
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): August 7, 2019

EMERALD BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada

(State or Other Jurisdiction of
Incorporation)

000-55136

(Commission
File Number)

45-0692882

(I.R.S. Employer
Identification Number)

130 North Marina Drive, Long Beach, CA 90803

(Address of principal executive offices)

(949) 396-0330

(Registrant's telephone number, including area code)

Nemus Bioscience, Inc.

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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 240.14d-2(b))
- 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))

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 1.01. Entry into a Material Definitive Agreement.

On August 7, 2019, Emerald Bioscience, Inc. (the “Company”) entered into a First Amendment (the “First Amendment”) to that certain Master Development and Clinical Supply Agreement, dated as of February 25, 2019 (the “Noramco Agreement”), by and between the Company and Noramco, Inc. (“Noramco”) to manufacture THCVHS. CBDVHS was previously being manufactured pursuant to the Noramco Agreement. The Company will pay \$257,800 upfront to add the manufacture of THCVHS to the Noramco Agreement and additional payments will be made upon Noramco shipping of the GMP active pharmaceutical ingredient to the Company. All other material terms of the Noramco Agreement remain the same.

The foregoing description of the First Amendment is not complete and is qualified in its entirety by reference to the text of the First Amendment, a copy of which is attached hereto as Exhibit 10.1 and incorporated herein by reference.

Item 1.02. Termination of a Material Definitive Agreement

The Company previously entered into a letter agreement with Albany Molecular Research, Inc. (“AMRI”), dated as of July 31, 2018 (the “Letter Agreement”), for the manufacture of THCVHS. On July 8, 2019, the Company notified AMRI of its intent to terminate the Letter Agreement, effective on August 7, 2019.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
10.1*	First Amendment to Master Development and Clinical Supply Agreement, dated as of August 7, 2019 by and between the Company and Noramco.

* Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“[****]”) because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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 hereunto duly authorized.

EMERALD BIOSCIENCE, INC.

Dated: August 8, 2019

By: /s/ Dr. Brian Murphy

Dr. Brian Murphy
Chief Executive Officer

THE SYMBOL “[**]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

FIRST AMENDMENT TO SUPPLY AGREEMENT

This First Amendment to the Supply Agreement (the “First Amendment”), dated as of July 30, 2019 (“First Amendment Effective Date”), is entered into by and between Noramco, Inc., a Georgia corporation, (“Noramco”) and EMERALD Bioscience, Inc., a Nevada corporation, with a place of business at 130 N. Marina Drive, Long Beach, CA 90803 (“Client”), to amend that certain Supply Agreement entered into between Noramco and NEMUS Bioscience, Inc. effective as of February 25, 2019 (the “Agreement”).

Whereas, NEMUS Bioscience, Inc. has changed its name to EMERALD Bioscience, Inc., and the parties wish to add a new API and SOW to the Agreement. Noramco and Client desire to amend the Agreement on the terms and conditions set forth herein. Now, therefore, for the promises exchanged herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. Amendments. The terms of the Agreement shall be modified and amended only as set forth below. Capitalized terms used, but not defined herein, shall have the meanings given to such terms in the Agreement.

(a) This Agreement is amended by deleting “NEMUS Bioscience, Inc.” in its entirety from the first paragraph and signatory line of the Agreement and replacing it with the following:

“EMERALD Bioscience, Inc.”

(b) Section 1.2 of the Agreement is amended by adding the following after “(CBDVHS)”:

“and Tetrahydrocannabinol-Mono-Valinate-Mono-Hemisuccinate (THCVHS)”

(c) Exhibit A is amended by adding the attached new SOW related to THCVHS.

(d) Section 9.3 and Exhibit B are each amended by deleting “NEMUS” and replacing with the following:

“Emerald”

2. This First Amendment will be effective and binding on the Parties from and after the First Amendment Effective Date. This First Amendment shall not amend or modify the covenants, terms, conditions, rights and obligations of the parties under the Agreement, except as specifically set forth herein. The Agreement shall continue in full force and effect in accordance with its terms as amended by this First Amendment.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this First Amendment as of the First Amendment Effective Date.

NORAMCO, INC.

EMERALD Bioscience, Inc.

By: /s/ T.L. Jones

By: /s/ Brian Murphy, MD

Name: T. L. Jones

Name: Brian Murphy, MD

Title: VP Business Development

Title: Chief Executive Officer

[Signature Page to First Amendment to Supply Agreement]

Exhibit A
Scope of Work
THCVHS

Part 1: Synthesis of [****] non-GMP THCVHS suitable for preclinical studies.

Part 2: GMP Manufacturing of [****] THCVHS suitable for Phase 1 human clinical trials.

- a. Process development to identify a suitable route to scale-up and manufacture Phase 1 clinical supplies.
- b. GMP production of up to [****] of THCVHS suitable for Phase 1 human clinical trials.
- c. Analytical development in support of Phase 1 API release testing, method qualification/validation for the Phase 1 API, and a certificate of analysis.
- d. A Phase 1 stability study to support API retest period and container closure selection of the clinical trial material.

Location: [****]

Testing: Full Analytical Certificate of Analysis: Chemical Identification, Solvent Impurities, Inorganic Impurities, Chromatographic Impurities, Micro Limits Testing. Validated/qualified methods for release of the Phase 1 supply.

Specifications: To be determined. Specifications will follow US FDA regulations and guidelines for Phase 1 human clinical use. Noramco and EMBI must agree to specifications before GMP production of [****] can begin.

Timing: Part 1: [****] from PO receipt
Part 2: GMP manufacturing initiation: [****] 2019*
GMP material shipment: [****] 2019*

*Manufacturing window is flexible and will be locked upon receipt of a PO. PO is required to support DEA quota submission request as well as reserving regulatory starting materials.

Payment Terms: For each respective part of the proposal, [****]% (\$257,800) paid in advance, [****]% ([****]) paid upon shipment of material.

Reporting: This project will be assigned a project manager to provide EMBI with a single point of contact for continuity. Regular teleconferences will be held throughout the duration of the project.

Stability: Noramco will conduct a stability study on the clinical API of not less than 12 months. The stability conditions and timepoints will follow the general guidance outlined in ICH Q1 so far as storage conditions and frequency of testing. Noramco will develop and use stability-indicating methods to conduct testing.

Reference Standards: Noramco will develop and qualify an API analytical reference standard to support EMBI's dosage form development as well as support release testing.

Assumptions:

- Noramco's manufacturing activities for [****] of material will be performed under GMP conditions and considered suitable for Phase I clinical trials in humans. The GMP clinical material will be manufactured as a non-sterile parenteral grade.
- Total volume of material may be delivered in multiple batches.
- This offer is contingent on Noramco being able to secure starting material from its existing supply chain.
- The proposal is contingent on approval of appropriate US DEA quota to execute the campaign for production of [****] GMP material.
- If the work cannot be completed in the time allotted, then Noramco will notify EMBI.
- If Noramco deems the chemistry to be unsafe at any time, Noramco reserves the right to stop research and notify EMBI within 5 business days.
- New IP or trade secret(s) specifically relating to EMBI's THCVHS product, as described in the scope of work under this proposal, will belong to EMBI.
- If EMBI has qualified/validated analytical methods for THCVHS available, Noramco will utilize the analytical package for release of GMP clinical use material. Otherwise, Noramco will develop/qualify analytical methods.
- CMC information will be provided to EMBI for the clinical regulatory filing, as requested.

Price for API and Services:

Part 1: [****] non-GMP THCVHS: \$[****]

Part 2: Up to [****] GMP THCVHS: \$[****]*

*Price above includes preparation of cGMP documentation, plant time, analytical method development/qualification/transfer, analytical release testing, stability testing (12 months), R&D, etc. The material will be a manufactured as a non-sterile parenteral grade (NSP), which could be suitable for a sterile dosage form.
