



Share ticker: ACE
Nasdaq Stockholm

WEBCAST:

16 February 2021, 10:00AM CET

<https://tv.streamfabriken.com/ascelia-pharma-q4-2020>

Dial-in teleconference:

SWE: +46 850 558 351

UK: +44 333 300 9270

US: +1 833 823 0587

DK: +45 787 232 52

PRESENTATION OF FY 2020 REPORT

Present from Ascelia Pharma:

CEO Magnus Corfitzen | CFO Kristian Borbos
CMO Carl Bjartmar | CCO Julie Waras Brogren

www.ascelia.com

 Follow us on LinkedIn

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 – ADVANCING ORPHAN ONCOLOGY



MANGORAL

- Diagnostic drug for liver MRI in population subset
- Global Phase 3 study ongoing
- \$500-600M annual addressable market with no competition

ONCORAL

- Oral daily chemotherapy – initial focus on gastric cancer
- Phase 2 ready

BUILDING GLOBAL CAPABILITIES

- Global network of KOLs and advisors
- Driving approval and commercialization of Mangoral

SOLID FINANCIAL POSITION

- Financed to reach key value creating milestones
- Listed on NASDAQ Stockholm

BUILDING ASCELIA PHARMA AND BUILDING VALUE

BUILDING A COMMERCIAL STAGE PHARMA COMPANY

MANGORAL in Phase 3

ONCORAL Phase 2 ready

WITH GLOBALLY LEADING PRODUCTS AND A PROMISING PIPELINE

MANGORAL launch in the US

ONCORAL phase 2 near closing

Pipeline expansion?

2021

2022

2023

RECENT KEY EVENTS

Q4-2020

- Oct** Raised estimate for Mangoral addressable market
- Nov** Mangoral eligible for centralized EU regulatory procedure
- Dec** Mangoral lesion visualization as effective as gadolinium (study)
- Dec** US patent for second-generation Mangoral

2021

- Jan** Presentation of clinical development plan for Oncoral



ASCELIA
PHARMA



PORTFOLIO

MANGORAL

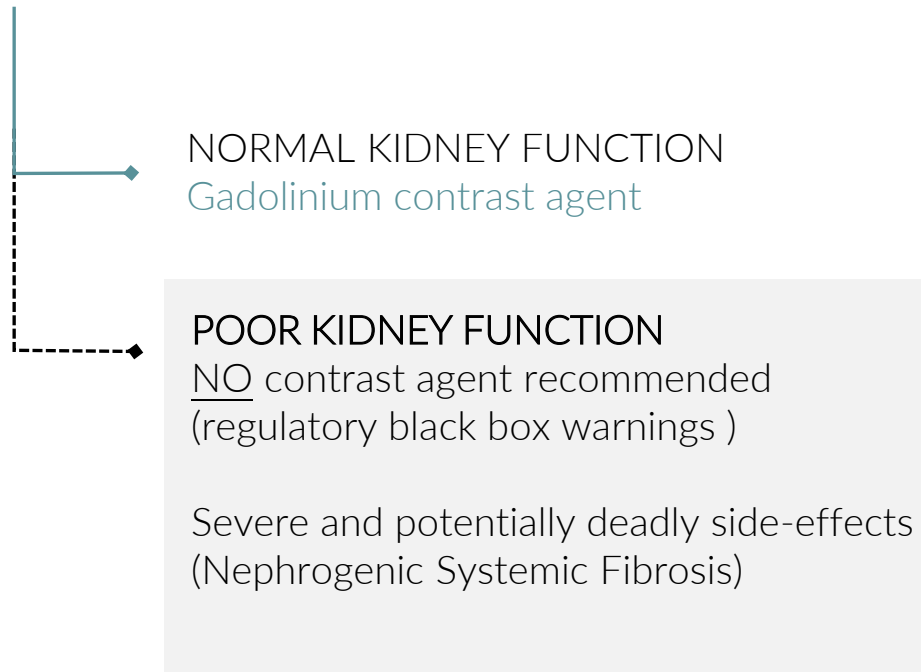
Liver diagnostic drug in ongoing Phase 3

ONCORAL

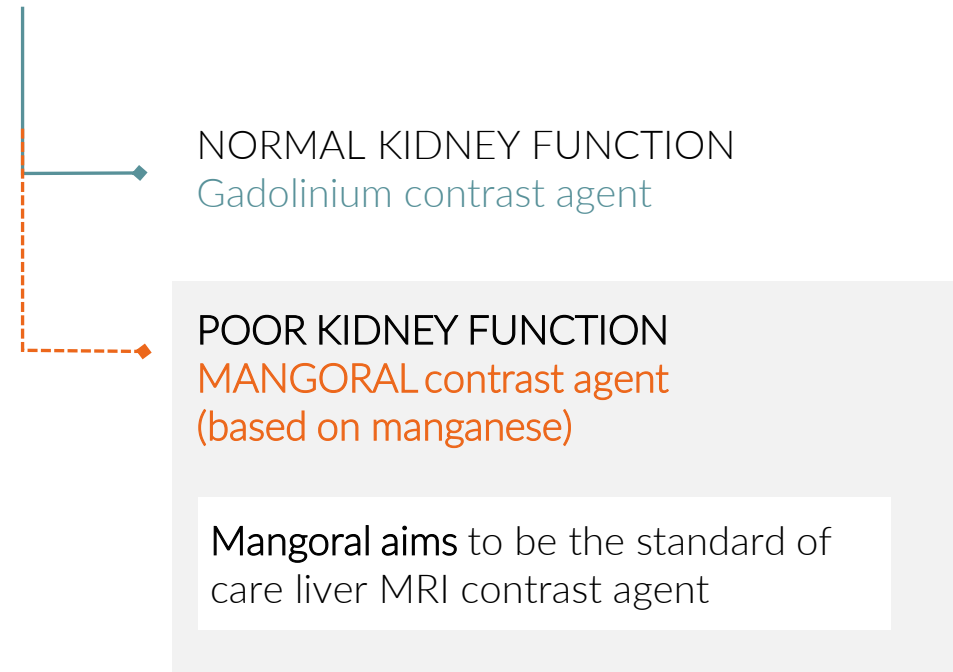
Daily oral chemotherapy ready for Phase 2

CLEAR UNMET MEDICAL NEED

TODAY



TOMORROW



ONGOING PHASE 3 STUDY SPARKLE

PHASE 1 AND PHASE 2 RESULTS

Consistent strong efficacy readout and safety profile

Blind read study of all images vs. unenhanced MRI
(178 persons)

- Significantly improved MRI
- 33% more lesions

• Lesion visualization

Delineation (border sharpness): p-value <0.0001
Conspicuity (contrast vs. background): p-value <0.0001

Re-read study vs. gadolinium contrast agent (GBCA)
(20 persons)

- Mangoral lesion visualization as effective as GBCA

PHASE 3 STUDY (ONGOING)

Patients



Global study, 200 patients
No randomisation – each patient as own control

Comparator



Unenhanced MRI + Mangoral MRI
vs.
Unenhanced MRI

Endpoint



Lesion visualization

- Lesion border delineation
- Conspicuity

Follow-up



Less than a week



RE-READ STUDY

STUDY RESULTS PUBLISHED IN DEC 2020

- Independent study where Mangoral was compared against a gadolinium contrast agent and against an MRI scan without contrast agent
- Endpoints and evaluation criteria same as in the ongoing Phase 3 study SPARKLE

RESULTS

1. Mangoral as effective as gadolinium for visualization of focal liver lesions (2 out of 3 readers reporting higher scores for Mangoral)
 2. Mangoral MRI provides improved diagnostic efficacy compared to MRI without a contrast agent
- *Robust evidence of the diagnostic value that Mangoral offers*
 - *Strengthens the data package to the regulatory authorities*
 - *Supports our expectations of positive outcome of the SPARKLE study*



COMMERCIAL OUTLOOK MANGORAL

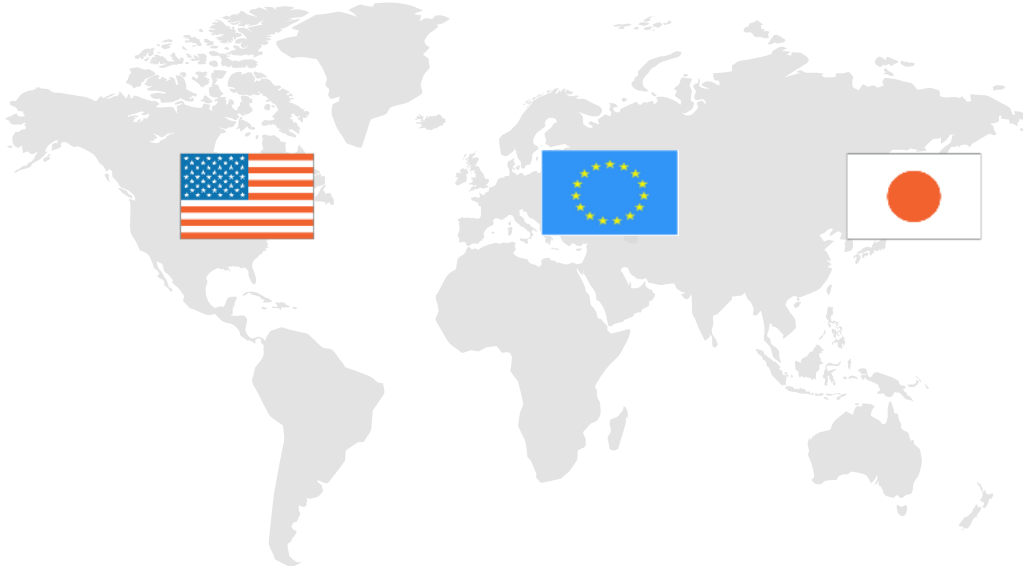
MANGORAL MARKET OPPORTUNITY AND COMMERCIAL PREPARATIONS

- **Addressable market** of **\$500-600 million** with no competition
- Decision makers **understand the value** that Mangoral provides
- **Launch preparations progress** with a strong case for own commercialization in the US
- **US patent** for second-generation Mangoral provides patent protection to **year 2040**

ADDRESSABLE MARKET OF \$500-600 MILLION

\$500-600M ADDRESSABLE MARKET IN US, EU AND JAPAN

- Large markets with mature clinical practices
- Clear regulatory and market access pathway
- No competing drugs



DRIVERS

- 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%

Sources:

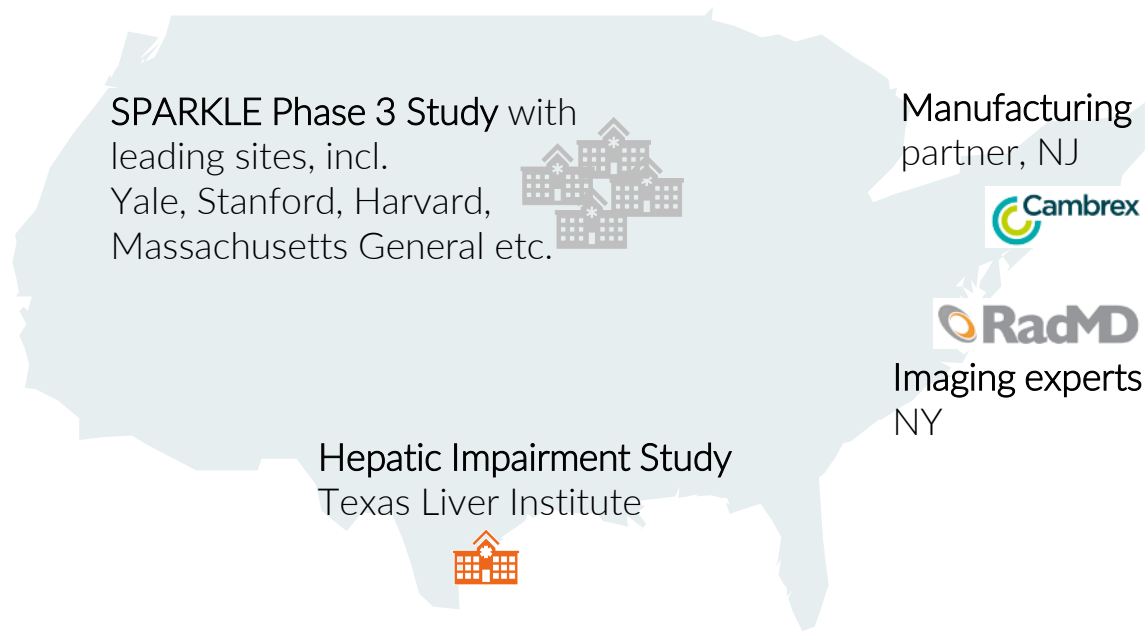
1) Market research with Decision Resources Group, 2020

2) Market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

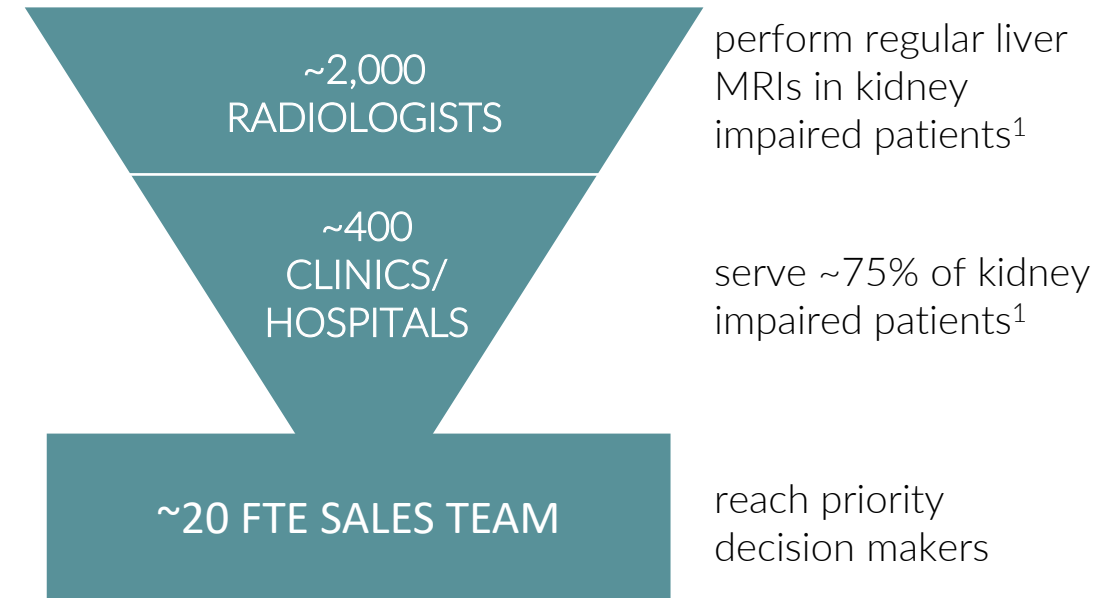
CAPTURING US MARKET VALUE WITH OWN TEAM



STRONG FOOTPRINT IN THE US



BUILDING AN ASCELIA US TEAM



US PATENT FOR SECOND GENERATION MANGORAL



US patent for second generation Mangoral granted

Provides patent protection until year 2040 in the US

A global patent application for 2nd generation Mangoral was also filed

Further improves the unique value proposition of the Mangoral franchise

Effervescent tablet formulation of Mangoral

Improved ease of use for patients and health care professionals



PORTFOLIO

MANGORAL

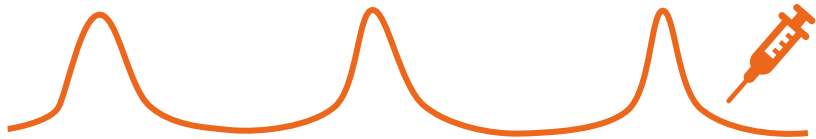
Liver contrast agent in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

ONCORAL – IRINOTECAN AS TABLET

TODAY – IV BOLUS INFUSION



- Widely used chemotherapy
- Established potent anti-tumour effect

UNMET NEEDS

- Toxicity and gastrointestinal side-effects common
- Sub-optimal compromise between tolerability and efficacy

TOMORROW – ONCORAL (ORAL, DAILY)



- Novel tablet formulation
- Enteric coating of active ingredient

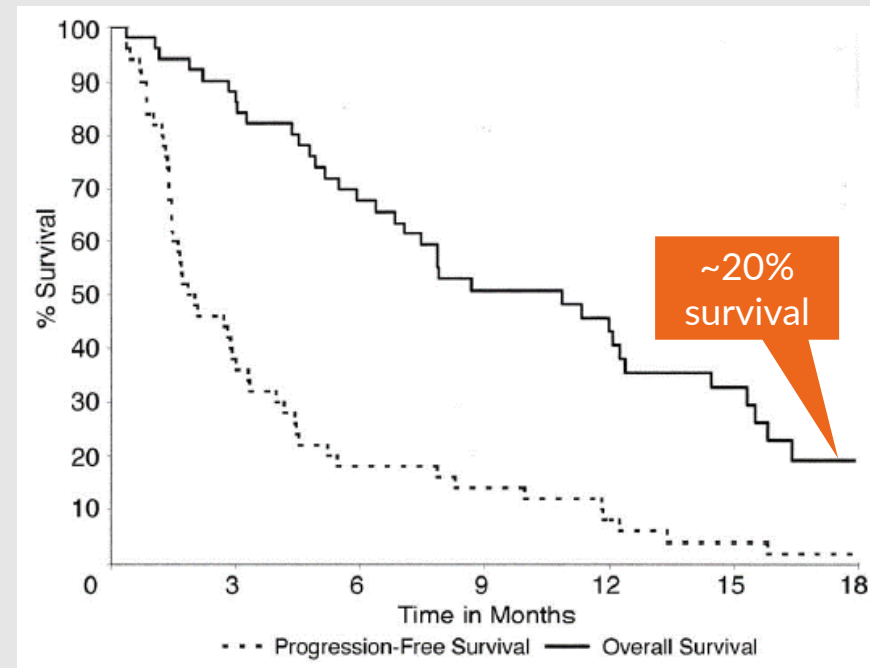
POTENTIAL

- 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

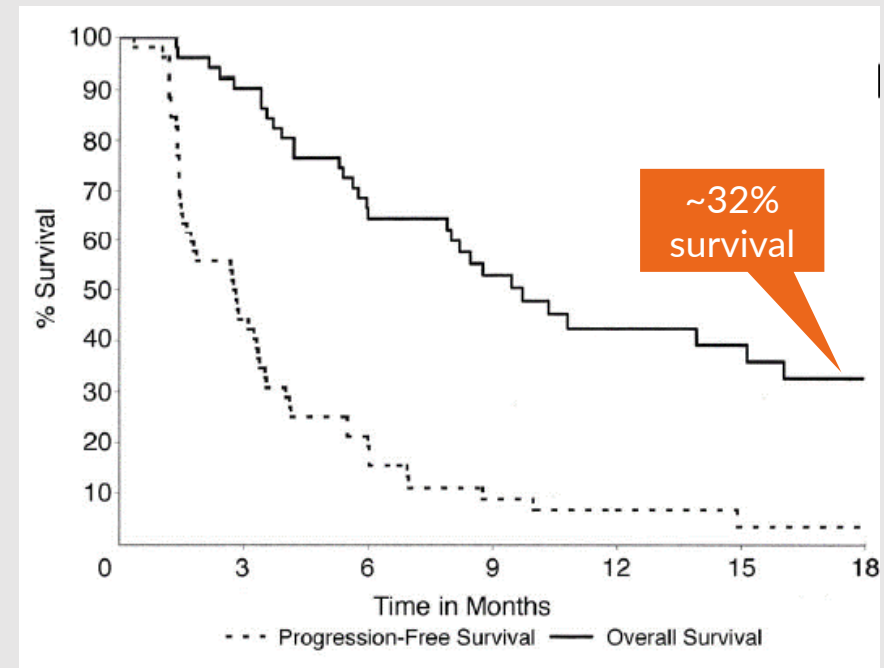
IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

Overall survival: Improved from 20% (dosing every third week) to 32% (weekly dosing)¹

Irinotecan every 3 weeks (IV)



Irinotecan weekly (IV)

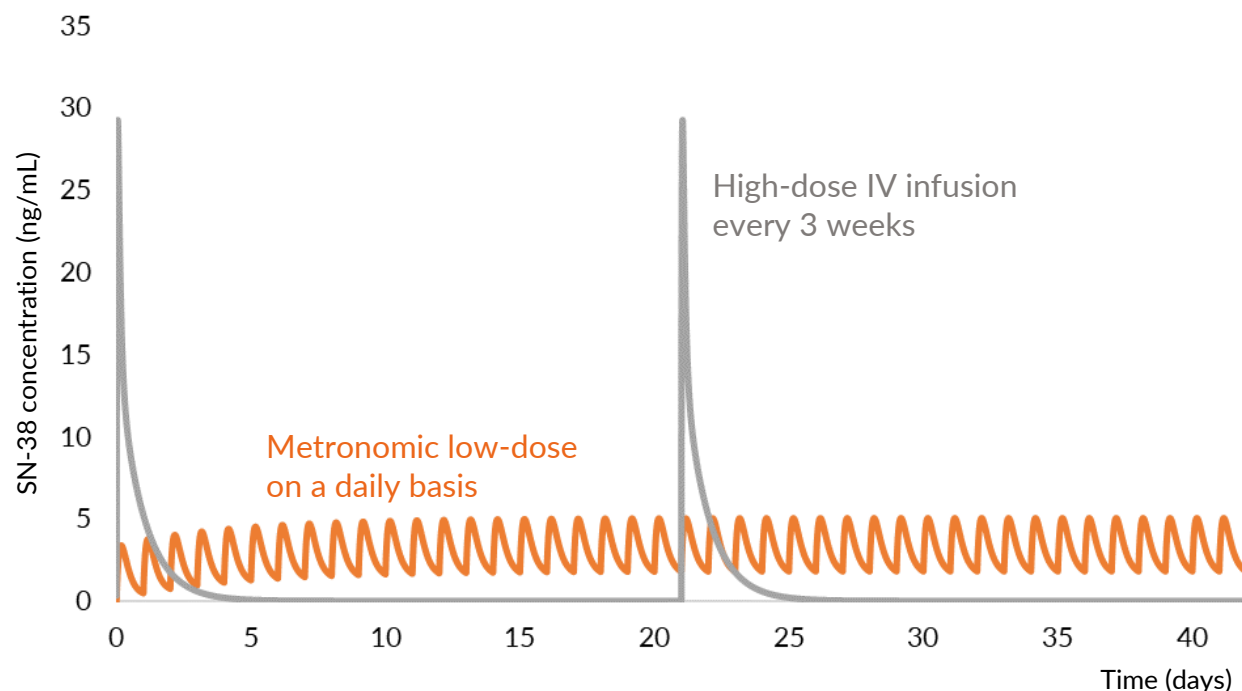


Study in patients with metastatic refractory breast cancer, N=103

1) Perez et al. J Clin Oncol 2004: Randomized Phase II Study of Two Irinotecan Schedules for Patients With Metastatic Breast Cancer Refractory to an Anthracycline, a Taxane, or Both

IMPROVING IRINOTECAN **TOLERABILITY** BY FREQUENT LOW DOSING

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar performed by Pkxpert AB

Infrequent high-dose IV irinotecan

Gastrointestinal and haematological side effects, ~30% severe or life-threatening (grade 3 or 4)¹

Frequent (metronomic) low-dose irinotecan

- Several studies show improved tolerability^{2,3}
- Daily dosing – adjust quickly if acute toxicity

Oncoral Phase 1 results

- Well tolerated, no unexpected side-effects
- Haematological toxicities mild-moderate (grade 1 or 2)⁴
- Efficacy: Stable disease even in patients previously treated with IV irinotecan

ONCORAL SCIENTIFIC ADVISORY BOARD

Prof Josep Tabernero, MD, PhD

Head of the Medical Oncology Department at the Vall d'Hebron Barcelona Hospital Campus, Director of the Vall d'Hebron Institute of Oncology (VHIO), and Professor of Medicine

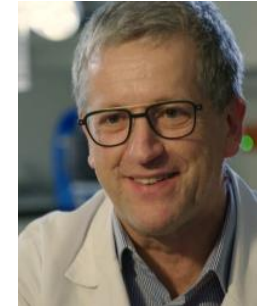
President (2018 – 2019) of ESMO and an Executive Board and Council Member



Prof Eric Van Cutsem, MD, PhD

Professor and Division Head of Digestive Oncology at University of Leuven (KUL) and University Hospitals Gasthuisberg, Leuven, Belgium

Co-founded ESMO GI/World Congress on GI Cancer. Serves/served on the board/ committee of ESMO, ASCO, ENET, EORTC, ECCO, ESDO



Prof Jaffer A Ajani, MD

Department of Gastrointestinal Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, USA

Chairs the NCCN committee for gastroesophageal cancers



Prof Jeff Evans, MD

Professor of Translational Cancer Research and Clinical Lead of the Institute of Cancer Sciences, University of Glasgow

Member of the NCRN Upper GI Cancer Pancreatic Cancer and Gastro-Oesophageal Cancer sub-groups







Joint view that Oncoral would be an important treatment option for cancer patients, especially in later disease stages

PHASE 2 - STUDY IN PREPARATION

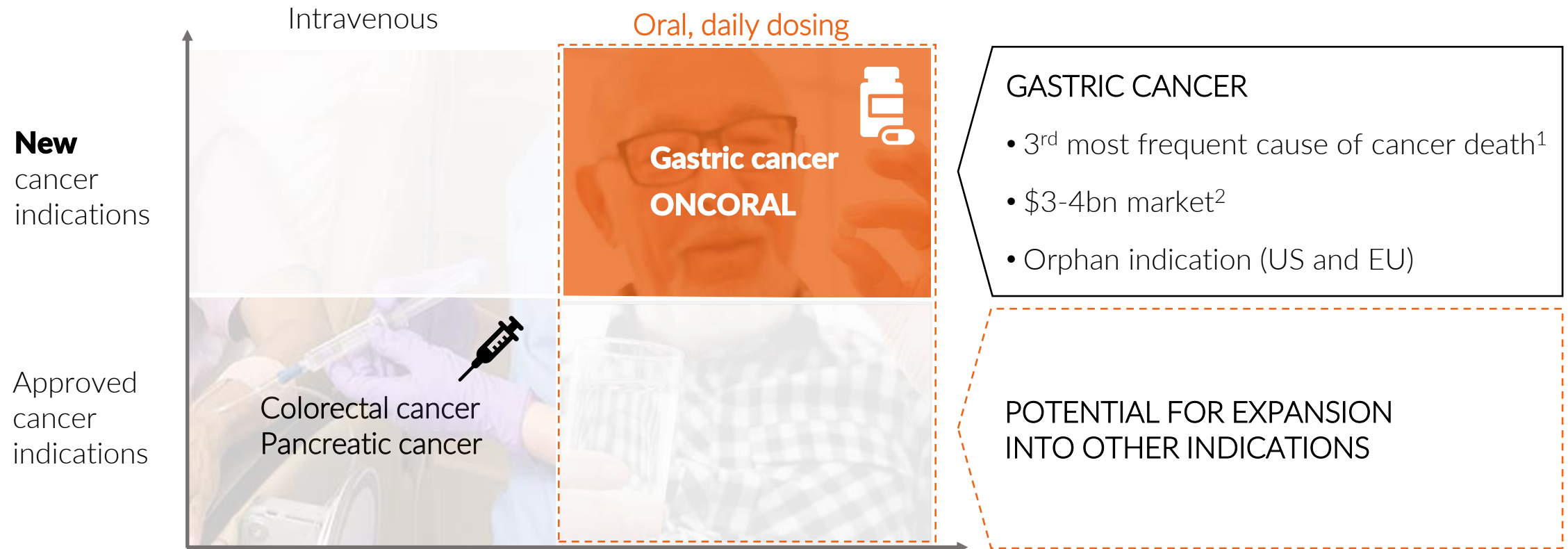
OBJECTIVES OF PHASE 2

- Clinical proof-of-concept in metastatic gastric cancer
 - Potential orphan drug designation
 - Clinical guidelines support efficacy of irinotecan
 - Potential for subsequent label expansion to other solid tumor indications
- Compelling Phase 2 data package for further development
- Solid data to design Phase 3 study

STUDY DESIGN

Type of study 	Randomized controlled, multicentre, multinational study: Oncoral + Standard of Care <u>vs.</u> Standard of Care
Endpoints 	Primary: Progression Free Survival Secondary: Response rate, PK, safety and Overall Survival data in a follow up analysis
No. of patients 	Approximately 100 patients
Study period 	H2 2021 – 2024

HIGH VALUE OPPORTUNITY IN GASTRIC CANCER



1) International Agency for Research on Cancer (IARC, 2021)
2) GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024

FINANCIALS AND PRIORITIES 2021

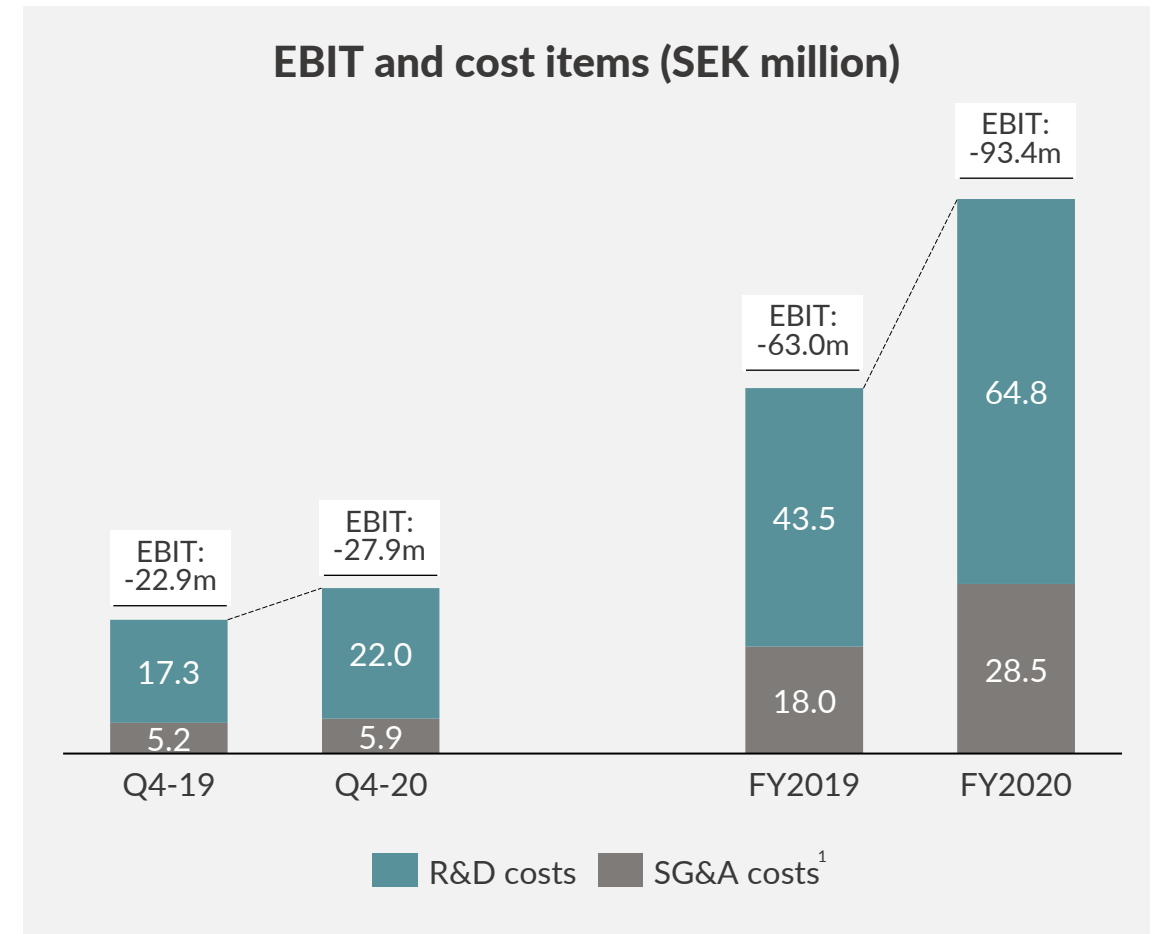


FINANCIAL HIGHLIGHTS Q4 2020 – OPERATING RESULTS

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

- Clinical development
- Manufacturing preparations
- Regulatory preparations

... And higher costs for commercial preparations for Mangoral (forming part of Selling, General & Administrative costs)



Notes:

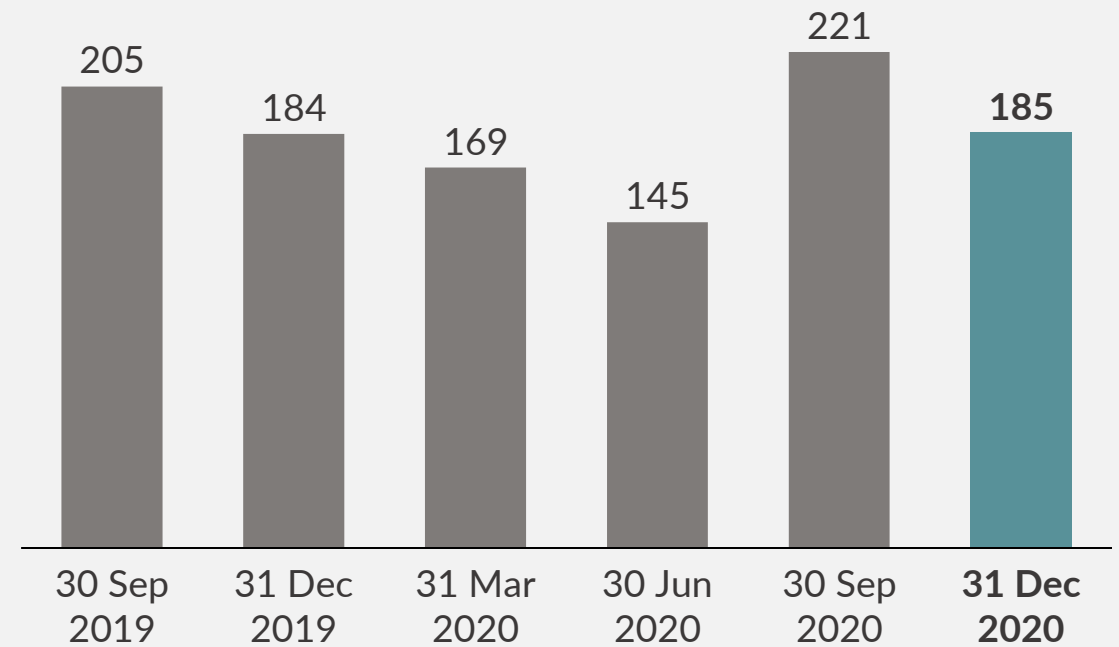
1) Other operating income and other operating costs included into SG&A

FINANCIAL HIGHLIGHTS Q4 2020 – LIQUIDITY POSITION

Solid liquidity position:

- Liquidity mainly to be used for Mangoral clinical Phase 3 and pre-commercial activities
- The liquidity position will take Ascelia Pharma into 2022 and consequently beyond the clinical milestone with topline Phase 3 from SPARKLE, which is expected in H2-2021

Liquid assets including marketable securities (SEK million)





PRIORITIES 2021

- Complete Mangoral Phase 3 patient enrolment (top line results planned for 2H 2021)¹
- Prepare for Mangoral launch (planned Q4-2022 – H1-2023)¹
- Initiate Phase 2 study for Oncoral (planned start in H2-2021)

1) Timelines incorporate the currently assessed impact from Covid-19. An extended Covid-19 situation may further affect timelines.

ASCELIA PHARMA

ascelia.com



[Follow us on LinkedIn](#)