ASCELIA PHARMA

Advancing Orphan Oncology

INTERIM REPORT 9M 2021

January – September 2021

Oncoral – entering clinical collaboration

SIGNIFICANT EVENTS IN Q3 2021

- Clinical collaboration agreement with Taiho Oncology Inc. for the development of Oncoral in combination with LONSURF®
- Abstract for Orviglance comparison study to gadolinium accepted as an oral paper presentation at the world's largest radiology conference RSNA
- FDA conditionally accepted Orviglance® as the brand name for Mangoral
- Guidance for expected recruitment completion to the SPARLE trial was extended to H1 2022 (previously H2 2021)

SIGNIFICANT EVENTS AFTER THE PERIOD

- Food Effect Study with Orviglance successfully completed

" The agreement with Taiho Oncology shows the potential for Oncoral to be part of a new all-oral treatment regimen for gastric cancer

KEY RATIOS GROUP

	Q3 (Jul-Sep)		9M (Jan-Sep)	
	2021	2020	**2021**	2020
OPERATING RESULT (SEKm)	**-32.7**	-16.3	**-98.8**	-65.5
EARNINGS PER SHARE (SEK)	**-0.82**	-0.51	**-2.80**	-2.47
CASH FLOW FROM OPERATIONS (SEKm)	**-30.7**	-18.9	**-84.3**	-58.0
LIQUID ASSETS INCL. MARKETABLE SECURITIES (SEKm)	**291.0**	220.7	**291.0**	220.7

CEO COMMENTS

In the third quarter we made good progress across our clinical portfolio, including signing an important collaboration agreement with Taiho Oncology for the upcoming global Phase 2 clinical study in gastric cancer with Oncoral in combination with Taiho Oncology's LONSURF® (trifluridine and tipiracil). We also continued the clinical development program and the commercial preparations for Orviglance® (formerly Mangoral), our diagnostic drug currently in Phase 3. The progress continued after the period when we completed our food effect study with Orviglance in October.

Important collaboration agreement around Oncoral. In September, we signed a clinical collaboration agreement with Taiho Oncology (part of the global pharma company Otsuka Group). Taiho Oncology is specialized in the development and commercialization of orally administered anti-cancer agents. The Phase 2 clinical study is planned to start in Q4 2021 and will include approximately 100 patients with metastatic gastric cancer. In this all-oral combination study, our novel irinotecan chemotherapy tablet Oncoral (ASC-201) will be evaluated in combination with Taiho Oncology's LONSURF film-coated tablets for oral use.
This is an important agreement for us and shows the potential for Oncoral to be a new treatment regimen for gastric cancer. We believe this investigational all-oral tablet combination has the potential to provide a significant treatment benefit to patients suffering from this very aggressive cancer form where there is a massive unmet medical need.

SPARKLE study with Orviglance – recruitment completion expected in H1 2022. In August 2021, we announced an expected extension of the recruitment period to H1 2022 (previously H2 2021) of the pivotal phase 3 clinical study SPARKLE. The delay is induced by the ongoing Covid-19 pandemic that impacts healthcare systems and clinical study activities and also recruitment pace to SPARKLE. We are responding to the Covid-19 impact by increasing the number of countries and clinics recruiting patients into the study, with the expectation to complete the recruitment in H1 2022.

Food effect study with Orviglance successfully completed. An important part of our pivotal clinical program with Orviglance are the two complementary studies that are run in parallel with SPARKLE. These studies will also be included in the marketing authorization package submitted to the health authorities including FDA and EMA. In October, we announced that the last patient visit was completed in the Food Effect study to evaluate the effect of food intake on the absorption of Orviglance. It is designed to assess whether the current fasting requirement before patients are given Orviglance is necessary. Preliminary data indicate that Orviglance has been well tolerated in the study. Final results are expected late 2021 or early 2022.

We are very satisfied to have completed the patient enrollment amid the Covid-19 pandemic. A potential removal of the current fasting requirement could further improve the convenience and ease the administration of Orviglance in clinical practice.

Continued scientific progress for Orviglance. We are very pleased that the study where Orviglance was compared against a gadolinium-based contrast agent has been accepted as an oral paper presentation at the world's largest radiology conference RSNA, which will be held November 28 – December 3 in Chicago, Illinois. The study provides robust evidence of the diagnostic value that Orviglance can offer once available to patients and physicians. The opportunity to present these results at this prominent conference is a further validation of Orviglance's potential to address the significant unmet medical need and ultimately help these patients.

Solid financial position. We have a strong balance sheet with 291 MSEK in cash at Q3 2021, which will take us well into 2023. The strong liquidity position will be used for the ongoing Phase 3 program for Orviglance and the market launch preparations as well as Oncoral's Phase 2 clinical program.

Looking ahead. Our focus is on the development program of Orviglance and the preparations to make it available to patients in need, and to initiate upcoming clinical studies with Oncoral. We work constantly to create shareholder value, and I will keep you updated about the future progress of Ascelia Pharma and our novel clinical portfolio.

Magnus Corfitzen,
CEO

ABOUT ASCELIA PHARMA

- Ascelia Pharma is a biotech company focused on orphan oncology treatments
- We develop and commercialize novel drugs that address unmet medical needs and have a clear development and market pathway
- Two drug candidates – Orviglance (Mangoral) and Oncoral – currently in clinical development
- Global headquarter in Malmö, Sweden, and shares listed on Nasdaq Stockholm (ticker: ACE)

ORVIGLANCE (Mangoral): Diagnostic drug for liver MRI in Phase 3

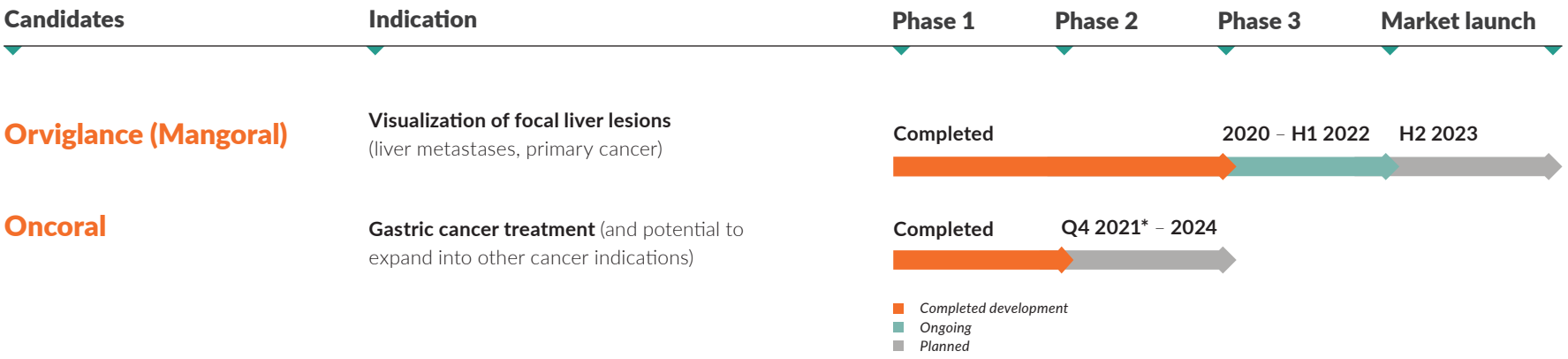
Orviglance is our novel non-gadolinium diagnostic drug (contrast agent) to be used in MRI-scans of the liver. Orviglance is developed to improve the visualization of focal liver lesions (liver metastases) in patients with impaired kidneys that are at risk of severe side-effects from the gadolinium contrast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

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

ONCORAL: Tablet chemotherapy ready for Phase 2

Oncoral is our novel oral chemotherapy tablet developed initialy 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 for both ongoing and planned development could be delayed in a prolonged Covid-19 situation
** Expected date for study start approval (IND approval)*

MANGORAL BECOMES ORVIGLANCE

Orviglance® is the brand name for manganese chloride tetrahydrate (previous working name Mangoral)

Mangoral

Brand name approved by FDA

In August 2021, the U.S. Food and Drug Administration (FDA) conditionally accepted Orviglance* as the proposed brand name for manganese chloride tetrahydrate (Mangoral). The name Orviglance was developed in accordance with FDA's guidance for the submission and evaluation of proprietary names and the name selection included a research study of healthcare practitioners across the U.S. to ensure accurate prescription and safety interpretation of the name.

Brand name also approved by EMA

Orviglance has earlier also received an invented name approval from the European Medicines Agency (EMA).

**Trademark is registered in Europe and several other markets and submitted for registration in the US.*

ORVIGLANCE (MANGORAL)

Liver MRI contrast 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 (Mangoral) 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.

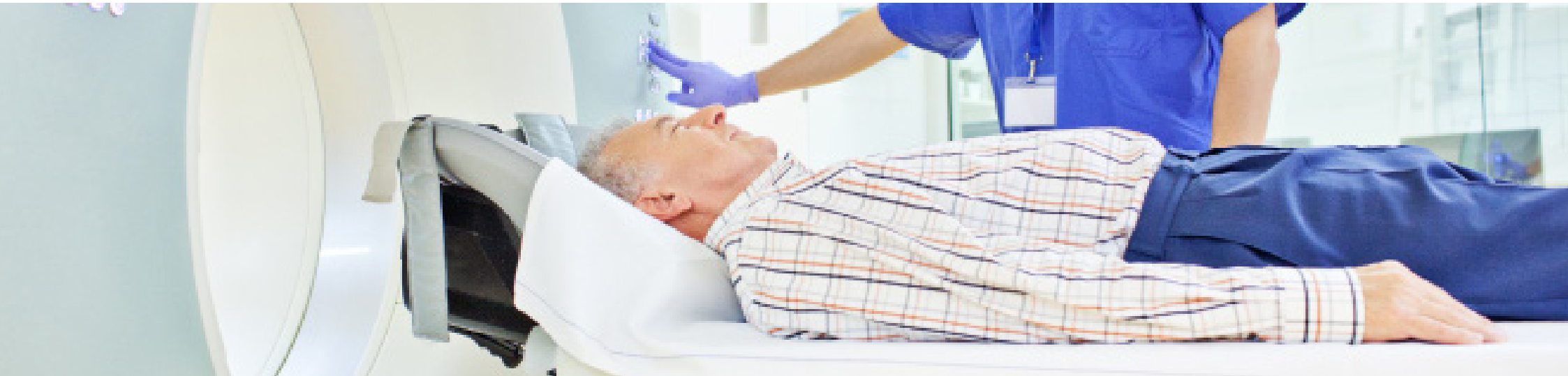
Latest development

In October 2021, last patient visit was completed in the Food Effect Study. Preliminary data indicate that Orviglance has been well tolerated in the study. Final results of the Food Effect Study are expected early 2022.

In August 2021, FDA conditionally accepted Orviglance as the proposed brand name for manganese chloride tetrahydrate (Mangoral).

In August 2021, the abstract for Orviglance comparison study to gadolinium was accepted as an oral paper presentation at the world's largest radiology conference RSNA.

In August 2021, Ascelia Pharma announced that due to Covid-19 the estimated timeline for completion of recruitment to the SPARKLE trial is extended into H1 2022.



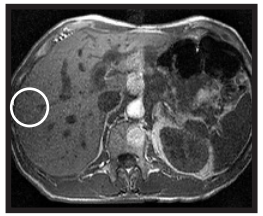
Patients referred for liver MRI scan

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

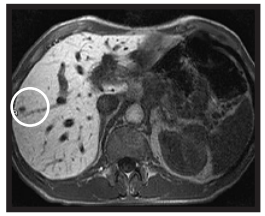


TOMORROW

NORMAL KIDNEY
Gadolinium imaging drug

POOR KIDNEY FUNCTION
ORVIGLANCE (MANGORAL) imaging drug

MRI scan with Orviglance:
Liver metastasis visible



Orviglance aims to be the standard of care liver MRI imaging drug for patients where gadolinium-based contrast agents may be medically inadvisable or cannot be administered

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 (Mangoral) 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 (Mangoral) 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 (Mangoral) 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 $500-600M

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

- Large markets with mature clinical practices
- Clear regulatory and market access pathway
- Orviglance to be the only gadolinium-free product for this patient group

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 Woodbridge, NJ
4. **Manufacturing** at Cambrex (partner), NJ
5. **Imaging experts** RadMD, NY

Building an Ascelia Pharma US team

Sales team	**~20 full-time employees reach priority decision makers**
Clinics/ Hospitals	**Around 400 clinics and hospitals serve 75% of the kidney impairment patients[1]**

Sources:
1: Market research with Decision Resources Group, 2020
2: Market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

ONCORAL

Oncoral is a novel daily irinotecan chemotherapy in development. Irinotecan chemotherapy has an established potent anti-tumor effect. Oncoral is a oral 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.

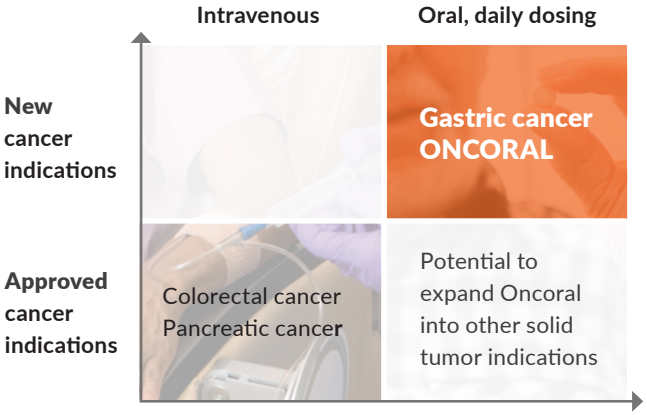
Potential to be the first oral irinotecan

Oncoral is a 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.

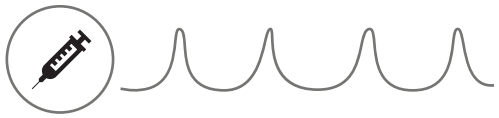
Latest development

In September 2021, a clinical collaboration agreement was signed with Taiho Oncology for the development of Oncoral in combination LONSURF. The collaboration concerns the upcoming Phase 2 clinical study in gastric cancer. As part of the agreement, Taiho Oncology will supply LONSURF and provide scientific expertise for the study. Ascelia Pharma retains full development and commercialization rights to Oncoral.

Oncoral – a novel formulation of irinotecan



TODAY – Intravenous bolus infusions



Infrequent high-dose IV irinotecan

- Gastrointestinal and hematological 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

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. Gastric cancer is chosen partly because of strategic reasons. 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 all, compelling Phase 2 data for further development and obtain solid data to 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**
STUDY PERIOD	**Q4-2021* - 2024**

** Expected date for study start approval (IND approval)*

FINANCIAL OVERVIEW: Q3-2021 (JUL–SEP 2021)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in Q3 (Jul-Sep 2021) 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 67 thousand (SEK 363 thousand).

Research and development costs (R&D)

R&D costs for the Group in Q3 were SEK 24.7 million (SEK 11.3 million). The cost increase of SEK 13.4 million underlines an overall higher activity level in Ascelia Pharma in the current quarter vis-à-vis corresponding quarter last year. This was driven by costs related to Orviglance Phase 3 clinical study and manufacturing preparations as well as increased costs for Oncoral Phase 2 preparations.

Commercial preparation costs

During Q3, costs related to commercial preparations of amounted to SEK 4.1 million (SEK 1.2 million). The cost increase compared with Q3-2020 reflects preparations towards launching of Orviglance to the market.

Administration costs

Administration costs for the Group in Q3 amounted to SEK 4.1 million (SEK 3.7 million).

Operating results (EBIT)

The operating result in Q3 amounted to SEK -32.7 million (SEK -16.3 million). The increased loss reflects the overall higher level of R&D activities and manufacturing preparations in Q3-2021.

Net Profit/Loss for the period

The Group's net loss in Q3 amounted to SEK -28.5 million (SEK -14.7 million). In the current quarter, net financial income of SEK 2.9 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 these currencies). The net loss corresponds to a loss per share, before and after dilution, of SEK -0.82 (SEK -0.51).

Financials key ratios for the Group	Q3 (July-September)	
	2021	2020
Operating result (SEK 000')	-32,736	-16,292
Net result (SEK 000')	-28,521	-14,690
Earnings per share (SEK)	-0.82	-0.51
Weighted avg. number of shares	34,576,448	28,645,610
R&D costs/operating costs (%)	75%	68%
Cash flow used in operating activities (SEK 000')	-30,729	-18,885
Equity (SEK 000')	341,251	270,614
Liquid assets incl. marketable securities (SEK 000')	291,029	220,739

CASH FLOW

Cash flow from operating activities before changes in working capital in Q3 amounted to SEK -31.3 million (SEK -14.4 million). The increased outflow y/y primarily reflects the higher level of R&D activities and manufacturing preparations in the current quarter. Changes in working capital in the current quarter totaled an inflow of SEK 0.5 million (outflow of SEK 4.5 million).

Cash flow from investing activities in Q3 totaled SEK 0 (SEK 0). Cash flow from financing activities amounted to an outflow of SEK 0.3 million (inflow of SEK 93.2 million), which reflects the amortization of loans (leasing of cars and office).

FINANCIAL POSITION

On the closing date, equity amounted to SEK 341.3 million, compared with SEK 236.1 million per 31 December 2020 and SEK 270.6 million per 30 September 2020. The increase since 31 December 2020 and 30 September 2020 reflects the issuance of new shares in the spring 2021, which outweighed the net losses incurred.

Liquid assets on the closing date amounted to SEK 291.0 million, compared to SEK 184.7 million per 31 December 2020 and SEK 220.7 million per 30 September 2020, which also is an effect of the share issuance in the spring 2021.

FINANCIAL OVERVIEW: 9M-2021 (JAN–SEP 2021)

EARNINGS AND PROFITABILITY

Net sales and other operating income

The Group's net sales in 9M (Jan-Sep 2021) 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 194 thousand (SEK 1.0 million).

Research and development costs (R&D)

R&D costs for the Group in 9M were SEK 79.7 million (SEK 42.8 million). The cost increase of SEK 36.9 million underlines an overall higher activity level in Ascelia Pharma in the current period vis-à-vis corresponding period last year. This was driven by costs related to Orviglance Phase 3 clinical study and manufacturing preparations as well as increased costs for Oncoral Phase 2 preparations.

Commercial preparation costs

During the first nine months, costs related to commercial preparations of amounted to SEK 7.1 million (SEK 9.2 million). The higher costs in 9M-2020 reflects timing of purchase of external expert work and studies in primarily Q2-2020.

Administration costs

Administration costs for the Group in 9M amounted to SEK 11.8 million (SEK 13.4 million). The cost decrease is partially explained by high recruitment costs in Q1-2020.

Operating results (EBIT)

The operating result in 9M amounted to SEK -98.8 million (SEK -65.5 million). The increased loss reflects the overall higher level of R&D activities and manufacturing preparations in 9M-2021.

Net Profit/Loss for the period

The Group's net loss in 9M amounted to SEK -90.8 million (SEK -62.8 million). In 9M, net financial income of SEK 5.4 million was recognized due to strengthening of USD, 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 these currencies). The net loss corresponds to a loss per share, before and after dilution, of SEK -2.80 (SEK -2.47).

Financials key ratios for the Group	9M (January-September)	
	2021	2020
Operating result (SEK 000')	-98,788	-65,549
Net result (SEK 000')	-90,830	-62,847
Earnings per share (SEK)	-2.80	-2.47
Weighted avg. number of shares	32,412,069	25,453,172
R&D costs/operating costs (%)	80%	64%
Cash flow used in operating activities (SEK 000')	-84,313	-57,974
Equity (SEK 000')	341,251	270,614
Liquid assets incl. marketable securities (SEK 000')	291,029	220,739

CASH FLOW

Cash flow from operating activities before changes in working capital in 9M amounted to SEK -94.5 million (SEK -62.3 million). The increased outflow y/y primarily reflects the higher level of R&D activities and manufacturing preparations in the current period. Changes in working capital in the current period totaled an inflow of SEK 10.2 million (inflow of SEK 4.3 million). The inflow in the current period primarily reflects the increase in accounts payable and accrued expenses.

Cash flow from investing activities in 9M totaled SEK 0 (SEK 6.6 million). Cash flow from financing activities amounted to an inflow of SEK 185.1 million (inflow of SEK 92.9 million), which reflects net proceeds from the share issuance in the spring.

FINANCIAL POSITION

On the closing date, equity amounted to SEK 341.3 million, compared with SEK 236.1 million per 31 December 2020 and SEK 270.6 million per 30 September 2020. The increase since 31 December 2020 and 30 September 2020 reflects the issuance of new shares in the spring 2021, which outweighed the net losses incurred.

Liquid assets on the closing date amounted to SEK 291.0 million, compared to SEK 184.7 million per 31 December 2020 and SEK 220.7 million per 30 September 2020, which also is an effect of the share issuance in the spring 2021.

Other information

Incentive programs

Ascelia Pharma has one employee option program that includes members of the management team and share-saving programs for employees. If the terms of the option programs 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 2020 on pages 63-64.

In case all incentive programs are exercised in full, a total of 2.0 million common shares will be issued (including hedge for future payment of social security charges). This corresponds to an aggregate dilution of approximately 5.5% of Ascelia Pharma's share capital after full dilution (calculated on the number of 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 Covid-19 and foreign exchange exposure.

With respect to Covid-19, the outbreak influences many sectors and companies, including the healthcare industry and Ascelia Pharma. For most biotech companies in clinical development, the main operational impact is potential delays in clinical trials as sites reduce or stop of patient enrolment. Patients could also be hesitant to visit clinical sites for the tests. In addition to the operational impact, the funding environment is negatively influenced by Covid-19 pandemic, causing constraints to capital access.

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 2020 on pages 27-32.

Significant events after the end of the reporting period

In October 2021, last patient visit was completed in Orviglance Food Effect Study. Preliminary data indicate that Orviglance has been well tolerated in the study. Final results of the Food Effect Study are expected early 2022.

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.

Magnus Corfitzen
CEO

Malmö, 4 November 2021
Ascelia Pharma AB (publ)

Consolidated Income Statement

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands (unless otherwise stated)**	2021	2020	2021	2020
Net sales	–	–	–	–
Gross profit/loss	**–**	**–**	**–**	**–**
Administrative costs	-4,050	-3,679	-11,794	-13,435
Research and development costs	-24,686	-11,315	-79,674	-42,794
Commercial preparation costs	-4,066	-1,233	-7,146	-9,215
Other operating income	67	363	194	1,029
Other operating costs	-1	-428	-368	-1,134
Operating result	**-32,736**	**-16,292**	**-98,788**	**-65,549**
Finance income	2,946	5,409	7,388	11,686
Finance costs	-27	-3,867	-1,990	-9,787
Net financial items	**2,919**	**1,542**	**5,398**	**1,899**
Loss before tax	**-29,817**	**-14,750**	**-93,390**	**-63,650**
Tax	1,296	60	2,560	803
Loss for the period	**-28,521**	**-14,690**	**-90,830**	**-62,847**
Attributable to:				
Owners of the Parent Company	-28,521	-14,690	-90,830	-62,847
Non-controlling interest	–	–	–	–
Earnings per share				
Before and after dilution (SEK)	-0.82	-0.51	-2.80	-2.47

Consolidated Statement of Comprehensive Income

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands (unless otherwise stated)**	2021	2020	2021	2020
Profit/loss for the period	**-28,521**	**-14,690**	**-90,830**	**-62,847**
Other comprehensive income				
Currency translation of subsidiaries**	61	-13	69	44
Other comprehensive income for the period	**61**	**-13**	**69**	**44**
Total comprehensive income for the period	**-28,460**	**-14,703**	**-90,761**	**-62,803**

* 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 2021	30 Sep 2020	31 Dec 2020
ASSETS			
Intangible assets	57,063	57,067	57,061
Tangible assets			
Equipment	256	331	301
Right-of-use assets	1,851	1,647	1,688
Total fixed assets	**59,170**	**59,045**	**59,050**
Current assets			
Advance payments to suppliers	7,419	6,264	8,279
Current receivables			
Income tax receivables	4,878	1,720	1,748
Other receivables	1,706	494	857
Prepaid expenses and accrued income	842	693	754
Marketable securities	–	69,301	–
Cash and bank balances	291,029	151,438	184,686
Total current assets	**305,874**	**229,910**	**196,324**
Total assets	**365,044**	**288,955**	**255,374**
EQUITY			
Share capital	34,576	28,697	28,697
Other paid-in capital	678,831	493,731	493,731
Loss brought forward (incl. net profit/loss for the period)	-372,156	-251,814	-286,372
Equity attributable to Parent Company shareholders	**341,251**	**270,614**	**236,056**
Total equity	**341,251**	**270,614**	**236,056**
LIABILITIES			
Long-term liabilities			
Leasing	822	992	956
Total long-term liabilities	**822**	**992**	**956**
Current liabilities			
Accounts payable	8,264	4,833	3,884
Tax payable	–	–	–
Other liabilities	1,406	757	672
Current lease liabilites	1,106	725	822
Accrued expenses and deferred income	12,195	11,034	12,984
Total current liabilities	**22,971**	**17,349**	**18,362**
Total liabilities	**23,793**	**18,341**	**19,318**
Total equity and liabilities	**365,044**	**288,955**	**255,374**

* 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**	2021	2020	2020
Equity at start of the period	**236,056**	**237,062**	**237,062**
Comprehensive income			
Profit/loss for the period	-90,830	-62,847	-98,697
Other comprehensive income	69	44	-5
Total comprehensive income	**-90,761**	**-62,803**	**-98,702**
Transactions with shareholders			
New issue of C-shares	398	511	511
Repurchase of own shares C-shares	-398	-511	-511
New share issue with cach contribution	200,000	98,653	98,653
Issurance expenses	-13,271	-5,285	-5,286
Redemption of warrants	3,852	–	–
Share based remuneration to employees	5,375	2,987	4,329
Total transactions with shareholders	**195,956**	**96,355**	**97,696**
Equity at end of the period	**341,251**	**270,614**	**236,056**

* 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**	**2021**	**2020**	**2021**	**2020**
Operating activities				
Operating result	-32,736	-16,293	-98,788	-65,549
Expensed share based remuneration	1,398	1,778	4,129	2,987
Adjustment for items not included in cash flow	286	226	724	598
Interest paid	-22	-20	-58	-66
Income tax paid/received	-200	-93	-539	-290
Cash flow from operating activities before changes in working capital	**-31,274**	**-14,402**	**-94,532**	**-62,320**
Cash flow from changes in working capital				
Increase (-)/Decrease (+) of advance payments	-1,883	-2,818	870	-2,247
Increase (-)/Decrease (+) of operating receivables	-220	263	-981	2,898
Increase (+)/Decrease (-) of accounts payable	-822	-450	4,377	-278
Increase (+)/Decrease (-) of other liabilities	3,470	-1,478	5,953	3,973
Change in working capital	545	-4,483	10,219	4,346
Cash flow used in operating activities	**-30,729**	**-18,885**	**-84,313**	**-57,974**
Investing activities				
Investment in equipment	–	–	-38	-397
Marketable securities/Other investments, net	–	–	–	7,000
Cash flow from investing activities	**–**	**–**	**-38**	**6,603**
Financing activities				
Issuance proceeds	–	98,653	200,000	98,653
Issuance costs	–	-5,286	-13,271	-5,286
Redemption of warrants net	–	–	-914	–
Amortisation of loan (leasing)	-271	-175	-671	-463
Cash flow from financing activities	**-271**	**93,192**	**185,144**	**92,904**
Cash flow for the period	**-31,000**	**74,307**	**100,793**	**41,533**
Cash flow for the period	-31,000	74,307	100,793	41,533
Cash and cash equivalents at start of period	319,014	76,981	184,686	108,516
Exchange rate differences in cash and cash equivalents	3,015	150	5,550	1,389
Cash and cash equivalents at end of period	**291,029**	**151,438**	**291,029**	**151,438**

* 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**	2021	2020	2021	2020
Net sales	1,817	109	4,298	385
Gross profit/loss	**1,817**	**109**	**4,298**	**385**
Administrative costs	-3,996	-3,677	-11,712	-13,412
Research and development costs	-19,544	-11,143	-70,487	-39,192
Commercial preparation costs	-4,073	-1,233	-7,162	-9,240
Other operating income	36	362	136	1,028
Other operating costs	–	-428	-344	-1,119
Operating result	**-25,760**	**-16,010**	**-85,271**	**-61,550**
Finance income	2,657	5,414	7,099	11,686
Finance costs	-6	-3,868	-1,936	-9,786
Result from other long-term receivables	393	179	1,181	408
Net financial costs	**3,044**	**1,725**	**6,344**	**2,308**
Loss before tax	-22,716	-14,285	-78,927	-59,242
Group contribution	–	–	–	–
Tax	–	–	–	–
Loss for the period	**-22,716**	**-14,285**	**-78,927**	**-59,242**

Parent Company – Statement of Comprehensive Income

	Q3 (Jul-Sep)		9M (Jan-Sep)	
*SEK in thousands**	2021	2020	2021	2020
Loss for the period	**-22,716**	**-14,285**	**-78,927**	**-59,242**
Other comprehensive income	–	–	–	–
Other comprehensive income for the period	**–**	**–**	**–**	**–**
Total comprehensive income for the period	**-22,716**	**-14,285**	**-78,927**	**-59,242**

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

Parent Company – Balance Sheet

*SEK in thousands**	30 Sep 2021	30 Sep 2020	31 Dec 2020
ASSETS			
Tangible assets			
Equipment	256	331	301
Right-of-use assets	–	1,647	–
Financial assets			
Shares in affiliated companies	58,068	58,068	58,068
Other long-term receivables	32,566	6,948	9,449
Total fixed assets	**90,890**	**66,994**	**67,818**
Current assets			
Advance payments to suppliers	5,476	6,264	8,279
Current receivables			
Receivables from affiliated companies	5,740	962	1,346
Income tax receivables	1,161	792	623
Other receivables	1,596	460	616
Prepaid expenses and accrued income	842	693	706
Marketable securities	–	69,301	–
Cash and bank balances	276,959	150,889	182,498
Total current assets	**291,774**	**229,361**	**194,068**
Total assets	**382,664**	**296,355**	**261,886**
EQUITY			
Restricted equity			
Share capital	34,576	28,697	28,697
Non-restricted equity			
Other paid-in capital	678,831	493,731	493,731
Loss brought forward	-272,884	-185,134	-183,792
Loss for the period	-78,927	-59,244	-94,070
Total equity	**361,596**	**278,050**	**244,566**
LIABILITIES			
Long-term liabilities			
Leasing	–	992	–
Total long-term liabilities	**–**	**992**	**–**
Current liabilities			
Accounts payable	7,938	4,797	3,733
Other liabilities	1,406	1,483	673
Accrued expenses and deferred income	11,724	11,033	12,914
Total current liabilities	**21,068**	**17,313**	**17,320**
Total equity and liabilities	**382,664**	**296,355**	**261,886**

* 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 2021, the owners of Solural ApS collectively owned 2.0% 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 2021, services for a value of around SEK 2.5 million 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 2021, 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 9M 2021, the first program reached its exercise period and all options related to this program, 481,573 in total, were exercised into common shares.

The total recognized costs for both option programs including social security charges in 9M 2021 were SEK 2.6 milion.

Share saving programs

Ascelia Pharma has implemented three 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 2021 were SEK 3.7 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**	2021	2020	2021	2020
R&D costs	-24,686	-11,315	-79,674	-42,794
Administration costs	-4,050	-3,679	-11,794	-13,435
Commercial preparation costs	-4,066	-1,233	-7,146	-9,215
Other operating costs	-1	-428	-368	-1,134
Total operating costs	**-32,803**	**-16,655**	**-98,982**	**-66,578**
R&D costs/Operating costs (%)	**75%**	**68%**	**80%**	**64%**

Financial calendar

Full-year report 2021 (Jan-Dec):	10 February 2022
Annual General Meeting 2022:	5 May 2022
Interim report Q1 2022 (Jan-Mar):	11 May 2022
Half-year report H1 2022 (Jan-Jun):	18 August 2022
Interim report 9M 2021 (Jan-Sep):	4 November 2022
Full-year report 2022 (Jan-Dec):	10 February 2023

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