

ASCELIA PHARMA

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WEBCAST:

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PRESENTATION OF Q3-2020 REPORT

JUL-SEP 2020

Present from Ascelia Pharma:

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

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ASCELIA PHARMA – ADVANCING ORPHAN ONCOLOGY



IMPROVING THE LIFE FOR PEOPLE
WITH RARE ONCOLOGY-RELATED
CONDITIONS

CURRENT ASSETS

Mangoral

- Global Phase 3 development ongoing
- For liver MRI in subset of overall population (Orphan Drug)

Oncoral

- Novel irinotecan tablet ready for Phase 2
- Focus on gastric cancer; potential in other cancer types

CAPABILITIES

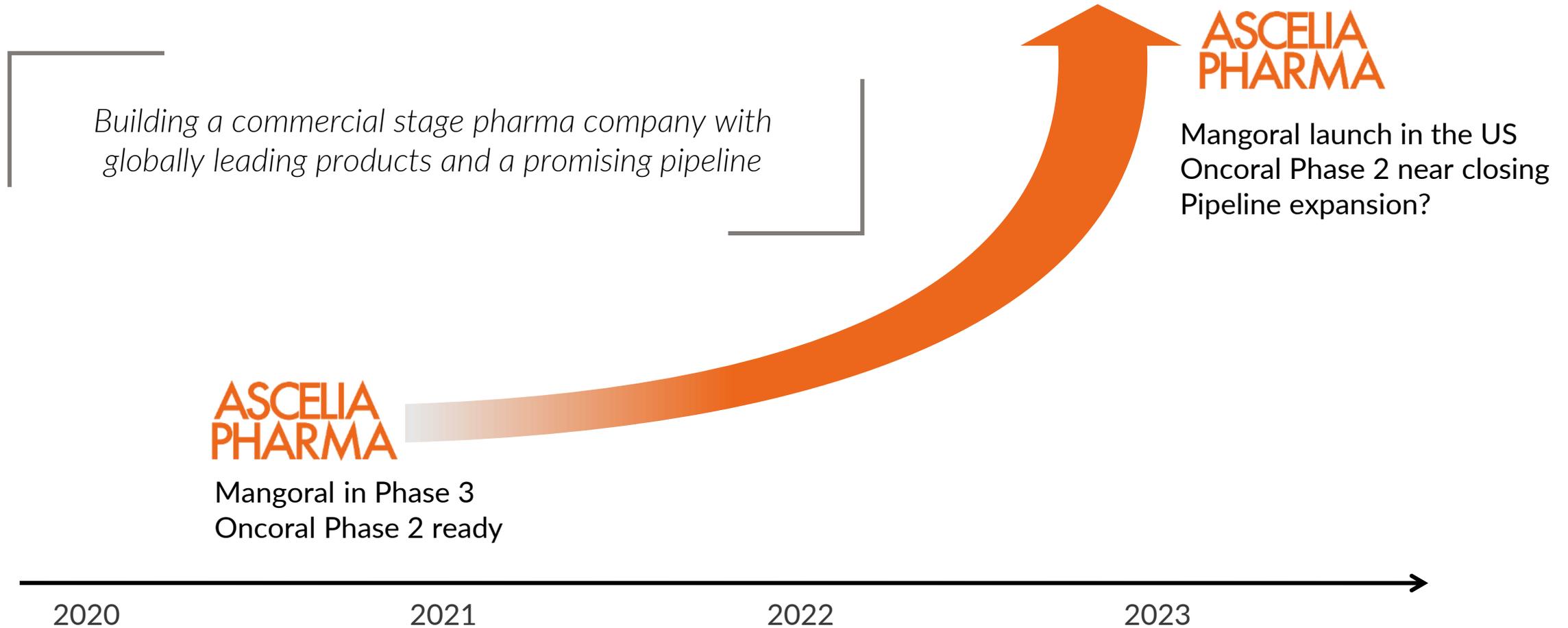
People & Partners

- Strong experienced team
- World class network of global KOLs and advisors
- Supply chain in place

Financial

- Fully financed to reach substantial value creating milestones
- Listed on NASDAQ Stockholm

BUILDING ASCELIA PHARMA AND BUILDING VALUE



RECENT 2020 KEY EVENTS



July

Proceeds received from the directed share issuance



September

First commercial scale production of Mangoral



October

Raised estimate for Mangoral addressable market



November

EMA confirms Mangoral is eligible for centralized regulatory procedure in the EU



CLINICAL PORTFOLIO

OUR CURRENT CLINICAL PORTFOLIO

Mangoral:

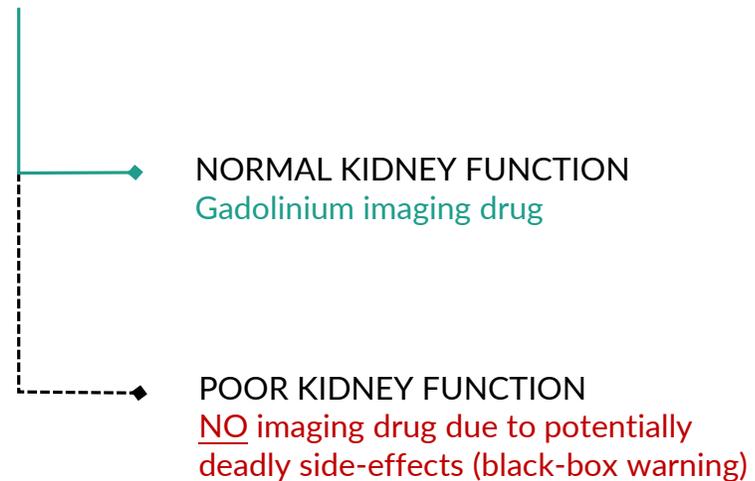
Liver contrast agent in ongoing Phase 3

Oncoral:

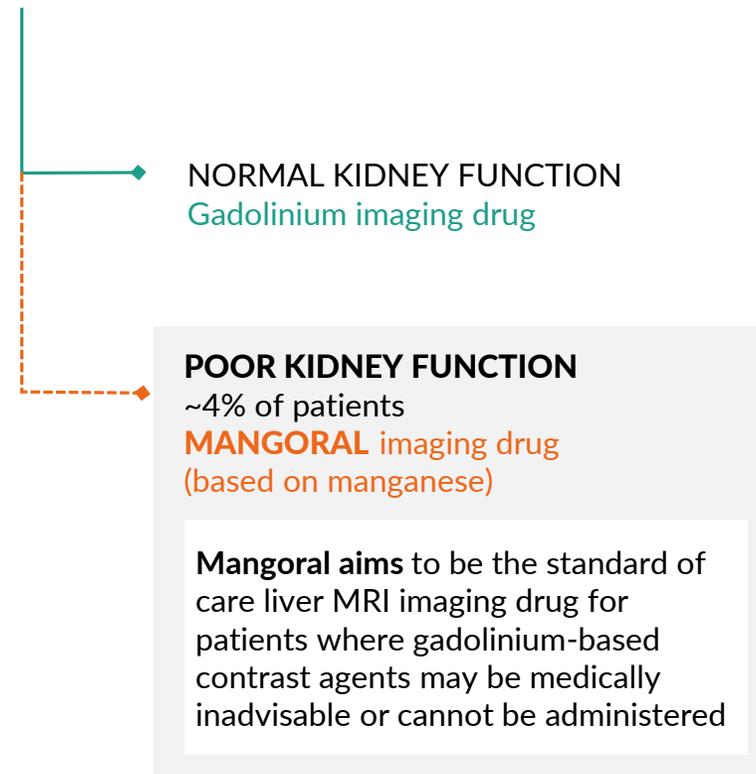
Chemotherapy tablet ready for Phase 2

MANGORAL – ADDRESSING A CLEAR UNMET MEDICAL NEED

TODAY



TOMORROW



MANGORAL – ONGOING PHASE 3 STUDY SPARKLE

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 visualization**
Delineation: p-value <0.0001
Conspicuity: p-value <0.0001

Phase 3 registration-enabling study (study ongoing)

Number of patients	Global study in up to 200 patients
Endpoint 	Lesion visualization <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

MANGORAL – WORLD-CLASS CLINICS PARTICIPATING IN SPARKLE

Global Phase 3 study (SPARKLE)

- 40–50 clinical sites including e.g.:
 - Yale University School of Medicine, USA
 - Harvard Medical School, USA
 - Stanford School of Medicine, USA
 - Charité Universitätsmedizin, Germany
 - Karolinska University Hospital, Sweden

Leading expert radiologists participating

- Strong relationship and support
- Awareness of Mangoral
- Validates the unmet medical need

MANGORAL – PHASE 3 DEVELOPMENT PROGRESSING

Mangoral indication	Phase 1	Phase 2	Phase 3	Filing	Market
Visualization of focal liver lesions: <ul style="list-style-type: none">• Liver metastases• Primary liver tumors• Malignant or benign	Completed	Completed	Ongoing 2020 – 2H 2021	1H 2022	Q4 2022- 1H 2023

ONCORAL – NOVEL IRINOTECAN TABLET READY FOR PHASE 2



1) IARC (2012)

2) Clinical Colorectal Cancer 2015; 14(4): 239-50

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

ONCORAL – PHASE 2 PREPARATIONS WELL UNDERWAY

ACHIEVEMENTS

- ✓ Phase 1a and 1b completed with promising results
- ✓ Potential for all-oral treatment regime established
- ✓ Attractive case in \$3-4bn gastric cancer market established with orphan indication (US/EU) and value premium

CURRENT FOCUS

- Phase 2 study design being finalized
- Expected study time: 2021-2023
- Advancement of case in gastric cancer and exploration of potential beyond gastric cancer



COMMERCIAL OUTLOOK MANGORAL

MANGORAL MARKET OPPORTUNITY AND COMMERCIAL PREPARATIONS

- At our Capital Markets Day in October 2020, the estimate of the **addressable market** was **increased to \$500-600 million** (previously \$350-500 million)
- Decision makers **understand the value** that Mangoral provides
- **Launch preparations progress** with a strong case for own commercialization in the US

ADDRESSABLE MARKET ESTIMATE UPGRADED IN OCTOBER 2020

Illustrative

PREVIOUS



Addressable market of \$350–500 million in US, EU and JP



UPGRADED¹



Addressable market of \$500-600 million in US, EU and JP

SAME PATIENT GROUP

NEW REAL-WORLD PROCEDURE DATA²

- Primary cancer type & liver imaging
- Kidney impairment
- Imaging frequency per patient

ADDITIONAL PAYER AND EXPERT INPUT³ (+50 stakeholders)

- Unmet need and clinical guidelines validation
- Value of Mangoral and required evidence
- Pricing potential and reimbursement paths

1) The addressable market estimate was upgraded in connection with the Capital Markets Day on 21 October 2020
2) Market research with Decision Resources Group, 2020
3) Market research and analyses with Charles River Associates, 2020

AIMING TO BECOME THE PREFERRED OPTION FOR PATIENTS WITH SEVERE KIDNEY IMPAIRMENT

Illustrative

MRI CONTRAST AGENT LANDSCAPE

NSF safety concerns	No concerns	No contrast agent available 
	Black-box warnings	Gadolinium based contrast agents
	<u>Non-liver</u> specific	<u>Liver</u> -specific
	Indication	

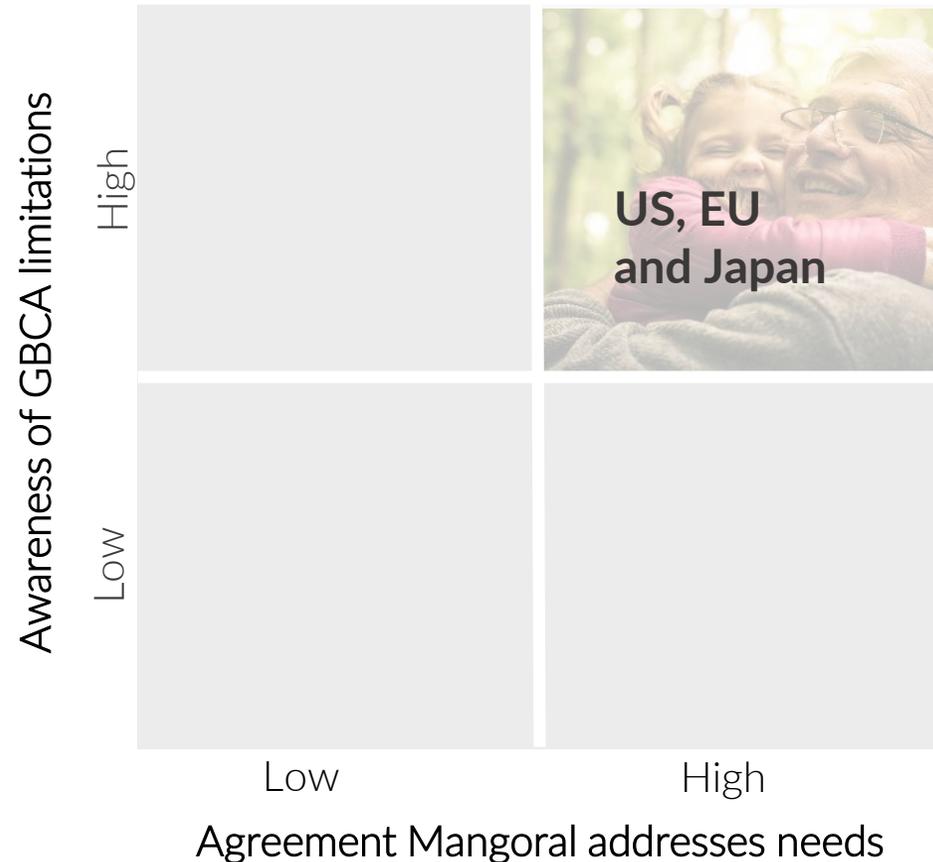
No contrast agent option is currently advised for liver imaging in patients with severe kidney impairment

Mangoral aims to be the only safe and effective liver imaging contrast agent for people with suspected primary liver cancer or metastases severely impaired kidney function

DECISION MAKERS UNDERSTAND THE VALUE OF MANGORAL

Illustrative

MANGORAL DECISION STAKEHOLDERS



Key stakeholders

Payers, Policy Makers and KOLs

...are aware of the limitations of gadolinium-based contrast agents (GCBAs)
...and agree that Mangoral addresses important unmet needs

*“There is room and a need for a new product – it could be a very positive market..”
– National payer*

*“...budget impact should not be a problem”
– Health Technology Assessor*

ADDRESSING UNMET NEEDS OF PATIENTS AND PROVIDERS

CLEAR VALUE PROPOSITION TO PATIENTS, PHYSICIANS AND HEALTH CARE SYSTEMS

85% of clinicians in a survey are likely or extremely likely to use Mangoral for target patient population¹

No MRI contrast agent advised

for patients with severe renal impairment or acute kidney failure²

Clear target patient population

Improved visualisation

of focal liver lesions (incl. metastases) compared to unenhanced MRI

+33% more lesions³

Early detection

of focal lesions and metastases allows early intervention and higher survival rate

94% clinicians confirm⁴

Sources:

1) Market research by Back Bay Life Science Advisors with survey of 84 US radiologists

2) Based on ACR clinical guidelines and regulatory drug class warning for gadolinium-based contrast agents in patients with severe renal impairment (an eGFR <30 ml/min/1.73 m²) or acute kidney failure.

3) Outcomes from Phase 1 and 2 studies

4) 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?'

MARKET SPECIFIC VALUE MAXIMIZING COMMERCIALIZATION

Illustrative



Ascelia Pharma to drive commercialization



Commercial partner



Ascelia Pharma global synergies

Commercial partner



Commercial partner

ATTRACTIVE COMMERCIAL OPPORTUNITY IN THE US



STRONG FOOTPRINT IN THE US

SPARKLE Phase 3 Study sites with leading US radiologists at approximately 15 sites, incl.

- Yale University School of Medicine
- Massachusetts General Hospital
- Standard School of Medicine
- Harvard Medical School

Manufacturing partner, New Jersey



Imaging experts
New York

Hepatic Impairment Study
Clinical research site
Texas Liver Institute



STRONG CASE FOR OWN US TEAM

Attractive potential

- Strong payer value and market access path
- Sizeable target patient population
- Clear clinical decision makers

US capability

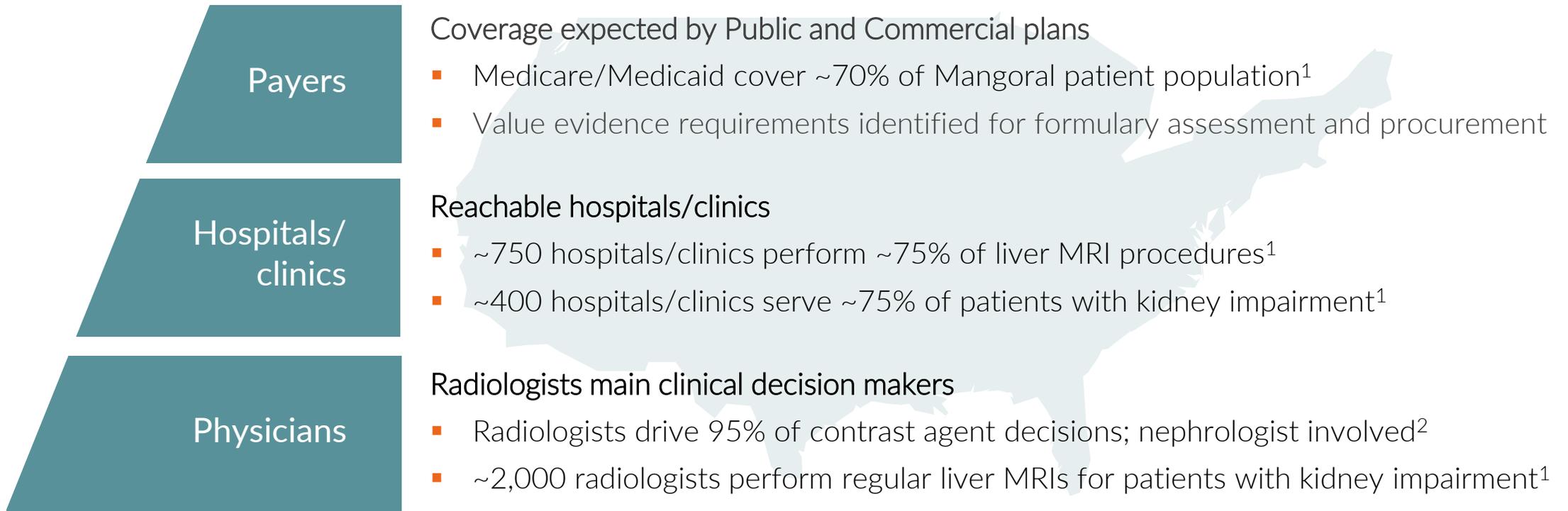
- Sales team of ~20 FTEs reach priority physicians
- Commercial and cross-functional support team
- Local logistics and distribution partnerships
- Leverage global synergies

Building an attractive top-line and retaining profit in Ascelia Pharma

WELL DEFINED DECISION MAKERS IN THE US



DECISION MAKERS TO REACH



Notes:

1) Ascelia Pharma analysis based on market research for Ascelia Pharma by Decision Resources Group, 2020

2) Back Bay Ascelia market research survey with 84 US radiologists, 2019

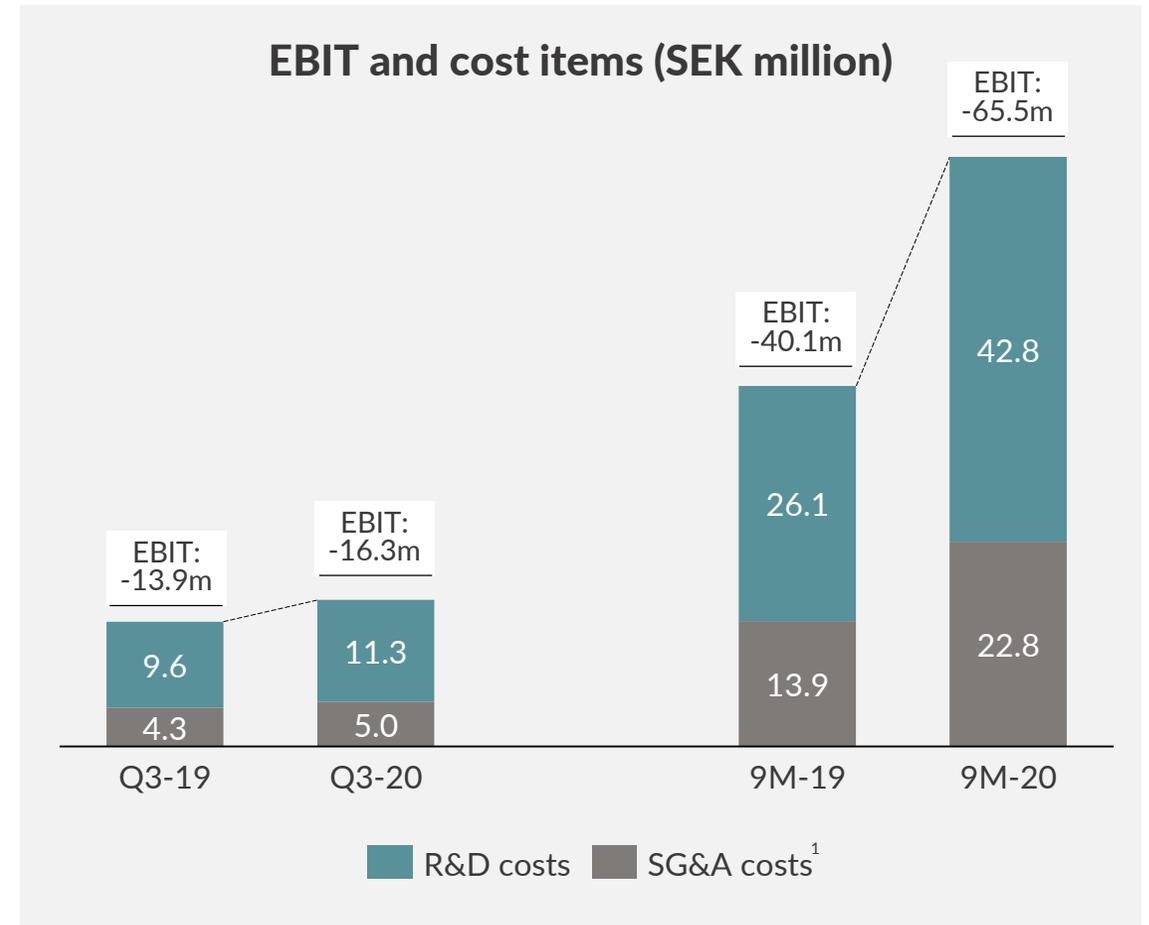
FINANCIALS

FINANCIAL HIGHLIGHTS – 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:

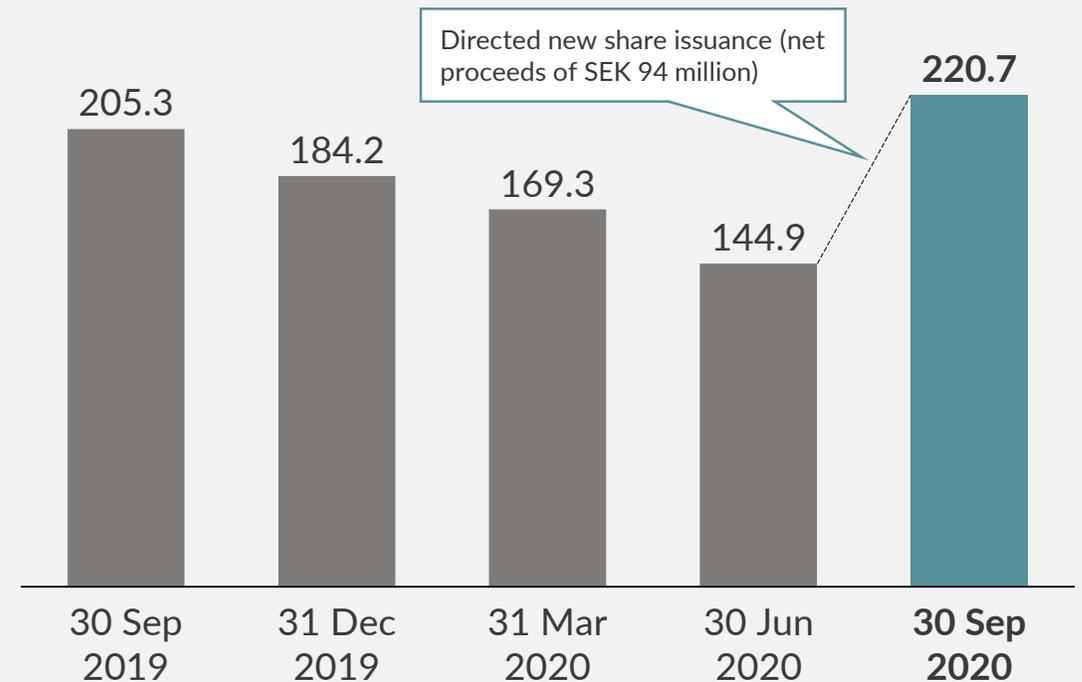
1) Other operating income and other operating costs included into SG&A

FINANCIAL HIGHLIGHTS – LIQUIDITY POSITION

Solid liquidity position:

- Liquid assets incl. marketable securities of SEK 221 million per 30 September 2020
- Liquidity strengthened by the directed share issue (funds received in July 2020)
- 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

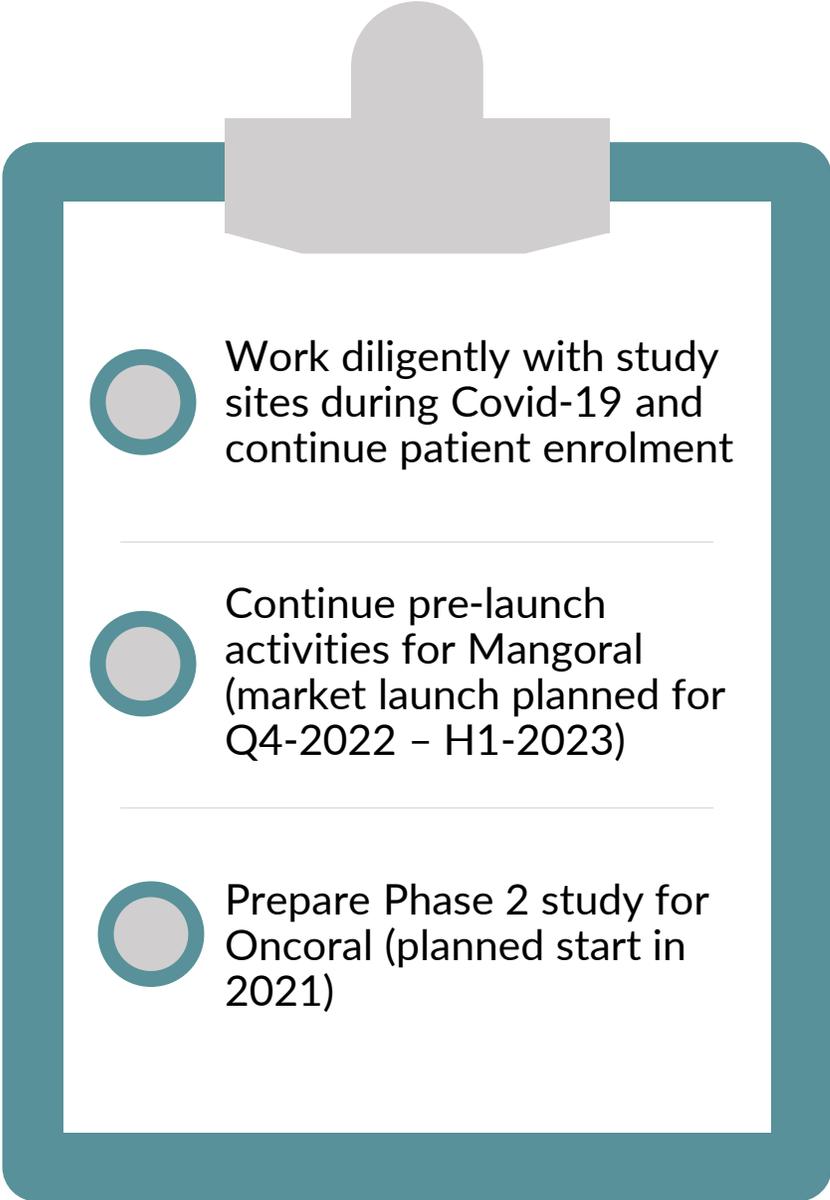
Liquid assets including marketable securities (SEK million)





PRIORITIES AND SUMMARY

Priorities

- 
- Work diligently with study sites during Covid-19 and continue patient enrolment

 - Continue pre-launch activities for Mangoral (market launch planned for Q4-2022 – H1-2023)

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

ASCELIA PHARMA IN SUMMARY



Ascelia Pharma (ticker: ACE) – Advancing orphan oncology

- Drugs targeting unmet medical needs with a clear development and market pathway
- Solid financial position



Mangoral – Phase 3 non-gadolinium liver imaging drug

- \$500-600 million annual addressable market
- No competing drugs
- Ongoing Phase 3 program with high likelihood of success – study results expected in H2-2021
- Orphan Drug Designation



Oncoral – Phase 2 ready oral chemotherapy for gastric cancer

- Novel tablet formulation with significant patient and hospital benefits
- The active molecule irinotecan is an established chemotherapy
- Promising Phase 1 results and preparing for Phase 2

ASCELIA PHARMA

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