BeOne (ONC US)

CDK4i showed preliminary efficacy while data still maturing

- **CDK4i demonstrated favourable hematologic safety with reduced neutropenia.** BeOne's CDK4 inhibitor (BGB-43395) shows a favorable hematologic safety profile, supported by improved CDK4/CDK6 selectivity that reduces off-target and CDK6-mediated toxicities. In dose optimization cohorts (n=61), grade ≥3 TRAEs occurred in only 19.7% of pre-treated breast cancer and solid tumor patients receiving BGB-43395 (240–600 mg BID) plus fulvestrant. Neutropenia incidence (grade ≥3) was notably lower—8.2% in dose optimization and 16.2% in dose escalation—compared to 29–55% seen with other approved CDK4/6 inhibitors and 18.2% with Pfizer's CDK4i atirmociclib (refer to Figure 2). However, grade ≥3 diarrhea was observed in 5.4–8.2% of patients, higher than CDK4i atirmociclib and CDK4/6 inhibitors palbociclib and ribociclib, all of which reported grade ≥3 diarrhea rates below 1%.
- **Efficacy data are still maturing**. It is too early to assess the efficacy of BeOne's CDK4 inhibitor (BGB-43395), with response data still immature due to limited follow-up. In the dose escalation study of BGB-43395 (240, 400 and 600mg BID) plus fulvestrant, the ORR was 11% (2/19) in heavily pre-treated HR+/HER2- breast cancer (BC) patients, who had a median of four prior treatment lines. The current ORR is not yet conclusive given the short median follow-up of just 3.0 months. The KOL expects an improvement in response rates with longer observation, noting that CDK4/6 inhibitors typically require 3–5 months to elicit a response. For example, the median time to response was 4.9 months for ribociclib in the RIGHT Choice trial (link) and 3.6 months for abemaciclib in MONARCH 3 (link). Thus, we think the DCR rate of 55.6% (15/27) could be an early indicator of efficacy. Mgmt remains confident in developing BGB-43395 and plans to initiate a Ph3 trial in 2L HR+/HER2- BC in 4Q25, with a 1L Ph3 trial also in planning.
- **Highly competitive hematology-oncology portfolio.** Zanubrutinib remains the class leader in new patient prescriptions for both first-line and R/R CLL, and is now the top-selling BTKi in the US. Sonrotoclax (Bcl2i) offers key differentiation over venetoclax, with greater potency and selectivity, as well as a shorter half-life to minimize drug accumulation and simplify tumor lysis syndrome (TLS) monitoring. Venetoclax requires a 5-week dose ramp-up and frequent clinic visits, while BeOne is optimizing sonrotoclax's ramp-up to enable >90% of patients to get through the ramp-up with just one clinic visit. Clinical development is progressing rapidly. The Ph3 trial of sonrotoclax + zanubrutinib in 1L CLL was fully enrolled in Feb. Ph3 trials in R/R MCL and R/R CLL have been initiated, with a Ph3 trial in MM in planning. BeOne has submitted NDAs for sonrotoclax in China for R/R MCL and R/R CLL, and global filing for R/R MCL is expected in 2H25, with the underlying data anticipated in 2H25. BGB-16673 (BTK CDAC) is positioned for leadership, with BeOne preparing to initiate a global Ph3 H2H superiority trial versus pirtobrutinib in CLL in 2H25. An NDA filing for BGB-16673 in CLL is planned in 2026.
- **Maintain BUY.** BeOne's multiple assets are expected to reach PoC in 2H25, including Pan-KRASi, FGFR2b ADC, PRMT5i, etc. BeOne is on track to achieve FY25 guidance of GAAP operating income breakeven. We maintain TP unchanged at US$359.47 (WACC: 9.32%, terminal growth rate: 3.0%).

Earnings Summary

(YE 31 Dec)	FY23A	FY24A	FY25E	FY26E	FY27E
Revenue (US$ mn)	2,459	3,810	5,261	6,442	7,385
Net profit (US$ mn)	(881.7)	(644.8)	256.2	824.4	1,220.7
EPS (Reported) (US$)	(8.45)	(6.12)	2.30	7.42	10.98
R&D expenses (US$ mn)	(1,779)	(1,953)	(2,052)	(2,061)	(2,142)
CAPEX (US$ mn)	(562)	(493)	(200)	(200)	(200)

Source: Company data, Bloomberg, CMBIGM estimates

BUY (Maintain)

Target Price	**US$359.47**
Up/Downside	**47.1%**
Current Price	**US$244.32**

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Stock Data

Mkt Cap (US$ mn)	27,161.9
Avg 3 mths t/o (US$ mn)	40.6
52w High/Low (US$)	278.38/144.35
Total Issued Shares (mn)	111.2

Source: FactSet

Shareholding Structure

Amgen	17.1%
Baker Bros	8.0%

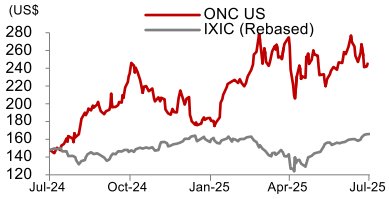
Source: ar

Share Performance

	Absolute	Relative
1-mth	-2.9%	-7.7%
3-mth	-7.6%	-25.0%
6-mth	35.1%	30.0%

Source: FactSet

12-mth Price Performance



Source: FactSet

Figure 1: Safety and efficacy profile of BGB-43395 (CDK4 inhibitor)

n (%)	CDK4i + fulvestrant (240 – 600mg BID)			
	Dose escalation (N=37)		Dose optimization (n=61)[1]	
Patient with any TEAE	36 (97.3%)		54 (88.5%)	
Related TEAE	35 (94.6%)		51 (83.6%)	
≥ G3 TEAE	19 (51.4%)		14 (23%)	
≥ G3 Related TEAE	10 (20.7%)		12 (19.7%)	
TRAE leading to discontinuation	1 (2.7%)		1 (1.6%)	
Key AEs	**All Grade TEAE**	**Gr3+ TEAE**	**All Grade TEAE**	**Gr3+ TEAE**
Diarrhea	83.8%	5.4%	65.6%	8.2%
Anemia	13.5%	0%	11.5%	1.6%
Neutrophil count decreased	21.6%	16.2%	29.5%	8.2%
Platelet count decreased	5.4%	2.7%	6.6%	1.6%

BGB-43395 + Fulvestrant Dose escalation	N=29; Breast Cancer	N=37; Total*
Number of prior lines of therapy in metastatic setting • Median (range) • >= 3 Lines	4 (0-11) 90%	4 (0-11) 73%
Prior chemotherapy (including ADC)	100%	100%
Prior endocrine therapy	100%	84%
Prior CDK4/6 inhibitor(s)	93%	76%
Median follow-up (months)	3.0	2.7
Objective response rate#	11% (2 of 19)	15% (4 of 27)

Source: Company data, R&D Day Slides (link), CMBIGM

Figure 2: Safety profile of major CDK4/6 inhibitors for HR+/HER2- mBC patients

Drugs	Palbociclib/ Ibrance	Ribociclib/ Kisqali	Abemaciclib/ Verzenio	Atirmociclib/ PF-07220060	BGB-43395
Company	Pfizer, Amgen	Novartis, Otsuka	Eli Lilly	Pfizer	BeOne
MoA	CDK4i,CDK6i	CDK4i,CDK6i	CDK4i,CDK6i	CDK4i	CDK4i
Trial ID	PALOMA-3, Ph3	MONALEESA-3, Ph3	MONARCH 2, Ph3	NCT04557449, Ph1/2a	NCT06120283, Ph1
Patient baseline	with prior ET; 75% with prior chemo	received no or only one line of prior ET; 56% with prior chemo, 60% with prior ET	with prior adjuvant or metastatic ET; no prior chemo	heavily pre-treated; all with prior CDK4/6i; 73% with prior fulvestrant, and 66.7% with prior chemo	heavily pre-treated; in the dose escalation cohort: all with prior chemo, ET; 93% with prior CDK4/6i
Patient number in treatment arm	347	484	441	33	37 in dose escalation (29 BC + 8 other tumors); 61 in dose optimization
Regimen	palbociclib + fulvestrant vs fulvestrant	ribociclib + fulvestrant vs fulvestrant	abemaciclib + fulvestrant vs fulvestrant	atirmociclib + letrozole /fulvestrant	BGB-43395 + fulvestrant

Dose reduction in treatment arm	36%	32%	43% (mainly due to diarrhea and neutropenia)	15%	-
Discontinuation due to AEs in treatment arm	5.5%	8%	9%	3%	2.7% (dose escalation) 1.6% (dose optimization)
Neutropenia (gr≥3)	55% vs 1%	53% vs 0.8%	29% vs 3.7%	18.2%	16.2% (dose escalation) 8.2% (dose optimization)
Neutropenia (gr≥3) - in pooled trials	66%; 1.8% febrile neutropenia (PALOMA-2 and 3)	62%; 1.7% febrile neutropenia (MONALEESA-2, 7, and 3)	19%-32%; <1% febrile neutropenia (monarchE, MONARCH 1, 2, and 3)	-	-
Leukopenia (gr≥3)	30% vs 1%	26% vs 0.4%	23% vs 0.9%	-	-
Diarrhea (gr≥3)	0 vs 1%	0.6% vs 0.8%	13% vs 0.4%	0	5.4% (dose escalation) 8.2% (dose optimization)
Nausea (gr≥3)	0 vs 1%	1.4% vs 0.8%	2.7% vs 0.9%	3.0%	
Source	Link	Link	Link	Link	Link

Source: Pharmacube, FDA labels, BeOne, CMBIGM

Figure 3: Efficacy of major drugs (or candidates) for HR+/HER2- BC post CDK4/6 inhibitors

	Dato-DXd	Trodelvy	DS-8201		Atirmociclib/ PF-07220060	BGB-43395
MoA	TROP2 ADC	TROP2 ADC	HER2 ADC		CDK4i	CDK4i
Company	Daiichi Sankyo/ AZ	Gilead	Daiichi Sankyo / AZ		Pfizer	BeOne
Trial	TROPION-Breast01	TROPiCS-02	DESTINY-Breast04	DESTINY-Breast06	NCT04557449	NCT06120283
Trial stage	Ph3	Ph3	Ph3	Ph3	Ph1/2a	Ph1
Primary endpoint	Dual primary endpoints: PFS, OS	PFS	PFS in HR+/HER2 low cohort	PFS	Safety	Safety, ORR
Treatment line	Median of 3 prior regimens; 83% treated with prior CDK4/6i; 88% with prior ET; 81% with prior chemo	Median of 3 prior chemo regimens; all with prior CDK4/6i; 86% with prior ET	Median of 3 prior regimens; 70% with prior CDK4/6i; nearly all with prior ET and chemo	Pts with prior endocrine, while without chemo	Median 4 prior regimens; all with prior CDK4/6i; 73% with prior ET; 67% with prior chemo	Median 4 prior regimens; all with prior chemo, ET; 93% with prior CDK4/6i
Regimen	Mono vs chemo	Mono vs chemo	Mono vs chemo		atirmociclib + letrozole or fulvestrant	BGB-43395 + fulvestrant
Patient number	365 vs 367	272 vs 271	331 vs 163 (HR+/HER2 low cohort)	713 HER2-low, 153 HER2-ultralow, both cohorts DS-8201 vs chemo	33	29
HER2 or HR level	HR+/HER2-low or negative (HER2 IHC 0, 1+ or 2+/ISH–)	HR+/HER2-low or negative	HR+/HER2-low (no HER-negative pts)	HR+/HER2-low and ultralow (HER2 IHC 1+ or 2+ or 0 with <10% HER2)	HR+/HER2-	HR+/HER2-
Follow-up (mo)	10.8	12.5				3.0
ORR	36.4% vs 22.9%	21.0% vs 14.0%	52.6% vs 16.3%	56.5% vs 32.2% (HER2-low cohort); 61.8% vs 26.3% (HER2-ultralow)	32.0%	11% (2/19)
CR	0.5% vs 0	1% vs 0	3.6% vs 0.6%			
mDoR (mo)		8.1 vs 5.6	10.7 vs 6.8			
mPFS (mo)	6.9 vs 4.9 HR=0.63, p<0.0001	5.5 vs 4.0, HR=0.66, p=0.0003	10.1 vs 5.4, HR=0.51, p<0.001	13.2 vs 8.1 HR=0.62, p<0.001 (HER2-low cohort); 13.2 vs 8.3 HR=0.78 (HER2- ultralow)	8.1	
mOS (mo)	OS endpoint missed	14.4 vs 11.2, HR=0.79, p=0.02	23.9 vs 17.5, HR=0.64, P=0.003			
Safety	3% all grade ILD. One grade 5 drug related ILD event, with death primarily	No patients treated with Trodelvy experienced ILD	12.1% pts in the DS-8201 arm had drug-related ILD or pneumonitis. 5 Gr3	11.3% pts in the DS-8201 arm had drug-related ILD or pneumonitis,		

	due to disease progression		ILD and 3 ILD-related deaths were reported	including 3 pts in grade 3, and 3 pts in grade 5		
TRAEs **Grade>=3**	20.8% vs 44.7%	74% vs 60% (TEAE)	NA			
Diarrhea	*0 vs 1%*	*9% vs 1%*	*1.1% vs 1.7%*		*0*	TEAE: 5.4% (dose escalation) 8.2% (dose optimization)
Stomatitis	*6% vs 3%*	*NA*	*NA*			
Decreased leukocyte count	*1% vs 7%*	*9% vs 5%*	*6.5% vs 19.2%*			
Decreased neutrophil count (neutropenia)	*1% vs 31%*	*51% vs 38%*	*13.7% vs 40.7%*		*18.2% (TEAE)*	TEAE: 16.2% (dose escalation) 8.2% (dose optimization)
Decreased lymphocyte count		*4% vs 3%*	*6.5% vs 19.2%*			
Anemia	*1% vs 2%*	*6% vs 3%*	*8.1% vs 4.7%*			
Decreased platelet count	*0 vs 1%*	*<1% vs 4%*	*5.1% vs 0.6%*			
Approval status	approved in the US	approved in the US and China	approved in the US and China	approved in the US	Ph3 ongoing	Ph3 to start
Data source	Link1, Link2	Link	Link	Link1; Link2	Link	Link

Source: Pharmacube, PubMed, CMBIGM

Figure 4: Risk-adjusted DCF valuation

DCF valuation (US$ mn)	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E
EBIT	**274**	**934**	**1,403**	**2,059**	**2,432**	**3,228**	**3,798**	**4,262**	**4,458**	**4,563**	**4,668**
Tax rate	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
EBIT*(1-tax rate)	233	794	1,193	1,750	2,067	2,744	3,228	3,623	3,789	3,878	3,968
+ D&A	175	177	179	181	183	185	186	188	189	190	191
- Change in working capital	(73)	(185)	(144)	(154)	25	(175)	(121)	(104)	(34)	2	14
- Capex	(200)	(200)	(200)	(200)	(200)	(200)	(200)	(200)	(200)	(200)	(200)
FCFF	**134**	**586**	**1,028**	**1,577**	**2,075**	**2,553**	**3,093**	**3,506**	**3,744**	**3,870**	**3,973**
Terminal value											**64,803**

PV of enterprise (US$ mn)	37,796
Net debt (US$ mn)	(2,167)
Equity value (US$ mn)	**39,963**
No. of ADS (mn)	111
DCF per ADS (US$)	**359.47**

Terminal growth rate	**3.0%**
WACC	**9.32%**
Cost of equity	12.5%
Cost of debt	4.0%
Equity beta	0.95
Risk-free rate	3.0%
Market risk premium	10.0%
Target debt to asset ratio	35.0%
Effective corporate tax rate	15.0%

Source: CMBIGM estimates

Figure 5: Sensitivity analysis (US$)

	WACC				
Terminal growth rate	**8.32%**	**8.82%**	**9.32%**	**9.82%**	**10.32%**
4.0%	506.67	449.46	403.16	364.96	332.93
3.5%	467.97	419.46	379.44	345.88	317.37
3.0%	436.56	394.62	**359.47**	329.60	303.94
2.5%	410.55	373.71	342.43	315.55	292.23
2.0%	388.66	355.87	327.72	303.29	281.93

Source: CMBIGM estimates

Figure 6: CMBIGM estimate vs consensus

	CMBIGM			Consensus			Diff (%)		
US$ mn	**FY25E**	**FY26E**	**FY27E**	**FY25E**	**FY26E**	**FY27E**	**FY25E**	**FY26E**	**FY27E**
Revenue	5,261	6,442	7,385	5,114	6,163	7,108	3%	5%	4%
Gross profit	4,482	5,508	6,352	4,366	5,318	6,170	3%	4%	3%
Operating profit	274	934	1,403	185	734	1,363	48%	27%	3%
Net profit	256	824	1,221	171	669	1,149	50%	23%	6%
EPS (US$)	2.30	7.42	10.98	1.55	5.46	9.29	49%	36%	18%
Gross margin	85.20%	85.50%	86.00%	85.37%	86.29%	86.81%	-0.17 ppt	-0.79 ppt	-0.81 ppt

Source: Company data, Bloomberg, CMBIGM estimates

Financial Summary

INCOME STATEMENT	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (US$ mn)						
Revenue	**1,416**	**2,459**	**3,810**	**5,261**	**6,442**	**7,385**
Cost of goods sold	(286)	(380)	(594)	(779)	(934)	(1,034)
Gross profit	**1,129**	**2,079**	**3,216**	**4,482**	**5,508**	**6,352**
Operating expenses	**(2,919)**	**(3,287)**	**(3,784)**	**(4,209)**	**(4,574)**	**(4,948)**
SG&A expense	(1,278)	(1,505)	(1,831)	(2,157)	(2,512)	(2,806)
R&D expense	(1,641)	(1,779)	(1,953)	(2,052)	(2,061)	(2,142)
Others	(1)	(4)	0	0	0	0
Other income	(171)	382	35	28	36	33
Pre-tax profit	**(1,961)**	**(826)**	**(533)**	**301**	**970**	**1,436**
Income tax	(43)	(56)	(112)	(45)	(145)	(215)
Minority interest	0	0	0	0	0	0
Net profit	**(2,004)**	**(882)**	**(645)**	**256**	**824**	**1,221**
Adjusted net profit	**(2,004)**	**(882)**	**(645)**	**256**	**824**	**1,221**

BALANCE SHEET	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (US$ mn)						
Current assets	**5,207**	**4,203**	**3,992**	**4,679**	**5,659**	**7,103**
Cash & equivalents	3,870	3,172	2,627	3,185	3,901	5,157
Account receivables	173	358	676	714	874	1,002
Inventories	282	416	495	586	691	750
Financial assets at FVTPL	665	3	0	0	0	0
Other current assets	217	255	193	193	193	193
Non-current assets	**1,172**	**1,602**	**1,929**	**1,955**	**1,978**	**1,998**
PP&E	846	1,324	1,578	1,604	1,627	1,648
Deferred income tax	0	0	0	0	0	0
Intangibles	41	57	51	51	51	51
Other non-current assets	286	221	300	300	300	300
Total assets	**6,379**	**5,805**	**5,921**	**6,633**	**7,637**	**9,101**
Current liabilities	**1,469**	**1,810**	**2,215**	**2,271**	**2,350**	**2,394**
Short-term borrowings	329	688	852	852	852	852
Account payables	295	315	405	461	541	584
Tax payable	25	23	26	26	26	26
Other current liabilities	820	784	932	932	932	932
Non-current liabilities	**527**	**458**	**374**	**374**	**74**	**(126)**
Long-term borrowings	209	198	166	166	(134)	(334)
Deferred income	42	0	0	0	0	0
Other non-current liabilities	276	260	207	207	207	207
Total liabilities	**1,996**	**2,268**	**2,589**	**2,645**	**2,424**	**2,268**
Share capital	11,541	11,599	12,088	12,488	12,888	13,288
Retained earnings	(7,080)	(7,962)	(8,607)	(8,351)	(7,526)	(6,306)
Other reserves	(77)	(99)	(149)	(149)	(149)	(149)
Total shareholders equity	**4,383**	**3,537**	**3,332**	**3,988**	**5,213**	**6,833**
Minority interest	0	0	0	0	0	0
Total equity and liabilities	**6,379**	**5,805**	**5,921**	**6,633**	**7,637**	**9,101**

CASH FLOW	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec (US$ mn)						
Operating						
Profit before taxation	**(1,961)**	**(826)**	**(533)**	**301**	**970**	**1,436**
Depreciation & amortization	66	88	172	175	177	179
Tax paid	(43)	(56)	(112)	(45)	(145)	(215)
Others	441	(363)	332	327	215	256
Net cash from operations	**(1,497)**	**(1,157)**	**(141)**	**758**	**1,216**	**1,656**
Investing						
Capital expenditure	(325)	(562)	(493)	(200)	(200)	(200)
Acquisition of subsidiaries/ investments	(17)	(17)	(22)	0	0	0
Net proceeds from disposal of short-term investments	1,564	673	3	0	0	0
Others	(144)	(34)	(36)	0	0	0
Net cash from investing	**1,077**	**60**	**(548)**	**(200)**	**(200)**	**(200)**
Financing						
Net borrowings	351	684	877	0	0	0
Proceeds from share issues	0	0	0	0	0	0
Others	(370)	(268)	(684)	0	(300)	(200)
Net cash from financing	**(19)**	**416**	**193**	**0**	**(300)**	**(200)**
Net change in cash						
Cash at the beginning of the year	4,383	3,875	3,186	2,627	3,185	3,901
Exchange difference	(69)	(8)	(52)	0	0	0
Cash at the end of the year	**3,875**	**3,186**	**2,639**	**3,185**	**3,901**	**5,157**

GROWTH	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Revenue	20.4%	73.7%	55.0%	38.1%	22.5%	14.6%
Gross profit	11.7%	84.1%	54.7%	39.4%	22.9%	15.3%
Net profit	na	na	na	na	221.8%	48.1%
Adj. net profit	na	na	na	na	221.8%	48.1%

PROFITABILITY	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Gross profit margin	79.8%	84.5%	84.4%	85.2%	85.5%	86.0%
Adj. net profit margin	(141.5%)	(35.9%)	(16.9%)	4.9%	12.8%	16.5%
Return on equity (ROE)	(37.7%)	(22.3%)	(18.8%)	7.0%	17.9%	20.3%

GEARING/LIQUIDITY/ACTIVITIES	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
Net debt to equity (x)	(0.9)	(0.7)	(0.5)	(0.5)	(0.6)	(0.7)
Current ratio (x)	3.5	2.3	1.8	2.1	2.4	3.0
Receivable turnover days	84.6	39.4	49.5	49.5	49.5	49.5
Inventory turnover days	334.4	335.5	279.9	274.9	269.9	264.9
Payable turnover days	355.0	293.0	221.2	216.2	211.2	206.2

VALUATION	2022A	2023A	2024A	2025E	2026E	2027E
YE 31 Dec						
P/E	ns	ns	ns	106.0	32.9	22.3
P/E (diluted)	ns	ns	ns	106.0	32.9	22.3
P/B	74.7	93.7	100.4	88.5	67.7	51.7

Source: Company data, CMBIGM estimates. Note: The calculation of net cash includes financial assets.

Disclosures & Disclaimers

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