*Initiation*

**BUY**

**3 September 2020**

# Oasmia Pharmaceutical AB

## Highly Apeal-ing

| | |
|---|---|
| Price | SEK 4.71 |
| Fair value | SEK 9 |
| Market capitalisation | SEK 1,997 million |
| Enterprise value | SEK 1,706 million |
| 12m high/low | SEK 11.45 / SEK 2.27 |
| Avg. daily volume | 11.9m |
| Bloomberg / Reuters | OASM SS / OASM.ST |
| Exchange | Stockholm |
| Adviser | Yes |
| Next results (Q1) | 9 September 2020 |

Top 5 Shareholders

| | |
|---|---|
| *Per Arwidsson* | *24.8%* |
| *Avanza Pension* | *7.0%* |
| *Mastan AB (Håkan Lagerberg)* | *1.8%* |
| *Swedbank Insurance* | *1.4%* |
| *Nordnet Pension Insurance* | *1.3%* |


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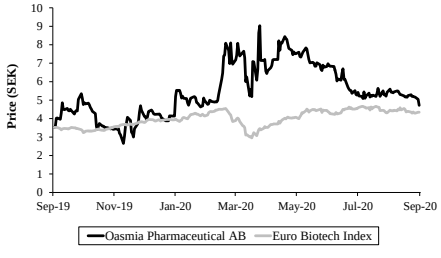
**Share price performance (1 year)**




Source: $R_x$ Securities

**Oasmia Pharmaceutical's key value driver Apealea® is an enhanced, patented formulation of paclitaxel that is approved in Europe for the treatment of advanced, first relapse, platinum-sensitive ovarian cancer. A higher dose of Apealea® can be infused quicker, does not require premedication to prevent sensitivity reactions, and is equally efficacious as standard paclitaxel. A licensing deal for Apealea® was signed with Elevar Therapeutics in March 2020, which we consider strong validation of the commercial opportunity. We forecast peak sales for Apealea® in ovarian cancer in the US and Europe of ~$275 million, but believe there is significant upside through possible geographic and label expansions (we believe it could become a "go-to" chemotherapy partner in immuno-oncology combination regimens). Oasmia's proprietary XR17™ platform, from which Apealea® is derived, has also yielded a novel formulation of docetaxel, which is set to start a Phase Ib trial in prostate cancer in Q1 2021 and could be an attractive licensing opportunity in our view. We believe XR17™ could also generate other valuable product candidates in the years to come. We anticipate several near-term catalysts for Oasmia's shares, including a sub-licensing deal for Apealea® in Europe and an NDA filing. Oasmia is well-financed, with a cash runway exceeding two years on our estimates. We initiate coverage with a BUY rating and fair value of SEK 9/share. In our view, the current valuation is underpinned by Apealea®, which accounts for half of our fair value.**

- **A major deal with Elevar Therapeutics for global rights to Apealea®** – excluding certain countries including the Nordics, where Oasmia is self-commercialising. Oasmia received an upfront payment of $20 million and is eligible for up to $678 million in development, regulatory and sales milestones, plus double-digit percentage royalties on Elevar's sales of the drug. We would expect a significant milestone upon US approval.

- **Docetaxel micellar could attract a substantial licensing deal in our view** – Oasmia has formed a partnership with a Swiss research group to initiate a Phase Ib trial in metastatic castration-resistant prostate cancer (where standard docetaxel is a mainstay treatment), in Q1 2021. We estimate the market opportunity of this indication at $1.5 billion, and with positive clinical data, we believe the drug could be the subject of a significant licensing deal.

**Key financial data (MSEK) – IFRS**

| Y/E 30 Apr | 2020A | 2021E | 2022E | 2023E | 2024E |
|---|---|---|---|---|---|
| Revenue | 201.8 | 2.5 | 26.6 | 81.4 | 170.9 |
| EBITDA | (10.1) | (158.6) | (73.7) | (22.2) | 64.0 |
| Net Income | (10.5) | (193.3) | (109.3) | (58.7) | 26.6 |
| EPS (SEK) | (0.0) | (0.4) | (0.2) | (0.1) | 0.1 |
| Net Cash | 355.1 | 145.2 | 18.5 | (58.6) | (51.3) |

Source: $R_X$ Securities estimates

| Consensus | 2021E | 2022E | 2023E | 2024E |
|---|---|---|---|---|
| Revenue | NA | NA | NA | NA |
| Net Income | NA | NA | NA | NA |

Source: Bloomberg

# *Contents*

# Company Description

Oasmia Pharmaceutical AB was founded in 1999 with the mission of improving existing cancer drugs, either through enhanced safety or efficacy. The Company is based in Uppsala, Sweden, and today employs 54 people. Oasmia is in the process of transitioning from a clinical-stage biotechnology company into a commercial-stage business with the launch of its first drug, and key value driver, Apealea®, a novel formulation of paclitaxel. We believe Apealea® has significant advantages over the standard formulation of paclitaxel. Notably, a higher dose can be infused over a shorter timeframe with a lower risk of hypersensitivity reactions, with no compromise on efficacy. In 2018, Apealea® was approved in Europe in combination with carboplatin for the treatment of advanced, relapsed, platinum-sensitive ovarian cancer. In March 2020, Oasmia signed a major deal with Elevar Therapeutics for global rights to Apealea® (excluding the Nordic countries where Oasmia retains rights), which included an upfront payment of $20 million, eligibility for up to $678 million in milestones, plus royalties on sales. We expect Oasmia to launch Apealea® in the Nordic countries during H2 pending normalisation of hospital operations in the wake of the COVID-19 pandemic. We expect Elevar to sub-license the drug in the rest of Europe and file an NDA this year for approval in the US. Apealea® is a product of Oasmia's proprietary XR17™ platform, which improves the water solubility of active pharmaceutical ingredients (APIs). This platform has broad utility (although Oasmia's current focus is oncology therapeutics) to generate a pipeline of low-risk (APIs are already validated), high-value (products are novel and patent-protected) drugs. XR17™ has broad intellectual protection globally out to 2036, with 66 patents granted to date. The platform has yielded a second drug candidate, docetaxel micellar, which we expect to start a Phase Ib trial in prostate cancer in Q1 2021. Furthermore, a novel chemotherapy combination (two APIs in one drug delivery vehicle) utilising the platform is being explored in the XR19 programme, which is currently at a preclinical stage. The Company also has a GMP manufacturing facility in Uppsala for the production of drug product for clinical trials. Oasmia has a veterinary subsidiary, AdvaVet, which is developing cancer therapeutics for dogs, although the Company plans to out-license or divest this business. Oasmia completed its IPO on the Nordic Growth Market in 2005, and today its shares are listed on Nasdaq Stockholm. The Company has raised nearly SEK 1 billion in secondary fundraises since IPO, most recently in December 2019 (SEK 399 million at SEK 2.0/share).

# Investment Positives

**Apealea® approved in Europe, and an NDA could be filed soon in the US**

Apealea® is approved in Europe for use in combination with carboplatin for the treatment of advanced, first relapse, platinum-sensitive ovarian cancer. The prescribing label does not mandate premedication with steroids (to prevent hypersensitivity reactions), an important advantage to standard paclitaxel in our view. Oasmia plans to directly market the drug in the Nordic countries while we expect the Company's partner Elevar Therapeutics to secure a sub-licensing deal (potentially before the end of the year) to facilitate launches in the rest of Europe, which we anticipate in H1 2021. In the US, Elevar is making preparations to file an NDA, which we believe could occur by the end of the year and lead to approval in H2 2021. We forecast peak sales of Apealea® of $275 million in first relapse, platinum-sensitive ovarian cancer in the US and Europe. However, we believe a higher sales potential is possible through geographic (e.g. Asia) and label expansion (e.g. for other cancer types).

**Elevar and Abraxane® provides validation of the commercial opportunity**

In March 2020, Oasmia signed a deal with Elevar Therapeutics for global rights (excluding certain territories) to Apealea®. As part of this deal, which we believe validates the commercial opportunity, Oasmia received $20 million upfront and is eligible for up to $678 million in development, regulatory and sales milestones, plus double-digit percentage royalties on Elevar's sales of the drug. Historically, reformulation of existing marketed drugs using novel patented technologies has been a commercially successful drug development strategy. There are several reformulation examples in the oncology field that add further validation of the commercial opportunity. These include Johnson & Johnson's Doxil®/Caelylyx® (liposomal doxorubicin, achieved peak sales of over $600 million in 2010 before going generic), Bristol-Myers Squibb's Abraxane® (albumin-bound paclitaxel, ~$1.6 billion sales in 2019) and Ipsen's Onivyde® (liposomal irinotecan, ~$233 million sales in 2019).

**Docetaxel micellar could attract a major licensing deal**

Docetaxel micellar is Oasmia's second XR17™-generated product candidate. Results from previous Phase I and Phase II trials suggest this drug could have consistent efficacy with the standard formulation of docetaxel, but with a superior safety profile (not requiring corticosteroid premedication). A Phase Ib trial in advanced prostate cancer (where standard docetaxel is approved) is slated to start in Q1 2021. In terms of addressable patients, this indication is nearly double the size of Apealea®'s in ovarian cancer, representing a market opportunity of ~$1.5 billion by our calculations. Oasmia could also develop docetaxel micellar in other indications where standard docetaxel is approved (breast, stomach, head and neck and non-small cell lung cancers). We believe the commercial opportunity for docetaxel micellar is substantial, and that with positive clinical data, the drug could be the subject of a major licensing deal.

**A potential "go-to" partner for immuno-oncology drug developers**

Over the last decade, the treatment of cancer has been revolutionised with the advent of immuno-oncology (IO), led by the approvals of the PD-1 inhibitor class of drugs including Merck's Keytruda® and Bristol-Myers Squibb's Opdivo®, both of which are now multi-blockbuster drugs. An exciting prospect that is being explored by many developers is combining these new IO agents with chemotherapies or targeted drugs (of 2,975 active trials of PD-1/PD-L1 inhibitors in 2019, 76% were combination studies). However, in the case of some chemotherapies, concomitant administration of corticosteroids is required to manage side effects, with paclitaxel and docetaxel being prime examples. Corticosteroids reduce the level of immune cells circulating around tumours, which are necessary for the activity of IO agents. Concomitant administration of corticosteroids has been shown to dampen the effects of PD-1 inhibitors both in preclinical experiments and in clinical trials. We, therefore, believe that there is an exciting opportunity for Oasmia to become a partner of choice for developers of IO agents, as its novel chemotherapy formulations do not require premedication with corticosteroids.

**Robust financial position and trading below our fair value of SEK 9/share**

Oasmia had cash and cash equivalents of SEK 436 million as at 30 April 2020, and we project a cash runway into H1 F2023. We forecast a growing income stream from Apealea® in the coming years and would highlight that the Company is eligible for significant milestones under its deal with Elevar (conservatively excluded from our forecasts). We believe Oasmia is in a strong position to progress its early-stage pipeline programmes and could even in-license or acquire additional developmental or marketed drugs. Furthermore, the Company is trading below our fair value of SEK 9/share, a ~91% upside to the current share price.

# Investment Risks

**Apealea® still needs to gain approval in the important US market**

Elevar held a pre-NDA meeting with the FDA on 30 April 2020 and based on this discussion, the company is making preparations to file an NDA (we believe this could occur this year). While this is a positive development (the FDA could have signalled a requirement for a further study during this meeting), it does not guarantee that the FDA would approve the drug on its existing data package. Indeed, despite the positive Phase III results generated already, there is a risk that the FDA could request further data, potentially even a new clinical trial. Any developments causing delays to US approval would likely have a negative impact on Oasmia's share price.

**Our forecasts for Apealea® may not be achieved**

We forecast peak sales of Apealea® of $275 million in advanced, relapsed, platinum-sensitive ovarian cancer in the US and Europe. We believe we have used conservative assumptions. For example, we assume only a modest proportion of oncologists already prescribing carboplatin plus paclitaxel would "swap in" Apealea® for the standard formulation. Where information is not already available, we assume a price in-line with Abraxane® (Bristol-Myers Squibb's blockbuster albumin-bound paclitaxel, which we believe validates the case for premium pricing of superior formulations of old APIs). However, the rate of switching to Apealea® could be lower than we expect and/or prescribing habits could change in the future due to competitive drugs/regimens (though we believe there is no near term competitive threat), which could ultimately lead to lower peak sales of Apealea® than we have forecast.

**Elevar is yet to sign a sub-licensing deal for Apealea® in Europe**

Oasmia's partner Elevar is currently seeking partners to commercialise Apealea® in Europe. With approval already secured for advanced, first relapse, platinum-sensitive ovarian cancer, we believe a sub-licensing deal for Apealea® could represent an attractive opportunity for a company with an established European commercial organisation. We understand that there has been interest from multiple parties. However, we would highlight three key risks: (1) the timeline to a deal could be longer than we expect (particularly with the ongoing COVID-19 pandemic); (2) a potential partner's capabilities and performance could fall below our expectations; or (3) a deal may not be signed, necessitating a change in strategy (unlikely in our view).

**Oasmia's pipeline programmes could fail**

In Q1 2021 Oasmia plans to initiate a Phase Ib trial of docetaxel micellar in advanced prostate cancer. In a Phase II trial in breast cancer, docetaxel micellar showed efficacy and signals of a superior safety profile (without premedication) vs standard docetaxel. However, this trial missed its overall response rate primary endpoint (achieved in a subgroup), showing that even for reformulations of approved drugs, there is some development risk. In addition, the XR19 programme is still early, and it is unclear if this concept will yield a drug candidate for clinical trials.

**Settlement of ongoing litigation could reduce financial resources**

MGC Capital has filed lawsuits against Oasmia relating to the settlement of a promissory note (claiming SEK 80 million) and warrants it alleges Oasmia did not grant (claiming SEK 230 million). Initial procedural objections have been tried but not conclusively adjudicated, and a final court date has yet to be set (we anticipate 2021). While Oasmia claims that these lawsuits are without merit, there is a risk that a court rules against the Company and that settlement for all or a significant proportion of the claimed damages must be made, which could substantially reduce financial resources.

# Financials (yearly)

**Table 1: Earnings Outlook – Annual Forecast Profit and Loss Statement (MSEK)**

| Y/E 30 April | 2020A | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E |
|---|---|---|---|---|---|---|---|---|
| **Revenue** | **201.8** | **2.5** | **26.6** | **81.4** | **170.9** | **272.5** | **357.2** | **402.2** |
| Apealea® sales | - | 2.1 | 6.2 | 14.3 | 22.0 | 27.0 | 30.2 | 32.3 |
| Apealea® royalties | 0.3 | - | 20.0 | 66.7 | 148.5 | 245.1 | 326.6 | 369.5 |
| Milestones | 201.1 | - | - | - | - | - | - | - |
| Other | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| Cost of sales* | 20.9 | (0.1) | (0.3) | (0.7) | (1.1) | (1.4) | (1.5) | (1.6) |
| **Gross Profit** | **222.7** | **2.4** | **26.3** | **80.7** | **169.8** | **271.2** | **355.7** | **400.6** |
| **Operating Costs** | **(253.3)** | **(189.0)** | **(128.8)** | **(132.6)** | **(136.4)** | **(140.4)** | **(144.5)** | **(148.7)** |
| Raw material costs | (11.3) | (4.0) | (4.0) | (4.0) | (4.0) | (4.0) | (4.0) | (4.0) |
| Other ext. expenses** | (158.2) | (110.0) | (60.0) | (61.8) | (63.7) | (65.6) | (67.5) | (69.6) |
| Employee expenses | (63.8) | (47.0) | (36.0) | (37.1) | (38.2) | (39.3) | (40.5) | (41.7) |
| D&A and impairment | (20.0) | (28.0) | (28.8) | (29.7) | (30.6) | (31.5) | (32.5) | (33.4) |
| Other operat. income | 0.4 | - | - | - | - | - | - | - |
| **Operating Profit** | **(30.1)** | **(186.6)** | **(102.6)** | **(51.9)** | **33.4** | **130.8** | **211.2** | **251.9** |
| **EBITDA** | **(10.1)** | **(158.6)** | **(73.7)** | **(22.2)** | **64.0** | **162.3** | **243.6** | **285.3** |
| Net Financial Income | (13.3) | (6.7) | (6.7) | (6.7) | (6.7) | (6.7) | (6.7) | (6.7) |
| **Profit Before Tax** | **(43.4)** | **(193.3)** | **(109.3)** | **(58.7)** | **26.6** | **124.0** | **204.4** | **245.1** |
| Tax | 32.8 | - | - | - | - | - | - | - |
| **Net Income** | **(10.5)** | **(193.3)** | **(109.3)** | **(58.7)** | **26.6** | **124.0** | **204.4** | **245.1** |
| **EPS (SEK)** | **(0.0)** | **(0.4)** | **(0.2)** | **(0.1)** | **0.1** | **0.3** | **0.5** | **0.5** |
| No. of Shares (m) | 398.4 | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 |
| **Gross cash** | **435.1** | **225.2** | **98.5** | **21.4** | **28.7** | **132.5** | **315.6** | **538.3** |
| **Debt** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** |
| **Net cash** | **355.1** | **145.2** | **18.5** | **(58.6)** | **(51.3)** | **52.5** | **235.6** | **458.3** |

Source: Company data, Rx Securities estimates; *includes changes in inventories (MSEK 20.9 in 2020); ** includes capitalised development costs (MSEK 4.4 in 2020); debt of MSEK 80 is in dispute (see page 5)

## Key Model Assumptions

- Following a strategic review (outcome announced May 2020) Oasmia is implementing a cost-control programme that it expects to produce annual cost savings of SEK 100 million by the end of F2022;
- We assume first royalties from Apealea® sales in other European countries in F2022 and the US in Q4 F2022;
- We assume Oasmia earns royalties on partner sales of 15% and conservatively exclude potential milestone income; and
- We assume that Oasmia may need to raise additional capital to fund operations from H1 F2023, though for simplicity our forecasts use a debt-based model.

# Financials (quarterly)

**Table 2: Earnings Outlook – Quarterly Forecast Profit and Loss Statement (MSEK)**

| Y/E 30 April | Q1 21E | Q2 21E | Q3 21E | Q4 21E | 2021E | Q1 22E | Q2 22E | Q3 22E | Q4 22E | 2022E |
|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue** | **0.1** | **0.6** | **0.8** | **1.0** | **2.5** | **3.2** | **4.5** | **5.8** | **13.1** | **26.6** |
| Apealea® sales | - | 0.5 | 0.7 | 0.9 | 2.1 | 1.1 | 1.4 | 1.7 | 2.0 | 6.2 |
| Apealea® royalties | - | - | - | - | - | 2.0 | 3.0 | 4.0 | 11.0 | 20.0 |
| Milestones | - | - | - | - | - | - | - | - | - | - |
| Other | 0.1 | 0.1 | 0.1 | 0.1 | 0.4 | 0.1 | 0.1 | 0.1 | 0.1 | 0.4 |
| Cost of sales | - | (0.0) | (0.0) | (0.0) | (0.1) | (0.1) | (0.1) | (0.1) | (0.1) | (0.3) |
| **Gross Profit** | **0.1** | **0.6** | **0.8** | **1.0** | **2.4** | **3.1** | **4.4** | **5.7** | **13.0** | **26.3** |
| **Operating Costs** | **(58.0)** | **(51.0)** | **(43.0)** | **(37.0)** | **(189.0)** | **(32.2)** | **(32.2)** | **(32.2)** | **(32.2)** | **(128.8)** |
| Raw material costs | (1.0) | (1.0) | (1.0) | (1.0) | (4.0) | (1.0) | (1.0) | (1.0) | (1.0) | (4.0) |
| Other ext. expenses | (35.0) | (30.0) | (25.0) | (20.0) | (110.0) | (15.0) | (15.0) | (15.0) | (15.0) | (60.0) |
| Employee expenses | (15.0) | (13.0) | (10.0) | (9.0) | (47.0) | (9.0) | (9.0) | (9.0) | (9.0) | (36.0) |
| D&A and impairment | (7.0) | (7.0) | (7.0) | (7.0) | (28.0) | (7.2) | (7.2) | (7.2) | (7.2) | (28.8) |
| Other operat. income | - | - | - | - | - | - | - | - | - | - |
| **Operating Profit** | **(57.9)** | **(50.4)** | **(42.2)** | **(36.0)** | **(186.6)** | **(29.1)** | **(27.8)** | **(26.5)** | **(19.2)** | **(102.6)** |
| **EBITDA** | **(50.9)** | **(43.4)** | **(35.2)** | **(29.0)** | **(158.6)** | **(21.9)** | **(20.6)** | **(19.3)** | **(12.0)** | **(73.7)** |
| Net Financial Income | (1.7) | (1.7) | (1.7) | (1.7) | (6.7) | (1.7) | (1.7) | (1.7) | (1.7) | (6.7) |
| **Profit Before Tax** | **(59.6)** | **(52.1)** | **(43.9)** | **(37.7)** | **(193.3)** | **(30.7)** | **(29.5)** | **(28.2)** | **(20.9)** | **(109.3)** |
| Tax | - | - | - | - | - | - | - | - | - | - |
| **Net Income** | **(59.6)** | **(52.1)** | **(43.9)** | **(37.7)** | **(193.3)** | **(30.7)** | **(29.5)** | **(28.2)** | **(20.9)** | **(109.3)** |
| **EPS (SEK)** | **(0.1)** | **(0.1)** | **(0.1)** | **(0.1)** | **(0.4)** | **(0.1)** | **(0.1)** | **(0.1)** | **(0.0)** | **(0.2)** |
| No. of Shares (m) | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 | 448.4 |
| **Gross cash** | **371.4** | **315.1** | **267.1** | **225.2** | **225.2** | **190.1** | **156.3** | **123.7** | **98.5** | **98.5** |
| **Debt** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** | **80.0** |
| **Net cash** | **291.4** | **235.1** | **187.1** | **145.2** | **145.2** | **110.1** | **76.3** | **43.7** | **18.5** | **18.5** |

Source: Company data, Rx Securities estimates

# Forecast News Flow

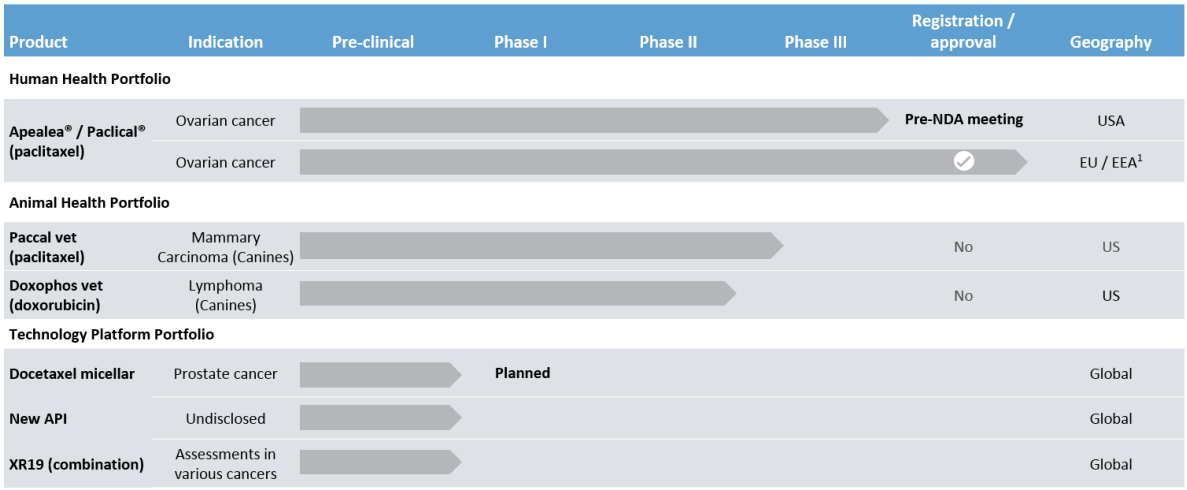
**Table 3: Oasmia Pharmaceutical's forecast news flow**

| Timing (calendar year) | Expected News | Programme |
|---|---|---|
| H2 2020 | Launch in the Nordics | Apealea® |
| H2 2020 | Potential NDA filing | Apealea® |
| H2 2020 | Potential sub-licensing deal for European commercialisation | Apealea® |
| 9 September 2020 | Q1 results (financial year ending 30 April 2021) | |
| 9 September 2020 | AGM | |
| 9 December 2020 | Q2 results (financial year ending 30 April 2021) | |
| H2 2020–2021 | Potential transaction regarding AdvaVet business or its key drugs | |
| Q1 2021 | Start of Phase Ib study | Docetaxel micellar |
| H1 2021 | Potential launch in Europe (ex-Nordics) | Apealea® |
| H2 2021 | Potential US approval | Apealea® |

Source: Company data, Rx Securities estimates

# Pipeline Summary

**Figure 1: Oasmia Pharmaceutical's pipeline**




Source: Oasmia Pharmaceutical

# Board and Management

**Table 4: Key members of the Board and Management**

| Name | Executive History |
|---|---|
| **Francois Martelet**<br>*Chief Executive Officer* | Francois Martelet assumed the role of CEO of Oasmia in March 2020. Francois is an experienced Pharma executive with a proven track record of shaping companies and turning around underperforming units. He has held three CEO positions in the last 12 years. Francois has spent most of his career in the oncology field, as CEO of Avax (2007–2009) and Topotarget (2010–2012), as well as in executive roles at senior level at Roche, Eli Lilly, Novartis and MSD. Most recently he served as CEO of NetScientific Group plc (2015–2019), a healthcare-focused IP commercialisation group. Francois is currently serving as a Non-Executive Director of Novigenix SA and is a member (as well as a former board member and Vice President) of European Biopharmaceutical Enterprises. He has been based in six countries in Europe (including Sweden) and in the US. Francois is a Medical Doctor by training and also holds a Master's Degree in Business. He speaks four languages, among them Swedish. |
| **Michael af Winklerfelt***<br>*Chief Financial Officer* | Michael af Winklerfelt has served as CFO of Oasmia since November 2019. Michael has more than 15 years of experience from senior finance roles in leading international companies. Most recently he was Managing Director of Archipelago Enterprises (2015–2018), a Boutique Venture Capital firm based in London. During his time at Archipelago, he worked with an Atlanta (US) based medical devices start-up company, which was successfully sold in 2018 to a leading orthopaedics company. Before this, he was Financial Controller at TitanX Engine Cooling (2014–2015), and he also worked for ten years in China for the Atlas Copco Group in different roles including as a Business Controller and Financial Controller. He has an MBA from Emory University Goizueta Business School, an MSc in Economics and Business from the Stockholm School of Economics and a BA in Chinese studies from Stockholm University. |
| **Elin Trampe**<br>*Chief Technical Officer* | Elin Trampe has served as Oasmia's Chief Technical Officer since June 2020 having previously been Head of Supply Chain and Head of Sourcing and Logistics at the Company. She has many years of experience from various leading positions within Supply Chain, Project Management and Category Development at large international companies. Most recently, she was a Regional Sourcing Leader at General Electric Global Operations, working within the Healthcare business (2016–2018). Before this, she was a Marketing Manager at Jacobs Douwe Egberts (2015–2016) and held different managerial positions at Mondelēz International (2009–2015). Elin has an MSc in Industrial Engineering and Management from Linköping University. |
| **Reinhard Koenig**<br>*Acting Chief Medical Officer,* | Reinhard Koenig joined Oasmia in 2019 as General Manager, US & Canada, and has since been appointed Acting Chief Medical Officer. Reinhard has more than 30 years of pharma and biotechnology experience. His has previously held CEO roles at Eqalix, Inc., Margin Surgical, Inc. and Skinvent Pharmaceuticals, Inc., and was also Chief Medical Officer and Deputy Chief Executive Officer in Piramal Critical Care, Inc. He has also held leadership positions at Genentech and Boehringer Mannheim. Reinhard has an MD and PhD from Philipps University Medical School. |
| **Peter Selin**<br>*Chief Business Officer* | Peter joined Oasmia as Chief Business Officer in August 2020. He has almost 20 years of business development experience, most recently serving as VP Pharma Business Operations at Inceptua Group (2017–2020), the pharmaceuticals company and services provider. During an extensive career including several senior roles, Peter also gained experience in finance and strategic planning as well as contract negotiations and alliance management. He was previously VP Corporate Development and Head of Strategic Sourcing, Biopharmaceuticals at Swedish Orphan Biovitrum (2008–2017) and Manager, Strategy & Transformation at Ernst & Young (2000–2002). |
| **Anders Härfstrand**<br>*Chairman of the Board* | Anders Härfstrand has been Chairman of the Board since May 2020 and a member of the Board since September 2019. He was a Director of Karolinska Development AB from 2017 to 2019 and CEO of BBB Therapeutics BV from 2014 to 2015. Before that, he was President and CEO Europe of Makhteshim Agan Industries Ltd. (now ADAMA); President and CEO of Humabs BioMed SA; and CEO of Nitec Pharma AG (now Horizon Pharmaceuticals). He has also served in various executive roles at Serono, Pfizer and Pharmacia. He has significant operational global experience of the pharmaceutical industry, especially from the US, Japan and Europe. He has an MD and a PhD from Karolinska Institute in Stockholm. |

Source: Oasmia Pharmaceutical; *CFO until 30 November 2020, Oasmia in the process of recruiting a new CFO

# XR17™ – validated drug formulation platform

**XR17™ is validated by Apealea® and could produce many drug candidates**

XR17™ is Oasmia's novel, proprietary drug formulation platform that improves the water solubility of active pharmaceutical ingredients (APIs). This platform is at the heart of the Company's low risk, potentially high reward strategy to take existing approved APIs and create improved formulations that may offer significant advantages to patients. XR17™ has already yielded Apealea®, a novel formulation of paclitaxel approved in Europe that we believe is superior to the standard formulation. Apealea®'s approval and a major global deal for the drug signed with Elevar Therapeutics in March 2020 provide significant validation to Oasmia's XR17™ technology in our view. A second XR17™ candidate, docetaxel micellar, is slated to start a Phase Ib trial in prostate cancer in Q1 2021 and we expect further drug candidates for cancer and other diseases to be produced by the platform in the coming years.

**A drug is composed of the API and excipients which have different functions…**

Almost all approved drugs can be separated into two components: (1) the API, which has proven therapeutic efficacy; and (2) an excipient – a substance or group of substances that act as a "carrier" for the API. There is a multitude of different excipients with different functions in addition to completing the volume of a final drug product. These include absorption enhancers, colouring agents, emulsifiers, extenders, diluents, fillers, flavours, preservatives, wetting agents, solvents and sustained-release matrices. An ideal excipient is one that facilitates an optimal volume, uniformity and dose of the API from manufacturing to the patient.

**…including improving water solubility**

To achieve high absorption into the target tissues, a drug needs to be present in the form of an aqueous solution at the site of absorption. This poses a significant problem in drug development, as approximately 40% of new chemical entities are poorly water-soluble. To circumvent this problem, developers have employed a plethora of different strategies to improve water solubility of APIs (see Table 5).

**Table 5: Approach used to improve API water solubility**

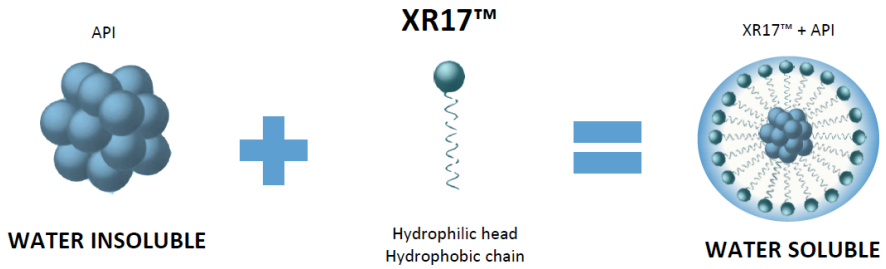
| Approach | Example where employed |
|---|---|
| pH modification and salt forms | Ciprofloxacin (bacterial infections)<br>Gleevec® – imatinib mesylate (CML, ALL, MDS) |
| Co-solvency and surfactants | Paclitaxel (ovarian cancer, breast cancer, NSCLC)<br>Docetaxel (breast cancer, NSCLC, CRPC, gastric cancer, SCCHN) |
| Amorphous forms, solid dispersions and cocrystals | Cefuroxime atexil (bacterial infections)<br>Tacrolimus (prevention of organ transplant rejection) |
| Polymeric micelles | Apealea® – paclitaxel (ovarian cancer) |
| Inclusion complexation (cyclodextrins) | Itraconazole (fungal infections) |
| Nanoparticle technology | Apealea® – paclitaxel (ovarian cancer)<br>Abraxane® – albumin-bound paclitaxel (pancreatic cancer, breast cancer, NSCLC) |
| Solid lipid nanoparticles | None yet marketed |
| Liposomes and proliposomes | Onivyde® – liposomal irinotecan (pancreatic cancer) |
| Microemulsions and self-emulsifying drug delivery systems | Cyclosporine (prevention of organ transplant rejection)<br>Ritonavir (HIV) |

Source: reviewed in Acta Pharmaceutica Sinica B. 2015, 5 (5): 442–453; ALL = acute lymphocytic leukaemia; CML = chronic myeloid leukaemia; CRPC = castration-resistant prostate cancer; MDS = myelodysplastic syndrome; NSCLC = non-small cell lung cancer; SCCHN = squamous cell carcinoma of the head and neck)

**Oasmia's XR17™ platform uses micelle nanoparticles to enhance solubility**

XR17™ is Oasmia's novel, proprietary drug formulation platform that improves the water solubility of APIs. XR17™ is based on a mixture of two derivatives of vitamin A, XMeNa and 13XMeNa. The combination of XR17™ with certain APIs creates "micelle" nanoparticles about 20–60 nanometres (nm) in size (by comparison a DNA strand is 2 nm wide and a red blood cell 7,000 nm). These micelles have a hydrophilic exterior which is soluble in water (see Figure 1). APIs that are poorly soluble in water are enclosed in the micelle core, providing them with water-soluble properties and accordingly allowing their administration into the blood by intravenous (IV) infusion. XR17™ enables a high API-to-carrier ratio and is free of alcohol and substances of animal or human origin, which is desirable as ideally, drug excipients should be as close to inert (inactive, i.e. no adverse effects) as possible.

**Figure 1: Oasmia's XR17™ technology for improving the water solubility of APIs**




Source: Oasmia Pharmaceutical

**Reformulation is a potentially low-risk, high-reward strategy**

XR17™ has been shown to be safe and well-tolerated in multiple clinical trials, and Oasmia is applying this technology to create improved formulations of existing marketed drugs, a low-risk, potentially high-reward drug development strategy which we endorse. The aim is to create new formulations with improved safety profiles (potentially allowing higher dosing), faster administration times (more convenient for patients) and in some cases enhanced efficacy. Historically, reformulation of existing marketed drugs using novel, patented technologies has been a commercially successful drug development strategy. For example, in the oncology field there are multiple liposomal doxorubicin products (including Johnson & Johnson's Doxil®/Caelyx®, peak sales of over $600 million in 2010); Celgene's (now Bristol-Myers Squibb) Abraxane® (albumin-bound paclitaxel, ~$1.6 billion sales in 2019) and Ipsen's Onivyde® (liposomal irinotecan, ~$233 million sales in 2019).

**XR17™ is validated by Apealea®, a safer form of paclitaxel approved in Europe…**

Oasmia's key value driver Apealea® is a novel formulation of paclitaxel generated from the XR17™ platform that has been approved in Europe for the treatment of advanced, relapsed, platinum-sensitive ovarian cancer. We believe this approval provides critical validation of the platform's potential to generate safe and efficacious cancer therapies. Furthermore, we would highlight the major deal for Apealea® signed with Elevar Therapeutics in March 2020 (including a $20 million upfront payment) as further validation of Oasmia's low-risk drug development strategy.

**…and we believe its potential is broader in the oncology space**

Looking beyond Apealea®, we believe Oasmia's XR17™ platform could yield multiple valuable cancer drugs, both improved formulations of known APIs and also of new chemical entities (NCEs). The Company is currently developing docetaxel micellar (slated to start Phase Ib for advanced prostate cancer in Q1 2021), a chemotherapy which is currently used to treat a variety of cancers. In the future, we expect Oasmia to develop novel formulations of other chemotherapies using XR17™. The Company also has an exciting early-stage programme, XR19, in which it aims to use XR17™ technology to develop a combination drug – two "frequently used" chemotherapies in the same micelle delivery vehicle. XR19 could create further incremental improvements in patient care in cancer indications where two-drug chemotherapy regimens are currently used, which include ovarian, breast and lung cancers.

**We believe Oasmia could become a "go-to" partner for IO developers**

Over the last decade, the treatment of cancer has been revolutionised with the advent of immuno-oncology (IO), led by the approvals of the PD-1 inhibitor class of drugs including Merck's Keytruda® and Bristol-Myers Squibb's Opdivo®, both of which are now multi-blockbuster drugs. An exciting prospect that is being explored by many developers is combining these new IO agents with chemotherapies or targeted drugs. Of 2,975 active trials of PD-1/PD-L1 inhibitors in 2019, 76% were combination studies (Nature Reviews Drug Discovery, March 2020, 19: 163-164). However, in the case of some chemotherapies, concomitant administration of corticosteroids is required to manage side effects, with paclitaxel and docetaxel being prime examples. Corticosteroids reduce the level of immune cells circulating around tumours, which are necessary for the activity of IO agents. Concomitant administration of corticosteroids has been shown to dampen the effects of PD-1 inhibitors both in preclinical experiments and in clinical trials. We, therefore, believe that there is an exciting opportunity for Oasmia to become a partner of choice for developers of IO agents, as the novel chemotherapy formulations generated using the Company's XR17™ platform, including Apealea® and docetaxel micellar, do not require premedication with corticosteroids.

**The XR17™ platform has application beyond cancer drugs**

The focus of XR17™ for Oasmia to date has been oncology. Still, the Company has stated that in the future, it may evaluate the potential of the technology in other therapeutic areas. Oasmia has not yet confirmed any potential non-cancer target indications, molecules (known APIs or NCEs) or timelines for the potential application of XR17™ outside of cancer. However, we expect further details to be disclosed in the future.

# Apealea® – the premium paclitaxel

**Apealea® – paclitaxel improved, approved, partnered and ready to launch**

Apealea® is Oasmia's novel formulation of paclitaxel that we believe has significant advantages over the standard formulation. It contains a higher dose of API, can be infused over a shorter timeframe, and has no mandatory requirement for premedication due to a lower risk of hypersensitivity reactions, with no compromise on efficacy. Apealea® has been approved for the treatment of advanced, relapsed, platinum-sensitive ovarian cancer in Europe. In March 2020, Oasmia signed a major deal with Elevar Therapeutics for global rights to Apealea®, receiving $20 million upfront and is eligible for a further $678 million in milestones, plus royalties. We view this deal as significant validation of the drug's commercial potential. In the near-term, we expect Oasmia to re-start the launch of the drug in Nordic countries following its pause due to the COVID-19 pandemic. Also, we expect a sub-licensing deal from Elevar for the major European territories and the filing of an NDA in the US. We forecast peak sales of $275 million in the US and Europe but believe there is significant upside to this projection in the form of additional country approvals (e.g. in Asian markets) and development for other cancer types and potentially in combination with IO drugs.

**Ovarian cancer is a group of cancers, most start in the epithelium**

Ovarian cancer is a diverse group of malignancies that arise from tissues of different origin, are located at different sites (fallopian tubes and peritoneal cavity as well as the ovaries) and have different treatment approaches and prognoses. Ovarian cancer is predominantly a disease of older, postmenopausal women with the majority (>80%) of cases being diagnosed in women over 50 years. The exact cause of ovarian cancer remains unknown, but many associated risk factors have been identified (e.g. reproductive history, early menarche, family history). By far the most common group, accounting for around 90% of all ovarian cancers, are the epithelial ovarian cancers, which form in the tissues that cover the ovary, line the fallopian tubes or line the peritoneal cavity (known as primary peritoneal cancer). Epithelial ovarian cancer is further broken into subtypes by histology. High-grade serous is the predominant histopathology in North American and European populations, comprising around 70% of all epithelial ovarian cancers.

**The symptoms often mimic those of common conditions…**

The common symptoms of ovarian cancer include abdominal swelling, pain or discomfort, feeling full quickly when eating, continually feeling bloated and more frequent urination than usual. These symptoms are similar to those of conditions which are more common than ovarian cancer, such as irritable bowel syndrome or pre-menstrual syndrome. Other symptoms include persistent indigestion or nausea, pain during sex, a change in bowel habits, back pain, vaginal bleeding, constant fatigue and unintentional weight loss.

**…which can lead to late diagnosis when the cancer is advanced…**

As the typical symptoms of ovarian cancer mimic those of other benign conditions, people frequently take longer before discussing with their primary care physician (PCP). For the same reasons, it is also possible that PCPs do not initially suspect ovarian cancer and a diagnosis is delayed. As a result, a significant proportion of ovarian cancer cases (~60% in the UK) are diagnosed at an advanced stage, where curative treatment is not possible. A variety of testing methods are used to diagnose ovarian cancer. Initially, a physical exam and blood test for the CA125 tumour biomarker are performed. However, CA125 is not always elevated with ovarian cancer (and sometimes it is elevated when there is no ovarian cancer). Women with suspected ovarian cancer usually have an ultrasound to look for morphological changes and CT,

MRI scans and X-rays can support a diagnosis. However, the only definitive way to diagnose ovarian cancer is by biopsy, and for ovarian, fallopian and peritoneal masses this is often performed during the first surgery.

**…at which stage treatment outcomes are poor**

As with all cancer types, treatment outcomes are significantly better when cancer is diagnosed at an early stage. The FIGO system commonly used for staging ovarian cancer classifies the disease into four stages (IV being the most advanced), depending on the location, size, invasiveness, lymph node involvement and metastasis. In the UK, five-year relative survival is 90% for patients diagnosed with Stage I ovarian cancer, 43% for Stage II, 19% for Stage III and 4% for Stage IV.

**There are nearly 90,000 new cases in the US and Europe annually**

In the US an estimated 21,750 women will receive a new diagnosis of ovarian cancer in 2020, and 13,940 women will die from it, making it the most deadly cancer of the female reproductive system and the fifth leading cause of cancer death in women. In Europe, the incidence of ovarian cancer is estimated to be higher than 65,000 new cases per year, with over 42,000 annual deaths. Age-specific incidence rates rise sharply from around age 30-34, peak in those aged 75-79, and subsequently drop sharply.

**Initial treatment depends on the stage at diagnosis…**

There is some variation in treatment approaches depending on the subtype and histology of the ovarian cancer. Patients with Stage I epithelial ovarian, fallopian tube or primary peritoneal cancer are treated with surgery – primarily a total hysterectomy (removal of the uterus) with unilateral or bilateral salpingo-oophorectomy (removal of one or both ovaries with fallopian tubes). This is often accompanied by adjuvant chemotherapy to decrease the risk of disease recurrence. For patients with Stages II-IV disease, the primary treatment is cytoreductive surgery (hysterectomy or oophorectomy with the removal of as much invasive visible disease as possible) with adjuvant chemotherapy. The US National Comprehensive Cancer Network (NCCN) clinical guidelines and guidance issued by the European Society for Medical Oncology (ESMO) recommend carboplatin in combination with paclitaxel chemotherapy as the preferred option for first-line chemotherapy of ovarian cancer, with or without Roche's angiogenesis-inhibiting MAb Avastin® (bevacizumab). In patients treated with carboplatin-paclitaxel plus Avastin® who achieve a complete or partial response (CR or PR) after completing their initial chemotherapy course, Avastin® may be continued as maintenance monotherapy for up to 15 months. In a Phase III pivotal study (GOG-0218), Avastin® plus carboplatin and paclitaxel did not meaningfully improve PFS (12.8 months vs 12.0 months), but patients treated with Avastin® plus carboplatin and paclitaxel followed by Avastin® maintenance had a clinically meaningful and statistically significant improvement in PFS (18.2 months vs 12.0 months, $p<0.0001$). There was a trend for improvement in OS in the maintenance arm, but this was not statistically significant (43.8 months vs 40.6 months for carboplatin and paclitaxel alone).

**…and relapsed patients are classified by their response to platinum chemotherapy**

Despite first-line treatment, ~10% of patients diagnosed at Stage I, ~30% of Stage II, 70–80% of Stage III and nearly 90% of Stage IV ovarian cancer patients who initially have disease remission will experience a relapse at some point. Relapsed patients are broadly classified into three groups based on their response to platinum-based chemotherapy: (1) platinum-sensitive – patients achieve remission, but then relapse more than six months after finishing their last cycle of platinum chemotherapy; (2) platinum-resistant – patients achieve remission, but then relapse within six months of finishing their last cycle of platinum chemotherapy; or (3) platinum-refractory – patients do not respond to platinum-based chemotherapy.

**Carboplatin + paclitaxel is a preferred treatment for platinum-sensitive relapse…**
The treatment of choice for platinum-sensitive relapse is to re-challenge with a platinum-based chemotherapy regimen, which may also be combined with Avastin® (the US and Europe). In Phase III, Avastin® plus carboplatin and paclitaxel improved PFS vs carboplatin and paclitaxel (12.3 vs 8.6 months, p<0.0001). There is a choice of preferred chemotherapy regimens listed in treatment guidelines: carboplatin with either paclitaxel, gemcitabine and pegylated liposomal doxorubicin (PLD); or cisplatin in combination with gemcitabine. Clinical trials of these combinations all showed PFS benefits vs comparators, but the only one to demonstrate an advantage in OS is the carboplatin plus paclitaxel regimen. In the Phase III ICON4 trial, OS with carboplatin plus paclitaxel was 29 months vs 24 months with either carboplatin or cisplatin alone or cisplatin in combination with other drugs (p=0.02). However, the choice of treatment is influenced by different factors, including tolerability. In the Phase III CALYPSO trial, OS was numerically lower with carboplatin plus PLD relative to carboplatin plus paclitaxel (30.7 months vs 33.0 months, not statistically significant) but was deemed to be better tolerated (namely patients experienced less carboplatin hypersensitivity, and less peripheral neuropathy). As patients could experience multiple platinum-sensitive relapses, the agent paired with carboplatin can be varied at subsequent lines of therapy.

**…and in Europe, BRCA mutation patients may receive PARP inhibitors**
Many other single-agent chemotherapies and regimens could also be used for platinum-sensitive relapse (though with lesser recommendations in guidelines we anticipate low uptake), while in Europe Yondelis® (trabectedin; PharmaMar) in combination with PLD is an option. In a Phase III pivotal trial, Yondelis® plus PLD significantly improved PFS vs PLD alone (7.3 months vs 5.8 months, p=0.019) with a trend for improved OS observed (27.0 months vs 24.1 months, not significant). Other than Avastin®, the only other approved targeted agent in the US and Europe for platinum-sensitive relapse is Clovis Oncology's poly-ADP ribose inhibitor Rubraca® (rucaparib; Clovis Oncology). This drug is restricted to use in patients with a mutation in the BRCA 1 or 2 gene (~15% of ovarian cancer cases). Supporting data for approvals in this population came from two clinical trials in which Rubraca® monotherapy led to an ORR of 64.6% and PFS of 11 months in platinum-sensitive patients with BRCA gene mutations (79 patients, most being treated for their second relapse). For ovarian cancer patients responding to their initial treatment for platinum-sensitive relapse Avastin® (the US only) and three PARP inhibitors, Rubraca®, Lynparza® (olaparib; AstraZeneca/Merck & Co.) and Zejula® (niraparib; GlaxoSmithKline), have secured approvals as maintenance therapy options having demonstrated they extend the time to disease progression.

**Standard paclitaxel therapy is formulated with Cremophor® EL…**
Originally isolated from the Pacific yew tree *Taxus brevifolia*, paclitaxel has shown anti-cancer activity in breast, lung and ovarian cancer, among others. It is a cytotoxic chemotherapy administered systemically that inhibits cell division, with cancer cells more susceptible than healthy cells. However, development was suspended for more than a decade after its discovery due to its poor water solubility. Bristol-Myers Squibb secured the first approval of the drug, branded Taxol®, in 1992 (for the treatment of ovarian cancer). Taxol® contains paclitaxel 6mg/ml dissolved in a 50% Cremophor® EL (Cr-EL, also called Kolliphor® EL) and 50% dehydrated ethanol solution. Cr-EL is a non-ionic surfactant derived from castor oil that provides a vehicle for solubilisation of paclitaxel, allowing it to be administered IV to patients. It is also used in a variety of other hydrophobic drugs, including anaesthetics, photosensitisers, sedatives and immunosuppressive agents. A patient receiving 175mg/m$^2$ paclitaxel (the approved dose in ovarian cancer) will also receive 14ml/m$^2$ of Cr-EL. The first generic versions of Taxol® launched in the early 2000s, and now many are marketed globally.

**…a solvent that can cause significant side effects for patients**

A major drawback of Cr-EL is that it can cause significant adverse events (AEs) to patients. This is clearly undesirable, especially given that it is not therapeutic. The most well-known AE associated with Cr-EL is anaphylaxis, a severe acute hypersensitivity reaction (HSR) characterised by breathing difficulties, flushing, rash, chest pain, fast heart rate, low blood pressure, angioedema (swelling), and generalised urticaria (hives). As the occurrence of severe HSRs can often be fatal, premedication of a patient with high-dose corticosteroids and antihistamines is mandatory before standard paclitaxel treatment. Minor reactions (flushing and rash) still occur in ~40% of patients despite premedication and major, potentially life-threatening reactions in 1.5–3%. The risk of HSRs is also why the drug is given over a longer infusion time, typically three hours (by comparison, carboplatin is infused over 30–60 minutes). Another potentially serious AE linked with Cr-EL is peripheral sensory neuropathy (weakness, numbness and/or pain usually in the hands and/or feet). Though the broader taxane class of drugs has been associated with this AE (which also includes docetaxel and cabazitaxel), Cr-EL directly causes nerve damage in preclinical studies (axonal swelling, degeneration, and demyelination). In the clinic, neuropathies in patients treated with paclitaxel and docetaxel persist long after discontinuation of therapy. Other AEs linked to Cr-EL include high cholesterol levels, abnormal lipoprotein patterns and aggregation of red blood cells.

**Apealea® is a novel paclitaxel formulation – better than the standard in our view…**

Oasmia has applied its XR17™ technology platform to develop Apealea®, a formulation of paclitaxel with improved solubility and pharmacokinetics (PK) compared with the standard formulation. Apealea® contains a higher dose of paclitaxel than the standard formulation and can be infused over a shorter timeframe with no mandatory requirement for premedication due to a lower risk of HSRs, with no compromise on efficacy.

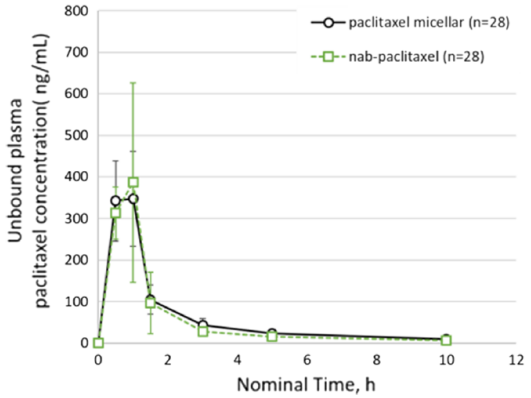
**…which is validated by a major deal with Elevar Therapeutics**

In March 2020, Oasmia signed a major deal with Elevar Therapeutics for global (excluding certain territories) rights to Apealea®. Oasmia received an upfront payment of $20 million and is entitled to up to $678 million in development, regulatory and sales milestones, plus double-digit percentage royalties on Elevar's sales of the drug. In return, Elevar has the exclusive right to commercialise Apealea® in the US, Europe (excluding the Nordic and Baltic countries, where Oasmia retains rights) and other countries (excluding Russia and the Commonwealth of Independent States) and the right to sub-license commercialisation to other strategic partners. Elevar is responsible for all regulatory application processes in its territories. Elevar (formerly known as LSK Biopharma) is a wholly-owned US subsidiary of HLB, a publicly listed Korean conglomerate (~$3.1 billion market capitalisation) that also has other pharmaceutical/biotech subsidiaries.

### Pharmacokinetic studies demonstrated proof-of-concept for Apealea®

Results from dose-escalation and PK studies of Apealea® in cancer patients have been published. These demonstrate proof-of-concept that the improved formulation of paclitaxel can be administered at higher doses, over a shorter timeframe, and without the requirement for premedication for HSR prophylaxis (Borga et al. 2019. Advances in Therapy, 36: 1150–1163, and Borga et al. 2019. Advances in Therapy, 36: 2825–2837). In the dose-escalation trial in 34 male and female patients with solid cancers, no unexpected AEs (given paclitaxel's known safety/tolerability profile) were observed. The maximum tolerated dose was determined as 250mg/m$^{2,}$ and no HSRs were observed. A separate trial in 28 breast cancer patients compared the PK of Apealea® and Abraxane®. The drugs behaved similarly following infusion, with experiments suggesting that paclitaxel dissociates from XR17™ (Apealea®) and albumin (Abraxane®) immediately in the blood and is rapidly distributed into the tissue. The two drugs were shown to be bioequivalent regarding both total and unbound paclitaxel (essentially the biologically active form that exerts therapeutic effect, see Figure 2), leading the study investigators to conclude that the drugs were clinically equivalent.

**Figure 2: Apealea® (paclitaxel micellar) shows bioequivalence to Abraxane® (nab-paclitaxel)**




Source: Borga et al. 2019. Advances in Therapy, 36: 2825–2837

### Results from a Phase III trial of Apealea® were published this year

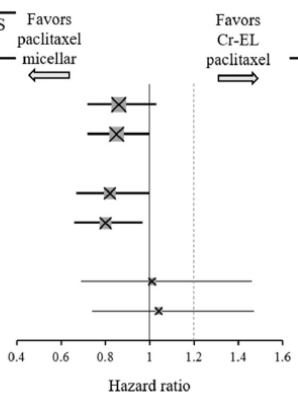
Oasmia has completed a Phase III trial of Apealea® in recurrent, platinum-sensitive epithelial ovarian cancer and positive results from this trial were published in 2020 (Vergote et al. 2020. Gynecologic Oncology, 156 (2): 293–300). This trial aimed to determine whether Apealea® could provide a safety/tolerability advantage over standard paclitaxel formulated with Cremophor-EL. In this European, multicentre, open-label trial, 789 patients with recurrent, platinum-sensitive ovarian cancer were randomised approximately 1:1 to receive either six three-week cycles of IV Apealea® 250mg/m$^2$ in combination with IV carboplatin (5–6 Area Under Curve) or standard IV paclitaxel (175mg/m$^2$) in combination with IV carboplatin. The majority of patients had advanced disease (64% with FIGO Stage III and 16% FIGO Stage IV) disease, serous histology (66%, the most common histology) and were being treated for their first relapse after platinum-based chemotherapy (76% vs 24% second relapse). All patients in the study met the criteria for platinum-sensitive relapse (platinum-free interval of 6–12 months = 42%; 12–24 months = 32%; >24 months = 26%).

**…demonstrating non-inferior efficacy to standard paclitaxel…**

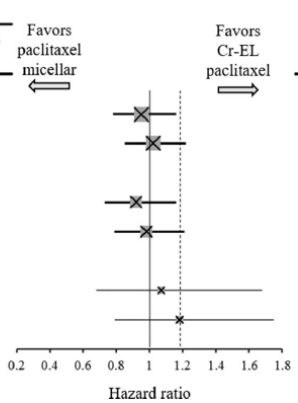
The study's PFS primary endpoint was achieved, with Apealea® demonstrating non-inferiority to standard paclitaxel. The hazard ratio (HR) was 0.86 (95% CI: 0.72;1.03) in the per-protocol population (PP, defined as a patients completing six treatment cycles) and 0.85 (95% CI: 0.72;1.00) in the intention-to-treat population (ITT, all randomised patients). The upper limit of the one-sided 97.5% CI was thus well below the 1.2 ceiling for non-inferiority. Median PFS was 10.3 months in the Apealea® arm and 10.1 months in the standard paclitaxel arm. Non-inferiority of Apealea® was also shown on the key secondary endpoint of OS in the PP population (HR of 0.95, 95% CI: 0.78;1.16), with median OS 25.7 months in the Apealea® arm vs 24.8 months in the standard paclitaxel arm. OS in the ITT population was similar between the arms, but non-inferiority could not be established (HR of 1.02, 95% CI: 0.85;1.22, median OS 23.8 months vs 23.5 months). A subgroup analysis was performed to determine differences in treatment effect between the drugs in first and second relapse (see Figure 3). This analysis suggested a small but significant benefit of Apealea® over standard paclitaxel in first relapse patients (HR 0.80, 95% CI: 0.66;0.97, median PFS 10.3 months vs 10.0 months) while OS in the PP population remained statistically non-inferior and could not be determined in the ITT population. In second relapse patients, PFS and OS were numerically marginally lower in the Apealea® arm than in the standard paclitaxel arm, and statistical non-inferiority of Apealea® was not demonstrated.

**Figure 3: PFS (top) and OS (bottom) by relapse from Phase III trial of Apealea® (paclitaxel micellar) vs standard paclitaxel (Cr-EL)**

| | | Paclitaxel micellar | | | Cr-EL paclitaxel | | | |
|---|---|---|---|---|---|---|---|---|
| | *N* (all) | *n* | events | Median PFS (months) | *n* | events | Median PFS (months) | HR* (95% CI) |
| All patients | | | | | | | | |
| PP | 644 | 311 | 239 | 10.3 | 333 | 270 | 10.1 | 0.86 (0.72-1.03) |
| ITT | 789 | 397 | 278 | 10.2 | 392 | 300 | 10.0 | 0.85 (0.72-1.00) |
| First relapse | | | | | | | | |
| PP | 497 | 240 | 180 | 10.3 | 257 | 209 | 10.1 | 0.82 (0.67-1.00) |
| ITT | 599 | 301 | 208 | 10.3 | 298 | 231 | 10.0 | 0.80 (0.66-0.97) |
| Second relapse | | | | | | | | |
| PP | 147 | 71 | 59 | 9.9 | 76 | 61 | 10.1 | 1.01 (0.69-1.46) |
| ITT | 190 | 96 | 70 | 9.9 | 94 | 69 | 10.1 | 1.04 (0.74-1.47) |




| | | Paclitaxel micellar | | | Cr-EL paclitaxel | | | |
|---|---|---|---|---|---|---|---|---|
| | *N* (all) | *n* | events | Median OS (months) | *n* | events | Median OS (months) | HR* (95% CI) |
| All patients | | | | | | | | |
| PP | 644 | 311 | 179 | 25.7 | 333 | 206 | 24.8 | 0.95 (0.78-1.16) |
| ITT | 789 | 397 | 223 | 23.8 | 392 | 237 | 23.5 | 1.02 (0.85-1.22) |
| First relapse | | | | | | | | |
| PP | 497 | 240 | 139 | 26.1 | 257 | 162 | 23.6 | 0.92 (0.73-1.16) |
| ITT | 599 | 301 | 172 | 24.7 | 298 | 186 | 23.4 | 0.98 (0.79-1.21) |
| Second relapse | | | | | | | | |
| PP | 147 | 71 | 40 | 23.2 | 76 | 44 | 24.8 | 1.07 (0.68-1.68) |
| ITT | 190 | 96 | 51 | 19.1 | 94 | 51 | 23.8 | 1.18 (0.79-1.75) |




Source: Vergote et al., Gynecologic Oncology. 2020, 156 (2): 293–300

**…with potentially no requirement for premedication, faster infusion and…**

Apealea® was considered safe and well-tolerated, with no unexpected toxicities observed (given paclitaxel's well-known profile). One of the main drawbacks of standard paclitaxel is its propensity to cause HSRs, which can be severe and even fatal (see page 16). In its Phase III trial, Apealea® was associated with a similar rate of HSRs as standard paclitaxel (15% for Apealea® vs 13% in standard paclitaxel patients). While the investigators' thesis was initially that Apealea® would lead to a lower rate of HSRs than standard paclitaxel, they commented that they expected a higher rate of HSRs in the standard paclitaxel arm than observed. Indeed, historical studies have shown rates of HSR of 41–44% of patients treated with standard paclitaxel despite premedication (mostly minor, but 1.5–3% are potentially life-threatening). In contrast to standard paclitaxel, the use of premedication for HSR prophylaxis in the Apealea® arm was far lower despite the higher dose being delivered (250mg/m$^2$ vs 175mg/m$^2$ for standard paclitaxel). Corticosteroid pre-treatment was administered before Apealea® in 6% of patients vs 97% of standard paclitaxel patients, and antihistamines in 4% of Apealea® patients vs 85% of standard paclitaxel patients (see Table 6). While more premedication was used before the administration of carboplatin in the Apealea® arm relative to the paclitaxel arm (a precaution available at the physicians' discretion), the overall use of premedication (whether given before Apealea®/paclitaxel or carboplatin) was still far lower in the Apealea® arm. We believe this shows a significant safety advantage in terms of lower HSR risk with Apealea®, which critically allows for three times faster infusion – one hour with Apealea® compared to three hours with standard paclitaxel. Having no mandatory requirement for premedication and a shorter infusion time could translate to a healthcare economic advantage for Apealea® in our view, something which has been observed with Abraxane®.

**Table 6: Premedication used in the Phase III trial of Apealea® (% patients)**

| | Apealea® arm | | | Standard paclitaxel arm | | |
|---|---|---|---|---|---|---|
| | Overall | Apealea | Carboplatin | Overall | Paclitaxel | Carboplatin |
| Antiemetics and antinauseants | 87% | 8% | 81% | 92% | 38% | 63% |
| Systemic corticosteroids | 43% | 6% | 39% | 99% | 97% | 15% |
| Systemic antihistamines | 19% | 4% | 16% | 85% | 85% | 9% |
| Drugs for acid-related disorders | 5% | 2% | 2% | 90% | 90% | 1% |

Source: Vergote et al., Gynecologic Oncology. 2020, 156 (2): 293–300

**…possibly a lower risk of neuropathy, but higher non-clinical haematological AEs**

The Cr-EL solvent is thought to contribute towards the neuropathy associated with standard paclitaxel, and therefore a formulation excluding Cr-EL could lower the rate of this AE. In the Phase III trial, a lower proportion of patients with at least one peripheral sensory neuropathy (any grade) was reported in the Apealea® arm vs the standard paclitaxel arm (16 vs 20%) despite the higher dose delivered with Apealea®. There was a numerically higher rate of >grade 3 haematological AEs in the Apealea® arm relative to the standard paclitaxel arm (thrombocytopenia 18% vs 10%, leukopenia 53% vs 34% and neutropenia 79% vs 66%). However, all of these events were considered uncomplicated and did not translate into relevant clinical consequences such as febrile neutropenia or more infections. The use of granulocyte colony-stimulating factor (G-CSF) was 35% in the Apealea® arm and 30% in the standard paclitaxel arm. At least one dose reduction was noted in 18% of patients in the Apealea® arm and 12% in the standard paclitaxel arm.

**Apealea® was approved in Europe in November 2018**

Oasmia filed a marketing authorisation application (MAA) with the EMA in February 2016 and in September 2018 received a positive CHMP opinion, with approval of the drug by the European Commission following in November 2018. In March 2019, Oasmia received a positive opinion from the EMA to add all efficacy data from the OAS-07OVA Phase III trial to the approved Apealea® product information, providing extensive information on the differences between Apealea® and standard paclitaxel. The approved use of Apealea® is in combination with carboplatin for the treatment of adult patients experiencing a first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer. The recommended dose of Apealea® is 250 mg/m$^2$ IV infusion over 1 hour, followed by carboplatin (5–6 AUC) every three weeks for six cycles. The drug had previously been approved in Russia and the Commonwealth of Independent States in April 2015 (branded as Paclical®), for the first-line treatment of advanced ovarian cancer as well as platinum-sensitive relapse.

**Nordic launch to resume and a sub-licensing deal for major European markets**

Oasmia began the launch process for Apealea® through distributors in Sweden, Denmark and Finland in late January 2020. However, by March 2020 the COVID-19 outbreak had transformed into a global pandemic with many European governments, including in Denmark and Finland, imposing lockdown measures. Unsurprisingly, this situation led to a pause in the launch of Apealea®. Oasmia plans to resume Apealea® launch activities in the Nordics by the end of the year. Elevar has stated its intention to sub-license commercialisation rights to Apealea® in other European countries (France, Germany, Italy, Spain and the UK being commercially the most important). While neither Oasmia or Elevar have provided guidance on the timeline for a deal, we assume that a transaction by the end of this year could pave the way for launch in other European countries in H1 2021. We note Elevar is prudently building awareness of Apealea® with oncologists in Europe and other countries (ex-US) through an early access programme on a named-patient basis (via a specialist partner, Tanner Pharma Group).

**Elevar is making preparations to file an NDA for US approval**

Elevar held a pre-NDA meeting with the FDA on 30 April 2020. In a pre-NDA meeting, the applicant has the chance to gain an understanding of the Agency's expectations for content and formatting of the NDA submission, which should leave them in a position to judge their readiness for filing and the likelihood of a drug approval. Elevar is making preparations for an NDA based on its discussion with the FDA at this meeting. We view this as a positive signal that the existing data package may satisfy the FDA requirements for approval (rather than requiring significant further work, for example, a new pivotal trial in a worst-case scenario). While Elevar has not provided specific guidance on the timing of an NDA filing, we assume a filing under the 505(b)(2) pathway could be made by the end of the year, which could lead to US approval of Apealea® in H2 2021. We understand that Elevar is in the process of building commercial infrastructure in the US.

**The success story of Abraxane®…**

We would highlight Abraxane® as an example of how a developer can take a known API and create a valuable new formulation which achieves commercial success. Abraxane® is a novel, albumin-bound, nanoparticle (~130 nm) formulation that contains a higher dose of paclitaxel than the standard formulation, is free from Cr-EL, does not require premedication and has a faster infusion time (30 minutes) than standard paclitaxel. It is approved for two indications for which standard paclitaxel was already a core treatment and one new indication (see Table 7). Abraxane® was initially developed by Abraxis BioScience, which was acquired by Celgene (now Bristol-Myers Squibb) in 2010 for $2.9 billion. It was first approved in the US in 2005 and Europe in 2008 for the treatment of relapsed/refractory advanced breast cancer. In a Phase III trial, it showed a significantly higher response rate than standard paclitaxel (21.5% vs 11.1%, p=0.003) although the increase in OS was not significant (65.0 vs 55.7 weeks, p=0.374). In terms of safety, no HSRs were documented despite the absence of premedication and rates of grade 4 neutropenia were improved over standard paclitaxel (9% vs 22%). However, grade 3 sensory neuropathy was more common (10% vs 2%). The drug subsequently was approved for the first-line treatment of advanced non-small cell lung cancer (NSCLC) in combination with carboplatin. In Phase III, this regimen showed significantly higher ORR than standard paclitaxel plus carboplatin (33% vs 25%, p=0.005) with no significant difference in OS (12.1 vs 11.2 months, p=0.271). In this trial, the rates of grade 3 or 4 neutropenia were lower with Abraxane® (47% vs 58%) though the rate of febrile neutropenia was similar. All-grade sensory neuropathy was also lower with Abraxane® (46% vs 62%). Abraxane® has also been approved in combination with gemcitabine for the first-line treatment of advanced pancreatic cancer, where standard paclitaxel was not an approved agent previously.

**Table 7: FDA-approved indications for standard paclitaxel vs Abraxane®**

| Standard paclitaxel (Taxol®) | Abraxane® |
|---|---|
| r/r metastatic breast cancer | r/r metastatic breast cancer |
| Adjuvant treatment of node-positive breast cancer (following surgery and adjuvant doxorubicin) | |
| r/r advanced ovarian cancer | |
| 1L advanced ovarian cancer in combination with cisplatin | |
| 1L advanced NSCLC in combination with cisplatin | 1L advanced NSCLC in combination with carboplatin |
| 2L AIDS-related Kaposi's sarcoma | |
| | 1L metastatic pancreatic cancer in combination with gemcitabine |

Source: Company information; 1L = first-line; 2L = second-line; NSCLC = non-small cell lung cancer; r/r = relapsed or refractory

**…validates Oasmia's approach in our view…**

Abraxane® has been a commercial success, with blockbuster sales achieved in each of the last five years, reaching $1.6 billion in 2019. However, we anticipate the onset of generic competition in 2022. While Apealea® and Abraxane® (as well as potential generics) use the same API, we would stress that we do not view Abraxane® as a competitive threat, at least initially. This is because Abraxane® is not approved for use in ovarian cancer. It is listed as an "Other Recommended Regimen" for recurrent platinum-sensitive patients in NCCN guidelines, though we anticipate uptake to be very low. However, should Oasmia expand Apealea®'s development into any of the indications for which Abraxane® is approved then we anticipate Apealea® needing to show significant differentiation to compete effectively.

**…as does a major deal to allegedly sequester Cynviloq™ from the market**

Samyang Biopharm has also developed a novel paclitaxel formulation similar to Apealea®, Genexol® PM (uses Samyang's plant cell culture and polymeric micelle technology which is distinct from Oasmia's), which is approved for use in Korea. The US Company Igdrasol licensed the US and European rights to the drug (branded Cynviloq™ in these territories) and was subsequently acquired by Sorrento Therapeutics. To file an NDA via the 505(b)(2) pathway, Sorrento conducted a 100-patient pivotal bioequivalence trial (TRIBECA) which generated positive results showing bioequivalence of Cynviloq™ to Abraxane®. Sorrento subsequently signed a major deal selling its Igdrasol unit with its primary asset Cynviloq™ to NantWorks for an upfront payment of $90 million and eligibility for up to $600 million in regulatory milestones and $600 million in sales milestones. While NantWorks was in a position to file an NDA at this point, this has not happened to date, causing Sorrento to file lawsuits against NantWorks and its founder, CEO and Chairman Dr Patrick Soon-Shiong, in 2019. Sorrento alleged that Dr Soon-Shiong was blocking Cynviloq™ from reaching the US market to prevent it competing with Abraxane® and thereby protecting his investment in Celgene (gained when selling Abraxis, which developed Abraxane®, to Celgene in 2010). The litigation is ongoing but from either perspective, enthusiasm for Cynviloq™ or defence of Abraxane®, we believe this substantial deal for Cynviloq™ provides significant validation of the market opportunity for another improved formulation of paclitaxel in the US and Europe, which we believe Apealea® can capitalise on.

**Another novel paclitaxel drug, Taclantis®, was recently rejected by the FDA**

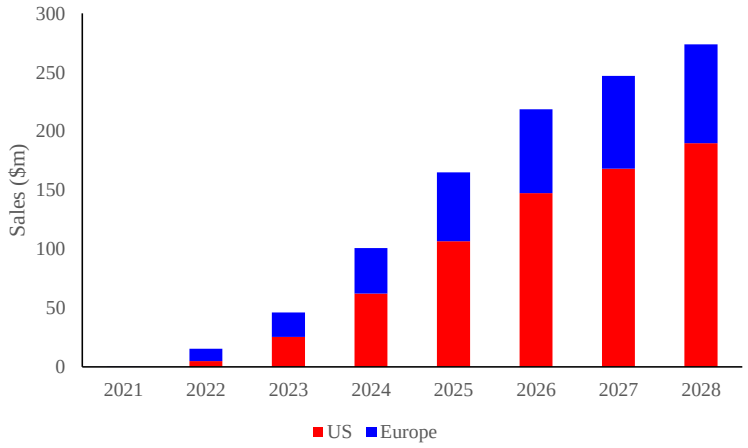
Sun Pharma Advanced Research Company (SPARC) has developed another novel formulation of paclitaxel, Taclantis®, which is approved in India. SPARC has been pursuing FDA approval of Taclantis® via the 505(b)(2) pathway based on bioequivalence to Abraxane®. Like Apealea® and Abraxane®, Taclantis® is also Cr-EL-free, does not require premedication, and has a higher dose of API and faster infusion time (25 minutes) than standard paclitaxel. The FDA accepted SPARC's NDA filing in July 2019, but in February 2020 issued a Complete Response Letter (CRL). According to SPARC, the FDA acknowledged bioequivalence but has concerns over the variability of the particle size distribution of the drug nanoparticles and that they could impact the drug's efficacy and safety. SPARC hoped to meet with the FDA in April to discuss the path to resubmission, though no update has since been provided. Regardless of the outcome, we do not consider Taclantis® as a direct competitor to Apealea® due to the fact its approval would be for the same indications as Abraxane®, i.e. not ovarian cancer.

**We forecast sales of approximately $275 million in the US and Europe**

We understand that Oasmia is making preparations to resume its launch activities for Apealea® in the Nordics. While progress is dependent on hospital operations continuing to normalise, we anticipate launch before the end of the year. We expect a launch in the rest of Europe to be conducted by a partner. We understand partnering discussions are ongoing, and our forecast assumes a deal in H2 2020, which would pave the way for additional European country launches in H1 2021. In the US, we assume an NDA is filed in H2 2020 and that US approval could occur in H2 2021. We believe US approval of Apealea® would trigger a significant milestone payment from Elevar to Oasmia, though we have conservatively excluded milestone income from our forecasts at this time. We project launch of Apealea® in the US in early 2022. Our forecasts assume modest penetration rates in ovarian cancer patients in their first platinum-sensitive relapse. In Europe, we note pricing information is already available for Apealea® in the Nordic countries (e.g. the Danish pharmacy price for six cycles is

~€9,300 per patient, in-line with the cost of six cycles of Abraxane® in metastatic breast cancer). In the US, we assume pricing in-line with Abraxane® (~$36,500 for six cycles). We forecast peak sales of Apealea® of $275 million in fiscal 2028 in the US and Europe (see Figure 4), assuming that Oasmia sells the drug directly in the Nordics and Baltics, and receives double-digit percentage royalty (we assume 15%) on sales in the US and other European countries.

**Figure 4: Apealea® sales forecast (fiscal year-end 30 April)**




Source: Rx Securities

**Geographic and label expansion provide upside potential to our forecasts**

We believe there is significant upside to our forecasts from different opportunities for Apealea® that could be exploited in the future. In its initial indication of platinum-sensitive ovarian cancer, geographic expansion is one avenue that Elevar has already highlighted. In particular, we believe there is a significant commercial opportunity in Asian markets – in China, Japan and South Korea combined there are approximately 66,300 new cases of ovarian cancer annually (similar to the incidence in the US and Europe combined). We believe Elevar could sign a sub-licensing deal for Apealea® in these territories soon. With greater clarity on pathways to market, we would likely revise our forecasts to reflect potential sales of the drug in these additional markets. Oasmia and Elevar could also seek to expand Apealea®'s label. In ovarian cancer, in terms of patient numbers, the advanced ovarian cancer first-line setting is larger than the first relapse platinum-sensitive setting, and standard paclitaxel plus carboplatin is the standard of care here. It is possible that Apealea® could benefit from some degree of off-label use in first-line patients in the future. While a pivotal trial to secure a label expansion for first-line use could fully unlock the opportunity, we believe the most exciting opportunity in terms of future development (and likely a larger commercial opportunity) lies in testing Apealea® in novel combination regimens with IO drugs (including the PD-1 inhibitors that have revolutionised cancer treatment, see page 12) and possibly targeted therapies. We understand that Elevar is currently thoroughly assessing potential future indications and combination regimen possibilities, and we anticipate an update on its development strategy in the near future.

# Docetaxel micellar for prostate cancer

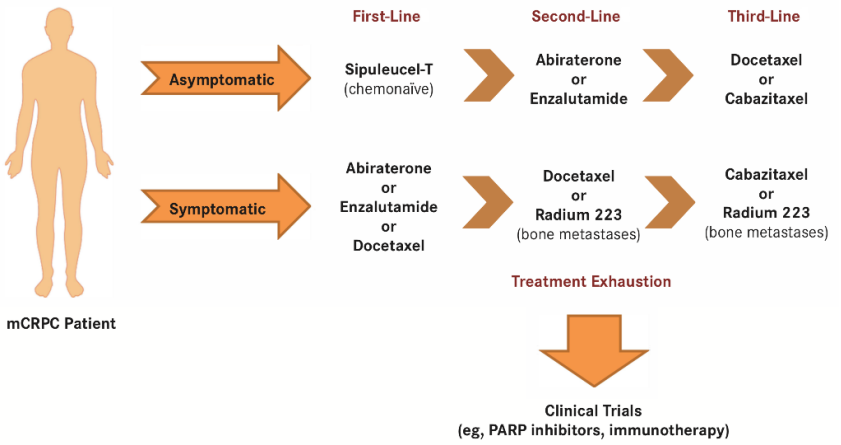
**Oasmia's docetaxel micellar is set to start a Phase Ib trial in prostate cancer**
Oasmia's second pipeline product is docetaxel micellar, a novel formulation of docetaxel produced using the Company's XR17™ platform. Docetaxel micellar could have safety advantages over the original formulation mitigating the need for premedication. The drug has already generated promising data from early trials in breast cancer, and Oasmia has recently formed a partnership with a Swiss research group to initiate a Phase Ib trial in advanced prostate cancer. In this large indication, docetaxel is a mainstay treatment. The commercial opportunity for docetaxel micellar could be even larger than for Apealea® in our view, and we believe this could be the subject of a major partnering deal.

**Prostate cancer is the most common cancer in men…**
Prostate cancer is the most common cancer in men, with ~192,000 new cases and 33,300 deaths expected in the US in 2020, and ~450,000 new cases in Europe with over 107,000 deaths. The single biggest risk factor for prostate cancer is advanced age (60% of cases occur in men over 65 years of age). Also, ethnicity (more common in men of African ancestry) and genetics (BRCA1 and BRCA2 mutations, and Lynch syndrome) are associated with increased risk. Prostate cancer is often slow-growing, and men of advanced age at diagnosis may die of other causes rather than their cancer. However, some tumours are more aggressive and/or diagnosis in younger patients or at a late disease stage would necessitate urgent treatment. Prostate cancer growth and development is driven by male hormones (androgens, e.g. testosterone) signalling.

**…and while curable if caught early, advanced disease survival rates remain low**
If caught at an early stage where the tumour is still localised, prostate cancer is curable by surgery or different radiotherapy techniques combined with hormonal therapy, which cuts off the androgen supply the tumours need for growth. Five-year survival for these patients approaches 100%. However, when the disease is diagnosed at an advanced stage where the cancer has metastasised to different sites in the body, the disease is generally not curable, and five-year survival drops to just 31%. There are several treatments available for patients with advanced prostate cancer. It is initially sensitive to androgen deprivation therapy (with first-generation anti-androgens, LHRH agonists or LHRH antagonists), which are hormonal therapies that block the androgen receptor. However, after an average of 12–18 months, almost all patients begin to fail the treatment and show the emergence of hormone-refractory disease, also known as metastatic "castration-resistant" prostate cancer (mCRPC).

**Docetaxel is a key treatment for advanced prostate cancer…**
Although several drugs for the treatment mCRPC have reached the market in the last decade, docetaxel has remained a mainstay option since its approval in 2004 (brand name Taxotere®, though now multiple generics are available globally). In its Phase III pivotal trial, Taxotere® plus prednisone once every three weeks conferred a significant OS advantage to mitoxantrone plus prednisone in mCRPC patients (18.9 months vs 16.5 months, p=0.0094). No other agent since has shown superiority in terms of efficacy to docetaxel, rather oncologists must choose how to sequence the various agents approved for mCRPC (see Figure 5), with a consensus not established. The NCCN guidelines for prostate cancer list docetaxel as a preferred regimen for mCRPC at first-line, second-line or even subsequent therapy lines depending on what treatment was given previously. We anticipate that the majority of mCRPC patients who receive pharmacological therapy would be treated with docetaxel at some point. Docetaxel, in combination with androgen deprivation therapy, is also a preferred regimen for the treatment of castration-sensitive metastatic prostate cancer.

**Figure 5: Sequencing of treatments for mCRPC**




Source: Li et al. 2017, AJHO, 13 (12): 26–31; Abiraterone = Zytiga®, Johnson & Johnson; Cabazitaxel = Jevtana®, Sanofi; Enzalutamide = Xtandi®, Astellas/Pfizer; Radium 223 = Xofigo®, Bayer; Sipuleucel-T = Provenge®, Dendreon Pharmaceuticals

**…but the current formulation has safety issues that necessitate premedication**

Docetaxel is from the same "taxane" family class of drugs as paclitaxel and is also poorly water-soluble. The approved formulation uses a 50:50 solution of polysorbate 80 (Tween® 80) and dehydrated ethanol to solubilise the API. Like Cr-EL, polysorbate 80 is a non-ionic surfactant that has been implicated in causing HSRs in patients (in clinical trials 5–40% of patients, with rare cases of severe HSRs including fatal events). Polysorbate 80 and the oleic acid released by its metabolism have been implicated in the HSRs seen with docetaxel therapy. Consequently, patients treated with docetaxel are premedicated with corticosteroids, though fatal HSRs have been documented even with premedication. Polysorbate 80 may also contribute to the neuropathy observed with docetaxel by causing degeneration of neuronal vesicles.

**Oasmia's docetaxel micellar could be a safer alternative**

Oasmia has used its XR17™ technology to develop docetaxel micellar, a formulation of docetaxel that is free from polysorbate 80 and ethanol. The composition of the excipient used in the development of docetaxel micellar differs from that used in Oasmia's other drug candidates and Apealea®, using only XMeNa instead of both XMeNa and 13XMeNa. Oasmia's aim with docetaxel micellar is the same as with Apealea® – to improve the standard formulation of the drug by removing toxic excipients (in this case polysorbate 80 and ethanol) and negating the mandatory requirement for premedication as HSR prophylaxis, ultimately leading to a safer and better-tolerated therapy with no compromise on efficacy.

**Results from first clinical trials showed early signs of a safety benefit vs Taxotere®**

Oasmia has conducted two clinical trials of docetaxel micellar to date – a Phase I PK study and a Phase II safety trial in metastatic breast cancer (MBC) patients, in total enrolling 230 patients at 17 sites in five European countries. Both trials began in 2016 and Oasmia announced results in 2019. In the Phase I PK study, 30 MBC patients received one dose of docetaxel micellar and one dose of Taxotere®. PK results indicated that docetaxel micellar is bioequivalent to Taxotere® with regards to the total fraction of docetaxel in plasma. Regarding unbound paclitaxel, this fraction was deemed low in both groups and often undetectable at time points 30 minutes post-infusion. No unexpected AEs were reported in the study. In the Phase II safety trial, patients were randomised (1:1) to receive either docetaxel micellar 100mg/m$^2$ without premedication, or Taxotere® 100mg/m$^2$ with its mandated oral corticosteroid

premedication, both every three weeks for up to six cycles. While patient numbers were relatively small, we believe docetaxel micellar showed a superior safety profile to Taxotere®. There were fewer AEs and SAEs reported with docetaxel micellar. The nature of the serious side effects was as expected with docetaxel's known profile, mainly neutropenia (docetaxel micellar 52% vs Taxotere® 83%), leukopenia (15% vs 27%) and febrile neutropenia (14% vs 23%). However, infusion site reactions were more common in the docetaxel micellar group (28% vs 0%), though the majority of these were not serious. On the primary endpoint of ORR, non-inferiority of docetaxel micellar to Taxotere® could not be determined, though it was met in an additional analysis of patients who completed all six treatment cycles. Taken together, we believe the outcomes of the Phase I and Phase II trials warrant further testing of docetaxel micellar for its potential to be a safer alternative to Taxotere®.

**…and now a Phase Ib trial is planned to begin in Q1 2021**

Oasmia has partnered with the Swiss Group for Clinical Cancer Research (SAKK) to conduct a Phase Ib trial of docetaxel micellar in advanced prostate cancer. The Executive Board of SAKK was unanimous in deciding to carry out the clinical trial, and several Swiss hospitals have confirmed their participation in the study. SAKK is the legal sponsor and is responsible for running the trial, while Oasmia is to supply the drug (the Company will manufacture at its facility in Uppsala) and finance the trial. We anticipate this Phase Ib trial starting in Q1 2021.

**We note others have identified the opportunity with novel docetaxel formulations**

We have reviewed the clinical pipeline for prostate cancer and have identified two other novel docetaxel formulations in clinical testing that could potentially be competitors to Oasmia's docetaxel micellar. Modra Pharmaceuticals is conducting a Phase IIb trial of docetaxel ModraDoc006/r in mCRPC. This drug is an oral formulation of docetaxel that Modra believes could bypass limitations associated with the standard IV formulation of docetaxel and at the same time, improve the bioavailability of the drug. The Phase IIb trial is currently randomising up to 100 patients to receive either ModraDoc006/r or the standard IV docetaxel formulation. The primary endpoint is ORR, and we anticipate readout in H1 2021. Cristal Therapeutics has developed a nanoparticle containing docetaxel using its proprietary CriPec® technology platform. This drug, CPC634, is in a Phase II trial for the treatment of platinum-resistant ovarian cancer. However, Cristal has stated a confirmatory trial in mCRPC is planned to begin this year. The company aims to register the drug via the 505(b)(2) and hybrid 10(3) routes in the US and Europe respectively. To date, neither ModraDoc006/r nor CPC634 have generated any clinical data in mCRPC.

**A large commercial opportunity that could attract a big deal**

We believe mCRPC represents a significant commercial opportunity for docetaxel micellar. In terms of addressable patients, this indication is far larger than Apealea®'s in ovarian cancer – ~43,000 people develop mCRPC in the US annually, nearly double the incidence of ovarian cancer. This is a market opportunity of ~$1.5 billion by our calculations. Furthermore, Sanofi secured a broad prescribing label for Taxotere® (which facilitated multi-blockbuster sales at its peak, over $3 billion in 2009, pre-generic entry). As well as mCRPC, Taxotere®, and now docetaxel generics, are approved for the treatment of MBC, NSCLC, advanced gastric cancer and advanced squamous cell carcinoma of the head and neck. As such, these indications represent additional logical opportunities for Oasmia to expand docetaxel micellar's development in the future in our view. We, therefore, believe the total market opportunity to be substantial and would expect that with positive clinical data, a major licensing deal for the drug could be consummated.

# AdvaVet – non-core veterinary applications

**Oasmia could divest or partner AdvaVet, which creates cancer drugs for dogs**

AdvaVet is a wholly-owned subsidiary of Oasmia that is focused on harnessing the XM17™ platform to develop drugs for the treatment of cancers in animals. Two drugs have been developed to date for the treatment of cancer in dogs: (1) Paccal Vet® (paclitaxel), which was approved in the US but could now be re-registered as a lower dose formulation; and (2) Doxophos Vet, which has completed a Phase II trial. In May 2020, Oasmia announced the outcome of a strategic review of its operations, confirming it intends to partner or out-license AdvaVet's assets or divest the business. We understand discussions regarding potential transactions are ongoing.

**There is a small but growing market for cancer therapeutics in pets**

In the US, there are 90 million dogs and 94 million cats kept as pets, and in Europe, there are an estimated 85 million dogs and 103 million cats kept as pets. An estimated six million dogs are diagnosed with cancer each year in the US. Cancer in animals is similar to cancer in humans, and the incidence increases with age. Some types of cancer are more common in certain species. For example, lymphoma is the most prevalent cancer in dogs (15–20% of all diagnoses). There are currently, only two FDA-approved drugs for the treatment of cancer in dogs (and one additional drug in Europe) and as such, the current size of the market for pet cancer drugs is small. However, we believe there is a growing interest in veterinarians for increasing research into pet cancer therapeutics to generate regulatory approved drugs.

**Paccal Vet® was approved in the US for the treatment of certain cancers in dogs…**

Paccal Vet® is AdvaVet's XR17™-based formulation of paclitaxel for the treatment of dogs with certain cancers. This drug is identical to Apealea®. Development of Paccal Vet® began in the early 2000s and in February 2014 the drug received FDA conditional approval for Minor Use and Minor Species for the treatment of non-operable mammary tumours in Stages III, IV or V and operable and non-operable squamous cell carcinoma, each in dogs that have not received previous chemotherapy or radiotherapy. However, its conditional approval was withdrawn in January 2017 in favour of developing a lower dose version of the drug (high dose paclitaxel in Paccal Vet® is associated with nausea in dogs). We understand that at least one trial of a low dose formulation would need to be conducted before pursuing re-registration in the US and approval in Europe.

**…and Doxophos Vet has completed Phase II for lymphoma in dogs**

Doxophos Vet is a patented formulation of doxorubicin formulated with the XR17™ platform, which is in development for the treatment of lymphoma in dogs. A Phase II trial was initiated in February 2015, and in October 2018 the results were compiled in a clinical study report. Though no detailed data have been disclosed, Oasmia stated that this trial showed positive efficacy and safety and that the reports from Phase I and Phase II studies were to form part of an application to file for conditional approval with the FDA.

**Oasmia is exploring external options to create value from its veterinary division**

In May 2020, Oasmia announced the outcome of a strategic review of its operations to deliver long-term, profitable growth as a specialty pharma company. The Company is looking for external opportunities to create value from AdvaVet, and we understand discussions are ongoing with a variety of transactions possible (partnering, licensing or divestment of the division).

# Valuation – our fair value is SEK 9/share

**We use discounted cash flow analysis to value Oasmia Pharmaceutical**

A generally accepted method for estimating the value of development-stage or early commercial-stage biotech companies is to model the potential cash flows from future drug sales. These future drug cash flows are then discounted back to determine a present-day value. Discount rates for publicly quoted companies in the biotechnology sector usually range from 10–16% in our experience, and this range can be supported using sector betas and the Capital Asset Pricing Model. The actual rate which we consider appropriate varies from company to company according to the financial strength and the requirement for additional capital. For Oasmia, we employ a discount rate of 10% as the company currently has a strong balance sheet. While we believe a future fundraise could be required, Apealea® is approved in Europe, and we expect it to generate sales and royalty income in the near-term.

**We value Oasmia's key value driver Apealea®…**

We view Apealea® as Oasmia's key value driver. The drug was approved in Europe in 2018, and its potential is validated by a licensing deal signed with Elevar Therapeutics in March 2020. We believe Abraxane® provides an excellent example of how a commercially successful novel drug can be developed from a reformulation of an existing API (see page 21) – we see parallels with Apealea®.

**…at SEK 4.5/share based on peak sales of $275 million in ovarian cancer**

Oasmia began the launch process for Apealea® through distributors in Sweden, Denmark and Finland in February in 2019, but was interrupted by the COVID-19 pandemic. The Company plans to resume launch activities in the Nordics by the end of the year. In other European countries including major markets (France, Germany, Italy, Spain and the UK) we assume that Elevar sub-licenses the drug for commercialisation with launches occurring in H1 2021. Elevar is currently making preparations to file an NDA with the FDA, and we anticipate this could occur by the end of the year. We project approval in the US in H2 2021 and launch in early 2022. We factor in a significant milestone payment from Elevar upon US approval of Apealea® (we assume $20 million, though we conservatively have not modelled any further milestone income). Applying modest penetration rates in platinum-sensitive ovarian cancer patients experiencing their first relapse and assuming pricing in line with Abraxane®, we forecast peak sales of Apealea® of $275 million in the US and Europe. We calculate a net present value (NPV) for Apealea® of SEK 4.5/share based on Oasmia self-commercialising the drug in the Nordics and earning approximately 15% royalties on Elevar's sales elsewhere in Europe and the US. We believe that there could be significant upside to our valuation of Apealea® from potential geographic and label expansions (novel combination regimens with IO drugs could provide a sizeable commercial opportunity in our view). We have conducted a sensitivity analysis to assess the impact of modelled peak sales on our derived NPV per share for Apealea® (see Table 8).

**Table 8: Apealea® NPV (SEK/share) sensitivity to peak sales**

| | | Annual peak sales | | |
|---|---|---|---|---|
| **$100 million** | **$200 million** | **$275 million** | **$500 million** | **$750 million** |
| **1.8** | **3.3** | **4.5** | **7.9** | **11.7** |

Source: Rx Securities

**We calculate an rNPV of SEK 2.5/share for docetaxel micellar…**

We believe docetaxel micellar's initial target indication of mCRPC represents a larger commercial opportunity than Apealea®'s in ovarian cancer (there is a market opportunity of ~$1.5 billion by our calculations, see page 26). A Phase Ib trial is slated to start in Q1 2021. We project a development pathway through Phase II and III trials and a licensing deal before Phase III. We assume first launches in 2027 and believe the drug could achieve annual peak sales of $500 million in mCRPC in the US and Europe. We assume Oasmia earns royalties on partner sales of ~20%. Applying a 50% probability of success (reflecting that a well-known API is lower risk than an NCE and considering the Phase I safety data already generated), we derive a risk-adjusted NPV (rNPV) for docetaxel micellar of SEK 2.5/share.

**…and attribute SEK 1.5/share for Oasmia's XR17™ platform**

Oasmia's novel XR17™ drug formulation platform has been validated by the European approval of Apealea® and the major licensing deal with Elevar in our view. We expect that in the coming years that XR17™ could generate several valuable product opportunities that Oasmia could partner or potentially even self-commercialise. This could include an XR19 drug (combination chemotherapy), reformulations of known APIs or even NCEs for cancer or other diseases. We have undertaken a DCF analysis that assumes three XR17™-derived products are approved and partnered, generating combined peak sales of $750 million in the period to F2050 (with Oasmia earning ~20% royalties on sales) with a 25% probability of success. This analysis yields an rNPV of SEK 1.5/share.

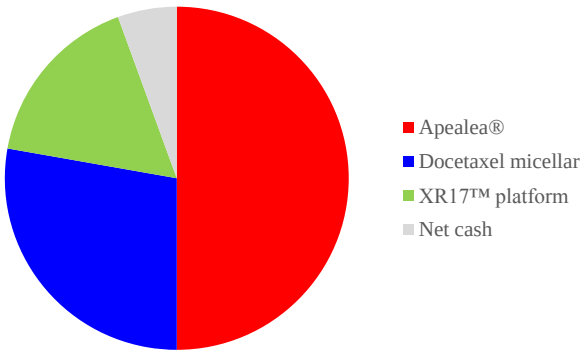
**We believe Oasmia is well-financed, with a cash runway through key catalysts**

We estimate that Oasmia ended Q1 F2021 with a strong net cash position of SEK 291.4 million (SEK 0.5/share). We project that this provides a cash runway into H1 F2023, beyond our projected dates for the Company's two key near-term catalysts: (1) Elevar signing a sub-licensing deal for Apealea® in Europe (we anticipate in H1 2021); and (2) approval of Apealea® in the US (we expect in H2 2021).

**We set a fair value of SEK 9/share for Oasmia Pharmaceutical**

We derive a fair value for Oasmia of SEK 9/share (see Figure 6), which represents an approximate 91% upside to its current valuation. Apealea® is the clear value driver, accounting for 50% of the overall valuation. As such, we believe that any positive or negative developments concerning Apealea® could cause pronounced movements in Oasmia's share price. Docetaxel micellar, the XR17™ platform, and net cash account for the remainder of our valuation. We have conservatively excluded the AdvaVet at this time, though we note divestment of this business or licensing of its assets as planned could further bolster Oasmia's balance sheet.

**Figure 6: Breakdown of our NPV-derived fair value for Oasmia Pharmaceutical of SEK 9/share**




Source: Rx Securities

# Notes

# Notes

# Important Disclosures

I, Joseph Hedden, hereby certify that the views about the companies and their securities discussed in this report are accurately expressed and I have not received and will not receive direct or indirect compensation in exchange for expressing specific recommendations or views in this report.

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