

27 May 2021

Oasmia Pharmaceutical AB

Q1 results update

Oasmia has reported a cash position at the end of Q1 of SEK 219.5 million, broadly in line with our SEK 222.8 million forecast (remains financed into 2023 on our estimates). The Company continues to experience drastically reduced access to healthcare providers and oncologists due to the ongoing COVID-19 pandemic in its launch efforts for key value-driver Apealea® (an enhanced formulation of paclitaxel for ovarian cancer) in ex-Nordic European countries. No update on launch in broader European countries by partner Inceptua Pharma has been provided, but we assume that COVID-19 has also hindered progress, and we now project first sales in H2 (previously Q2). Oasmia has stated that partner Elevar Therapeutics has received FDA authorisation to start a pharmacokinetic study of Apealea® in the US, and preparations for a new clinical trial are also ongoing. Both of these trials are to support a future NDA for Apealea®, and we now assume they will start in H2 2021 rather than H1 (but we maintain our projection for US launch in mid-2025 at this time). Beyond Apealea®, in March, Oasmia in-licensed a potential first-in-class cancer stem cell targeting drug, cantrixil, from Kazia Therapeutics. Encouraging Phase I results for cantrixil were reported at AACR in April. Oasmia recently received clearance to begin a Phase Ib trial of docetaxel micellar in metastatic castration-resistant prostate cancer (mCRPC), and we anticipate dosing of the first patient in the coming weeks. We maintain our BUY rating and fair value of SEK 7/share.

- **Positive results from cantrixil Phase I ovarian cancer trial at AACR** – in 16 evaluable patients with heavily pre-treated advanced, platinum-resistant ovarian cancer, the overall response rate was 18%, which we believe compares favourably to the ~10% observed historically with other agents in similar patient groups. We anticipate the trial's full results being published in a peer-reviewed journal, potentially in H2 2021.
- **Phase Ib trial of docetaxel micellar in mCRPC to start dosing soon** – this open-label, 3+3 design dose-escalation trial is to recruit up to 18 chemotherapy-naïve mCRPC patients. Patients are to be treated with up to 10, 21-day cycles of one of three dose levels of docetaxel. The primary endpoint is to determine the maximum tolerated dose, and secondary efficacy endpoints include progression-free survival and prostate-specific antigen progression. The study has a primary endpoint completion date (as listed on ClinicalTrials.gov) of June 2023.

Price	SEK 3.01
Fair value	SEK 7
Market capitalisation	SEK 1,387 million
Enterprise value	SEK 1,248 million
12m high/low	SEK 7.19 / SEK 2.97
Avg. daily volume	4.6m
Bloomberg / Reuters	OASM.SS / OASM.ST
Exchange	Stockholm
Adviser	Yes
Next results (Q2)	19 August 2021

Top 5 Shareholders

Per Arwidsson	24.8%
Avanza Pension	6.6%
Mastan AB (Håkan Lagerberg)	2.1%
Nordnet Pension Insurance	1.7%
Swedbank Insurance	1.5%

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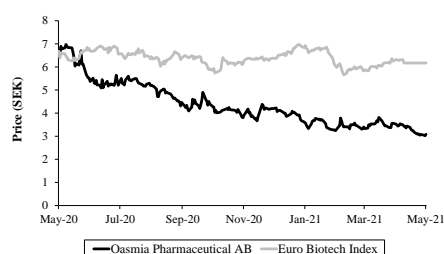
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Share price performance (1 year)



Key financial data (MSEK) – IFRS

Y/E 30 Apr	2020A*	2021E	2022E	2023E	2024E
Revenue	0.5	13.4	36.4	44.2	82.2
EBITDA	(102.6)	(123.9)	(130.0)	(117.7)	(90.1)
Net Income	(140.3)	(157.0)	(163.6)	(152.2)	(125.4)
EPS (SEK)	(0.3)	(0.4)	(0.4)	(0.3)	(0.3)
Net Cash	207.4	52.8	(72.2)	(184.9)	(270.1)

Source: R_x Securities estimates; *1 May 2020 to 31 December 2020, in January 2021 Oasmia's financial year-end changed from 30 April to 31 December

Consensus	2021E	2022E	2023E	2024E
Revenue	10.7	27.2	42.7	41.7
EBITDA	(110.9)	(114.8)	(123.9)	(140.0)

Source: Bloomberg

R_x Securities (www.rxsecurities.com) is authorised and regulated by the Financial Conduct Authority

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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 30 people. Oasmia is 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, and no compromise on efficacy. In 2018, Apealea[®] was approved in Europe in combination with carboplatin to treat advanced, first relapse, 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. Oasmia is in the process of launching Apealea[®] in the Nordic countries. In December 2020, Elevar sublicensed ex-Nordic European commercialisation rights to Apealea[®] to Inceptua Group, and we expect the first launches in ex-Nordic European countries in H2 2021. Elevar plans to initiate two new clinical trials of the drug in ovarian cancer (we expect in H2 2021) in the US to support a future NDA. Apealea[®] is a product of Oasmia's proprietary XR-17[™] platform, which improves the water solubility of active pharmaceutical ingredients (APIs). XR-17[™] has broad, global intellectual property protection out to 2036. The platform has yielded a second drug candidate, docetaxel micellar. We expect a Phase Ib trial of this drug in prostate cancer to start dosing in H1 2021. Oasmia is also developing follow-on technology platforms XR-18 (next-generation to XR-17[™]) and XR-19 (encapsulation of two APIs). In March 2021, Oasmia in-licensed cantrixil from Kazia Therapeutics, paying \$4 million upfront (Kazia is also eligible for milestones up to \$42 million plus double-digit royalties). Cantrixil has generated promising data in a Phase I trial in ovarian cancer and is slated to enter Phase II in 2022. Oasmia also has a veterinary subsidiary (AdvaVet, the Company plans to out-license or divest). Oasmia's shares are listed on Nasdaq Stockholm, and the Company has raised nearly SEK 1 billion since its 2005 IPO, most recently in December 2019 (SEK 399 million in a rights issue at SEK 2/share).

Investment Positives

Apealea[®] is approved in Europe, and we expect rollout over H2 2021

Apealea[®] is approved in Europe for use in combination with carboplatin to treat advanced, first relapse, platinum-sensitive ovarian cancer. The prescribing label does not mandate premedication with steroids (to prevent hypersensitivity reactions). This is an important advantage to standard paclitaxel in our view. Oasmia is marketing the drug in the Nordic countries, with the first sales recorded in Finland in November 2020. In the rest of Europe, Elevar has sublicensed commercialisation rights to Inceptua Group. We expect the first launches in ex-Nordic European countries in H2 2021. In the US, Elevar is planning to initiate two new trials of Apealea[®] in ovarian cancer (an ~12-month PK study and a 24–36 month pivotal efficacy study, both anticipated to commence in H2 2021) to support a future NDA, and we project launch in mid-2025. We forecast peak sales of Apealea[®] of \$275 million in first relapse, platinum-sensitive ovarian cancer in Europe and the US. However, we believe a higher sales potential is possible through geographic and label expansion.

Elevar and Abraxane® provide validation of the commercial opportunity

In March 2020, Oasmia signed a deal with Elevar Therapeutics for the 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®/Caelyx® (liposomal doxorubicin, achieved peak sales of over \$600 million in 2010 before going generic), Bristol-Myers Squibb's Abraxane® (albumin-bound paclitaxel, ~\$1.5 billion sales in 2020) and Ipsen's Onivyde® (liposomal irinotecan, over \$230 million sales in 2020).

Docetaxel micellar could be the subject of a major licensing deal

Docetaxel micellar is Oasmia's second XR-17™-generated product candidate. Results from previous Phase I and Phase II trials suggest this drug could have consistent efficacy with superior safety compared to the standard formulation of docetaxel (as well as not requiring corticosteroid premedication). A Phase Ib trial in advanced prostate cancer (where standard docetaxel is approved) is slated to start in H1 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 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.

Early data for cantrixil encouraging, and Oasmia is preparing for Phase II

In March 2021, Oasmia in-licensed a potential first-in-class cancer drug, cantrixil (targets cancer stem cells), from Kazia Therapeutics. In a Phase I trial, cantrixil elicited an 18% overall response (ORR) rate in 16 heavily pre-treated, advanced, relapsed, platinum-resistant/refractory/intolerant ovarian cancer patients, including a long-lasting complete response. We believe that this compares favourably to the ~10% ORRs observed historically with other agents in similar patients groups. We expect Oasmia to provide details on the design of a Phase II trial of cantrixil in H2 2021, which we expect to start in 2022.

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

Corticosteroids reduce the level of immune cells such as T cells circulating around tumours, which are necessary for the activity of immuno-oncology (IO) agents like the multi-blockbuster anti-PD-1 MAbs. Their use has been shown to dampen the effects of PD-1 inhibitors 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 7/share

Oasmia reported a gross cash position of SEK 219.5 million as of 31 March 2021, which we project finances the Company's operations into 2023. We forecast a growing income stream from Apealea® in the coming years. We 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 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 7/share, a ~133% upside to the current share price.

Investment Risks

Clinical risk of new Apealea[®] pivotal efficacy trial required for NDA

We believe that the US is commercially the most important market for Apealea[®]. Following discussions with the FDA, Elevar plans to initiate two further clinical studies of Apealea[®] in ovarian cancer (we expect in H2 2021) to support a future NDA. Elevar has stated that it expects a new pivotal efficacy trial to determine the superiority of Apealea[®] to standard paclitaxel. We note that this is a higher hurdle than set by the previous pivotal trial, which used a non-inferiority (on progression-free survival) primary endpoint. Demonstrating superiority would facilitate an enhanced product label and a marketing advantage, but it also increases the risk of the trial's failure.

Our forecasts for Apealea[®] may not be achieved

We forecast peak sales of Apealea[®] of \$275 million in advanced, first relapse, platinum-sensitive ovarian cancer in Europe and the US. 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. However, we believe there is no near-term competitive threat that could ultimately lead to lower peak sales of Apealea[®] than we have forecast.

Development of docetaxel micellar may not be successful

We expect Oasmia to start dosing in a Phase Ib trial of docetaxel micellar in advanced prostate cancer in H1 2021. 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. Our valuation of Oasmia incorporates SEK 2.5/share for docetaxel micellar, and we, therefore, believe that negative clinical trial data could have a significant detrimental impact on the Company's share price. We believe there is also a risk that further development of cantrixil may not be successful. However, this asset represents an upside option in our valuation of Oasmia at this time.

The XR-19 platform is early and may not reach a clinical stage

Oasmia's XR-19 programme for the encapsulation of two APIs within the same micelle delivery vehicle is still at an early stage. The Company has internally generated positive preclinical data for XR-19, though these results are yet to be published. Further internal studies are underway, and Oasmia has recently commented that XR-19 may be directed to non-oncology indications (in oncology, dosing by body weight or surface area would complicate dual formulations). We believe that there is a risk that the ongoing preclinical studies may not 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 31 December ¹	2020A*	2021E	2022E	2023E	2024E	2025E	2026E	2027E
Revenue	0.5	13.4	36.4	44.2	82.2	136.9	192.4	255.8
Apealea [®] sales	-	2.1	7.4	14.3	22.0	27.0	30.2	32.3
Apealea [®] royalties	0.1	1.3	9.0	20.0	44.0	83.8	127.3	184.7
Milestones	-	-	-	-	-	-	-	-
Other	0.4	10.0	20.0	9.9	16.1	26.1	34.9	38.7
Cost of sales ²	21.7	(9.3)	(18.4)	(9.6)	(15.6)	(24.9)	(32.9)	(36.5)
Gross Profit	22.2	4.2	18.0	34.5	66.6	112.1	159.4	219.3
Operating Costs	(156.1)	(154.9)	(174.9)	(180.0)	(185.2)	(190.6)	(196.1)	(201.8)
Raw material costs	(4.1)	(4.4)	(6.0)	(6.0)	(6.0)	(6.0)	(6.0)	(6.0)
Other ext. expenses	(77.6)	(81.3)	(92.0)	(94.8)	(97.6)	(100.5)	(103.5)	(106.7)
Employee expenses	(45.5)	(43.2)	(50.0)	(51.5)	(53.0)	(54.6)	(56.3)	(58.0)
D&A and impairment	(28.9)	(26.1)	(26.9)	(27.7)	(28.6)	(29.4)	(30.3)	(31.2)
Other operat. income	2.5	0.7	-	-	-	-	-	-
Operating Profit	(131.5)	(150.0)	(156.9)	(145.4)	(118.6)	(78.5)	(36.7)	17.5
EBITDA	(102.6)	(123.9)	(130.0)	(117.7)	(90.1)	(49.1)	(6.4)	48.7
Net Financial Income	(8.8)	(7.0)	(6.7)	(6.7)	(6.7)	(6.7)	(6.7)	(6.7)
Profit Before Tax	(140.3)	(157.0)	(163.6)	(152.2)	(125.4)	(85.2)	(43.4)	10.8
Tax	-	-	-	-	-	-	-	-
Net Income	(140.3)	(157.0)	(163.6)	(152.2)	(125.4)	(85.2)	(43.4)	10.8
EPS (SEK)	(0.3)	(0.4)	(0.4)	(0.3)	(0.3)	(0.2)	(0.1)	0.0
No. of Shares (m)	448.4	448.4	448.4	448.4	448.4	448.4	448.4	448.4
Gross cash	287.4	132.8	7.8	(104.9)	(190.1)	(234.4)	(236.0)	(182.5)
Debt ³	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0
Net cash	207.4	52.8	(72.2)	(184.9)	(270.1)	(314.4)	(316.0)	(262.5)

Source: Company data, Rx Securities estimates; *shortened financial year from 1 May 2020 to 31 December 2020; 1 = from January 2021 Oasmia's financial year-end changed from 30 April to 31 December; 2 = includes changes in inventories (MSEK 21.7 in 2020*); 3 = debt of MSEK 80 is in dispute

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 Q1 2022;
- We assume first royalties from Apealea[®] sales in other European countries in H2 2021 and the US in 2025;
- 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 2023, 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 31 December	Q1 21A	Q2 21E	Q3 21E	Q4 21E	2021E	Q1 22E	Q2 22E	Q3 22E	Q4 22E	2022E
Revenue	0.0	2.4	4.2	6.8	13.4	7.5	8.4	9.5	11.0	36.4
Apealea® sales	-	0.4	0.7	1.0	2.1	1.3	1.6	2.0	2.5	7.4
Apealea® royalties	0.0	-	0.5	0.8	1.3	1.2	1.8	2.5	3.5	9.0
Milestones	-	-	-	-	-	-	-	-	-	-
Other	-	2.0	3.0	5.0	10.0	5.0	5.0	5.0	5.0	20.0
Cost of sales	(0.2)	(1.8)	(2.7)	(4.6)	(9.3)	(4.6)	(4.6)	(4.6)	(4.6)	(18.4)
Gross Profit	(0.1)	0.6	1.5	2.3	4.2	2.9	3.8	4.9	6.4	18.0
Operating Costs	(41.4)	(37.5)	(38.5)	(37.5)	(154.9)	(43.3)	(43.2)	(44.2)	(44.2)	(174.9)
Raw material costs	0.1	(1.5)	(1.5)	(1.5)	(4.4)	(1.5)	(1.5)	(1.5)	(1.5)	(6.0)
Other ext. expenses	(23.3)	(18.0)	(20.0)	(20.0)	(81.3)	(22.0)	(22.0)	(24.0)	(24.0)	(92.0)
Employee expenses	(11.2)	(11.0)	(11.0)	(10.0)	(43.2)	(12.5)	(12.5)	(12.5)	(12.5)	(50.0)
D&A and impairment	(7.1)	(7.0)	(6.0)	(6.0)	(26.1)	(7.3)	(7.2)	(6.2)	(6.2)	(26.9)
Other operat. income	0.7	-	-	-	0.7	-	-	-	-	-
Operating Profit	(40.8)	(36.9)	(37.0)	(35.3)	(150.0)	(40.4)	(39.4)	(39.3)	(37.8)	(156.9)
EBITDA	(33.7)	(29.9)	(31.0)	(29.3)	(123.9)	(33.1)	(32.2)	(33.1)	(31.6)	(130.0)
Net Financial Income	(0.4)	(1.7)	(1.7)	(1.7)	(7.0)	(1.7)	(1.7)	(1.7)	(1.7)	(6.7)
Profit Before Tax	(41.2)	(38.6)	(38.7)	(36.9)	(157.0)	(42.1)	(41.1)	(41.0)	(39.5)	(163.6)
Tax	-	-	-	-	-	-	-	-	-	-
Net Income	(41.2)	(38.6)	(38.7)	(36.9)	(157.0)	(42.1)	(41.1)	(41.0)	(39.5)	(163.6)
EPS (SEK)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)
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	219.5	190.7	160.9	132.8	132.8	101.3	70.2	38.3	7.8	7.8
Debt	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0
Net cash	139.5	110.7	80.9	52.8	52.8	21.3	(9.8)	(41.7)	(72.2)	(72.2)

Source: Company data, Rx Securities estimates;

Forecast News Flow

Table 3: Oasmia Pharmaceutical's forecast news flow

Timing	Expected News	Programme
H1 2021	Phase Ib trial in prostate cancer to start dosing	Docetaxel micellar
H2 2021	Potential launch in Europe (ex-Nordics)	Apealea®
H2 2021	Start of a US pharmacokinetics study	Apealea®
H2 2021	Start of a US pivotal efficacy trial in epithelial ovarian cancer	Apealea®
H2 2021	Journal publication of the full Phase I ovarian cancer trials results	Cantrixil
H2 2021	Potential update on Phase II trial design	Cantrixil
19 August 2021	Q2 results	
18 November 2021	Q3 results	
2021	Potential transaction regarding AdvaVet business or its key drugs	
2021–2022	Updates on the programme, potentially with a target indication	XR-19
2021–2022	Updates on the programme	XR-18
2022	Start of Phase II trial	Cantrixil

Source: Company data, Rx Securities estimates

Important Disclosures

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