May 16, 2022

Benitec Biopharma Releases Q3 2022 Financial Results

HAYWARD, Calif., May 16, 2022 (GLOBE NEWSWIRE) -- Benitec Biopharma Inc. (NASDAQ: BNTC) (“Benitec” or “the 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 Fiscal Year Q3 ended March 31, 2022. The Company has filed its quarterly report on Form 10-Q for the quarter ended March 31, 2022, with the U.S. Securities and Exchange Commission.

“With our key submission to the Central Ethics Committee in France completed in April, we are well-positioned to begin the clinical development program this year,” said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec Biopharma. “The Benitec team remains committed to initiating the clinical development program for BB-301 and improving the lives of patients suffering from OPMD.”

Operational Updates

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

BB-301 Clinical Development Program Overview:

- The BB-301 clinical development program will be conducted in France, Canada, and the United States, and the primary elements of the clinical development plan are summarized below.
    - The Clinical development plan will begin in 2022 and comprise approximately 76 weeks of follow-up:
        - 6 month pre-treatment observation periods for the evaluation of 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 (NH) Study will facilitate the characterization of OPMD patient disposition at baseline and assess subsequent rates of

progression of dysphagia (swallowing impairment) via the use of the following quantitative radiographic measures of global swallowing function and pharyngeal constrictor muscle function inclusive of Videofluoroscopic Swallowing Studies (VFSS):

- 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)
- Clinical measures of global swallowing capacity and oropharyngeal dysphagia
- Patient-reported measures of oropharyngeal dysphagia

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

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

  - 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.

  - The primary endpoints will be safety and tolerability, with secondary endpoints comprising quantitative radiographic measures of global swallowing function and pharyngeal constrictor muscle function as well as clinical assessments equivalent to those employed for the NH study. These 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 study participant, as characterized by the quantitative measures and clinical 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.

Operational and Regulatory Updates for the Clinical Development Program in France:

- The NH Study Protocol, the Informed Consent Form (ICF), the patient-facing documents and the physician-facing documents have been completed.

- Primary clinical sites (staffed by neurologists with decades of experience managing OPMD patients) and auxiliary clinical sites (for the conduct of the NH Study-specific videofluoroscopic swallowing studies) have been formally qualified.

- Principal Investigators (PIs), and sub-investigators, have been identified at the respective clinical sites.

- The central reader for the videofluoroscopic swallowing studies has been selected.

- Submission of the comprehensive NH Study trial package to the Central Ethics Committee (CEC) was completed in April 2022.

    - Approval of the NH Study trial package by the CEC allows for clinical site activation and OPMD patient enrollment to begin in France.

    - The final CEC decision is expected in July 2022 (allowing for NH Study screening visits to begin in July/August 2022).

Operational and Regulatory Updates for the Clinical Development Program in North America:

- Primary clinical sites in Canada and the United States and auxiliary clinical sites have been identified.

- Formal site qualification has been completed in Canada, and site qualifications are underway in the United States.

- PIs have been identified at the respective clinical sites.

- Submission of the comprehensive NH Study trial package to the Research Ethics Board (REB) in Canada is anticipated for June 2022, and submissions to the Independent Ethics Committees (IECs) in the United States will follow.

Clinical Trial Application (CTA) and Investigational New Drug (IND) Application Filing Timelines and Phase 1b/2a Treatment Study Initiation:

- CTA and IND filings are anticipated for January 2023 (required to initiate the Phase 1b/2a Treatment Study in France, Canada, and the United States).

- The first NH study subject is anticipated to be eligible for BB-301 administration in April 2023 (following 6-months of NH Study enrollment and follow-up and final confirmation of eligibility for the BB-301 Phase 1b/2a Treatment Study).

- Interim safety and efficacy data is anticipated for release every 90-days following BB-301 administration.

    - In preclinical proof-of-concept studies for BB-301, the OPMD disease phenotype was reversed 14-to-20 weeks after the administration of BB-301 (with muscle strength restored and microscopic signs of muscle damage significantly improved).

Financial Highlights

Total Revenues for the three months ended March 31, 2022 were $48 thousand compared

to $1 thousand in total revenue for three months ended March 31, 2021. The increase in revenues from customers is due to the increase in licensing revenue in the third quarter.

Total Operating Expenses were $3.5 million for the quarter ended March 31, 2022 compared to $3.79 million for the comparable period in 2021. For the three months ended March 31, 2022, Benitec did not incur any royalties and license fees, compared to $7 thousand for the three months ended March 31, 2021. During the three months ended March 31, 2022, the Company incurred $2.17 million in research and development expenses, compared to $2.75 million for the three months ended March 31, 2021. The decrease in research and development expenses is primarily related to the BB-301 Regulatory Toxicology Study in Beagles at Charles River Laboratories in Evreux, France. As milestones were reached, the Company began incurring lower costs related to the execution of two large nonclinical studies in Beagles, along with the commercial-scale GMP-grade manufacturing of BB-301, all of which are required to facilitate the CTA filing and the IND filing for BB-301. For the three months ended March 31, 2022, general and administrative expenses were $1.3 million compared to $1 million for the three months ended March 31, 2021. The increase during this period was due to increases in insurance, consultants, legal and accounting fees, and share-based compensation.

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

	March 31, 2022	June 30, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 8,630	$ 19,769
Trade and other receivables	5	25
Prepaid and other assets	206	814
Total current assets	8,841	20,608
Property and equipment, net	214	375
Deposits	25	9
Other assets	156	185
Right-of-use assets	828	202
Total assets	$ 10,064	$ 21,379
Liabilities and Stockholders' Equity		
Current liabilities:		
Trade and other payables	$ 1,320	$ 880
Accrued employee benefits	357	276
Lease liabilities, current portion	232	213
Total current liabilities	1,909	1,369
Lease liabilities, less current portion	635	—
Total liabilities	2,544	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 March 31, 2022 and June 30, 2021	1	1
Additional paid-in capital	152,285	151,583
Accumulated deficit	(143,260)	(130,119)
Accumulated other comprehensive loss	(1,506)	(1,455)
Total stockholders' equity	7,520	20,010
Total liabilities and stockholders' equity	$ 10,064	$ 21,379

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2022	2021	2022	2021
Revenue:				
Licensing revenues from customers	$ 48	$ 1	$ 73	$ 57
Total revenues	48	1	73	57
Operating expenses				
Royalties and license fees	—	7	—	122
Research and development	2,171	2,758	8,096	4,700
General and administrative	1,337	1,029	5,093	4,976
Total operating expenses	3,508	3,794	13,189	9,798
Loss from operations	(3,460)	(3,793)	(13,116)	(9,741)
Other income (loss):				
Foreign currency transaction gain (loss)	229	(112)	36	(167)
Interest expense, net	(10)	(2)	(22)	(5)
Other income (expense), net	(29)	—	(29)	37
Unrealized loss on investment	(5)	(2)	(10)	(3)
Total other income (loss), net	185	(116)	(25)	(138)
Net loss	$ (3,275)	$ (3,909)	$ (13,141)	$ (9,879)
Other comprehensive income:				
Unrealized foreign currency translation (loss) gain	(233)	(24)	(51)	362
Total other comprehensive (loss) income	(233)	(24)	(51)	362
Total comprehensive loss	$ (3,508)	$ (3,933)	$ (13,192)	$ (9,517)
Net loss	$ (3,275)	$ (3,909)	$ (13,141)	$ (9,879)
Net loss per share:				
Basic and diluted	$ (0.40)	$ (0.82)	$ (1.61)	$ (2.93)
Weighted average number of shares outstanding: basic and diluted	8,171,690	4,747,059	8,171,690	3,375,228

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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