

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): December 17, 2019

Innovate Biopharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-37797
(Commission
File Number)

27-3948465
(I.R.S. Employer
Identification No.)

8480 Honeycutt Road, Suite 120, Raleigh, NC 27615
(Address of principal executive offices) (Zip Code)

(919) 275-1933
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

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 \$0.0001 Par Value	INNT	The Nasdaq Stock Market LLC

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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.

Agreement and Plan of Merger and Reorganization

On December 17, 2019, Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), entered into a First Amendment (the "Amendment") to the previously disclosed Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), originally dated October 6, 2019, with INNT Merger Sub 1 Ltd., a company organized under the laws of Israel and a directly, wholly-owned subsidiary of the Company ("Merger Sub"), RDD Pharma Ltd., a company organized under the laws of Israel ("RDD") and Orbimed Israel Partners, Limited Partnership, as the Shareholder Representative. The Merger Agreement was previously filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission (the "SEC") on October 7, 2019.

The parties to the Merger Agreement entered into the Amendment to, among other things: (i) amend the RDD Fully Diluted Ownership Ratio, (ii) increase the amount of time that RDD has to obtain the approval of the Merger from its stockholders and (iii) increase the termination fee payable by RDD to the Company in certain circumstances, from \$250,000 to \$1 million. Except as modified by the Amendment, the terms of the Merger Agreement in the form attached as Exhibit 2.1 to the Current Report on Form 8-K filed by the Company with the SEC on October 7, 2019 are unchanged.

The description of the Amendment set forth herein does not purport to be complete and is qualified in its entirety by reference to the full text of the Amendment, which is filed as Exhibit 2.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Cautionary Statement Regarding Forward-Looking Statements

This report, including the exhibits attached hereto, contain forward-looking statements based upon the Company's and RDD's current expectations. Forward-looking statements involve risks and uncertainties, and include, but are not limited to, statements about the structure, timing and completion of the proposed Merger; the combined company's listing on Nasdaq after closing of the proposed Merger; expectations regarding the ownership structure of the combined company; the expected executive officers and directors of the combined company; the combined company's expected cash position at the closing of the proposed Merger; expectations regarding the Financing; the future operations of the combined company; the nature, strategy and focus of the combined company; the development and commercial potential and potential benefits of any product candidates of the combined company; the executive and board structure of the combined company; the location of the combined company's corporate headquarters; anticipated preclinical and clinical drug development activities and related timelines, including the expected timing for data and other clinical and preclinical results; RDD having sufficient resources to advance its pipeline; and other statements that are not historical fact. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: (i) the risk that the conditions to the closing of the proposed Merger are not satisfied, including the failure to timely obtain stockholder approval for the transaction, if at all; (ii) uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of the Company and RDD to consummate the proposed Merger; (iii) risks related to the Company's ability to manage its operating expenses and its expenses associated with the proposed Merger pending closing; (iv) risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the proposed Merger; (v) the risk that as a result of adjustments to the exchange ratio, Company stockholders and RDD stockholders could own more or less of the combined company than is currently anticipated; (vi) risks related to the market price of the Company's common stock relative to the exchange ratio; (vii) unexpected costs, charges or expenses resulting from the transaction; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed Merger; (ix) the uncertainties associated with the clinical development and regulatory approval of product candidates; (x) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical

programs; (xi) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (xii) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and (xiii) risks associated with the possible failure to realize certain anticipated benefits of the proposed Merger, including with respect to future financial and operating results. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019 filed with the SEC, and in other filings that the Company makes and will make with the SEC. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
2.1	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated as of December 17, 2019, by and between Innovate Biopharmaceuticals, Inc., INNT Merger Sub 1 Ltd., RDD Pharma Ltd. and Orbimed Israel Partners, Limited Partnership*
*	The appendix to Amendment No. 1 to Agreement and Plan of Merger and Reorganization has been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of any such schedules or exhibits to the SEC upon request.

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.

Innovate Biopharmaceuticals, Inc.

Date: December 17, 2019

By:

/s/ Edward J. Sitar

Edward J. Sitar

Chief Financial Officer

**FIRST AMENDMENT TO
AGREEMENT AND PLAN OF MERGER**

This First Amendment to Agreement And Plan of Merger (this "*First Amendment*") is entered effective as of December 17, 2019, by and among Innovate Biopharmaceuticals, Inc., a Delaware corporation ("*Innovate*"), Innt Merger Sub 1, Ltd., a company organized under the laws of Israel and a direct, wholly owned subsidiary of Innovate ("*Merger Sub*"), RDD Pharma Ltd., a company organized under the laws of Israel (the "*Company*") and OrbiMed Israel Partners, Limited Partnership, in the capacity as the representative from and after the Effective Time for the shareholders of the Company as of immediately prior to the Effective Time in accordance with the terms and conditions of the Merger Agreement (as defined below) (the "*Shareholder Representative*"). Each of Innovate, Merger Sub, the Company, and the Shareholder Representative is referred to as a "*Party*" and collectively as the "*Parties*."

A . The Parties are parties to that certain Agreement and Plan of Merger and Reorganization made and entered into as of October 6, 2019 (the "*Agreement*").

B. Pursuant to Section 11.2 of the Agreement, the Agreement may be amended with the approval of the respective Boards of Directors of the Company and Innovate at any time (whether before or after approval of the Company Shareholder Proposals by the Company's shareholders and whether before or after approval of the Innovate Shareholder Proposals by Innovate's shareholders and whether before or after approval of the Merger, the other Contemplated Transactions and the Agreement by the sole shareholder of Merger Sub), except that after any such adoption and approval of the Agreement by a Party's shareholders, no amendment shall be made which by Law requires further approval of the shareholders of such Party without the further approval of such shareholders. The Agreement may not be amended except by an instrument in writing signed on behalf of each of the Parties to the Agreement.

C . The respective Boards of Directors of the Company and Innovate have approved this Amendment, and neither the shareholders of the Company nor the stockholders of Innovate have approved the Company Shareholder Proposals or Innovate Shareholder Proposals, respectively.

D. The Parties desire to amend the Agreement on the terms and conditions set forth in this First Amendment.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises set forth herein and in the Agreement, the Parties agree as follows:

1. Capitalized Terms. Capitalized terms used but not otherwise defined in this Amendment (including in the preamble and recitals to this Amendment) have the meanings ascribed to them in the Agreement.

2. Amendment of Recital B. Recital B of the Agreement is hereby deleted in its entirety and replaced with the following:

“B. The Board of Directors of Innovate (i) has determined that the Merger and the other transactions contemplated by this agreement are advisable, and in the best interests of Innovate and its shareholders, and (ii) has determined to recommend that the shareholders of Innovate vote to approve the Innovate Shareholder Proposals, and such other actions as contemplated by this Agreement.”

3. Amendment of Section 1.5(a). Section 1.5(a) of the Agreement is hereby deleted in its entirety and replaced with the following:

“(a) Calculation of Shares. The number of shares of Innovate Preferred Stock calculated based on the definitions in this Section 1.5 are calculated on an as-converted to Innovate Common Stock basis. If the Innovate stockholders duly approve the Preferred Stock Conversion Proposal prior to the Effective Time, then rather than issue any Innovate Preferred Stock pursuant to this Agreement, Innovate instead shall issue Innovate Common Stock (subject in all respects to the terms of this Agreement).”

4. Amendment of Section 1.5(b). Section 1.5(b) of the Agreement is hereby deleted in its entirety and replaced with the following:

(a) “(b) Definitions. For purposes of this Agreement, the following terms have the meanings ascribed to them as set forth below:

(1) “**Combined Company Amount**” means the number of shares Innovate capital stock equal to the Innovate Fully Diluted Shares divided by the Innovate Fully Diluted Ownership Ratio.

(2) “**Common Stock Derivative Amount**” means the portion of the Common Stock Limit, if any, allocable to the Company Options pursuant to Section 5.4.

(3) “**Common Stock Issued Amount**” means the number of shares of Innovate Common Stock equal to the Common Stock Limit minus the Common Stock Derivative Amount.

(4) “**Common Stock Limit**” means the number of shares of Innovate Common Stock that represent 19.5% of the voting power of Innovate as of immediately prior to the Effective Time.

(5) “**Innovate Fully Diluted Ownership Ratio**” means a percentage equal to 100% minus the RDD Fully Diluted Ownership Ratio.

(6) “**Innovate Fully Diluted Shares**” means the number of shares of Innovate capital stock, on a fully diluted basis, immediately prior to the Effective Time.

(7) “**Merger Consideration**” means the RDD Share Portion, as allocated among and issued to (or subject to and issuable in respect of) the Company Share Capital and Company Options pursuant to this Agreement.

(8) “**Preferred Stock Derivative Amount**” means the portion of the Preferred Stock Merger Amount, if any, allocable to the Company Options pursuant to Section 5.4.

(9) “**Preferred Stock Issued Amount**” means the number of shares of Innovate Preferred Stock equal to the Preferred Stock Merger Amount minus the Preferred Stock Derivative Amount.

(10) “**Preferred Stock Merger Amount**” means the number of shares of Innovate Preferred Stock equal to (i) the RDD Share Portion minus the Common Stock Limit.

(11) “**RDD Fully Diluted Ownership Ratio**” means a percentage equal to 38.0%.

(12) “**RDD Share Portion**” means the number of shares of Innovate capital stock equal to the Combined Company Amount multiplied by the RDD Fully Diluted Ownership Ratio.

(13) “**Stock Ratio**” means the ratio of the Common Stock Limit to the Preferred Stock Merger Amount.”

5. Amendment of Section 1.5(c)(i). Section 1.5(c)(i) of the Agreement is hereby deleted in its entirety and replaced with the following:

“Subject to the remaining provisions of this *Section 1.5*, all of the Company Share Capital issued and outstanding immediately prior to the Effective Time (other than shares described in *Section 1.5(c)(iii)*) shall be deemed to have been transferred to Innovate solely in consideration for the right to receive from Innovate, in accordance with the terms of this Agreement and the Allocation Certificate, (i) the number of shares of validly issued, fully paid and nonassessable shares of Innovate Common Stock equal to the Common Stock Issued Amount and (ii) the number of shares of validly issued, fully paid and nonassessable shares of Innovate Preferred Stock equal to the Preferred Stock Issued Amount. The allocation of the Common Stock Issued Amount and Preferred Stock Issued Amount among the Company Share Capital will be determined pursuant to the Allocation Certificate and

consistent with the Stock Ratio. The Allocation Certificate calculates the portions of the Common Stock Issued Amount and Preferred Stock Issued Amount issuable in respect of the Company Share Capital consistent with the Company Charter, taking into account the liquidation preferences set forth in the Company Charter. Notwithstanding the foregoing, if the Innovate stockholders duly approve the Preferred Stock Conversion Proposal prior to the Effective Time, then rather than issue any Innovate Preferred Stock pursuant to this Agreement, Innovate instead shall issue Innovate Common Stock (subject in all respects to the terms of this Agreement).”

6. Amendment of Section 1.5(c)(ii). The first sentence in Section 1.5(c)(ii) of the Agreement is hereby deleted in its entirety and replaced with the following:

“Each share of Innovate Preferred Stock shall be convertible into shares of Innovate Common Stock, subject to and contingent upon the affirmative vote of a majority of the Innovate Common Stock present or represented and entitled to vote at a meeting of stockholders of Innovate to approve, for purposes of the Nasdaq Stock Market Rules, the issuance of shares of Innovate Common Stock to the stockholders of the Company upon conversion of the shares of Innovate Preferred Stock in accordance with the terms of the Certificate of Designation in substantially the form attached hereto as *Exhibit F* (the “**Preferred Stock Conversion Proposal**”).”

7. Amendment of Section 1.12(a). Section 1.12(a) of the Agreement is hereby deleted in its entirety and replaced with the following:

“At or prior to the Closing, Innovate, the Shareholder Representative, and a mutually agreeable escrow agent (the “**Escrow Agent**”), shall enter into an Escrow Agreement, effective as of the Effective Time, in form and substance reasonably satisfactory to the Parties (the “**Escrow Agreement**”), pursuant to which Innovate shall deposit Innovate Preferred Stock in an amount comprising ten percent (10%) of the Merger Consideration otherwise deliverable to the Company Shareholders (including any equity securities paid as dividends or distributions with respect to such shares or into which such shares are exchanged or converted, the “**Escrow Shares**”); to be held and disbursed by the Escrow Agent in a segregated escrow account (the “**Escrow Account**”) in accordance with the terms hereof and of the Escrow Agreement. The Escrow Shares shall be allocated among the Company Shareholders pro rata based on their respective Pro Rata Shares. The Escrow Shares shall serve as a security for, and a source of payment of, the Innovate Indemnified Parties’ indemnity rights pursuant to *Section 10*. Unless otherwise required by Law, all distributions made from the Escrow Account shall be treated by the Parties as an adjustment to the number of shares of Merger Consideration received by the Company Shareholders pursuant to *Section 1* hereof. Notwithstanding the foregoing, if the Innovate stockholders duly approve the Preferred Stock Conversion Proposal prior to the Effective Time, then Innovate shall deposit Innovate Common Stock (instead of Innovate Preferred Stock) into the Escrow

Account in amount comprising ten percent (10%) of the Merger Consideration otherwise deliverable to the Company Shareholders to serve as the Escrow Shares.”

8. Amendment of Section 4.4(a)(vi). Section 4.4(a)(vi) of the Agreement is hereby deleted in its entirety and replaced with the following:

“(vi) lend money to any Person; incur or guarantee any Indebtedness for borrowed money in an amount in excess of \$2,750,000; issue or sell any debt securities or option, warrants, calls or other rights to acquire any debt securities; guarantee any debt securities of others; or make any capital expenditure, or commitment therefor in excess of \$250,000;”

9. Amendment of Section 6.5. Section 6.5 of the Agreement is hereby deleted in its entirety and replaced with the following:

“Innovate Post-Closing Financing. Investors shall have made written commitments to participate in the Innovate Post-Closing Financing in an aggregate amount equal to at least \$10,000,000.

10. Amendment of Section 9.1(d). Section 9.1(d) of the Agreement is hereby deleted in its entirety and replaced with the following:

“by Innovate if the Company Shareholder Approval shall not have been obtained within one hundred twenty (120) days following the execution of this Agreement; *provided, however*, that once the Company Shareholder Approval has been obtained, Innovate may not terminate this Agreement pursuant to this *Section 9.1(d)*;”

11. Amendment of Section 9.1(g). Section 9.1(g) of the Agreement is hereby deleted in its entirety and replaced with the following:

“by Innovate if written commitments to participate in the Innovate Post-Closing Financing in an amount equal to at least \$10,000,000 have not been received prior to the Effective Time;”

12. Amendment of Section 9.3(b)(i). Section 9.3(b)(i) of the Agreement is hereby deleted in its entirety and replaced with the following:

“If (A) this Agreement is terminated by Innovate pursuant to *Section 9.1(d)* and (B) within twelve (12) months after the date of such termination, the Company enters into a definitive written agreement with respect to a Company Subsequent Transaction and ultimately consummates such Company Subsequent Transaction (which, for the avoidance of doubt, may be consummated any time within, on or after the date of such Agreement), then the Company shall pay, or cause to be paid, to Innovate, upon the consummation of such Company Subsequent Transaction, a nonrefundable fee in an amount equal to \$1,000,000.”

13. Amendment of Exhibit A.

- a. The defined term “Equity Term Sheet” and its corresponding definition is hereby deleted from Exhibit A to the Agreement.
- b. The definition of “Innovate Post-Closing Financing” is hereby deleted in its entirety and replaced with the following:

“**Innovate Post-Closing Financing**” means an acquisition by investors of Innovate Common Stock and warrants convertible into Innovate Common Stock to be consummated immediately following the Closing with the aggregate gross proceeds of such financing to be paid to Innovate.”

- c. The exhibit reference for the defined term “Innovate Preferred Stock” is hereby corrected and replaced with “*Exhibit F*”.
- d. The defined term “Preferred Stock Consideration” and its corresponding definition is hereby deleted from Exhibit A to the Agreement.
- e. The section reference for the defined term “Preferred Stock Conversion Proposal” is hereby corrected and replaced with “*Section 1.5(c)(ii)*.”

14. Amendment of Exhibit G. Exhibit G to the Agreement is hereby deleted in its entirety and replaced with the version of Exhibit G attached hereto as Appendix A.

15. Amendment of Company Schedule of Exceptions. Schedules 4.3(a) and 4.4(b)(iv) of the Company Schedule of Exceptions are hereby modified to include the following:

“The Company is expressly permitted to enter into a non-binding letter of intent with respect to the acquisition of Naia Rare Diseases.”

16. Amendment of Company Schedule of Exceptions. References to the bridge loan in Schedules 4.3(a) and 4.4(b)(iv) of the Company Schedule of Exceptions are hereby deleted in their entirety and replaced with the following:

“The Company is permitted to enter into a bridge loan agreement prior to Closing pursuant to which the Company may borrow a principal amount of up to \$750,000 on terms to be determined by the Company.”

17. Amendment of Schedule I-C. Schedule I-C to the Agreement is hereby modified to delete all references to “Sharro Trustees Limited.”

18. Full Force and Effect. Except as modified and amended by this First Amendment, the terms and conditions of the Agreement remain in full force and effect.

19. Conflict. In the event of conflict between the provisions of the Agreement and this First Amendment, the provisions of this First Amendment shall control.

20. Counterparts; Electronic Signatures. This First Amendment may be executed in one or more counterparts (including by transmission-mail), all of which shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party.

21. Governing Law. Sections 11.5 and 11.10 of the Agreement are incorporated by reference into this Amendment, *mutatis mutandis*.

[signature page follows]

IN WITNESS WHEREOF, the parties have caused this First Amendment to be duly executed as of the date first set forth above.

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Edward J. Sitar

Name: Edward J. Sitar

Title: Chief Financial Officer

INNT MERGER SUB 1 LTD.

By: /s/ Edward J. Sitar

Name: Edward J. Sitar

Title: Authorized Signatory

RDD PHARMA LTD.

By: /s/ John Temperato

Name: John Temperato

Title: CEO

SHAREHOLDER

REPRESENTATIVE:

ORBIMED ISRAEL PARTNERS, LIMITED PARTNERSHIP

/s/ Nissim Darvish

L.P.

Name: Nissim Darvish

By: OrbiMed Israel Biofund GP,

Its General Partner

By: OrbiMed Israel GP Limited

Its General Partner