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

FORM 8-K

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

Date of Report (Date of earliest event reported): February 14, 2025

BENITEC BIOPHARMA INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39267
(Commission
File Number)

84-4620206
(IRS 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

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 14, 2025, Benitec Biopharma Inc. (the “Company”) issued a press release announcing the Company’s financial results for its fiscal quarter ended December 31, 2024 and an operational update. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Benitec Biopharma Inc. dated February 14, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: February 14, 2025

BENITEC BIOPHARMA INC.

By: /s/ Dr. Jerel A. Banks
Name: Dr. Jerel A. Banks
Title: Chief Executive Officer



Benitec Biopharma Releases Second Quarter 2025 Financial Results and Provides Operational Update

-Fifth Subject in BB-301 Phase 1b/2a Clinical Treatment Study safely treated in February 2025-

-Interim clinical study update to be presented in late-breaking oral presentation at the 2025 Muscular Dystrophy Association Clinical & Scientific Conference on March 19, 2025-

HAYWARD, Calif., February 14, 2025 — Benitec Biopharma Inc. (NASDAQ: BNTC) (“Benitec” or “Company”), a clinical-stage, gene therapy-focused, biotechnology company developing novel genetic medicines based on its proprietary “Silence and Replace” DNA-directed RNA interference (“ddRNAi”) platform, today announced financial results for its second fiscal quarter ended December 31, 2024. The Company has filed its quarterly report on Form 10-Q with the U.S. Securities and Exchange Commission. The Company also announced the acceptance of a late breaking oral abstract for the BB-301 Phase 1b/2a Clinical Treatment Study ongoing in Subjects diagnosed with Oculopharyngeal Muscular Dystrophy (OPMD) with moderate dysphagia.

“In 2024 the interim clinical study data demonstrated durable, clinically meaningful improvements in swallowing function for the first Subjects safely treated with BB-301, and we remain highly optimistic about the potential for continued benefit in Subjects enrolled in the ongoing clinical study” said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. “We continue to be extremely grateful for the strong support of the Subjects and their families and for their continued participation in the BB-301 clinical development program, and we look forward to enrolling additional Subjects at the low dose and, this year, at the next, higher dose of BB-301.”

The key milestones related to the development of BB-301 for the treatment of Oculopharyngeal Muscular Dystrophy-related Dysphagia, are outlined below:

Summary of Interim Clinical Study Results for Subject 1 and Subject 2 as Disclosed in October 2024:

Oculopharyngeal Muscular Dystrophy (OPMD) is a rare, autosomal dominant, late-onset degenerative muscle disorder presenting in patients at 40-60 years of age. OPMD is principally characterized by severe progressive dysphagia, impacting 97% of patients, which can lead to chronic choking, malnutrition, aspiration pneumonia and, in severe cases, death. OPMD is caused by a mutation in the poly(A)-binding protein nuclear 1 (PABPN1) gene.

There is no effective drug therapy available for OPMD. Current interventions are limited to palliative surgical procedures and dietary modifications, which do not address the underlying cause of disease.

BB-301, a novel investigational gene therapy designed to improve the dysphagic symptoms of OPMD, is being evaluated in a Phase 1b/2a, open-label dose escalation study (NCT06185673) to assess safety and clinical activity.

Two causes of dysphagia have been observed in study Subjects: excessive accumulation of solid and liquid residue (Total Pharyngeal Residue or “TPR”) remaining post-swallow or “inefficient swallowing”, and recurrent pathologic sequential swallowing (i.e., rapid involuntary contractions of the pharyngeal muscles, between which the resting diameter of the pharynx is not restored) or “ineffective swallowing”. Pathologic sequential swallowing is experienced by Subjects as involuntary swallows.

Outcome measures for NCT06185673 include videofluoroscopic swallowing studies for serial assessment of TPR and frequency of pathologic sequential swallowing, and the use of a patient-reported outcome instrument (Sydney Swallow Questionnaire).

Five Subjects have been safely treated with the lowest-dose of BB-301, and interim results for the first two Subjects were presented in October 2024 and are summarized here:

Interim study results for the first two Subjects treated with BB-301 following 9-months and 6-months on treatment, respectively, demonstrated durable, clinically significant reductions in both causes of dysphagic deficits. There have been no Severe Adverse Events in study Subjects.

These data represent successful improvements in swallowing function driven by a novel gene therapy for OPMD.

Enrollment into the BB-301 Phase 1b/2a Clinical Treatment Study is Ongoing:

- The fourth Subject was safely treated with the low-dose of BB-301 in December 2024, and the fifth Subject was safely treated with the low-dose of BB-301 in early February 2025. The sixth Subject is expected to be treated with the low-dose of BB-301 in 2Q 2025.
- Benitec expects to begin treating a second cohort of OPMD Subjects with a higher dose of BB-301 later in the year.

Corporate Updates:

- On March 18th Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec will be giving an oral presentation in the first session dedicated to OPMD at the 2025 Muscular Dystrophy Association Clinical & Scientific Conference, in Dallas, TX, from 11 AM to 12 PM Central Time.
- An interim study update for the Phase 1b/2a Clinical Treatment Study of BB-301 in OPMD Subjects with moderate dysphagia will be presented in a late-breaking oral presentation entitled “Interim Study Update for the BB-301 Gene Therapy Phase 1b/2a First in Human Trial in Subjects with Oculopharyngeal Muscular Dystrophy with Dysphagia” at 1:15 pm Central Time on March 19th at the 2025 Muscular Dystrophy Association Clinical & Scientific Conference in room Coronado ABCD.

Financial Highlights***Second Quarter 2025 Financial Results***

Total Revenues for the quarter ended December 31, 2024, were \$0.0 million, equivalent to the quarter ended December 31, 2023.

Total Expenses for the quarter ended December 31, 2024 were \$8.6 million compared to \$6.9 million for the quarter ended December 31, 2023. The Company incurred \$5.1 million of research and development expenses which was in line with \$5.1 million for the comparable quarter ended December 31, 2023. Research and development expenses relate primarily to ongoing clinical development of BB-301 for the treatment of OPMD. General and administrative expenses were \$3.5 million compared to \$1.8 million for the quarter ended December 31, 2023.

The loss from operations for the quarter ended December 31, 2024, was \$8.6 million compared to a loss of \$6.9 million for the quarter ended December 31, 2023. Net loss attributable to shareholders for the quarter ended December 31, 2024, was \$7.4 million, or \$(0.33) per basic and diluted share, compared to a net loss of \$6.8 million, or \$(2.64) per basic and diluted share for the quarter ended December 31, 2023. As of December 31, 2024, the Company had \$78.3 million in cash and cash equivalents, which includes \$39.5 million from the exercise of warrants during the six month period.

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

	December 31, 2024 <u>(Unaudited)</u>	June 30, 2024 <u></u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 78,283	\$ 50,866
Restricted Cash	62	63
Trade and other receivables	2	229
Prepaid and other assets	366	516
Total current assets	<u>78,713</u>	<u>51,674</u>
Property and equipment, net	151	179
Deposits	25	25
Other assets	42	62
Right-of-use assets	137	270
Total assets	<u>\$ 79,068</u>	<u>\$ 52,210</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Trade and other payables	\$ 2,415	\$ 4,165
Accrued employee benefits	537	475
Lease liabilities, current portion	137	284
Total current liabilities	<u>3,089</u>	<u>4,924</u>
Non-current accrued employee benefits	38	38
Total liabilities	<u>3,127</u>	<u>4,962</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value - 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2024 and June 30, 2024, respectively	—	—
Common stock, \$0.0001 par value - 160,000,000 shares authorized; 23,451,475 and 10,086,119 shares issued and outstanding at December 31, 2024 and June 30, 2024, respectively	2	1
Additional paid-in capital	279,302	238,398
Accumulated deficit	(202,675)	(190,259)
Accumulated other comprehensive loss	(688)	(892)
Total stockholders' equity	<u>75,941</u>	<u>47,248</u>
Total liabilities and stockholders' equity	<u>\$ 79,068</u>	<u>\$ 52,210</u>

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2024	2023	2024	2023
Revenue:				
Licensing revenues from customers	\$ —	\$ —	\$ —	\$ —
Total revenues	—	—	—	—
Operating expenses				
Royalties and license fees	—	1	—	(105)
Research and development	5,072	5,102	8,657	9,531
General and administrative	3,538	1,824	5,744	3,375
Total operating expenses	8,610	6,927	14,401	12,801
Loss from operations	(8,610)	(6,927)	(14,401)	(12,801)
Other income (loss):				
Foreign currency transaction gain (loss)	(294)	152	(201)	96
Interest income (expense), net	823	(6)	1,427	(12)
Other income (expense), net	(40)	(16)	(5)	(34)
Gain on extinguishment of liabilities	764	—	764	—
Unrealized gain (loss) on investment	—	(1)	—	(1)
Total other income (loss), net	1,253	129	1,985	49
Net loss	\$ (7,357)	\$ (6,798)	\$ (12,416)	\$ (12,752)
Other comprehensive income:				
Unrealized foreign currency translation gain (loss)	305	(172)	204	(122)
Total other comprehensive income	305	(172)	204	(122)
Total comprehensive loss	\$ (7,052)	\$ (6,970)	\$ (12,212)	\$ (12,874)
Net loss	\$ (7,357)	\$ (6,798)	\$ (12,416)	\$ (12,752)
Deemed dividends	—	—	—	(619)
Net loss attributable to common shareholders	\$ (7,357)	\$ (6,798)	\$ (12,416)	\$ (13,371)
Net loss per share:				
Basic and diluted	\$ (0.33)	\$ (2.64)	\$ (0.76)	\$ (5.65)
Weighted average number of shares outstanding: basic and diluted	22,075,332	2,576,347	16,368,314	2,366,706

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 causative gene for OPMD). 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 the silence and replace mechanism of BB-301 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 “Silence and Replace” DNA-directed RNA interference 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.

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 completion of pre-clinical and clinical trials, the timing of the availability of data from our clinical trials, the timing and sufficiency of patient enrollment and dosing in clinical trials, the timing of expected regulatory filings, and the clinical utility and potential attributes and benefits of ddRNAi and Benitec's product candidates, 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: the success of our plans to develop and potentially commercialize our product candidates; the timing of the completion of preclinical studies and clinical trials; the timing and sufficiency of patient enrollment and dosing in any future clinical trials; the timing of the availability of data from our clinical trials; the timing and outcome of regulatory filings and approvals; the development of novel AAV vectors; our potential future out-licenses and collaborations; the plans of licensees of our technology; the clinical utility and potential attributes and benefits of ddRNAi and our product candidates, including the potential duration of treatment effects and the potential for a "one shot" cure; our intellectual property position and the duration of our patent portfolio; expenses, ongoing losses, future revenue, capital needs and needs for additional financing, and our ability to access additional financing given market conditions and other factors, including our capital structure; the length of time over which we expect our cash and cash equivalents to be sufficient to execute on our business plan; 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 and other regulatory developments; 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 impact of, and our ability to remediate, the identified material weakness in our internal controls over financial reporting; 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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