Innovate Biopharmaceuticals to Merge with RDD Pharma Creating New Gastroenterology Company Focused on Specialty, Rare and Orphan Diseases

October 7, 2019

Deep Clinical-Stage Pipeline Combined With World-Class Leadership Team

OrbiMed Advisors LLC to Lead a Concurrent Capital Raise

9 Meters Biopharma, Inc. Will Be the New Name of the Combined NASDAQ-Listed Public Company

Conference Call on October 7, 2019 at 8:00 a.m. EDT / 5:00 a.m. PDT

RALEIGH, NC and TEL AVIV, ISRAEL / ACCESSWIRE / October 7, 2019 / Innovate Biopharmaceuticals, Inc. (NASDAQ:INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases ("Innovate"), and RDD Pharma, Ltd. focused on orphan and innovative therapies for gastrointestinal disorders ("RDD"), announced today that the two companies entered into a definitive merger agreement pursuant to which Innovate agreed to acquire all of the outstanding capital stock of privately-held RDD in exchange for a combination of common and preferred shares. After the merger closing, Innovate will be renamed 9 Meters Biopharma, Inc. Innovate believes that the proposed transaction will position the combined company to recognize multiple value inflection points over the next 24 months based on the combined clinical pipeline, seasoned Board of Directors and world class management and prominent healthcare-dedicated institutional investors.

"People living with gastrointestinal (GI) diseases, such as celiac disease, are waiting for treatment options," said Nissim Darvish, M.D., Ph.D., a member of the Board of Directors of RDD and Senior Managing Director of OrbiMed Advisors LLC, a lead investor in the transaction. "The proposed merger will create a powerful platform company with a pipeline of late development-stage therapeutic candidates already demonstrating proof of concept. We are excited about our investment and future involvement in this new company and the opportunities it presents."

The combined company will focus on developing urgently needed treatments for specialty, rare and orphan patient populations with GI diseases. "With a diversified pipeline of novel compounds, active clinical studies - including the first-ever drug to enter a Phase 3 registration trial in celiac disease - 9 Meters Biopharma expects to deliver multiple value creating milestones over the next 24 months" said John Temperato, the current CEO of RDD, who will become the CEO of 9 Meters Biopharma and intends to continue to build a top talent management team of industry veterans who bring a proven track record of in-licensing, developing and commercializing multibillion-dollar assets. Mr. Temperato was instrumental in the commercial and operational buildout of Salix Pharmaceuticals for more than a decade, which culminated in Salix's acquisition for ~$16 billion in 2015.

"The merger of Innovate and RDD to create 9 Meters Biopharma represents a bold new chapter in drug development for GI diseases and is a transformative deal for Innovate shareholders with tremendous benefits. The merger attracts a highly seasoned board and management team led by a proven CEO, fundamentally driven healthcare-dedicated institutional investors and a shared vision to build a truly world-class platform biopharmaceutical company, which can be the partner of choice for near-term business development opportunities as well, jumpstarted with an exciting clinical pipeline," said Sandeep Laumas, M.D., Executive Chairman of Innovate.

About the Transaction

The transaction has been approved unanimously by the Board of Directors of Innovate and RDD, and Innovate stockholders and insiders representing more than one-third of Innovate voting shares have signed voting support agreements. Pursuant to the merger agreement, Innovate will acquire all of the outstanding capital stock of RDD in exchange for the issuance of newly issued shares of Innovate common stock, representing approximately 19.5% of the voting power of Innovate as of immediately prior to the issuance of such shares, and shares of Innovate convertible preferred stock convertible into shares of Innovate common stock upon receipt of the required approval of the Innovate stockholders under Nasdaq rules. The shares of convertible preferred stock are not tradeable by the holders of the shares. Following completion of the merger, the former Innovate stockholders will own up to approximately 58.5% of the combined company's capital stock and the former RDD stockholders will own at least 41.5% of the combined company's capital stock (on a fully diluted basis). The actual allocation is subject to adjustment based on the final capital invested concurrent with the closing of the merger of up to $25 million with an initial tranche of $10 million. In connection with the merger, Innovate Biopharmaceuticals, Inc. will be renamed 9 Meters Biopharma, Inc. and is expected to continue to trade on the Nasdaq Capital Market. Closing is expected in 2019, subject to customary legal and regulatory clearances and procedures, including receipt of an Israeli tax ruling. The corporate headquarters for the combined company will be located in Raleigh, North Carolina.

The Benchmark Company, LLC provided financial advice to the Board of Directors of Innovate with Sheppard, Mullin, Richter & Hampton LLP and Agmon & Co. Rosenberg Hacohen & Co. serving as legal counsel. Wyrick Robbins Yates & Ponton LLP and Shibolet & Co. are serving as legal counsel to RDD.

Management and Organization

Effective as of the closing of the merger, Mr. Temperato will become the Chief Executive Officer and join the Board of Directors of 9 Meters Biopharma, the combined company. In addition, at such time Mark Sirgo, PharmD, CEO of ArunA Bio, Inc., Vice Chairman of BioDelivery Sciences International, Inc. (NASDAQ: BDSI) and current Chairman of RDD Pharma, will become Chairman of the Board of Directors and Dr. Laumas, will continue as members of the Board of Directors of 9 Meters Biopharma. Other member of the continuing Board will include Dr. Darvish, Senior Managing Director of OrbiMed Advisors LLC and Lorin Johnson, Ph.D., co-founder of Salix Pharmaceuticals.

Conference Call and Webcast
Management will host a conference call at 8:00 AM today for investors regarding this announcement with details as follows:

Conference Call and Webcast Details:
Date: October 7, 2019
Time: 8:00 AM EDT, 5:00 AM PDT
Toll-free: 844-369-8770
International: 862-298-0840
Webcast URL: https://www.investornetwork.com/event/presentation/53994

The archived webcast will be available on the Investors section of the Innovate website and the Investor section of the RDD website.

About RDD Pharma

RDD Pharma, Ltd. ("RDD"), is a privately held biopharmaceutical company focused on orphan and innovative therapies for gastrointestinal disorders. The company has two clinical stage products which serve significant unmet needs. RDD-0315 is currently in Phase 2 development for the treatment of fecal incontinence in spinal cord injury patients. RDD-0315 has received Orphan Drug status in the E.U. and Fast Track designation in the U.S. RDD-1609 is being developed for the treatment of Pruritus Ani. RDD is also exploring other potential therapies for anorectal and lower gastrointestinal disorders for future clinical development. For more information, please visit www.rddpharma.com.

About Innovate Biopharmaceuticals, Inc.

Innovate is a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases. Innovate's lead drug candidate, larazotide acetate, has a mechanism of action that renormalizes the dysfunctional intestinal barrier by decreasing intestinal permeability and reducing antigen trafficking, such as gliadin fragments in celiac disease, and bacterial toxins and immunogenic antigens in NASH. In several diseases, including celiac disease, NASH, Crohn's disease, ulcerative colitis, irritable bowel syndrome (IBS), type 1 diabetes mellitus (T1DM), chronic kidney disease (CKD), the intestinal barrier is dysfunctional with increased permeability. In celiac disease, larazotide is the only drug which has successfully met the primary endpoint with statistical significance in a Phase 2b efficacy clinical trial (342 patients). Larazotide has been exposed to nearly 600 subjects in clinical trials demonstrating a favorable safety profile comparable to placebo for long-term chronic administration. Larazotide has received Fast Track designation from the FDA for celiac disease.

Forward-Looking Statements
This press release includes forward-looking statements based upon Innovate'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; the company 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; (ii) uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of Innovate and RDD to consummate the proposed Merger; (iii) risks related to Innovate'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, Innovate 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 Innovate 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 Innovate's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 filed with the SEC, and in other filings that Innovate 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. Innovate 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.

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