
**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): May 13, 2024

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 May 13, 2024, Benitec Biopharma Inc. (the “Company”) issued a press release announcing the Company’s financial results for its fiscal quarter ended March 31, 2024. 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 May 13, 2024
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.

BENITEC BIOPHARMA INC.

Date: May 13, 2024

By: /s/ Jerel A. Banks

Name: Jerel A. Banks

Title: Chief Executive Officer



Benitec Biopharma Releases Third Quarter 2024 Financial Results and Provides Operational Update

-Positive Interim Clinical Trial Data for the First Oculopharyngeal Muscular Dystrophy (OPMD) Subject Dosed with BB-301 in the Phase 1b/2a Clinical Treatment Study Reported in April-

-The Second OPMD Subject was Safely Dosed with BB-301 in February-

-Additional Interim Clinical Safety Data and Clinical Efficacy Data are Expected for Several Study Subjects in the Second Half of 2024-

-23 OPMD Subjects have Enrolled into the OPMD Natural History Study with Multiple Subjects Eligible for Entry into the BB-301 Phase 1b/2a Clinical Treatment Study-

-Closed an Oversubscribed Private Placement Financing of \$40.0 Million on April 22^d, Cash Runway Extended Through 2025-

HAYWARD, Calif., May 13, 2024 (GLOBE NEWSWIRE) — 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 third fiscal quarter ended March 31, 2024. The Company has filed its quarterly report on Form 10-Q with the U.S. Securities and Exchange Commission.

“The interim clinical trial results for the first subject enrolled onto the BB-301 Phase 1b/2a Clinical Treatment Study demonstrated consistent, clinically meaningful improvements in each of the central study endpoints, with significant improvements noted across the radiographic assessments of swallowing and corresponding improvements observed for the key subject-reported outcome measure,” said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. “We look forward to presenting the results of longer-term follow-up for the first study subject, along with the accruing data for additional study subjects, later this year”. “Following the recent financing, Benitec is well-positioned to advance the BB-301 clinical development program through the end of 2025.”

Operational Updates

On April 18th the Company announced an oversubscribed \$40.0 million private investment in public equity (PIPE) financing from the sale of 5,749,152 shares of its common stock at a price per share of \$4.80, and, in lieu of shares of common stock, pre-funded warrants to purchase up to an aggregate of 2,584,239 shares of its common stock at a price per pre-funded warrant of \$4.7999, to certain institutional accredited investors.

The financing was led by Suvretta Capital Management, LLC with participation from new and existing investors including Adage Capital Partners L.P., Nantahala Capital, multiple healthcare-focused funds, and a leading mutual fund. Gross proceeds from the PIPE financing totaled approximately \$40.0 million, before deducting offering expenses. The closing of the PIPE occurred on April 22, 2024.

In connection with the PIPE financing, the Company has agreed with long-term investor Suvretta Capital Management to consider Kishen Mehta, a portfolio manager at Suvretta Capital Management, for appointment to the Company's board of directors.

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

Interim BB-301 Phase 1b/2a Clinical Treatment Study Results for Subject 1:

- During the OPMD Natural History (NH) Study, which represents the pre-dose observational period for each subject, Subject 1 experienced progressive worsening of dysphagia as demonstrated by the results of the videofluoroscopic swallowing studies (VFSS), the cold water timed drinking test, and the key subject-reported outcome measure (the Sydney Swallow Questionnaire). VFSS represents the gold standard analytical method for the quantitative assessment of dysphagia (swallowing difficulty) in the clinical setting.
- At the 90-day post-dose assessment following the administration of BB-301, Subject 1 demonstrated improvements in key videofluoroscopic assessments which correlated with the observation of similar improvement in the key subject-reported outcome measure as compared to the average values for the respective assessments completed during the pre-dose observational period (as summarized in Figure 1). Notably, the results of many assessments completed at the 90-day timepoint demonstrated improvements over the initial measurements assessed at the subject's first visit for the natural history observational study which occurred more than 12 months prior to the 90-day post-dose assessment.
- The most significant VFSS improvements at Day 90 were observed for swallowing tasks centered on the evaluation of pharyngeal constrictor muscle function and swallowing efficiency in the context of the consumption of thin liquids (e.g., water), solid foods, and thick non-solid foods (e.g., yogurt or pudding) (Figure 1). The VFSS improvements correlated with an improvement in the key subject-reported outcome measure (the Sydney Swallow Questionnaire), indicating an improvement in swallowing function as reported by Subject 1 (Figure 1).

Figure 1: Improvement in All Outcomes at 90-Days Post-BB-301 Injection*

Radiographic Assessments of Pharyngeal Area at Maximum Constriction to Determine Pharyngeal Constrictor Muscle Function During Swallowing			
Barium-Containing Food Items	OPMD Natural History Study	Phase 1b/2a BB-301 Dosing Study	Improvement in Pharyngeal Closure During Swallowing After BB-301 Dose
	Pre-Dose Period	Post-Dose Period	
	Average PHAMPC During Swallowing	Day 90 PHAMPC During Swallowing	
Thin Liquid	9.1	3.9	5.2 Units (-57.1%)
Moderately Thick Liquid	20.0	14.8	5.2 Units (-26.0%)
Extremely Thick Liquid	21.8	18.5	3.3 Units (-15.1%)
Solid Food	18.0	10.9	7.1 Units (-39.4%)

Radiographic Assessments of Pharyngeal Residue (i.e., food or liquid material) Remaining Post-Swallow to Determine Swallowing Efficiency			
Barium-Containing Food Items	OPMD Natural History Study	Phase 1b/2a BB-301 Dosing Study	Reduction in Post-Swallow Pharyngeal Residue After BB-301 Dose
	Pre-Dose Period	Post-Dose Period	
	Average Pharyngeal Residue Remaining Post-Swallow	Day 90 Pharyngeal Residue Remaining Post-Swallow	
Thin Liquid	4.9	0.9	4.0 Units (-81.6%)
Moderately Thick Liquid	18.2	11.0	7.2 Units (-39.6%)
Extremely Thick Liquid	21.5	11.9	9.6 Units (-44.7%)
Solid Food	19.0	12.3	6.7 Units (-35.3%)

Subject Reported Outcome Measure: Sydney Swallow Questionnaire or "SSQ" (17-Question Self-Report Inventory Assessing Subjective Symptoms of Oropharyngeal Dysphagia)			
Barium-Containing Food Items	OPMD Natural History Study	Phase 1b/2a BB-301 Dosing Study	Reduction in SSQ Score After BB-301 Dose
	Pre-Dose Period	Post-Dose Period	
	Average SSQ Score for the Study Subject	Day 90 SSQ Score for the Study Subject	
Thin Liquid	1,136	935	201 Points (-17.7%)

Cold Water Timed Drinking Test: Time in Seconds the Subject Requires to Consume 80 mL of Cold Water			
Barium-Containing Food Items	OPMD Natural History Study	Phase 1b/2a BB-301 Dosing Study	Reduction in Total Drinking Time (sec) After BB-301 Dose
	Pre-Dose Period	Post-Dose Period	
	Average Time (sec) Recorded for the Study Subject	Day 90 Time (sec) Recorded for the Study Subject	
Thin Liquid	30	26	4.0 Seconds (-13.3%)

* Company data on file

- Regarding the BB-301 safety profile observed to date, no Serious Adverse Events (SAEs) have been observed for the two subjects that have received BB-301. Transient Grade 2 Gastroesophageal Reflux Disease or "GERD" (i.e., "acid reflux" or "heartburn") was observed for the two subjects that received BB-301. For both study subjects, the GERD resolved following the use of common prescription medications approved for the treatment of GERD.

Corporate Updates:

- Twenty-three (23) subjects have been enrolled into the OPMD NH Study, and the BB-301 Phase 1b/2a Clinical Treatment Study is designed to treat 21-to-30 subjects. Two (2) subjects have rolled over from the OPMD NH Study into the BB-301 Phase 1b/2a Clinical Treatment Study, and a third OPMD subject is expected to enter the BB-301 Phase 1b/2a Clinical Treatment Study in June 2024.

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- Additional interim safety data and efficacy data are expected to be reported from the BB-301 Phase 1b/2a Clinical Treatment Study in 2H 2024.

Financial Highlights

Third Fiscal Quarter 2024 Financial Results

Total Revenues for the quarter ended March 31, 2024, were \$0 compared to \$54,000 in licensing revenues collected for the quarter ended March 31, 2023.

Total Expenses for the quarter ended March 31, 2024, were \$4.1 million compared to \$4.4 million for the quarter ended March 31, 2023. For the quarter ended March 31, 2024, the Company incurred (\$3,000) in royalties and license fees due to the reversal of an accrual compared to \$0 for the three months ended March 31, 2023. The Company incurred \$2.6 million of research and development expenses compared to \$3.2 million for the comparable quarter ended March 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 \$1.6 million compared to \$1.2 million for the quarter ended March 31, 2023.

The loss from operations for the quarter ended March 31, 2024, was \$4.1 million compared to a loss of \$4.3 million for the quarter ended March 31, 2023. Net loss attributable to shareholders for the quarter ended March 31, 2024, was \$4.3 million, or \$1.64 per basic and diluted share, compared to a net loss of \$4.4 million, or \$2.67 per basic and diluted share for the quarter ended March 31, 2023. As of March 31, 2024, the Company had \$14.1 million in cash and cash equivalents. Following the closing of the recent PIPE transaction on April 22, 2024, the Company received approximately \$37.2 million.

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

	March 31, 2024 (Unaudited)	June 30, 2023
Assets		
Current assets:		
Cash at bank	\$ 14,143	\$ 2,477
Restricted cash	13	13
Trade and other receivables	53	55
Prepaid and other assets	157	1,184
Total current assets	14,366	3,729
Property and equipment, net	204	87
Deposits	25	25
Prepaid and other assets	69	97
Right-of-use assets	335	526
Total assets	\$ 14,999	\$ 4,464
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	\$ 2,628	\$ 3,231
Accrued employee benefits	517	472
Lease liabilities, current portion	292	275
Total current liabilities	3,437	3,978
Lease liabilities, less current portion	62	284
Total liabilities	3,499	\$ 4,262
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, \$0.0001 par value—160,000,000 shares authorized; 2,724,794 shares and 1,671,485 shares issued and outstanding at March 31, 2024 and June 30, 2023, respectively	—	—
Additional paid-in capital	197,255	168,921
Accumulated deficit	(184,920)	(167,889)
Accumulated other comprehensive loss	(835)	(830)
Total stockholders' equity	11,500	202
Total liabilities and stockholders equity	\$ 14,999	\$ 4,464

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		Nine Months Ended	
	March 31		March 31,	
	2024	2023	2024	2023
Revenue:				
Licensing revenues from customers	\$ —	\$ 54	\$ —	\$ 68
Total revenues	—	54	—	68
Operating expenses:				
Royalties and license fees	(3)	—	(108)	—
Research and development	2,566	3,167	12,097	9,588
General and administrative	1,578	1,228	4,953	5,011
Total operating expenses	4,141	4,395	16,942	14,599
Loss from operations	(4,141)	(4,341)	(16,942)	(14,531)
Other income (loss):				
Foreign currency transaction loss	(118)	(45)	(22)	(391)
Interest expense, net	(4)	(7)	(16)	(25)
Other income (expense), net	(16)	—	(50)	50
Unrealized loss on investment	—	(4)	(1)	(4)
Total other income (loss), net	(138)	(56)	(89)	(370)
Net loss	\$ (4,279)	\$ (4,397)	\$ (17,031)	\$ (14,901)
Other comprehensive income (loss):				
Unrealized foreign currency translation gain (loss)	117	45	(5)	392
Total other comprehensive income (loss)	117	45	(5)	392
Total comprehensive loss	\$ (4,162)	\$ (4,352)	\$ (17,036)	\$ (14,509)
Net loss	\$ (4,279)	\$ (4,397)	\$ (17,031)	\$ (14,901)
Net loss per share:				
Basic and diluted	\$ (1.64)	\$ (2.67)	\$ (6.95)	\$ (11.47)
Weighted average number of shares outstanding: basic and diluted	2,616,288	1,645,951	2,449,295	1,299,423

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 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, the clinical utility and potential attributes and benefits of ddRNAi and Benitec’s product candidates, the intellectual property position, the length of time over which the Company expects its cash and cash equivalents to be sufficient to execute on its business plan, 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 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 Company’s ability to satisfy its capital needs through increasing its revenue and obtaining additional financing; the impact of the COVID-19 pandemic, the disease caused by the SARS-CoV-2 virus or any similar events, which may adversely impact the Company’s business and pre-clinical and 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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