BioNTech Announces Second Quarter 2020 Financial Results and Corporate Progress

- *Pivotal Phase 2b/3 trial for BNT162 vaccine program against COVID-19 initiated with first clinical results expected as early as October 2020*
- *Initial commercial supply agreements for BNT162 signed with the United States, Japan, Canada and the United Kingdom for more than 250 million doses in 2020 and 2021*
- *Published data update for the lead FixVac product candidate BNT111 in Nature and announced a partnership with Regeneron to advance combination therapy with anti-PD-1 into Phase 2 trial in melanoma*
- *Presented data for BNT122 Phase 1 trial in multiple solid tumors at AACR Annual Meeting; on track to initiate randomized Phase 2 trials in adjuvant NSCLC and adjuvant CRC by the end of 2020*
- *Ended Q2 2020 with cash and cash equivalents of €573 million ($642 million[1]) and raised an additional €681 million ($762 million[1]) in gross proceeds from an equity private placement and follow-on underwritten offering leading to an expected pro-forma cash and cash equivalents balance of €1.25 billion ($1.40 billion[1]). In addition, up to €100 million ($112 million[1]) secured in loan financing from the European Investment Bank in June 2020. Financing transactions are subject to closing conditions which were not fulfilled before June 30, 2020*

Conference call and webcast for analysts and investors
scheduled for August 11, 2020 at 08:00 a.m. ET (2:00 p.m. CET)

MAINZ, Germany, August 11, 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 June 30, 2020.

"We made significant progress in the second quarter toward our goal of advancing our oncology programs and toward bringing a COVID-19 vaccine to market as quickly as possible. I am incredibly proud of our team, who has worked tirelessly to initiate our BNT162 Phase 2b/3 trial in record time and put us in a position to seek regulatory review as early as October of this year, if our trials are successful," said **Ugur Sahin, BioNTech's CEO and Co-founder**. "In addition, we have significantly strengthened our balance sheet, providing financial resources to advance our broad pipeline of novel immunotherapies targeting oncology and infectious disease."

Second Quarter 2020 and Subsequent Updates

Infectious disease

COVID-19 Vaccine Program – BNT162

- Released data from the ongoing U.S. Phase 1/2 placebo-controlled, observer-blinded clinical trial, evaluating nucleoside-modified messenger RNA vaccine candidate (BNT162b1) in 45 subjects, and data from the ongoing Germany trial in 60 subjects.
- Received Fast Track designation for BNT162b1 and BNT162b2 from the U.S. Food and Drug Administration (FDA).
- Initiated a Phase 2b/3 study for BNT162b2 in up to 30,000 participants aged 18 to 85 years at approximately 120 sites globally; if successful, BioNTech and Pfizer plan to file for market authorization or regulatory approval as early as October 2020.
- Initiation of a Phase 1 study for BNT162b1 to evaluate safety and immunogenicity in Chinese participants to support potential regulatory approval in China.
- Announced initial commercial supply agreements totaling more than 250 million doses with the United Kingdom, the United States, Japan and Canada in 2020 and 2021, with an option to purchase up to an additional 500 million doses. All agreements are subject to clinical success and regulatory approval.

Oncology

FixVac

- BNT111 – On July 30, BioNTech announced the publication of interim Phase 1 data for BNT111, the Company's lead mRNA-based FixVac cancer vaccine program, in *Nature*. The trial, designed to evaluate safety and tolerability of vaccinated patients with stage IIIB-C and stage IV melanoma, included 89 patients and highlighted a favorable tolerability profile of BNT111. An efficacy analysis conducted within a subset of 42 checkpoint-inhibitor (CPI)-experienced metastatic melanoma patients showed that BNT111 mediates durable responses both as a single agent and in combination with anti-PD-1 antibodies by establishing an association with activation and strong expansion of tumor-antigen-specific CD4+ and CD8+ T cells.
- BNT111 – On July 31, BioNTech and Regeneron Pharmaceuticals, Inc. announced a strategic collaboration to jointly conduct a randomized Phase 2 study for the treatment of melanoma that has progressed after prior PD-1 blockade, utilizing BNT111 FixVac and Regeneron's Libtayo® in combination.
- BNT111 – BioNTech expects to initiate this Phase 2 trial with registrational potential in the second half of 2020.
- BNT113 – Planned initiation of a potentially registrational Phase 2 trial in HPV16+ head and neck cancer expected in 2H 2020.
- BNT114[2] – Planned data update from a Phase 1 trial in triple negative breast cancer (TNBC) is expected in 2H 2020. The exploratory Phase 1 study tests immunogenicity

and safety of vaccination with individualized neoantigen immunotherapy and non-mutated tumor-associated antigens in TNBC.

Individualized neoantigen specific immunotherapy (iNeST)

- BNT122 – BioNTech and Genentech reported a data update for the Phase 1a and 1b trial in multiple solid tumors in June 2020 as part of the American Association for Cancer Research (AACR) Virtual Annual Meeting II. As a monotherapy and in combination with atezolizumab, RO7198457 (BNT122/RG6180) was observed to have a manageable safety profile and to induce significant levels of neoantigen-specific immune responses, even in late-stage, heavily pre-treated patients. RO7198457 (BNT122/RG6180) is partnered with Genentech.
- BNT122 – BioNTech expects to provide an enrollment update from the Phase 2 trial (IMCODE-001) in first line melanoma in 2H 2020 with an interim data update anticipated in 2H 2021.
- BNT122 – Two Phase 2 clinical trials are planned in the adjuvant setting. The first adjuvant Phase 2 study is currently recruiting for patients and first patient dosing is expected in 2H 2020. The trial is designed to evaluate the efficacy and safety of RO7198457 (BNT122/RG6180) plus atezolizumab compared with atezolizumab alone in patients with early and adjuvant stage non-small-cell lung cancer (NSCLC). The second Phase 2 study will be in colorectal cancer in adjuvant setting and is expected to initiate in 2H 2020. This trial will be a multi-site, open-label, Phase 2, randomized trial to compare the efficacy of RO7198457 (BNT122/ RG6180) versus watchful waiting in patients with circulating tumor DNA (ctDNA) positive, surgically resected Stage 2/3 rectal cancer, or Stage 2 (high risk)/Stage 3 colon cancer.

mRNA intratumoral immunotherapy

- BNT131 – BioNTech expects to provide a data update from the Phase 1 trial in solid tumors in 2H 2020. The trial is a first-in-human (FIH), multi-site, open-label, Phase 1, dose escalation and expansion trial to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of SAR441000/BNT131 administered intratumorally as a monotherapy and in combination with cemiplimab in patients with advanced solid tumors. The data to be presented will include safety, tolerability and pharmacodynamic biomarkers. SAR441000/BNT131 is partnered with Sanofi.

CAR-T cell immunotherapy

- BNT211 – Initiation of a Phase 1/2a open-label, multi-site dose escalation and dose expansion basket trial with or without a CLDN6 CARVac immunotherapy is expected in 2H 2020. While the preclinical focus has mainly been on ovarian cancer, patients with uterine, testicular, lung and gastric cancers may also be enrolled.

Neoantigen-Targeting T Cells

- BNT221 (NEO-PTC-01) – Initiation of a Phase 1 dose escalation trial of BNT221 is expected in 2H 2020 for the treatment of metastatic melanoma in patients who are refractory or unresponsive to checkpoint inhibitors. The primary objectives will be to evaluate the safety and feasibility of administering BNT221 to patients. Additional objectives include evaluation of immunogenicity and clinical efficacy.

Next-generation checkpoint immunomodulators

- BNT311 – BioNTech expects to provide a data update in 2H 2020, which will include dose-escalation data from the Phase 1/2 trial in multiple solid tumors for GEN1042/BNT311 (PD-L1x4-1BB). The program is partnered with Genmab.

Toll-Like receptor binding agonist

- BNT411 – On July 8, the first patient was dosed in a Phase 1/2a, first-in-human, open-label, dose-escalation trial with expansion cohorts to evaluate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve extensive-stage small cell lung cancer (ES-SCLC).

Corporate Development

During the second quarter, BioNTech completed the acquisition of Neon Therapeutics, Inc. BioNTech continues to integrate the new subsidiary, based in Cambridge, Massachusetts, which serves as BioNTech's U.S. headquarters.

Second Quarter 2020 Financial Results

Cash Position: Cash and cash equivalents as of June 30, 2020, were €573.0 million.

- On July 27, 2020, BioNTech announced the closing of an underwritten offering of 5,500,000 American Depositary Shares ("ADSs"), each representing one of BioNTech's ordinary shares, at a public offering price of $93.00 per ADS, for gross proceeds of €456.8 million ($511.5 million[1]). The underwritten offering had no accounting impact within the second quarter 2020.
- On July 22, 2020, BioNTech announced the terms of a rights offering of rights to subscribe for ordinary shares, including ordinary shares represented by ADSs, extended to holders of its ordinary shares and ADSs. Certain holders irrevocably agreed not to transfer or exercise their rights in the rights offering, and the shares underlying those rights were offered in the underwritten offering. The ADS rights exercise period expires at 12:01 a.m. (New York City time) on August 14, 2020 and the ordinary share rights exercise period expires one minute after 11:59 p.m. (Mainz, Germany time) on August 14, 2020. The rights offering had no accounting impact within the second quarter 2020.
- On June 29, 2020, BioNTech announced the signing of a private investment of €223.9 million ($250.7 million[1]) by Temasek and another accredited investor. The private placement includes an investment of approximately €123.9 million ($138.7 million[1]) in ordinary shares and a €100.0 million ($112.0 million[1]) investment in a 4-year mandatory convertible note. Upon closing, private placement investors will receive 2,595,996 ordinary shares in BioNTech, which will be subject to a 180-day lock-up agreement. The 4-year mandatory convertible note will come with a coupon of 4.5% per annum and a conversion premium of 20% above the reference price. The investment is subject to customary closing conditions, which were not fulfilled before June 30, 2020 and had no accounting impact within the second quarter 2020.

- On June 11, 2020, the European Investment Bank (EIB) and BioNTech entered into a €100.0 million ($112.0 million[1]) loan financing agreement to support the development of BNT162. The deal will also allow the Company to expand its manufacturing capacity in order to rapidly supply the vaccine, worldwide, in response to the pandemic. The EIB debt investment will be disbursed in two tranches of €50.0 million ($56.0 million[1]) each. The closing of the financing agreement, subject to achieving certain milestone events, was not fulfilled before June 30, 2020 and had no accounting impact within the second quarter 2020.
- In Q2 2020 BioNTech received an aggregate of €216.7 million ($236.0 million) in non-refundable upfront payments from the BNT162 collaboration agreements and equity investments with Pfizer and Fosun Pharma.

Revenue: Total revenue, consisting primarily of revenue from collaboration agreements, was €41.8 million for the three months ended June 30, 2020, compared to €25.8 million for the three months ended June 30, 2019. For the period of six months ended June 30, 2020, total revenue was €69.4 million, compared to €51.9 million for the comparative prior year period. The revenue from collaboration agreements overall increased due to the recognition of revenue from our new collaboration agreements signed with Pfizer and Fosun Pharma as part of the Company's BNT162 vaccine program against COVID-19. The revenues from other sales transactions increased due to increased orders and include sales of diagnostic products, peptides, retroviral vectors for clinical supply and development and manufacturing services sold to third-party customers.

Research and Development Expenses: Research and development expenses were €95.2 million for the three months ended June 30, 2020, compared to €53.4 million for the three months ended June 30, 2019. For the period of six months ended June 30, 2020, total research and development expenses were €160.3 million, compared to €110.6 million for the comparative prior year period. The increase was mainly 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 and development services, especially with respect to our BNT162 program. In addition, from the date of acquisition, the new U.S.-based subsidiary, BioNTech US Inc., contributed to our research and development expenses.

General and Administrative Expenses: General and administrative expenses were €18.8 million for the three months ended June 30, 2020, compared to €14.6 million for the three months ended June 30, 2019. For the period of six months ended June 30, 2020, total general and administrative expenses were €34.6 million, compared to €23.9 million for the comparative prior year period. The increase was mainly influenced by higher expenses for purchased management consulting and legal services as well as an increase in headcount leading to higher wages, benefits and social security expenses. In addition, from the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc., contributed to our general and administrative expenses.

Net Loss: Net loss was €88.3 million for the three months ended June 30, 2020, compared to €50.1 million for the three months ended June 30, 2019. For the period of six months ended June 30, 2020, total net loss was €141.7 million, compared to €90.8 million for the comparative prior year period.

Shares Outstanding: Shares outstanding as of June 30, 2020 were 232,673,455.

Financial Guidance:

- As a result of increased spending related to BNT162, BioNTech now expects net cash used in operating activities and for purchases of property and equipment to be between €450 million and €600 million in the full year 2020.

- BioNTech anticipates that existing cash and cash equivalents, the net proceeds from the recent underwritten offering and the expected net proceeds from the private investment announced in June 2020 will enable the Company to fund operating expenses and capital requirements through at least the next 24 months.

Full 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 June 30, 2020 and provide a corporate update.

To participate in the conference call, please dial the following numbers 15-20 minutes prior to the start of the call and provide the Conference ID: 1963889.

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.

[1] All amounts translated using the exchange rate published by the German Central Bank (Deutsche Bundesbank) in effect as of June 30, 2020.

[2] IVAC_M_uID is also being investigated in arm 2 (N=15) of the 3 arm TNBC-MERIT trial, with BNT114 as an optional treatment; BNT114 is investigated in arm 1 (N=12) and arm 3 (N=15) of the TNBC-MERIT trial (total patients in study: N=42).

About BioNTech
Biopharmaceutical New Technologies 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 Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer.

For more information, please visit www.BioNTech.de

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: our expected cash usage for 2020 and beyond; our anticipated cash runway; the timing, completion and extent of subscription of the rights offering; 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 product candidates; expectations for data announcements with respect to BioNTech's clinical trials; the timing for any potential emergency use authorizations or approvals for BNT162; and our ability to scale-up manufacturing capacity for BNT162 and supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021. 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.

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Interim Condensed Consolidated Statements of Financial Position

(in thousands) **Assets**	**June 30, 2020** *(unaudited)*	**December 31, 2019**
Non-current assets		
Intangible assets	€ 183,281	€ 89,434
Property, plant and equipment	112,829	93,044
Right-of-use assets	54,905	55,018
Other assets	1,316	-
Total non-current assets	**€ 352,331**	**€ 237,496**
Current assets		
Inventories	8,615	11,722
Trade receivables	7,679	11,913
Contract assets	1,621	-
Other financial assets	1,953	1,680
Other assets	16,329	9,069
Income tax assets	1,012	756
Deferred expense	10,896	5,862
Cash and cash equivalents	573,011	519,149
Total current assets	**€ 621,116**	**€ 560,151**
Total assets	**€ 973,447**	**€ 797,647**
Equity and liabilities		
Equity		
Share capital	238,198	232,304
Capital reserve	918,174	686,714
Treasury shares	(5,525)	(5,525)
Accumulated losses	(566,509)	(424,827)
Other reserves	17,596	4,826
Total equity	**€ 601,934**	**€ 493,492**
Non-current liabilities		
Financial liabilities	70,289	68,904
Other liabilities	431	-
Contract liabilities	86,793	97,109
Deferred tax liabilities	5,434	-
Total non-current liabilities	**€ 162,947**	**€ 166,013**
Current liabilities		
Tax provisions	150	150
Provisions	833	762
Financial liabilities	2,591	1,823
Trade payables	35,690	20,498
Contract liabilities	117,661	93,583
Other financial liabilities	33,763	13,836
Other liabilities	17,878	7,490
Total current liabilities	**€ 208,566**	**€ 138,142**
Total liabilities	**€ 371,513**	**€ 304,155**
Total equity and liabilities	**€ 973,447**	**€ 797,647**

Interim Condensed Consolidated Statements of Operations

(in thousands, except per share data)	Three months ended June 30,		Six months ended June 30,	
	2020	**2019**	**2020**	**2019**
	(unaudited)		*(unaudited)*	
Revenues from contracts with customers	€ 41,762	€ 25,785	€ 69,425	€ 51,939
Cost of sales	(5,662)	(5,489)	(11,504)	(8,694)
Gross profit	**€ 36,100**	**€ 20,296**	**€ 57,921**	**€ 43,245**
Research and development expenses	(95,189)	(53,402)	(160,311)	(110,643)
Sales and marketing expenses	(3,054)	(678)	(3,540)	(1,238)
General and administrative expenses	(18,813)	(14,623)	(34,628)	(23,899)
Other operating income	773	660	1,198	991
Other operating expenses	(759)	(120)	(859)	(158)
Operating loss	**€ (80,942)**	**€ (47,867)**	**€ (140,219)**	**€ (91,702)**
Finance income*	205	425	593	1,876
Finance expenses*	(9,300)	(2,204)	(3,374)	(151)
Interest expense related to lease liability	(465)	(425)	(880)	(850)
Loss before tax	**€ (90,502)**	**€ (50,071)**	**€ (143,880)**	**€ (90,827)**
Income taxes	2,206	(13)	2,198	(19)
Loss for the period	**€ (88,296)**	**€ (50,084)**	**€ (141,682)**	**€ (90,846)**
Attributable to:				
Equity holders of the parent	(88,296)	(50,084)	(141,682)	(90,730)
Non-controlling interests	-	-	-	(116)
	€ (88,296)	**€ (50,084)**	**€ (141,682)**	**€ (90,846)**
Earnings per share				
in EUR				
Basic & diluted, loss per share for the period attributable to equity holders of the parent**	€ (0.38)	€ (0.24)	€ (0.62)	€ (0.45)

* Foreign exchange differences on a cumulative basis are either shown as finance income or expenses and might switch between those two positions during the year-to-date reporting periods.

** Numbers of shares for calculating the earnings per share for the three and six months ended June 30, 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

(in thousands)	Six months ended June 30, 2020 *(unaudited)*	2019 *(unaudited)*
Operating activities		
Loss for the period	€ (141,682)	€ (90,846)
Income taxes	(2,198)	19
Loss before tax	**€ (143,880)**	**€ (90,827)**
Adjustments to reconcile loss before tax to net cash flows:		
Depreciation and amortization of property, plant, equipment and intangible assets	17,425	15,595
Share-based payment expense	16,263	17,986
Net foreign exchange differences	(50)	143
Loss on disposal of property, plant and equipment	80	9
Finance income	(593)	(769)
Interest on lease liability	880	850
Finance expense	208	151
Other non-cash income	(151)	-
Working capital adjustments:		
Decrease/(Increase) in trade receivable and contract assets	(9,770)	9,715
Decrease/(Increase) in inventories	3,246	(1,355)
(Decrease)/Increase in trade payables, other liabilities, contract liabilities and provisions	46,918	(36,936)
Interest received	576	769
Interest paid	(985)	(1,001)
Income tax paid	(375)	(19)
Net cash flows used in operating activities	**€ (70,208)**	**€ (85,689)**
Investing activities		
Purchase of property, plant and equipment	(21,396)	(10,608)
Proceeds from sale of property, plant and equipment	2	557
Purchase of intangibles assets	(4,174)	(29,665)
Acquisition of subsidiaries and businesses, net of cash acquired	891	(6,050)
Net cash flows used in investing activities	**€ (24,677)**	**€ (45,766)**
Financing activities		
Proceeds from issuance of share capital, net of costs	147,806	175
Proceeds from loans and borrowings	2,899	6,035
Repayment of loans and borrowings	(319)	-
Payments related to lease liabilities	(2,173)	(1,291)
Net cash flows from financing activities	**€ 148,213**	**€ 4,919**
Net increase/(decrease) in cash and cash equivalents	53,328	(126,536)
Change in cash resulting from exchange rate differences	534	(69)
Cash and cash equivalents at January 1	519,149	411,495
Cash and cash equivalents at June 30	**€ 573,011**	**€ 284,890**