Trinity Delta

BerGenBio

Update

Advancing towards randomised studies

26 November 2018

BerGenBio continues to report promising data from the Phase II study in non-small cell lung cancer (NSCLC) with bemcentinib in combination with pembrolizumab, on this occasion progression free survival (PFS) data at SITC 2018. The final data from the current trials are due over the next six months. But, the results to date are sufficiently compelling that the company has already started to prepare a randomised Phase II trial programme with bemcentinib to begin in H219. No details of the Phase II studies have been disclosed; but we expect the company to run a series of trials in various NSCLC settings (including with pembrolizumab) and in AML. We have raised our valuation of BerGenBio from NOK52.65 to NOK54.21 per share.

Year-end: December 31	2016	2017	2018E	2019E
Sales (NOKm)	0.0	0.0	0.0	0.0
Adj. PBT (NOKm)	(129.8)	(182.2)	(197.5)	(240.2)
Net Income (NOKm)	(129.8)	(182.2)	(197.5)	(240.2)
Adj. EPS (NOK)	(419.7)	(4.0)	(3.8)	(4.4)
Cash (NOKm)	161.8	370.4	345.1	109.5
EBITDA (NOKm)	(131.4)	(183.5)	(200.0)	(239.2)

Source: Trinity Delta. Note: Adjusted numbers exclude exceptionals

- **PFS data further emphasises potential of bemcentinib with pembrolizumab** BerGenBio previously reported promising overall response rate (ORR) data from stage 1 of the Phase II study with pembrolizumab (Merck's Keytruda). The ORR of patients (n=10) with Axl+ tumours was 40% vs 9% in those with Axl- tumours. Consistent with this, BerGenBio reported at SITC 2018 median PFS of 5.9 months and 3.3 months in patients with Axl+ and Axl- tumours, respectively; in historical trials with pembrolizumab or nivolumab monotherapy in PD-L1 low NSCLC, median PFS was c 2 months. Stage 2 is actively recruiting an extra 24 patients to the trial.
- **Randomised Phase II studies to be initiated in H219** BerGenBio is planning randomised Phase II trials to start in H219. No details have been disclosed by the company, but they are likely to centre on bemcentinib's potential in second-line NSCLC, in particular with pembrolizumab, and in AML/MDS. The studies will probably include pre-specified analyses of patients stratified using biomarkers, such as Axl or sAxl expression, to confirm the observations made in the current trials.
- **BGB149 to enter the clinic in Q418** A Phase I study in healthy volunteers with Axl antibody, BGB149, is due to start in December 2018. It will be a single-ascending dose trial with six patients per cohort. The trial is expected to be completed in Q319, with the aim of initiating in H219 a Phase I/II study in patients. BerGenBio is yet to indicate in which indications BGB149 will be developed; but, as it inhibits Axl signalling like bemcentinib, it could be developed in oncology or fibrosis.
- **Valuation increased by NOK1.56 to NOK54.21/share** We have raised our valuation of BerGenBio by NOK86m to NOK2,966m ($349m or NOK54.21/share), following the Q318 results, the promising data in NSCLC and the termination of the development programme in triple-negative breast cancer. We have also revised our estimates to take into account the tight cost control in FY18 and the expanding clinical trial programmes from H219 with the randomised Phase II trials. BerGenBio had a cash position of NOK398m at Q318, sufficient to operate into FY20.

Price	NOK26.90
Market Cap	NOK1,472m
Enterprise Value	NOK1,074m
Shares in issue	54.7m
12-month range	NOK18.60-54.80
Free float	57%
Primary exchange	Oslo
Other exchanges	N/A
Sector	Healthcare
Company Code	BGBIO
Corporate client	Yes

Company description

BerGenBio is a clinical-stage, biopharmaceutical company based in Bergen, Norway and Oxford, UK. It is developing innovative therapies for aggressive cancers by way of inhibiting the Axl signalling pathway. The lead oncology compound, bemcentinib, is in multiple Phase II trials.

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Valuation and Financials

Valuation of BerGenBio is increased from NOK52.65/share to NOK54.21/share

We have revised our valuation to take into account the company's progress in clinical trials. We have increased our valuation of BerGenBio by NOK1.56 to NOK54.21/share, as detailed in Exhibit 1. The main changes to our model are the removal of TNBC, and increases in the probability of success from 20% to 30% for both NSCLC with pembrolizumab and with docetaxel, due to the promising data that has been presented since the ASCO meeting in June 2018.

Exhibit 1: rNPV-based valuation of BerGenBio

Indication	Total NPV ($m)	Total NPV (NOKm)	Likelihood of success	rNPV ($m)	rNPV (NOKm)	rNPV/share (NOK)	Notes
AML/MDS	39.2	333.4	30%	10.4	88.8	1.62	Peak sales: $126m Launch year: 2023
NSCLC with erlotinib	240.8	2,046.5	30%	69.5	590.7	10.80	Peak sales: $749m Launch year: 2023
NSCLC with pembrolizumab	391.2	3,325.0	30%	114.4	972.1	17.77	Peak sales: $1,210m Launch year: 2023
NSCLC with docetaxel	70.2	596.6	30%	20.4	173.2	3.16	Peak sales: $218m Launch year: 2023
Metastatic melanoma	43.1	366.6	20%	7.9	66.9	1.22	Peak sales: $200m Launch year: 2025
Milestones	269.1	2,287.6	See notes	94.0	798.9	14.60	Milestones totalling $400m, Likelihood of receipt: 50% to 20%
Rigel payments	(435.8)	(3,704.4)		(133.3)	(1,132.8)	(20.70)	35% of revenues payable to Rigel
Net cash	40.6	345.1		40.6	345.1	6.31	At FY18E
Core valuation	**658.4**	**5,596.4**		**223.9**	**1,902.8**	**34.78**	
Broader immuno-oncology potential (based on the indications in which pembrolizumab is approved)	833.9	7,088.5	15%	125.1	1063.3	19.43	NSCLC (non-adenocarcinoma): Peak sales: $1,361m HNSCC: Peak sales: $1,183m Urothelial: Peak sales: $1,677m cHL: Peak sales: $167m MSI-H cancer: Peak sales: $702m Gastric cancer: Peak sales: $745m Launch year: 2025
Total valuation	**1,492.3**	**12,684.9**		**348.9**	**2966.0**	**54.21**	

Royalty rate	18%	
Discount rate	12.5%	
Exchange rate (NOK/$)	8.5	
Tax rate	27%	Starting in 2025

Source: Trinity Delta. Note: Valuation assumes BGB324 is out-licensed in 2019. The value of each indication includes the current R&D expenses associated with the current clinical trials. HNSCC: Head & neck squamous cell carcinoma; cHL: classical Hodgkin lymphoma; MSI-H: microsatellite instability-high cancers (primarily colorectal cancer).

We still consider it reasonable to include bemcentinib's broader potential as an immuno-oncology therapy, given the promising data to data in NSCLC. However, we note that BerGenBio's shares are currently trading at a discount of 29.3% to our core valuation, which also places no value on the antibody BGB149.

Additional data from the current clinical trials will be presented over the next six months at various conferences, which will probably include ASH on 1 to 4 December, AACR on 29 March to 3 April, and ASCO on 31 May to 4 June. The new data could act as share price catalysts. The most eagerly awaited results will be the overall survival data from the first stage of the Phase II study in NSCLC with pembrolizumab and the results from the trial's second stage, which will hopefully confirm the findings from the first stage. These data should be reported in Q219.

We have also amended our estimates as summarised in Exhibit 2. The changes reflect the company's tight cost control and the lower R&D spending due to the termination of the TNBC study in the short-term. We then anticipate that R&D investment will increase significantly from H219 as BerGenBio rolls out its randomised Phase II programme. We will refine our estimates for FY19 and beyond, once BerGenBio has announced the development programme for the randomised Phase II studies.

Exhibit 2: Summary of changes to estimates

	Sales (NOKm)			EBITDA (NOKm)			Adj. EPS (NOK)		
	Old	New	Change	Old	New	Change	Old	New	Change
2018E	0.0	0.0	N/A	(236.4)	(200.0)	N/A	(4.7)	(3.8)	N/A
2019E	0.0	0.0	N/A	(232.9)	(239.2)	N/A	(4.8)	(4.4)	N/A

Source: Trinity Delta

Exhibit 3: Summary of financials

Year-end: Dec 31 NOKm	2015	2016	2017	2018E	2019E
INCOME STATEMENT					
Revenues	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Cost of goods sold	0.0	0.0	0.0	0.0	0.0
Gross Profit	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Personnel costs	(25.2)	(20.6)	(28.8)	(39.5)	(32.9)
Other expenses	(47.6)	(110.8)	(154.7)	(160.5)	(206.1)
Amortisation & depreciation	(0.2)	(0.2)	(0.2)	(0.2)	(0.1)
Underlying operating profit	**(72.9)**	**(131.6)**	**(183.7)**	**(200.2)**	**(239.2)**
Other revenue/expenses	0.0	0.0	0.0	0.0	0.0
EBITDA	**(72.7)**	**(131.4)**	**(183.5)**	**(200.0)**	**(239.0)**
Operating Profit	**(72.9)**	**(131.6)**	**(183.7)**	**(200.2)**	**(239.2)**
Interest income	2.5	3.0	4.2	3.8	0.5
Interest expense	(1.7)	(1.3)	(2.7)	(1.1)	(1.5)
Other financing costs/income	0.0	0.0	0.0	0.0	0.0
Profit Before Taxes	**(72.1)**	**(129.8)**	**(182.2)**	**(197.5)**	**(240.2)**
Adj. PBT	**(72.1)**	**(129.8)**	**(182.2)**	**(197.5)**	**(240.2)**
Current tax income	0.0	0.0	0.0	0.0	0.0
Net Income	**(72.1)**	**(129.8)**	**(182.2)**	**(197.5)**	**(240.2)**
EPS (NOK)	**(296.3)**	**(419.7)**	**(4.0)**	**(3.8)**	**(4.4)**
Adj. EPS (NOK)	**(296.3)**	**(419.7)**	**(4.0)**	**(3.8)**	**(4.4)**
DPS (NOK)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)	0.2	0.3	45.5	52.3	54.7
Gross margin	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
EBITDA margin	*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
BALANCE SHEET					
Current assets	**82.0**	**174.1**	**383.8**	**366.9**	**131.4**
Cash and cash equivalents	74.0	161.8	370.4	345.1	109.5
Short-term investments	0.0	0.0	0.0	0.0	0.0
Accounts receivable	0.0	0.0	0.0	0.0	0.0
Other current assets	8.0	12.3	13.4	21.9	21.9
Non-current assets	**0.4**	**0.4**	**0.6**	**0.7**	**0.9**
Property, plant & equipment	0.4	0.4	0.6	0.7	0.9
Investments in portfolio companies	0.0	0.0	0.0	0.0	0.0
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Current liabilities	**(12.1)**	**(21.3)**	**(34.0)**	**(36.6)**	**(40.3)**
Short-term debt	0.0	0.0	0.0	0.0	0.0
Accounts payable	(5.3)	(10.7)	(21.6)	(13.2)	(16.9)
Other current liabilities	(6.8)	(10.6)	(12.4)	(23.4)	(23.4)
Non-current liabilities	**(5.6)**	**0.0**	**0.0**	**0.0**	**0.0**
Long-term debt	0.0	0.0	0.0	0.0	0.0
Other non-current liabilities	(5.6)	0.0	0.0	0.0	0.0
Equity	**64.7**	**153.3**	**350.4**	**331.0**	**92.0**
Share capital	2.5	3.4	5.0	5.5	5.5
Other	62.3	149.9	345.4	325.6	86.5
CASH FLOW STATEMENTS					
Operating cash flow	**(62.9)**	**(124.3)**	**(168.1)**	**(201.9)**	**(235.1)**
Profit before tax	(72.1)	(129.8)	(182.2)	(197.5)	(240.2)
Non-cash adjustments	6.5	3.8	0.7	6.4	0.9
Change in working capital	2.7	1.7	13.4	(11.0)	3.7
Interest paid	0.0	0.0	0.0	0.2	0.5
Taxes paid	0.0	0.0	0.0	0.0	0.0
Investing cash flow	**0.0**	**(0.3)**	**(0.3)**	**(0.3)**	**(0.5)**
CAPEX on tangible assets	0.0	(0.3)	(0.3)	(0.3)	(0.5)
Change in investments in portfolio companies	0.0	0.0	0.0	0.0	0.0
Other investing cash flows	0.0	0.0	0.0	0.0	0.0
Financing cash flow	**10.5**	**212.4**	**377.0**	**177.0**	**0.0**
Proceeds from equity	9.2	213.7	377.0	177.0	0.0
Increase in loans	1.3	(1.3)	0.0	0.0	0.0
Dividends	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	0.0	0.0	0.0
Net increase in cash	**(52.4)**	**87.8**	**208.5**	**(25.3)**	**(235.6)**
Exchange rate effects	0.0	0.0	0.0	0.0	0.0
Cash at start of year	126.4	74.0	161.8	370.4	345.1
Cash at end of year	**74.0**	**161.8**	**370.4**	**345.1**	**109.5**
Net cash at end of year	**74.0**	**161.8**	**370.4**	**345.1**	**109.5**

Source: Company, Trinity Delta

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