19 August 2021

Oasmia Pharmaceutical AB

Q2 results update

Oasmia Pharmaceutical has announced Q2 results that are broadly in line with our expectations. The Company reported a cash position at the end of Q2 of SEK 176.3 million vs our SEK 190.4 million forecast (difference due to working capital), and we continue to project a cash runway for Oasmia into 2023. There are no significant new developments reported today. We continue to await news from Oasmia's partner Inceptua Pharma regarding its planned European launch of Apealea® (an enhanced formulation of paclitaxel for ovarian cancer and Oasmia's key value-driver), which we currently assume to occur during H2 2021. Meanwhile, we continue to expect Oasmia's partner Elevar Therapeutics' to initiate two new clinical trials of Apealea® in the US during H2 (a pharmacokinetic study and a Phase III pivotal trial) to support a future NDA. Beyond Apealea®, in June positive Phase I results for the Company's cancer stem cell targeting drug cantrixil were published in the peer-reviewed journal, Cancers. Management has begun interactions with the FDA and EMA and we continue to expect an update on the Phase II plan for cantrixil later this year and for a trial to start in 2022. Oasmia is hosting a conference call today to discuss its Q2 results at 10am CEST (dial-in +443333009269). We maintain our BUY rating and fair value of SEK 7/share.

- **Phase Ib trial of docetaxel micellar in mCRPC ongoing** – up to 18 chemotherapy-naïve mCRPC patients are to be recruited into this open-label, 3+3 design dose-escalation trial. Patients are to be treated with up to 10, 21-day cycles of one of three dose levels of docetaxel. The primary aim 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.

- **Cantrixil to move to Phase II with positive Phase I data published** – in the peer-reviewed journal, Cancers. The maximum-tolerated dose was 5mg/kg and in 16 patients evaluable for efficacy, monotherapy yielded a stable disease rate of 56% while combination with chemotherapy produced an objective response rate of 19% (including one patient with a complete response ongoing over three years). We note this compares favourably to the ~10% observed historically with other agents in similar patient groups. Median progression-free survival was 13.1 weeks, rising to 19.4 weeks in platinum-resistant and -refractory patients (n=11).

Price	SEK 2.72
Fair value	SEK 7
Market capitalisation	SEK 1,221 million
Enterprise value	SEK 1,180 million
12m high/low	SEK 5.46 / SEK 2.72
Avg. daily volume	3.0m
Bloomberg / Reuters	OASM SS / OASM.ST
Exchange	Stockholm
Adviser	Yes
Next results (Q3)	18 November 2021

Top 5 Shareholders

Per Arwidsson	*24.8%*
Avanza Pension	*6.1%*
Nordnet Pension Insurance	*2.5%*
Mastan AB (Håkan Lagerberg)	*2.0%*
Swedbank Insurance	*1.5%*

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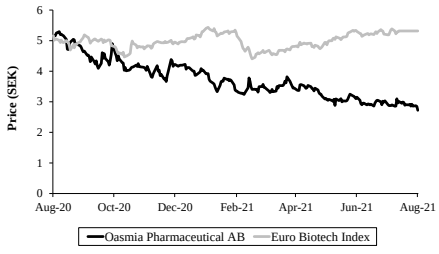
Share price performance (1 year)



Source: Rx Securities

Key financial data (MSEK) – IFRS

Y/E 30 Apr	2020A*	2021E	2022E	2023E	2024E
Revenue	0.5	15.4	29.0	29.9	63.5
EBITDA	(102.6)	(143.4)	(125.0)	(118.9)	(95.0)
Net Income	(140.3)	(179.4)	(161.3)	(156.1)	(133.1)
EPS (SEK)	(0.3)	(0.4)	(0.4)	(0.3)	(0.3)
Net Cash	207.4	40.9	(79.3)	(193.5)	(283.8)

Source: Rx 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	14.6	41.2	54.2	82.2
EBITDA	(125.3)	(110.3)	(108.8)	(101.0)

Source: Bloomberg

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 25 people. Oasmia's key value-driver is Apealea®, a novel formulation of paclitaxel that was approved in Europe in 2018 to be used in combination with carboplatin for the treatment of advanced, first relapse, platinum-sensitive ovarian cancer. 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 March 2020, Oasmia signed a major deal with Elevar Therapeutics for global (ex-Nordic) rights to Apealea®, which included an upfront payment of $20 million, eligibility for up to $678 million in milestones, plus royalties on sales. In December 2020, Elevar sublicensed ex-Nordic European commercialisation rights to Apealea® to Inceptua Group. In June 2021, Oasmia transferred Nordic rights to the drug to Inceptua. We expect Inceptua to launch Apealea® in Europe 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. A Phase Ib trial of this drug in prostate cancer is ongoing and slated to readout in 2023. 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's partner Elevar has sublicensed commercialisation rights to Apealea® in Europe to Inceptua Group. We expect Inceptua to conduct the first European country launches of the drug 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®/Caelylyx® (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 ongoing and we expect results in 2023. 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 attract 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. Phase I results have been published. The maximum-tolerated dose was 5mg/kg and in 16 patients evaluable for efficacy, monotherapy yielded a stable disease rate of 56% while combination with chemotherapy led to a 19% objective response rate (including one CR lasting over three years). We note this compares favourably to the ~10% observed historically with other agents in similar patient 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 176.3 million as of 30 June 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 ~157% 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

A Phase Ib trial of docetaxel micellar in advanced prostate cancer is ongoing. 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**	**15.4**	**29.0**	**29.9**	**63.5**	**113.9**	**166.7**	**228.3**
Apealea® royalties	0.1	1.4	9.0	20.0	47.3	87.8	131.8	189.6
Milestones	-	-	-	-	-	-	-	-
Other	0.4	14.1	20.0	9.9	16.1	26.1	34.9	38.7
Cost of sales[2]	21.7	(31.3)	(18.0)	(8.9)	(14.5)	(23.5)	(31.4)	(34.8)
Gross Profit	**22.2**	**(15.9)**	**11.0**	**21.0**	**48.9**	**90.4**	**135.3**	**193.5**
Operating Costs	**(156.1)**	**(158.6)**	**(165.6)**	**(170.4)**	**(175.3)**	**(180.4)**	**(185.6)**	**(191.0)**
Raw material costs	(4.1)	(3.3)	(6.0)	(6.0)	(6.0)	(6.0)	(6.0)	(6.0)
Other ext. expenses	(77.6)	(83.9)	(86.0)	(88.6)	(91.2)	(94.0)	(96.8)	(99.7)
Employee expenses	(45.5)	(42.6)	(44.0)	(45.3)	(46.7)	(48.1)	(49.5)	(51.0)
D&A and impairment	(28.9)	(28.7)	(29.6)	(30.5)	(31.4)	(32.3)	(33.3)	(34.3)
Other operat. income	2.5	2.3	-	-	-	-	-	-
Operating Profit	**(131.5)**	**(172.2)**	**(154.6)**	**(149.4)**	**(126.4)**	**(89.9)**	**(50.3)**	**2.5**
EBITDA	**(102.6)**	**(143.4)**	**(125.0)**	**(118.9)**	**(95.0)**	**(57.6)**	**(17.0)**	**36.8**
Net Financial Income	(8.8)	(7.2)	(6.7)	(6.7)	(6.7)	(6.7)	(6.7)	(6.7)
Profit Before Tax	**(140.3)**	**(179.4)**	**(161.3)**	**(156.1)**	**(133.1)**	**(96.7)**	**(57.0)**	**(4.3)**
Tax	-	-	-	-	-	-	-	-
Net Income	**(140.3)**	**(179.4)**	**(161.3)**	**(156.1)**	**(133.1)**	**(96.7)**	**(57.0)**	**(4.3)**
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**	**120.9**	**0.7**	**(113.5)**	**(203.8)**	**(256.8)**	**(269.2)**	**(227.9)**
Debt[3]	80.0	80.0	80.0	80.0	80.0	80.0	80.0	80.0
Net cash	**207.4**	**40.9**	**(79.3)**	**(193.5)**	**(283.8)**	**(336.8)**	**(349.2)**	**(307.9)**

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 21A	Q3 21E	Q4 21E	2021E	Q1 22E	Q2 22E	Q3 22E	Q4 22E	2022E
Revenue	**0.0**	**4.6**	**5.0**	**5.8**	**15.4**	**6.2**	**6.8**	**7.5**	**8.5**	**29.0**
Apealea® sales	-	-	-	-	-	-	-	-	-	-
Apealea® royalties	0.0	0.0	0.5	0.8	1.4	1.2	1.8	2.5	3.5	9.0
Milestones	-	-	-	-	-	-	-	-	-	-
Other	-	4.6	4.5	5.0	14.1	5.0	5.0	5.0	5.0	20.0
Cost of sales	(0.2)	(22.6)	(4.1)	(4.5)	(31.3)	(4.5)	(4.5)	(4.5)	(4.5)	(18.0)
Gross Profit	**(0.1)**	**(18.0)**	**1.0**	**1.3**	**(15.9)**	**1.7**	**2.3**	**3.0**	**4.0**	**11.0**
Operating Costs	**(41.4)**	**(39.8)**	**(38.7)**	**(38.7)**	**(158.6)**	**(40.8)**	**(40.9)**	**(41.9)**	**(41.9)**	**(165.6)**
Raw material costs	0.1	(0.4)	(1.5)	(1.5)	(3.3)	(1.5)	(1.5)	(1.5)	(1.5)	(6.0)
Other ext. expenses	(23.3)	(20.7)	(20.0)	(20.0)	(83.9)	(21.0)	(21.0)	(22.0)	(22.0)	(86.0)
Employee expenses	(11.2)	(11.4)	(10.0)	(10.0)	(42.6)	(11.0)	(11.0)	(11.0)	(11.0)	(44.0)
D&A and impairment	(7.1)	(7.2)	(7.2)	(7.2)	(28.7)	(7.3)	(7.4)	(7.4)	(7.4)	(29.6)
Other operat. income	0.7	1.5	-	-	2.3	-	-	-	-	-
Operating Profit	**(40.8)**	**(56.2)**	**(37.8)**	**(37.4)**	**(172.2)**	**(39.1)**	**(38.6)**	**(38.9)**	**(37.9)**	**(154.6)**
EBITDA	**(33.7)**	**(49.0)**	**(30.6)**	**(30.2)**	**(143.4)**	**(31.8)**	**(31.2)**	**(31.5)**	**(30.5)**	**(125.0)**
Net Financial Income	(0.4)	(1.5)	(1.7)	(1.7)	(7.2)	(1.7)	(1.7)	(1.7)	(1.7)	(6.7)
Profit Before Tax	**(41.2)**	**(57.7)**	**(39.4)**	**(39.1)**	**(179.4)**	**(40.8)**	**(40.3)**	**(40.6)**	**(39.6)**	**(161.3)**
Tax	-	-	-	-	-	-	-	-	-	-
Net Income	**(41.2)**	**(57.7)**	**(39.4)**	**(39.1)**	**(179.4)**	**(40.8)**	**(40.3)**	**(40.6)**	**(39.6)**	**(161.3)**
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**	**176.3**	**148.9**	**120.9**	**120.9**	**90.6**	**60.4**	**30.0**	**0.7**	**0.7**
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**	**96.3**	**68.9**	**40.9**	**40.9**	**10.6**	**(19.6)**	**(50.0)**	**(79.3)**	**(79.3)**

Source: Company data, Rx Securities estimates;

Forecast News Flow

Table 3: Oasmia Pharmaceutical's forecast news flow

Timing	Expected News	Programme
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	Potential update on Phase II trial design	Cantrixil
18 November 2021	Q3 results	
2021–2022	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

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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