BioNTech Announces First Quarter 2020 Financial Results and Corporate Progress

May 12, 2020

- *Global Phase 1/2 clinical trial for BNT162 vaccine program to prevent COVID-19 infection in dose escalation phase in Europe and the U.S.; first cohorts dosed in both regions*
- *BNT122 Phase 1/2 trial update expected at AACR Virtual Annual Meeting II in June*
- *Ended 1Q 2020 with cash equivalents of $495* million *(€452 million) with additional $236 million (€217 million) in equity investments and non-dilutive upfront payments due in 2Q 2020 from Pfizer and Fosun Pharma*
- Conference call and webcast scheduled for May 12, 2020 at 08:00 a.m. ET (2:00 p.m. CEST)

MAINZ, Germany, May 12, 2020 (GLOBE NEWSWIRE) -- BioNTech SE (Nasdaq: BNTX, "BioNTech" or "the Company"), a clinical-stage biotechnology company focused on patient-specific immunotherapies for the treatment of cancer and infectious diseases, today provided an update on its corporate progress and reported financial results for the quarter ended March 31, 2020.

"BioNTech has demonstrated significant progress to date in 2020. We advanced our oncology pipeline, announced the closing of our acquisition of Neon Therapeutics in the U.S., and signed several new value-adding partnerships," said **Ugur Sahin, BioNTech's CEO** . "Most notably, we have rapidly initiated a global clinical development program in Europe and the U.S. for multiple COVID-19 vaccine candidates."

First Quarter 2020 and Subsequent Updates
BioNTech continues to monitor the effect of the current COVID-19 pandemic situation on its overall operations. As previously announced, the company has put significant measures in place to protect supply chain, operations, employees and the execution of clinical trials. The Company has not seen any impact on its mRNA manufacturing, nor on its CAR-T manufacturing operations. BioNTech has implemented a plan to manage the evolving disruptions on the Company's clinical programs, and as previously detailed, is prioritizing execution of ongoing clinical trials, whereas certain first-in-human (FIH) clinical trial timelines have been affected. BioNTech intends to initiate Phase 2 trials planned for end of 2020, manage ongoing Phase 1 trials to support completion and optimize ability to initiate and conduct FIH studies. BioNTech will continue to evaluate potential effects and provide updates as appropriate.

Infectious disease

BioNTech has made significant progress in its efforts to develop a potential vaccine to induce immunity and prevent COVID-19 infection in response to the global health threat posed by the disease. During the first quarter, the company assembled a global consortium of partners including Pfizer (worldwide collaboration outside of China) and Fosun Pharma (China). BioNTech's goal is to make a vaccine available to the public worldwide as quickly as possible.

COVID-19 Vaccine Program

BNT162 - BioNTech's vaccine program against COVID-19, BNT162, leverages the Company's proprietary mRNA platform. Currently there are four vaccine candidates, two of the four vaccine candidates include a nucleoside modified mRNA (modRNA), one includes a uridine containing mRNA (uRNA), and the fourth vaccine candidate utilizes self-amplifying mRNA (saRNA). Each mRNA format is combined with a lipid nanoparticle (LNP) formulation. The larger spike sequence is included in two of the vaccine candidates, and the smaller optimized receptor binding domain (RBD) from the spike protein is included in the other two candidates.

- BNT162 (Europe) - The first cohort of BioNTech's Phase 1/2 clinical trial was dosed. BNT162 is the first COVID-19 vaccine candidate in Europe which entered clinical trials. Twelve study participants were dosed with the first BNT162 vaccine candidate as of April 29th. The dose escalation portion of the Phase 1/2 trial will include approximately 200 healthy subjects between the ages of 18 to 55 and will target a dose range of 1 µg to 100 µg, aiming to determine the optimal dose for further studies as well as to evaluate the safety and immunogenicity of the vaccine. The three vaccine candidates that utilize uRNA or modRNA will be administered as two injections. The fourth vaccine candidate, which contains saRNA, will be evaluated after a single dose of vaccine. Subjects with a higher risk of severe COVID-19 disease will be included in the second part of the study. First clinical data from the trial is expected end of June or in July 2020.
- BNT162 (U.S) – The first cohort has been dosed in the U.S. in the Phase 1/2 clinical trial for the BNT162 vaccine program. The Phase 1/2 study is designed to determine the safety, immunogenicity and optimal dose level of the four mRNA vaccine candidates. The dose level escalation portion (Stage 1) of the Phase 1/2 trial in the U.S. will enroll up to 360 healthy subjects into two age cohorts (18-55 and 65-85 years of age) and will be seamlessly followed by a part in which the selected vaccine candidate will be administered to several thousands of subjects. The first subjects immunized in Stage 1 of the study will be healthy adults 18-55 years of age.
- BioNTech will provide clinical supply of the BNT162 vaccine from its GMP-certified mRNA manufacturing facilities in Europe. BioNTech and Pfizer will work together to scale-up manufacturing capacity at risk to provide worldwide supply in response to the pandemic. BioNTech believes it has the potential to supply millions of vaccine doses by the end of 2020 subject to technical success of the development program and approval by regulatory authorities, and then rapidly scale up capacity to produce hundreds of millions of doses in 2021.

Oncology

BioNTech has also continued to advance its broad oncology pipeline. There are currently ten oncology products in 11 ongoing trials with multiple data readouts expected in 2020. BioNTech intends to initiate four Phase 2 trials (BNT111, BNT113, BNT122) and two additional FIH trials (BNT211, BNT411) in 2020.

FixVac

- BNT111 – Data from a Phase 1 trial in advanced melanoma remains on track for publication in late 1H 2020. BioNTech expects to initiate a Phase 2 trial in advanced melanoma with registrational potential for BNT111 in 2H 2020.
- BNT 113 – Initiation of a Phase 2 trial in HPV+ head and neck cancer with registrational potential is on track for 2H 2020.
- BNT114 – Data update from a Phase 1 trial in triple negative breast cancer (TNBC) is expected in 2H 2020.

Individualized neoantigen specific immunotherapy (iNeST)

- BNT122 – BioNTech expects the data update presentation for the Phase 1 trial in multiple solid tumors to be disclosed in June 2020 as part of the American Association for Cancer Research (AACR) Virtual Annual Meeting II. Safety, immunogenicity and tumor response data will be included. BioNTech expects to provide an enrollment update[1] from the Phase 2 trial (IMCODE-001) in first line melanoma in 2H 2020 with an interim data update anticipated in 2021. BNT122 is partnered with Genentech.
- BNT122 – Two Phase 2 clinical trials are expected to be initiated in the adjuvant setting in 2H 2020. The first adjuvant Phase 2 study will evaluate the efficacy and safety of RO7198457 plus atezolizumab compared with atezolizumab alone in patients with Stage 2-3 non-small cell lung cancer (NSCLC) who are circulating tumor DNA (ctDNA) positive following surgical resection and have received standard-of-care adjuvant platinum-doublet chemotherapy.

mRNA intratumoral immunotherapy

- BNT131 – Data update from Phase 1/2 trial in solid tumors remains on track for 2H 2020. BNT131 is partnered with Sanofi.

CAR-T cell immunotherapy

- BNT211 – Initiation of a Phase 1/2a trial in multiple solid tumors (CLDN6) is now expected in 2H 2020.

Next-generation checkpoint immunomodulators

- BNT311 – The expansion cohort has been initiated in the Phase 1/2 trial in multiple solid tumors for BNT311 (PD-L1x4-1BB). BioNTech expects to provide a data update, to include dose-escalation and potentially some limited expansion data from the trial in 2H 2020. BNT311 is partnered with Genmab.

Toll-Like Receptor Binding

- BNT411 – A Phase 1/2a clinical trial of BNT411 is still expected to be initiated in multiple solid tumors in 2H 2020.

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[1] We expect this data update to include an update on the ongoing study, including patient enrollment numbers, with full efficacy and safety data for an interim update expected in the second half of 2021.

Corporate Development

Recently, BioNTech completed the acquisition of Neon Therapeutics, Inc. in an all-stock transaction. BioNTech is now in the integration phase and expects the new subsidiary, based in Cambridge, Massachusetts, to serve as BioNTech's U.S. headquarters.

First Quarter 2020 Financial Results

Cash Position: Cash and cash equivalents as of March 31, 2020, were €451.6 million.

Revenue: Total revenue, consisting primarily of revenue from collaborative agreements, was €27.7 million for the three months ended March 31, 2020, compared to €26.2 million for the three months ended March 31, 2019. The increase was mainly due to revenues resulting from other sales transactions i.e. development and manufacturing services sold to third-party customers, retroviral vectors for clinical supply, and sales of peptides.

Research and Development Expenses: Research and development expenses were €65.1 million for the three months ended March 31, 2020, compared to €57.2 million for the three months ended March 31, 2019. The increase was primarily due to an increase in headcount leading to higher wages, benefits and social security expenses as well as an increase in expenses for purchased research services.

General and Administrative Expenses: General and administrative expenses were €15.8 million for the three months ended March 31, 2020, compared to €9.3 million for the three months ended March 31, 2019. This increase was mainly driven by higher legal expenses, an increase in headcount leading to higher wages, benefits and social security expenses as well as higher expenses due to newly concluded insurance premiums.

Net Loss: Net loss was €53.4 million for the three months ended March 31, 2020, compared to a net loss of €40.8 million for the three months ended March 31, 2019.

Shares Outstanding: Shares outstanding as of March 31, 2020 were 226,779,744.

Financial Guidance:

- On track with previous guidance of approximately €300 million net cash to be used for operating activities and investments into property, plant and equipment in 2020 base business plan (prior to impact of Neon acquisition and BNT162 program).
- Majority of BioNTech development costs for our BNT162 program in 2020 will be funded via Pfizer and Fosun Pharma cost sharing, equity investments and upfront payments.
- Also anticipate additional funding to support the manufact uring scale-up for our BNT162 program in 2020.

Interim quarterly financial statements can be found in the 6-K filing as published on the SEC website under https://www.sec.gov/.

Conference Call and Webcast Information
BioNTech SE will host a conference call and webcast today at 08:00 a.m. ET (2:00 p.m. CET) to report its financial results for the quarter ended March 31, 2020 and provide a corporate update.

To participate in the conference call, please dial the following numbers 10-15 minutes prior to the start of the call and provide the Conference ID: 9282359.

United States international:	+1 646 741 3167
United States domestic (toll-free):	+1 877 870 9135
Germany:	+49 692 2222 625

Participants may also access the slides and the webcast of the conference call via the “Events & Presentations” page of the Investor Relations section of the Company’s website at https://biontech.de/. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company’s website for 30 days following the call.

About BioNTech
Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Eli Lilly and Company, Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Genevant, Fosun Pharma, and Pfizer.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended including, but not limited to, statements concerning: the planned next steps in BioNTech’s pipeline programs and specifically including, but not limited to, statements regarding plans to initiate clinical trials of BioNTech’s BNT111, BNT113, iNeST (BNT122), BNT211 and BNT411; expectations for data announcements with respect to BioNTech’s BNT111, BNT114, iNeST (BNT122), BNT131, BNT162 and BNT311 clinical trials; and our ability to scale-up manufacturing capacity for BNT162 and supply millions of vaccine doses by the end of 2020. In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond BioNTech’s control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. You should review the risks and uncertainties described under the heading “Risk Factors” in BioNTech’s Annual report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 31, 2020 and in subsequent filings made by BioNTech with the SEC, which are available on the SEC’s website at https://www.sec.gov/. Except as required by law, BioNTech disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on BioNTech’s current expectations and speak only as of the date hereof.

Interim Condensed Consolidated Statements of Financial Position

(in thousands)	**As of March 31, 2020**	**As of December 31, 2019**
Assets	*(unaudited)*	
Non-current assets		
Intangible assets	€93,932	€89,434
Property, plant and equipment	96,290	93,044
Right-of-use assets	49,131	55,018
Total non-current assets	**€239,353**	**€237,496**
Current assets		
Inventories	9,629	11,722
Trade receivables	10,310	11,913
Contract assets	1,191	-
Other financial assets	1,723	1,680

Other assets	9,263	9,069
Income tax assets	980	756
Deferred expense	8,162	5,862
Cash and cash equivalents	451,597	519,149
Total current assets	**€492,855**	**€560,151**
Total assets	**€732,208**	**€797,647**
Equity and liabilities		
Equity		
Share capital	232,304	232,304
Capital reserve	686,714	686,714
Treasury shares	(5,525)	(5,525)
Accumulated losses	(478,213)	(424,827)
Other reserves	12,850	4,826
Total equity	**€448,130**	**€493,492**
Non-current liabilities		
Financial liabilities	66,641	68,904
Other liabilities	207	-
Contract liabilities	75,187	97,109
Total non-current liabilities	**€142,035**	**€166,013**
Current liabilities		
Tax provisions	150	150
Provisions	957	762
Financial liabilities	2,247	1,823
Trade payables	19,417	20,498
Contract liabilities	94,824	93,583
Other financial liabilities	14,030	13,836
Other liabilities	10,418	7,490
Total current liabilities	**€142,043**	**€138,142**
Total liabilities	**€284,078**	**€304,155**
Total equity and liabilities	**€732,208**	**€797,647**

Interim Condensed Consolidated Statements of Operations

	Three months ended March 31,	
	2020	**2019**
(in thousands, except per share data)	*(unaudited)*	
Revenues from contracts with customers	€27,663	€26,154
Cost of sales	(5,842)	(3,205)
Gross profit	**€21,821**	**€22,949**
Research and development expenses	(65,122)	(57,241)
Sales and marketing expenses	(486)	(560)
General and administrative expenses	(15,815)	(9,276)
Other operating income	425	331
Other operating expenses	(100)	(38)
Operating loss	**€(59,277)**	**€(43,835)**
Finance income	6,417	3,578
Finance expenses	(103)	(74)
Interest expense related to lease liability	(415)	(425)
Loss before tax	**€(53,378)**	**€(40,756)**
Income taxes	(8)	(6)
Loss for the period	**€(53,386)**	**€(40,762)**
Attributable to:		

Equity holders of the parent	(53,386)	(40,646)
Non-controlling interests	-	(116)
	€(53,386)	**€(40,762)**
Earnings per share		
in EUR		
Basic & diluted, loss per share for the period attributable to ordinary equity holders of the parent*	€(0.24)	€(0.20)

* Numbers of shares for calculating the earnings per share for the three months ended March 31, 2019 have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

Interim Condensed Consolidated Statements of Cash Flows

	Three months ended March 31,	
	2020	**2019**
(in thousands)	*(unaudited)*	
Operating activities		
Loss for the period	€(53,386)	€(40,762)
Income taxes	8	6
Loss before tax	**€(53,378)**	**€(40,756)**
Adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment and intangible assets	8,593	7,185
Share-based payment expense	8,150	13,496
Net foreign exchange differences	(268)	(9)
(Gain)/Loss on disposal of property, plant and equipment	62	8
Finance income	(388)	(344)
Interest on lease liability	415	425
Finance expense	103	74
Working capital adjustments:		
Decrease/(Increase) in trade receivable and contract assets	(2,059)	9,710
Decrease/(Increase) in inventories	2,231	(684)
(Decrease)/Increase in trade and other payables, contract liabilities and provisions	(17,768)	(20,161)
Interest received	323	344
Interest paid	(471)	(499)
Income tax paid	(231)	(6)
Net cash flows used in operating activities	**€(54,686)**	**€(31,217)**
Investing activities		
Purchase of property, plant and equipment	(6,295)	(6,300)
Proceeds from sale of property, plant and equipment	-	539
Purchase of intangibles assets	(2,122)	(27,407)
Acquisition of subsidiaries and businesses, net of cash acquired	(6,516)	-
Net cash flows used in investing activities	**€(14,933)**	**€(33,168)**
Financing activities		
Proceeds from issuance of share capital, net of costs	-	9
Proceeds from loans and borrowings	2,899	1,565
Payments related to lease liabilities	(889)	(615)
Net cash flows from financing activities	**€2,010**	**€959**
Decrease in cash and cash equivalents	(67,609)	(63,426)
Change in cash resulting from exchange rate differences	57	9
Cash and cash equivalents at January 1	519,149	411,495
Cash and cash equivalents at March 31	**€451,597**	**€348,078**

Investor Relations
Sylke Maas, Ph.D.
VP Investor Relations & Business Strategy

Tel: +49 (0)6131 9084 1074
E-mail: Investors@biontech.de

Media Relations
Jasmina Alatovic
Senior Manager Global External Communications
Tel: +49 (0)6131 9084 1513 or +49 (0)151 1978 1385
E-mail: Media@biontech.de