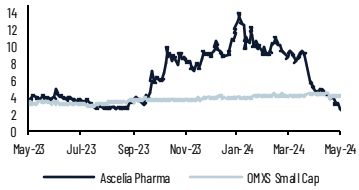
Ascelia Pharma

Market: Nasdaq Stockholm	Ticker: ACE	Share price (SEK): 2.465	Market cap (SEKm): 83.2	Net debt (SEKm): 4.1	Enterprise value (SEKm): 87.3

Share information



YTD:	-29.8%	1 year:	-36.2%
1 month:	-54.0%	3 year:	-94.1%

Note: Closing prices and market data as of 16.08.2024 (Source: Capital IQ)

Financials

(SEKm)	2022	2023	2024E*
Revenue	0.0	0.0	0.0*
Revenue growth	*0%*	*0%*	*0%**
Research & Development	118.1	81.3	N/A*
EBIT	-147.0	-110.9	N/A*
Cash flow from operations	-139.9	-126.8	N/A*
Cash position	149.6	21.9	N/A*

Note: *No company guidance announced for 2024

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: *Awaiting filing of submission approval, expected mid-2025

Company description

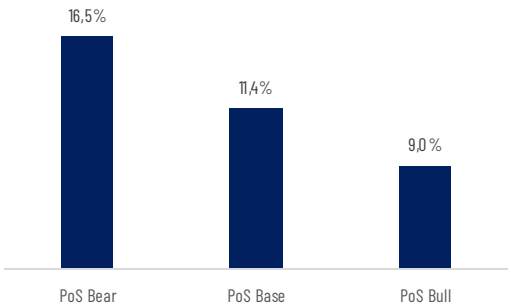
Ascelia Pharma is a Swedish biotech company focused on cancer diagnostics and treatments with headquarters in Malmo, Sweden. The company was founded in 1999 and listed on Nasdaq Stockholm in 2019. Ascelia Pharma is focused on Orviglance in Phase 3, which is a contrast agent developed to be used in MRI scannings to detect potential liver metastases for patients who cannot tolerate gadolinium-based contrast agents, estimated to be approx. 4% of patients. Ascelia Pharma also has the product candidate Oncoral, which is an irinotecan tablet to be offered in daily low dosage at home with the potential to offer better efficacy with improved safety. The Oncoral project is currently put on hold as Ascelia Pharma is focusing on Orviglance.

Investment case

The investment case is driven by an approval and subsequent successful launch of Orviglance through partnership. According to Ascelia Pharma, the addressable market for Orviglance serving an unmet need is estimated at USD 800m globally (of which USD 5-600m is in the US, EU, and Japan combined) with an annual growth rate of 4-5%. To achieve this, Ascelia Pharma has now completed its phase 3 study (called SPARKLE) and has released positive headline data, which is expected to support a submission of a New Drug Application to the FDA in the middle of 2025.

Ascelia Pharma is currently about to conduct a partly guaranteed rights issue that will raise up to SEK 105m which will strengthen the company's balance sheet and improve Ascelia Pharma's negotiation power with potential partners. Since the rights issue was announced on July 10th, the share price has come down almost 80 percent reflecting that the market implicitly assumes there is just over 10% Probabillity of Success (PoS) for an approval and successful launch of Orviglance in the base case scenario. See page 2-3 for further discussions of the model and its results.

PoS - Bear/Base/Bull Scenarios



Key investment reasons

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

There are currently no competitors, and as it is a niche market addressing only around 5% of patients, it is likely that the market will continue to be with no or few competitors, suggesting that profitability will be higher for longer. Also, a partner-based commercialization strategy will reduce the funding requirement.

The recent strong and final data from the SPARKLE phase 3 study has documented very high efficacy of Orviglance similar to, or better than, current gadolinium-based imaging agents and is safe and convenient to use, according to two recently held studies. Market research shows more than 80 percent of healthcare professionals will likely, or definitely, use Orviglance. If approved, Orvilgance could also be used for patients with normal kidney functions in an additional off-label market usage opportunity.

The strong SPARKLE data could increase the likelihood that Ascelia Pharma will follow a priority status when their submission of approval is evaluated leading to a potential launch with a partner already in late 2025 or in the beginning of 2026.

Based on the current share price, a PoS of approx. 10% suggests the market is still only implicitly discounting a low valuation potential according to our DCF model. Also, Ascelia Pharma's second product candidate, Oncoral, offers significant additional value potential if the future phase 2 combination study with Taiho Oncology´s LONSURF cancer product, proves successful.

Key investment risks

As it has not launched or commercialized any product yet, Ascelia Pharma is highly and almost entirely dependent on the successful approval and launch of Orviglance through a partnership.

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 can also be more expensive than expected.

If Ascelia Pharma does not receive priority status, the approval process can be delayed, and the company will perhaps have to raise more capital than otherwise required or planned.

As Ascelia Pharma is based in Sweden, the company is subject to currency risk as its potential future main market is in the US.

Appendix – Discussion of assumptions in DCF-model

The model

The objective of this One-Pager is not to calculate a price target for Ascelia Pharma's share. Instead, the objective is to use a simplified DCF (Discounted Cash Flow) model to give investment perspectives based on different scenarios. In particular, the model can use simulations to give an indication as to how much the current market cap of Ascelia Pharma is implicitly discounting in terms of the likelihood of drug approval and launch (PoS) of Orviglance. The DCF model considers the company's future potential cash flow once Orviglance is launched. To do this, the inputs in the DCF model are based on several assumptions, which will be evaluated and discussed below. As mentioned, Ascelia Pharma has pipeline products in phases 2 (Oncoral) and 3 (Orviglance), but when simulating, only estimates regarding Orviglance are included as Oncoral is on hold. The PoS can be compared with the average historical likelihood of a phase 3 pipeline project passing through to launch of approx. 60%.

Market size and market growth

According to Ascelia Pharma, the addressable market for Orviglance is approx. USD 800m globally (of which USD 5-600m is in the US, EU, and Japan combined) in annual revenue, with an expected demographics-based growth of 4-5% in number of patients per year. The patents on Orviglance is assumed to effectively run for 10 years, but after that, the value of the market is assumed to show negative growth of 25% per year due to increased competition and lower prices. The negative growth is also a typical assumption used from a modelling perspective to avoid an unrealistic compound effect of the value of the cash flows after the patents expire. 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 likely superior 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 often difficult to obtain immediately after a product launch due to established workflow processes within hospitals, which sometimes limits adoption of new products. The shape of the penetration curve can take different paths, but for simplistic reasons, the penetration curve is assumed to be almost linear, growing 2.5 percentage points a year from the expected launch year in the first 2 years, after which growth accelerates to 5 percentage points per year.

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 can 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 passing through to launch is approx. 60%. 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 it reflects normal risk assessment of a product that hasn't been approved or launched and suggests a corresponding potential value increase in the market value of the company if Orviglance is approved and successfully launched - all things being equal.

EBIT-margin and royalty rates

According to Refinitiv 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 and higher economies of scale. Although a peak EBIT-margin of 50% is not unrealistic, the likely margin diluting effect from pursuing a potential partner-based strategy as well as a general conservative approach, it is considered relevant for the model to use an EBIT-Margin of 40% for most of the budget period in the model. The royalty rate is assumed to be 25 % reflecting the attractive profile for a partner to market a low-risk 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 scenario using different levels of peak market shares as the main way to differentiate between scenarios. Consequently, and for simplicity reasons, most of the remaining criteria discussed are assumed to be the same in all scenarios.

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%. The model uses industry average levels of profitability conservatively set to an EBIT margin of 40%, a royalty rate of 25%, a peak market share assumption of 35%, and a discount rate of 15%. This equals to a revenue estimate of approx. USD 75m five years after launch in 2026. Based on this, the market currently implicitly assumes there is approx. 10% possibility of successful launch (PoS) for Orviglance according to the model. This compares to a historical average level of success of approx. 60% for pipeline projects across all indications, and likely even higher likelihood for biotech companies developing diagnostic products, similar to Orviglance at Ascelia Pharma. In other words, the market attributes less than a fifth of a chance for Ascelia Pharma to become commercially successful through its partnership.

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% and keeping the remaining criteria from the base case. This equates to a revenue estimate of approx. USD 50m after five years, but after that, the market share only grows a little. Based on this, the market currently implicitly assumes there is approx. a 15% possibility of successful launch (PoS) for Orviglance, according to the model.

Bull case scenario

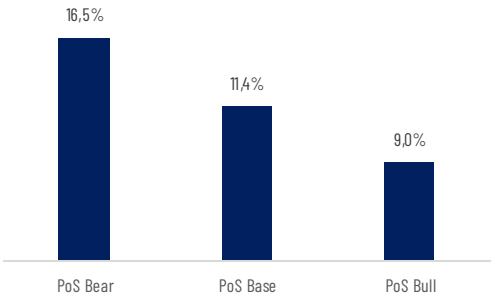
In the bull case scenario, the model uses a peak market share of 50%, still growing the number of patients by 4.5%, and an EBIT margin of 50%, keeping the remaining criteria from the base case. This equals a revenue estimate of approx. USD 95m after five years, after which the market share continues to grow. Based on this, the market currently implicitly assumes there is a below 10% possibility of a successful launch (PoS) for Orviglance according to the model.

Conclusion

In the base case scenario, the model suggests a relatively low level of market confidence in Ascelia Pharma as far as the likelihood of a successful approval and launch is concerned when compared to historical industry data. In absolute terms, the market discounts just above 10 percent 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 implicit market confidence for Orviglance becomes smaller, suggesting a correspondingly higher upside.

Lastly, and most importantly, a low implied likelihood of success for any biotech typically also reflects the high likelihood for the company to engage into one or more diluting capital raises. Since Ascelia Pharma is about to conduct a rights issue, the uncertainty regarding the timing and conditions of an upcoming partnership deal is probably the primary reason for the low implied likelihood of commercial success for Ascelia Pharma.

POS – Bear/Base/Bull Scenarios



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