# 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): July 9, 2025**

# 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 7.01 Regulation FD Disclosure.**

On July 9, 2025, Benitec Biopharma Inc. (the "Company") issued a press release providing an update that the sixth and final Subject of Cohort 1 was safely treated with the Low Dose of BB-301 in the Phase 1b/2a Clinical Treatment Study (NCT06185673), the Data Safety Monitoring Board recommended the continuation of Subject enrollment for the Phase 1b/2a Clinical Treatment Study and that the enrollment of Cohort 2 is expected to begin in the fourth calendar quarter of 2025. A copy of the press release, which is attached hereto as Exhibit 99.1, is furnished pursuant to this Item 7.01.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be incorporated by reference into any filing of the Company, whether made before, on or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information contained in Item 7.01 of this Current Report on Form 8-K Report, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release |
| 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: July 9, 2025

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

**Exhibit 99.1**

**Benitec Biopharma Provides Operational Updates**

*-In April 2025 the Sixth and Final Subject of Cohort 1 was Safely Treated with the Low Dose of BB-301 in the Phase 1b/2a Clinical Treatment Study (NCT06185673)-*

*-Independent Data Safety Monitoring Board Review Has Been Completed for All Six Subjects Enrolled into Cohort 1, and the Data Safety Monitoring Board Recommended Continuation of Subject Enrollment for the Phase 1b/2a Clinical Treatment Study -*

*-Following the Positive Data Safety Monitoring Board Recommendation, Enrollment of Cohort 2 is Expected to Begin in Q4 2025-*

HAYWARD, Calif., July 9, 2025 (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 the recommendation of the independent Data Safety Monitoring Board (DSMB) to continue enrollment of the Phase 1b/2a Clinical Treatment Study (NCT06185673) following completion of the comprehensive review of safety information for all six Subjects enrolled into Cohort 1. Following the positive DSMB recommendation, enrollment of Cohort 2 is expected to begin in Q4 2025.

In accordance with the Protocol for the BB-301 Phase 1b/2a Clinical Treatment Study, a meeting of the DSMB was convened following the completion of the 28-day post BB-301 dosing visit for the sixth Subject enrolled into Cohort 1. The DSMB recommended the continuation of Subject enrollment for the Phase 1b/2a Clinical Treatment Study. Following the positive DSMB recommendation, enrollment of Cohort 2 is expected to begin in Q4 2025.

"We are extremely thankful and humbled to have the opportunity to continue our collaborative development work for BB-301 with the OPMD patient community and the OPMD clinical community," said Jerel A. Banks, M.D., Ph.D., Executive Chairman and Chief Executive Officer of Benitec. "The sixth and final Subject of Cohort 1 was safely treated with the low dose of BB-301 in April 2025 and, following the favorable DSMB recommendation, we look forward to beginning the enrollment of Cohort 2 in the fourth calendar quarter of this year. We continue to be encouraged by the benign safety profile of BB-301 associated with our local route of direct intramuscular delivery, as this method of administration enables the use of lower doses of our gene therapy agent relative to the doses employed for other gene therapy programs which rely on systemic routes of administration. Additional clinical study updates for Subjects enrolled in Cohort 1 are planned for the fourth calendar quarter of this year."

**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.

**Investor Relations Contact:**
Irina Koffler
LifeSci Advisors, LLC
(917) 734-7387
ikoffler@lifesciadvisors.com