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InvaGen (a Cipla subsidiary) Announces Acquisition Agreement with Avenue Therapeutics for Specialty Hospital Business in the U.S.

November 13, 2018

- Upon first stage closing, InvaGen Pharmaceuticals Inc., a Cipla subsidiary ("InvaGen"), to acquire shares representing a 33.3% stake in Avenue Therapeutics, Inc. ("Avenue") on a fully diluted basis for \$35 million (currently expected to be 5,833,333 shares at \$6.00 per share)
- Upon second stage closing, InvaGen to purchase the remaining issued and outstanding shares of Avenue pursuant to a merger transaction for up to \$18 million in the aggregate (currently expected to be approximately \$13.92 per share), subject to certain terms to be outlined in the 8-K and proxy
- Post second stage closing, Avenue shareholders to receive certain contingent value rights relating to certain annual net sales and gross profit targets of IV Tramadol
- Avenue's management to host conference call today at 8:30 a.m. EST

MUMBAI, India & NEW YORK, Nov. 13, 2018 (GLOBE NEWSWIRE) -- InvaGen Pharmaceuticals Inc. ("InvaGen"), a subsidiary of the leading global pharmaceutical company Cipla Limited, today announced that it has entered into definitive agreements with two closing stages for a proposed acquisition of Avenue Therapeutics, Inc. (NASDAQ: ATXI) ("Avenue"), a Fortress Biotech (NASDAQ: FBIO) company focused on the development and commercialization of intravenous (IV) Tramadol. The transaction will be subject to Avenue stockholders' and regulatory approvals, and other closing conditions.

At the first stage closing, InvaGen or its affiliates will acquire, through the issuance by Avenue of new shares, shares representing a 33.3% stake in Avenue capital stock on a fully diluted basis for \$35 million. Based on current assumptions, such stake is expected to consist of 5,833,333 shares of Avenue's common stock issued at \$6.00 per share. Simultaneously with the closing of the stock issuance, InvaGen or its affiliates will appoint three members (including one independent) on Avenue's seven-member Board of Directors.

At the second stage closing, InvaGen or its affiliates will acquire the remaining shares of Avenue's common stock, pursuant to a reverse triangular merger with Avenue remaining as the surviving entity, for up to \$180 million in the aggregate, which is currently expected to represent approximately \$13.92 per share, subject to certain terms to be outlined in the Form 8-K and proxy statement to be filed by Avenue with the SEC in connection with the proposed transactions. The second stage closing is subject to the satisfaction of certain closing conditions, including conditions pertaining to U.S. FDA approval, labeling, scheduling and the absence of any REMS or similar restrictions in effect with respect to IV Tramadol.

Umang Vohra, Managing Director & Global Chief Executive Officer, Cipla, said: "Our investment in and proposed acquisition of Avenue establishes our presence in the specialty institutional business in the U.S. The novel intravenous drug delivery method of Tramadol addresses extremely crucial and hitherto unmet needs in pain management. This investment is in keeping with our stated intention to build a specialty pipeline in the U.S. market, and reinforces Cipla's innovation-led approach and commitment to caring for the life of patients."

Lucy Lu, M.D., President & Chief Executive Officer, Avenue, said: "We are very pleased to partner with InvaGen to accelerate the Phase 3 clinical development and potential commercialization of IV Tramadol in the United States. IV Tramadol offers a novel mechanism of action among intravenous analgesics and could be an important new therapy that fills a significant gap in pain management. We believe that this transaction creates significant value for our shareholders and creates a path to maximize their return on investment."

Torrey Capital LLC is acting as exclusive financial advisor to Avenue. Oppenheimer & Co, Inc. provided a fairness opinion on the transaction to Avenue's Board of Directors. Alston & Bird LLP and Richards, Layton & Finger, P.A. served as legal counsel to Avenue, and Hughes Hubbard & Reed LLP served as legal counsel to Cipla.

About IV Tramadol:

Tramadol is a centrally acting analgesic with a unique dual mode of action. Oral Tramadol, a Schedule IV drug, has a well-established efficacy and safety profile and is currently approved and marketed in the U.S. for moderate to moderately severe pain in adults. There is currently no approved intravenous formulation in the U.S.

Avenue is evaluating IV Tramadol in a pivotal Phase 3 clinical program: a trial in patients following bunionectomy surgery ([NCT03290378](#)) has been complete and a safety study ([NCT03395808](#)) is ongoing. A pivotal Phase 3 trial in patients following abdominoplasty surgery is expected to commence later this year in 2018.

About Cipla Limited:

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology and CNS segments are well-known. Our 44 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Sept'18), 3rd largest in the pharma private market in South Africa (IQVIA YTD Aug'18), and is among the most dispensed generic players in the US. For over eight decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility and affordability to the centre of the movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit [www.cipla.com](#), or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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About Avenue Therapeutics:

Avenue, a Fortress Biotech company, is a specialty pharmaceutical company focused on the development and commercialization of intravenous (IV) Tramadol for the management of moderate to moderately severe post-operative pain. IV Tramadol may fill a gap in the acute pain market between IV acetaminophen/NSAID and IV conventional narcotics. Avenue is currently evaluating IV Tramadol in a pivotal Phase 3 program for the management of post-operative pain. Avenue headquartered in New York City. For more information, visit [www.avenuetx.com](#).

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Avenue Conference Call and Webcast:

Avenue will host a conference call and webcast on Tuesday, November 13 at 8:30 a.m. EST to discuss the transaction. To participate in Avenue's conference call please dial (888) 208-1711 (domestic) or (323) 994-2082 (international) and enter the conference code: 7975358. A live audio webcast will be available on the Events page of the Investors section of Avenue's website at [www.avenuetx.com](#). A replay of the audio webcast will be available approximately one hour after the call on the Events page of the Investors section of Avenue's website for a period of 30 days following the call.

About Fortress Biotech:

Fortress Biotech, Inc. ("Fortress") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress develops and commercializes products both within Fortress and through certain of its subsidiary companies, also known as Fortress Companies. In addition to its internal development programs, Fortress leverages its biopharmaceutical business expertise and drug development capabilities and provides funding and management services to help the Fortress Companies achieve their goals. Fortress and the Fortress Companies may see licensing arrangements, acquisitions, partnerships, joint ventures and/or public and private financings to accelerate and provide additional funding to support the research and development programs. For more information, visit [www.fortressbiotech.com](#).

Additional Information and Where to Find It:

This communication relates to the proposed stock purchase and merger transactions involving Avenue and InvaGen. In connection with the proposed transactions, Avenue intends to file relevant materials with the SEC, including Avenue's proxy statement on Schedule 14A (the "Proxy Statement"). This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval, and is not a substitute for the Proxy Statement or any other document that Avenue may file with the SEC or send to its stockholders in connection with the proposed transaction. STOCKHOLDERS OF AVENUE ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH THE SEC, INCLUDING THE PROXY STATEMENT, WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders will be able to obtain the documents (when available) free of charge at the SEC's web site, <http://www.sec.gov>, and Avenue's website www.avenuetx.com, and Avenue stockholders will receive information at an appropriate time on how to obtain transaction-related documents for free from Avenue. In addition, the documents (when available) may be obtained free of charge by directing a request to Avenue's Corporate Secretary, Joseph Vazzano, Avenue Therapeutics, Inc., 2 Gansevoort Street, 9th Floor, New York, New York 10014, or by calling (781) 652-4500.

Participants in Solicitation:

Avenue, InvaGen and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from the holders of Avenue capital stock in respect of the proposed transactions. Information about the directors and executive officers of Avenue is set forth in the proxy statement for Avenue's 2018 annual meeting of stockholders, which was filed with the SEC on April 30, 2018, and in Avenue's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on March 1, 2018. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the Proxy Statement and other relevant materials to be filed with the SEC in respect of the proposed transaction when they become available.

Disclaimer: Except for the historical information contained herein, statements in this document may constitute "forward looking statements" within the meaning of relevant securities laws, including without limitation those of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Forward-looking statements involve a number of risks, uncertainties and other factors that could cause actual results to differ materially from those suggested by the forward-looking statements. These risks and uncertainties include, but are not limited to, the ability of Cipla Limited and Avenue to successfully implement their respective strategies, growth and expansion plans, their abilities to obtain regulatory approvals, technological changes, cash flow projections, their exposure to market risks, risks relating to the timing of starting and completing clinical trials; their abilities to obtain, perform under and maintain financing and strategic agreements and relationships, uncertainties relating to clinical testing; their dependences on third-party suppliers, their abilities to attract, integrate and retain key personnel, their need for substantial additional funds, patent and intellectual property matters, and other risks. Neither Cipla Limited nor Avenue undertakes any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.



Source: Avenue Therapeutics

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