE data to be presented as late breaking abstract at Kidney Week 2024
- Completion of Full Study Report reinforces the successful outcomes of SPARKLE

"With the completion of the Full Study Report, we are pleased to pass yet another milestone on our path to obtaining regulatory approval and entering into commercialization partnerships for Orviglance."

KEY RATIOS GROUP

	Q3 (Jul-Sep)		9M (Jan-Sep)	
	2024	2023	**2024**	2023
OPERATING RESULT (SEKm)	**-17.8**	-21.4	**-45.8**	-99.9
EARNINGS PER SHARE (SEK)	**-0.42**	-0.63	**-1.30**	-2.93
CASH FLOW FROM OPERATIONS (SEKm)	**-17.0**	-31.0	**-44.1**	-110.9
LIQUID ASSETS (SEKm)	**95.7**	39.0	**95.7**	39.0

CEO STATEMENT

We have met a major milestone this year with the successful headline results from our pivotal Phase 3 study, SPARKLE and hereby the completion of clinical development for Orviglance. The results showed that Orviglance significantly improved the visualization of focal liver lesions, successfully meeting the primary endpoint with statistical significance for all three readers (<0.001). As communicated early November, the Full Study Report has also been completed and includes the results of secondary endpoints, which further reinforce the successful study outcomes and support the NDA process and potential clinical value of Orviglance.

The Rights Issue financing launched in July was completed early September with a fully subscribed SEK 105 million financing. With the full financing in place, the cash runway of the company extends until late 2025 well beyond the NDA submission.

With this financing in place we are in a strong position to deliver on our key priorities ahead; bringing Orviglance through the regulatory submission and approval process with a submission of the New Drug Application (NDA) to the US Food and Drug Administration (FDA) expected by mid-2025 and continue. In parallel, we continue to advance the dialogue with potential commercialization partners to launch Orviglance and make it available to patients in need of a high-quality liver imaging option without gadolinium-related safety risks.

Positive Orviglance Phase 3 results. As announced in May 2024, the pivotal Phase 3 study for Orviglance, SPARKLE successfully met the primary endpoint and demonstrated that the company's magnetic resonance imaging (MRI) contrast agent, Orviglance 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.

Early November, we announced the planned completion of the Full Study Report. It includes the previously announced strong results of primary endpoints. In addition, the results of secondary endpoints further reinforce the successful study outcomes and support the NDA process.

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.

Completion of Orviglance clinical development. With the positive headline results for SPARKLE, clinical development of Orviglance 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 Orviglance. We will now focus on bringing Orviglance through the regulatory submission and approval process. We expect to submit the NDA file to the FDA by mid-2025 to obtain regulatory approval.

In parallel, we continue to advance the dialogues with potential commercialization partners to make Orviglance available to patients who need high-quality liver imaging without the safety risks associated with gadolinium.

”We have met a major milestone with the successful results from our Orviglance Phase 3 study. We look forward to meeting the regulatory milestones ahead and to progress commercial partnering on our journey to making Orviglance available to patients”.

Recognition in the scientific community. We are pleased to see the first successful acceptances of our SPARKLE data for presentation at prestigious scientific conferences. This underscores the support for an alternative to gadolinium-based contrast agents for patients with reduced kidney function in the medical and scientific community.

Early October, we announced the acceptance of Orviglance SPARKLE study primary results as an oral presentation in Cutting-Edge Research at the annual conference of the Radiological Society of North America, RSNA 2024; the world's largest radiology conference. Later in October, we announced the acceptance of an abstract on SPARKLE data as part of the Late-Breaking Science Posters session at American Society of Nephrology Kidney Week Congress 2024.

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

Our commercialization strategy is to launch 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 that Orviglance is ready for our partner's launch when approved.

Strengthened financial position. In September we completed a fully subscribed Rights Issue of units, consisting of ordinary shares and warrants, reaching SEK 105 million before costs. This financing ensures that we have a solid financial position, which will strengthen our ability to obtain an attractive agreement with commercialization partners. It also ensures that we can complete all activities for the NDA submission by mid-2025.

With the fully subscribed Rights Issue and the remaining loan and convertibles issued to Fenja, the company has a cash runway to late 2025, well beyond the NDA submission. This cash runway excludes potential payments from commercialization partnerships and financing from exercise of issued warrants series TO 1 of up to SEK 70 million as well as the repayment of the remaining SEK 27.5 million loans to Fenja.

A transformative 2024 with opportunities ahead. With positive headline results from SPARKLE and the successful Rights Issue financing, we are excited to advance Orviglance to the registration phase and make it available for patients together with a partner.

I would like to thank our long-term and new shareholders for the continued support. We have an exiting journey ahead of us with opportunities for growing Ascelia Pharma into 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

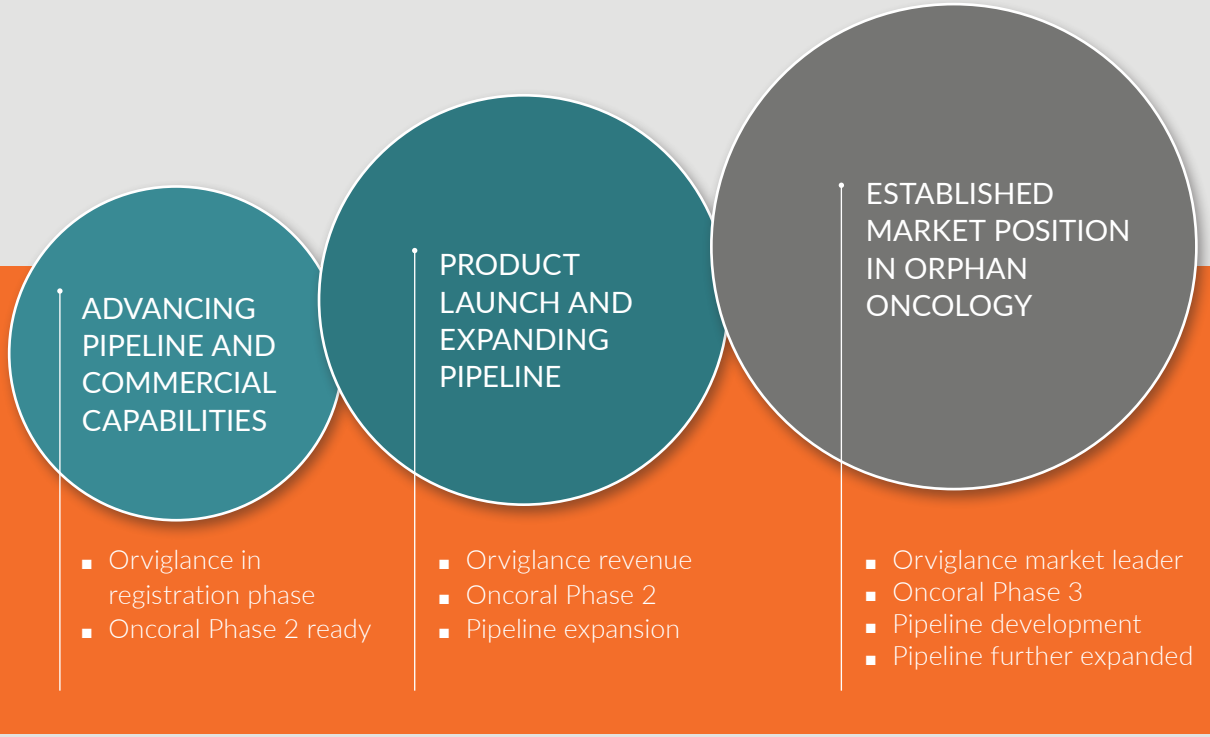
To be a leader in identifying, developing and commercializing novel drugs that address unmet needs of people with rare cancer conditions.

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



OUR PIPELINE

ORVIGLANCE
Diagnostic drug for liver MRI in registration phase

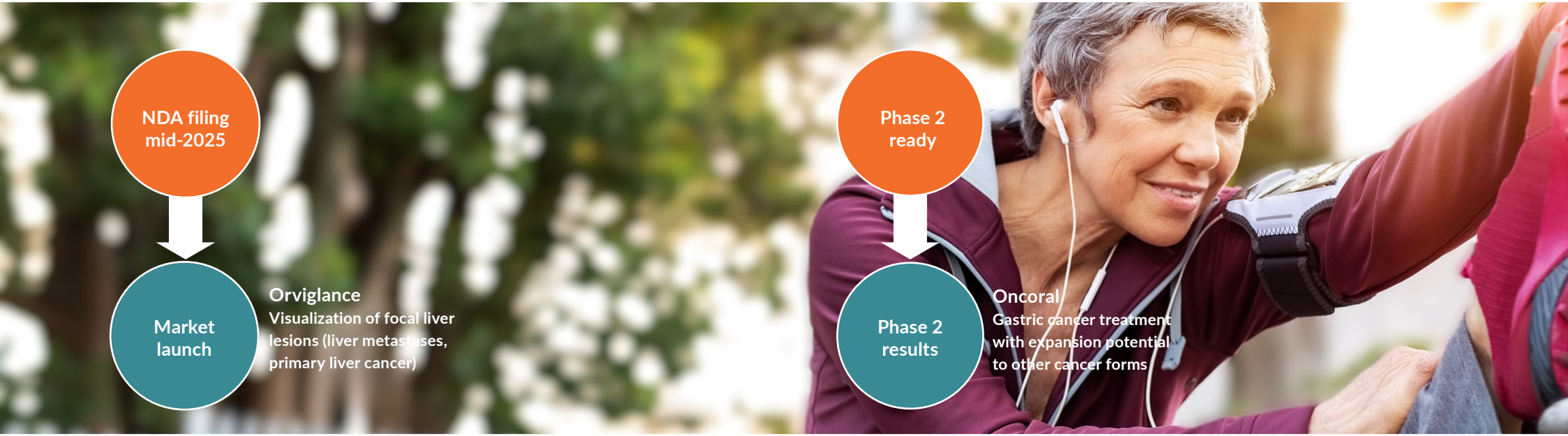
Orviglance is our first-in-class non-gadolinium diagnostic drug (contrast agent) to be used for magnetic resonance imaging (MRI) of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases and primary liver cancer) in patients with impaired kidney function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

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

ONCORAL
Daily tablet chemotherapy ready for Phase 2

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

- Oral daily dosing of irinotecan chemotherapy
- Potential for better efficacy and safety by frequent low dosing
- Ready for Phase 2 in gastric cancer; potential to expand into other cancers



ORVIGLANCE 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.

$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.

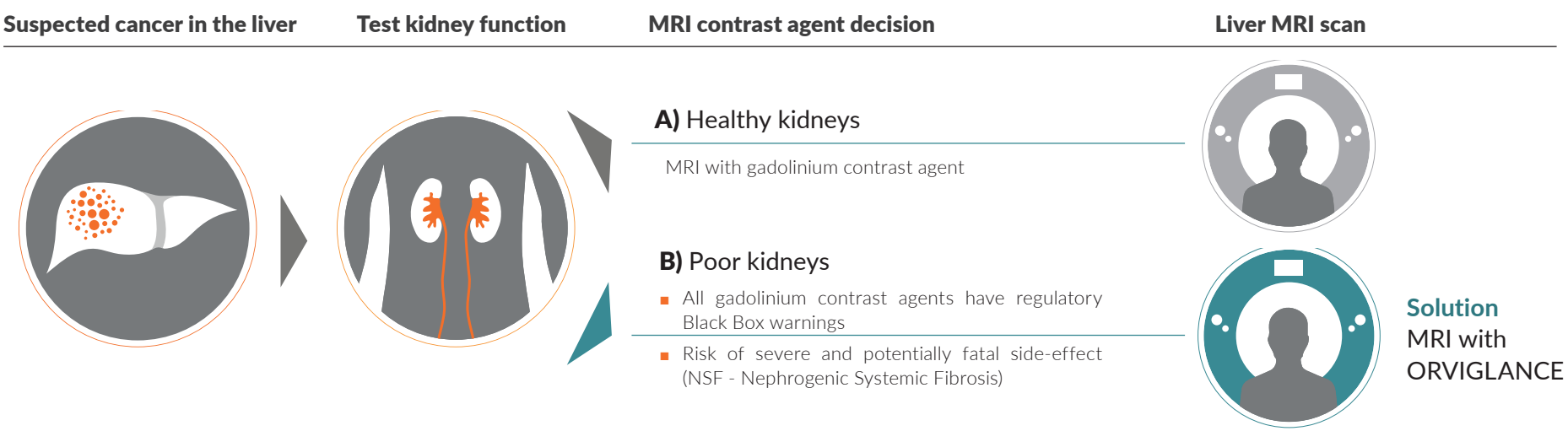
The immediate addressable market for Orviglance is estimated at $800 million yearly and Orviglance is expected to be the only gadolinium-free product on the market for this patient segment.

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 possibilityfor surgical resection, but also for monitoring of treatment effect and surveillance for recurrence of the disease.



ORVIGLANCE CLINICAL DEVELOPMENT COMPLETED

Orphan liver MRI contrast agent in registration phase

How Orviglance works

Orviglance is an orally 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

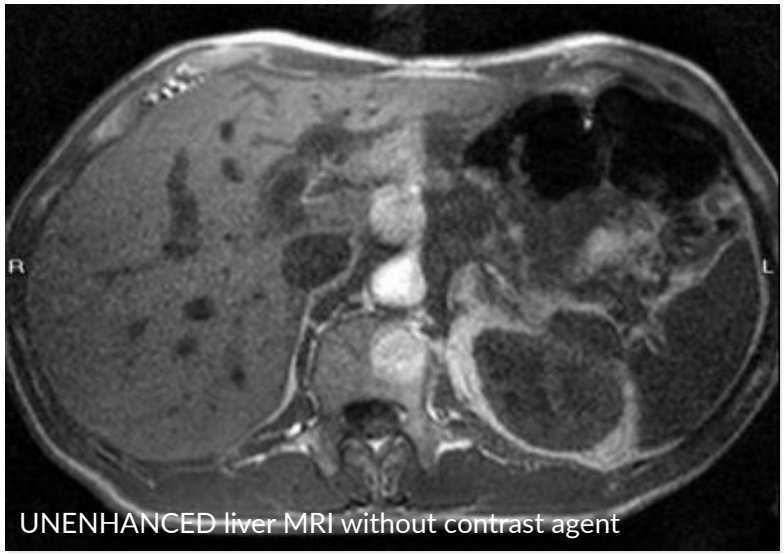
Clinical development of Orviglance has been completed with consistent positive efficacy and safety data from nine studies with 286 patients and healthy volunteers.

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.

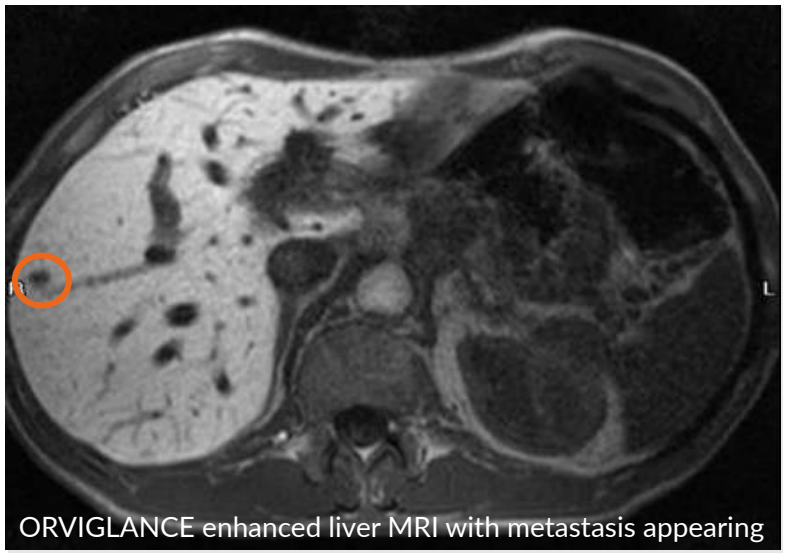
Common adverse events in this vulnerable patient population were in line with previous studies with Orviglance, such as mild- to moderate nausea. No serious adverse drug reactions were observed.

Advanced to registration phase

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



UNENHANCED liver MRI without contrast agent



ORVIGLANCE enhanced liver MRI with metastasis appearing

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 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**
PRIMARY ENDPOINT	**Lesion visualization scoring using scales from 1 ('poor') to 4 ('excellent') for all lesions for each patient** ■ 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**

Strong positive Phase 3 results

- For unenhanced images, the median BD and LC scores rangedfrom 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

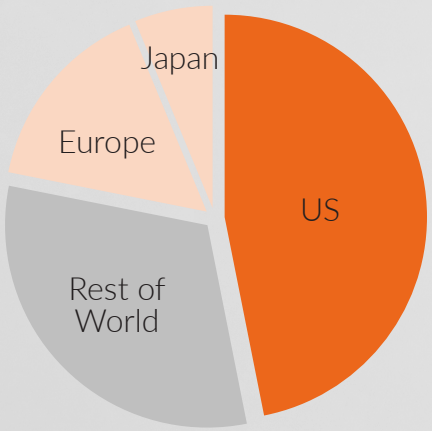
The results for secondary endpoints generally support the superiority of Orviglance to unenhanced MRI and no analysis favours unenhanced MRI. This includes e.g. detection of lesions and patient sub-group analysis

ANNUAL ADDRESSABLE MARKET OF $800 MILLION

Clear and attractive addressable market

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

- Patients with primary liver cancer or liver metastases and severe kidney impairment (~4 percent)
- Actual imaging procedures (real-world data)[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 NSF[3].

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

Partnering strategy

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

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

UNIQUE OPPORTUNITY

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

CLEAR AMBITION

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

FOCUSED, AMBITIOUS STRATEGY

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

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

1) Ascelia Pharma market research on real-world volumes with DRG (2020)
2) Market access research and analyses with Charles River Associates (2020), Triangle (2022) and Trinity (2022), incl. 75 stakeholder and expert interactions. Final pricing and access strategy subject to Phase 3 data and payer evidence
3) Ascelia Pharma market research with Two Labs including 254 US HCPs (2022).

POTENTIAL BENEFITS OF DAILY DOSING

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

Proven anti-cancer effect

The active substance in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is a so-called antineoplastic agent that after metabolic activation inhibits the enzyme topoisomerase 1, thereby inducing cancer cell death via the prevention of their DNA replication. Irinotecan is converted by carboxylesterases, primarily in the liver, to the active metabolite SN-38 which is 100–1,000 more potent than irinotecan in killing tumor cells.

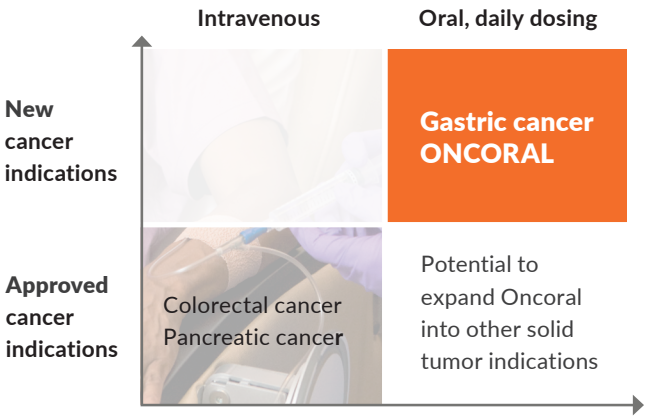
Potential to be the first oral version of irinotecan

Oncoral is a new patented oral tablet formulation of irinotecan, which enables a reliable release and efficient absorption of irinotecan from the gastro intestinal tract after oral administration. With oral administration, irinotecan can be given with low daily doses. This is very different from the current standard of giving a high intravenous doses every third week.

All-oral chemo combination

Oncoral has the potential to be combined with other chemotherapies and targeted cancer drugs and enable an all oral combination chemotherapy option with improved clinical outcomes.

ONCORAL – a novel formulation of irinotecan



TODAY – Intravenous bolus infusions

Infrequent high-dose IV irinotecan

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

TOMORROW – Oncoral oral daily dosing

Potential – Frequent low-dose irinotecan

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

PHASE 2 STUDY DESIGN AND COLLABORATION

Phase 2 study design

PATIENTS	■ 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 Q3 (JUL-SEP 2024)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q3 (Jul-Sep 2024) amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognize revenue before products have been launched on the market. Other operating income totalled SEK 6 thousand (SEK 0.5 million). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in Q3 amounted to SEK 14.2 million (SEK 14.0 million). The costs during the quarter are primarily related to preparations for the NDA submission.

Commercial preparation costs

During Q3, the costs related to commercial preparations amounted to SEK 31 thousand (SEK 2.6 million). The costs are related to recognized costs for employee incentive programs.

Administration costs

Administration costs for the Group in Q3 amounted to SEK 3.6 million (SEK 4.9 million). The decrease in costs primarily reflects a reduced cost for employees.

Operating results (EBIT)

The operating result in Q3 amounted to SEK -17.8 million (SEK -21.4 million). The decreased loss reflects a reduced cost for employees as well as a decrease in costs for commercial preparation following the strategic focus on a partnered launch.

Financial key ratios for the Group	Q3 (Jul-Sep)	
	2024	2023
Operating result (SEK 000')	-17,790	-21,362
Net result (SEK 000')	-21,732	-21,219
Earnings per share (SEK)	-0.42	-0.63
Weighted avg. number of shares	51,370,478*	33,722,762
R&D costs/operating costs (%)	80%	77%
Cash flow used in operating activities (SEK 000')	-17,043	-31,031
Equity (SEK 000')	107,582	84,568
Liquid assets incl. marketable securities (SEK 000')	95,718	38,992

*In September, the number of ordinary shares increased to 96.079.722 showing a small effect on earnings per share for the quarter. The weighted avg. numbers of shares will increase in coming quarters resulting in a higher impact on earnings per share.

Net Profit/Loss for the period

The Group's net loss in Q3 amounted to SEK -21.7 million (SEK -21.2 million). During Q3, net financial costs of SEK -4.0 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 -0.42 (SEK -0.63).

CASH FLOW

Cash flow from operating activities before changes in working capital in Q3 amounted to SEK -19.1 million (SEK -21.5 million). Changes in working capital for the quarter totalled a positive impact of SEK 2.0 million (outflow of SEK -9.5 million). The changes in working capital reflect an increase in other liabilities. Cash flow from investing activities in Q3 amounted to SEK 0 (inflow of SEK 47 thousand). Cash flow from financing activities amounted to an inflow of SEK 83.1 million (outflow of SEK -0.2 million), which reflects the net proceeds from the issuance in September.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 107.6 million, compared with SEK 74.3 million per 31 December 2023 and SEK 84.6 million per 30 September 2023. The increase since 31 December 2023 reflects the issuance of shares. With the net proceeds from the issuance, liquid assets amounted to SEK 95.7 million on the closing date, compared to SEK 21.9 million per 31 December 2023 and SEK 39.0 million per 30 September 2023.

The Rights Issue comprised a maximum of 20,773,992 units whereof each unit consists of three (3) ordinary shares and one (1) warrant series TO 1. The new ordinary shares (62,321,976) and warrants series TO 1 (20,773,992) was admitted to trading on Nasdaq Stockholm in September.

Upon exercise of issued warrants series TO 1, Ascelia Pharma might receive additional proceeds of approximately SEK 21 – 70 million in April 2025, before issue costs.

FINANCIAL OVERVIEW 9M (JAN–SEP 2024)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales during the first 9 months 2024 (Jan-Sep) amounted to SEK 0 (SEK 0). Ascelia Pharma does not expect to recognize revenue before products have been launched on the market. Other operating income totalled SEK 0.5 million (SEK 1.2 million). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group during 9M amounted to SEK 32.5 million (SEK 74.8 million). The cost decrease of SEK 42.3 million reflects the completion of SPARKLE patient recruitment activities and previous communicated cost-cutting initiatives.

Commercial preparation costs

During the first 9 months 2024, a positive result of SEK 0.7 million (SEK -11.3 million) was recognized. The positive effect is related to cost savings for employees as well as the reduced activity related to commercial preparations.

Administration costs

Administration costs for the Group in 9M amounted to SEK 14.3 million (SEK 14.3 million). The costs are mainly related to cost for employees.

Operating results (EBIT)

The first 9 months 2024 show an operating result of SEK -45.8 million (SEK -99.9 million). The decreased loss mainly reflects the implemented cost-cutting initiatives with focus to complete the NDA.

Net Profit/Loss for the period

The Group's net loss in 9M 2024 amounted to SEK -51.7 million (SEK -98.7 million). In the period, a net financial loss of SEK -5.9 million was recognized, which mainly reflects interest expenses related to loans. The net loss corresponds to a loss per share, before and after dilution, of SEK -1.30 (SEK -2.93).

FINANCIAL POSITION AND CASH FLOW

Cash flow from operating activities before changes in working capital in 9M 2024 amounted to SEK -45.1 million (SEK -97.7 million). The decreased outflow reflects the lower level of activities following the completion of clinical development for Orviglance. Cash flow from investing activities amounted to SEK 0 (inflow of SEK 47 thousand). Cash flow from financing activities totalled an inflow of SEK 117.2 million (outflow of SEK -0.7 million). The inflow during the period is attributable to loans received and the net cash from the completed Rights Issue.

On the closing date, equity amounted to SEK 107.6 million, compared with SEK 74.3 million per 31 December 2023 and SEK 84.6 million per 30 September 2023. The increase since 31 December 2023 reflects the issuance of shares. With the net proceeds from the issuance, liquid assets amounted to SEK 95.7 million on the closing date, compared to SEK 21.9 million per 31 December 2023 and SEK 39.0 million per 30 September 2023.

The Rights Issue launched on 10 July 2024 was completed with a fully subscribed SEK 105 million. No guarantee commitments were executed.

The financing announced on 4 February 2024 consisted of a loan and convertible financing of SEK 35 million. As part of the Rights Issue, a SEK 7.5 million partial repayment of the outstanding amount under the convertibles issued to Fenja Capital II A/S (Fenja) was carried out. The Company has also issued new convertibles to Fenja for a total nominal amount of SEK 7.5 million by offsetting the corresponding amount outstanding under the convertibles issued in February 2024.

The Rights Issue was carried out to secure the resources required to finalize the Orviglance NDA and to secure partnerships for the market launch of Orviglance. With the fully subscribed Rights Issue and the remaining loan and convertibles issued to Fenja, the company has a cash runway to late 2025, well beyond the NDA submission. This cash runway excludes potential payments from commercialization partnerships and financing from exercise of issued warrants series TO 1 of up to SEK 70 million as well as the repayment of the remaining SEK 27.5 million loans to Fenja.

Financial key ratios for the Group	9M (January-September)	
	2024	2023
Operating result (SEK 000')	-45,837	-99,861
Net result (SEK 000')	-51,697	-98,689
Earnings per share (SEK)	-1.30	-2.93
Weighted avg. number of shares	39,671,510*	33,711,982
R&D costs/operating costs (%)	70%	78%
Cash flow used in operating activities (SEK 000')	-44,060	-110,865
Equity (SEK 000')	107,582	84,568
Liquid assets incl. marketable securities (SEK 000')	95,718	38,992

*In September, the number of ordinary shares increased to 96.079.722 showing a small effect on earnings per share year to date. The weighted avg. numbers of shares will increase in coming quarters resulting in a higher impact on earnings per share.

OTHER INFORMATION

Incentive programs

Ascelia Pharma has one outstanding employee option program as well as four share saving programs. If the terms of the option program are met at the time for utilization, employees have the right to purchase shares at a pre-determined price. For the share-saving program, employees are entitled to receive matching and performance shares according to the terms of the program.

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

In case all outstanding incentive programs per 30 Sep 2024 (incl. a new share-saving program approved by the AGM in May 2024) are exercised in full, a total of 4.9 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 4.8 percent of Ascelia Pharma's share capital after full dilution (calculated on the number of common shares that will be added upon full exercise of all incentive programs).

Warrants TO 1

The warrants are valued at fair value based on the necessary variables using a Monte Carlo simulation. A first valuation was made after the Rights Issue in September, which yielded a value of SEK 12.4 million. This value is recognized as a liability on the balance sheet. A new fair value is calculated at each quarterly period. On September 30, 2024, the value of the warrants was SEK 12.6 million, which generates a financial cost of SEK 0.2 million in Q3 2024. The cost has no cash impact.

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

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

From an operational perspective, the Company is exposed to a number of risks and uncertainties which impact, or could impact, it's 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 2023 on pages 35–37.

Significant events after the end of the reporting period

Late-Breaking Abstract on SPARKLE Data was presented at the American Society of Nephrology Kidney Week Congress in October, 2024.

Orviglance SPARKLE Study Primary Results has been accepted as an oral presentation in Cutting-Edge Research at the 2024 RSNA Annual Meeting in December.

Ascelia Pharma has announced a proposal for election of Marianne Kock as a new member of the Board of Directors and therefore convened an Extraordinary General Meeting on 30 October. Bulletin from the meeting is available on the website.

Early November, the planned completion of the Full Study Report was announced.

Auditor's review

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

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

Malmö, 6 November 2024
Ascelia Pharma AB (publ)

Magnus Corfitzen
CEO

Consolidated Income Statement

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands (unless otherwise stated)**	2024	2023	2024	2023
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	**–**	**–**
Administrative costs	-3,550	-4,929	-14,313	-14,302
Research and development costs	-14,173	-13,953	-32,470	-74,784
Commercial preparation costs	-31	-2,589	669	-11,343
Other operating income	6	494	376	1,230
Other operating costs	-42	-386	-99	-662
Operating result	**-17,790**	**-21,362**	**-45,837**	**-99,861**
Finance income	168	586	1,161	2,665
Finance costs	-4,136	-478	-7,077	-1,702
Net financial items	**-3,968**	**108**	**-5,916**	**963**
Loss before tax	**-21,758**	**-21,255**	**-51,753**	**-98,898**
Tax	26	35	55	209
Loss for the period	**-21,732**	**-21,219**	**-51,697**	**-98,689**
Attributable to:				
Owners of the Parent Company	-21,732	-21,219	-51,697	-98,689
Non-controlling interest	–	–	–	–
Earnings per share				
Before and after dilution (SEK)	-0.42	-0.63	-1.30	-2.93

Consolidated Statement of Comprehensive Income

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands (unless otherwise stated)**	2024	2023	2024	2023
Profit/loss for the period	**-21,732**	**-21,219**	**-51,697**	**-98,689**
Other comprehensive income				
Currency translation of subsidiaries**	32	-177	-20	-568
Other comprehensive income for the period	**32**	**-177**	**-20**	**-568**
Total comprehensive income for the period	**-21,700**	**-21,397**	**-51,717**	**-99,256**

* 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**	30 Sep 2024	30 Sep 2023	31 Dec 2023
ASSETS			
Non-current assets			
Intangible assets	57,076	57,078	57,074
Tangible assets - Equipment	34	108	89
Right-of-use assets	325	1,195	973
Total non-current assets	**57,434**	**58,381**	**58,135**
Current assets			
Advance payments to suppliers	3,255	3,038	3,433
Current receivables			
Income tax receivables	1,688	3,733	1,981
Other receivables	913	1,271	480
Prepaid expenses and accrued income	2,401	953	1,188
Cash and bank balances	95,718	38,992	21,855
Total current assets	**103,975**	**47,988**	**28,937**
Total assets	**161,409**	**106,369**	**87,072**
EQUITY			
Share capital	97,193	34,871	34,871
Other paid-in capital	721,750	678,747	678,747
Reserve of exchange differences on translation	651	150	671
Loss brought forward (incl. net profit/loss for the period)	-712,012	-629,201	-639,962
Equity attributable to Parent Company shareholders	**107,582**	**84,568**	**74,328**
Total equity	**107,582**	**84,568**	**74,328**
LIABILITIES			
Long-term liabilities			
Long-term interest bearing liabilities	26,215	–	–
Lease liabilities	–	381	176
Total long-term liabilities	**26,215**	**381**	**176**
Current liabilities			
Accounts payable	2,596	4,618	1,525
Tax payable	1	–	–
Other liabilities	13,479	2,063	1,640
Current lease liabilities	402	885	884
Accrued expenses and deferred income	11,133	13,855	8,519
Total current liabilities	**27,612**	**21,420**	**12,568**
Total liabilities	**53,827**	**21,801**	**12,744**
Total equity and liabilities	**161,409**	**106,369**	**87,072**

Consolidated Statements of Changes in Equity

	9M (Jan-Sep)		FY (Jan-Dec)
*SEK in thousands**	2024	2023	2023
Equity at start of the period	**74,328**	**180,859**	**180,859**
Comprehensive income			
Profit/loss for the period	-51,498	-98,689	-109,288
Other comprehensive income	-20	150	-301
Total comprehensive income	**-51,518**	**-98,539**	**-109,589**
Transactions with shareholders			
New issue of common shares	105,324	–	–
Warrants	-12,385	–	–
New issue of C-shares	–	–	–
Common shares: Conversion from C-shares	–	-55	-89
C-shares: Resolution of C-shares	–	55	89
Issuance expenses	-14,452	-15	-30
Call option premium in relation to loan facility	2,165	–	–
Share based remuneration to employees	4,320	2,262	3,088
Total transactions with shareholders	**84,973**	**2,247**	**3,058**
Equity at end of the period	**107,782**	**84,568**	**74,328**

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

Consolidated Cash Flow Statement

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands**	**2024**	**2023**	**2024**	**2023**
Operating activities				
Operating result	-17,790	-21,362	-45,837	-99,861
Expensed share based remuneration	811	109	4,289	2,131
Adjustment for items not included in cash flow	-539	-68	-69	343
Interest received	3	71	38	432
Interest paid	-1,425	-27	-3,857	-92
Income tax paid/received	-147	-239	354	-678
Cash flow from operating activities before changes in working capital	**-19,087**	**-21,515**	**-45,084**	**-97,724**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	297	417	178	2,320
Increase (-)/Decrease (+) of operating receivables	-812	1,401	-2,121	1,103
Increase (+)/Decrease (-) of accounts payable	-73	-1,878	1,069	-11,259
Increase (+)/Decrease (-) of other liabilities	2,632	-9,456	1,898	-5,304
Change in working capital	2,044	-9,516	1,024	-13,140
Cash flow used in operating activities	**-17,043**	**-31,031**	**-44,060**	**-110,865**
Investing activities				
Investment in equipment	–	–	–	–
Divestment of right-of-use assets	–	47	–	47
Cash flow from investing activities	**–**	**47**	**–**	**47**
Financing activities				
New share issue	105,324	–	105,324	–
Transaction costs for issuance	-14,023	–	-14,452	-15
Conversion from C-shares	–	–	–	-55
Resolution of C-shares	–	–	–	55
Convertible bond issue	-700	–	733	–
New loans	272	–	33,715	–
Amortisation of loan	-7,500	–	-7,500	–
Amortisation of lease liabilities	-224	-234	-658	-701
Cash flow from financing activities	**83,149**	**-234**	**117,162**	**-716**
Cash flow for the period	66,106	-31,218	73,103	-111,533
Cash and cash equivalents at start of period	29,775	70,500	21,855	149,555
Exchange rate differences in cash and cash equivalents	-163	-290	760	970
Cash and cash equivalents at end of period	**95,718**	**38,992**	**95,718**	**38,992**

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

Parent Company – Income Statement

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands**	**2024**	**2023**	**2024**	**2023**
Net sales	21	74	159	293
Gross profit/loss	**21**	**74**	**159**	**293**
Administrative costs	-3,524	-4,877	-14,185	-14,040
Research and development costs	-14,099	-13,880	-32,312	-74,233
Commercial preparation costs	-31	-2,595	669	-11,355
Other operating income	7	384	10	847
Other operating costs	-2	-131	-30	-202
Operating result	**-17,628**	**-21,024**	**-45,689**	**-98,690**
Finance income	167	2,430	1,037	4,205
Finance costs	-3,922	-426	-6,820	-1,172
Result from other long-term receivables	773	-1,993	2,570	-1,208
Net financial costs	**-2,982**	**11**	**-3,213**	**1,826**
Loss before tax	-20,610	-21,013	-48,901	-96,865
Group contribution	–	–	–	–
Tax	–	–	–	–
Loss for the period	**-20,610**	**-21,013**	**-48,901**	**-96,865**

Parent Company – Statement of Comprehensive Income

	Q3 (Jul-Sep)		9M (Jan-Sep)	
SEK in thousands*	**2024**	**2023**	**2024**	**2023**
Loss for the period	**-20,610**	**-21,013**	**-48,901**	**-96,865**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total comprehensive income for the period	**-20,610**	**-21,013**	**-48,901**	**-96,865**

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

Parent Company – Balance Sheet

*SEK in thousands**	30 Sep 2024	30 Sep 2023	31 Dec 2023
ASSETS			
Non-current assets			
Tangible assets			
Equipment	34	108	89
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	38,076	36,519	35,874
Total non-current assets	**96,178**	**94,695**	**94,032**
Current assets			
Advance payments to suppliers	3,255	3,038	3,433
Current receivables			
Receivables from group companies	2,469	13,098	15,114
Income tax receivables	1,310	1,430	1,668
Other receivables	892	1,259	453
Prepaid expenses and accrued income	2,352	863	1,129
Cash and bank balances	95,223	26,738	8,199
Total current assets	**105,501**	**46,425**	**29,996**
Total assets	**201,679**	**141,120**	**124,027**
EQUITY			
Restricted equity			
Share capital	97,193	34,871	34,871
Non-restricted equity			
Other paid-in capital	721,750	678,747	678,747
Loss brought forward	-609,108	-496,389	-495,578
Loss for the period	-48,901	-96,865	-105,563
Total equity	**160,933**	**120,364**	**112,477**
LIABILITIES			
Long-term liabilities			
Long-term interest bearing liabilities	26,215	–	–
Total long-term liabilities	**26,215**	**–**	**–**
Current liabilities			
Accounts payable	2,587	4,933	1,489
Other liabilities	894	2,063	1,640
Accrued expenses and deferred income	11,050	13,759	8,422
Total current liabilities	**14,531**	**20,756**	**11,551**
Total equity and liabilities	**201,679**	**141,120**	**124,027**

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

Notes

General information

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

Fair value of financial instruments

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

Purchases from related parties

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

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

Reference is made in this interim report to alternative performance measures that are not defined according to IFRS. Ascelia Pharma considers these performance measures to be an important complement since they enable a better evaluation of the company´s economic trends. The company believes that these alternative performance measures give a better understanding of the company´s financial development and that such key performance measures contain additional information to the investors to those performance measures already defined by IFRS. Furthermore, the key performance measures are widely used by the management in order to assess the financial development of the company. These financial key performance measures should not be viewed in isolation or be considered to substitute the key performance measures prepared by IFRS.

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

Important estimations and judgements

Valuation of intangible assets

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

Capitalization of development expenses

In 9M 2024, the criteria for classifying R&D costs as an asset according to IAS 38 has not been met (capitalization of development expenses is normally done in connection with final regulatory approval). Hence, all R&D costs related to the development of the product candidates have been expensed.

Share-based incentive programs

Employee option programs

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

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

The total recognized costs for the option programs including social security charges in 9M 2024 were SEK 2.4 million.

Share saving programs

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

The total recognized costs for the share saving programs including social security charges in 9M 2024 were SEK 1.9 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

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands**	**2024**	**2023**	**2024**	**2023**
R&D costs	-14,173	-13,953	-32,470	-74,784
Administration costs	-3,550	-4,929	-14,313	-14,302
Commercial preparation costs	-31	-2,589	669	-11,343
Other operating costs	-42	-386	-99	-662
Total operating costs	**-17,796**	**-21,857**	**-46,213**	**-101,091**
R&D costs/Operating costs (%)	**80%**	**64%**	**70%**	**74%**

Financial calendar

Full-year report 2024 (Jan-Dec):	7 February 2025
Annual General Meeting 2025:	7 May 2025
Interim report Q1 2025 (Jan-Mar):	16 May 2025
Half-year report 2025 (Jan-Jun):	21 August 2025
Interim report 9M 2025 (Jan-Sep):	5 November 2025
Full-year report 2025 (Jan-Dec):	5 February 2025

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