BeiGene

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BeiGene Reports First Quarter 2018 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, May 09, 2018 (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 recent business highlights and financial results for the first quarter of 2018.

“We continue to make great progress launching new clinical trials on a global scale for patients with a wide variety of cancers, where we believe our investigational treatments can have a profound impact,” said John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene. “We have now enrolled more than 2,300 patients worldwide in more than 30 clinical trials of our investigational agents as of the end of March 2018 and remain on target for our first NDA filings in China later this year.”

“Given the significantly reformed regulatory environment in China, as well as important additions to our senior leadership team highlighted by the appointment of Dr. Xiaobin Wu as our General Manager of China and President of BeiGene, Ltd., we are excited about our China and global prospects,” continued Mr. Oyler.

Recent Business Highlights

Clinical Programs:

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

- Completed enrollment in the Phase 2 pivotal trial in China in patients with Waldenström macroglobulinemia (WM).

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

- Initiated the following trials:

  • Global Phase 2 trial in patients with relapsed or refractory mature T- and natural killer (NK)-cell lymphomas; and

  • Global Phase 2 trial in patients with previously treated hepatocellular carcinoma (HCC or liver cancer), under collaboration with Celgene Corporation for solid tumors.

Pamiparib (BGB-290)*, an investigational small molecule PARP inhibitor*

- Presented preliminary Phase 1 clinical data in Chinese patients with ovarian or triple-negative breast cancer at the 2018 American Association for Cancer Research (AACR) Annual Meeting in Chicago.

Commercial Products:

- Continued to expand potential patient access to ABRAXANE® (nanoparticle albumin-bound paclitaxel) in China by obtaining inclusion in the provincial reimbursement drug list in Jiangsu and critical illness insurance in Zhejiang; and

- Launched a first-line indication of REVLIMID® (lenalidomide) in China following its regulatory approval by the China Food and Drug Administration (CFDA) for the treatment of multiple myeloma (MM) in combination with dexamethasone in adult patients with previously untreated MM who are not eligible for transplant.

Corporate Development:

- Appointed J. Samuel Su, former Vice Chairman of the Board of Directors of Yum! Brands, Inc. and Chairman and CEO of its China division, to the BeiGene Board of Directors;
- Appointed Dr. Xiaobin Wu to the position of General Manager of China and President of BeiGene, Ltd.;
- Appointed Yifei Zhu to the position of China Co-Commercial Head, Sales and Market Access; and
- Appointed Dr. Guillaume Vignon to the position of Senior Vice President, Business Development.

Expected Upcoming Milestones in 2018

Zanubrutinib

- Present updated Phase 1 clinical data in patients with WM and pooled safety analysis in patients with hematologic malignancies at the 2018 European Hematology Association (EHA) Annual Congress in Stockholm, Sweden, June 14-17;
- Present other updated Phase 1 data and China pivotal trial data;
- Submit first new drug application (NDA) in China for mantle cell lymphoma;
- Complete enrollment in the global Phase 3 trial for WM in Q3 2018; and
- Initiate a global head-to-head Phase 3 trial versus ibrutinib in relapsed/refractory chronic lymphocytic leukemia.

Tislelizumab

- Present updated Phase 1 data and China pivotal trial data;
- Submit first NDA in China for Hodgkin's lymphoma;
- Complete enrollment in the Phase 2 pivotal trial in China for urothelial carcinoma; and
- Initiate additional pivotal trials.

Pamiparib

- Present updated Phase 1 data;
- Initiate a global Phase 3 trial in gastric cancer in Q2 or Q3 2018; and
- Initiate a Phase 3 trial in China as maintenance therapy in patients with platinum-sensitive recurrent ovarian cancer.

Commercial Products

- Continue to expand provincial reimbursement for ABRAXANE in China.

First Quarter 2018 Financial Results

Cash, Cash Equivalents, Restricted Cash and Short-Term Investments were $1,481.48 million as of March 31, 2018, compared to $837.52 million as of December 31, 2017. The increase was primarily due to net proceeds of $757.59 million raised in a public offering in January 2018. Cash, cash equivalents, restricted cash and short-term investments include approximately $131.04 million held by our 95%-owned joint venture, BeiGene Biologics, to build a commercial biologics facility under construction in Guangzhou, China. Restricted cash of $17.46 million relates to BeiGene Guangzhou Factory's secured deposits that are held in designated bank accounts for the issuance of a letter of credit.

Cash used in operations for the quarter ended March 31, 2018 was $104.50 million, compared to $35.71 million for the same period in 2017. The increase was primarily attributable to higher operating expenses in support of our clinical programs and organizational growth. Capital expenditures for the quarter ended March 31, 2018 were $9.70 million, compared to $7.39 million for the same period in 2017. The increase was primarily attributable to the construction of our manufacturing facilities in Guangzhou.

Revenues for the three months ended March 31, 2018 were $32.54 million, compared to nil in the same period in 2017, attributable to product and collaboration revenue under our collaboration with Celgene.

- Product revenue from sales of ABRAXANE, REVLIMID and VIDAZA® in China totaled $23.25 million for the first quarter 2018.

- Collaboration revenue totaled $9.29 million for the first quarter 2018, reflecting $7.55 million that was recognized as research and development reimbursement revenue from Celgene and $1.74 million of deferred upfront fees from Celgene recognized in the first quarter of 2018. In addition, unbilled receivables of $23.86 million on the balance sheet reflect research and development reimbursement under the Celgene collaboration for expenses incurred through the first quarter of 2018.

Expenses for the quarter ended March 31, 2018 were $143.35 million, compared to $51.54 million in the same period 2017, consisting primarily of the following:

- **Cost of sales** for the first quarter were $4.55 million, compared to nil in the first quarter of 2017. Cost of sales relates to the cost of acquiring ABRAXANE, REVLIMID and VIDAZA for distribution in China.

- **R&D Expenses** for the three months ended March 31, 2018 were $109.70, compared to $42.77 million in the same period in 2017. The increase in R&D expenses was primarily attributable to increased spending on our ongoing late-stage clinical trials and increased employee compensation expense as a result of increased headcount to support our clinical programs. Also contributing to the increase was the up-front license fee of $10 million paid to Mirati Therapeutics for the license of sitravatinib in Asia (excluding Japan), Australia and New Zealand. R&D-associated share-based compensation expense was $12.05 million for the three months ended March 31, 2018, compared to $4.53 million for the same period in 2017, due to increased headcount and a higher share price.

- **SG&A Expenses** for the three months ended March 31, 2018 were $28.92 million, compared to $8.77 million in the same period in 2017. The increase in SG&A expenses was primarily attributable to increased headcount, including employees transferred from Celgene China in connection with the license agreement for Celgene's commercial products in China, as well as higher professional service fees and costs to support our growing operations. SG&A-associated share-based compensation expense was $5.34 million for the three months ended March 31, 2018, compared to $1.46 million for the same period in 2017, due to increased headcount and a higher share price.

- **Net Loss** for the first quarter of 2018 was $105.12 million, or $2.03 per American Depositary Share (ADS), compared to a net loss of $50.62 million, or $1.27 per ADS in the same period in 2017.

Financial Summary

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

	As of	
	March 31, 2018 (unaudited)	December 31, 2017 (audited)
Cash, cash equivalents, restricted cash and short-term investments	$ 1,481,475	$ 837,516
Accounts receivable	23,485	29,428
Unbilled receivables	23,862	—
Working capital	1,443,806	763,509
Property and equipment, net	76,990	62,568
Total assets	1,708,927	1,046,479
Accounts payable	52,719	69,779
Accrued expenses and other payables	55,712	49,598
Shareholder loan	154,551	146,271
Total liabilities	350,205	362,248
Noncontrolling interest	14,341	14,422
Total equity	$ 1,358,722	$ 684,231

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 March 31,	
	2018	2017
Revenues		
Product revenue, net	$ 23,250	$ —
Collaboration revenue	9,294	—
Total revenues	32,544	—
Expenses		
Cost of sales - product	(4,550)	—
Research and development	(109,700)	(42,773)
Selling, general and administrative	(28,915)	(8,769)
Amortization of intangible assets	(188)	—
Total expenses	(143,353)	(51,542)
Loss from operations	(110,809)	(51,542)
Interest income, net	1,552	186
Other income, net	729	913
Loss before income tax expense	(108,528)	(50,443)
Income tax benefit (expense)	3,412	(180)
Net loss	(105,116)	(50,623)
Less: net loss attributable to noncontrolling interests	(520)	—
Net loss attributable to BeiGene, Ltd.	$ (104,596)	$ (50,623)
Net loss per ADS, basic and diluted	$ (2.03)	$ (1.27)
Weighted-average number of ADSs outstanding – basic and diluted	51,577,739	39,725,977

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

	Three Months Ended March 31,	
	2018	2017
Net loss	$ (105,116)	$ (50,623)
Other comprehensive loss, net of tax of nil:		
Foreign currency translation adjustments	272	90
Unrealized holding gain (loss), net	329	(12)
Comprehensive loss	(104,515)	(50,545)
Less: comprehensive loss attributable to noncontrolling interests	(456)	—
Comprehensive loss attributable to BeiGene, Ltd.	$ (104,059)	$ (50,545)

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 1,100 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.[i]

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 advancement of, and anticipated clinical development, regulatory milestones and commercialization of its drugs and drug candidates, the potential for the Company's drugs and drug candidates, and the expected milestones under the caption "Expected Upcoming Milestones in 2018". 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 products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; 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.

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