September 2, 2022

Benitec Biopharma Releases Full Year 2022 Financial Results and Provides Operational Update

HAYWARD, Calif., Sept. 02, 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 ended June 30, 2022. The Company has filed its annual report on Form 10-K for the quarter ended June 30, 2022, with the U.S. Securities and Exchange Commission.

"We continue to move closer to the initiation of the clinical evaluation of BB-301," said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec Biopharma. "The Benitec team remains committed to improving the lives of patients suffering from Oculopharyngeal Muscular Dystrophy."

Operational Updates

The key milestones related to the development of BB-301 for Oculopharyngeal Muscular Dystrophy (OPMD) by the Company, along with 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 (swallowing impairment) 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 (i.e., the 6-month pre-treatment

observation period) will facilitate the characterization of OPMD patient disposition at baseline and assess subsequent rates of progression of dysphagia via the use of the following quantitative radiographic measures (i.e., videofluoroscopic swallowing studies or "VFSS"), with the VFSS outlined below collectively providing 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 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 NH Study, participants will be eligible for enrollment onto the BB-301 Phase 1b/2a treatment study.

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

  - This first-in-human (FIH) study 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 of the FIH study will be safety and tolerability, with secondary endpoints comprising quantitative radiographic measures of global swallowing function and pharyngeal constrictor muscle function (i.e., VFSS) as well as clinical assessments (all of which will be 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 VFSS and clinical swallowing 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:

France:

- In the Second Calendar Quarter 2022, the NH Study Protocol, the Patient Informed Consent Form, the patient-facing documents and the physician-facing documents were completed; primary clinical study sites were formally qualified; Principal Investigators and Sub-Investigators were identified at the clinical study sites; the core VFSS site was selected and qualified; and the central reader for the VFSS data was selected.
    - Upon completion of these operational milestones, a formal submission was made to the Central Ethics Committee (CEC) in France.
- In the Third Calendar Quarter 2022, Benitec received feedback from the CEC advising minor changes to the text of the Patient Informed Consent form (ICF).
    - The suggested updates were incorporated into the ICF, and the formal re-submission process for CEC final review has been completed.
    - Approval of the updated ICF, and the overall NH Study trial package, by the CEC allows for clinical study site activation and OPMD patient screening and enrollment to begin in France.
    - The final CEC decision is expected in October 2022 (allowing for NH Study screening visits and patient enrollment to begin in the Fourth Calendar Quarter 2022).

North America:

- Formal submission of the comprehensive NH Study trial package to the Institutional Review Board (IRB) at the lead clinical study site in the United States was completed in August 2022.
    - Approval of the overall NH Study trial package by the IRB allows for clinical study site activation and OPMD patient screening and enrollment to begin in the United States.
    - The IRB decision is expected in October 2022 (allowing for NH Study screening visits and patient enrollment to begin in the Fourth Calendar Quarter 2022).
- Benitec plans to complete the formal submission of the comprehensive NH Study trial package to the Research Ethics Board (REB) for the lead clinical site in Canada in the Fourth Calendar Quarter 2022.
    - Approval of the overall NH Study trial package by the REB allows for clinical study site activation and OPMD patient screening and enrollment to begin in Canada.

BB-301 Phase 1b/2a Regulatory Updates:

- Clinical Trial Application (CTA) and Investigational New Drug (IND) filings are anticipated in the First Calendar Quarter 2023.

- CTA and IND filings are required to initiate the BB-301 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 the Second Calendar Quarter 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 for subjects enrolled onto the BB-301 Phase 1b/2a Treatment Study are anticipated to become available for disclosure every 90-days following BB-301 administration.

    - In preclinical proof-of-concept studies for BB-301, the OPMD disease phenotype was reversed at 14 weeks (i.e., approximately 90-days) after the administration of BB-301 (with the strength of BB-301 injected muscles being restored in the diseased animals and robust evidence of anatomical and microscopic improvement of the BB-301 injected muscle tissues being observed).

Financial Highlights

Full Year 2022 Financial Results

Total Revenues for the year ended June 30, 2022, were $73 thousand compared to $59 thousand for the year ended June 30, 2021. The increase in revenues from customers is due to the increase in licensing and royalty revenues in the current year.

Total Expenses for the year ended June 30, 2022, were $17.9 million compared to $13.7 million for the year ended June 30, 2021. For the year ended June 30, 2022, Benitec incurred $9 thousand in royalties and license fees compared to $123 thousand for the comparable year ended June 30, 2021. The change is primarily due to a decrease in license fees. The Company incurred $11.2 million of research and development expenses compared to $7 million for the comparable year ended June 30, 2021. The increase in research and development expenses relates primarily to the OPMD project. The Company concluded the BB-301 Regulatory Toxicology Study and the Parallel Assay Method Development, Qualification, and Validation project, and continued with the GMP Manufacturing project.

General and administrative expenses were $6.6 million compared to $6.5 million for the year ended June 30, 2021.

The loss from operations for the fiscal year ended June 30, 2022, was $18.2 million compared to a loss of $13.9 million for the year ended June 30, 2021. Net loss attributable to shareholders for the year ended June 30, 2022, was $18.2 million, or $2.23 per basic and diluted share, compared to a net loss of $13.9 million, or $3.23 per basic and diluted share for the year ended June 30, 2021. As of June 30, 2022, the Company had $4.1 million in cash and cash equivalents.

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

	June 30, 2022	June 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 4,062	$ 19,769
Restricted Cash	14	15
Trade and other receivables	3	25
Prepaid and other assets	741	799
Total current assets	4,820	20,608
Property and equipment, net	222	375
Deposits	25	9
Other assets	135	185
Right-of-use assets	771	202
Total assets	$ 5,973	$ 21,379
Liabilities and Stockholders' Equity		
Current liabilities:		
Trade and other payables	$ 1,880	$ 880
Accrued employee benefits	400	276
Lease liabilities, current portion	252	213
Total current liabilities	2,532	1,369
Lease liabilities, less current portion	559	—
Total liabilities	3,091	1,369
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.0001 par value—40,000,000 shares authorized; 8,171,690 shares issued and outstanding at June 30, 2022 and 2021	1	1
Additional paid-in capital	152,453	151,583
Accumulated deficit	(148,327)	(130,119)
Accumulated other comprehensive loss	(1,245)	(1,455)
Total stockholders' equity	2,882	20,010
Total liabilities and stockholders' equity	$ 5,973	$ 21,379

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,	
	2022	2021
Revenue:		
Revenues from customers	$ 73	$ 59
Operating expenses		
Royalties and license fees	9	123
Research and development	11,272	7,020
General and administrative	6,646	6,512
Total operating expenses	17,927	13,655
Loss from operations	(17,854)	(13,596)
Other income (loss):		
Foreign currency transaction loss	(232)	(333)
Interest expense, net	(32)	(6)
Other income (expense), net	(79)	37
Unrealized gain (loss) on investment	(11)	16
Total other loss, net	(354)	(286)
Net loss	$ (18,208)	$ (13,882)
Other comprehensive income (loss):		
Unrealized foreign currency translation gain	210	498
Total other comprehensive income	210	498
Total comprehensive loss	$ (17,998)	$ (13,384)
Net loss	$ (18,208)	$ (13,882)
Net loss per share:		
Basic and diluted	$ (2.23)	$ (3.23)
Weighted-average shares outstanding:		
Basic and diluted	8,171,690	4,295,416

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

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; 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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BENITEC BIOPHARMA
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Source: Benitec Biopharma Inc.