

ADVANCING
ORPHAN
ONCOLOGY

FDA Accepts Orviglance® NDA for Review

Conference call presentation on 5 Feb 2026, 10:00 CEST

Ticker symbol: ACE
Nasdaq Stockholm
www.ascelia.com

**ASCELIA
PHARMA**

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QUARTERLY REPORT Q4 2025 INVESTOR CONFERENCE CALL

Agenda

Overview and recent key events

Portfolio

Financials and priorities ahead

Presenters

CEO - Magnus Corfitzen

Deputy CEO - Julie Waras Brogren

CSO – Andreas Norlin

CFO – Anton Hansson



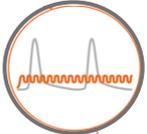
At Ascelia Pharma,

we identify, develop and commercialize novel drugs that address unmet needs of people with rare cancer conditions

Global outlook and Nordic roots

Based in Malmö (Sweden), US entity in New Jersey (US)
Listed on NASDAQ Stockholm (Ticker: ACE)

ADVANCED ORPHAN ONCOLOGY PIPELINE

Drug candidate	Indication	Phase 1	Phase 2	Phase 3	Registration	Market
 ORVIGLANCE	<p>Improved detection and visualization of focal liver lesions</p> <ul style="list-style-type: none"> ▪ First-in-class contrast agent for use in liver MRI in patients with severely impaired kidney function ▪ FDA Orphan Drug Designation ▪ Global addressable market of USD 800 million 	Completed			Ongoing NDA submitted 3 Sept 2025	PDUFA 3 July 2026
 ONCORAL	<p>Improved efficacy and safety of solid tumor treatment</p> <ul style="list-style-type: none"> ▪ Daily, oral irinotecan chemotherapy ▪ Clinical collaboration with Taiho Oncology ▪ Opportunity in gastric cancer and other solid tumors 	Completed	Ready			

ATTRACTIVE ORVIGLANCE OPPORTUNITY

- A **well-defined unmet need** for liver imaging in cancer patients with impaired kidney function
- A global addressable market opportunity of **USD 800 million**
- Commercial scale **manufacturing**
- **Clinical development completed** with 9 studies and strong phase 3 results
- **NDA submitted** to the FDA
- Commercialization with **partner**



Q4 2025 PROGRESS

Key events in Q4 2025

- ✦ FDA acceptance of Orvigance NDA for review aiming for a decision by 3 July 2026 as the PDUFA date
- ✦ Filing of a new patent application for Orvigance
- ✦ Management changes to support future growth
- ✦ Conversion of series C shares into ordinary shares for delivery to participants in incentive program
- ✦ Nomination Committee appointed for AGM 2026

Key events after the period

- ✦ Deputy CEO Julie Waras Brogren to leave the company



SUBSTANTIAL ORVIGLANCE VALUE CREATION OPPORTUNITIES



Advance Orviglance to approval

Secure partnering and commercialization readiness

Objectives

Timely approval by the US FDA as an orphan drug for the use in liver MRI for patients with severe renal impairment or when gadolinium may otherwise be medically inadvisable

Focused launch for well-defined patient population with 800 MUSD annual addressable market

Partner driven global commercialization

Looking ahead

- ✓ NDA submission 3 September 2025
- ✓ FDA communication of PDUFA date 15 November 2025
- Orviglance PDUFA date 3 July 2026

- Advance **launch** readiness
- Establish commercialization **partnership(s)**

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy

PORTFOLIO



ORVIGLANCE – FILLING AN UNMET NEED IN LIVER MRI

Patient Landscape

Liver metastases are critical in cancer care



Liver metastases are common in many cancer types and often the cause of mortality¹⁻³

- Colorectal cancer, metastatic breast cancer, gastric cancer

Treatments

Contrast enhanced MRI is the gold standard

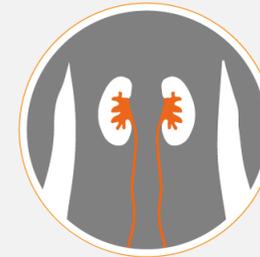


Contrast enhanced MRI

- Detection and visualization
- Surgery & drug treatment plan
- Post-treatment surveillance

Unmet Need

A role for ORVIGLANCE in patients with severe kidney impairment



Patients with healthy kidneys

- Receive MRI with gadolinium-based contrast agent (GBCA)

Patients with severe kidney impairment

- Black Box warning for gadolinium contrast agents
- Risk of severe side effects, incl. Nephrogenic Systemic Fibrosis (NSF)

ORVIGLANCE

Aims to be the imaging option without gadolinium-related safety risks in patients with severe kidney impairment

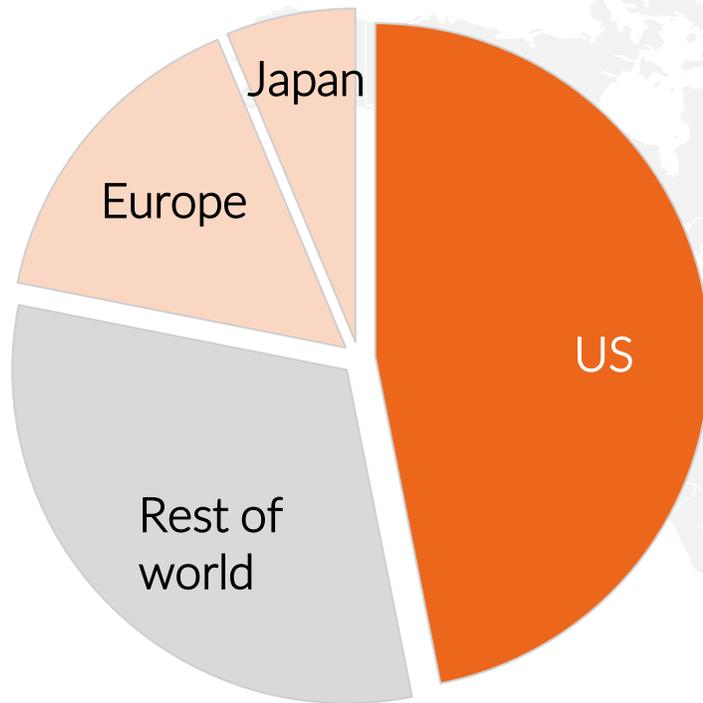
- Manganese based
- Liver specific

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

ADDRESSABLE MARKET OF USD 800 MILLION ANNUALLY



Global addressable market of USD 800 million, half of this in the US

Focused launch for well-defined patient population in liver imaging in cancer patients with severe kidney impairment

Global commercialization through partners

Sources:

Ascelia Pharma market research on real-world volumes with Decision Resources Group, 2020.. Ascelia Pharma market access research and analyses with Revenue Reimbursement Solutions and Charles River Associates (2020), Triangle (2022) and Trinity (2022), incl. 75 stakeholder and expoert interactions. 1) Final pricing strategy is subject to Phase 3 data, payer evidence, negotiations, discounts and access strategy



ATTRACTIVE US OPPORTUNITY

Abdominal imaging procedures in cancer patients with severe kidney impairment based on epidemiology and real-world data¹

Around 400 healthcare provider accounts serve 75% of kidney impaired patients⁴

Pricing range benchmarks based on innovative diagnostics, payer and expert input and price testing^{2, 3}

~100,000
procedures annually

~400 accounts

\$3,000-4,500

Sources:

- 1) Ascelia Pharma market research with Decision Resources Group, 2020. Literature on prevalence and epidemiology of kidney disease, cancer and liver metastases.
- 2) Ascelia Pharma market access research and analyses with Revenue Reimbursement Solutions and Charles River Associates (2020), Triangle (2022) and Trinity (2022)
- 3) Final pricing strategy is subject to Phase 3 data, payer evidence, negotiations, discounts and access strategy
- 4) Ascelia Pharma analysis based on market research with Decision Resources Group, 2020

UNMET NEED RECOGNIZED IN CLINICAL PRACTICE

NSF* risk
with warnings for target population

“Those of us who have seen NSF are frightened by it... you’ll get **buy-in** from a lot of nephrologists...”
- Head of Renal section at US university hospital
(from Ascelia Pharma Advisory Board meeting)

+90%



of HCPs are concerned by issues relating to GBCAs (including NSF)

+16%



of providers have experienced GBCA-induced NSF

*nephrogenic systemic fibrosis

““The college [American Colleague of Radiology]...have a **growing sense of responsibility and accountability** about using these agents in high-risk patients.... our perception of which agents are “safe” has changed... this is another place where practice needed to evolve”
- SPARKLE Investigator and Head of Radiology at US university hospital

MOMENTUM FOR CHANGE ALSO BEYOND RENAL IMPAIRMENT

Current challenges with gadolinium use

Black-box warning for use in renally impaired patients

Risk of potentially fatal side effects of gadolinium, incl. nephrogenic systemic fibrosis, in patients with severe renal impairment

Deposition in brain & organs concerns around safety for all patients

New category for Symptoms Associated with Gado. Exposure (SAGE, Am. College of Rad., 2022)

Multiple-GBCA effect on movement and mental skills study requested by the FDA (ODYSSEY, 2020)

Water contamination scrutiny of environmental impact

Gadolinium excreted in urine is discharged into our environment and drinking water

A future with less gadolinium

Manganese

Orviglance, a first in class oral manganese agent targeting patients with severe renal impairment (Ascelia Pharma)

Completion of Phase 1 of full-body IV manganese-based contrast agent (GE HealthCare)

Gadolinium

Low dose full-body gadolinium contrast agents pursued by GBCA players with one approved by the FDA (Guerbet/Bracco) and another in regulatory review (Bayer)

1) Brünjes R. et al. Anthropogenic gadolinium in freshwater and drinking water systems, Water Research, Volume 182, 2020..

Other sources include:

Macke et al. Fast and automated monitoring of gadolinium-based contrast agents in surface waters, Water Research, Volume 207, 2021.

Oluwasola et al. Gadolinium based contrast agents (GBCAs): Uniqueness, aquatic toxicity concerns, and prospective remediation. Journal of Contaminant Hydrology, Volume 250, 2022.

M. Nicholl. Seeking alternatives to gadolinium-based contrast agents. Healthcareineurope.com. July 22022

Bang G. Gadolinium Deposition in Brain: Current Scientific Evidence and Future Perspectives. Mol. Neurosci., 20 September 2018.

OPTIMAL COMMERCIALIZATION THROUGH PARTNERS



Partner led commercialization

Maximizes overall value of Orviglance by leveraging established capabilities

Optimizes capital requirements vs. future revenues

Attractive partner opportunity

De-risked asset in registration phase

Unmet need with high value for payers – high value per patient

Clear decision maker value - patients, physicians and payers

Focused launch efforts for hospital/imaging units

Wide synergy potential within e.g. radiology/nephrology/oncology or high-value/orphan drug

Dialogue with potential partners progressing

REVIEW ARTICLE

OPEN

Oral Manganese Chloride Tetrahydrate: A Novel Magnetic Resonance Liver Imaging Agent for Patients With Renal Impairment

Efficacy, Safety, and Clinical Implication

Torkel B. Brismar, MD, PhD, Dominik Geisel, MD, Nikolaos Kartalis, MD, PhD, Beatrice I. Hanna Persson Hedman, PhD, and Andreas Norlin, PhD



Constructs with or without modified uridines

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ORIGINAL ARTICLE

Lesion Visualization of an Oral Manganese Contrast Agent Compared to Unenhanced MRI and Gadobenate Dimeglumine in Patients Undergoing Liver Magnetic Resonance Imaging for Evaluation of Colorectal Cancer Metastases

Centralized Assessment of a Randomized, Crossover, Phase II Study

Torkel B. Brismar, MD, PhD, Nikolaos Kartalis, MD, PhD, Nadilka Hettiarachchige, MD, and Andreas Norlin, PhD

Ascelia Pharma Successfully Meets Primary Endpoint with Strong Headline Results in Orviglance Phase 3 Study

Published: May 02, 2024

ASCELIA PHARMA AB (PUBL) (TICKER: ACE), A BIOTECH FOCUSED ON IMPROVING THE

A New Approach to Imaging Focal Liver Lesions in Patients With Reduced Kidney Function

Current magnetic resonance imaging (MRI) methods used to identify liver cancer are inadequate in identifying a potentially fatal side effect in patients with poor kidney function – nephrogenic systemic fibrosis (NSF). Alternative imaging techniques are being developed to address this clinical need.

Conf Sponsor at Ascelia Pharma

The early detection and localization of focal liver lesions is critical for optimal management of patients with liver cancer or a range of cancers that metastasize to the liver, including colorectal, breast, and gastric cancer. The gold standard method for detecting focal liver lesions is contrast-enhanced MRI. However, in patients with poor kidney function, all gadolinium-based contrast agents (GBCAs) have regulatory black box warnings, as they put those patients at risk of the severe and sometimes lethal side effect, NSF. As patients with poor kidney function may not be able to tolerate these contrast agents, the imaging methods currently used – unenhanced MRI or non-liver specific low-risk GBCAs – significantly reduce the ability of clinicians to find and treat focal liver lesions, ultimately impacting the patient's chance of survival. This patient population, which is estimated to account for around 4% of all patients requiring a liver MRI, is in dire need of an alternative solution that provides similar imaging insights to those who undergo contrast drug-enhanced MRI, but without the risk of NSF.

The Risk of NSF

Although a rare condition, NSF is serious and potentially life-threatening. It causes sclerotic transformation and hardening of the skin, and can lead to joint contractures, and muscle and facial fibrosis, which may lead to severe immobility. It can also affect the liver organs. NSF worsens over time and can cause death, which typically results from multi-system failure. The FDA database has reported 3000+ cases of NSF since 2006, of which 24% were fatal and the severity of illness, time to disease manifestation, and GBCA dosing exposure vary individually (1, 2). It is critical to note that not all global cases of NSF are reported to the FDA, however.

Regulatory agencies, including the FDA and EMA, have issued warnings about the use of GBCAs, and clinical guidelines restrict use in patients with severe kidney impairment. The American College of Radiology guidelines for GBCA administration advise against administration of group I and group II agents (see Table 1) in those on dialysis or with chronic kidney disease stage four or five to

Group	Classification
I	Gadobenate, gadopentate dimeglumine
II	Gadobenate dimeglumine, gadobutol, gadoterate acid, gadoteridol
III	Gadobutrol

Table 1. American College of Radiology 2018 classification of gadolinium-based contrast agents (19). Accessed 11/1/2023.

International Clinical Trials | February 2022

Reimagine imaging for people with poor kidney function



Orviglance data accepted for 4 oral and 6 poster presentations at major conferences since Phase 3

orviglance®
800 mg powder for oral solution
manganese chloride tetrahydrate

NDA SUPPORTED BY ROBUST CLINICAL PROGRAM



Nine studies with consistent positive efficacy and safety results¹⁻⁸

286 patients and healthy volunteers

Superior efficacy compared to unenhanced imaging

- Superior visualization of focal liver lesions
- More lesions detected, in particular small lesions (< 1cm)
- Consistent improvement of visualization across main patient groups
- Efficacy further supported by secondary endpoints across studies

Favorable safety profile

- Robust non-clinical and clinical safety data with no concerning findings
- Minimal systemic exposure of manganese
- Mild GI-related adverse reactions most frequently reported
- No serious drug-related reactions

1) Thomsen HS et al, Acad Radiol 2004; 11: 630-636

2) Thomsen HS et al, Eur Radiol 2007, 17: 273-278

3) Rief M et al, Invest Radiol, 2010; 45: 565-71

4) Brismar TB et al., Eur Radiol 2012; 22:633-41

5) Albiin N et al. MAGMA, 2012; 25:361-368

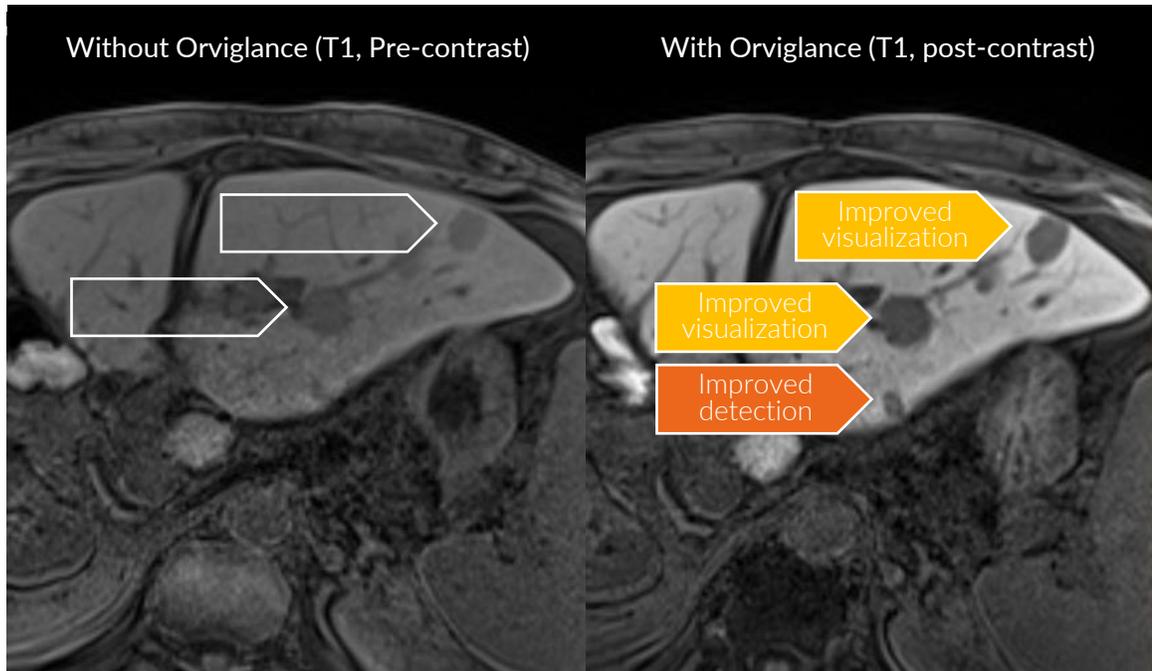
6) Brismar TB, et al., Invest Radiol 2025: Apr 8. doi: 10.1097/RLI.0000000000001184. Online ahead of print.

7) Study CMC-P005, primary objective to study of Orviglance for imaging of bile ducts (not published)

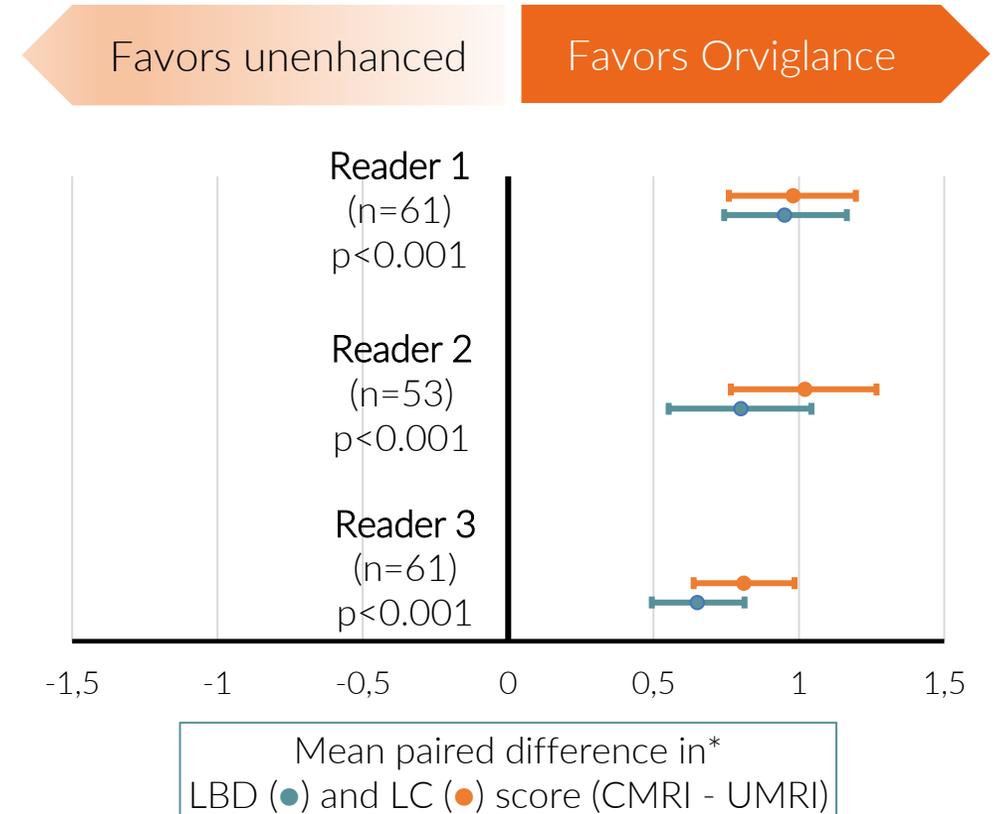
8) Results from Phase 1 and 2 and Food Effect and Hepatic Impairment Studies presented at RSNA and ESGAR conferences between 2022 and 2023

SUPERIORITY OF ORVIGLANCE DEMONSTRATED IN PHASE 3

Improved visualization of focal liver lesions with Orviglance



Example from a patient with metastases in the SPARKLE Phase 3 study



*Visualization assessed by 3 independent readers as the improvement of Lesion border delineation (LBD) and Lesion contrast (LC) on combined Orviglance-enhanced + unenhanced (CMRI) images compared to unenhanced (UMRI) images for all matched lesions, using a 4-point scale (from 1 ("poor") to 4 ("excellent")).

Data presented as mean paired differences for matched lesions per patient for CMRI and UMRI with 95% Confidence Intervals. One-sided paired t-test ($\alpha=0.025$).

Total N=85, n=number of patients with matched lesions (per reader).

ORVIGLANCE NDA ON TRACK FOR FDA APPROVAL IN JULY 2026



Obtain approval for Orviglance

as a liver MRI contrast agent for patients with severe kidney impairment or when gadolinium may be otherwise medically inadvisable

NDA with PDUFA date 3 July 2026

- NDA submitted 3 September 2025 with FDA acceptance of filing 15 November 2025
- Orphan Drug Designation granted, offering regulatory and commercial benefits
- Attractive benefit-risk profile
- Established commercial-scale manufacturing

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



PORTFOLIO

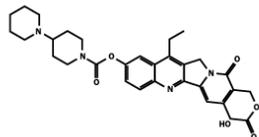
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IMPROVING IRINOTECAN EFFICACY AND TOLERABILITY

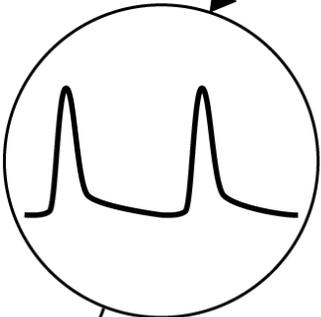
Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing

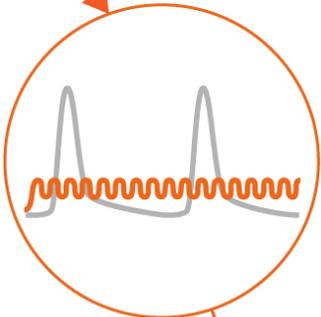
irinotecan



High-dose IV infusion every 3 weeks



Oncoral low-dosing daily tablet

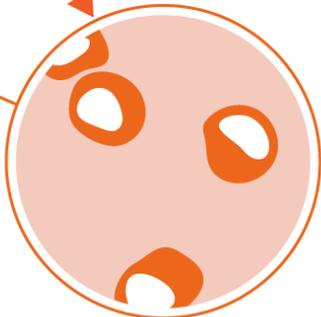


Serious side-effects limit efficacy



Tumor cells

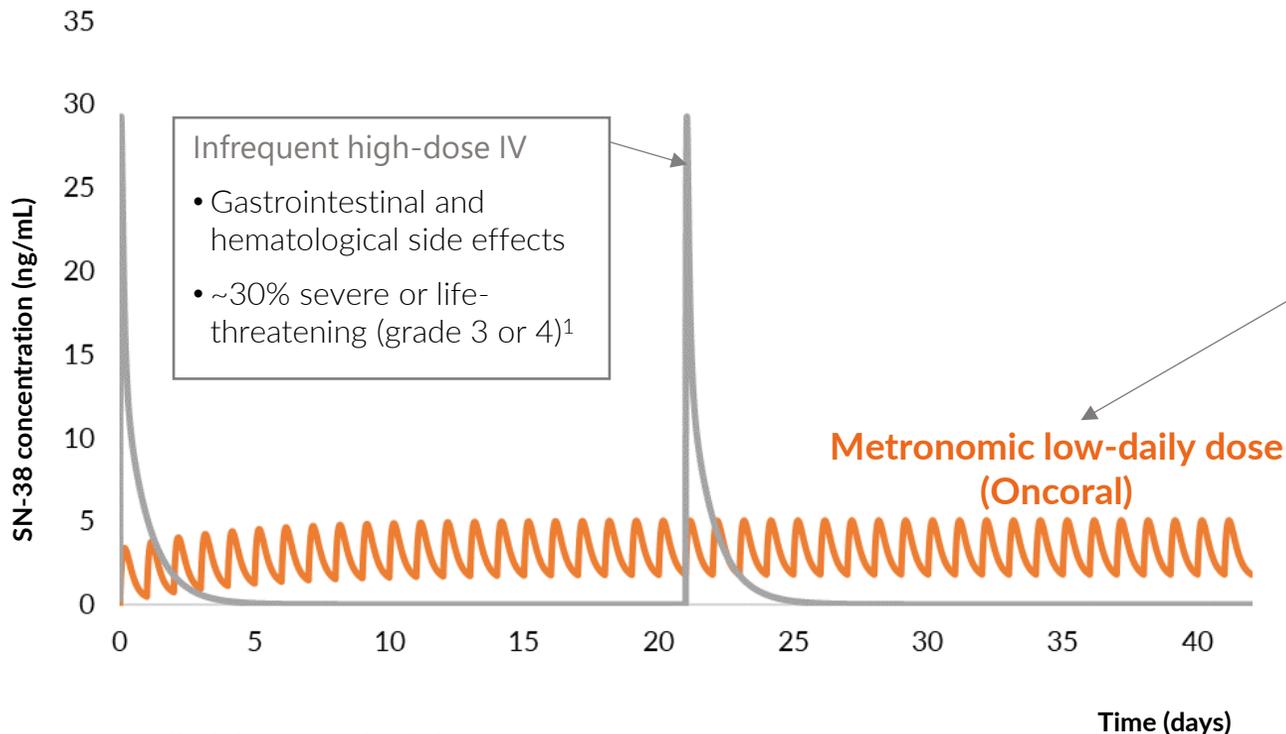
Potential for improved efficacy with reduced side-effects



Tumor cells

ENCOURAGING SAFETY PROFILE IN PHASE 1

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar

Frequent (metronomic) low-dose irinotecan

- Several studies show potential for improved efficacy and tolerability²⁻⁵
- Daily dosing – adjust quickly if acute toxicity

Oncoral Phase 1 results⁶

- Well tolerated, no unexpected side-effects
- Hematological toxicities mild-moderate (grade 1 or 2)
- 36% of patients with stable disease, in patients previously treated with IV irinotecan
- Pharmacokinetic profile suitable for daily dosing

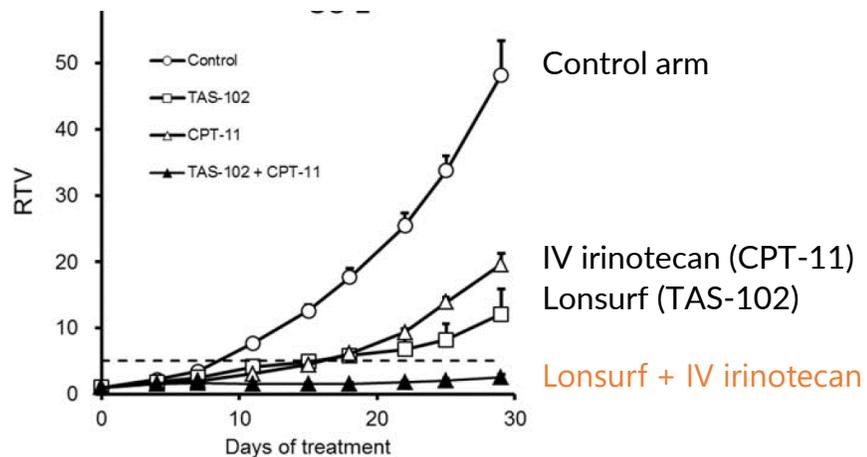
1) Camptosar prescribing information 2) Furman et al, J Clin Oncol 17:1815, 1999 3) Perez et al. J Clin Oncol, 22:2849, 2004 4) Allegrini et al, Br J Cancer 98:1312, 2008
5) Bocci et al, Br J Cancer 98:1619, 2008 6) Kümler et al, Cancer Chemother Pharmacol 83:169, 2019

ONCORAL PHASE 2 IN GASTRIC CANCER

STRONG RATIONALE FOR GASTRIC CANCER

- High unmet need and clinically demonstrated
- Potential for synergistic effect between Lonsurf and irinotecan

Efficacy study in an animal model of gastric cancer¹
(Relative Tumor Volume, RTV)



PHASE 2 STUDY OUTLINE

- ~100 patients with metastatic gastric cancer
- Study arms: Oncoral + Lonsurf vs. Lonsurf
- Endpoints: Progression Free Survival (Primary), Response Rate, PK, Safety (Secondary) and Overall Survival (follow-up)
- IND approved in the US

Clinical collaboration with

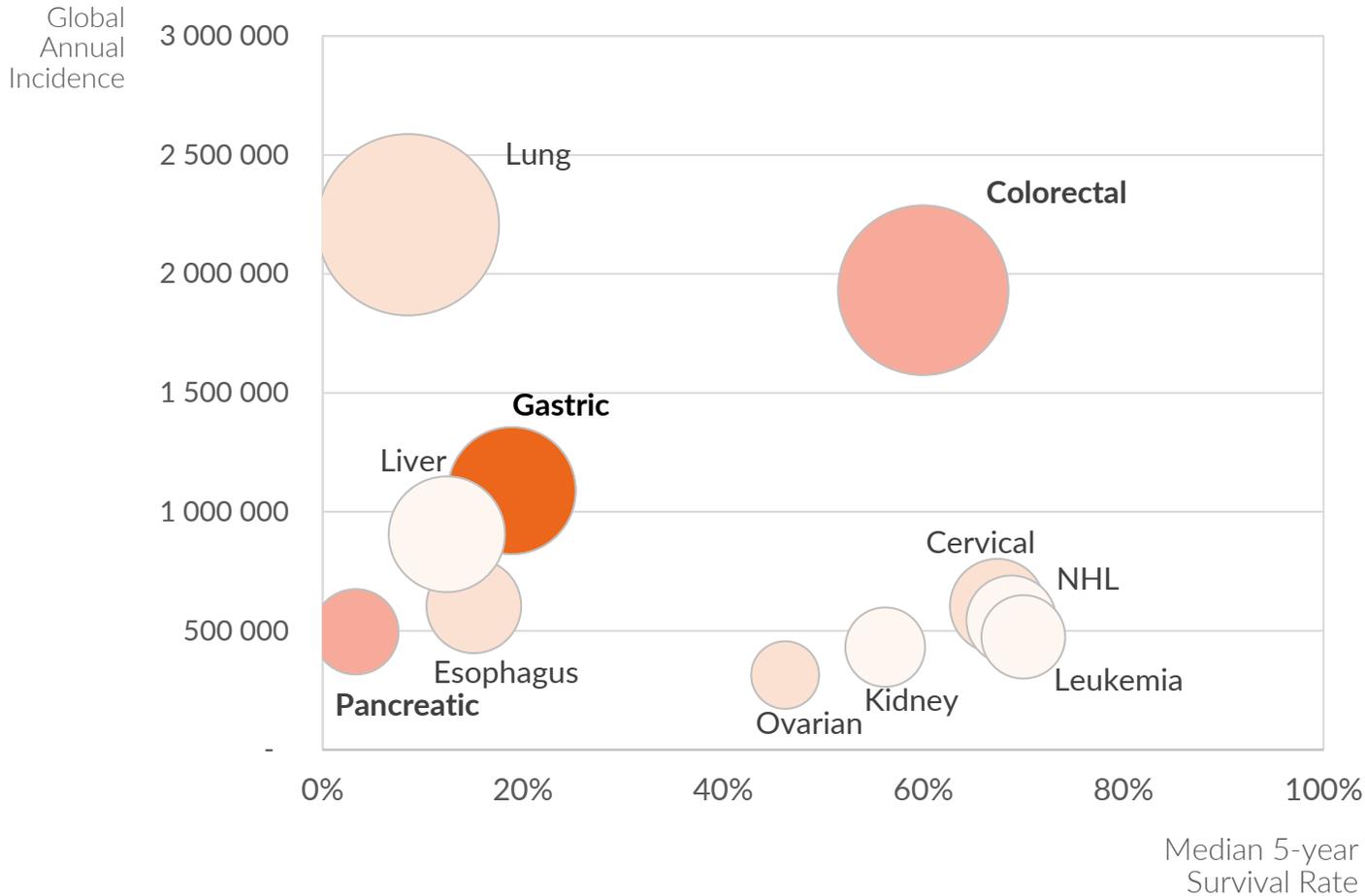


LONSURF is approved for treatment of metastatic gastric cancer and metastatic colorectal cancer

1) Nukatsuka et al, Anticancer Res 35:1437, 2015

HIGH VALUE OPPORTUNITY IN GASTRIC CANCER AND EXPANSION

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN³



A WELL-ESTABLISHED CHEMOTHERAPY with recognized anti-tumor effect in solid tumors

- Current focus: Gastric cancer
 - Clinically demonstrated
 - Guidelines recognized
 - 3rd highest cancer deaths¹
 - Orphan disease (US and EU)
 - \$3-4bn market²
- Approved indications for IV irinotecan
- Indications where IV irinotecan are clinically demonstrated & guidelines recognized
- Indications where IV irinotecan 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

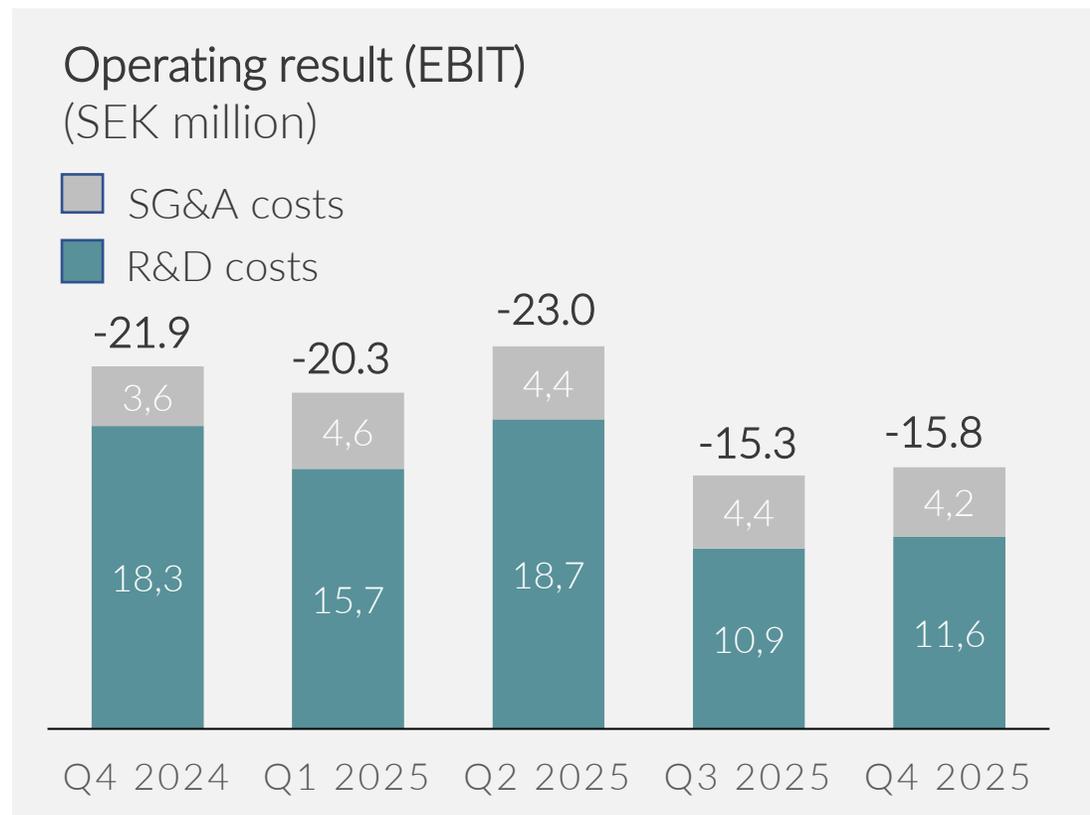


FINANCIALS & OUTLOOK

OPERATING RESULT– MAINTAINED LOW OPERATING EXPENSES

Operating loss of SEK 16 million in Q4 2025

Quarterly costs lower than during 1H 2025 due to finalization of the NDA.

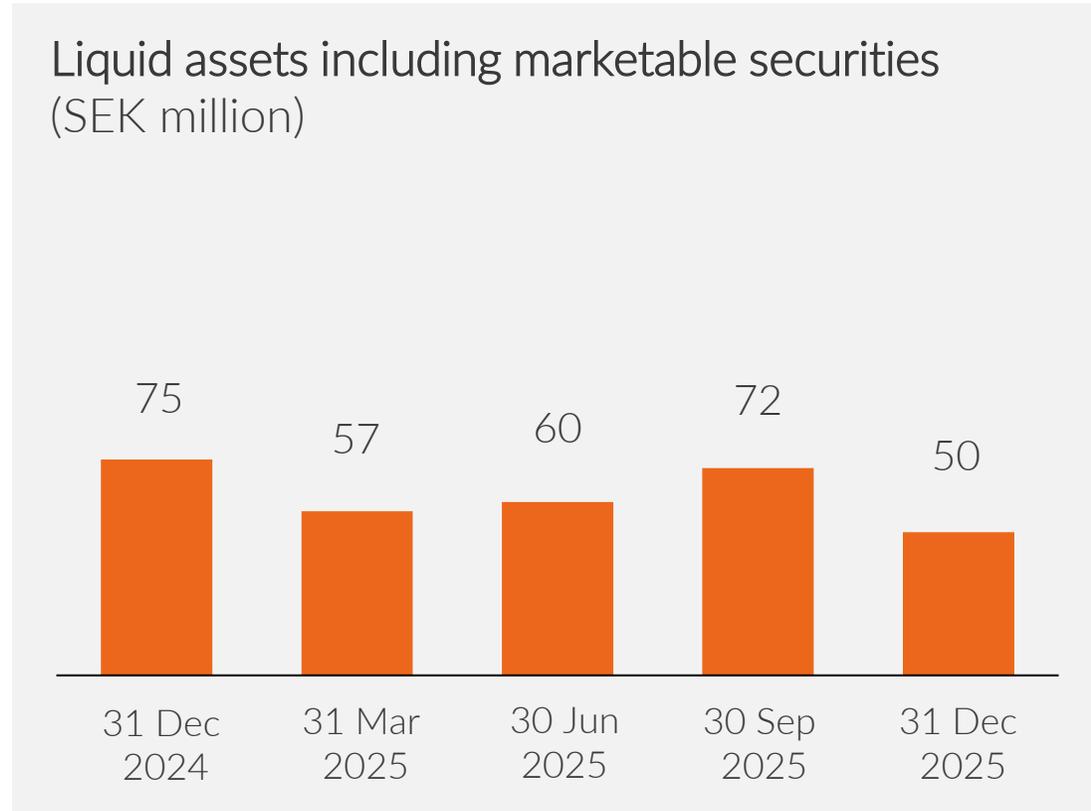


LIQUIDITY - CASH RUNWAY INTO Q4 2026

Liquid assets of SEK 50 million (31 Dec 2025)

Directed issue raising SEK 30 million before cost based on inbound investor interest (22 Sept 2025).

Cash runway into Q4 2026 well beyond expected FDA approval date of Orviglance.



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Partner driven global commercialization

Looking ahead

- ✓ NDA submission September 2025
- ✓ FDA communication of PDUFA date November 2025
- FDA approval following 10 months review July 2026

- Advance **launch** readiness
- Establish commercialization **partnership(s)**

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