



# BeiGene

*Source : BeiGene, LTD.*

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## BeiGene Reports Third Quarter 2017 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, Nov. 13, 2017 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ:BGNE), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today reported business highlights and financial results for the third quarter and first nine months of 2017.

“BeiGene has achieved several important milestones since the beginning of the third quarter. Our strategic collaboration with Celgene Corporation has transformed us into a commercial-stage company in China and is expected to enhance the potential of our investigational PD-1 inhibitor, BGB-A317. We have also made important clinical progress with the expansion of the global pivotal program for our BTK inhibitor BGB-3111, the initiation of the first Phase 3 study for BGB-A317 in China, and the completion of patient enrollment of our first China pivotal trials for both BGB-3111 and BGB-A317. In addition, we strengthened our balance sheet with the upfront payment and investment from Celgene as well as our public offering in August,” said John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

“Looking ahead, we plan to present additional data on BGB-3111 at the 59<sup>th</sup> American Society of Hematology Annual Meeting in December. We also look forward to initiating additional pivotal trials for our portfolio assets in the coming months,” commented Mr. Oyler.

### Third Quarter 2017 and Recent Business Highlights

#### *Clinical Programs:*

#### **BGB-3111**, *an investigational small molecule inhibitor of Bruton's tyrosine kinase (BTK)*

- Completed enrollment in the pivotal Phase 2 trial in China of BGB-3111 in relapsed/refractory mantle cell lymphoma;
- Initiated the following trials:
  - Global Phase 3 trial of BGB-3111 compared to bendamustine and rituximab in treatment-naïve chronic lymphocytic leukemia / small lymphocytic lymphoma patients;
  - Global pivotal Phase 2 trial of BGB-3111 in combination with GAZYVA® (obinutuzumab) in relapsed or refractory follicular lymphoma patients; and
  - Pivotal Phase 2 trial in China of BGB-3111 in Waldenström's macroglobulinemia.

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

- Presented data from patients with gastric cancer, esophageal cancer, head and neck squamous cell carcinoma, and ovarian cancer enrolled in the global Phase 1 trial of BGB-A317 in patients with advanced solid tumors at the European Society for Medical Oncology (ESMO) 2017 Congress;
- Presented preliminary Phase 1 data on BGB-A317 in Chinese patients with advanced tumors at the 20<sup>th</sup> Annual Meeting of the Chinese Society of Clinical Oncology;
- Completed enrollment in the pivotal Phase 2 trial of BGB-A317 in China in relapsed/refractory classical Hodgkin's lymphoma;

- Completed enrollment in the global Phase 1a/1b trial of BGB-A317 in advanced tumors with a total of over 450 patients;

- Initiated the following trials:

- Phase 3 trial in China of BGB-A317 as a second- or third-line treatment for patients with advanced lung cancer;
- Pivotal Phase 2 trial in China of BGB-A317 in previously treated, PD-L1-positive, locally advanced or metastatic urothelial cancer;
- Phase 2 trial in China of BGB-A317 in combination with chemotherapy as a first-line treatment for patients with advanced lung cancer; and
- Phase 2 trial in China of BGB-A317 in combination with chemotherapy as a first-line treatment for patients with locally advanced or metastatic esophageal, gastric, or gastroesophageal junction carcinoma.

#### **BGB-290, an investigational small molecule PARP inhibitor**

- Presented updated data from the global Phase 1 trial of BGB-290 in patients with advanced solid tumors at the ESMO 2017 Congress;

- Initiated the following trials:

- Global Phase 1 trial of BGB-290 in combination with temozolomide in locally advanced or metastatic solid tumors; and
- Global Phase 1b/2 trial of BGB-290 in combination with radiation therapy and/or temozolomide in glioblastoma.

#### ***Corporate Development:***

- Closed our global strategic collaboration with Celgene Corporation.

#### **Expected Upcoming Milestones**

##### ***BGB-3111 (BTK Inhibitor)***

- Present additional Phase 1 data for BGB-3111 in non-Hodgkin's lymphoma, updated Phase 1 data for the combination of BGB-3111 and Gazyva® (obinutuzumab), and initial Phase 1 data for the combination of BGB-3111 and BGB-A317 at the 59<sup>th</sup> American Society of Hematology (ASH) Annual Meeting in Atlanta, GA, December 9-12, 2017.

##### ***BGB-A317 (PD-1 Antibody)***

- Present initial Phase 1 data for the combination of BGB-3111 and BGB-A317 at the 59<sup>th</sup> ASH Annual Meeting in Atlanta, GA, December 9-12, 2017; and
- Initiate Phase 3 trials of BGB-A317 in China in the fourth quarter of 2017 or the first quarter of 2018.

##### ***BGB-290 (PARP Inhibitor)***

- Initiate a pivotal trial in China in the fourth quarter of 2017.

#### **Third Quarter 2017 Financial Results**

**Cash, Cash Equivalents, and Short-Term Investments** were \$757.44 million as of September 30, 2017, compared to \$407.43 million as of June 30, 2017 and \$368.17 million as of December 31, 2016. The increase in the quarter was primarily attributable to the Celgene strategic collaboration. Funding from Celgene includes upfront licensing fees of \$263.00 million, \$92.05 million of which was received as of September 30, 2017 and the rest of which is payable in the fourth quarter of 2017, and an equity investment of \$150.00 million. In addition, net proceeds from our August 2017 follow-on public offering contributed \$188.52 million, after deducting underwriting discounts and offering-related expenses. These were partially offset by cash used in operating activities and for capital expenditures during the three months ended September 30, 2017.

The Company consolidates the BeiGene Biologics joint venture in its consolidated financial statements. As of September 30, 2017, cash, cash equivalents and short-term investments included \$141.64 million of cash held by BeiGene Biologics.

Cash provided by operations for the three months ended September 30, 2017 was \$6.60 million, compared to a use of cash of \$24.28 million for the same period in 2016. The increase in cash flow from operating activities was primarily attributable to upfront licensing fees of the Celgene collaboration, which offset increased research and development (R&D) and selling, general and administrative (SG&A) expenses in the period. Capital expenditures for the quarter ended September 30, 2017 were \$18.79 million, including \$13.94 million attributable to BeiGene Biologics, compared to \$6.68 million for the same period in 2016. The increase was primarily attributable to increased investment in our manufacturing facilities in Guangzhou and Suzhou.

**Revenue** for the three months ended September 30, 2017 was \$220.21 million, compared to nil in the same period in 2016, and was comprised of \$8.82 million of net product revenue and \$211.39 million of collaboration revenue. The product revenues represent net product sales of Abraxane and Revlimid in China following the effective date of the Celgene transaction, August 31, 2017. The collaboration revenue recognized in the period relates to the upfront fee allocated to the BGB-A317 license element of the arrangement.

**R&D Expenses** for the three months ended September 30, 2017 were \$87.66 million, compared to \$30.11 million in the same period in 2016. The increase was primarily attributable to increased spending on clinical activities and manufacturing for BGB-3111, BGB-A317, and BGB-290 due to expansion of ongoing clinical programs and increased employee compensation-related expenses as a result of increased headcount to support a broader clinical program. R&D-associated share-based compensation expense was \$10.38 million for the three months ended September 30, 2017, compared to \$2.14 million for the same period in 2016, primarily due to increased headcount, higher share price, and increased expense attributable to non-employee consultant awards.

**SG&A Expenses** for the three months ended September 30, 2017 were \$15.64 million compared to \$4.72 million in the same period in 2016. The increase was primarily attributable to increased employee compensation-related expenses as a result of increased headcount, including personnel costs for the employees transferred from Celgene China and higher share price as well as higher professional service fees, including legal, finance and accounting fees related to the Celgene transaction, patent prosecution activities and costs to support our growing operations. In addition, SG&A-associated share-based compensation expense was \$2.95 million for the three months ended September 30, 2017, compared to \$0.64 million for the same period in 2016.

**Net Income** attributable to BeiGene, Ltd. for the three months ended September 30, 2017 was \$117.39 million compared to a net loss of \$35.49 million in the same period in 2016.

## Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	September 30, 2017 (unaudited)	December 31, 2016 (audited)
Cash, cash equivalents and short-term investments	\$ 757,435	\$ 368,174
Unbilled receivable	170,950	—
Prepaid expenses and other current assets	33,945	6,225
Property and equipment, net	55,322	25,977
Goodwill and other intangible assets	9,421	—
Total assets	1,049,059	405,813
Accounts payable	35,168	11,957
Accrued expenses and other payables	46,991	22,297
Deferred revenue	38,609	—
Bank loan	18,036	17,284
Shareholder loan	140,311	—
Noncontrolling interest	14,349	—
Total equity	\$ 764,489	\$ 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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue				
Product revenue, net	\$ 8,822	\$ —	\$ 8,822	\$ —
Collaboration revenue	211,391	—	211,391	1,070
Total revenues	<u>220,213</u>	<u>—</u>	<u>220,213</u>	<u>1,070</u>
Expenses:				
Cost of sales – products	(1,944)	—	(1,944)	—
Research and development	(87,660)	(30,106)	(177,678)	(69,100)
Selling, general and administrative	(15,641)	(4,722)	(35,187)	(11,760)
Amortization of intangible assets	(63)	—	(63)	—
Total expenses	<u>(105,308)</u>	<u>(34,828)</u>	<u>(214,872)</u>	<u>(80,860)</u>
Income (loss) from operations	114,905	(34,828)	5,341	(79,790)
Interest (expense) income, net	(1,785)	(75)	(3,581)	336
Changes in fair value of financial instruments	—	—	—	(1,514)
(Loss) gain on sale of available-for-sale securities	—	(137)	10	(1,077)
Other income (expense), net	1,103	(327)	1,531	732
Income (loss) before income taxes	114,223	(35,367)	3,301	(81,313)
Income tax benefit (expense)	3,061	(127)	2,680	(306)
Net income (loss)	\$ 117,284	\$ (35,494)	\$ 5,981	\$ (81,619)
Less: Net loss attributable to noncontrolling interest	(102)	—	(237)	—
Net income (loss) attributable to BeiGene, Ltd.	\$ 117,386	\$ (35,494)	\$ 6,218	\$ (81,619)
Net income (loss) attributable to common shareholders per ADS, basic	\$ 2.79	\$ (1.08)	\$ 0.15	\$ (2.77)
Net income (loss) attributable to common shareholders per ADS, diluted	\$ 2.54	\$ (1.08)	\$ 0.14	\$ (2.77)
Weighted-average number of ADS outstanding - basic	<u>42,118,973</u>	<u>32,933,655</u>	<u>40,563,845</u>	<u>29,497,875</u>
Weighted-average number of ADS outstanding - diluted	<u>46,200,975</u>	<u>32,933,655</u>	<u>43,172,139</u>	<u>29,497,875</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income (loss)	\$ 117,284	\$ (35,494)	\$ 5,981	\$ (81,619)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	341	377	985	(13)
Unrealized holding gain, net	51	121	58	857
Comprehensive income (loss)	<u>117,676</u>	<u>(34,996)</u>	<u>7,024</u>	<u>(80,775)</u>
Less: Comprehensive loss attributable to noncontrolling	(70)	—	(178)	—

interests

Comprehensive income (loss) attributable to BeiGene, Ltd.	<u>\$ 117,746</u>	<u>\$ (34,996)</u>	<u>\$ 7,202</u>	<u>\$ (80,775)</u>
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## About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 700 employees in China, the United States, and Australia, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE® (nanoparticle albumin-bound paclitaxel), REVLIMID® (lenalidomide), and VIDAZA® (azacitidine) in China under a license from Celgene Corporation.<sup>i</sup>

## 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 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 new 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 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 products and 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.

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