September 26, 2024

Benitec Biopharma Releases Full Year 2024 Financial Results and Provides Operational Update

-Positive 90-day and 180-day Interim Clinical Trial Data for the First Oculopharyngeal Muscular Dystrophy (OPMD) Subject Dosed with the Low-Dose of BB-301 in the Phase 1b/2a Clinical Treatment Study Reported in April and July-

-Second Subject Dosed with the Low-Dose of BB-301 in February 2024, and Third Subject Expected to Receive the Low-Dose of BB-301 in Calendar Quarter Four of 2024-

-Closed an Oversubscribed Private Placement Financing of $40.0 Million on April 22nd, Cash Runway Extended Through 2025-

HAYWARD, Calif., Sept. 26, 2024 (GLOBE NEWSWIRE) -- Benitec Biopharma Inc. (NASDAQ: BNTC) ("Benitec" or the "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 full year ended June 30, 2024. The Company has filed its annual report on Form 10-K with the U.S. Securities and Exchange Commission.

"The 90-day and 180-day interim clinical study results for the first subject enrolled into the low-dose cohort of the BB-301 Phase 1b/2a Clinical Treatment Study demonstrated clinically meaningful improvements in the central study endpoints, with significant improvements noted across the radiographic assessments of swallowing efficiency and corresponding improvements observed for the key dysphagia-focused subject-reported outcome measure," said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. "Additional clinical data for the BB-301 Phase 1b/2a Clinical Treatment Study were accepted for oral presentation during the Late Breaking session of the 29th Annual Congress of the World Muscle Society on October 12, 2024. The recent financing comfortably positions Benitec to advance the BB-301 clinical development program through the end of 2025."

Operational Updates

The key milestones related to the development of BB-301 for the treatment of OPMD-related Dysphagia, are outlined below:

Interim BB-301 Phase 1b/2a Clinical Treatment Study Results for Subject 1:

Background Information Regarding the Key Clinical Assessments and Radiographic Outcome Measures Employed in the BB-301 Phase 1b/2a:

- Total Pharyngeal Residue (TPR) comprises the total amount of solid food or liquid

material remaining in the pharynx after the completion of the first swallow of the bolus. TPR is objectively characterized via the completion of videofluoroscopic swallowing studies (VFSS) which evaluate the complete swallowing process for each subject in the context of four food types (i.e., Thin Liquid, Moderately Thick Liquid, Extremely Thick Liquid, and Solid Food). The consistency of Thin Liquid is similar to that of water. The consistency of Moderately Thick Liquid is similar to that of a smoothie. The consistency of Extremely Thick Liquid is similar to that of yogurt or pudding.

- The Sydney Swallow Questionnaire (SSQ) is a paper-based questionnaire assessing subjective symptoms of oral-pharyngeal dysphagia, and the questionnaire is completed independently by the study subject at each clinical study visit. The 17-item questionnaire measures the symptomatic severity of oral-pharyngeal dysphagia.

90-Day Post-Dose Interim Clinical Study Results:

- At the 90-day post-dose assessment following the administration of the low-dose of BB-301, Subject 1 demonstrated improvements in key VFSS assessments which correlated with the observation of similar levels of improvement in the SSQ as compared to the pre-dose average values recorded for Subject 1 during the OPMD Natural History Study, indicating an improvement in swallowing function as reported by Subject 1.

180-Day Post-Dose Interim Clinical Study Results:

- The post-dose average values for TPR remained meaningfully reduced (i.e., smaller amounts of solid food and liquid material remained in the pharynx after the completion of the first swallow) at the 180-day post-dose assessment following the administration of the low-dose of gene therapy BB-301 as compared to the pre-dose average values recorded for Subject 1 during the OPMD Natural History Study.

- The Total Score recorded for the Subject-Reported SSQ also demonstrated continued reductions in the Subject's dysphagic symptoms (i.e., improvements in the Subject's ability to swallow) at the 180-day post-dose timepoint, with the Total SSQ Score continuing to decline and remaining meaningfully reduced as compared to the pre-dose average value recorded for Subject 1 during the OPMD Natural History Study, indicating a greater improvement in swallowing function as reported by Subject 1.

- Key Opinion Leaders (KOLs) participating in the recent BB-301 Research and Development Day webcast (April 2024) highlighted VFSS assessments of TPR and the Subject-Reported Outcome SSQ Total Score as the central markers of value for the long-term evaluation of clinically meaningful improvement in subjects diagnosed with OPMD.

Continued Enrollment for the BB-301 Phase 1b/2a Clinical Treatment Study:

- The second subject received the Low-Dose of BB-301 in February 2024, and the third subject is expected to receive the low-dose of BB-301 in calendar quarter four of 2024.

Safety and Tolerability:

- Regarding the BB-301 safety profile observed to date, transient Grade 2 Gastroesophageal Reflux Disease or "GERD" (i.e., "acid reflux" or "heartburn") has been reported previously in April 2024 at the time of the Research and Development Day webcast. No Serious Adverse Events (SAEs) have been observed for the two subjects that have received the low-dose of BB-301.

Corporate Updates:

- On April 18th the Company announced an oversubscribed $40.0 million private investment in public equity (PIPE) financing. The closing of the PIPE occurred on April 22, 2024.

- On July 1st the company announced the appointment of Kishen Mehta to the board of directors (BOD) of the Company, effective June 26, 2024. Mr. Mehta's appointment follows the $40.0 million PIPE financing announced on April 18th, led by long-term investor Suvretta Capital, where he serves as portfolio manager.

- On September 23rd Jerel A. Banks, M.D., Ph.D. participated in the OPMD Awareness Day Webinar organized by the OPMD Association. A replay of the event can be found here.

- On October 12th the Principal Investigator of the BB-301 Phase 1b/2a Clinical Treatment Study will make an oral presentation of a Late Breaking Abstract entitled "Interim Clinical Data Summary: A Phase 1b/2a Open-label, Dose Escalation Study to Evaluate the Safety and Clinical Activity of Intramuscular Doses of an AAV9-based gene therapy (BB-301) Administered to Subjects with Oculopharyngeal Muscular Dystrophy (OPMD) with Dysphagia" at the 29th Annual Congress of the World Muscle Society.

Financial Highlights

Full Year 2024 Financial Results

Total Revenues for the year ended June 30, 2024, were $0 million compared to $75,000 in licensing revenues collected for the year ended June 30, 2023.

Total Expenses for the year ended June 30, 2024, were $22.5 million compared to $19.2 million for the year ended June 30, 2023. For the year ended June 30, 2024, the Company incurred ($108,000) in royalties and license fees due to the reversal of an accrual for the year ended June 30, 2024 compared to $0 for the year ended June 30, 2023. The Company incurred $15.6 million of research and development expenses for the year ended June 30, 2024 compared to $12.8 million for the year ended June 30, 2023. Research and development expenses relate primarily to ongoing clinical development of BB-301 for the treatment of OPMD. General and administrative expenses were $7.0 million for the year ended June 30, 2024 compared to $6.4 million for the year ended June 30, 2023.

The loss from operations for the year ended June 30, 2024, was $21.8 million compared to a loss of $19.6 million for the year ended June 30, 2023. Net loss attributable to shareholders for the year ended June 30, 2024, was $22.4 million, or $5.51 per basic and diluted share,

compared to a net loss of $19.6 million, or $14.12 per basic and diluted share for the year ended June 30, 2023. As of June 30, 2024, the Company had $50.9 million in cash and cash equivalents.

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 causative gene for OPMD). 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 completion of pre-clinical and clinical trials, the timing of the availability of data from our clinical trials, the timing and sufficiency of patient enrollment and dosing in clinical trials, the timing of expected regulatory filings, and the clinical utility and potential attributes and benefits of ddRNAi and Benitec’s product candidates, 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: the success of our plans to develop and potentially commercialize our product candidates; the timing of the completion of preclinical studies and clinical trials; the timing and sufficiency of patient enrollment and dosing in any future clinical trials; the timing of the availability of data from our clinical trials; the timing and outcome of regulatory filings and approvals; the development of novel AAV vectors; our potential future out-licenses and collaborations; the plans of licensees of our technology; the clinical utility and potential attributes and benefits of ddRNAi and our product candidates, including the potential duration of treatment effects and the potential for a “one shot” cure; our intellectual property position and the duration of our patent portfolio; expenses, ongoing losses, future revenue, capital needs and needs for additional financing, and our ability to

access additional financing given market conditions and other factors, including our capital structure; the length of time over which we expect our cash and cash equivalents to be sufficient to execute on our business plan; 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 and other regulatory developments; 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 impact of, and our ability to remediate, the identified material weakness in our internal controls over financial reporting; 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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BENITEC BIOPHARMA INC.
Consolidated Balance Sheets
(in thousands, except par value and share amounts)

	June 30, 2024	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 50,866	$ 2,477
Restricted Cash	63	13
Trade and other receivables	229	55
Prepaid and other assets	516	1,184
Total current assets	51,674	3,729
Property and equipment, net	179	87
Deposits	25	25
Other assets	62	97
Right-of-use assets	270	526
Total assets	$ 52,210	$ 4,464
Liabilities and Stockholders' Equity		
Current liabilities:		
Trade and other payables	$ 4,165	$ 3,231
Accrued employee benefits	475	472
Lease liabilities, current portion	284	275
Total current liabilities	4,924	3,978
Non-current accrued employee benefits	38	-
Lease liabilities, less current portion	-	284
Total liabilities	4,962	4,262
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value - 160,000,000 shares authorized; 10,086,119 and 1,671,485 shares issued and outstanding at June 30, 2024 and 2023, respectively	1	-
Additional paid-in capital	238,398	168,921
Accumulated deficit	(190,259)	(167,889)
Accumulated other comprehensive loss	(892)	(830)
Total stockholders' equity	47,248	202
Total liabilities and stockholders' equity	$ 52,210	$ 4,464

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

	Year Ended June 30,	
	2024	**2023**
Revenue:		
Licensing revenues from customers	$ -	$ 75
Total revenues	-	75
Operating expenses		
Royalties and license fees	(108)	-
Research and development	15,609	12,774
General and administrative	6,989	6,382
Total operating expenses	22,490	19,156
Loss from operations	(22,490)	(19,081)
Other income (loss):		
Foreign currency transaction gain (loss)	40	(415)
Interest income (expense), net	904	(33)
Other income (expense), net	(204)	(30)
Unrealized gain (loss) on investment	(1)	(3)
Total other income (loss), net	739	(481)
Provsion for income tax	-	-
Net loss	$ (21,751)	$ (19,562)
Other comprehensive income:		
Unrealized foreign currency translation gain (loss)	(62)	415
Total other comprehensive income	(62)	415
Total comprehensive loss	$ (21,813)	$ (19,147)
Net loss	$ (21,751)	$ (19,562)
Deemed dividends	(619)	$ -
Net loss attributable to common shareholders	$ (22,370)	$ (19,562)
Net loss per share:		
Basic and diluted	$ (6)	$ (14)
Weighted average number of shares outstanding: basic and diluted	4,060,182	1,385,818

Source: Benitec Biopharma Inc.