February 13, 2023

Benitec Biopharma Releases Second Quarter 2023 Financial Results and Provides Operational Update

First subject enrolled into the OPMD clinical development program

HAYWARD, Calif., Feb. 13, 2023 (GLOBE NEWSWIRE) -- Benitec Biopharma Inc. (NASDAQ: BNTC) (“Benitec” or “Company”), a development-stage, gene therapy-focused, biotechnology company developing novel genetic medicines based on its proprietary DNA-directed RNA interference ("ddRNAi") platform, today announced financial results for its Second Fiscal Quarter ended December 31, 2022. The Company has filed its quarterly report on Form 10-Q for the quarter ended December 31, 2022 with the U.S. Securities and Exchange Commission.

“In January, we were excited to announce the enrollment of the first OPMD patient into the natural history phase of the BB-301 development program, and the screening process has continued at a rapid pace. The enrollment of the first patient supports our central clinical development goal of administering the first dose of BB-301 and reporting interim clinical results in 2023,” said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec.

Dr. Banks continued, “The OPMD Natural History (NH) Study represents the 6-month pre-treatment observation period for each OPMD subject prior to the administration of BB-301 for the treatment of OPMD-related dysphagia. Upon the completion of 6-months of radiographic and clinical assessments required for the NH Study, participants will be eligible for enrollment into the BB-301 Phase 1b/2a treatment study in which BB-301 will be administered.”

Operational Updates

The key milestones related to the development of BB-301 for the treatment of Oculopharyngeal Muscular Dystrophy (OPMD), along with other corporate updates, are outlined below:

BB-301 Clinical Development Program Overview:

- The BB-301 clinical development program will be conducted in the United States, Canada, and France, and the primary elements of the program are summarized below:
    - The program will comprise approximately 76 weeks of follow-up which we anticipate will consist of:

- **The OPMD Natural History (NH) Study:** 6-month pre-treatment observation periods for the evaluation of baseline disposition and natural history of OPMD-derived dysphagia (swallowing impairment) in each study participant.

- **Dosing with BB-301:** 1-day of BB-301 dosing to initiate participation in the Phase 1b/2a single-arm, open-label, sequential, dose-escalation cohort study. BB-301 will be delivered directly to the pharyngeal muscles of each study subject.

- **Phase 1b/2a Treatment Evaluation:** 52-weeks of post-dosing follow-up for conclusive evaluation of the primary and secondary endpoints of the BB-301 Phase 1b/2a treatment study, with interim clinical results expected to be available at each 90-day period following the administration of BB-301.

- The OPMD NH Study will characterize the level of dysphagia borne by each OPMD subject at baseline and assess subsequent progression of dysphagia via the use of the following quantitative radiographic measures (i.e., videofluoroscopic swallowing studies or "VFSS"). The VFSS outlined below collectively provide objective assessments of global swallowing function and the function of the pharyngeal constrictor muscles (i.e., the muscles whose functional deterioration drives disease progression in OPMD):

    - Total Pharyngeal Residue $\%(C2\text{-}4)^2$
    - Pharyngeal Area at Maximum Constriction (PhAMPC)
    - Dynamic Imaging Grade of Swallowing Toxicity Scale (DIGEST)
    - Vallecular Residue $\%(C2\text{-}4)^2$, Pyriform Sinus Residue $\%(C2\text{-}4)^2$, and Other Pharyngeal Residue $\%(C2\text{-}4)^2$
    - Normalized Residue Ratio Scale ($NRRS_V$, $NRRS_P$)
    - Pharyngeal Construction Ratio (PCR)

- The NH study will also employ clinical measures of global swallowing capacity and oropharyngeal dysphagia, along with two distinct patient-reported outcome instruments targeting the assessment of oropharyngeal dysphagia.

- Upon the achievement of 6-months of follow-up in the NH Study, participants will be eligible for enrollment into the BB-301 Phase 1b/2a treatment study.

- BB-301 Phase 1b/2a Treatment Study:

    - This first-in-human (FIH) study will evaluate the safety and clinical activity of intramuscular doses of BB-301 administered to subjects with OPMD.

    - The primary endpoint of the FIH study will be safety.

    - Secondary endpoints are designed to determine the impact of BB-301 on swallowing efficiency, swallowing safety, and pharyngeal constrictor muscle function in subjects diagnosed with OPMD with dysphagia via the use of

serial clinical and videofluoroscopic assessments. Critically, each of the clinical and videofluoroscopic assessments employed in the FIH study will be equivalent to those employed for the NH study to facilitate comparative clinical and statistical analyses.

- The primary and secondary endpoints will be evaluated during each 90-day period following BB-301 intramuscular injection (Day 1).

- The NH of dysphagia observed for each OPMD study participant, as characterized by the VFSS and clinical swallowing assessments carried out during the NH Study, will serve as the baseline for comparative assessment of safety and efficacy of BB-301 upon rollover from the NH Study onto the Treatment Study.

Regulatory Updates for the Clinical Development Program:

North America:

- In the Fourth Calendar Quarter 2022, the lead clinical site in the United States opened and has now begun enrolling subjects onto the NH Study.

- Planning for the formal submission of the comprehensive NH Study trial package to the Research Ethics Board (REB) for the lead clinical site in Canada is ongoing and planned for completion in the Second Calendar Quarter 2023.

    - Approval of the overall NH Study trial package by the REB is required for clinical study site activation and OPMD patient screening and enrollment to begin in Canada.

- Investigational New Drug (IND) application and Clinical Trial Application (CTA) clearance is expected in the Second Calendar Quarter 2023. IND clearance is required to initiate the dosing of OPMD subjects with BB-301 in the Phase 1b/2a Treatment Study in the United States. CTA clearance is required to initiate the dosing of OPMD subjects with BB-301 in the Phase 1b/2a Treatment Study in Canada.

- The first NH Study subject is anticipated to be eligible for BB-301 administration in the Third Calendar Quarter 2023, following 6 months of NH Study follow-up and confirmation of eligibility for the BB-301 Phase 1b/2a Treatment Study. Interim clinical results are expected to become available approximately 90 days following the administration of BB-301.

France:

- CTA filing for a comprehensive BB-301 study, inclusive of a 6-month pre-treatment observation period, one day of BB-301 dosing, and a subsequent 52-week follow-up period, is planned for completion in the Second Calendar Quarter 2023.

Financial Highlights

Second Quarter 2023 Financial Results

Revenue for the quarter ended December 31, 2022, was $14,000 compared to $25,000 for the quarter ended December 31, 2021.

Operating expenses for the quarter ended December 31, 2022, were $5.6 million compared to $4.9 million for the quarter ended December 31, 2021. The Company incurred $3.8 million of research and development expenses compared to $3.1 million for the comparable quarter ended December 31, 2021. Research and development expenses relate primarily to the OPMD project. The year-over-year increases for the six-month period reflect conclusion of the BB-301 Regulatory Toxicology Study and the Parallel Assay Method Development, Qualification, and Validation project, and the continuation of the GMP manufacturing project and Natural History Study. For the quarter ended December 31, 2022, general and administrative expenses were $1.9 million compared to $1.7 million for the quarter ended December 31, 2021. The year-over-year increase for the three-month periods ended December 31 relates to higher bonuses and legal fees, partially offset by lower listing and filing fees and stock-based compensation.

The loss from operations for the quarter ended December 31, 2022, was $5.6 million compared to a loss of $4.8 million for the quarter ended December 31, 2021. Net loss attributable to stockholders for the quarter ended December 31, 2022, was $5.4 million, or $0.20 per basic and diluted share, compared to a net loss of $4.8 million, or $0.59 per basic and diluted share for the quarter ended December 31, 2021. As of December 31, 2022, the Company had $10.5 million in cash and cash equivalents.

BENITEC BIOPHARMA INC.
Consolidated Balance Sheets
(in thousands, except par value and share amounts)

	December 31, 2022	June 30, 2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 10,537	$ 4,062
Restricted cash	14	14
Trade and other receivables	68	3
Prepaid and other assets	356	741
Total current assets	10,975	4,820
Property and equipment, net	139	222
Deposits	25	25
Other assets	116	135
Right-of-use assets	650	771
Total assets	$ 11,905	$ 5,973
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 1,830	$ 1,880
Accrued employee benefits	396	400
Lease liabilities, current portion	263	252
Total current liabilities	2,489	2,532
Lease liabilities, less current portion	422	559
Total liabilities	2,911	3,091
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value-160,000,000 shares authorized; 27,981,161 shares and 8,171,690 shares issued and outstanding at December 31, 2022 and June 30, 2022, respectively	3	1
Additional paid-in capital	168,720	152,453
Accumulated deficit	(158,831)	(148,327)
Accumulated other comprehensive loss	(898)	(1,245)
Total stockholders' equity	8,994	2,882
Total liabilities and stockholders' equity	$ 11,905	$ 5,973

The accompanying notes are an integral part of these consolidated financial statements

BENITEC BIOPHARMA INC.
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
Revenue:				
Licensing revenues from customers	$ 14	$ 25	$ 14	$ 25
Total revenues	14	25	14	25
Operating Expenses				
Research and development	3,761	3,146	6,421	5,926
General and admininstrative	1,863	1,714	3,783	3,756
Total operating expenses	5,624	4,860	10,204	9,682
Loss from operations	(5,610)	(4,835)	(10,190)	(9,657)
Other income (loss):				
Foreign currency transaction gain (loss)	161	48	(346)	(193)
Interest expense, net	(9)	(11)	(18)	(12)
Other income, net	50	-	50	-
Unrealized loss on investment	(3)	(23)	-	(5)
Total other income (loss), net	199	14	(314)	(210)
Net loss	$ (5,411)	$ (4,821)	$ (10,504)	$ (9,867)
Other comprehensive income:				
Unrealized foreign currency translation (loss) gain	(160)	(57)	347	182
Total other comprehensive (loss) income	(160)	(57)	347	182
Total comprehensive loss	$ (5,571)	$ (4,878)	$ (10,157)	$ (9,685)
Net loss	$ (5,411)	$ (4,821)	$ (10,504)	$ (9,867)
Net loss per share:				
Basid and diluted	$ (0.20)	$ (0.59)	$ (0.55)	$ (1.21)
Weighted average number of shares outstanding: basic and diluted	27,561,766	8,171,690	19,208,738	8,171,690

The accompanying notes are an integral part of these consolidated financial statements.

About Benitec Biopharma Inc.

Benitec Biopharma Inc. (“Benitec” or the “Company”) is a development-stage biotechnology company focused on the advancement of novel genetic medicines with headquarters in Hayward, California. The proprietary platform, called DNA-directed RNA interference, or ddRNAi, combines RNA interference, or RNAi, with gene therapy to create medicines that facilitate sustained silencing of disease-causing genes following a single administration. The Company is developing ddRNAi-based therapeutics for chronic and life-threatening human conditions including Oculopharyngeal Muscular Dystrophy (OPMD). A comprehensive overview of the Company can be found on Benitec’s website at www.benitec.com.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release include forward-looking statements, including statements regarding Benitec's plans to develop and commercialize its product candidates, the timing of the initiation and completion of pre-clinical and clinical trials, the timing of patient enrolment and dosing in clinical trials, the timing of expected regulatory filings, the clinical utility and potential attributes and benefits of ddRNAi and Benitec's product candidates, potential future out-licenses and collaborations, the intellectual property position and the ability to procure

additional sources of financing, and other forward-looking statements.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA and other governmental authorities; the Company's ability to protect and enforce its patents and other intellectual property rights; the Company's dependence on its relationships with its collaboration partners and other third parties; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; the Company's ability to satisfy its capital needs through increasing its revenue and obtaining additional financing; given market conditions and other factors, including our capital structure; our ability to continue as a going concern; the length of time over which the Company expects its cash and cash equivalents to be sufficient to execute on its business plan; the impact of the current COVID-19 pandemic, the disease caused by the SARS-CoV-2 virus, which may adversely impact the Company's business and pre-clinical and future clinical trials; the impact of local, regional, and national and international economic conditions and events; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission. The Company disclaims any intent or obligation to update these forward-looking statements.

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Source: Benitec Biopharma Inc.