

BerGenBio

Interim results

Advancing towards pivotal studies

Pharma & biotech

BerGenBio (BGBIO) has made continued progress in H121 in advancing the development of lead asset bemcentinib (an oral, once-a-day, highly selective AXL inhibitor). A deluge of data presentations from Phase II studies in COVID-19, AML and NSCLC continue to highlight the broad potential of this first-in-class treatment. Discussions with regulators are ongoing regarding a pivotal study in [relapsed AML in combination with LDAC](#), which could enable potential approval and launch in 2024. COVID-19 presents a potential opportunity to expedite bemcentinib's route to market in 2022. Discussions with regulators will determine the next steps following top-line data from two Phase II trials. We value BGBIO at NOK4.91bn.

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	(322.1)	(3.67)	0.0	N/A	N/A
12/22e	0.0	(335.1)	(3.81)	0.0	N/A	N/A

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

Multiple opportunities in oncology

In June, the FDA granted bemcentinib [fast track designation](#) in combination with an anti-PD-L1 agent (like Keytruda) for second-line, AXL-positive NSCLC patients (without driver mutations). This highlights the regulator's recognition of AXL-positive patients as a molecular targetable patient population and provides strong validation of AXL as a negative prognostic marker in NSCLC. First efficacy data, expected in H221 from Cohort C of the ongoing [Phase II study](#), will be critical to defining bemcentinib's utility in this setting. BGBIO presented data from the ongoing [Phase II trial](#) in combination with LDAC in AML at [EHA](#). Notably, durable responses were observed in relapsed AML patients (ORR of 31%; 5/16), together with impressive median overall survival of 13.3 months (more than double historical survival data).

COVID-19 regulatory discussions ongoing

BGBIO presented encouraging combined data from two Phase II studies of bemcentinib in addition to standard of care in hospitalised COVID-19 patients at [ECCMID](#). Post hoc analysis in a subgroup of patients with a higher disease severity (>60% of evaluable patients) showed a significantly reduced likelihood (69%) of progression to ventilation and significantly increased likelihood (88%) of shorter time to recovery or discharge. Treatment with bemcentinib also led to numerically fewer deaths and preclinical studies highlight potential continued efficacy against COVID-19 variants. BGBIO is in discussions with regulators about the next steps. We expect an additional global Phase III study will be required before approval.

Valuation: NOK4.91bn or NOK55.8 per share

We value BGBIO at NOK4.91bn or NOK 55.8/share vs NOK4.72bn or NOK53.8/share previously. We have rolled forward our model and reflect net cash of NOK572.8m at 30 June 2021. We have updated our financial forecasts to reflect H121 results and increased R&D expenses (FY21: NOK228.8m vs NOK205.9m, FY22: NOK233.4m vs NOK216.2m) due to growing clinical trial activities.

20 August 2021

Price **NOK22.9**
Market cap **NOK2,011m**

NOK8.50/US\$

Net cash (NOKm) at 30 June 2021 572.8

Shares in issue 88.0m

Free float 60%

Code BGBIO

Primary exchange Oslo

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 2.9 (2.3) (33.9)

Rel (local) 0.7 (7.5) (47.5)

52-week high/low NOK38.1 NOK22.1

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

Potential start of global Phase III pivotal study in COVID-19	H221
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Bemcentinib plus Keytruda Phase II NSCLC Cohort C efficacy data	H221
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Start of bemcentinib plus LDAC Phase III registrational study in relapsed AML	2021/2022
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Exhibit 1: Financial summary

Accounts: IFRS, year-end 31 December, NOK'000s	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)	(328,830)	(337,280)
Other operating expenses (R&D)	(133,699)	(141,630)	(163,442)	(228,819)	(233,395)
EBITDA (reported)	(194,335)	(203,589)	(260,365)	(328,002)	(336,724)
Depreciation and amortisation	(204)	(785)	(726)	(829)	(556)
Reported operating income	(194,539)	(204,374)	(261,091)	(328,830)	(337,280)
Operating margin %	N/A	N/A	N/A	N/A	N/A
Finance income/(expense)	2,793	5,096	4,062	6,775	2,176
Exceptionals and adjustments		0	0	0	0
Profit before tax (reported)	(191,746)	(199,278)	(257,029)	(322,056)	(335,104)
Income tax expense	0	0	0	0	0
Net income (reported)	(191,746)	(199,278)	(257,029)	(322,056)	(335,104)
Basic average number of shares (m)	53.3	58.0	74.9	87.8	88.0
Year-end number of shares (m)	54.7	61.1	87.3	88.0	88.0
Basic EPS (NOK)	(3.60)	(3.43)	(3.43)	(3.67)	(3.81)
Adjusted EPS (NOK)	(3.60)	(3.43)	(3.43)	(3.67)	(3.81)
Dividend per share (NOK)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Property, plant and equipment	581	974	2,332	1,570	1,081
Intangible assets	0	0	0	0	0
Total non-current assets	581	974	2,332	1,570	1,081
Cash and equivalents	360,414	253,586	721,641	422,577	90,787
Other current assets	17,831	15,818	14,228	15,023	14,626
Total current assets	378,245	269,404	735,869	437,600	105,412
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	2,439	2,439
Total current liabilities	41,546	50,623	66,604	74,865	77,292
Equity attributable to company	337,280	219,754	670,229	362,937	27,833
CASH FLOW STATEMENT					
Profit before taxes	(191,746)	(199,278)	(257,029)	(322,056)	(335,104)
Depreciation and amortisation	204	785	726	829	556
Share based payments	1,678	3,842	7,412	4,514	0
Other adjustments	1,712	(2,990)	4,644	(3,569)	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)	(308,662)	(331,138)
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	10,250	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	9,665	(585)
Cash and equivalents at beginning of period	370,350	360,414	253,586	721,641	422,577
Increase/(decrease) in cash and equivalents	(9,936)	(107,160)	468,765	(299,064)	(331,790)
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	422,577	90,787
Net (debt)/cash	360,414	253,586	720,274	421,210	89,420

Source: Company accounts, Edison Investment Research

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