ASCELIA PHARMA

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PRESENTATION AT AVANZA BÖRSDAG

22 May 2019

Presenter: CEO Magnus Corfitzen

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ASCELIA PHARMA IN BRIEF

Orphan oncology-dedicated drug development company

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

Two clinical stage assets targeting attractive market opportunities

Founded in 2000 and headquartered in Malmö, Sweden

Listed on Nasdaq Stockholm in 2019 (ticker: ACE)

ASCELIA PHARMA HIGHLIGHTS AND PIPELINE

Mangoral®

- Novel imaging drug with Orphan Drug Designation
- No competing products
- $350-500M market with substantial upside potential
- De-risked Phase III clinical program starting in 2019

Oncoral

- Novel tablet chemo formulation
- Gastric cancer is an Orphan indication
- Phase I clinical study completed
- Recent acquisition of comparable product >$1 billion

Candidate	Indication	Phase I	Phase II	Phase III	Rights
Mangoral® 	**Visualization of Focal Liver Lesions** • *Liver metastases* • *Primary liver cancer* • *Benign lesions*	Completed		2019-2020	Wholly-owned
Oncoral 	**Treatment of Gastric cancer**	Completed	2020-2022		Wholly-owned
	Treatment of other solid cancers *(label expansion)*				

Completed development Planned development

RECENT KEY EVENTS

Key events in Q3 (Jan-Mar 2019)

IPO Nasdaq Stockholm main market

- Amount raised: SEK 200 million
- Substantially oversubscribed
- Fully financed Phase III for Mangoral
- Ticker: ACE

Key events after Q3 (Apr-May 2019)

Mangoral®

Supportive feedback from EMA on the Phase III program for Mangoral

Oncoral

Encouraging results from the Phase I combination study with Oncoral and oral capecitabine published in journal

Raised SEK 22 million in utilised IPO overallotment

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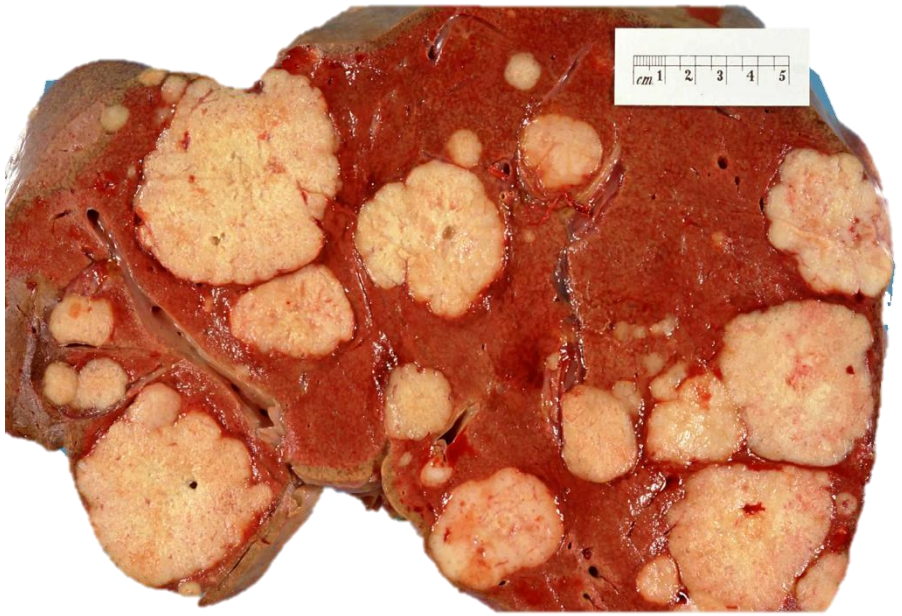
SELECTED UPCOMING KEY EVENTS IN 2019 AND 2020

	H2-2019	2020
Mangoral®	Phase III: First Patent First Visit	Phase III: Last Patent Last Visit (H2-2020) Final study results (H2-2020 / early 2021)
Oncoral	Phase II preparations	Phase II study

MANGORAL®

LIVER METASTASES – A MAJOR CHALLENGE IN ONCOLOGY

- 70% of patients with colon cancer will develop liver metastases[1]
- Liver metastates are also common in other cancer types such as lung cancer, gastric cancer, metastatic breast cancer[2,3] etc.
- The liver is the most frequent organ for metastases after lymph node[3] and often the first site of metastasis
- Often liver metastases are the cause of death (not primary tumor)[4]



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) Oncotarget, 2016, 7(32):52307; Lung Cancer, 2014, 86:78-84 (6):29765
3) 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
4) 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

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LIVER METASTASES: HOW TO FIND AND WHAT TO DO

DETECT AND LOCALISE

Liver MRI is the **most sensitive** method for detection of liver metastases[1)]

Gadolinium based imaging drugs are given to maximize accuracy of liver metastasis detection in MRI

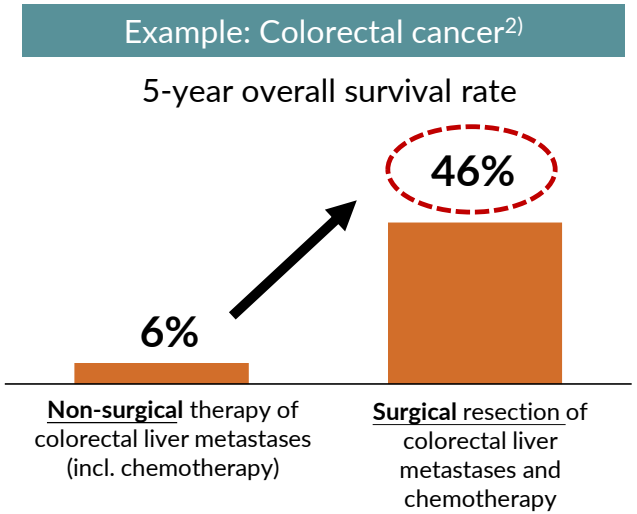
TREAT

Treatment options for liver metastases are:

- Surgical resection (only if detected early)
- Localised therapies (ablation embolization, radiation)
- Drug therapy

IMPROVE SURVIVAL

Accurate, early detection of liver metastases significantly impact treatment decisions and patient survival



1) Albiin N et al. Manganese chloride tetrahydrate (CMC-001) enhanced liver MRI: evaluation of efficacy and safety in healthy volunteers. MAGMA. 2012 Mar 8
2) Clinical Colorectal Cancer, Vol. 15, No. 4, Dec 2016, e183-192

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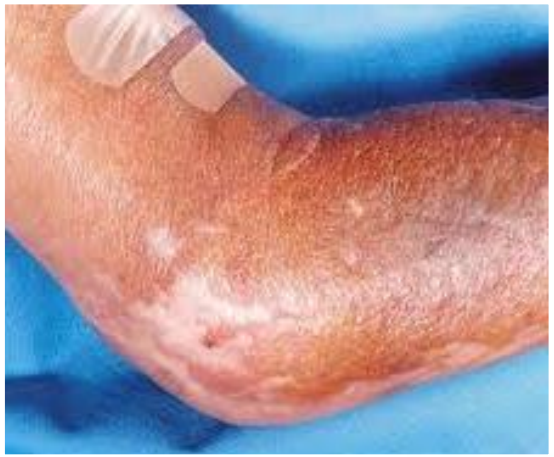
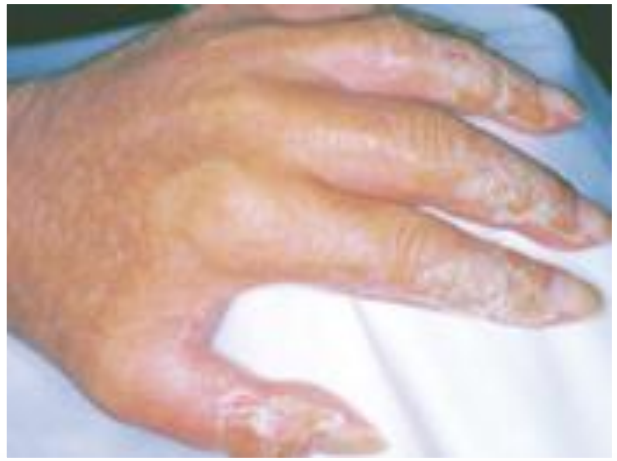
GADOLINIUM CAN CAUSE NEPHROGENIC SYSTEMIC FIBROSIS IN PATIENTS WITH POORLY FUNCTIONING KIDNEYS





No alternative MRI imaging drug for cancer patients with severely impaired kidneys

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/1.73m^2), 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).**

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PATIENTS REFERRED FOR LIVER MRI SCAN

TODAY

- NORMAL KIDNEY FUNCTION
  Gadolinium imaging drug
- POOR KIDNEY FUNCTION
  NO imaging drug

TOMORROW

- NORMAL KIDNEY FUNCTION
  Gadolinium imaging drug
- POOR KIDNEY FUNCTION
  MANGORAL® imaging drug

Mangoral aims to be the new gold standard liver MRI imaging drug for patients with impaired kidney function

280,000
patients with impaired kidney function in major markets

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MANGORAL® STRONG CLINICAL RESULTS AND KEY BENEFITS

MANGORAL PROFILE AND KEY ADVANTAGES

- Mangoral is based on manganese – a natural trace element in the body
- FDA Orphan Drug Designation
- Strong enhancement of liver on MRI – metastases do not take up manganese and appear darker on the MRI
- No risk of Nephrogenic Systemic Fibrosis
- Limited systemic exposure and good safety profile
- No competing drug
- Provides ease of use for patients and clinicians alike

STRONG CLINICAL RESULTS

Six Phase I and Phase II trials completed

- The clinical trials have shown strong clinical efficacy without any safety concerns

Blinded read study

- The study with 178 subjects 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)

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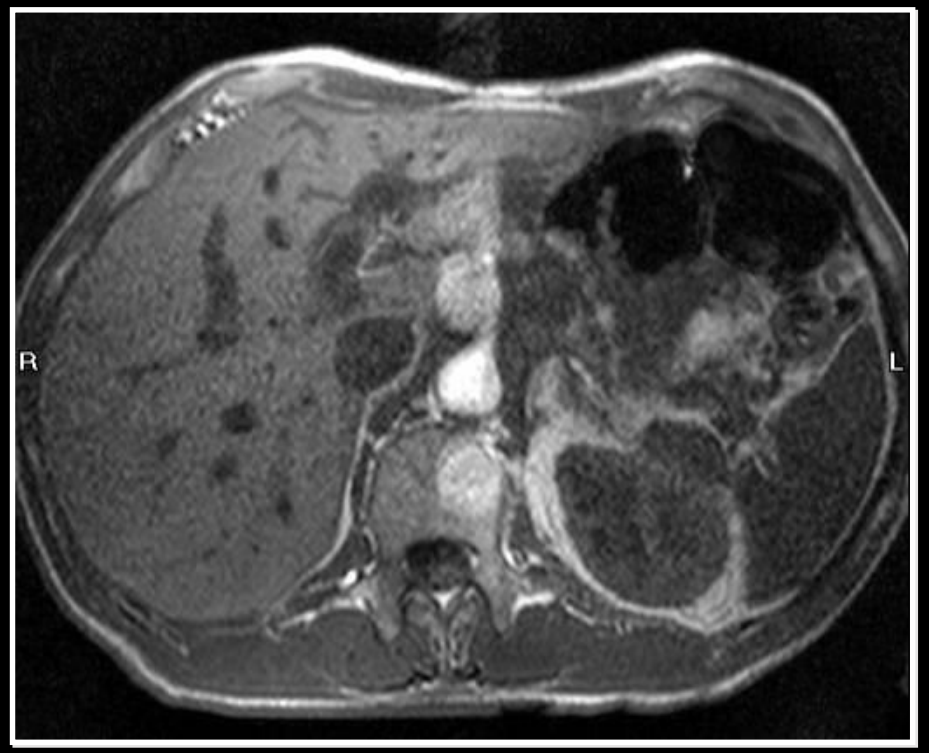
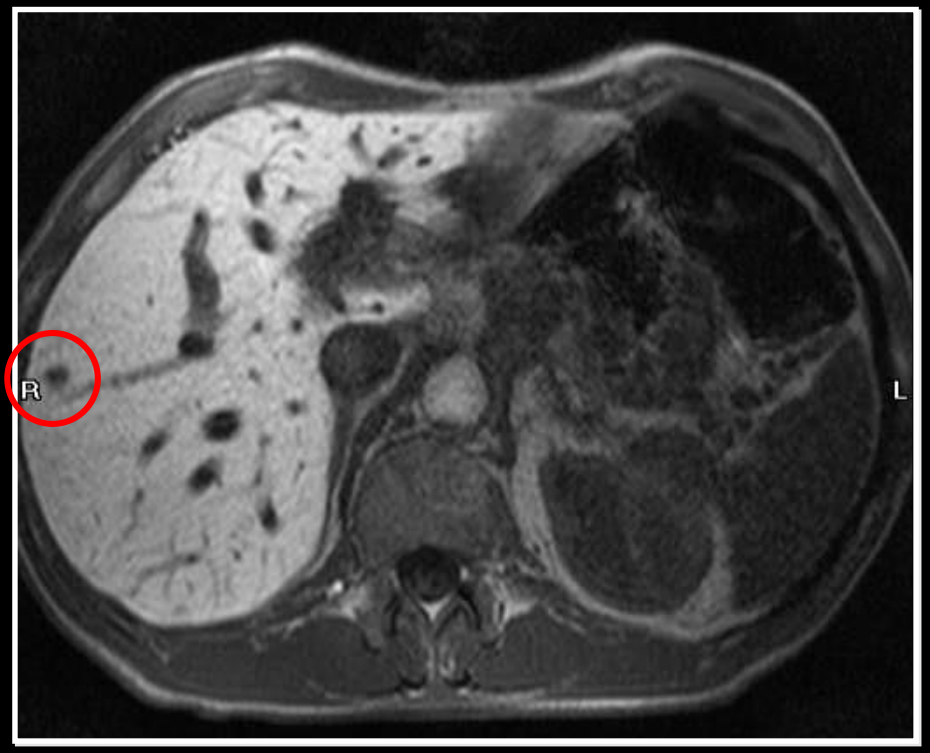
MANGORAL® MAKES A REAL DIFFERENCE

PATIENT EXAMPLE FROM PHASE II STUDY



Unenhanced liver MRI

(standard of care today in target patient population)



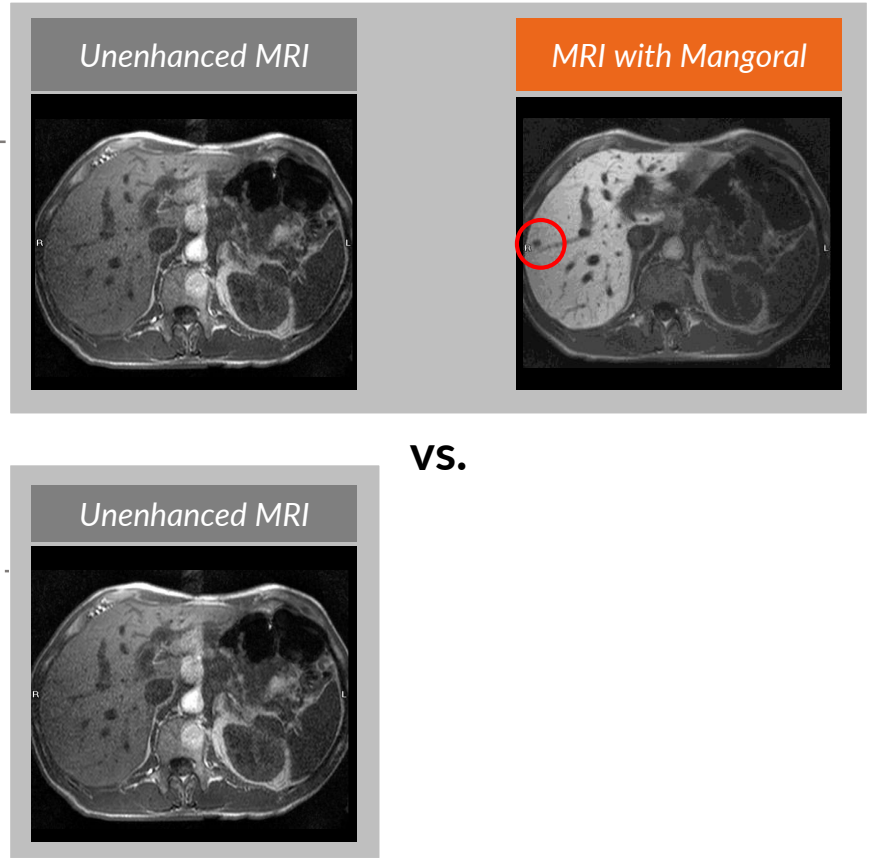
Mangoral enhanced liver MRI

Source: Patient with colorectal cancer. (Study CMC-P002)

MANGORAL® PHASE III CLINICAL STUDY DESIGN IMPLIES INCREASED LIKELIHOOD OF SUCCESS

Mangoral clinical phase III study design – based on Phase III protocol meeting with FDA and EMA

Number of patients	Up to 200 patients
Endpoint	Lesion visualisation • No. of lesions visualised • Semi-quantitative & Semi-qualitative parameters
Comparator	Unenhanced MRI + Mangoral MRI *vs.* Unenhanced MRI
Evaluation	Centralised evaluation by 3 radiologists
Randomisation	**No** – each patient will be in both study arms
Follow-up	72 hours



MANGORAL® IS THE ONLY PRODUCT IN A $350-500M MARKET

Overview of Mangoral's addressable market

280,000 patients having risk of cancer in the liver and poor kidney function

Mangoral useful for diagnosis, monitoring and surveillance

$1,500 - $3,000 per dose of Mangoral based on Value-based-pricing

$350-500 million addressable market for Mangoral

Source

Detailed epidemiology analysis by geography, age groups and primary disease

Use of liver MRI today and clinical guidelines

>25 interviews with payors/health insurers in US and EU and analysis of value provided by Mangoral

Note: 280,000 is estimated relevant patient population with cancer in USA, Europe and Japan

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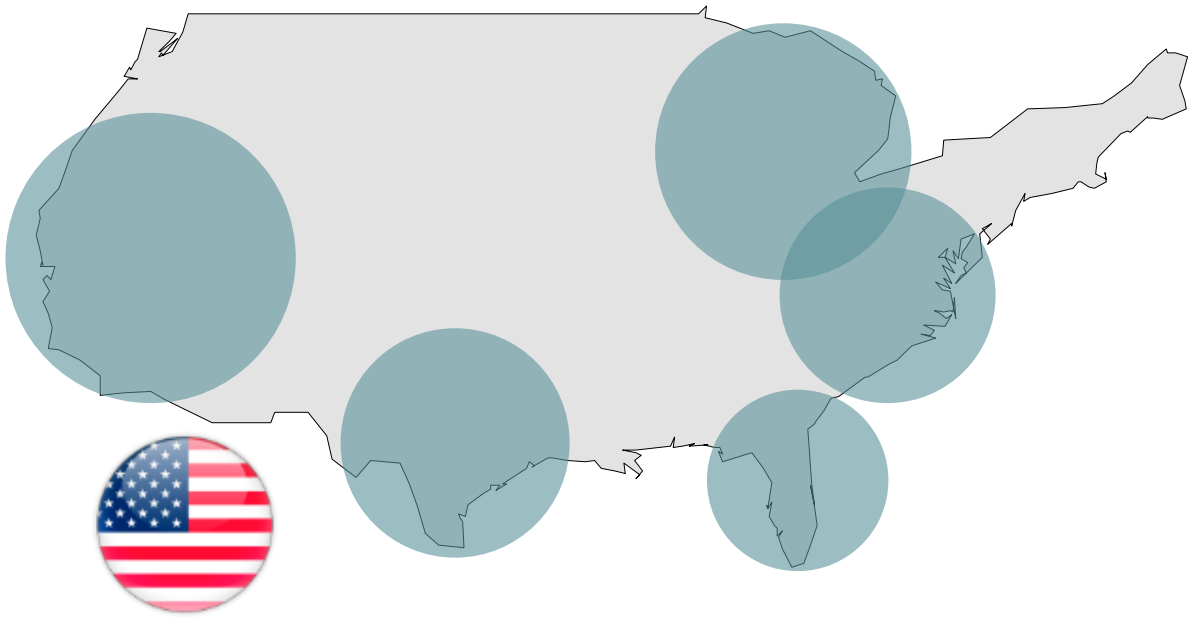
MANGORAL®
COMMERCIAL STRATEGY FOR A 2022 SALES LAUNCH

10-20 Sales Reps sufficient for penetration in concentrated regions



- **Ascelia's sales force** will target **major hospitals** with nephrology units
- **10-20 sales reps in the US** sufficient for significant penetration
- **Reimbursement** expected shortly after sales launch
- **Chief Commercial Officer will be recruited during the Phase III** clinical study to finalize commercial strategy and prepare launch
- **No recent innovation in the MRI space** Mangoral has attracted major attention. This will be utilized in the pre marketing phase
- Ascelia sales force in Europe being evaluated
- Find commercial partners in Japan, South Korea and China

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ONCORAL

ONCORAL – A NOVEL IRINOTECAN TABLET FOR ANTI-CANCER TREATMENT

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**

PHARMACEAUTICAL INGRIEDIENT 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

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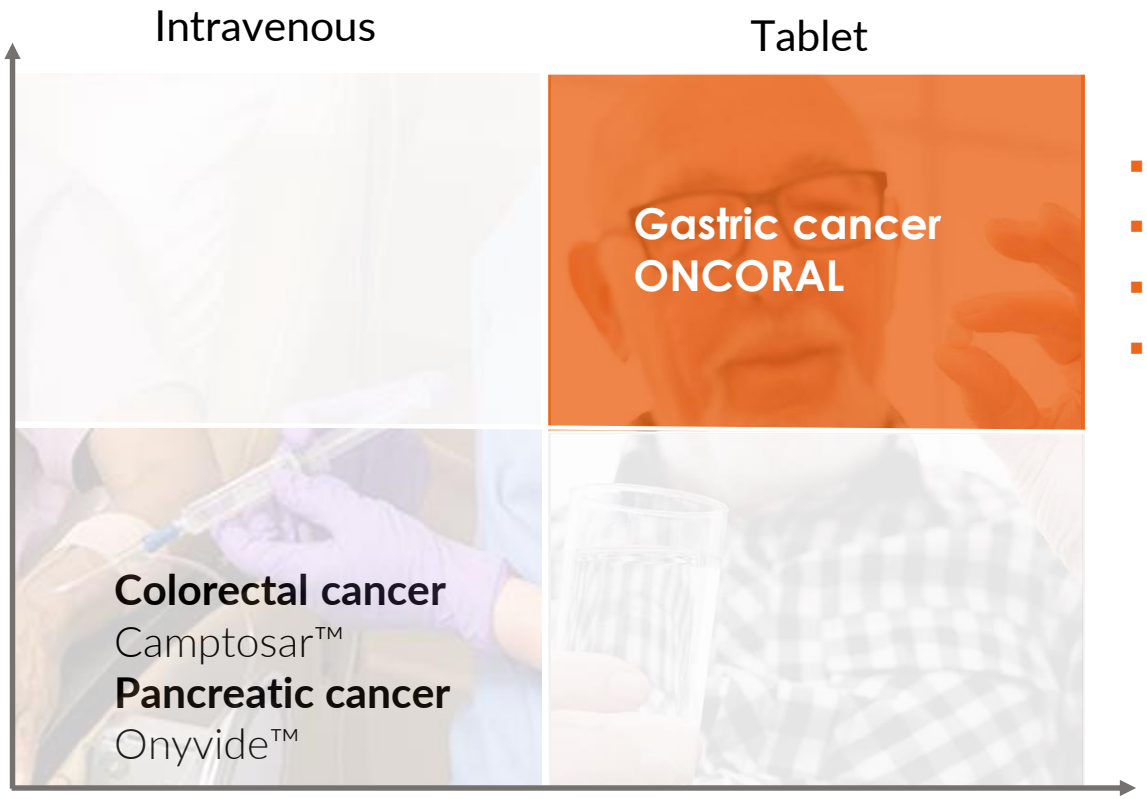
ONCORAL HIGHLY DIFFERENTIATED FROM OTHER IRINOTECAN PRODUCTS



- Significant unmet medical need in gastric cancer
- Gastric cancer is an orphan indication
- Irinotecan approved in Japan in gastric cancer
- Strong interest from oncologists

ENCOURAGING ONCORAL PHASE I STUDY RESULTS

Phase I *single agent study* published in Jan 2019

Results showed that Oncoral was well tolerated; side effects were generally mild to moderate, manageable and similar in type to those observed with intravenous irinotecan

Hematological toxicities were few and all were mild to moderate

Pharmaco-Kinetic (PK) data showed consistent daily exposures during treatment at days 1 and 14 with no drug accumulation

The active metabolite, SN-38, interpatient variability was in the same range as after infusion of irinotecan

In this heavily pre-treated patient population, Oncoral indicated activity even among patients previously treated with irinotecan infusion

The study was presented at ESMO congress in October 2018

Phase I *combination study* published in April 2019

The combination of Oncoral with another oral chemotherapy, capecitabine, was encouraging which could enable an all-oral chemotherapy combination

The study data demonstrated reassuring tolerability of Oncoral together with capecitabine

The combination with capecitabine could become a more convenient and patient friendly treatment option compared to the intravenous formulations of these compounds

The encouraging tolerability profile justifies further clinical studies to assess the efficacy of this treatment regimen

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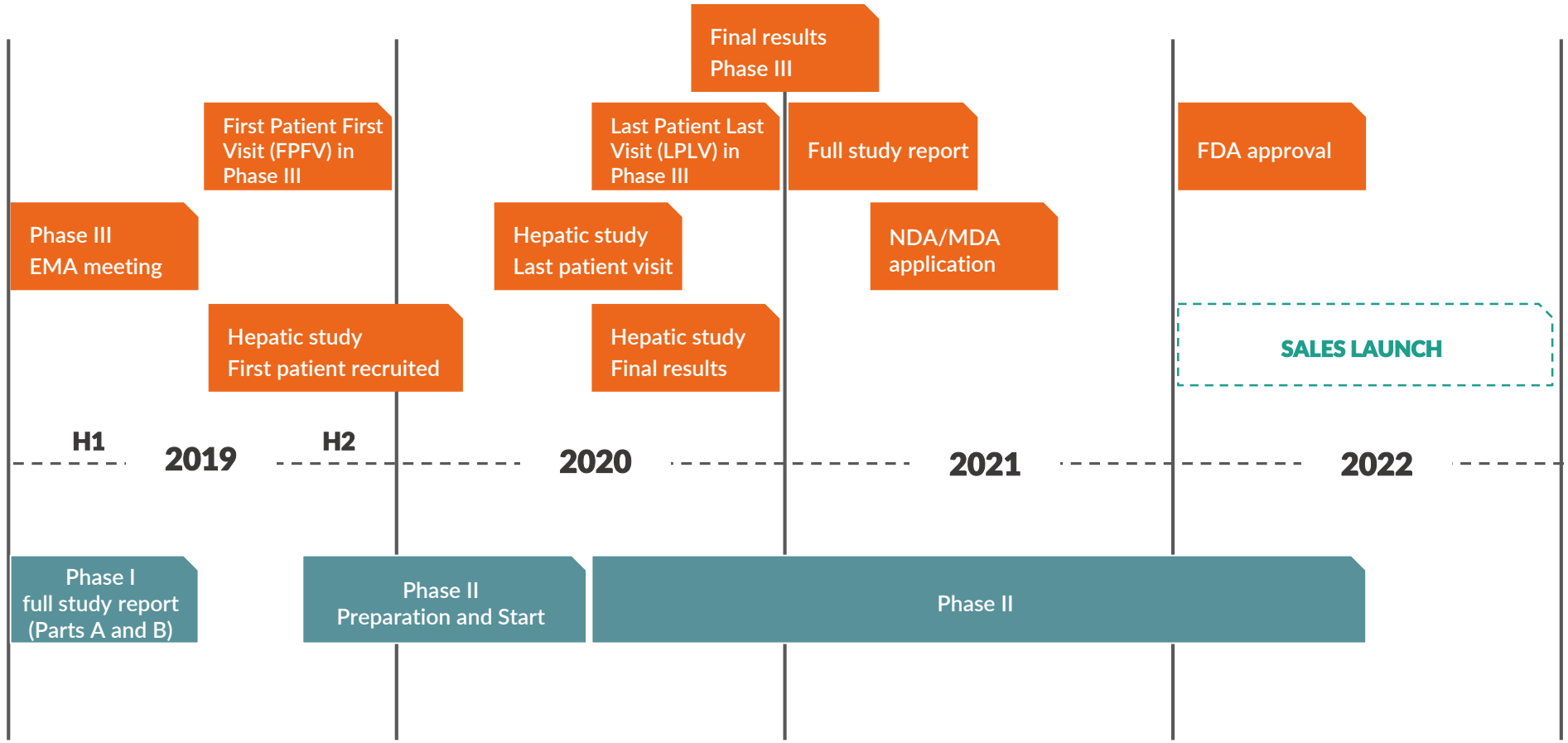
MILESTONES AND STRATEGIC OUTLOOK

SIGNIFICANT VALUE DRIVERS AHEAD

MANGORAL®

ONCORAL

Development timeline



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STRONG AND EXPERIENCED MANAGEMENT AND BOARD OF DIRECTORS

MANAGEMENT

Magnus Corfitzen
Chief Executive Officer

Kristian Borbos
Chief Financial Officer

Carl Bjartmar, MD, Ph.D
Chief Medical Officer

Dorthe da Graça Thrige, M.Sc, Ph.D
Chief Operating Officer

Mikael Widell
Head of IR and Communications

BOARD OF DIRECTORS

Bo Jesper Hansen, MD, Ph.D
Director

Peter Benson
Chairman

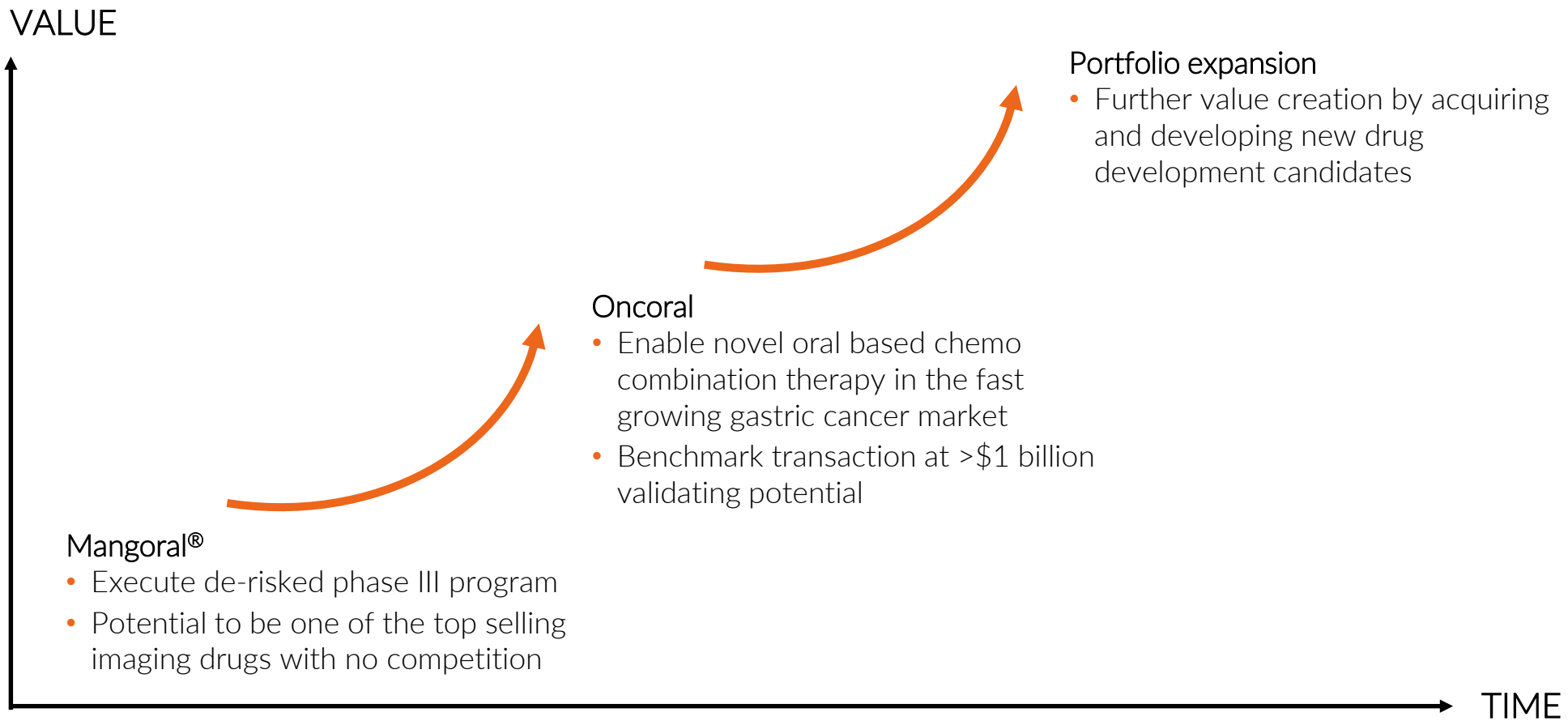
Hans Maier, Ph.D, Prof.
Director

Helena Wennerström
Director

Niels Mengel
Director

René Spogárd
Director

ASCELIA PHARMA STRATEGIC OUTLOOK



INVESTMENT HIGHLIGHTS

Mangoral® – Phase III ready liver imaging drug

- $350-500 million annual addressable market
- No competing drugs
- Phase III program with high likelihood of success – results end 2020 / early 2021
- Orphan Drug Designation

Oncoral – Phase II ready oral chemotherapy for gastric cancer

- Novel tablet formulation with significant patient and hospital benefits
- Effective molecule for killing cancer
- Promising Phase I results

Highly experienced Management and Board

- Supported by a wide network of highly reputable KOLs and advisors

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