

INSMED INC  
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549  
SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

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## Forward-Looking Statements

This document 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

Insmed 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 with Transave into Insmed 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 Insmed with the SEC will be available free of charge through the web site maintained by the SEC at [www.sec.gov](http://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 Insmed's website at [www.insmed.com](http://www.insmed.com) or by writing to: Insmed Incorporated, 8720 Stony Point Parkway, Suite 200, Richmond, Virginia 23235, Attention: Mr. W. McIlwaine Thompson, Corporate Secretary. Insmed and its directors and executive officers are deemed to be participants in the solicitation of proxies from the shareholders of Insmed in connection with the Shareholder Approval. Information regarding Insmed's directors and executive officers is included in Insmed'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 document 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.



FINAL TRANSCRIPT

INSM - Insmmed Incorporated and Transave, Inc. Announce Business Combination- Corp call

Event Date/Time: Dec. 02. 2010 / 1:30PM GMT

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Financial Dynamics - IR

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Insmmed Incorporated - Director

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PRESENTATION

Operator

Good day, ladies and gentlemen and welcome to discuss Insmmed Inc. and Transave, Inc. business combination conference call.

My name is Ahmed and I will be your operator for today. At this time, all participants are in listen-only mode. Later, we will

conduct a question-and-answer session. (Operator Instructions). As a reminder, this conference is being recorded for replay

purposes. I would now like to turn the conference over to your host for today, Mr. Brian Ritchie, of FD. Please proceed.

Brian Ritchie - Financial Dynamics - IR

Thank you, operator and good morning, everyone. This is Brian Ritchie from FD and I would like to welcome you to today's call to discuss the Insmmed/Transave business combination that was announced today and closed yesterday.

On this call, we are joined by Mr. Donald J. Hayden, Jr., Transave's former Chairman, who will serve as Chairman of the combined entity; Dr. Mel Sharoky, Insmmed's former Chairman of the Board, who will serve as Director on the combined company's Board; Mr. Timothy Whitten, Transave's President and Chief Executive Officer, who will serve in the same role for the combined entity; and Mr. Kevin Tully, who will remain as Insmmed's Chief Financial Officer.

Mel will first give a brief overview of the strategic rationale for the transaction, followed by Kevin's review of the transaction terms. Don will then provide some further details on the combined company and lastly, Tim will briefly discuss the Insmmed value proposition. There will be a question-and-answer session following the prepared remarks. We would, however, ask you to please limit yourself to one question, so we have time for as many questions as possible.

Before we proceed with the call, I would like to remind everyone that the Safe Harbor language contained in today's press release also pertains to this conference call and webcast. Please go ahead, Mel.

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Mel Sharoky - Insmmed Incorporated - Director

Thank you, Brian. Hello, everyone. Welcome to what I believe is the defining moment for Insmmed and its shareholders. I am pleased to have the opportunity today to discuss with you the business combination we have completed with Transave, Inc., a privately held, New Jersey-based, biopharmaceutical company that is focused on the development of differentiated, innovative inhaled pharmaceuticals for site-specific treatment of serious lung infections.

From the outset of the strategic review, we have stated that our goal was to execute a transaction that had the potential to create substantial long-term shareholder value. We think we have accomplished that. Throughout the strategic review process, 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, which is a Phase III-ready product in multiple indications.

The drug's previously completed Phase II and earlier stage clinical studies highlight the potential of ARIKACE to become a leading treatment in two high-growth orphan indications, cystic fibrosis patients with pseudomonas lung infections and lung infections due to non-TB Mycobacteria 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.

As the extended timeline of the strategic review would indicate, and as we've communicated to you many times in the past, this was an exhaustive process where many assets and opportunities were considered. It is always easier to be a buyer than a seller, and with our significant balance sheet, we certainly were not constrained in any way by our financial position. Our objective all along was to complete a transaction that was in the best interest of all shareholders and we think we have done that with this transaction.

Kevin will get into the specifics of the transaction shortly, but I wanted to elaborate a bit on why the deal was structured so as to be closed and announced immediately. As I stated above, ARIKACE is Phase III-ready now. It simply requires the cash to continue moving the development program forward. Our strategic review sought exactly this type of late-stage asset and our due diligence determined that we should look to progress the development of ARIKACE as soon as possible.

Thus, we structured a transaction in a manner that allowed us to begin this clinical work in the most expeditious fashion possible. You will hear more shortly about the upcoming development plan for ARIKACE, as well as the substantial potential market opportunities. But I thought it was important for you to understand the rationale for why this transaction was put together in the way in which it was.

With that said, I am not only extremely excited about the ARIKACE asset, but also about the Board and management team charged with moving it forward as well. I truly believe the right team is in place to leverage this unique opportunity with ARIKACE for shareholders. So let me be the first to introduce you to and provide a bit of color on the new Chairman of Insmmed, Don Hayden, as well as the Company's new President and CEO, Tim Whitten.

Don has had an illustrious 30-year career in pharma and biotech, highlighted by a 25-year stint at Bristol-Myers Squibb where he held multiple senior-level positions. Tim has 25 years of industry experience, primarily focused on the commercial aspect of drug development. Of significance, Tim had a large hand in the commercial launch of Bristol-Myers Squibb's blockbuster cancer drug, Taxol.

Before I turn the call over to Kevin, I wanted to touch a bit on Insmmed's current plans concerning IPLEX. First, we continue to view IPLEX as a valuable asset. As such, the new Board and management team will decide over the coming months how best to leverage this asset. In the interim, Premacure's Phase II trial in retinopathy of prematurity with IPLEX continues and they have dosed two patients to date.

In addition, the expanded access program in Europe for IPLEX also continues, with our expectation being that our supply of IPLEX be fully depleted in mid-2011.

Finally, I want to thank all the shareholders of Insmmed for their continued support. We view this transaction as the rollout of a unique biotechnology company, one with an exciting near commercial asset, which is fiscally strong. I would now like to pass the call on to Kevin for a closer look at the details of the transaction. Kevin?

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Kevin Tully - Insmmed Incorporated - EVP & CFO

Thanks, Mel. To start, I would like to cover a few important points related to the deal structure this morning. Under the terms of the merger agreement, Insmmed acquired all of the outstanding capital stock of Transave and paid off approximately \$8 million of Transave's 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 \$0.71 per share and cash consideration of approximately \$561,000.

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 shareholders have a 53.3% interest on a fully diluted as-exercised basis.

Our net cash balance, as Mel stated, is approximately \$110 million and we are debt-free. More importantly, we believe that we have sufficient capital to bring ARIKACE to commercialization.

As a result of this transaction, we will have approximately 248 million shares outstanding, made up of about 156 million of common shares and about 92 million contingently convertible preferred shares. Further granular details concerning this transaction primarily related to the stock component of the deal can be found towards the end of this morning's press release.

Turning to the leadership structure of the Company, the Board will consist of three incumbent Insmmed Directors -- Mel, Dr.



Randall Whitcomb and Dr. Steinar Engelsen. We will have a strong and experienced management team that will be comprised of former Transave incumbent and incumbent Insmmed management.

In addition to Tim serving as President and CEO, and myself remaining in the CFO role, Dr. Renu Gupta will serve as Executive Vice President of Development and Chief Medical Officer. Dr. Gupta has substantial clinical development and regulatory experience within the class of compounds that ARIKACE belongs to.

Finally, Nick LaBella will continue to serve as Insmmed's Chief Scientific Officer. As you know, Nick has extensive drug development, clinical operations and regulatory (inaudible) experience. Transition logistics for the combined company, which are expected to be completed in the first quarter of 2011, are already underway.

Before I turn the call over to Don, I would like to echo Mel's sentiments regarding my excitement over this transaction. I believe

Insmmed and its shareholders have a wonderful opportunity with ARIKACE and that we have the appropriate team and the resources to successfully leverage that opportunity. With that, I will now turn the call over to Don.

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Donald Hayden - Insmmed Incorporated - Chairman

Thank you, Kevin. And good morning, everyone. Like Mel and Kevin, I am very excited about the opportunity presented by combining the strengths of Transave and Insmmed, and I am delighted to serve as the Chairman of the new Insmmed. Our combined company is now advancing a differentiated, innovative, late-stage opportunity in ARIKACE with the capital to support the continued development of this very important drug.

In addition, as Kevin noted, we have drawn upon the leadership in both companies to put in place a deep management team with the experience and success in areas that are critical to the future success of Insmmed as a company. It is an exciting combination that I believe will produce benefits for patients and shareholders alike.

Tim will go into more detail in just a moment on the Insmmed value proposition, but I wanted to take just a minute to discuss a few of the significant milestones that we have just ahead of us, which is yet another reason why we are all so enthusiastic about this combination.

Most near term, the Company expects to initiate Phase III clinical trials in cystic fibrosis and non-TB Mycobacteria in parallel in the second half of 2011 with results expected in the first half of 2013.

Also of importance, I would like to stress that both of our lead indications for ARIKACE, CF and NTM, are orphan areas with high

unmet medical needs, substantial market potential and limited infrastructure requirements for commercial infrastructure. We believe the differentiated profile of ARIKACE in the context of these two lead indications offers us the potential to create significant value. I will now let Tim walk you through the ARIKACE-focused Insmed value proposition. Tim?

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Timothy Whitten - Insmed Incorporated - President & CEO

Thank you, Don and hello, everyone. Before I get into the bulk of my comments, let me first say what a privilege it is to serve as President and CEO of Insmed. I really truly believe that we have some tremendous opportunities ahead of us and I look forward to working with our stakeholders to successfully realize all of these opportunities.

You have already heard a bit about why Mel, Kevin, Don and I are so energized about being a part of this Company and what drew us all to the ARIKACE opportunity. So for the next few minutes, I would like to briefly expand on the attributes we believe make Insmed such a potentially attractive investment. I would also like to give you a bit more information on ARIKACE, which is our Company's primary Phase III-ready asset.

ARIKACE, which is a liposomal formulation of amikacin for inhalation, represents an attractive late-stage opportunity for Insmed and I will point out that the Company owns worldwide rights to the compound, so ARIKACE is truly a global opportunity. As you have heard, the drug is Phase III-ready in both pseudomonas lung infections in cystic fibrosis patients and also we expect to file with FDA in the first quarter 2011 to enter Phase III trials for treating lung infections due to non-TB Mycobacteria, which is sometimes known as NTM for short.

We believe ARIKACE has already generated best-in-class Phase II efficacy and safety data in CF patients with pseudomonas lung infections, and we are excited about taking the drug into Phase III clinical trials.

To put the risk profile in perspective, amikacin is an FDA-approved antibiotic in the aminoglycoside class that has delivered primarily via intravenous administration. It has long been viewed as one of the most effective treatments available for gram-negative infection such as pseudomonas and also for treating NTM.

As I said, ARIKACE is a liposomal formulation of amikacin that is designed specifically, specifically for delivery of antibody directly to the lung to treat serious pulmonary infections. Both cystic fibrosis and non-TB Mycobacteria are orphan indications, both of which are growing in size and have high unmet medical needs. These are serious, serious diseases and we think ARIKACE has the potential to address some of these unmet needs with a potentially better efficacy and safety profile.

Making the Insmmed opportunity even more compelling is the presence of multiple significant near-term milestones. Don mentioned these, but they bear repeating. We believe we will initiate Phase III clinical trials in CF and NTM in parallel in the second half of 2011 with results expected in the first half of 2013. And with positive results, we believe there is a unique opportunity to create substantial shareholder value.

From a commercial standpoint, the CF and NTM treatment populations are highly concentrated in specialty treatment centers at or near major hospitals, which allows for efficient commercialization. Therefore, we plan to commercialize ARIKACE ourselves in the US and outside the US, we will likely see commercial partners.

Aiding ARIKACE's commercial potential is a strong intellectual property portfolio, including a recently issued composition of matter patent in the US. Our development and commercialization plans are supported by a strong balance sheet, which has been previously stated several times is that it will include a net cash position of about \$110 million and this substantial cash position is certainly rare for a biotech company in a similar stage of development.

Also, while Kevin mentioned this earlier, it is a critical point and worth repeating. We project that the Company will have sufficient cash to advance ARIKACE to commercialization. ARIKACE has the potential to be the source of its own product pipeline. Behind CF and PA and non-TB Mycobacteria are a number of other potentially significant market opportunities for ARIKACE, including, for example, non-cystic fibrosis bronchiectasis patients that have pseudomonas lung infections for which the Company has already completed a Phase II clinical trial.

Before we move to the question-and-answer session, I would like to say that I am looking forward to working with the new Board and also the new team here at Insmmed. We have a lot of work to do in the months ahead, but we are highly, highly motivated by the opportunities we have presented to you this morning.

I'd like to conclude by comments and my remarks by thanking all of our stakeholders, including and especially our employees for their continued dedication, as well as investors for their interest in the Company. So with that, to give the operator a heads-up, I will pass the call back over to the operator for the question-and-answer session. Operator?

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## QUESTIONS AND ANSWERS

Operator  
(Operator Instructions). Brett Reiss, Janney Montgomery Scott.

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Brett Reiss - Janney Montgomery Scott - Analyst

Good morning, gentlemen. Could you -- do you have a number on what the market opportunity of ARIKACE is and do you have a budget number on what the cost of bringing it through the Phase III trial might be?

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Timothy Whitten - Insmmed Incorporated - President & CEO

Sure. This is Tim Whitten. I will take that question, especially the first part of that. So our two lead indications are both orphan indications. Cystic fibrosis patients have pseudomonas lung infections, as well as patients that have lung infections due to non-TB Mycobacteria. Both of those have significant market potential and the way we estimate the market is that there is more than \$1 billion in market potential for those first two indications alone.

In terms of the cost of the trial, we will have -- for cystic fibrosis, we will have one trial for the US and one primary efficacy trial for the EMEA or for Europe, as well as a long-term extension trial. Each of those three trials will cost approximately \$20 million, \$20 million to \$25 million and the trial for NTM, which, again, we are filing with the FDA in the first quarter, we expect that that trial will cost us about \$10 million to \$12 million.

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Brett Reiss - Janney Montgomery Scott - Analyst

All right, so three times \$20 million is \$60 million, plus the \$10 million or \$15 million, so it is all under \$100 million.

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Kevin Tully - Insmmed Incorporated - EVP & CFO

Well under.

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Timothy Whitten - Insmmed Incorporated - President & CEO

Yes

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Kevin Tully - Insmmed Incorporated - EVP & CFO

We have got sufficient runway to easily cover our clinical trials and give us a good launch, getting ready for launch for commercialization.

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Brett Reiss - Janney Montgomery Scott - Analyst

Okay. Now, December 15 is coming upon us. If the stock does not move over \$1, it is going to get delisted. If that happens, what kind of reporting requirements do you have? And if they are less than as a listed company, do we have a commitment from the new management team that the reporting will be as vigorous as if it was a listed company?

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Kevin Tully - Insmmed Incorporated - EVP & CFO

Well, first of all, there is not a dropdead deadline for December 15 for a delisting. We do have the opportunity to take a 180-day extension and we believe we have got sufficient good news coming out that will help us. And if we don't meet the full 10 days by December 15, we will simply take the full 180-day extension because we think we have got some good news coming out

over the several months, which will help us in that regard.

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Brett Reiss - Janney Montgomery Scott - Analyst

That is good to hear. One final question, because I haven't been able to ask anything in the last six months, and I forgot what I was going to say, so I will drop back into queue.

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Operator

[David Graysimon].

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David Graysimon - - Private Investor

Hi, I have been a shareholder for many years and am I reading the press release right that shareholders do not have a right to approve, that there won't be an up or down vote on this?

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Kevin Tully - Insmmed Incorporated - EVP & CFO

That is correct. This deal is concluded. There will be an opportunity to vote on the convertible preferred into common, which will be done as part of a proxy in 2011.

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David Graysimon - - Private Investor

Okay, but with all due respect, shareholders own the Company. Why wouldn't they have a right to vote? I want to be respectful, but this is an outrage. Why wouldn't shareholders have the right to vote since they own the Company?

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Mel Sharoky - Insmmed Incorporated - Director

Let me address that. Let me explain this transaction structure. Transave has a Phase III-ready asset, which needs cash to move it along, move it forward. Insmmed has cash, which it wanted to put to work in a late-stage asset. We have talked about that; that is what we have been looking for for the last 18 to 20 months. And our due diligence determined this was a good fit and that ARIKACE should be progressed as quickly as possible. So this structure was put in place for that reason. It was the most expeditious route to move this promising development program forward quickly.

The opportunity for shareholders to vote will be, as Kevin has indicated, when we put out a proxy that deals with the preferred shares being converted to common. So this was not a deal that was done for any reason other than expediting the development of this program. As you know, in the development of pharmaceuticals, time is everything and with a product like ARIKACE with unbelievable Phase II data to move this into Phase III as quickly as possible was the motivation.

And recall that this is not the only transaction that has been completed by the Insmmed Board without shareholder approval. If you recall, I think we resulted in making a decision that gave the Company \$130 million from the Merck transaction that also was completed without shareholder approval.

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Donald Hayden - Insmmed Incorporated - Chairman

And this is Don Hayden. I'd just, Mel, just like to build on that a little bit. This transaction was structured as it was for all the reasons Mel just described and I think to maybe translate that into the benefits, it was announced this morning and the new management team and the new company is up and running as a company today, doing the work necessary to advance ARIKACE into those Phase III clinical trials and realize the value of having done that as quickly as possible.

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David Graysimon - - Private Investor

All right, thank you. I want to be respectful because I want to be able to take questions in future calls. So, thank you. I hope we have some good news coming because shareholders have been put through a lot of pain. They honestly have and thank you, thanks for taking the call.

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Mel Sharoky - Insmmed Incorporated - Director

Thank you for the question.

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Operator

[Craig Glass], Private Investor.

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Craig Glass - - Private Investor

Hey, good morning. How are we doing, guys? Part of my question was answered already, but it is to the delisting. What about a share buyback? It seems like we have enough money to continue this process, \$75 million maybe cutting the deal here. What about doing a share buyback? Let's show some strength.

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Mel Sharoky - Insmmed Incorporated - Director

Well, let me address that. I think one of the motivating factors to put these two companies together was the assessment of where ARIKACE stood and how the money that Insmmed brings to the program could be used and when we look at it, the opportunities around this product, as Tim has indicated, with multiple indications really is going to require this bank account that we have here.

The development program to be able to do the critical trials in parallel for both non-tuberculosis Mycobacteria, as well as the cystic fibrosis and possibly one of the other indications, are just, we believe, a better use of the money at this point in time and with the opportunity to bring it to commercialization.

So while we could have a discussion/debate about the value of share buyback, at this point in time, we think the money is better used in the development program and it allows our shareholders to know that we believe that we don't need to go back to the marketplace in order to launch this product if and when it is approved.

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Craig Glass - - Private Investor

Okay. What about the cost of manufacturing IPLEX? Do we have any data on that as we are coming closer to being depleted?

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Mel Sharoky - Insmmed Incorporated - Director

Well, the answer around IPLEX is the following. As you have indicated and I have said on quarterly calls, our inventory most likely will be depleted in the second half of midyear 2011. And it is obviously related to -- that change is based on how many patients are still on the drug.

The concept of manufacturing additional IPLEX has always been put on the back burner with the thought that as data surfaces from -- some data from the ALS patients, but more importantly probably the retinopathy of prematurity that is being conducted by Premacure would then be able to have us look at what do we do with that asset.

So it's not that IPLEX is no longer an asset, it is just a different way to approach it. I mean the cost to manufacture IPLEX is enormous and the quantity that would be needed for retinopathy of prematurity for that indication is a much smaller amount.

So we have been actually kind of very careful in not making a commitment to manufacture additional IPLEX until we get the results of the study in particular for retinopathy of prematurity.

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Craig Glass - - Private Investor

Are we hoping that some of the cost basis for production of IPLEX is going to be shared with possibly Premacure from the results that they have?

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Mel Sharoky - Insmmed Incorporated - Director

Well, our relationship with Premacure is one where we've supplied drug, we've supplied dossier, regulatory information and have supported their trial at this point in time, but any further decisions about what that relationship ultimately will look like, we are going to look into in 2011 under the new group and the new regime and as data surfaces, try to make an assessment of that.

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Craig Glass - - Private Investor

Sure. All longs here that have been through all this pain I am sure that are still here firmly believe in IPLEX and its potential. We want to hear about IPLEX definitely.

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Mel Sharoky - Insmmed Incorporated - Director

Well, and I have tried to respond to your question. I hope I have.

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Craig Glass - - Private Investor

Yes, for now. Okay, well, thank you very much, guys. Look forward to some more questions on the next quarter.

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Operator  
Shekhar Basu, Basu Capital.

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Shekhar Basu - Basu Capital - Analyst

Good morning. Can you please help us understand the Phase II data so far achieved on the liposomal amikacin and what endpoint you are planning on in the Phase III? Is it FEV1 or are you planning on reduction in exacerbations as well?

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Timothy Whitten - Insmmed Incorporated - President & CEO

Sure. This is Tim Whitten. I will take that question, provide a response. Let me set the background a little bit in terms of inhaled treatment before I give you the data on ARIKACE in cystic fibrosis patients that have pseudomonas lung infections. But inhaled therapies, inhaled antibiotics, there are two approved inhaled antibiotics in the US. They are both given on a 28-day on and a 28-day offcycle and that cycle is repeated on a chronic basis.

And in the most recent North American cystic fibrosis conference, there was data presented on both of those compounds that showed that their efficacy declines over time. In fact, by the end of their third cycle, the pulmonary function of those patients was below baseline and importantly in that 28-day off period, efficacy declined in that point too. So what you have is sort of going down the escalator on pulmonary function from after that first cycle.

When you look at the ARIKACE data, and these are from patients in both the US and Europe that were combined into one trial, what you see is a few things that are really important. At the end of 28 days, you see a statistically significant difference from placebo in improvement in pulmonary function and importantly something that has never been seen before with an inhaled antibiotic is you see that that pulmonary function in the Phase II trial was maintained for that off-treatment period. So that sustained effect of ARIKACE as an inhaled antibiotic again has never been seen before in a Phase II trial or a Phase III trial and that is really important.

We also have data, and we are the first Phase II compound to ever have multi-cycle data, we now have data out to over a year with the compound and a 28-day on and actually a 56-day off treatment cycle and again, 56 days off has never been studied before. And what you see is you don't see that down-the-escalator pattern. You see lung function being maintained in the off-treatment period at least at about 50% to 70% and so that is a really important benefit.

So you are seeing two things. You are not seeing down-the-escalator in terms of pulmonary function and you are seeing the benefit in the off-treatment period being maintained. The other thing we have seen in each of our Phase II trials, we have seen a statistically significant reduction in pseudomonas and that is really important because this is an antibiotic.



The last point I want to make is that ARIKACE we believe will be the first once-a-day inhaled antibiotic into the marketplace. If you look at the current therapies, they are given two to three times a day. In fact, the market leader, which is TOBI or tobramycin, is given twice a day for 15 to 20 minutes, so a total of 30 to 40 minutes a day. ARIKACE will be delivered once a day for 12 minutes.

So just think about that for a minute. If you are a patient and you are getting this treatment 28 days on, 28 days off, let's say for a year, with ARIKACE versus the market leader, you are saving 170 doses and you are probably saving more than 50 hours of your life, which is really important for these patients who are getting three to four hours of treatment every day. So we feel really good about where we stand right now with ARIKACE in the clinic and that is why we so are so excited about taking it forward into Phase III trials.

In terms of the trial design, we have one trial in Europe that is a multi-cycle trial with the primary endpoint being change in pulmonary function at the end of the third cycle. We have a second trial for the US that is looking at time to pulmonary exacerbation as a primary endpoint with the secondary endpoint being change in pulmonary function. And that trial is compared to placebo. The first trial, if I didn't mention, is head to head versus tobramycin, the market leader. The US trial is versus placebo. Each of those patients then go into an open-label study.

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Shekhar Basu - Basu Capital - Analyst

Thank you. So the idea is not to maintain pulmonary function, but to improve it over and above tobramycin, correct?

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Timothy Whitten - Insmmed Incorporated - President & CEO

Well, the trial in Europe is going head to head with tobramycin and based on the recent data with tobramycin and our Phase

II data, we do plan to look at the superiority of our compound in terms of change in pulmonary function versus TOBI.

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Shekhar Basu - Basu Capital - Analyst

Sorry, one last question. Will this mean Pulmozyme nonresponders?

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Timothy Whitten - Insmmed Incorporated - President & CEO

In our trials to date, if patients were on Pulmozyme, they could stay on Pulmozyme. If they weren't on Pulmozyme, then they

wouldn't add it. The same goes for other common treatments. So patients -- we will take allcomers when it comes to whether

they are on Pulmozyme or not.

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Shekhar Basu - Basu Capital - Analyst

Thank you very much.

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Operator

[Greg Mansuri], (inaudible) Asset Management.

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Greg Mansuri - - Analyst

Yes, thank you. I have about six questions, if you don't mind. First question is approximately how much of the venture capital firm is invested in Transave to date?

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Donald Hayden - Insmmed Incorporated - Chairman

The venture capital investment in Transave to date, this is Don Hayden, is approximately \$100 million, a little more than that.

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Greg Mansuri - - Analyst

And the accumulated deficit would be approximately the same?

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Donald Hayden - Insmmed Incorporated - Chairman

Yes, it would be.

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Greg Mansuri - - Analyst

And what happens if the shareholders don't vote to approve the convertibility of the preferred?

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Kevin Tully - Insmmed Incorporated - EVP & CFO

They remain as preferred stock and there could be -- a further proxy could be put forward in the future. There are dividends associated with those, so they would remain on the balance sheet.

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Greg Mansuri - - Analyst

Is there a fixed liquidation preference and a maturity date for this preferred?

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Kevin Tully - Insmmed Incorporated - EVP & CFO

I don't believe there is a fixed liquidation preference and I will have to check on the maturity date for those. I will get that information, feed it on to Brian Ritchie and we can shout that out later on.

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Greg Mansuri - - Analyst

Understood. Now, how does this compare to Nektar's inhaled amikacin program? Can anyone speak to that?

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Donald Hayden - Insmmed Incorporated - Chairman

Sure, I can. When you think about ARIKACE, I think what you need to think about first is the liposome, the formulation technology, because that is really what differentiates ARIKACE from any other particular amikacin compound. And the liposome does two or three really important things.

Number one, with the liposome, you get sustained lung deposition. That is we get a lot of drug in the lung and we keep it there, which means that you have the potential for better efficacy and you have once-a-day dosing. For example, if you just took amikacin or tobramycin off the shelf and inhaled it, the half-life in the lung of those compounds is about an hour and a half.

When you look at ARIKACE, the half-life in the lung is biphasic and up to about 48 hours. So we are, again, putting a lot of drug in the lung and we are keeping it there.

The other advantage you get from ARIKACE, and in particular we are focused on chronic administration, is amikacin is an FDA-approved compound, it has well-established efficacy in pseudomonas, as well as non-TV Mycobacteria infections. But the issue with giving it IV has been that the serum levels that you get that result in oto and nephrotoxicity in some instances.

With ARIKACE, you get levels of drug and the systemic circulation that are well below the levels known to cause to oto and nephrotoxicity. So that is what you get with ARIKACE. Whenever you deliver it specifically for cystic fibrosis patients that you won't see with any other formulation of amikacin is pseudomonas produce these biofilms that protect the bacteria and allow it to grow in a protective environment. ARIKACE is the only aminoglycoside that has ever been shown to penetrate that biofilm and so it gets to the site of the infection better than with any other aminoglycoside that is not in our liposomes.

And for NTM, you have the advantage of non-TB Mycobacterias in intracellular bacteria. That is it grows inside the macrophages and our liposomes cause ARIKACE to be preferentially taken up into the macrophages and again get to where the infection is growing and residing. And that is one of the reasons why the NIH actually contacted us to do a trial with ARIKACE in non-TB Mycobacteria lung infections. And the liposome is also the reason or one of the main reasons why the FDA considers ARIKACE a new chemical entity that is distinct and different from amikacin.

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Timothy Whitten - Insmmed Incorporated - President & CEO

And just to step back a little bit, ARIKACE, as a product, is built off of the unique liposomal technology that was developed at Transave, technology that really was designed specifically to deliver drugs into the lung. And as Tim said, the benefits derived from that technology and the delivery of amikacin through ARIKACE is you get sustained deposition of high levels, high concentrations of amikacin at the site of infection in the lung. You get penetration of the biofilm, which allows the active drug to be delivered directly to the site of infection, the bacteria and that sustained deposition provides for that once-daily treatment that Tim described earlier, which is so important when patients are being treated chronically for lung infections.

So we are excited about the technology and that technology I think provides features and benefits that are unique to ARIKACE, not available with currently marketed products and not available with products that are in development elsewhere.

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Greg Mansuri - - Analyst

Okay, thank you. Two last questions. One, there has been a lot of talk from a number of people on this call on the

management

side about how, I am paraphrasing, how exciting this transaction is. Will any of you commit to buy stock concurrent or shortly thereafter? Has anyone made any plans about buying stock in the Company to show their belief and the excitement of this transaction?

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Mel Sharoky - Insmmed Incorporated - Director

Well, I think the answer to that is that we have always, for the last 20 months, you haven't been able to ask questions, we haven't been able to talk to you because we have been in this transaction mode and we have not been able to do anything regarding the stock as individuals. So as we go forward, and when and if the window opens up for us, we will always consider that.

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Donald Hayden - Insmmed Incorporated - Chairman

Yes and I would echo that.

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Greg Mansuri - - Analyst

Okay, and lastly, maybe you can just -- someone had asked the question beforehand about buying back stock and I understand, post this transaction, you guys expect to have something like \$110 million and then doing the math regarding advancing the clinical trials, it is going to cost some amount less than that. So it seems like there is still some, for lack of better terminology, free cash that the Company would have access to and I guess I am just trying to understand, looking at where the stock is versus where the Company is on a cash-per-share basis, it looks like, prior to this transaction, the Company had close to \$1 a share in cash. So I guess what I'm trying to understand is why would the Company not deploy some of its excess cash to buying back stock if you would be effectively buying back stock at a tantamount to a discount to cash? Please explain this to me.

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Donald Hayden - Insmmed Incorporated - Chairman

It is Don Hayden. Let me take a shot at building on what Mel had said earlier. I think that the clinical development plans for ARIKACE in pseudomonas infections in cystic fibrosis patients and in non-TB Mycobacteria are very focused, tightly developed plans. And what we have in ARIKACE is the opportunity to bring the product through Phase III development for two indications each in the US and Europe. And that is the plan that Tim described earlier and the cost that Tim described earlier.

But delivering Phase III data alone is not the means by which you deliver shareholder value with a pharmaceutical or biotech company. We believe it is important to have the opportunity to advance ARIKACE through to commercialization to secure

approval of the product and to launch the product. In company after company, that is the means by which you build true value

for shareholders. So to run in affect at the risk of not being able to do that by reducing the cash balance of the Company at the outset to us at least doesn't seem like the most effective way to deliver shareholder value.

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Mel Sharoky - Insmmed Incorporated - Director

And if I could add one thing. When you are doing drug development and clinical trials, things occur. A lot of times, there are setbacks, but sometimes you get a surprise and you discover something that really is special and if you think about, and you will get to know the Company better I think over the ensuing months, but when Tim was talking about the non-tuberculosis mycobacterium, that would be a perfect example.

The trials that have been conducted and the focus on the cystic fibrosis and then you have the NIH come and approach the Company and say, listen, we would really like you to do something with ARIKACE in this indication. I mean that just doesn't happen that often and when you are in that situation and you have been given the opportunity possibly to have support from that kind of organization and possibly the regulatory agency, you have to take that opportunity.

And if we were to use the cash to buy back stock, I am not sure we could do that. We would have to go out into the marketplace to raise money to convince people that this is a real opportunity rather than be able to feel comfortable that, with the number of trials we have to do and the commercialization, I think we just have the right amount of money. I don't think there really is excess here.

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Kevin Tully - Insmmed Incorporated - EVP & CFO

I agree. The last thing we would want to do is get this premier product and then starve it at launch. We want to do this right, we want to make sure that we hit the market appropriately and we want to make sure we keep our powder dry so we do that right at the end of the game when we get across the finish line. So I echo those sentiments that both Don and Mel have just said.

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Greg Mansuri - - Analyst

I understand. Thank you, everyone, for taking these questions.

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Operator

[Bobby Cohen], (inaudible) Group.

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Bobby Cohen - - Analyst

Hi, guys. Thanks for taking my call and it looks like a real good combination. My focus is kind of on the opposite side of everyone else so far. I get it. I am connecting the dots. I see the pedigree both on the investor side and the management team at Transave.

My question to you guys is, with the potential new investor base, I would like to know if the stock was to trade at a base always on fundamentals, would you consider doing a secondary if the stock was to trade at \$5, \$6, \$7, \$10 because I get it? You have something so special. I want to make sure you have enough money.

It is unfortunate what has happened to the shareholders prior to this event, but I do believe that the new management team has to monetize to everyone going forward. So I get it. I am connecting the dots. I know you guys are talking code. You guys believe you have it. So my question is would you consider, if the stock was to trade significantly higher based on fundamentals, would you think about raising additional capital but at a significantly higher level?

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Mel Sharoky - Insmmed Incorporated - Director

It's a great question and the answer is yes. I think that we are a public company and I think that based on where we are at, where you go and what develops over the ensuing years, months, that we are always considering that, just like we are always considering opportunities. Over the last 20 months while we have been in radio silence, and I know how difficult that has been for shareholders, we have spent a lot of energy looking at a lot of different options for the Company.

So if we are as successful as we believe we are going to be around this table, and there is a significant appreciation in the stock and we believe that the money that we would raise in the secondary could be used to move forward a clinical program, a new indication, something else that is developed in our R&D group, then the answer would be yes if we thought that we could use that opportunity to increase shareholder value. I don't think we would do it just to raise money, but we would do it if we saw an opportunity.

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Bobby Cohen - - Analyst

Yes, I mean I get it. I mean I took a hard look. Again, the pedigree, the investors that were in the private company, Transave, the management team, I mean I think it is going to be a homerun. It is unfortunate that there is a lot of old investors that have, over the years, have gotten their legs blown off, so to speak, but we can only move forward. We can't go backwards and I think you guys are going to do a terrific job and I just want to say good luck.

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Donald Hayden - Insmmed Incorporated - Chairman

I appreciate that and just to build a little bit on what Mel said. A really good position to be in as a company is in a position to not have to raise capital, but to be able to make choices around what we do going forward. And I think that is one of the reasons why the four of us sitting here today are particularly excited about this opportunity. We believe we have a very good product with a clear plan that has near-term deliverables and the capital necessary to get there. We don't have to raise capital,

but to

Mel's point, we will obviously look at circumstances as we go forward and make decisions around that.

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Bobby Cohen - - Analyst

Yes. Okay, guys. Thanks, again, okay?

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Operator

Jamie (inaudible), Moab Capital (inaudible).

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David Sackler - Moab - Analyst

Hi, guys. It's David Sackler calling from Moab. Good morning. Well, first, a comment. I mean I would reiterate the notion that

has been raised that a transaction of this size, this transformative that does not go to a vote of shareholders is highly unusual

and is pretty disgusting, frankly.

That said, we want to try and understand the Transave opportunity. I had a couple of specific questions. I assume, given the

length of time between now and the initiation of Phase III, that the Company has not met with the FDA and has not designed

a Phase III protocol, is that correct?

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Donald Hayden - Insmmed Incorporated - Chairman

No, it's not. Tim?

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Timothy Whitten - Insmmed Incorporated - President & CEO

No, that is not correct actually. We have agreement with both the EMEA for the Phase III trial design, the endpoint and the

endpoints for the trial for Europe or the EMEA and we also have agreement with the FDA on the primary efficacy study, as I

mentioned before, that would take the drug to approval in the US. And I walked everybody through kind of what those two

trial designs are and we have full agreement with both regulatory authorities going forward in the cystic fibrosis patients that

have pseudomonas lung infections.

For NTM, as I mentioned in my remarks, we plan to file in the first quarter of next year to the FDA for our proposal for going into

Phase III. We have already had the correspondence with them, discussions with them, so we are filing again to go into Phase III

for NTM in the first quarter of next year.

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David Sackler - Moab - Analyst

Okay, so I might have missed it, but I just have two specific questions. One is the Phase III protocol that you have agreement

with the FDA on, is that running against placebo or is that against TOBI or the other drug that you mentioned that is being

used?

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Timothy Whitten - Insmmed Incorporated - President & CEO

Sure. So for the US, for the FDA, we have one primary efficacy study, that is ARIKACE versus placebo with a primary endpoint of time to pulmonary exacerbation with a secondary endpoint of change in FEV1, pulmonary function -- sorry -- pulmonary function, yes.

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David Sackler - Moab - Analyst

Okay. So pulmonary exacerbation is measured by what?

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Timothy Whitten - Insmmed Incorporated - President & CEO

So there are very specific criteria that we are using to measure exacerbations. We consider that proprietary right now with the FDA and we may release that at some point in the future, but it is a very well, commonly known criteria that we've worked specifically with the FDA for CF patients that have pseudomonas lung infections.

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David Sackler - Moab - Analyst

Why would it be proprietary? That makes no sense. How can we evaluate the likelihood of the trial success or failure if we don't even know what the primary endpoint is measuring?

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Timothy Whitten - Insmmed Incorporated - President & CEO

So I think we will release more of that information, but the reason we say it is proprietary is because other companies out there that haven't gone to the FDA and haven't worked through what the endpoint is. We think that is a competitive advantage.

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David Sackler - Moab - Analyst

So why? You have an orphan drug designation. You believe that there is nothing in development that is anywhere close to your drug. You have said it 100 times and you are doing a transformative acquisition with no vote and telling us that we can't even assess the merits of the clinical trial because you won't tell us what it is measured on?

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Donald Hayden - Insmmed Incorporated - Chairman

Let me take a shot at this. It is Don Hayden. The two trials in the US and Europe are approved by the regulatory authorities and ready to be initiated. In Europe, the trial design is a comparison versus TOBI, primary endpoint of pulmonary function, FEV1, very straightforward and ready to go.

In the US, similarly, the trial is ready to go. The primary endpoint is time to pulmonary exacerbation with a secondary of change in pulmonary function. We believe that we've worked very hard to get approval of a trial design, which will allow us to efficiently effectively study the drug and get to what we expect will be a positive answer on the efficacy of the product. There is no benefit to disclosing the exact trial design at this point in time. As we get --.

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David Sackler - Moab - Analyst



Well, I will tell you what the benefit is. Your stock is down significantly this morning. The market is voting with their feet and telling you they don't get your deal, they don't like your deal, they don't like the way it was structured and then you are not even allowing people like us who might want to evaluate the drug on the merits to know whether or not it has a shot at the FDA of hitting its primary endpoint in the Phase III. I couldn't tell you today whether the hurdle is impossible or whether it is really easy and all I have to base it on is your word. These are -- and your word frankly, if you look at the stock, isn't so great today.

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Donald Hayden - Insmmed Incorporated - Chairman

And I think you have more than enough information on the profile of ARIKACE, the data on the product to date and the design of the clinical trials to make that determination. We will provide full details on the clinical trials as it becomes appropriate to do that and as it is to the Company's benefit to do that.

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David Sackler - Moab - Analyst

This is getting nowhere, but the Company is owned by your shareholders and we have a right to a vote, we have a right to information. It is not owned by management, so you guys really need to realign your thinking; otherwise, you are never going to return value for shareholders.

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Donald Hayden - Insmmed Incorporated - Chairman

Well, I think they are two separate issues. I mean obviously you are upset about the structure. We got that and our job is to be smart enough to maintain and release information at the appropriate time based on the work we do. So when you do drug development, and you can talk to anybody and you are a very smart man and you know that if we give out information that, in any shape or form, could give an advantage to a competitor, okay, and when we say, well, we know nothing else is in development, that is based on our current knowledge. We don't know that, so a lot of work went into the design.

I think we just described the design in Europe. I think Don just told you what the design in Europe was. So I am confused about

-- there are two separate issues. I got you are upset about the structure. But let's go back to the design. What question did we not answer?

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Operator

[Don Ford], Private Investor.

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Don Ford - - Private Investor

Hi, guys. I have got two hopefully simple questions. The first is what is the revenue of TOBI on an annual basis?

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Mel Sharoky - Insmmed Incorporated - Director

Certainly. According to the IMS data, the global revenue for TOBI is about \$320 million with two-thirds of that, approximately two-thirds of that being from the US.

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Don Ford - - Private Investor

Okay, so you have got a \$1 billion market potential. Where is the rest of that coming from?

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Mel Sharoky - Insmmed Incorporated - Director

Remember, TOBI's sole approval is for cystic fibrosis patients that have pseudomonas lung infections. ARIKACE has the potential

not only in -- cystic fibrosis patients have pseudomonas lung infections, but that total that we talked about also included the non-TB Mycobacteria potential use.

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Don Ford - - Private Investor

Okay, so you see that as a larger market.

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Donald Hayden - Insmmed Incorporated - Chairman

Yes, for which TOBI is not indicated and is seldom if ever used.

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Don Ford - - Private Investor

Okay. My second question, after the deal, what is the cash price per share going to be?

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Kevin Tully - Insmmed Incorporated - EVP & CFO

Cash price per share basically will be the same, not too much different. We are at \$0.92 previously. We have gone about the same level and that was based on \$120 million cash and we have got a net of \$110 million. So on a net cash per share basis, it would be the same. We are diluted by 50% obviously with the number of shares, but the cash level will remain relatively the same, apart from paying the debt off. So I think, in answer to your question, it will -- previously \$0.92, number of shares available will be about 55.

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Don Ford - - Private Investor

Okay, thanks.

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Operator

Brett Reiss, Janney Montgomery Scott.

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Brett Reiss - Janney Montgomery Scott - Analyst

Hi, the question I had forgotten to ask you, the apportionment of the common stock in the transaction and the (technical difficulty)

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Mel Sharoky - Insmmed Incorporated - Director

Hello? Operator, are you still there?

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Operator

Yes, sir. Let me just find Brett. Brett, your line is open.

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Brett Reiss - Janney Montgomery Scott - Analyst  
Can you hear me?

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Mel Sharoky - Insmmed Incorporated - Director  
Yes, we can now. We lost you.

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Brett Reiss - Janney Montgomery Scott - Analyst  
Great, great. Okay. The apportionment of the common versus the preferred, can you give us some color on that? I guess Transave would have preferred all preferred, you would have preferred to give them all common and the one-quarter, three-quarter structure is what you ultimately negotiated. If you could just help me understand that a little bit.

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Kevin Tully - Insmmed Incorporated - EVP & CFO  
The 25 million basically gives just under 20%, which we were able to close the deal on because it was under 20%. The convertible will take it from 20% to the 46.7% if it is fully converted from preferred to common. And that latter point will need a shareholder vote.

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Brett Reiss - Janney Montgomery Scott - Analyst  
Okay, and I just want to make sure, subject to the regulators doing what you think they are going to do, you are confident that you are going to be able to get an extension and the stock will not delist?

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Kevin Tully - Insmmed Incorporated - EVP & CFO  
Yes, we have already been in touch with NASDAQ and confirmed that our extension is available to us.

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Brett Reiss - Janney Montgomery Scott - Analyst  
Okay, thank you for answering all my questions and I wish you good luck.

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Timothy Whitten - Insmmed Incorporated - President & CEO  
Thank you.

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Mel Sharoky - Insmmed Incorporated - Director  
Thank you.

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Operator  
That concludes the question-and-answer session. I would now like to hand the call back to Tim Whitten for closing remarks.

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Timothy Whitten - Insmmed Incorporated - President & CEO  
So, Mel, I think you have the closing remarks.

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Mel Sharoky - Insmmed Incorporated - Director

Yes, I just want to say that, and I think the question was appropriate asking us about the clinical design, and I hope -- I think you had already hung up. I hope that you understand there are things that we feel comfortable in sharing and there are things that we don't. Although I think the design of the trial was described by Don.

But what I want to say is this. This has been a long process. We sold our asset to Merck for \$130 million and we have spent an extensive period of time looking at a number of different opportunities over the last 20 months. And I have been doing -- I have been in this industry for quite some time, involved with a lot of successful programs and I've met a lot of management teams. And I just have to say, and I think it will be shown over time, upset about the deal structure, everyone has the right. Where the stock is trading at today, I don't control where the stock trades at.

What I can share with you is what I hope we got across in an hour and we will over the ensuing days and weeks as we meet with various investors is that this is a remarkable opportunity. This is a drug that is well-known. It is an aminoglycoside. It has been around a long time. It is a potent drug. It is being delivered in a unique system, a liposome. It is being delivered via an unbelievable delivery system that is extremely unique. It is convenient. It has fantastic Phase II data and it is in a category where Phase II data generally translates to Phase III results.

Now we all know that clinical trials go where they go, but it is a remarkable opportunity with a combined company that has enough cash to get this to conclusion for not only one indication. So this is a not a binary event. This is a series of opportunities for a well-known drug that has been classified as an NCE with a remarkable team. We are lean, we have excellent staff, we have a remarkable Chief Medical Officer, a remarkable Chief Scientific Officer. You have gotten to know Kevin over the last years and obviously, Tim Whitten and Don Hayden in the leadership role makes it very exciting. I am not sure I have been involved with anything that has been this exciting in my entire career.

Now you all get the choices that you make. You are on this call because you care, you could be doing something else. I think over the next year or two, I am hoping we are having conversations about what are we going to do with the revenue that we have generated and what is our next plan. And we intend to get out and talk to people and make ourselves available, but I am absolutely elated to be working with Don Hayden, Tim Whitten, their team and bringing our team into this combination.

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Timothy Whitten - Insmmed Incorporated - President & CEO  
Thanks, Mel.

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Donald Hayden - Insmmed Incorporated - Chairman  
Thank you.

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Mel Sharoky - Insmmed Incorporated - Director  
So with that, we thank you all and we will talk to you later.

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Operator

Ladies and gentlemen, that concludes today's conference. Thank you for your participation. You may now disconnect.  
Have a  
great day.