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BeiGene Reports Fourth Quarter and Full Year 2017 Financial Results

CAMBRIDGE, Mass. and BEIJING, China, Feb. 28, 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, anticipated 2018 milestones and financial results for the fourth quarter and full year of 2017.

“We had a transformative year in 2017, highlighted by the collaboration with Celgene Corporation for our anti-PD1 antibody, tislelizumab, expansion of the commercial team in China, and execution on the development plans that we believe will be critical to realizing the potential of our portfolio compounds in China and globally,” said John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene. “We have now enrolled more than 2,300 patients and healthy subjects worldwide in clinical trials of our investigational agents as of the end of January 2018 and are on target for our first NDA filings in China later this year.”

“We also strengthened our balance sheet with an $800 million offering this January. This successful financing will support our efforts to further develop our near-term clinical and pipeline programs, as well as continue to build our development and commercial capabilities to help maximize our opportunities in the rapidly evolving Chinese oncology market,” continued Mr. Oyler.

Fourth Quarter 2017 and Recent Business Highlights

Clinical Programs:

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

- Presented preliminary clinical data from the Phase 1 trial of zanubrutinib in patients with non-Hodgkin’s lymphoma in an oral presentation at the 59th American Society of Hematology (ASH) Annual Meeting in Atlanta;
- Presented updated Phase 1b data for the combination of zanubrutinib and GAZYVA® (obinutuzumab) in patients with chronic lymphocytic leukemia / small lymphocytic lymphoma (CLL/SLL) and follicular lymphoma (FL) at the ASH annual meeting;
- Presented initial Phase 1b data for the combination of zanubrutinib and the Company’s investigational anti-PD-1 antibody, tislelizumab (BGB-A317), in patients with B-cell malignancies at the ASH annual meeting;
- Completed enrollment in the Phase 2 pivotal trial in China in patients with CLL/SLL; and
- Initiated a Phase 1b/2 trial in China of zanubrutinib in combination with rituximab in patients with diffuse large B-cell lymphoma, FL, and marginal zone lymphoma.

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

- Presented preliminary results from the Phase 1 trial of tislelizumab in patients with urothelial carcinoma at the 2018 Genitourinary Cancers Symposium;
- Presented initial Phase 1b data for the combination of zanubrutinib and tislelizumab in patients with B-cell malignancies at the ASH annual meeting;
- Initiated the following trials:
  -- Global Phase 3 trial of tislelizumab in patients with previously untreated advanced hepatocellular

carcinoma (HCC); and

-- Global Phase 3 trial of tislelizumab in patients with advanced unresectable or metastatic esophageal squamous cell carcinoma.

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

- Initiated a Phase 2 pivotal trial in China of pamiparib in patients with advanced ovarian cancer.

***BGB-A333**, an investigational humanized monoclonal antibody against the immune checkpoint receptor ligand PD-L1*

- Initiated a global Phase 1/2 trial of BGB-A333 monotherapy and in combination with tislelizumab in advanced solid tumors.

Commercial Products

- Received approval in China for a new indication for REVLIMID® (lenalidomide) in combination with dexamethasone as a treatment for adult patients with previously untreated multiple myeloma who are not eligible for transplant; and

- Initiated commercialization of VIDAZA® (azacitidine) in China.

Corporate Development:

- Entered an exclusive license agreement with Mirati Therapeutics for the development, manufacturing and commercialization of Mirati's sitravatinib, an investigational tyrosine kinase inhibitor targeting TAM family receptors (TYRO3, Axl, MER), split family receptors (VEGFR2, KIT) and RET, in Asia (excluding Japan), Australia and New Zealand; and

- Entered into a commercial supply agreement for tislelizumab with Boehringer Ingelheim.

Expected 2018 Milestones

Zanubrutinib

- Present updated Phase 1 and China pivotal trial data;

- Submit first NDA in China for mantle cell lymphoma;

- Complete enrollment in the global Phase 3 trial for Waldenstrom's macroglobulinemia in Q3 2018; and

- Initiate a global head-to-head Phase 3 trial versus ibrutinib in relapsed/refractory CLL.

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 global and China-focused pivotal trials.

Pamiparib

- Present updated Phase 1 data;

- Initiate a global Phase 3 trial in gastric cancer in 1H 2018; and

- Initiate a Phase 3 trial in China as a maintenance therapy in patients with platinum-sensitive recurrent ovarian cancer.

Commercial Products

- Expand provincial reimbursement for ABRAXANE® (nanoparticle albumin-bound paclitaxel) in China.

Fourth Quarter and Full Year 2017 Financial Results

Cash, Cash Equivalents, and Short-Term Investments were $837.52 million as of December 31, 2017, compared to $757.44 million at September 30, 2017 and $368.17 million at December 31, 2016. This includes approximately $139.50 million of cash, cash equivalents and short-term investments at December 31, 2017, held by our joint venture, BeiGene Biologics, to build a commercial biologics facility in Guangzhou, China and to fund research and development of biologics drug candidates in China. Cash and cash equivalents as of December 31, 2017 do not include the net proceeds raised in the January 2018 public offering.

- The increase of $80.08 million in the in the fourth quarter of 2017 was primarily due to the receipt of $170.95 million from Celgene as part of upfront licensing fees from the tislelizumab collaboration, offset by increased research and development spending and capital expenditures as we continue to advance our pipeline.

- The increase of $469.35 million from the prior year period was primarily due to cash received from Celgene from the tislelizumab collaboration, including upfront licensing fees of $263.00 million and an equity investment of $150.00 million, and net proceeds of $188.52 million from our August 2017 follow-on public offering, offset by increased cash used in operations and for capital expenditures.

- Capital expenditures for the quarter and year ended December 31, 2017 were $18.93 million and $58.73 million, compared to $8.06 million and $23.50 million, respectively, for the same periods in 2016, primarily attributable to increased investment in our manufacturing facilities in Guangzhou and Suzhou.

Revenue for the fourth quarter and year ended December 31, 2017 was $18.17 million and $238.39 million, respectively, compared to nil and $1.07 million in the same periods in 2016, attributable to product and collaboration revenue under the Celgene collaboration.

- Product revenue from sales of ABRAXANE and REVLIMID in China totaled $15.61 million and $24.43 million for the fourth quarter and from August 31, 2017 (the closing of the Celgene transaction) to December 31, 2017, respectively.

- Collaboration revenue totaled $2.57 million and $213.96 million for the fourth quarter and year ended December 31, 2017, respectively, reflecting recognition of the upfront licensing fees from Celgene in the third quarter and deferred upfront fees recognized in the fourth quarter.

Expenses for the fourth quarter and year ended December 31, 2017 were $121.97 million and $336.84 million, respectively, compared to $37.27 million and $118.13 million in the same periods in 2016.

- **Cost of sales** for the fourth quarter and from August 31 to December 31, 2017 were $3.03 million and $4.97 million, respectively. Cost of sales relates to the cost of acquiring ABRAXANE and REVLIMID for distribution in China.

- **R&D Expenses** for the fourth quarter and year ended December 31, 2017 were $91.34 million and $269.02 million, respectively, compared to $28.93 million and $98.03 million in the same periods in 2016. The increase in R&D expenses was primarily attributable to increased spending on our ongoing late-stage clinical trials, increased manufacturing costs for our drug candidates due to expansion of ongoing clinical programs, and increased employee compensation expense as a result of increased headcount to support our clinical programs. Additionally, R&D-associated share-based compensation expense was $10.95 million and $30.61 million for the fourth quarter and year ended December 31, 2017, respectively, compared to $2.90 million and $8.08 million for the same periods in 2016, due to increased headcount and a higher share price.

- **SG&A Expenses** for the fourth quarter and year ended December 31, 2017 were $27.42 million and $62.60 million, respectively, compared to $8.34 million and $20.10 million in the same periods in 2016. 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 related to the Celgene transaction and patent prosecution activities, and costs to support our growing operations. In addition, SG&A-associated share-based compensation expense was $5.51 million and $12.25 million for the fourth quarter and year ended December 31, 2017, respectively, compared to $1.05 million and $2.55 million for the same periods in 2016.

Net Loss for the fourth quarter and year ended December 31, 2017 was $99.28 million and $93.30 million, respectively, compared to a net loss of $37.60 million and $119.22 million in the same periods in 2016.

Financial Summary

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

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

	December 31, 2017	December 31, 2016
Cash, cash equivalents and short-term investments	$ 837,516	$ 368,174
Working capital	763,509	339,341
Property and equipment, net	62,568	25,977
Total assets	1,046,479	405,813
Total liabilities	362,248	52,906
Noncontrolling interest	14,422	—
Total equity	$ 684,231	$ 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)

	Three Months Ended December 31, (Unaudited)		Twelve Months Ended December 31, (Audited)	
	2017	2016	2017	2016
Revenue				
Product revenue, net	$ 15,606	$ —	$ 24,428	$ —
Collaboration revenue	2,568	—	213,959	1,070
Total revenues	18,174	—	238,387	1,070
Expenses				
Cost of sales – products	(3,030)	—	(4,974)	—
Research and development	(91,340)	(28,933)	(269,018)	(98,033)
Selling, general and administrative	(27,415)	(8,337)	(62,602)	(20,097)
Amortization of intangible assets	(187)	—	(250)	—
Total expenses	(121,972)	(37,270)	(336,844)	(118,130)
Loss from operations	(103,798)	(37,270)	(98,457)	(117,060)
Interest (expense) income, net	(527)	47	(4,108)	383
Changes in fair value of financial instruments	—	—	—	(1,514)
Gain (loss) on sale of available-for-sale securities	34	(338)	44	(1,415)
Other income (expense), net	9,926	(289)	11,457	443
Loss before income taxes	(94,365)	(37,850)	(91,064)	(119,163)
Income tax (expense) benefit	(4,915)	252	(2,235)	(54)
Net loss	$ (99,280)	$ (37,598)	$ (93,299)	$ (119,217)
Less: Net loss attributable to noncontrolling interest	43	—	(194)	—
Net loss attributable to BeiGene, Ltd.	$ (99,323)	$ (37,598)	$ (93,105)	(119,217)
Net Loss per ADS, basic and diluted	$ (2.19)	$ (1.05)	$ (2.23)	$ (3.84)
Weighted-average number of ADSs outstanding – basic and diluted	45,402,681	35,663,284	41,783,497	31,047,650

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

	Three Months Ended	Twelve Months Ended

	December 31, (Unaudited)		December 31, (Audited)	
	2017	2016	2017	2016
Net loss	$ (99,280)	$ (37,598)	$ (93,299)	$ (119,217)
Other comprehensive (loss) income, net of tax of nil:				
Foreign currency translation adjustments	(134)	(232)	851	(245)
Unrealized holding gain, net	(354)	251	(296)	1,108
Comprehensive loss	(99,768)	(37,579)	(92,744)	(118,354)
Less: Comprehensive loss attributable to noncontrolling interests	73	—	(105)	—
Comprehensive loss attributable to BeiGene, Ltd.	$ (99,841)	$ (37,579)	$ (92,639)	$ (118,354)

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 900 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 2018 Milestones". 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 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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