



BeiGene

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BeiGene Reports Second Quarter 2017 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, Aug. 09, 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 second quarter and first six months of 2017.

“This quarter has been transformative for BeiGene. Our announced strategic collaboration with Celgene, which is expected to close in the third quarter, is an important step in the buildout of our internal capabilities from a research organization into a fully integrated biopharmaceutical company with clinical development, manufacturing, and soon a commercial platform. The planned addition of Celgene’s China commercial team and three commercial-stage drugs in China positions us well ahead of the potential launches of our own internally developed drug candidates in China. Importantly, we also expect that the Celgene collaboration will maximize the value of our PD-1 antibody BGB-A317 globally. In addition, during the quarter we announced late-stage development plans for BGB-3111, including two additional global registrational trials, supported by our data updates at the 14th International Conference on Malignant Lymphoma. Our other clinical programs remain on track with the initiation of several new trials, including two registrational trials of BGB-A317 in China,” said John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

“We expect to continue our momentum through the second half of the year. In the near-term, we will present updated Phase 1 monotherapy data on BGB-A317 and BGB-290 at the European Society of Medical Oncology 2017 Congress. We also expect to initiate additional registrational trials before the end of the year,” commented Mr. Oyler.

Second Quarter 2017 and Recent Business Highlights

Clinical Programs:

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

- Presented updated Phase 1 data on BGB-3111 in chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and Waldenström’s macroglobulinemia (WM), as well as initial data from the combination trial of BGB-3111 and obinutuzumab, an anti-CD20 antibody, in CLL/SLL and follicular lymphoma (FL) at the 14th International Conference on Malignant Lymphoma.
- Initiated a Phase 2 trial of BGB-3111 in Chinese patients with non-germinal center B-cell-like diffuse large B-cell lymphoma.
- Continued enrollment in the following trials:
 - Global Phase 3 trial of BGB-3111 compared with ibrutinib in WM
 - Registrational trial of BGB-3111 in Chinese patients with relapsed/refractory mantle cell lymphoma
 - Registrational trial of BGB-3111 in Chinese patients with relapsed/refractory CLL/SLL
 - Dose-expansion phase of the global BGB-3111 Phase 1 monotherapy trial in B-cell malignancies
 - Dose-expansion phase of the global Phase 1 combination trial of BGB-3111 and obinutuzumab in B-cell malignancies
 - Phase 1 combination trial of BGB-3111 and BGB-A317 in B-cell malignancies in Australia
- Continued follow-up on patients enrolled in the Phase 1 monotherapy trial of BGB-3111 in Chinese patients with B-cell lymphoma.

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

- Presented initial data from the Phase 1 trial of BGB-A317 in combination with BGB-290 in advanced solid tumors at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting.

- Presented preliminary Phase 1 data on BGB-A317 in hepatocellular carcinoma at the European Society for Medical Oncology (ESMO) 19th World Congress on Gastrointestinal Cancer.
- Initiated registrational trials of BGB-A317 in China: one in relapsed/refractory classical Hodgkin lymphoma and another in previously treated, PD-L1-positive, locally advanced or metastatic urothelial cancer.
- Initiated a Phase 2 trial of BGB-A317 in combination with chemotherapy for the first-line treatment of Chinese patients with locally advanced or metastatic esophageal, gastric, or gastroesophageal junction carcinoma.
- Continued enrollment in the following trials:
 - Dose-expansion phase of the global BGB-A317 Phase 1 monotherapy trial in advanced solid tumors
 - Phase 1 trial of BGB-A317 in Chinese patients with advanced solid tumors
 - Phase 1 combination trial of BGB-A317 and BGB-290 in advanced solid tumors in Australia
 - Phase 1 combination trial of BGB-A317 and BGB-3111 in B-cell malignancies in Australia

BGB-290, a potent and highly selective PARP inhibitor

- Presented initial data from the Phase 1 trial of BGB-290 in combination with BGB-A317 in advanced solid tumors at the 2017 ASCO Annual Meeting.
- Initiated a global Phase 1 trial of BGB-290 in combination with temozolomide in locally advanced or metastatic solid tumors.
- Initiated a global Phase 1b/2 trial of BGB-290 in combination with radiation therapy and/or temozolomide in glioblastoma.
- Continued enrollment in the following trials:
 - Dose-expansion phase of the BGB-290 Phase 1 monotherapy trial in advanced solid tumors in Australia
 - Phase 1 trial of BGB-290 in Chinese patients with advanced solid tumors
 - Phase 1 combination trial of BGB-290 and BGB-A317 in advanced solid tumors in Australia.

Corporate Development:

- Entered into a strategic collaboration with Celgene Corporation. Upon closing, BeiGene will acquire Celgene's commercial operations in China and assume commercial responsibility for Celgene's approved therapies in China (Abraxane[®], Revlimid[®], and Vidaza[®]) and pipeline agent CC-122. Celgene will gain exclusive rights to develop and commercialize BGB-A317 for solid tumors in the United States, the European Union, Japan, and the rest of the world outside of Asia. BeiGene will retain rights for solid tumors in Asia (ex-Japan) and for hematological malignancies and internal combinations globally. Subject to closing, BeiGene will receive \$413 million from Celgene in upfront licensing fees and an equity investment and will be eligible for up to \$980 million in development, regulatory, and sales milestones, as well as royalties on future sales of BGB-A317. The transaction is expected to close in the third quarter of 2017.

Expected Upcoming Milestones

BGB-3111 (BTK Inhibitor)

- Present data from the Phase 1 combination trial of BGB-3111 with BGB-A317 in 2017.
- Present additional data from the dose-expansion phase of the Phase 1 monotherapy trial.
- Present additional data from the Phase 1 combination trial of BGB-3111 with obinutuzumab.
- Initiate global Phase 3 trial of BGB-3111 in comparison with bendamustine and rituximab in treatment naïve CLL/SLL
- Initiate global registrational Phase 2 trial of BGB-3111 and obinutuzumab in comparison with obinutuzumab alone in relapsed/refractory FL

BGB-A317 (PD-1 Antibody)

- Present updated Phase 1 monotherapy data at the ESMO 2017 Congress in Madrid, Spain, September 8-12, 2017.
- Present data from the Phase 1 combination trial of BGB-A317 and BGB-3111 in 2017.
- Present data from the Phase 1 trial in Chinese patients with advanced solid tumors in 2017.

BGB-290 (PARP Inhibitor)

- Present updated Phase 1 monotherapy data at the ESMO 2017 Congress in Madrid, Spain, September 8-12, 2017.

Second Quarter 2017 Financial Results

Cash, Cash Equivalents, and Short-term Investments were \$407.43 million as of June 30, 2017, compared to \$368.17 million as of December 31, 2016. The increase was due primarily to proceeds from an equity investment in and a shareholder loan to BeiGene Biologics by Guangzhou GET Technology Development Co.,

Ltd (GET) to build a commercial-scale biologics plant in Guangzhou, China, and to fund research and development of biologics drug candidates in China. These proceeds were partially offset by cash used in operating activities and for capital expenditures during the three months ended June 30, 2017. The Company consolidates the BeiGene Biologics joint venture and recognizes GET's equity interest as a noncontrolling interest in its consolidated financial statements. As of June 30, 2017, cash and cash equivalents included \$155.24 million of cash held by BeiGene Biologics.

Cash used in operations for the three months ended June 30, 2017 was \$51.89 million, compared to \$19.26 million for the same period in 2016. The increase was primarily attributable to higher research and development (R&D) and general and administrative (G&A) expenses in support of our clinical trials and the expansion of our workforce, as further detailed below. Capital expenditures for the quarter ended June 30, 2017 were \$13.62 million, compared to \$5.46 million for the same period in 2016. The increase was primarily attributable to increased investment in our manufacturing capabilities.

Revenue for the three months ended June 30, 2017 was nil, compared to \$0.39 million in the same period in 2016. The decrease in revenue in the period was due to the completion of R&D service deliverables under our collaboration agreement for BGB-283.

R&D Expenses for the three months ended June 30, 2017 were \$47.25 million, compared to \$21.12 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 registrational trials and increased employee compensation-related expenses as a result of increased headcount to support growing clinical trials. Increased costs were also incurred related to activities for our preclinical assets. In addition, R&D-associated share-based compensation expense was \$4.75 million for the three months ended June 30, 2017, compared to \$0.74 million for the same period in 2016.

G&A Expenses for the three months ended June 30, 2017 were \$10.78 million compared to \$3.90 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 our growing operations. In addition, G&A-associated share-based compensation expense was \$2.33 million for the three months ended June 30, 2017, compared to \$0.54 million for the same period in 2016.

Net Loss Attributable to BeiGene, Ltd. for the three months ended June 30, 2017 was \$60.55 million compared to \$24.12 million in the same period in 2016.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	June 30, 2017 (unaudited)	December 31, 2016 (audited)
Cash, cash equivalents and short-term investments	\$ 407,430	\$ 368,174
Prepaid expenses and other current assets	11,261	6,225
Property and equipment, net	33,770	25,977
Total assets	473,975	405,813
Accounts payable	24,419	11,957
Long-term bank loan	17,701	17,284
Shareholder loan	135,027	—
Noncontrolling interest	14,419	—
Total equity	\$ 270,172	\$ 352,907

Consolidated Statements of Operations (U.S. GAAP)

(Amounts in thousands of U.S. Dollars, except for number of American Depositary Shares (ADSs) and per ADS data) (unaudited)

Three Months Ended June 30,	Six Months Ended June 30,
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	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Collaboration revenue	\$ —	\$ 393	\$ —	\$ 1,070
Operating expenses:				
Research and development	(47,245)	(21,117)	(90,018)	(38,994)
General and administrative	(10,777)	(3,904)	(19,546)	(7,038)
Total operating expenses	<u>(58,022)</u>	<u>(25,021)</u>	<u>(109,564)</u>	<u>(46,032)</u>
Loss from operations	(58,022)	(24,628)	(109,564)	(44,962)
Interest (expense) income, net	(1,982)	121	(1,796)	411
Changes in fair value of financial instruments	—	—	—	(1,514)
Gain (loss) on sale of available-for-sale securities	2	(228)	10	(940)
Other (expense) income, net	(477)	746	428	1,059
Loss before income tax expense	<u>(60,479)</u>	<u>(23,989)</u>	<u>(110,922)</u>	<u>(45,946)</u>
Income tax expense	(201)	(135)	(381)	(179)
Net loss	<u>\$ (60,680)</u>	<u>\$ (24,124)</u>	<u>\$ (111,303)</u>	<u>\$ (46,125)</u>
Less: Net loss attributable to noncontrolling interest	(135)	—	(135)	—
Net loss attributable to BeiGene, Ltd.	<u>\$ (60,545)</u>	<u>\$ (24,124)</u>	<u>\$ (111,168)</u>	<u>\$ (46,125)</u>
Net loss attributable to common shareholders per ADS, basic and diluted	<u>\$ (1.52)</u>	<u>\$ (0.73)</u>	<u>\$ (2.80)</u>	<u>\$ (1.66)</u>
Weighted-average number of ADS used in net loss per ADS calculation - basic and diluted	<u>39,820,287</u>	<u>32,903,593</u>	<u>39,773,393</u>	<u>27,761,107</u>

Consolidated Statements of Comprehensive Loss (U.S. GAAP)

(Amounts in thousands of U.S. Dollars) (unaudited)

	Three Months		Six Months Ended	
	Ended		June 30,	
	June 30,		June 30,	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Net loss	\$ (60,680)	\$ (24,124)	\$ (111,303)	\$ (46,125)
Other comprehensive loss, net of tax of nil:				
Foreign currency translation adjustments	554	(486)	644	(390)
Unrealized holding gain, net	19	275	7	736
Comprehensive loss	<u>(60,107)</u>	<u>(24,335)</u>	<u>(110,652)</u>	<u>(45,779)</u>
Less: Comprehensive loss attributable to noncontrolling interests	(108)	—	(108)	—
Comprehensive loss attributable to BeiGene, Ltd.	<u>\$ (59,999)</u>	<u>\$ (24,335)</u>	<u>\$ (110,544)</u>	<u>\$ (45,779)</u>

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 400 employees in China, the United States, and Australia, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for the treatment of 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 expected closing of the strategic transaction with Celgene and the benefits of that transaction; the sufficiency of its cash, cash equivalents and short-term

investments; plans for its manufacturing joint venture; and momentum of its business, 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 registrational and combination trials and providing data readouts and updates for its drug candidates. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including risks related to the proposed strategic transaction with Celgene; 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 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.