ASCELIA PHARMA

Contrast enhanced liver MRI focusing on orphan indication

Ascelia Pharma is a Swedish based oncology company in late-stage development with a primary focus on contrast enhanced liver MRI for those with severely impaired kidney function. The use of contrast agents in this population is today generally not recommended due to safety concerns. Another focus area for product development is an oral version, Oncoral, of the well established injectable cancer medicine irinotecan. Oncoral may start phase 2 development during 2019. The company's management has extensive experience from rare diseases at large corporations, including Genzyme (acquired by Sanofi) and Wilson Therapeutics (acquired by Alexion).

Mangoral entering phase 3 development for contrast enhanced liver MRI

The lead product, Mangoral, has orphan drug status in the US, and initially targets a population of close to 300,000 patients undergoing more than 200,000 scans per year. Based on pre-market pricing discussions with payers, the company sees a Mangoral price per scan in the range of USD 1,500-3,000 as reasonable. A phase 2 study in 178 subjects indicated a more than 30% improvement in lesion detection with Mangoral enhanced liver MRI compared to a scan without contrast. The aim is now to confirm these results in a phase 3 study due to start in H2 2019, and report head-line data in H2 2020. FDA has confirmed the design and scope of the trial, and a similar meeting with the regulator in Europe will be held in H1 2019. Ascelia Pharma will start to establish a commercial organization to support the launch of Mangoral in the US and Europe in 2022, and prepare a strategy to enable a launch in the important Japanese market.

Three main reasons for the mid- to long-term attraction of the shares

We see three main reasons for the market to see the mid- and long-term attraction in the Ascelia Pharma shares. First, the phase 3 study that will include around 200 participants with suspected or known focal liver lesions and severely impaired kidney function should have high likelihood of success since the comparison is MRI without contrast enhancement. Second, since each study participant is only monitored for three days during the trial, the risks for significant study delays should be fairly limited. Third, the ongoing launch of a contrast agent, Axumin, for PET-imaging of biochemically recurring prostate cancer, indicates that there is significant commercial potential for new contrast agents, assuming relevant marketing support and continued clinical trials.

Stepwise approach to valuation

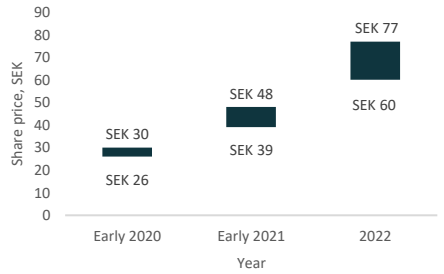
Since Ascelia Pharma, in our view, is several years from reaching profitability, we would adopt a stepwise valuation approach at this stage instead of a long-term standard discounted cash flow valuation approach. In early 2020, prior to trial results and the timely execution of the pivotal phase 3 trial, we see a valuation range between SEK 26-30 (600-700m market cap). In early 2021, when head-line data from the pivotal phase 3 trial is available, we see a valuation range of SEK 39-48 (SEK 0.9-1.1bn). After regulatory approvals have been received and Ascelia Pharma is ready to launch Mangoral in key markets in 2022, we see a reasonable valuation range between SEK 60-77 per share (SEK 1.4-1.8bn market cap).

OUTPERFORM

Initiating Coverage

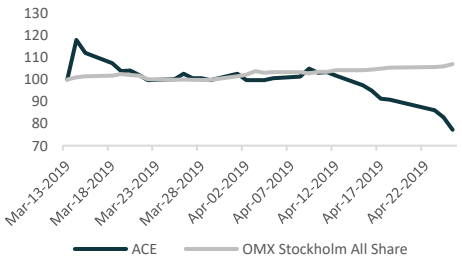
We initiate coverage on Ascelia Pharma with a stepwise valuation approach. For **early 2020**, we see a reasonable valuation range between **SEK 26-30** per share suggesting **35-56% upside** to the current share price. For **early 2021**, we see a range between **SEK 39-48** per share suggesting **103-150% upside** to the current share price. For **2022**, we see a reasonable valuation range between **SEK 60-77**, suggesting **213-301% upside** to the current share price

Stepwise valuation approach



Key Data	As of April 25, 2019
Ticker	ACE
Share price (close)	19.20
Free float	72%
Market cap	SEK 451.0m
Website	www.ascelia.com
Average daily volume (March 13-April 25)	SEK 2.5m

Share Price (Index=March 13, 2019)



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The investment case

Ascelia Pharma is a Swedish based oncology company in late-stage development with a primary focus on contrast enhanced liver MRI for those with severely impaired kidney function. It has two products in clinical stage development with the most advanced, Mangoral, about to start phase 3 development during H2 2019.

Based on our step wise valuation approach, we see a reasonable valuation range between SEK 26-30 per share suggesting 35-56% upside to the current share price towards early 2020. Towards early 2021, we see a valuation range between SEK 39-48 per share suggesting 103-150 % upside to the current share price. When the company is ready to launch Mangoral in key markets towards 2022, we see a valuation range between SEK 60-77 per share, suggesting an upside of 213-301%.

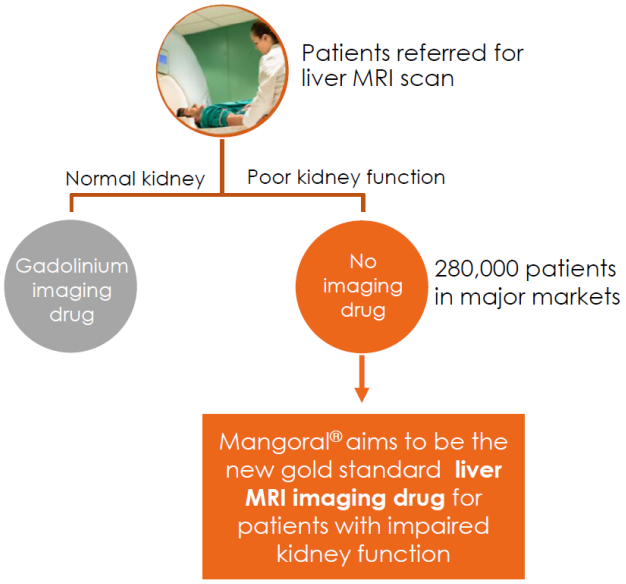
We see three main reasons for the market to see the long-term attraction in the Ascelia Pharma shares.

A phase 3 contrast agent trial where the control is no contrast agent

First, the phase 3 study with Mangoral that will include around 200 participants with suspected or known focal liver lesions and severely impaired kidney function should have high likelihood of success since the comparison is MRI without contrast enhancement. Mangoral targets an unmet medical need and has FDA orphan drug designation.

The key analysis, "Evaluation of a new manganese-based orally-administered hepatobiliary MR contrast agent", examined Mangoral in 178 subjects and was presented at congresses in 2014-2015, with the main result being an increased number of focal liver lesions detected.

CHART 1: Mangoral's target population



Source: Company information

The primary endpoint of the study will be lesion visualisation in terms of the number of focal (localised) liver lesions (damages), lesion delineation and lesion to liver contrast,

in patients with severely impaired kidney function with known or suspected liver lesions, with Mangoral-enhanced liver MRI compared with no contrast agent.

The kidney function is routinely tested before a liver MRI, particularly in the presence of known risk factors such as aged above 60, hypertension and diabetes.

Second, since each study participant is only monitored for three days during the trial, the risks for significant study delays should be fairly limited. After study inclusion, each patient will undergo one liver MRI procedure without contrast enhancement, and one with Mangoral contrast enhancement, and then each patient will be monitored for three days for safety reasons before study participation is complete for the individual.

Axumin demonstrates that there is a clear path to sales success

Third, the ongoing launch of a contrast agent, Axumin, for PET-imaging of biochemically recurring prostate cancer, indicates that there is significant commercial potential for new contrast agents, assuming relevant marketing support and continued clinical trials.

Blue Earth Diagnostics was formed in March 2014 and acquired Axumin from GE Healthcare in the same year. It received US marketing approval for Axumin in mid-2016 and European marketing approval in mid-2017.

Already in the quarter that ended 31 March 2018, Syncona reported that Blue Earth Diagnostics became profitable in the period, i.e. less than two years after launch. Axumin unit sales were 5,000 in the quarter when the company became profitable.

The owner of Blue Earth Diagnostics, Syncona, has so far reported sales figures for the quarters until the end of September 2018. For the quarter that ended in December 2018, Syncona reported a volume of 7,575 doses of Axumin.

If realised prices from previous quarters were upheld in the quarter ending in December 2018, Axumin's quarterly sales were USD 26m, i.e. annualising more than USD 100m sales less than three years after launch.

Syncona funded Blue Earth Diagnostics with equity investments of GBP 35.3m. Already in the quarter ending December 2018, Syncona received a GBP 10.8m cash return on invested capital. Syncona valued Blue Earth Diagnostics at GBP 230m at the end of December 2018.

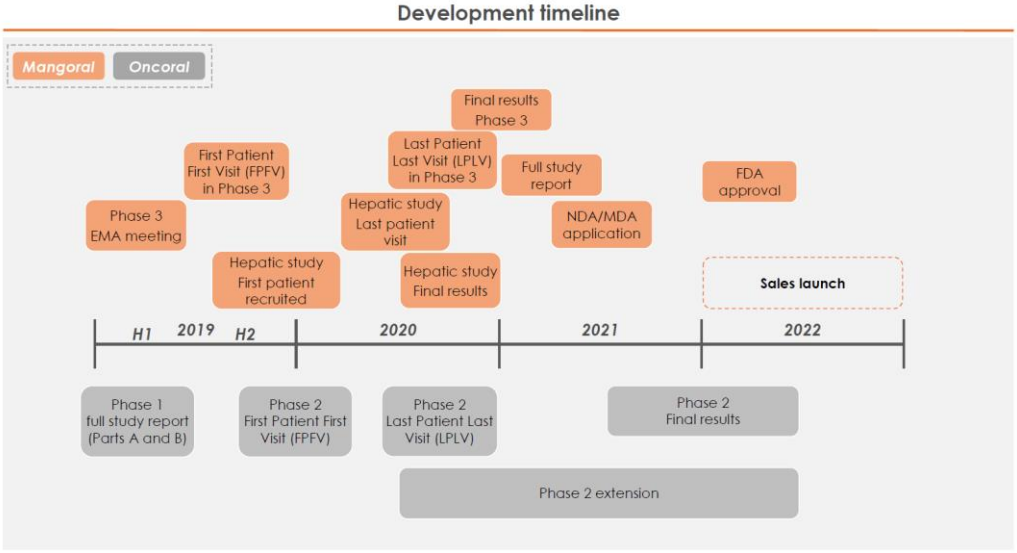
Syncona's calender year is April-March and preliminary full year figures are due 13 June 2019.

We believe the value that Blue Earth Diagnostics 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 sufficient investment in the commercial sales and sales support infrastructure, continued sales support from new clinical trials, successful regulatory submissions and outcomes, broadened commercial reimbursement coverage, and meaningful commercial sales uptake.

Apart from the pending phase 3 start with Mangoral, phase 1 results with Oncoral were recently published, and the product may be entering phase 2 development later in 2019 or the beginning of 2020.

Beyond Mangoral and Oncoral, Ascelia Pharma may seek to establish a position as a niche oncology development and marketing company, promoting multiple products that targets niche populations. In connection with the phase 3 start later in 2019 with Mangoral, Ascelia Pharma will start to establish a commercial infrastructure with a primary focus on the US and in a later stage a few selected European countries.

CHART 2: Key development timelines for Mangoral and Oncoral



Source: Company information

Why the interest now?

Ascelia Pharma is now making the final preparations ahead of its first pivotal phase 3 trial for Mangoral use in contrast enhanced liver MRI in people with severely impaired kidney function.

At a meeting with the FDA in November 2018, the company received confirmation about the scope and design of its pivotal trial which is due to start enrolling participants during H2 2019.

The primary endpoint of the study will be lesion visualisation in terms of the number of focal (localized) liver lesions (damages) detected with Mangoral, lesion delineation and lesion to liver contrast, in patients with severely impaired kidney function with known or suspected liver lesions.

We would summarise recent and near-term events as follows:

- **2018**: SEK 60m private placement
- **2018**: Oncoral formulation patent granted in Europe
- **2018**: Oncoral formulation patent granted in the US
- **October 2018**: phase 1A results presented and published with Oncoral
- **October 2018**: Chief Medical Officer, Carl Bjartmar, recruited from Wilson Therapeutics
- **November 2018**: Mangoral phase 3 preparation meeting with the FDA
- **March 2019**: SEK 200m share issue in connection to the Nasdaq Stockholm IPO

November 2018 FDA meeting defined the scope and design of the phase 3 trial

- **April 2019**: publication of phase 1 with investigator sponsored extension study with Oncoral
- **H1 2019**: Mangoral phase 3 preparation meeting with EMA
- **H2 2019**: first patient enrolled into Mangoral phase 3 pivotal trial
- **Q4 2019**: first patient enrolled into Mangoral impaired hepatic function study
- **H2 2019 - H1 2020**: first patient enrolled into Oncoral phase 2 gastric cancer trial
- **2019**: in parallel with the Mangoral phase 3 trial, initiate the build-up of US commercial organisation
- **2019**: define and implement a strategy to launch Mangoral in Japan

The size of the Mangoral phase 3 study will naturally depend on the hypothesized improvement with Mangoral contrast enhanced MRI and the number of lesions in the study population. Assuming up to 200 patients will be enrolled at 30 clinical trial centers, starting in August-September 2019, and that each participant will be monitored for three days for safety reasons, results should be available from the trial towards late 2020 or early 2021.

Targeting first Mangoral sales in 2022

Assuming a successful read-out of the study and filings around mid-2021, Mangoral could start its commercial phase towards mid-2022, and gain sales momentum with gradually improved reimbursement backing.

In parallel to the pivotal phase 3 trial, Ascelia Pharma will initiate pre-launch activities in Japan through a development partner. Japan accounts for around 25% of Mangoral's target market. The build-up of Ascelia Pharma's commercial organisation will also continue during 2019-2020 to prepare for pre-market activities, and the marketing of potential line extension studies.

Two important target populations for liver MRI are patients with colorectal or breast cancer disease, two common cancer types that are known to often spread to the liver.

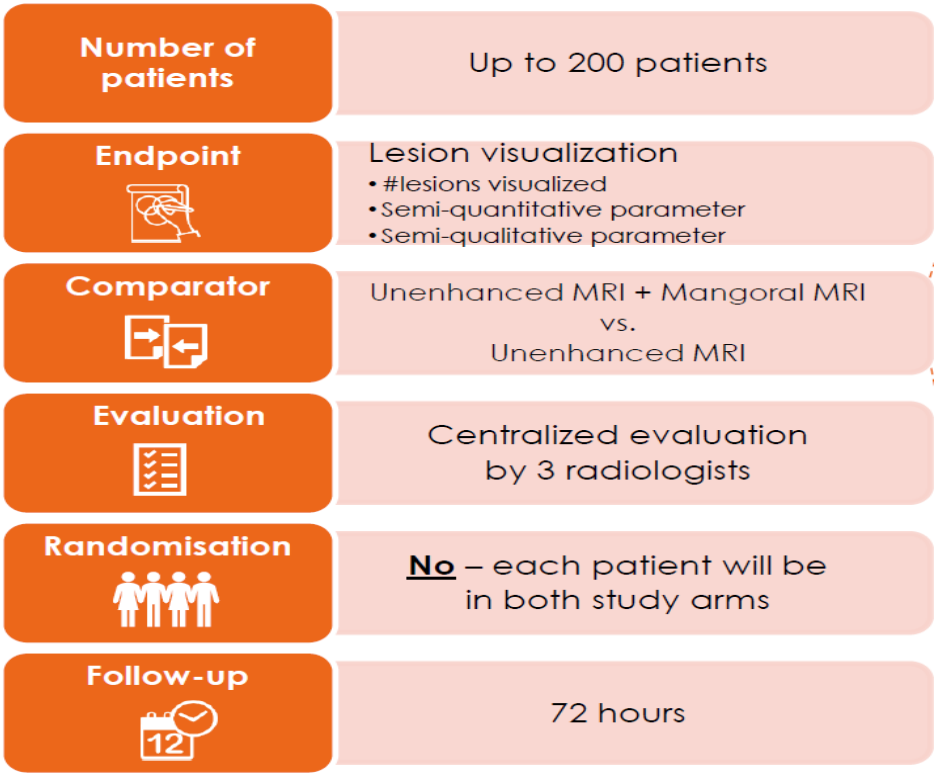
What makes this case unique?

The design of the pivotal phase 3 trial with Mangoral for the improved detection of focal liver lesions in people with severely impaired kidney function undergoing liver MRI seems very straightforward.

Each patient being its own control, with follow-up of three days

The follow-up with each participant in the pivotal Mangoral trial will be three days. Moreover, each participant will be its own control since a scan without contrast is compared with a scan with contrast. Mangoral's use of peroral administration also seems fairly convenient since it is a powder that is mixed with absorption enhancers and dissolved into 200 mL of water. Contrast agents otherwise are typically injected.

CHART 3: Mangoral phase 3 design



Source: Company information

Offering contrast enhanced liver MRI for those with very poor kidney function

Mangoral is an orphan imaging product. Patients undergoing liver MRI today typically receives contrast agents to improve the imaging quality. However, for patients with severely impaired kidney function (less than 30% of normal kidney function, also called stage 4 and 5 kidney disease), which accounts for around 3-4% of those eligible for liver MRI, contrast agents have Black Box warnings or are contraindicated for safety reasons, and these patients typically undergo the MRI procedure without contrast.

The market for contrast agents is worth around USD 6bn globally whereof MRI related contrast account for around USD 1.5bn. Product development in the broad category of gadolinium-based contrast agents, which dominates the MRI area, has stalled since the knowledge about rare but potentially very serious side effects emerged 10 years ago.

Valuation summary

We expect to see the following five key determinants for Ascelia Pharma's mid- and longer-term valuation: product technology, clinical utility, regulatory, payer coverage, and commercial adoption.

Product technology refers to the outcome of clinical trials. Clinical utility refers to that the outcome of clinical trials proves to be clinically relevant, i.e. that patient inclusion and exclusion criteria and other factors are relevant in a commercial setting. Regulatory refers to product approval, without requests for additional information, as issued by regulators.

Payer coverage refers to the post-approval process of establishing a specific reimbursement code for Mangoral, and the inclusion of the product in commercial and Medicare healthcare plans. Commercial adoption refers to the extent of use in the around 300,000 patients that is Mangoral's initial main target group.

At this early stage, we believe that the equity market's view on Ascelia Pharma is reflecting the fact that the company's lead product has not yet entered phase 3 development, with an uncertain outcome, despite that the design of the trial may seem unusually straightforward.

The value from proven clinical utility, regulatory progress, reimbursement coverage and commercial adoption should be captured in the years ahead, we believe.

Focus on H1 2022, and the valuation build-up steps in the run-up to the first product launch

Our valuation approach is to focus on where we believe Ascelia Pharma will be valued at its early commercial phase (H1 2022E), and the valuation build-up steps in the run-up to the first product launch of Mangoral.

The first step in this stepwise valuation approach will be the valuation during the coming year, towards early 2020 where Ascelia Pharma in the months ahead will start a phase 3 for Mangoral and recently has reported the full details of the investigator sponsored extension study of the phase 1 trial with Oncoral. During this period, we see a reasonable valuation range of SEK 26-30 per share (SEK 600-700m market capitalization).

We believe the second major step in the valuation build-up will be when head-line data from the phase 3 trial has been announced. When this happens, which should be around H2 2020E, the path towards regulatory filing and approval for commercial sales should be perceived as open.

At this second stage towards early 2021, we believe the valuation of the company should be in the range of SEK 39-48 per share (SEK 900m-1.1bn).

We believe that in 2022, when Ascelia Pharma has completed and reported its pivotal phase 3 trial with Mangoral, market approvals have been achieved by the FDA and European commission, a clear strategy has been outlined for the market in Japan, and Oncoral is well underway with its phase 2 trial, we see a reasonable valuation range of SEK 60-77 per share (SEK 1.4-1.8bn) assuming the company at that stage will be seen as an early stage commercial phase company.

Sales forecast summary

Targeting more than 200,000 liver MRI procedures per year

The main basis for our market cap assumptions is that Mangoral in early 2022 should be in the starting phase of targeting a market of more than 200,000 liver MRI procedures per year, i.e. the niche population of people with severely impaired kidney function. For US market sales, we have assumed a price per Mangoral in the mid of the USD 1,500-3,000 price range that the company sees as reasonable, based on its pre-market discussions with payers.

Based on a target volume of 220,000 yearly scans, and price per scan of USD 2,250 in the US, we believe Mangoral will have an initial sales potential of SEK 510m in 2026E including sales in the US, Europe and Japan.

Table 1: Target population and share (%) of target cancer population

ADDRESSABLE PATIENTS WITH KIDNEY DISEASE (CKD)	CKD STAGE 4/5	ACUTE CKD	TOTAL	SHARE (%) OF TARGET CANCER POPULATION
US	37,000	55,000	92,000	4
EUROPE	46,000	69,000	115,000	3
JAPAN	30,000	45,000	75,000	5
TOTAL TARGET POPULATION	**113,000**	**169,000**	**282,000**	**3**

Source: Company information

Table 2: Price and sales assumptions in USDm and SEKm

SALES (USDM)	2022E	2023E	2024E	2025E	2026E
US (USD 2,250 PRICE/SCAN)	3	13	24	35	45
EUROPE (USD 500 PRICE/SCAN)	0	1	4	7	10
OTHER REGIONS (25% OF EUROPE)		0	1	2	2
TOTAL SALES (USDM)	3	14	29	44	57
TOTAL SALES (SEKM)	29	126	259	397	510

Source: Vator estimates

Activities in the contrast imaging space

Axumin successfully developed and launched by a 60-employee company

We view the ongoing launch of Blue Earth Diagnostic's PET diagnostic Axumin as a role model for a successful development and launch of a niche based new imaging product. Blue Earth Diagnostic, which has around 60 employees, is funded through GBP 35m investments by the UK listed investment company Syncona.

Here are the main timelines behind Axumin's recent and ongoing success:

- **March 2014**: Blue Earth licensed Axumin from GE Healthcare, targeting PET imaging of men who have undergone surgery for prostate cancer but who have biochemical recurrence of the disease
- **December 2015**: FDA accepted Axumin for regulatory review
- **May 2016**: FDA approved Axumin for US market sales
- **September 2016**: first commercial delivery of Axumin in the US market
- **January 2017**: a product specific reimbursement code designated for Axumin in the US
- **March 2017**: Axumin recommended for approval in Europe
- **May 2017**: Axumin approved in Europe
- **November 2018**: Syncona reported that Blue Earth is now profitable, and that six-month sales (April-September 2018) were GBP 35m, compared with sales six months earlier (October 2017-March 2018) at GBP 24m

Overall, it took Blue Earth slightly more than two years from approval to reach Axumin volumes annualising 25,000 scans, and sales annualising SEK 800m.

Axumin's sales and volume figures indicates a realised price of around USD 3,500 per Axumin dose on top of the PET imaging procedure cost.

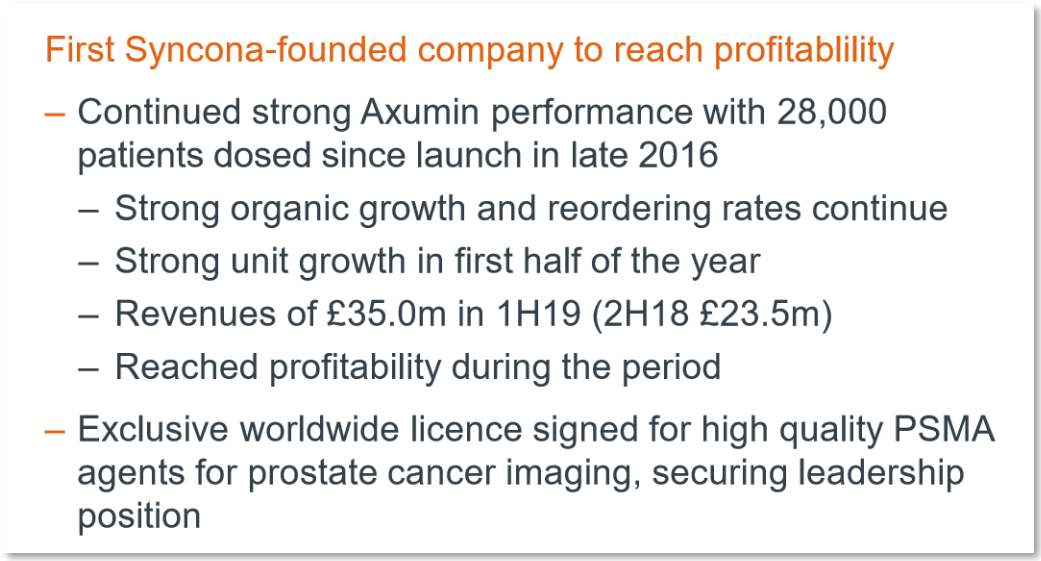
Axumin peer-launch: a case study of success

Axumin approved mid-2016, profitable in 2018

A very interesting peer and role model about the development and very recent launch of a niche diagnostic imaging product is the launch of Axumin by Blue Earth Diagnostics (BED). The company is owned by the UK based listed investment company Syncona.

In terms of establishing a diagnostic imaging product's various characteristics through regulatory clinical trials, line extension trials, regulatory approvals across key regions, commercial organisation build-up, the signing of several manufacturing and marketing collaborations, and patient access to the product through product reimbursement, Axumin demonstrates a very clear path to success in the area.

CHART 4: Axumin performance update (April-September 2018 is 1H19)



Source: Syncona corporate presentation, March 2019

Syncona reported for H1 2019 (from April to September 2018) sales for Axumin (fluciclovine F18) at GBP 35m, compared with GBP 24m six months earlier (Syncona's H2 2018, October 2017-March 2018).

Volumes increased from around 8,700 Axumin units in H2 2018 to around 12,500 in H1 2019, indicating a realised price of GBP 2,700-2,800 (around USD 3,500) per Axumin scan.

In connection to its H1 2019 results release, Syncona added that Blue Earth Diagnostics is now a profitable company, and that they had increased the valuation of the company from GBP 187m six months earlier to an updated valuation of GBP 232m, which is close to 7x invested capital of GBP 35m for Syncona.

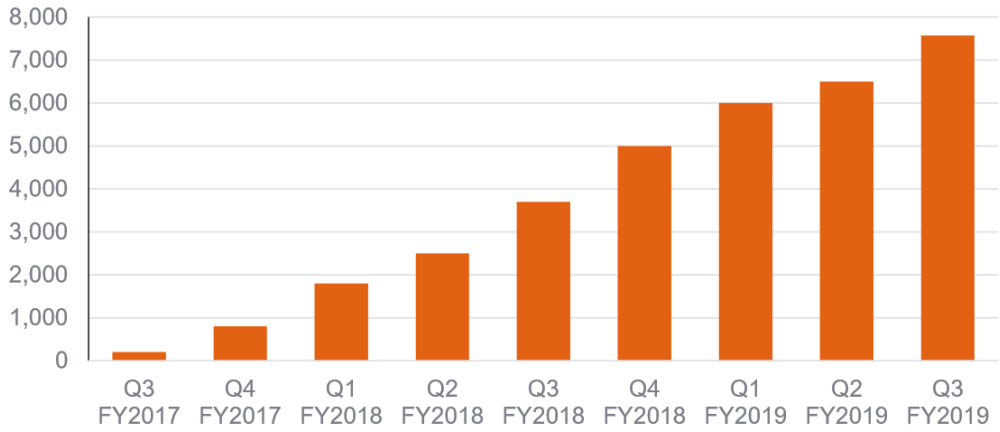
Since Blue Earth's sales is annualising GBP 70m only two years after launch, Syncona's valuation of Blue Earth may be viewed as fairly conservative.

During the two years after launch (mid-2016 to mid-2018), Axumin volumes have reached close to 30,000.

October-December 2018 volumes increased by 17% compared with the prior quarter

In February 2019, Syncona reported that US unit sales of Axumin had increased to 7,575 in the period covering October to December 2018, a 17% increase on the previous quarter, and that they saw continued progress towards a label extension for Axumin since following positive results from an investigational Phase 3 blinded image evaluation study, the FDA had accepted a supplemental new drug application for expanded use of Axumin in adults for glioma (a form of brain cancer).

CHART 5: Axumin volume performance (October-December 2018 is Q3 FY 2019)



Source: Syncona corporate presentation, March 2019

Overall, it took Blue Earth three years from product filings to profitability, and two years from the first marketing approval (US) to profitability.

Mangoral 2019-2024 timelines

If we would use Axumin's development and commercial timelines as a benchmark for Ascelia Pharma's Mangoral, the timelines and catalysts would look like follows:

- **September 2019**: first patient enrolled into the pivotal phase 3 trial with Mangoral
- **During 2019**: marketing organisation build-up, including strategy for launch in Japan which accounts for 25% of Mangoral's target market
- **During 2019**: updates on the progress of the phase 3 trial; a timely inclusion of patients is a very important validation of the market size and medical need, we believe
- **December 2020**: top-line data from the phase 3 trial
- **October 2021**: FDA accepts Mangoral for regulatory review
- **March 2022**: FDA approves Mangoral for US market sales
- **July 2022**: first commercial delivery of Mangoral in the US market
- **November 2022**: a product specific reimbursement code designated for Mangoral in the US
- **January 2023**: Mangoral recommended for approval in Europe
- **March 2023**: Mangoral approved in Europe
- **September 2024**: Ascelia Pharma reports that the company is now profitable

Background: Very straightforward phase 3 trial design

A phase 3 trial with 3-day follow-up in up to 200 patients

Mangoral's pivotal phase 3 trial, targeting enrolment of up to 200 patients, will be a 3-day safety follow-up of each participant. Apart from the very short safety follow-up period, a number of other aspects separates the imaging trial with Mangoral from a standard drug trial.

Mangoral will be compared with an unenhanced scan and each participant will be its own control. In pharma trials, participants are typically randomised to separate treatment groups. In the evaluation of the trial results, each participating patient will be its own control, instead of patients being randomised to different treatment arms.

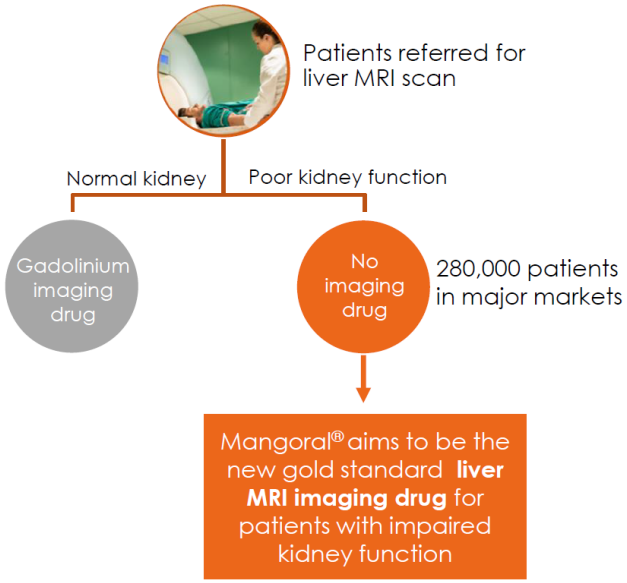
The peroral route of administration for Mangoral also seems fairly easy. Mangoral is a powder that is mixed with absorption enhancers (alanine and vitamin D3) and dissolved into water before ingestion, compared with standard contrast agents that are typically injected. After Mangoral administration, the patient waits for a couple of hours, and then there is a window of around four hours when the Mangoral concentration is high enough to enable contrast enhanced liver MRI.

The combination of a safety follow-up period of three days and each participant being its own control seems like a very straightforward design for a pivotal phase 3 trial.

Targeting 3-4% of the liver MRI population

Since the target population is so small, i.e. only around 3-4% of people undergoing a liver MRI procedure, we assume that Ascelia Pharma can and will market Mangoral on its own, at least in the US where a sales force and support organisation of around 20 people should be able to cover the market.

CHART 6: Mangoral's target population

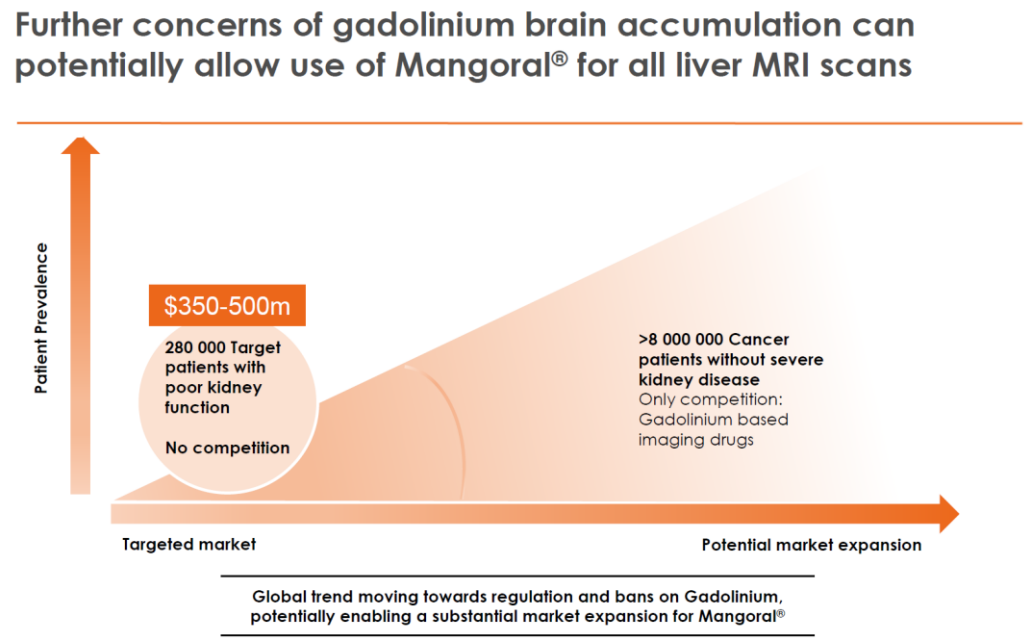


Source: Company information

In Europe, it may well be possible to establish an own marketing organisation in some countries, but there could also be opportunities to partner with companies that have a strong marketing presence in one or several European countries.

The competitive landscape in this target market seems not very active, so it seems unlikely with any market competition during the 7-10 years of orphan drug market exclusivity that Mangoral should have in the US, Europe and Japan.

CHART 7: Potential long-term market expansion for Mangoral



Source: Company information

Forecasts: initial target market is 220,000 liver MRI per year

8 million cancer patients in need for liver MRI; company initially targeting 280,000

Ascelia Pharma's first target market, people with severely impaired kidney function undergoing liver MRI, is around 220,000 imaging procedures per year in the US, Europe and Japan combined. Ascelia Pharma sees a total initial target market of 280,000 people with severely impaired kidney function in need for liver MRI, and more than 8 million cancer patients in need of liver MRI, if people with preserved as well as impaired kidney function are included. Hence, the company's initial target population only accounts for 3-4% of the total population.

Table 3: Mangoral's initial target market, number of scans

TARGET POPULATION ('000), YEARLY SCANS		YEARLY SCANS/PATIENT
US	64,000	0.7
EUROPE	95,000	0.8
JAPAN	61,000	0.8
TOTAL NUMBER OF YEARLY SCANS	220,000	

Source: Company information

To put the potential pricing of a Mangoral enhanced liver MRI into context, in the US, estimated average prices for liver MRI at a hospital setting is closer to USD 2,000, and less than USD 1,000 at a freestanding clinic. The lowest prices are around USD 500-600 per procedure at freestanding clinics, and the highest prices are above USD 1,000.

At the hospital setting, the lowest prices are around USD 1,000, while many hospitals would charge more than USD 2,000 for the procedure. However, the variations between clinics are significant.

Against this background, some examples of the clinical value that Mangoral could add in the future could be the following:

- First, for those where any liver lesion is not visible without contrast enhancement but where Mangoral contrast imaging makes one or several lesions visible. This could lead to life saving surgery, or other treatments with significant impact on the patient's outcome

- Second, for those where a few liver lesions are visible without contrast enhancement but where Mangoral contrast imaging makes even more liver lesions visible. In such cases, the potential benefits of any surgical procedure may be deemed too small and hence a major procedure could be avoided.

- Third, in people where there are plans for multiple liver MRI procedures, which is often the case in the early follow-up of a treatment, Mangoral's safety and lack of systemic uptake may be seen as an attractive alternative

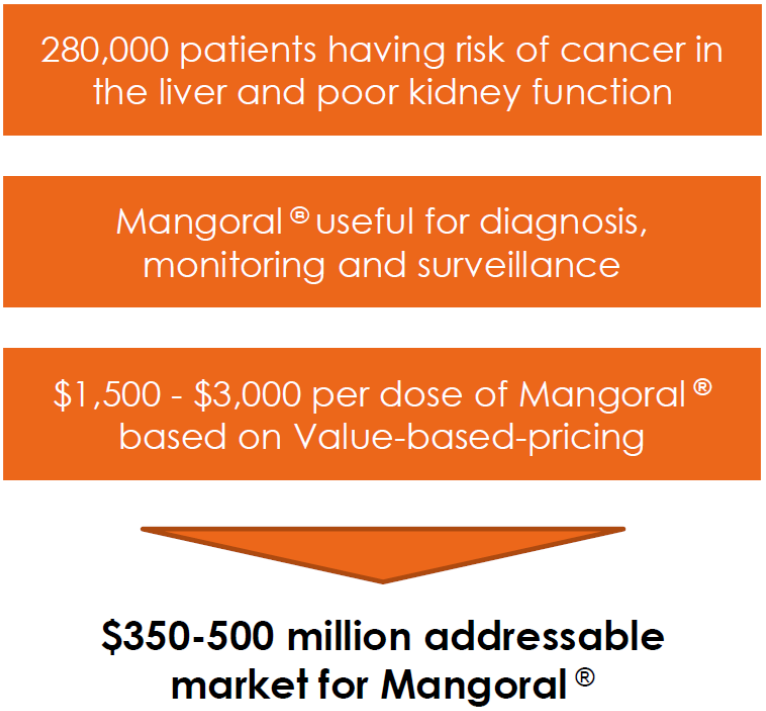
Pricing: company target is USD 1,500-3,000 per procedure

From the company's pre-market pricing discussions with payers and reimbursement companies, the value of being able to perform contrast enhanced liver MRI for this niche population of around 280,000 people per year could be around USD 1,500-USD 3,000 per MRI procedure.

Ascelia Pharma estimates that around 220,000 liver MRI procedures are conducted yearly on its target population of 280,000. The number of scans naturally depend on where patients are in a treatment cycle, and scanning intervals become longer when the underlying disease is viewed as having stabilised.

Overall, Ascelia Pharma sees a yearly market of around 95,000 liver MRI for people with severely impaired kidney function in Europe, and 60,000-65,000 in the US and Japan each.

Chart 8: Mangoral's addressable market



Source: Company information

Assuming that half of the US procedures in the niche population would be done with Mangoral contrast enhancement, the yearly US volume would be around 30,000 scans (32,000 in 2026E). Assuming a product price per procedure of USD 2,250, US market sales would be USD 72m/SEK 648m for Mangoral in 2026E.

We believe that a slightly lower penetration rate assumption than 50%, at least in the early launch phase, for a diagnostic product with proven efficacy and safety and no competition will be a reasonable assumption since the target population is fairly broad, in terms of the number of hospitals where the target patients are undergoing MRI.

Needs to establish a new treatment standard, since there is no existing treatment to replace

Also, there is no existing contrast agent to replace in this niche setting, so Ascelia Pharma's sales force will need to actively establish a treatment standard where there exists no treatment today.

A higher penetration rate assumption, i.e. 50% or more, would be a reasonable assumption, we believe, if Mangoral's target market would be very concentrated to a few hospitals, and preferably that a high portion of these hospitals would have detailed knowledge about the product prior to approval through participation in clinical trials.

For Mangoral, there is naturally the alternative to perform the MRI procedure without contrast (or to use a low-cost gadolinium based agent despite the safety warnings for use in the impaired kidney function population), but we believe the clinical value in terms of safety and changed treatment plans following Mangoral contrast enhanced MRI, should mean that adoption rates will steadily increase for several years after launch.

For a hospital with 100 liver MRI (or abdominal MRI) at cost today at USD 150,000 (USD 1,500 per scan), the total cost would increase to USD 154,500, or 3%, if people with severely impaired kidney function would account for 4% of the population, and half of these would undergo an MRI with a Mangoral at a cost of USD 2,250. Also, abdominal MRI is only one of many different MRI procedures, so the total MRI procedure cost increase would be significantly less than the mentioned 3%.

We believe that no hospital function, administration, or physician speciality, would bill less money, should Mangoral be used in connection to liver MRI.

Sales uptake in Europe should be slower we believe due to the heterogeneity of European markets and requirements for national reimbursement in each country.

Mangoral sales in Japan, South Korea and China will depend on the partnering of the product. In terms of procedure volumes, the market in Japan seems particularly important. Until we have more clarity on the commercial strategy in the region, we have only assumed that sales in the region will be 25% of sales in Europe, despite that the market in Japan is almost as big as in the US in terms of volumes.

Table 4: Assumptions on market adoption and volumes, US and Europe

MARKET ADOPTION (%)	2022E	2023E	2024E	2025E	2026E
US	2	8	15	22	28
EUROPE	0	2	8	15	20
NUMBER OF SCANS ('000)	2022E	2023E	2024E	2025E	2026E
US	1.3	5.1	9.6	14.1	17.9
EUROPE	0.0	1.9	7.6	14.3	19.0
TOTAL	**1.3**	**7.0**	**17.2**	**28.3**	**36.9**

Source: Vator estimates

In three years' time from now, i.e. around H1 2022, Ascelia Pharma should be in the process of launching Mangoral in the US, prepare for launch in Europe and Japan, and should have received results from the phase 2 development of Oncoral. At that stage, we believe the company's valuation will reflect the expected near-term launch uptake, the potential from other ongoing line extension studies, and how successful its pre-marketing activities have been in terms of building commercial scale and adding marketing support from clinical trials.

The company will be loss making in 2019-2021 and probably also in 2022, but the sales ramp-up and the build-up of reimbursement coverage should be more important for early-stage valuation accretion than near-term earnings effects, we believe.

Mangoral sales forecast of around SEK 500m assuming 15% target market penetration three years after launch

Based on the initial target population of around 200,000 people, an assumption of market penetration of 15% three years after launch, and a price of USD 2,250 in the US for Mangoral, we believe that sales forecast up to around SEK 500m (SEK 510m in our 2026E forecast) during the fairly early 2022-2026E phase of Mangoral's commersialisation will be a reasonable scenario.

The expected pricing level has been discussed by the company with more than 25 payers in the US and Europe, and Ascelia Pharma targets a price per Mangoral dose of USD 1,500-3,000 based on the feedback received at these discussions. The basis for the pricing discussion has been to offer an imaging product in this population where typically no imaging product today is being used.

Company's peak sales target is USD 350-500m for Mangoral in the liver MRI orphan indication

Based on these pricing discussions and Ascelia Pharma's work on the volume potential, the company has set a peak sales target of USD 350-500m for Mangoral sales in the orphan indication liver MRI in people with severely impaired kidney function. There are no competing imaging drugs in development targeting the same niche population.

Moreover, the peak sales target is based on the company's view on the number of relevant cancer patients (particularly colorectal and breast patients) in the main regions the US, Europe and Japan, the prevalence of chronic kidney disease (CKD) in the population, and the number of yearly liver MRI scans per CKD patient.

In the US for example, the company estimates an addressable pool of 92,000 CKD patients (40% being colorectal cancer patients), either with severely impaired kidney function (kidney disease in stage 4 and 5) or CKD stage 3 with acute worsening, out of a relevant cancer population of around 2.4 million. Out of this target population, an estimated 64,000 MRI scans are performed per year.

In Europe, an estimated 95,000 MRI scans are performed each year, and in Japan 61,000, which in total leads to a target population of 280,000 per year in the US, Europe and Japan combined, with severely impaired kidney function or acute worsening of kidney function, and the number of target liver MRI scans for Mangoral being 220,000.

At the pre-operative stage, typically one scan is conducted, depending on the status of the patient, disease stage and other factors. During follow-up drug therapy, the response to chemotherapy and re-assessment of colorectal metastatic resectability may occur as often as six week intervals, so the number of MRI scans per patients may differ significantly. Hence, there may well be specific patients where Mangoral would be particularly useful, i.e. those where there are plans for repeated MRI scans.

The difficulty with such pre-market pricing sensitivity evaluation is naturally that the responses are based on how payers should behave, or believe they should behave, which naturally could differ compared with how they behave in a real life setting when the product is available and the payment is due.

We believe any comparison to pricing of rare disease orphan drugs are not relevant, since orphan drug treatment, as with other drug treatments, could be life-long treatments and imaging products are for one-time or intermittent use.

However, there are high priced niche contrast agents available on the market, one recent example being Blue Earth Diagnostic's Axumin PET imaging contrast for prostate cancer detection, which based on reported volumes and sales figures seem to be selling for a net realised price of around USD 3,500.

Regarding Ascelia Pharma's peak sales targets for Mangoral (USD 350-500m), we believe that if they would reach less than 15% of the mid-point of that sales target by 2026E (our 2026E sales forecast of USD 57m compared with the USD 425m mid-point of the company's peak sales target), there is a case for significant valuation accretion.

More significant sales, a more tangible strategy for the market in Japan, progress in the development of Oncoral, or other products being added to the portfolio, could be other sources for value accretion.

Assuming pivotal trial start in H2 2019 for Mangoral and study results in H2 2020, first sales could start in 2022E with full-scale commercial sales and a separate reimbursement code 3-6 months after the initial FDA approval.

Market volumes in Japan similar to the US

Again, since the target number of yearly Mangoral scans in Japan is close to the target for the US market, an important value driver for Ascelia Pharma should be any clarity in terms of development and commercial steps to enable a market launch.

Ascelia Pharma will sell the product through a partner in Japan with an established position in the marketplace which should make that market less valuable for Ascelia Pharma compared with the US, however we still believe sales in a high-end market such as Japan is very important.

Table 5: Mangoral sales forecasts

SALES (USDM)	2022E	2023E	2024E	2025E	2026E
US (USD 2,250 PRICE/SCAN)	3	13	24	35	45
EUROPE (USD 500 PRICE/SCAN)	0	1	4	7	10
OTHER REGIONS (25% OF EUROPE)		0	1	2	2
TOTAL SALES (USDM)	3	14	29	44	57
TOTAL SALES (SEKM)	**29**	**126**	**259**	**397**	**510**

Source: Vator estimates

Manufacturing and clinical trials by external partners

Ascelia Pharma has out-licensed Mangoral manufacturing to US based Cambrex, and most clinical trial activities are done by external clinical trial organisations. Operating expenses in the twelve-month period from July 2017-June 2018 were SEK 25m.

We assume 80% gross margin for Ascelia Pharma with Mangoral available as a commercial product, and operating expenses to increase to SEK 50-65m in 2019-2020E, with SEK 115m expenses in 2023E, the first full year with Mangoral sales in Europe, US and other regions, and a first profitable year in 2024E.

Table 6: 2019-2026E sales and cost estimates

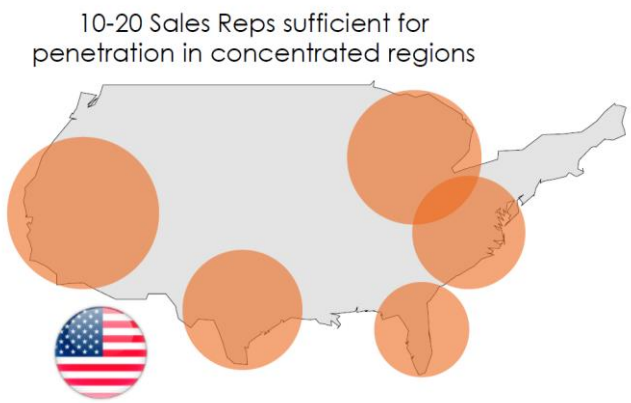
(SEKM)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
SALES	0	0	0	29	126	259	397	510
COGS				-6	-25	-52	-79	-102
OPEX	-50	-65	-80	-95	-115	-120	-130	-140
EBIT	**-50**	**-65**	**-80**	**-72**	**-14**	**87**	**188**	**268**

Source: Vator estimates

At the end of September 2018, Ascelia Pharma had a SEK 112m balance sheet, whereof SEK 57m is related to intangible assets (primarily the acquisition of Oncoral) and most of the remainder is cash. The balance sheet increased from SEK 67m in March 2018 to SEK 116m in June 2018 following a SEK 60m share issue in June.

Operating cash flow in the twelve months from July 2017-June 2018 was negative SEK 21m, and negative SEK 4m in the three months from July 2018-September 2018.

Chart 9: Mangoral commercial strategy for a 2022E launch



- **Ascelia's sales force** will target **major hospitals** with nephrology units
- **10-20 sales reps in the US** sufficient for significant penetration
- **Reimbursement** expected shortly after sales launch
- **Chief Commercial Officer will be recruited during the Phase 3** clinical study to finalize commercial strategy and prepare launch
- **No recent innovation in the MRI space** Mangoral has attracted major attention. This will be utilized in the pre marketing phase
- Ascelia sales force in Europe being evaluated
- Find commercial partners in Japan, South Korea and China

Source: Company information

Operating expenses in the years ahead for Ascelia Pharma will primarily be driven by the phase 3 trial for Mangoral and the commercial pre-marketing activities, but also to conclude the phase 1 trial program with Oncoral and start preparation for phase 2 development. The latter may be together with a development partner.

20 people seen as sufficient US market sales organisation

The company sees a sales organisation of up to 20 people as sufficient to cover the US market, with a focus on five key regions and major hospitals with significant nephrology units.

Sales through partners in key Asian countries

A chief commercial officer in the US will be recruited during the phase 3 trial with Mangoral, towards late 2019 or 2020, and the scope and presence of a Mangoral sales force in Europe is being evaluated by the company. Regarding development and sales in Japan, China and South Korea, Ascelia Pharma will work through partners.

Valuation

In the 2019-2021 run-up to our longer term (2022E) valuation scenario, we believe that the following stepwise valuation assumptions are reasonable, the starting point being one product in preparation for a pivotal phase 3 trial and one product recently having published phase 1 investigator sponsored extension study results.

First step is prior to initiation of the first phase 3 trial

At this fairly early stage, we see a reasonable valuation range of the company towards early 2020at SEK 26-30 per share (SEK 600-700m in market capitalization).

We believe at this early stage prior to the initiation of the first phase 3 program, the company will be close to halfway to the equity valuation it should have when head-line results from the pivotal phase 3 trial with Mangoral has been reported. The near-term highlights are as follows:

- H1 2019: phase 3 preparation meeting with EMA on Mangoral
- H2 2019: the enrolment of the first patient into the pivotal phase 3 trial with Mangoral. This means the background work of the regulator's review of the product's safety, hypothesis about potential efficacy, dose findings and all other preparatory parameters have gone well
- H2 2019: phase 2 preparation with Oncoral in gastric cancer
- H1 2020: the timely continuation of the pivotal phase 3 trial. This means that the decided inclusion criterias have not been too strict (which would make too many potential participants ineligible for study enrolment), and that the participating centers have the number of patients they thought they had. At the commercial stage, the background of having a timely conducted pivotal trial is very important, we believe. If a product fails to enrol the targeted number of patients into a clinical trial, or if the enrolment stage takes too much time, the target population and sales potential of the product is probably smaller than was the initial idea. Also, if patient enrolment goes faster than planned, this should be seen as a very positive indication about market size and sales potential
- H1 2020: phase 2 initiation with Oncoral in gastric cancer

Second step is after top-line data from the pivotal phase 3 trial

Looking into H2 2020, Mangoral should have reported top-line data from the pivotal phase 3 trial, and towards early 2021 we see a reasonable valuation of the company in the range of SEK 39-48 per share (SEK 900m-1.1bn).

We believe at this stage, the company will be close to halfway to the equity valuation it should have at an early commercial stage.

The reporting of the phase 3 trial results is naturally a major milestone for the company, since the product hypothesis has been confirmed, and the way to commercial sales is now open, barring any different views about the validity of the trial design between regulators approving drugs and regulators approving the design and clinical relevance of results from clinical trials.

At this point, the expected near-term key developments should be:

- H1 2021: Filing for Mangoral approval, first in the US, followed by filing for approval in Europe. The product filing is a time-consuming time process, since there is a big workload gap between reporting initial headline data from a trial and collecting all study details to enable a filing for approval.
- H1 2022: Regulatory approval, the final go-ahead for initial commercial sales activities and pre-marketing activities
- H1 2022: Initial sales, based on test use by early adopting clinicians. A target group for initial sales will naturally be the clinical trial centers that have participated in the pivotal clinical trial. This is as far as our 3-year stepwise valuation thinking goes.
- H2 2022: Full-scale commercial sales, after the receipt of a separate reimbursement code. A separate reimbursement code makes the administrative prescription process much easier. Without the code, the clinic must seek increased payments for other services to compensate for the cost of Mangoral.

Third step is during the final launch preparations in 2022

Assuming initial sales in 2022E and 2026E sales around SEK 500m for Mangoral (our forecast: SEK 510m by 2026E), including revenues related to Japan and other regions, would be seen as reasonable at the time of pre-launch in H1 2022, we see a valuation range of SEK 60-77 per share (SEK 1.4-1.8bn).

With 2023E sales forecast at SEK 126m and 2024E sales forecast at SEK 259m, such equity valuation could be viewed as rich, however we believe the equity valuation at that early stage of the launch process will be based on longer term expectations.

Assuming 80% gross margin and operating expenses around SEK 100-130m at the commercial stage, profitability should be reached when sales is exceeding SEK 150m. We forecast an operating loss in 2023E, and SEK 87-188m EBIT in 2024-2025E.

Our H1 2022E valuation assumption would mean 16x 2-year forward (2024E) EBIT, and 7x 3-year forward (2025E) EBIT. If the confidence in these forecasts would increase from 2022 and onwards, there should be significant scope for continued valuation accretion, even without any significant increases in these forecasts, we believe.

There are naturally a number of upsides and downsides to such a scenario, one important upside being our price per scan assumption. Another potential upside is naturally from Mangoral use beyond the niche population of severely impaired kidney function, based on Mangoral's safety profile relative to existing contrast enhancement agents.

To illustrate the sales forecast sensitivity to our volume and price assumptions, the below table includes a range of a 10-70% penetration of the yearly 220,000 MRI scans that are Mangoral's target market, and an average (all regions combined) price/scan range from USD 250-3,000, the upper end of that price range being the upper end of Ascelia Pharma's own price target.

Hence, if one would assume a price of USD 2,250 per Mangoral scan (the mid of the company's price target) and a 50% market penetration would mean USD 248m sales, compared with our 2026E sales forecast at USD 57m.

Table 7: Sales forecast sensitivity (USDm) based on various assumptions on market adoption and average price/scan

SHARE (%) OF TARGET YEARLY SCANS	10	20	30	40	50	60	70
NUMBER OF SCANS ('000)	22	44	66	88	110	132	154
AVERAGE PRICE/SCAN (USD)	Sales (USDm)						
250	6	11	17	22	28	33	39
500	11	22	33	44	55	66	77
750	17	33	50	66	83	99	116
1 000	22	44	66	88	110	132	154
1 250	28	55	83	110	138	165	193
1 500	33	66	99	132	165	198	231
1 750	39	77	116	154	193	231	270
2 000	44	88	132	176	220	264	308
2 250	50	99	149	198	248	297	347
2 500	55	110	165	220	275	330	385
2 750	61	121	182	242	303	363	424
3 000	66	132	198	264	330	396	462

Source: Vator estimates

The sensitivity ranges on number of scans and price per scan in the table below is the same as the prior table, but the figures are instead in SEK.

Again, if one would assume a price of USD 2,250 per Mangoral scan (the low end of the company's price target) and a 50% market penetration would mean SEK 2.228bn sales, compared with our 2026E sales forecast at SEK 510m.

Table 8: Sales forecast sensitivity (SEKm) based on various assumptions on market adoption and average price/scan

SHARE (%) OF TARGET YEARLY SCANS	10	20	30	40	50	60
NUMBER OF SCANS ('000)	22	44	66	88	110	132
AVERAGE PRICE/SCAN (USD)	Sales (SEKm)					
250	50	99	149	198	248	297
500	99	198	297	396	495	594
750	149	297	446	594	743	891
1 000	198	396	594	792	990	1,188
1 250	248	495	743	990	1,238	1,485
1 500	297	594	891	1,188	1,485	1,782
1 750	347	693	1,040	1,386	1,733	2,079
2 000	396	792	1,188	1,584	1,980	2,376
2 250	446	891	1,337	1,782	2,228	2,673
2 500	495	990	1,485	1,980	2,475	2,970
2 750	545	1,089	1,634	2,178	2,723	3,267
3 000	594	1,188	1,782	2,376	2,970	3,564

Source: Vator estimates

Ascelia Pharma is an oncology company with a prime focus on developing an agent for contrast enhanced liver MRI with no direct relevant listed local peer companies. However, when the company moves through phase 3 development and a commercial launch seems increasingly likely, we believe Ascelia Pharma will gradually be compared with the small selection of locally listed revenue generating life science companies.

Some of these companies, such as Vitrolife, Biotage and Cellavision, are well established companies with long-term track records of sustainable and high growth.

Xvivo Perfusion FY 2018 revenues: SEK 188m

Other, smaller, companies are e.g. Xvivo Perfusion that has a market cap of around SEK 4bn. Xvivo Perfusion reported FY 2018 sales of SEK 188m, equal to 23% y/y organic sales growth. FY EBITDA increased 40% y/y to SEK 31m, equal to an EBITDA margin of 16%.

Xvivo Perfusion sells products aiming at improving organ transplant processes outcomes, and expanding the organ donor pool. Its product range include Perfadex plus which is a standard product within lung preservation ahead of organ surgery.

Sedana Medical FY 2018 revenues: SEK 58m

Sedana Medical (SEK 500m guidance for sales in Europe post launch of lead product) has a market cap around SEK 2bn and is at the very early stage of its commercial phase. Sedana Medical has total yearly costs currently around SEK 60m, and is gradually building its marketing presence in more and more countries, and has recently established a timeframe for product development and launch into the US market, with a launch plan set for 2024.

SyntheticMR FY 2018 revenues: SEK 58m

SyntheticMR had FY 2018 sales at SEK 48m (36% y/y increase compared with SEK 36m in FY 2017), SEK 20m EBIT (41% margin) in the period, and has a market cap around SEK 1.3bn.

Other listed life science companies in the region such as Camurus, Oncopeptides, Isofol Medical, BioArctic, Calliditas and Asarina Pharma are more difficult to compare with Ascelia Pharma, we believe, since they are based on pharmaceutical product development with product development risks and market potential unique for each company. A listed company also may be compared with includes Spago Nanomedical, which is entering phase 1 clinical development in early 2019 with a contrast enhanced MRI.

Disease area and company background

Ascelia Pharma was founded in 2000 in Lund, Sweden, and conducted several phase 1 and 2 studies during 2004-2011. In the following years, the orphan drug strategy was implemented, end of phase 2 meeting was held with the FDA, significant work on price sensitivity and pricing acceptance were done, and in November 2018, a meeting with the FDA were held to enable the finalisation of the phase 3 pivotal study preparations for Mangoral for the diagnostic use in connection to liver MRI for people with severely impaired kidney function.

Ascelia Pharma was known as CMC Contrast AB until 2017 when it acquired the Oncoral product and changed name to Ascelia Pharma AB. Oncoral is the main component of Ascelia Pharma's SEK 57m balance sheet intangible assets.

During the early development years of Mangoral, there was an increased knowledge that gadolinium-based contrast enhanced MRI was probably not an ideal choice for everyone undergoing the procedure.

125 subjects have received administrations of Mangoral to date

In the development program to date, 125 subjects have received 185 administrations of Mangoral, with gastrointestinal side effects (such as diarrhea), nausea and headache being the most frequently reported side effects with the majority of side effects being of mild intensity and transient. Furthermore, 77 patients have received Mangoral as part of a compassionate use program at Herlev Hospital, Denmark.

First link between gadolinium and risk for severe side effects was reported in 2006

In 2006, the association between gadolinium and severe side effects were first reported by Danish nephrologists.

In patients with severely impaired kidney function, i.e. who have an estimated glomerular filtration rate (eGFR) below 30 ml/min/1.73 m2 or acute kidney injury (AKI), gadolinium may accumulate in the body and cause a rare but serious side effect called nephrogenic systemic fibrosis (NSF). eGFR is one of several standard measurements of kidney function.

NSF symptoms include scaling, hardening and tightening of the skin, with red or dark patches on the skin, sometimes followed by fibrosis of internal organs that may be lethal. The link between gadolinium use and NSF has been verified by the FDA as well as EMA.

Prescription changes for gadolinium-based contrast agents in 2010

In 2010, both the FDA and EMA changed the prescribing information of gadolinium-based contrast agents for safety reasons in relation to risk of NSF, and FDA also advised routine screening for acute and chronic severe kidney disease for patients undergoing contrast enhanced MRI.

Further FDA warnings in December 2017

More recently, FDA warned in December 2017 that gadolinium-based contrast agents are retained in the body including the brain and required a new drug class warning.

Also, in December 2017, Japan's Ministry of Health, Labour and Welfare asked makers of gadolinium-based contrast agents for MRI scans to revise their warning texts. EMA has also taken action in terms of revised labeling and product withdrawals.

Gadolinium based contrast is used in around 2/3 of abdominal (which includes the liver) MRI examinations, while the rest of the procedures is being done without contrast enhancement due to the suspected clinical issue, localisation of the lesions, knowledge about the patient history, the patient's age and medical status, or other, such as safety reasons.

Mangoral is based on manganese which is normally circulating in our bodies, but the contrast drug dosing is very different, 800mg per dose, compared to the total levels of an estimated 10-20mg that would be measurable in our bodies (the concentration differs between organs, and plasma levels of manganese are expressed by a different unit) and recommended daily intake of up to 1.8-2.3mg.

Mangoral an oral solution which is specific to healthy liver tissue

Mangoral, which is administered as an oral solution, also contains two absorption promoters, alanine and vitamin D3. After the product has been ingested by the patients, it is absorbed in the small intestines, transported to the liver and taken up by normal hepatocytes (liver cells), but not by damaged tissue or cells with a non-hepatocytic origin. This means healthy tissue should appear bright at the scan while damaged tissue should appear dark.

CHART 10: Overview of conducted clinical trials with Mangoral

Trial		No. subjects	Subject type	Study design	Key results
CMC-P001 (Chabanova et al, MAGMA, 2004, 17:28-35)	Phase I	18 (+2 placebo)	Healthy	Open-label dose-rising	✓ Data suggested that Mangoral® may be an effective MRI contrast agents
CMC-P002 (Dekker et al, RSNA, 2009, abstract SSG08-03)	Phase II	18	Liver metastasis	Open-label	✓ Diagnostic quality scores improved after Mangoral®
CMC-P003 (Rief et al, Invest Radiol, 2010, 45:565-71)	Phase II	20	Liver metastasis	Randomised, parallel group, open-label	✓ Improved MRI quality of Mangoral® most pronounced at 3 and 6 hours after use
CMC-P004 (Brismar et al, Eur Radiol, 2012, 22:633-41)	Phase II	20	Liver metastasis	Randomised cross-over	✓ In comparison with MultiHance (gadolinium agent) there was no significant difference in number of detected liver metastases after Mangoral®
CMC-P005	Phase II	17	Liver lesions	Randomised, parallel group, open-label	✓ Improvement of the delineation of focal liver lesions after Mangoral®
CMC-P010 (Albiin et al, MAGMA, 2012, 25:361-8)	Phase II	32	Healthy	Randomised, double-blind, cross-over, dose-response	✓ Liver signal intensity increase most pronounced at 800 mg dose

Source: Syncona H1 presentation, 21 November 2018

A re-read of all available images presented in 2014

A blind re-read of all available images by an independent experienced reader evaluated all available images with Mangoral in order to make an overall conclusion of efficacy, and data was presented in 2014 at RSNA (Radiological Society of North America) and 2015 at ECR (European Society of Radiology).

The overall conclusion from the clinical experience so far was that compared to unenhanced MRI, 33% more lesions were detected with Mangoral enhanced MRI, and

it also improved MRI performance in terms of localisation and delineation. Also, quantitative measures such as lesion to liver contrast ratio was significantly improved with Mangoral enhanced MRI.

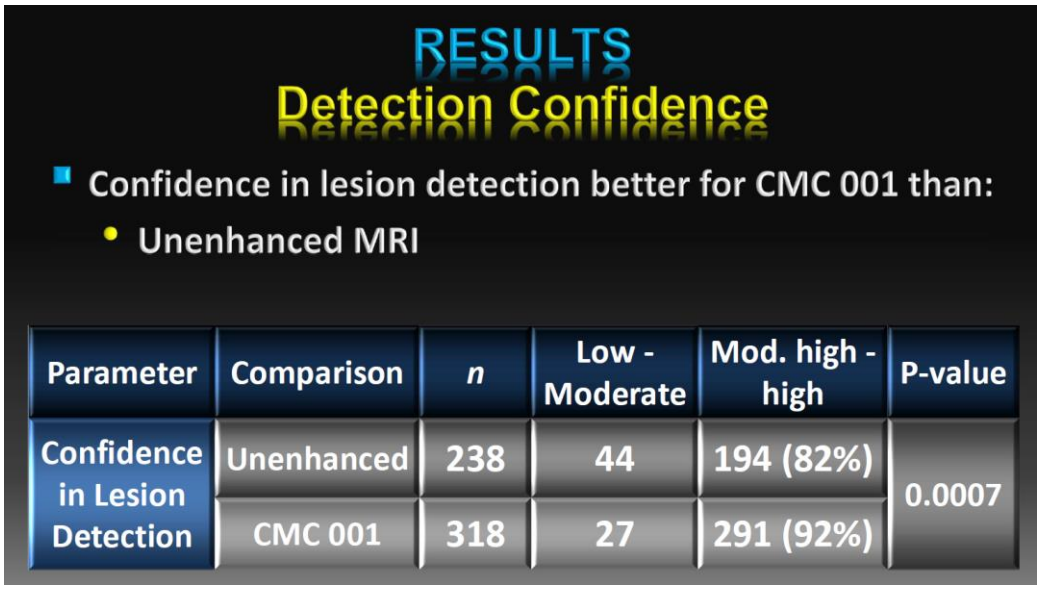
A total of 178 subjects (105 men, 73 women) with a mean age of 50 (including 100 healthy subjects and 72 with known liver metastasis). All images T1 and T2 weighted images with 1.5T, with 45 participants receiving the 800mg Mangoral dose, and 115 receiving the 1,600 mg dose.

According to the results from the study CMC-P003, the 800mg and 1,600mg doses were considered equivalent in terms of diagnostic efficacy, with more side effects seen at the 1,600mg dose level.

Timing from administration to MRI was 2.5-4.0 hours post oral intake of Mangoral.

One main finding in the study was that the confidence in lesion detection increased from 238 detected lesions without contrast to 318 lesions with Mangoral contrast, and that the level of confidence increased from 82% having "moderately high to high" confidence of detected lesions without contrast, to 92% with Mangoral contrast.

CHART 11: Detection confidence with Mangoral enhanced MRI compared with unenhanced MRI



Source: "Evaluation of a new manganese-based orally-administered hepatobiliary MR contrast agent", Rendon C. Nelson, MD, Duke University, Kohkan Shamsi, MD, PhD, RadMD, RSNA 2014

Mangoral has been tested at four dose levels (200, 400, 800 and 1,600 mg) in the phase 1 and 2 clinical trials. A phase 1 study in 18 healthy subjects was reported in 2004 and phase 2 trials were reported in the years after.

One trial, called CMC-P004 included 20 patients with liver metastasis with a cross-over design, with no significant difference in the number of detected liver lesions of Mangoral contrast enhancement compared with MultiHance, which is a gadolinium-based MRI contrast agent.

In another trial, called CMC-P005, 17 patients with liver lesions received Mangoral, indicating improvement of the delineation (the detailed spreading) of focal liver lesions,

and in CMC-P010, 32 healthy subjects received Mangoral in a cross-over dose-response trial, suggesting the liver signal intensity increased the most at the 800mg dose.

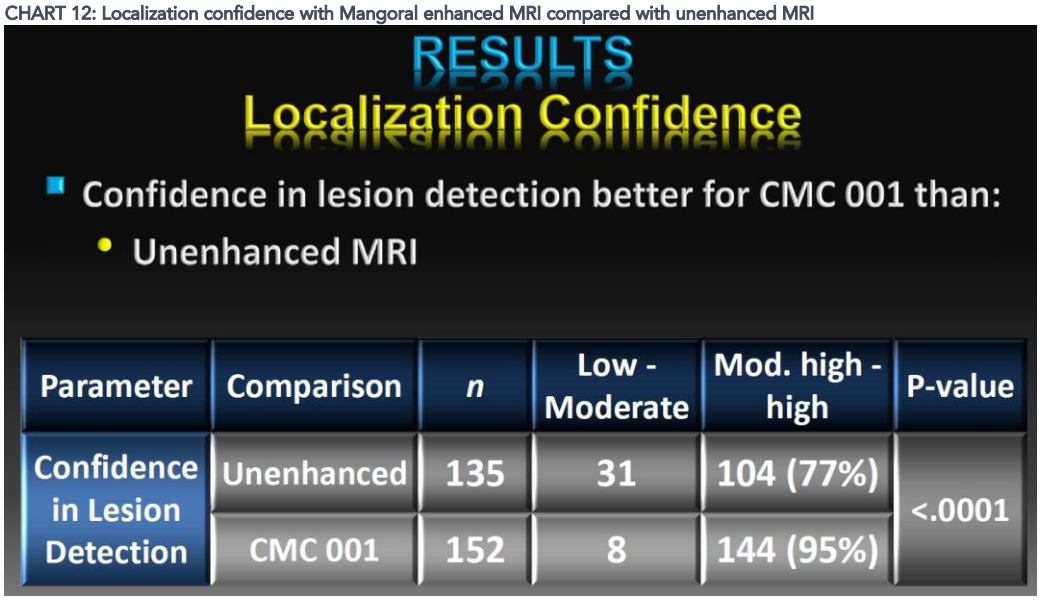
One example of the published trials from the phase 1 and 2 program with Mangoral is the 2012 publication "MRI of colorectal cancer liver metastases: comparison of orally administered manganese with intravenously administered gadobenate dimeglumine, Eur Radiol. 2012 Mar;22(3):633-41. Brismar TB, Kartalis N, Kylander C, Albiin N". The study was published online in 2011.

The objective of the study was to compare the sensitivity of MRI to detect colorectal cancer liver metastases (CRLM) after ingestion of Mangoral manganese-based contrast agent (CMC-001) with that of a comprehensive intravenous gadobenate dimeglumine protocol (standard gadolinium based contrast), and to assess the safety and acceptability of oral manganese.

20 patients suspected of having 1–6 colorectal cancer liver metastases were included prospectively in this randomised cross-over study. Liver MRI was performed with a one-week interval at 1.5T and included so called T1-w VIBE and T2-HASTE (standard imaging pictures), before and after administration of 1,600mg Mangoral or 0.1mmol/kg gadobenate dimeglumine. The metastasis-to-liver signal intensity (SI) ratio was calculated. Standard of reference was histopathology after surgery, or combination of other imaging studies and/or follow up.

Results showed that of 44 metastases, 41 were detected after Mangoral (93%) and 42 after gadobenate dimeglumine (95%).

CHART 12: Localization confidence with Mangoral enhanced MRI compared with unenhanced MRI



Parameter	Comparison	*n*	Low - Moderate	Mod. high - high	P-value
Confidence in Lesion Detection	Unenhanced	135	31	104 (77%)	<.0001
	CMC 001	152	8	144 (95%)	

Source: "Evaluation of a new manganese-based orally-administered hepatobiliary MR contrast agent", Rendon C. Nelson, MD, Duke University, Kohkan Shamsi, MD, PhD, RadMD, RSNA 2014

In the study, 15 false–positive scans were said to be reported after Mangoral and 2 after gadobenate dimeglumine. However, of the 15 false-positives, 10 were focal liver lesions which will be true positives according to the phase 3 study protocol. The metastasis-to-liver SI ratio was significantly higher after CMC-001 than after gadobenate dimeglumine (0.51 and 0.21 respectively, P<0.0001). More adverse events occurred after Mangoral compared to gadobenate dimeglumine.

The main conclusion from this 20-patient study was that 1,600 mg Mangoral is as sensitive as an extensive intravenous gadobenate dimeglumine protocol in detecting CRLM, and that Mangoral was relatively well tolerated but had higher rates of gastrointestinal adverse events such as nausea.

The main side effect in this study was diarrhea, reported after 12 Mangoral administrations. All side effects apart from one was reported to be mild. The side effect that was reported as severe in intensity was one report of back pain which was assessed as possibly related to Mangoral by the investigator. No side effect was reported to be serious in the trial.

One conclusion was that Mangoral should therefore be of special value in patients where repeated MRI exams are needed, i.e. in the surveillance situation, due to its ease of use and safety. Also, in the study setting, the radiologists were not allowed to evaluate previous examinations or patient history which was said to be a limitation of the study, because the number of false–positive lesions has probably been overestimated.

In order to improve the detection and characterisation of liver lesions, a number of intravenous MRI contrast agents have been developed and among these, two have liver-specific characteristics: gadoxetic acid (brand name: Primovist (Eovist in the US)) and gadobenate dimeglumine (MultiHance). However, in patients with low glomerular filtration rate (GFR), the contrast agents increase the risk of NSF.

The uptake of manganese from the bowel is normally very limited, so Mangoral is mixed with alanine (0.5g) and vitamin D3 (800 IU) as absorption promoters. Mangoral is then extracted from the blood circulation by the liver and is subsequently excreted with bile.

The high Mangoral uptake in the liver by the hepatocytes (liver cells) significantly decreases the so called T1 relaxation time, which causes the liver parenchyma (the main part of the liver) to appear bright on T1-weighted images, while non-functioning hepatocytes and metastases will not take up Mangoral and therefore will be of low signal intensity on T1-weighted images.

Mangoral is dissolved into 200mL of water before oral administration.

In a dose finding study with 32 healthy volunteers, 200mg, 400mg and 800mg Mangoral was administered, concluding that the 800mg dose level is the preferred dosing based on better efficacy and image quality. Regarding safety in the dose finding study, there were differences between the three dosages. The most common adverse event was diarrhea, followed by nausea, flatulence, and headache.

Of the 89 adverse events reported in the study, 74 were considered mild, 13 moderate and 2 severe in intensity. The two adverse events reported as severe were cases of diarrhea (800mg and 200mg dose levels). The participant with severe diarrhea after administration of 800mg Mangoral reported diarrhea of mild intensity before the Mangoral administration. The participant with severe diarrhea after Mangoral 200mg had no diarrhea after administration of the higher dose levels.

When discussing the side effect profile, the authors concluded that none of the adverse event reactions led to discontinuation of Mangoral, and none required hospitalization or medication, with the exception of analgesics for headache.

As a background, lesion detection is evaluated at a scale ranging from lesion detected with low confidence to lesion detected with high confidence. Lesion visualization is evaluated from poor to excellent visualization, while lesion margin delineation also is evaluated at a scale from poor to excellent delineation of the margin of the lesion. Lesion characterisation is evaluation on a scale from definitely benign to definitely malignant.

Seven years of market exclusivity following an FDA approval, with potential extensions

Regarding intellectual properties, Mangoral will have seven years of market exclusivity following an FDA approval. Six months extension can be rewarded if there is a so-called pediatric extension approved during the market exclusivity period. In Europe, there will be a 10-year period of data exclusivity, meaning that no other product can launch and refer to Mangoral's clinical trials.

An orphan drug designation in Japan will be discussed with the Japanese health authorities, PMDA, during the course of the phase 3 clinical development, and an application for such market exclusivity, which would be 10 years, will be applied for at the same time of the product submission for approval.

Marketing exclusivity for an orphan drug is in general valid until there is a head-to-head trial available, demonstrating superior results with a competing drug.

Regarding the non-clinical development, the data package behind Mangoral is based on pre-clinical studies by Ascelia Pharma as well as references to the literature, and the substance manganese chloride tetra hydrate is considered to be "generally recognized as safe" by the FDA.

The manufacturing of the product for phase 1 and 2 trials was done by Recipharm, Sweden, while the manufacturing of Mangoral for the clinical trials in the phase 3 program is planned to be carried out by Cambrex, NJ, in the US.

Oncoral – a novel tablet formulation of irinotecan (former brand name: Camptosar)

Apart from Mangoral, Ascelia Pharma's other clinical stage development product is Oncoral. Oncoral is a tablet formulation of irinotecan, a widely used treatment for several forms of cancer. When irinotecan was patent protected, the brand name was Camptosar, originally developed by Pharmacia which was acquired by Pfizer.

Target indication for tablet Oncoral will be for combination use in advanced gastric cancer disease

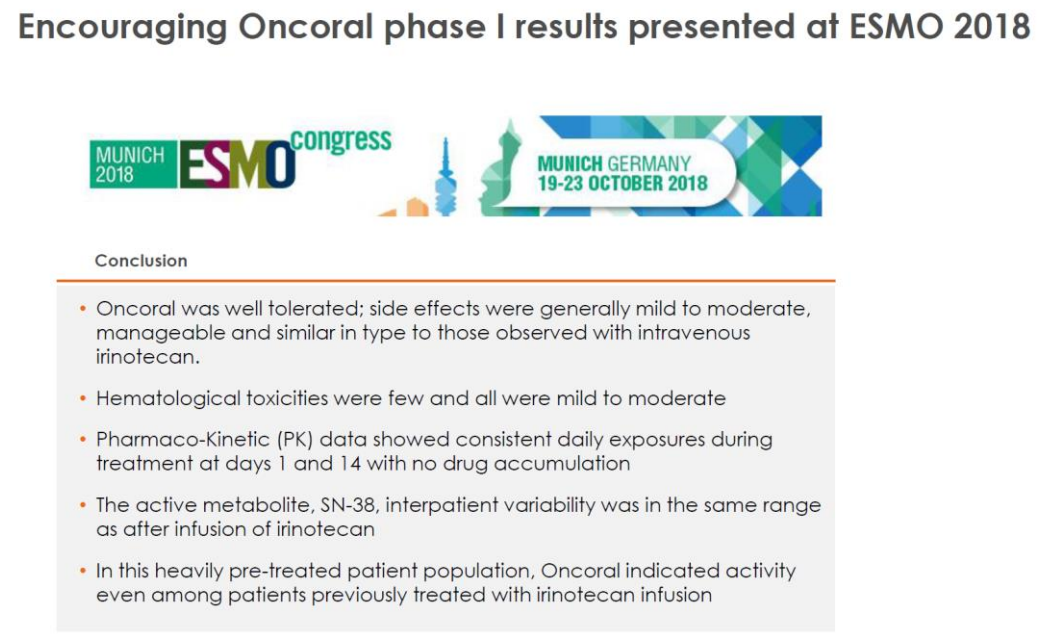
The main use for intravenous irinotecan is metastatic colorectal cancer, particularly in combination with other chemotherapeutic agents, while the target indication for tablet Oncoral will be for combination use in the treatment of non-resectable and metastatic gastric cancer, i.e. an advanced stage of the disease. In this setting, chemotherapy remains standard therapy.

In Japan, intravenous irinotecan is approved for the treatment of metastatic gastric cancer, while the product is included in various clinical guidelines in Europe and the US in this setting.

Phase 1 results for Oncoral was presented at the ESMO annual congress in Germany in October 2018. The poster included data from the first part of the study where Oncoral

was administered as a single agent. 25 patients with a median age of 67 were included across four cohorts, and the majority of patients had cholangiocarcinoma, colon, pancreas or prostate as a primary cancer.

CHART 13: Summary of Oncoral's first phase 1 presentation



Source: Company information

The first patient was enrolled in July 2015 in the single agent part of the trial.

Results in combination part of the trial was published in April 2019

In the second part of the study, Oncoral was administered in combination with capecitabine (brand name Xeloda, marketed by Roche). This part of the study was initiated in June 2017 and results were published in April 2019.

The objectives of the first part of the phase 1 study included to determine the safety, tolerability and maximum tolerated dose of Oncoral given as a single agent and in combination with the oral chemotherapeutic drug capecitabine. Additional objectives include to determine tumor response and disease stabilisation, and to determine the pharmacokinetics properties of oral irinotecan when administered as a single agent. The maximum tolerated dose was established at 21 mg/m2.

Nine of 25 patients in the first part of the phase 1 trial achieved disease stabilisation

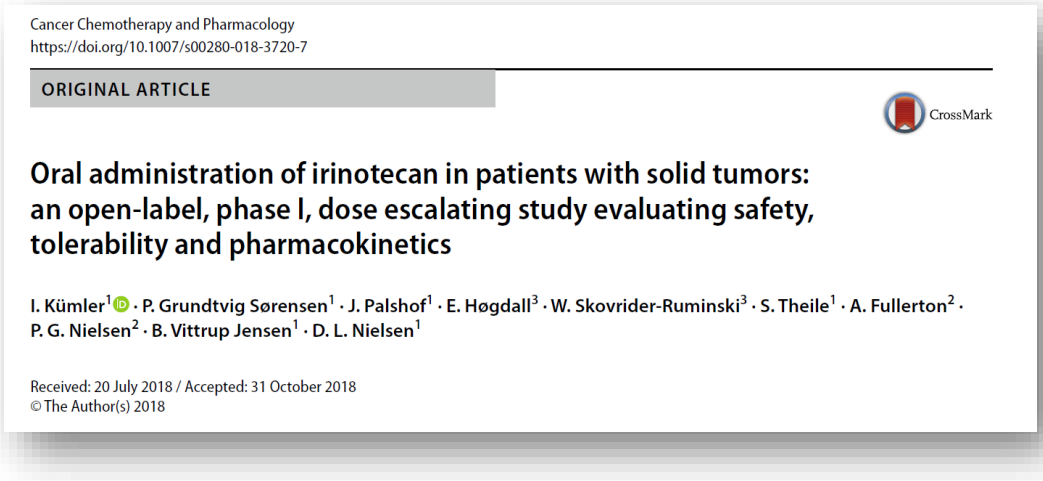
One initial conclusion from the phase 1 trial was that nine of the participating 25 patients achieved disease stabilisation for a median period of 19 weeks, with a range between 7-45 weeks. Of those nine patients, five had previously been treated with intravenous irinotecan. Again, this part of the trial did not include any combination use with capecitabine.

In the combination trial the maximum tolerated dose was 17.5 mg/m2 once daily for 14 consecutive days in combination with capecitabine 800 mg/m2 twice daily. Eligible patients were adults with metastatic or unresectable solid tumors for which no standard curative or palliative therapies existed.

Five of 14 patients in the extension part of the phase 1 trial achieved disease stabilisation

14 patients were included in the extension part. No grade 3 or 4 hematologic toxicities were observed. No objective responses were observed, however five patients had stable disease lasting median 14 weeks with the conclusion that oral capecitabine in combination with oral irinotecan could be a new treatment option offering a more convenient and patient friendly treatment strategy compared to intravenous irinotecan, however further investigations are needed to assess the efficacy of this regimen.

CHART 14: Oncoral study publication



Cancer Chemotherapy and Pharmacology
https://doi.org/10.1007/s00280-018-3720-7

ORIGINAL ARTICLE

CrossMark

Oral administration of irinotecan in patients with solid tumors: an open-label, phase I, dose escalating study evaluating safety, tolerability and pharmacokinetics

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The plan is then to include the first patient into the following phase 2 trial towards late 2019 or beginning of 2020, with patient inclusion continuing for around a year, through 2020, and study results becoming available towards late 2021.

The idea is to study Oncoral in combination with capecitabine (Roche's Xeloda) and a selected targeted anti-cancer agent, in patients that have not previously been treated with irinotecan, that are HER2 negative, and with locally advanced or metastatic gastric cancer patients.

The phase 2 study plan involves a dose-escalation part with Oncoral, capecitabine and the selected targeted agent in order to determine safety and tolerability, and define the doses for the extension part of the phase 2 study.

Oncoral may receive orphan drug designation, beyond existing formulation patents

According to Ascelia Pharma, Oncoral may receive orphan drug designation, beyond existing formulation patents. If such designation and approval would be granted, data and marketing exclusivity would protect the product from competition for 7-10 years after launch, unless another irinotecan-based product with superior results in a head-to-head study versus Oncoral would be developed.

Oncoral's target, gastric cancer, is affecting around 237,000 people per year in the US, the five biggest countries in Europe, and Japan combined, and is the sixth most prevalent cancer type in the world. The five-year survival of gastric cancer is said to be around 20%.

Gastric cancer is a market currently worth around USD 2bn. However, it is expected to grow to around USD 4bn by 2022E according to the company's sources, driven by increased use of checkpoint inhibitors, angiogenesis inhibitors, and HER-2 targeted therapies. Apart from the increased number of patients, improved survival times are naturally another driver of market growth, as well as an expected increase in treatment rates.

By brand, Lilly's Cyramza is expected to be the biggest product within gastric cancer treatment with USD 1.5bn sales by 2022E, followed by Roche's Perjeta at USD 700m. The use of checkpoint inhibitors such as Merck's Keytruda and Bristol Myers Squibb's Opdivo is expected to account for around USD 600m sales by 2022E in this setting, and various generic chemotherapies for around USD 500m.

Cyramza (ramicirumab) is approved for the treatment of non-small cell lung cancer, colorectal cancer, and advanced stomach or esophageal cancer, and is used for patients whose cancer has progressed on or after being treated with other initial types of chemotherapy.

In December 2017, Lilly announced that Cyramza has hit its primary endpoint showing extended progression-free survival in patients with advanced gastric cancer, but the drug failed to improve the secondary endpoint of overall survival. Cyramza was given in combination with cisplatin and capecitabine or 5-FU (5-fluorouracil) in the first-line treatment of patients with HER2-negative metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma.

There have been no major advances over standard chemotherapy in the first-line HER2-negative gastric cancer treatment setting in the last decade. The market leader Cyramza is used as a second-line treatment for advanced gastric cancer patients, but Lilly said it would not pursue approval in the first-line setting.

A specific challenge with the substance irinotecan is that it is a pro-drug which is enzymatically converted to the biologically active metabolite SN-38. Whereas irinotecan is water soluble, SN-38 is practically insoluble in water. Following metabolism in the liver, SN-38 is converted to the water-soluble but inactive metabolite SN-38G. SN-38 is 100–1,000 times more potent than irinotecan, but the fraction of irinotecan actually converted to active SN-38 is small and exhibits a very large inter-patient variability. Due to severe side effects, this problem is not readily solved by increasing the dose of irinotecan.

Oral bioavailability for both irinotecan and SN-38 has differed substantially among patients in various studies with novel irinotecan formulations. Despite evidence of efficacy, none of the previously tested oral irinotecan formulations have gone into phase II trials, mainly because of problems concerning poor solubility and a substantial interpatient variability in oral bioavailability.

The overlaps between Mangoral and Oncoral may seem limited, however both products could be promoted by niche sales forces, Mangoral in most regions and Oncoral at least in selected regions. The competitive landscape could change more for Oncoral compared with Mangoral, we believe, both since Oncoral is at an earlier stage of development, and also that there is a fair amount of clinical trials ongoing across

various stages of gastric cancer, so the perceived standard of care that Oncoral is targeting may well change during the course of clinical trial development.

Significant deals signed with a novel injectable formulation of irinotecan

Ascelia Pharma sees the development of Onivyde, a novel injectable formulation of irinotecan, as a benchmark development for Oncoral.

Onivyde reported positive phase 3 trial results in a 417-patient second-line pancreatic cancer study in May 2014. In September 2014, it announced a deal with Baxalta for ex-US marketing rights. The deal included a USD 100m up-front payment and potential further payments of USD 870m.

The product subsequently achieved marketing approvals in the US in September 2015 and in Europe in September 2016.

In January 2017, Ipsen acquired US rights for the product, an acquisition that included a USD 575m up-front payment, USD 450m in potential milestone payments, and a partnership with Baxalta.

Onivyde was developed by Merrimack which in total received USD 675m payments for the product.

Onivyde received priority review status by the FDA based on the phase 3 study where those who received the Onivyde-5-FU (fluorouracil and leucovorin) combination lived an average of 6.1 months, compared to 4.2 months for those who received 5-FU only. Patients who received the Onivyde-5-FU combination also had a longer time (3.1 months) before their tumors began growing than those who received 5-FU only (1.5 months).

Risk assessment

Before Mangoral, Oncoral, and potentially other products from Ascelia Pharma can be introduced on the market, sufficient tolerability and efficacy studies must be established through adequate and well controlled clinical trials. Clinical studies are costly and time consuming, and the timing may be difficult to predict due to slower than expected patient enrolment.

Also, the clinical characteristics of participating patients may be different compared with the hypothesis of the trial, since standard of care for a disease may have changed.

Results from pre-clinical safety studies are available before the onset of clinical trials, however results from longer term pre-clinical safety trials are typically not available until after the onset of clinical trials. Results from such longer pre-clinical safety studies may not always correspond to the results that are obtained from shorter trials.

There is a risk that the comparison imaging procedure in the pivotal phase 3 trial with Mangoral, MRI without a contrast enhancing agent, turns out to be better than hypothesized, which would make it more difficult to demonstrate superiority with statistical significant in terms of detection of focal liver lesions.

In order to market and sell drugs or imaging products, registration and approval must be obtained from relevant regulatory authorities in respective markets, for example from the FDA regarding sale in the US market. Current rules and interpretations of clinical trials may also change, which could impact the company's possibilities to meet regulatory requirements.

While designing and executing on a phase 3 program may be viewed as a straightforward process, the path to commercial success may be viewed as a more risky and unpredictable process.

Also, price acceptance among payers for a product such as Mangoral that adds to liver MRI procedure costs may also be different in the marketplace compared with the indications that the company has received through pre-market interviews.

As with drug treatments, imaging products are usually financed by public or private reimbursement systems, and Mangoral's potential product offer, the improved detection of focal liver lesions, may not be sufficient for achieving payers' acceptance of an attractive price.

Also, in the US, the commercial acceptance is dependent on the granting of a specific reimbursement code. With such a code, the reimbursement level is set based on the insurance status of the patient. Without such a code, the hospital needs to find alternative ways to cover the cost for the product, or the patient may need to pay for the imaging product.

The sales force presence in key markets may also be inadequate to achieve a sufficient level of awareness of Mangoral prescribers. Since the product targets a niche population, people undergoing liver MRI with severely impaired kidney function, prescribing radiologists must learn to remember a new procedure in a population that is fairly small.

In Europe, the recommendation for approval by the regulator is typically followed by the final approval from the European Commission two or three months after the recommendation for approval. After that, national approvals and reimbursement must be obtained in each country, which typically is a process requiring a few months in major countries such as Germany and the UK, and a process requiring more than a year in countries such as France and Italy.

Ascelia Pharma is a small, development-stage, company preparing for its first pivotal phase 3 trial and its first build-up of a commercial sales and support organization. During the years ahead, Ascelia will depend on attracting and keeping key personnel for executing on clinical trial programs, regulatory procedures, reimbursement issues, launch activities and important sales force support functions.

Apart from funding the regulatory phase 3 program with Mangoral and the phase 2 program Oncoral, Ascelia Pharma may decide to launch other clinical trials, particularly with Mangoral, to support the commercial uptake of the product.

For example, line extension trials with Mangoral could be focused on comparing the clinical treatment decision without and with contrast enhanced liver MRI, i.e. how Mangoral would change the planned treatment decision. If, for example, the improved detection of liver lesions would lead to that a significant number of patients in a clinical trial would be treated differently, the likelihood to prescribe Mangoral could increase.

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.

Dorthe da Graça Thrige, COO.

Extensive experience in R&D and executive management from positions at leading Swedish and Danish biotech and pharma companies. Ph.D. in Structural Medicinal Chemistry from University of Copenhagen, M.Sc. in Pharmacy from University of Copenhagen and studies in Business Administration and Management at Lund University.

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.

Managing Partner at 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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I, Lars Hevreng, the author of this report, certify that notwithstanding the existence of any such potential conflicts of interests referred to below, the views expressed in this report accurately reflect my personal view about the companies and securities covered in this report.

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