ASCELIA PHARMA

Advancing Orphan Oncology

INTERIM REPORT 9M 2022

January – September

Orviglance - Successful completion of two out of three studies for regulatory submission

SIGNIFICANT EVENTS IN Q3 2022

- Final results for the Hepatic Impairment Study marks the completion of the second study in the ongoing Phase 3 clinical program for registration of Orviglance.
- Results from the Orviglance Food Effect Study have been accepted as an oral presentation at the world's largest radiology conference, RSNA.

SIGNIFICANT EVENTS AFTER THE PERIOD

- Leadership team expanded to seven members to prepare for expected growth.

"Successful final results from Orviglance Hepatic impairment study marks the completion of the second study in the ongoing clinical program for registration."

KEY RATIOS GROUP

	Q3 (Jul-Sep)		9M (Jan-Sep)	
	2022	2021	**2022**	2021
OPERATING RESULTS (SEKm)				
	-29.6	-32.7	**-94.8**	-98.8
EARNINGS PER SHARE (SEK)				
	-0.77	-0.82	**-2.25**	-2.80
CASH FLOW FROM OPERATIONS (SEKm)				
	-32.5	-30.7	**-96.6**	-84.3
LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)				
	179.8	291.0	**179.8**	291.0

CEO COMMENTS

Ascelia Pharma continued to make strong progress on our clinical projects in Q3 2022, particularly the important Phase 3 program with our investigational magnetic resonance imaging (MRI) contrast agent Orviglance®. We have successfully completed two clinical studies – Hepatic Impairment Study and Food Effect Study – that have run in parallel with the pivotal clinical study SPARKLE, which is a solid step forward in our preparations for regulatory submission and approval of Orviglance.

Orviglance Phase 3 program. In September, we announced the successful final results of the Hepatic Impairment Study confirming that Orviglance is well tolerated in patients with hepatic impairment. These results mark the completion of the second of three studies in the ongoing Phase 3 clinical program for registration of Orviglance. Data from the Hepatic Impairment Study will be included in the marketing authorization application to health authorities, including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). The previously announced Food Effect study successfully concluded that Orviglance image enhancement was not impacted by a light meal. The ongoing Phase 3 study SPARKLE, which is required for a subsequent regulatory submission, is expected to complete patient enrollment by the end of this year. We continue to provide support to study investigators at all active hospitals to enroll patients.

Continued strong scientific interest in Orviglance. Results from the Food Effect Study were accepted as an oral presentation at the world's largest radiology conference, RSNA, which will be held November 27 – December 1 in Chicago. We are very pleased that the study has been selected for presentation. The results further support our previous findings on the ability to provide image enhancement to MRI scans with Orviglance.

We remain committed to Oncoral. We continue to plan for a Phase 2 study of our other candidate drug Oncoral, which is a novel daily irinotecan chemotherapy. Our clinical development team is now fully focused on Orviglance and we will start patient enrollment in the Oncoral study once we are certain this will have no impact on Orviglance devlopment.

Expanded leadership team and management changes. After the Q3 reporting period, the Ascelia Pharma leadership team was expanded to seven members who are responsible for all the important line functions. The expansion of our leadership team is an important step in our preparations to successfully transform Ascelia Pharma into a commercial stage company. In September, Déspina Georgiadou Hedin joined us as our new Chief Financial Officer (CFO), and I am confident that she will contribute strongly to our growth journey ahead. Our Chief Medical Officer (CMO) Carl Bjartmar has decided to retire by the end of 2022. I want to thank Carl for his invaluable contributions to Ascelia Pharma over these years and wish him all the best.

Solid financial position. Our progress requires access to liquidity. We have a solid balance sheet and closed the third quarter with 180 MSEK in cash, which will take us into Q4 2023. The liquidity position will primarily be used for the ongoing Phase 3 program with Orviglance regulatory submission and market launch preparations.

Looking ahead. Our prime focus in 2022 is unchanged – to complete the clinical Phase 3 program for Orviglance and continue preparations for NDA filing and commercialization. I look forward to updating you on our achievements as we bring Ascelia Pharma successfully forward.

Magnus Corfitzen
CEO

ADVANCING ORPHAN ONCOLOGY

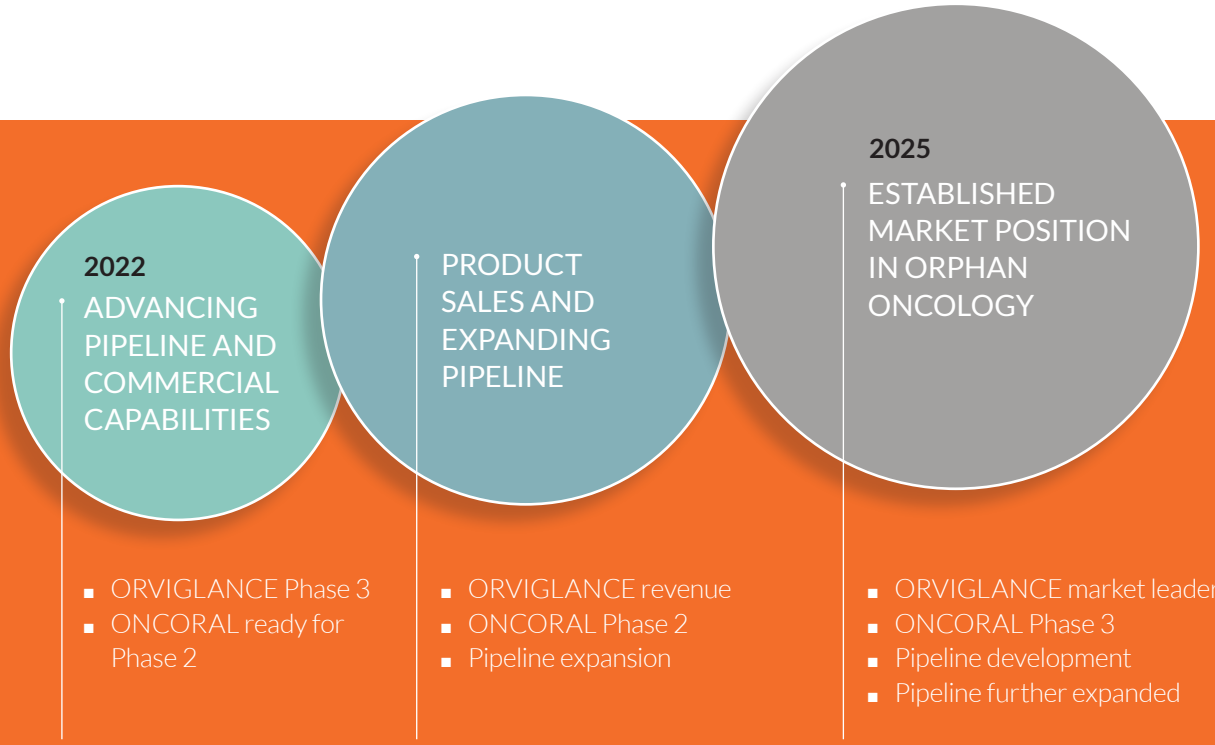
OUR VISION

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 the company and building value



OUR PIPELINE

ORVIGLANCE (Mangoral)
Diagnostic drug for liver 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. Orviglance characteristics:

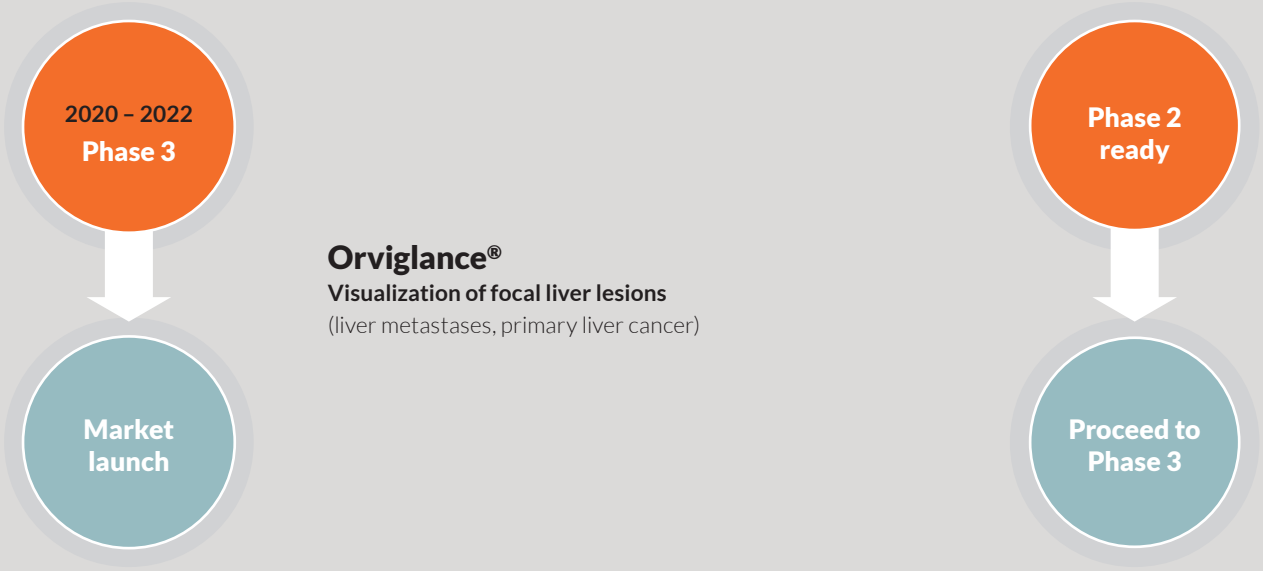
- Manganese-based diagnostic drug with Orphan Drug Designation (FDA)
- The only late-stage gadolinium-free agent
- $500-600 million annual addressable market

ONCORAL
Tablet chemotherapy ready for Phase 2

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

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

Expected timelines



ORVIGLANCE

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% to 46% 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 used in 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 increase the absorption of manganese from the small intestine into the portal liver vein. From there the manganese is transported to the liver where it is taken up by and retained in the normal liver cells, also known as the hepatocytes. The high manganese uptake causes the liver parenchyma to appear bright on MR images. As liver metastases are not liver cells, they do not take up manganese and consequently metastases appear dark on MR images. With Orviglance, liver metastases are consequently easier to identify due to this contrast effect.

Latest development

In November 2022, final results from the Orviglance Food Effect Study will be presented at the RSNA annual meeting in Chicago, Illinois. The conference will be held November 27 – December 1.

In September 2022, the successful final results of the Orviglance Hepatic Impairment Study was announced marking the completion of the second of three studies in the ongoing Phase 3 clinical program.

During Q2 2022, results from the Food Effect Study was announced. The results showed intake of a light meal prior to Orviglance administration provides similar liver MRI enhancement compared to a fasting condition. Further, results from an independent market research with 270 healthcare professionals in the US was announced. The results showed, among other things, that 84% of healthcare professionals will likely use Orviglance for MRI scans of patients with cancer in the liver and reduced kidney function.

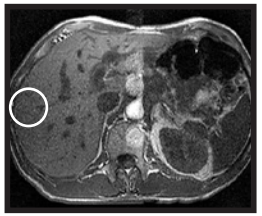
Patients referred for liver MRI scan

TODAY

NORMAL KIDNEY
Gadolinium imaging drug

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

MRI scan <u>without</u> contrast agent:
No liver metastasis visible

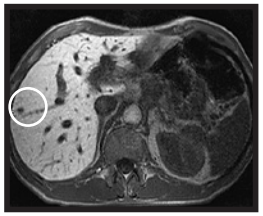


TOMORROW

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
ORVIGLANCE imaging drug

MRI scan <u>with</u> Orviglance:
Liver metastasis becomes visible



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

Addressable market of $500-600 million

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 conducted clinical trials show that Orviglance is a safe and effective contrast agent 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 $500-600 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 market exclusivity for a number of years after market approval (seven years in the US and ten years in the EU/EEA). For orphan drugs in general, the time to approval is also usually shorter and the proportion of orphan drugs that are approved is higher than for non-orphan drugs.

ONGOING PHASE 3 STUDY (SPARKLE)

The ongoing pivotal Phase 3 study SPARKLE is a global multicentre study in up to 200 patients. The strong results in the Phase 1 and Phase 2, both in terms of safety and efficacy, studies provide a solid foundation for the ongoing Phase 3 program. This is underpinned by the high degree of similarity between the primary endpoints in Phase 2 and Phase 3, and since the Phase 3 study comparator for Orviglance is MRI with no contrast agent. In addition, the follow-up time is less than a week, compared to months or years for the typical Phase 3 oncology study.

Orviglance's clinical Phase 3 study (based on Phase 3 protocol meeting with FDA and EMA)

NUMBER OF PATIENTS	**Global ongoing study in up to 200 patients**
ENDPOINT	**Lesion visualisation** • 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**
RANDOMISATION	**No – each patient at 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 underpin that Orviglance significantly improves MRI performance.

[1] The above mentioned results stem from of a blinded-read study, which comprised all imaging data including Phase 1 and Phase 2 data. The blinded-read results have been presented at major radiology conferences

ADDRESSABLE MARKET OF $500-600 MILLION

$500-600M annual addresable market in US, EU and Japan

Market estimate based on:

- Patients with primary liver cancer or liver metastases and severe kidney impairment (~4%)
- Actual imaging procedures (real-world data)[1]
- Payer and expert input (+75 stakeholders)[2]

Upsides

- Other markets, e.g., China
- Annual growth of 4-5%

Value maximizing go-to-market

US	**Ascelia Pharma to drive commercialization**	
EU	**Ascelia Pharma global synergies**	**Commercial partner**
Japan		**Commercial partner**
Other		**Commercial partner**

Strong footprint in the US

1. **SPARKLE Phase 3 Study** at leading US sites
2. **Hepatic Impairment Study** at Texas liver institute
3. **Ascelia Pharma Inc.** Office in New Jersey
4. **Manufacturing** at Cambrex (partner), NJ
5. **Imaging experts** RadMD, NY

Building an Ascelia Pharma US team

US team	**Around 40 FTEs at launch**
Clinics/ Hospitals	**Around 400 clinics and hospitals serve 75% of the target patient population[1]**

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

ONCORAL – IRINOTECAN 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.

Proven anti-cancer effect

The active pharmaceutical ingredient (API) in Oncoral is irinotecan, which has an established and proven effect in killing cancer cells. Irinotecan is 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.

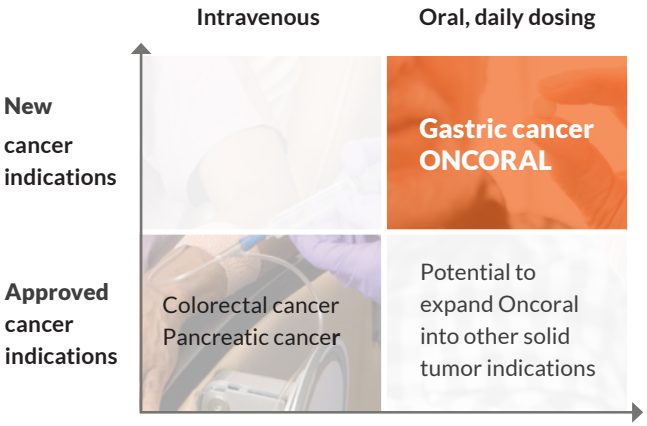
Potential to be the first oral irinotecan

Oncoral is a new patented oral tablet formulation of irinotecan. Oncoral enables a secure and efficient release and absorption of irinotecan from the gastro-intestinal tract after oral administration with a high conversion rate of irinotecan to the active metabolite SN-38, which has a high anti-tumor activity. Oncoral has the potential to be combined with other chemotherapies and targeted cancer drugs and enable an all oral chemo combination.

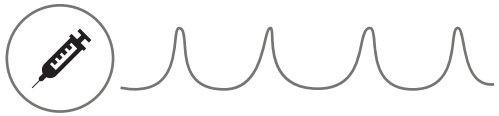
Latest development

We remain committed to Oncoral. We still plan for a Phase 2 study of Oncoral. However, as our clinical development team is now fully focused on SPARKLE, we will start patient enrollment in study when we are able to do this without impacting SPARKLE.

Oncoral - a novel formulation of irinotecan



TODAY – Intravenous bolus infusions



Infrequent high-dose IV irinotecan

- Gastrointestinal and haematological side effects
- Side-effects: 30% severe or life-threatening (grade 3 or 4)

TOMORROW – Oncoral oral daily dosing

Potential – Frequent low-dose irinotecan

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

ONCORAL PHASE 2 STUDY DESIGN

Following an initial dose-finding part, the Phase 2 study will be a randomized controlled multicenter study. In the study, Oncoral will be added to LONSURF (trifluridine and tipiracil) film-coated tablets for oral use compared to LONSURF alone. The objectives of the planned Phase 2 study are several. First of all, to establish a clinical proof of concept in metastatic gastric cancer. There is a potential for Orphan Drug Designation in gastric cancer and also the clinical guidelines and clinical data support efficacy of irinotecan in gastric cancer. Then there is potential for subsequent label expansion into other solid tumor indications. Another objective is to generate, compelling Phase 2 data for further development and design a Phase 3 study.

Phase 2 study design (an all-oral combination study)

TYPE OF STUDY	Randomized controlled, multicentre, multinational study: Oncoral + LONSURF vs. LONSURF
ENDPOINTS	**Primary:** Progression Free Survival **Secondary:** Response rate, PK, Safety and Overall Survival data in a follow up analysis
NUMBER OF PATIENTS	**Approximately 100 patients**

FINANCIAL OVERVIEW: Q3-2022 (JUL–SEP 2022)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q3 (Jul-Sep 2022) 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 totaled SEK 352 thousand (SEK 67 thousand). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in Q3 were SEK 23.0 million (SEK 24.7 million). The cost decrease of SEK 1.7 million primarily reflects lower costs for Oncoral Phase 2 preparations in current quarter.

Commercial preparation costs

During Q3, costs related to commercial preparations for Orviglance amounted to SEK 3.2 million (SEK 4.1 million). This reflects further investments in market launch preparations.

Administration costs

Administration costs for the Group in Q3 amounted to SEK 3.7 million (SEK 4.1 million). The cost decrease in the current quarter compared with Q3-2021 primarily reflects a decrease in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in Q3 amounted to SEK -29.6 million (SEK -32.7 million). The decreased loss primarily reflects the reduced costs of incentive programs for employees.

Net Profit/Loss for the period

The Group's net loss in Q3 amounted to SEK -26.0 million (SEK -28.5 million). In the current quarter, net financial income of SEK 3.5 million was recognized due to primarily 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 -0.77(SEK -0.82).

CASH FLOW

Cash flow from operating activities before changes in working capital in Q3 amounted to SEK -30.8 million (SEK -31.3 million). The outflow when compared to the same quarter previous year are at the same level. This reflects the continuously high levels of R&D activities and commercial preparations in current quarter. Changes in working capital in the current quarter totaled an outflow of SEK -1.7 million (inflow of SEK 0.5 million). The outflow in the current quarter primarily reflects the decrease in accounts payable and other liabilities.

Cash flow from investing activities in Q3 totaled to SEK -1 thousand (SEK 0 thousand). Cash flow from financing activities amounted to an outflow of SEK -0.3 million (outflow of SEK -0.3 million).

FINANCIAL POSITION

On the closing date, equity amounted to SEK 230.3 million, compared with SEK 307.8 million per 31 December 2021 and SEK 341.3 million per 30 September 2021. The decrease since 31 December 2021 and 30 September 2021 reflects the net losses incurred.

Liquid assets on the closing date amounted to SEK 179.8 million, compared to SEK 261.6 million per 31 December 2021 and SEK 291.0 million per 30 September 2021. The decrease since 31 December 2021 and 30 September 2021 reflects the net losses incurred.

Financials key ratios for the Group	Q3 (July-September)	
	2022	2021
Operating result (SEK 000')	-29,619	-32,736
Net result (SEK 000')	-25,959	-28,521
Earnings per share (SEK)	-0.77	-0.82
Weighted avg. number of shares	33,668,262	34,576,448
R&D costs/operating costs (%)	77%	75%
Cash flow used in operating activities (SEK 000')	-32,492	-30,729
Equity (SEK 000')	230,295	341,251
Liquid assets incl. marketable securities (SEK 000')	179,811	291,029

FINANCIAL OVERVIEW: 9M-2022 (JAN–SEP 2022)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in 9M (Jan-Sep 2022) 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 totaled SEK 747 thousand (SEK 194 thousand). The income refers to exchange rate gains.

Research and development costs (R&D)

R&D costs for the Group in 9M were SEK 74.4 million (SEK 79.7 million). The cost decrease of SEK 5.3 million primarily reflects timing of milestone payments for Orviglance Phase 3 study, which caused higher cost recognition in first quarter last year compared to the first quarter this year.

Commercial preparation costs

During 9M, costs related to commercial preparations for Orviglance amounted to SEK 11.1 million (SEK 7.1 million). The cost increase compared with 9M 2021 reflects a step-up in market launch preparations.

Administration costs

Administration costs for the Group in 9M amounted to SEK 9.9 million (SEK 11.8 million). The cost decrease primarily reflects a decrease in recognized costs for employee incentive programs.

Operating results (EBIT)

The operating result in 9M amounted to SEK -94.8 million (SEK -98.8 million). The reduced loss reflects the timing effect with lower R&D costs in Q1-2022, which was partly counterbalanced by higher commercial preparation costs.

Net Profit/Loss for the period

The Group's net loss in 9M amounted to SEK -77.8 million (SEK -90.8 million). In the current period, net financial income of SEK 14.9 million was recognized due to primarily 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 -2.25 (SEK -2.80).

Financials key ratios for the Group	9M (January-September)	
	2022	2021
Operating result (SEK 000')	-94,840	-98,788
Net result (SEK 000')	-77,841	-90,830
Earnings per share (SEK)	-2.25	-2.80
Weighted avg. number of shares	34,576,448	32,412,069
R&D costs/operating costs (%)	78%	80%
Cash flow used in operating activities (SEK 000')	-96,549	-84,313
Equity (SEK 000')	230,295	341,251
Liquid assets incl. marketable securities (SEK 000')	179,811	291,029

CASH FLOW

Cash flow from operating activities before changes in working capital in 9M amounted to SEK -96.5 million (SEK -94.5 million). The increased outflow y/y primarily reflects the higher level of commercial preparation in the current period. Changes in working capital in the current quarter totaled an outflow of SEK -16 thousand (inflow of SEK 10.2 million). The outflow in the current period primarily reflects the decrease in accounts payable.

Cash flow from investing activities in 9M totaled an outflow of SEK -65 thousand (SEK -38 thousand), which reflects a value loss indivestment of a leasing car. Cash flow from financing activities amounted to an outflow of SEK -0.9 million (inflow of SEK 185.1 million), which mainly reflects amortization of lease liabilities.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 230.3 million, compared with SEK 307.8 million per 31 December 2021 and SEK 341.3 million per 30 September 2021. The decrease since 31 December 2021 and 30 September 2021 reflects the net losses incurred.

Liquid assets on the closing date amounted to SEK 179.8 million, compared to SEK 261.6 million per 31 December 2021 and SEK 291.0 million per 30 September 2021. The decrease since 31 December 2021 and 30 September 2021 reflects the net losses incurred.

Other information

Incentive programs

Ascelia Pharma has one outstanding employee option program as well as share saving programs. If the terms of the option program are met at the time for utilization, the management team 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 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 2021 on pages 67-68.

In case all outstanding incentive programs per 30 September 2022 (incl. a new share-saving program approved by the AGM in May 2022) are exercised in full, a total of 2.2 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate maximum dilution of approximately 6.2% 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.

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 2021 on pages 34-36.

Siginificant events after the end of the reporting period

On 5 October 2022, it was annonced that Ascelia Pharma expands its leadership team to seven members.

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, 4 November 2022
Ascelia Pharma AB (publ)

Magnus Corfitzen
CEO

Consolidated Income Statement

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands (unless otherwise stated)**	2022	2021	2022	2021
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	**–**	**–**
Administrative costs	-3,736	-4,050	-9,868	-11,794
Research and development costs	-22,993	-24,686	-74,439	-79,674
Commercial preparation costs	-3,233	-4,066	-11,149	-7,146
Other operating income	352	67	747	194
Other operating costs	-9	-1	-131	-368
Operating result	**-29,619**	**-32,736**	**-94,840**	**-98,788**
Finance income	3,572	2,946	14,992	7,388
Finance costs	-43	-27	-69	-1,990
Net financial items	**3,529**	**2,919**	**14,923**	**5,398**
Loss before tax	**-26,090**	**-29,817**	**-79,917**	**-93,390**
Tax	131	1,296	2,076	2,560
Loss for the period	**-25,959**	**-28,521**	**-77,841**	**-90,830**
Attributable to:				
Owners of the Parent Company	-25,959	-28,521	-77,841	-90,830
Non-controlling interest	–	–	–	–
Earnings per share				
Before and after dilution (SEK)	-0.77	-0.82	-2.25	-2.80

Consolidated Statement of Comprehensive Income

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands (unless otherwise stated)**	2022	2021	2022	2021
Profit/loss for the period	**-25,959**	**-28,521**	**-77,841**	**-90,830**
Other comprehensive income				
Currency translation of subsidiaries**	124	61	381	69
Other comprehensive income for the period	**124**	**61**	**381**	**69**
Total comprehensive income for the period	**-25,835**	**-28,460**	**-77,460**	**-90,761**

* 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 2022	30 Sep 2021	31 Dec 2021
ASSETS			
Non-current assets			
Intangible assets	57,072	57,063	57,063
Tangible assets - Equipment	182	256	238
Right-of-use assets	688	1,851	1,581
Total non-current assets	**57,942**	**59,170**	**58,882**
Current assets			
Advance payments to suppliers	5,131	7,419	6,175
Current receivables			
Income tax receivables	7,436	4,878	4,395
Receivables from shareholders	–	–	–
Other receivables	1,369	1,706	1,165
Prepaid expenses and accrued income	2,402	842	1,277
Cash and bank balances	179,811	291,029	261,599
Total current assets	**196,148**	**305,874**	**274,611**
Total assets	**254,090**	**365,044**	**333,493**
EQUITY			
Share capital	34,871	34,576	34,576
Other paid-in capital	678,747	678,831	678,831
Reserve of exchange differences on translation	381	188	254
Loss brought forward (incl. net profit/loss for the period)	-483,705	-372,344	-405,827
Equity attributable to Parent Company shareholders	**230,295**	**341,251**	**307,834**
Total equity	**230,295**	**341,251**	**307,834**
LIABILITIES			
Long-term liabilities			
Leasing	240	822	553
Total long-term liabilities	**240**	**822**	**553**
Current liabilities			
Accounts payable	3,858	8,264	6,147
Tax payable	–	–	5
Other liabilities	2,448	1,406	1,509
Current lease liabilities	483	1,106	1,102
Accrued expenses and deferred income	16,767	12,195	16,343
Total current liabilities	**23,556**	**22,971**	**25,106**
Total liabilities	**23,796**	**23,793**	**25,659**
Total equity and liabilities	**254,090**	**365,044**	**333,493**

* 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**	2022	2021	2021
Equity at start of the period	**307,834**	**236,056**	**236,056**
Comprehensive income			
Profit/loss for the period	-77,841	-90,830	-125,903
Other comprehensive income	381	69	135
Total comprehensive income	**-77,460**	**-90,761**	**-125,768**
Transactions with shareholders			
New issue of C-shares	295	398	397
Repurchase of own shares C-shares	-295	-398	-397
New issue of common shares	–	200,000	200,000
Issuance expenses	-84	-13,271	-13,271
Redemption of warrants	–	3,852	3,853
Share based remuneration to employees	5	3,545	6,964
Total transactions with shareholders	**-79**	**194,127**	**197,546**
Equity at end of the period	**230,295**	**339,422**	**307,834**

* 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**	**2022**	**2021**	**2022**	**2021**
Operating activities				
Operating result	-29,619	-32,736	-94,840	-98,788
Expensed share based remuneration	-1,247	1,398	-1,867	4,129
Adjustment for items not included in cash flow	253	286	853	724
Interest received	5	–	5	–
Interest paid	-12	-22	-38	-58
Income tax paid/received	-207	-200	-644	-539
Cash flow from operating activities before changes in working capital	**-30,829**	**-31,274**	**-96,533**	**-94,532**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	550	-1,883	1,069	870
Increase (-)/Decrease (+) of operating receivables	-642	-220	-1,987	-981
Increase (+)/Decrease (-) of accounts payable	-5,041	-822	-2,323	4,377
Increase (+)/Decrease (-) of other liabilities	3,469	3,470	3,224	5,953
Change in working capital	-1,663	545	-16	10,219
Cash flow used in operating activities	**-32,492**	**-30,729**	**-96,549**	**-84,313**
Investing activities				
Investment in equipment	–	–	–	-38
Divestment of right-of-use assets	-1	–	-65	–
Cash flow from investing activities	**1**	**0**	**-65**	**-38**
Financing activities				
Issuance proceeds	–	–	–	200,000
Issuance costs	–	–	-84	-13,271
Redemption of warrants net	–	–	–	-914
Amortisation of loan (leasing)	-250	-271	-777	-671
Cash flow from financing activities	**-250**	**-271**	**-861**	**185,144**
Cash flow for the period	**-32,742**	**-31,000**	**-97,474**	**100,793**
Cash flow for the period	-32,742	-31,000	-97,474	100,793
Cash and cash equivalents at start of period	208,861	319,014	261,599	184,686
Exchange rate differences in cash and cash equivalents	3,692	3,015	15,686	5,550
Cash and cash equivalents at end of period	**179,811**	**291,029**	**179,811**	**291,029**

* 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**	2022	2021	2022	2021
Net sales	60	1,817	1,050	4,298
Gross profit/loss	**60**	**1,817**	**1,050**	**4,298**
Administrative costs	-3,687	-3,996	-9,711	-11,712
Research and development costs	-20,794	-19,544	-64,268	-70,487
Commercial preparation costs	-3,218	-4,073	-11,149	-7,162
Other operating income	–	36	57	136
Other operating costs	-9	–	-131	-344
Operating result	**-27,648**	**-25,760**	**-84,152**	**-85,271**
Finance income	3,171	2,657	13,930	7,099
Finance costs	-69	-6	-69	-1,936
Result from other long-term receivables	730	393	1,188	1,181
Net financial costs	**3,832**	**3,044**	**15,049**	**6,344**
Loss before tax	-23,816	-22,716	-69,103	-78,927
Group contribution	–	–	–	–
Tax	–	–	–	–
Loss for the period	**-23,816**	**-22,716**	**-69,103**	**-78,927**

Parent Company – Statement of Comprehensive Income

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands**	2022	2021	2022	2021
Loss for the period	**-23,816**	**-22,716**	**-69,103**	**-78,927**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total comprehensive income for the period	**-23,816**	**-22,716**	**-69,103**	**-78,927**

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

Parent Company – Balance Sheet

SEK in thousands*	30 Sep 2022	30 Sep 2021	31 Dec 2021
ASSETS			
Non-current assets			
Tangible assets			
Equipment	182	256	238
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables from group companies	37,983	32,566	36,620
Total non-current assets	**96,233**	**90,890**	**94,926**
Current assets			
Advance payments to suppliers	5,131	5,476	5,323
Current receivables			
Receivables from group companies	8,000	5,740	6,971
Income tax receivables	1,375	1,161	739
Other receivables	1,315	1,596	656
Prepaid expenses and accrued income	2,303	842	1,183
Cash and bank balances	171,730	276,959	246,311
Total current assets	**189,854**	**291,774**	**261,183**
Total assets	**286,087**	**382,664**	**356,109**
EQUITY			
Restricted equity			
Share capital	34,871	34,576	34,576
Non-restricted equity			
Other paid-in capital	678,747	678,831	678,831
Loss brought forward	-380,875	-272,884	-271,295
Loss for the period	-69,142	-78,927	-109,288
Total equity	**263,601**	**361,596**	**332,824**
LIABILITIES			
Current liabilities			
Accounts payable	3,296	7,938	5,700
Other liabilities	2,448	1,406	1,509
Accrued expenses and deferred income	16,742	11,724	16,076
Total current liabilities	**22,486**	**21,068**	**23,285**
Total equity and liabilities	**286,087**	**382,664**	**356,109**

* 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 2022, the owners of Solural ApS collectively owned 1.9% 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 2022, services for a value of around SEK 483 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 2022, 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, one program reached its exercise period and all options related to this program, 481,573 in total, were exercised into common shares.

For the outstanding option program, a gain of SEK 0.9 million including social security charges was recognized in 9M 2022. The gain primarily reflects the decline is Ascelia Pharma's share price during the period resulting in a lower liability for social security charges.

Share saving programs

Ascelia Pharma has implemented four 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 2022 were SEK 0.9 million.

Notes

Definitions of alternative performance measures

Alternative performance measures	Definition	Aim
Operating results (TSEK)	Profit before financial items and tax.	The performance measure shows the company´s operational performance.
Research and development costs/Operating costs (%)	The research and development expenses in relation to total operating costs (consisting of the sum of administrative expenses, R&D, costs for commercial preparations and other operating expenses).	The performance measure is useful in order to understand how much of the operating costs that are related to research- and development expenses.

Reconciliation table for alternative performance measures for the Group

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands**	2022	2021	2022	2021
R&D costs	-22,993	-24,686	-74,439	-79,674
Administration costs	-3,736	-4,050	-9,868	-11,794
Commercial preparation costs	-3,233	-4,066	-11,149	-7,146
Other operating costs	-9	-1	-131	-368
Total operating costs	**-29,971**	**-32,803**	**-95,587**	**-98,982**
R&D costs/Operating costs (%)	**77%**	**75%**	**78%**	**80%**

Financial calendar

Full-year report 2022 (Jan-Dec):	10 February 2023
Annual General Meeting 2022:	4 May 2023
Interim report Q1 2023 (Jan-Mar):	11 May 2023
Half-year report H1 2023 (Jan-Jun):	18 August 2023
Interim report 9M 2023 (Jan-Sep):	8 November 2023
Full-year report 2023 (Jan-Dec):	9 February 2024

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