EDISON

BerGenBio

Full year results

AXLeration of data catalysts in 2021

Pharma & biotech

BerGenBio (BGBIO) has made steady progress during 2020. Lead asset bemcentinib (oral, once a day, highly selective AXL inhibitor) reported encouraging efficacy data from ongoing Phase II trials. Multiple catalysts expected in 2021 will define BGBIO's clinical trial strategy in AML/MDS and/or NSCLC. The FY20 operating loss was significantly higher than in FY19 (NOK261.1m vs NOK204.4m) due to higher set-up costs and increased investment in programme expenses. We expect operating expenses to increase significantly across 2021/22 as BGBIO further progresses its innovative AXL-centred pipeline, which includes bemcentinib in oncology (and COVID-19 potential) and the initiation of a Phase Ib/IIa trial to evaluate its AXL antibody tilvestamab in an undisclosed indication. BGBIO remains well funded following net c NOK700m raised in 2020. We value the company at NOK4.72bn or NOK54.1 per share.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/19	8.9	(199.3)	(3.43)	0.0	N/A	N/A
12/20	0.6	(257.0)	(3.43)	0.0	N/A	N/A
12/21e	0.0	(300.3)	(3.44)	0.0	N/A	N/A
12/22e	0.0	(317.6)	(3.64)	0.0	N/A	N/A

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

Dual approach to AXL inhibition

We expect a plethora of bemcentinib efficacy data in 2021 to define its pivotal clinical trial strategy. This includes median overall survival data in relapsed AML and top-line data in NSCLC in combination with Keytruda. We believe BGBIO will focus on the relapsed AML/MDS setting (Phase III study of bemcentinib plus LDAC in relapsed elderly AML patients could start in 2021). We forecast the NDA submission for this indication in 2023 (FDA has granted fast-track status). BGBIO's second clinical asset, tilvestamab (first-in-class AXL-targeting antibody), developed in-house and wholly owned by BGBIO, is set to start a Phase Ib/IIa trial shortly.

Eyes on COVID-19 trial readout

COVID-19 represents an additional opportunity that could expediate bemcentinib's route to market in 2022. Bemcentinib has presented a unique dual mechanism of action in the potential treatment of COVID-19. Given the numerous emerging variants of COVID-19, we believe innovative therapies will be required alongside global vaccination strategies. Two Phase II trials are exploring bemcentinib efficacy (in combination with SOC) in hospitalised patients (the IDMC has confirmed safety). Top-line clinical data are expected in Q121 and will define the route to approval.

Valuation: NOK4.72bn or NOK54.1 per share

We value BGBIO at NOK4.72bn or NOK54.1/share (NOK5.16bn or NOK59.1/share previously). Our forecasts remain unchanged, but our valuation has been affected by FX. The key value drivers are bemcentinib in second-line NSCLC (peak sales $1.2bn, NOK37.4/share) and AML (peak sales $598m, NOK12.3/share) plus the COVID-19 opportunity (peak sales $300m, NOK5.4/share). We do not include tilvestamab in our valuation, but will revisit this when we have clarity on the indications prioritised for development.

26 February 2021

Price	**NOK32.2**
Market cap	**NOK2,811m**
	NOK8.50/US$
Net cash (NOKm) at 31 December 2020	720.3
Shares in issue	87.3m
Free float	61%
Code	BGBIO
Primary exchange	Oslo
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(7.6)	11.0	102.5
Rel (local)	(10.5)	1.2	85.8
52-week high/low	NOK46.1		NOK11.69

Business description

BerGenBio is a clinical-stage biopharmaceutical company developing innovative drugs for aggressive diseases, including immune-evasive, drug-resistant and metastatic cancers. It focuses on AXL inhibitors bemcentinib (small molecule) and tilvestamab (mAb).

Next events

Bemcentinib top-line data from BGBC020 in COVID-19	Q121
Start of bemcentinib plus LDAC Phase III registrational study in relapsed AML	2021
Start of tilvestamab Phase Ib/IIa trial	2021

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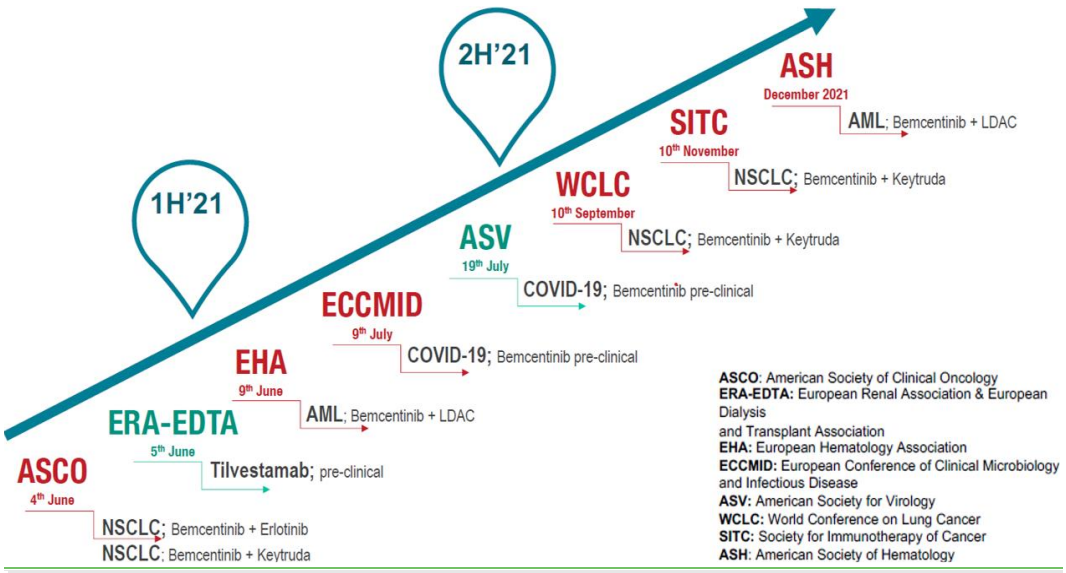
Edison profile page

Bemcentinib 2021 data to define registrational trials

BGBIO is a pioneer in AXL biology and the development of AXL inhibitors: its R&D pipeline includes bemcentinib and tilvestamab. AXL expression is a negative prognostic marker in most cancers. Its upregulation drives aggressive disease including drug-resistant, immune-evasive and metastatic cancers, as well as fibrosis and viral infection. BGBIO has shown that selective AXL inhibition may prevent and reverse acquired drug resistance and stop immune suppression, potentially augmenting the efficacy of other cancer drug classes. Bemcentinib (BGB324) is a highly selective small tyrosine kinase inhibitor (TKI) of the intracellular kinase domain, and tilvestamab (BGB149) is a fully humanised IgG1 monoclonal antibody that exhibits high affinity and selectivity for the extracellular domain. This two-pronged strategy increases the chance of success by using complementary but orthogonal treatment modalities. Importantly, bemcentinib's mechanism of action is synergistic with other therapies, making it an ideal candidate for combination therapy approaches. Parallel development of biomarkers or a companion diagnostic test could also aid monetisation.

2021 is a pivotal year, following the bemcentinib proof-of-concept data presented in 2020. Key R&D inflection points in 2021 will determine registration pathways, including median OS data (once mature) in relapsed acute myeloid leukaemia (AML), relapsed high-risk myelodysplastic syndromes (HR-MDS) and top-line clinical data from the checkpoint inhibitor refractory, non-small cell lung cancer (NSCLC) combination trial. Bemcentinib's first NDA filing (expected in 2023) is likely to be in AML and we expect the bemcentinib plus low-dose cytarabine (LDAC) combination in relapsed AML patients (FDA fast-track designation and orphan drug status granted) to form the registration-enabling Phase IIb/III study. This represents a currently unmet medical need and is a sizeable market. With the COVID-19 pandemic in focus and the BGBC020 trial rapidly enrolling in South Africa and India, top-line clinical data are anticipated in Q121. This could lead to the initiation of a Phase III trial depending on the strength of the data and the status of the pandemic later in the year.

Exhibit 1: Key R&D-driven catalysts in 2021



Source: BGBIO corporate presentation

2021 is a pivotal year for bemcentinib

BGBIO's strategy in oncology is to establish efficacy in proof-of-concept studies for rapid regulatory approval (bemcentinib plus LDAC in relapsed AML) and concurrently to develop line extensions (second-line NSCLC in combination with CPI Keytruda (pembrolizumab), and other indications) and move higher up the treatment paradigm. We believe that commercial prospects for the AXL inhibitor class could be propelled from defined subsets in a handful of cancer types to broader use in AXL-positive tumours (diagnosed by companion drug testing or biomarkers), and potentially in an earlier line of therapy in combination with chemotherapy, immunotherapy or targeted therapies (due to its treatment-enhancing effects).

Promising data in relapsed AML warrant clinical progression

BGBIO is exploring multiple development options for bemcentinib in AML with two Phase II studies underway in AML/MDS. While the bemcentinib plus LDAC combination in relapsed AML patients will be the initial focus of registration-enabling studies, it could also find utility as a first-line treatment for elderly (>60 years old) patients unsuitable for hypomethylating agents (HMAs) plus venetoclax. Furthermore, due to limited treatment options, bemcentinib could find utility as a monotherapy treatment in the second line and above for heavily pre-treated elderly patients. The ongoing multi-arm BGBC003 trial is evaluating these potential treatment scenarios.

Multi-cohort study illuminates path to regulatory approval in AML

The BGBC003 study includes five cohorts in the Phase II expansion. The cohorts to focus on in the near term are Cohort B2: bemcentinib combination with LDAC in newly diagnosed (ND) or relapsed AML; and Cohort B5: further expansion of the Cohort B2 LDAC combination in relapsed AML, as these will likely define Phase IIb/III clinical trial design and registration strategy. The FDA has granted bemcentinib orphan drug and fast-track designation in AML.

At ASH 2020, BGBIO presented promising interim Phase II (n=11) data for bemcentinib in combination with LDAC in elderly relapsed AML patients (Cohort B2/B5). The combination showed a significant improvement on LDAC monotherapy (ORR of 45%, CR/CRi of 36% and DCR of 73%) and could lead to a shift in the treatment paradigm for this unmet need. It is noteworthy that the median time to remission was 3.8 months, which is indicative of an immune response. Additionally, the AXL status of patients was not reported and these high response rates could negate the need for selecting patients with high AXL expression. Key overall survival data are expected to be presented at a scientific conference in 2021 (Exhibit 1), once mature.

BERGAMO study success warrants further investigation

In August, the investigator-initiated Phase II BERGAMO study of bemcentinib monotherapy in AML and high-risk MDS patients met its primary endpoint of ORR. This trial recruited patients who had failed (r/r) first-line treatment with HMAs, an unmet need. Data presented at ASH 2020 highlight meaningful clinical efficacy in the MDS population (CR/CRi of 18% and DCR of 36%). The mDOR was already longer than the current mOS for this patient population (nine vs six months). Patient AXL status was predictive of responders. This population is less frail and has a higher likelihood of achieving an immune response and clinical benefit such that these results warrant further development and additional translational analyses are ongoing. Key overall survival data is expected to be presented at a scientific conference in 2021 (Exhibit 1).

Significant opportunity in second-line NSCLC

NSCLC, in our view, represents a significant opportunity. Bemcentinib in combination with Keytruda (CPI) could enable a treatment paradigm shift by addressing PD-L1 resistance. Bemcentinib is being evaluated in a broad Phase II study (BGBC008) with multiple cohorts including monotherapy and combination with standard-of-care Keytruda. CPIs are increasingly used as a first-line standard of care for patients not harbouring a specific driver mutation (approximately 75% of patients). The advancement of Keytruda to the first-line setting in metastatic NSCLC has left a vacuum in the second line, with limited treatment options (chemotherapy agents such as docetaxel or Taxol that achieve ORR <10% for a limited duration). This has created a high unmet medical need and a large market potential for a well-tolerated therapy such as bemcentinib that could increase patient responses to Keytruda.

The pivotal registration study is likely to focus on a bemcentinib plus Keytruda combination in PD-L1 resistant NSCLC patients, an unmet need. Additionally, we highlight that bemcentinib's utility in NSCLC could be further defined in earlier lines of treatment and in combination with targeted therapies (the combination with Tarceva showed a deepening of response in a Phase II study in first/second-line NSCLC). BGBIO is currently in discussions with regulatory authorities regarding the registrational Phase IIb/III trial design, but we believe it is likely to compare the combination of bemcentinib and Keytruda vs current standard-of-care docetaxel (chemotherapy). The ongoing BGBC008 consists of three cohorts.

Cohort B points to C for registrational study

Positive interim Phase II data were recently presented at WCLC 2020 for bemcentinib in combination with Keytruda as a second/third-line treatment option in NSCLC patients who have relapsed after checkpoint inhibitor therapy. The number of biomarker evaluable patients has increased to 14 (from 12). However, the additional patients were both cAXL negative. The headline DCR for cAXL-positive patients was unchanged (86%), but increased to 29% for cAXL-negative patients. This builds on data presented at the Next Gen Immuno-Oncology Congress in June 2020 (median progression-free survival 2.5x longer for cAXL-positive patients), underlining a real clinical benefit. Although in small patient numbers, these results are meaningful and suggest that bemcentinib has the potential to reverse acquired resistance to CPIs in previously treated AXL-positive NSCLC patients and extend the efficacy of these immunotherapies (data presented at SITC 2020). The combination continues to be well tolerated. Top-line data from Cohort B are expected to be presented at a scientific conference in 2021 (Exhibit 1). These results further validate BGBIO's cAXL score and the hypothesis that AXL status is predictive of treatment response.

Multiple opportunities in COVID-19

COVID-19 represents an additional opportunity that could expediate bemcentinib's route to market in 2022. Two ongoing Phase II trials (ACCORD-2 in the UK and BGBC020 in South Africa and India) will determine efficacy (suppression of viral entry and activation of the patient's immune system) in hospitalised patients. While both Phase II studies are randomised and statistically powered, we note the broad inclusion criteria for both and the likely requirement for an additional, more focused trial to confirm efficacy in a specific patient population. Top-line data from BGBC020 are anticipated in Q121 and will define the route to regulatory approval.

We believe the continued approval of multiple COVID-19 vaccines is likely to lead to widespread vaccination. However, this will take time on a global level and, furthermore, data on durability and the impact of mutagenicity will increasingly become evident as new strains of the virus continue to emerge. In the meantime, for the next few years, from a global public health perspective, there remains a need for effective treatment options, at least until wide-scale vaccination has curbed the

pandemic, assuming mutagenicity does not have an impact on vaccine efficacy. There remains an urgent need for a range of treatments that work in different ways across the entire treatment spectrum of mild to severe disease.

Bemcentinib has presented a unique dual mechanism of action that could prevent viral intracellular entry and augment the type 1 interferon response (a key antiviral defence mechanism). It does not directly target the SARS-CoV-2 spike protein ACE2 interaction, an approach taken by the majority of vaccines, which could be a significant advantage given that the emergence of new variants with mutations of the spike protein have brought the efficacy and durability of these vaccines into question. Bemcentinib may therefore be variant (spike protein) agnostic and could find use in combination with a treatment that targets the spike protein ACE2 pathway.

The Phase II BGBC020 trial is enrolling rapidly and two independent data monitoring committee (IDMC) meetings have confirmed safety and that bemcentinib is well tolerated in these patients. The totality of the data expected in Q121 will include patients enrolled in different countries and will likely include a range of COVID-19 variants, providing a robust data set to determine the best pathway to regulatory approval. The standard of care and competitive landscape are evolving rapidly, with many potential therapies in the late stages of development for the treatment of COVID-19 pointing towards a likely fragmented market. We maintain our peak sales of $300m and adopt a 'wait-and-see' approach in light of this and global vaccination programmes.

Global partnering deal economics will depend on data

Given the potential breadth of use for the AXL inhibitor class, we believe a global partnering deal to be the most value-maximising proposition. As the data unfold and bemcentinib progresses in Phase III, positive registrational intent data would validate the class and could command significant deal economics. A global partner with additional resources to invest in a fuller and wider programme in oncology would make sense, while BGBIO could focus its own efforts on fibrosis and virology. We also believe that a proof-of-concept in one indication could have a read across effect to other indications with known overexpression of AXL, for a potential partner (one with an established PD-1 inhibitor, for example, would make sense). In our assumptions on a deal (our model assumes 2023), we reflect biotech licensing deals that have included assets with potential in multiple indications as the benchmark. Based on deals that have occurred since 2015, we assume an upfront payment of c $250m and c $1.4bn in total milestones (one-third allocated to R&D-related payments and the rest commercial milestones). We assume tiered royalty rates of 15–18% on sales.

Tilvestamab moving into Phase Ib/IIa development

The Phase Ia first-in-human study evaluating anti-AXL monoclonal antibody (mAb) tilvestamab has completed, confirming pharmacokinetics with no dose-limiting toxicity up to the maximum tested dose of 3mg/kg. mAbs such as tilvestamab are administered intravenously (unlike small molecule bemcentinib, which can be taken orally) and this lends to longer half-life, which allows weeks between dosing instead of the daily dosing of small molecules. This can prove advantageous for treating chronic diseases (like fibrosis) as it increases treatment adherence, although it is less convenient. BGBIO has not yet disclosed its development plans for tilvestamab, which has the potential to be used in both oncology and fibrotic indications. Following completion of the Phase Ia study, BGBIO expects to initiate the Phase Ib/IIa multiple ascending dose trial. We believe that the development of tilvestamab is most likely to be pursued primarily in fibrosis due to the potential for pricing negotiations without affecting other indications, as fibrotic treatments in general reimburse at a lower rate than oncology treatments. We note that approximately 30% of people with SARS or Middle East Respiratory Syndrome (MERS) had persistent lung abnormalities after their acute

illness. The NHS recently published guidance that sets out the expected aftercare needs of patients recovering from COVID-19 infections and identifies potential longer-term respiratory problems, including chronic cough, fibrotic lung disease, bronchiectasis and pulmonary vascular disease. We believe BGBIO's fully humanised antibody tilvestamab (administered intravenously), which is highly selective for AXL, could have the potential to be developed for chronic COVID-19-related lung fibrosis.

Valuation

We value BGBIO at NOK4.72bn or NOK54.1/share, previously NOK5.16bn or NOK59.1/share based on a risk-adjusted NPV analysis, which includes net cash of NOK720.3m at 31 December 2020. Our forecast assumptions are unchanged. FX (US$/NOK spot rate) has negatively affected the valuation, but has marginally increased our forecast peak sales (€/US$ spot rate) as ex-US sales are forecast in euros. Our risk-adjusted valuation includes bemcentinib in second-line NSCLC (peak sales $1.2bn, NOK37.4/share) and second-line AML (peak sales $598m, NOK12.3/share) oncology indications plus the COVID-19 opportunity ($300m peak sales, NOK5.4/share), Exhibit 2. We assume a licensing deal for bemcentinib (in all oncology) after registrational intent data in AML and include a pay away to Rigel Pharmaceuticals based on the original in-licensing deal. We do not assign any value to tilvestamab, as BGBIO is progressing this asset, and when we have clarity on the prioritised indications for development, we will review its potential. We highlight that as a wholly owned asset, high economic value potentially resides in tilvestamab.

Exhibit 2: Sum-of-the-parts BerGenBio valuation

Product	Indication	Launch	Peak sales ($m)	NPV (NOKm)	Probability of success	rNPV (NOKm)	NPV/share (NOK)
Bemcentinib	2L AML	2024	598	3,010.5	35%	1,072.7	12.29
Bemcentinib	2L NSCLC	2025	1,183	7,453.3	35%	3,263.1	37.40
Bemcentinib	COVID-19	2022	300	3,363.6	15%	472.0	5.41
Payments to Rigel						(805.1)	(9.23)
Net cash at 31 Dec 2020				720.3	100%	720.3	8.25
Valuation				14,547.7		4,723.0	54.1

Source: Edison Investment Research. Note: WACC = 12.5%.

Financials

BGBIO reported an operating loss of NOK261.1m in FY20, significantly higher than FY19 (NOK204.4m) due to higher set-up costs and increased investment in programme expenses (c 80% of total operating expenses are attributable to R&D activities). We expect R&D expenses to increase from 2021 to support the advancing clinical trials of bemcentinib across its oncology indications and the potential Phase III study in COVID-19. Additionally, BGBIO expects to progress tilvestamab into Phase Ib/IIa trials. Thus, we forecast the operating loss will increase to NOK305.5m in 2021 and to NOK319.9m in 2022. Following a net capital raise of c NOK700m in 2020, BGBIO is well funded in the near term and had a comfortable net cash position of NOK720.3m at 31 December 2020. If the COVID-19 programme does not proceed into Phase IIb/III, the cash reach is likely to extend into 2023 but, if it does proceed, existing cash would be sufficient until 2022. Given the numerous emerging variants of COVID-19, we believe innovative therapies will be required alongside global vaccination strategies such that the rapidly developing COVID-19 programme is the main focus area for us in terms of cash flows in the near term (2021/22).

Furthermore, under the licensing deal with Rigel, a total of $36m could become payable in 2021/22, but only if all goes well with the COVID-19 programme. $8m is due on Phase IIb/III trial initiation, but if the Phase IIb/III trial in COVID-19 is successful, the remainder of the R&D-related payments

could be covered from multiple sources, in our view. Additionally, in 2021, BGBIO could initiate pivotal trials in AML and/or NSCLC. Funding these programmes will depend on the interplay of whether the COVID-19 programme moves into a Phase III trial, what payments to Rigel will be made and how successful the initial launch of bemcentinib for the treatment of COVID-19 is. For the COVID-19 opportunity, we have modelled peak sales immediately after the launch. So, even though the new COVID-19 programme decreases the visibility of cash burn in the next two years, the potentially rapid uptake of the drug is a significant prize. Our current financial projections do not include the milestones to Rigel, nor the potential sales in 2022.

Exhibit 3: Financial summary

Accounts: IFRS, year-end 31 December, NOK000s	2018	2019	2020	2021e	2022e
PROFIT & LOSS					
Operating revenues	2,335	8,900	601	0	0
Licensing revenues	2,335	8,900	601	0	0
Other revenues	0	0	0	0	0
Total operating expenses	(196,874)	(213,274)	(261,692)	(305,499)	(319,862)
Other operating expenses (R&D)	(133,699)	(141,630)	(163,442)	(205,937)	(216,234)
EBITDA (reported)	(194,335)	(203,589)	(260,365)	(305,120)	(319,562)
Depreciation and amortisation	(204)	(785)	(726)	(379)	(299)
Reported operating income	(194,539)	(204,374)	(261,091)	(305,499)	(319,862)
Operating margin %	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	2,793	5,096	4,062	5,166	2,277
Exceptionals and adjustments		0	0	0	0
Profit before tax (reported)	(191,746)	(199,278)	(257,029)	(300,333)	(317,585)
Income tax expense	0	0	0	0	0
Net income (reported)	(191,746)	(199,278)	(257,029)	(300,333)	(317,585)
Basic average number of shares (m)	53.3	58.0	74.9	87.3	87.3
Year-end number of shares (m)	54.7	61.1	87.3	87.3	87.3
Basic EPS (NOK)	(3.60)	(3.43)	(3.43)	(3.44)	(3.64)
Adjusted EPS (NOK)	(3.60)	(3.43)	(3.43)	(3.44)	(3.64)
Dividend per share (NOK)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Property, plant and equipment	581	974	2,332	2,020	1,787
Intangible assets	0	0	0	0	0
Total non-current assets	581	974	2,332	2,020	1,787
Cash and equivalents	360,414	253,586	721,641	432,656	118,128
Other current assets	17,831	15,818	14,228	15,023	14,626
Total current assets	378,245	269,404	735,869	447,679	132,753
Total non-current liabilities	0	0	1,367	1,367	1,367
Trade and other payables	23,939	26,746	22,550	33,841	35,668
Other current liabilities	12,875	21,803	38,046	38,585	39,185
Provisions	4,732	2,074	6,008	6,008	6,008
Total current liabilities	41,546	50,623	66,604	78,434	80,861
Equity attributable to company	337,280	219,754	670,229	369,896	52,311
CASH FLOW STATEMENT					
Profit before taxes	(191,746)	(199,278)	(257,029)	(300,333)	(317,585)
Depreciation and amortisation	204	785	726	379	299
Share based payments	1,678	3,842	7,412	0	0
Other adjustments	1,712	(2,990)	4,644	0	0
Movements in working capital	1,446	13,164	13,572	11,620	3,410
Interest paid/received	0	(2,206)	(3,614)	0	0
Income taxes paid	0	0	0	0	0
Cash from operations (CFO)	(186,706)	(186,683)	(234,290)	(288,333)	(313,876)
Capex	(228)	0	(67)	(67)	(67)
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	0	2,206	3,614	0	0
Cash used in investing activities (CFIA)	(228)	2,206	3,548	(67)	(67)
Net proceeds from issue of shares	176,998	77,910	700,092	0	0
Movements in debt	0	0	0	0	0
Other financing activities	0	(593)	(585)	(585)	(585)
Cash from financing activities (CFF)	176,998	77,317	699,507	(585)	(585)
Cash and equivalents at beginning of period	370,350	360,414	253,586	721,641	432,656
Increase/(decrease) in cash and equivalents	(9,936)	(107,160)	468,765	(288,985)	(314,528)
Effect of FX on cash and equivalents	0	332	(710)	0	0
Cash and equivalents at end of period	360,414	253,586	721,641	432,656	118,128
Net (debt)/cash	360,414	253,586	720,274	431,289	116,761

Source: Company accounts, Edison Investment Research

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