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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 13, 2023

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**BENITEC BIOPHARMA INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or Other Jurisdiction  
of Incorporation)

001-39267  
(Commission  
File Number)

84-4620206  
(I.R.S. Employer  
Identification No.)

3940 Trust Way, Hayward, California  
(Address of Principal Executive Offices)

94545  
(Zip Code)

Registrant's Telephone Number, Including Area Code: (510) 780-0819

(Former Name or Former Address, if Changed Since Last Report): Not Applicable

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001	BNTC	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02 Results of Operations and Financial Condition.**

On November 13, 2023, Benitec Biopharma Inc. (the “Company”) issued a press release announcing the Company’s financial results for its fiscal quarter ended September 30, 2023. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K (including Exhibit 99.1 hereto) that is furnished pursuant to this Item 2.02 shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, the information included in this Current Report on Form 8-K (including Exhibit 99.1 hereto) that is furnished pursuant to this Item 2.02 shall not be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference into such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

No.	Description
99.1	<a href="#">Press Release of Benitec Biopharma Inc. dated November 13, 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**BENITEC BIOPHARMA INC.**

Date: November 13, 2023

/s/ Jerel A. Banks

Name: Jerel A. Banks

Title: Chief Executive Officer

## Benitec Biopharma Releases First Quarter 2024 Financial Results and Provides Operational Update

*19 subjects enrolled in the OPMD Natural History Study, with multiple subjects entering the eligibility period this year for entry into the BB-301 Phase 1b/2a Clinical Treatment Study*

**HAYWARD, Calif., November 13, 2023** — Benitec Biopharma Inc. (NASDAQ: BNTC) (“Benitec” or “Company”), a clinical-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 First Fiscal Quarter ended September 30, 2023. The Company has filed its quarterly report on Form 10-Q for the quarter ended September 30, 2023, with the U.S. Securities and Exchange Commission.

“With the receipt of FDA clearance for the BB-301 IND application this year and the pace of enrollment into the OPMD Natural History Study continuing to exceed our expectations, we are well positioned to begin the evaluation of BB-301 in subjects diagnosed with Oculopharyngeal Muscular Dystrophy,” said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. “The Principal Investigator and the clinical team at the U.S. clinical trial site are finalizing the plan to dose the first study subject with BB-301 in December 2023 or January 2024. The strong interest from members of the Oculopharyngeal Muscular Dystrophy community, and the exceptional clinical trial execution by the U.S. clinical trial site, will support the generation of robust safety and efficacy data for BB-301 over the coming months.”

### Operational Updates

The key milestones related to the development of BB-301 for the treatment of Oculopharyngeal Muscular Dystrophy (OPMD)-related Dysphagia, along with other corporate updates, are outlined below:

### BB-301 Clinical Development Program Overview:

- The BB-301 Phase 1b/2a clinical development program will be conducted in the United States and Canada, and the primary elements of the program are summarized below:
  - The program will comprise approximately 76 weeks of follow-up which we anticipate will consist of:
    - **The OPMD Natural History (NH) Study:** 6-month pre-treatment observation periods for the evaluation of baseline disposition and natural history of OPMD-related dysphagia (swallowing impairment) in each study participant.
    - **Dosing with BB-301:** 1-day of BB-301 dosing to initiate participation in the Phase 1b/2a single-arm, open-label, sequential, dose-escalation cohort study. BB-301 will be delivered directly to the pharyngeal constrictor muscles of each study subject.
    - **Phase 1b/2a Treatment Evaluation:** 52-weeks of post-dosing follow-up for conclusive evaluation of the primary and secondary endpoints of the BB-301 Phase 1b/2a Clinical Treatment Study, with interim safety and efficacy results expected to be available at the end of each 90-day period following the administration of BB-301.

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- The OPMD NH Study will characterize the level of dysphagia borne by each OPMD subject at baseline and assess subsequent progression of dysphagia via the use of the following quantitative radiographic measures (i.e., videofluoroscopic swallowing studies or “VFSS”). The VFSS outlined below collectively provide 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 % $(C2-4)^2$
    - Pharyngeal Area at Maximum Constriction (PhAMPC)
    - Dynamic Imaging Grade of Swallowing Toxicity Scale (DIGEST)
    - Vallecular Residue % $(C2-4)^2$ , Pyriform Sinus Residue % $(C2-4)^2$ , and Other Pharyngeal Residue % $(C2-4)^2$
    - Normalized Residue Ratio Scale (NRRS<sub>v</sub>, NRRS<sub>p</sub>)
    - Pharyngeal Construction Ratio (PCR)
  - The OPMD 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 OPMD NH Study, participants will, potentially, be eligible for enrollment into the BB-301 Phase 1b/2a Clinical Treatment Study.
  - BB-301 Phase 1b/2a Clinical Treatment Study:
    - This first-in-human (FIH) study will evaluate the safety and clinical activity of intramuscular doses of BB-301 administered to subjects with OPMD-related Dysphagia.
    - The primary endpoint of the FIH study will be safety.
    - Secondary endpoints are designed to determine the impact of BB-301 on swallowing efficiency, swallowing safety, and pharyngeal constrictor muscle function in subjects diagnosed with OPMD with dysphagia via the use of serial clinical and videofluoroscopic assessments. Critically, each of the clinical and videofluoroscopic assessments employed in the FIH study will be equivalent to those employed for the OPMD NH study to facilitate comparative clinical and statistical analyses for each study subject.
    - The primary and secondary endpoints will be evaluated during each 90-day period following BB-301 intramuscular injection (Day 1).

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- The NH of dysphagia observed for each OPMD study participant, as characterized by the VFSS and clinical swallowing assessments carried out during the OPMD NH Study, will serve as the baseline for comparative assessments of safety and efficacy of BB-301 upon rollover from the OPMD NH Study onto the BB-301 Phase 1b/2a Clinical Treatment Study.

#### **Corporate Updates:**

- In December 2022, Benitec began screening OPMD subjects at the lead clinical study site in the United States.
- In January 2023, Benitec announced the enrollment of the first OPMD subject into the OPMD NH Study in the United States.
- As of October 2023, 19 subjects have been enrolled into the OPMD NH study in the United States.
- The pace of enrollment of OPMD subjects into the OPMD NH Study at the U.S. clinical trial site supports our central clinical development goals of: (1) initiating the clinical dosing of BB-301 to OPMD subjects in December 2023 or January 2024, and (2) disclosing the initial interim safety and efficacy data over the next 12 months for subjects that have received BB-301.

#### **Regulatory Updates for the Clinical Development Program:**

##### North America:

- Formal submission of the comprehensive OPMD NH Study trial package to the Research Ethics Board (REB) for the lead clinical study site in Canada was completed, and Benitec awaits the formal response from the REB.
  - Approval of the OPMD NH Study trial package by the REB is required for clinical study site activation and OPMD patient screening and enrollment to begin in Canada.

#### **Financial Highlights**

##### *First Quarter 2024 Financial Results*

Total Revenues for the quarter ended September 30, 2023, were \$0 compared to \$0 for the quarter ended September 30, 2022.

Total Expenses for the quarter ended September 30, 2023 were \$5.9 million compared to \$4.6 million for the quarter ended September 30, 2022. For the quarter ended September 30, 2023, the Company received royalties and license fee credits of \$106 thousand compared to \$0 for the three months ended September 30, 2022. The credit to expense during the quarter ended September 30, 2023, reflects the reversal of an accrual for license fees no longer due. The Company incurred \$4.4 million of research and development expenses compared to \$2.7 million for the comparable quarter ended September 30, 2022. Research and development expenses relate primarily to ongoing clinical development of BB-301 for the treatment of OPMD. General and administrative expenses were \$1.6 million compared to \$1.9 million for the quarter ended September 30, 2022.

The loss from operations for the quarter ended September 30, 2023, was \$5.9 million compared to a loss of \$4.6 million for the quarter ended September 30, 2022. Net loss attributable to shareholders for the quarter ended September 30, 2023, was \$6 million, or \$2.76 per basic and diluted share, compared to a net loss of \$5.1 million, or \$7.98 per basic and diluted share for the quarter ended September 30, 2022. As of September 30, 2023, the Company had \$25.9 million in cash and cash equivalents.

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

	September 30, 2023 (Unaudited)	June 30, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 25,864	\$ 2,477
Restricted cash	13	13
Trade and other receivables	53	55
Prepaid and other assets	482	1,184
Total current assets	26,412	3,729
Property and equipment, net	68	87
Deposits	25	25
Prepaid and other assets	85	97
Right-of-use assets	463	526
Total assets	<u>\$ 27,053</u>	<u>\$ 4,464</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Trade and other payables	\$ 3,794	\$ 3,231
Accrued employee benefits	460	472
Lease liabilities, current portion	280	275
Total current liabilities	4,534	3,978
Lease liabilities, less current portion	211	284
Total liabilities	<u>4,745</u>	<u>4,262</u>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.0001 par value-160,000,000 shares authorized; 2,547,434 shares and 1,671,485 shares issued and outstanding at September 30, 2023 and June 30, 2023, respectively	—	—
Additional paid-in capital	196,931	168,921
Accumulated deficit	(173,843)	(167,889)
Accumulated other comprehensive loss	(780)	(830)
Total stockholders' equity	<u>22,308</u>	<u>202</u>
Total liabilities and stockholders' equity	<u>\$ 27,053</u>	<u>\$ 4,464</u>

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)

	Three Months Ended September 30,	
	2023	2022
<b>Revenue:</b>		
Licensing revenues from customers		
<b>Total revenues</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Operating expenses:</b>		
Royalties and license fees	(106)	—
Research and development	4,429	2,660
General and administrative	1,551	1,920
<b>Total operating expenses</b>	<b>5,874</b>	<b>4,580</b>
<b>Loss from operations</b>	<b>(5,874)</b>	<b>(4,580)</b>
<b>Other income (loss):</b>		
Foreign currency transaction loss	(56)	(507)
Interest expense, net	(6)	(9)
Other expense, net	(18)	—
Unrealized gain on investment	—	3
<b>Total other loss, net</b>	<b>(80)</b>	<b>(513)</b>
<b>Net loss</b>	<b>\$ (5,954)</b>	<b>\$ (5,093)</b>
<b>Other comprehensive income:</b>		
Unrealized foreign currency translation gain	50	507
<b>Total other comprehensive income</b>	<b>50</b>	<b>507</b>
<b>Total comprehensive loss</b>	<b>\$ (5,904)</b>	<b>\$ (4,586)</b>
<b>Net loss</b>	<b>\$ (5,954)</b>	<b>\$ (5,093)</b>
<b>Net loss per share: basic and diluted</b>	<b>\$ (2.76)</b>	<b>\$ (7.98)</b>
<b>Weighted average number of shares outstanding: basic and diluted</b>	<b>2,157,065</b>	<b>638,572</b>

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

**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 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 BB-301's silence and replace mechanism 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 DNA-directed RNA interference "Silence and Replace" 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](http://www.benitec.com).



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## **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 COVID-19 pandemic, the disease caused by the SARS-CoV-2 virus and similar events, 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.

### **Investor Relations Contact:**

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