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): March 20, 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 8.01 Other Events

On March 19, 2025, Benitec Biopharma Inc. ("Benitec," or the "Company") announced continued durable improvements in swallowing function and reductions in total dysphagic symptom burden following administration of the low-dose of BB-301 in the first three Subjects treated in the BB-301 Phase 1b/2a single-arm, open-label, sequential, dose-escalation cohort study (NCT06185673) in Oculopharyngeal Muscular Dystrophy (OPMD). The Company presented the interim clinical study results on March 19, 2025 in an oral late-breaking podium presentation at the 2025 Muscular Dystrophy Association Clinical & Scientific Conference, taking place in Dallas, Texas. The following summarizes the presented results:

Summary of Results:

Subjects Enrolled into the BB-301 Clinical Development Program are Impacted by Two Discrete Drivers of Total Dysphagic Symptom Burden:

- OPMD Subjects enrolled into the OPMD Natural History Study and the BB-301 Phase 1b/2a Clinical Treatment Study can be impacted by the post swallow accumulation of food and liquid ("Inefficient Swallowing").
- OPMD Subjects enrolled into the OPMD Natural History Study and the BB-301 Phase 1b/2a Clinical Treatment Study can be impacted by pathologic sequential swallows comprising rapid involuntary contractions of the pharyngeal muscles without restoration of the resting pharyngeal diameter between pharyngeal contractions ("Ineffective Swallowing").

Clinical Utility, Sensitivity, and Specificity of the Key Assessment Methods:

- In the BB-301 Phase 1b/2a Clinical Treatment Study, Radiologists and Speech Language Pathologists employ serial VFSS to objectively characterize the nature and severity of anatomical and functional abnormalities present in each Subject during the pre-treatment period and the post-treatment period.
- Serial SSQ assessments are employed to characterize the contribution of the VFSS findings to the total symptom burden experienced by each Subject, thus, linking the VFSS findings to the changes in Subject-reported symptom burden for the pre-treatment period and the post-treatment period.
- The SSQ has been used in conjunction with VFSS in several controlled clinical studies which compared the results for healthy subjects with those of dysphagic patients:
    - The clinical studies demonstrated strong correlations between the results of VFSS-based assessments and SSQ-based assessments and facilitated the identification of SSQ cut-off values of 111.0[1] and 118.5[2], below which swallowing is clinically normal.

- Audag, et al.[2] obtained a sensitivity of 93% and a specificity of 82% with the use of an SSQ cut-off score of 118.5.
- Additionally, these clinical studies provide robust support for the discriminant validity of the SSQ which is critical to its use in the accurate characterization of responses to treatment and the establishment of efficacy for a given treatment.

- Subjects in the BB-301 Phase 1b/2a Treatment Study are blinded to their SSQ Total Scores and VFSS (TPR and pathologic sequential swallowing frequency) assessment results, and the Central Reader for the VFSS assessments is blinded to the SSQ Total Scores for each Subject.

Summary of the Interim Clinical Study Results for Subject 1, Subject 2, and Subject 3:

- Three Subjects with distinct causes of their respective dysphagic symptom burdens were safely treated with BB-301 (1.2e13 vg/Subject) and experienced significant, clinically meaningful improvements in swallowing function.
- There were no Severe Adverse Events.
- All three Subjects experienced significant reductions in their total dysphagic symptom burdens:
  - Subject 1, plagued by Inefficient Swallowing, experienced clinically significant reductions in post swallow accumulation of foods and liquids per the VFSS Total Pharyngeal Residue (TPR) results and achieved a correspondingly significant reduction in total dysphagic symptom burden per the Total SSQ Scores 12-months post-BB-301 administration. This Subject has completed the statistical follow-up period of the BB-301 Phase 1b/2a Treatment Study.
  - Subject 2, plagued by Ineffective Swallowing, experienced an almost complete resolution of pathologic sequential swallows per the VFSS results and achieved a correspondingly significant reduction in total dysphagic symptom burden per the Total SSQ Scores, achieving an SSQ score indicative of a clinically normal swallowing profile 12-months post-BB-301 administration. This Subject has completed the statistical follow-up period of the BB-301 Phase 1b/2a Treatment Study.
  - Subject 3, plagued by Ineffective Swallowing, experienced complete resolution of pathologic sequential swallows per the VFSS results and achieved a correspondingly significant reduction in total dysphagic symptom burden per the Total SSQ Score, achieving an SSQ score indicative of a clinically normal swallowing profile 3-months post BB-301 administration.

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1 Bua, B.A. and Bülow, M., BMC Research Notes (2014) 7:742;
2 Audag N., et al., Dysphagia (2019) 34:556-566

Clinical Study Results for Subject 1 (365-Days Post Treatment with BB-301):

Subject 1, plagued by Inefficient Swallowing, experienced significant, clinically meaningful reductions of post swallow residue across all food and liquid consistencies 12-months post treatment with BB-301 per the VFSS results, and the VFSS results were accompanied by significant reductions in total dysphagic symptom burden.

Subject 1 displayed significant reductions (i.e., improvements) in VFSS TPR (37% reduction for Thin Liquid, 18% reduction for Solid Food, and 29% reduction for Thick Liquids) following the administration of the low-dose of BB-301 as compared to the average values recorded for Subject 1 during the pre-treatment period.

Subject 1 also displayed continued clinically meaningful reductions (i.e., improvements) in total dysphagic symptom burden with an average 12-month post-treatment SSQ Total Score demonstrating a 41% reduction as compared to the average values recorded for Subject 1 during the pre-treatment period.

Clinical Study Results for Subject 2 (365-Days Post Treatment with BB-301):

Subject 2, plagued by Ineffective Swallowing, experienced significant, clinically meaningful reductions in the frequency of pathologic sequential swallows 12-months post treatment with BB-301 per the VFSS results, and the VFSS results were accompanied by significant reductions in total dysphagic symptom burden with Subject 2 achieving an SSQ score indicative of a clinically normal swallowing profile.

During the fifteen pre-treatment VFSS assessments conducted for Thin Liquid in the OPMD Natural History Study, Subject 2 experienced a high frequency of pathologic sequential swallows (observed during 80% of the swallowing assessments). During the twelve post-treatment VFSS assessments conducted for Thin Liquid in the Phase 1b/2a Clinical Treatment Study, Subject 2 experienced a significantly lower frequency of pathologic sequential swallows (observed during 17% of the swallowing assessments). Critically, the magnitude of reduction in the frequency of pathologic sequential swallows reported for Thin Liquid at the 6-month post-treatment interim clinical update in October 2024 (observed during 17% of the swallowing assessments) was maintained at month 12 (again observed during 17% of the swallowing assessments).

Subject 2 also displayed continued clinically meaningful reductions (i.e., improvements) in total dysphagic symptom burden with an average 12-month post-treatment SSQ Total Score demonstrating a 91% reduction as compared to the average values recorded for Subject 2 during the pre-treatment period. The 12-month post-treatment average SSQ value of 68 units for Subject 2 represents a clinically normal swallowing profile.

Interim Clinical Study Results for Subject 3 (90-Days Post Treatment with BB-301):

Subject 3, plagued by Ineffective Swallowing, experienced significant, clinically meaningful reductions in the frequency of pathologic sequential swallows 3-months post treatment with BB-301 per the VFSS results, and the VFSS results were accompanied by a significant reduction in total dysphagic symptom burden with Subject 3 achieving an SSQ score indicative of a clinically normal swallowing profile.

During the twenty-five pre-treatment VFSS assessments conducted for Thin Liquid and Thick Liquids in the OPMD Natural History Study, Subject 3 experienced a high frequency of pathologic sequential swallows (observed during 84% of the swallowing assessments). During the five post-treatment VFSS assessment conducted for Thin Liquid and Thick Liquids in the Phase 1b/2a Clinical Treatment Study, Subject 3 experienced no pathologic sequential swallows (observed during 0% of the swallowing assessments).

Subject 3 also displayed a clinically meaningful reduction (i.e., improvement) in total dysphagic symptom burden with a 3-month post-treatment SSQ Total Score demonstrating a 68% reduction as compared to the average values recorded for Subject 3 during the pre-treatment period. The 3-month post-treatment SSQ value of 70 units for Subject 3 represents a clinically normal swallowing profile.

The Subjects were blinded to their SSQ Total Scores and VFSS (TPR and pathologic sequential swallowing frequency) assessment results, and the Central Reader for the VFSS assessments was blinded to the SSQ Total Scores for each Subject.

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

Five Subjects have been safely treated with the low-dose of BB-301, and the sixth and final Subject of Cohort 1 is anticipated to receive the low-dose of BB-301 in 2Q 2025.

Adverse Events:

No Severe Adverse Events have been observed for the Subjects treated with BB-301.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this Current Report on Form 8-K include forward-looking statements, including statements regarding Benitec's plans to develop and potentially commercialize its product candidates, the timing of 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, 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 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.

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: March 20, 2025

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