Company Update

BUY

Oasmia Pharmaceutical AB

18 November 2021

Q3 results update

Oasmia Pharmaceutical has announced Q3 results that are in line with our expectations. The Company reported a net loss of SEK 31.0 million vs our SEK 38.9 million estimate (lower operating expenses than our forecasts) and ended Q3 with a cash position of SEK 149.7 million vs our SEK 149.5 million forecast. Post period in October, the Company settled a number of legal disputes for a net cash outflow of SEK 24.5 million (we believe a good result given the much higher potential liability) and we now project a cash runway for Oasmia into Q4 2022 (previously Q1 2023). Oasmia has been informed that partner Inceptua Pharma's launch planning activities for Apealea® (an enhanced formulation of paclitaxel for ovarian cancer) in Europe are underway and launches in first European countries are expected in H1 2022. We have revised our model to reflect this timeline (we previously estimated H2 2021). Regarding US development of Apealea®, Oasmia's partner Elevar Therapeutics is reviewing the clinical and regulatory pathway for Apealea® in the US in order to maximise its commercial potential. This may impact development timelines and we now believe it is unlikely that new trials in the US will commence in 2021. We await further updates from Elevar. We continue to project a US launch for Apealea® in 2025 at this time, though now caution our projection could slip. Oasmia's communication on cantrixil Phase II plans has been delayed by efforts to secure drug supply, though we continue to expect a trial starting in 2022. We maintain our BUY rating and reduce our fair value to SEK 5.5/share, primarily reflecting the delayed European launch of Apealea®.

- **"Excellent progress" in recruitment for Phase Ib trial of docetaxel micellar** – in metastatic castration-resistant prostate cancer (mCRPC). The Company expects that recruitment of up to 18 chemotherapy-naïve mCRPC patients should be completed by the end of 2022. Patients are 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.

- **XR-19 development ended** – this technology platform is for encapsulation of two drugs into one micelle delivery vehicle. Oasmia stated that encouraging preclinical proof-of-concept has been generated, but it believes XR-19's commercial utility is limited and the Company will focus on other opportunities.

Price	SEK 2.23
Fair value	SEK 5.5
Market capitalisation	SEK 999 million
Enterprise value	SEK 903 million
12m high/low	SEK 4.59 / SEK 2.06
Avg. daily volume	2.1m
Bloomberg / Reuters	OASM SS / OASM.ST
Exchange	Stockholm
Adviser	Yes
Next results (FY)	24 February 2022

Top 5 Shareholders

Per Arwidsson	*24.8%*
Avanza Pension	*5.7%*
Nordnet Pension Insurance	*2.5%*
Mastan AB (Håkan Lagerberg)	*2.0%*
Swedbank Insurance	*1.7%*

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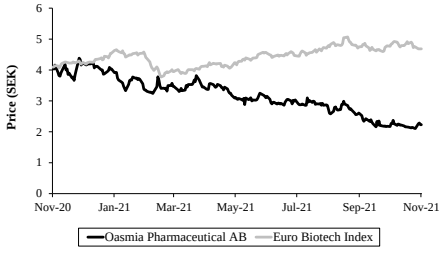
Share price performance (1 year)



Source: R_x Securities

Key financial data (MSEK) – IFRS

Y/E 30 Apr	2020A*	2021E	2022E	2023E	2024E
Revenue	0.5	21.6	23.5	19.5	39.2
EBITDA	(102.6)	(102.4)	(124.5)	(118.8)	(107.4)
Net Income	(140.3)	(137.0)	(154.1)	(149.3)	(138.9)
EPS (SEK)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
Net Cash	207.4	96.2	(29.7)	(149.9)	(258.8)

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	21.6	40.2	53.5	39.2
EBITDA	(102.4)	(112.0)	(115.0)	(107.4)

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 2022. Meanwhile, Elevar is currently planning the clinical development path to support an NDA in the US, and we await further updates. 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 a next-generation follow on platform to XR-17™, XR-18. 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 launch in Q2 2022

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 Q2 2022. In the US, Elevar has stated that it is reviewing the clinical and regulatory pathway for Apealea® in order to maximize the product's commercial potential. The company had previously announced two new trials of Apealea® in ovarian cancer (an ~12-month PK study and a 24–36 month pivotal efficacy study) to support a future NDA. We expect new trials of the drug to support an NDA to start in 2022. We project US launch of Apealea® in 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 equivalent 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 initiate a Phase II trial of cantrixil in H1 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.

Oasmia's shares trade below our fair value of SEK 5.5/share

While Oasmia is operating in the historically high-risk oncology segment of drug development, we believe the Company's current share price does not appropriately reflect the commercial potential of Apealea®, docetaxel micellar, or its XR-17™ platform. From a valuation perspective, we view Apealea® and docetaxel micellar as Oasmia's key value-drivers, accounting for SEK 2/share each of our SEK 5.5/share valuation for the Company, which represents a ~150% upside from 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®. Elevar is reviewing the clinical and regulatory pathway for Apealea® in the US. The company had previously announced two new clinical trials to support an NDA (we expect new studies in 2022). One of these trials would be a new pivotal efficacy trial to determine the superiority of Apealea® to standard paclitaxel, which we note is a higher hurdle than set by the previous pivotal trial (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-18 platform is early and may not reach a clinical stage

Oasmia's XR-18 programme is to develop an improved, next-generation version of its XR-17™ drug formulation platform and could be used to reformulate cantrixil. While XR-17™ has been validated by an approved drug (Apealea®), XR-18 remains at an early stage of development, with preclinical proof-of-concept data not yet announced. We believe that there is a risk that the ongoing preclinical studies may not yield a drug candidate for clinical trials.

We anticipate Oasmia requiring further capital in the future

With cash of SEK 149.7 million at the end of Q3 and having settled multiple lawsuits recently, we project that Oasmia currently has a cash runway into Q4 2022. We anticipate the Company needing to raise significant additional capital to reach key milestones such as completing the Phase Ib trial of docetaxel micellar and planned Phase I trial of cantrixil. We anticipate Oasmia conducting further equity capital raises and potentially raising cash through the sale of its veterinary subsidiary. A licensing deal for docetaxel micellar could also generate cash, though we expect further positive clinical data are required to attract a partner.

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**	**21.6**	**23.5**	**19.5**	**39.2**	**80.3**	**144.5**	**240.4**
Apealea® royalties	0.1	0.1	3.5	14.5	29.2	64.1	118.3	205.5
Milestones	-	-	-	-	-	-	-	-
Other	0.4	21.4	20.0	5.0	9.9	16.2	26.2	35.0
Cost of sales[2]	21.7	(39.5)	(18.0)	(4.5)	(8.9)	(14.6)	(23.6)	(31.5)
Gross Profit	**22.2**	**(17.9)**	**5.5**	**15.0**	**30.2**	**65.8**	**120.9**	**209.0**
Operating Costs	**(156.1)**	**(152.5)**	**(159.7)**	**(164.3)**	**(169.1)**	**(174.1)**	**(179.2)**	**(184.5)**
Raw material costs	(4.1)	(0.7)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0)
Other ext. expenses	(77.6)	(79.9)	(86.0)	(88.6)	(91.2)	(94.0)	(96.8)	(99.7)
Employee expenses	(45.5)	(43.0)	(40.0)	(41.2)	(42.4)	(43.7)	(45.0)	(46.4)
D&A and impairment	(28.9)	(28.8)	(29.7)	(30.6)	(31.5)	(32.4)	(33.4)	(34.4)
Other operat. income	2.5	39.1	-	-	-	-	-	-
Operating Profit	**(131.5)**	**(131.2)**	**(154.1)**	**(149.3)**	**(138.9)**	**(108.3)**	**(58.3)**	**24.5**
EBITDA	**(102.6)**	**(102.4)**	**(124.5)**	**(118.8)**	**(107.4)**	**(75.9)**	**(24.9)**	**58.9**
Net Financial Income	(8.8)	(5.7)	-	-	-	-	-	-
Profit Before Tax	**(140.3)**	**(137.0)**	**(154.1)**	**(149.3)**	**(138.9)**	**(108.3)**	**(58.3)**	**24.5**
Tax	-	-	-	-	-	-	-	-
Net Income	**(140.3)**	**(137.0)**	**(154.1)**	**(149.3)**	**(138.9)**	**(108.3)**	**(58.3)**	**24.5**
EPS (SEK)	**(0.3)**	**(0.3)**	**(0.3)**	**(0.3)**	**(0.3)**	**(0.2)**	**(0.1)**	**0.1**
No. of Shares (m)	448.4	448.4	448.4	448.4	448.4	448.4	448.4	448.4
Gross cash	**287.4**	**96.2**	**(29.7)**	**(149.9)**	**(258.8)**	**(336.3)**	**(362.8)**	**(305.5)**
Debt	80.0	-	-	-	-	-	-	-
Net cash	**207.4**	**96.2**	**(29.7)**	**(149.9)**	**(258.8)**	**(336.3)**	**(362.8)**	**(305.5)**

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*)

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 2022 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 Q4 2022, 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 21A	Q4 21E	2021E	Q1 22E	Q2 22E	Q3 22E	Q4 22E	2022E
Revenue	**0.0**	**4.6**	**11.9**	**5.0**	**21.6**	**5.0**	**5.5**	**6.0**	**7.0**	**23.5**
Apealea® royalties	0.0	0.0	0.0	0.0	0.1	0.0	0.5	1.0	2.0	3.5
Milestones	-	-	-	-	-	-	-	-	-	-
Other	-	4.6	11.9	5.0	21.4	5.0	5.0	5.0	5.0	20.0
Cost of sales	(0.2)	(22.6)	(12.2)	(4.5)	(39.5)	(4.5)	(4.5)	(4.5)	(4.5)	(18.0)
Gross Profit	**(0.1)**	**(18.0)**	**(0.3)**	**0.5**	**(17.9)**	**0.5**	**1.0**	**1.5**	**2.5**	**5.5**
Operating Costs	**(41.4)**	**(39.8)**	**(33.6)**	**(37.7)**	**(152.5)**	**(39.3)**	**(39.4)**	**(40.5)**	**(40.4)**	**(159.7)**
Raw material costs	0.1	(0.4)	0.1	(0.5)	(0.7)	(1.0)	(1.0)	(1.0)	(1.0)	(4.0)
Other ext. expenses	(23.3)	(20.7)	(16.0)	(20.0)	(79.9)	(21.0)	(21.0)	(22.0)	(22.0)	(86.0)
Employee expenses	(11.2)	(11.4)	(10.4)	(10.0)	(43.0)	(10.0)	(10.0)	(10.0)	(10.0)	(40.0)
D&A and impairment	(7.1)	(7.2)	(7.3)	(7.2)	(28.8)	(7.3)	(7.4)	(7.5)	(7.4)	(29.7)
Other operat. income	0.7	1.5	4.4	32.5	39.1	-	-	-	-	-
Operating Profit	**(40.8)**	**(56.2)**	**(29.6)**	**(4.7)**	**(131.2)**	**(38.8)**	**(38.4)**	**(39.0)**	**(37.9)**	**(154.1)**
EBITDA	**(33.7)**	**(49.0)**	**(22.3)**	**2.5**	**(102.4)**	**(31.5)**	**(31.0)**	**(31.5)**	**(30.5)**	**(124.5)**
Net Financial Income	(0.4)	(1.5)	(1.4)	-	(5.7)	-	-	-	-	-
Profit Before Tax	**(41.2)**	**(57.7)**	**(31.0)**	**(4.7)**	**(137.0)**	**(38.8)**	**(38.4)**	**(39.0)**	**(37.9)**	**(154.1)**
Tax	-	-	-	-	-	-	-	-	-	-
Net Income	**(41.2)**	**(57.7)**	**(31.0)**	**(4.7)**	**(137.0)**	**(38.8)**	**(38.4)**	**(39.0)**	**(37.9)**	**(154.1)**
EPS (SEK)	**(0.1)**	**(0.1)**	**(0.1)**	**(0.0)**	**(0.3)**	**(0.1)**	**(0.1)**	**(0.1)**	**(0.1)**	**(0.3)**
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**	**149.7**	**96.2**	**96.2**	**64.6**	**32.9**	**1.4**	**(29.7)**	**(29.7)**
Debt	80.0	80.0	80.0	-	-	-	-	-	-	-
Net cash	**139.5**	**96.3**	**69.7**	**96.2**	**96.2**	**64.6**	**32.9**	**1.4**	**(29.7)**	**(29.7)**

Source: Company data, Rx Securities estimates;

Forecast News Flow

Table 3: Oasmia Pharmaceutical's forecast news flow

Timing	Expected News	Programme
Q4 2021–2022	Potential transaction regarding AdvaVet business or its key drugs	
Q4 2021–2022	Updates on the programme	XR-18
H1 2022	Potential update on Phase II trial design	Cantrixil
H1 2022	Start of Phase II trial	Cantrixil
24 February 2022	FY 2021 results update	
Q2 2022	Launch in Europe	Apealea®
2022	Start of a US pharmacokinetics study	Apealea®
2022	Start of a US pivotal efficacy trial in epithelial ovarian cancer	Apealea®

Source: Company data, R_X Securities estimates

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