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 15, 2023

BENITEC BIOPHARMA INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39267**	**84-4620206**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3940 Trust Way, Hayward, California	**94545**
(Address of Principal Executive Offices)	**(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 15, 2023 Benitec Biopharma Inc. (the "Company") issued a press release announcing the Company's financial results for its fiscal quarter ended March 31, 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	Press Release of Benitec Biopharma Inc. dated May 15, 2023
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 15, 2023

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

Exhibit 99.1

Benitec Biopharma Releases Third Quarter 2023 Financial Results and Provides Operational Update

9 subjects enrolled into the OPMD clinical development program

HAYWARD, Calif., May 15, 2023 — Benitec Biopharma Inc. (NASDAQ: BNTC) ("Benitec" or "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 Third Fiscal Quarter ended March 31, 2023. The Company has filed its quarterly report on Form 10-Q for the quarter ended March 31, 2023 with the U.S. Securities and Exchange Commission.

"We continue to screen and enroll OPMD subjects into the Natural History Study at the U.S. clinical study site, and enrollment is proceeding at a rapid pace," said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. "With 9 subjects enrolled to date, the current pace of enrollment supports our central clinical development goals of administering BB-301 to OPMD subjects in 2H2023 and disclosing interim safety and efficacy data in 2H2023 for one or more subjects that have received BB-301."

Dr. Banks continued, "We remain focused on opening additional clinical study sites in Canada and France, pending ongoing discussions with Institutional Review Boards and regional regulators. While those discussions progress, we continue to advance the development of BB-301 in the United States and expect to receive a response from the U.S. FDA regarding the Investigational New Drug (IND) application for BB-301 in the Second Calendar Quarter of 2023."

Operational Updates

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

BB-301 Clinical Development Program Overview:

- The BB-301 clinical development program will be conducted in the United States, Canada, and France, 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-derived 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 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 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.

- 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 %$(C2\text{-}4)^2$
    - 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 into the BB-301 Phase 1b/2a treatment study.
- BB-301 Phase 1b/2a 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.
    - 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 NH study to facilitate comparative clinical and statistical analyses.
    - The primary and secondary endpoints will be evaluated during each 90-day period following BB-301 intramuscular injection (Day 1).
    - The NH 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 assessments of safety and efficacy of BB-301 upon rollover from the NH Study onto the BB-301 Phase 1b/2a Treatment Study.

- 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 NH Study. As of today, 9 subjects have been enrolled into the NH study in the United States.
- The pace of enrollment of OPMD subjects into the NH Study at the U.S. clinical study site supports our central clinical development goals of: (1) administering BB-301 to OPMD subjects in 2H2023, and (2) disclosing interim safety and efficacy data in 2H2023 for one or more subjects that have received BB-301.
- Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec, will present at the OPMD International Conference in Tel Aviv, Israel, taking place on Tuesday, May 16th, 2023.

Regulatory Updates for the Clinical Development Program:

North America:

- Formal submission of the comprehensive 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 NH Study trial package by the REB is required for clinical study site activation and OPMD patient screening and enrollment to begin in Canada.
- BB-301 Investigational New Drug (IND) application acceptance by the U.S. FDA is expected in the Second Calendar Quarter of 2023.
  - BB-301 IND acceptance is required to initiate the dosing of OPMD subjects with BB-301 in the Phase 1b/2a Treatment Study in the United States.
- BB-301 Clinical Trial Application (CTA) clearance is expected in 2H2023.
  - BB-301 CTA clearance is required to initiate the dosing of OPMD subjects with BB-301 in the Phase 1b/2a Treatment Study in Canada.
- The first NH Study subject is anticipated to be eligible for BB-301 administration in the Third Calendar Quarter of 2023, following the completion of 6 months of NH Study clinical follow-up and confirmation of eligibility for the BB-301 Phase 1b/2a Treatment Study. Interim safety and efficacy results are expected to become available approximately 90 days following the administration of BB-301.

France:

- BB-301 CTA filing to support the conduct of a comprehensive BB-301 clinical study in France, inclusive of a 6-month pre-treatment observation period, one day of BB-301 dosing, and a subsequent 52-week follow-up period, is planned for completion in the Third Calendar Quarter of 2023.

Financial Highlights

Third Quarter 2023 Financial Results

Revenue for the quarter ended March 31, 2023, was $54 thousand compared to $48 thousand for the quarter ended March 31, 2022.

Operating expenses for the quarter ended March 31, 2023, were $4.4 million compared to $3.5 million for the quarter ended March 31, 2022. The Company incurred $3.17 million of research and development expenses compared to $2.17 million for the comparable quarter ended March 31, 2022. Research and development expenses relate primarily to the OPMD project. The year over year increase in research and development costs for the period relates primarily to the continuation of the GMP manufacturing project and the Natural History Study. For the quarter ended March 31, 2023, general and administrative expenses were $1.2 million compared to $1.3 million for the quarter ended March 31, 2022. The year over year decrease for the three-month periods ended March 31 relates to lower listing and filing fees and stock-based compensation.

The loss from operations for the quarter ended March 31, 2023, was $4.4 million compared to a loss of $3.5 million for the quarter ended March 31, 2022. Net loss attributable to stockholders for the quarter ended March 31, 2023, was $4.4 million, or $0.16 per basic and diluted share, compared to a net loss of $3.3 million, or $0.40 per basic and diluted share for the quarter ended March 31, 2022. As of March 31, 2023, the Company had $6.6 million in cash and cash equivalents.

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

	March 31, 2023 (Unaudited)	June 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 6,551	$ 4,062
Restricted cash	14	14
Trade and other receivables	56	3
Prepaid and other assets	774	741
Total current assets	7,395	4,820
Property and equipment, net	106	222
Deposits	25	25
Other assets	105	135
Right-of-use assets	589	771
Total assets	$ 8,220	$ 5,973
Liabilities and stockholders' equity		
Current liabilities:		
Trade and other payables	$ 2,455	$ 1,880
Accrued employee benefits	429	400
Lease liabilities, current portion	269	252
Total current liabilities	3,153	2,532
Lease liabilities, less current portion	354	559
Total liabilities	3,507	3,091
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.0001 par value-160,000,000 shares authorized; 27,981,161 shares and 8,171,690 shares issued and outstanding at March 30, 2022 and June 30, 2022, respectively	3	1
Additional paid-in capital	168,791	152,453
Accumulated deficit	(163,228)	(148,327)
Accumulated other comprehensive loss	(853)	(1,245)
Total stockholders' equity	4,713	2,882
Total liabilities and stockholders' equity	$ 8,220	$ 5,973

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 March 31,		Nine Months Ended March 31,	
	2023	2022	2023	2022
Revenue:				
Licensing revenues from customers	$ 54	$ 48	$ 68	$ 73
Total revenues	54	48	68	73
Operating Expenses				
Research and development	3,167	2,171	9,588	8,096
General and admininstrative	1,228	1,337	5,011	5,093
Total operating expenses	4,395	3,508	14,599	13,189
Loss from operations	(4,341)	(3,460)	(14,531)	(13,116)
Other income (loss):				
Foreign currency transaction gain (loss)	(45)	229	(391)	36
Interest expense, net	(7)	(10)	(25)	(22)
Other income, net	—	(29)	50	(29)
Unrealized loss on investment	(4)	(5)	(4)	(10)
Total other income (loss), net	(56)	185	(370)	(25)
Net loss	$ (4,397)	$ (3,275)	$ (14,901)	$ (13,141)
Other comprehensive income:				
Unrealized foreign currency translation gain (loss)	45	(233)	392	(51)
Total other comprehensive income (loss)	45	(233)	392	(51)
Total comprehensive loss	$ (4,352)	$ (3,508)	$ (14,509)	$ (13,192)
Net loss	$ (4,397)	$ (3,275)	$ (14,901)	$ (13,141)
Net loss per share:				
Basid and diluted	$ (0.16)	$ (0.40)	$ (0.67)	$ (1.61)
Weighted average number of shares outstanding: basic and diluted	27,981,161	8,171,690	22,090,191	8,171,690

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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