EDISON

Oasmia Pharmaceutical

Corporate update

Onwards and upwards

Pharma & biotech

Oasmia is at a major inflection point as it focuses on its transformation into an R&D-driven, specialty pharma company, with commercially available assets. During 2020, with new management at the helm, much progress was made, including the global partnership deal with Elevar Therapeutics for lead oncology asset Apealea (Cremophor-free paclitaxel), and the implementation of significant cost saving programs. Management has kickstarted 2021 with the in-licensing of Cantrixil (in all indications) from Kazia Therapeutics for $4m upfront, the first of 'a string of pearls' strategy to bolster the oncology pipeline. Start of the Phase Ib docetaxel micellar trial in prostate cancer, divestment of the animal health business and optimisation of its platform technologies represent value drivers beyond Apealea. Our revised valuation is SEK2.84bn or SEK6.34/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
12/21e**	21.0	(160.5)	(0.3)	0.00	N/A	N/A
12/22e**	46.8	(139.0)	(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. ** New reporting period from 1 January 2021.

Focus on oncology drivers

During 2021, Elevar expects to initiate the additional trials (PK study and Phase III trial) required by the FDA to enable the NDA submission for Apealea in ovarian cancer (forecast US launch in 2025). Under its partnership with the Swiss Group for Clinical Cancer Research (SAKK), docetaxel micellar will start a Phase Ib trial in prostate cancer; if positive, this could lead to the initiation of registration intent trials. The in-licensing of Cantrixil provides validation of Oasmia's commitment to its new strategy and is likely the first in a series of planned in-licensing deals to broaden the portfolio offering in oncology. Oasmia will also investigate potential synergies with lead asset Apealea and its XR-17 technology platform, which could enable different methods of administration.

Financials: Optimising a lower cost base

Oasmia has reduced its cost base by SEK100m, such that the monthly cash burn run rate is now SEK12m. However, as the business progresses and in licenced pipeline opportunities are identified, we would expect costs, particularly R&D, to increase to support pipeline development. We expect royalties on sales from Apealea to start to flow through in 2021, partly mitigating the potentially higher opex requirements, and we forecast maiden profitability in FY25. Divestiture of the animal health business could free up significant funds for reinvestment.

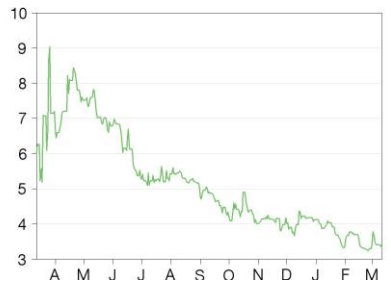
Valuation: SEK2.84bn or SEK6.34/share

Our updated valuation is SEK2.84bn or SEK6.34/share, versus SEK2.42bn or SEK5.41/share previously. We have added Cantrixil (peak sales $302m) but all our other underlying assumptions are unchanged. Our valuation includes net cash of SEK287.4m plus rNPVs for Apealea (ovarian cancer) and 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.

12 March 2021

Price	**SEK3.31**
Market cap	**SEK1,484m**
	$0.12/SEK
Net cash (SEKm) at 31 December 2020 (including short-term investments)	287.4
Shares in issue	448.4m
Free float	75%
Code	OASM
Primary exchange	Stockholm
Secondary exchange	Frankfurt

Share price performance



%	1m	3m	12m
Abs	(11.0)	(16.8)	(54.6)
Rel (local)	(16.2)	(27.3)	(69.7)
52-week high/low	SEK9.03		SEK3.24

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), docetaxel micellar and Cantrixil.

Next events

Start of Apealea US studies (PK and Phase III in ovarian cancer)	2021
Potential divestment of animal health business	Late 2021/ early 2022
Oncology in-licensing/M&A deals	2021/22

Analysts

Dr Susie Jana +44 (0)20 3077 5700

Dr John Priestner +44 (0)20 3077 5700

healthcare@edisongroup.com

Edison profile page

Strategic turnaround on track

Management has outlined the four pillars of its growth strategy for investors to focus on and benchmark the company's progress; these were identified in March 2020 as necessary to transform the business. Execution is critical; however, we believe the goals are sensible and achievable in the near term. Oasmia has expanded its leadership team further with the appointment of Dr Heidi Ramstad as chief medical officer to aid the assessment of potential clinical-stage in-licensing opportunities across oncology (not restricted to new formulations or small molecules) and to optimise its core technology platforms through R&D tie ups.

Executing on Apealea commercialisation

The deal with Elevar Therapeutics (terms include $20m upfront plus up to $678m in milestones and double-digit royalties on sales) 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 concentrate on its core drug development competencies and new strategic focuses. Apealea, a water-soluble, iv formulation of paclitaxel that is solvent free (no Cremophor EL solubilising agent used in Taxol), can be viewed as a bioequivalent, cost-effective alternative to Abraxane (albumin-bound paclitaxel formulation), which is approved for multiple cancer indications but not ovarian cancer. In H220, Elevar achieved sublicence agreements for the commercialisation of Apealea including Taiba Middle East in the Middle East and North Africa region and Inceptua Group in Europe. Inceptua is a privately held managed care company that will focus on expanding its sales and marketing infrastructure to support Apealea launch (late 2021) once the marketing application authorisation (MAA) has been transferred over to it. A partnership agreement with Tanner Pharma will facilitate access to Apealea on a named patient basis ex US in countries where Apealea is not commercially available.

In the US, two additional studies are required by the FDA 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 aims to start them in the first half of 2021. We forecast launch at end 2025, 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. We expect royalties on sales to start trickling in for 2021 and expect further sublicensing deals covering Latin America and Asia through the year. Our valuation of the Elevar deal largely focuses on the potential milestone payments in the near term, with tiered royalties on sales (15–18%) for Apealea in ovarian cancer. We forecast global peak sales of $282m in this indication.

Docetaxel micellar second asset to enter clinical development

Docetaxel micellar is a nanoparticulate formulation (using Oasmia's XR-17 platform technology) of docetaxel, the pharmaceutically active ingredient of Sanofi's Taxotere, one of the most commercially successful and widely used chemotherapies (it generated global sales in excess of €2.2bn in 2009, prior to the expiration of the patent in 2010). In June 2020, Oasmia signed a partnership agreement with SAKK to conduct the first clinical trial of docetaxel micellar in patients with advanced prostate cancer in Switzerland. SAKK will be responsible for the management of the Phase Ib trial (n=18), while Oasmia will supply docetaxel micellar and fund the costs of the trial, which are not deemed material. The trial is expected to initiate in H121, with top-line results expected within the next 12–18 months that will determine the future development path. The

dossier prepared from the Phase Ib Switzerland trial will be US compatible, allowing Oasmia to launch into a global Phase II study if the results are positive.

Enhancing and partnering technology platforms

Apealea was developed through Oasmia's proprietary XR-17 platform technology, which solubilises water insoluble substances and can be applied to a wide range of compounds (including established drugs such as paclitaxel). De novo drug development is both costly and time consuming. This is magnified by the high rates of attrition during clinical trials and the difficulty of meeting rising safety standards while maintaining clinical efficacy and an overall disease benefit. Oasmia is able to significantly de-risk this development process by using its proprietary XR-17 platform technology to reformulate approved drugs that are off patent and already have proven safety and efficacy. Oasmia's proprietary XR-17 solubility-enhancing technology enables water-soluble nanoparticulate formulations of previously insoluble active pharmaceutical ingredients (APIs) that can be intravenously administered to patients. Oasmia is also developing a next-generation solubility-enhancing technology platform XR-18 and dual encapsulation solubilisation platform XR-19, which could have the potential to enable combination therapies to be delivered in a single IV administration. The rationale for the latter is the increasing trend towards use of combination treatments in oncology. Oasmia is looking to potentially enhance XR-17 and additional platforms in development by partnering to leverage on its R&D competencies. In March 2021 Oasmia announced a collaboration with the Karolinska Institute in Sweden aiming to develop new APIs. It will also work to gain a deeper understanding of the biological properties of the XR-17 platform, which could enable new study protocols and the development of new therapeutics.

In/out-licensing, partnering and M&A in oncology

As part of the strategic review, Oasmia has reduced its cost base to focus financial resources and, despite the addition to the leadership team, has decreased personnel to 29, and will move its HQ to a more cost-efficient building in Stockholm. This means it has reduced annualised costs by SEK100m and current cash burn stands at SEK12m per month. The conservation of cash will enable investment in areas of greater expected return, which includes building a critical mass in oncology through M&A/in-licensing and leveraging on its core platform technology competencies. Oasmia has extensive discussions ongoing for potential in-licensing candidates and we note that management has expressed interest in assets with clinical proof-of-concept data (Phase Ib or higher) that could benefit from synergies with existing assets or use in combination with the XR-17 platform. Management has indicated that early-stage discussions are ongoing for its animal health business with medium to large specialty companies. Multiple outcomes are possible, including partnering, licensing, spinoff or divestment. We believe divestment 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.

Cantrixil the first in the 'string of pearls' strategy

In March 2021 Oasmia acquired the global development rights for Cantrixil (in all indications) from Kazia Therapeutics for $4m upfront, with $42m worth of development milestones and double-digit royalties on sales. Cantrixil consists of the pharmaceutically active ingredient TRXE-002-01, a third-generation benzopyran SMETI inhibitor, encapsulated in a cyclodextrin excipient to improve its solubility. Cantrixil is a potential first-in-class antineoplastic agent (inhibits the development of tumours) and while its novel mechanism is still poorly defined, it is believed to target an array of cancer cells, including tumour-initiating cells (cancer stem cells) that are thought to play a key role in metastasis and disease relapse.

Cantrixil proof-of-concept was successfully established in 16 relapsed and refractory ovarian cancer patients in an open-label Phase I study in the US and Australia (19% ORR). Notably, one patient

treated with a combination of Cantrixil and paclitaxel achieved a complete response and remained in remission three years after the final dose. Complete data from the Phase I study are expected to be published in a scientific journal later this year. Cantrixil was granted orphan drug designation for ovarian cancer by the US FDA in 2015.

Oasmia expects to initiate a Phase II study in relapsed and refractory ovarian cancer in 2022 with Cantrixil in its original formulation. While initial development will focus on ovarian cancer, Cantrixil also has the potential to find utility in other cancers that have spread to the abdominal cavity (bladder and colorectal cancer), as well as potential use as a first-line treatment (it may complement the use of standard of care platinum-based chemotherapy). Oasmia will also investigate potential synergies with lead asset Apealea and its XR-17 technology platform, which could enable different methods of administration (currently administered via intraperitoneal injection).

Valuation

Our updated valuation of Oasmia is SEK2.84bn or SEK6.34/share (Exhibit 1) versus SEK2.42bn or SEK5.41/share previously and is based on a risk-adjusted NPV model of Apealea for the treatment of ovarian cancer (US, EU5 and RoW), docetaxel micellar in prostate cancer plus an indicative value of the animal health business. We now include Cantrixil but all of our other underlying assumptions are unchanged. For Cantrixil, we assume a 40% blended royalty rate on sales to capture both sales milestones and royalties from a potential partnership deal for valuation purposes and include a 10% pay away to Kazia Therapeutics for royalties on sales. We use a 35% risk adjustment to reflect the assets Phase II ready status and a discount rate of 12.5%. We have preliminarily priced the product at $4,000 per cycle in the US and $2,000 per cycle in EU and assume eight cycles per treatment. We note this pricing could be conservative if the asset is able to demonstrate a significant improvement in patient outcomes. We will revisit our initial assumptions as the clinical trial data evolve. With a Phase II study in relapsed and refractory ovarian cancer expected to initiate in 2022, we forecast potential approval and launch in 2027, with peak sales of $302m in 2032 (our assumptions include both intraperitoneal and iv administration). Our US analysts have used different assumptions for Kazia Therapeutics. We model both US and European sales to composition of matter patent expiry in 2035. We assume Oasmia will continue to fund the clinical development costs into Phase II/III in ovarian cancer. We do not value Cantrixil in any additional indications that have not yet been announced, earlier lines of treatment or in combination with Apealea. All of these possibilities represent upside to our valuation and we will revisit our assumptions as Cantrixil progresses through clinical development. We have rolled our model forward, updated for FX and include net cash of SEK287.4m (at 31 December 2020). 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. Oasmia's valuation is sensitive to the contribution from Apealea. Given Elevar's intention to fund and conduct additional clinical trials (Phase II/III required for other indications) we have previously illustrated the potential value of an additional indication to Oasmia shareholders.

Exhibit 1: Oasmia SOTP NPV

Product	Indication	Launch	Peak sales ($m)	Value (SEKm)	Probability of success	rNPV (SEKm)	NPV/share (SEK/share)
Apealea US	Ovarian cancer	2025	128	643.0	75%	482.3	1.08
Apealea EU5	Ovarian cancer	2020/21	62	556.5	100%	556.5	1.24
Apealea RoW	Ovarian cancer	2020	92	449.2	90%	404.3	0.90
Docetaxel micellar Global	Prostate cancer	2025	239	1,375.1	25%	353.6	0.79
Cantrixil Global	Ovarian cancer	2027	302	1,039.2	35%	300.6	0.67
Animal health	Multiple cancers	2024	163	914.5	50%	457.2	1.02
Net cash at 31 December 2020				287.4	100%	287.4	0.64
Valuation				**5,264.9**		**2,841.9**	**6.34**

Source: Edison Investment Research

Financials

From 1 January 2021, Oasmia will use the calendar year as its financial year (previously 1 May to 30 April). To bridge this gap, it recently reported an abbreviated financial year for the period 1 May to 31 December 2020 (eight months). Consolidated net sales were slightly lower at SEK0.482m (vs SEK0.565m in the prior comparable period) and comprised largely of sales of supplies of SEK0.288m, as the launch of Apealea in the Nordics was hampered by COVID-19. Operating loss for the period amounted to SEK131.5m (vs SEK117.3m). The increase was primarily due to higher depreciation, amortisation and impairment costs (SEK28.9m vs SEK8.2m) as the amortisation of Apealea capitalised development costs started in 2020. Additionally, employee benefit expenses increased (SEK45.5m vs SEK39.8m) due to one off severance costs relating to the strategic cost-reduction programme. The number of employees at the end of the period was 29 (vs 61) and Oasmia reported a monthly cash burn in line with its SEK12m target for the final months of the period. Oasmia had a net cash position of SEK287.4m at 31 December 2020. We do not include the short-term liability relating to the MGC Capital claim (SEK80m) in our net cash calculation and note that this contingent liability is largely offset by a counter claim held by Oasmia that has a face value of SEK60m (book value SEK40m).

The last reported full financial year was for 1 May 2019 to 30 April 2020 and is described in detail in our initiation, An appealing metamorphosis.

We forecast total revenues of SEK21.0m in FY21 and SEK46.8m in FY22 due to increased contributions from supply of XR-17 to Elevar and other distribution partners, royalty revenues and milestone payments based on company guidance. We expect the tightening of the cost base after restructuring to be somewhat offset by an increase in R&D expenses as docetaxel micellar and Cantrixil enter the next stage of clinical development. We forecast R&D expenses of SEK17.1m in FY21 and SEK34.2m in FY22, this includes the docetaxel micellar Phase Ib prostate cancer trial and preparatory costs for Cantrixil in FY21, ahead of the expected start of the Phase II Cantrixil study in FY22. We forecast an operating loss of SEK153.0m in FY21 and SEK129.4m FY22. As the business evolves and Oasmia looks to expand its clinical pipeline, R&D and capex costs (in-licensing/M&A) could increase. Under our current assumptions, Oasmia has sufficient capital to fund operations beyond FY22. Additionally, divestment of the animal health business, Apealea royalties and revenues from potential out-licensing/partnering of the XR-17 platform could extend the cash reach further. Given Oasmia's current cash burn rate and our forecast Apealea revenues in Europe and RoW, we forecast maiden profitability in FY25, contingent on timely US launch in 2025.

Exhibit 2: Financial summary

Accounts: IFRS, Yr end: December 31, SEK: Thousands	2019	2020	2019 (8m)	2020 (8m)	2021e	2022e
	01/05/18–30/04/19	01/05/19–30/04/20	01/05/19–31/12/19	01/05/20–31/12/20	01/01/21–31/12/21	01/01/22–31/12/22
Profit & Loss						
Operating revenues	1,980	201,843	565	482	21,006	46,780
Total operating expenses*	(121,211)	(211,897)	(109,629)	(103,047)	(150,644)	(153,238)
EBITDA (reported)	(119,231)	(10,054)	(109,064)	(102,565)	(129,638)	(106,458)
Depreciation and amortisation	(31,005)	(20,032)	(8,193)	(28,930)	(23,336)	(22,953)
Reported operating Income	(150,236)	(30,086)	(117,257)	(131,495)	(152,974)	(129,411)
Operating margin %	N/A	N/A	N/A	N/A	N/A	N/A
Finance income/(expense) excl lease expense	(18,240)	(12,267)	(8,829)	(8,777)	(7,030)	(9,060)
Leasing expense	0	(1,003)	0	0	(502)	(502)
Exceptionals and adjustments	0	0	0	0	0	0
Reported PBT	(168,476)	(43,356)	(126,086)	(140,272)	(160,506)	(138,973)
Income tax expense (includes exceptionals)	(32,822)	32,822	32,822	0	0	0
Reported net income	(201,298)	(10,534)	(93,264)	(140,272)	(160,506)	(138,973)
Basic average number of shares, m	253.3	398.4	260.4	448.4	448.4	448.4
Year-end number of shares, m	294.6	448.4	447.4	448.4	448.4	448.4
Basic EPS (SEK)	(0.8)	(0.0)	(0.4)	(0.3)	(0.4)	(0.3)
Adjusted EPS (SEK)	(0.7)	0.0	(0.3)	(0.2)	(0.3)	(0.3)
Dividend per share (SEK)	0	0	0	0	0	0
Balance sheet						
Property, plant and equipment	14,701	28,014	36,322	17,630	16,067	14,887
Intangible assets	10,497	9,759	10,040	9,197	47,545	51,705
Capitalised development costs	433,130	433,357	433,507	420,334	400,901	381,468
Other non-current assets	2,002	2,002	2,002	302	302	302
Total non-current assets	460,330	473,132	481,871	447,463	464,815	448,362
Cash and equivalents	116,272	201,018	325,658	40,128	38,164	6,451
Short-term investments	0	234,080	0	247,277	97,277	2,277
Inventories	7,420	28,837	15,833	51,496	16,850	17,535
Trade and other receivables	6,545	43,907	50,634	44,552	50,738	54,576
Other current assets	14,472	24,372	19,863	32,628	32,628	32,628
Total current assets	144,709	532,214	411,988	416,081	235,657	113,467
Non-current loans and borrowings	0	0	0	0	0	0
Long-term leasing liabilities	0	8,845	10,183	6,545	6,545	6,545
Other non-current liabilities	32,822	0	0	0	0	0
Total non-current liabilities	32,822	8,845	10,183	6,545	6,545	6,545
Trade and other payables	17,666	22,524	22,570	10,678	8,111	8,440
Current loans and borrowings	139,568	80,000	80,000	80,000	80,000	80,000
Short-term leasing liabilities	0	5,320	5,296	4,204	4,204	4,204
Other current liabilities	31,485	69,268	37,321	81,919	81,919	81,919
Total current liabilities	188,719	177,112	145,187	176,801	174,234	174,563
Equity attributable to company	383,498	819,390	738,491	680,197	519,691	380,718
Cashflow statement						
Operating Profit/(loss)	(150,236)	(30,086)	(117,257)	(131,495)	(152,974)	(129,411)
Depreciation and amortisation	6,005	13,651	0	0	23,336	22,953
Share based payments	0	120	0	0	0	0
Other adjustments	32,086	12,738	0	0	0	0
Movements in working capital	(3,657)	1,065	(10,176)	(33,817)	25,893	(4,193)
Interest paid / received	(3,037)	(4,354)	(4,125)	(677)	(5,030)	(7,060)
Income taxes paid	0	0	0	0	0	0
Other financing charges	0	0	0	0	(2,502)	(2,502)
Cash from operations (CFO)	(118,839)	(6,866)	(131,558)	(165,989)	(111,277)	(120,213)
Capex**	(12,031)	(12,873)	(9,749)	(4,366)	(6,500)	(6,500)
Acquisitions & disposals net	0	0	0	0	(34,188)	0
Other investing activities	(2,000)	(275,251)	(40,251)	(10,000)	150,000	95,000
Cash used in investing activities (CFIA)	(14,031)	(288,124)	(50,000)	(14,366)	109,312	88,500
Net proceeds from issue of shares	151,852	401,863	402,951	0	0	0
Movements in debt	81,648	0	0	0	0	0
Other financing activities	0	(22,141)	(20,616)	(4,010)	0	0
Cash from financing activities (CFF)	233,500	379,722	382,335	(4,010)	0	0
Cash and equivalents at beginning of period	15,580	116,272	116,272	201,018	40,129	38,164
Increase/(decrease) in cash and equivalents	100,630	84,732	200,777	(184,365)	(1,965)	(31,713)
Effect of FX on cash and equivalents	62	15	8	(5,938)	0	0
Cash and equivalents at end of period	116,272	201,019	317,057	10,715	38,164	6,451
Net (debt) cash	56,704	435,098	325,658	287,405	135,441	8,728

Source: Company accounts, Edison Investment Research. Note: From 1 January 2021, Oasmia will use the calendar year as its financial year. *Includes non-capitalised R&D costs of SEK84.8m in FY19/20 (year-end April). **Includes capitalised development costs of SEK4.4m in FY19/20 (year-end April).

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holbom
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia