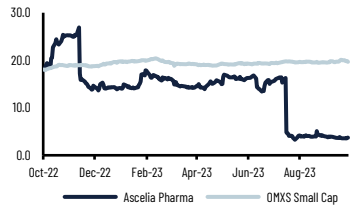
Ascelia Pharma – One-Pager

Market: Nasdaq Stockholm	Ticker: ACE	Share price (SEK): 3.54	Market cap (SEKm): 119.4	Net cash (SEKm): 68.9 (Q223)	Enterprise value (SEKm): 50.4

Share information



YTD:	-78.7%	1 year:	-82.5%
1 month:	-20.2%	Since IPO*:	-87.8%

Note: Closing prices as of 20.10.2023

Financials

(SEKm)	2021	2022	2023E*
Revenue	0.0	0.0	0.0*
Revenue growth	*0%*	*0%*	*0%**
Research & Development	107.6	118.1	N/A*
EBIT	-129.5	-147.0	N/A*
Cash flow from operations	-130.0	-139.9	N/A*
Cash position	261.6	149.6	N/A*

Note: *Not announced

Pipeline

Candidate	Indication	Phase I	Phase II	Phase III
Orviglance	MRI imaging	Completed	Completed	Ongoing
Oncoral	Oral cancer treatment	Completed	Ongoing	

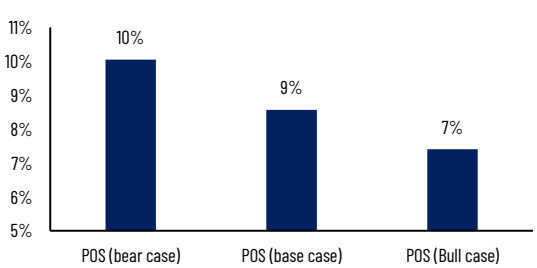
Company description

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 currently 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 that cannot tolerate gadolinium-based contrast agents (approx. 5% 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 compared to intravenous high-dose infusions at the hospital every three weeks, which is the current treatment used. The Oncoral project is currently put on hold as Ascelia Pharma is focusing on finalizing its Orviglance study.

Investment case

The investment case is driven by an approval and subsequent successful launch of Orviglance – potentially through partnership deals. According to Ascelia Pharma, the addressable market for Orviglance serving an unmet need is estimated to be USD 500-600m (US, Europe and Japan) with an annual growth rate of 4-5%. Ascelia Pharma is currently about to re-evaluate data from the already completed SPARKLE phase 3 study. The re-evaluation is expected to be finalized mid-2024 (previously mid-2023), and follows a recent strategy update, where Ascelia Pharma importantly said it would now consider a partnership deal to launch in the US. It expects to have sufficient funding to finalize the study due to the implementation of a cost-cutting program. All things being equal, the investment case is in principle unchanged, but the financial implications have been postponed one year.

According to our model, the market is less optimistic as it is currently implicitly assuming there is less than 10% possibility of a successful approval (PoS) and launch of Orviglance., which is markedly lower than before the postponement was announced. See page 2-3 for further discussions of the model and its results.



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 5-600m annually and growing 4-5 %.

There are currently no competitors in the market, 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, making it likely that the profitability will be higher for longer. Also, a likely partner-based commercialization strategy will reduce the funding requirement.

The Orviglance product has documented very high efficacy similar to or better than current gadolinium-based imaging agents and is safe and convenient to use compared to existing products, according to two recently held studies. Market research indicates that 84 percent of healthcare professionals will use Orviglance.

The re-evaluation of the already collected imaging data for the last remaining SPARKLE study is expected by management to confirm the positive results from the previously completed studies by mid-2024. The one-year delayed completion of the SPARKLE study has affected the share price of Ascelia Pharma markedly negatively, implying a very low valuation by the market according to our DCF model. If indeed the case is unchanged, but the financial implications have been postponed for one year, the value should in theory, fall only 15%, corresponding to the annual discount rate.

Although currently on hold, Ascelia Pharma's second product candidate, Oncoral, offers 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.

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 - even if a partner strategy is chosen. It can also be more expensive than expected.

If the re-evaluation of the Orviglance SPARKLE study is further delayed until after mid-2024, 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 a drug approval and launch (PoS) of Orviglance. The DCF model considers the future potential cash flow of the company when 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 and 3, but when simulating, only estimates regarding phase 3 pipeline product candidates are included. The PoS is compared with the average historical likelihood of a phase 3 pipeline project passing through to launch from phase 2 of approximately 55%.

Market size and market growth

According to Ascelia Pharma, the addressable market for Orviglance is approximately USD 500-600m in yearly revenue, with an expected growth of 4-5% per year. The addressable market only includes the US, Europe and Japan, although there is also a potential market in Emerging Markets. The patents on Orviglance is assumed to effectively run for 7-10 years, but after that, the value of the market is assumed to show negative growth of 5% 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 they will obtain an estimated peak market share of 40% by the year 2031, corresponding to USD 285-370m that year, depending on whether the model uses a bear, base or bull 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 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 linear, growing 5 percentage points a year from the expected launch 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)

Based on historical data from Biostatistics research containing 5764 pipeline projects in pharmaceutical and biotech companies, the average historical likelihood of a Phase 3 pipeline project passing through to launch from Phase 2 is appr. 55%. This is calculated across all medical indication, including those areas that are typically perceived as being very difficult to pass.

A lower-than-average PoS indicates that the market implicitly thinks 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 approved or launched and suggest 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

According to Refinitiv Financial System, five-year average EBIT-margins within major pharmaceutical and biotech companies are approximately 30%. Looking at biotech companies specifically, the five-year average is approximately 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.

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 the indicated market's size and growth by Ascelia Pharma. For simplicity reasons, 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 midpoint of the indicated market size by Ascelia Pharma, USD 550m, growing 4.5%. The model uses industry average levels of profitability conservatively set to an EBIT margin of 40% and a peak market share assumption of 25%, and a discount rate of 15%. This equals to a revenue estimate of above USD 90m five years after launch in 2026. Based on this, the market currently implicitly assumes there is less than 10% (9%) possibility of successful launch (PoS) for Orviglance according to the model. This compares to a historical average level of success of approximately 55% 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 one-fifth of a chance for Ascelia Pharma to become successful compared to other biotech companies developing diagnostic products.

Bear case scenario

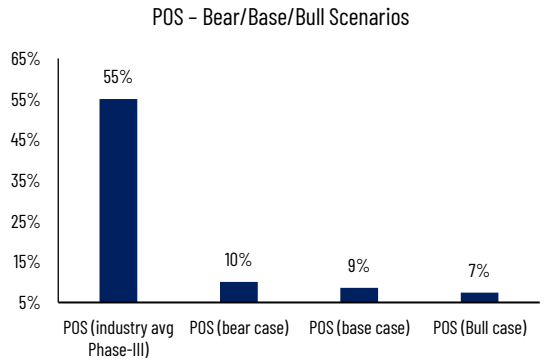
In the bear case scenario, the model uses the low point of the indicated market size by Ascelia Pharma, USD 500m, growing 4% and keeping the remaining criteria from the base case. This equals a revenue estimate of approximately USD 80m in 2030. Based on this, the market currently implicitly assumes there is 10% possibility of successful launch (PoS) for Orviglance according to the model.

Bull case scenario

In the bull case scenario, the model uses the high point of the indicated market size by Ascelia Pharma, USD 600m, growing 5% and keeping the remaining criteria from the base case. This equals a revenue estimate of USD 105m in 2030. Based on this, the market currently implicitly assumes there is 7% possibility of launch (PoS) for Orviglance according to the model.

Conclusion

The three examples of simulations all suggest a very low level of market confidence in Ascelia Pharma as far as the likelihood of a successful launch is concerned. 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, the collaboration with Taiho Oncology and a potentially prolonged patent period to Orviglance. If the investor does not agree and instead does pay value to this, the implicit market confidence for Orviglance becomes even smaller. Lastly, and most importantly, a (very) low implied likelihood of success for any biotech generally reflects the high likelihood for the company to engage into one or more diluting capital raises.



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