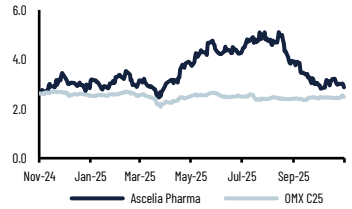
Ascelia Pharma

Market: Nasdaq Stockholm	Ticker: ACE	Share price (DKK): 2.86	Market cap (SEK): 363m	Net cash (SEK): -71m	Enterprise value (SEK): 292m

Share information



YTD	-2.1%	1 year:	9.0%
1 month:	-3.1%	3 years:	-88.7%

Note: Closing prices and market data as of 14.11.2025. Rebased to 15.11.2024.
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. New Drug Application (NDA) filed in September 2025 and awaiting FDA decision by 3 July 2026

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. Ascelia Pharma submitted its New Drug Application (NDA) in September 2025 and was formally accepted on 15 November, validating that the submission was sufficient for review and with the FDA aiming for a decision by 3 July 2026. Scientific recognition is growing, with 2025 data accepted at ESGAR, ISPOR, and RSNA, underlining clinical relevance and engagement from radiologists, nephrologists, and oncologists.

Ascelia Pharma has strengthened its financial position during Q3 2025, raising SEK 30m from a directed issue (September) and conversion of SEK 7.5m of convertible debt (September), extending its cash runway through year-end 2026, 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 outlined on pages 2-3 and company guidance where available, implies a market probability of success (PoS) of around 35% in the base case. This compares to the historical ~90% Phase III success rate observed in biostatistical benchmarks. We see FDA approval and a partnership agreement as key triggers to narrow this gap. The market may also be pricing in slower commercialization, lower peak market share, or potential dilution (partly de-risked following the Q3 financing), however, there remains a significant gap between the market implied PoS and the benchmark.

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.

Ascelia Pharma has been granted Orphan Drug Designation (ODD) for Orviglance, which provides 7.5 years of market exclusivity in the United States and 10 years of exclusivity in Europe. With no current competitors and a narrow target population (~4% of patients), Orviglance is expected to remain competition-free during the 7.5-year FDA exclusivity period, suggesting higher-for-longer profitability. Ascelia Pharma's Orviglance 2nd generation patent can further extend the patent protection period to 2040.

Ascelia Pharma's NDA acceptance and expected FDA decision by 3 July 2026, strengthens ongoing partner negotiations. A partnership can enable a faster commercial rollout of Orviglance and significantly reduce Ascelia's cash requirements for launch.

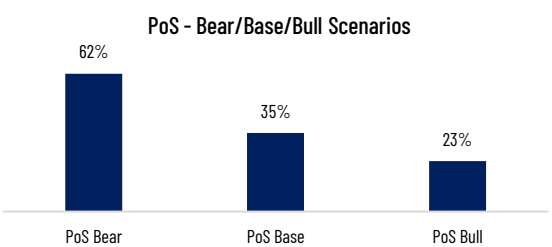
Ascelia Pharma's second product candidate, Oncoral, offers value potential if the future phase II combination study with Taiho Oncology´s LONSURF cancer product, is successful, but is not currently assigned value in our model due to its paused status.

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 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 direct issue in September 2025, Ascelia is funded until the end of 2026, ex-partner agreement payment/milestones. 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 currently been included in the model. To remain conservative, we also exclude the potential to address part of the gadolinium-based market, despite study data suggesting that Orviglance is "comparable" to gadolinium-based imaging agents used with patients with normal kidney function.

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 milestones are achieved and/or funding risks fall, the market-implied probability of success can trend towards the statistical implied POS, assuming similar assumptions on the market and commercialization. Current market pricing and model assumptions suggest that final FDA marketing 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.

Capital structure

In September 2025, Ascelia Pharma strengthened its capital structure through a convertible conversion and a directed share issue. On 2 September, Fenja Capital converted SEK 7.5m of convertibles into 2.2m new shares at SEK 3.38, (1.9% dilution). This has been followed by a direct issue on 22 September 2025 of 8.6m shares at SEK 3.50, raising around SEK 30m. The direct issue was executed at approx. 9% discount to market prices and around 6.8% dilution. The combined capital raises have extended Ascelia Pharma's cash runway to Q4 2026 beyond the expected FDA decision on Orviglance by 3 July 2026, with total new shares of 9.9m, an increase of 7.7%. Ascelia Pharma is now well capitalized to finalize partnership discussions ahead of an expected FDA decision on Orviglance in 2026.

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. 35% possibility of successful launch and commercialization (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 slightly below benchmark possibility of successful launch (PoS) of around 60% for Orviglance, according to the model.

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 implies a slightly below benchmark possibility of successful launch (PoS) of around 25% for Orviglance, according to the model.

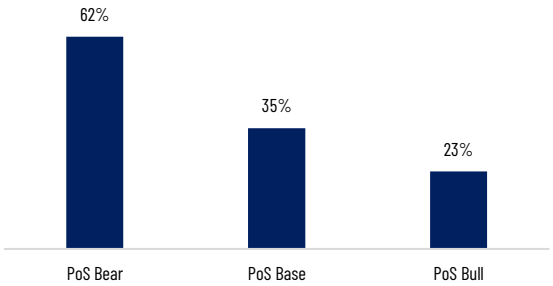
Conclusion

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 around a 35% probability of success in line with our assumptions. The market implied PoS has fallen from around 50% prior to the recent capital raise, despite the runway extension reducing funding risks and future need for capital. A greater capital position can also strengthen Ascelia Pharma's bargaining position during partnership negotiations.

Our 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 and the associated funding risk. However, following the cash runway extension to Q4 2026, funding risk has been reduced. A partnership agreement and greater clarity relating to the commercialization of Orviglance are likely the key triggers to drive the market implied PoS.

POS – Bear/Base/Bull Scenarios



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