February 13, 2024

Benitec Biopharma Releases Second Quarter 2024 Financial Results and Provides Operational Update

-First Subject Dosed with BB-301 in Phase 1b/2a Clinical Treatment Study (NCT06185673) in November 2023-

-Data Safety Monitoring Board Review for First Subject Completed After Day 28 Study Visit-

-Second Subject Scheduled to Receive BB-301 in February 2024-

-23 Subjects Enrolled into the Oculopharyngeal Muscular Dystrophy Natural History Study with Multiple Subjects Eligible for entry into the Phase 1b/2a Clinical Treatment Study in 2024-

HAYWARD, Calif., Feb. 13, 2024 (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 "Silence and Replace" DNA-directed RNA interference ("ddRNAi") platform, today announced financial results for its second fiscal quarter ended December 31, 2023. The Company has filed its quarterly report on Form 10-Q with the U.S. Securities and Exchange Commission.

"In 2023 we formally began the journey towards clinical validation of our Silence and Replace-based approach to the management of genetically defined disorders, and our central goals remain focused on the improvement of the lives of patients suffering from Oculopharyngeal Muscular Dystrophy," said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. "No dose-limiting toxicities have been observed in the first subject treated with BB-301, and the Data Safety Monitoring Board recommended the continuation of subject enrollment for the Phase 1b/2a Clinical Treatment Study without any modifications to the study. We are grateful to have the opportunity to continue the clinical evaluation of BB-301, and we look forward to reporting interim safety data and efficacy data in mid-2024."

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 is currently underway in the

United States, and the primary elements of the program are summarized below:

- The program comprises 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 (NCT06185673). BB-301 will be delivered directly into 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 (NCT06185673), 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 (NCT06185673).
- BB-301 Phase 1b/2a Clinical Treatment Study (NCT06185673):
  - This first-in-human (FIH) study is evaluating 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 is 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 natural history of dysphagia observed for each OPMD NH Study participant, as characterized by the VFSS, clinical assessments of global swallowing capacity, and patient-reported outcome measures conducted 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 (NCT06185673).

Corporate Updates:

- As of January 2024, 23 subjects have been enrolled into the OPMD NH Study in the United States, and the BB-301 development program is designed to treat 21-to-30 subjects.
- In accordance with the Protocol for the BB-301 Phase 1b/2a Clinical Treatment Study (NCT06185673), a meeting of the Data Safety Monitoring Board (DSMB) was convened in January 2024 following the completion of the 28-day post BB-301 dosing visit. No dose-limiting toxicities were observed in the first subject treated with BB-301, and the DSMB recommended the continuation of subject enrollment for the Phase 1b/2a Clinical Treatment Study without any modifications to the study. Following the DSMB recommendation, a second subject has been scheduled to receive BB-301 in February 2024. The next DSMB meeting is anticipated to occur in June 2024 following the 28-day post BB-301 dosing visit of the third subject in Cohort 1 of the BB-301 Phase 1b/2a Clinical Treatment Study (NCT06185673).
- Interim safety data and efficacy data are expected to become available from the BB-301 Phase 1b/2a Clinical Treatment Study (NCT06185673) in mid-2024.

Financial Highlights

Second Quarter 2024 Financial Results

Total Revenues for the quarter ended December 31, 2023, were $0 compared to $14,000 in licensing revenues collected for the quarter ended December 31, 2022.

Total Expenses for the quarter ended December 31, 2023, were $6.9 million compared to $5.6 million for the quarter ended December 31, 2022. For the quarter ended December 31, 2023, the Company incurred royalties and license fees of $1,000 compared to $0 for the three months ended December 31, 2022. The Company incurred $5.1 million of research and development expenses compared to $3.8 million for the comparable quarter ended December 31, 2022. Research and development expenses relate primarily to ongoing clinical development of BB-301 for the treatment of OPMD. General and administrative expenses were $1.8 million compared to $1.9 million for the quarter ended December 31, 2022.

The loss from operations for the quarter ended December 31, 2023, was $6.9 million compared to a loss of $5.6 million for the quarter ended December 31, 2022. Net loss attributable to shareholders for the quarter ended December 31, 2023, was $6.8 million, or $2.64 per basic and diluted share, compared to a net loss of $5.4 million, or $3.34 per basic and diluted share for the quarter ended December 31, 2022. As of December 31, 2023, the

Company had $20.4 million in cash and cash equivalents.

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

	December 31, 2023 (Unaudited)	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 20,374	$ 2,477
Restricted cash	14	13
Trade and other receivables	53	55
Prepaid and other assets	355	1,184
Total current assets	20,796	3,729
Property and equipment, net	51	87
Deposits	25	25
Prepaid and other assets	81	97
Right-of-use assets	400	526
Total assets	$ 21,353	$ 4,464
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 4,937	$ 3,231
Accrued employee benefits	523	472
Lease liabilities, current portion	286	275
Total current liabilities	5,746	3,978
Lease liabilities, less current portion	137	284
Total liabilities	5,883	4,262
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value - 160,000,000 shares authorized; 2,592,434 shares and 1,671,485 shares issued and outstanding at December 31, 2023 and June 30, 2023, respectively	—	—
Additional paid-in capital	197,063	168,921
Accumulated deficit	(180,641)	(167,889)
Accumulated other comprehensive loss	(952)	(830)
Total stockholders' equity	15,470	202
Total liabilities and stockholders' equity	$ 21,353	$ 4,464

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,	
	2023	2022	2023	2022
Revenue:				
Licensing revenues from customers	$ —	$ 14	$ —	$ 14
Total revenues	—	14	—	14
Operating expenses:				
Royalties and license fees	1	—	(105)	—
Research and development	5,102	3,761	9,531	6,421
General and administrative	1,824	1,863	3,375	3,783
Total operating expenses	6,927	5,624	12,801	10,204
Loss from operations	(6,927)	(5,610)	(12,801)	(10,190)
Other income (loss):				
Foreign currency transaction gain (loss)	152	161	96	(346)
Interest expense, net	(6)	(9)	(12)	(18)
Other income (expense), net	(16)	50	(34)	50
Unrealized loss on investment	(1)	(3)	(1)	—
Total other income (loss), net	129	199	49	(314)
Net loss	$ (6,798)	$ (5,411)	$ (12,752)	$ (10,504)
Other comprehensive income (loss):				
Unrealized foreign currency translation gain (loss)	(172)	(160)	(122)	347
Total other comprehensive income (loss)	(172)	(160)	(122)	347
Total comprehensive loss	$ (6,970)	$ (5,571)	$ (12,874)	$ (10,157)
Net loss	$ (6,798)	$ (5,411)	$ (12,752)	$ (10,504)
Net loss per share:				
Basic and diluted	$ (2.64)	$ (3.34)	$ (5.39)	$ (9.30)
Weighted average number of shares outstanding: basic and diluted	2,576,347	1,621,280	2,366,706	1,129,926

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 the silence and replace mechanism of BB-301 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 “Silence and Replace” DNA-directed RNA interference 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 enrollment 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 COVID-19 pandemic, the disease caused by the SARS-CoV-2 virus and similar events, which may adversely impact the Company's business and pre-clinical and 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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