ADVANCING
ORPHAN
ONCOLOGY

Focus on the Path Forward for Orviglance®

Conference call presentation on 20 August 2026, 10:00 CEST

Ticker symbol: ACE
Nasdaq Stockholm
www.ascelia.com

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QUARTERLY REPORT Q2 2026 INVESTOR CONFERENCE CALL

Agenda

Overview and recent key events

Portfolio

Financials and priorities ahead

Presenters

CEO - Magnus Corfitzen

CSO – Andreas Norlin

CFO – Anton Hansson

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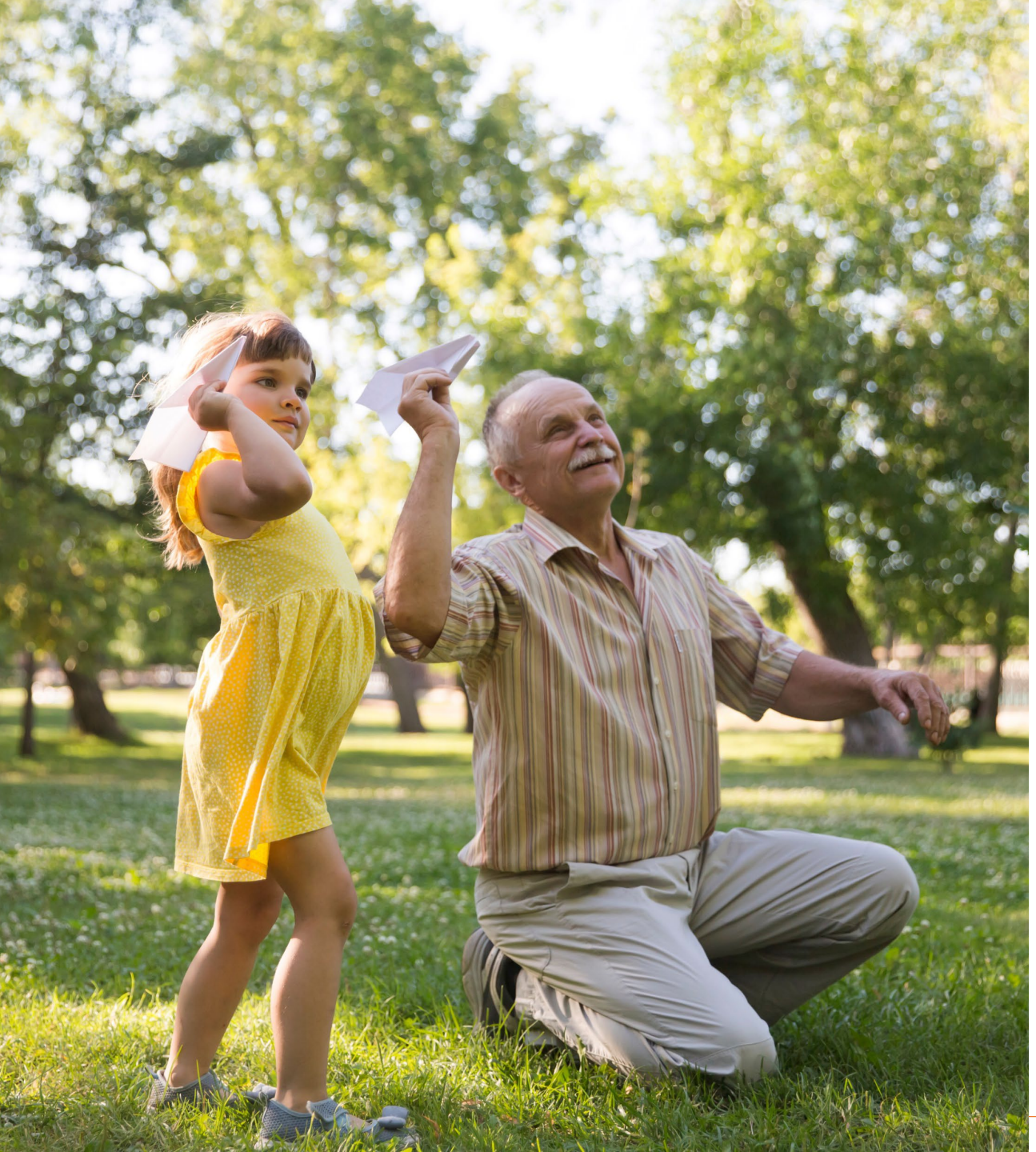

At Ascelia Pharma,

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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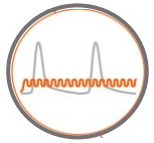
ADVANCED ORPHAN ONCOLOGY PIPELINE

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	Completed			Type A meeting Sep 9, 2026	
 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	Completed	Ready			

Q2 2026 PROGRESS

Key events in Q2 2026

- Ascelia Pharma completes directed share issue of SEK 20 million before transaction costs
- Bulletin from the Annual General Meeting in Ascelia Pharma AB on May 4, 2026
- Orviglance data presented at the European Society of Gastrointestinal and Abdominal Radiology (ESGAR)
- Ascelia Pharma Expands Orviglance IP Portfolio with new patent filing

Key events after the period

- Ascelia provides Orviglance update after Complete Response Letter
- Ascelia announces Organizational changes and cost reductions
- Type A meeting with FDA scheduled for Sep 9, 2026

ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy

PORTFOLIO

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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
- **FDA Type A meeting** scheduled for Sep 9, 2026
- Commercialization with **partner**

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COMPLETE RESPONSE LETTER WAS UNEXPECTED

Ascelia Pharma was expecting an approval of Orviglance based on the NDA submission, regulatory interactions including prior meetings and outcome of audits

The type A meeting on Sep 9, 2026 will provide an opportunity to understand the FDA decision and define the path forward to bring Orviglance to patients

Ascelia Pharma remains confident that the Orviglance NDA is supported by substantial evidence demonstrating the efficacy and safety of Orviglance in its intended patient population, and believes the totality of the clinical, safety, and imaging data generated across the development program supports approval

SUMMARY OF FDA'S CONCERNS IN THE COMPLETE RESPONSE LETTER

Complete Response Letter issues:

Clinical/Statistical

- Justification of the re-read of images
- Introduction of new bias in the training of new readers
- The ability of the re-read to demonstrate added clinical utility versus standard of care based (use of T1-WI only for visualization scoring)

Product quality

- Issues related to specifications of drug product

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ASCELIA PHARMA POSITION

Complete Response Letter issues:

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Product quality

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Ascelia Pharma position:

Clinical/Statistical

- Significant systematic bias[a] in lesion visualization scoring materially affected the reliability of the primary results, supporting the need for a re-read of the images
- Training of new readers was appropriate
- Orviglance is a T1-enhancing agent and therefore evaluating T1 images is appropriate for evaluating efficacy

Product quality

- Ascelia Pharma has aligned with FDA recommendations and implemented the actions requested by the FDA

[a] 2 out of the 3 readers evaluating the images showed a systematic shift in the scoring over time, The magnitude of this error was larger than the anticipated mean effect, which prevent reliable interpretation of data.

PATH TO APPROVAL FOCUSED ON INTERPRETATION OF CLINICAL IMAGING DATA

FDA inspections were completed without critical findings for the NDA

Product quality issues have been addressed through alignment with FDA recommendations

The remaining discussion is centered on the interpretation of the clinical imaging data

The upcoming Type A meeting provides an opportunity to align with FDA on the path forward for Orviglance

Ascelia continues to believe that the totality of the efficacy, safety, and imaging data supports approval

ORVIGLANCE MILESTONES AHEAD

US Regulatory path ahead

- Type A meeting with the FDA on Sep 9, 2026
- Minutes expected no later than 30 days after the meeting

Commercial opportunity

- Unmet medical need and global addressable market of $800m
- Market in the US represents almost half of global market

Exclusivity and IP

- Orphan Drug Designation provides 7 years exclusivity
- Food effect and manufacturing patents filed in 2022, 2025 and 2026 to extend exclusivity

Partnering

Interest from potential partners has remained intact following the CRL

Clarity on path to approval is important for the partnering process

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ORVIGLANCE®

Liver diagnostic imaging drug

ONCORAL

Daily, oral chemotherapy

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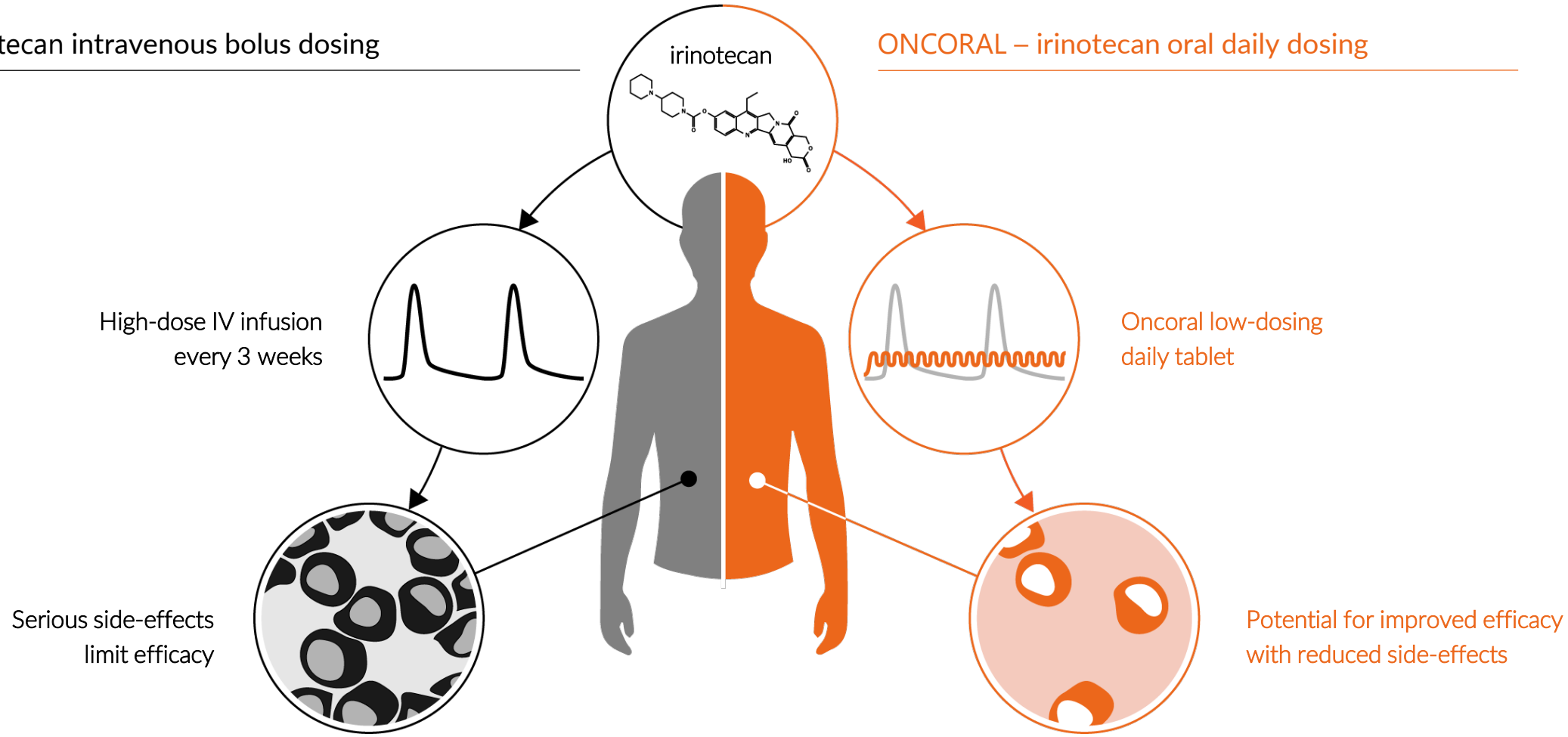
IMPROVING IRINOTECAN **EFFICACY** AND **TOLERABILITY**

Irinotecan intravenous bolus dosing

ONCORAL – irinotecan oral daily dosing



ONCORAL UNLOCKS THE POTENTIAL OF LOW-DOSE, FREQUENT ORAL IRINOTECAN

	Conventional IV irinotecan	Oncoral – Oral irinotecan
Dosing regimen	Established chemotherapy paradigm - High-dose intermittent therapy	Novel low-dose daily metronomic therapy paradigm, enabled by proprietary novel oral drug delivery technology[a]
Drug exposure profile	Exposure characterized by peak concentrations	Designed for sustained drug exposure
Primary treatment mechanism	Direct cytotoxic effect on tumor cells	Direct cytotoxic effect on tumor cells and potential added value through anti-angiogenic effects[b,c,d], immune-modulation[e,f], and remodeling of the tumor micro-environment[g], which are distinct from direct tumor-cell cytotoxicity
Safety and tolerability	Safety often limiting to treatment effect	Potential for improved tolerability and safety
Treatment burden	Requires IV administration and clinic visits	Convenient oral administration, suitable for home administration

[a] Kümler *et al.* Cancer Chemother Pharmacol, 83:169-178, 2019. [b] Browder *et al.*, Cancer Res 60:1878, 2000, [c] Kerbel & Kamen. Nature Rev Cancer 4:423, 2004, [d] Bocci *et al.*, Br J Cancer 98:1619, 2008, [e] Ghiringhelli *et al.*, Cancer Immunol Immunother 56: 641, 2007, [f] Peerebom *et al.*, JCI Insight 4:1, 2019, [g] Chan *et al.*, J Exp Med 213:2967, 2016, [h] Kümler *et al.*, Cancer Chemother Pharmacol, 84:441, 2019

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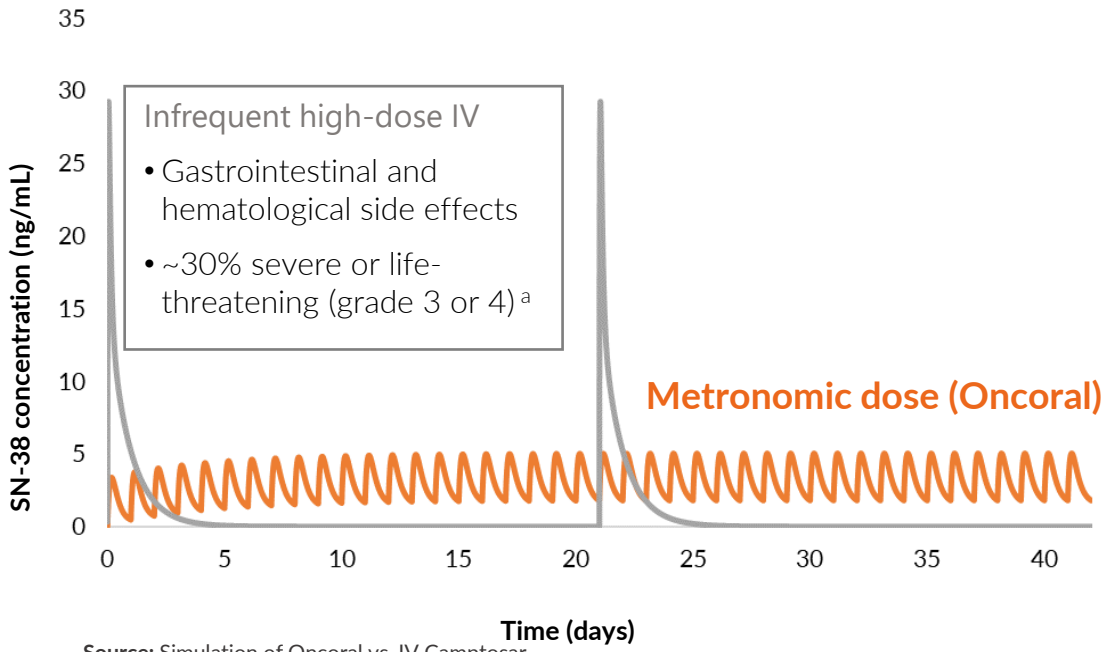
ONCORAL IS ALIGNED WITH THE EMERGING DOSE OPTIMIZATION PARADIGM IN ONCOLOGY

PLASMA EXPOSURE LEVELS OF SN-38



Source: Simulation of Oncoral vs. IV Camptosar.
Illustration of the principal differences in drug exposure for classical intravenous Maximum Tolerated Dose (MTD) dosing and metronomic dosing. Classical MTD dosing is characterized by high exposure peaks that may drive dose-limiting toxicity and treatment interruptions. Metronomic dosing aims to maintain biologically active drug levels over time, potentially optimizing the balance between efficacy, safety, and long-term treatment adherence.

Oncoral is not simply an oral irinotecan formulation - It is a platform for optimizing how irinotecan is dosed

FDA's Project Optimus[b] reflects a paradigm shift from finding the highest tolerable dose to identifying the optimal biological dose in oncology drug development.

Oncoral's daily oral dosing design is inherently suited to this paradigm, creating opportunities to maintain efficacy while reducing treatment burden and improving tolerability

Oncoral Phase 1 results[c]

- 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] Camptosar prescribing information, [b] https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus, [c] Kümler *et al.*, Cancer Chemother Pharmacol 83:169, 2019

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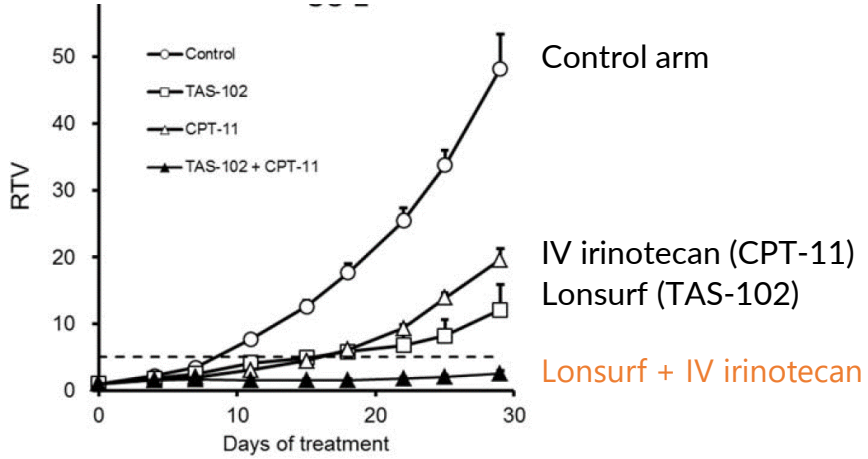
ONCORAL PHASE 2 IN GASTRIC CANCER

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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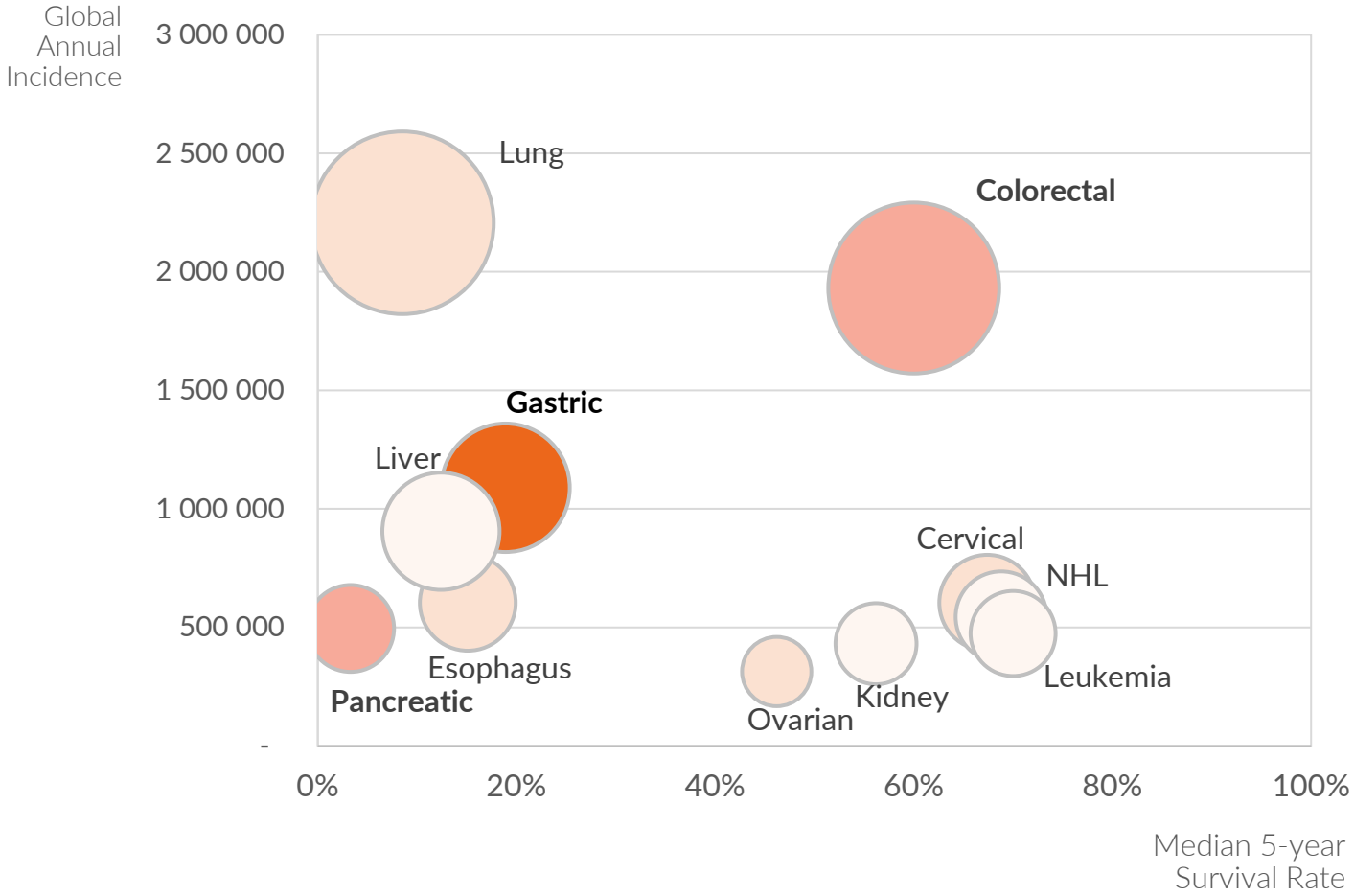
MULTIPLE OPPORTUNITIES ACROSS SEVERAL CANCER INDICATIONS

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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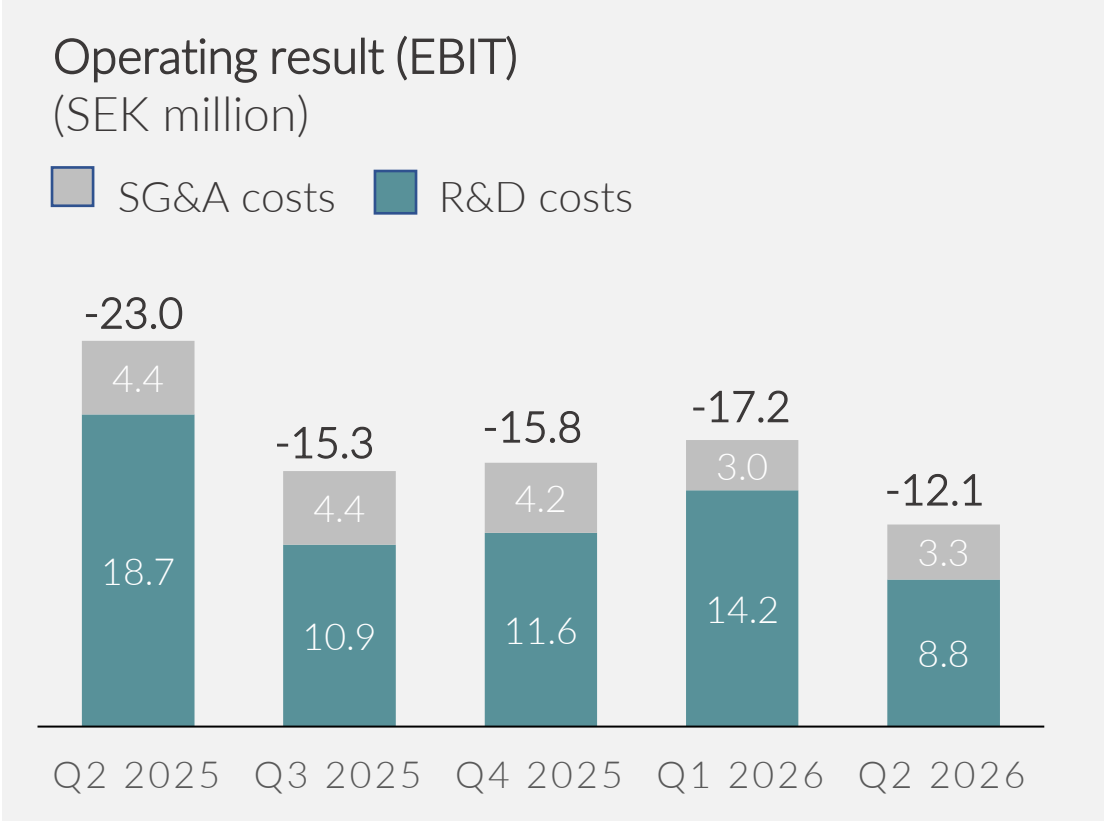
FINANCIALS & OUTLOOK

OPERATING RESULT– LOW OPERATING EXPENSES

Operating loss of SEK 12 million in Q2 2026

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



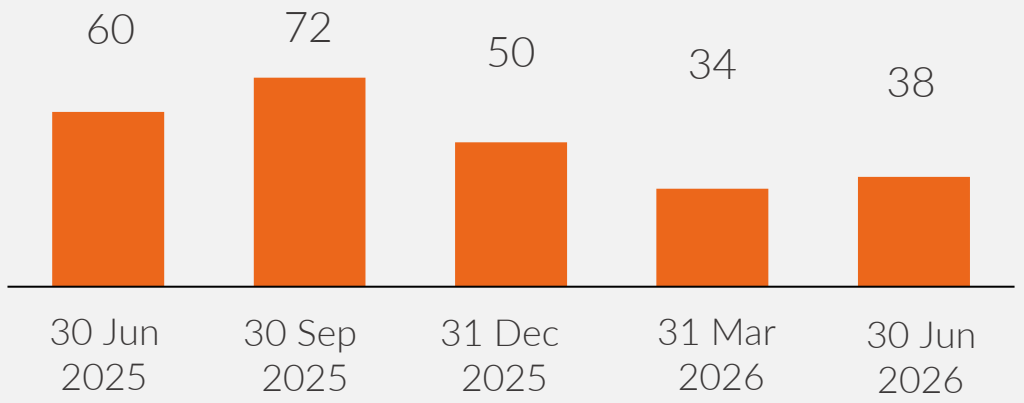
Notes:
Other operating income and other operating costs added to SG&A

LIQUIDITY - CASH RUNWAY INTO Q2 2027

Liquid assets of SEK 38 million (30 Jun 2026)

Directed issue raising SEK 20 million before transaction costs (Apr 2026) and cost saving initiatives **extending the cash runway into Q2 2027**

Liquid assets including marketable securities
(SEK million)



ASCELIA PHARMA OUTLOOK

US Regulatory path ahead

- Type A meeting with the FDA on Sep 9, 2026
- Minutes expected no later than 30 days after the meeting

Partnering

- Interest from potential partners has remained intact following the CRL
- Clarity on path to approval is important for the partnering process

Financial outlook

- Cost reduction initiatives implemented
- Cash runway into Q2 2027

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