ASCELIA PHARMA
Advancing Orphan Oncology

INTERIM REPORT 9M 2023

January – September 2023

Re-evaluation of SPARKLE phase 3 study images progresses according to plan

KEY EVENTS IN Q3 2023

- Re-evaluation required after intra-reader inconsistency in scoring of images from phase 3 study SPARKLE
- Ascelia Pharma significantly reduces organization to reach SPARKLE headline results
- Ascelia Pharma to reach headline results from SPARKLE re-evaluation by May 2024 with current funding

KEY EVENTS AFTER THE PERIOD

- Ascelia Pharma gets acceptance for publication of Orviglance® review article in Investigative Radiology
- Ascelia Pharma convenes an Extraordinary General Meeting on November 13, 2023 to vote on a proposal to introduce an employee stock option program

"We expect to reach SPARKLE headline results by May 2024 with currently available funding."

KEY RATIOS GROUP

	Q3 (Jul-Sep)		9M (Jan-Sep)	
	2023	2022	**2023**	2022
OPERATING RESULT (SEKm)				
	-21.4	-29.6	**-99.9**	-94.8
EARNINGS PER SHARE (SEK)				
	-0.63	-0.77	**-2.93**	-2.25
CASH FLOW FROM OPERATIONS (SEKm)				
	-31.0	-32.5	**-110.9**	-96.6
LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)				
	39.0	179.8	**39.0**	179.8

CEO STATEMENT

This year, our focus has been on completing 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, it was discovered that high intra-reader variability in the study image scoring by independent radiologists prevented us from evaluating the efficacy data from SPARKLE. Due to this finding, we are now conducting a new evaluation of the images with new independent readers. With the aim of completing the re-evaluation with current funding, we have undergone significant cost-cutting initiatives and a reduction of the organization, as communicated end August. All our efforts and resources are now focused on the image re-evaluation, and in September we communicated that we expect headline results from SPARKLE by May 2024, and that we can complete the re-evaluation with currently available funding. In addition, we expanded the commercialization strategy for Orviglance to also consider launching Orviglance in the US with a partner. While the re-evaluation is a regrettable setback on our timelines, our confidence in the potential of Orviglance is unchanged and we are dedicated to making the product available for patients in need of a gadolinium free liver imaging agent.

Reaching results for Phase 3 SPARKLE study. We completed the global multi-center SPARKLE study in early March 2023 with 85 patients. The MRI 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 a different time point.

The intra-reader variability analysis was specified in the clinical trial protocol and adheres to FDA guidance to industry. A high intra-reader varability means that this set of read-out data from SPARKLE cannot be used to conclude on the contrast effect and a re-evaluation is required. However, and importantly, the patient recruitment as well as collection and transfer of MR images and other study data to the central database remain fully valid.

In September, we completed the planning for the required re-evaluation of SPARKLE images. In this plan, headline results from SPARKLE are expected by May 2024. While the need to complete a re-evaluation of images from our SPARKLE study was unexpected, we now have clarity on what is required and how long it will take to reach headline results. Our entire team is focused on executing this plan and dedicated to ensuring the delivery of the results by May next year. We look forward to bringing Orviglance to patients in need and continue to have confidence in the commercial opportunity.

Expanded commercialization strategy. Orviglance addresses a well-defined unmet medical need. Our in-depth market research and launch preparations 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.

Until now the commercial strategy has been focused on building our own launch organization in the US with selected outsourced operations and finding commercial partners in the rest of the world. In light of the new timeline for Orviglance development, we have now expanded the commercialization strategy to also consider partnership opportunities for launch in the US.

”Our confidence in the potential of Orviglance is unchanged and we are dedicated to making the product available for patients in need of a gadolinium-free liver imaging agent.”

Organizational changes and financial position. In order to complete the re-evaluation with currently available funding, significant cost-cutting initiatives have been implemented, including a reduction of the organization which was announced at the end of August. The reorganization means that the Ascelia Pharma team now consist of 13 employees focused on completing the re-evaluation of SPARKLE images and reaching headline results, while maintaining the ability to ramp-up in all functional areas after the results from SPARKLE.

This was a very difficult decision for us to take. The dedication and ambition that we all share define Ascelia Pharma, and it is therefore very regrettable that many of our valued colleagues have had to leave the company. Unfortunately, these steps are necessary to pursue our ambition to reach SPARKLE headline results with our existing funding.

We ended the third quarter with SEK 39 million in cash and cash equivalents. Our significant cost savings will lead to a substantially lower cost level going forward, and we expect to reach headline results with currently available funding. With our savings and current plans, we have a cash runway into Q3 2024. We will need additional funding to continue and grow operations beyond this, and we will explore suitable funding options in due time as part of our efforts to progress Ascelia Pharma.

Unchanged opportunities. The unexpected and unfortunate outcome preventing us from obtaining a readout of the efficacy data from the SPARKLE study in the middle of the year changes our timelines. However, it does not change our confidence in Orviglance, nor does it change the global medical need for a liver imaging contrast agent without gadolinium.

I look forward to updating you on our progress and plans going forward and we are continuing our efforts to allow Orviglance to reach patients in need of a gadolinium-free contrast agent.

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.

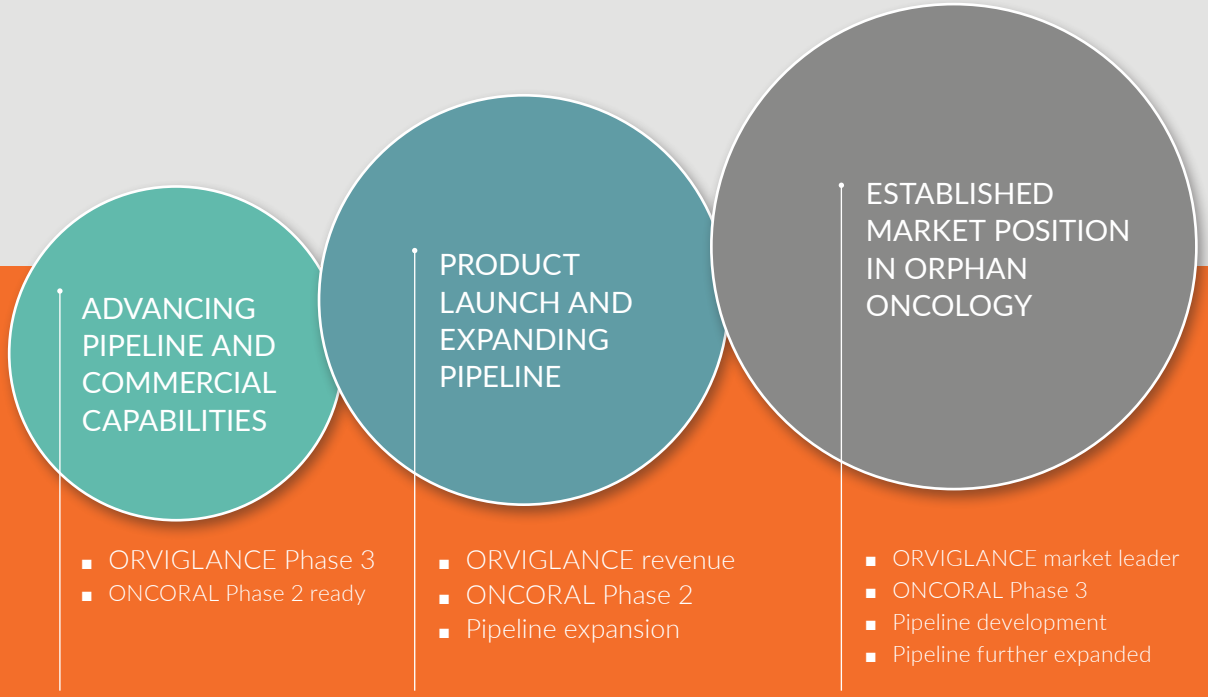
OUR VISION

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



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 will be re-evaluated before a reliable conclusion of the efficacy of Orviglance can be made. Common adverse events in the SPARKLE study were in line with previous studies with Orviglance, such as mild to moderate nausea. No drug related serious adverse reactions were reported.

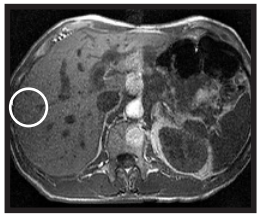
Patients referred for liver MRI scan

TODAY

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
All gadolinium contrast agents have regulatory Black Box warnings

MRI scan without contrast agent:
No liver metastasis visible

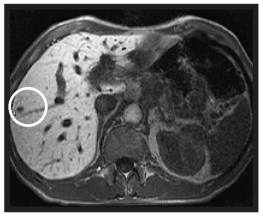


TOMORROW

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
ORVIGLANCE imaging drug

MRI scan with Orviglance:
Liver metastasis becomes visible



Orviglance aims to be the standard liver MRI contrast agent in patients with severely impaired kidney function

$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** ■ 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 total[1], 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.

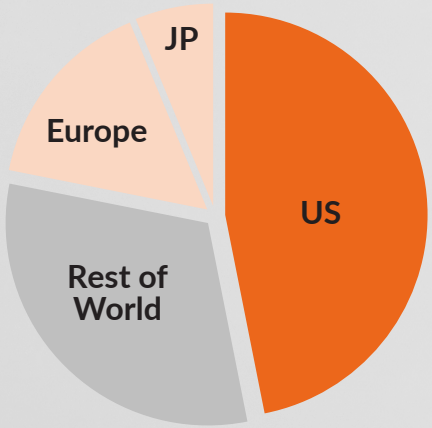
[1] The above mentioned results stem from of a blinded-read study, which comprised all imaging data from six phase 1 and 2 studies completed before start of the phase 3 program. The blinded-read results have been presented at major radiology conferences

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 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.

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

"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)

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.

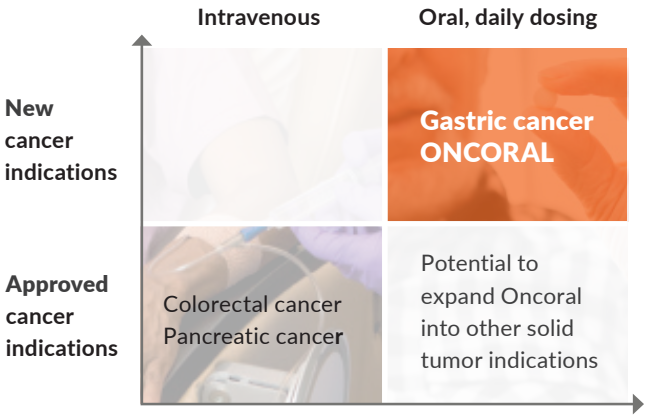
Anti-cancer effect is proven. The active pharmaceutical ingredient (API) in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is a so-called antineoplastic agent that after metabolic activation inhibits the enzyme topoisomerase 1, thereby inducing cancer 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 ofirinotecan. 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, iriontecan 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	■ 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 Q3 2023 (JUL-SEP)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q3 (Jul-Sep 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 494 thousand (SEK 352 thousand). The income mainly refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in Q3 were SEK 14.0 million (SEK 23.0 million). The cost decrease of SEK 9.0 million reflects decreased activity in the final stage of the phase 3 study.

Commercial preparation costs

During Q3, costs related to commercial preparations for Orviglance amounted to SEK 2.6 million (SEK 3.2 million). This primarily reflects a decrease in commercial employee costs.

Administration costs

Administration costs for the Group in Q3 amounted to SEK 4.9 million (SEK 3.7 million). The costs primarily relates to employees for the period.

Operating results (EBIT)

The operating result in Q3 amounted to SEK -21.4 million (SEK -29.6 million). The decreased loss reflects the lower level of R&D and commercialization activities. The operating result for Q3 is impacted by the costs for the organizational reduction.

Net Profit/Loss for the period

The Group's net loss in Q3 amounted to SEK -21.2 million (SEK -26.0 million). In the current quarter, net financial income of SEK 0.1 million was recognized due to strengthening of USD against SEK, which translated into an increase in the value of bank deposits (a significant part of bank deposit is held in USD to match upcoming cash outflow in this currency). The net loss corresponds to a loss per share, before and after dilution, of SEK -0.63 (SEK -0.77).

CASH FLOW

Cash flow from operating activities before changes in working capital in Q3 amounted to SEK -21.5 million (SEK -30.8 million). The decreased outflow reflects the lower level of R&D activities in current quarter. Changes in working capital in the current quarter totalled an outflow of SEK -9.5 million (outflow of SEK -1.7). The outflow in the current quarter mainly reflects the decrease in other liabilities. Cash flow from investing activities in Q3 totalled to an inflow of SEK 47 thousand (outflow of SEK -1 thousand). Cash flow from financing activities amounted to an outflow of SEK -0.2 million (outflow of SEK -0.3 million), which reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 84.6 million, compared with SEK 180.9 million per 31 December 2022 and SEK 230.3 million per 30 September 2022. The decrease since 31 December 2022 and 30 September 2022 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 39.0 million, compared to SEK 149.6 million per 31 December 2022 and 179.8 million per 30 September 2022. The decrease in liquid assets reflects the net loss incurred.

Financials key ratios for the Group	Q3 (July-September)	
	2023	2022
Operating result (SEK 000')	-21,362	-29,619
Net result (SEK 000')	-21,219	-25,959
Earnings per share (SEK)	-0.63	-0.77
Weighted avg. number of shares	33,722,762	33,668,262
R&D costs/operating costs (%)	77%	77%
Cash flow used in operating activities (SEK 000')	-31,031	-32,492
Equity (SEK 000')	84,568	230,295
Liquid assets incl. marketable securities (SEK 000')	38,992	179,811

FINANCIAL OVERVIEW 9M 2023 (JAN–SEPT 2023)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in 9M (Jan-Sep 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 1.2 million (SEK 0.7 million). The income mainly refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in 9M were SEK 74.8 million (SEK 74.4 million). The costs relate to the Orviglance phase 3 study.

Commercial preparation costs

During 9M, costs related to commercial preparations for Orviglance amounted to SEK 11.3 million (SEK 11.1 million).

Administration costs

Administration costs for the Group in 9M amounted to SEK 14.3 million (SEK 9.9 million). The cost increase primarily reflects a difference in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in 9M 2023 amounted to SEK -99.9 million (SEK -94.8 million). The increased loss mainly reflects the difference in recognized cost for employee incentive programs.

Net Profit/Loss for the period

The Group's net loss in 9M amounted to SEK -98.7 million (SEK -77.8 million). In the current period, net financial income of SEK 1.0 million was recognized due to strengthening of USD against SEK, which translated into an increase in the value of bank deposits. The decrease in net financial income compared to the same period last year (SEK 15.0 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 -2.93 (SEK -2.25).

CASH FLOW

Cash flow from operating activities before changes in working capital in 9M amounted to SEK -97.7 million (SEK -96.5 million).

The increased outflow primarily reflects the higher level of R&D activities in the current period. Changes in working capital in the current period totalled an outflow of SEK -13.1 million (outflow of SEK 16 thousand). The outflow in the current period primarily reflects the decrease in accounts payable and other liabilities. Cash flow from investing activities in 9M totalled an inflow of SEK 47 thousand (outflow of SEK -65 thousand). Cash flow from financing activities amounted to an outflow of SEK -0.7 million (outflow of SEK -0.9 million), which reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 84.6 million, compared with SEK 180.9 million per 31 December 2022 and SEK 230.3 million per 30 September 2022. The decrease since 31 December 2022 and 30 September 2022 reflects the net loss incurred. Liquid assets on the closing date amounted to SEK 39.0 million, compared to SEK 149.6 million per 31 December 2022 and 179.8 million per 30 September 2022. The decrease in liquid assets reflects the net loss incurred.

Financials key ratios for the Group	9M (January-September)	
	2023	2022
Operating result (SEK 000')	-99,861	-94,840
Net result (SEK 000')	-98,689	-77,841
Earnings per share (SEK)	-2.93	-2.25
Weighted avg. number of shares	33,711,982	34,576,448
R&D costs/operating costs (%)	78%	78%
Cash flow used in operating activities (SEK 000')	-110,865	-96,549
Equity (SEK 000')	84,568	230,295
Liquid assets incl. marketable securities (SEK 000')	38,992	179,811

OTHER INFORMATION

Incentive programs

In January 2023, the last option program was expired and the options were not exercised. Ascelia Pharma has outstanding share saving programs. The board of directors of Ascelia Pharma has during Q1 2023, in accordance with the provisions of LTI 2019, resolved to convert 54,500 series C shares for allotment of 54,500 ordinary shares to the participants in LTI 2019. For the share-saving program, employees are entitled to receive matching and performance shares according to 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 2022 on pages 70–72.

In case all outstanding incentive programs per 30 September 2023 (incl. a new share-saving program approved by the AGM in May 2023) are exercised in full, a total of 1.3 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 3.6 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 4 October, it was announced that Ascelia Pharma gets acceptance for publication of Orviglance review article in Investigative Radiology.

On 19 October Ascelia Pharma sent out a notice for an Extraordinary General Meeting on November 13 to vote on a proposal to introduce an employee stock option program.

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, 7 November 2023
Ascelia Pharma AB (publ)

Magnus Corfitzen
CEO

Consolidated Income Statement

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands (unless otherwise stated)**	2023	2022	2023	2022
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	**–**	**–**
Administrative costs	-4,929	-3,736	-14,302	-9,868
Research and development costs	-13,953	-22,993	-74,784	-74,439
Commercial preparation costs	-2,589	-3,233	-11,343	-11,149
Other operating income	494	352	1,230	747
Other operating costs	-386	-9	-662	-131
Operating result	**-21,362**	**-29,619**	**-99,861**	**-94,840**
Finance income	586	3,572	2,665	14,992
Finance costs	-478	-43	-1,702	-69
Net financial items	**108**	**3,529**	**963**	**14,923**
Loss before tax	**-21,255**	**-26,090**	**-98,898**	**-79,917**
Tax	35	131	209	2,076
Loss for the period	**-21,219**	**-25,959**	**-98,689**	**-77,841**
Attributable to:				
Owners of the Parent Company	-21,219	-25,959	-98,689	-77,841
Non-controlling interest	–	–	–	–
Earnings per share				
Before and after dilution (SEK)	-0.63	-0.77	-2.93	-2.25

Consolidated Statement of Comprehensive Income

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands (unless otherwise stated)**	2023	2022	2023	2022
Profit/loss for the period	**-21,219**	**-25,959**	**-98,689**	**-77,841**
Other comprehensive income				
Currency translation of subsidiaries**	-177	124	-568	381
Other comprehensive income for the period	**-177**	**124**	**-568**	**381**
Total comprehensive income for the period	**-21,397**	**-25,835**	**-99,256**	**-77,460**

* 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 2023	30 Sep 2022	31 Dec 2022
ASSETS			
Non-current assets			
Intangible assets	57,078	57,072	57,074
Tangible assets - Equipment	108	182	163
Right-of-use assets	1,195	688	462
Total non-current assets	**58,381**	**57,942**	**57,700**
Current assets			
Advance payments to suppliers	3,038	5,131	5,359
Current receivables			
Income tax receivables	3,733	7,436	2,785
Other receivables	1,271	1,369	1,745
Prepaid expenses and accrued income	953	2,402	1,426
Cash and bank balances	38,992	179,811	149,555
Total current assets	**47,988**	**196,148**	**160,869**
Total assets	**106,369**	**254,090**	**218,569**
EQUITY			
Share capital	34,871	34,871	34,871
Other paid-in capital	678,747	678,747	678,747
Reserve of exchange differences on translation	150	381	718
Loss brought forward (incl. net profit/loss for the period)	-629,201	-483,705	-533,478
Equity attributable to Parent Company shareholders	**84,568**	**230,295**	**180,859**
Total equity	**84,568**	**230,295**	**180,859**
LIABILITIES			
Long-term liabilities			
Lease liabilities	381	240	193
Total long-term liabilities	**381**	**240**	**193**
Current liabilities			
Accounts payable	4,618	3,858	15,881
Tax payable	–	–	–
Other liabilities	2,063	2,448	1,688
Current lease liabilities	885	483	291
Accrued expenses and deferred income	13,855	16,767	19,657
Total current liabilities	**21,420**	**23,556**	**37,518**
Total liabilities	**21,801**	**23,796**	**37,711**
Total equity and liabilities	**106,369**	**254,090**	**218,569**

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

Consolidated Statements of Changes in Equity

	9M (Jan-Sep)		FY (Jan-Dec)
*SEK in thousands**	2023	2022	2022
Equity at start of the period	**180,859**	**307,834**	**307,834**
Comprehensive income			
Profit/loss for the period	-98,689	-77,841	-131,223
Other comprehensive income	150	381	718
Total comprehensive income	**-98,539**	**-77,460**	**-130,505**
Transactions with shareholders			
New issue of C-shares	–	295	295
Repurchase of own shares C-shares	–	-295	-295
New issue of common shares	–	–	–
Common shares: Conversion from C-shares	-55	–	–
C-shares: Resolution of C-shares	55	–	–
Issuance expenses	-15	-84	-84
Redemption of warrants	–	–	–
Share based remuneration to employees	2,262	5	3,612
Total transactions with shareholders	**2,247**	**-79**	**3,529**
Equity at end of the period	**84,568**	**230,295**	**180,859**

* 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**	**2023**	**2022**	**2023**	**2022**
Operating activities				
Operating result	-21,362	-29,619	-99,861	-94,840
Expensed share based remuneration	109	-1,247	2,131	-1,867
Adjustment for items not included in cash flow	-68	253	343	853
Interest received	71	5	432	5
Interest paid	-27	-12	-92	-38
Income tax paid/received	-239	-207	-678	-644
Cash flow from operating activities before changes in working capital	**-21,515**	**-30,829**	**-97,724**	**-96,533**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	417	550	2,320	1,069
Increase (-)/Decrease (+) of operating receivables	1,401	-642	1,103	-1,987
Increase (+)/Decrease (-) of accounts payable	-1,878	-5,041	-11,259	-2,323
Increase (+)/Decrease (-) of other liabilities	-9,456	3,469	-5,304	3,224
Change in working capital	-9,516	-1,663	-13,141	-16
Cash flow used in operating activities	**-31,031**	**-32,492**	**-110,865**	**-96,549**
Investing activities				
Investment in equipment	–	–	–	–
Divestment of right-of-use assets	47	-1	47	-65
Cash flow from investing activities	**47**	**-1**	**47**	**-65**
Financing activities				
Issuance proceeds	–	–	–	–
Issuance costs	–	–	-15	-84
Conversion from C-shares	–	–	-55	–
Resolution of C-shares	–	–	55	–
Redemption of warrants net	–	–	–	–
Amortisation of loan (leasing)	-234	-250	-701	-777
Cash flow from financing activities	**-234**	**-250**	**-716**	**-861**
Cash flow for the period	-31,218	-32,742	-111,533	-97,474
Cash flow for the period	-31,218	-32,742	-111,533	-97,474
Cash and cash equivalents at start of period	70,500	208,861	149,555	261,599
Exchange rate differences in cash and cash equivalents	-290	3,692	970	15,686
Cash and cash equivalents at end of period	**38,992**	**179,811**	**38,992**	**179,811**

* 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**	**2023**	**2022**	**2023**	**2022**
Net sales	74	60	293	1,050
Gross profit/loss	**74**	**60**	**293**	**1,050**
Administrative costs	-4,877	-3,687	-14,040	-9,711
Research and development costs	-13,880	-20,794	-74,233	-64,268
Commercial preparation costs	-2,595	-3,218	-11,355	-11,149
Other operating income	384	–	847	57
Other operating costs	-131	-9	-202	-131
Operating result	**-21,024**	**-27,648**	**-98,690**	**-84,152**
Finance income	2,430	3,171	4,205	13,930
Finance costs	-426	-69	-1,172	-69
Result from other long-term receivables	-1,993	730	-1,208	1,188
Net financial costs	**11**	**3,832**	**1,826**	**15,049**
Loss before tax	-21,013	-23,816	-96,865	-69,103
Group contribution	–	–	–	–
Tax	–	–	–	–
Loss for the period	**-21,013**	**-23,816**	**-96,865**	**-69,103**

Parent Company – Statement of Comprehensive Income

	Q3 (Jul-Sep)		9M (Jan-Sep)	
SEK in thousands*	**2023**	**2022**	**2023**	**2022**
Loss for the period	**-21,013**	**-23,816**	**-96,865**	**-69,103**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total comprehensive income for the period	**-21,013**	**-23,816**	**-96,865**	**-69,103**

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

Parent Company – Balance Sheet

*SEK in thousands**	30 Sep 2023	30 Sep 2022	31 Dec 2022
ASSETS			
Non-current assets			
Tangible assets			
Equipment	108	182	163
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	36,519	37,983	38,486
Total non-current assets	**94,695**	**96,233**	**96,717**
Current assets			
Advance payments to suppliers	3,038	5,131	5,359
Current receivables			
Receivables from group companies	13,098	8,000	8,395
Income tax receivables	1,430	1,375	756
Other receivables	1,259	1,315	1,627
Prepaid expenses and accrued income	863	2,303	1,349
Cash and bank balances	26,738	171,730	137,879
Total current assets	**46,425**	**189,854**	**155,365**
Total assets	**141,120**	**286,087**	**252,082**
EQUITY			
Restricted equity			
Share capital	34,871	34,871	34,871
Non-restricted equity			
Other paid-in capital	678,747	678,747	678,747
Loss brought forward	-496,389	-380,875	-377,266
Loss for the period	-96,865	-69,142	-121,371
Total equity	**120,364**	**263,601**	**214,982**
LIABILITIES			
Current liabilities			
Accounts payable	4,933	3,296	16,022
Other liabilities	2,063	2,448	1,688
Accrued expenses and deferred income	13,759	16,742	19,390
Total current liabilities	**20,756**	**22,486**	**37,101**
Total equity and liabilities	**141,120**	**286,087**	**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

Oncoral Pharma ApS has an agreement with Solural Pharma ApS according to which, Solural Pharma ApS provides development and manufacturing of clinical study material. The owners of Solural Pharma ApS are the founders of Oncoral Pharma ApS and are, after the sale of Oncoral Pharma ApS to Ascelia Pharma AB in 2017, shareholders in Ascelia Pharma AB. Per 30 September 2023, the owners of Solural ApS collectively owned 1.16 percent of the shares in Ascelia Pharma AB. In addition to payment for services performed, Solural Pharma ApS has the right to receive a bonus of maximum SEK 10 million if commercialization occurs through a sale or a 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 Solural Pharma ApS right for remuneration by payment of SEK 10 million. In 9M 2023, services for a value of around SEK 290 thousand were acquired from Solural Pharma ApS.

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 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 implemented two employee option programs with individual terms and conditions. The parameter, which have the largest impact on the value of the options, is the publicly traded share price.

In 2021, the first program reached its exercise period and all options related to this program, 481,573 in total, were exercised into common shares.

In January 2023, the last option program was expired and the options were not exercised.

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 9M 2023 were SEK 2.1 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**	**2023**	**2022**	**2023**	**2022**
R&D costs	-13,953	-22,993	-74,784	-74,439
Administration costs	-4,929	-3,736	-14,302	-9,868
Commercial preparation costs	-2,589	-3,233	-11,343	-11,149
Other operating costs	-386	-9	-662	-131
Total operating costs	**-21,857**	**-29,971**	**-101,091**	**-95,587**
R&D costs/Operating costs (%)	**64%**	**77%**	**74%**	**78%**

Financial calendar

Full-year report 2023 (Jan-Dec):	9 February 2024
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

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