businesswire
A BERKSHIRE HATHAWAY COMPANY

BeiGene Reports Third Quarter 2020 Financial Results

November 05, 2020 04:05 PM Eastern Standard Time

CAMBRIDGE, Mass. & BEIJING--(BUSINESS WIRE)--BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today reported recent business highlights, anticipated upcoming milestones, and financial results for the third quarter and first nine months of 2020.

“Our commercial teams continue to execute and sales of our recently launched internally developed products drove total product revenue to $91 million for the third quarter, a 39 percent increase compared to last quarter,” said John V. Oyler, Co-Founder, Chief Executive Officer, and Chairman of BeiGene. “We believe that we are well-positioned to accelerate the development of our deep pipeline, further expand our portfolio in oncology and into other therapeutic areas, and continue to build our capabilities and operations for our products to serve more patients worldwide. In the remainder of 2020 and 2021, we look forward to key clinical readouts, as well as potential expanded commercial opportunities for our products through approvals in additional indications and geographic markets and by growing our commercial-stage portfolio in China to up to 12 products.”

Howard Liang, Ph.D., Chief Financial Officer and Chief Strategy Officer, plans to retire from BeiGene following a transition period and the appointment of a new chief financial officer, which is expected to occur around the end of the first quarter of 2021.

“Howard has contributed greatly to our success since joining BeiGene in 2015. Since that time, Howard has been instrumental in each milestone and accomplishment as we expanded our footprint and became a truly global commercial organization with world-class research, development and manufacturing. We are grateful for everything he has done for BeiGene,” said John V. Oyler.

Recent Business Highlights and Upcoming Milestones

Commercial Operations

- Generated $91.08 million in product revenue in the three months ended September 30, 2020, representing an 81.6% increase compared to the comparable period of the prior year. Product revenue was driven by sales of our recently launched internally developed products tislelizumab in China and BRUKINSA in China and the United States.

Development Programs

BRUKINSA® (zanubrutinib), *a small molecule inhibitor of Bruton's tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects. BRUKINSA has received accelerated approval in the United States for the treatment of adult patients with MCL who have received at least one prior therapy; and approval in China in two indications - the treatment of adult patients with CLL/SLL who have received at least one prior therapy, and the treatment of adult patients with MCL who have received at least one prior therapy. BRUKINSA is under development globally for additional approvals.*

- Received acceptance from the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) for a supplemental new drug application (sNDA) of BRUKINSA for the treatment of patients with Waldenström's macroglobulinemia (WM) with priority review;
- Announced acceptance and priority review by Health Canada of a New Drug Submission (NDS) for BRUKINSA in WM; a subsequent NDS for patients with MCL in Canada has been accepted;
- Initiated patient enrollment in a Phase 1 trial (NCT04436107) of BRUKINSA in combination with lenalidomide, with or without rituximab, in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma; and
- Received Fast Track designation in the U.S. for patients with marginal zone lymphoma (MZL).

Expected Milestones for BRUKINSA

- Present data from the pivotal Phase 2 MAGNOLIA trial (NCT03846427) in patients with R/R MZL, the pivotal Phase 2 trial in patients with WM in China (NCT03332173), the Phase 2 trial (NCT04116437) in patients with R/R B-cell malignancies who are intolerant to ibrutinib or acalabrutinib, and from Arm C of the SEQUOIA trial (NCT03336333) in patients with treatment-naïve CLL or SLL with del(17p) at the upcoming 62nd ASH Annual Meeting being held virtually December 5-8, 2020;
- Announce top-line results from the SEQUOIA trial (NCT03336333) comparing BRUKINSA with bendamustine plus rituximab in patients with treatment-naïve CLL or SLL as early as the first half of 2021;
- Continue to discuss data from the Phase 3 ASPEN trial (NCT03053440) comparing BRUKINSA to ibrutinib in patients with WM with the U.S. Food and Drug Administration (FDA); and
- Complete enrollment in the Phase 3 ALPINE trial (NCT03734016) comparing BRUKINSA with ibrutinib in patients with R/R CLL/SLL in 2020.

Tislelizumab*, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China in two indications - the treatment of patients with classical Hodgkin's lymphoma (cHL) who received at least two prior therapies, and the treatment of patients with locally advanced or metastatic urothelial carcinoma with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Tislelizumab is under development globally for additional approvals.*

- Presented the first reported data from the Phase 3 RATIONALE 304 trial (NCT03663205) of tislelizumab combined with chemotherapy for the first-line treatment of patients with advanced non-squamous non-small cell lung cancer (NSCLC) at the 2020 European Society for Medical Oncology (ESMO) Virtual Congress. Data from this trial were included in the supplemental biologics license application (sBLA) currently under review by the NMPA;
- Began patient enrollment in a Phase 2 trial (NCT04401800) of tislelizumab in combination with lenvatinib in patients with hepatocellular carcinoma; and
- Completed patient enrollment in the Phase 3 clinical trial (NCT03924986) of tislelizumab combined with chemotherapy versus chemotherapy alone in recurrent or metastatic nasopharyngeal cancer.

Expected Milestones for Tislelizumab

- Announce top-line results from the global Phase 3 trial (NCT03358875) comparing tislelizumab versus docetaxel in second- or third-line patients with NSCLC and the global Phase 3 trial (NCT03430843) comparing tislelizumab versus chemotherapy in second-line patients with advanced esophageal squamous cell carcinoma (ESCC) before the end of 2020 or in 2021.

***Pamiparib**, an investigational selective small molecule inhibitor of PARP1 and PARP2*

- Presented data from the pivotal Phase 2 trial (NCT03333915) of pamiparib in patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy, at the 2020 ESMO Virtual Congress. Data from this trial were included in the NDA currently under review by the NMPA.

Expected Milestones for Pamiparib

- Announce top-line results from the Phase 3 trial (NCT03519230) of pamiparib as a maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer (OC) before the end of 2020 or in 2021.

***BGB-A1217,** an investigational TIGIT monoclonal antibody*

- Continued to enroll patients in the global Phase 1 clinical trial (NCT04047862) in combination with tislelizumab. The recommended Phase 2 dose has been determined and pivotal trials are in planning globally.

Early-Stage Proprietary Programs

- Received acceptance of the investigational new drug (IND) submission in China for BGB-11417 (BCL-2 inhibitor) for mature B-cell malignancies; and
- Continued to advance our earlier-stage pipeline of internally-developed assets, including BGB-11417 (BCL-2 inhibitor in Phase 1 development for cancer), BGB-A445 (non-ligand competing OX40 monoclonal antibody in Phase 1 development in combination with tislelizumab for solid tumor), BGB-10188 (PI3Kδ inhibitor in Phase 1 development in combination with BRUKINSA or tislelizumab for cancer), and BGB-15025 (HPK1 inhibitor in preclinical development for cancer).

Collaboration Programs

Amgen

- Our collaboration with Amgen continues to progress, with ongoing commercial activities for XGEVA® (denosumab) in China for patients with giant cell tumor of the bone (GCTB), as well as preparation for the launch of:
  - XGEVA® (120-mg denosumab) for the prevention of skeletal-related events in patients with bone metastases from solid tumors and in patients with multiple myeloma following potential approval expected in the fourth quarter 2020 or in early 2021;
  - BLINCYTO® (blinatumomab) for the treatment of adult patients with R/R B-cell precursor acute lymphoblastic leukemia (ALL) following potential approval expected in the fourth quarter 2020 or in early 2021; and
  - KYPROLIS® (carfilzomib) for patients with R/R multiple myeloma following potential approval expected in 2021;
- Amgen has advised BeiGene that its applications to the Human Genetic Resources Administration of China (HGRAC) to obtain approval to conduct clinical studies in China for assets that are part of the Amgen-BeiGene Collaboration, including its application for sotorasib (AMG 510), a first-in-class investigational KRAS G12C inhibitor, are currently delayed. Approval from the HGRAC is required for the initiation of clinical trials involving the collection of human genetic materials in China. BeiGene and Amgen continue to plan for the commencement of these clinical trials while Amgen awaits further information from HGRAC. BeiGene does not expect this to affect the conduct of the clinical trials in China for its drug candidates other than assets that are part of the Amgen-BeiGene collaboration.

***Zanidatamab (ZW25)**, a novel investigational Azymetric™ bispecific antibody against HER2 currently in late-stage clinical development with Zymeworks Inc.*

- Began patient enrollment in a registration-enabling Phase 2 clinical trial (NCT04466891) in patients with advanced or metastatic HER2-amplified biliary tract cancers.

***DKN-01**, a humanized monoclonal antibody that binds to and blocks the activity of the Dickkopf-1 (DKK1) protein, in development with Leap Therapeutics.*

- Announced the first patient dosed in the DisTinGuish trial (NCT04363801), a Phase 2a clinical trial initiated by Leap, evaluating DKN-01 in combination with tislelizumab, with or without chemotherapy, in patients with gastric or gastroesophageal junction cancer (G/GEJ).

***DXP-593 and DXP-604**, SARS-CoV-2 neutralizing antibody drug candidates identified by Singlomics (Beijing DanXu) Biopharmaceuticals Co., Ltd. and licensed to BeiGene outside of Greater China. DXP-593 and DXP-604 can potentially be used as a cocktail treatment option that could avoid resistance due to viral mutation.*

- Initiated a Phase 1 clinical trial of healthy volunteers (NCT04532294) in Australia.

***BA3071,** a novel, investigational conditionally-active CTLA-4 inhibitor discovered by BioAtla, Inc.*

- Announced an amended agreement with BioAtla to license in BA3071 globally.

Manufacturing Operations

- Completed facility and process validation for the first plant of our biologics manufacturing facility in Guangzhou;
- Initiated expansion of the second and third plants of our biologics manufacturing facility in Guangzhou to significantly increase manufacturing capacity and introduce new manufacturing technology platforms, expected to be completed by the end of 2020 and 2021, respectively; and
- Entered into an agreement to acquire the 5% equity interest in BeiGene Biologics Co., Ltd. (“BeiGene Biologics”) held by the Guangzhou High-tech Zone Technology Group Co., Ltd. (formerly Guangzhou GET Technology Development Co., Ltd.) (“GET”), an affiliate of Guangzhou Development District, and repay the related shareholder loan. Upon the update of the business license, which is expected to occur in the fourth quarter of 2020, our Guangzhou biologics facility will become a wholly-owned subsidiary of BeiGene Hong Kong Co., Limited.

COVID-19 Impact and Response

- The Company expects that the worldwide health crisis of COVID-19 will continue to have a negative impact on its operations, including commercial sales, regulatory interactions, inspections, filings, and clinical trial recruitment, participation, and data read outs. Although the impact of COVID-19 on operations in China lessened in the second and third quarters of 2020 compared to the first quarter of 2020, there remains uncertainty regarding the future impact of the pandemic both in China and the United States, as well as globally. The Company is striving to minimize delays and disruptions, and continues to execute on its commercialization, regulatory and clinical development goals globally.

Other Developments

- Announced the appointment of Corsee Sanders, Ph.D. to the Company's Board of Directors and the Audit and Scientific Advisory Committees of the Board;
- Announced a license, distribution, and supply agreement with Bio-Thera Solutions, Ltd., to develop, manufacture, and commercialize BAT1706, an investigational biosimilar to Avastin® (bevacizumab), in China, including Hong Kong, Macau, and Taiwan; and
- Announced the inclusion of the Company's ordinary shares, which trade on the Hong Kong Stock Exchange, in the Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect programs and the Hang Seng Composite Index (HSCI).

Third Quarter 2020 Financial Results

Cash, Cash Equivalents, Restricted Cash, and Short-Term Investments were $4.7 billion as of September 30, 2020, compared to $3.2 billion as of June 30, 2020, and $985.5 million as of December 31, 2019. Our cash, cash equivalents and short-term investments balance as of September 30, 2020 includes net proceeds of approximately $2.07 billion received on July 15, 2020 from a registered direct offering of our ordinary shares to certain existing shareholders.

- In the three months ended September 30, 2020, cash used in operating activities totaled $346.24 million and capital expenditures were $28.68 million, compared to $265.01 million and $30.87 million, respectively, in the prior year period. Cash used in operating activities for the three months ended September 30, 2020 includes $36.56 million of accrued interest paid to GET in connection with the repayment of the Shareholder Loan.

Revenue for the three months ended September 30, 2020 was $91.08 million, compared to $50.14 million in the same period of 2019. Revenue was comprised entirely of net product revenues in both periods, with the increase primarily attributable to sales of tislelizumab in China and BRUKINSA in the United States and China, partially offset by decreased product sales of in-licensed products in China from Celgene Logistics Sàrl, a Bristol Myers Squibb company (BMS).

- Net product revenues for the three months ended September 30, 2020 were comprised of:
  - $49.94 million from sales of tislelizumab in China, compared to none in the prior year period;
  - $15.66 million from sales of BRUKINSA in China and the United States, compared to none in the prior year period;
  - $22.43 million from sales of BMS in-licensed products in China, compared to $50.14 million in the same period of the prior year. The decrease was primarily due to decreased product sales of ABRAXANE® following the suspension by the NMPA and voluntary recall by BMS in March 2020; and
  - $3.05 million from sales of XGEVA®, the first product transferred to BeiGene from the Amgen collaboration, which BeiGene commenced sales and marketing in China in the third quarter of 2020.

Expenses for the three months ended September 30, 2020 were $531.22 million, compared to $362.41 million in the same period of 2019.

- **Cost of Sales** for the three months ended September 30, 2020 were $21.12 million, compared to $20.11 million in the same period of 2019. Cost of sales primarily included costs of tislelizumab and BRUKINSA that were sold during the period, as well as acquisition costs for supply of Amgen and BMS in-licensed products that were sold during the period in China.
- **R&D Expenses** for the three months ended September 30, 2020 were $349.07 million, compared to $236.97 million in the same period of 2019. The increase in R&D expenses was primarily attributable to continued increases in spending on our ongoing and newly initiated late-stage pivotal clinical trials, R&D expense related to upfront license payments for our in-licensed assets, development expenses associated with the Amgen collaboration, the preparation for additional regulatory submissions, and manufacturing costs related to pre-commercial activities and supply. In-process R&D expense for in-licensed assets totaled $66.5 million in the three months ended September 30, 2020, compared to none in the prior year period. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the three months ended September 30, 2020 was $60.85 million, of which $30.80 million was recorded as R&D expense. The remaining $30.05 million was recorded as a reduction of the R&D cost share liability. R&D-related share-based compensation expense was $25.41 million for the three months ended September 30, 2020, compared to $20.67 million for the same period of 2019.
- **SG&A Expenses** for the three months ended September 30, 2020 were $160.84 million, compared to $105.00 million in the same period of 2019. The increase in SG&A expenses was primarily attributable to increased headcount, primarily related to the expansion of our commercial team to support the distribution of our products in China and the United States, as well as higher professional service fees and costs to support our growing operations. SG&A-related share-based compensation expense was $24.89 million for the three months ended September 30, 2020, compared to $16.14 million for the same period of 2019.
- **Net Loss** for the three months ended September 30, 2020 was $425.22 million, or $0.37 per share, and $4.81 per American Depositary Shares (ADS), compared to $307.36 million, or $0.39 per share, and $5.11 per ADS in the same period of 2019.

Financial Summary

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

(Amounts in thousands of U.S. Dollars)

	As of	
	September 30, 2020	**December 31, 2019**
	(unaudited)	(audited)
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 4,724,015	$ 985,503
Accounts receivable, net	60,266	70,878
Working capital	4,320,015	862,384
Property and equipment, net	291,218	242,402
Total assets	5,566,390	1,612,289
Liabilities and equity:		
Accounts payable and accrued expenses	425,588	286,044
Debt [1]	201,773	240,695
Research and development cost share liability	531,538	—
Total liabilities	1,269,876	633,934
Noncontrolling interest	9,020	16,150
Total equity	$ 4,296,514	$ 978,355

[1] Total debt includes the shareholder loan balance from our joint venture partner of nil and $157,384, as of September 30, 2020 and December 31, 2019, respectively.

Condensed Consolidated Statements of Operations (U.S. GAAP)

(Amounts in thousands of U.S. dollars, except for shares, American Depositary Shares (ADSs), per share and per ADS data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(Unaudited)		(Unaudited)	
Revenue:				
Product revenue, net	$ 91,080	$ 50,141	$ 208,774	$ 165,704
Collaboration revenue	—	—	—	205,616
Total revenues	91,080	50,141	208,774	371,320
Expenses:				
Cost of sales	21,123	20,106	49,579	53,206
Research and development [1]	349,070	236,968	939,340	644,079
Selling, general and administrative	160,837	105,002	391,967	244,895
Amortization of intangible assets	187	331	658	994
Total expenses	531,217	362,407	1,381,544	943,174
Loss from operations	(440,137)	(312,266)	(1,172,770)	(571,854)
Interest (expense) income, net	(614)	2,206	7,184	9,569
Other income (expense), net	5,711	(1,817)	29,368	(967)
Loss before income taxes	(435,040)	(311,877)	(1,136,218)	(563,252)
Income tax benefit	(8,423)	(3,217)	(8,344)	(569)
Net loss	(426,617)	(308,660)	(1,127,874)	(562,683)
Less: Net loss attributable to noncontrolling interest	(1,393)	(1,303)	(3,713)	(2,116)
Net loss attributable to BeiGene, Ltd.	$ (425,224)	$ (307,357)	$ (1,124,161)	$ (560,567)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	$ (0.37)	$ (0.39)	$ (1.07)	$ (0.72)
Weighted-average shares outstanding, basic and diluted	1,148,973,077	781,482,459	1,052,940,583	777,938,599
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	$ (4.81)	$ (5.11)	$ (13.88)	$ (9.37)
Weighted-average ADSs outstanding, basic and diluted	88,382,544	60,114,035	80,995,429	59,841,431

[1] Research and development expense for the third quarter and nine months ended September 30, 2020 includes expenses related to in-process research and development collaborations totaling $66.5 million and $109.5 million, respectively, compared to nil and $30.0 million in the comparable periods of the prior year.

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 4,700+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: BTK inhibitor

BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 clinical data for BeiGene's product candidates and approvals of its products; the conduct of late-stage clinical trials and expected data readouts; additional planned product approvals and launches; the advancement of and anticipated clinical development, regulatory milestones and commercialization of BeiGene's drugs and drug candidates; the success of BeiGene's commercialization efforts and revenue growth; plans to expand the Company's portfolio in oncology and other therapeutic areas and to expand the Company's capabilities and operations for its products to serve more patients worldwide; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations; and BeiGene's plans and the expected events and milestones under the caption "Recent Business Highlights and Upcoming 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; the impact of the COVID-19 pandemic on BeiGene's clinical development, commercial and other operations, 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.

Contacts

Investor Contact
Craig West
+1 857-302-5189
ir@beigene.com

Media Contact
Liza Heapes or Vivian Ni
+1 857-302-5663 or +1 857-302-7596
media@beigene.com

Tweets by @BeiGeneUSA

#Hashtags

#BeiGene #BGNE #earnings

$Cashtags

$BGNE

Social Media Profiles

BeiGene Twitter

BeiGene on LinkedIn