A rocket roll out is the key to success

ASCELIA PHARMA

Ascelia Pharma has included the first patient in its pivotal, fully financed and an exceptionally straightforward phase III SPARKLE study with the lead asset Mangoral, targeting global launch in 2022. We estimate a relatively high 75% likelihood that the imaging drug Mangoral will reach the market on the back of strong cumulative clinical data and a solid, straightforward Phase III design. As the global trend move towards regulations and bans of standard liver-MRI contrast imaging agents, Mangoral's market potential becomes evidently clearer. Furthermore, the successful commercial advances by the closest peer Blue Earth Diagnostics provides a blueprint for Ascelia Pharma and illustrates that there is significant commercial value potential in differentiated oncology imaging drugs targeting an unmet medical need. Our impression is that this case is misunderstood and share price deeply discounted, probably because the market sees it as a typical drug development company with the traditional clinical development risks. We argue that these risks are low, while the main pertains to commercialization. The recent recruitment of Julie Waras Brogren as Chief Commercial Officer is a positive de-risking catalyst. This is not just another recruitment and we believe this should be seen as evidence of the board's and management's commitment plan to play it real big on executing the commercialization steps according to the blueprint provided by Blue Earth Diagnostics. This is not a clinical risk story – it's a commercialization risk story and Ascelia Pharma's recent move increases our confidence that the company is building up what it takes to successfully commercialize Mangoral. Our base case risk-adjusted DCF valuation suggests that Ascelia Pharma's current market value is unrealistically low, reflecting a deep discount. We maintain our Outperform rating and raise the target price to SEK 54 share, corresponding to >140% upside to the current market cap, suffering from low consensus expectations.

OUTPERFORM

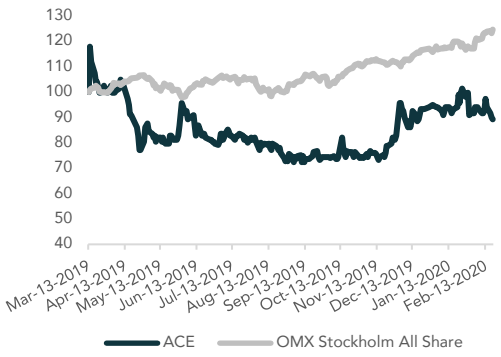
Update Report

Target price: SEK 54
Share price: SEK 22.2
Implied upside potential: 143%

Ascelia Pharma at a glance

Ascelia Pharma AB is an oncology-dedicated company in late-stage clinical development. The lead asset Mangoral is a MRI liver-specific contrast agent in development for improved visualization of focal liver lesions, including liver metastases, in patients with severe renal insufficiency where today's standard of care is contraindicated. The company's pipeline also includes Oncoral, an oral version of the well-established chemotherapeutic agent irinotecan. Oncoral has completed phase I.

Share price development (index= Mar 13, 2019)



Key Data	As per 2020-02-19
Ticker	ACE
Share price (close)	SEK 22.2
Free float	52.8%
Market cap	SEK 521.5m
Website	www.ascelia.com
Average daily volume	SEK 0.85m

Financials (SEKm)	FY18A	FY19A	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E
Probability Adjusted Net Sales	0	0	0	0	52	149	302	416	533	638	738	839	799	744
EBITDA	(25)	(37)	(100)	(96)	(154)	(59)	28	128	231	322	410	498	460	433
Net income	(24)	(38)	(101)	(96)	(155)	(59)	27	128	230	272	321	390	360	339

Source: Vator Securities

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Mangoral advanced into fully funded pivotal Phase 3 study, with an estimated 75% LOA

Ascelia Pharma has progressed its medical imaging drug Mangoral into the fully funded, pivotal phase III study SPARKLE, from which results are due late 2020 or early 2021. The candidate is a new MRI liver-specific contrast agent aimed for improved visualization of focal liver lesions, including liver metastases, in patients with severe renal insufficiency, who cannot tolerate today's standard of care gadolinium-based contrast agents.

The pivotal SPARKLE trial will be conducted at 30-35 sites in Europe, US and South Korea in up to 200 patients with suspected or known focal liver lesions and renal insufficiency, where standard of care is currently unenhanced MRI (without a contrast agent). Mangoral will be compared to unenhanced MRI, where each patient will undergo both unenhanced MRI and MRI with Mangoral. The primary efficacy endpoint is based on lesion visualization[1], measured by lesion delineation and lesion to liver contrast, of Mangoral-enhanced liver MRI compared to unenhanced MRI and will be evaluated by three independent blinded readers. MRI will be performed before and within few hours after oral Mangoral administration, and safety parameters will be followed up for 3 days. Provided that Ascelia Pharma finalizes enrollment during H2 2020, the company expects to report results in late 2020 or early 2021. These results will be the basis for the NDA that the company plans to submit in 2021, followed by approval and launch in 2022.

We believe that SPARKLE benefits from a very straightforward and solid phase III design which has been planned in accordance with feedback from FDA and EMA to maximize the likelihood of success. There are a number of important parameters that lowers the risk of this imaging trial compared to a typical phase III oncology trial:

- The mechanism of action of Mangoral is well established (Manganese)
- There is high degree of similarity between Phase II and Phase III primary endpoints for Mangoral.
- The comparator for Mangoral is MRI with no contrast agent, meaning the company does not have to show superiority compared to another contrast agent. In addition, each patient serves as his/her own control, thus minimizing variation.
- The follow-up time is only a few days, compared to months or years for the typical Phase III oncology study. This should limit the risk for significant study delays.

Table 1 on the following page shows a comparison of Mangoral's Phase III trial with a typical Phase III oncology trial.

[1] The primary efficacy endpoint is the visualization of detected focal liver lesions, measured by 2 co-primary variables: lesion border delineation and lesion contrast compared to liver background

Table 1. Comparison of Mangoral's Phase III trial to typical Phase III oncology trial

Parameter	Typical pivotal Phase III oncology trial	*Mangoral* pivotal Phase III trial
Patient sample size	• 500-1 000+	✓ Up to 200 patients
Mechanism of action	• Often not fully understood	✓ Established
Study design	• Patients randomized into separate study subgroups thus increasing variation	✓ Each patient his/her own control thus minimizing variation
API	• Often a novel molecule	✓ Manganese
Study comparator	• Add-on to standard of care or evaluated head-to-head vs. another active treatment regimen	✓ Add-on to standard of care, i.e. unenhanced MRI vs unenhanced MRI + Mangoral enhanced MRI
Follow-up time to endpoint	• Months to years	✓ 3 days

Source: Company information

Clinical trial development is an inherently risky business. However, we take confidence in the statistical fact that six previous Phase I and Phase II studies have found Mangoral to significantly improve the performance of liver MRI compared to MRI without contrast agent with a very benign side-effect profile. Importantly, robust evidence of efficacy has been demonstrated in parameters that are included in the primary endpoint in the SPARKLE study: a blinded read study of all available imaging data from individual clinical studies with 178 subjects in total showed that Mangoral significantly improved MRI performance in terms of lesion visualisation (conspicuity; p-value <0.0001) and delineation (p-value <0.0001), and quantitative parameters like lesion to liver contrast ratio. In addition, 33% more lesions were detected with Mangoral enhanced MRI compared to unenhanced MRI. Based on the cumulative clinical data that is available to date combined with the straightforward phase III design detailed above together with its benefits, we set a relatively high 75% LOA for Mangoral from its current stage in development to the market. This contrasts with a 37%[2] LOA for an oncology therapeutic in phase III. Accordingly, we believe that the development of Mangoral is, relatively speaking, a low-risk project from a clinical development perspective.

Our view going forward of the SPARKLE study is that the statistically highly significant efficacy of Mangoral demonstrated to date and the high degree of similarity between Phase II and Phase III (SPARKLE) primary efficacy endpoint poises SPARKLE for a successful outcome that is likely to provide sufficient basis for approval. It is important to bear in mind that there are already very few medical imaging drugs on the market, in contrast to therapeutic drugs. Mangoral is intended to be used in a very niche indication with a small patient group for which there are no other available options and for which Mangoral is the first contrast agent in the world to obtain Orphan Drug Designation by the FDA, thus underscoring its need.

The clinical utility of Mangoral enhanced MRI, i.e. its impact on patient management, will be assessed through secondary endpoints in the SPARKLE study. We expect that

[2] Hay et al. Nature Biotechnology 32.1 (2014): 40-51

these results will be essential to support the company's estimated pricing in the range of USD 1500-3000 per dose and qualify for reimbursement, which in turn will drive market adoption to achieve meaningful uptake. Accordingly, we deem activities establishing the clinical utility of Mangoral as catalysts that will determine the company's commercial success.

Emerging body of evidence demonstrating negative effects of gadolinium emphasizes Mangoral's market potential

The currently used MRI contrast agents are based on gadolinium, a toxic heavy metal, and have since 2006 been found to accumulate in the body and be associated with potentially lethal Nephrogenic Systemic Fibrosis in patients with severely impaired kidney function. Consequently in 2010, both FDA and EMA contraindicated or warned against the use of these contrast agents in this patient population.

More recently, increasing knowledge of gadolinium contrast agents and the risks they pose, not only limited to patients with severely impaired kidney function, have led regulatory authorities to act . After evidence of gadolinium accumulation in the body, including the brain, after repeated dosing, the EMA recommended market authorization withdrawal of three of the least stable and most toxic gadolinium contrast agents. Based on EMA's recommendation, the European Commission decided to remove these products from the market in all EU member states effective from late 2017. Shortly thereafter, Japan's Ministry of Health, Labour and Welfare asked makers of gadolinium-based contrast agents for MRI scans to revise their warning text. Furthermore, in late 2017, the FDA concluded that it, amongst other things required changes to the labelling of all gadolinium-based contrast agents to include warning and precaution.

Emerging findings point towards additional, potentially serious issues associated with gadolinium-based contrast agents. Gadolinium-based contrast agents are very problematic to clear in wastewater treatment plans and may therefore enter the groundwater followed by tap water. A recent study[3] in six major cities in Germany found gadolinium (originating from human use) in municipal tap water and tap-water based soft drinks (i.e. Coca Cola) in all cities investigated. Moreover, the study proved that polluted surface water exposes shallow groundwater to pollution and that gadolinium from contrast agents enters the human food chain. Another recent study[4] highlighted that pregnant women are at risk of exposure to gadolinium-based contrast agents while they undergo MRI scans in the first trimester. While the effects on fetuses are unknown, it is established that gadolinium contrast enters the placenta and fetal circulation.

While the extent of the health effects of gadolinium retention in the body is not yet fully understood, product development in the broad category of gadolinium-based contrast agents, which dominates the MRI area, has stalled since the knowledge about

[3] Science of The Total Environment 2019 687:1401-1408, Anthropogenic gadolinium in tap water and in tap water-based beverages from fast-food franchises in six major cities in Germany, Schmidt et al.

[4] Radiology 2019 293:1, 193-200, First-Trimester Exposure to Gadolinium-based Contrast Agents: A Utilization Study of 4.6 Million U.S. Pregnancies, Bird et al.

rare but potentially very serious side effects emerged 10 years ago. Today, 2/3 of abdominal (including liver) MRI examinations are performed with gadolinium-based contrast agents, and screening for any risk of gadolinium side effects is part of clinical practice. The remaining 1/3 of the procedures are being done without contrast enhancement due to, for instance, medical status or safety reasons. For these patients, the diagnostic accuracy is suboptimal.

Overall, the situation detailed above highlights both the need for new contrast agents that are safe, effective and gadolinium-free, primarily for patients with severely impaired kidney function for whom there are no other available options. Mangoral is based on manganese and is administered orally rather than through an injection, giving the product several advantages over today's standard of care. For instance, the majority of the agent is absorbed by the liver in the first pass from the small intestines to the liver, allowing for a very targeted approach and limited systemic exposure. Moreover, Mangoral is excreted via the bile, instead of the kidneys as other agents, making it suitable for patients with impaired renal function. The current strategy for Mangoral was implemented when knowledge about the risks with gadolinium-based contrast agents emerged, and Ascelia Pharma conducted early on extensive pricing and reimbursement analyses early on to validate the market opportunity and to price Mangoral on value-based pricing principles. Subsequently, the company pioneered getting US orphan drug designation for a diagnostic drug. In conclusion, it is evident that the company has taken diligent steps to verify the business case for Mangoral. On that note, we want to emphasize that it is irrelevant to benchmark pricing of Mangoral against low-cost gadolinium contrast agents as these are not an alternative for patients with severely impaired renal function.

Blue Earth Diagnostics success story provides blueprint for Ascelia Pharma

Ascelia Pharma's peer Blue Earth Diagnostics (BED) has with the development and commercialization of Axumin, a novel contrast agent for use with PET imaging to detect recurrent prostate cancer, demonstrated that there is significant commercial potential in the niche molecular imaging diagnostics area. After slightly more than three years since FDA approval for US market sales in May 2016, BED was in August 2019 acquired by Bracco Imaging from the London-listed investment company Syncona for GBP 374m. In context of BED's financial performance at the time of the acquisition, this transaction value corresponds to a multiple of 4.5x 2019 revenues of GBP 83.9m and a multiple of 13x EBITDA of GBP 28.7m (Syncona calendar year April-March).

We referred to BED already in our initiation report of Ascelia Pharma (April 25, 2019), and we believe that it is worth reconnecting to the case again to further our thinking as Ascelia Pharma is approaching commercialization stage. The successful commercialization of Axumin and acquisition of BED illustrates, in our view, that there is significant commercial value potential in differentiated oncology imaging drugs targeting an unmet medical need. It also illustrates that the large industry players within

contrast media are willing to pay for late-stage innovation. In addition, it is important to point out that Axumin's case demonstrates the ability to obtain premium pricing for a differentiated imaging drug (Axumin is priced at USD 3700 per dose in the US). With that said, it provides validation to the price estimate that Ascelia Pharma has for Mangoral (USD 1500-3000 per dose). This price estimate is based on more than 25 interviews with EU and US payors, and the upper-end of the company's price range is below the actual price for Axumin, which provides comfort. Moreover, Mangoral also has Orphan Drug Designation from FDA and orphan drugs are normally priced at a significant premium to ordinary drugs. As Mangoral targets a niche indication in which there are no available options, it should be clear with the information detailed above that price comparison to low-cost gadolinium-based agents is irrelevant in this case.

We expect Ascelia Pharma to increasingly ramp up communication regarding their commercialization roll out plan

We expect to hear more about a comprehensive plan we assume the management is working on to enroll to secure a successful product roll out. BED established Axumin on the market through regulatory clinical trials, line extension trials, regulatory approvals across key regions, commercial organisation build-up, signing of several manufacturing and marketing collaborations, and patient access to the product through reimbursement. It took BED two years from the first marketing approval (US) to reach profitability. We believe the value that BED has created with Axumin may well serve as a role model for how Ascelia Pharma's value creation could develop during the next few years, assuming it undertakes the above-mentioned activities with successful outcome.

We note that BED has successfully broadened reimbursement coverage and driven market adoption of Axumin through establishing the clinical utility of Axumin PET imaging in the management of patients with recurrent prostate cancer in line extension trials. We expect that demonstration of the clinical utility of Mangoral will correspondingly be a key catalyst for Ascelia Pharma to achieve commercial success. The clinical impact in conjunction with significant health-economic benefits will presumably be of particular importance since the company will have to establish a new treatment standard as there is no existing treatment to replace. Our view is, consequently, that the main present risk in Ascelia Pharma's case pertains to market adoption and commercial execution.

As we are hypersensitive to the build-up of commercial capabilities, we view the recent recruitment of Julie Waras Brogren as Chief Commercial Officer to lead the commercial preparations for the launch of Mangoral as a de-risking factor. She brings more than 18 years of senior, extensive commercial experience in biopharma and medtech industries, from among others, BresoTEC and Novo Nordisk where she was instrumental in the launch preparations and pre-commercialization of the blockbuster drugs Victoza® and Tresiba®. With this significant commercial know-how brought into Ascelia Pharma, we

recognize that the company is on track to transforming into a commercial stage organization positioned for successful launch and commercialization of a new treatment standard.

Outlook

Below follows near-term events that we forecast for Mangoral. Ascelia Pharma has not communicated when they expect to provide updates on the commerical set-up in the US or commercial strategy in Europe and Japan, so forecasts related to these events reflects our current expectations .

- **H2 2020**: Last Patient enrolled into pivotal Phase III SPARKLE study
- **Q4 2020/Q1 2021:** Topline data from SPARKLE study
- **2020:** Updates regarding commercial set-up and pre-launch activities in USA.
- **2020:** Present plan for go-to market strategy in Europe
- **H1 2021:** Full study report from SPARKLE study
- **2021**: Regulatory submissions, pre-launch activities and continued build-up of US commercial organization
- **2021:** Clarity on commercialization plan in Japan through, for instance, announcement of agreement with commercial partner.
- **2022**: Regulatory approval and launch

Valuation

Outperform rating and target price SEK 54

We maintain the Outperform rating and raise the target price to SEK 54 per share. Our target price is based on a risk-adjusted DCF valuation combined with comparison to peer group valuation and transaction multiples. Since Ascelia Pharma is presently a project-driven company using its resources to develop the lead candidate to generate future revenue streams, we argue that the DCF analysis is the most appropriate valuation method. For companies like Ascelia Pharma, it is difficult to find comparable companies and to apply peer group valuation approach and draw firm conclusions from it. In particular, fundamental company specific circumstances differ between peers resulting in a wide spread of key ratios. Therefore, we mainly use the peer group valuation approach to put the risk-adjusted DCF-derived value into context and focus relatively more on transaction multiples.

Our valuation is only based on Mangoral for use in its initial target indication. Given the early stage of Oncoral, where the details and funding of a future Phase II study are not set yet, we consider this project as free upside rather than a value driver for the company at the current stage.

Risk-adjusted DCF valuation

We estimate the addressable market for Mangoral to 214k patients in 2022 in US, EU5, Japan

To estimate the market potential for Mangoral, we applied a bottom-up calculation for the addressable patient population in the US, EU5[5] and Japan.

First, we gathered data[6] on the prevalence pool of liver cancer and other relevant cancer indications that are prone to metastasize to the liver such as colorectal cancer, breast cancer, lung cancer[7] and gastric cancer. From that pool of patients, we only looked at patients aged over 60 since we believe that this will be the main target population for Mangoral. To generate the prevalence pool of patients over the age of 60, we assumed that the split in terms of age distribution is the same as for the incidence[8].

In the second step, we adjusted the prevalence pool with data on the prevalence of severe renal impairment, or CKD stage 4/5, to generate the proportion of cancer patients who also has severe renal impairment. Based on the company's guidance, we also estimated that 10% of patients with CKD stage 3 can be expected to experience acute worsening.

Table 2. CKD prevalence rates across selected geographies, age ≥60

	US	Japan	France	Germany	UK	Spain	Italy
CKD stage 4/5	1.8%	1.8%	1.04%	1.43%	1.31%	0.82%	0.8%
CKD stage 3 with acute worsening	2.63%	2.63%	1.52%	2.09%	1.91%	1.2%	1.17%

Source: GlobalData, USRDS2010, Clin Exp Nephrol. 2009 Dec;13(6):621-30, company estimates.

The risk of developing colorectal cancer has been found to be 1.64x larger for patients with CKD than others[9]. To adjust for this, the CKD prevalence figures (see table 2) were multiplied by this factor when the addressable CKD cases in the colorectal cancer population were calculated.

From the procedure described above, we estimate that there are c214k addressable cancer patients (including liver, colorectal, breast, lung and gastric cancer) with severe renal impairment in 2022, rising to c241k in 2031. Based on company guidance, we estimate c. 1.5 MRI scans on average per patient per year for colorectal and liver cancer patients, and c0.4 MRI scans on average per patient per year for breast, lung and gastric cancer patients. This leads to a total of c191k addressable MRI scans in 2022 for Mangoral, rising to c219k in 2031.

We forecast SEK 1118m Mangoral peak sales to Ascelia Pharma in 2029 in US, EU5 and Japan

In our base case financial outlook, we assume that Ascelia Pharma will commercialize Mangoral on its own in EU and US. For Japan, we predict that the company will license

[5] UK, Germany, France, Italy and Spain

[6] Source: GlobalData

[7] Including both small cell and non-small cell lung cancer

[8] Source: GlobalData

[9] Ann Surg Oncol (2013) 20:3885–3891, Risk of Colorectal Cancer in Chronic Kidney Disease: A Matched Cohort Study Based on Administrative Data, Wu et al.

the commercial rights of Mangoral to a partner. We estimate the following key parameters for our forecast:

- 75% LOA for Mangoral
- Launch of Mangoral in 2022 globally
- Addressable market for Mangoral is c214k patients in 2022, rising to c241k in 2031. This translates into c191k addressable yearly MRI scans in 2022, rising to c219k yearly MRI scans over the forecast period
- In line with the company's price range (USD 1500-3000 per dose) we assume a price of USD 2500 per dose in the US and USD 1800 per dose in EU5 and Japan, corresponding to 70% of US prices.
- In this small niche market where there is no direct competition, we believe the company could at least achieve a peak market share of 40% in the US and Japan and 30% in Europe in 2029, 8 years post launch. Overall, the area of liver-MRI contrast agents has seen little innovation for a long time, and it seems unlikely with any major market competition during the 7-10 years of exclusivity that Mangoral should have in US, Europe and Japan. We expect slower sales uptake in Europe due to the heterogeneity of European markets and requirements for national reimbursement in each country. We estimate that Mangoral receives a separate reimbursement code 3-6 months after the initial FDA approval.
- Ascelia Pharma has communicated that it intends to commercialize Mangoral in Japan through a commercial partner. The Japanese market is in terms of procedure volumes similar to the US market, and it is therefore of particular importance. We expect that Ascelia Pharma will secure a license partner on the back of positive Phase III results in late 2020/early 2021. While a partnership deal prior to the Phase III results would be a positive and de-risking event, the highest shareholder value is likely to come from a deal post-positive phase III results. We have looked at licensing deals[10] signed at Phase III or pre-registration stage for Japanese commercialization rights and found that the midpoint typically includes an upfront of USD 15-20m, milestone payments of USD 20-50m and a royalty rate around 20% based on net sales. Based on this, we assume a relatively conservative deal structure including 1) an upfront fee of USD 10m due upon signing; 2) milestone payments of USD 15m made upon regulatory filing and approval; and 3) a royalty rate of 20% on annual net sales. In our forecast, we have included the upfront and milestone-payments in 2021. In this scenario, Ascelia Pharma would be able to execute its strategy without additional funds.
- Mangoral has presently no granted IP protection. With the US Orphan Designation, Mangoral will have seven years of market exclusivity following FDA approval, with potential for extensions. In Europe, there will be a 10-year period of data exclusivity, i.e. no other product can launch and refer to Mangoral's clinical trials. The company is currently evaluating how to obtain orphan drug designation for Mangoral in EU and Japan. An orphan drug designation in Japan would

[10] Source: GlobalData

provide market exclusivity for 10 years. In our forecast, we assume a 10- year period of exclusivity in Japan and Europe and a 7-year period of exclusivity in the US. We assume a relatively slow decline in market penetration post exclusivity period in the US. However, upon grant of the patent application filed in Q2 2019 for the next generation Mangoral product, the protection rights can be further strengthened and extended until year 2040. This significant extension of the sales cycle would naturally trigger a higher valuation of the Mangoral project.

- Based on Ascelia Pharma's communication, we assume a 90% gross margin for Mangoral. The manufacturing of Mangoral is outsourced to Cambrex in Whippany, New Jersey, USA. We do not foresee that the company will tie up any significant amounts of capital in inventories.
- Sales force and organizational build up to continue during 2020 and at peak include 40 sales and marketing representatives covering the US and European market (included in sales and marketing costs). As the exclusivity period would start once Mangoral obtains regulatory approval, we believe that it is in Ascelia Pharma's best interest to be fully ready to penetrate the market. Therefore, we assume a quick ramp up of sales and marketing costs. We also believe that it is important that the company makes sufficient investments in pre-launch activities as the company has to establish a new treatment standard.
- Research and development costs are through 2021 mainly driven by the pivotal SPARKLE study. In our forecast, we have not included costs for any larger additional trials with Mangoral.

Risk-adjusted P&L (SEK m)

P&L (SEK million)	FY18A	FY19A	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E
Net sales	**0**	**0**	**0**	**0**	**69**	**199**	**403**	**555**	**711**	**851**	**984**	**1 118**	**1 065**	**992**
Probability, %	100%	100%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%
Probability Adjusted Net Sales	**0**	**0**	**0**	**0**	**52**	**149**	**302**	**416**	**533**	**638**	**738**	**839**	**799**	**744**
Sales growth (YoY)	*n/a*	*0*	*0*	*0*	*0*	*2*	*1*	*0*	*0*	*0*	*0*	*0*	*(0)*	*(0)*
COGS	0.0	0.0	0	0	(5)	(15)	(30)	(42)	(53)	(64)	(74)	(84)	(80)	(74)
Gross Profit	**0.0**	**0.0**	**0**	**0**	**46**	**134**	**272**	**375**	**480**	**574**	**664**	**755**	**719**	**670**
Gross margin	*n/m*	*n/m*	*n/m*	*n/m*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*
Other revenues	1.1	0.2	0	0	0	0	0	0	0	0	0	0	0	0
Sales and marketing costs	0.0	0.0	(10)	(30)	(150)	(150)	(200)	(200)	(200)	(200)	(200)	(200)	(200)	(175)
Personnel costs	(16.4)	(14.4)	(17)	(22)	(26)	(27)	(28)	(29)	(29)	(30)	(31)	(32)	(33)	(34)
R&D expenses	(9.4)	(22.9)	(70)	(40)	(20)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)	(10)
Other operating costs	(0.0)	(0.3)	(4)	(4)	(5)	(6)	(7)	(8)	(10)	(12)	(13)	(14)	(16)	(17)
Total operating costs	**(25.8)**	**(37.6)**	**(100)**	**(96)**	**(201)**	**(193)**	**(245)**	**(247)**	**(249)**	**(252)**	**(254)**	**(256)**	**(259)**	**(236)**
Operating costs as % of Net Sales	*n/m*	*n/m*	*n/m*	*n/m*	*292%*	*97%*	*61%*	*44%*	*35%*	*30%*	*26%*	*23%*	*24%*	*24%*
EBITDA	**(24.7)**	**(37.4)**	**(100)**	**(96)**	**(154)**	**(59)**	**28**	**128**	**231**	**322**	**410**	**498**	**460**	**433**
EBITDA-margin	*n/m*	*n/m*	*n/m*	*n/m*	*n/m*	*n/m*	*7%*	*23%*	*32%*	*38%*	*42%*	*45%*	*43%*	*44%*
Depreciation	1	0	0	0	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Amortization	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EBIT	**(24.0)**	**(37.4)**	**(100)**	**(96)**	**(154)**	**(59)**	**28**	**128**	**231**	**322**	**410**	**498**	**460**	**433**
EBIT-margin	*n/m*	*n/m*	*n/m*	*n/m*	*n/m*	*n/m*	*7%*	*23%*	*32%*	*38%*	*42%*	*45%*	*43%*	*44%*
Net financial items	(0.0)	(0.2)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
EBT	**(24.1)**	**(37.6)**	**(101)**	**(96)**	**(155)**	**(59)**	**27**	**128**	**230**	**322**	**410**	**498**	**460**	**433**
Tax	0.0	0.0	0	0	0	0	0	0	0	(50)	(88)	(108)	(99)	(93)
Net income	**(24.1)**	**(37.6)**	**(101)**	**(96)**	**(155)**	**(59)**	**27**	**128**	**230**	**272**	**321**	**390**	**360**	**339**
Profit margin	*n/m*	*n/m*	*n/m*	*n/m*	*n/m*	*n/m*	*7%*	*23%*	*32%*	*32%*	*33%*	*35%*	*34%*	*34%*

Source: Vator Securities

The current market valuation, in our opinion, does not fully factor in the commercial prospects

We use a discount rate (WACC) of 12.3%, as well as 2% terminal growth (in line with GDP growth) and a a 75% life cycle adjustment of the terminal value. The risk-free rate is 0%, based on the Swedish government ten-year bond, and the risk premium is 10.1%, based on a size and market risk premium of 2.9% and 7.2% respectively. Lastly, we use an equity beta value of 1.3. We have also included a net present value of the cumulative tax shield. With our estimates and DCF input variables, our DCF model indicates an equity value for Ascelia Pharma of SEK 1 269m, equivalent to SEK 54 per share (based on approximately 23.5m outstanding shares).

DCF valuation (SEK m)

DCF (SEK)	FY18A	FY19A	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E
EBIT	(24.0)	(37.4)	(100)	(96)	(154)	(59)	28	128	231	322	410	498	460	433
Paid tax	0.0	0.0	0	0	0	0	0	0	0	50	88	108	99	93
NOPLAT	(24.0)	(37.4)	(100)	(96)	(154)	(59)	28	128	231	272	321	391	361	340
Adj. for non-cash items	(0.7)	0.0	0	0	0	0	0	0	0	0	0	0	0	0
Changes in NWC	(1.4)	(5.8)	0	0	11	11	17	13	2	4	4	(6)	(2)	(0)
Capex	0.0	0.0	0	0	0	0	0	0	0	0	0	0	0	0
Free cash flow	**(23.4)**	**(31.6)**	**(101)**	**(96)**	**(166)**	**(70)**	**10**	**115**	**229**	**268**	**317**	**396**	**363**	**3 309**
Discount factor (formula based)	-	-	*1.06*	*1.19*	*1.34*	*1.50*	*1.68*	*1.89*	*2.12*	*2.38*	*2.67*	*3.00*	*3.37*	*3.37*
Net Present Value - Free Cash Flows	**n/a**	**n/a**	**(95)**	**(81)**	**(124)**	**(47)**	**6**	**61**	**108**	**113**	**119**	**132**	**108**	**737**

DCF output		
Terminal value	**3 309**	SEKm
Life cycle adjustment TV	75%	
Adjusted Terminal value	**2 482**	SEKm
Net Present Terminal Value	**737**	SEKm
Net Present Value FCF	**299**	SEKm
NPV of FCF incl. TV	**1 035**	SEKm
Tax shield value, NPV	50	SEKm
Interest bearing net debt	(184)	SEKm
Equity Value	**1 269**	SEKm
Number of shares, non-diluted, million	23.5	m
SEK/Share	**54.0**	

Source: Vator Securities

Our risk-adjusted DCF valuation above suggests that Ascelia Pharma's current market value is unrealistically low, reflecting a deep discount. We suspect that the case is misunderstood and probably discounted in accordance with a traditional drug development company with a therapeutic drug candidate, where the clinical development risks are different and higher. In contrast to this, we argue that the clinical development risk in this case is, relatively speaking, low and that the main risks pertains to commercialization. With that said, we believe that a present- risk-adjusted- target price of SEK 54 is reasonable, assuming impeccable execution of commercial strategy in accordance with the blueprint that Blue Earth Diagnostics has provided. We believe that the recent appointment of Julie Waras Brogren as Chief Commercial Officer to lead build-up of the commercial organization and launch preparations is a positive, de-risking factor. The significant track-record that she brings to Ascelia Pharma strengthens our confidence in the company's future ability to successfully launch and commercialize Mangoral.

If we discount our base-case sales forecast with 25% per year to simulate a scenario where market adoption and sales develop slower, we arrive at a target price of SEK 28 which is 26% higher than the current share price. This reflects the low expectations in the company.

Peer group comparison

Ascelia Pharma develops a molecular imaging drug, Mangoral, for liver- MRI scans and has no direct relevant listed local peer companies. However, when the company reaches commercialization, we believe that it will be compared with locally listed revenue generating life science companies included in the table below. We have also included Veracyte (Nasdaq: VCYT), a US based established company offering several diagnostic products.

It is difficult in this case to use the peer group valuation approach and draw any conclusions from it, in particular due to fundamental circumstances differing between the peers and resulting in a wide spread of key ratios.

Peer group comparison
(SEKm)

CIQ Identifier	Company Name	Country	Market cap	EV	EV/Sales			P/E			EV/EBIT			Sales CAGR	EBIT margin	
					FY19A	FY20E	FY21E	FY19A	FY20E	FY21E	FY19A	FY20E	FY21E	2017-19	FY19A	FY20E
IQ39098844	Synthetic MR	Sweden	840	805	15.2x	11.5x	8.3x	72.0x	51.0x	24.3x	59.5x	38.0x	18.1x	24.6%	25.5%	30.3%
IQ182486692	Xvivo	Sweden	4 469	4 315	19.5x	15.8x	11.2x	NM	167.2x	70.8x	NM	129.5x	52.6x	22.0%	1.8%	12.2%
IQ418775109	Sedana Medical	Sweden	3 606	3 484	51.2x	40.8x	25.4x	NM	NM	NM	NM	NM	NM	28.2%	-21.9%	-21.1%
IQ419303	Cellavision	Sweden	7 597	7 720	16.6x	12.7x	10.9x	76.7x	60.5x	45.2x	60.6x	46.3x	35.7x	22.2%	27.4%	30.5%
IQ42154124	Veracyte	United States	12 794	11 014	9.7x	8.2x	6.8x	NM	NM	NM	NM	NM	NM	28.4%	-8.6%	-8.9%
	Peer universe			**Average**	**22.4x**	**17.8x**	**12.5x**	**74.3x**	**92.9x**	**46.8x**	**60.1x**	**71.3x**	**35.4x**	**25.1%**	**4.8%**	**8.6%**
				Median	**16.6x**	**12.7x**	**10.9x**	**74.3x**	**60.5x**	**45.2x**	**60.1x**	**46.3x**	**35.7x**	**24.6%**	**1.8%**	**12.2%**

Source: Vator Securities

Comparison to Transaction multiples

The closest peer to Ascelia Pharma is Blue Earth Diagnostics (BED). BED was in August 2019 acquired by Bracco Imaging from the London-listed investment company Syncona for GBP 374m. In context of BED's financial performance at the time of the acquisition, this transaction value corresponds to a multiple of 4.5x 2019 revenues of GBP 83.9m and a multiple of 13x EBITDA of GBP 28.7 (Syncona calendar year April-March).

If we apply the multiples from the BED-transaction to Ascelia Pharma's risk-adjusted sales in 2026, i.e similarly to the timeframe between BED's launch and acquisition of BED, and discount the resulting enterprise value for 2026 to the present value, we arrive at a weighted, collected share price of SEK 64. This comparison adds substance to the risk-adjusted DCF valuation and suggests that there is a potential upside to our base case if Ascelia Pharma progresses in accordance with BED's blueprint.

Comparison to transaction multiples

Close peer universe			
Peer valuation	Sales	EBITDA	
Ascelia Pharma FY26E	533	231	SEKm
Probability adjustment	100%	100%	
Probability Adjusted Ascelia Pharma FY26E	533	231	SEKm
FY20E median multiples	4.5x	13.0x	
Ascelia Pharma EV FY26E	2 400	2 997	SEKm
Discount factor	2.12	2.12	
Ascelia Pharma implied EV FY20E	1 132	1 413	SEKm
Net debt	-184	-184	SEKm
Tax shield value, NPV	50	50	SEKm
Ascelia Pharma implied Equity Value FY20E	1 366	1 647	SEKm
Implied share price	**58**	**70**	SEK
Market cap adjustment factor	0%	0%	
Adjusted implied share price	**58**	**70**	SEK
Current share price	**22.2**	**22.2**	SEK
Comparables valuation / Current share price	**262%**	**316%**	
Weight	50%	50%	
Collected share price based on 0m shares		**64**	

Source: Vator Securities

Key personnel

Magnus Corfitzen, CEO.
Extensive experience from investing in the Life Science sector and growing companies. Board experience from 12 life science companies. M.Sc. in Mathematical Economics from Aarhus University and studies in Corporate Governance & International Business at Harvard University.

Kristian Borbos, CFO.
Extensive experience from finance and investor relation roles in listed large companies, including the IPO of DONG Energy. M.Sc. in Finance from Lund University and studies at Newcastle University and Stockholm School of Economics.

Carl Bjartmar, CMO.
Extensive drug development experience from senior positions in big pharma (Sanofi, Genzyme and Lundbeck) and Chief Medical Officer for the Swedish biotech company Wilson Therapeutics. Outstanding track record in orphan drug development. Medical Doctor (M.D.) and PhD from University of Linköping.

Julie Waras Brogren, CCO
Will start in the beginning of January 2020. More than 18 years of leadership experience in global product launches, market access and life cycle management from senior roles in biopharma and medtech industries. Previosly held positions include Chief Operating Officer and later President of BrescoTEC, Head of Marketing & Market Access for the Latin America Region at Novo Nordisk. She was instrumental in the launch of multi-blockbuster drug liraglutide (Victoza®) and
insulin degludec (Tresiba®)

Mikael Widell, IR responsible.
More than 30 years' experience within communications, journalism incl. 14 years within financial media, e.g. Dagens Industri, and has had different positions within in-house corporate communications, e.g. AstraZeneca, Biovitrum (Sobi) and Nordic Capital as well as strategic work as a communications advisor within financial PR and IR. Mikael is a partner and co-founder of the IR/PR firm Cord Communications.

Board of Directors

Peter Benson, Chairman of the Board.
Chairman and co-founder of Sunstone Capital Life Science Ventures and Chairman of NASDAQ listed Alligator Bioscience. Extensive experience from the life science sector as an investor and in management positions. Previous positions include: head of life science ventures at the Danish Growth Fund, President Hospital Care at Pharmacia, VP Marketing & Sales at Kabi Pharmacia Parenterals.

Dr. Bo Jesper Hansen, Director of the Board.
Chairman of Laborie and non-executive Director of a number of biotech and pharma companies including Orphazyme, InnoventaMedica, and Azanta. Extensive experience from orphan drug research and development, international marketing and business development. Previous positions include: Executive Chairman of SOBI and Karolinska

Development, CEO and President at Swedish Orphan, non-executive Director of Gambro and Executive Chairman of Topotarget, Chairman of Ablynx.

René Spogaard, Director of the Board

Chairman and investor in a number of companies including JEKA Fish A/S (fish) and Bollerup Jensen A/S (chemicals) and Flexfunding. Extensive experience from investing in the healthcare sector and board positions in a public environment. Previous positions include: owner and Managing Director at TNS Gallup and Director at TNS plc (London Stock Exchange). Previous major shareholder and chairman of the Growth House Group (speciality pharma and generics).

Professor Hans Maier, Director of the Board

Founder and Managing Partner of BGM Associates GmbH. Hans Maier has held senior positions within Schering AG and Bayer AG in Europe and Asia, inter alia as Managing Director in Korea and in Japan, Head of Corporate Strategy and Business Development of Schering AG and Head of the Global Business Unit Diagnostic Imaging in both Schering AG and Bayer AG. Hans Maier is member of several advisory boards, inter alia the Fraunhofer Institute for Medical Image Computing and the German Heart Center Berlin.

Niels Mengel, Director of the Board

Founding Partner and CEO at Øresund-Healthcare Capital. Extensive experience from the healthcare industry as an investor and Chairman of Danish Shareholders Association. Previous positions include: Executive Vice President at ISS World Services A/S and Director at PA Consulting Group

Helena Wennerström, Director of the Board

Helena Wennerström has been Executive Vice President of Bulten AB (publ) since 2014 and has been its Chief Financial Officer since 2006. The work within Bulten AB also includes IR, communication and IT. Helena Wennerström has earlier served finance roles at Digitalfabriken and Topcon.

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