EDISON

Oasmia Pharmaceutical

Interim results

Clarity on pathway to US approval

Pharma & biotech

Oasmia's H1 FY21 results highlight recent developments made to realign the business. In December, global partner Elevar Therapeutics announced it had concluded discussions with the FDA on the pathway to US approval for Apealea (Cremophor-free paclitaxel) in ovarian cancer. The FDA has stated it requires two additional trials to form the basis of the NDA submission. We have delayed our forecast US launch by two years to 2025, which means our forecast timeframe to maiden profitability has now shifted to 2025. In Europe (ex-Nordics), Elevar is in final-round discussions for a distribution partner and has signed an agreement with Taiba Middle East FZ for the Middle East and North Africa (MENA) region. Our revised valuation of Oasmia is SEK2.42bn or SEK5.41/share.

Year end	Revenue (SEKm)	PBT* (SEKm)	EPS* (SEK)	DPS (SEK)	P/E (x)	Yield (%)
04/19	2.0	(168.5)	(0.7)	0.00	N/A	N/A
04/20	201.8	(43.4)	0.0	0.00	N/A	N/A
04/21e	0.8	(170.1)	(0.3)	0.00	N/A	N/A
04/22e	8.9	(149.9)	(0.3)	0.00	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Two additional studies required for the US NDA

Elevar has established a clear pathway for the US regulatory submission for Apealea. Two additional studies are required to enable the NDA filing; this includes a pharmacokinetic (PK) study that will take ~12 months to complete and a pivotal Phase III superiority study to demonstrate Apealea safety and efficacy in second-line epithelial ovarian cancer (expected to take 24–36 months to complete). Elevar will fund both and aim to start them in the first half of 2021. We now forecast launch at end 2025 (vs 2023), assuming the Phase III study completes recruitment by mid-2022. Establishing superiority is a higher risk strategy but, if confirmed, could lead to improved reimbursement and higher uptake in the US and other key territories.

Apealea first sales despite COVID-19 headwind

Oasmia reported first sales and treatment of a patient with Apealea in Finland during the period, a milestone in the Nordics. However, in Denmark, the negative outcome of the compulsory Health Technology Assessment (HTA) application due to a lack of health economic data has stalled reimbursement negotiations. Oasmia is working on alternatives to generate clinical data. Elevar has secured a partner in MENA and we expect additional regional partnerships will be announced in 2021.

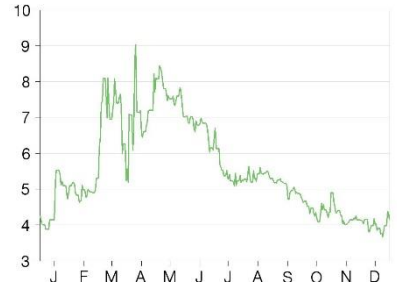
Valuation: SEK2.42bn or SEK5.41/share

Our revised valuation is SEK2.42bn (SEK5.41/share) versus SEK2.82bn (SEK6.29/share) previously. The main effect is the delay of Apealea US launch and we maintain our peak sales forecasts but push them out to 2030. Our valuation includes net cash of SEK249.6m plus rNPV for Apealea (ovarian cancer), docetaxel micellar (prostate cancer) and an indicative value for the animal health business. We do not include the XR-17 platform or other cancer indications in our valuation.

17 December 2020

Price	**SEK4.16**
Market cap	**SEK1,865m**
	$0.12/SEK
Net cash (SEKm) at 31 October 2020 (including short-term investments)	249.6
Shares in issue	448.4m
Free float	75%
Code	OASM
Primary exchange	Stockholm
Secondary exchange	Frankfurt

Share price performance



%	1m	3m	12m
Abs	0.7	(11.3)	(1.9)
Rel (local)	(0.1)	(15.4)	(12.9)
52-week high/low	SEK9.03	SEK3.66	

Business description

Oasmia Pharmaceutical is a Swedish speciality pharma company focusing on its proprietary XR-17 technology platform to develop novel formulations of well-established cytostatic oncology treatments for human and animal health. Key assets include Apealea (partnered with Elevar) and Docetaxel micellar.

Next events

Apealea EU commercialisation partner	2020/21
Start of Apealea PK study in the US	H121
Start of Apealea pivotal Phase III superiority study in the US	H121

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Edison profile page

Longer timeline to Apealea US approval

Oasmia's key asset Apealea is a water-soluble, intravenous formulation of paclitaxel that is solvent free (no Cremophor EL solubilising agent used in Taxol). This is a particularly attractive value proposition as it significantly improves on the profile of a widely used chemotherapeutic agent with lower infusion time and removal of mandatory corticosteroid premedication versus conventional paclitaxel (Taxol). Apealea received approval in the EU for the treatment of second-line platinum-sensitive ovarian cancer in 2018. The deal with Elevar Therapeutics means the worldwide commercialisation of Apealea (ex-Nordics, Baltics, Kazakhstan and the Russian Federation) is now mainly in the hands of a partner, which will enable Oasmia to focus on its core drug development competencies and new strategic focuses.

Two additional trials required for Apealea NDA submission

Following discussions with the FDA, Elevar has now outlined the pathway to regulatory submission in the US for Apealea and will complete two additional studies before filing an NDA. The first is a PK study that will take ~12 months to complete. The second is a pivotal Phase III superiority study in second-line epithelial ovarian cancer to demonstrate Apealea safety and efficacy and is expected to take 24–36 months to complete. Elevar will initiate the two additional trials required during the first half of 2021 and is responsible for the full funding of both. Elevar will work closely with the GOG foundation to plan and execute the Phase III study. Elevar is still finalising the trial design but it will likely compare Apealea versus paclitaxel in combination with platinum chemotherapy (potentially with/without Avastin), which is the current standard of care in second-line platinum sensitive ovarian cancer. We note that Apealea non-inferiority in PFS and OS versus paclitaxel was successfully demonstrated in combination with carboplatin in the Phase III OAS-07OVA study that led to EU approval in 2018 (for further details see our initiation report, An appealing metamorphosis). Establishing superiority is a higher-risk strategy but, if confirmed, could lead to improved reimbursement and higher uptake. This could also have a positive read-across to Europe, potentially strengthening and expanding the label. Elevar also plans to collect health economic data that could be applicable to reimbursement negotiations in all territories.

Revised US launch affects our maiden profitability timeframe

We now forecast launch at end 2025 (vs 2023) and note that prompt execution is required to meet these timelines. We maintain our Apealea US peak sales forecasts of $128m in ovarian cancer and have pushed the timeframe to reach peak sales out by two years. The US is a key part of total sales and represents c 44% in 2030. Oasmia's prior strategic goal is to be cash positive and achieve operational profitability from FY23. Timings of cash flows are difficult to predict as they depend on differing factors; however, our previous forecasts assumed Apealea US launch in FY23. The delay to our forecast US approval has also affected our forecast timeframe to maiden profitability, which has now shifted to FY25 (vs FY23), largely due to the delays in regulatory and launch related milestones (our previous forecasts assumed a $10m milestone on US approval in FY22 and $20m on US launch in FY23, with smaller milestones in additional countries in Europe and RoW). We now forecast a $10m milestone on US approval and $20m on US launch at end FY25. Key to our assumption is timely patient recruitment for the Phase III study. Given Oasmia's current cash position, cash burn rate and our forecast Apealea revenues in Europe and RoW, we expect Oasmia to have sufficient capital to reach our new forecast maiden profitability in FY25.

Europe partnering deal announcement by Elevar on the horizon

Oasmia reported first sale and treatment of a patient with Apealea in Finland during the period. This is a significant milestone given the launch of Apealea in Nordic regions in February 2020 was

hampered by COVID-19. Oasmia has seen positive interest from Sweden, although the effect of COVID-19 restrictions on its salesforce has led to little progress in this highly competitive market. A national registry trial is also under discussion in Sweden that, if required, could delay first sales further. In Denmark, the negative outcome of the compulsory HTA application due to a lack of health economic data has stalled reimbursement negotiations. Oasmia is working on alternatives to generate clinical data. We note that Elevar will be looking to generate health economic data in addition to the Phase III superiority study in the US, but this will unlikely be available for a number of years. As a result, management no longer expects significant prescription and sales volumes to originate from Denmark. It has stated that it does not expect the negative outcome of the Denmark HTA application to affect negotiations in other European countries and will be counting on a European partner to acquire any additional data that may be required for reimbursement in these countries.

In July Elevar announced a partnership agreement with US-based Tanner Pharma, a global provider of integrated specialty access solutions, which will facilitate access to Apealea on a named-patient basis ex-US in countries where Apealea is not commercially available. Under the named-patient programme (early or expanded access programme), physicians can prescribe investigational or approved drugs before their commercial availability to patients with no therapeutic alternatives. Elevar is in the final round of discussions for a distribution partner in Europe and we expect a partnering deal to be announced shortly to enable full launches across Europe with the accompanying country by country reimbursement negotiations. Positive results from the pivotal superiority study needed for the US NDA filing for Apealea could have a positive read across to Europe, leading to a label expansion, improved reimbursement and higher uptake, although the time frame for this is ~2025.

Further indications are key to Apealea value extraction

Apealea's potential for use across multiple cancers represents upside (additional clinical trials required) and is critical for value maximisation. In terms of resource allocation, Elevar will need to optimise investment into two or three value-driving indications (we believe Apealea will not be developed for indications for which Abraxane (human albumin-bound paclitaxel) is approved and we note combination studies with targeted therapies and/or PD-1 inhibitors will be a critical element of its future success. We do not include other indications in our forecasts and valuation as we have no visibility on future development plans. Elevar plans to reveal additional indications in due course.

In October Elevar signed an agreement with Taiba Middle East FZ LLC for the commercialisation of Apealea in the MENA region. This is the first regional partnership and Taiba has initiated the process of obtaining the required regulatory approvals for commercialisation of Apealea. We expect the first market where Apealea is available to be Saudi Arabia, which is also the largest market in this region. Taiba is also responsible for managing named-patient programmes in this region, which will allow patients early access to Apealea before commercial launch and availability. Elevar is in active discussions with a number of other potential regional partners around the world.

Progressing on other fronts

A key pillar of OASM's refocused strategy is to explore licensing and partnership opportunities for its existing assets. At the interim results Oasmia announced it has appointed consultancy firms that will aid in identifying potential partners for the animal health franchise and the wider XR-17 platform. Oasmia has also appointed an international investment bank to provide strategic advisory services relating to the animal health business. It is assessing strategic options for its animal health business and multiple outcomes are possible, including in-house development, partnering, licensing, spinoff or divestment. We believe divestment is the strategy that maximises shareholder value as cash

proceeds could be reinvested in building the human health pipeline (potentially through in-licensing opportunities), the company's primary business. Our indicative valuation of the animal health business is SEK443.7m (for further details see our initiation report, An appealing metamorphosis).

Oasmia has a strong cash position and is actively pursuing partnering opportunities (in-licensing and M&A) for its proprietary XR-17 platform technology. We expect Nordic-based oncology companies to be the likely targets and note that management has expressed interest in assets with clinical proof-of-concept data (Phase Ib or higher). While OASM's focus has been on oncology and chemotherapeutics, its XR-17 technology is applicable to APIs in other therapeutic areas and we expect to see Oasmia move into non-oncology indications in the near future. Oasmia has instructed a consultancy firm to initiate a four-step project to assess the positioning of the XR-17 platform versus competitors and the perceived industry needs. Oasmia also has the opportunity to out-license its XR-17 technology and forge partnerships with companies that have promising APIs that could benefit from its proven solubility-enhancing technology. The XR-17 technology is compatible with 10–15 different cytostatic therapies.

The expansion of its pipeline is necessary to allow Oasmia to build the critical mass required to attain its ultimate goal of becoming a profitable specialty pharmaceutical company with multiple assets spanning a range of phases of development. OASM's second asset docetaxel micellar, an ethanol and polysorbate 80 free formulation of widely used chemotherapy agent docetaxel, is poised to enter clinical development in early 2021. In June 2020, Oasmia signed a partnership agreement with the Swiss Group for Clinical Cancer Research to conduct the Phase Ib study of docetaxel micellar in patients with advanced prostate cancer in Switzerland. Top-line results expected within the next 12–24 months will determine the future development path. The dossier prepared from the Phase Ib Switzerland trial will be US compatible, allowing Oasmia to quickly launch into a global Phase II study if the results are positive. Oasmia is also progressing an in-house developed 'new API' candidate through preclinical development. The target indication is undisclosed but is very likely in the oncology arena.

Beyond XR-17, Oasmia is looking to further develop its platform technology by leveraging its R&D capabilities. Promising preclinical results observed with its dual encapsulation XR-19 technology are being validated and may be best suited to non-oncology indications where lower doses are required. At the interim results Oasmia introduced XR-18 for the first time. This next generation of the XR-17 solubility-enhancing platform looks to provide technical improvements (stability and storage) and long-term IP protection. R&D is underway and XR-18 is in the very early stages of development.

Valuation

Our revised valuation of Oasmia Pharmaceutical is SEK2.42bn or SEK5.41/share (Exhibit 1) versus SEK2.82bn or SEK6.29/share previously and is based on a risk-adjusted NPV model of Apealea for treatment of ovarian cancer (US, EU5 and RoW) and docetaxel micellar in prostate cancer. Our forecasts have been affected by our delay to US Apealea launch by two years (we forecast peak sales in ovarian cancer of $128m in FY30 in the US; given its commercial availability, we use a 10% discount rate but we now risk adjust the US opportunity by 75% (previously 90%) to reflect the need for an additional Phase III trial. Our EU5 and RoW sales forecasts are unchanged. We forecast docetaxel micellar peak sales of SEK239m. Adding in net cash of SEK249.6m (at 31 October 2020), rolling our model forward in time and updating for FX, we reach our risk-adjusted NPV of SEK2.42bn. Our valuation does not include Oasmia's proprietary technology platform and unconfirmed candidates at an early stage in preclinical development; consequently, additional indications for Apealea and docetaxel micellar, plus advancing new candidates into the clinic would provide further upside.

Exhibit 1: Oasmia SOTP NPV

Product	Indication	Launch	Peak sales ($m)	Value (SEKm)	Probability	rNPV (SEKm)	NPV/share (SEK/share)
Apealea US	Ovarian cancer	2025	128	619.7	75%	464.8	1.04
Apealea EU5	Ovarian cancer	2020/21	62	536.5	100%	536.5	1.20
Apealea RoW	Ovarian cancer	2020	92	431.0	90%	387.9	0.87
Docetaxel micellar Global	Prostate cancer	2025	239	1,326.9	25%	344.0	0.77
Animal health	Multiple cancers	2024	163	883.7	50%	441.9	0.99
Net cash at 31 October 2020				249.6	100%	249.6	0.56
Valuation				**4,047.4**		**2,424.7**	**5.41**

Source: Edison Investment Research

Financials

Oasmia reported slightly lower consolidated net sales of SEK0.362m in H1 FY21 (SEK0.433m in H1 FY20), which comprised largely of sales of supplies of SEK0.288m as the launch of Apealea in the Nordics was affected by COVID-19. Operating loss for the period amounted to SEK102.9m (SEK83.2m in H1 FY20). The increase was in part due to higher depreciation, amortisation and impairment (SEK17.7m vs SEK6.1m) as the amortisation of Apealea capitalised development costs started in Q4 FY20. Additionally, employee benefit expenses increased (SEK40.0m vs SEK29.1m) primarily due to severance costs relating to the strategic cost-reduction programme. The number of employees at the end of H1 FY21 was 49. The operating loss was also affected by a SEK3.1m fine imposed by Nasdaq Stockholm relating to the previous board of directors' breach of good stock market practices in 2019. Following the H1 FY21 results we have reviewed our operating expenses for the year and now forecast an increased operating loss of SEK162.8m.

Taking into consideration cash and cash equivalents plus short-term investments of SEK329.6m, Oasmia had a net cash position of SEK249.6m at 31 October 2020. Our net cash calculation includes a deduction of SEK80m for the short-term liability relating to the MGC Capital claim. However, we note that this is largely offset by a counter claim held by Oasmia that has a face value of SEK60m (book value SEK40m). This in addition to our forecast revenues is sufficient to fund Oasmia through to our revised forecast breakeven year of FY25, given our expectations of costs to stabilise at a lower run rate and the top line to start contributing meaningfully.

Exhibit 2: Financial summary

Accounts: IFRS, year-end: April 30, SEK000s	2018	2019	2020	2021e	2022e
PROFIT & LOSS					
Operating revenues	3,169	1,980	201,843	816	8,926
Licensing revenues	2,377	417	201,442	316	8,176
Other revenues	792	1,563	401	500	750
Total operating expenses*	(102,099)	(121,211)	(211,897)	(139,073)	(121,823)
EBITDA (reported)	(98,930)	(119,231)	(10,054)	(138,257)	(112,897)
Depreciation and amortisation	(4,794)	(31,005)	(20,032)	(24,587)	(24,150)
Reported operating income	(103,724)	(150,236)	(30,086)	(162,844)	(137,047)
Operating margin %	n/a	n/a	n/a	n/a	n/a
Finance income/(expense) excl lease expense	(14,289)	(18,240)	(12,267)	(6,221)	(11,881)
Leasing expense	0	0	(1,003)	(1,003)	(1,003)
Exceptionals and adjustments	0	0	0	0	0
Reported PBT	(118,013)	(168,476)	(43,356)	(170,069)	(149,931)
Income tax expense (includes exceptionals)	0	(32,822)	32,822	0	0
Reported net income	(118,013)	(201,298)	(10,534)	(170,069)	(149,931)
Basic average number of shares, m	166.2	253.3	398.4	448.4	448.4
Year-end number of shares, m	176.4	294.6	448.4	448.4	448.4
Basic EPS (SEK)	(0.7)	(0.8)	(0.0)	(0.4)	(0.3)
Adjusted EPS (SEK)	(0.7)	(0.7)	0.0	(0.3)	(0.3)
Dividend per share (SEK)	0	0	0	0	0
BALANCE SHEET					
Property, plant and equipment	15,527	14,701	28,014	26,014	24,451
Intangible assets	35,697	10,497	9,759	13,919	18,079
Capitalised development costs	426,079	433,130	433,357	413,110	392,863
Other non-current assets	2	2,002	2,002	2,002	2,002
Total non-current assets	477,305	460,330	473,132	455,045	437,395
Cash and equivalents	15,580	116,272	201,018	261,667	129,670
Short-term investments	0	0	234,080	34,080	34,080
Inventories	9,746	7,420	28,837	11,123	11,651
Trade and other receivables	35,949	6,545	43,907	43,875	43,889
Other current assets	17,807	14,472	24,372	24,372	24,372
Total current assets	79,082	144,709	532,214	375,118	243,662
Non-current loans and borrowings	0	0	0	0	0
Long-term leasing liabilities	0	0	8,845	8,845	8,845
Other non-current liabilities	0	32,822	0	0	0
Total non-current liabilities	0	32,822	8,845	8,845	8,845
Trade and other payables	9,256	17,666	22,524	17,408	18,233
Current loans and borrowings	187,260	139,568	80,001	80,001	80,001
Short-term leasing liabilities	0	0	5,320	5,320	5,320
Other current liabilities	26,523	31,485	69,268	69,268	69,268
Total current liabilities	223,039	188,719	177,113	171,997	172,822
Equity attributable to company	333,349	383,498	819,390	649,321	499,390
CASH FLOW STATEMENT					
Operating Profit/(loss)	(103,724)	(150,236)	(30,086)	(162,844)	(137,047)
Depreciation and amortisation	4,768	6,005	13,651	24,587	24,150
Share based payments	0	0	120	0	0
Other adjustments	1,652	32,086	12,738	0	0
Movements in working capital	(16,305)	(3,657)	1,065	12,629	284
Interest paid / received	(10,025)	(3,037)	(4,354)	(5,721)	(6,381)
Income taxes paid	0	0	0	0	0
Other financing charges	0	0	0	(1,503)	(6,503)
Cash from operations (CFO)	(123,634)	(118,839)	(6,866)	(132,852)	(125,497)
Capex**	(21,452)	(12,031)	(12,873)	(6,500)	(6,500)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	0	(2,000)	(275,251)	200,000	0
Cash used in investing activities (CFIA)	(21,452)	(14,031)	(288,124)	193,500	(6,500)
Net proceeds from issue of shares	147,456	151,852	401,863	0	0
Movements in debt	(15,000)	81,648	0	0	0
Other financing activities	199	0	(22,141)	0	0
Cash from financing activities (CFF)	132,655	233,500	379,722	0	0
Cash and equivalents at beginning of period	28,001	15,580	116,272	201,019	261,667
Increase/(decrease) in cash and equivalents	(12,431)	100,630	84,732	60,648	(131,997)
Effect of FX on cash and equivalents	10	62	15	0	0
Cash and equivalents at end of period	15,580	116,272	201,019	261,667	129,670
Net (debt)/cash	(171,680)	(23,296)	355,097	215,746	83,749

Source: Company accounts, Edison Investment Research. Note: *Includes non-capitalised R&D costs of SEK84.8m in FY20. **Includes capitalised development costs of SEK4.4m in FY20.

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