

BerGenBio

Bemcentinib preliminary data in COVID-19

BerGenBio (BGBIO) has announced preliminary data for lead asset bemcentinib, an oral once daily highly selective AXL inhibitor for the treatment of severe COVID-19 infections requiring hospitalisation. In the Phase II ACCORD-2 and BGBC020 trials, treatment with bemcentinib led to numerically fewer deaths versus standard of care up to day 29. **Preliminary analysis** of the primary endpoint, time to clinical improvement of at least two points on the WHO nine-point ordinal scale, or live discharge from the hospital, was numerically in bemcentinib's favour but not statistically significant in this small study with a diverse patient population and demographic. Detailed top-line data are expected in May. If favourable, we expect an additional global Phase III study will be required before emergency use authorisation. We value BGBIO at NOK4.72bn.

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)	(3.43)	0.0	N/A	N/A
12/22e	0.0	(317.6)	(3.62)	0.0	N/A	N/A

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

Early data, more details expected in May

Bemcentinib has a unique dual mechanism of action that could prevent viral intracellular entry and augment the type 1 interferon response (a key antiviral defence mechanism). Additionally, as it does not directly target the SARS-CoV-2 spike protein-ACE2 pathway, it is expected to be variant (spike protein) agnostic. Bemcentinib was given as an add-on therapy to current standard of care (remdesivir and dexamethasone) for hospitalised patients who were not intubated or ventilated. Both studies used the same trial design and clinical endpoints. Preliminary data reported that in ACCORD-2 there was one death in 28 patients in the bemcentinib arm versus five in 32 patients receiving only standard of care, and two versus three in BGBC020 (115 patients enrolled, 58 received bemcentinib).

COVID-19 could expedite route to market

While bemcentinib is primarily being developed for oncology indications (see '[Bemcentinib leading the AXL charge](#)'), COVID-19 could expedite its route to market in 2022. Its potential dual mechanism of action and convenient once-a-day oral dosing is initially being assessed in a hospitalised setting. Clinical development work to assess its potential use in a community setting or as a post-exposure prophylactic may be appropriate depending on the future status of the pandemic. We maintain our peak sales of \$300m and adopt a 'wait-and-see' approach in light of global vaccination programmes and the progress of other potential treatments.

Valuation: NOK4.72bn or NOK53.8 per share

We continue to value BerGenBio at NOK4.72bn or NOK 53.8/share. Our forecasts remain unchanged. The key value drivers are bemcentinib in second-line NSCLC (peak sales \$1.2bn, NOK37.2/share) and AML (peak sales \$598m, NOK12.2/share) plus the [COVID-19 opportunity](#) (peak sales \$300m, NOK5.4/share).

COVID-19 clinical update

Pharma & biotech

20 April 2021

Price **NOK30.1**

Market cap **NOK2,640m**

NOK8.50/US\$

Net cash (NOKm) at 31 December 2020 720.3

Shares in issue 87.8m

Free float 61%

Code BGBIO

Primary exchange Oslo

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (9.2) (18.7) 79.1

Rel (local) (10.7) (22.7) 33.9

52-week high/low NOK46.1 NOK16.79

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 ACCORD-2 and BGBC020 in COVID-19 May 2021

Potential start of global Phase III pivotal study in COVID-19 H221

Start of bemcentinib plus LDAC Phase III registrational study in relapsed AML 2021

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BerGenBio is a research client of Edison Investment Research Limited

Exhibit 1: 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	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	87.7	87.8
Year-end number of shares (m)	54.7	61.1	87.3	87.8	87.8
Basic EPS (NOK)	(3.60)	(3.43)	(3.43)	(3.43)	(3.62)
Adjusted EPS (NOK)	(3.60)	(3.43)	(3.43)	(3.43)	(3.62)
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
Cashflow 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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