September 21, 2023

Benitec Biopharma Releases Full Year 2023 Financial Results and Provides Operational Update

Received FDA Clearance of the Investigational New Drug (IND) application for BB-301 for the Treatment of Oculopharyngeal Muscular Dystrophy (OPMD)-Related Dysphagia

15 subjects enrolled in the OPMD Natural History Study, with multiple subjects entering the eligibility period this year for entry into the BB-301 Phase 1b/2a Clinical Treatment Study

Successful Closing of a $30.9 M Public Offering

HAYWARD, Calif., Sept. 21, 2023 (GLOBE NEWSWIRE) -- Benitec Biopharma Inc. (NASDAQ: BNTC) ("Benitec" or "Company"), a clinical-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 Fiscal Year ended June 30, 2023. The Company has filed its annual report on Form 10-K for the quarter ended June 30, 2023, with the U.S. Securities and Exchange Commission.

"The pace of enrollment into the OPMD Natural History Study continues to exceed our expectations and, with the receipt of FDA clearance for the BB-301 IND application this year, we have made tremendous progress towards the initiation of the clinical evaluation of BB-301 for the treatment of Oculopharyngeal Muscular Dystrophy-related Dysphagia. " said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. "The Principal Investigator and the clinical team at the U.S. clinical trial site are now preparing to dose the first subject with BB-301 this year, and the strong support that we have received from investors positions the Benitec team and our clinical collaborators well to generate critical safety and efficacy data for BB-301 over the coming months."

Operational Updates

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

BB-301 Clinical Development Program Overview:

- The BB-301 Phase 1b/2a clinical development program will be conducted in the United States and Canada, 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-related 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 constrictor 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 Clinical Treatment Study, with interim safety and efficacy results expected to be available at the end of 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 OPMD 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 OPMD NH Study, participants will, potentially, be eligible for enrollment into the BB-301 Phase 1b/2a Clinical Treatment Study.
- BB-301 Phase 1b/2a Clinical 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-related Dysphagia.
    - 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 OPMD NH study to facilitate

comparative clinical and statistical analyses for each study subject.
    - 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 OPMD NH Study, will serve as the baseline for comparative assessments of safety and efficacy of BB-301 upon rollover from the OPMD NH Study onto the BB-301 Phase 1b/2a Clinical Treatment Study.

Corporate Updates:

- In December 2022, Benitec began screening OPMD subjects at the lead clinical study site in the United States.

- In January 2023, Benitec announced the enrollment of the first OPMD subject into the OPMD NH Study in the United States.

- As of September 2023, 15 subjects have been enrolled into the OPMD NH study in the United States.

- The pace of enrollment of OPMD subjects into the NH Study at the U.S. clinical trial site supports our central clinical development goals of: (1) initiating the clinical dosing of BB-301 in 2H2023, and (2) disclosing the initial interim safety and efficacy data over the next 12 months for subjects that have received BB-301.

- In August 2023, Benitec announced the closing of a $30.9 million underwritten public offering. The Company intends to use the net proceeds from this financing to support the clinical development of BB-301, including the OPMD Natural History Study and the Phase 1b/2a BB-301 Clinical Treatment Study, for the continued advancement of development activities for other existing and new product candidates, for general corporate purposes and for strategic growth opportunities.

Regulatory Updates for the Clinical Development Program:

North America:

- In June 2023, the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for BB-301 which allows dosing of BB-301 to begin for OPMD subjects that are eligible for enrollment into the Phase 1b/2a Clinical Treatment Study.

- Formal submission of the comprehensive OPMD NH Study trial package to the Research Ethics Board (REB) for the lead clinical study site in Canada was completed, and Benitec awaits the formal response from the REB.

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

Financial Highlights

Full Year 2023 Financial Results

Total Revenues for the year ended June 30, 2023, were $75 thousand compared to $73 thousand for the year ended June 30, 2022. The increase in revenues from customers is due to the increase in licensing revenue in the current year.

Total Expenses for the year ended June 30, 2023, were $19.2 million compared to $17.9 million for the year ended June 30, 2022. For the year ended June 30, 2023, Benitec did not incur any royalties and license fees, compared to $9 thousand for the comparable year ended June 30, 2022. The change is primarily due to a decrease in license fees. The Company incurred $12.8 million of research and development expenses compared to $11.3 million for the comparable year ended June 30, 2022. The increase in research and development expenses relates primarily to the OPMD project.

General and administrative expenses were $6.4 million compared to $6.6 million for the year ended June 30, 2022.

The loss from operations for the fiscal year ended June 30, 2023, was $19.6 million compared to a loss of $18.2 million for the year ended June 30, 2022. Net loss attributable to shareholders for the year ended June 30, 2023, was $19.6 million, or $14.12 per basic and diluted share, compared to a net loss of $18.2 million, or $37.88 per basic and diluted share for the year ended June 30, 2022. As of June 30, 2023, the Company had $2.5 million in cash and cash equivalents.

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

	Year Ended June 30,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,477	$ 4,062
Restricted cash	13	14
Trade and other receivables	55	3
Prepaid and other assets	1,184	741
Total current assets	3,729	4,820
Property and equipment, net	87	222
Deposits	25	25
Other assets	97	135
Right-of-use assets	526	771
Total assets	$ 4,464	$ 5,973
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 3,231	$ 1,880
Accrued employee benefits	472	400
Lease liabilities, current portion	275	252
Total current liabilities	3,978	2,532
Lease liabilities, less current portion	284	559
Total liabilities	4,262	3,091
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value-160,000,000 shares authorized; 1,645,951 shares and 480,688 shares issued and outstanding at June 30, 2023 and June 30, 2022, respectively	-	-
Additional paid-in capital	168,921	152,454
Accumulated deficit	(167,889)	(148,327)
Accumulated other comprehensive loss	(830)	(1,245)
Total stockholders' equity	202	2,882
Total liabilities and stockholders' equity	$ 4,464	$ 5,973

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

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

	Year Ended June 30,	
	2023	2022
Revenue:		
Licensing revenues from customers	$ 75	$ 73
Total revenues	75	73
Operating Expenses		
Royalties and license fees	-	9
Research and development	12,774	11,272
General and admininstrative	6,382	6,646
Total operating expenses	19,156	17,927
Loss from operations	(19,081)	(17,854)
Other income (loss):		
Foreign currency transaction loss	(415)	(232)
Interest expense, net	(33)	(32)
Other income (expense), net	(30)	(79)
Unrealized gain (loss) on investment	(3)	(11)
Total other income (loss), net	(481)	(354)
Net loss	$ (19,562)	$ (18,208)
Other comprehensive income:		
Unrealized foreign currency translation gain (loss)	415	210
Total other comprehensive income	415	210
Total comprehensive loss	$ (19,147)	$ (17,998)
Net loss	$ (19,562)	$ (18,208)
Net loss per share:		
Basid and diluted	$ (14.12)	$ (37.88)
Weighted average number of shares outstanding: basic and diluted	1,385,818	480,688

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

About BB-301

BB-301 is a novel, modified AAV9 capsid expressing a unique, single bifunctional construct promoting co-expression of both codon-optimized Poly-A Binding Protein Nuclear-1 (PABPN1) and two small inhibitory RNAs (siRNAs) against mutant PABPN1. The two siRNAs are modeled into microRNA backbones to silence expression of faulty mutant PABPN1, while allowing expression of the codon-optimized PABPN1 to replace the mutant with a functional version of the protein. We believe BB-301's silence and replace strategy is uniquely positioned for the treatment of OPMD by halting mutant expression while providing a functional replacement protein.

About Benitec Biopharma Inc.

Benitec Biopharma Inc. ("Benitec" or the "Company") is a clinical-stage biotechnology company focused on the advancement of novel genetic medicines with headquarters in Hayward, California. The proprietary DNA-directed RNA interference "Silence and Replace" platform combines RNA interference, or RNAi, with gene therapy to create medicines that simultaneously facilitate sustained silencing of disease-causing genes and concomitant delivery of wildtype replacement genes following a single administration of the therapeutic construct. The Company is developing Silence and Replace-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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