ADVANCING
ORPHAN
ONCOLOGY



ASCELIA PHARMA
Q3 2026 Financial report

Conference call presentation on 5 Nov 2026, 10:00 CET

Ticker symbol: ACE
Nasdaq Stockholm
www.ascelia.com

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QUARTERLY REPORT Q3 2026
INVESTOR CONFERENCE CALL

Agenda

Overview and recent key events

Portfolio

Financials and priorities ahead

Presenters

CEO - Magnus Corfitzen

CSO – Andreas Norlin

ASCELIA PHARMA



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)

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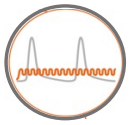
ADVANCED ORPHAN ONCOLOGY PIPELINE

Drug candidate	Indication	Phase 1	Phase 2	Phase 3	Registration	Market
 ORVIGLANCE	**Improved detection and visualization of focal liver lesions** ▪ 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					
 ONCORAL	**Improved efficacy and safety of solid tumor treatment** ▪ Daily, oral irinotecan chemotherapy ▪ Clinical collaboration with Taiho Oncology ▪ Opportunity in gastric cancer and other solid tumors					

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Q3 2026 PROGRESS

Key events in Q3 2026

- Publication of Orviglance clinical study in Journal of Magnetic Resonance Imaging
- FDA Type A meeting completed on 9 September
- A Complete Response Letter received from the FDA
- CFO Anton Hansson left, alongside cost reductions

Key events after the period

- Official minutes received from the FDA Type A meeting



ASCELIA PHARMA STRATEGIC PRIORITIES

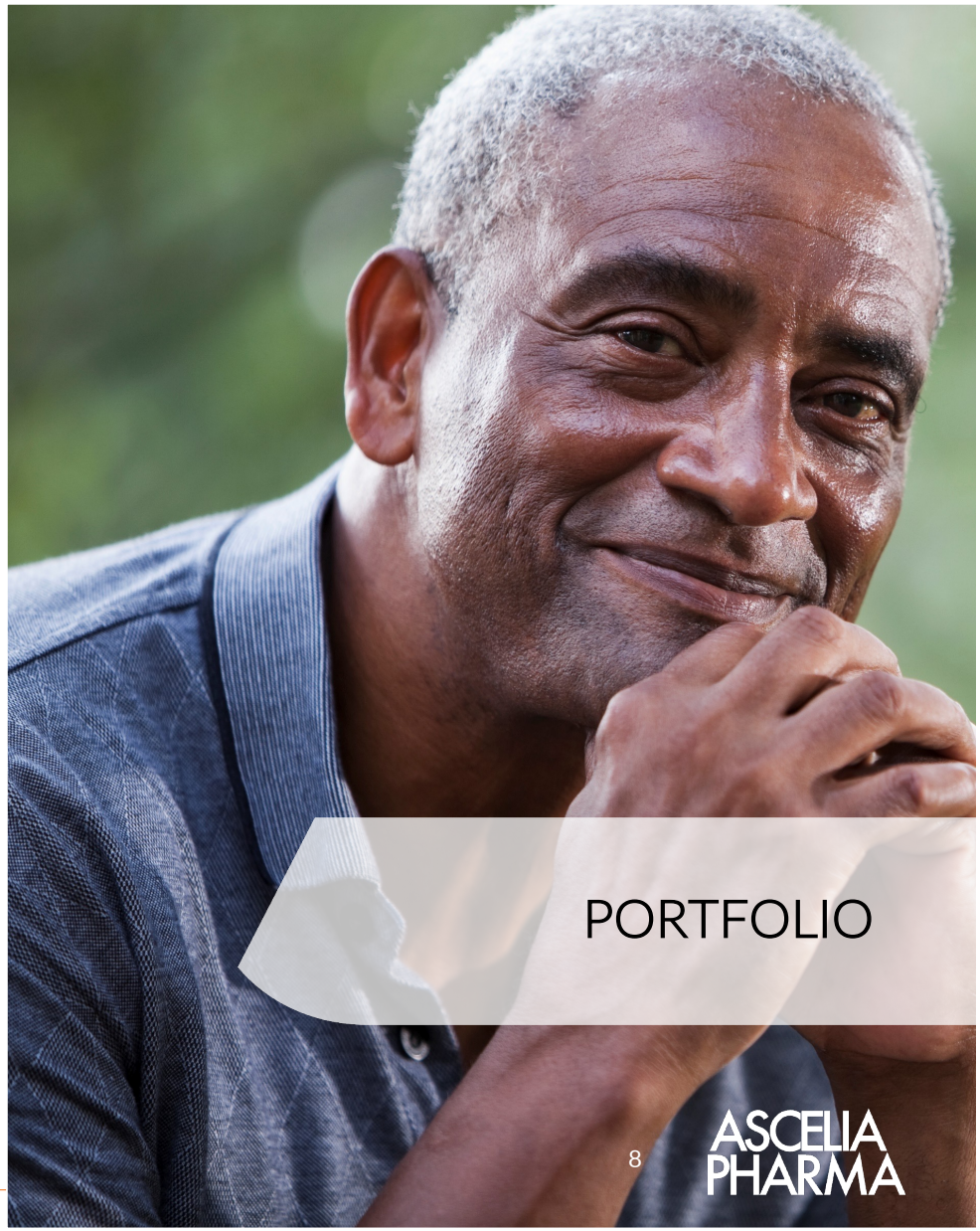
Orviglance partnering	Continue partner process
Orviglance approval in the US	Select new primary endpoint for use in reading of SPARKLE images FDA acceptance of endpoint prior to starting image reading
Orviglance approval in Europe	Seek feedback from European regulatory authorities on approvability based on current data package
Oncoral development	Continue preparations for Oncoral development and partnering outreach

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy



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**
- Extensive clinical development program with 9 studies consistently demonstrating a **strong safety and efficacy profile**
- Commercialization with **partner**



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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 mortality[1-3]

- 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

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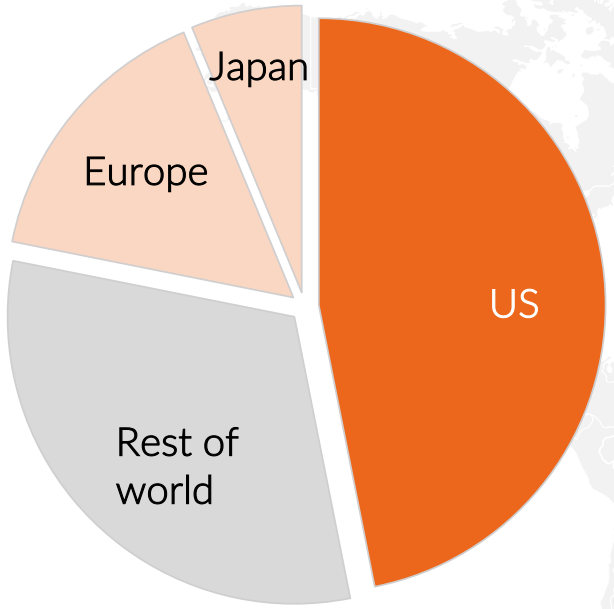
ADDRESSABLE MARKET OF USD 800 MILLION ANNUALLY



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

AREAS OF ALIGNMENT ESTABLISHED DURING FDA TYPE A MEETING

1

Significant unmet medical need acknowledged

Patients with severe renal impairment have limited MRI contrast-enhanced imaging options

Orphan setting remains an important consideration

2

Favourable safety profile acknowledged

No major safety concerns identified during review

3

Technical performance acknowledged

FDA acknowledged that Orviglance improves liver lesion visualization

4

Existing clinical data retain value

FDA acknowledged that current data may contribute as supportive evidence in a future submission

5

Issue relating to Drug Procuct Quality in CRL thoroughly discussed

Alignment on proposed strategy to address product quality-related observations

Ascelia has begun implementation to address FDA comments

6

Alignment on the key remaining question

Discussion clarified that approvability is primarily dependent on demonstrating clinical utility

FDA MEETING OPENS ANOTHER PATH TO US APPROVAL

Complete Response Letter:

1. FDA recommended a new clinical study with new patients to obtain approval

Type A meeting minutes:

1. FDA recommended a new clinical study with new patients to obtain approval
2. Alternative strategy to generate requied data: **Image evaluation of existing SPARKLE images with a new primary endpoint**

Ascelia is evaluting potential new primary endpoints that could lead to FDA approval

Type C meeting with FDA as soon as possible to align on the endpoint will be obtained prior to initation of an image reading process

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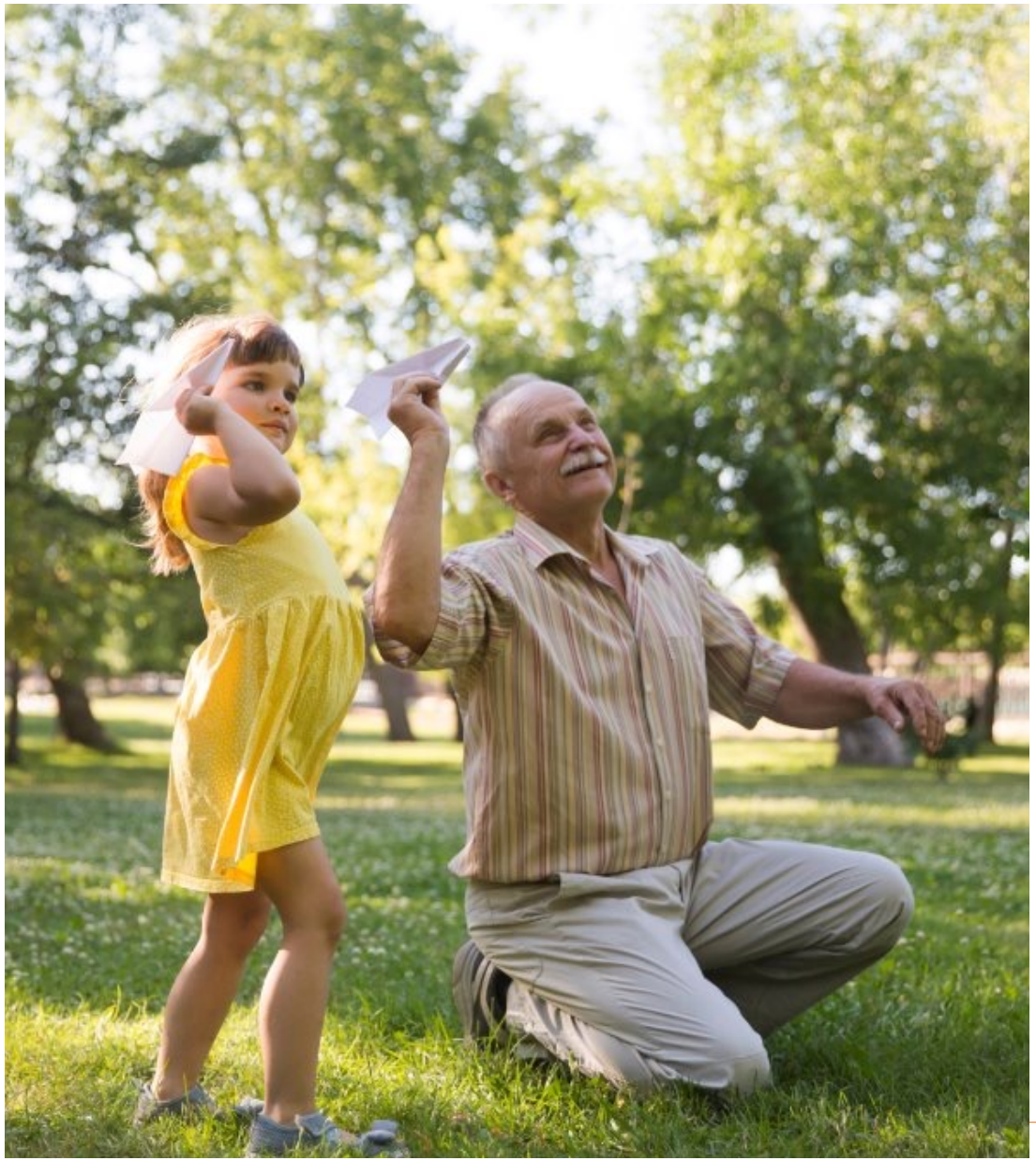
ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy





THE NEXT CHALLENGE IN ONCOLOGY: HELPING PATIENTS LIVE BETTER, NOT JUST LONGER

- Despite advances in immunotherapy and targeted therapies, chemotherapy remains a cornerstone of treatment for most solid tumors.
- As patients live longer, cumulative toxicity, treatment burden and quality of life are becoming critical measures of therapeutic value.
- Leading oncology organisations increasingly recognise quality of life as an important component of clinical benefit.

There remains a significant need for chemotherapy approaches that preserve efficacy while improving tolerability and quality of life

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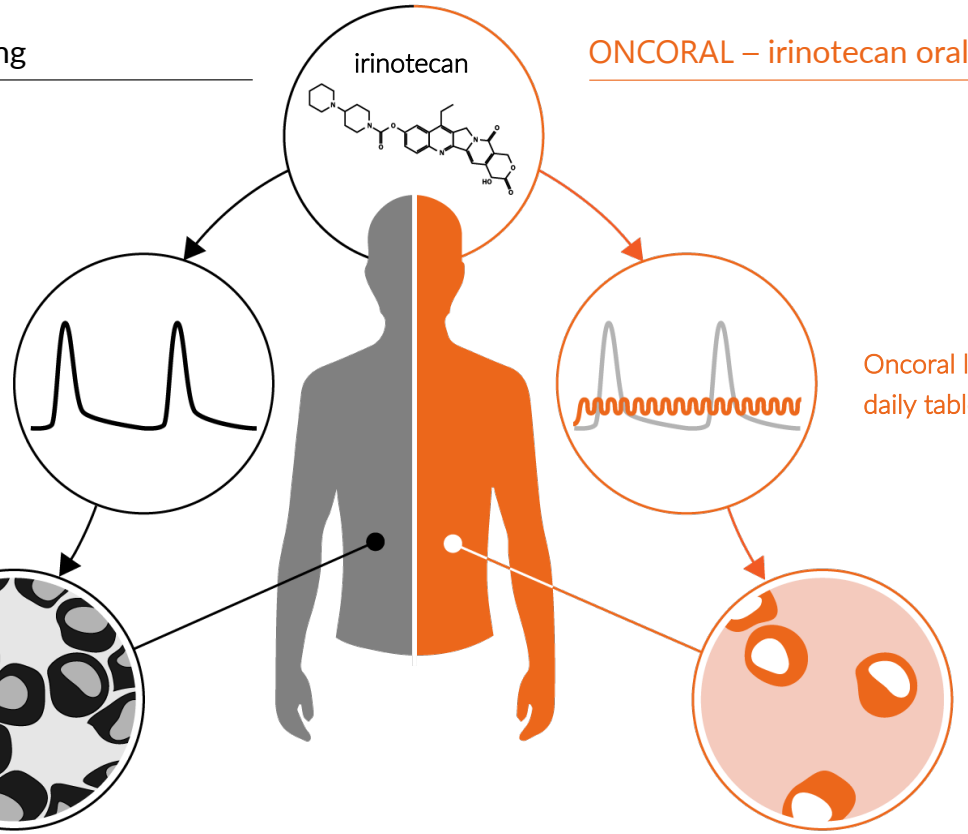
IMPROVING IRINOTECAN **EFFICACY** AND **TOLERABILITY**

Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



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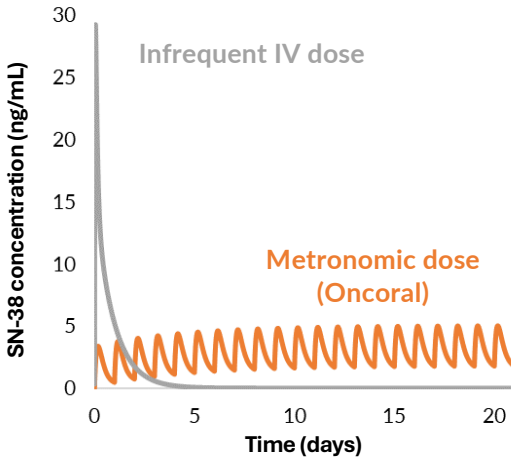
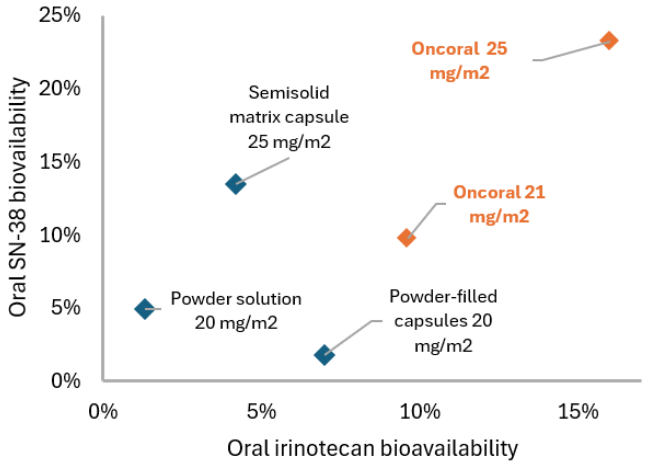
TURNING A PROVEN ONCOLOGY DRUG INTO A NEW TREATMENT PARADIGM

Plasma SN-38 concentration for Oncoral



Simulated SN-38 plasma concentrations after oral (Oncoral, 25 mg/m²)[a] and intravenous (Camptosar, 125 mg/m²)[b] administration of irinotecan, based on single dose pharmacokinetic data.

Irinotecan and SN-38 exposure for Oncoral compared to other oral irinotecan technologies



Relationship between oral irinotecan and SN-38 bioavailability. Bioavailability (BA) calculated as the AUC0-24h for Oncoral (21 and 25 mg/m²)[a], semisolid oral capsule[c], powder-filled capsules[d], and powder (solution)[e] divided by AUC0-24h for intravenous product (Camptosar, 125 mg/ m²)[b], for irinotecan and SN-38, respectively.

Oncoral is a platform for optimizing dosing of irinotecan

The Oncoral proprietary technology has solved a technical problem that enables daily oral administration with more predictable pharmacokinetics, suitable for the metronomic dosing paradigm

Oncoral Phase 1 results[a,f]

- 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

[a] Kümler *et al.*, Cancer Chemother Pharmacol 83:169, 2019; [b] Schaaf *et al.*, Clin Cancer Res 12:3728, 2006; [c] Kuppens *et al.*, Clin Cancer Res 12:3774, 2006; [d] Schoemaker et al., Cancer Chemother Pharmacol 55:263, 2005; [e] Drengler *et al.*, J Clin Oncol 17:685, 1999. [f] Kümler *et al.*, Cancer Chemother Pharmacol 84:441, 2019.

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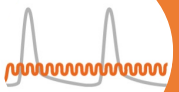
ONCORAL IS MORE THAN JUST ANOTHER DOSAGE FORM OF IRINOTECAN



Different pharmacology

- Continuous low-dose exposure versus intermittent high-dose treatment



Different biology

- Designed to leverage anti-angiogenic and immunomodulatory effects associated with metronomic chemotherapy



Different treatment feasibility

- Chronic daily treatment not practically achievable with conventional IV irinotecan



Different clinical opportunity

- Potential use in maintenance and combination settings beyond traditional irinotecan regimens

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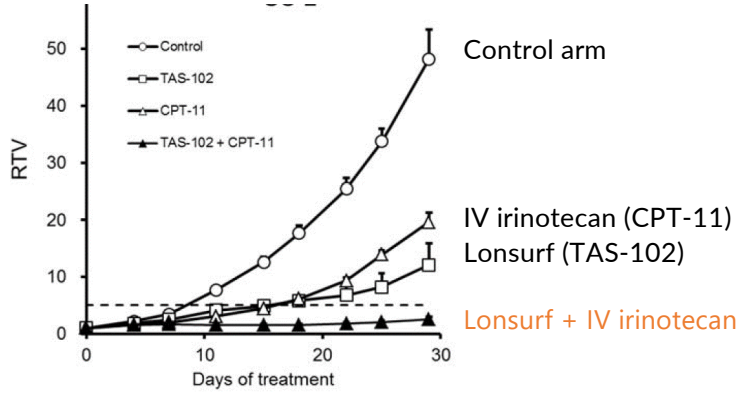
ONCORAL PHASE 2 IN GASTRIC CANCER

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 cancer[1]
(Relative Tumor Volume, RTV)



Control arm

IV irinotecan (CPT-11)
Lonsurf (TAS-102)

Lonsurf + IV irinotecan

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

TAIHO ONCOLOGY

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

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

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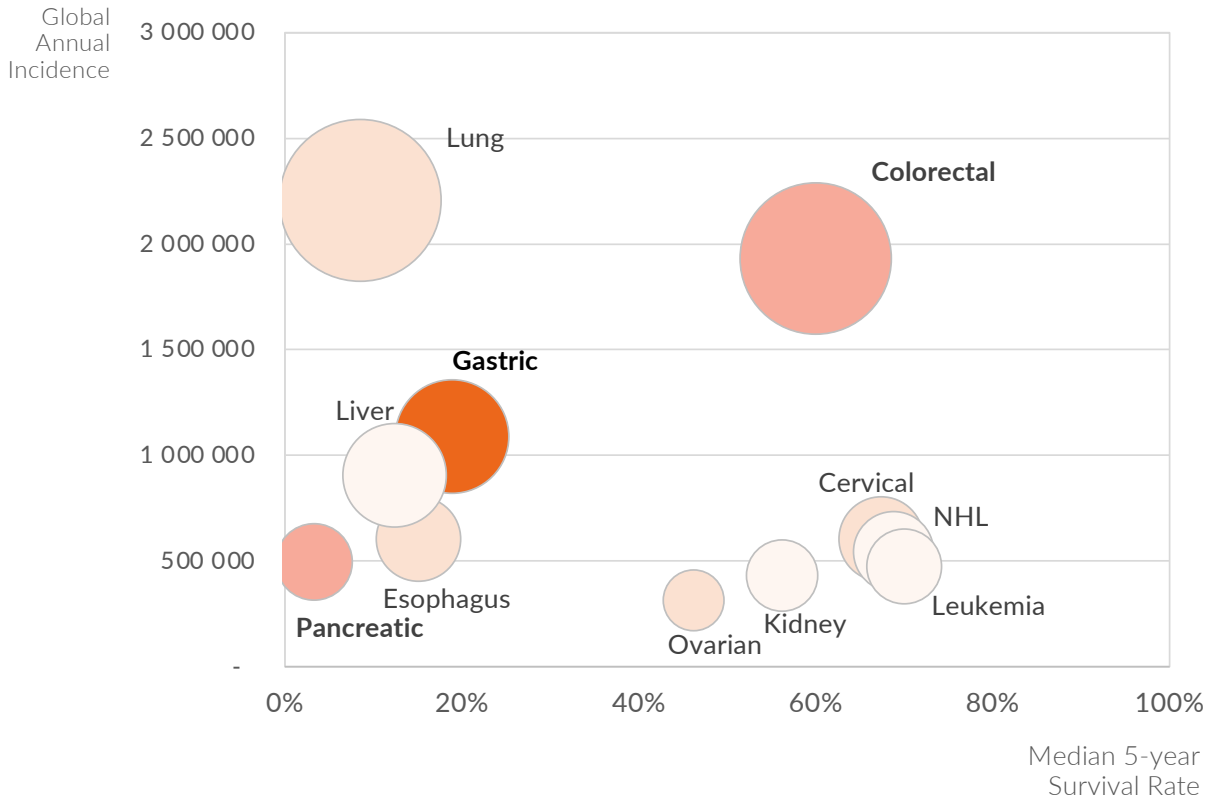
MULTIPLE OPPORTUNITIES ACROSS SEVERAL CANCER INDICATIONS

POTENTIAL FOR ORAL, DAILY DOSING OF IRINOTECAN[3]



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

- Current focus: **Gastric cancer**
  - Clinically demonstrated
  - Guidelines recognized
  - 3rd highest cancer deaths[1]
  - Orphan disease (US and EU)
  - $3-4bn market[2]
- **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

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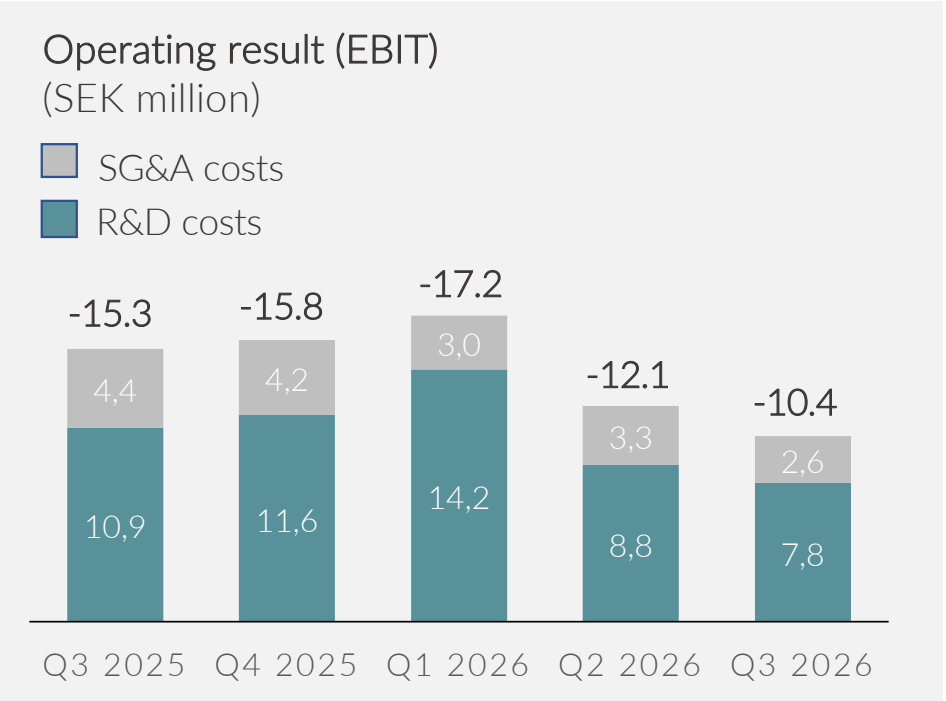
FINANCIALS & OUTLOOK

OPERATING RESULT – REDUCED OPERATING EXPENSES

Operating loss of SEK 10 million in Q3 2026

Quarterly costs lower than in H1 2026 due to finalization of the NDA and cost saving initiatives



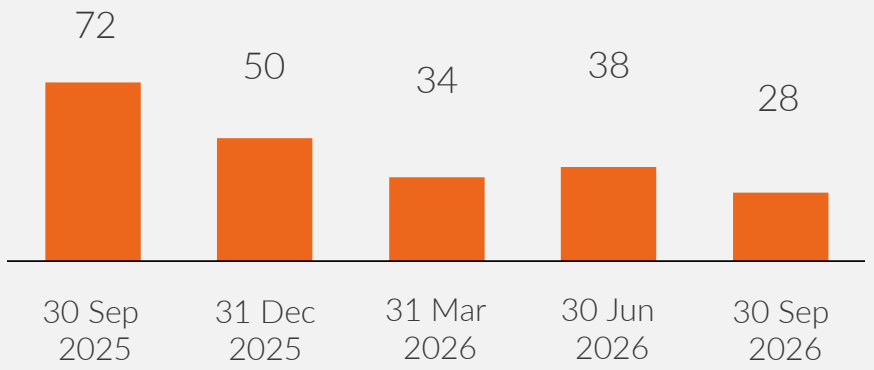
Notes:
Other operating income and other operating costs added to SG&A

LIQUIDITY - CASH RUNWAY INTO Q2 2027

Liquid assets of SEK 28 million (30 Sep 2026)

Focused operations and cost discipline extends the cash runway into Q2 2027

Liquid assets including marketable securities
(SEK million)



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