



ADVANCING
ORPHAN
ONCOLOGY

Share ticker: ACE
Nasdaq Stockholm
www.ascelia.com

ASCELIA PHARMA

COMPANY PRESENTATION

MARCH 2021

ASCELIA
PHARMA

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



IMPROVING THE LIFE OF PEOPLE
WITH RARE ONCOLOGY-
RELATED CONDITIONS

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

A CLINICAL STAGE PORTFOLIO WITH CLEAR MARKET PATHWAY

Drug candidate	Indication	Phase 1	Phase 2	Phase 3	Filing	Market
Mangoral <ul style="list-style-type: none">• Diagnostic drug (contrast agent)• Manganese-based Orphan Drug (FDA)• No competing drugs• \$500-600M addressable market	Detection and visualization of focal liver lesions	Completed		Ongoing 2020 – H2 2021	H1 2022	Q4 2022 – H1 2023
Oncoral <ul style="list-style-type: none">• Oral daily dosing of chemotherapy• Potential for better efficacy and safety• Phase 2 in gastric cancer	Gastric cancer treatment; expansions to other solid cancers	Completed	2H 2021 – 2024			

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

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
- Feb** Opening of US office in New Jersey





PORTFOLIO

MANGORAL

Liver diagnostic drug in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

EARLY DETECTION OF LIVER METASTASES IS CRITICAL

LIVER METASTASES CRITICAL IN CANCER CARE

Liver metastases are common and often

- First site of metastases
- The cause of mortality

Incidence liver metastases per primary cancer ¹⁻³



* Metastatic breast cancer

CONTRAST ENHANCED MRI IS GOLD STANDARD

Contrast drug enhanced MRI enables

- Accurate detection and visualization
- Planning of surgery or drug treatment
- Post-treatment surveillance

1) Riihimäki, M. *et al.* Patterns of metastasis in colon and rectal cancer. *Sci. Rep.* 6, 29765; doi: 10.1038/srep29765 (2016); *Journal of Pathology*, 2014, 232:23-31
2) Guy diSibio and Samuel W. French (2008) Metastatic Patterns of Cancers: Results From a Large Autopsy Study. *Archives of Pathology & Laboratory Medicine*: June 2008, Vol. 132, No. 6, pp. 931-939
3) Rahbari *et al.* Metastatic Spread Emerging From Liver Metastases of Colorectal Cancer: Does the Seed Leave the Soil Again? *Annals of Surgery*: February 2016 - Volume 263 - Issue 2 - p 345-352

CLEAR UNMET MEDICAL NEED

TODAY

NORMAL KIDNEY FUNCTION
Gadolinium contrast agent

POOR KIDNEY FUNCTION
NO contrast agent recommended
(Regulatory black box warnings)

Severe and potentially deadly side-effects
(Nephrogenic Systemic Fibrosis)

TOMORROW

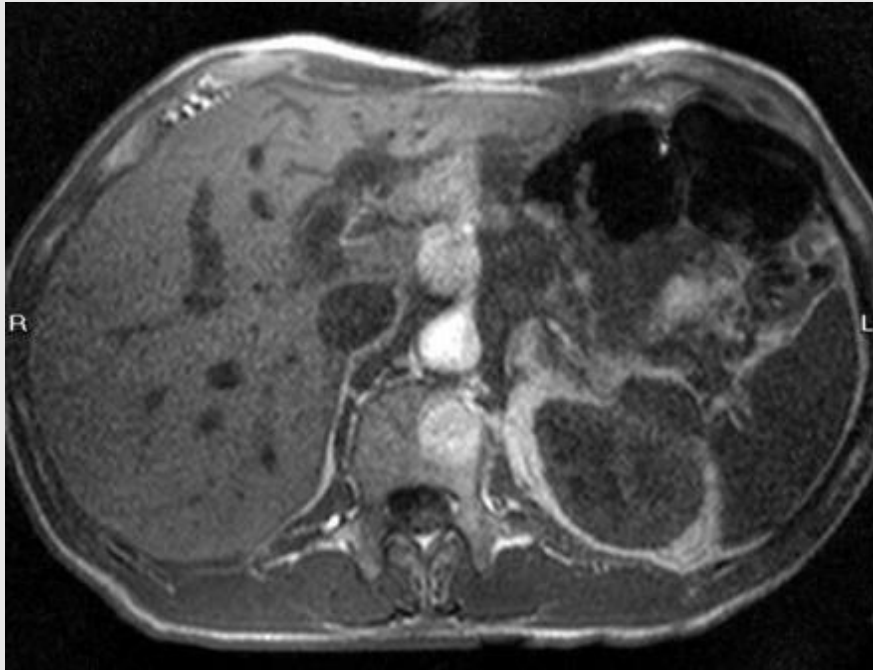
NORMAL KIDNEY FUNCTION
Gadolinium contrast agent

POOR KIDNEY FUNCTION
MANGORAL contrast agent
(Based on manganese)

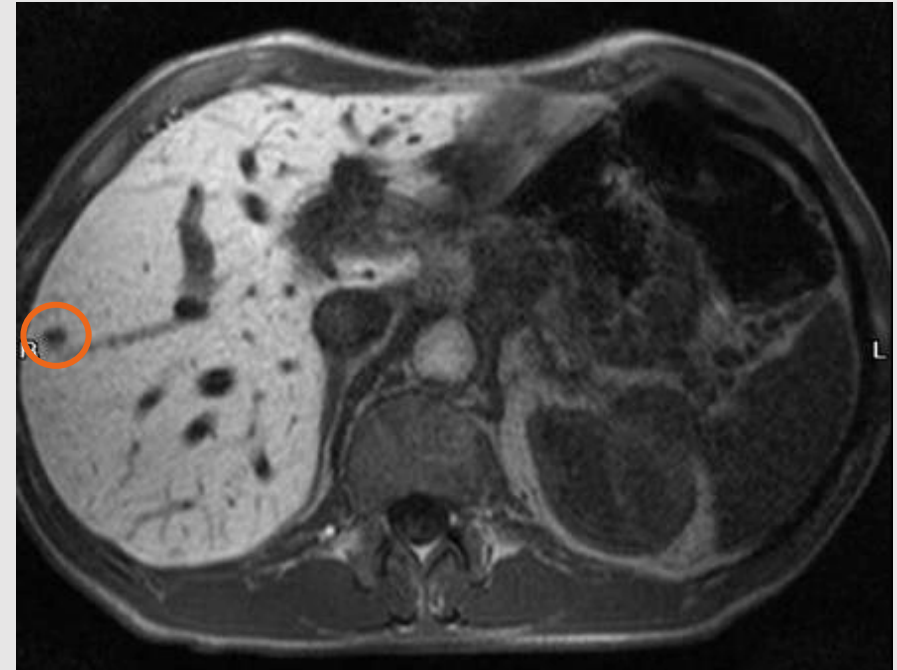
Mangoral aims to be the standard of care
liver MRI contrast agent

STRONG LIVER ENHANCEMENT WITH MANGORAL

PATIENT EXAMPLE FROM PHASE 2 STUDY



UNENHANCED liver MRI (without contrast agent)
Standard of care today in target population



MANGORAL contrast enhanced liver MRI
Liver metastasis appear with Mangoral

ONGOING PHASE 3 STUDY SPARKLE

PHASE 1 AND PHASE 2 RESULTS (6 STUDIES)

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 patients)

- 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

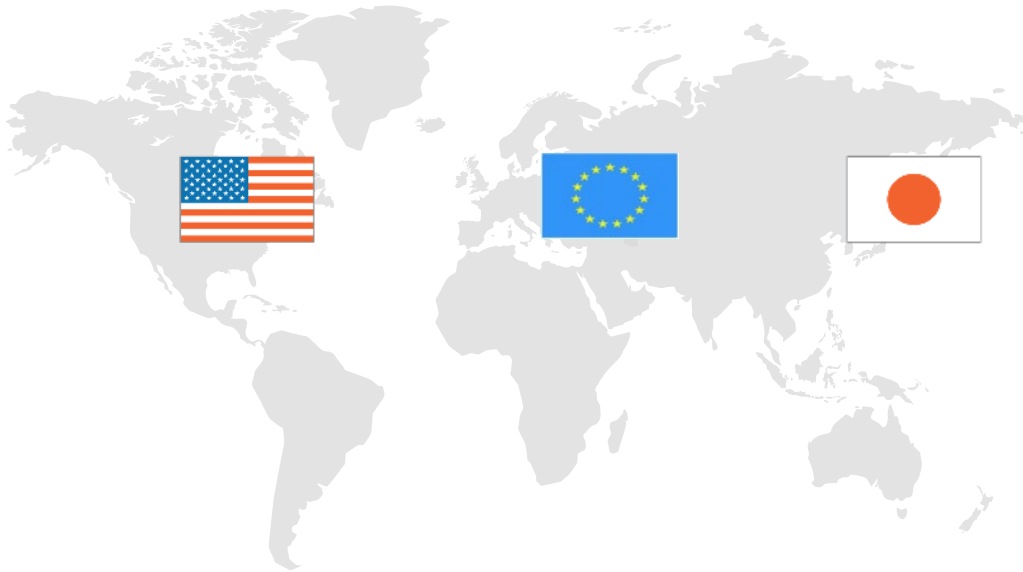


Less than a week

ADDRESSABLE MARKET OF \$500-600 MILLION ANNUALLY

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

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



DRIVERS

- Patients with suspected 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

VALUE MAXIMIZING GO-TO-MARKET

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



Ascelia Pharma to drive commercialization



Commercial partner



Ascelia Pharma global synergies

Commercial partner

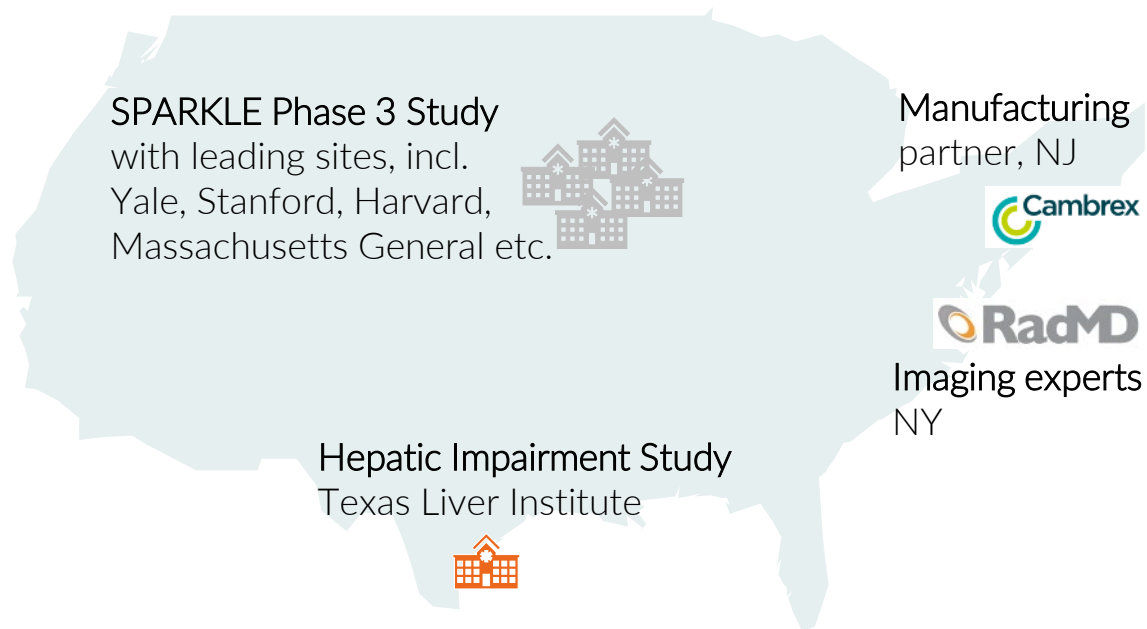


Commercial partner

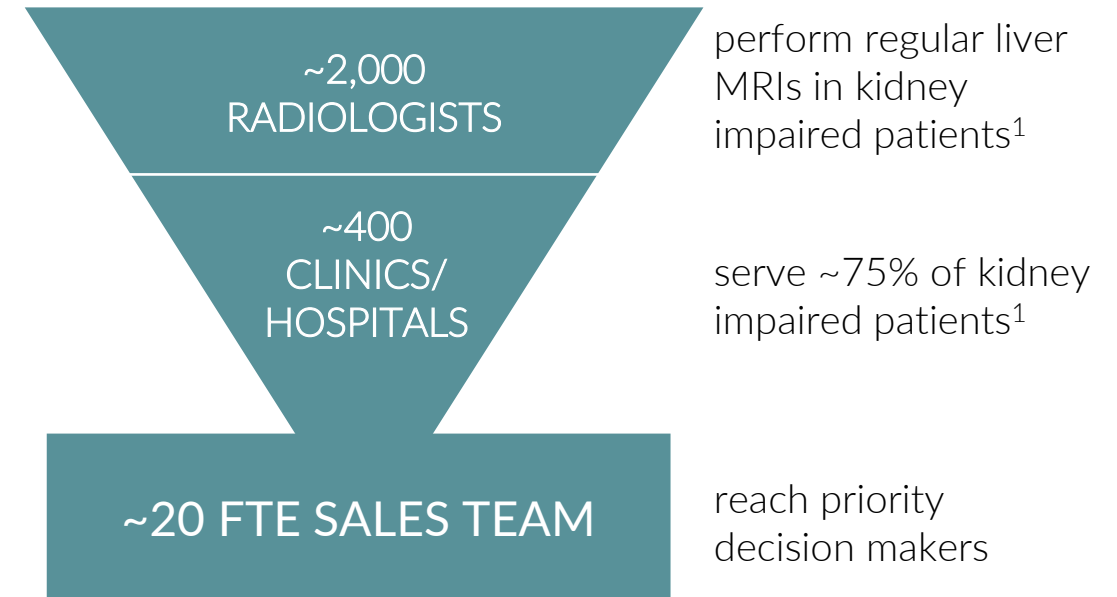
CAPTURING US MARKET VALUE WITH OWN TEAM



STRONG FOOTPRINT IN THE US



BUILDING AN ASCELIA US TEAM





PORTFOLIO

MANGORAL

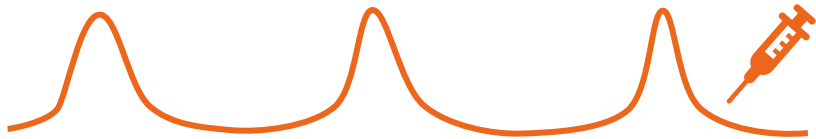
Liver contrast agent in ongoing Phase 3

ONCORAL

Daily oral chemotherapy ready for Phase 2

ONCORAL – IRINOTECAN AS DAILY TABLET

TODAY – IV BOLUS INFUSION



- Widely used chemotherapy
- Established potent anti-tumour effect

UNMET NEED

- **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

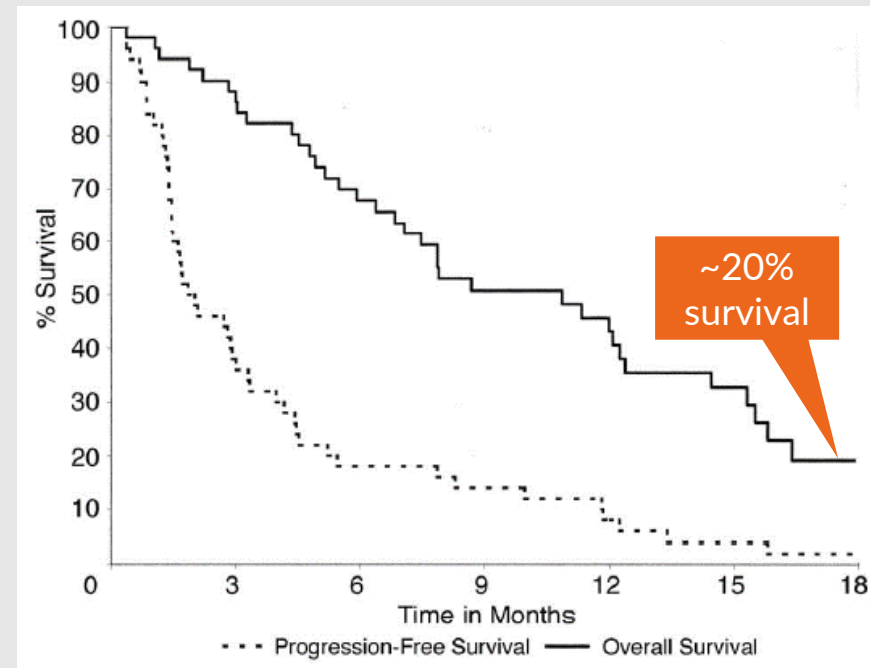
POTENTIAL

- **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

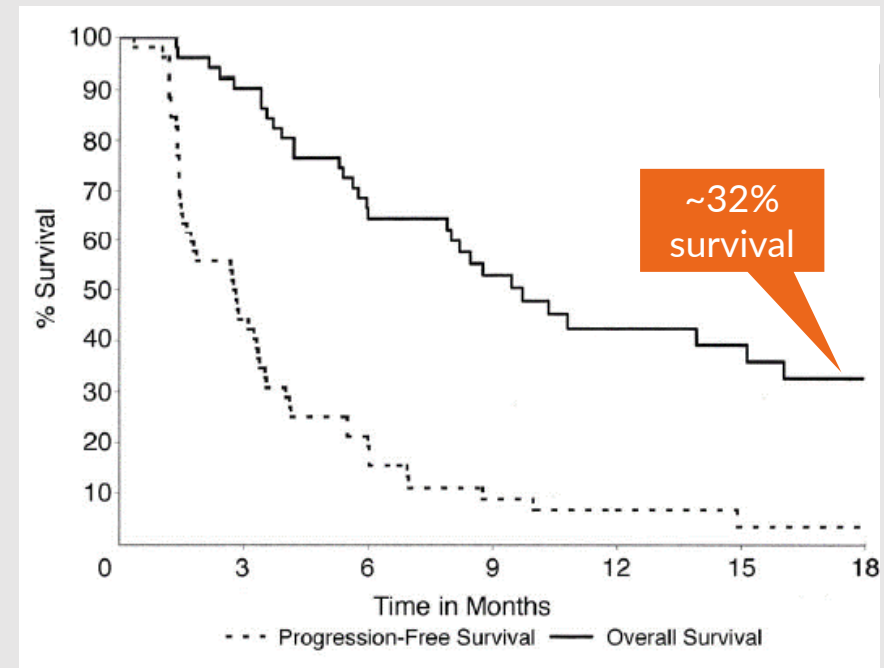
IMPROVING IRINOTECAN **EFFICACY** BY FREQUENT LOW DOSING

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

Irinotecan every 3 weeks (IV)



Irinotecan weekly (IV)

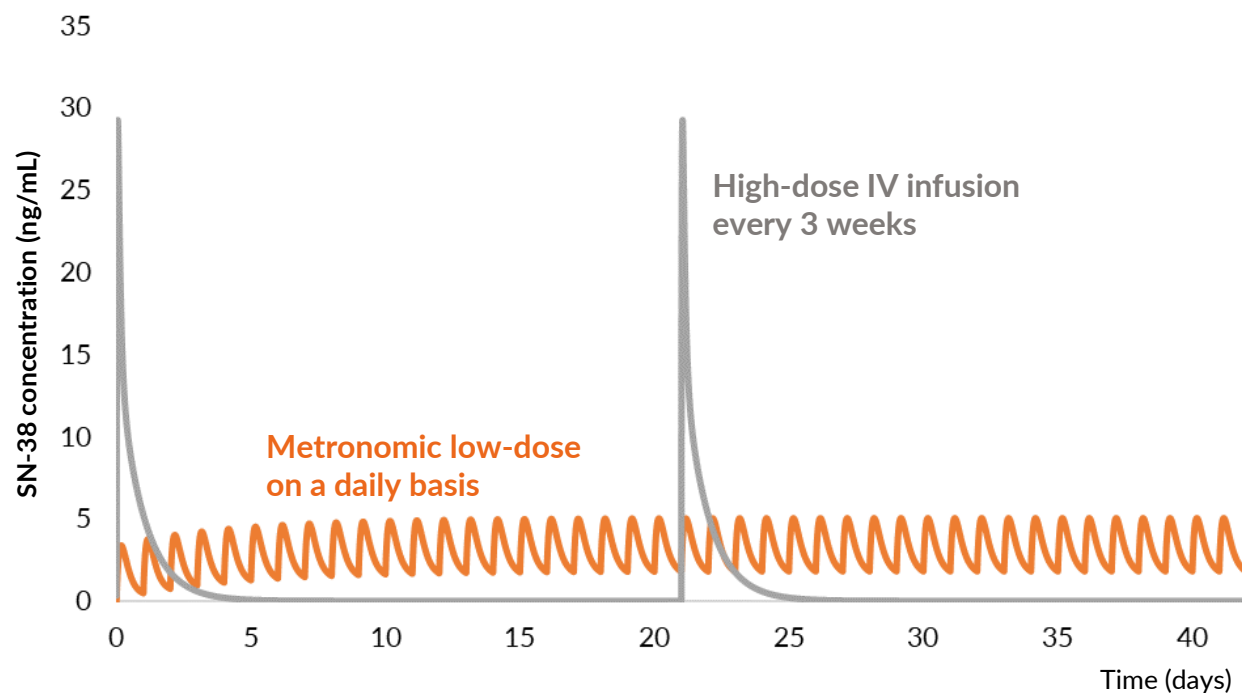


Study in patients with metastatic refractory breast cancer, N=103

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 vs. 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



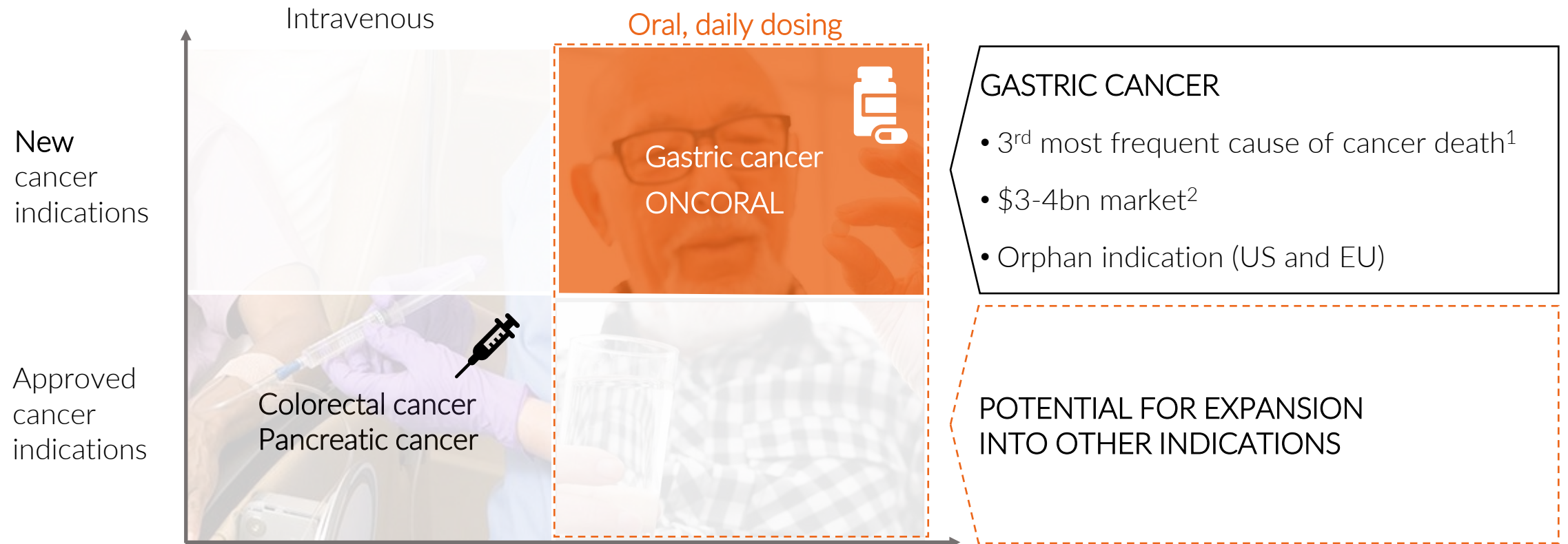
Approximately 100 patients

Study period



H2 2021 – 2024

HIGH VALUE OPPORTUNITY IN GASTRIC CANCER

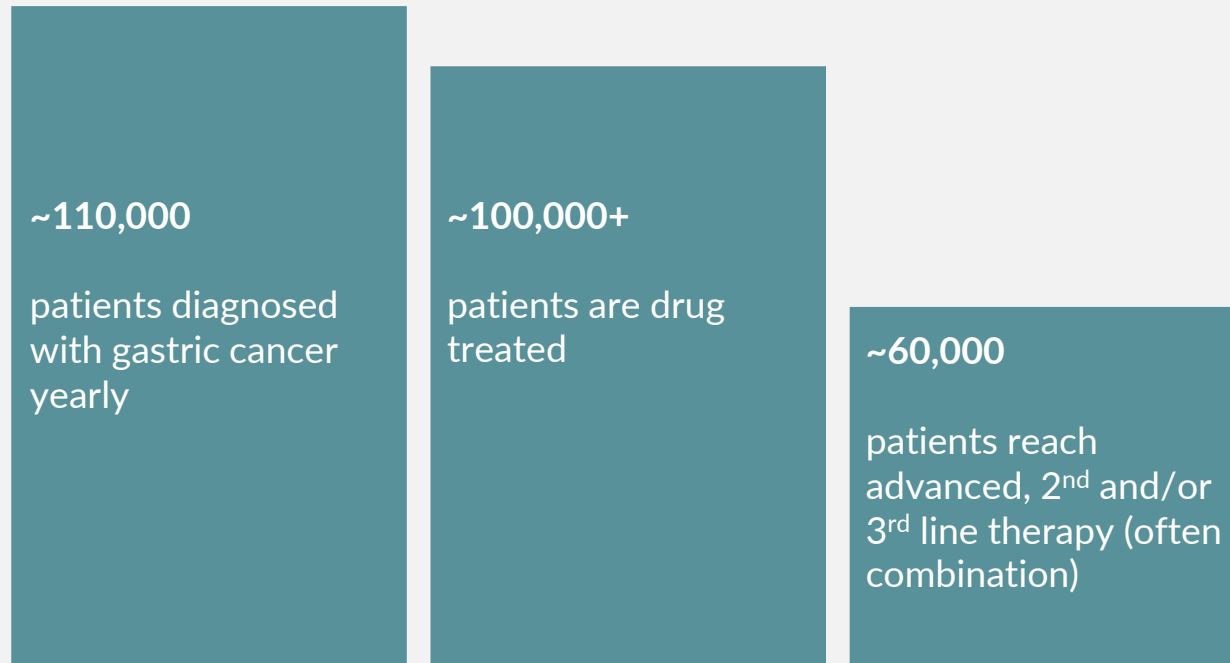


1) International Agency for Research on Cancer (IARC, 2021)

2) GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024

GASTRIC CANCER IS A \$3BN+ MARKET IN NEED OF BETTER TREATMENT OPTIONS

US and EU target patient population (orphan disease)



Other key market

Japan and South Korea has high prevalence and high diagnosis rates
(~150,000 diagnosed patients/year)

China is the country in the world with the highest number of gastric cancer patients
(~400,000 diagnosed patients/year)

...other markets
(~400,000 diagnosed patients/year)

Sources:

International Agency for Research on Cancer (IARC, 2021, input from key opinion leaders and Ascelia analysis
GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024

EXPANSION OPPORTUNITIES BEYOND GASTRIC CANCER

18M+ new incidences of cancer yearly¹

Broadly demonstrated effect of irinotecan (to date)²

	0	500	1,000	1,500	2,000	2,500	% of cases ¹	Examples
Lung							12.3	Clinically demonstrated (non/small cell) & NCCN recognized (small cell)
Colorectal							10.6	Approved indication for 1 st to 3 rd line metastatic
Gastric							6.1	Clinically demonstrated and NCCN recognized (JP/CN approved)
Liver							5.0	Clinically demonstrated
Oesophagus							3.4	Clinically demonstrated and NCCN recognized
Non-Hodgkin lymphoma							3.0	Clinically demonstrated
Pancreatic							2.7	Approved indication for 1 st to 3 rd line metastatic
Leukemia							2.6	Clinically demonstrated
Kidney							2.4	Clinically demonstrated
Cervical							1.7	Clinically demonstrated and NCCN recognized
Ovarian							1.7	Clinically demonstrated and NCCN recognized
Bone, bile duct, CNS..							Rare	Clinically demonstrated and/or NCCN recognized

Source:

1) <https://www.wcrf.org/dietandcancer/cancer-trends/worldwide-cancer-data>

2) ESMO Clinical Practice Guidelines. ASCO Clinical Practice Guidelines. NCCN Guidelines and www.clinicaltrials.com.

A man and a woman are standing in a grassy park area with trees in the background. The man is holding a bicycle with a basket on the front. The woman is standing next to him, looking at him. The scene is bathed in warm, golden light, suggesting late afternoon or early morning. A semi-transparent white shape is overlaid on the image, containing the text 'PRIORITIES & SUMMARY'.

PRIORITIES & SUMMARY



PRIORITIES 2021

- Complete Mangoral Phase 3 patient enrolment (top line results planned for 2H 2021)

- Prepare for Mangoral launch (planned Q4-2022 – H1-2023)

- Initiate Phase 2 study for Oncoral (planned start in H2-2021)

ASCELIA PHARMA – INVESTMENT CASE



ASCELIA PHARMA (ticker: ACE) – Advancing orphan oncology

- Drugs with a clear development and market pathway
- Transforming to commercial stage
- Solid financial position

MANGORAL – Phase 3 non-gadolinium liver diagnostic drug

- \$500-600M/year addressable market with no competing drugs
- Orphan Drug Designation
- Ongoing Phase 3 – results expected H2-2021

ONCORAL – Phase 2 ready daily chemotherapy

- Oral daily dosing of irinotecan chemotherapy
- Potential for better efficacy and safety
- Phase 2 in gastric cancer

ASCELIA PHARMA

ascelia.com



[Follow us on LinkedIn](#)

EXECUTIVE MANAGEMENT



Magnus Corfitzen
Chief Executive Officer

- 20+ years experience from investing, building and growing Life Science companies
- Board experience from 10+ life science companies
- M.Sc. in Mathematical Economics from Aarhus University and studies at Harvard University



Julie Waras Brogren
Chief Commercial Officer

- 20+ years experience from life science incl. leadership positions at Novo Nordisk and COO of Bresotec, Canada
- Excellent track record in global product launches and launch preparations incl. e.g. multi-blockbuster Victoza®
- M.Sc. in International Business from Copenhagen Business School and in Finance from ESC/EM Lyon France



Carl Bjartmar
Chief Medical Officer, MD, Ph.D.

- 20+ years experience from senior positions in big pharma and CMO for Wilson Therapeutics
- Outstanding track record in orphan drug development
- Medical Doctor (M.D.) and PhD from University of Linköping



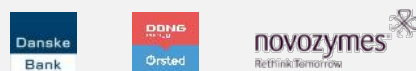
Mikael Widell
Head of IR and Communications

- 30+ years experience within communications, journalism incl. 14 years within financial media, e.g. Dagens Industri
- Corporate communications for e.g. AstraZeneca, Biovitrum (Sobi) and Nordic Capital
- M.A. in English from Lund University and studies in Economics at Lund University.



Kristian Borbos
Chief Financial Officer

- 20 years experience from finance and IR positions in large caps and banking (sell-side, advisory)
- Completed and lead several capital market transactions
- M.Sc. in Business Administration from Lund University and studies at Stockholm School of Economics



BOARD OF DIRECTORS



Peter Benson
Chairman

- Chairman and General Partner at Sunstone Capital Life Science Ventures
- Extensive experience from the Life Science sector from executive positions in Big Pharma and board member in listed companies as well as an investor
- Previous positions include: EVP and President Hospital Care at Pharmacia, VP Marketing & Sales at Kabi Pharmacia Parenterals and Head of Life Science Ventures at the Danish Growth Fund



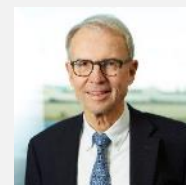
Prof. Hans Maier
Director

- Co-Founder and Managing Partner of BGM Associates GmbH
- Extensive big pharma experience from executive positions within Schering AG and Bayer AG
- Previous positions include: President of the Global Business Unit Diagnostic Imaging at both Schering AG and Bayer AG and part of the Executive Committee of Bayer-Schering AG



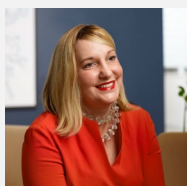
Dr. Bo Jesper Hansen
Director

- Chairman of Laborie and non-executive Director of a number of biotech and pharma companies incl. Orphazyme and Ablynx
- Extensive experience from orphan drug research and development, international marketing and business development
- Previous positions include: Executive Chairman of SOBI and Karolinska Development, CEO and President at Swedish Orphan, non-executive Director of Gambro and Executive Chairman of Topotarget



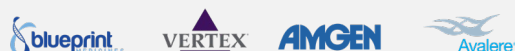
Niels Mengel
Director

- Founding Partner and CEO at Øresund-Healthcare Capital
- Extensive experience from the healthcare industry as an investor and Board member of Danish Shareholders Association
- Previous positions include: EVP at ISS World Services A/S and Director at PA Consulting Group



Lauren Barnes
Director

- SVP Market Access at Blueprint Medicines (listed on Nasdaq US)
- Extensive expertise and experience in pricing, market access, pre-commercialization and managed markets in particular for the US market. Involved in launch planning of more than 50 drugs
- Previous positions include: VP at Vertex Pharmaceuticals, SVP Avalere Health and led their Reimbursement & Commercialization practice. Various roles at Amgen and the agency that runs the United States Medicare Program, the Centers for Medicare and Medicaid Services



René Spogård
Director

- Chairman and investor in a number of companies including JEKA Fish A/S (fish) and Bollerup Jensen A/S (chemicals) and Flexfunding
- Extensive experience from investing in the healthcare sector and board positions in a public environment
- Previous positions include: Managing Director at TNS Gallup and Director at TNS plc (London Stock Exchange)



Helena Wennerström
Director

- Chief Financial Officer ViaCon Group
- Extensive finance executive experience from listed companies
- Previous position include: EVP and CFO of NASDAQ-listed Bulten AB and finance roles at Digitalfabriken and Topcon.





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

US PATENT FOR SECOND GENERATION MANGORAL



US PATENT FOR SECOND GENERATION MANGORAL GRANTED IN DECEMBER 2020

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

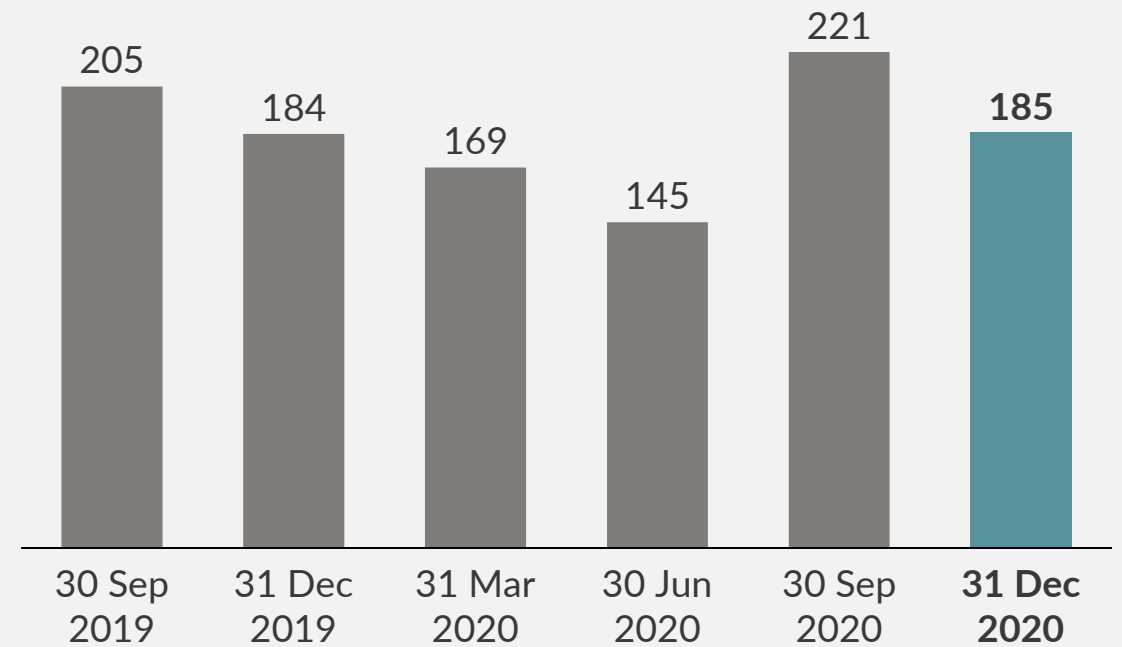
Improved ease of use for patients and health care professionals

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)

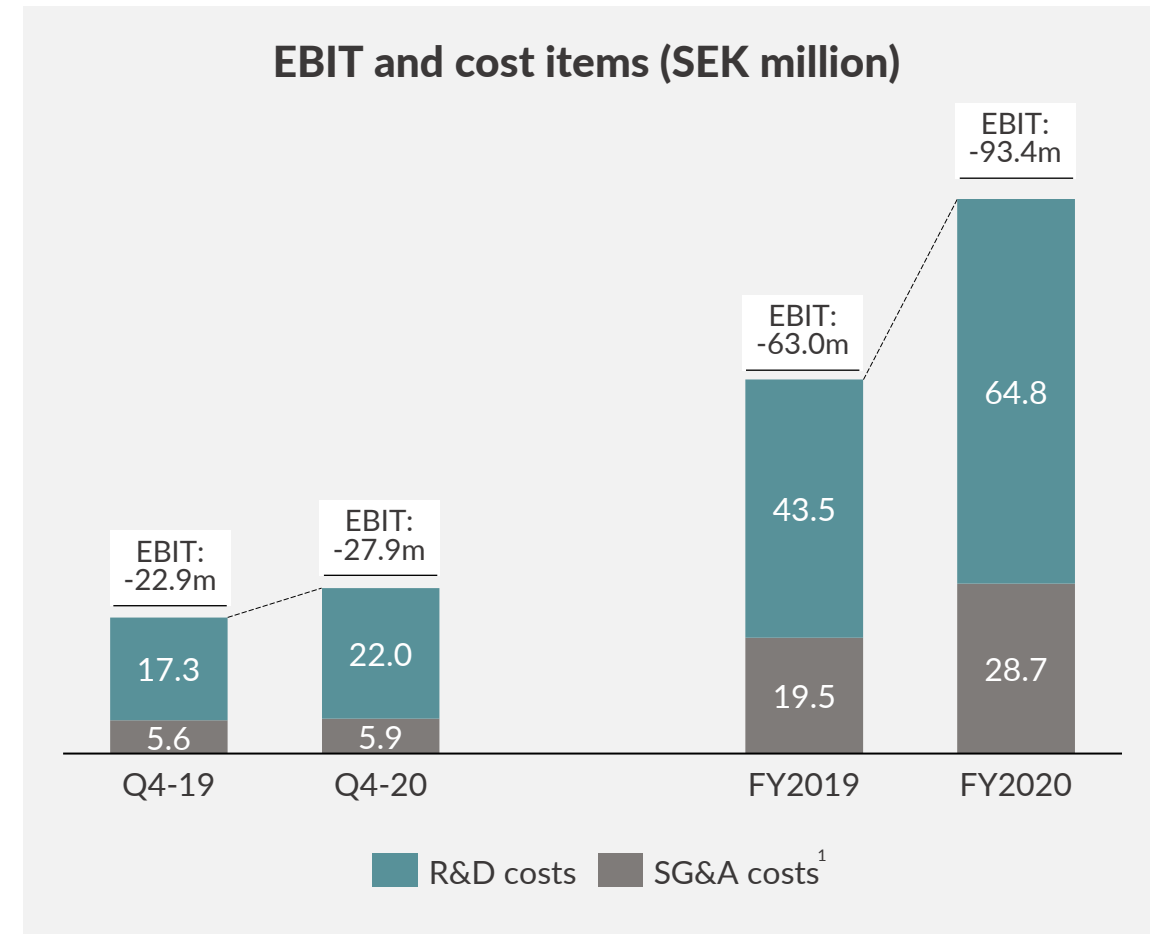


FINANCIAL HIGHLIGHTS Q4 2020 – OPERATING RESULTS

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