Ascelia Pharma

Improving cancer contrast

- Alternative MRI contrast agent for frail cancer patients
- Ph 3 finished and ready for FDA filing
- Initiating coverage, fair value range of SEK 2.6-5.1

Addressing unmet medical needs in oncology

We initiate coverage on Ascelia Pharma, a Swedish biotech company focused on the development of novel drugs to detect and treat cancer. The lead product is Orviglance, a novel manganese-based magnetic resonance imaging (MRI) contrast agent developed for the detection of liver tumours in cancer patients with impaired kidney function. The drug passed Ph 3 successfully in 2024, and is currently in preparations for a US FDA filing by mid-'25. The company's second Ph 2-ready product Oncoral is an improved formulation of the chemotherapy irinotecan for the treatment of gastric cancer.

A better option for frail cancer patients

Current medical standard of care (SoC) relies on gadolinium-based MRI contrast agents. However, in patients with impaired kidney function—a common comorbidity of cancer—their use has been associated with a rare but severe complication called nephrogenic systemic fibrosis (NSF). Additionally, studies have shown accumulation of gadolinium in certain body tissues, with unknown consequences for human health. Ascelia's manganese-based Orviglance has the potential to provide a safe option for frail cancer patients with limited diagnostic alternatives. Ascelia's second product candidate Oncoral - a novel irinotecan formulation - completed Ph 1 and is parked Ph 2-ready.

Initiating coverage with fair value range of SEK 2.6-5.1

We value the commercial opportunity for Orviglance and Oncoral with a bottom-up approach, using clinical literature/databases to estimate the market sizes. Our valuation is based on three pricing scenarios in the lead and most important market, the US. Our DCF yields risk-adjusted fair values (NPV) of SEK 2.6, 3.9 and 5.1 per share.

Reason: Initiating coverage

Commissioned research

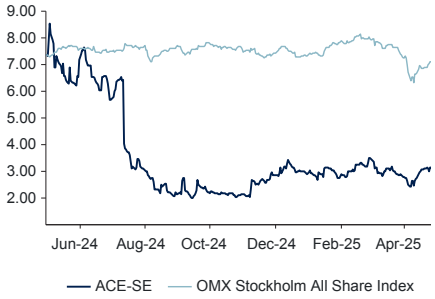
Not rated

Healthcare

ACE-SE/ACE SS

Share price (SEK)	25/4/2025	3.14
Fair value range		2.6-5.1
MCap (SEKm)		302
MCap (EURm)		28
No. of shares (m)		96.1
Free float (%)		94.4
Next event		AGM 7 May 2025

Performance



Analyst(s): alexander.kramer@abgsc.se, +46 8 566 286 91
georg.tigalonov-bjerke@abgsc.no, +47 22 01 60 84

SEKm	2023	2024	2025e	2026e	2027e
Sales	0	0	70	61	135
EBITDA	-111	-68	-10	-38	24
EBITDA margin (%)	--	--	-13.7	-61.7	17.8
EBIT adj.	-111	-68	-10	-38	24
EBIT adj. margin (%)	--	--	-13.7	-61.7	17.8
Pretax profit	-110	-80	-15	-38	24
EPS	-3.24	-0.83	-0.13	-0.32	0.21
EPS adj.	-3.24	-0.83	-0.13	-0.32	0.21
Sales growth (%)	--	--	--	-12.8	121.4
EPS growth (%)	-16.8	-74.3	-84.5	nm	-164.0

	2025e	2026e	2027e
P/E (x)	nm	nm	15.1
P/E adj. (x)	nm	nm	15.1
P/BVPS (x)	2.98	4.30	3.35
EV/EBITDA (x)	-30.2	-8.7	12.6
EV/EBIT adj. (x)	-30.2	-8.7	12.6
EV/sales (x)	4.14	5.37	2.25
ROE adj. (%)	-14.9	-36.3	24.9
Dividend yield (%)	0.0	0.0	0.0
FCF yield (%)	-3.9	-10.3	6.6
Le. adj. FCF yld. (%)	-3.9	-10.3	6.6
Net IB debt/EBITDA (x)	7.7	1.0	-2.5
Le. adj. ND/EBITDA (x)	7.8	1.0	-2.5

Source: ABG Sundal Collier, Company Data

This report is intended for alexander.kramer@abgsc.se. Unauthorized distribution prohibited.

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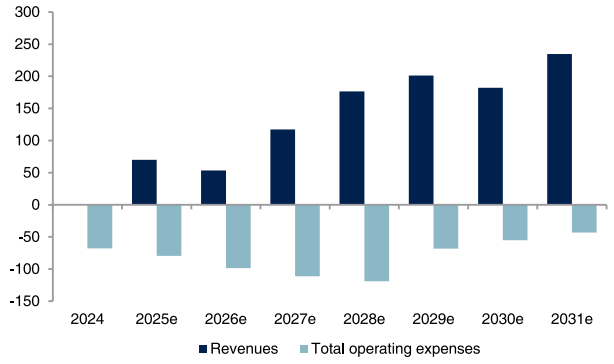
Company description

Ascelia Pharma is a Swedish biopharma company listed on the Nasdaq Stockholm main market since March 2019. The company is focused on the development of a novel non-gadolinium based MRI contrast agent for the detection of liver metastases in cancer patients with impaired kidney function. The product Orviglance has successfully completed clinical Ph 3 (SPARKLE) in 2024 and is now in preparations towards submission of a NDA to the US FDA by mid'25. The second pipeline candidate Oncoral (novel chemotherapy formulation for gastric cancer) completed Ph 1 successfully and is Ph 2-ready.

Risks

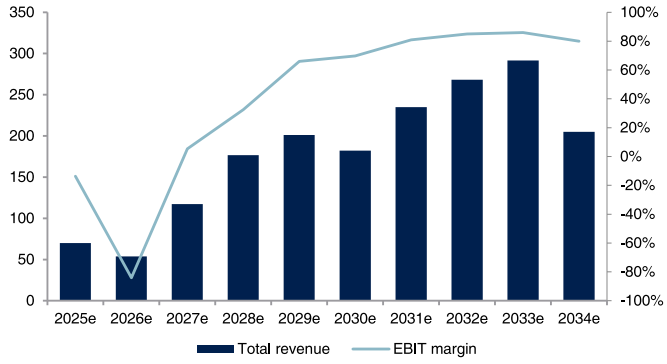
Ascelia's lead drug candidate Orviglance has passed clinical development. Remaining risks remain FDA approval (small risk) and failure of meeting commercial targets (greater risk). Ascelia will also need to find a licensing partner to successfully launch the product in the US and prolong the company's financial runway until sufficient revenue is generated from partner milestones and royalties to reach profitability.

Annual revenues (risk-adj.) and total opex (SEKm)



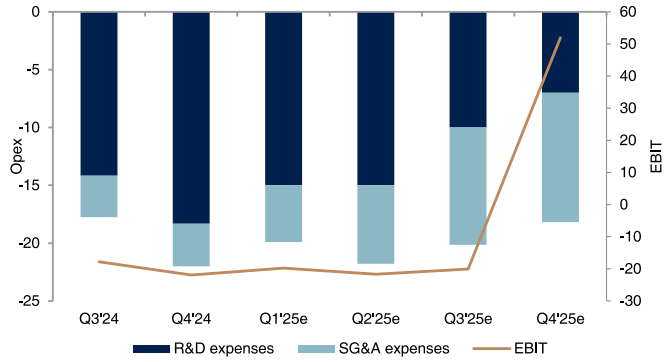
Source: ABG Sundal Collier

Annual revenues (SEKm) and EBIT margin (%)



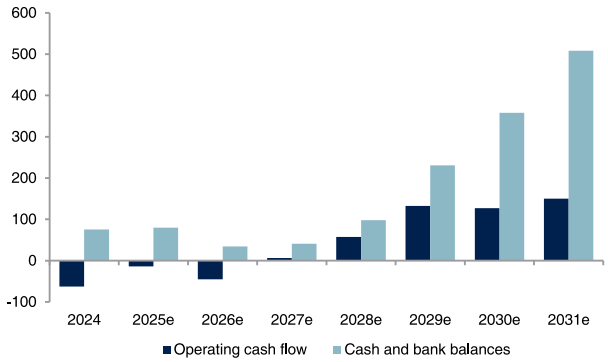
Source: ABG Sundal Collier

Quarterly opex and EBIT (SEKm)



Source: ABG Sundal Collier

Annual operating cashflows and cash position (SEKm)



Source: ABG Sundal Collier

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Summary

Ascelia Pharma is a clinical stage biopharma company listed on Nasdaq Stockholm focused on developing a novel magnetic resonance imaging (MRI) contrast agent —Orviglance—for detection of primary/metastatic liver tumours in patients with impaired kidney function. Advanced cancer patients with liver metastases often suffer also from impaired kidney function. This patient group is not suitable for standard of care MRI, which uses gadolinium-based contrast agents, due to the associated risk of developing a rare but serious and potentially fatal complication called NSF. These patients currently rely on the use of lower dose standard of care agents or MRI without contrast agent (unenhanced), both of which offer only suboptimal clinical efficacy. Ascelia's Orviglance addresses this issue by offering an equally effective alternative to gadolinium, serving a high unmet medical need.

Last year, Orviglance's pivotal Ph 3 study SPARKLE reported positive results, showing that liver imaging with Orviglance was superior to unenhanced MRI. In H1'25, Ascelia is preparing for submission of the Orviglance new drug application (NDA) to the FDA, with potential regulatory approval in the lead market—the US—expected in '26. Ascelia is seeking a partnership to drive commercialisation of the product in the US. Ascelia also holds the rights to a novel formulation of the chemotherapy agent irinotecan (Oncoral), planned to be developed as a late-line treatment in gastric cancer. To this end, a collaboration agreement with the Japanese pharma company Taiho was signed in 2021. We value Ascelia Pharma using a discounted cash flow approach, modelling three different scenarios yielding fair values of SEK 2.6, 3.9, and 5.1 per share.

Orviglance

Orviglance is Ascelia's lead pipeline project, and was developed as an oral imaging agent for the detection of focal liver lesions in patients with impaired kidney function by magnetic resonance imaging (MRI). Focal liver lesions occur in patients with primary liver tumours, but also with tumours secondary to another (primary) tumour in the body, which is called a metastasis. MRI is the best method to detect such lesions, and specific and sensitive tumour lesion detection is crucial to guide future therapy decisions. Current standard of care tumour detection often relies on contrast agents to improve the detection and visualisation of small tumours in the liver.

Gadolinium-based contrast agents (GBCAs) are the gold standard contrast agents used in the clinic. The drugs are administered intravenously and are eventually excreted into the urine. However, the use of these agents in cancer patients with AKI or CKD (poor kidney function) has been associated with a rare but very severe side effect: nephrogenic systemic fibrosis (NSF). All current GBCAs carry a boxed warning in the FDA label ("black box warning") concerning the NSF risk and advising users (radiologists) to test the individual patient's kidney function prior to GBCA use. The FDA recommends avoiding the use of GBCAs in patients with poor kidney function, e.g. suffering from AKI or CKD, unless the diagnostic information is essential and unavailable with unenhanced MRI (i.e. without a contrast agent).

Over the last ~20 years, Ascelia has conducted an extensive clinical programme in 286 patients and healthy volunteers across nine clinical trials (Ph 1-3), proving the clinical benefits of the manganese chloride tetrahydrate, the active pharmaceutical ingredient (API) in Orviglance. Most importantly, Orviglance met the primary and multiple endpoint in the pivotal SPARKLE Ph 3 study, which compared the drug candidate with unenhanced MRI. Based on these promising results, Ascelia successfully completed a pre-NDA meeting with the FDA in Q1'25 and is planning to submit the new drug application (NDA) in mid-'25 (mid-May to mid-Aug).

Additional issues addressed by Orviglance

In addition to the clinical benefit to the cancer patient, it is notable that gadolinium compounds used in MRI procedures accumulate in certain body tissues, such as the brain. The long-term effects of gadolinium deposition on health are unknown. Unlike manganese, gadolinium is not a natural trace element, and not playing a role in the physiology of living

organisms. Another major concern is that gadolinium cannot be removed in sewage plants, so it is discharged into the environment, contaminating waters.

Oncoral

Oncoral is Ascelia's second asset, a novel oral formulation of the chemotherapy irinotecan. The standard route of administration for irinotecan is intravenous injection, and it is used off-label as a late-line therapy option for gastric cancer. However, the bolus infusions lead to high drug peaks in the patient's blood, causing common and severe side effects.

In 2021, Ascelia entered into a collaboration agreement with Japan's Taiho Pharma aiming to test the combination of Oncoral with Taiho's combination drug Lonsurf in gastric cancer. Lonsurf is a combination of trifluridine and tipiracil, indicated for the treatment of 3L+ gastric cancer, i.e. patients who have progressed on at least two previous lines of therapy. Oncoral finished a Ph 1 programme and a Ph 2 has been designed to test the combination of Lonsurf +Oncoral vs. Lonsurf monotherapy. The programme is currently on hold, as Ascelia's main focus is the advancement of Orviglance.

Valuation

Our valuation is based on a discounted cash flow valuation approach: we model three valuation scenarios, yielding rNPV/share values of SEK 2.6, 3.9, and 5.1, forming the basis for our fair value range of SEK 2.6-5.1/share.

We base our valuation on a bottom-up approach where we first calculate the number of patients with liver metastases and the number of primary liver cancer cases. Next, we estimate the number of patients that also suffer from impaired kidney function, either due to acute kidney injury (AKI) or chronic kidney disease (CKD). Notably, the prevalence of impairment of kidney function is higher in advanced metastatic cancer patients compared to the general population. This calculation yields an estimate of the number of MRI procedures potentially eligible for future Orviglance use.

Given the high unmet medical need, we forecast a market penetration of 60% for Orviglance. Achieving premium pricing vs. current standard of care MRI contrast agents will be crucial. Thus, we have modelled three valuation scenarios A/B/C, corresponding to US list prices per dose of USD 1,500/2,500/3,500. In the ex-US geographies (EU5 & JP) we calculate with a flat net price of USD 1,000 per dose.

Ascelia is seeking a commercial partnership for Orviglance. We expect a back-end loaded WW licensing deal to be signed by YE'25, with an upfront payment of USD 10m + potential sales milestones of up to USD 50m + 20% royalties on net sales. Our upfront+milestones estimate of USD 60m is derived from the annual US peak sales in the most conservative scenario A (see table below).

MRI contrast agents are a specialty pharma market and there has been no similar or precedent deal before. To account for the post-launch commercial risks, we apply progressive risk adjustments on the upfront + following milestone payments.

The US will be the most important market for Orviglance, so Ascelia has focused all its resources on preparing the new drug application (NDA) to the FDA. The Orviglance data package (NDA) will be submitted to the FDA by mid-2025, and we expect a straightforward approval process leading to approval by mid-2026 with potential market launch in H2'26.

US Orviglance model price sensitivity analysis

Scenario	US list price (USD/dose)	Annual US peak sales (USDm)*	Annual WW peak sales (USDm)*	Peak sales split US	Potential annual peak royalty income* (USDm)	rNPV/share (SEK)
A	1,500	49	101	49%	20	2.6
B	2,500	82	133	62%	27	3.9
C	3,500	115	165	70%	33	5.1

Source: ABG Sundal Collier

*Footnote: *non-risk-adjusted, royalty rate 20%*

Orviglance revenue stream model (Scenario B, SEKm)

Orviglance license deal	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2034e	2035e
Upfront	100									
Milestones		50	100	150	200					
Risk adjustment on upfront & milestones	***70%***	***70%***	***60%***	***50%***	***30%***					
Upfront	70									
Milestones		35	60	75	60					
20% royalties on net sales*		19	57	102	141	182	218	234	143	123
Total revenue	*70*	*54*	*117*	*177*	*201*	*182*	*218*	*234*	*143*	*123*

*Scenario B, est. US & EU Annual sales risk-adjusted by 90%, JP risk-adj. by 70%
Assumption: Worldwide Orviglance licensing deal

Source: ABG Sundal Collier estimates

Company history

Ascelia Pharma is a Swedish biopharma company with roots dating back to 1999. It focuses on the development of novel medicines in the field of oncology to improve diagnosis and treatment. Its initial focus was Orviglance (previously called Mangoral, manganese chloride), a novel MRI contrast agent, which was also reflected in the company's earlier name, CMC Contrast AB. In 2017, the company acquired Oncoral Pharma ApS with its own shares, adding a novel oral formulation of the chemotherapy compound irinotecan (Oncoral) to its pipeline. At the same time, the company changed its name to Ascelia Pharma.

Financial history and perspectives

In 2019, Ascelia Pharma completed its IPO, yielding gross proceeds of SEK 200m and securing the financing of its pivotal Ph 3 programme SPARKLE, a registrational trial for its lead product Orviglance. The IPO attracted more than 6,000 new shareholders.

In 2020, Ascelia completed a directed share issue to existing and a group of new investors, raising proceeds of SEK 99m. In March 2021, another directed share issue was carried out, raising gross proceeds of SEK 200m. The proceeds of both share issues were used to finance the Ph 3 SPARKLE study and for general corporate purposes.

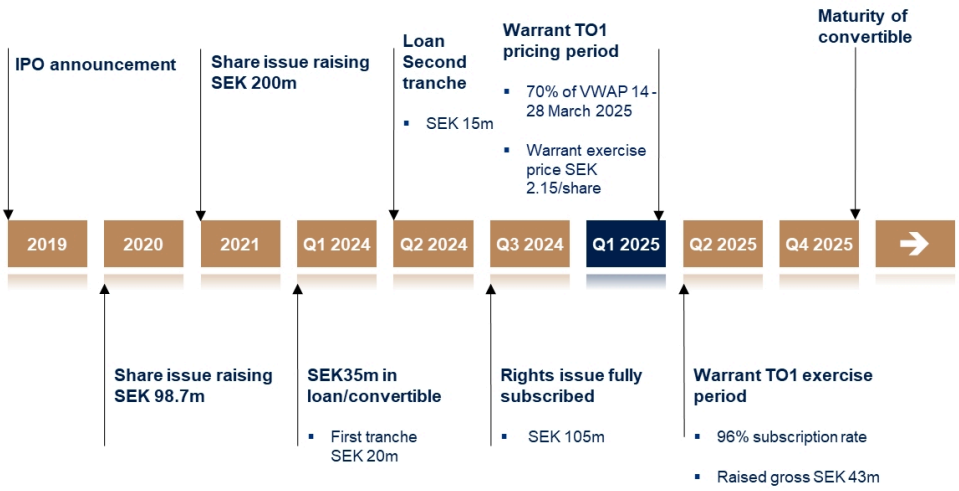
In February 2024, Ascelia secured a SEK 35m combined loan/convertible financing deal from Formue Nord Fokus A/S. It is composed of a SEK 20m loan + SEK 15m convertible. In May '24, Ascelia announced positive top-line data from the Ph 3 SPARKLE study, after which the company conducted a rights issue during the summer.

Ascelia issued units, where 1 unit consists of 3 ordinary shares plus one warrant series TO 1. In Sept'24, the rights issue was successfully completed, initially raising gross proceeds of ~SEK 105m. Additionally, each warrant TO 1 entitled the holder to subscribe for 1 new share during the period 1 April - 15 April '25. The subscription price has been set at 70% of the volume-weighted average price (VWAP) of the period 14 March-28 March 2025, but not less than 50% and not more than 200% of the subscription price per share in the rights issue (i.e. 1/3 of the subscription price per unit).

Furthermore, Ascelia has renegotiated the loan terms with Formue Nord (changed name to Fenja Capital), determining that a part of the share issue proceeds (SEK 7.5m) are to be used to repay half of the SEK 15m Fenja Capital convertible. Moreover, the maturity date of the Fenja Capital loan (SEK 20m) and the remaining convertible (SEK 7.5m) have been extended to 31 December 2025.

On 16 April, Ascelia announced the outcome from the TO1 warrants exercise period: 95.9% were exercised, yielding gross proceeds of SEK 42.8m. Ascelia will use SEK 20m to repay the Fenja Capital loan, while the convertible portion of SEK 7.5m can be converted until 31 Dec '25 at a conversion price of SEK 3.38 per share. Following the transaction, the total number of Ascelia shares increases by ~19.9m to ~117.1m, of which ~1.1m are series C shares.

Financial timeline since IPO



Source: ABG Sundal Collier

Warrants TO1	
No. of warrants	20,773,992
VWAP 14-28 March (SEK)	3.07
Subscription price (SEK)	2.15
No. of warrants exercised	19,919,494
Subscription rate	95.9%
Gross proceeds (SEKm)	**42.8**
Share count before*	96,106,032
Share count after (end of Q2'25)*	116,025,526

Source: ABG Sundal Collier, Company

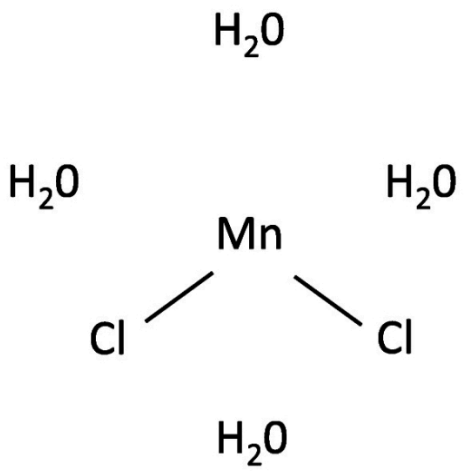
*Footnote: *excl. C-shares (~1.1m, 1/10 vote)*

Orviglance

Mechanism of action

Manganese is a natural trace element that plays a role in many physiological processes such as energy metabolism. The active pharmaceutical ingredient (API) of Orviglance (CMC-001, ACE-MBCA) is manganese (Mn(II)) chloride tetrahydrate. Like gadolinium, Mn(II) ions are paramagnetic, which makes them "visible" with MRI. After ingestion (oral solution), the manganese ions are taken up in the small intestine and reach the liver, where they are taken up into liver cells (hepatocytes). Hepatocytes have a higher uptake of manganese, as they are rich in mitochondria, which require manganese for energy metabolism. Orviglance is developed to detect and visualise focal liver lesions, of which liver tumours are an important subgroup. Focal liver lesions have less uptake of manganese, which is then visible in the MRI image as a contrast between tumour and healthy tissue areas. In Orviglance, the manganese chloride is co-formulated with vitamin D and l-alanine. Following ingestion and the time required for the manganese to reach an adequate uptake in the liver, the MRI procedure can be conducted in the time window of between 2 and 6 hours from ingestion.

Ascelia's Orviglance: Manganese chloride tetrahydrate



Source: Brismar et al. Invest Radiol. 2023

Target population: Cancer patients with poor kidney function

Compared to healthy individuals, cancer patients have a higher risk of suffering from kidney injury/impairment, which manifests as either acute kidney injury (AKI) or chronic kidney disease (CKD). These patients have a limited capacity to excrete the MRI contrast agent, causing toxicity and increasing the risk of nephrogenic systemic fibrosis (NSF). NSF leads to a progressive fibrosis in the body, affecting the skin, muscles and multiple organs. It is fortunately rare, but GBCAs carry black box warnings in the FDA labelfor use in patients with impaired kidney function.

Currently, patients with suspected liver tumours need to be assessed for proper kidney function. To this end, the GBCA FDA black box warning, requests that patients at risk (age >60, hypertension, diabetes) will be tested for eGFR (estimated glomerular filtration rate). If the eGFR value is < 30 mL/min/1.73m2, alternative diagnostic approaches with less accuracy such as unenhanced MRI (i.e. without contrast agent) are indicated. Orviglance is developed as a safe alternative to GBCAs in these patients, as it used a manganese-based active ingredient, replacing the heavy metal gadolinium.

Extensive clinical data package

Orviglance was tested in nine clinical studies in both healthy subjects (Ph 1) and in patients with liver lesions, including tumours (Ph 2/3). Importantly, the Ph 1 studies conducted in 126 healthy individuals confirmed that Orviglance was safe, showed good PK/PD and has contrast-enhancing properties. Importantly, systemic manganese exposure was generally low and manganese levels returned to predose levels after 12 hrs, showing that the agent is eliminated from the bloodstream rapidly.

A total of four Ph 2 studies were run with 75 patients with suspected or known liver lesions. The studies featured different designs to investigate the dosing, timing and Orviglance's contrast-enhancing properties as measured by liver lesion border delineation/ contrast. The lesion visualisation with Orviglance was compared against unenhanced MRI and gadolinium-based contrast enhancing. Orviglance improved lesion visualisation vs. unenhanced MRI and the diagnostic performance was comparable to gadolinium (gadobenate dimeglumine). The studies allowed Ascelia to decide on optimal dosing (800 mg) and the optimal diagnostic time window (2-6 after dosing, peak at 3 hrs). Across all Ph 1&2 studies, diarrhoea (27%) and nausea (22%) were the most common reported AEs, which is above the rate typically observed with GBCAs, but seems acceptable given the proposed added value of the drug. The rate of diarrhoea and nausea decreased to 10/15% (resp.) in the following Ph 3 SPARKLE study (800 mg dose).

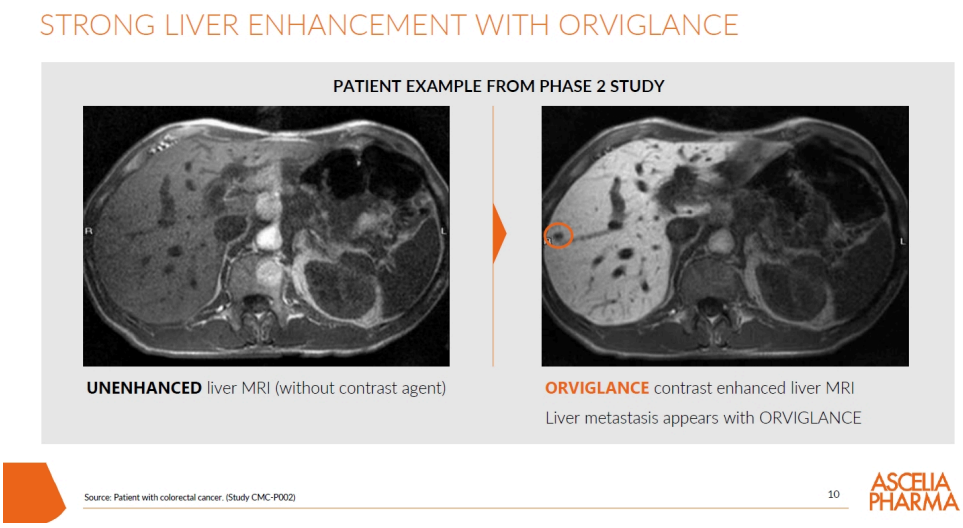
Study Characteristics of Ph 2/3 studies of ACE-MBCA (Orviglance) for Liver Imaging

Phase	Study ID; Reference	Study Population	Dose (mg)	Note
2	CMC-P002; Dekker et al. *Contrast Media Mol Imaging* 2009	18 patients with liver metastases	1600	
2	CMC-P003; Rief et al. *Invest Radiol.* 2010	20 patients with liver metastases	800 and 1600	
2	CMC-P004; Brismar et al. *Eur Radiol.* 2012, Brismar et al. *Invest Radiol.* 2025	20 patients with liver metastases from colorectal cancer	1600	Crossover study, each patient performed one MRI with ACE-MBCA and one with gadolinium
2	CMC-P005; Unpublished	17 patients with suspected liver lesions	800 and 1600	
3	ASC-Man-P016 (SPARKLE, NCT04119843)	87 patients with severe renal impairment	800	

Source: Adapted from Brismar et al. Invest Radiol. 2023

Recently, Ascelia Pharma published a new analysis of the Ph 2 CMC-P004 dataset in collaboration with researchers from Karolinska Institutet (Brismar et al. Invest Radiol. 2025). Importantly, the CMC-P004 dataset allows direct comparison of the diagnostic performance of Orviglance vs. gadolinium-based contrast agents, as each patient underwent one MRI procedure with Orviglance and one procedure with gadobenate dimeglumine (MultiHance, see 'Competitive landscape' chapter below). In this study design, each patient can serve as her/his own control, as the reader (radiologist) can assess unenhanced MRI vs. Orviglance-enhanced MRI vs. gadolinium-enhanced MRI in the same patient. The first CMC-P004 dataset analysis was already published in 2012; however the new recent publication features a centralized and blinded data assessment by three independent readers, in accordance with the methodology used in the Ph 3 SPARKLE programme. Most importantly, the re-analysis confirmed the previous conclusions and is in line with the conclusions from the pivotal Ph 3 SPARKLE (see below). The new analysis also confirmed that the diagnostic performance of Orviglance is comparable to gadobenate dimeglumine (MultiHance).

Case example - Liver enhancement with Orviglance



Source: Ascelia Pharma

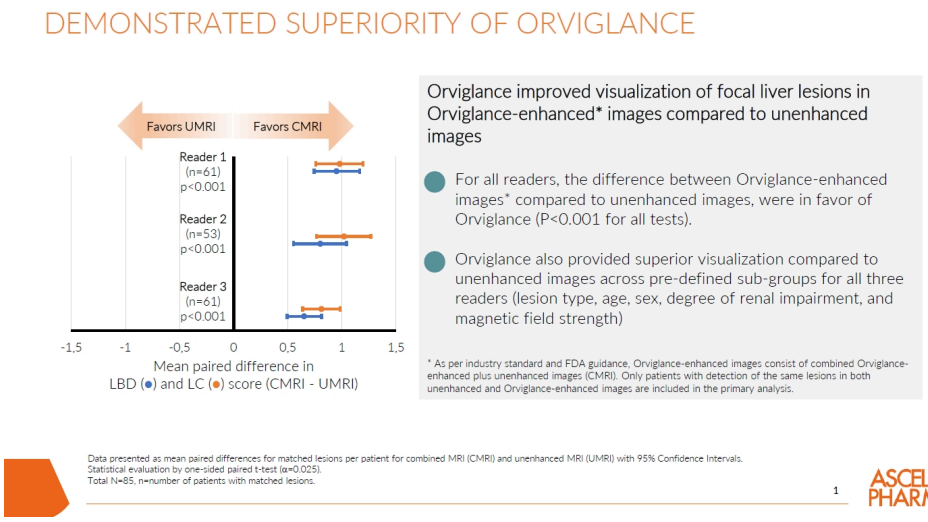
Successful Ph 3 SPARKLE

In 2020, Ascelia started the Ph 3 SPARKLE trial (NCT04119843), which sought to investigate the diagnostic efficacy and safety of Orviglance. Eighty-seven patients with suspected or known liver lesions and impaired kidney function (eGFR <30 mL/min/1.73 m^2) were recruited into the study. The primary endpoint of the study was the visualisation of focal liver lesions in Orviglance-enhanced MRI vs. unenhanced MRI (UMRI) vs. combined Orviglance+unenhanced MRI (CMRI) as read by three central independent readers. Secondary endpoints included — among others — number of lesions detected by each MRI method and visualisation of focal liver lesions.

The study finished in 2023 and Ascelia announced in Aug'23 that a re-evaluation of the images had to be conducted after a high intra-reader variability (inconsistency) was identified. The images were re-evaluated by new independent readers (radiologists) who received extensive training in the study protocol and scoring system. Also, the reading process was more rigorously structured and monitored. Finally, in May '24, Ascelia reported positive top-line results, showing that the study met the primary endpoint of improving visualisation of focal liver lesions with CMRI Orviglance vs. unenhanced MRI (statistically significant, p <0.001). Visualisation of focal liver lesions was assessed by scoring the lesion border delineation (BD) and lesion contrast (LC) on a scale from 1 to 4. The median BD score increased from2.1 (unenhanced) to 3.0 (Orviglance), while the median LC score increased from 3.0 (unenhanced) to 4.0 (Orviglance).

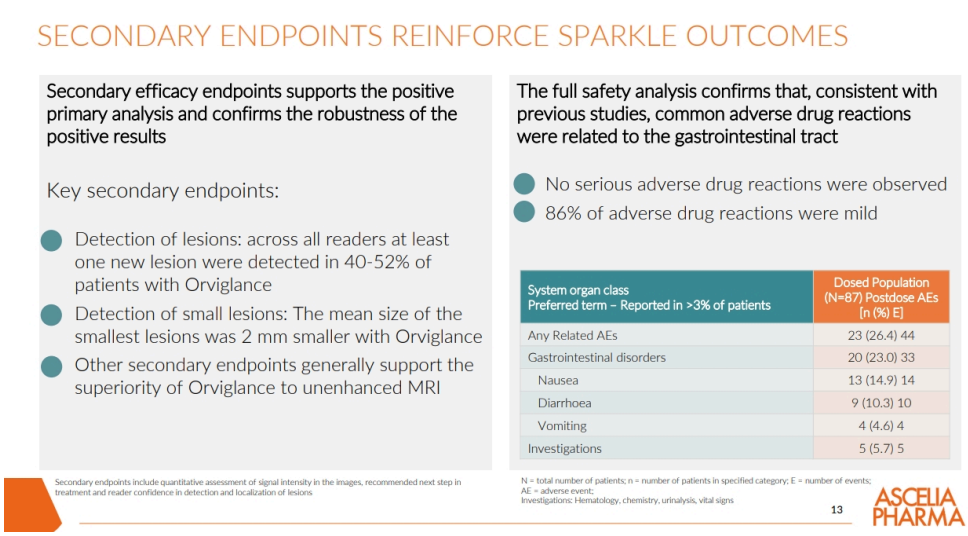
Analysis of the study's secondary endpoints showed that one additional lesion was detected in 40-52% of patients with Orviglance vs. unenhanced control, with the mean smallest lesion size being 2 mm smaller with Orviglance vs. control. Interestingly, even analysis of Orviglance-enhanced images alone, i.e. without the use of an unenhanced image as a reference, showed “comparable outcomes” to combined MRI (CMRI, Orviglance +unenhanced).

SPARKLE data demonstrates superiority of Orviglance (CMRI) vs unenhanced MRI (UMRI)



Source: Ascelia Pharma

Orviglance met secondary endpoints and has a mild tox (AE) profile



Source: Ascelia Pharma

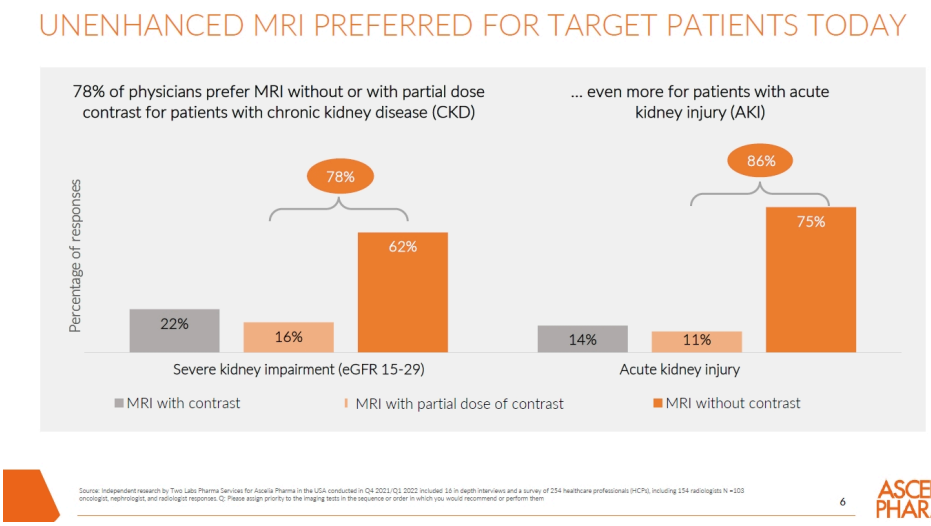
GBCAs are the current gold standard in MRI

Gadolinium-based contrast agents (GBCAs) are the gold standard in MRI imaging of body tissues. As free gadolinium is toxic, it is combined with a chelating ligand, making it suitable for use in humans. Several GBCAs have been developed, and based on their chemical structure they can be classified into two categories: linear or macrocyclic GBCAs.

First in 2006 the scientific community noted an association of GBCA-MRI and nephrogenic systemic fibrosis (NSF) in patients with impaired kidney function. After this observation, the FDA issued a class warning ("black box warning") for GBCAs, and both the US and EU regulatory authorities have retracted the marketing authorisation for four linear GBCA products associated with NSF. In the medical literature, cases of NSF after GBCA-MRI are reported as either confounded or unconfounded. Unconfounded means that only one type of GBCA was administered to the patient while confounded cases cannot rule out the implication of other compounds administered to the patient on a case-by-case basis.

Over the last ~20 years, the treatment paradigm for cancer patients with impaired kidney function (Orviglance target population) has shifted. Ascelia-sponsored market research among clinicians (HCPs) shows that a majority of physicians prefer to run MRI without a contrast agent (unenhanced MRI) in cancer patients with impaired kidney function (see survey results below). Unenhanced MRI is known to be inferior and provide less clinical value compared to contrast-enhanced MRI, as also shown in the SPARKLE trial. Therefore, some doctors (25-38%) still use MRI with a contrast agent (either at half or full dose), despite the risk of NSF. Notably, no beneficial effect of lower doses on the risk of developing NSF has been reported in the medical literature.

Majority of Orviglance target population undergo unenhanced MRI today



Source: Ascelia Pharma

ACR recommendations do not fully align with FDA

Interestingly, the Manual on Contrast Media issued by the American College of Radiology (ACR) contains guidance on risk assessment relative to NSF. The medical society classified GBCAs into group I agents associated with the greatest number of NSF cases and group II agents that were found to be associated with few, if any, unconfounded cases of NSF. Group I comprises three linear GBCAs that are no longer commercially available, while group II comprises a list of six GBCA molecules currently in use. Notably, the ACR suggests that renal function testing is optional prior to group II GBCA administration, deviating from the FDA guidelines/labelling:

"Based on the most recent scientific and clinical evidence [32-39] the ACR Committee on Drugs and Contrast Media considers the risk of NSF among patients exposed to standard or lower than standard doses of group II GBCAs is sufficiently low or possibly nonexistent such that assessment of renal function with a questionnaire or laboratory testing is optional prior to intravenous administration. As in all instances, group II GBCAs should only be administered if they are deemed necessary by the supervising radiologist, and the lowest dose needed for diagnosis should be used as deemed necessary by the supervising radiologist.[1]

[1]The ACR Committee on Drugs and Contrast Media recognises that as of this writing (4-6-2017), U.S. Food and Drug Administration (FDA) guidelines and drug labelling for GBCA have the same recommendations for each GBCA with respect to assessing renal function prior to GBCA administration. Nevertheless, the committee authoring this Manual has reviewed the evidence and believes that the prevailing weight of clinical evidence on this matter allows less stringent yet safe patient management which should reduce patient cost and inconvenience. This footnote is designed to alert readers that the ACR recommendations differ in case their personal philosophy or institutional policies necessitate adherence to the more restrictive FDA guidelines."

We believe that a majority of radiologists aware of NSF risks will preferably consult the nephrologist and run renal tests in patients with impaired kidney function to minimise patient and liability risks.

Classification of GBCAs relative to the risk of nephrogenic systemic fibrosis (NSF)

TABLE 1. ACR Manual Classification of Gadolinium-Based Agents Relative to Nephrogenic Systemic Fibrosis

Group I: Agents associated with the greatest number of NSF cases:
• Gadodiamide (Omniscan® – GE Healthcare)
• Gadopentetate dimeglumine (Magnevist® – Bayer HealthCare Pharmaceuticals)
• Gadoversetamide (OptiMARK® – Guerbet)
Group II: Agents associated with few, if any, unconfounded cases of NSF:
• Gadobenate dimeglumine (MultiHance® – Bracco Diagnostics)
• Gadobutrol (Gadavist® – Bayer HealthCare Pharmaceuticals; Gadovist in many countries)
• Gadoteric acid (Dotarem® – Guerbet, Clariscan – GE Healthcare)
• Gadoteridol (ProHance® – Bracco Diagnostics)
• Gadopiclenol* (Elucirem® – Guerbet, Vueway® – Bracco Diagnostics)
• Gadoxetate disodium (Eovist – Bayer HealthCare Pharmaceuticals; Primovist in many countries)
Group III: Agents for which data remains limited regarding NSF risk, but for which few, if any unconfounded cases of NSF have been reported:
• No agents currently in this category (as of April 2024)

*Gadopiclenol demonstrates kinetic stability and a long dissociation half-life that are comparable to other Group II macrocyclic agents. Based on the most recent scientific and clinical evidence [47-50], the ACR Committee on Drugs and Contrast Media considers the risk of NSF among patients exposed to standard or lower than standard doses of Gadopiclenol is sufficiently low or possibly nonexistent such that it has been classified as a Group II agent.

Source: American College of Radiology - 2024 Manual on Contrast Media

GBCAs have issues beyond NSF

GBCAs are administered intravenously, dosed according to weight. Specifically in the liver MRI setting, the two products gadoxetate disodium (Eovist by Bayer) and gadobenate dimeglumine (MultiHance by Bracco) are used in the clinic. The latter was used as a comparator in one of Orviglance's Ph 2 studies (CMC-P004, Brismar et al. 2012). While compounds belong to the class of linear GBCAs, they are classified into group II, i.e. of lower risk compared to group I agents.

Eovist is indicated for the detection of focal liver lesions, while MultiHance is indicated for the MRI of the central nervous system (FDA label). Notably, it has been observed that Eovist induces significantly more cases of transient dyspnea (shortness of breath), with negative effects on both the patient and the MRI image quality (Davenport et al. Radiology 2013). Furthermore, long-term accumulation of gadolinium in the brain of some patients has been observed. In contrast to manganese, gadolinium is not a natural trace element with a physiological function. Today, the associated risks are unknown but the use of GBCAs is ongoing due to the lack of alternatives and MRI's clinical value currently outweighs the unknown risk. Additionally, gadolinium is an environmental risk factor, as it cannot be removed in sewage plants, leading to contamination of aquatic systems.

Oncoral

Oncoral is a novel oral tablet formulation of the chemotherapy irinotecan, developed for the treatment of heavily pretreated metastatic gastric cancer. The project was added to Ascelia's portfolio through the acquisition of Oncoral Pharma ApS in 2017. Irinotecan is FDA-approved for the treatment of metastatic colon and metastatic pancreatic cancer and is administered intravenously. The drug is not approved for the treatment of gastric cancer in the US/EU, but is often used off-label as a late-line therapy.

Depending on the regimen (monotherapy or combo), intravenous irinotecan is initially administered weekly, followed by maintenance therapy every two or three weeks. A daily administration of irinotecan as an oral tablet would allow splitting today's standard high-dose iv infusion dose into smaller doses, decreasing the maximum serum concentration (Cmax) peaks following bolus infusions. This is believed to improve irinotecan's pharmacokinetic (PK) profile, as well as improve the toxicities associated with peak Cmax with current dosing regimens. One problem with currently approved irinotecan products is their poor tolerability/ toxicity profile. For example, Onivyde (irinotecan liposome), approved for pancreatic cancer, carries two black box warnings for severe or life-threatening neutropenia and diarrhoea.

Ph 1 programme completed

Oncoral was tested in a Ph 1 study in advanced late-line metastatic cancer patients, i.e. patients with no or limited treatment options (Kümler et al. Cancer Chemother Pharmacol 2019). The group comprised a wide variety of cancer types and the study's main goal was to test safety, tolerability and the maximum tolerated dose (MTD) of Oncoral. The first cohort of 25 patients was divided into four dose groups, and the MTD was determined at 21 mg/m^2. Diarrhoea was reported as the dose-limiting toxicity. Most patients in the study suffered from cholangiocarcinoma (bile duct cancer), some suffering from colon and pancreas cancer and none from gastric cancer. The study confirmed a beneficial PK profile of daily irinotecan and its active metabolite SN-38. Adverse events were reported at low frequencies and were of mild grade (1/2).

In a second cohort of 14 patients, the combination of Oncoral with the chemotherapy agent capecitabine was investigated. As in the first part, MTD was determined at a slightly lower dose of 17.5 mg/m^2, which is not surprising given that the drug was part of a combo regimen. The Ph 1 programme was not designed/powered to assess efficacy. None of the patients in the study achieved a response and some achieved stable disease (SD). Notably, 60%/21% of patients in part 1/2 (respectively) of the Ph 1 programme had prior treatment with “classic” intravenous irinotecan.

Lonsurf combo collaboration with Taiho

In 2021, Ascelia signed a collaboration agreement with Japanese Taiho Pharmaceutical (part of Otsuka Group), to investigate the combination of Ascelia's Oncoral with Taiho's Lonsurf in a Ph 2 study in metastatic gastric cancer. Lonsurf is an oral combination chemotherapy product FDA-approved for 3L+ metastatic gastric cancer (since 2019) and late-line heavily pretreated colorectal cancer. Taiho committed to supply Lonsurf to a Ph 2 study, which is planned to test the combination of Oncoral+Lonsurf against Lonsurf monotherapy in approx. 100 patients. The primary endpoint of the study would be progression-free survival (PFS), with secondary endpoints assessing response rate, safety and pharmacokinetics (PK).

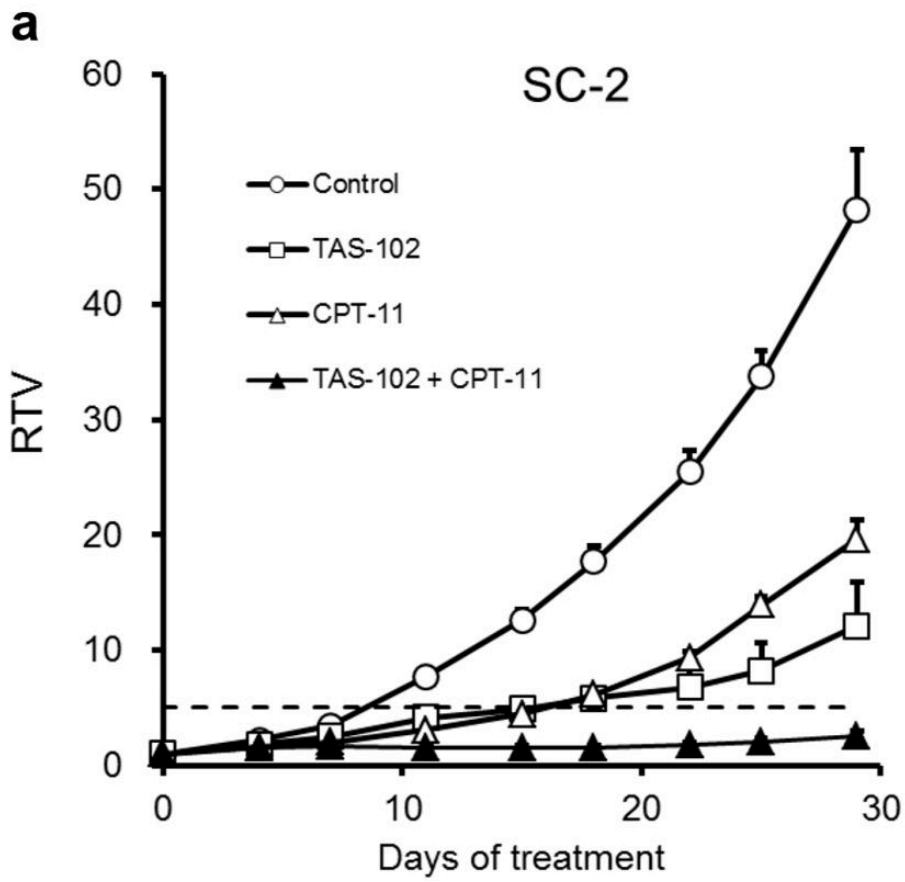
At longer follow-up, overall survival (OS) will be assessed. The key readout overall survival (OS) will also be assessed, as patients are followed up for a longer period of time. The Ph 2 programme has not been initiated yet (on hold). Once initiated, such a study is planned to take 2-2.5 years. Ascelia management has communicated that Oncoral development will be advanced once sufficient resources (cash) are available to finance such a study. We believe that this could happen once Ascelia has signed a licence agreement regarding Orviglance.

Early evidence for Lonsurf + irinotecan efficacy

Interestingly, the efficacy of Lonsurf in combination with Oncoral's API irinotecan was tested previously in mouse models of gastric and colorectal cancer, showing promising efficacy data (Nukatsuka et al. Anticancer Res. 2015, see below). An academic investigator-

sponsored single-arm Ph 1b trial (Dayyani et al. Med Oncol 2022) reported encouraging results of the combination of Lonsurf+ intravenous irinotean in 2L+ gastric cancer patients. The combination was tested in 20 patients, reporting progression-free survival results that were numerically higher compared to historical control (older irinotecan studies).

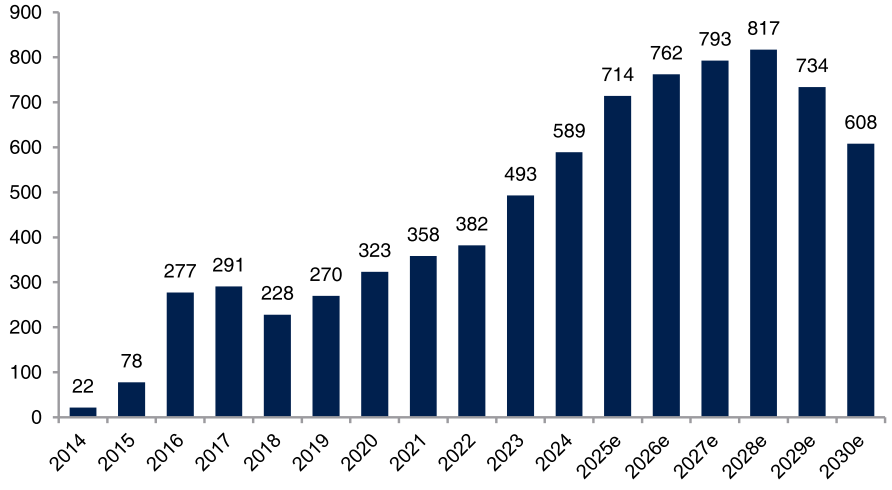
Relative tumour volume in mice with a gastric tumour treated with TAS-102 (Lonsurf) and CPT-11 (irinotecan)



Source: Nukatsuka et al. Anticancer Res. 2015

Footnote: RTV: Relative tumour volume, TAS-102: Lonsurf, CPT-11: Irinotecan

Lonsurf sales WW (USDm)



Source: Evaluate Pharma

Competitive landscape

Orviglance - no direct competition in sight

We do not foresee any direct competition for Ascelia that would provide a novel non-gadolinium option for the liver imaging market. However, we note that the Orviglance target population is subjected either to unenhanced MRI (without contrast agent) or to MRI with decreased GBCA dose. Some physicians might decide to continue with the current standard of care, despite it being subpar to Orviglance. Reasons could be cost/reimbursement, sufficient diagnostic accuracy in the case of unenhanced MRI, and an acceptable benefit/risk profile in certain patient subgroups (half-dose GBCA MRI).

In this context, it is noteworthy that another manganese-based MRI contrast agent was approved and marketed in the past:

Teslascan was the first manganese-based MRI contrast agent

Teslascan (mangafodipir trisodium, GE Healthcare) was approved by the FDA for the visualisation of liver lesions in 1997. However, the product was withdrawn from the US market in 2003 and from the EU market in 2012. Of note, the US retraction happened before the NSF issues with gadolinium-based contrast agents were known, i.e. the radiologists at that time did not see the need for a gadolinium alternative. The main reason for Teslascan's discontinuation was poor commercial performance and concerns about the accumulation and associated toxicity of free manganese in several body tissues.

Importantly — in contrast to Orviglance — the manganese ion in Teslascan would dissociate from the chelate (=> free manganese). Also, Teslascan was administered intravenously, in contrast to Orviglance's oral administration route. Studies with Orviglance have shown that the contrast-enhancing manganese, after absorption in the intestine, is transported through the blood stream to the liver. There, most of the metal ions are taken up by hepatocytes, reducing systemic toxicity effects. In the case of Orviglance, the drug also benefits from the “first pass effect”, which is the phenomenon that some (oral) drugs are being absorbed in the gut and the liver before reaching their target tissue, effectively reducing the drug's blood plasma concentration.

MRI contrast agent market peers

Several pharmaceutical companies are active in the MRI contrast agent space, including Bayer Healthcare, Bracco, GE Healthcare and Guerbet. Bayer Healthcare's Eovist/Primovist is currently the MRI contrast agent market leader for the detection of liver lesions. Bracco's MultiHance is only approved for the liver indication in Europe.

Currently approved MRI contrast agent products

Company	Product brand name	Active pharmaceutical ingredient (API)	Initial US approval	Structure	MRI indications (use)
Bayer Healthcare	**Eovist/Primovist**	gadoxetate disodium	2008	linear	**Liver**
	Gadavist/Gadovist	gadobutrol	2011	macrocyclic	CNS, breast cancer, cardiovascular
Bracco	ProHance	gadoteridol	1992	macrocyclic	CNS, head and neck
	MultiHance* (Gd-BOPTA)	gadobenate dimeglumine	2004	linear	CNS, angiography, **liver***
	Vueway	gadopiclenol**	2022	macrocyclic	CNS, Body
GE Healthcare	Omniscan***	gadodiamide	1993	linear	CNS, Body
	Clariscan (Gd-DOTA)	gadoterate meglumine	2019	macrocyclic	see Dotarem
Guerbet	Dotarem (Gd-DOTA)	gadoterate meglumine	2013	macrocyclic	CNS, Body and angiography
	Elucirem	gadopiclenol**	2022	macrocyclic	CNS, Body

*liver indication only in EU, not FDA-approved

**low-dose next-generation GBCA, collab. Bracco-Guerbet

***suspended marketing authorisation in EU, in US available but excl. patients with impaired kidney function

Source: ABG Sundal Collier

Footnote: Identical APIs marked in blue and copper.

New MRI contrast agents in development

The field of gadolinium-based contrast agents (GBCAs) is shifting towards novel, more potent gadolinium-based compounds that enable dose reductions. One example is the approved GBCA gadopiclenol (Vueway/Elucirem; see table above). Another novel GBCA in development is gadoquatrane by Bayer, which reported positive top-line results from a Ph 3 programme in Jan'25, showing that gadoquatrane has a non-inferior efficacy at a 60% lower dose compared to older macrocyclic GBCAs.

Gadoquatrane was tested in the CNS and other body regions (QUANTI CNS and QUANTI OBR studies). Bayer is going to submit the data package to regulatory authorities to secure approval. Notably, the novel macrocyclic Gd-based contrast agents are designed to stay in the blood circulation and are excreted through the kidneys. They are not liver-specific, such as Eovist/Primovist and Orviglance, which provide enhancement of healthy liver cells (hepatobiliary phase imaging). Therefore, we do not expect direct competition from the novel macrocyclic GBCAs.

Apart from Ascelia, three companies are pursuing the development of a novel manganese-based contrast agent:

1) The US biotech Reveal Pharmaceuticals is currently developing another manganese-based MRI contrast agent (RVP-001/Mn-PyC3A). The drug candidate completed a Ph 1 study in 2022 and is currently in Ph 2 testing in patients with gadolinium-enhancing CNS lesions (due to a tumour or multiple sclerosis). The study is expected to complete by YE'25. In contrast to Ascelia's Orviglance, the drug is administered intravenously, but due to its chemical design it is expected to release only minor amounts of free manganese in the body.

2) GE Healthcare reported positive results of a “first-of-its-kind” macrocyclic manganese-based contrast agent from a Ph 1 clinical trial in Oct'24. While no specific further development plans were disclosed, the company communicated that the compound is expected “to be diagnostically similar” to current GBCAs.

3) Spago Nanomedical develops a nanoparticle-based manganese contrast agent for the detection of breast cancer.

Of note, when administered intravenously, the liver uptake of manganese-based contrast agents is relatively low compared to a liver-specific agent, such as Orviglance. Consequently, they would provide only suboptimal contrast in the liver, and we expect the two intravenous agents under development to target a general purpose MRI (CNS, body scan), rather than liver-specific MRI (Orviglance).

Novel MRI contrast agents currently in development

Company	Active pharmaceutical ingredient (API)	Current clinical development status	Structure	MRI indications
Gadolinium-based				
Bayer Healthcare	gadoquatrane	Ph 3 completed	Macrocyclic	CNS, Body
Manganese-based				
GE Healthcare	?	Ph 1 completed	Macrocyclic	?
Reveal Pharmaceuticals	RVP-001/Mn-PyC3A	Ph 2 ongoing	Macrocyclic	CNS
Spago Nanomedical	pegfosimer manganese	Ph 1 completed	Nanoparticle	Breast cancer/endometriosis

Source: ABG Sundal Collier

Oncoral

Interestingly, an oral irinotecan was under development by the US company Athenex Inc. The drug candidate, called oratecan, is a combination of irinotecan and encequidar methanesulfonate. The latter compound increases the oral bioavailability of irinotecan. In 2022, Ph 1 study results in heavily pretreated advanced cancer patients were reported, concluding that the “safety profile of oratecan was comparable to that of intravenous irinotecan”. The trial's sponsor Athenex filed for bankruptcy in 2023 and no additional updates have appeared since then.

Intellectual property

Ascelia's lead product Orviglance received orphan drug designation (ODD) from the FDA in 2013. ODD grants drug developing companies (sponsors) a set of incentives incl. tax credits, exemption from FDA fees and — importantly — seven years of market exclusivity post-approval. Additionally, Ascelia holds patents on an effervescent tablet formulation of Orviglance (2G Orviglance). Oncoral's composition of matter patent was filed in January 2015 and has been granted in the US, the EU, Canada Japan and South Korea. An additional composition patent focused on the intended product was filed in July 2016, which has been granted in the US and is pending in China.

2G Orviglance - IP overview - 13 March 2025

Ref. no.	Country	Status	Application no.
P5268-family - 2G Orviglance			
P5268AU00	Australia	Pending	2020288337
P5268BR00	Brazil	Pending	BR 11 2021 024212 0
P5268CA00	Canada	Pending	3140098.0
P5268CN00	China	Granted	202080052687.7
P5268EP00	European Patent Application	Closed, Priority Founding	19179015.3
P5268EP01	European Patent Application	Pending	*20730067.4*
P5268IN00	India	Granted	*2.02117E+11*
P5268JP00	Japan	Granted	*2021-572307*
P5268KR00	South Korea	pending	10-2021-7040297
P5268US00	United States	Granted	16/895,263
P5268US01	United States	Pending	17/617,131
P5987-family - food effect			
P5987AU00	Australia	Pending	2023264268
P5987BR00	Brazil	Pending	BR 11 2024 022993 9
P5987CA00	Canada	Pending	3251759
P5987CN00	China	Pending	202380045161.X
P5987EP00	European Patent Application	Closed, Priority Founding	22171769.7
P5987EP01	European Patent Application	Pending	23724770.5
P5987JP00	Japan	Pending	2024-565085
P5987PC00	PCT Application	Closed, Priority Founding	PCR/EP2023/061741
P5987KR00	South Korea	Pending	10-2024-7039505
P5987US00	United States	Pending	18/861,742

Source: Ascelia Pharma

Oncoral IP overview - 19 March 2025

Ref. no.	Country	Status	Application no.
P5786-family - solid oral dosage form of irinotecan			
P5786CA00	Canada	Granted	2973906
P5786CN00	China	Granted	201580013710.0
P5786CN01	China	Pending	201910899370.6
P5786EP00	European Patent Application	Closed	14151688.0
P5786EP01	European Patent Application	Granted	15700474.8
	Netherlands	Granted	*15700474.8*
	France	Granted	*15700474.8*
	United Kingdom	Granted	*15700474.8*
	Germany	Granted	*15700474.8*
	Ireland	Granted	*15700474.8*
	Italy	Granted	*15700474.8*
	Turkey	Granted	*15700474.8*
	Switzerland	Granted	*15700474.8*
	Spain	Granted	*15700474.8*
P5786JP00	Japan	Granted	2016-545356
P5786PC00	PCT Application	Closed	PCT/EP2015/050728
P5786KR00	South Korea	Granted	10-2016-7022358
P5786US00	United States	Granted	15/112,157
P5786US01	United States	Granted	16/120,451
P5786US02	United States	Granted	17/865,734

Source: Ascelia Pharma

Outlook

Following the positive SPARKLE top-line results, Ascelia conducted a pre-submission meeting with the FDA in Q1'25. The submission of the new drug application (NDA) to the FDA is expected by mid-'25. Ascelia aims for the following US FDA label:

"Orviglance is a manganese-based contrast agent indicated for oral use with magnetic resonance imaging (MRI) to improve detection and visualization of lesions in patients with focal liver disease for patients with severe renal insufficiency or acute kidney injury or where use of gadolinium may be otherwise medically inadvisable."

In parallel, Ascelia is working on establishing commercialisation partnerships and advance launch readiness, with an initial focus on the US.

Meanwhile, Ascelia engages in public outreach activities in the scientific community. For example, the SPARKLE dataset was presented at the American Society of Nephrology (ASN) Kidney Week in October 2024, and at the Radiological Society of North America (RSNA) Annual Meeting in Dec'24. This year, SPARKLE was presented at the Society of Abdominal Radiology Congress 2025 in February 2025. In May, Ascelia will present its dataset at the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Annual Meeting.

Additionally, a real-world claims analysis on the "burden of illness in US patients with liver cancer and kidney disease" is scheduled to be presented at the ISPOR Health Economics conference, also in May. These activities are very important to increase product awareness ahead of the planned US market launch in 2026.

Market forecasts and estimates

Orviglance

We apply a bottom-up approach to estimate the Orviglance market opportunity. Orviglance's target patient population is very niched, which makes it inherently difficult to precisely assess the market sizes. Incidence rates of secondary liver metastases vary a lot depending on the primary cancer type. The same applies to rates of kidney impairment (CKD, AKI) among different cancer patients, which also vary with the cancer patient's disease stage. Advanced cancer patients with metastases usually have higher rates of kidney impairment.

We focus our valuation of Orviglance on the US market, which is the largest commercial opportunity and Ascelia's initial focus market. Furthermore, we focus on the cancer types that commonly develop liver metastases. The list below is sorted according to the primary cancer type with the highest to the lowest incidence rate of liver metastasis at diagnosis. Liver metastases in pancreatic cancer are very common, and we therefore assume that all primary pancreatic cancer cases will directly be referred to MRI screening to identify liver metastases.

In the case of upper GI tract cancers (oesophagus, stomach, small intestine), we assume an average screening rate of 150%, i.e. we model with an “overscreening”, as not all cancer patients referred to MRI will be confirmed to have liver metastases. In other words, a 150% screening rate implies that out of 3 MRI procedures performed, 2 are confirmed to have liver lesions/metastases (detection rate of 67%). We believe such a high detection rate is warranted, considering that many patients will be examined with alternative liver imaging methods, such as ultrasound and CT. In the case of colorectal cancer, we increase our screening rate estimate to 375%, which implies that ~60% of all primary tumour cases will eventually be referred to MRI. The reason for this higher estimate comes from literature showing that up to 50-70% of colorectal cancer patients will develop liver metastases.

In lung cancer, and particularly in breast cancer, liver metastases are less common, but we also apply a screening rate of 150% for these two cancer types. Our calculation yields approximately 270k cancer patients subjected to MRI in the US every year. Ascelia aims for an Orviglance label including cancer patients with acute kidney injury (AKI) or chronic kidney disease (CKD) grade 4 or 5.

US incident cases of primary/secondary liver tumours by primary indication

Primary cancer type	Primary tumour cases (SEER est. incident cases per year)	Incidence of liver metastasis at diagnosis	Cases with secondary liver metastases (literature)	Screening rate (function of actual cases detected)	Est. no. of patients subjected to MRI	% of primary tumour patients sent to MRI
Pancreas	66,440	40%	26,549	All primary cases	66,440	100%
Small intestine	12,000	17%	2,098	150%	3,146	26%
Oesophagus	22,000	17%	3,630	150%	5,445	25%
Stomach	27,000	16%	4,444	150%	6,666	25%
Colon & rectum	153,000	16%	24,480	375%	91,800	60%*
All lung	235,000	13%	29,798	150%	44,697	19%
All breast	310,000	1%	4,557	150%	6,836	2%
Liver	42,000				42,000	
Total	867,440		95,556		267,030	

Source: Wang et al. Am J Cancer Res 2020, NIH NCI SEER, ABGSC estimates

*Footnote: *50-70% of advanced colorectal cancer patients will develop liver metastases (Ascelia IPO prospectus, NCCN guidelines)*

Prevalence of chronic kidney disease (CKD) in cancer patients

A Romanian database study (Ciorcan, Chisavu et al. PLoS One 2022) found that the prevalence of CKD among cancer patients varies between 2.5-50%, dependent on the primary cancer type. Not surprisingly, about 50% of patients with kidney cancer suffer also from CKD. Among the cancer types listed above, i.e. common tumours that often develop liver metastases, the prevalence ranges between 5% and 20%, with most of the tumour types in the range 10-20%. Importantly, the definition of CKD in the cited study included CKD gr. 3 patients, which are not targeted by Ascelia.

The study notes that ~25% of patients in the study suffered from gr. 4&5 CKD. The study was run with a global cohort of cancer patients, i.e. it included patients with early-stage cancer and patients with advanced-stage cancer. Notably, patients with liver metastases are already in an advanced stage, often old/frail people. All in all, we assume conservatively that on average ~2.5% of cancer patients with liver lesions suffer from comorbid CKD gr. 4-5.

Prevalence of acute kidney injury (AKI) in cancer

Ascelia aims for the inclusion of acute kidney injury (AKI) in the Orviglance FDA label. As mentioned above, the Ph 3 SPARKLE study enrolled a broad patient population with impaired kidney function (eGFR <30 mL/min/1.73 m^2). Therefore, we see a good probability that Ascelia will get a label incl. both AKI and chronic kidney disease (CKD) patients. The incidence of AKI in cancer patients has been described in the literature as between 7.5% in a Chinese study and 17.5% in a Danish study (Meraz-Munoz et al. Diagnostics 2021). A Canadian, population-based study reported a cumulative AKI incidence of 9.3%. In our model we assume a conservative AKI prevalence of ~2.5% in the US.

Notably, as the name implies, AKI is an acute condition, i.e. the oncology-radiology clinical team might decide to postpone the MRI until clinical remission/improvement, instead of running MRI with contrast agent on an acutely ill patient.

Potentially ~12k US cancer patients eligible for Orviglance

In the next step, we apply the estimated prevalence of AKI/CKD on the number of cancer patients with liver metastases, yielding an Orviglance target patient population of ~6k patients with AKI and ~6k patients with CKD. Typically, a cancer patient will undergo multiple MRI procedures to follow the development of liver metastases. We assume that each patient will undergo on average five MRI procedures, as cancer progression will need to be assessed at regular intervals (before/during/after therapy). As our initial model starts from incidence rates, we believe it is reasonable to assume that half of the MRI procedures, i.e. 2.5 are run in “new”, incident patients, while the remaining 2.5 procedures are run in prevalent (i.e. ex-incident) patients as a follow-up screening later. When liver metastases are detected, the average patient will be referred to surgery or alternative treatment regimens (if unresectable). If the patient has undergone treatment, follow-up MRIs are necessary in the following years to track potential cancer recurrence.

Our calculation yields a total number of ~60k potential MRI procedures with Orviglance per year. We expect that Orviglance could take 60% of the market, i.e. cancer patients with liver lesions and impaired kidney function, corresponding to ~36k MRI procedures with Orviglance p.a. in the US. For the important ex-US markets EU5 and Japan (JP), we assume the same prevalence of cancer patients with liver lesions and impaired kidney function in the general population. To simplify the calculation, we divide the number of target MRI procedures for Orviglance in the US (~60k) by the total US population, yielding a value of ~181 Orviglance-target MRI procedures per million population in the US. Then, we apply this number on the population of EU5 and JP, but cut the net treatment price to USD 1,000 per dose in EU+JP.

US cancer patients with liver tumours and impaired kidney function

Total cases referred to MRI	267,030
% receiving liver MRI	90%
% with advanced CKD (G4/5+)	2.5%
% with AKI (ABGSCe, literature)	2.5%
No. cancer pts with liver tumours and CKD in US	6,008
No. cancer pts with liver tumours and AKI in US	6,008
Number of annual procedures per incident patient	2.5
Number of annual procedures per prevalent (ex-incident) patient	2.5
Number of MRI procedures - candidates for Orviglance	60,082
Market penetration	60%
No. of MRI procedures with Orviglance	36,049

Source: ABGSC estimates

Pricing will be the key variable

Current gold-standard gadolinium-based contrast agents sell at list prices of USD 100-150 per dose (Eovist, MultiHance; Source: drugs.com). Ascelia's own market research suggests a price range benchmark of USD 3,000-4,500 for one Orviglance dose (analyses with Revenue Reimbursement Solutions and Charles River associates (2020), Triangle and (2022) Trinity (2022)).

US premium pricing will be key for Orviglance and it has a profound impact on Ascelia's valuation. Therefore, we have performed a sensitivity analysis on US pricing, assuming Orviglance gross prices of USD 1,500/2,500/3,500 per dose, applying a 25% gross-to-net discount. We also incorporate annual price increases (inflation adjustments) of 2% p.a. after launch in 2026e. For the ex-US markets EU5 and JP, we assume a flat net price of USD 1k per dose of Orviglance (not detailed here). Accounting for the remaining commercial risk, we apply a 90% risk adjustment on future US & EU5 sales. We have limited visibility on potential regulatory requirements in Japan, and we believe a Japanese study will be required to obtain regulatory approval there, so we lower the risk adjustment for this market to 70%. We anticipate Orviglance launch in the US in H2'26e, followed by EU5 and JP in '27/'28e, respectively.

US Orviglance model price sensitivity analysis

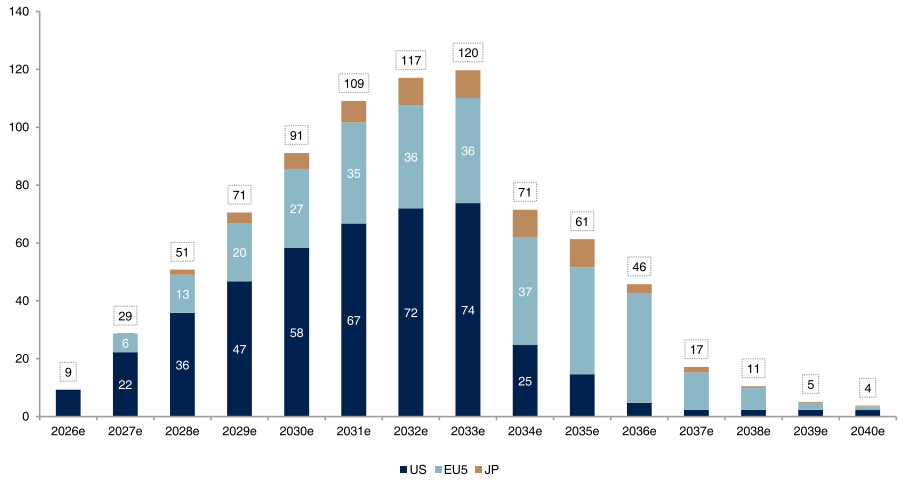
Scenario	US list price (USD/dose)	Net treatment price (USD)	Annual US peak sales (USDm)*	Annual WW peak sales (USDm)*	Peak sales split US	Potential annual peak royalty income* (USDm)
A	1,500	1,125	49	101	49%	20
B	2,500	1,875	82	133	62%	27
C	3,500	2,625	115	165	70%	33

Source: ABGSC estimates

*Footnote: *non-risk-adjusted, royalty rate 20%*

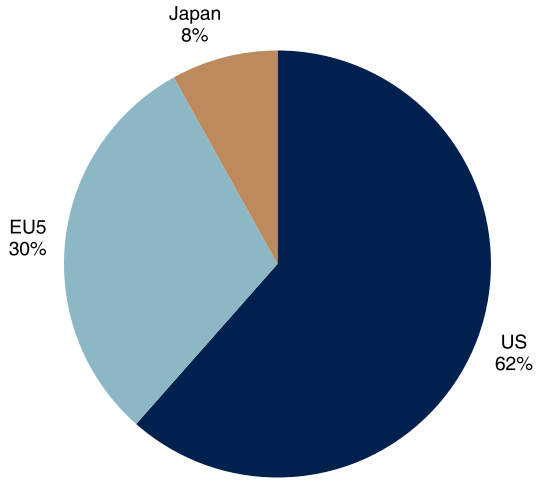
Risk-adj. WW Orviglance sales (USDm)

Scenario B - USD 2,500 per dose



Source: ABG Sundal Collier

Orviglance annual peak sales regional split, risk-adjusted (Scenario B)



Source: ABG Sundal Collier

Footnote: Risk-adjustments: US&EU5 90%, JP 70%

MRI market peer deals

The MRI contrast agent market is characterised by generally slow innovation cycles. In 2019, the large player Bracco Diagnostics acquired Blue Earth Diagnostics for ~USD 450m. Blue Earth is the original developer of an imaging agent for PET scans (Axumin). In 2015, Mallinckrodt sold its contrast media and delivery systems (CMDS) unit to French Guerbet for USD 270m.

Ascelia aims to outlicense the commercial rights to Orviglance to a partner. We assume a classic Biopharma licensing deal composed of an upfront (USD 10m), milestones (up to USD 50m), and royalty payments (20% on net sales). Ideally, the partner company should have a commercial footprint in the MRI contrast agent space, facilitating Orviglance's commercialisation. Based on our peak sales & market estimates, we model a licensing deal with the following structure:

Orviglance License deal assumptions (USDm)

Upfront	10
Milestones	up to 50
Royalties	20%

Source: ABG Sundal Collier

Oncoral

We model Oncoral's commercial opportunity in the 3L+ gastric cancer setting in the US, EU15 and Japan (JP) using epidemiological data. Every year ~27k patients in the US are diagnosed with gastric cancer (NCI SEER). Of these, approximately one third (35%) have metastases at diagnosis (Sirody et al. Am J Surg. 2022). Since a significant proportion of non-metastatic gastric cancer patients will progress to advanced/metastatic disease, we add a 10pp premium to account for patients progressing to metastatic stage.

Prognosis of gastric cancer remains poor, with some patient subpopulations barely reaching a median overall survival (mOS) of ~12 months. In the last decades, some improvement was achieved with novel immunotherapies (Keytruda, Opdivo, Herceptin, Enhertu), which are used in combination with chemotherapy, in the first- or late-line. To be eligible for immunotherapy, the presence of certain tumour biomarkers (e.g. HER2 positivity for Herceptin, Enhertu) is required.

According to Lonsurf's FDA label, patients with gastric or gastroesophageal junction adenocarcinoma are eligible for the treatment. Adenocarcinoma is by far the most common gastric tumour type (~95%). Furthermore, to be eligible for Lonsurf, gastric cancer patients need to have been treated with "at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy". Importantly, some patients will refrain from further therapy after one or more failed therapies, while others might not reach 3L+ due to death. Hence, we estimate that ~70% of all metastatic gastric cancer patients will eventually be eligible and willing to take Lonsurf+Oncoral combination therapy.

We estimate a market launch in 2030e, and forecast a rather rapid market uptake, since Lonsurf is already an established product, facilitating market access for the Oncoral combo. Given the lack of alternative treatment at this cancer stage, we do not foresee any considerable competition, hence our 50% peak market penetration estimate. To estimate an approximate pricing point for Oncoral, we assessed the current Lonsurf pricing scheme:

Calculation Lonsurf average annual gross treatment price:

Lonsurf's recommended dosing scheme (body surface area-based dosing applied to an "average" person) **x**

The drug's price of ~ USD 230 per tablet (drugs.com) **x**

The treatment period (10 days of treatment per 28 days time interval).

This estimate yields an average annual gross treatment price of USD 276k for Lonsurf. We estimate that Oncoral could offer an incremental clinical benefit for patients, and apply a 75% discount on the Lonsurf estimate to reach an Oncoral annual gross treatment price of USD 69k in the US. As a reference, we calculated the annual list price for Onivyde (liposomal irinotecan) at USD 216k per year, although many patients will not take the drug for a year but instead discontinue it earlier due to toxicity.

Also, considering the advanced stage of disease these patients are in (poor survival prognosis), we assume that an average treatment duration is only ~3 months (~USD 17k gross price for a 3-month period). Of note, the price premium for the Oncoral combo vs. Lonsurf monotherapy will be dependent on the clinical benefit proven in late-stage clinical studies: Oncoral+Lonsurf will need to show a statistically significant and clinically meaningful benefits vs Lonsurf monotherapy. We discount the potential annual Oncoral gross treatment price of USD 69k by 25/50% in the US and EU15+JP, respectively. Our model yields non-risk-adj. peak sales of USD 125m in '34e (US+EU5+JP).

To account for the future risks of clinical development, we apply a conservative risk adjustment of 5% on our annual revenue estimates: On the one hand, irinotecan is already in off-label use in gastric cancer and on-label use in multiple other tumours with a known efficacy and toxicity profile, which improves the prospects for Oncoral. On the other hand, we acknowledge that the project has been on clinical hold in the recent years, delaying Oncoral's path to market. Besides, our low risk adjustment reflects the uncertainty around pricing power, which will depend on the added clinical benefit in late-line gastric cancer

patients. Another risk is that Oncoral might be superseded by novel drugs by the time it reaches the market.

We believe that Taiho could decide to license Oncoral for worldwide commercialisation rights as part of Lonsurf's commercial life-cycle management, but leave this is an upside optionality at this moment and do not incorporate this into our model. Instead, our assumption is that Oncoral will be co-commercialised with Lonsurf, leading to positive business synergies for both Ascelia and Taiho. Ascelia will book Oncoral sales, while Taiho will benefit from an extended commercial lifecycle for Lonsurf.

Valuation summary

Orviglance could become a novel option for advanced cancer patients with a kidney comorbidity (AKI/CKD), which are currently excluded from the use of gold standard gadolinium-based contrast agents, due to the risk of the severe adverse effect nephrogenic systemic fibrosis (NSF). In the last twenty years, companies active in the MRI contrast agent space have become increasingly aware of these issues, leading to discontinuations of old linear GBCAs associated with the highest risk of NSF. Recently, companies have also worked on testing gadolinium dose reductions, reducing environmental impact while maintaining clinical value (MRI contrast). However, an effect of dose on the risk of developing NSF has not been established. Following FDA submission and the signing of a partnership deal, Ascelia will likely take up development of its 2nd asset Oncoral again.

Our valuation is based on a discounted cash flow (DCF) calculation, which includes the projected revenue stream for Ascelia in the period '25e-'40e, mostly derived from the expected Orviglance licensing deal, yielding upfront, milestones and royalty payments in the future.

We model three different DCF scenarios:

In **scenario A**, we assume an Orviglance US list price of USD 1,500 (see market model above), yielding a DCF-fair value of **SEK 2.6/share**.

In **scenario B**, we assume an Orviglance US list price of USD 2,500 (see market model above), yielding a DCF-fair value of **SEK 3.9/share**.

In **scenario C**, we assume an Orviglance US list price of USD 3,500 (see market model above), yielding a DCF-fair value of **SEK 5.1/share**.

For all three scenarios, we use a weighted average cost of capital **(WACC) of 15%** over the period '25e-'40e and incorporate the proceeds and dilution effect from the recent warrants TO1 exercise period into the model. As outlined above, the vast majority of income over this period is modelled as derived from a WW licensing deal for Orviglance, while only a minority of the revenue stream is derived from Oncoral sales, which still has a long path to market ahead.

At the bottom line, this yields our fair value range of SEK 2.6-5.1 per share for Ascelia Pharma.

DCF scenarios

Common DCF assumptions	
Ordinary shares, Q2'25e	116.0m
Debt Q2'25e (SEKm)	7.5m
Cash Q2'25e (SEKm)	48.5m
FX USD/SEK	10.0

DCF Scenario A

Discount rate	DCF '25e-'40e	+	Terminal Value	=	Enterprise Value
13.0%	294		0		294
14.0%	274		0		274
15.0%	**266**		**0**		**266**
16.0%	239		0		239
17.0%	224		0		224

Discount rate	+	Net Debt	=	Equity Value	Price per Share
13.0%		-41		335	2.9
14.0%		-41		315	2.7
15.0%		**-41**		**307**	**2.6**
16.0%		-41		280	2.4
17.0%		-41		265	2.3

Source: ABG Sundal Collier

DCF Scenario B

Discount rate	DCF '25e-'40e	+	Terminal Value	=	Enterprise Value
13.0%	449		0		449
14.0%	423		0		423
15.0%	**408**		**0**		**408**
16.0%	375		0		375
17.0%	354		0		354

Discount rate	+	Net Debt	=	Equity Value	Price per Share
13.0%		-41		490	4.2
14.0%		-41		464	4.0
15.0%		**-41**		**449**	**3.9**
16.0%		-41		416	3.6
17.0%		-41		395	3.4

Source: ABG Sundal Collier

DCF Scenario C

Discount rate	DCF '25e-'40e	+	Terminal Value	=	Enterprise Value
13.0%	605		0		605
14.0%	572		0		572
15.0%	**550**		**0**		**550**
16.0%	512		0		512
17.0%	484		0		484

Discount rate	+	Net Debt	=	Equity Value	Price per Share
13.0%		-41		646	5.6
14.0%		-41		613	5.3
15.0%		**-41**		**591**	**5.1**
16.0%		-41		553	4.8
17.0%		-41		525	4.5

Source: ABG Sundal Collier

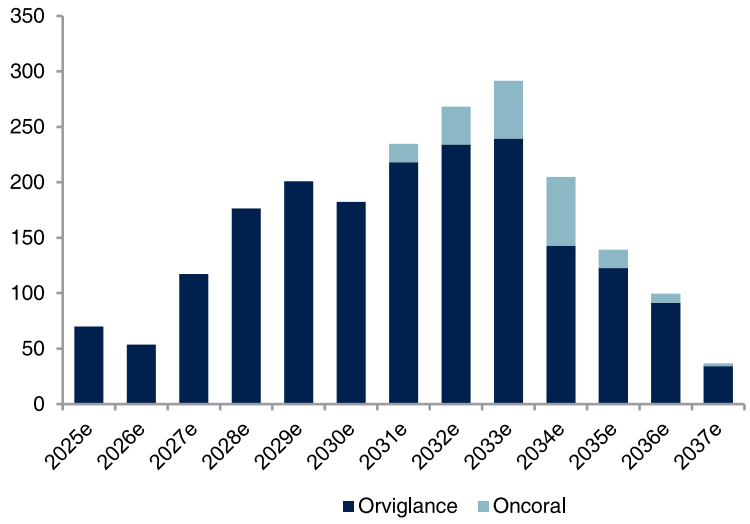
Orviglance revenue stream model (Scenario B, SEKm)

Orviglance license deal	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2034e	2035e
Upfront	100									
Milestones		50	100	150	200					
Risk adjustment on upfront & milestones	***70%***	***70%***	***60%***	***50%***	***30%***					
Upfront	70									
Milestones		35	60	75	60					
20% royalties on net sales*		19	57	102	141	182	218	234	143	123
Total revenue	*70*	*54*	*117*	*177*	*201*	*182*	*218*	*234*	*143*	*123*

*Scenario B, est. US & EU Annual sales risk-adjusted by 90%, JP risk-adj. by 70%
Assumption: Worldwide Orviglance licensing deal

Source: ABG Sundal Collier estimates

Revenue stream Orviglance & Oncoral (SEKm)



Source: ABG Sundal Collier

Footnote: Orviglance license Upfront: 2025e, Milestones 2026-29e, Royalties from 2026e onwards

P&L estimates (Scenario B)

SEKm, risk-adjusted	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e
Orviglance income (license deal)	70	54	117	177	201	182	218	234	239	143	123
Oncoral net sales	0	0	0	0	0	0	17	34	52	62	17
Total revenue	**70**	**54**	**117**	**177**	**201**	**182**	**235**	**268**	**292**	**205**	**139**
Gross profit	**70**	**54**	**117**	**177**	**201**	**182**	**233**	**265**	**288**	**201**	**138**
Total operating expenses	**-80**	**-99**	**-111**	**-119**	**-68**	**-55**	**-43**	**-38**	**-37**	**-37**	**-34**
R&D	*-47*	*-51*	*-56*	*-61*	*-40*	*-26*	*-13*	*-6*	*-5*	*-5*	*-5*
SG&A	*-33*	*-48*	*-56*	*-58*	*-29*	*-30*	*-31*	*-32*	*-33*	*-33*	*-30*
Other	*0.4*	*0.5*	*0.5*	*0.6*	*0.8*	*0.9*	*0.9*	*0.8*	*0.8*	*0.7*	*0.7*
EBIT (Operating result)	**-10**	**-45**	**6**	**57**	**133**	**127**	**190**	**228**	**251**	**164**	**105**
EBIT margin	-14%	-84%	5%	33%	66%	70%	81%	85%	86%	80%	75%
Net financial items	**-5**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Pretax profit	**-15**	**-45**	**6**	**57**	**133**	**127**	**190**	**228**	**251**	**164**	**105**
Net profit	**-15**	**-45**	**6**	**57**	**133**	**127**	**150**	**180**	**198**	**129**	**83**
Ordinary share no. (m)	116	116	116	116	116	116	116	116	116	116	116
EPS	**-0.13**	**-0.39**	**0.05**	**0.50**	**1.14**	**1.10**	**1.29**	**1.55**	**1.71**	**1.12**	**0.71**
Operating cash flow	**-14**	**-45**	**6**	**57**	**133**	**127**	**150**	**180**	**198**	**129**	**83**
Free cash flow	**-29**	**-45**	**6**	**57**	**133**	**127**	**230**	**276**	**303**	**198**	**127**

Source: ABG Sundal Collier

Footnote: Orviglance market launch in 2026e and Oncoral market launch in 2031e

P&L assumptions

R&D expenses include costs for future Oncoral clinical development until the end of Ph 2, at which point Ascelia will likely out-license the asset due to high capital requirements for pivotal Ph 3 development. Dependent on the targeted Oncoral label (i.e. prove superiority or non-inferiority vs. standard of care) the associated costs for a Ph 3 programme and the commercial opportunity could vary a lot. Therefore, we do not currently include any late-stage clinical development estimates for Oncoral and we also do not include an Oncoral licence deal in our estimates at this time.

SG&A expenses include costs for Orviglance regulatory filings in all geographies and commercial preparation in the US. Furthermore, they include the base run-rate of the company, i.e. administrative costs (mostly employee salaries, office rent, etc.). We assume increasing costs for filings and commercial preparation in the coming years.

In a licence deal, Ascelia will likely keep full ownership of the Orviglance clinical data and regulatory process expertise. This means that Ascelia will finish regulatory filings alone in the most important US and EU geographies and carry the associated costs. Additionally, a potential licence partner would likely require support for commercial preparation, which we include under “commercial preparation costs”. The more responsibilities Ascelia keeps, the higher the potential value of an Orviglance licence deal, while a full out-sourcing of the Orviglance programme would lower internal Ascelia costs to a minimum (basically only administrative costs), although the value from the licence deal could be reduced.

COGS: Orviglance COGS is carried by the licence partner, although we believe that COGS is negligible for Orviglance, as manufacturing of manganese chloride tetrahydrate is very inexpensive. For Oncoral, we calculate single-digit % COGS on sales.

Risks

Product development risk

Ascelia's lead product Orviglance has completed clinical development with the full readout of the Ph 3 SPARKLE trial. The Orviglance development risk can therefore be considered minor. Oncoral has only completed Ph 1 and is subject to a significant future development risk. The novel formulation of the chemotherapy irinotecan will need to prove its clinical efficacy in combination with Taiho's Lonsurf in late-stage clinical development (Ph 2/3).

Regulatory risk

Orviglance's pivotal Ph 3 SPARKLE trial was designed to meet the regulatory prerequisites, but it cannot be excluded that the FDA will request additional data or analyses before potentially granting approval. SPARKLE's first readout failed due to high intra-reader inconsistency, which may cast doubts of the regulatory authorities on the objectivity of the results.

Commercial risk

Ascelia is seeking a commercial partnership to launch Orviglance in the US. The failure to find such a partner is a risk. A commercial salesforce will need to be built in the US to address radiologists and convince them to use Orviglance in clinical practice. The achievement of profitable premium pricing and payor (health insurance) reimbursement is another component of Ascelia's commercial risk.

Competitive risk

To our knowledge, there is no potential direct competition to Orviglance currently in clinical development. However, competition might arise from cheaper SoC gadolinium-based MRI agents, which some radiologists might use at a lower dose. Novel drugs in development for the treatment of gastric cancer with a potentially better efficacy could impact Oncoral's market prospects negatively.

Liquidity risk

Costly investments are required to launch Orviglance in the US. Currently, it is planned that a commercialisation partner will take these costs and in return book most of the revenue. If a partner is not found, Ascelia might decide to commercialise the product on its own initiative. This comes with a significant cost to build up a salesforce, for which additional capital beyond Ascelia's current cash reserves is required. Ascelia's current financial runway excl. warrants and a potential partnership extends to YE'25.

Currency risk

Ascelia will derive its revenue mostly from the US and EU. Therefore, Ascelia will be exposed to a currency risk and the revenue is subject to exchange rate (FX) movements.

Appendix 1: Financial history since IPO

Date	Description
2019-05-15	Ascelia Pharma completed its IPO, raising SEK 200 million and gaining over 6,000 new institutional and private shareholders. Shortly after, the overallotment option was exercised, generating an additional SEK 22 million. This successfully financed the Phase III clinical program for Mangoral (Orviglance), the company's lead product candidate.
2020-06-30	Directed share issue raising approximately SEK98.7m, including the existing shareholders AP4 and Handelsbanken Fonder together with a group of new investors: Healthinvest Partners, Länsförsäkringar Fondförvaltning, Unionen and ÖstVäst Capital Management, among others.
2021-03-17	Directed share issue, raising SEK 200m from Swedish and international investors (AP4, Healthinvest Partners, Handelsbanken Fonder)
2024-02-04	Loan financing with Formue Nord Fokus A/S (SEK 35m). Consisting of a loan facility of up to SEK 20 m + convertibles (SEK 15m). On the same day, payment of first tranche: SEK 5m loan facility + SEK 15m convertible. Arrangement fee of 5%.
2024-04-18	Draws down the SEK15m second tranche of the loan.
2024-07-10 → 2024-09-05	The rights issue, announced on July 10, was fully subscribed, raising SEK 105m. The subscription price per unit was SEK 5.07 (1 unit = 3 shares + 1 Warrant TO1).
2025-04-16	96% of the warrants TO 1 were exercised at a price of SEK 2.15 (70% of VWAP 14-28 March), yielding gross proceeds of ~SEK 43m. Use of proceeds for repayment of Fenja Capital loan (SEK 20m).
2025-12-31	Maturity date for outstanding convertible (SEK 7.5m, conversion price SEK 3.38).

Source: Ascelia Pharma

Appendix 2: Shareholders

Shareholder list

No.	Shareholder	Ownership
1	Avanza Pension	8.5%
2	Nordnet Pensionsförsäkring	3.7%
3	ÖstVäst Capital Management	3.5%
4	AP4	2.9%
5	Mats Thorén	2.5%
6	Salén Group	1.7%
7	Oscar Ahlgren	1.6%
8	Kibegeon ApS (Niels Mengel)	1.4%
9	Connys Alltransporter AB	1.3%
10	Jakob Svensson	1.2%
11	Spogård Holding ApS	1.1%
12	John Haurum	0.8%
13	Swedbank Försäkring	0.8%
14	Investment AB Pilhamn	0.8%
15	Søren Evald Andresen	0.8%
16	Jens Olsson	0.7%
17	Johan Irvena	0.7%
18	Svante Larsson	0.7%
19	Magnus Corfitzen (CEO)	0.7%
20	Handelsbanken Fonder	0.6%
20 largest shareholders		36%
Other shareholders		64%

Source: Holdings.se 25/04/2025

Footnote: Insiders in italic

Insider ownership

Insider	Position	No. of shares	Stock options
Kibegeon ApS (Niels Mengel)	Board member	1,340,457	
Magnus Corfitzen	CEO	781,745	990,000
Peter Benson	Chairman of the board	391,463	
Niels Mengel	Board member	269,385	
Julie Waras Brogren	Deputy CEO, CFO, CCO	245,114	825,000
Carin Linde	VP Pharmaceutical Dev.	229,519	440,000
Andreas Norlin	CSO	136,410	660,000
Jelly Bean AB (Peter Benson)	Chairman of the board	100,319	
Marie Källström	VP Regulatory Affairs	95,305	440,000
Helena Wennerström	Board member	89,208	
Jennie Wilborgsson	VP Clinical Development	77,672	440,000
Hans Maier	Board member	20,000	
Marianne Kock	Board member	0	
Lauren Barnes	Board member	0	

Source: Ascelia Pharma website 25/04/2025

Appendix 3: Management and Board

Management



Magnus Corfitzen
CEO

Education: M.Sc. in Mathematical Economics, University of Aarhus, Denmark
Previous experience: Extensive experience from investing, building and growing Life Science companies, including operational activities or investment responsibilities for public and private biotech and medtech companies. Investment Director at Sunstone Capital A/S and Vækstfonden, Portfolio Manager at Danske Capital, and Consultant at McKinsey & Company.
Shareholdings: 781,745



Julie Waras Brogren
Deputy CEO, CFO, CCO

Education: M.Sc. in International Business, Copenhagen Business School
Previous experience: 20+ years of experience from life science leadership and commercialization. President of BresoTEC, leadership roles at Novo Nordisk (Senior Director of Victoza Launch Office), and Accenture.
Shareholdings: 245,114



Andreas Norlin
CSO

Education: M.Sc. in Biology and PhD in Animal Physiology, Lund University, Sweden.
Previous experience: 25+ years of experience from research, preclinical- and clinical-stage drug development within e.g., oncology, inflammatory disease and diabetes. Project Vice President at Novo Nordisk, executive roles in biotech start-ups, and preclinical R&D at Camurus AB.
Shareholdings: 136,410

Board of Directors



Peter Benson
Chairman

Education: MA in Economics from University of California, US Diploma, IMD Switzerland
Previous experience: Founder of Sunstone Life Science Ventures, serving as Managing Partner from 2007-2019. Experience in the global life science industry, including roles as Head of Life Science Ventures at Vækstfonden, President of Hospital Care and Senior Vice President at Pharmacia AB as well as Executive Vice President Marketing & Sales at Kabi Pharmacia Parenterals.
Shareholdings: 391,463+100,319



Lauren Barnes
Board member

Education: MHS in Public Health, Johns Hopkins School of Public Health
Previous experience: Senior Vice President of Strategic Market Development and Access at Blueprint Medicines. Experience in pricing, market access, and pre-commercialization, with a focus on the US market. Barnes has held senior roles at Vertex Pharmaceuticals, Avalere Health, Amgen, and the Centers for Medicare and Medicaid Services.
Shareholdings: 0



Hans Maier
Board member

Education: Certified public accountant NHH Norwegian School of Economics
Previous experience: Managing Partner and Co-Founder of BGM Associates GmbH. Held executive roles at Schering AG and Bayer AG, including as President of Diagnostic Imaging and Head of Corporate Strategy. He has also served on various boards, including the German Heart Center Berlin Foundation.
Shareholdings: 20,000



Niels Mengel
Board member

Education: Cand. Pharm. degree from the University of Oslo
Previous experience: Founding Partner and former CEO of Øresund-Healthcare Capital. Executive roles at ISS World Services A/S and PA Consulting Group, with expertise in healthcare investments. Involved in several board roles and investment companies.
Shareholdings: 1,340,457+269,385



Helena Wennerström
Board member

Education: Bachelor of Chartered Accounting from BI NBS
Previous experience: Former Vice President of Corporate Finance at ViaCon Group. She has held senior finance roles at Bulten AB, Finnveden Bulten AB, Digitalfabriken AB, and Topcon Sweden AB. Currently a deputy board member at TVM Consulting in Göteborg AB.
Shareholdings: 89,208



Marianne Kock
Board member

Education: M. Pharm. degree from University of Oslo
Previous experience: Senior roles at Ferring Pharmaceuticals and Novo Nordisk, including Vice President of Regulatory Support and Senior VP of Global Regulatory Affairs at Ferring. Extensive experience in regulatory affairs and R&D, particularly in Japan and China.
Shareholdings: 0

Income Statement (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Sales	0	0	0	0	0	0	0	70	61	135
COGS	0	0	0	0	0	0	0	0	0	0
Gross profit	0	0	0	0	0	0	0	70	61	135
Other operating items	0	-37	-93	-138	-147	-111	-68	-80	-99	-111
EBITDA	**0**	**-37**	**-93**	**-138**	**-147**	**-111**	**-68**	**-10**	**-38**	**24**
Depreciation and amortisation	0	0	0	0	0	0	0	0	0	0
of which leasing depreciation	-	-	-	-	-	-	-	-	-	-
EBITA	**0**	**-37**	**-93**	**-138**	**-147**	**-111**	**-68**	**-10**	**-38**	**24**
EO Items	-	-	-	-	-	-	-	-	-	-
Impairment and PPA amortisation	0	0	0	0	0	0	0	0	0	0
EBIT	**0**	**-37**	**-93**	**-138**	**-147**	**-111**	**-68**	**-10**	**-38**	**24**
Net financial items	0	-3	-6	8	14	1	-12	-5	0	0
Pretax profit	**0**	**-40**	**-100**	**-130**	**-133**	**-110**	**-80**	**-15**	**-38**	**24**
Tax	0	0	1	4	2	0	0	0	0	0
Net profit	**0**	**-40**	**-99**	**-126**	**-131**	**-109**	**-80**	**-15**	**-38**	**24**
Minority interest	-	-	-	-	-	-	-	-	-	-
Net profit discontinued	-	-	-	-	-	-	-	-	-	-
Net profit to shareholders	**0**	**-40**	**-99**	**-126**	**-131**	**-109**	**-80**	**-15**	**-38**	**24**
EPS	-	-1.70	-3.50	-3.74	-3.90	-3.24	-0.83	-0.13	-0.32	0.21
EPS adj.	-	-1.70	-3.50	-3.74	-3.90	-3.24	-0.83	-0.13	-0.32	0.21
Total extraordinary items after tax	0	0	0	0	0	0	0	0	0	0
Leasing payments	-	-	-	-	-	-	-	-	-	-
Tax rate (%)	--	*0.2*	*1.1*	*2.8*	*1.5*	*0.3*	*0.1*	*0.6*	*0.0*	*0.0*
Gross margin (%)	--	--	--	--	--	--	--	*100.0*	*100.0*	*100.0*
EBITDA margin (%)	--	--	--	--	--	--	--	*-13.7*	*-61.7*	*17.8*
EBITA margin (%)	--	--	--	--	--	--	--	*-13.7*	*-61.7*	*17.8*
EBIT margin (%)	--	--	--	--	--	--	--	*-13.7*	*-61.7*	*17.8*
Pre-tax margin (%)	--	--	--	--	--	--	--	*-21.6*	*-61.7*	*17.8*
Net margin (%)	--	--	--	--	--	--	--	*-21.4*	*-61.7*	*17.8*
Growth Rates y-o-y	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Sales growth (%)	--	--	--	--	--	--	--	--	*-12.8*	*121.4*
EBITDA growth (%)	--	--	*153.7*	*47.7*	*6.6*	*-24.6*	*-38.9*	*-85.8*	*292.3*	*-164.0*
EBITA growth (%)	--	--	*153.7*	*47.7*	*6.6*	*-24.6*	*-38.9*	*-85.8*	*292.3*	*-164.0*
EBIT growth (%)	--	--	*nm*	*47.7*	*6.6*	*-24.6*	*-38.9*	*-85.8*	*nm*	*-164.0*
Net profit growth (%)	--	--	*147.3*	*27.6*	*4.2*	*-16.7*	*-26.8*	*-81.3*	*151.1*	*-164.0*
EPS growth (%)	--	--	*nm*	*6.8*	*4.2*	*-16.8*	*-74.3*	*-84.5*	*nm*	*-164.0*
Profitability	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
ROE (%)	--	*-33.7*	*-41.7*	*-46.3*	*-53.7*	*-85.7*	*-104.4*	*-14.9*	*-36.3*	*24.9*
ROE adj. (%)	--	*-33.7*	*-41.7*	*-46.3*	*-53.7*	*-85.7*	*-104.4*	*-14.9*	*-36.3*	*24.9*
ROCE (%)	--	*-29.8*	*-34.4*	*-46.6*	*-52.6*	*-83.5*	*-73.6*	*-7.8*	*-34.5*	*23.6*
ROCE adj. (%)	--	*-29.8*	*-34.4*	*-46.6*	*-52.6*	*-83.5*	*-73.6*	*-7.8*	*-34.5*	*23.6*
ROIC (%)	--	*-57.1*	*-101.6*	*-265.4*	*-363.6*	*-259.2*	*-163.8*	*-24.7*	*-78.1*	*50.0*
ROIC adj. (%)	--	*-57.1*	*-101.6*	*-265.4*	*-363.6*	*-259.2*	*-163.8*	*-24.7*	*-78.1*	*50.0*
Adj. earnings numbers	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
EBITDA adj.	*0*	*-37*	*-93*	*-138*	*-147*	*-111*	*-68*	*-10*	*-38*	*24*
EBITDA adj. margin (%)	--	--	--	--	--	--	--	*-13.7*	*-61.7*	*17.8*
EBITDA lease adj.	0	-37	-93	-138	-147	-111	-68	-10	-38	24
EBITDA lease adj. margin (%)	--	--	--	--	--	--	--	*-13.7*	*-61.7*	*17.8*
EBITA adj.	0	-37	-93	-138	-147	-111	-68	-10	-38	24
EBITA adj. margin (%)	--	--	--	--	--	--	--	*-13.7*	*-61.7*	*17.8*
EBIT adj.	0	-37	-93	-138	-147	-111	-68	-10	-38	24
EBIT adj. margin (%)	--	--	--	--	--	--	--	*-13.7*	*-61.7*	*17.8*
Pretax profit Adj.	0	-40	-100	-130	-133	-110	-80	-15	-38	24
Net profit Adj.	0	-40	-99	-126	-131	-109	-80	-15	-38	24
Net profit to shareholders adj.	0	-40	-99	-126	-131	-109	-80	-15	-38	24
Net adj. margin (%)	--	--	--	--	--	--	--	*-21.4*	*-61.7*	*17.8*

Source: ABG Sundal Collier, Company Data

Cash Flow (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
EBITDA	0	-37	-93	-138	-147	-111	-68	-10	-38	24
Net financial items	0	-3	-6	8	14	1	-12	-5	0	0
Paid tax	0	0	-0	1	4	1	1	0	0	0
Non-cash items	0	75	-63	7	-11	3	-8	20	0	0
Cash flow before change in WC	0	35	-163	-122	-140	-105	-86	5	-38	24
Change in working capital	0	-71	77	5	15	-21	24	-19	0	0

Cash Flow (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Operating cash flow	**0**	**-37**	**-86**	**-117**	**-125**	**-127**	**-63**	**-14**	**-38**	**24**
Capex tangible fixed assets	0	0	-0	-0	0	0	0	0	0	0
Capex intangible fixed assets	0	0	76	0	-0	0	0	0	0	0
Acquisitions and Disposals	0	0	0	0	0	0	0	0	0	0
Free cash flow	**0**	**-37**	**-10**	**-117**	**-125**	**-127**	**-63**	**-14**	**-38**	**24**
Dividend paid	-	-	-	-	-	-	-	-	-	-
Share issues and buybacks	0	0	93	187	0	-0	90	39	0	0
Leasing liability amortisation	0	-0	-1	-1	-1	-1	-1	0	0	0
Other non-cash items	0	145	-9	8	15	-1	3	0	0	0
Balance Sheet (SEKm)	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025e**	**2026e**	**2027e**
Goodwill	-	-	-	-	-	-	-	-	-	-
Other intangible assets	0	57	57	57	57	57	57	57	57	57
Tangible fixed assets	0	0	0	0	0	0	0	0	0	0
Right-of-use asset	0	0	2	2	0	1	0	0	0	0
Total other fixed assets	0	0	0	0	0	0	0	0	0	0
Fixed assets	0	57	59	59	58	58	57	57	57	57
Inventories	-	-	-	-	-	-	-	-	-	-
Receivables	0	1	3	6	5	2	6	6	6	6
Other current assets	0	83	9	7	7	5	3	3	3	3
Cash and liquid assets	0	109	185	262	150	22	75	80	42	66
Total assets	**0**	**250**	**255**	**333**	**219**	**87**	**141**	**145**	**108**	**132**
Shareholders equity	0	237	236	308	181	74	79	122	85	109
Minority	-	-	-	-	-	-	-	-	-	-
Total equity	**0**	**237**	**236**	**308**	**181**	**74**	**79**	**122**	**85**	**109**
Long-term debt	-	0	0	0	0	0	0	0	0	0
Pension debt	-	-	-	-	-	-	-	-	-	-
Convertible debt	-	-	-	-	-	-	-	-	-	-
Leasing liability	0	0	2	2	0	1	0	0	0	0
Total other long-term liabilities	0	0	0	0	0	0	0	0	0	0
Short-term debt	-	-	-	-	-	-	25	5	5	5
Accounts payable	0	5	4	6	16	2	5	5	5	5
Other current liabilities	0	8	14	18	21	10	32	13	13	13
Total liabilities and equity	**0**	**250**	**255**	**333**	**219**	**87**	**141**	**145**	**108**	**132**
Net IB debt	0	-108	-183	-260	-149	-21	-50	-74	-37	-61
Net IB debt excl. pension debt	0	-108	-183	-260	-149	-21	-50	-74	-37	-61
Net IB debt excl. leasing	0	-109	-185	-262	-150	-22	-50	-74	-37	-61
Capital employed	0	237	238	309	181	75	104	128	90	114
Capital invested	0	129	53	48	32	54	29	48	48	48
Working capital	0	71	-6	-11	-26	-5	-28	-9	-9	-9
EV breakdown	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Market cap. diluted (m)	0	74	89	106	106	106	302	364	364	364
Net IB debt adj.	0	-108	-183	-260	-149	-21	-50	-74	-37	-61
Market value of minority	0	0	0	0	0	0	0	0	0	0
Reversal of shares and participations	0	0	0	0	0	0	0	0	0	0
Reversal of conv. debt assumed equity	-	-	-	-	-	-	-	-	-	-
EV	**0**	**-35**	**-94**	**-154**	**-43**	**85**	**252**	**290**	**328**	**304**
Total assets turnover (%)	--	0.0	0.0	0.0	0.0	0.0	0.0	48.9	48.3	113.0
Working capital/sales (%)	--	--	--	--	--	--	--	-26.5	-14.7	-6.7
Financial risk and debt service	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Net debt/equity (%)	--	-45.7	-77.5	-84.4	-82.4	-28.0	-63.2	-60.6	-43.1	-55.7
Net debt / market cap (%)	--	-146.8	-206.7	-245.9	-141.0	-19.7	-16.5	-20.4	-10.0	-16.7
Equity ratio (%)	--	94.7	92.4	92.3	82.7	85.4	56.0	84.3	78.8	82.6
Net IB debt adj. / equity (%)	--	-45.7	-77.5	-84.4	-82.4	-28.0	-63.2	-60.6	-43.1	-55.7
Current ratio	--	14.90	11.19	11.44	4.32	2.48	1.35	3.88	2.22	3.28
EBITDA/net interest	--	11.6	14.8	16.4	10.6	84.9	5.5	1.7	--	--
Net IB debt/EBITDA (x)	--	2.9	2.0	1.9	1.0	0.2	0.7	7.7	1.0	-2.5
Net IB debt/EBITDA lease adj. (x)	--	2.9	2.0	1.9	1.0	0.2	0.7	7.8	1.0	-2.5
Interest coverage	--	7.5	4.5	63.3	32.6	44.3	4.7	1.5	--	--

Source: ABG Sundal Collier, Company Data

Share Data (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Actual shares outstanding	0	23	28	34	34	34	96	116	116	116
Actual shares outstanding (avg)	0	23	28	34	34	34	96	116	116	116

Share Data (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
All additional shares	-	-	-	-	-	-	-	-	-	-
Issue month	-	-	-	-	-	-	-	-	-	-
Assumed dil. of shares from conv.	-	-	-	-	-	-	-	-	-	-
As. dil. of shares from conv. (avg)	-	-	-	-	-	-	-	-	-	-
Conv. debt not assumed as equity	-	-	-	-	-	-	-	-	-	-
No. of warrants	-	-	-	-	-	-	-	-	-	-
Market value per warrant	-	-	-	-	-	-	-	-	-	-
Dilution from warrants	-	-	-	-	-	-	-	-	-	-
Issue factor	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Actual dividend per share	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
Reported earnings per share	-	-	-	-	-	-	-	-	-	-

Source: ABG Sundal Collier, Company Data

Valuation and Ratios (SEKm)	2018	2019	2020	2021	2022	2023	2024	2025e	2026e	2027e
Shares outstanding adj.	0	23	28	34	34	34	96	116	116	116
Diluted shares adj.	0	23	28	34	34	34	96	116	116	116
EPS	-	-1.70	-3.50	-3.74	-3.90	-3.24	-0.83	-0.13	-0.32	0.21
Dividend per share	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	-
EPS adj.	-	-1.70	-3.50	-3.74	-3.90	-3.24	-0.83	-0.13	-0.32	0.21
BVPS	-	10.09	8.37	9.14	5.37	2.21	0.82	1.06	0.73	0.94
BVPS adj.	-	7.66	6.35	7.45	3.68	0.51	0.23	0.56	0.24	0.45
Net IB debt/share	-	-4.61	-6.49	-7.72	-4.43	-0.62	-0.52	-0.64	-0.32	-0.52
Share price	3.14	3.14	3.14	3.14	3.14	3.14	3.14	3.14	3.14	3.14
Market cap. (m)	0	74	89	106	106	106	302	364	364	364
Valuation	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
P/E (x)	--	nm	nm	nm	nm	nm	nm	nm	nm	15.1
EV/sales (x)	--	--	--	--	--	--	--	4.14	5.37	2.25
EV/EBITDA (x)	--	0.9	1.0	1.1	0.3	-0.8	-3.7	-30.2	-8.7	12.6
EV/EBITA (x)	--	0.9	1.0	1.1	0.3	-0.8	-3.7	-30.2	-8.7	12.6
EV/EBIT (x)	--	0.9	1.0	1.1	0.3	-0.8	-3.7	-30.2	-8.7	12.6
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	0.0	-50.1	-10.8	-110.3	-118.5	-119.8	-20.8	-3.9	-10.3	6.6
Le. adj. FCF yld. (%)	0.0	-50.1	-11.5	-111.2	-119.5	-120.7	-21.1	-3.9	-10.3	6.6
P/BVPS (x)	--	0.31	0.37	0.34	0.58	1.42	3.82	2.98	4.30	3.35
P/BVPS adj. (x)	3.14	0.41	0.49	0.42	0.85	6.13	13.80	5.58	13.16	7.03
P/E adj. (x)	--	nm	nm	nm	nm	nm	nm	nm	nm	15.1
EV/EBITDA adj. (x)	--	0.9	1.0	1.1	0.3	-0.8	-3.7	-30.2	-8.7	12.6
EV/EBITA adj. (x)	--	0.9	1.0	1.1	0.3	-0.8	-3.7	-30.2	-8.7	12.6
EV/EBIT adj. (x)	--	0.9	1.0	1.1	0.3	-0.8	-3.7	-30.2	-8.7	12.6
EV/CE (x)	--	-0.1	-0.4	-0.5	-0.2	1.1	2.4	2.3	3.6	2.7
Investment ratios	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Capex/sales (%)	--	--	--	--	--	--	--	0.0	0.0	0.0
Capex/depreciation	--	--	--	--	--	--	--	--	--	--
Capex tangibles / tangible fixed assets	--	0.0	131.9	16.0	0.0	0.0	0.0	0.0	0.0	0.0
Capex intangibles / definite intangibles	--	0.0	133.9	0.0	0.1	0.1	0.0	0.0	0.0	0.0
Depreciation on intang / def. intang	--	0	0	0	0	0	0	0	0	0
Depreciation on tangibles / tangibles	--	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Source: ABG Sundal Collier, Company Data

Analyst Certification

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Norway
Ruseløkkveien 26, 8th floor
0251 Oslo
Norway
Tel: +47 22 01 60 00
Fax: +47 22 01 60 60

Denmark
Forbindelsesvej 12,
2100 Copenhagen
Denmark
Tel: +45 35 46 61 00
Fax: +45 35 46 61 10

Sweden
Regeringsgatan 25, 8th floor
111 53 Stockholm
Sweden
Tel: +46 8 566 286 00
Fax: +46 8 566 286 01

United Kingdom
10 Paternoster Row, 5th floor
London EC4M 7EJ
UK
Tel: +44 20 7905 5600
Fax: +44 20 7905 5601

USA
140 Broadway, Suite 4604
New York, NY 10005
USA
Tel. +1 212 605 3800
Fax. +1 212 605 3801

Singapore
10 Collyer Quay
Ocean Financial Center
#40-07, Singapore 049315
Tel +65 6808 6082

Germany
Schillerstrasse 2, 5. OG
60313 Frankfurt
Germany
Tel +49 69 96 86 96 0
Fax +49 69 96 86 96 99

Switzerland
ABG Sundal Collier AG
Representative Office
Schwanenplatz 4
6004 Lucerne
Switzerland
Tel +41 79 502 33 39