ASCELIA PHARMA

INVESTMENT CASE

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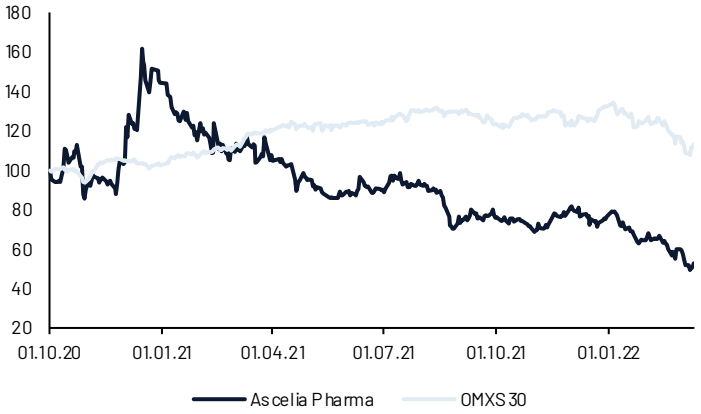
COMPANY-SPONSORED MATERIAL

ASCELIA PHARMA

Ascelia Pharma is a biotech company focused on cancer diagnostic and treatments, headquartered in Malmo, Sweden. Ascelia Pharma was listed on Nasdaq, Stockholm in 2019.

Ticker: ACE
Share price (SEK): 22.25 (23 March 2022)
Market capitalization (SEK) : 749,000,000



KEY FINANCIALS (SEKm)

	2019	2020	2021E	2022E
Revenue	0	0	0	0
EBIT	- 36.8	-93.4	NA	NA

INVESTMENT CASE

- The investment case of Ascelia Pharma is primarily driven by an approval and successful launch of its **phase 3 pipeline product, Orviglance, which has an addressable market of USD 500-600m with an annual growth rate of 4-5%** and has **no competition and serves an unmet need** being a novel imaging agent for those patients with liver cancer that cannot tolerate current imaging agents based on gadolinium.
- The **next share price inflection point** is the completion of recruitment of patients for the phase 3 study **in H1 2022** and simultaneously gathering of study results that will be used for an application to FDA, most likely in H2 2022.
- **Orviglance has an orphan drug designation** which is given in relation to rare and life-threatening diseases, and Ascelia Pharma expects to establish its own US sales organization with limited sales force, reflecting high conviction by the management. In combination with no competition, **an above average profit margin is likely** when compared to the already high margins in the biotech and pharmaceutical industry.
- Ascelia Pharma has a **strong liquidity position of SEK 261.6m** as of Dec. 31st, 2021, which **is expected to last into 2023**, where the Orviglance phase 3 study is expected to be completed, followed by an application to FDA for an approval of Orviglance and a subsequent **launch in H2 2023.**
- According to our proprietary financial model, the **market currently assess there is a 24% likelihood of success for Orviglance in phase 3** compared to an **industry average of 55%** across all indications. This doesn't seem justified based on the strong phase 2 data. Also, Orviglance is a diagnostic product typically reflecting higher likelihood of success.
- Ascelia Pharma is **not a one product company**. It's second pipeline product, **Oncoral**, which is addressing the gastric cancer market, **is in collaboration agreement with Taiho Oncology Inc. regarding an upcoming phase 2 combination study** with Taiho Oncology´s LONSURF cancer product which is already on the market.

KEY INVESTMENT REASONS

- Addressable market serving an unmet need and has no competition, and likelihood of approval rate for diagnostic being higher.
- Strong cash position to complete Orviglance phase 3 study.
- The market currently discounts a very low likelihood of Orviglance approval and launch.

KEY INVESTMENT RISKS

- No products has been launched and commercialized yet. The transition from drug development to full scale production and marketing can be challenging.
- Highly dependent on funding if Orviglance phase 3 study is significantly delayed and highly dependent on phase 3 success for Orviglance.

DISCLAIMER

SELECTED RISK FACTORS POTENTIALLY AFFECTING THE INVESTMENT CASE

We have identified general risks associated with the investment case of which we believe investors should be aware of

Biotech is high risk: Generally, developing a new medical product is very risky as the likelihood of launch and success is very small. Also, patience is an integral part of biotech investing as pipeline projects can take many years to complete and evaluate, followed by a commercialization process than can last for years before an acceptable level of revenue and profitability is reached. Building a biotech company typically also requires extensive and ongoing securement of funding.

No products on the market: Ascelia Pharma currently has two major pipeline products (Orviglance and Oncoral) but none of them has been launched, so the company has no revenue and no earnings.

No experience of commercializing a product: If Orviglance is approved, Ascelia Pharma wants to build their own US sales organization for an expected launch in the second half of 2023. Although this is a sign of very high conviction, there is no guarantee the launch will be commercially successful. This is particularly relevant considering the special sales, reimbursement and payer structure of the US market for pharmaceutical products.

Currency risk: As Ascelia Pharma is based in Sweden, the currency risk when translating revenue and income from US dollars can have huge effects due to the potential changes in the development of the US dollar relative to Swedish kroner. Other non-US companies that have the major part of their sales on the US market will sometimes see changes in their market share compensate changes in US dollars due to the changed competitiveness. This relation does not necessarily apply to the market where Orviglance is being sold as this can sometimes be part of a fixed pricing system. Also, Danish investors should consider the currency risk between Danish and Swedish kroner when trading the stock as the stock is quoted in Swedish kroner.

Dependent on raising capital: Ascelia Pharma is dependent on new funding if the launch of Orviglance is significantly delayed. It can require willingness for investors to participate in ongoing increases of capital to avoid being diluted. As with many other biotech companies, Ascelia Pharma also have some dependence on the issue of warrants and options to internal management and employees to secure funding of the company. If exercised, some dilution can be expected.

Dependance on key employees: As a small and relatively new company, Ascelia Pharma is highly dependent on attracting and keeping management and employee talent. Particularly as Ascelia Pharma has the ambitious plan to launch and commercialize Orviglance themselves. Even for larger and more established companies with organizational structures in place dependence on key personnel can be a challenge.

The market implies low conviction of success: When investing in Ascelia Pharma the investor must consider and assess the huge difference between management and market conviction of success for Orviglance. The investor should be aware that investing contradict the efficient market hypothesis (that 'the market is always right') which is a generally accepted concept within investment theory and practice.

Share price: The share price development in biotech companies can be very volatile and Ascelia Pharma is no exception which the history has already shown. In general changes to the perception of risk in the stock market can have a huge influence on the Ascelia Pharma share price even though the reasons for these changes had nothing to do with Ascelia Pharma. The share price can also be affected other external factors like changes in macroeconomic development, interest rates, tax regimes etc..

ASCELIA PHARMA – IN BRIEF

Ascelia Pharma has developed its current pipeline products since 1999

Overview: Ascelia Pharma was established in 1999 and was listed on Nasdaq Stockholm (TICKER: ACE) in 2019. The company is based in Malmo, Sweden and Woodbridge, New Jersey (US), with 21 employees led by CEO Magnus Corfitzen, who currently owns 252,645 shares and 183,671 stock options.

Ascelia Pharmas key objective is to be a leader in identifying, developing and commercializing novel drugs that address unmet needs of people with rare cancer conditions. Currently, Ascelia Pharma has a pipeline containing two product candidates, Orviglance and Oncoral. The company's main product candidate is Orviglance in phase 3 with an expected market launch in H2 2023.

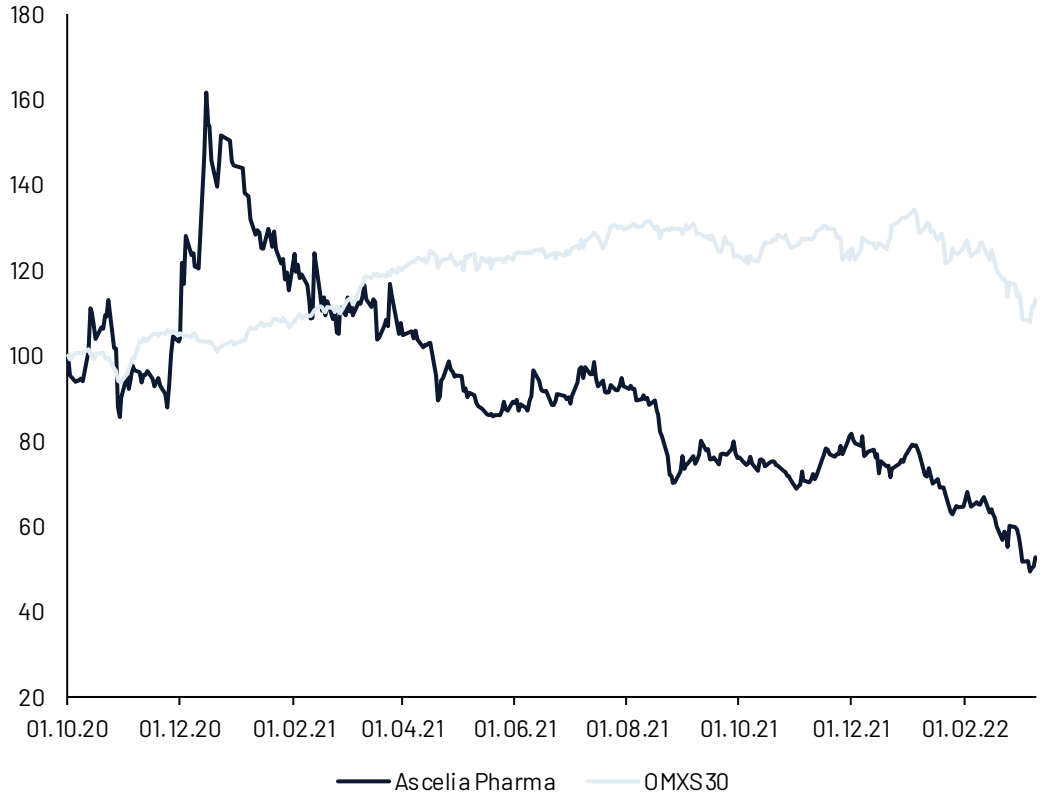
Market potential: Ascelia Pharmas main pipeline product candidate Orviglance has an addressable market of USD 500-600m with an annual growth rate of 4-5%. Orviglance provide a new solution to a specific market that currently has no treatment. Potentially this can lead to a high share of this market. Oncoral is the second pipeline product addressing a market which is expected to exceed USD 4B by 2022 according to Global Data. Although bigger, this market already has established competing product, but Oncoral offers a new approach to these competing products.

Unmet market need: According to Ascelia Pharma, Orviglance is serving an unmet medical need. This means that there is potential a high demand for the product with no current solution. This has led to high conviction of success by the company, and Ascelia Pharma has decided not to use distribution channels or other intermediaries, but instead take Orviglance to the market themselves through their own sales channels. This suggests a potentially higher profit margin.

Liquidity position. Ascelia Pharma has a liquidity position of SEK 261.6m as of Dec. 31st, 2021. This is expected to last into 2023, where the Orviglance phase 3 study is expected to be completed, followed by an application to FDA for an approval of Orviglance and a launch in H2 2023.

Share price: The share is currently traded at SEK 22.25. The all time high of the stock was in mid December 2020 where the share price was SEK 65. As of March 23th, 2022, the market cap is SEK 749m.

Indexed share price development (Index 100 = 1 October 2020)



KEY INVESTMENT REASONS

We have identified the key investment reasons, that makes the investment case attractive.

Unmet need. Ascelia Pharma's main product, Orviglance is entering a market with an unmet need. Currently cancer clinics are using gadolinium as a contrast agent for MR imaging of the liver to better detect cancer (liver metastases and primary liver cancer). Patients that also suffer from poor functioning kidneys are, however, at risk of using these gadolinium-based contrast agents since malfunctioning kidneys cannot excrete gadolinium. Gadolinium is a heavy metal and can cause serious and potentially fatal side-effects (Nephrogenic System Fibrosis, NSF). Therefore, these gadolinium products carry black-box warnings for patients with reduced kidney function. Orviglance (manganese based) aims to be the standard of care liver MRI contrast agent for patients with poor kidney functions.

No competition: As mentioned, there is an unmet need within the market of MRI contrast agents for the diagnosis of the liver in patients also suffering from poor functioning kidneys. This means Orviglance will be, if they pass their phase III study, the only MRI contrast agent for this target patient population with no competitors.

Market size: According to Ascelia Pharma, the estimated market size is USD500-600m, and is based on the number of patients with suspected primary liver cancer or liver metastases and severe kidney impairment, which is estimated by Real-World-Data to be just below 4 pct. of total relevant cancer patients or approx. 225.000 patients across the three regions US, Europe and Japan[1]. Based on inputs from 75 experts and payers[2], an average price across the three regions of USD 2500 can be estimated. Assuming an average of one scan per patient per year, the likely addressable market size is USD500-600m.

1) Market research with Decision Resources Group, 2020
2) Market research and analyses with Revenue Reimbursement Solutions and Charles River Associates, 2020

Diagnosis less risky: As Orviglance is a diagnostic product rather than a new medical product, Orviglance should generally be perceived as less risky, which in terms of approval from the authorities increases the likelihood of approval.

Highly profitable model for market approach: The typical structure of the MR imaging market of cancer patients makes it possible to reach the potential decision makers with a relatively low number of staff. Ascelia Pharma expects that 20 sales representatives will be able to cover a total of 400 clinics which represents approx. 75 pct. of the market. This suggests a very high operational leverage is likely which bodes very well for the EBIT-margin level.

Strong liquidity position: Ascelia Pharma has a net cash position of SEK 261.6m as of Dec. 31st, 2021, which is expected to last into 2023, where the Orviglance phase 3 study is expected to be completed, followed by an application to FDA for an approval of Orviglance and a subsequent launch in H2 2023. Assuming no further delay, the ability by Ascelia Pharma to fund its required investments and operational spend until the company starts generating positive cash flow can be very important, as the stock market environment is currently in a risk off mode. In that environment the ability to access the stock market to raise more capital can be more challenging than usual in terms of pricing and speed.

Not a one product company: While the natural focus is on the expected Orviglance approval and launch, it's important to notice that the Oncoral product candidate is showing good progress and has received an important validation by 'Big Pharma' as Ascelia Pharma has entered into a collaboration agreement with Taiho Oncology Inc. regarding an upcoming phase 2 combination study with Taiho Oncology´s LONSURF cancer product.

HOW IT WORKS (ORVIGLANCE PHASE III STUDY)

Orviglance show good efficiency and tolerability for patients with severe kidney impairment

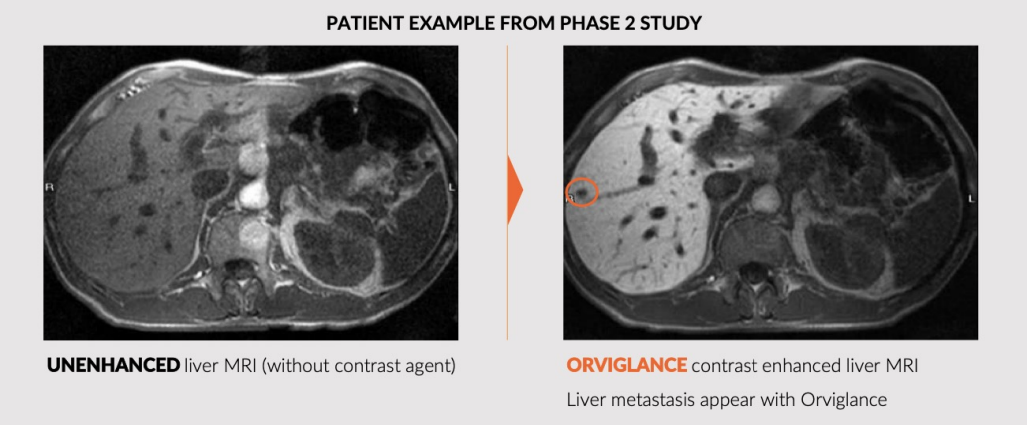
Orviglance: Orviglance, formerly known as Mangoral, is a novel oral imaging agent in development for use in MR (Magnetic Resonance)-Imaging of the liver. The purpose of Orviglance is to make MR-imaging based detection and visualization of focal liver lesions (including liver metastases and primary tumors) available for patients with severe kidney impairment that cannot tolerate gadolinium-based contrast agents currently available in the market. These patients are at risk of developing the serious and potentially fatal condition Nephrogenic Systemic Fibrosis (NSF) if they use gadolinium-based agents. Instead, Orviglance is an orally administrated contrast agent based on the chemical element manganese, which is a natural trace element in the body.

Orviglance also contains an amino acid and a fat-soluble vitamin to increase the absorption of manganese from the small intestine into the portal liver vein. From here, the manganese is transported to the liver where it is taken up by and retained in the normal liver cells, also known as the hepatocytes. The picture to the right is an imaging example from the liver of a patient. It shows how Orviglance helps to visualize liver metastasis, which potentially can be lifesaving if detected in an early stage.

A recent study indicates that Orviglance is slightly superior to current established imaging agent products in terms of the number and size of liver lesions detected, which suggests that there is no efficiency risk of using Orviglance compared to gadolinium bases imaging agents – even for patients with normal kidney functions. As Ascelia Pharma has an orphan drug designation for its manganese based Orviglance product, the priority will most likely be for Ascelia Pharma to focus on the patients with severe kidney impairment. These patients is estimated to constitute approximately 4% of the patients required to be scanned.

What is the problem? Currently it is difficult for doctors to detect potentially lethal liver lesions. Therefore, the liver lesions can, unfortunately, be overlooked. Detecting these lesions can potentially be lifesaving for the patients. If they use the gadolinium-based contrast agents currently available the liver lesions can be detected, but patients with severe kidney impairment cannot tolerate the gadolinium.

How is the problem solved? Ascelia Pharma has developed a novel drug based on manganese that will make the liver lesions appear clearly which means the chances of detecting enhanced liver lesions is being increased, but at the same time can be tolerated by patients with severe kidney impairment that cannot tolerate gadolinium-based contrast agents currently available in the market.



Source: Ascelia Pharma

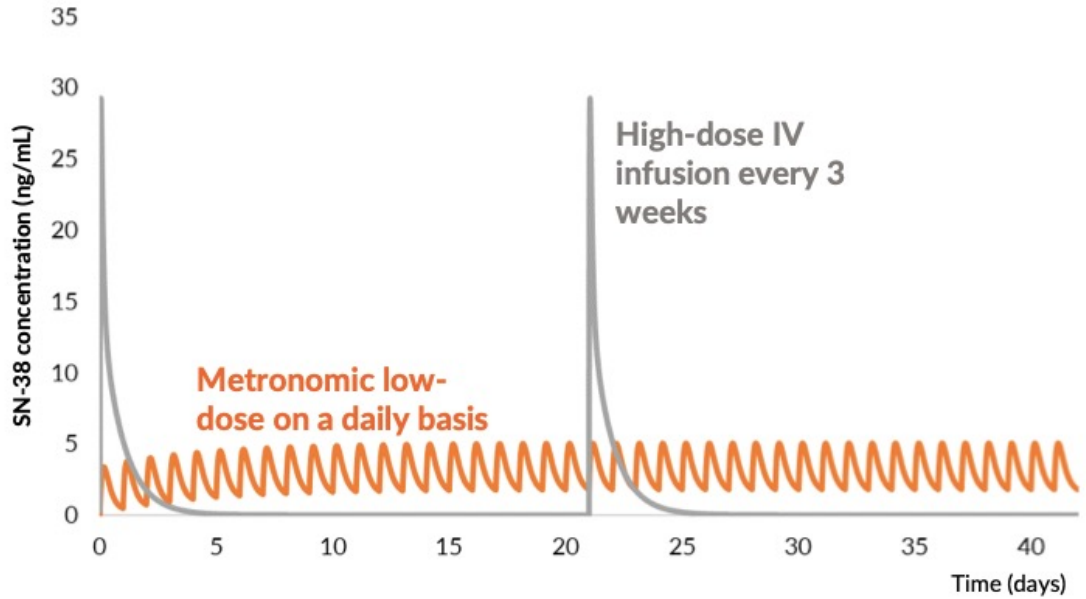
HOW IT WORKS (ONCORAL – PHASE II STUDY)

Oncoral is an oral administered alternative to infusion of irinotican

Oncoral is a daily irinotecan tablet with the potential to offer better patient outcomes with improved safety following a daily low dosing at home compared to intravenous high-dose infusions at the hospital every three weeks. Following successful Phase 1 results, Phase 2 clinical development for Oncoral is in preparation. Oncoral is initially being developed for the treatment of gastric cancer in combination with other anti-cancer treatments. Irinotecan is a so called antineoplastic agent that after metabolic activation inhibits the enzyme topoisomerase 1, thereby inducing cancer cell death via the prevention of their DNA replication. Irinotecan is converted by carboxylesterases, primarily in the liver, to the active metabolite SN-38 which is 100–1,000 more potent than irinotecan in killing tumor cells.

Ascelia Pharma has signed a clinical collaboration agreement with Taiho Oncology for the development of Oncoral in combination with LONSURF. Oncoral will be evaluated in combination with LONSURF, which is an already approved gastric cancer drug on the market. Taiho Oncology will, as part of the agreement, provide scientific expertise for the study. According to Ascelia Pharma, Oncoral has the potential to be a new treatment regimen for gastric cancer, as the all-oral tablet combination provide a treatment benefit to patients suffering from the aggressive gastric cancer form.

PLASMA LEVELS OF IRINOTECAN



Source: Simulation of Oncoral vs. IV Camptosar performed by Pkxpert AB

Oncoral Phase 1 results

- Well tolerated, no unexpected side-effects
- Hematological toxicities mild-moderate (grade 1 or 2)[4]
- Efficacy: Stable disease even in patients previously treated with IV irinotecan

Infrequent high-dose IV irinotecan

Gastrointestinal and hematological side effects, ~30% severe or life-threatening (grade 3 or 4)[1]

Frequent (metronomic) low-dose irinotecan

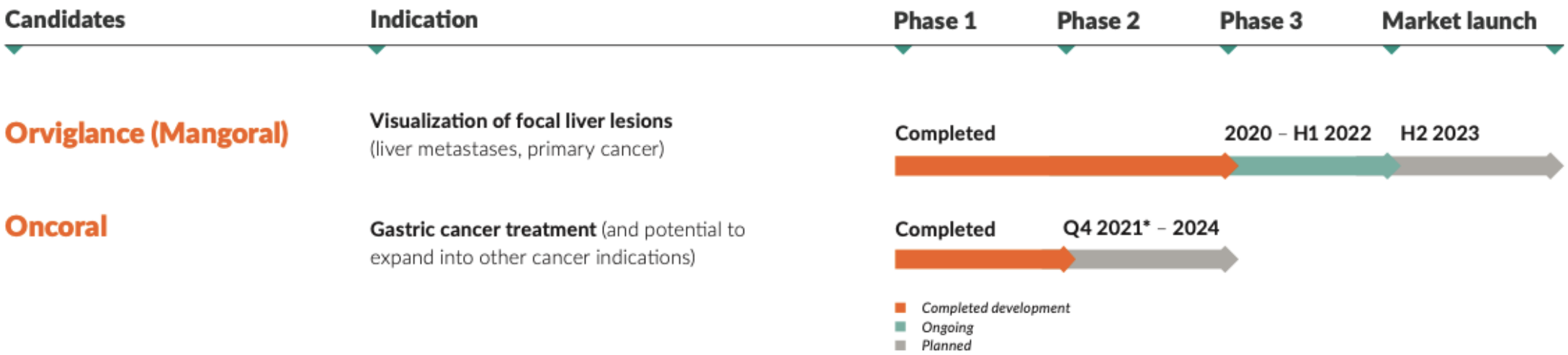
- Several studies show improved tolerability[2,3]
- Daily dosing – adjust quickly if acute toxicity

PIPELINE - TIMELINE

Current pipeline funded until 2023

Orviglance: As the timeline shows below, Orviglance has completed both phase 1 and 2 studies and is currently in an ongoing phase 3 study with an estimated completion of patient enrollment in H1 2022. Unlike data collection, analysis and conclusions relating to medical pipeline products that can be very lengthy, analysis of data and conclusions relating to diagnostic pipeline products like Orviglance can be done almost simultaneously while patients are being enrolled due to the nature of the data. This way, an application to FDA can be made shortly after enrollment is completed, and assuming a subsequent approval from FDA, a market launch is estimated to take place in H2 2023.

Oncoral: Oncoral has successfully completed its phase 1 study with strong result. Oncoral has begun its Phase 2 study. Completion of phase 2 is estimated to take place in 2024 following the cooperation with Taiho Oncology.



ASCELIA PHARMA – DISCUSSION OF ASSUMPTIONS IN PROPRIETARY SIMULATION MODEL

Biotech companies can be assessed based on a number of different metrics

The objective of this investment case is not to calculate a price target for Ascelia Pharma share. Instead, the investment case uses a simple 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 likelihood of a drug approval and launch (POS) of Orviglance. The DCF model takes into account 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 phase 2 and 3, but when simulating, only estimates regarding phase 3 pipeline products candidates are included in the DCF.

Market size and Market Growth: According to Ascelia Pharma the addressable market for Orviglance is approx. USD 500-600m in yearly revenue with an expected growth of 4-5% per year. In the base case scenario, the midpoint of the addressable market size of USD 550m and growth of 4.5% is used in the model. The addressable market only includes the US, Europe and Japan although there is also a potential market in Emerging Markets. When the patent on Orviglance runs out in 7-10 years, the market is expected to show negative growth of 5% per year. 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 that market is not included at this point.

Ascelia Pharma Market Share and Revenue: If Ascelia Pharma succeed in launching Orgviglance, It is estimated that they will obtain an estimated peak market share of 40% in the year of 2030, corresponding to USD 300-390m that year depending on whether the model uses the bear, base or bull case. 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 likely penetration curve can take different paths, but for simplistic reasons, the penetration curve is expected 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) as reference in the model: 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 approximately 55%. This is calculated across all medical indication, including those areas that are typically perceived as being very difficult to pass. Ascelia Pharma is within diagnostics which is generally considered to be an area where it is easier to get approval of new products.

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. Confidence by Ascelia Pharma to market Orviglance themselves suggest a high EBIT-margin of 50% in the model is appropriate, and perhaps even conservative. In the period 2023-2026 an EBIT-Margin of 40% has been used. For the period 2020-2023 an estimated cash burn of USD 20m per year has been used as the company has communicated their cash position will last into 2023.

ASCELIA PHARMA – VALUATION PERSPECTIVES

Based on the current share price (as of March 23nd 2022) the market implicitly discount a low likelihood of Orviglance launch

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 the indicated level of markets size and growth by Ascelia Pharma. For simplicity reasons, the remaining criteria discussed on the previous page are assumed to be the same in all scenarios (using industry average levels).

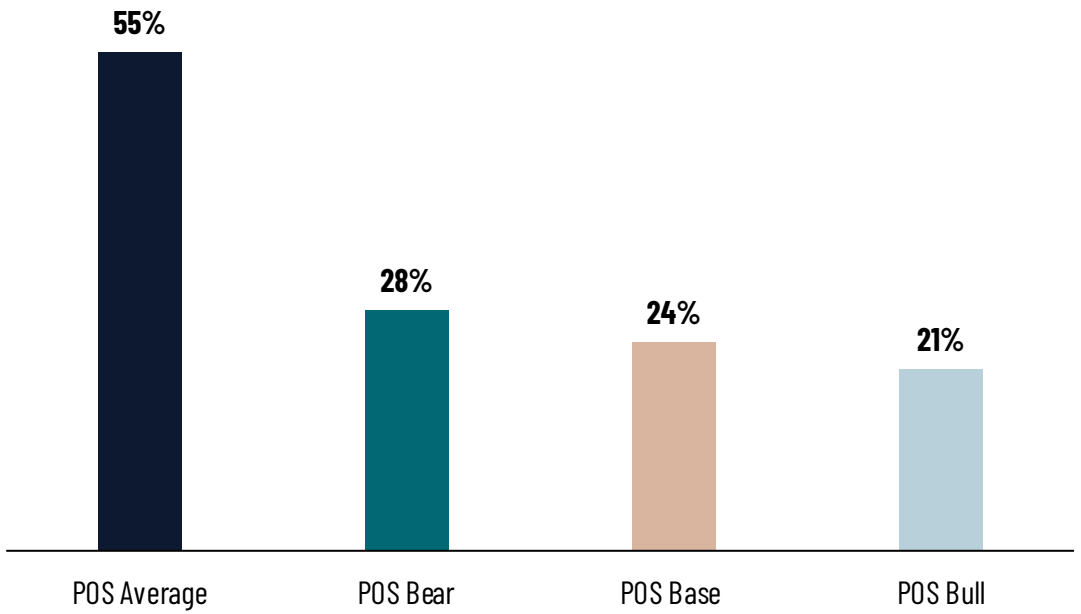
1) **In the base case scenario**, the model uses the midpoint of the indicated market size by Ascelia Pharma, USD 550m growing 4,5%. The model also uses industry average levels of profitability (EBIT margin of 50%) and the beforementioned peak market share assumption of 40% and a discount rate of 15%. This equals a **revenue estimate of USD 340m in 2030**. Based on this, **the market currently implicitly assumes there is 24% possibility of 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 type products, similarly to those currently in development at Ascelia Pharma.

2) **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 USD 300m in 2030.** Based on this, **the market currently implicitly assumes there is 28% possibility of launch (POS) for Orviglance** according to the model.

3) **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 390m in 2030.** Based on this, **the market currently implicitly assumes there is 21% possibility of launch (POS) for Orviglance** according to the model.

The three examples of simulations all suggests a very low level of market confidence in Ascelia Pharma as far as the likelihood of launch is concerned. As described, the model only includes potential cash flows from Orviglance, thereby implicitly assuming the market paying no value to all the other potential future cash flows from Oncoral, the collaboration with Taiho Onchology and a potentially prolonged patent period to Orviglance. If the investor does not agree and instead do pay value to this, the implicit market confidence for Orviglance becomes even smaller.

Industry average POS compared to Bear/Base/Bull scenarios



MANAGEMENT TEAM, MEMBERS OF THE BOARD OF DIRECTORS AND MAJOR SHAREHOLDERS

Magnus Corfitzen
CEO

Carl Bjartmar
CMO

Kristian Borbos
CFO

Julie Waras Brogren
CCO

Peter Benson
Chairman of the board

CEO Magnus Corfitzen Magnus Corfitzen (born 1975) has experience from investing, building and growing life science companies in various roles including operational activities or investment responsibilities for public and private biotech and MedTech companies.

CMO Carl Bjartmar Carl Bjartmar (born 1963) has a track record in late-stage orphan drug development. He has previously served in senior roles at large international pharmaceutical companies such as Lundbeck, Sanofi and Genzyme, where he gained experience in clinical development, in particular the development of novel therapies for rare diseases.

CFO Kristian Borbos Kristian Borbos (born 1978) has banking and finance experience from large listed companies as e.g, sell-side analyst as well as various financial positions in large corporates including treasury, financial reporting and financial planning and IR activities.

CCO Julie Waras Brogren (born 1972) has experience from life science leadership and commercialization, including cross-functional drug launches and medical devices. Julie Waras Brogren was previously President of BresoTEC, Canada and has held various leadership positions at Novo Nordisk in Denmark and Brazil, including as Senior Director of the Launch Office for the Victoza® GLP-1 and degludec insulin launches.

Chairman of the board Peter Benson: Peter Benson (born 1955) is Chairman and co-founder of Sunstone Capital Life Science Ventures and board member of PainDrainer AB.

APPENDIX – PHASES OF PRODUCT DEVELOPMENT

Ascelia Pharma is going through the industry framework for testing and trials

When a pharma, biotech or life science company wants to bring its drug candidate to the market it has to pass three clinical stages (phases). Before entering the three clinical phases, the company has to pass an "In vitro" trial which means "In glass"-trial format in the laboratory. After this, the company has to pass a "In vivo" trial which is testing on laboratory animals. These trials can take many month or even years.

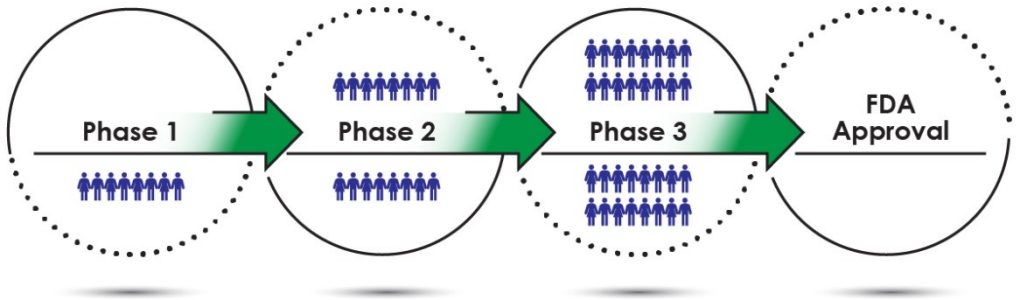
Phase 1: The first phase of clinical studies (phase 1) could be an FIH (First In Human) study, but it could also be a study where an already approved medicine is tested on a new disease/indication or patient group, e.g., children. Phase 1 trials typically involve an assessment of one or more of the following aspects of the investigational drug candidate: A preliminary assessment of the safety and tolerance, pharmacokinetic properties (absorption, distribution, metabolism and excretion), pharmacodynamics (the medicine's mechanism of action in the body) and a preliminary measurement of the effect of the drug candidate.

In phase 1, the drug candidate is usually only tested in a few people (typically 10 persons). If the mechanism of action from the drug candidate is new and might be particularly strong, the drug is tested in one trial subject at a time to reduce the risk that several trial subjects are exposed to potentially unpleasant side effects. This phase has an average possibility of success (POS) of 38,8% across all indications (Biostatistics, 2019)

Phase 2: If the phase 1 trial delivers positive results, phase 2 can begin. In phase 2, the drug candidate is tested in a larger group of people who have the specific disease the drug candidate is targeting (approximately 100 persons). In this phase, the drug candidate is tested in patients rather than in healthy individuals since the main purpose is to test the therapeutic effect of the drug. Phase 2 also studies the safety profile of the drug and tests which dose is most effective. This phase has an average POS of 38,2% (Biostatistics, 2019)

Phase 3: The next phase is phase 3 where the medicine is tested in a large group of patients under conditions more like everyday settings to confirm the effect of the drug candidate. In this large group of persons, the objective is to get a more detailed picture of the drug's efficacy and side effects. Also, the usage of placebo treatment is sometimes being used in this phase to better test the effect. A phase 3 trial usually takes several years and may include several thousand of individuals. This phase has an average POS of 55% (Biostatistics, 2019)

Source: Lægemiddelstyrelsen, Danish Medicines Agency.



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