Source: *BeiGene, LTD.*

May 10, 2017 16:15 ET

BeiGene Reports First Quarter 2017 Financial Results

CAMBRIDGE, Mass., May 10, 2017 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ:BGNE) a clinical-stage biopharmaceutical company developing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today reported business highlights and financial results for the first quarter of 2017.

“BeiGene has transitioned into a late-stage biotechnology company with the recent initiation of four pivotal clinical trials for our BTK inhibitor BGB-3111 and PD-1 antibody BGB-A317. We also continue to build our capabilities through our agreement with the Guangzhou Development District to establish a commercial-scale biologics manufacturing joint venture and through the expansion of our global team,” said John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

“We expect 2017 to be a data-rich year for BeiGene, and our near-term presentations include initial data from our internal combination of BGB-A317 and our PARP inhibitor BGB-290 at the 2017 American Society of Clinical Oncology Annual Meeting, BGB-3111 data as monotherapy and in combination with CD20 antibody obinutuzumab at the 14th International Conference on Malignant Lymphoma, and initial data on BGB-A317 in liver cancer at the ESMO 19th World Congress on Gastrointestinal Cancer. We look forward to initiating additional pivotal studies of our portfolio compounds this year,” commented Mr. Oyler.

First Quarter 2017 and Recent Business Highlights

Clinical Programs:

BGB-3111, *a potent and highly selective small molecule inhibitor of Bruton’s tyrosine kinase (BTK)*

- Initiated a global Phase III trial of BGB-3111 compared with ibrutinib in patients with Waldenström’s macroglobulinemia (WM).
- Initiated pivotal clinical studies with BGB-3111 in China, including a study in patients with relapsed / refractory mantle cell lymphoma (MCL) and a study in patients with relapsed / refractory chronic lymphocytic leukemia / small lymphocytic lymphoma (CLL / SLL).
- Continued enrollment in the multi-indication dose-expansion phase of the BGB-3111 Phase I monotherapy trial in Australia, New Zealand, the United States, and South Korea.
- Continued follow-up on patients enrolled in the Phase I monotherapy trial of BGB-3111 in Chinese patients with B-cell malignancies.
- Continued enrollment in the dose-expansion phase of the global combination trial of BGB-3111 and obinutuzumab, an anti-CD20 antibody, in patients with B-cell malignancies.
- Continued enrollment in the combination trial of BGB-3111 and BGB-A317 in Australia in patients with B-cell malignancies.

BGB-A317, *an investigational humanized monoclonal antibody against the immune checkpoint receptor PD-1*

- Initiated a pivotal clinical study of BGB-A317 in Chinese patients with relapsed or refractory classical Hodgkin lymphoma.
- Continued enrollment in the Phase I study of BGB-A317 in Chinese patients with advanced solid tumors.

- Continued enrollment in the multi-indication dose-expansion phase of the BGB-A317 Phase I monotherapy trial in Australia, New Zealand, the United States, South Korea, and Taiwan.

- Continued enrollment in the global combination trial of BGB-A317 and BGB-290 in patients with advanced solid tumors.

- Continued enrollment in the combination trial of BGB-A317 and BGB-3111 in patients with B-cell malignancies.

BGB-290, *a potent and highly selective PARP inhibitor*

- Continued enrollment in the Phase I study of BGB-290 in Chinese patients with advanced solid tumors.

- Continued enrollment in the dose-expansion phase of the BGB-290 Phase I monotherapy trial in Australia in patients with advanced solid tumors.

- Continued enrollment in the global combination trial of BGB-290 and BGB-A317 in patients with advanced solid tumors.

BGB-283, *a novel RAF dimer inhibitor that targets both B-RAF- and RAS-mutated cancers*

- Presented data from the Phase Ib study of BGB-283 in patients with B-RAF- or K-RAS/N-RAS-mutated solid tumors at the 2017 American Association for Cancer Research (AACR) Annual Meeting.

Corporate Development:

- Established a joint venture with the Guangzhou Development District to build a commercial biologics manufacturing facility in Guangzhou, Guangdong Province, China. Expected direct investments total RMB 2.2 billion ($330 million) and include support for the research and development of our biologic drug candidates in China.

- Continued to expand the senior management team with the appointments of Eric Hedrick, M.D. as Chief Advisor and Scott Samuels, Esq., as Senior Vice President, General Counsel.

Expected Upcoming Milestones

BGB-3111 (BTK Inhibitor)

- Present updated Phase I monotherapy data and initial data from the combination study of BGB-3111 with obinutuzumab at the 14th International Conference on Malignant Lymphoma in Lugano, June 10 – 13, 2017.

- Present data from the Phase I combination study of BGB-3111 with BGB-A317 in 2017.

- Present additional data from the dose-expansion phase of the Phase I monotherapy study in 2017.

- Present data from the China Phase I study of BGB-3111 in 2017

BGB-A317 (PD-1 Antibody)

- Present data from the Phase I combination study of BGB-A317 and BGB-290 at the 2017 American Society of Clinical Oncology Annual meeting in Chicago on June 5, 2017.

- Present data from the Phase Ia/Ib study of BGB-A317 in patients with advanced hepatocellular carcinoma at the ESMO 19th World Congress on Gastrointestinal Cancer in Barcelona, June 28 – July 1, 2017.

- Present data from the Phase I combination study of BGB-A317 and BGB-3111 in 2017.

- Present data from the dose-expansion phase of the ongoing Phase I trials in 2017.

BGB-290 (PARP Inhibitor)

- Present data from the Phase I combination study of BGB-A317 and BGB-290 at the 2017 American Society of Clinical Oncology Annual meeting in Chicago on June 5, 2017.

- Present updated Phase I monotherapy data in 2017.

First Quarter 2017 Financial Results

Cash, Cash Equivalents, and Short-term Investments were $327.48 million as of March 31, 2017, compared to $368.17 million as of December 31, 2016. The decrease reflects cash used in operating activities and cash used for capital expenditures during the three months ended March 31, 2017.

The cash used in operations for the quarter ended March 31, 2017 was $35.71 million, compared to $19.84 million for the same period in 2016. The increase was primarily attributable to higher operating expense. Capital expenditures for the quarter ended March 31, 2017 were $7.39 million, compared to $3.30 million for the same period in 2016. The increase was primarily attributable to the construction of the manufacturing facility in Suzhou and the payment of a land auction deposit in Guangzhou.

Revenue for the three months ended March 31, 2017 was nil, compared to $0.68 million in the same period in 2016. Changes in revenue are primarily attributable to a decrease of revenue recognized under our collaboration agreement for BGB-283.

Research & Development (R&D) Expenses for the three months ended March 31, 2017 were $42.77 million, compared to $17.88 million in the same period in 2016. The increase in R&D expenses was primarily attributable to increased spending on clinical activities for BGB-3111, BGB-A317 and BGB-290, due to expansion of ongoing clinical programs, start-up activities for registration trials and increased employee compensation-related expenses as a result of increased headcount to support growing clinical studies. In addition, R&D-associated share-based compensation expense was $4.53 million for the three months ended March 31, 2017, compared to $2.30 million for the same period in 2016.

General & Administrative (G&A) Expenses for the three months ended March 31, 2017 were $8.77 million compared to $3.13 million in the same period in 2016. The increase in G&A expenses was primarily attributable to increased employee compensation-related expenses as a result of increased headcount and higher professional service fees to support growing operations. In addition, G&A-associated share-based compensation expense was $1.46 million for the three months ended March 31, 2017, compared to $0.32 million for the same period in 2016.

Net Loss for the three months ended March 31, 2017 was $50.62 million compared to $22.00 million in the same period in 2016.

Financial Summary:

Select Consolidated Balance Sheet Data (U.S. GAAP)
(Amounts in thousands of U.S. Dollars)

	March 31, 2017 (unaudited)	December 31, 2016 (audited)
Cash, cash equivalents, and short-term investments	$ 327,476	$ 368,174
Prepaid expenses and other current assets	8,702	6,225
Property and equipment, net	30,723	25,977
Total assets	376,729	405,813
Accounts payable	20,482	11,957
Long-term bank loan	17,434	17,284
Total shareholders' equity	$ 308,417	$ 352,907

Consolidated Statements of Operations (U.S. GAAP)
(Amounts in thousands of U.S. Dollars, except for number of ADSs and per ADS data) (unaudited)

	Three Months Ended March 31,	
	2017	2016
Collaboration revenue	$ —	$ 677
Operating expenses:		
Research and development	(42,773)	(17,877)
General and administrative	(8,769)	(3,134)

Total operating expenses	(51,542)	(21,011)
Loss from operations	(51,542)	(20,334)
Interest income, net	186	290
Other income (expense), net	913	(1,913)
Loss before income tax expense	(50,443)	(21,957)
Income tax expense	(180)	(44)
Net loss	$ (50,623)	$ (22,001)
Net loss per ADS, basic and diluted	$ (1.27)	$ (0.97)
Weighted-average number of ADS used in net loss per ADS calculation - basic and diluted	39,725,977	22,618,659

Consolidated Statements of Comprehensive Loss (U.S. GAAP)
(Amounts in thousands of U.S. Dollars) (unaudited)

	Three Months Ended March 31,	
	2017	2016
Net loss	$ (50,623)	$ (22,001)
Other comprehensive loss, net of tax of nil:		
Foreign currency translation adjustments	90	97
Unrealized holding (loss)/gain, net	(12)	461
Comprehensive loss	$ (50,545)	$ (21,443)

About BeiGene

BeiGene is a global, clinical-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 300 scientists, clinicians and staff in mainland China, the United States, Australia and Taiwan, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is working to create combination solutions aimed at having both a meaningful and lasting impact on cancer patients.

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 BeiGene's financial condition; results of operations and business outlook; the sufficiency of its cash, cash equivalents and short-term investments; plans for its manufacturing joint venture and expansion of its global team; and momentum of its product pipeline, as well as the advancement of, and anticipated clinical development and regulatory milestones and plans related to BeiGene's drug candidates and clinical trials, including commencing registration and combination trials and providing data readouts and updates for its clinical candidates. 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; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; BeiGene's ability to achieve market acceptance in the medical community necessary for commercial success; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct preclinical studies and clinical trials and to manufacture its product candidates; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent annual report on Form 10-K, 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.