

November 15, 2021



# Benitec Biopharma Discloses Q1 2022 Financial Results

HAYWARD, Calif., Nov. 15, 2021 /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 Q1 ended September 30, 2021. The Company has filed its quarterly report on Form 10-Q for the quarter ended September 30, 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:

### **BB-301 (Oculopharyngeal Muscular Dystrophy Program)**

- On September 8, 2021, Benitec provided three key updates related to the progress of the BB-301 development program, including: updated results for the BB-301 Pilot Dosing Study in large animals, updates on European and North American regulatory interactions for the BB-301 development program, and a comprehensive overview of the design of, and key primary and secondary endpoints for, the Phase 1b/2a clinical trial which is planned for initiation in 2022. All of the updates were positive and demonstrated the significant progress that has been achieved for the BB-301 development program; below is a summary of each update:
  - **BB-301 Pilot Dosing Study in Large Animals:** On September 8<sup>th</sup> the Company disclosed updated analyses for the animal subjects dosed with BB-301 in the Pilot Dosing Study. The updated data continued to demonstrate dose-dependent transduction of the target pharyngeal muscle tissues by BB-301, dose-dependent gene expression for the three distinct components of the therapeutic BB-301 transgene, and biologically significant levels of gene silencing ("knock-down") of the target PABPN1 protein. These updated data provide continued support for the planned advancement of BB-301 into the Phase 1b/2a clinical study in 2022.

- **Regulatory Interactions in Europe:** Following the disclosure in February 2021 of the positive interim data from the BB-301 Pilot Dosing Study in large animals, Benitec completed a 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") in the first half of 2021. At the conclusion of the meeting:
  - The BB-301 Pilot Dosing Study in large animals was viewed as an appropriate dose range finding study.
  - The design of the ongoing GLP Toxicology and Biodistribution study was viewed as appropriate to support Phase 1b/2a testing of BB-301.
  - The manufacturing plan for clinical grade BB-301 drug product can be conducted under GMP conditions with a production process analogous to that employed in prior large-scale production runs for BB-301.
  - The design of the Phase 1b/2a clinical trial can support the evaluation of BB-301 safety and clinical efficacy in key populations of OPMD patients.
- **Regulatory Interactions in the United States:** Benitec has been granted a Type C Meeting with the U.S. Food and Drug Administration ("FDA") in the fourth quarter of 2021.
- **Regulatory Interactions in Canada:** Benitec has been granted a Pre-CTA Consultation Meeting with Health Canada in the fourth quarter of 2021.
- **BB-301 Phase 1b/2a Clinical Study Design:** On September 8<sup>th</sup> the Company provided a comprehensive overview of the key design elements of the upcoming BB-301 Phase 1b/2a clinical trial. The Phase 1b/2a study is planned for 2022. In addition to the determination of the safety and tolerability profiles of BB-301, the secondary endpoints of the trial will facilitate the accurate and reproducible characterization of the key physiological processes underlying the successful completion of the pharyngeal phase of swallowing. The core analytical tools and methods that will be employed during the clinical study will focus on functional measures of swallowing efficiency for OPMD patients during the pharyngeal phase of swallowing.

### **Financial Highlights**

Total Revenues for the quarter ended September 30, 2021 were \$0 compared to fifty-five thousand dollars in total revenue for three months ended September 30, 2020. The decrease in revenues from customers is due to the decrease in licensing and royalty revenues in the current period.

Total Operating Expenses were \$4.8 million for the quarter ended September 30, 2021 compared to \$2.7 million for the comparable period in 2020. For the quarters ended September 30, 2021 and 2020, respectively, Benitec incurred \$0 and \$134 thousand in royalties and license fees. During the three months ended September 30, 2021 and 2020, respectively, the Company incurred \$2.8 million and \$0.8 million in research and

development expenses. The increase in research and development expenses is primarily related to the commencement of the BB-301 GLP Toxicology and Biodistribution Study in large animals at Charles River Laboratories. Additionally, the Company incurred expenses related to the production of GMP-grade drug product to facilitate submissions of the Clinical Trial Applications outside of the United States and the Investigational New Drug Application in the United States, as these activities are critical to the planned initiation of the Phase 1b/2a clinical trial for BB-301 in 2022. General and administrative expenses were \$2.0 million and \$1.8 million for the three months ended September 30, 2021 and 2020, respectively. The increase during this three-month period was due to small increases in insurance costs, consultant fees, and legal and accounting fees.

Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec Biopharma commented, "Our team continues to focus on the core development activities that will ensure the advancement of BB-301 into the first-in-human study. Our primary goal has been, and will continue to be, the improvement of the lives of patients suffering from genetic disorders for which no curative interventions exist. We believe that the initiation of the Phase 1b/2a study is critical for patients in the Oculopharyngeal Muscular Dystrophy community and represents an important milestone with respect to our long-term goals as a company."

**PART I – FINANCIAL INFORMATION**  
**ITEM 1. Financial Statements**

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

	<b>September 30, 2021</b>	<b>June 30, 2021</b>
	<b>(Unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,727	\$ 19,769
Trade and other receivables	3	25
Prepaid and other assets	642	814
Total current assets	16,372	20,608
Property and equipment, net	323	375
Deposits	25	9
Other assets	169	185
Right-of-use assets	947	202
Total assets	\$ 17,836	\$ 21,379
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Trade and other payables	\$ 1,106	\$ 880
Accrued employee benefits	301	276
Lease liabilities, current portion	194	213
Total current liabilities	1,601	1,369
Lease liabilities, less current portion	760	—
Total liabilities	2,361	1,369
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, \$0.0001 par value—10,000,000 shares authorized; 8,171,690 shares issued and outstanding at September 30, 2021 and June 30, 2021, respectively	1	1
Additional paid-in capital	151,854	151,583
Accumulated deficit	(135,164)	(130,119)
Accumulated other comprehensive loss	(1,216)	(1,455)
Total stockholders' equity	15,475	20,010
Total liabilities and stockholders' equity	\$ 17, 836	\$ 21,379

*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)**

	<b>Three Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Revenue:		
Revenues from customers	\$ —	\$ 55
Total revenues	—	55
Operating expenses		
Royalties and license fees	—	134
Research and development	2,780	774
General and administrative	2,042	1,837
Total operating expenses	4,822	2,745
Loss from operations	(4,822)	(2,690)
Other income (loss):		
Foreign currency transaction loss	(240)	(54)
Interest expense, net	(1)	(1)
Other income, net	—	27
Unrealized gain on investment	18	—
Total other loss, net	(223)	(28)
Net loss	\$ (5,045)	\$ (2,718)
Other comprehensive income:		
Unrealized foreign currency translation gain	239	178
Total other comprehensive income	239	178
Total comprehensive loss	\$ (4,806)	\$ (2,540)
Net loss	\$ (5,045)	\$ (2,718)
Net loss per share:		
Basic and diluted	\$ (0.62)	\$ (2.45)
Weighted-average shares outstanding:		
Basic and diluted	8,171,690	1,108,374

*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), and Chronic Hepatitis B. A comprehensive overview of the Company can be found on Benitec's website at [www.benitec.com](http://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 preclinical 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 preclinical 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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