Ascelia Pharma

Market: Nasdaq Stockholm	Ticker: ACE	Share price (DKK): 2.205	Market cap (SEK): 211.9m	Net debt (SEK): 101m	Enterprise value (SEK): 312.9m

*Includes Q3'24 rights issue, net of announced fees

Share information

Ytd	51.1%	1 year:	44.9%
1 month:	15.2%	3 year:	770.9%

Note: Closing prices and market data as of 18.10.2024. Rebased to October 2023. Source: S&P 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: *received Phase III headline data. Full data expected Q4 2024. Filing of new drug authorization (NDA), expected mid-2025

Company description

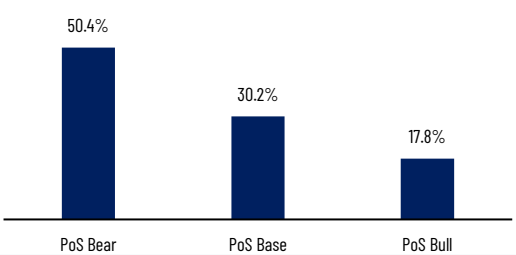
Ascelia Pharma is a Swedish biotech company focused on cancer diagnostics and treatments with headquarters in Malmo, Sweden. The company was founded in 1999 and listed on Nasdaq Stockholm in 2019. Ascelia Pharma is focused on its primary pipeline candidate Orviglance with strong Phase III headline data, which is a contrast agent developed to be used in MRI scans 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, 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

Ascelia Pharma has successfully conducted a rights issue raising gross proceeds of SEK 105m, which strengthens its balance sheet and improves the company's negotiation power with potential partners. Combined with its TO 1 warrants, to be exercised in April 2025, the company is fully financed until end-2025, excluding potential additional partnership milestones. Since the latest rights issue was announced on 10 June 2024, the share price has retreated 78%, reflecting that the market implicitly assumes there is just over 30% probability of success (PoS) for approval and successful launch of Orviglance in the base case scenario. See page 2-3 for further discussions of the model and results.

The investment case is driven by 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 III study (called SPARKLE) and has released positive headline data, which is expected to support a submission of a New Drug Application (NDA) to the FDA around mid-2025. We expect as communicated by the company, further insights into the full data package from the SPARKLE study will be announced early Q4-2024 and abstracts are to be presented at the yearly radiology conference RSNA at the beginning of December 2024.

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 worth USD 800m annually and growing 4-5% per year.

There are currently no competitors and given its niche market, addressing only around 4% of patients, the market will likely remain competition-free during the 7-year FDA regulatory exclusivity period, suggesting that profitability will be higher for longer. Also, a partner-based commercialization strategy will reduce the funding requirement and support commercial launch around early 2026.

The strong Phase III SPARKLE study headline data has documented high efficacy of Orviglance, which has demonstrated "comparable" results to current gadolinium-based imaging agents, as per study data. Ascelia Pharma's market research shows over 80% of healthcare professionals will likely, or definitely, use Orviglance. If approved, patients with normal kidney functions may also use Orviglance, in an additional off-label market use opportunity.

Ascelia Pharma has been granted Orphan Drug Designation (ODD) for Orviglance, which provides 7 years of market exclusivity in the United States. In Europe, Orviglance benefits from 10 years of exclusivity, as is the case for all drugs approved in the EU. The company has also filed for an Orviglance 2nd generation patent.

A current market-implied PoS of around. 30%, according to our base case DCF model is below the market average PoS for a drug in Phase III. Also, 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.

Key investment risks

As Ascelia Pharma has not launched or commercialized any product yet, it 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.

Investors should expect a dilution of up to 17% from the outstanding TO 1 warrant program (April 2025). If the warrant program raises insufficient capital and a partner has not yet been found current funding may not extend to end-2025.

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

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 Phase III complete drug meeting an unmet market need.

TO 1 warrant program

Following Ascelia Pharma's latest rights issue, 16.5m warrant series TO 1 units were issued, which entitle holders to buy one new ordinary share at a subscription price corresponding to 70% of the volume-weighted average price from 14-28 March. We model the warrant program will be fully subscribed at 70% of the current 14-day average share price, with a 17.0% dilutive effect.

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 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 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 final Phase III data and a solid 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 and higher economies of scale. Although a peak EBIT margin of 50% is not unrealistic, we model a peak EBIT margin of 40% to reflect the resuming of R&D relating to Oncoral and the somewhat margin-diluting effect of pursuing a potential partner-based strategy. 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, 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 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 relates to a peak revenue estimate of approx. SEK 1.0bn six years after launch in 2026. Based on this, the market currently implicitly assumes there is around. 30% 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, going into Phase III. The statistical POS rises to around 90% for marketing approval after successful Phase III results. In other words, the market attributes around a third 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 peak revenue estimate of around. SEK 550m after six years, but after that, the market share only grows a little. Based on this, the market currently implicitly assumes there is around 50% possibility of successful launch (PoS) for Orviglance, according to the model.

Bull case scenario

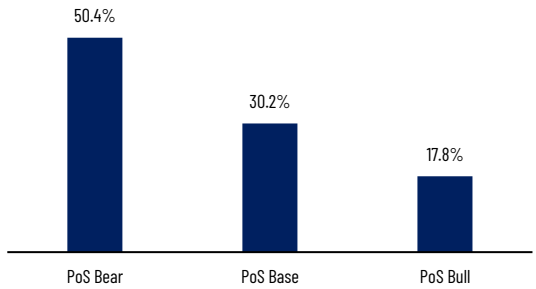
In the bull case scenario, the model uses a peak market share of 50%, still growing the number of patients by 4.5%, and an EBIT margin of 50%, keeping the remaining criteria from the base case. This equals a revenue estimate of approx. SEK 1.3bn after six years, after which the market share continues to grow. Based on this, the market currently implicitly assumes there is a below 20% 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 30% 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 Ascelia Pharma becomes smaller, suggesting a correspondingly higher upside.

Lastly, a low implied probability of success (PoS) for any biotech typically also reflects the high likelihood for the company to engage into one or more diluting capital raises. Since Ascelia Pharma has finalised its most recent rights issue, and our model has accounted for dilution from the TO 1 warrant program scheduled for 2025, we do not see significant risk of further unplanned capital raises. We expect the primary reasons for a lower-than-expected PoS relates to uncertainty regarding an upcoming partnership model and the rate of commercialization 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