



ADVANCING
ORPHAN
ONCOLOGY

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Nasdaq Stockholm
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ASCELIA PHARMA

COMPANY PRESENTATION

October 2021

ASCELIA
PHARMA

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INVESTMENT HIGHLIGHTS



ADVANCING ORPHAN ONCOLOGY

- Identify, develop and commercialize novel drugs that address unmet needs in rare cancers
- Two drugs in advanced clinical development
 - **ORVIGLANCE** (MANGORAL) – in global Phase 3; U.S. launch H2 2023
 - **ONCORAL** – starting Phase 2 in H2 2021

BUILDING GLOBAL CAPABILITIES

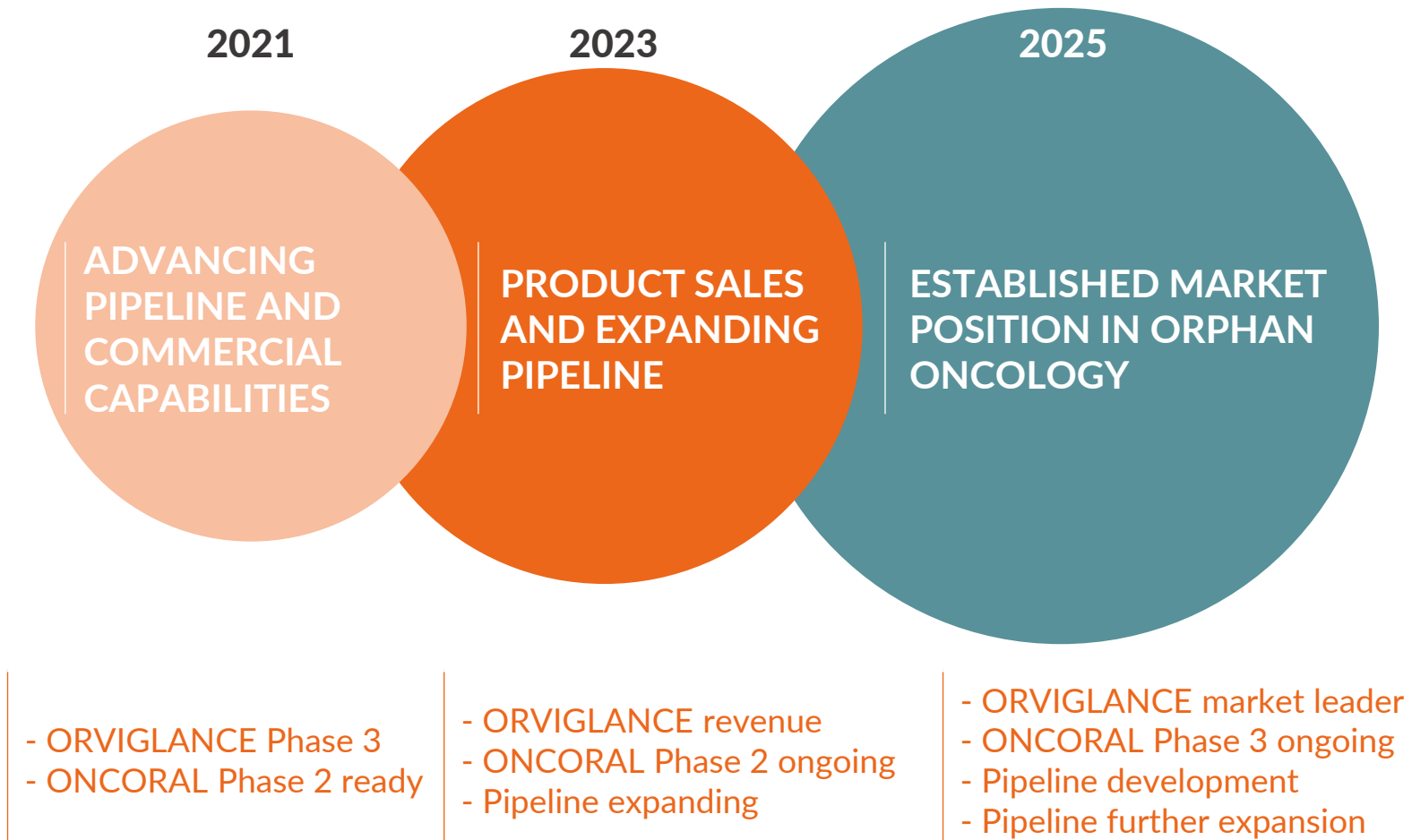
- Financed well into 2023
- Based in Malmö (Sweden) & Woodbridge, NJ (US)
- Listed on NASDAQ Stockholm (Ticker: ACE)

CURRENT CLINICAL STAGE PIPELINE

Drug candidate	Indication	Phase 1	Phase 2	Phase 3	Market launch
ORVIGLANCE (Mangoral)	Detection and visualization of focal liver lesions	completed		Ongoing 2020 – H1 2022	H2 2023
ONCORAL	Gastric cancer	completed	H2 2021 – 2024		
	Other solid tumors	completed			

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

BUILDING VALUE





PORTFOLIO

ORVIGLANCE (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

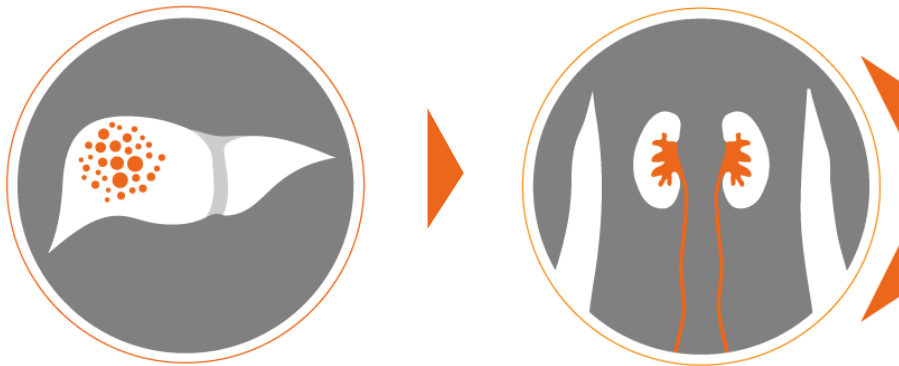
1) Riihimäki, M. et al. Patterns of metastasis in colon and rectal cancer. *Sci. Rep.* 6, 29765; doi: 10.1038/srep29765 (2016); *Journal of Pathology*, 2014, 232:23-31
2) Guy diSibio and Samuel W. French (2008) Metastatic Patterns of Cancers: Results From a Large Autopsy Study. *Archives of Pathology & 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

ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Suspected liver metastases
or primary liver cancer

Check kidney
status before MRI

Liver
MRI scan



A) Healthy kidneys

MRI with gadolinium contrast agent



B) Poor kidneys

- All gadolinium contrast agents have regulatory Black Box warnings
- Risk of severe and potentially fatal side-effect (Nephrogenic Systemic Fibrosis)

Solution:

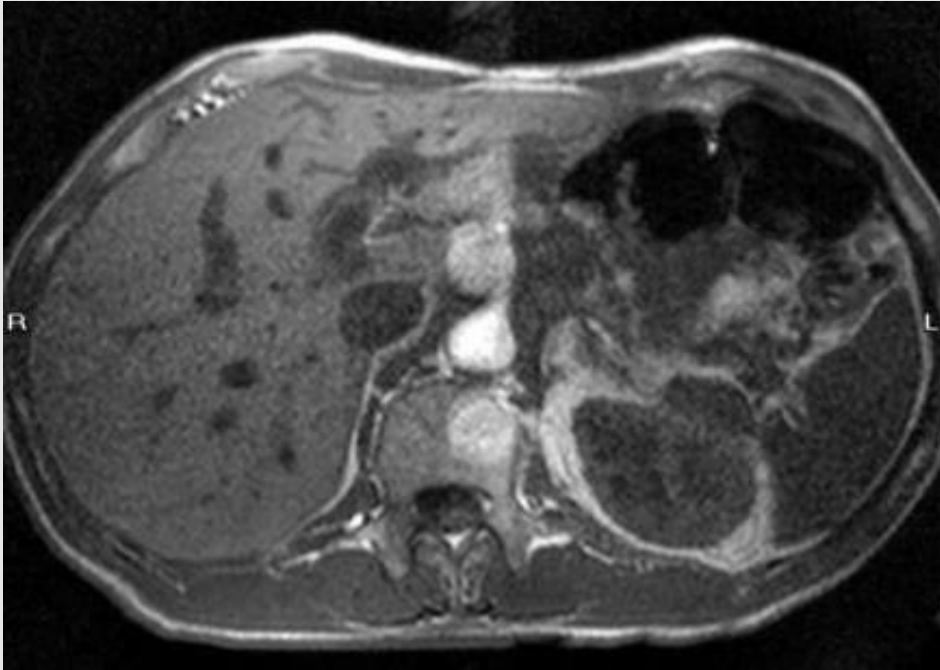
MRI with **ORVIGLANCE** (manganese based)



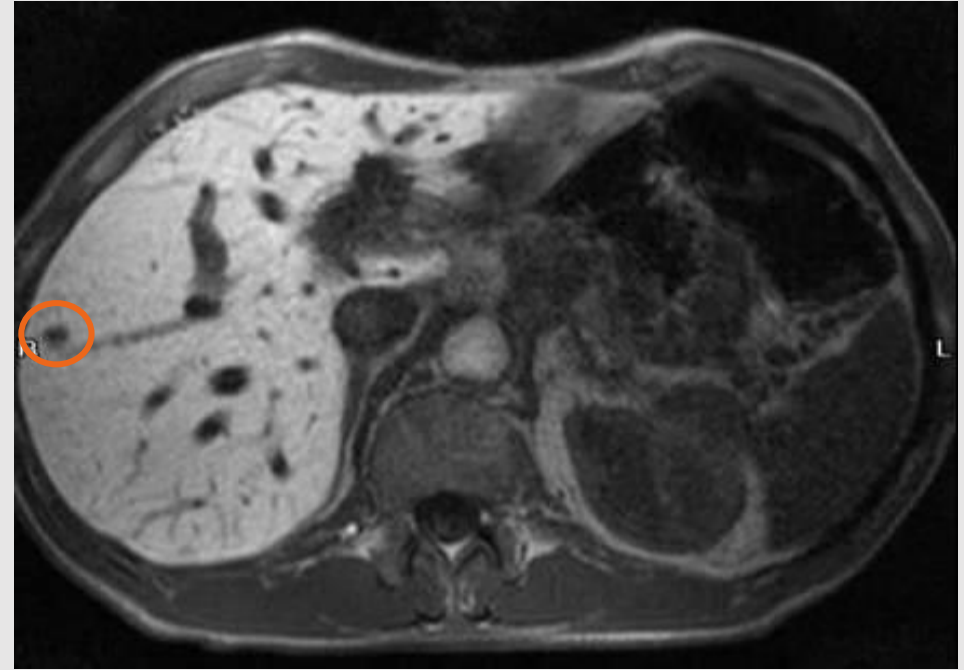
ORVIGLANCE aims to be
the standard of care liver
MRI contrast agent for
target patients

STRONG LIVER ENHANCEMENT WITH ORVIGLANCE

PATIENT EXAMPLE FROM PHASE 2 STUDY



UNENHANCED liver MRI (without contrast agent)



ORVIGLANCE contrast enhanced liver MRI

Liver metastasis appear with Orviglance

ORVIGLANCE PHASE 1 & 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)

- ORVIGLANCE lesion visualization as effective as GBCA
(2 out of 3 readers favoured Orviglance)

Proceed into Phase 3

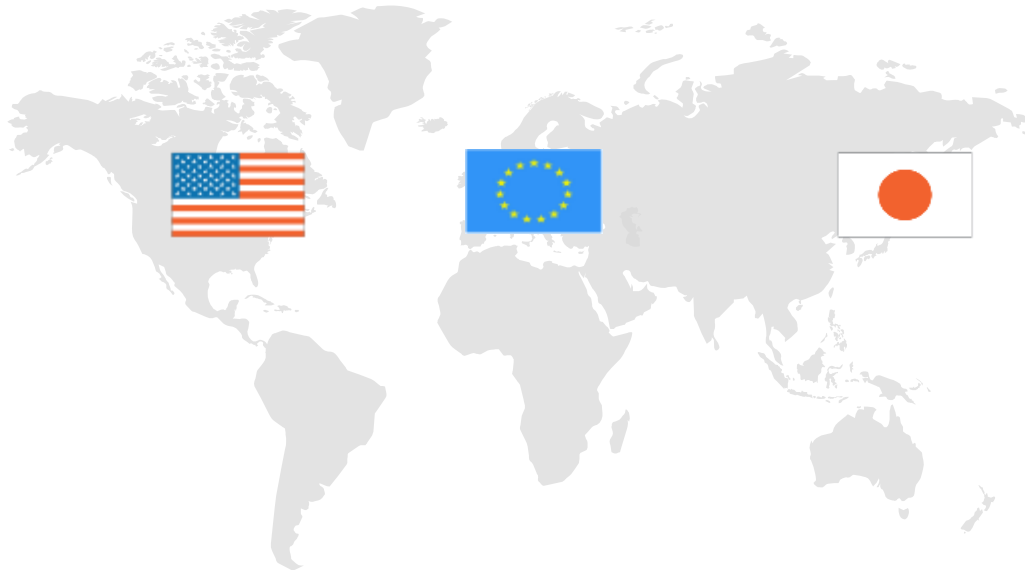
ORVIGLANCE ONGOING PHASE 3 STUDY – SPARKLE

Patients 	Global study, 200 patients No randomization – each patient as own control	▶	Status update: US, Europe, Latin America 40+ sites increasing to over 50 sites
Comparator 	Unenhanced MRI + ORVIGLANCE MRI vs. Unenhanced MRI	▶	Internal control so not randomized
Endpoint 	Lesion visualization <ul style="list-style-type: none">• Lesion border delineation• Conspicuity	▶	Same endpoints as Phase 2
Follow-up 	Less than a week	▶	Pivotal study completion: H1 2022

ORVIGLANCE MARKET \$500-600 MILLION ANNUALLY

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

- Ascelia Pharma to commercialize in the U.S
- RoW commercialization with partners



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



PORTFOLIO

ORVIGLANCE (Mangoral)

Liver contrast agent in ongoing Phase 3

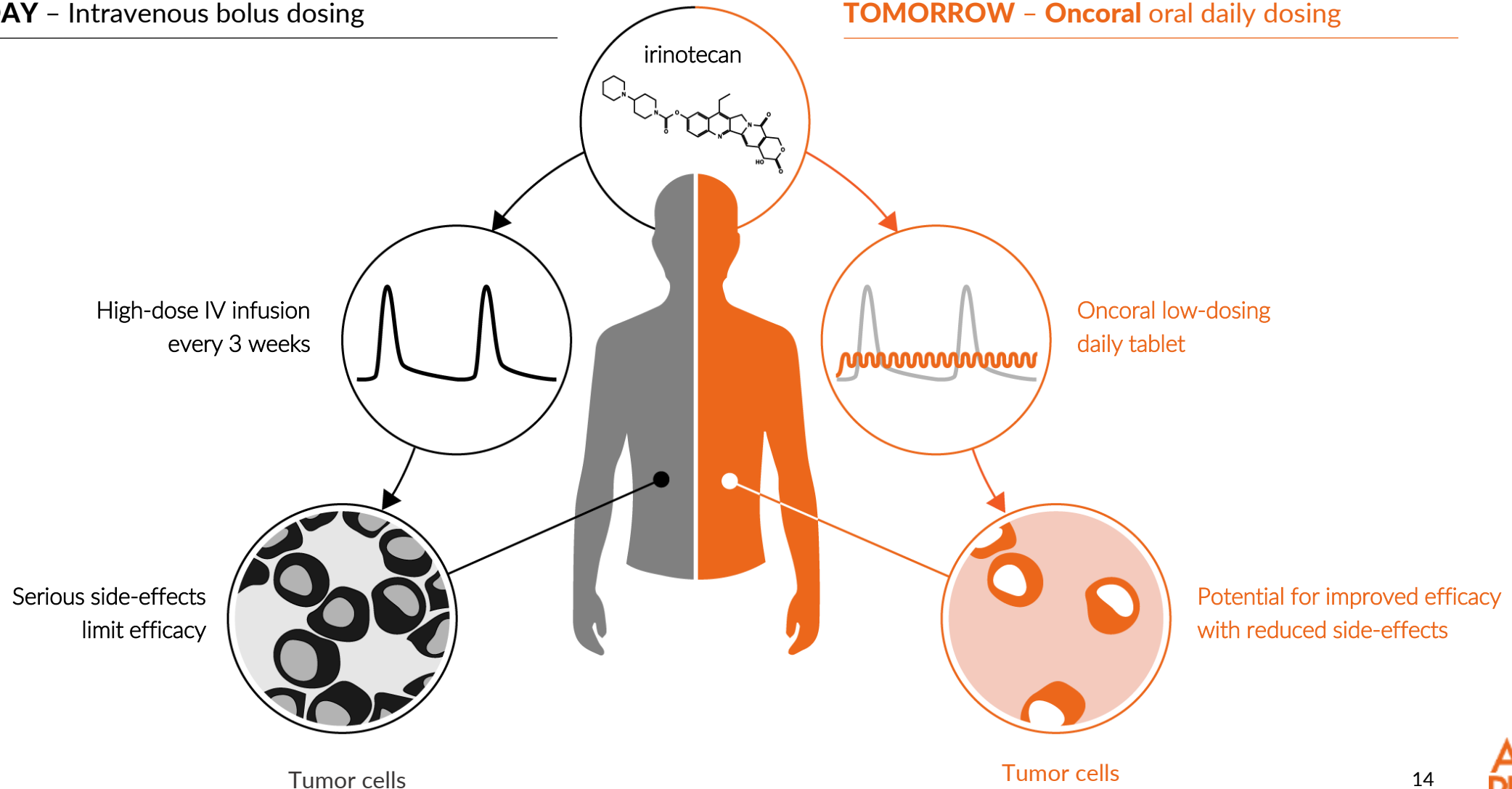
ONCORAL

Daily oral chemotherapy ready for Phase 2

IMPROVING IRINOTECAN **EFFICACY** and **TOLERABILITY**

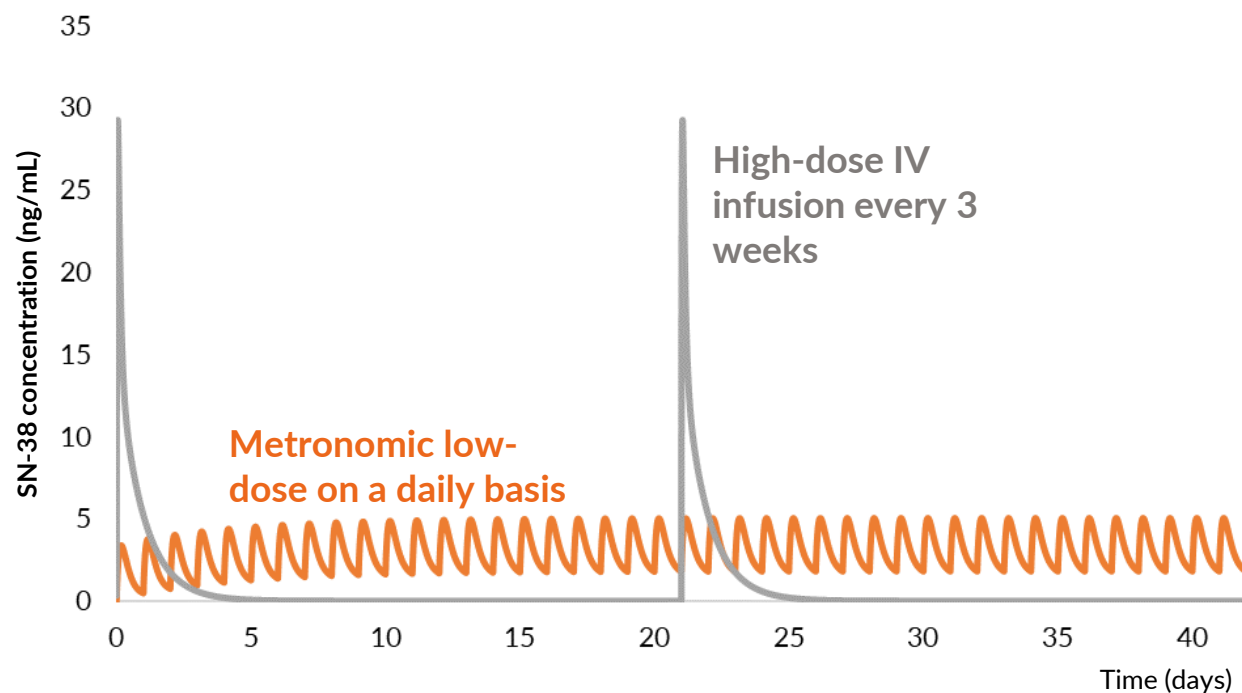
TODAY – Intravenous bolus dosing

TOMORROW – **Oncoral** oral daily dosing



ONCORAL PHASE 1 RESULTS

PLASMA LEVELS OF IRINOTECAN



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

Oncoral Phase 1 results

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

Infrequent high-dose IV irinotecan

Gastrointestinal and hematological 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 2

OBJECTIVES OF PHASE 2

- Clinical proof-of-concept in metastatic gastric cancer
 - Potential orphan drug designation
 - Clinical guidelines support efficacy of irinotecan
- Compelling Phase 2 data package for further development
 - Potential for subsequent expansion to other solid tumors

STUDY DESIGN (ALL-ORAL COMBINATION STUDY)

Type of study 	Randomized controlled, multicenter, multinational study: Oncoral + Lonsurf® <u>vs.</u> Lonsurf®
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

CLINICAL COLLABORATION WITH TAIHO ONCOLOGY INC.

DEVELOPMENT OF ONCORAL IN COMBINATION WITH LONSURF®

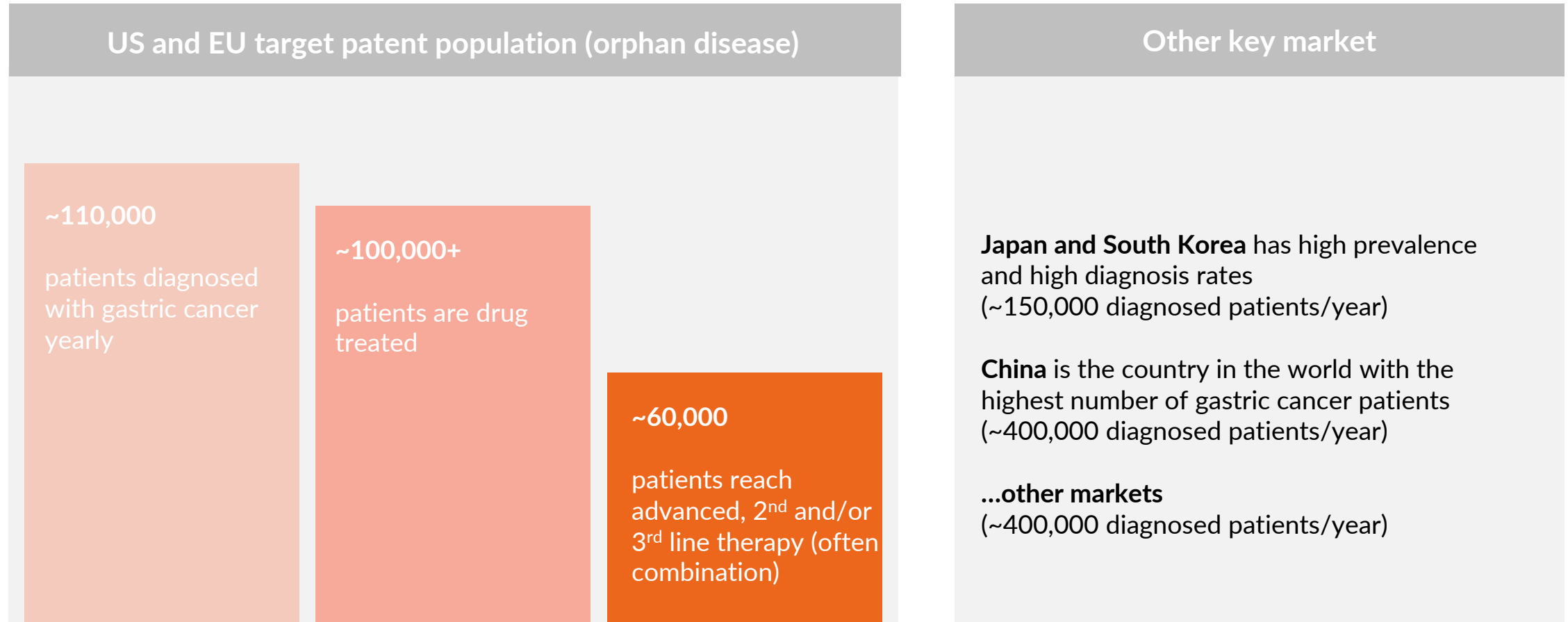
- Clinical Phase 2 collaboration with Taiho Oncology Inc. (part of the Otsuka Group)
- Taiho Oncology will supply Lonsurf as well as provide scientific expertise for the study
- Depending on the results, the collaboration may be extended for further development
- Ascelia Pharma retains full development and commercialization rights to Oncoral

Clinical collaboration with



LONSURF is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

GASTRIC CANCER – A \$3BN+ MARKET OPPORTUNITY

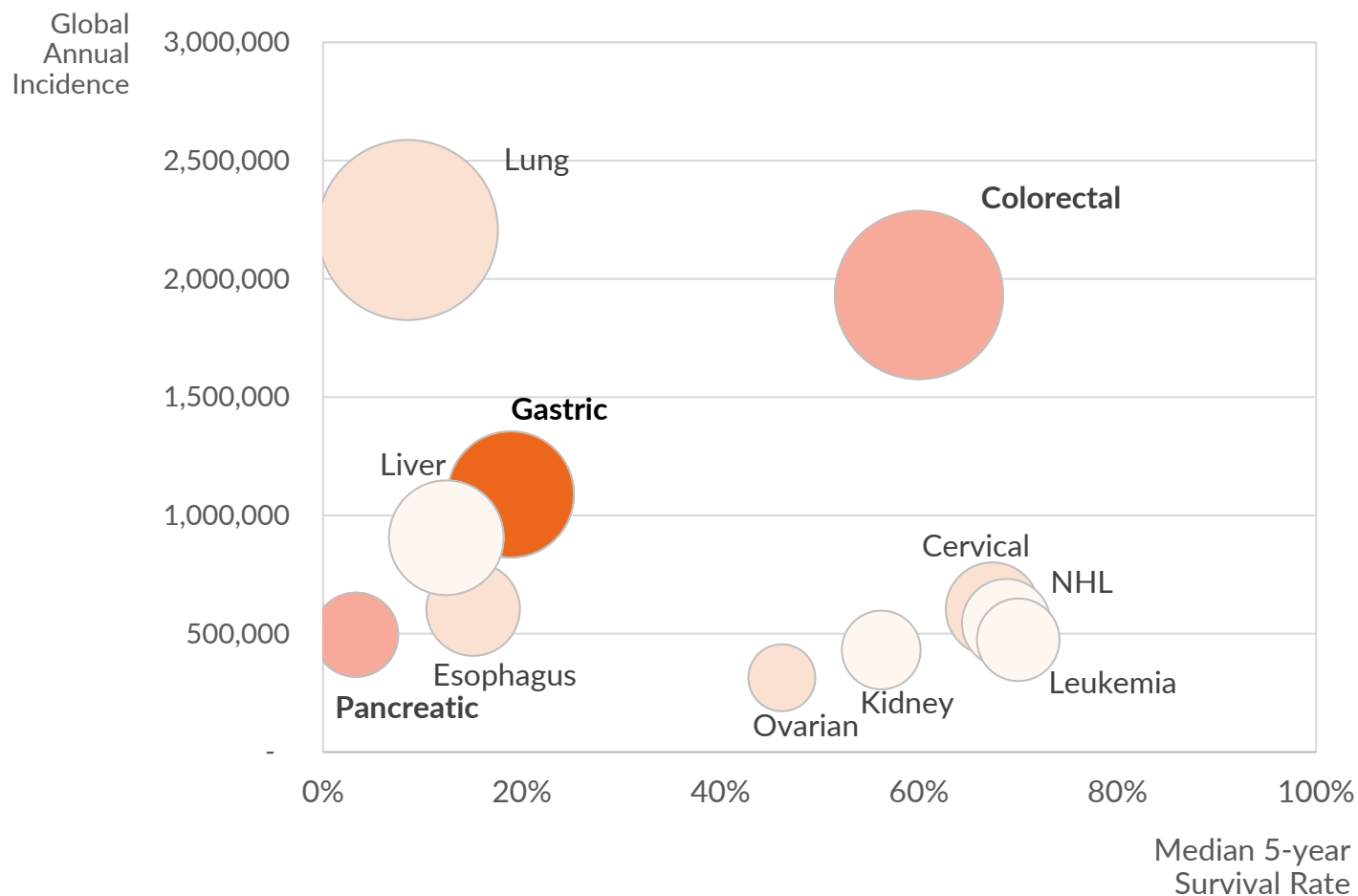


Sources:

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

HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN³



- **Current focus: Gastric cancer**
 - 3rd highest cancer deaths¹
 - Orphan opportunity (U.S. and EU)
 - \$3-4bn market²
- Approved indications for IV irinotecan infusions
- Indications for which IV irinotecan infusions are clinically demonstrated & NCCN recognized
- Indications for which IV irinotecan infusions are clinically demonstrated

1) International Agency for Research on Cancer (IARC, 2021)
2) GlobalData - Gastric and Gastroesophageal Junction Adenocarcinoma – Global Drug Forecast and Market Analysis to 2024
3) Globocan 2020, WHO, Cancer Research UK

FINANCIALS AND MILESTONES

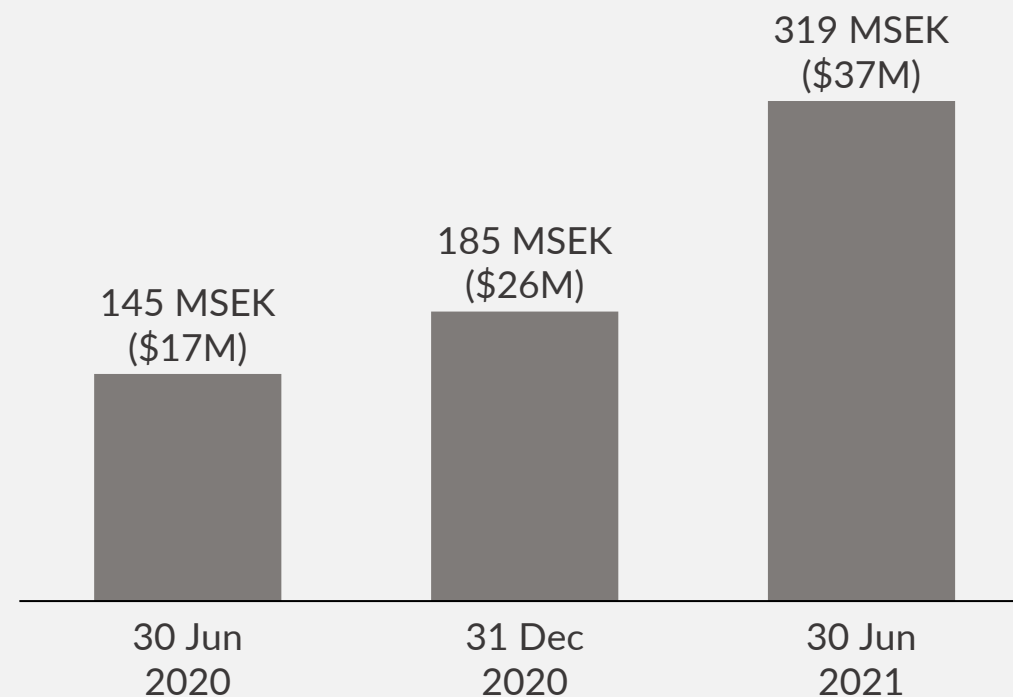


FINANCIAL HIGHLIGHTS Q2 2021 – LIQUIDITY POSITION

Solid liquidity position:

- Liquid assets of 319 MSEK (\$37 million) by 30 June 2021
- Liquidity strengthened in Q2-2021 from new share issuance of 200 MSEK (net proceeds of 187 MSEK)
- Current cash position provides financing well into 2023
- Liquidity mainly to be used for:
 - Orvigance – Ongoing Phase 3 study
 - Orvigance – Commercial preparations
 - Oncoral Phase 2 study

Liquid assets including marketable securities (million)

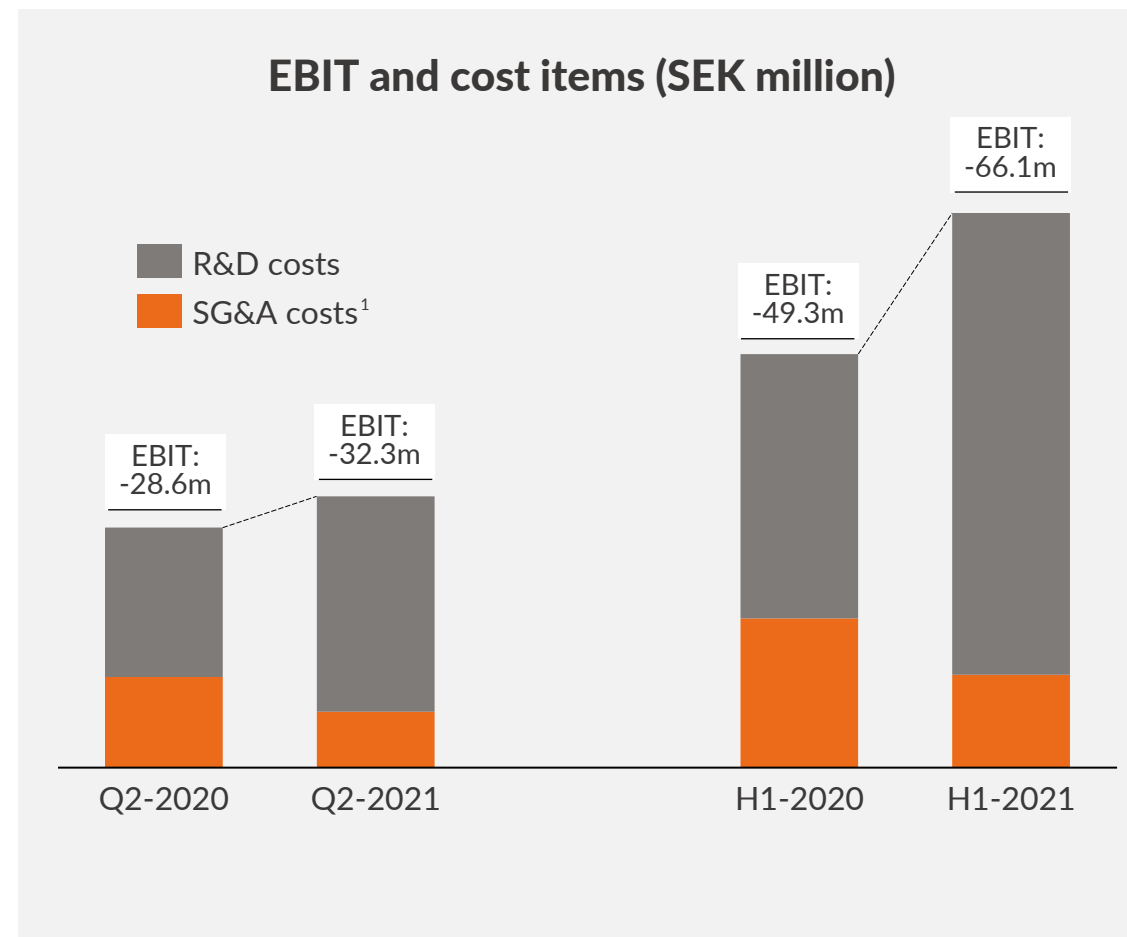


FINANCIAL HIGHLIGHTS Q2 2021 – OPERATING RESULTS

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

- Clinical development
- Manufacturing preparations
- Regulatory preparations

Also higher R&D costs y/y due to Oncoral Phase 2 preparations



Notes:

1) Other operating income and other operating costs added to SG&A



PRIORITIES AND KEY MILESTONES

- 1 Initiate Phase 2 study for Oncoral (planned start in H2-2021)¹
- 2 Complete Orvigance Phase 3 patient enrollment (expected H1-2022)¹
- 3 Prepare Orvigance launch (planned for H2-2023)¹

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