



Q4 and Full Year Report 2023

January – December 2023

Strengthened Financial Position Ahead of SPARKLE Phase 3 Study Headline Results in May

KEY EVENTS IN Q4 2023

- Ascelia Pharma gets acceptance for publication of Orvigance® review article in Investigative Radiology
- Conversion of series C shares into ordinary shares for delivery to participants in incentive program and subsequent change in number of shares and votes
- Extraordinary General Meeting held on November 13, 2023 resolved on proposal to introduce an employee stock option program
- Ascelia Pharma starts image reading phase and re-confirms Phase 3 SPARKLE results by May 2024

KEY EVENTS AFTER THE PERIOD

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

“The start of the image reading in December 2023 keeps us on track for reporting headline results by May this year.”

KEY RATIOS GROUP

Q4 (Oct-Dec)		FY (Jan-Dec)	
2023	2022	2023	2022
OPERATING RESULT (SEKm)			
-11.1	-52.2	-110.9	-147.0
EARNINGS PER SHARE (SEK)			
-0.31	-1.53	-3.24	-3.77
CASH FLOW FROM OPERATIONS (SEKm)			
-15.9	-28.7	-126.8	-125.3
LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)			
21.9	149.6	21.9	149.6

CEO STATEMENT



In 2023, our focus was on SPARKLE, the pivotal Phase 3 study for our orphan magnetic resonance imaging (MRI) contrast agent for liver imaging, Orviglance®. We successfully completed patient enrollment in March. In early August, the discovery of high intra-reader variability in the study image scoring by independent radiologists prevented us from evaluating the efficacy data from SPARKLE. Therefore, a new evaluation of the images with new independent readers was required. With the aim of reaching headline results with available funding, we focused all resources on the re-evaluation and implemented cost-cutting initiatives, including a significant reduction of the organization. In September, we shared our plan to complete the re-evaluation and reach headline results from SPARKLE by May 2024. In addition, we expanded the commercialization strategy for Orviglance to also consider launching in the US with a partner. Early December, we communicated that the image reading process had started according to plan, putting us on track for the May 2024 headline results read-out. While the re-evaluation was a regrettable setback on our timelines, it does not change our high confidence in Orviglance, nor does it change the global medical need for a liver imaging contrast agent without gadolinium. On 4 February 2024, we were pleased to announce that we secured a directed issue of convertibles raising gross proceeds of SEK 15 million and an agreement for a loan facility of up to SEK 20 million, extending our cash runway into Q2 2025 with the full financing. This strengthened financial position is an important and value-adding step to maintain financial and strategic flexibility. We are also very pleased to be able to secure a financing solution with a maximum dilution of only around 4 percent for our shareholders. We look very much forward to executing on the opportunities ahead for Ascelia Pharma in 2024 and beyond – starting with the announcement of headline results by May.

Reaching results for Phase 3 SPARKLE study. We completed patient recruitment in the global multi-center SPARKLE study with 85 patients in early March 2023. The MR images were then evaluated by three independent radiologists, in accordance with regulatory guidance. During the analysis process, we identified a high level of inconsistency in the evaluation of the contrast effect by two of the readers, commonly known as high intra-reader variability. This occurs when a reader reports significantly different scores for the same image when seen at two different time points.

The intra-reader variability analysis was specified in the clinical trial protocol and adheres to the US Food and Drug Administration (FDA) guidance to industry. A high intra-reader variability

means that this set of read-out data from SPARKLE cannot be used to conclude on the contrast effect and that a re-evaluation of all images is required. While this finding was unexpected and unfortunate, we are pleased that the patient recruitment is complete and that the images from these patients are available for the re-evaluation.

In September, we shared the plan to complete the re-evaluation of SPARKLE images and the expectation to reach headline results by May 2024. In December, we shared that the new independent readers had successfully completed the training program according to plan and that the image reading phase had started. Our entire team is focused on executing a high-quality re-evaluation according to plan and

dedicated to ensuring the delivery of the results by May 2024. We look forward to bringing Orviglance to patients in need and continue to have confidence in the global medical need for a MRI liver imaging contrast agent without gadolinium.

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

"Our strengthened financial position ensures financial and strategic flexibility."

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

Expanded commercialization strategy. Orviglance addresses a well-defined unmet medical need. Our in-depth market research and real-world data point to an attractive commercial potential with an annual global addressable market of USD 800 million, with 100,000 procedures in the target patient population in the US alone.

A focused launch plan built on advanced market insights is in place. In October, we expanded our strategy to commercialize globally through partners, while maintaining the previous option for an Ascelia Pharma led launch in the US with selected outsourcing partners.

Strengthened financial position. We ended the fourth quarter with SEK 22 million in cash and cash equivalents. Our significant cost savings initiatives, which were implemented in Q3, led to a substantially lower cost level in Q4. This trend will continue into 2024.

On 4 February 2024, we announced that we have secured additional financing of up to SEK 35 million. With the currently available cash and the full SEK 35 million financing, we have a cash runway into Q2 2025, covering both the ongoing re-evaluation of images from the Phase 3 study with Orviglance, and completion of time critical activities for the New Drug Application (NDA) for the FDA. Additional funding is needed to continue and grow the company longer term.

Attractive opportunities ahead. Our 2023 timelines and progress were changed by the unexpected and unfortunate outcome preventing us from obtaining a readout of the efficacy data from the SPARKLE. However, the need for a re-evaluation does not change our confidence in a positive headline readout, nor does it change the global medical need for a liver imaging contrast agent without gadolinium.

I look forward to sharing headline results by May and to the subsequent opportunities and progress ahead for Ascelia Pharma in 2024 and beyond.

Magnus Corfitzen
CEO

ADVANCING ORPHAN ONCOLOGY

OUR VALUES

FOCUS

We are devoted to improving the lives of patients and creating values for our stakeholders.

COURAGE

We work tirelessly and follow our convictions even when it means changing status quo.

INTEGRITY

We build powerful relationship with mutual respect and adhere to the high ethical standards of our industry.

OUR VISION

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

OUR BASE

Our headquarter is in Malmö, Sweden, and our US base is in New Jersey. The shares in the company are listed on NASDAQ Stockholm (ticker: ACE).

Building Ascelia and building value

ADVANCING PIPELINE AND COMMERCIAL CAPABILITIES

- ORVIGLANCE Phase 3
- 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 magnetic resonance imaging (MRI) in ongoing Phase 3

Orviglance is our novel non-gadolinium diagnostic drug (contrast agent) to be used in MRI-scans of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases and primary liver cancer) in patients with impaired kidneys at risk of severe side-effects from the gadolinium contrast agents currently on the market.

- Manganese-based diagnostic drug with Orphan Drug Designation (FDA)
- The only late-stage gadolinium-free agent
- \$800 million annual global addressable market

ONCORAL

Daily tablet chemotherapy ready for Phase 2

Oncoral is our novel oral irinotecan chemotherapy tablet developed initially for the treatment of gastric cancer. Irinotecan has an established potent anti-tumor effect.

- 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

Orphan liver MRI contrast agent in the final clinical phase

Detecting liver metastases early is essential for survival

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

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. With Orviglance, liver metastases are consequently easier to identify due to this contrast effect.

Latest development

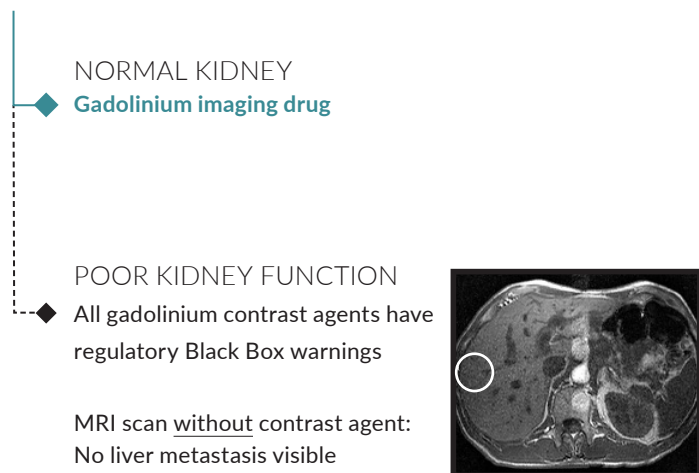
The phase 3 study, SPARKLE has completed enrollment with 85 patients. The evaluation of the primary endpoint was independently carried out by three blinded radiologists (readers), who assessed both changes of visualization of liver lesions with and without Orviglance (the primary endpoint), as well as other secondary efficacy endpoints.

During the evaluation of the reading result a very high, and unexpected, intra-reader (within reader) variability in the assessment of the primary efficacy variables were detected for some of the readers, making the readout-data unreliable. All images are being re-evaluated by new independent readers and results are expected available by May 2024.

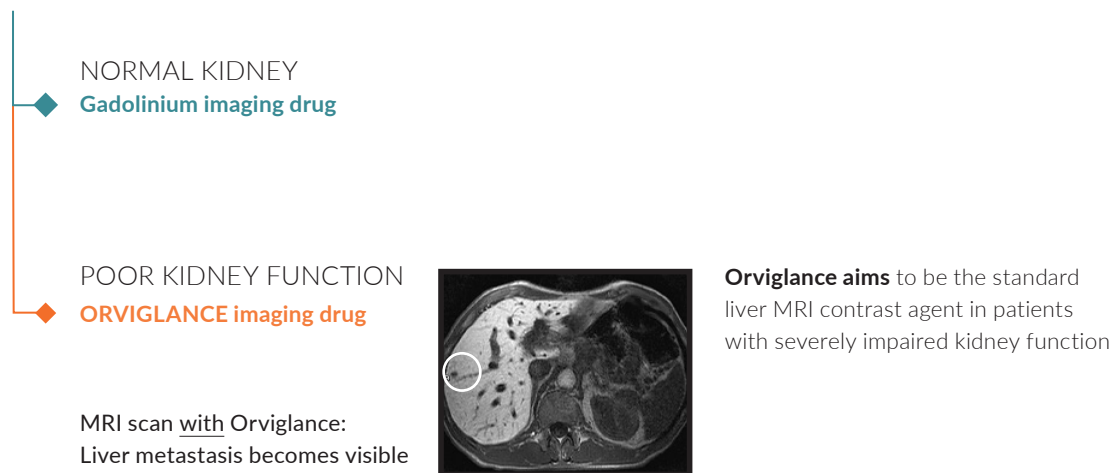


Patients referred for liver MRI scan

TODAY



TOMORROW



\$800 million global annual addressable market

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

The clinical trials completed to date show that Orviglance has a potential to improve the diagnostic performance of MRI and offers a significantly better alternative than unenhanced MRI (i.e., MRI without contrast agent).

Consequently, Orviglance fills a significant unmet medical need to improve the diagnosis, and subsequently, the treatment of liver metastases and primary liver cancer.

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

Orviglance has Orphan Drug Designation

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

PHASE 3 STUDY (SPARKLE)

The pivotal Phase 3 study (SPARKLE) is a global multicentre study, which has been completed with 85 enrolled patients with suspected or known focal liver lesions and severely impaired kidney function. The primary objective is to demonstrate an improved visualization of liver lesions compared to MRI without contrast, unenhanced MRI.

The primary endpoint of the SPARKLE study is similar to what was studied in the phase 1 and 2 studies. The strong results in the Phase 1 and Phase 2 studies, both in terms of safety and efficacy, provide a solid foundation for the ongoing Phase 3 program.

Orviglance clinical Phase 3 study

NUMBER OF PATIENTS	Global study with 85 patients
PRIMARY ENDPOINT	Lesion visualization <ul style="list-style-type: none"> ■ Lesions border delineation (border sharpness of lesions) ■ Conspicuity (lesion contrast compared to liver background)
COMPARATOR	Unenhanced MRI + Orviglance MRI vs. Unenhanced MRI
EVALUATION	Centralised evaluation by 3 radiologists
RANDOMIZATION	None – each patient is his/her own control
FOLLOW-UP	Less than a week

Strong support to Phase 3 endpoints from completed studies

The completed Phase 1 and Phase 2 studies have shown strong efficacy results regarding the endpoints that will be evaluated in the Phase 3 study. The completed studies, involving 178 persons in total¹, have showed a highly significant improvement compared to unenhanced MRI in:

- Delineation: p-value <0.0001
- Conspicuity: p-value <0.0001



Results from both variables show that Orviglance significantly improves MRI performance.

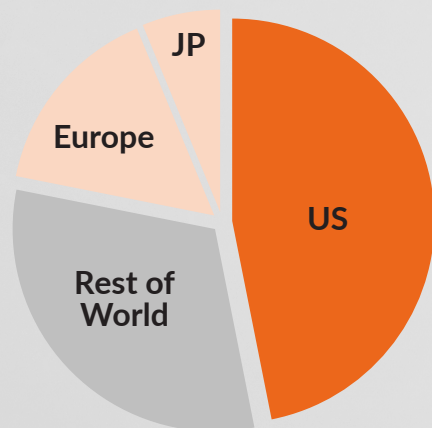
¹ The above mentioned results stem from of a blinded-read study, which comprised all imaging data from six phase 1 and 2 studies completed before start of the phase 3 program. The blinded-read results have been presented at major radiology conferences

ANNUAL ADDRESSABLE MARKET OF \$800 MILLION

\$800 M global annual addressable market

Market estimate 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 nephrogenic systemic fibrosis, 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.

"In light of the new timeline for Orviglance development, our commercialization strategy is expanded to also consider partnership opportunities for launch in the US. Our confidence in the commercial potential of Orviglance is unchanged, and having a partner would significantly reduce our investments in the launch.", says Julie Waras Brogren, Deputy CEO (Finance, Investor Relations & Commercial)

A clear strategy

Our go-to-market model for Orviglance is opportunity driven and allows for BOTH partnering options to leverage established capabilities with a lower investment requirement by Ascelia Pharma AND own commercialization allowing Ascelia Pharma to create an attractive top-line and expand value adding commercialization capabilities.

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 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

Sources:

1: Ascelia Pharma market research with Decision Resources Group, 2020

2: Ascelia Pharma market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

3: Ascelia Pharma market research with 274 healthcare professionals in the US with TwoLabs 2022

ONCORAL CHEMOTHERAPY AS TABLET

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.

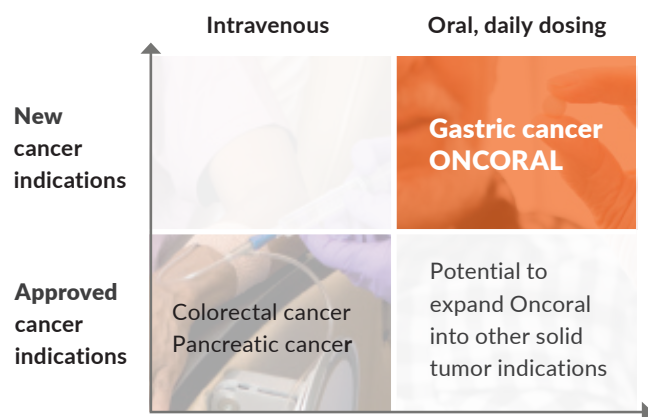
Anti-cancer effect is proven. The active pharmaceutical ingredient (API) in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is a so-called antineoplastic agent that after metabolic activation inhibits the enzyme topoisomerase 1, thereby inducing cancer 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.

Latest development. A new patent covering the tablet composition of Oncoral, providing protection until 2035 plus potential extension in the US, received a positive Notice of Allowance from the United States Patent and Trademark Office (USPTO) in March 2023.

ONCORAL – a novel formulation of irinotecan



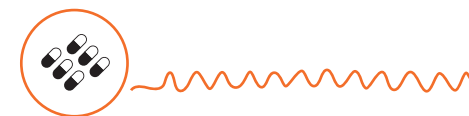
TODAY – Intravenous bolus infusions



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

Clinical collaboration with Taiho Oncology Inc.

- Clinical Phase 2 collaboration with Taiho Oncology Inc. (part of Otsuka Group)
- Taiho Oncology Inc. will supply Lonsurf® and provide scientific expertise
- Ascelia Pharma retains full development and commercialization rights



TAIHO ONCOLOGY

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

FINANCIAL OVERVIEW Q4 2023 (OCT-DEC)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q4 (Oct-Dec 2023) 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 357 thousand (SEK 80 thousand). The income mainly refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in Q4 were SEK 6.5 million (SEK 43.7 million). The cost decrease reflects completion of SPARKLE patient recruitment activities and the significant cost-cutting initiatives communicated in Q3.

Commercial preparation costs

During Q4, the result related to commercial preparations for Orvigance amounted to a positive effect of SEK 0.9 million (cost of SEK 3.8 million). This reflects the decrease in commercial preparations due to cost-cutting initiatives and reversed costs from employee incentive programs due to organizational change.

Administration costs

Administration costs for the Group in Q4 amounted to SEK 5.5 million (SEK 4.8 million). The costs primarily relates to employees for the period.

Operating results (EBIT)

The operating result in Q4 amounted to SEK -11.1 million (SEK -52.2 million). The decreased loss reflects the undergone cost-cutting initiatives.

Net Profit/Loss for the period

The Group's net loss in Q4 amounted to SEK -10.6 million (SEK -53.4 million). In the current quarter, net financial costs of SEK 0.3 million was recognized which primarily reflects interest gain from the bank. The net loss corresponds to a loss per share, before and after dilution, of SEK -0.31 (SEK -1.53).

CASH FLOW

Cash flow from operating activities before changes in working capital in Q4 amounted to SEK -7.2 million (SEK -43.4 million). The decreased outflow reflects the initiated cost-cutting initiatives in the current quarter. Changes in working capital in the current quarter totalled an outflow of SEK -8.7 million (inflow of SEK 14.7 million). The outflow in the current quarter reflects the decrease in accounts payable and other liabilities. Cash flow from investing activities in Q4 amounted to SEK 0 (SEK 0). Cash flow from financing activities amounted to an outflow of SEK -0.2 million (outflow of SEK -0.2 million), which reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 74.3 million, compared with SEK 180.9 million per 31 December 2022. The decrease since 31 December 2022 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 21.9 million, compared to SEK 149.6 million per 31 December 2022. The decrease in liquid assets reflects the net loss incurred.

Financials key ratios for the Group	Q4 (October-December)	
	2023	2022
Operating result (SEK 000')	-11,054	-52,167
Net result (SEK 000')	-10,599	-53,382
Earnings per share (SEK)	-0.31	-1.53
Weighted avg. number of shares	33,742,916	34,871,177*
R&D costs/operating costs (%)	57%	84%
Cash flow used in operating activities (SEK 000')	-15,928	-28,714
Equity (SEK 000')	74,328	180,859
Liquid assets incl. marketable securities (SEK 000')	21,855	149,555

*The amount for 2022 includes common shares and c-shares. The amount for 2023 includes common shares.

FINANCIAL OVERVIEW FY 2023 (JAN–DEC 2023)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in FY-2023 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 1.6 million (SEK 0.8 million). The income mainly refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in FY-2023 amounted to SEK 81.3 million (SEK 118.1 million). The cost decrease reflects the significant cost-cutting initiatives communicated in Q3.

Commercial preparation costs

During FY-2023, costs related to commercial preparations for Orvigance amounted to SEK 10.4 million (SEK 14.9 million). The cost decrease mainly reflects the decrease in commercial activities.

Administration costs

Administration costs for the Group in FY-2023 amounted to SEK 19.8 million (SEK 14.6 million). The cost increase primarily reflects a difference in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in FY-2023 amounted to SEK -110.9 million (SEK -147.0 million). The decreased loss reflects the cost-cutting initiatives communicated at the end of Q3.

Net Profit/Loss for the period

The Group's net loss in FY-2023 amounted to SEK -109.3 million (SEK -131.2 million). In the current period, net financial income of SEK 1.3 million was recognized which primarily reflects interest gain from the bank. The decrease in net financial income compared to the same period last year (SEK 13.9 million) is explained by a significant decrease in the bank deposit held in USD. The net loss corresponds to a loss per share, before and after dilution, of SEK -3.24 (SEK -3.77).

CASH FLOW

Cash flow from operating activities before changes in working capital in FY-2023 amounted to SEK -105.0 million (SEK -139.9 million). The decreased outflow reflects the cost-cutting initiatives from Q3. Changes in working capital in the current period totalled an outflow of SEK -21.8 million (inflow of SEK 14.7 million) reflecting the decrease in accounts payable and other liabilities. Cash flow from investing activities for the period totalled an inflow of SEK 47 thousand (outflow of SEK -65 thousand). Cash flow from financing activities amounted to an outflow of SEK -0.9 million (outflow of SEK -1.1 million), which reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 74.3 million, compared with SEK 180.9 million per 31 December 2022. The decrease since 31 December 2022 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 21.9 million, compared to SEK 149.6 million per 31 December 2022. The decrease in liquid assets reflects the net loss incurred.

4 February 2024 financing

The financing agreement with Formue Nord Fokus A/S announced on 4 February 2024 consists of a first tranche of SEK 20 million, of which SEK 15 million is convertibles and SEK 5 million is a loan, and a second tranche loan of the remaining SEK 15 million, available provided that the total financing does not exceed 10 percent of the company's market capitalization at the time of the second tranche. The conversion price is set at 10.53 SEK per share. If the outstanding total financing represents more than 15 percent of the market capitalization at the end of a calendar quarter, the Company is required to repay SEK 2.5 million. The financing shall be repaid at the latest on 20 May 2025, but Ascelia Pharma has the option to repay the financing at any time and with no additional costs.

Financials key ratios for the Group

	FY (January–December)	
	2023	2022
Operating result (SEK 000')	-110,914	-147,007
Net result (SEK 000')	-109,288	-131,223
Earnings per share (SEK)	-3.24	-3.77
Weighted avg. number of shares	33,719,779	34,798,504*
R&D costs/operating costs (%)	72%	80%
Cash flow used in operating activities (SEK 000')	-126,792	-125,263
Equity (SEK 000')	74,328	180,859
Liquid assets incl. marketable securities (SEK 000')	21,855	149,555

*The amount for 2022 includes common shares and c-shares. The amount for 2023 includes common shares.

OTHER INFORMATION

Incentive programs

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

The board of directors of Ascelia Pharma has during 2023, in accordance with the provisions of LTI 2019 and LTI 2020, resolved to convert 89,484 series C shares for allotment of 89,484 ordinary shares to the participants in LTI 2019 and LTI 2020.

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 2022 on pages 70–72.

In case all outstanding incentive programs per 31 December 2023 (incl. a new share-saving program approved by the AGM in May 2023 and a new option program approved by the EGM in November 2023) are exercised in full, a total of 3.1 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 8.5 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).

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

Ascelia Pharma's activities and markets are exposed to a number of risks and uncertainties which impact, or could impact, the company's business, financial position and result. The risks and uncertainties, which Ascelia Pharma considers to have the

largest impact on its results are clinical drug development, regulatory conditions, commercialization and licensing, intellectual property rights and other forms of protection, financing conditions, macroeconomic conditions including impact from pandemics, geopolitical effects, inflation and foreign exchange exposure.

Other information

The Group's overall strategy for risk management is to limit undesirable impact on its result and financial position, to the extent it is possible. The Group's risks and uncertainties are described in more detail in the Annual Report 2022 on pages 36–40.

Significant events after the end of the reporting period

On 24 January 2024 Ascelia Pharma announced that the Nomination Committee for the Annual General Meeting 2024 has been appointed.

On 24 January 2024 Ascelia Pharma announced that Orviglance ® review article is published in Investigative Radiology.

On 4 February Ascelia Pharma announced that a financing of up to SEK 35 million has been secured.

Auditor's review

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

Annual General Meeting (AGM) 2024

The AGM of Ascelia Pharma AB (publ) will be held on 6 May, 2024. Shareholders wishing to have a matter discussed at the AGM should send their suggestion by e-mail to:

jwb@ascelia.com or by mail to:

ASCELIA PHARMA AB

Hyllie Boulevard 34; SE-215 32 Malmö

Suggestions to the AGM must reach the Board of Directors at least seven weeks prior to the meeting (18 March) or in good time for the matter, if necessary, to be included in the notice to the AGM.

Dividend

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

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

Malmö, 9 February 2024
Ascelia Pharma AB (publ)

Magnus Corfitzen
CEO

Consolidated Income Statement

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
SEK in thousands (unless otherwise stated)*	2023	2022	2023	2022
Net sales	-	-	-	-
Gross profit/loss	-	-	-	-
Administrative costs	-5,472	-4,760	-19,774	-14,628
Research and development costs	-6,482	-43,674	-81,266	-118,113
Commercial preparation costs	905	-3,780	-10,438	-14,929
Other operating income	357	80	1,587	827
Other operating costs	-361	-33	-1,023	-163
Operating result	-11,054	-52,167	-110,914	-147,007
Finance income	1,060	2,824	3,725	17,816
Finance costs	-716	-3,896	-2,418	-3,965
Net financial items	344	-1,072	1,307	13,851
Loss before tax	-10,709	-53,239	-109,607	-133,155
Tax	110	-143	319	1,933
Loss for the period	-10,599	-53,382	-109,288	-131,223
Attributable to:				
Owners of the Parent Company	-10,599	-53,382	-109,288	-131,223
Non-controlling interest	-	-	-	-
Earnings per share				
Before and after dilution (SEK)	-0.31	-1.53	-3.24	-3.77

Consolidated Statement of Comprehensive Income

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
SEK in thousands (unless otherwise stated)*	2023	2022	2023	2022
Profit/loss for the period	-10,599	-53,382	-109,288	-131,223
Other comprehensive income				
Currency translation of subsidiaries**	-451	594	-1,019	718
Other comprehensive income for the period	-451	594	-1,019	718
Total comprehensive income for the period	-11,050	-52,788	-110,307	-130,505

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

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

Consolidated Balance Sheet

	31 Dec	31 Dec
SEK in thousands*	2023	2022
ASSETS		
Non-current assets		
Intangible assets	57,074	57,074
Tangible assets - Equipment	89	163
Right-of-use assets	973	462
Total non-current assets	58,135	57,700
Current assets		
Advance payments to suppliers	3,433	5,359
Current receivables		
Income tax receivables	1,981	2,785
Other receivables	480	1,745
Prepaid expenses and accrued income	1,188	1,426
Cash and bank balances	21,855	149,555
Total current assets	28,937	160,869
Total assets	87,072	218,569
EQUITY		
Share capital	34,871	34,871
Other paid-in capital	678,747	678,747
Reserve of exchange differences on translation	-301	718
Loss brought forward (incl. net profit/loss for the period)	-638,989	-533,478
Equity attributable to Parent Company shareholders	74,328	180,859
Total equity	74,328	180,859
LIABILITIES		
Long-term liabilities		
Lease liabilities	176	193
Total long-term liabilities	176	193
Current liabilities		
Accounts payable	1,525	15,881
Tax payable	-	-
Other liabilities	1,640	1,688
Current lease liabilities	884	291
Accrued expenses and deferred income	8,519	19,657
Total current liabilities	12,568	37,518
Total liabilities	12,744	37,711
Total equity and liabilities	87,072	218,569

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

Consolidated Statements of Changes in Equity

	Full Year (Jan-Dec)	
	2023	2022
<i>SEK in thousands*</i>		
Equity at start of the period	180,859	307,834
Comprehensive income		
Profit/loss for the period	-109,288	-131,223
Other comprehensive income	-301	718
Total comprehensive income	-109,589	-130,505
Transactions with shareholders		
New issue of C-shares	-	295
Repurchase of own shares C-shares	-	-295
New issue of common shares	-	-
Common shares: Conversion from C-shares	-89	-
C-shares: Resolution of C-shares	89	-
Issuance expenses	-30	-84
Redemption of warrants	-	-
Share based remuneration to employees	3,088	3,612
Total transactions with shareholders	3,058	3,529
Equity at end of the period	74,328	180,859

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

Consolidated Cash Flow Statement

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
SEK in thousands*	2023	2022	2023	2022
Operating activities				
Operating result	-11,054	-52,167	-110,914	-147,007
Expensed share based remuneration	800	3,494	2,931	1,627
Adjustment for items not included in cash flow	320	238	664	1,091
Interest received	882	630	1,314	635
Interest paid	-29	-10	-121	-48
Income tax paid/received	1,850	4,416	1,172	3,772
Cash flow from operating activities before changes in working capital	-7,230	-43,397	-104,954	-139,930
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	-394	-219	1,926	850
Increase (-)/Decrease (+) of operating receivables	517	625	1,620	-1,362
Increase (+)/Decrease (-) of accounts payable	-3,091	12,045	-14,351	9,722
Increase (+)/Decrease (-) of other liabilities	-5,729	2,232	-11,033	5,456
Change in working capital	-8,698	14,683	-21,838	14,667
Cash flow used in operating activities	-15,928	-28,714	-126,792	-125,263
Investing activities				
Investment in equipment	-	-	-	-
Divestment of right-of-use assets	-	-	47	-65
Cash flow from investing activities	-	-	47	-65
Financing activities				
Issuance proceeds	-	-	-	-
Issuance costs	-15	-	-30	-84
Conversion from C-shares	-35	-	-89	-
Resolution of C-shares	35	-	89	-
Redemption of warrants net	-	-	-	-
Amortisation of loan (leasing)	-206	-239	-906	-1,016
Cash flow from financing activities	-221	-239	-936	-1,100
Cash flow for the period	-16,149	-28,954	-127,682	-126,428
Cash flow for the period	-16,149	-28,954	-127,682	-126,428
Cash and cash equivalents at start of period	38,992	179,811	149,555	261,599
Exchange rate differences in cash and cash equivalents	-988	-1,302	-18	14,384
Cash and cash equivalents at end of period	21,855	149,555	21,855	149,555

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

Parent Company – Income Statement

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
SEK in thousands*	2023	2022	2023	2022
Net sales	59	92	351	1,142
Gross profit/loss	59	92	351	1,142
Administrative costs	-5,454	-4,730	-19,494	-14,441
Research and development costs	-6,011	-43,809	-80,244	-108,077
Commercial preparation costs	907	-3,814	-10,448	-14,963
Other operating income	9	67	856	124
Other operating costs	14	-	-187	-131
Operating result	-10,476	-52,194	-109,167	-136,346
Finance income	1,935	2,791	6,140	16,721
Finance costs	-405	-3,315	-1,576	-3,384
Result from other long-term receivables	273	451	-935	1,639
Net financial costs	1,803	-73	3,628	14,976
Loss before tax	-8,674	-52,268	-105,538	-121,371
Group contribution	-25	-	-25	-
Tax	-	-	-	-
Loss for the period	-8,699	-52,268	-105,563	-121,371

Parent Company – Statement of Comprehensive Income

	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
SEK in thousands*	2023	2022	2023	2022
Loss for the period	-8,699	-52,268	-105,563	-121,371
Other comprehensive income	-	-	-	-
Other comprehensive income for the period	-	-	-	-
Total comprehensive income for the period	-8,699	-52,268	-105,563	-121,371

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

Parent Company – Balance Sheet

	31 Dec	31 Dec
SEK in thousands*	2023	2022
ASSETS		
Non-current assets		
Tangible assets		
Equipment	89	163
Financial assets		
Shares in affiliated companies	58,068	58,068
Other long-term receivables from group companies	35,874	38,486
Total non-current assets	94,032	96,717
Current assets		
Advance payments to suppliers	3,433	5,359
Current receivables		
Receivables from group companies	15,114	8,395
Income tax receivables	1,668	756
Other receivables	453	1,627
Prepaid expenses and accrued income	1,129	1,349
Cash and bank balances	8,199	137,879
Total current assets	29,996	155,365
Total assets	124,027	252,082
EQUITY		
Restricted equity		
Share capital	34,871	34,871
Non-restricted equity		
Other paid-in capital	678,747	678,747
Loss brought forward	-495,578	-377,266
Loss for the period	-105,563	-121,371
Total equity	112,477	214,982
LIABILITIES		
Current liabilities		
Accounts payable	1,489	16,022
Other liabilities	1,640	1,688
Accrued expenses and deferred income	8,422	19,390
Total current liabilities	11,551	37,101
Total equity and liabilities	124,027	252,082

* 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.

Related parties Purchases from related parties

In November 2023 Solural Pharma ApS had a change of ownership. This entails that Solural Pharma ApS is no longer considered a related party. Solural Pharma ApS previous right to receive bonus if Oncoral is commercialized has in connection with the change of ownership been transferred to the previous owners of Solural, now Pebean ApS, with the same previous terms. Pebean ApS has the right to receive a bonus of maximum SEK 10 million if commercialization occurs through a sale or an outlicensing and SEK 12 million if commercialization is carried out by Oncoral Pharma ApS or Ascelia Pharma AB itself. Regardless the commercialization method, Oncoral Pharma ApS has the right to, at any time, finally settle Pebean ApS right for remuneration by payment of SEK 10 million.

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

Reference is made in this interim report to alternative performance mea-

sures 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 FY 2023, the criteria for classifying R&D costs as an asset according to IAS 38 has not been met (capitalization of development expenses is normally done in connection with final regulatory approval). Hence, all R&D costs related to the development of the product candidates have been expensed.

Share-based incentive programs

Employee option programs

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

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

The total recognized costs for the option programs including social security charges in 2023 were SEK 0.5 million.

Share saving programs

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

The total recognized costs for the share saving programs including social security charges in 2023 were SEK 2.9 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

SEK in thousands*	Q4 (Oct-Dec)		Full Year (Jan-Dec)	
	2023	2022	2023	2022
R&D costs	-6,482	-43,674	-81,266	-118,113
Administration costs	-5,472	-4,760	-19,774	-14,628
Commercial preparation costs	905	-3,780	-10,438	-14,929
Other operating costs	-361	-33	-1,023	-163
Total operating costs	-11,410	-52,246	-112,501	-147,834
R&D costs/Operating costs (%)	57%	84%	72%	80%

Financial calendar

Annual General Meeting 2024:	6 May 2024
Interim report Q1 2024 (Jan-Mar):	16 May 2024
Half-year report H1 2024 (Jan-Jun):	15 August 2024
Interim report 9M 2024 (Jan-Sep):	7 November 2024
Full-year report 2024 (Jan-Dec):	7 February 2025

Contact

Magnus Corfitzen, CEO
moc@ascelia.com | +46 735 179 118

Julie Waras Brogren, Deputy CEO (Finance, Investor Relations & Commercial)
jwb@ascelia.com | +46 735 179 116

**ASCELIA
PHARMA**

ASCELIA PHARMA AB (publ)
Hyllie Boulevard 34
SE-215 32 Malmö, Sweden

ascelia.com