

---

---

**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): June 26, 2023**

---

**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 7.01 Regulation FD Disclosure**

On June 26, 2023, Benitec Biopharma Inc. (the “Company”) issued a press release. A copy of this press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein to this Item 7.01.

The information included in this Current Report on Form 8-K (including Exhibit 99.1 hereto) that is furnished pursuant to this Item 7.01 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 7.01 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	<a href="#">Press Release of Benitec Biopharma Inc. dated June 26, 2023.</a>
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: June 26, 2023

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

**Benitec Biopharma Receives FDA Clearance of the IND for BB-301 for the Treatment of Oculopharyngeal Muscular Dystrophy**

*Dosing of the first subject with BB-301 is expected in the second half of 2023, following the rollover of subjects currently enrolled in the ongoing Natural History (NH) study*

**HAYWARD, Calif., June 26, 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 the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for BB-301, its silence and replace gene therapy for the treatment of Oculopharyngeal Muscular Dystrophy-related Dysphagia.

Oculopharyngeal Muscular Dystrophy (OPMD) is a chronic, life-threatening genetic disorder affecting approximately 15,000 patients in the United States, Canada, Western Europe, and Israel. OPMD patients lose the ability to swallow liquids and solids, resulting in chronic malnutrition, aspiration, and fatal episodes of aspiration pneumonia. Currently, there are no approved therapeutic agents for the treatment of OPMD.

“The FDA’s clearance of our IND for BB-301 is a significant milestone for OPMD patients and for Benitec as a Company,” said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. “The clearance of BB-301 for clinical use represents the first potential treatment for these frequently debilitating and possibly fatal symptoms of OPMD.”

Subjects from Benitec’s ongoing NH study will be eligible for rollover onto the Phase 1b/2a clinical study of BB-301 for the treatment of OPMD-related Dysphagia after 6 months of baseline data collection. Following a 1-day dosing procedure for BB-301, each study subject will be evaluated for the same radiographic and clinical outcome measures as were evaluated during the NH study, including quantitative radiographic swallowing studies to facilitate objective assessments of swallowing safety, swallowing efficiency, and functional performance of the pharyngeal muscles underlying the OPMD-related Dysphagia. Currently, there are 13 subjects enrolled into the NH study, with each subject having the potential to rollover onto the Phase 1b/2a clinical dosing study for BB-301. Interim safety and efficacy data is expected to become available from the BB-301 Phase 1b/2a study approximately every 90 days following the dosing of each subject.

**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 strategy 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 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](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 pre-clinical and clinical trials, the timing 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, 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 COVID-19, 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.

**Investor Relations Contact:**

William Windham  
VP, Solebury Strategic Communications  
Phone: 646-378-2946  
Email: [wwindham@soleburystrat.com](mailto:wwindham@soleburystrat.com)