



BioNTech Announces Full Year 2019 Financial Results and Corporate Update

March 31, 2020

- *BNT111 FixVac Melanoma registrational trial start planned for 2H 2020*
- *BNT122 (iNeST) adjuvant Phase 2 study in NSCLC to start in 2H 2020*
- *COVID-19 vaccine program BNT162 set to enter the clinic in April 2020*
- *Ended 2019 with cash equivalents of \$583 million (€520 million)*
- *Company to host conference call today at 8:00 AM ET (2:00 PM CET)*

MAINZ, Germany, March 31, 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 and full year ended December 31, 2019.

"2019 was transformational for BioNTech with pipeline advancements, additional collaborations with leading life science companies, and the completion of our initial public offering," said **Ugur Sahin, BioNTech's CEO**. "We have continued this strong momentum into 2020 against a challenging market backdrop. We are continuing to advance our oncology pipeline and, along with our partners Pfizer and Fosun Pharma, aim to dose the first patient with our COVID-19 vaccine candidate within weeks. We also continued our efforts to strengthen our cell therapy capabilities and global footprint with our planned acquisition of Neon Therapeutics in the U.S., and look forward to multiple new trial starts and data read-outs across our pipeline during the year."

COVID-19 Vaccine Program Update

In early March 2020 BioNTech announced details of its efforts to develop a potential vaccine to induce immunity and prevent COVID-19 infection. BioNTech is working to initiate clinical testing for BNT162, a potential first-in-class mRNA vaccine against COVID-19, in late April 2020.

As part of the program, BioNTech announced two strategic collaborations with large pharma companies to ensure global development of a vaccine candidate and global access to any approved vaccine. BioNTech and Pfizer signed a letter of intent regarding the co-development and distribution of a potential mRNA-based coronavirus vaccine aimed at preventing COVID-19 infection. The collaboration aims to accelerate the development of BNT162, building on the existing research and development partnership between Pfizer and BioNTech signed in 2018, under which the companies have been working together to develop mRNA-based vaccines for prevention of influenza. The companies expect to utilize multiple research and development sites from both companies. Details of the agreement regarding financial terms and all activities related to the development, manufacturing and potential commercialization are expected to be finalized shortly.

BioNTech also announced a strategic alliance with Fosun Pharma to develop its COVID-19 vaccine in China. Under the terms of the agreement, the two companies will work together on the development of BNT162 in China, conducting clinical trials in China and leveraging Fosun Pharma's extensive clinical development, regulatory, and commercial capabilities in the country. If approved, Fosun Pharma will commercialize the vaccine in China.

Under the terms of the agreement, Fosun Pharma agreed to make an equity investment of \$50 million (€44 million) for 1,580,777 ordinary shares in BioNTech, subject to execution of share subscription documentation and approval from regulatory authorities in China.

Fourth Quarter 2019 and Subsequent Updates

In addition to its development efforts, as the global COVID-19 pandemic continues to evolve, BioNTech has continuously monitored the situation in regards to its operations and has put significant measures in place to protect supply chain, operations, employees and the execution of clinical trials. Given the dynamic global situation, BioNTech notes there will be impacts to certain clinical trial timelines, as noted below. BioNTech will continue to evaluate potential effects and will provide updates as appropriate.

Oncology

FixVac

- **BNT111** – Data from the ongoing Phase 1 trial in advanced melanoma remains on track for publication in late 1H 2020. Based on further regulatory discussions, the Company expects to initiate a Phase 2 trial with registrational potential for BNT111 in 2H 2020.
- **BNT112** – The first patient was dosed in a Phase 1/2a study in patients with prostate cancer. Eligible patients for dose titration have metastatic castration-resistant prostate cancer and will be treated with BNT112 as a single agent. For the expansion phase, patients with mCRPC and newly diagnosed high-risk, localized prostate cancer (LPC) are eligible and will be treated with BNT112 alone or in combination.
- **BNT114** – Data update from a Phase 1 trial in triple negative breast cancer (TNBC) is now expected in 2H 2020. Data was previously expected to be presented at The Association for Cancer Immunotherapy (CIMT) Annual Meeting in May 2020. Given the postponement of the conference, BioNTech is evaluating the appropriate opportunity to present the data.
- **BNT116** – The product candidate has been added to the FixVac portfolio and is currently in preclinical development for non-small cell lung cancer (NSCLC).

Individualized neoantigen specific immunotherapy (iNeST)

- BNT121 – At the J.P. Morgan Health Care Conference in January 2020, BioNTech provided updated data from a Phase 1 trial for BNT121, the precursor to RO7198457 (BNT122), our lead iNeST product candidate. The data showed stable disease up to 60 months post vaccination in a cohort of eight advanced melanoma patients who were followed for relapse-free disease control following vaccination with iNeST.
- BNT122 – BioNTech and Genentech disclosed that two additional Phase 2 clinical trials in the adjuvant setting are planned for initiation in 2020. The first adjuvant Phase 2 study will evaluate the efficacy, safety, pharmacokinetics, immunogenicity and biomarkers 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.
- BNT122 – Following changes to the timing of the American Association for Cancer Research (AACR) Annual Meeting due to the COVID-19 pandemic, we now expect the data update for the Phase 1/2 trial in multiple solid tumors to be presented in August 2020. BioNTech expects to provide an enrollment update¹ from the Phase 2 trial in first line melanoma in 2H 2020 with an interim data update anticipated in 2021.

mRNA intratumoral immunotherapy

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

Next-generation checkpoint immunomodulators

- BNT311 – BioNTech now expects to provide a data update from the Phase 1/2 trial in multiple solid tumors (PD-L1x4-1BB) in 2H 2020, ahead of our previous 1H 2021 expectations.

Targeted cancer antibodies

- BNT321 (MVT-5873) – Dosing has begun in the resumed Phase 1 study, evaluating the safety, maximum tolerated dose and recommended Phase 2 dose of BNT321 as a single agent in patients with pancreatic and other CA19-9 positive malignancies.

CAR-T cell immunotherapy

- BNT211 – Initiation of a Phase 1/2a trial in multiple solid tumors (CLDN6) remains on track for 1H 2020.
- Publication in [Science](#) on the Company's novel CAR-T therapeutic approach for solid tumors which utilizes a **C**AR-T Cell **A**mplifying **R**NA **V**accine, or CARVac. The report entitled “*An RNA vaccine drives expansion and efficacy of claudin-CAR-T cells against solid tumors*” provides preclinical proof-of-concept data for BioNTech's first CAR-T product candidate BNT211.

Trial initiations for the following programs have been delayed as a result of the COVID-19 pandemic.

Toll-Like Receptor Binding

- BNT411 – U.S. IND was approved in Q4 2019. A Phase 1/2a clinical trial of BNT411 is now expected to be initiated as a mono- or combination therapy in multiple solid tumors in 2H 2020.

Ribomabs

- BNT141 – Initiation of a Phase 1 trial in multiple solid tumors is now expected in 1H 2021.
- BNT142 – Initiation of a Phase 1 trial in multiple solid tumors (CD3+CLDN6) is now expected in 1H 2021.

RiboCytokines

- BNT151 – Initiation of a Phase 1 trial in multiple solid tumors (optimized IL-2) is now expected in 1H 2021.
- BNT152+153 – Initiation of a Phase 1 trial in multiple solid tumors is now expected in 1H 2021.

Rare Diseases

- BNT171 – Initiation of a Phase 1 trial in undisclosed indication is now expected in 1H 2021.

Infectious Diseases

- BNT162 – Initiation of clinical testing for COVID-19 vaccine is expected in April 2020.
- BNT161 – Initiation of clinical testing for a vaccine against influenza is now expected in 1H 2021.

Corporate Development

BioNTech and Neon Therapeutics, Inc. (Nasdaq: NTGN) announced that they have entered into a definitive merger agreement under which BioNTech will acquire Neon in an all-stock transaction. Neon is a biotechnology company developing novel neoantigen-based T cell therapies and has deep expertise in the development of neoantigen therapies, with both vaccine and T-cell capabilities. At closing, BioNTech will issue, and Neon shareholders

will receive, 0.063 American Depositary Shares (ADS) (each ADS representing one ordinary share of BioNTech) in exchange for each of their shares of Neon's common stock. The transaction is expected to close during the second quarter of 2020.

Operations

In response to the COVID-19 outbreak, we are continuing to assess our supply chain and operations, which includes mRNA manufacturing for FixVac and iNeST platform products, as well as our CAR-T manufacturing operations. Our manufacturing operations are currently unaffected, but we will continue to monitor the potential impact as the pandemic develops.

In terms of our personnel, we have instituted a range of precautionary measures to ensure their continued safety. We are closely monitoring any employee that has potentially been in any contact with affected individuals or in affected areas and limiting access to BioNTech facilities as appropriate.

Full Year 2019 Financial Results

Cash Position: Cash and cash equivalents as of December 31, 2019, were €519.1 million.

Revenue: Total revenue, consisting primarily of revenue from collaborative agreements, was €28.0 million for the quarter ended December 31, 2019, compared to €63.8 million for the quarter ended December 31, 2018. The decrease was primarily due to decreased revenues from our collaboration with Sanofi. Total revenue, consisting primarily of revenue from collaborative agreements, was €108.6 million for the year ended December 31, 2019, compared to €127.6 million for the year ended December 31, 2018. The decrease was primarily due to decreased revenues from our collaboration with Sanofi. The decrease in revenue from Sanofi is primarily driven by a revenue of €33.2 million for a one-time reimbursement of certain sublicense costs that was fully recognized in the year ended December 31, 2018.

Research and Development Expenses: Research and development expenses were €65.4 million for the quarter ended December 31, 2019, compared to €51.8 million for the quarter ended December 31, 2018. The increase was primarily due to an increase in headcount and higher expenses incurred in our collaboration and own clinical projects. Research and development expenses were €226.5 million for the year ended December 31, 2019, compared to €143.0 million for the year ended December 31, 2018. The increase was primarily due to an increase in headcount, the full year impact of our ESOP program and higher spending for purchased services and laboratory supplies for our collaboration and own projects.

General and Administrative Expenses: General and administrative expenses were €11.1 million for the quarter ended December 31, 2019, compared to €10.1 million for the quarter ended December 31, 2018. General and administrative expenses were €45.5 million for the year ended December 31, 2019, compared to €26.3 million for the year ended December 31, 2018. The increase was primarily due to an increase in headcount and the full year impact of our ESOP program.

Net Loss: Net loss was €58.2 million for the quarter ended December 31, 2019, compared to net loss of €1.5 million for the quarter ended December 31, 2018. Net loss was €179.2 million for the year ended December 31, 2019, compared to net loss of €48.3 million for the year ended December 31, 2018.

Shares Outstanding: Shares outstanding as of December 31, 2019 were 226,779,744.

Full financial statements can be found in the 20-F 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 full year ended December 31, 2019 and provide a corporate update.

The slide presentation and audio of the webcast will be available via the following link: <https://edge.media-server.com/mmc/p/kxzxy7k>

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: 1957628.

United States international: +1 631 510 7495
United States domestic (toll-free): +1 866 966 1396
Germany: +49 692 443 7351

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 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.

For more information, please visit: www.BioNTech.de

Important Additional Information and Where to Find It

In connection with the proposed merger, BioNTech will file with the Securities and Exchange Commission (the "SEC") a Registration Statement on Form F-4 containing a proxy statement of Neon and a prospectus of BioNTech, and each of Neon and BioNTech may file with the SEC other documents regarding the proposed merger. The definitive proxy statement will be mailed to stockholders of Neon. INVESTORS AND SECURITY

HOLDERS ARE URGED TO READ THE REGISTRATION STATEMENT ON FORM F-4 AND THE PROXY STATEMENT/PROSPECTUS, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THOSE DOCUMENTS AND ANY OTHER RELEVANT DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER, WHEN THEY BECOME AVAILABLE, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT BIONTECH, Neon AND THE PROPOSED MERGER.

Investors and security holders may obtain copies of these documents free of charge through the website maintained by the SEC at <https://www.sec.gov> or from BioNTech at its website, <https://biontech.de>, or from Neon at its website, <https://Neon.com>. Documents filed with the SEC by BioNTech will be available free of charge by accessing BioNTech's website under the heading Investors & Media, or, alternatively, by directing a request by telephone or mail to BioNTech at An der Goldgrube 12, 55131 Mainz, Germany, and documents filed with the SEC by Neon will be available free of charge by accessing Neon's website at <https://neontherapeutics.com> under the heading Investor Resources or, alternatively, by directing a request by telephone or mail to Neon at 40 Erie Street, Suite 110, Cambridge, MA 02139, USA.

No Offer or Solicitation

This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities nor a solicitation of any vote or approval with respect to the proposed transaction or otherwise. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

Participants in Solicitation

BioNTech and Neon and certain of their respective directors and executive officers and other members of management and employees may be deemed to be participants in the solicitation of proxies from the stockholders of Neon in respect of the proposed merger under the rules of the SEC. Information about Neon's directors and executive officers is available in Neon's definitive proxy statement dated April 26, 2019 for its 2019 Annual Meeting of Stockholders and certain of its Current Reports on Form 8-K. Information about BioNTech's directors and executive officers is available in BioNTech's Registration Statement on Form F-1 filed with the SEC on September 9, 2019, as amended. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement/prospectus and other relevant materials to be filed with the SEC regarding the proposed merger when they become available. Investors should read the proxy statement/prospectus carefully when it becomes available before making any voting or investment decisions. You may obtain free copies of these documents from Neon or BioNTech using the sources indicated above.

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, iNeST (BNT122), BNT141, BNT142, BNT151, BNT152/153, BNT211, and BNT411, and; expectations for data announcements with respect to BioNTech's BNT111, BNT114, iNeST (BNT122), BNT131 and BNT311 clinical trials. 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" and those described in BioNTech's Prospectus filed with the U.S. Securities and Exchange Commission (SEC) on September 9, 2019 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.

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.

Consolidated Statements of Financial Position

<i>(in thousands)</i>	As of December 31, 2019	As of December 31, 2018
Assets		
Non-current assets		
Intangible assets	€89,434	€88,042
Property, plant and equipment	93,044	66,200
Right-of-use assets	55,018	49,766
Other financial assets	-	18
Total non-current assets	€237,496	€204,025
Current assets		
Inventories	11,722	5,789
Trade receivables	11,913	18,938
Other financial assets	1,680	336
Other assets	9,069	9,164
Income tax assets	756	891
Deferred expense	5,862	2,348

Cash and cash equivalents	519,149	411,495
Total current assets	€560,151	€448,961
Total assets	€797,647	€652,986
Equity and liabilities		
Equity		
Share capital*	232,304	193,296
Capital reserve*	686,714	344,115
Treasury shares*	(5,525)	-
Accumulated losses	(424,827)	(245,771)
Other reserves	4,826	(25,487)
Equity attributable to equity holders of the parent	€493,492	€266,153
Non-controlling interest	-	847
Total equity	€493,492	€267,000
Non-current liabilities		
Financial liabilities	68,904	54,218
Contract liabilities	97,109	205,647
Total non-current liabilities	€166,013	€259,865
Current liabilities		
Tax provisions	150	297
Provisions	762	710
Financial liabilities	1,823	-
Trade payables	20,498	41,721
Contract liabilities	93,583	66,027
Other financial liabilities	13,836	8,266
Other liabilities	7,490	9,100
Total current liabilities	€138,142	€126,121
Total liabilities	€304,155	€385,986
Total equity and liabilities	€797,647	€652,986

* Numbers have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

Consolidated Statements of Operations

	Years ended December 31,		
	2019	2018	2017
<i>(in thousands, except per share data)</i>			
Revenues from contracts with customers	€108,589	€127,575	€61,598
Cost of sales	(17,361)	(13,690)	(9,318)
Gross profit	€91,228	€113,885	€52,280
Research and development expenses	(226,466)	(143,040)	(85,496)
Sales and marketing expenses	(2,718)	(3,041)	(6,603)
General and administrative expenses	(45,547)	(26,334)	(23,520)
Other operating income	2,724	5,396	2,349
Other operating expenses	(739)	(720)	(288)
Operating loss	€(181,518)	€(53,854)	€(61,277)
Finance income	4,122	8,046	2,133
Finance expenses	(326)	(48)	(26,007)
Interest expense related to lease liability	(1,718)	(1,721)	(676)
Share of loss of equity method investees	-	(84)	(78)
Loss before tax	€(179,440)	€(47,662)	€(85,905)
Income taxes	268	(600)	(45)
Loss for the period	€(179,172)	€(48,262)	€(85,950)
Attributable to:			
Equity holders of the parent	(179,056)	(48,019)	(85,653)

Non-controlling interests	(116)	(243)	(297)
	€(179,172)	€(48,262)	€(85,950)
Earnings per share			
<i>in EUR</i>			
Basic & diluted, loss per share for the year attributable to ordinary equity holders of the parent	€(0.85)	€(0.25)	€(0.51)

Consolidated Statements of Cash Flows

<i>(in thousands)</i>	Years ended December 31,		
	2019	2018	2017
Operating activities			
Loss for the period	€(179,172)	€(48,262)	€(85,950)
Income taxes	(268)	600	45
Loss before tax	€(179,440)	€(47,662)	€(85,905)
Adjustments to reconcile loss before tax to net cash flows:			
Depreciation and amortization of property, plant, equipment and intangible assets	33,896	21,984	10,529
Share-based payment expense	30,235	7,641	5,909
Net foreign exchange differences	70	459	24,820
(Gain)/Loss on disposal of property, plant and equipment	542	(14)	15
Finance income	(1,782)	(1,996)	(2,133)
Interest on lease liability	1,718	1,721	676
Finance expense	326	48	53
Share of loss of an associate and a joint venture	-	84	78
Working capital adjustments:			
Decrease/(Increase) in trade receivable and contract assets	2,939	(18,732)	(2,816)
Decrease/(Increase) in inventories	(5,798)	(1,253)	(574)
(Decrease)/Increase in trade and other payables, contract liabilities and provisions	(80,577)	(21,080)	(4,574)
Interest received	1,256	1,996	2,133
Interest paid	(2,044)	(1,769)	(729)
Income tax received (paid), net	122	(304)	(45)
Net cash flows used in operating activities	€(198,537)	€(58,877)	€(52,562)
Investing activities			
Purchase of property, plant and equipment	(38,592)	(29,901)	(24,320)
Proceeds from sale of property, plant and equipment	21	705	5,193
Purchase of intangibles assets	(32,488)	(37,256)	(33,422)
Acquisition of subsidiaries and businesses, net of cash acquired	(6,056)	-	-
Net cash flows used in investing activities	€(77,115)	€(66,452)	€(52,549)
Financing activities			
Proceeds from issuance of share capital, net of costs	375,351	361,725	-
Proceeds from loans and borrowings	11,000	5,600	-
Payment of finance lease liabilities	(3,061)	(2,148)	(1,643)
Net cash flows from/(used in) financing activities	€383,290	€365,177	€(1,643)
Net increase/(decrease) in cash and cash equivalents	107,638	239,848	(106,753)
Change in cash resulting from exchange rate differences	16	(459)	(24,820)
Cash and cash equivalents at January 1	411,495	172,106	303,680
Cash and cash equivalents at December 31	€519,149	€411,495	€172,106

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