SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

February 9, 2011
Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(Address of principal executive offices)

(215) 488-9300
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

Conference Call Update on Activities to Support Surfaxin® Complete Response

On February 1, 2011, Discovery Laboratories, Inc. (the "Company") held a pre-announced public conference call and webcast to discuss its ongoing efforts to conclude its comprehensive preclinical program and file a Complete Response intended to gain U.S. Food and Drug Administration ("FDA") marketing authorization of Surfaxin® for the prevention of respiratory distress syndrome ("RDS") in premature infants.

A copy of the conference call transcript is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. At the start of the call, the Company referenced certain forward-looking statements that the Company intended to be covered by the Safe Harbor provided by the Private Securities Litigation Reform Act and directed call participants to refer to the factors that could cause actual results to materially differ from those in the forward-looking statements contained in the transcript because of a number of factors including those set forth in the Company's Annual Report on Form 10-K and any subsequent SEC filings, as they may have been amended. The filing of the transcript is not intended to constitute a representation, and shall not be deemed to be an admission, that such filing is required by Regulation FD or that the transcript includes information that is not otherwise publicly available. The filing of the attached information is not an admission as to the materiality of any of the information set forth therein. In addition, except as required by law, the Company does not assume any obligation to update such information in the future.

Surfaxin® for the Prevention of RDS

The Company believes that a key remaining step to potentially gain FDA marketing approval for Surfaxin is to satisfy the FDA as to the final validation of its fetal rabbit biological activity test ("BAT"), an important quality control release and stability test for Surfaxin. The Company has been conducting a comprehensive preclinical program in this regard. The Company has previously optimized the BAT and its final validation is intended to satisfy the FDA with respect to the ability of the optimized BAT to adequately reflect the biological activity of Surfaxin throughout its shelf life and to discriminate biologically active from inactive Surfaxin drug product. The comprehensive preclinical program will also provide data that will be used to gain the FDA's agreement on final acceptance criteria, with respect to biological activity as assessed by the BAT, for release and ongoing stability of Surfaxin drug product.

The comprehensive preclinical program also calls for multiple Surfaxin batches to be used to demonstrate concordance between the BAT and the well-established preterm lamb model of RDS by performing a series of prospectively-designed, side-by-side preclinical studies (i.e., concordance studies). Data from the preterm lamb model and BAT concordance studies are intended to support final BAT validation and to demonstrate comparability of drug product used in the Phase 3 clinical program with Surfaxin drug product to be manufactured for commercial use.

As noted in the Company's recent press release of February 1, 2011 and the conference call transcript, the Company has been interacting with the FDA throughout the conduct of its comprehensive preclinical program to gain Surfaxin approval and has been incorporating the FDA's guidance into its efforts to complete the program and file the Surfaxin Complete Response. As previously reported, a recent communication from the FDA focused on certain technical criteria relating to final BAT validation and directed the Company to increase the sample size of specified data sets by testing additional Surfaxin batches. To respond to the FDA's direction, the Company plans to submit data from several Surfaxin batches that have been previously manufactured and analyzed, as well as from newly-manufactured Surfaxin batches.

Since it acquired its manufacturing operations in Totowa, NJ, in December 2005, the Company has a record of manufacturing in each year batches of Surfaxin drug product, all of which met release and stability specifications. In December 2010, the Company began manufacturing additional Surfaxin batches for use in the comprehensive preclinical program. Since December 2010, the Company has manufactured four Surfaxin batches for this purpose. Of these four batches, the first has been fully tested and has met all release specifications. Preliminary testing of the next two batches indicates that they do not meet one of the release specifications and cannot be used in the comprehensive preclinical program. At this time, preliminary testing of the fourth batch indicates that it meets specifications, including the specification that the prior two batches did not meet. In accordance with the Company's quality assurance procedures and pharmaceutical manufacturing practices, the Company is conducting an investigation into the manufacture of the Surfaxin batches that did not meet specification to determine the probable cause. Although the investigation is ongoing, based on its preliminary assessment, the Company presently anticipates resuming the manufacture of Surfaxin batches for use in the comprehensive preclinical program in February 2011.

The Company originally anticipated manufacturing additional Surfaxin batches to complete the comprehensive preclinical program and be in a position to file a Surfaxin Complete Response by early third quarter 2011, which, after an anticipated six-month FDA review cycle, could lead to potential Surfaxin approval early in the first quarter 2012. In light of the foregoing and assuming that the Company resumes manufacturing in February 2011 as planned, the Company now believes that the filing of the Complete Response could occur in the third quarter 2011 and, as a result, potential Surfaxin approval could occur in the first quarter 2012.

The Surfaxin Complete Response, in addition to including the results of the comprehensive preclinical program, will also require that the Company provide other routine regulatory submissions, such as an updated clinical trial safety report for Surfaxin. In April 2008, the FDA completed a pre-approval inspection ("PAI") of the Company's manufacturing facility in Totowa, NJ and issued an Establishment Inspection Report ("EIR") reflecting a successful inspection. Following the filing of the Complete Response and prior to gaining potential FDA marketing authorization, the Company believes that the FDA will likely conduct another PAI of its Totowa, NJ manufacturing facility and assess the quality assurance/quality control facilities for Surfaxin including those of third-party raw material suppliers and testing laboratories. Although the Company and the FDA have previously discussed the principal content of the Surfaxin package insert, the Company presently anticipates that the FDA may want to update the format and content of the package insert in connection with a potential Surfaxin approval to comply with mandated format changes as well as to reflect updated information regarding Surfaxin.

Other RDS Programs

With respect to the Company's development program for Surfaxin LS™, a lyophilized formulation of Surfaxin, the Company is in the process of conducting a technology transfer of its manufacturing process to a cGMP-compliant, third-party contract manufacturer with expertise in lyophilized formulations. The Company also presently plans to seek regulatory and scientific guidance with respect to its planned Surfaxin LS development program with the FDA and the European Medicines Agency ("EMA") in 2011.

Aerosurf® is the Company's drug/device combination development program for noninvasive administration of aerosolized KL_4 surfactant to address neonatal RDS. Aerosurf combines the Company's KL_4 drug product technology with the Company's novel capillary aerosolization technology. The Company, with the assistance of third-party medical device engineers, is presently optimizing the design of the capillary aerosolization device for anticipated clinical development use. The Company presently anticipates that 2011 activities will include finalizing the Aerosurf clinical device design, producing devices for design verification testing, and seeking regulatory guidance from the FDA and EMA for the planned Aerosurf development program.

Disclosure Notice

The information in this Form 8-K includes certain "forward-looking" statements relating, among other things, to the Company's understanding of recently-received written guidance from the FDA and the remaining questions identified in the FDA's April 2009 Complete Response Letter that must be addressed to gain FDA approval of Surfaxin. The Company has interacted and plans to further interact with the FDA on certain technical aspects of the comprehensive preclinical program. Such potential interactions with the FDA could affect the ultimate timing, conduct and outcomes of remaining steps necessary to gain Surfaxin approval, including the potential filing of the Complete Response. In addition, the Company is conducting an investigation into the probable cause of two batches that did not meet one of the release specifications, and is planning to resume manufacture of a number of Surfaxin batches that are needed to support the filing of the Complete Response. All of the foregoing activities are subject to potential delays or outcomes that may materially impact the Company's present plans. In any event, there can be no assurance that the Company will be successful in completing the comprehensive preclinical program within the timeline outlined above, or that the FDA will be satisfied with the comprehensive preclinical program and the Complete Response. In addition to uncertainties related to the FDA's review of the Complete Response, the Company presently anticipates that the FDA will likely inspect and otherwise assess the manufacturing and quality assurance facilities for Surfaxin including those of third-party raw material suppliers and testing laboratories. The outcomes of such FDA activities could also affect the ultimate timing and remaining steps necessary to gain Surfaxin approval.

The completion of the comprehensive preclinical program and other related activities will require the Company to raise significant amounts of additional capital and the ultimate outcomes remain subject to a variety of risks and uncertainties that could cause actual results to be materially different. These risks and uncertainties include, but are not limited to, risks that (i) the FDA may not approve Surfaxin or may subject the marketing of Surfaxin to onerous requirements that significantly impair marketing activities; (ii) the Company may be unable to resume or complete the manufacture of a sufficient number of additional Surfaxin batches within the time frame set forth above, (iii) the Company may identify unforeseen problems that have not yet been discovered or the FDA could in the future impose additional requirements to gain approval of Surfaxin; and (iv) the Company may be unable to raise sufficient additional capital, through financings, strategic collaborations, or otherwise. Any failure to satisfy the issues raised by the FDA, in the Complete Response letter or in related discussions, could significantly delay, or preclude outright, gaining approval of Surfaxin, which could potentially delay or prevent the approval of the Company' other products.

Item 9.01. **Financial Statements and Exhibits.**

(d) Exhibits

99.1 Conference call transcript dated February 1, 2011

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company’s product development or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such risks and others are further described in the Company's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Discovery Laboratories, Inc.

By: /s/ W. Thomas Amick
Name: W. Thomas Amick
Title: Chairman of the Board and Chief Executive Officer

Date: February 9, 2011

DISCOVERY LABORATORIES

Moderator: John Tattory
February 1, 2011
10:00 a.m. ET

Operator: Good morning, my name is (Melissa) and I will be your conference operator today. At this time, I would like to welcome everyone to the Surfaxin Update conference call. All lines have been placed on mute to prevent any background noise.

After the speaker's remarks, there will be a question-and-answer session. If you would like to ask a question during this time, simply press star then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key.

Thank you. Mr. Tattory, you may begin your conference.

John Tattory: Thank you (Melissa). Good morning and thank you for participating in Discovery Labs conference call. This morning's call will provide an update regarding the company's Surfaxin complete response initiatives.

Before we start, I will read the safe harbor statement. This webcast conference call will contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

These statements relate to future events or the company's future financial performance. Such statements are subject to certain risks and uncertainties which could cause our actual results to differ materially from any future results expressed or implied by such statements; predominantly those inherent in the process of discovering, developing and commercializing drugs.

The listener is cautioned not to rely on these forward-looking statements. Actual results could vary materially, from those described, as a result of a number of factors including those set forth in Discovery's annual report on form 10-K and any subsequent SEC filings, as they may have been amended.

Today we have with us Mr. Tom Amick, Chairman and Chief Executive Officer, Dr. Tom Miller, Chief Operating Officer, Dr. Rusty Clayton, Vice President of research and development with oversight and regulatory affairs, and Mr. John Cooper, President and Chief Financial Officer.

I would now like to turn the call over to Mr. Amick.

Tom Amick: Thank you, John. And thanks to everyone who is participating in this call. I know you all have busy schedules, but we really appreciate your interest – continued interest in Discovery Labs and our Surfaxin technology.

On January 10, of this year, we did issue a press release in which we detailed to you that we had received direction from the FDA. In that press release we also committed to get back to you to give you a further update. Today is the purpose of that update.

We have made tremendous progress on many fronts during the first quarter and since the January 10th press release. I also would like to make a comment here about the purpose of this call, is to give you a Surfaxin update. I want to encourage each of you to ask any questions that come to mind regarding Surfaxin and our complete response, which we do plan to file early third quarter of this year.

And, as I mentioned many times before, we had a unique Surfaxin and aerosol device technology program. Our KL4 Surfaxin pipeline holds a promise to significantly expand treatment options, improve the medical outcomes of patients suffering with debilitating respiratory disease.

Again, I'd like to remind you though our initial focus continues to be on the management of neonatal RDS in the NICU initially by advancing our lead program, again, Surfaxin. We continue to benefit from multiple FDA interactions that provide valuable direction.

We have recently received a detailed written communication from the agency currently targeting, again early three quarter – third quarter of this year for Surfaxin Complete Response.

Without further delay, I'd like to turn this over to doctors, Tom Miller and Rusty Clayton, who are here to give you a comprehensive program overview. First, Tom Miller. Tom.

Tom Miller: Thanks, Tom. For those of you that have followed our company's progress, you'll know that we've been focused on working with FDA to find a productive path leading to a Surfaxin Complete Response filing and potential product approval.

For those of you that are new to the company, we thought a brief overview would be of use to help you understand why we've been so persistent in this regard.

Neonatal respiratory distress syndrome, or RDS, is an orphan disease. And more than 650,000 children are born at risk for this disease on an annual basis in the (G-7) each year. About 350,000 of those children reside here in the United States.

Risk is defined by either birth weight or gestational age for the child. Children that are born before 32 weeks, out of a normal 40 weeks of pregnancy, meet the at-risk criteria for this condition.

And this condition largely results from birth prior to normal and full lung development in utero which meets the surfactant deficiency. This essentially means that a natural surfactant has not yet been produced in the lungs and this very typically leads to respiratory failure of children that are born with this timing dilemma.

Current standard of care entails invasive ventilatory support, and in a large proportion of RDS – RDS diagnosed infants, therapeutic surfactant administration.

Today these available medications are all animal derived and we believe have a number of limitations that can be improved upon. No meaningful innovation relating to the management of RDS has occurred through the course of the last decade. And certainly, from my perspective, clinical outcomes today are unacceptable, with a significant mortality rate, a very high follow on morbidity rate. And, again, I'll emphasize that this clinical picture has not changed for some time.

Surfaxin hopes to potentially become the first completely synthetic peptide containing surfactant. We conducted a multinational clinical development program which involved more than 1,500 preterm children in multiple continents throughout the world.

Two highly successful phase three clinical trials were published in the “Journal of Pediatrics,” the most relevant clinical journal for the practicing neonatologists, and depicted outcomes from these trials with direct and favorable comparisons to current standard of care animal-derived surfactants.

This very large data set continues to support new medical publications and presentations at key medical congresses each year for us as a company.

The medical need for this product is high, as is the interest in Surfaxin among the practicing neonatology community. This community understands that Surfaxin represents the first of several potential products that are related in many respects, including our lyophilized product initiatives and our aerosolized surfactant product initiative, all of which have the potential to redefine standard of care for neonatal RDS.

We have maintained significant visibility with the neonatology community, as we advance the Surfaxin initiative, and we continue to collaborate with the best and brightest neonatology thought leaders with our expansion Surfaxin development programs.

On the regulatory front I am very pleased with the recent progress relating to Surfaxin Complete Response initiative. And I’m joined today by our Vice President of research and development, Dr. Rusty Clayton, who will provide additional perspective in this regard. Rusty, please.

Rusty Clayton: Thanks, Tom. As some of you will recall, since our last complete response letter from the FDA, our primary regulatory focus has been the execution of a nonclinical program that was intended to support the FDA approval of Surfaxin.

This centers around issues that the U.S. FDA had with regard to our biological activity test which is a release and stability method that we use to assure the quality of our Surfaxin product. Very specifically, the FDA, when we met with them in June of 2009, expressed concern regarding the consistency of our biological activity test.

And, based on that, we had to undertake a three prong program that I'm going to go over with you step by step. First, to optimize that biological activity test, then because an optimization would involve change of the test, we would then have to revalidate that biological activity test. And that would be step two.

And then once validated we would have to use that biological activity test to demonstrate a link a between our currently manufactured and to be marketed product and the product that was used in the Surfaxin in the clinical trial.

And I'm going to kind of break that down further, as to why we have to provide that link, a little bit later on.

But first let me talk about what this biological activity test is and why we need it. In the United States, at least initially, surfactants need to demonstrate biological activity as part of their quality assurance. The biological activity very simply is demonstrated in a surfactant deficient model. In our case it's a preterm rabbit.

And the surfactant is administered to these rabbits and any change in the lung function of this rabbit is measured. And that's how biological activity is assessed.

We had to provide optimization of that method. We did have that method in place for several years but the method did not have the consistency that the FDA wanted and so we needed to optimize that method and validate that. And I'm going to go into more detail with that shortly.

Now why do we have to bridge this rabbit method with this preterm lamb model of respiratory distress? As it turns out, the preterm lamb model of respiratory distress was performed – was the model used in a study that was done during our clinical trial that demonstrated the biological activity of our product at the time.

And so we have an understanding with the FDA that we will provide a link between that preterm lamb study and our current biological activity test in order to fully validate this biological activity test in the eyes of the FDA.

So let me first talk about the optimization of the biological activity test. We have, since our meeting – meetings with the FDA after their complete response letter, on several occasions, discussed the possible optimization path for the biological activity test.

And, in fact, we did, at one point, have a detailed proposal in front of the FDA regarding the optimization. The FDA reviewed and commented on that proposal. And then, based on the FDA's comments, we went ahead and did optimize the biological activity test and even tested that optimization through some pilot experimentation to make sure that we did in fact optimize.

So let me provide a little bit more detail on the optimization itself. The optimization goal was to decrease the variability of a biological activity test. A biological activity test is inherently variable. Of all of the analytical methods used and tested -- the biological activity test will have the greatest degree of variability relative to other tests such as chemical or physical testing.

To decrease this variability, in general terms, one can take several approaches. For example, we can increase the sample size, the number of subjects used in that biological activity test. That should decrease the biological variability.

And we should also insure – and this is another method that was – that we can use, insure that the subjects that were being used are as uniform as possible. So if there are – if there are subjects that are not uniform with the rest of the population that would potentially add to the variability. So it makes sense to decrease variability by making sure your subjects are as uniform as possible.

Even with the best efforts though there would still be outliers to this biological activity test. And we have to have a proactive method in place for when these outliers occur. And so the other plan to limit the variability is to identify the outliers immediately and assess the outlying values.

And the identification of the outliers would immediately trigger additional testing in real time so that we can assess fully whether that outlier is a true outlier or is that they trend in the test or with the formulation.

So that, in a sense – that in essence, rather, is how one would optimize this particular assay. This optimization has been complete for over a year now. And we have been able to gather substantial data going forward after the optimization process. And I'm happy to report that this optimization process has resulted in greater than a 40 percent reduction in the variability of this assay.

Discovery Labs feels that this is very significant decrease in the reduction and therefore a significant increase in the improvement of the assay. But I do have to caution that the FDA needs to be the final judge of that particular assessment.

Having said that let me move on to the validation process. As I said before, once the assay is optimized it needs to be validated. And validation is the application of several parameters to evaluate the method itself.

These are parameters such as repeatability, specificity. In essence you're testing the test to make sure that the test is repeatable, it provides for a very specific result; things like that.

Over the last year we have had several interactions with the FDA with regard to how the FDA would like us to validate this particular assay. A biological activity test for surfactant is not a – what I would consider to be a standard assay. It's not something that you would find on the U.S. Pharmacopeia for example.

And so it's, we believe, in the company's best interest to make sure that the FDA is completely satisfied with our validation approach and that they see the data that they need to be assured that this assay is in fact validated.

So that has really been our approach throughout the last year and since optimization. And we have had several interactions with the FDA with regard to this validation and we have taken their advice into account to try to provide a most robust data set so that both parties can agree that the assay is fully validated.

Once we achieve this validation we then – our goal then – our final goal is to take the optimized and validated biological activity test and compare that with the preterm lamb model of respiratory distress and demonstrate concordance between the methods, the assay method, and the preterm lamb model.

We do this by testing different lots of surfactant that are taken at different time points along the shelf life of the product. And we test it in both the rabbit and the lamb. And basically we compare the biological activity results both as the regression analysis and as a point to point comparison to make sure that both the lamb and the rabbit are reflecting the same values in terms of the change in product over time.

Again, the data to date leaves us with – leaves Discovery with a lot of confidence that we have demonstrated this concordance between the assay and the preterm lamb model. But I must remind folks again that the FDA has to be the final arbiter of this particular assessment, and that is our plan as we go forward.

Now we've disclosed previously that we had a recent communication with the FDA. I'd like to provide some background about that. We actually have been communicating on a regular basis with the FDA with regard to this issue regarding the biological activity test. And I think I've explained before that we do this to insure that we provide the FDA with every piece of data that they – that they need that we can provide to help them come to a decision that we've done what they've asked us to do.

Last year, at the FDA's suggestion, Discovery Lab submitted a proposal seeking clarification regarding very specific and detailed aspects of the final biological activity test validation. The FDA responded, as we disclosed on January 10, and advised Discovery Labs to increase the sample size of the specified data set for the biological activity test and for the demonstration of concordance by testing some additional surfactant batches.

This is a direction from the FDA that the company at once embraced and was incorporated into Discovery's plan for the biological activity test validation. The company already had several lots that had been participating in the validation exercise, however, to help satisfy the FDA and in response to this latest communication, we are manufacturing additional batches.

That manufacturing campaign has already initiated in early January and we will continue to manufacture lots to the point where we believe the FDA will be satisfied. And this manufacturing campaign is expected to complete in the first quarter of 2011.

So, given all that, why would one assume success, which is obviously what we've been building for over the last almost two years now? And I wanted to close with these – with these thoughts.

First of all, as I've expressed before, we have a fundamentally better biological activity test. The FDA came back to us and said we think that this test can be more consistent. We responded by an optimization program and a validation program that we believe is successful. The data trends much more consistently and, in our analysis of the data to date, has demonstrated a greater than 40 percent reduction in the variability.

With regard to the concordance study, we have both internally – and I'm speaking about myself as well as some others in the company – extensive experience with regard to the preterm lamb model. And we are partnering with some leading institutions with ultimate expertise in this model to provide the necessary data that we need to demonstrate the concordance.

Throughout this process both Discovery Labs and the FDA have gained a tremendous amount of sophistication with regard to how to demonstrate this concordance as well as sophistication over this biological activity test. And we believe that this sophistication has paid dividends particularly with our latest communications with the FDA.

In the process of these interactions we also believe that our relationship, as a company, has improved with the FDA. Our communications continue to be collaborative, collegial and, in our opinion, very positive with this regard.

And these four factors, I believe, combine to provide us with a reason to believe that we will be successful in filing a complete response that will lead to Surfaxin approval. And that complete response filing is on target for the third quarter of this year.

That concludes my comments and, with that, I'd like to turn the call back over to Mr. Amick.

Tom Amick: Thank you Rusty. As you can see, we're at a very important point in the history of our company. I'm pleased with the progress that our technical team has made during the conduct of the comprehensive nonclinical program, which is intended to support the Surfaxin Complete Response filing.

Also, I'd like to give thanks to our colleagues down at the FDA who continued to work with us and continued to provide what we think is good clear direction on how we should be moving forward with our complete response.

And I will assure you we will continue to have those collaborative sessions with our colleagues at the FDA. We're very dependent on them and we really appreciate their cooperation to date.

Before I turn the call back to the operator for Q and A I'd like to, again, stress the fact that we would appreciate it if you could keep your questions to you know what's going on with our comprehensive nonclinical programs and our complete response, and that way we can be sure that all questions regarding these issues will be answered.

So thank you. Operator.

Operator: At this time, I'd like to remind everyone in order to ask a question touch star then the number one on your telephone keypad. We'll pause for just a moment to compile the Q and A roster.

Your first question comes from (Kim Lee).

John Tattory: Good morning (Kim).

(Kim Lee): Good morning. Thank you so much for the clarifications on the Surfaxin program today. Much appreciated. Just have a few follow up questions here. First is as far as optimization goes, what percentage reduction in assay variability relative to the prior BAT methodology do you think is acceptable to the FDA?

I know you've found the percentage to be 40 percent but do you think that's a reasonable reduction or do you think the FDA – has a different number in mind?

Rusty Clayton: Yes, Kim. This is Rusty Clayton. Thanks, for the question. That's a really difficult question to answer. First of all a biological activity test of any sort, the baseline variability range is very wide.

Approved test can range anywhere from 15 percent variability up to 70 percent variability. So on that basis and on that background, the FDA did not provide us with a guidance as to what percentage would be acceptable.

It was basically the direction it needs to be optimized, do your best. And that is what we're representing here with the optimization. Ultimately I think it's a matter of getting them to provide the validation – for up to agree the FDA and Discovery Labs to come to some sort of understanding with the validation because the validation will of and by itself serve to the FDA has agreed that the variability is low enough at this point.

But I don't believe that there's any set number that we can – that we could – we could dictate. I would say that a 40 percent reduction in variability of any test is a very substantial and significant reduction.

So in that case – in that point, I believe the FDA was correct in saying that you can do better. We have responded by doing better. And you know I have to remind everybody that this biological activity test is part of an array of quality control assay's including chemical and physical assays with very, very tight control.

So, with that as a background, our believe is that our current assay in terms of the consistency is going to – is going to meet the – with the FDA's approval. But that of course is going to have to be decided by the FDA.

(Kim Lee): Understood. Great. And can you remind us what is the proposed shelf life of this optimized BAT?

Rusty Clayton: Well, there's – the – I think what you mean to ask is what is the proposed shelf life of our product, Surfaxin…

(Kim Lee): Right. Right, using this – yes.

Rusty Clayton: Yes. I'm sorry.

Tom Miller: Yes, this is Tom Miller. We haven't provided public guidance in that regard for – of course it's – that would be a component of disclosure around potential approval. But I think we have indicated previously that our target is to be you know reasonably consistent with the existing animal-derived surfactants with shelf lives ranging in the 12 to 15 month range.

(Kim Lee): OK, very helpful, thank you. And what further data is needed through – for the concordance testing?

Rusty Clayton: We had proposed some data that we had generated in both the rabbit and the lamb. Some of those data have already been generated. We had asked that question to the FDA specifically and they had indicated that they would like some additional time points with some additional lots tested in both the rabbit and the lamb.

So without getting too granular, because this is a – somewhat of a proprietary issue, there – we have we believe most of the data but we need to generate just one or two more time points which is easily accomplished.

(Kim Lee): Finally, look – I guess looking at the bigger picture, will this final stability validation be necessary to be used in the rest of your programs, like Surfaxin LS, Aerosurf and KL4?

Rusty Clayton: The release and stability of the KL4 surfactant product, we believe, at least in the United States, will include a biological activity test. And it is our intention that this biological activity test optimized, as it is, and with as much effort as we've spent on this, will be used for the release and stability of all KL4 surfactant products.

Tom Miller: (Kim), just – and just one related comment in agreement with Rusty's prior comment. The concordance acceptance between the BAT and the preterm lambs is a surfactant liquid instillate-centric initiative, at least as we understand it currently.

(Kim Lee): OK. OK. So, just to liquid form. So any aerosolized product will not need – would not – you would not make a use of that test. Is that correct?

Rusty Clayton: Well, if you're going to aerosolize the surfactants before you even aerosolize the surfactant you have to assure that it's biologically active. And then that the rest of it becomes a developmental issue, what we have to demonstrate and what we have demonstrated so far to date is that when we aerosolize our product it is biologically active after aerosolization.

Once that bridge is established we believe that it's the assurance of the product biological activity that is going to be required. But that, again, is going to have to be more declaratively nailed down in future interactions with the FDA specific to the Aerosurf program.

(Kim Lee): So just to be clear that some part of this – the test that you're doing now and the revalidation of the – from the BAT, all this will be – likely be necessary to form the basis of your future programs, like the KL4 Surfaxin. Is that correct?

Dave Lopez: With the absence of the concordance study between the rabbit and the lamb, that is a correct statement. We believe that the U.S. FDA will continue to require biological activity testing of any surfactant product which would include our products, at least initially, for release and stability of the product.

(Kim Lee): OK. Thanks, again for the clarity.

John Tattory: Thanks, (Kim).

Operator: Your next question comes from (Larry Smith).

(Larry Smith): Hi. The FDA, as we've all seen as being ultra, ultra conservative. You know must recently we've just seen today with the (inaudible) where they asked for a long (inaudible) cardiovascular study.

And in the case of Surfaxin the ultra conservative strategy would be why don't you just go out and do a human trial and demonstrate that the BAT is – works in a small human trial. But what kind of confidence or what kind of assurance can you give me – I mean give us that the FDA will accept this bridging study between – on the BAT between the lamb and the rabbit model as opposed to asking for a human study at the end of the day?

Rusty Clayton: (Larry), this is Rusty Clayton. Thanks, for the question. First, let me point out that in our entire history with this particular new drug application the FDA has not once called into question our clinical program. And at our last face to face meeting with them, and a review meeting in 2009, they in fact indicated that our clinical program from and efficacy and safety point – standpoint was very robust.

So your question really regards to validating the biological assay by doing a clinical trial. And we in fact explored that with the FDA in 2009, early 2010 timeframe. Ultimately, after back and forth correspondence with the FDA, it was determined that we could not proceed with that route. It was not because of issues with the BAT, the biological activity test, or issues with the clinical trial.

Remember that this drug is being used in preterm infants, some of the most fragile humans on earth. And the FDA internally, and I think to their credit, had some question with regard to the ethical consideration of using the human clinical trial for the sole purpose of validating a biological activity test.

So after we, I think, very exhaustively explored that option with them, the FDA advised us that this bridging study would be the preferred method to go.

(Larry Smith): OK. Thank you.

Operator: Again, if you would like to ask a question, press star one. Your next question comes from (Shiv Kapoor).

John Tattory: Good morning.

(Shiv Kapoor): Good morning. Thanks, for taking my questions. I am a little new to the story, so forgive me if I ask some questions that takes you back in history. But can you – can you tell me what the possible excipients are in your – in your testing and were there certain excipients that historically the FDA's been more concerned about? And what have we learned over the – over your testing about these excipients?

Rusty Clayton: Well, I can't share some of the fine details with our excipients at this time because that remains proprietary. I will tell you that in our reviews of the FDA, dating back as long as I've been with the company in 2005, they have not expressed any concerns with regard to the excipients.

Further, the FDA has asked certain questions regarding our active pharmaceutical ingredients and some of the impurities that have been detected through our leading edge technology detecting those impurities, and we have satisfactorily, at least to our correspondence with the FDA, answered all of those – all of those questions.

So, as of our last complete response letter with the FDA, there remained only one very minor point of discussion with regard to exactly one impurity, and that was answered completely at our end of review meeting in 2009.

So we do not have any outstanding issues with regard to excipients, active pharmaceutical ingredients or impurities in our product.

(Shiv Kapoor): OK. That's good to know. What about the optimization of the dosage of your surfactant? When was that done and were there any questions with relating – related to the activity of vis-à-vis the optimal dosage of the surfactant?

Rusty Clayton: The dosage optimization in general in pharmaceutical development occurs during the preclinical phase and that's when our optimization occurred. That optimized dose was then confirmed in clinical studies and we had a dose that we went forward in the Phase 3 clinical trial. That Phase 3 clinical trial was actually constructed with FDA input all along the way and ultimately accepted by the FDA.

So we have a dose that has been used, has been used through a very stable and very solid Phase 3 clinical trial – Phase 3 clinical program and that's basically the dose that we have.

Tom Miller: The results of that successful phase three clinical initiative, again, has been published in "Pediatrics." The efficacy associated with our selected dose for that trial is quite comprehensively depicted and I would advise you to review those manuscripts.

(Shiv Kapoor): Fair enough. One more question. Once you have the filing complete perhaps by third quarter, how long – how long of a response do you think the FDA – how long would you think the FDA will take? It seems like you've been in very active discussions with them.

Rusty Clayton: Well, I mean to be fair to the FDA, with regard to our status as a new drug application, and given the data that they need to review, the guidance that we are providing is that the FDA will deem this a class two review and this typically, by guidance, will take six months.

So once from the date we – they receive the complete response, we expect that they will issue a PDUFA date within six months of that submission.

(Shiv Kapoor): OK. Thanks, a lot.

Rusty Clayton: No problem.

Operator: There are no further questions at this time.

John Tattory: OK. Then I would like to thank everyone for their participation, thank everyone for their questions and look forward our next conference call that will be later on this quarter. Thank you all very much.

Operator: This concludes today's conference call. You may now disconnect.

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