



PRESENTATION OF Q1-2020 REPORT

JANUARY-MARCH 2020

AUDIO CONFERENCE: 13 MAY 2020, 10:00AM CET

Present from Ascelia Pharma:

CEO Magnus Corfitzen | CFO Kristian Borbos

CMO Carl Bjartmar | CCO Julie Waras Brogren

Direct link audiocast: <https://tv.streamfabriken.com/ascelia-pharma-q1-2020>

Teleconference dial-in:

SWE: +46 856 642 693 | UK: +44 333 300 9030 | US: +1 833 823 0590

ASCELIA PHARMA

Share ticker: ACE
Nasdaq Stockholm (small cap)

FORWARD LOOKING STATEMENTS

This presentation, which includes all information and data on the following slides, any oral statements made when presenting these slides, and any other material distributed or statements made at, or in connection with, such presentation (the “Presentation”), relates to Ascelia Pharma AB (publ) (hereinafter, together with its subsidiaries, the “Company”) is furnished to you solely for your information and may not be reproduced or redistributed, in whole or in part, to any other person without the prior written consent of the Company. You should not rely upon it or use it to form the definitive basis for any decision, contract, commitment or action whatsoever, with respect to any transaction or otherwise.

The information included in this Presentation may contain certain forward-looking statements relating to the business, financial performance and results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, sometimes identified by the words “believes”, “expects”, “predicts”, “intends”, “projects”, “plans”, “estimates”, “aims”, “foresees”, “anticipates”, “targets”, and similar expressions. The forward-looking statements contained in this Presentation, including assumptions, opinions and views of the Company or cited from third party sources are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause actual events to differ materially from any anticipated development. Neither the Company nor any of its affiliates, directors, employees or advisors provides any assurance that the assumptions underlying such forward-looking statements are free from errors nor do any of them accept any responsibility for the future accuracy of the opinions expressed in this Presentation or the actual occurrence of the forecasted developments. This Presentation speaks as of the applicable reporting date, and there may have been changes in matters which affect the Company subsequent to the date of this Presentation. Neither the issue nor delivery of this Presentation shall under any circumstance create any implication that the information contained herein is correct as of any time subsequent to the date hereof or that the affairs of the Company have not since changed, and the Company does not intend, and does not assume any obligation, to update or correct any information included in this Presentation.

Each person should make their own independent assessment of the merits of the Company and should consult their own professional advisors. By receiving this Presentation, you acknowledge that you will be solely responsible for your own assessment of the market and the market position of the Company and that you will conduct your own analysis and be solely responsible for forming your own opinion of the potential future performance of the Company’s business.

ASCELIA PHARMA – OVERVIEW



We aim to improve **life expectancy** and **quality of life** for people living with cancer



We develop **orphan drugs** which target unmet medical needs, have an established mode of action and a relatively low development risk

Drug candidates	Indication	Phase 1	Phase 2	Phase 3	Filing	Launch
Mangoral <ul style="list-style-type: none">• Only <u>non</u>-gadolinium based imaging drug• No competing products• \$350-500M market with upside potential• De-risked Phase 3 clinical program	Visualisation of focal liver lesions <ul style="list-style-type: none">• Liver metastases• Primary liver cancer• Benign lesions	✓	✓	2020 – Full study report H1 2021	2021	2022
Oncoral <ul style="list-style-type: none">• Novel tablet chemotherapy formulation• Phase 1 completed with promising results• Gastric cancer is an Orphan indication	Treatment of gastric cancer	✓	2021 – 2023	Strong case for development and commercialisation partnering after phase 2		

SIGNIFICANT MILESTONES REACHED IN 2020

Key events in Q1-2020



First patient in Mangoral's Phase 3 study SPARKLE



Ascelia Pharma wins the award as Malmö's Best Life Science company

Key events after the period



First participant in the hepatic study for Mangoral (May 2020)



Patent approval for Oncoral in Japan (Apr 2020)

A photograph of an older couple walking a beagle dog on a leash through a park with trees showing autumn foliage. The man is wearing a grey sweater and blue jeans, and the woman is wearing a white shirt, a pink scarf, and a brown cardigan. They are both smiling and looking at each other.

Leading Ascelia Pharma through Covid-19

- ▶ We have taken steps to minimise risk for the patients, our employees and their families, and our communities
- ▶ Strong financial position with SEK 169 million in liquid assets per 31 Mar 2020 and a low cost base
- ▶ Our assets Mangoral and Oncoral are strong and fundamentally unchanged. There still is – and will be – a significant unmet medical need and attractive commercial opportunities for these projects
- ▶ A prolonged Corona situation could, however, impact our expected timelines
- ▶ Enrollment of the first participant in the hepatic study in May 2020 shows that selected parts of our community are still in operation

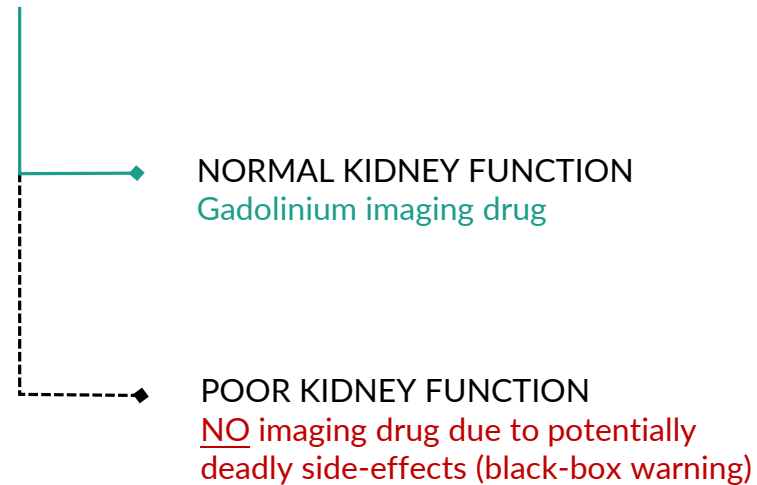
An elderly couple is walking through a sun-dappled park. The woman, on the left, has short brown hair and is wearing a red short-sleeved top and light-colored pants. The man, on the right, has white hair and a mustache, wearing a blue and white checkered short-sleeved shirt and blue jeans. They are holding hands and smiling. In the foreground, a dark wicker picnic basket is visible, containing two bottles of dark liquid, a banana, and some bread. The background is filled with large, leafy trees.

MANGORAL

Liver MRI contrast agent in
Phase 3 clinical studies

MANGORAL – NOVEL LIVER CONTRAST AGENT IN PHASE 3

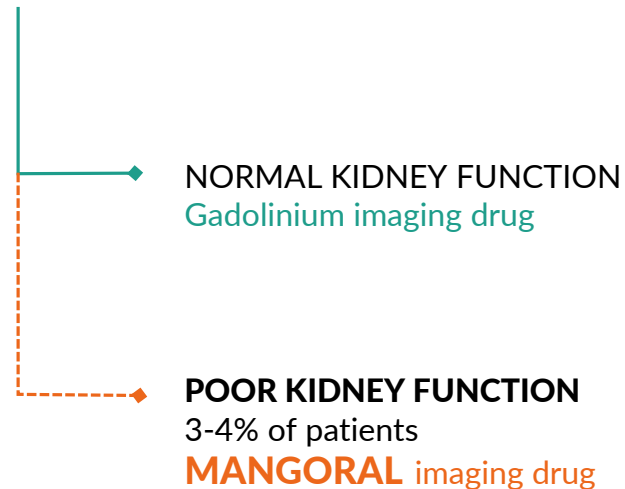
TODAY



WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)
See full prescribing information for complete boxed warning.
Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities.

- The risk for NSF appears highest among patients with:
 - Chronic, severe kidney disease (GFR < 30 mL/min/1.73m²), or
 - Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function.
- For patients at risk for chronically reduced renal function (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing (5.1).

TOMORROW



Mangoral aims to be the only standard of care liver MRI imaging drug for patients with impaired kidney function



280,000

patients with impaired kidney function in major markets

MANGORAL CLINICAL ACTIVITIES

Study	Objective of the study	Site location and no. of patients	Time schedule
Pivotal Phase 3 study ("SPARKLE")	Assess efficacy and safety of Mangoral in patients with severely reduced kidney function and with known or suspected liver lesions	Global multicentre study in up to 200 patients	<ul style="list-style-type: none"> • Study ongoing • Full study report expected in H1-2021
Hepatic study	Assess the influence of hepatic impairment on the safety, pharmacokinetics and pharmacodynamics of Mangoral	Open-label study on 24 healthy and hepatically impaired participants at the Texas Liver Institute, San Antonio, US	<ul style="list-style-type: none"> • Study ongoing • Study expected to be completed in 2020
Food effect study	Assess the effect of food intake on Mangoral uptake	Study contract to be awarded	<ul style="list-style-type: none"> • Study preparations ongoing • Short study, expected to be completed in 2020

These studies, together with the already completed Phase 1 and 2 studies, ensure a comprehensive data package for the regulatory submissions in key markets

DE-RISKED PHASE 3 STUDY UNDERPINNED BY STRONG DATA FROM COMPLETED STUDIES AND STUDY DESIGN

Strong data package for Mangoral






Six phase 1 and 2 clinical studies completed

Consistent strong efficacy readout and safety profile

Blind read study of all imaging data presented at major conferences

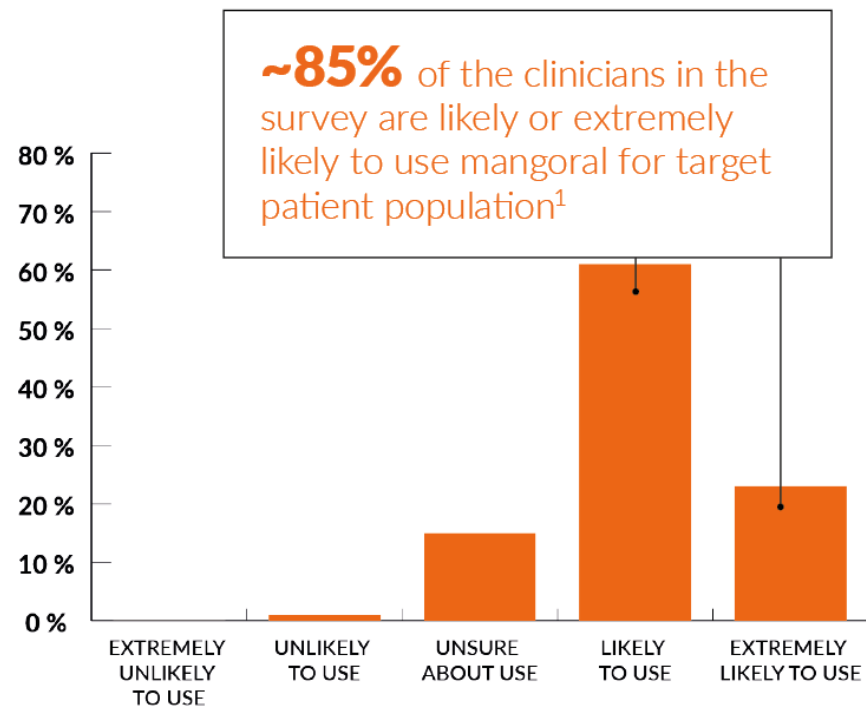
- The study with 178 persons further underlined that Mangoral significantly improves MRI performance
- 33% more lesions were detected after Mangoral enhanced MRI
- Mangoral significantly improved lesion visualisation (conspicuity; p-value <0.0001) and delineation (p-value <0.0001)

Phase 3 registration-enabling study (study ongoing)

Number of patients	Global study in up to 200 patients
Endpoint 	Lesion visualisation <ul style="list-style-type: none">• Lesion border delineation (border sharpness of lesions)• Conspicuity (lesion contrast compared to liver background)
Comparator 	Unenhanced MRI + Mangoral MRI vs. Unenhanced MRI
Follow-up 	72 hours
Randomisation 	No – each patient at his/her own control
Validation 	Phase 3 program has been discussed with FDA and EMA

CLEAR DEMAND CONFIRMS USD 350-500M MARKET POTENTIAL

Confirmed unmet medical need



Payer and clinician value proposition

Only liver MRI contrast agent for patients
with poor kidney function or acute kidney failure²
(~280,000 patients in major markets)

~280,000

Improved visualisation of focal liver lesions
(incl. metastases) compared to unenhanced MRI.
(+33% more lesions in phase 1&2 studies)

+33%

Early detection of focal lesions and metastases
allows early intervention and higher survival rate
(94% of clinicians confirm³)

94%

¹ Market research by Back Bay Life Science Advisors with interview of 84 radiologists across the US regarding clinical practices in liver MRI scanning, the use of gadolinium and mangoral product profile. Notes: 1) Survey answers to question: 'What is your overall opinion of this product for its target population of patients with known or suspected liver metastases and severe renal insufficiency or acute kidney injury?' 2) Based on regulatory drug class warning on use of gadolinium-based contrast agents in patients with renal impairment (an eGFR <30 ml/min/1.73 m²) or acute kidney failure. 3) Survey answers to 'Using contrast MRI is important for early intervention, to detect small lesions, which if removed can be curative e.g. colorectal cancer metastases?'

PREPARING FOR COMMERCIALISATION

PREPARE THE PRODUCT

2020

Phase 3 study SPARKLE (ongoing)

Detail pricing & access strategy

Define roll-out priorities & projections

Develop pre-launch & launch plans

Build blueprint for own US commercialisation & RoW partnering

Expand key opinion leader network and unmet needs understanding

PREPARE THE MARKET

2021

Complete phase 3 study

Submit NDA filing

Initiate dialogue with payers & clinical decision makers

Build US commercial capability & RoW partnering

Develop supply & logistics partnering

DRIVE THE LAUNCH

2022

Reach timely market authorisation

Secure supply and logistics operations

Mobilise US operations

Develop RoW partnership operations

Execute cross-functional launch

- Payer adoption
- Medical advocacy
- Early adoption and preference

An elderly couple with grey hair is sitting on a thick layer of fallen autumn leaves in a park. The man is wearing a pink long-sleeved shirt and dark trousers, and the woman is wearing a light pink long-sleeved shirt and grey trousers. They are both smiling and looking towards the right. A wicker picnic basket filled with fruit is on the ground next to them. The background is a lush green forest with sunlight filtering through the trees.

ONCORAL

Chemotherapy tablet for gastric
cancer ready for Phase 2

ONCORAL – NOVEL IRINOTECAN TABLET READY FOR PHASE 2

NOVEL ORAL FORMULATION



Formulated as a **tablet** for convenient dosing and health-economic benefits



Promising safety potential of oral administration



Potential for **all-tablet chemo-combination**

PHARMACEUTICAL INGREDIENT HAS PROVEN EFFECT



Irinotecan shown to be effective in **killing cancer cells**



Expected to be efficacious and safe **together** with other well-recognized anti-cancer drugs



Orphan drug indication for gastric cancer by the FDA and EMA

With promising Phase 1 results, we are now preparing for Phase 2



FINANCIALS

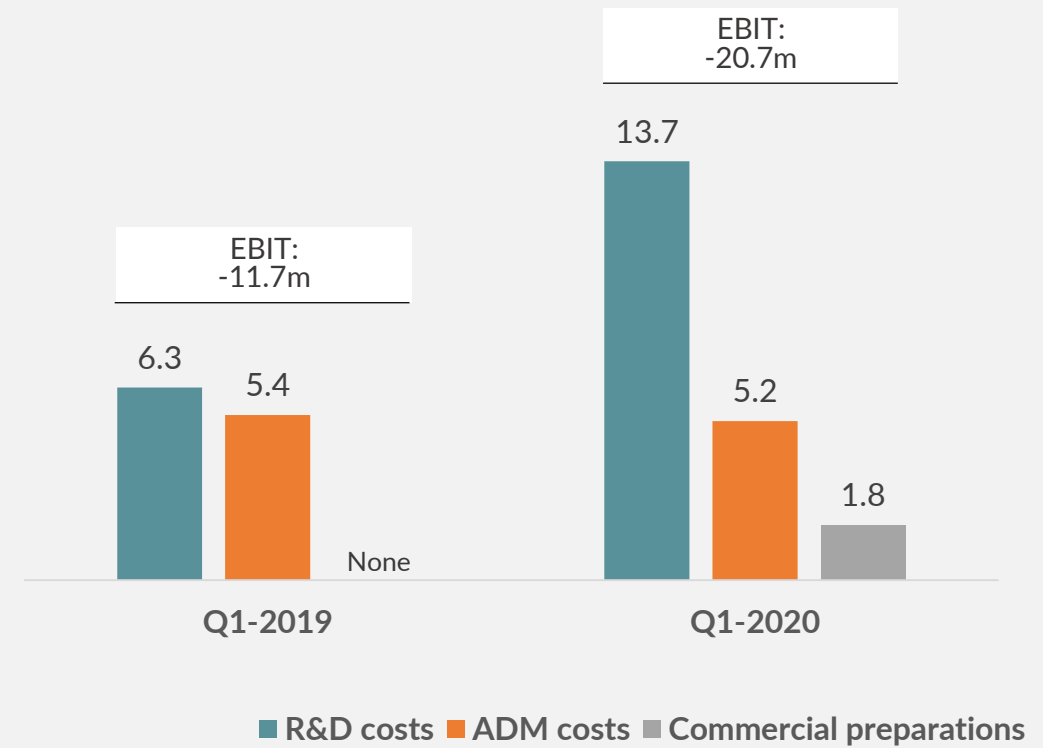
FINANCIAL HIGHLIGHTS – OPERATING RESULTS

Increased operating loss y/y mainly driven by higher R&D activity for Mangoral's Phase 3 study:

- Preparing and opening of clinical study sites
- Manufacturing preparations
- Regulatory preparations

Also cost for commercial preparations for Mangoral incurred in Q1-2020 (none in Q1-2019)

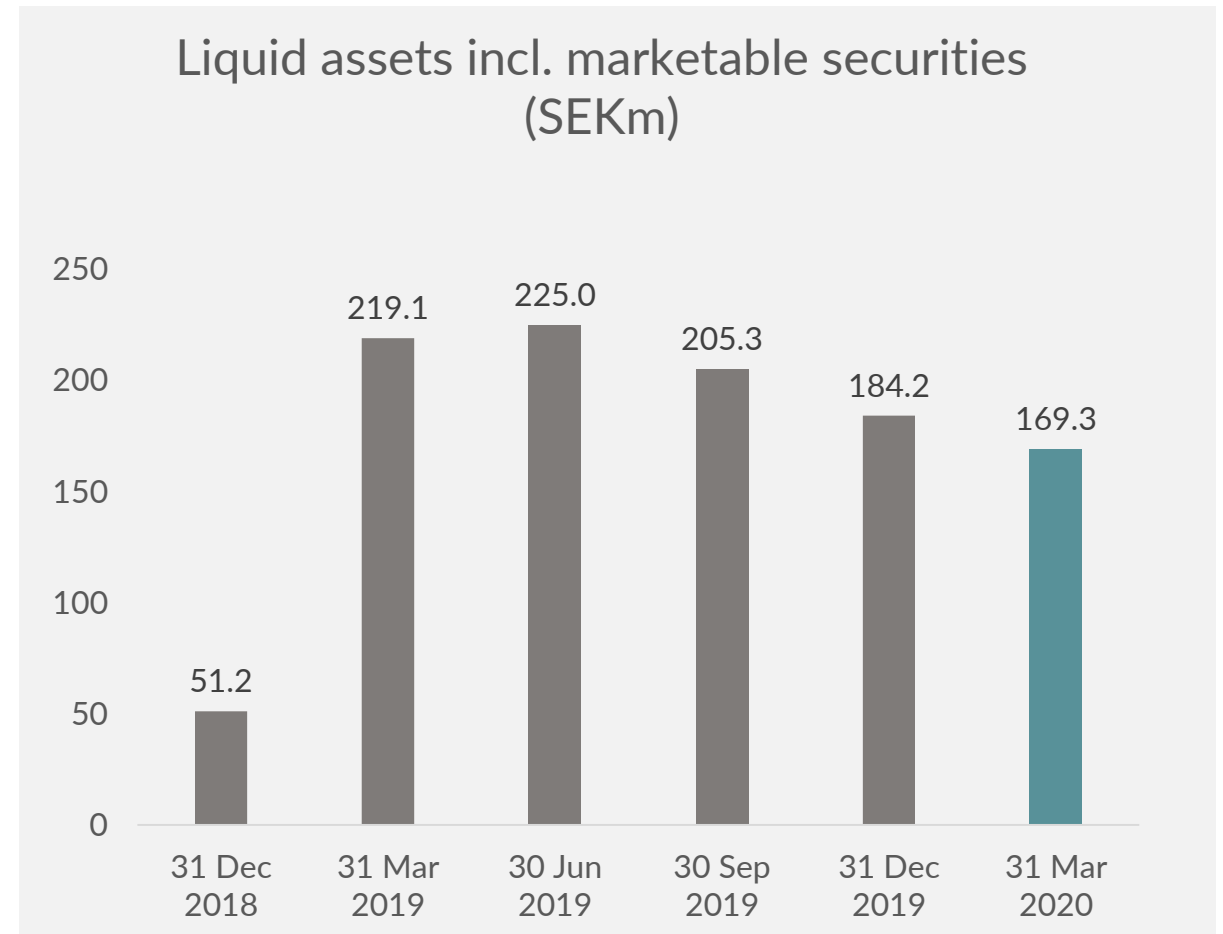
Main operating costs and EBIT (SEKm)



FINANCIAL HIGHLIGHTS – LIQUIDITY POSITION

Continued strong liquidity:

- Liquid assets incl. marketable securities of SEK 169.3 million per 31 Mar 2020
- Liquidity to fund Mangoral clinical development and pre-commercial activities



Priorities in 2020



First patient in the Phase 3 SPARKLE study



First participant in the hepatic study



Work diligently with study sites during Covid-19 and enrol additional patients



Pre-launch activities and preparations for Mangoral (market launch planned for 2022)



Prepare Phase 2 study for Oncoral (planned start in 2021)

ASCELIA PHARMA

ascelia.com