



[Home](#) / [Investors](#) / [News Releases](#)

Insmmed Incorporated and Transave, Inc. Announce Business Combination

RICHMOND, Va., Dec. 2, 2010 [/PRNewswire-FirstCall/](#) -- Insmmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, announced today that it has entered into a business combination, effective immediately, with Transave, Inc., a privately-held, NJ-based biopharmaceutical company focused on the development of differentiated, innovative inhaled pharmaceuticals for the site-specific treatment of serious lung infections.

Under the terms of the merger agreement, Insmmed acquired all of the outstanding capital stock of Transave and paid off all of Transave's \$7.8 million debt, for approximately 25.9 million shares of Insmmed common stock, and approximately 91.7 million shares of Insmmed Series B Conditional Convertible Preferred Stock with a stated value of \$0.7114 per share and cash consideration of \$561,280. After giving effect to the merger, former Transave stockholders have approximately a 46.7% equity interest in the combined company (on an as-converted, fully diluted basis), and Insmmed Incorporated shareholders have a 53.3% interest on a fully diluted, as exercised, basis.

Transition logistics for the combined company, which are expected to be completed in the first quarter of 2011, are already underway. The combined company will be governed by a four person Board of Directors with three directors remaining from the Insmmed board and one director joining them from the former Transave board. Mr. Donald J. Hayden, Jr., Transave's former Chairman, will serve as Chairman of the combined entity. The executive team will include from Transave, Mr. Timothy Whitten, who will be President and Chief Executive Officer (CEO) of the combined company, and Dr. Renu Gupta, who will serve as Executive Vice President, Development, and Chief Medical Officer, along with Mr. Kevin Tully, who will remain as Insmmed's Chief Financial Officer, and Nicholas LaBella, Jr., who will remain as Insmmed's Chief Scientific Officer.

Transave was backed by multiple well-known biotechnology venture capital funds, including Quaker BioVentures, Fidelity Biosciences, Prospect Venture Partners, TVM Capital, Forbion Capital Partners, Bessemer Venture Partners, and Easton Hunt Capital Partners.

Transave's lead product candidate, ARIKACE™ (liposomal amikacin for inhalation), is initially being developed for cystic fibrosis (CF) patients with Pseudomonas lung infections and lung infections due to non-TB Mycobacteria (NTM). The combined company intends to initiate phase 3 clinical trials for ARIKACE™ in both indications in parallel during the second half of 2011. The results of these trials are expected in the first half of 2013, and will be followed by regulatory filings in the U.S. and Europe for both indications, pending successful trial outcomes. Based on current assumptions, the combined company believes it will have sufficient cash to progress ARIKACE™ to commercialization in the U.S.

Transave, which holds worldwide rights to ARIKACE™, was previously granted orphan drug status for the drug candidate from the U.S. Food and Drug Administration (FDA), as well as the European Medicines Agency (EMA), for the CF indication. The combined company intends to file for orphan status with the FDA and EMA for the NTM indication in 2011.

ARIKACE™ has the potential to be differentiated from other marketed drugs for the treatment of chronic lung infections due to its ability to deliver high, sustained levels of amikacin directly to the lung, providing sustained improvement in lung function. ARIKACE™ has been shown to improve lung function both during and between treatment periods in patients with cystic fibrosis and could potentially be the first inhaled antibiotic to be administered once-daily.

ARIKACE™ will be administered once daily via inhalation using an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH). The optimized, investigational eFlow® Nebulizer System significantly reduces treatment time, thereby easing a patient's treatment burden and potentially improving patient compliance.

"We believe this transaction has the potential to create substantial shareholder value," said Dr. Melvin Sharoky, Insmmed's previous Chairman and current board member. "Throughout Insmmed's strategic review, we were committed to identifying a high-value, late-stage product candidate, and we believe we have been successful in doing that through the addition of ARIKACE™. The drug's previously completed Phase 2 and earlier stage clinical studies highlighted the potential of ARIKACE™ to become a leading treatment in two high-growth orphan indications with significant unmet medical needs. In addition, we believe the strength of the combined company's balance sheet, which after fees, debt payoff and other current liabilities, is presently estimated to be approximately \$110 million, provides Insmmed with the appropriate leverage to continue advancing ARIKACE™ through to commercialization."

"I'm excited about the opportunity presented by combining the strengths of Transave and Insmmed," said Donald J. Hayden, Jr., Insmmed's new Chairman. "Transave provides a differentiated, innovative late-stage opportunity in ARIKACE™ and Insmmed provides the capital to support the continued development of this important drug. In addition, we have drawn upon the leadership in both companies to put in place a strong, experienced management team. It is an exciting combination that I believe will produce benefits for patients and shareholders alike."

"I'm looking forward to working with the new board and our employees to continue the development of ARIKACE™ with a goal of commercialization," said Timothy Whitten, Insmmed's new President and CEO. "We have a substantial opportunity with ARIKACE™ in multiple indications and we are now in a strong financial position with the appropriate resources to move the drug forward."

The development of Insmmed's IPLEX™ product in areas such as Retinopathy of Prematurity will continue, and the company will also maintain the shipment of IPLEX™ to amyotrophic lateral sclerosis patients currently receiving drug until the present inventory is fully depleted.

RBC Capital Markets, LLC served as exclusive financial advisor to Insmmed on the transaction. Lazard Freres & Co. LLC served as exclusive financial advisor to Transave on the transaction. Greenberg Traurig, LLP served as Insmmed's legal counsel in connection with the transaction, and Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP served as Transave's legal counsel.

Additional Details

- The Series B Conditional Convertible Preferred Stock issued in connection with the transaction is non-voting and will convert into shares of Insmmed common stock upon the approval of Insmmed's shareholders. Insmmed expects to file a proxy statement with respect to the conversion of the Series B Conditional Convertible Preferred Stock with the Securities and Exchange Commission in the first half of 2011.

Immediately following such approval, the Series B Conditional Convertible Preferred Stock will convert into Insmmed common stock at a conversion rate of one-to-one, subject to adjustment. The conversion rate will increase in the event that there are accrued but unpaid dividends on the Series B Conditional Convertible Preferred Stock at the time of conversion.

- The Series B Conditional Convertible Preferred Stock, if not converted, will receive dividends at a rate of 12.5% per annum starting the earlier of (i) the one-year anniversary of the closing of the transaction and (ii) the first date upon which at least 50 patients have been given at least one dose in Phase III clinical trials for ARIKACE™, but in no event less than nine months from the closing of the transaction. These dividends may be paid in cash or stock at Insmmed's discretion.
- As part of this transaction, Insmmed has paid off Transave's existing debt facility of \$7.8 million.

Conference Call

Insmmed will host a conference call today at 8:30 AM ET to discuss this transaction. To participate in the live conference call, please dial 800-510-0146 (U.S. callers) or 617-614-3449 (international), and provide passcode 29839294. A live webcast of the call will also be available at <http://phx.corporate-ir.net/playerlink.zhtml?c=122332&s=wm&e=3566307>. Please allow extra time prior to the webcast to register, download and install any necessary audio software.

The webcast will be archived for 30 days, and a telephone replay of the call will be available for seven days, beginning today at 11:30 AM ET, at 888-286-8010 (U.S. callers) or 617-801-6888 (international), using passcode 69293823.

About Insmmed

Insmmed Incorporated is a biopharmaceutical company with unique protein process development and manufacturing experience and a proprietary protein platform aimed at niche markets with unmet medical needs. For more information, please visit <http://www.insmed.com>.

About Transave

Transave, Inc. is a biopharmaceutical company focused on the development of innovative inhaled pharmaceuticals for the site-specific treatment of serious lung diseases. The company's major focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced pulmonary liposome technology in areas of high unmet need in lung diseases. The Transave team is dedicated to leveraging its development and commercialization expertise, along with its intellectual property, to bring life-extending and life-enhancing medicines to patients. For more information about Transave's technology and development programs, visit www.transaveinc.com.

About eFlow® Technology and PARI Pharma

ARIKACE™ is delivered by an investigational eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for ARIKACE™. The investigational eFlow Nebulizer System uses eFlow Technology to enable highly efficient aerosolization of medication including liposomal formulations via a vibrating, perforated membrane that includes thousands of laser-drilled holes. Compared to other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size, and a high proportion of respirable droplets delivered in the shortest possible period of time. eFlow Technology is not an ultrasonic nebulizer technology. Combined with its quiet mode of operation, small size (it fits in the palm of the patient's hand), light weight, and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments. PARI Pharma focuses on the development of aerosol delivery devices and comprehensive inhalation drug development to advance aerosol therapies where drug and device can be optimized together. Online at www.pari-pharma.com.

Forward-Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to expectations regarding the anticipated benefits of the business combination, the results of clinical trials, the development of the combined company's products, the anticipated shareholder vote and the business strategies, plans and objectives of management, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, we may be unsuccessful in integrating the operations of the combined company, we may be unsuccessful in developing our product candidates, our expenses may be higher than anticipated and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2009 and Quarterly Report on Form 10-Q for the fiscal quarters ended March 31, 2010, June 30, 2010 and September 30, 2010. Readers are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

Important Information

Insmmed intends to file a proxy statement and other relevant materials with the Securities and Exchange Commission (the "SEC") to obtain shareholder approval of the conversion of the Series B Conditional Convertible Preferred Stock issued in the business combination into Insmmed common stock (the "Shareholder Approval"). INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT AND OTHER RELEVANT MATERIALS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY AS THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE SHAREHOLDER APPROVAL. The proxy statement, any amendments or supplements to the proxy statement and other relevant documents filed by Insmmed with the SEC will be available free of charge through the web site maintained by the SEC at www.sec.gov or by calling the SEC at telephone number 1-800-SEC-0330. Free copies of these documents may also be obtained from Insmmed's website at www.insmed.com or by writing to: Insmmed Incorporated, 8720 Stony Point Parkway, Suite 200, Richmond, Virginia 23235, Attention: Mr. W. McIlwaine Thompson, Corporate Secretary.

Insmmed and its directors and executive officers are deemed to be participants in the solicitation of proxies from the shareholders of Insmmed in connection with the Shareholder Approval. Information regarding Insmmed's previous directors and executive officers is included in Insmmed's definitive proxy statement for its 2010 annual meeting of stockholders held on June 9, 2010, which was filed with the SEC on April 30, 2010. Other information regarding the participants in such proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be included in the proxy statement to be filed in connection with the Shareholder Approval.

Cautionary Statement

The issuance of the securities in the transactions described in this press release have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or any state securities laws and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act and applicable state securities laws. This press release shall not constitute an offer to sell or the solicitation of an offer to buy the securities, nor shall there be any sale of the securities in any jurisdiction or

state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction or state.
