BeiGene Announces First Quarter 2025 Financial Results and Business Updates

- *First quarter 2025 total revenues increased 49% to $1.1 billion with BRUKINSA® (zanubrutinib) global sales increasing 62% to $792 million on strong demand growth versus first quarter 2024*
- *Achieved GAAP profitability and significantly improved operating cash flow*
- *Advanced late-stage hematology and solid tumor pipelines with plan to host Investor R&D Day on June 26*
- *Secured shareholder approval to rename the Company to BeOne Medicines Ltd. and redomicile to Switzerland*

SAN CARLOS, Calif. – (BUSINESS WIRE) – BeiGene, Ltd. (NASDAQ: ONC; HKEX: 06160; SSE: 688235), a global oncology company that will change its name to BeOne Medicines, Ltd., today announced financial results and corporate updates from the first quarter 2025.

"We delivered another exceptional quarter, achieving our first quarter of GAAP profitability with continued global revenue growth. In the U.S., BRUKINSA remains the leader in new chronic lymphocytic leukemia (CLL) patient starts across all lines of therapy, and for the first time has become the overall BTKi market share leader," said John V. Oyler, Co-Founder, Chairman, and CEO of BeiGene. "We've made significant strides across our late-stage hematology and solid tumor pipelines, with multiple proof-of-concept readouts expected this year across our broad portfolio of antibody-drug conjugates, multispecific antibodies and targeted protein degraders. With accelerating financial momentum and a diversified global footprint spanning six continents, we are well positioned — as we transition to BeOne Medicines and redomicile to Switzerland — to become one of the world's most impactful oncology innovators."

First Quarter 2025 Financial Snapshot

(Amounts in thousands of U.S. dollars and unaudited)

	Three Months Ended March 31,		
	2025	2024	% Change
Net product revenues	$1,108,530	$746,918	48%
Net revenue from collaborations	$8,749	$4,734	85%
Total revenue	$1,117,279	$751,652	49%
GAAP income (loss) from operations	$11,102	$(261,348)	104%
Adjusted income (loss) from operations*	$139,357	$(147,341)	195%
GAAP net income (loss)	$1,270	$(251,150)	101%
Adjusted net income (loss)*	$136,137	$(145,896)	193%
GAAP basic EPS per ADS	$0.01	$(2.41)	100%
Adjusted basic EPS per ADS*	$1.27	$(1.40)	191%
GAAP diluted EPS per ADS	$0.01	$(2.41)	100%
Adjusted diluted EPS per ADS*	$1.22	$(1.40)	187%

* For an explanation of our use of non-GAAP financial measures refer to the "Note Regarding Use of Non-GAAP Financial Measures" section later in this press release and for a reconciliation of each non-GAAP financial measure to the most comparable GAAP measures, see the table at the end of this press release.

First Quarter 2025 Financial Results

Revenue for the first quarter of 2025 was $1.1 billion, compared to $752 million in the prior-year period driven primarily by growth in BRUKINSA product sales in the U.S. and Europe.

Product Revenue totaled $1.1 billion for the first quarter of 2025 compared to $747 million in the prior-year period. The increase in product revenue was primarily attributable to increased sales of BRUKINSA. The U.S. continued to be the Company's largest market, with product revenue of $563 million compared to $351 million in the prior-year period. In-licensed products from Amgen and TEVIMBRA also contributed to product revenue growth.

- U.S. sales of BRUKINSA totaled $563 million in the first quarter of 2025, representing growth of 60% over the prior-year period driven primarily by demand, with more than 60% of the quarter-over-quarter growth coming from expanded use in CLL as BRUKINSA continued to gain share as the leader in new patient starts in the U.S. in CLL and all other approved indications; BRUKINSA sales in Europe totaled $116 million in the first quarter of 2025, representing growth of 73% compared to the prior-year period, driven by increased market share across all major European markets, including Germany, Italy, Spain, France and the UK.

- Sales of TEVIMBRA totaled $171 million in the first quarter of 2025, representing growth of 18% compared to the prior-year period.

Gross Margin as a percentage of global product sales for the first quarter of 2025 was 85.1% compared to 83.3% in the prior-year period on a GAAP basis. The gross margin percentage increased due to a proportionally higher sales mix of global BRUKINSA compared to other products in our portfolio. Gross margins also benefited from cost of sales productivity improvements for both BRUKINSA and TEVIMBRA. On an adjusted basis, which does not include depreciation and amortization, gross margin as a percentage of product sales increased to 85.5% for the first quarter of 2025, compared to 83.7% in the prior-year period.

Operating Expenses

The following table summarizes operating expenses for the first quarter of 2025:

	GAAP			Non-GAAP		
(unaudited, in thousands, except percentages)	Q1 2025	Q1 2024	% Change	Q1 2025	Q1 2024	% Change
Research and development	$481,887	$460,638	5%	$421,195	$405,440	4%
Selling, general and administrative	$459,288	$427,427	7%	$395,511	$372,146	6%
Total operating expenses	$941,175	$888,065	6%	$816,706	$777,586	5%

Research and Development (R&D) Expenses increased for the first quarter of 2025 compared to the prior-year period on both a GAAP and adjusted basis primarily due to advancing preclinical programs into the clinic and early clinical programs into late stage. Upfront fees and milestone payments related to in-process R&D for in-licensed assets totaled nil and $35 million in the first quarter of 2025 and 2024, respectively.

Selling, General and Administrative (SG&A) Expenses increased for the first quarter of 2025 compared to the prior-year period on both a GAAP and adjusted basis due to continued investment in the global commercial expansion of BRUKINSA primarily in the U.S. and Europe. SG&A expenses as a percentage of product sales were 41% for the first quarter of 2025, compared to 57% in the prior-year period.

Net Income/(Loss) and Earnings Per Share

GAAP net income improved for the first quarter of 2025, as compared to the prior-year period loss, primarily attributable to revenue growth and improved operating leverage.

For the first quarter of 2025, both basic and diluted earnings per share was $0.00 per share and $0.01 per American Depositary Share (ADS), respectively, compared to basic loss of $0.19 per share and $2.41 per ADS in the prior-year period.

Cash Provided by Operations for the first quarter of 2025 was $44 million, an increase of $353 million over the prior-year period.

For further details on BeiGene's First Quarter 2025 Financial Statements, please see BeiGene's Quarterly Report on Form 10-Q for the first quarter of 2025 filed with the U.S. Securities and Exchange Commission.

Full Year 2025 Guidance

BeiGene is maintaining its full year 2025 revenue and expense guidance. Guidance is summarized below:

	FY 2025[1]
Total Revenue	$4.9 billion to $5.3 billion
GAAP Operating Expenses (R&D and SG&A)	$4.1 billion to $4.4 billion

Additional: GAAP Gross Margin Percentage in mid-80% range
Positive Full Year GAAP Operating Income
Generation of Positive Cash Flow from Operations

[1] Does not assume any potential new, material business development activity or unusual/non-recurring items. Assumes January 31, 2025 foreign exchange rates.

BeiGene's total revenue guidance for full year 2025 of $4.9 billion to $5.3 billion includes expectations for strong revenue growth driven by BRUKINSA's U.S. leadership position and continued global expansion in both Europe and other important rest of world markets. Gross margin percentage is expected to be in the mid-80% range due to mix and production efficiencies as compared to 2024. BeiGene's guidance for combined operating expenses on a GAAP basis includes expectations of investment to support growth in both commercial and research at a pace that continues to deliver meaningful operating leverage. Non-GAAP operating expenses, which exclude costs related to share-based compensation, depreciation and amortization expense, are expected to track with GAAP operating expenses, with reconciling items unchanged from existing practice. Operating expense guidance does not assume any potential new, material business development activity or unusual/non-recurring items.

First Quarter Business Highlights

Core Marketed Products

BRUKINSA

- BRUKINSA is now approved in 75 markets globally with 11 new or expanded reimbursements in the quarter, including in Japan, Europe and Brazil.
- Received approval for the addition of Siegfried in Switzerland as an alternate Drug Substance manufacturer by the European Medicines Agency.

TEVIMBRA

- TEVIMBRA is now approved in 46 markets globally with 11 new reimbursements in the quarter, including in the U.S., Europe and China.

- Received U.S. Food and Drug Administration (FDA) approval in combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
- Received FDA approval for 150 mg Q2W and 300 mg Q4W alternate dosing regimens in addition to the already approved 200 mg Q3W dosing.
- Received Japan approval in combination with platinum-containing chemotherapy for the first- and second-line treatment of adult patients with unresectable or metastatic ESCC.
- Received European Commission approval in combination with etoposide and platinum chemotherapy as a first-line treatment for adult patients with extensive-stage small cell lung cancer.

Select Clinical-Stage Programs

Hematology

- Sonrotoclax (BCL2 inhibitor): Continued enrollment of global Phase 2 trial for the treatment of Waldenström's macroglobulinemia.
- Sonrotoclax BGB-11417-202: Filed in China for the treatment of relapsed/refractory (R/R) CLL.
- Sonrotoclax CELESTIAL-RR MCL BGB-11417-302: Achieved first subject enrolled for Phase 3 trial for the treatment of R/R MCL.
- Sonrotoclax CELESTIAL-TN CLL BGB-11417-301: Achieved last subject enrolled for Phase 3 trial for the treatment of treatment-naïve (TN) CLL.
- BGB-16673 (BTK CDAC): Continued enrollment of potentially registration enabling Phase 2 trial for the treatment of R/R CLL with data readout expected in 2026.
- BGB-16673: Initiated Phase 3 trial compared to physician's choice (IR/VR/BR) for treatment of R/R CLL.

Lung Cancer

- Tarlatamab (AMG757, DLL3xCD3 BiTE): Announced positive data readout from Phase 3 trial for the treatment of second-line small cell lung cancer in collaboration with Amgen.
- Anti-TIGIT antibody: Discontinued clinical development of ociperlimab as a potential treatment for lung cancer.

Anticipated R&D Milestones

- The Company will hold an Investor R&D Day on June 26 highlighting its emerging breast cancer franchise and broader solid tumor portfolio.

Programs	Milestones	Timing
BRUKINSA	• Tablet formulation: FDA and European Commission approvals.	2H 2025
	• MANGROVE trial for TN MCL: Interim analysis of Phase 3 trial.	2H 2025
	• MAHOGANY trial for the treatment of R/R follicular lymphoma: Complete enrollment of the FL portion of Phase 3 trial.	2H 2025
TEVIMBRA	• EU approvals for the treatment of:	
	○ Neoadjuvant/adjuvant non-small cell lung cancer.	2H 2025
	○ First-line nasopharyngeal carcinoma.	2H 2025
	• Subcutaneous formulation: Initiate Phase 3 trial.	2H 2025
Hematology	• Sonrotoclax in combination with anti-CD20 antibody for the treatment of R/R CLL: First subject enrolled in global Phase 3 trial.	1H 2025 2H 2025

	• Sonrotoclax for the treatment of R/R MCL: Data readout of Phase 2 trial and potential global accelerated approval submissions. • BGB-16673 compared to noncovalent BTK inhibitor pirtobrutinib for the treatment of R/R CLL: Initiate Phase 3 head-to-head trial.	2H 2025
Lung Cancer	• BGB-58067 (PRMT5 inhibitor) and BG-89894 (MAT2A inhibitor): First subject enrolled in combination trial.	2H 2025
Breast and Gynecologic Cancers	• BGB-43395 (CDK4 inhibitor): Proof-of-concept data.	1H 2025
GI Cancers	• Zanidatamab (HER2-bispecific antibody) for the treatment of first-line HER2-positive gastroesophageal adenocarcinoma: Readout of primary progression-free survival data from Phase 3 trial of in collaboration with Zymeworks/Jazz.	2H 2025
Inflammation and Immunology	• BGB-45035 (IRAK4 CDAC): First subject enrolled in Phase 2 trial. • BGB-45035: Proof-of-concept data for tissue IRAK4 degradation.	2H 2025 2H 2025

Other Highlights

- Received shareholder approval on April 28, 2025, to rename the Company to BeOne Medicines Ltd. and redomicile to Switzerland with the transaction set to close later this year.
- As previously disclosed, announced a U.S. Patent Trademark Office Final Written Decision invalidating all claims of Pharmacyclics LLC's U.S. Patent No. 11,672,803 that were challenged by BeiGene in a post-grant review (PGR) proceeding.
- Appointed Marcello Damiani as Chief Technology Officer.

Conference Call and Webcast

The Company's earnings conference call for the first quarter 2025 will be broadcast via webcast at 8:00 a.m. ET on Wednesday, May 7, 2025, and will be accessible through the Investors section of BeiGene's website, www.beigene.com. Supplemental information in the form of a slide presentation and a replay of the webcast will also be available.

About BeiGene

BeiGene, which will change its name to BeOne Medicines Ltd., is a global oncology company that is discovering and developing innovative treatments that are more affordable and accessible to cancer patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 11,000 colleagues spans six continents.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the anticipated milestones to be achieved by BeiGene in 2025; BeiGene's ability to become one of the world's most impactful oncology innovators; BeiGene's future revenue, operating income, cash flow, operating expenses and gross margin percentage; and BeiGene's plans, commitments, aspirations and goals under the caption "About BeiGene". Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing, commercialization, and other services; BeiGene's limited experience in

obtaining regulatory approvals and commercializing pharmaceutical products; BeiGene's ability to obtain additional funding for operations and to complete the development of its drug candidates and achieve and maintain profitability; and those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law. BeiGene's financial guidance is based on estimates and assumptions that are subject to significant uncertainties.

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BeiGene

Condensed Consolidated Statements of Operations (U.S. GAAP)

(Amounts in thousands of U.S. dollars, except for shares, American Depositary Shares (ADSs), per share and per ADS data)

	Three Months Ended March 31,	
	2025	2024
	(Unaudited)	
Revenues		
Product revenue, net	$1,108,530	$746,918
Collaboration revenue	8,749	4,734
Total revenues	1,117,279	751,652
Cost of sales - products	165,002	124,935
Gross profit	952,277	626,717
Operating expenses:		
Research and development	481,887	460,638
Selling, general and administrative	459,288	427,427
Total operating expenses	941,175	888,065
Income (loss) from operations	11,102	(261,348)
Interest income, net	5,848	16,160
Other income, net	3,950	1,762
Income (loss) before income taxes	20,900	(243,426)
Income tax expense	19,630	7,724
Net income (loss)	$1,270	$(251,150)
Earnings (loss) per share		
Basic	$ 0.00	$(0.19)
Diluted	$ 0.00	$(0.19)
Weighted-average shares outstanding—basic	1,390,052,966	1,355,547,626
Weighted-average shares outstanding—diluted	1,445,253,219	1,355,547,626
Earnings (loss) per American Depositary Share (“ADS”)		
Basic	$0.01	$(2.41)
Diluted	$0.01	$(2.41)
Weighted-average ADSs outstanding—basic	106,927,151	104,272,894
Weighted-average ADSs outstanding—diluted	111,173,325	104,272,894

Select Condensed Consolidated Balance Sheet Data (U.S. GAAP)

(Amounts in thousands of U.S. Dollars)

	As of	
	March 31, 2025	December 31, 2024
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents and restricted cash	$2,530,591	$2,638,747
Accounts receivable, net	717,239	676,278
Inventories	494,660	494,986
Property, plant and equipment, net	1,598,588	1,578,423
Total assets	5,841,526	5,920,910
Liabilities and equity:		
Accounts payable	364,498	404,997
Accrued expenses and other payables	692,179	803,713
R&D cost share liability	145,628	165,440
Debt	923,627	1,018,013
Total liabilities	2,342,013	2,588,688
Total equity	$3,499,513	$3,332,222

Select Unaudited Condensed Consolidated Statements of Cash Flows (U.S. GAAP)

(Amounts in thousands of U.S. Dollars)

	Three Months Ended March 31,	
	2025	2024
	(unaudited)	
Cash, cash equivalents and restricted cash at beginning of period	$2,638,747	$3,185,984
Net cash provided by (used in) operating activities	44,082	(308,572)
Net cash used in investing activities	(121,941)	(209,831)
Net cash (used in) provided by financing activities	(33,777)	162,293
Net effect of foreign exchange rate changes	3,480	(22,438)
Net decrease in cash, cash equivalents, and restricted cash	(108,156)	(378,548)
Cash, cash equivalents and restricted cash at end of period	$2,530,591	$2,807,436

Note Regarding Use of Non-GAAP Financial Measures

BeiGene provides certain non-GAAP financial measures, including Adjusted Operating Expenses Adjusted Operating Loss, Adjusted Net Income, Adjusted Earnings Per Share and certain other non-GAAP income statement line items, each of which include adjustments to GAAP figures. These non-GAAP financial measures are intended to provide additional information on BeiGene's operating performance. Adjustments to BeiGene's GAAP figures exclude, as applicable, non-cash items such as share-based compensation, depreciation and amortization. Certain other special items or substantive events may also be included in the non-GAAP adjustments periodically when their magnitude is significant within the periods incurred. Non-GAAP adjustments are tax effected to the extent there is US GAAP current tax expense. The Company currently records a valuation allowance on its net deferred tax assets, so there is no net impact recorded for deferred tax effects. BeiGene maintains an established non-GAAP policy that guides the determination of what costs will be excluded in non-GAAP financial measures and the related protocols, controls and approval with respect to the use of such measures. BeiGene believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of BeiGene's operating performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of the Company's historical and expected financial results and trends and to facilitate comparisons between periods and with respect to projected information. In addition, these non-GAAP financial measures are among the indicators BeiGene's management uses for planning and forecasting purposes and measuring the Company's performance. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The non-GAAP financial measures used by the Company may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies.

BeiGene

RECONCILIATION OF SELECTED GAAP MEASURES TO NON-GAAP MEASURES

(Amounts in thousands of U.S. Dollars)

(unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Reconciliation of GAAP to adjusted cost of sales - products:		
GAAP cost of sales - products	$165,002	$124,935
Less: Depreciation	2,613	2,345
Less: Amortization of intangibles	1,173	1,183
Adjusted cost of sales - products	$161,216	$121,407
Reconciliation of GAAP to adjusted research and development:		
GAAP research and development	$481,887	$460,638
Less: Share-based compensation cost	41,767	38,045
Less: Depreciation	18,925	17,153
Adjusted research and development	$421,195	$405,440
Reconciliation of GAAP to adjusted selling, general and administrative:		
GAAP selling, general and administrative	$459,288	$427,427
Less: Share-based compensation cost	53,684	50,669
Less: Depreciation	10,076	4,612
Less: Amortization of intangibles	17	—
Adjusted selling, general and administrative	$395,511	$372,146
Reconciliation of GAAP to adjusted operating expenses		
GAAP operating expenses	$941,175	$888,065
Less: Share-based compensation cost	95,451	88,714
Less: Depreciation	29,001	21,765
Less: Amortization of intangibles	17	—
Adjusted operating expenses	$816,706	$777,586
Reconciliation of GAAP to adjusted income (loss) from operations:		
GAAP income (loss) from operations	$11,102	$(261,348)
Plus: Share-based compensation cost	95,451	88,714
Plus: Depreciation	31,614	24,110
Plus: Amortization of intangibles	1,190	1,183
Adjusted income (loss) from operations	$139,357	$(147,341)

Reconciliation of GAAP to adjusted net income (loss):		
GAAP net income (loss)	$1,270	$(251,150)
Plus: Share-based compensation expenses	95,451	88,714
Plus: Depreciation	31,614	24,110
Plus: Amortization of intangibles	1,190	1,183
Plus: Impairment of equity investments	12,376	—
Plus: Income tax effect of non-GAAP adjustments	(5,764)	(8,753)
Adjusted net income (loss)	$136,137	$(145,896)
Reconciliation of GAAP to adjusted EPS - basic		
GAAP earnings (loss) per share - basic	$0.00	$(0.19)
Plus: Share-based compensation expenses	0.07	0.07
Plus: Depreciation	0.02	0.02
Plus: Amortization of intangibles	0.00	0.00
Plus: Impairment of equity investments	0.01	0.00
Plus: Income tax effect of non-GAAP adjustments*	(0.00)	(0.01)
Adjusted earnings (loss) per share - basic	$0.10	$(0.11)
Reconciliation of GAAP to adjusted EPS - diluted		
GAAP earnings (loss) per share - diluted	$0.00	$(0.19)
Plus: Share-based compensation expenses	0.07	0.07
Plus: Depreciation	0.02	0.02
Plus: Amortization of intangibles	0.00	0.00
Plus: Impairment of equity investments	0.01	0.00
Plus: Income tax effect of non-GAAP adjustments*	(0.00)	(0.01)
Adjusted earnings (loss) per share - diluted	$0.09	$(0.11)
Reconciliation of GAAP to adjusted earnings (loss) per ADS - basic		
GAAP earnings (loss) per ADS - basic	$0.01	$(2.41)
Plus: Share-based compensation expenses	0.89	0.85
Plus: Depreciation	0.30	0.23
Plus: Amortization of intangibles	0.01	0.01
Plus: Impairment of equity investments	0.12	0.00
Plus: Income tax effect of non-GAAP adjustments*	(0.05)	(0.08)
Adjusted earnings (loss) per ADS - basic	$1.27	$(1.40)
Reconciliation of GAAP to adjusted earnings (loss) per ADS - diluted		
GAAP earnings (loss) per ADS - diluted	$0.01	$(2.41)
Plus: Share-based compensation expenses	0.86	0.85

Plus: Depreciation	0.28	0.23
Plus: Amortization of intangibles	0.01	0.01
Plus: Impairment of equity investments	0.11	0.00
Plus: Income tax effect of non-GAAP adjustments*	(0.05)	(0.08)
Adjusted earnings (loss) per ADS - diluted	$1.22	$(1.40)

***Tax effect of Non-GAAP adjustments is based on the statutory tax rate in the relevant tax jurisdiction. Please note that the Company currently records a valuation allowance on its net deferred tax assets, so there is no net impact recorded for deferred tax effects.**