February 14, 2022

Benitec Biopharma Discloses Q2 2022 Financial Results

HAYWARD, Calif., Feb. 14, 2022 /PRNewswire/ -- Benitec Biopharma Inc. (NASDAQ: BNTC) ("Benitec" or "the Company"), a development-stage, gene therapy-focused, biotechnology company developing novel genetic medicines based on the proprietary DNA-directed RNA interference ("ddRNAi") platform, today announced the financial results for its Fiscal Year Q2 ended December 31, 2021. The Company has filed its quarterly report on Form 10-Q for the quarter ended December 31, 2021, with the U.S. Securities and Exchange Commission.

Operational Updates

The key milestones related to the investigational agents under development by the Company and other corporate updates are outlined below:

Regulatory Interactions:

- Benitec successfully completed the regulatory interactions required to support initiation of the BB-301 clinical development program in 2022
- Successful regulatory engagement comprised the completion of the following meetings:
  - Pre-Clinical Trial Application (Pre-CTA) Consultation Meeting with Health Canada
  - Scientific Advice Meeting with The National Agency for the Safety of Medicines and Health Products in France (L'Agence nationale de sécurité du médicament et des produits de santé or "ANSM")
  - Type C Meeting with the U.S. Food and Drug Administration ("FDA")

BB-301 Clinical Development Program:

- The BB-301 clinical development program will begin in mid-2022, and the conduct of the development program will comprise approximately 76-weeks of follow-up for each Oculopharyngeal Muscular Dystrophy (OPMD) study participant, inclusive of :
  - 6-month pre-treatment observation periods for evaluation of the baseline disposition and natural history of OPMD-derived dysphagia in each study participant

    - 1 day of BB-301 dosing to initiate participation in the Phase 1b/2a single-arm, open-label, sequential, dose escalation cohort study
    - 52-weeks of post-dosing follow-up for conclusive evaluation of the primary and secondary endpoints of the Phase 1b/2a BB-301 treatment study
- The OPMD Natural History Study will begin in mid-2022 and this observational study will facilitate the characterization of OPMD patient disposition at baseline and assess subsequent rates of progression of dysphagia (swallowing impairment) in subjects with OPMD via the use of:
    - Quantitative radiographic measures of global swallowing function and pharyngeal constrictor muscle force generation
        - Inclusive of Videofluoroscopic Swallowing Studies (VFSS) conducted to complete the following methodological assessments:
            - Dynamic Imaging Grade of Swallowing Toxicity Scale (DIGEST)
            - Pharyngeal Area at Maximum Constriction (PAMC)
            - Pharyngeal Constriction Ratio (PCR)
    - Clinical measures of global swallowing capacity and oropharyngeal dysphagia
    - Patient-reported measures of oropharyngeal dysphagia
- The natural history of dysphagia observed for each OPMD study participant, as characterized by the quantitative measures and clinical assessments outlined above, will serve as the baseline for comparative assessment of safety and efficacy of BB-301 upon rollover of OPMD patients from the Natural History Study onto the Phase 1b/2a treatment study
- Upon the achievement of 6-months of follow-up in the Natural History Study, OPMD study participants will become eligible for enrollment onto the treatment study with the investigational genetic medicine, BB-301, which uses an AAV9-based gene therapy approach for the treatment of OPMD-derived dysphagia
    - This first-in-human study (FIH) will be a Phase 1b/2a, open-label, dose escalation study to evaluate the safety and clinical activity of intramuscular doses of BB-301 administered to subjects with OPMD
- Upon rollover onto the Phase 1b/2a BB-301 treatment study, the follow-up of OPMD study participants will continue for 52-weeks, and the primary endpoints (safety and tolerability) and secondary endpoints (comprising the quantitative radiographic measures of global swallowing function and pharyngeal constrictor muscle force generation and the clinical assessments noted above) will be evaluated during each 90-day period following Day 0 (the day of BB-301 intramuscular injection)
- On September 8, 2021 Benitec provided key updates related to the primary and secondary endpoints for the Phase 1b/2a BB-301 treatment study

<u>BB-301 Pre-Clinical Development Program:</u>

- On September 8, 2021 Benitec provided key updates related to the progress of the BB-301 pre-clinical development program, including updated results for the BB-301 Pilot Dosing Study in large animals

<u>Financial Highlights</u>

Total Revenues for the quarter ended December 31, 2021 were twenty-five thousand compared to one thousand dollars in total revenue for three months ended December 31, 2020. The increase in revenues from customers is due to the increase in licensing and

royalty revenues in the current period.

Total Operating Expenses were $4.9 million for the quarter ended December 31, 2021 compared to $3.2 million for the comparable period in 2020. For the quarters ended December 31, 2021, and 2020, respectively, Benitec incurred $0 and $19 thousand in royalties and license fees. During the three months ended December 31, 2021 and 2020, respectively, the Company incurred $3.2 million and $1.2 million in research and development expenses. The increase in research and development expenses is primarily related to the commencement of the BB-301 Regulatory Toxicology Study in Beagle dogs at Charles River Laboratories in Evreux, France. As planned, the Company began incurring more costs related to the execution of two large non-clinical studies in Beagle dogs, along with the commercial-scale GMP-grade manufacturing of BB-301, all of which is required to facilitate the Clinical Trial Application (CTA) filing and the Investigational New Drug (IND) filing for BB-301 during 2022. General and administrative expenses were $1.7 million and $2.1 million for the three months ended December 31, 2021 and 2020, respectively. The increase during this three-month period was due to increases in costs related to insurance, consultant fees, legal fees, and accounting fees.

Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec Biopharma commented, "The robust biological activity observed for BB-301 in our Pilot Dosing Study underpins our enthusiasm for the initiation of the BB-301 clinical development program in 2022. We remain dedicated to our central goal of improving the lives of patients with OPMD."

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

	December 31, 2021	June 30, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 12,329	$ 19,769
Trade and other receivables	5	25
Prepaid and other assets	338	814
Total current assets	12,672	20,608
Property and equipment, net	268	375
Deposits	25	9
Other assets	161	185
Right-of-use assets	888	202
Total assets	$ 14, 014	$ 21,379
Liabilities and Stockholders' Equity		
Current liabilities:		
Trade and other payables	$ 1,946	$ 880
Accrued employee benefits	321	276
Lease liabilities, current portion	213	213
Total current liabilities	2,480	1,369
Lease liabilities, less current portion	698	—
Total liabilities	3,178	1,369
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value-40,000,000 shares authorized; 8,171,690 shares issued and outstanding at December 31, 2021 and June 30, 2021	1	1
Additional paid-in capital	152,093	151,583
Accumulated deficit	(139,985)	(130,119)
Accumulated other comprehensive loss	(1,273)	(1,455)
Total stockholders' equity	10,836	20,010
Total liabilities and stockholders' equity	$ 14,014	$ 21,379

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,	
	2021	2020	2021	2020
Revenue:				
Licensing revenues from customers	$ 25	$ 1	$ 25	$ 56
Total revenues	25	1	25	56
Operating expenses				
Royalties and license fees	—	(19)	—	114
Research and development	3,146	1,168	5,926	1,942
General and administrative	1,714	2,111	3,756	3,948
Total operating expenses	4,860	3,260	9,682	6,004
Loss from operations	(4,835)	(3,259)	(9,657)	(5,948)
Other income (loss):				
Foreign currency transaction gain (loss)	48	—	(193)	(54)
Interest expense, net	(11)	(2)	(12)	(3)
Other income, net	—	10	—	36
Unrealized loss on investment	(23)	(1)	(5)	(1)
Total other income (loss), net	14	7	(210)	(22)
Net loss	$ (4,821)	$ (3,252)	$ (9,867)	$ (5,970)
Other comprehensive income:				
Unrealized foreign currency translation (loss) gain	(57)	208	182	386
Total other comprehensive (loss) income	(57)	208	182	386
Total comprehensive loss	$ (4,878)	$ (3,044)	$ (9,685)	$ (5,584)
Net loss	$ (4,821)	$ (3,252)	$ (9,867)	$ (5,970)
Net loss per share:				
Basic and diluted	$ (0.59)	$ (0.76)	$ (1.21)	$ (2.21)
Weighted average number of shares outstanding: basic and diluted	8,171,690	4,300,073	8,171,690	2,704,223

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; 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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