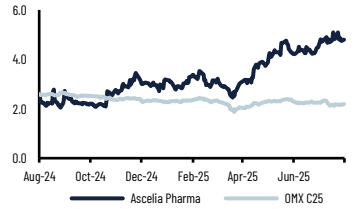
Ascelia Pharma

Market: Nasdaq Stockholm	Ticker: ACE	Share price (DKK): 4.8	Market cap (SEK): 557m	Net cash (SEK): 73m	Enterprise value (SEK): 484m

*Includes Q2'25 TO 1 warrants, gross proceeds SEK 43m

Share information



YTD	64.4%	1 year:	94.7%
1 month:	7.0%	3 years:	-78.2%

Note: Closing prices and market data as of 18.08.2025. Rebased to 19.08.2024. Source: S&P Capital IQ

Financials

(SEKm)	2023	2024	2025E*
Revenue	0.0	0.0	0.0
Revenue growth	*0%*	*0%*	*0%*
Research & Development	-81.3	-50.8	N/A
Operating result	-110.9	-67.8	N/A
Cash flow from operations	-126.8	-62.8	N/A
Cash position	21.9	75.3	N/A

Note: *No company guidance announced for 2025E

Pipeline

Candidate	Indication	Phase I	Phase II	Phase III
Orviglance	MRI imaging	Completed	Completed	Completed*
Oncoral (on hold)	Oral cancer treatment	Completed	On hold	

Note: *received Phase III headline and full data. Filing of new drug Application (NDA), expected early-September 2025

Company description

Ascelia Pharma is a Swedish biotech company focused on cancer diagnostics and treatments with headquarters in Malmö, Sweden. The company was founded in 1999 and listed on Nasdaq Stockholm in 2019. Ascelia Pharma is focused on its primary pipeline candidate Orviglance, which has achieved strong Phase III SPARKLE results, meeting all primary and secondary endpoints, with statistically significant improvements to visualizing focal liver lesions for patients who cannot tolerate gadolinium-based contrast agents, estimated to be approx. 4% of patients. Ascelia Pharma also has the product candidate Oncoral, currently put on hold, which is an irinotecan tablet to be offered in daily low dosage at home with the potential to offer better efficacy with improved safety.

Investment case

The product, positioned as the first and only gadolinium-free liver MRI contrast agent for this patient group, has received Orphan Drug Designation. Constructive feedback from the FDA has confirmed the NDA filing remains on track for mid-2025. Scientific recognition is growing, with 2025 data accepted at ESGAR, ISPOR, and RSNA, underlining clinical relevance and engagement from radiologists, nephrologists, and oncologists.

The company has strengthened its financial position with SEK 43m gross proceeds from the April 2025 warrant exercise, extending its cash runway beyond the NDA filing and through year-end 2025, excluding potential milestone payments from partnerships. The investment case is anchored in regulatory approval and a partner-led launch, targeting a global addressable market of USD 800m (USD 500-600m in the US, EU, and Japan) with 4-5% annual growth. The strong SPARKLE study headline data showing high Orviglance efficacy, "comparable" to current gadolinium-based imaging agents, may enable additional upside from off-label use in patients with normal kidney function. Particularly, as Ascelia Pharma research indicates over 80% of clinicians would likely adopt Orviglance upon approval.

Our DCF scenario analysis based on assumptions described on p2-3 and company guided where possible, currently reflects a market implied probability of success (PoS) of around 50% in the base case. The implied PoS can be benchmarked against the biostatistics historical likelihood of successful launch for a Phase III candidate of around 90%. We assess that FDA approval and a partnership agreement will be key triggers to closing this gap.

Key investment reasons

Ascelia Pharma is a focused biotech company that has developed Orviglance, which addresses an unmet need in a market potentially worth USD 800m annually and growing 4-5% per year.

With no current competitors and a narrow target population (~4% of patients), Orviglance is expected to remain competition-free during the 7-year FDA exclusivity period, suggesting higher-for-longe profitability. A partner-led launch strategy also limits funding needs and supports a 2026 commercial rollout.

Ascelia Pharma has been granted Orphan Drug Designation (ODD) for Orviglance, which provides 7 years of market exclusivity in the United States and 10 years of exclusivity in Europe. ODD may also offer regulatory benefits such as fee waivers, tax credits for clinical trials, and access to accelerated review pathways. The company has also filed for an Orviglance 2nd generation patent.

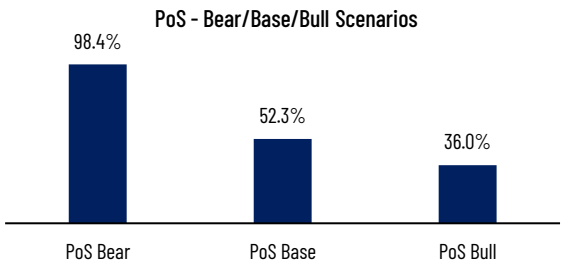
Ascelia Pharma's second product candidate, Oncoral, offers value potential if the future phase II combination study with Taiho Oncology´s LONSURF cancer product, is successful, but is not currently assigned value in our model due to its paused status.

Key investment risks

Investing in drug development is inherently high-risk and requires both patience and a strong risk appetite. While the positive Phase III SPARKLE results support the efficacy of Orviglance, and regulatory milestones are progressing, FDA approval and commercial success are not assured. With only one primary pipeline candidate, Ascelia Pharma is highly reliant on Orviglance.

The transition from drug development to full-scale commercialization can be a long and challenging process in which the company has little or no experience, increasing the dependence on a partner. It may also be more expensive than expected.

Following completion of the Warrant TO1 programme in April 2025, the company has a cash runway to beyond end 2025, however, further dilutive capital raises may be necessary to support commercialization, depending on a potential partner agreement.



Appendix – Discussion of assumptions in DCF-model

The model

This one-pager does not aim to determine a price target for Ascelia Pharma shares, but rather to provide investment perspectives using a simplified Discounted Cash Flow (DCF) model across different scenarios. The model uses scenarios to indicate the degree to which Ascelia Pharma's current market capitalization reflects the implied probability of success (PoS) for its Orviglance product to reach marketing authority and successful commercialization.

The DCF model considers the company's future potential cash flow once Orviglance is launched, based on several assumptions evaluated and discussed below. As mentioned, Ascelia Pharma's primary pipeline product, Orviglance, is awaiting Phase III results, while on hold, Oncoral is ready for Phase II. We currently only consider Orviglance in our model. The PoS can be compared with the average historical likelihood of a phase III pipeline project passing through to launch of approx. 60%.

Market size and market growth

According to Ascelia Pharma, the global addressable market for Orviglance is approx. USD 800m annually (of which USD 5-600m is in the US, EU, and Japan combined), with expected demographic and prevalence-driven growth of 4-5% per year. We assume Orviglance's patent will expire 7 years after launch in 2033, with a negative terminal growth rate of -25%, after patent expiry to reflect competitive pressures driving down prices.

According to Ascelia Pharma, there can be a potential prolonged patent protection period until 2040 if a second generation of Orviglance is approved, but this has not been included in the model at this point. Also, although recent studies suggest that Orviglance is "comparable" to gadolinium-based imaging agents used with patients with normal kidney function, the potential to address the gadolinium-based market is not included at this point.

Market share and revenue

If Ascelia Pharma succeeds in launching Orviglance, it is estimated that the company will reach a peak market share of 35% by the year 2031 in the base case scenario. As Orviglance is not expected to face major competition, a higher peak market share cannot be ruled out. Generally, a high market share is difficult to obtain immediately after product launch, due to established workflow processes within hospitals, which can slow adoption. The shape of the penetration curve can take different paths, and we model initial market share growth of 2.5 percentage points in the first year (2026), followed by linear market penetration over the following 5 years towards the peak market share assumption. We model a royalty rate of 25%, a competitive level for a Phase III complete drug meeting an unmet market need.

Discount rate

The model uses a discount rate of 15%, reflecting the generally high level of investment risk and uncertainty typically associated with forecasting future cash flows from biotech companies. As Ascelia Pharma is active within the space of diagnostic products, which is generally perceived as being less risky, it could be argued that a lower discount rate is appropriate, but the model uses the widely accepted 15% within the industry.

Possibility of successful launch (PoS) reference

Based on historical data from Biostatistics research containing 5,764 pipeline projects in pharmaceutical and biotech companies, the average historical likelihood of a Phase 3 pipeline project with strong data passing through to launch is approx. 90%. This is calculated across all medical indications, including those areas that are typically perceived as being very difficult to pass.

A lower-than-average PoS indicates that the market implicitly assesses there is a lower-than-average likelihood for Ascelia Pharma to successfully launch Orviglance and/or that further diluting capital raises should be expected. Another way to interpret a low PoS is that as clinical development progress is made, and funding risks fall, the market-implied probability of success, based on our assumptions, should trend towards the statistical implied POS. Current market pricing and model assumptions suggest that final NDA submission and approval, and a partnership agreement could see market value increases towards the statistical POS.

EBIT-margin and royalty rates

According to the S&P Capital IQ Financial System, five-year average EBIT margins within major pharmaceutical and biotech companies are approx. 30%. Looking at biotech companies specifically, the five-year average is approx. 50%, reflecting a generally more focused business model. We model an EBIT margin ramping up to 50% by 2030 to reflect the lower operating cost partner strategy supporting stronger margins from lower cost commercialization. The royalty rate is assumed to be 25% reflecting the attractive profile for a partner to market a Phase III complete (on NDA submission and approval) diagnostic product with an orphan drug designation and no immediate competition.

Scenarios

Based on the previously mentioned assumptions regarding market size and growth, level of profitability, market share, and discount rate, different scenarios can be simulated to assess how much the market is implicitly discounting as far as the likelihood of launch of Orviglance is concerned. As illustrated, the model has simulated the implicit likelihood in 3 scenarios: a bear-, base-, and bull-case, using different levels of peak market shares as the main way to differentiate between scenarios. See further details on P3.

Appendix – Results and Conclusion

Base case scenario

In the base case scenario, the model uses the indicated market size by Ascelia Pharma of USD 800m, growing 4.5% annually. The model uses industry average levels of profitability set to a peak EBIT margin of 50%, a royalty rate of 25%, a peak market share assumption of 35%, and a discount rate of 15%. This relates to a peak revenue estimate of approx. SEK 1.0bn by 2032, six years after launch in 2026. Based on this, the market currently implicitly assumes there is around. 50% possibility of successful launch (PoS) for Orviglance according to the model. This compares to a historical average level of success of around 90% for pipeline projects across all indications that have completed Phase III and received positive results. In other words, the market attributes around half the chance for Ascelia Pharma to become commercially successful through a partnership, under our assumptions.

Bear case scenario

In the bear case scenario, the model uses a peak market share of 20%, still growing the number of patients 4.5% annually, and maintaining other core assumptions from the base case described on P2, except for a lower peak EBIT margin of 40%. This corresponds to a peak revenue estimate of around. SEK 570m after six years. Based on the conservative bear case assumptions, the market currently implies a roughly in-line-with-benchmark possibility of successful launch (PoS) for Orviglance.

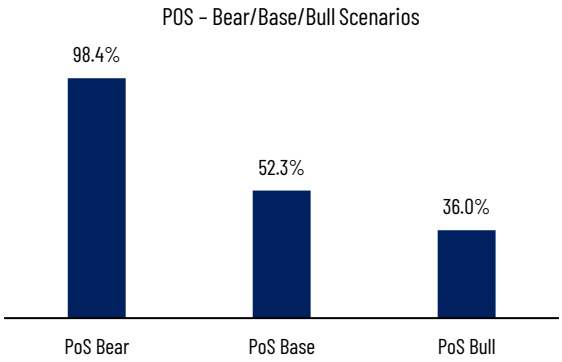
Bull case scenario

In the bull case scenario, the model uses a peak market share of 50%, still growing the number of patients by 4.5% annually and maintaining other core assumptions from the base case described on P2. This equals a revenue estimate of approx. SEK 1.3bn after six years. Based on the Bull-case assumptions, the market currently implicitly assumes there is around a one-third possibility of a successful launch (PoS) for Orviglance according to the model.

Conclusion

In the base case scenario, the model suggests a significantly lower market confidence in Ascelia Pharma's likelihood of a successful approval and commercialization of Orviglance, than is typically associated with pipeline candidates with strong Phase III data, based on historical industry data (Biostatistics). In absolute terms, the market discounts just above 50% chance of success. As described, the model only includes potential cash flows from Orviglance, thereby implicitly assuming the market pays no value to all the other potential future cash flows from Oncoral, and a potential usage of Orviglance for patients with normal kidney functions. If these opportunities are included, the implied PoS will all-else-equal retreat further, widening the gap to the benchmark.

Lastly, a low implied probability of success (PoS) for any biotech typically also reflects the high likelihood for the company to engage in one or more diluting capital raises. Since Ascelia Pharma completed its TO 1 warrant program in April 2025, we do not see significant risk of further unplanned capital raises – at least not until further details regarding a potential partnership and commercialization are announced. We expect NDA approval and details regarding a potential partnership and the rate of commercialization as key triggers to support a narrowing of implied PoS to the benchmark.



Note: Probability of success (PoS) model based on general market assumptions and HC Andersen Capital assumptions. Graph is illustrative