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HEADLINE: NexMed Announces Decision for AntiFungal Product - Final

BODY:

Corporate Participants

* Linda Burns NexMed, Inc. - Senior Director of Corporate Relations * Vivian Liu NexMed, Inc. - President and CEO

Conference Call Participants

* Mark Greenstein Financial Concepts - Analyst

Presentation

OPERATOR: Greetings and welcome to the NexMed investor update. At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. (Operator Instructions). As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Linda Burns, Senior Director of Corporate Relations for NexMed. Please go ahead, Ms. Burns.

LINDA BURNS, SENIOR DIRECTOR OF CORPORATE RELATIONS, NEXMED, INC.: Thank you, Diego. Good morning. I am Linda Burns, Senior Director of Corporate Relations. On the call with us today are Vivian Liu, our Chief Executive Officer, and Mark Westgate, Chief Financial Officer, and Vivian will lead the discussion. Before we begin, I will read the forward-looking language statement and then turn the call over to Vivian. Following her remarks, we will open the call for your questions and comments.

Just a reminder to everyone that during the course of the call the management team will make forward-looking statements regarding future events or the future financial performance of the Company. Please keep in mind that such statements are predictions based on current expectations and actual results could differ materially. You should refer to our most recent filings with the Securities and Exchange Commission for additional discussion on factors affecting our business.

Now I will turn the call over to Vivian.

VIVIAN LIU, PRESIDENT AND CEO, **NEXMED**, INC.: Thank you, Linda, and thank you, everyone, for joining us this morning. Yesterday we appounced the termination of the licensee agreement

OCKEI LARM Find authenticated court documents without watermarks at <u>docketalarm.com</u>. assumed all clinical development, regulatory, manufacturing and commercialization responsibilities for the product.

The decision to terminate was mutual and amicable and was based on various key considerations. The primary reason for termination was that the product had not clinically performed up to their expectations. In the three Phase III trials conducted by **Novartis**, the product showed an excellent safety profile. However, while the efficacy was comparable to the currently marketed topical treatment Penlac and Loceryl, the study results were insufficient to support filing for marketing approval.

Based on various discussions with Novartis, we know that the protocol for the Phase III studies deviated in some areas from what we had done in our US and China studies. Certain parameters which we view as less favorable had been built into the design and execution of the study. Ultimately we believe that certain assumptions may have contributed negatively to the product's clinical performance.

We are currently in the process of reassembling a clinical team of internal and external experts to work with Novartis on transferring the data and knowledge gained and also to reposition the product for potential licensing discussions.

These were very hard lessons learned not just for us but also for Novartis. They do believe that with the insight gained from the studies, a viable product can still be developed but it would no longer be a strategic fit for them. When they signed the agreement in 2005, we understood that they were looking for a second-generation Lamisil product in a topical form which they could quickly ramp up to \$500 million in sales.

At that time, they were one of the leaders in dermatology. However, due to the patent expiration of the oral Lamisil tablets and other internal priorities, their presence in the field has eroded significantly.

Even with the launch of the generic oral **terbinafine** product, the fungal market in 2008 was still about \$1.5 billion. The competitive landscape for the development of a viable topical treatment remains about the same since 2005. As far as I know, we still have the most advanced product in development. And equally important, the clinical results continue to validate NexACT as a safe, efficacious and patient friendly drug delivery technology.

We concurred with **Novartis** that the best option for us was to terminate the agreement in order to regain the rights and control of the relicensing efforts with support from Novartis. The alternative would have been to allow Novartis to control the entire process of relicensing the product and our major concern was that the product would have languished under that scenario.

In addition to regaining the product rights, we also obtained a very expansive intellectual property dossier that includes and issued US patent which provides product coverage to April 2026. We also gain a clinical dossier of about 2000 patients who have been tested with the product. We know a lot more now than we did in 2005 when we licensed the product to Novartis before we had completed our Phase I trial in the US.

The lessons learned from Novartis's clinical efforts will help fine tune the development plan going forward and we believe that ultimate market entry is lower than the threshold that Novartis has set for the product.

So what's next? The first step is to reach out to companies who we think will have an interest in continuing to develop this product. During the past few months, we received several inquiries for companies who are focused in dermatology and who expressed interest in the product in the event that Novartis decided not to pursue the program.

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friendly and/or has greater efficacy than the currently marketed products. We believe that with the right partner and a well-designed clinical program, our product could fulfill that void in the market. We also believe that if we are successful in developing a superior product to the currently available topical treatments, it still has the potential to generate about \$100 million in sales annually.

It's our job now to convince potential licensing partners of that opportunity based on the work done by Novartis.

With regard to the current financial status of NexMed, not much has changed since our March 31, 2009 Form 10-Q that was filed. Our current cash reserve is about \$2.8 million which should provide us with sufficient cash to fund our operations into 2010. Our current overhead burden is about \$250,000 per month which includes \$50,000 per month received from Warner Chilcott as they continue to use our facility for the manufacturing of the Vitaros product samples.

As previously indicated, Warner Chilcott will use our facilities through September 15, 2009 but can extend on a month-to-month basis upon our mutual agreement for an ongoing monthly fee of \$50,000 a month.

We are continuing to cut costs and are actively trying to sell our facility so that we can further reduce our monthly operating expenses. Finally, as we discussed on our last conference call in May, we were working with FTN Equity Capital Markets as our financial advisor to assist us in valuating our ongoing operations and explore possible value-added strategic business alternatives.

Our top priority remains to be to regain the Company's value and maximize our shareholders' return on investment while continuing to position ourselves as an emerging drug delivery company offering our core NexACT technology to the dermatology sector within the pharmaceutical industry.

This concludes the formal presentation and at this time, I'd like to ask Diego to open the call up for questions from the conference participants.

Questions and Answers

OPERATOR: (Operator Instructions). [Mark Greenstein], [Financial Concepts].

MARK GREENSTEIN, ANALYST, FINANCIAL CONCEPTS: Yes, well the question is what is going on with Femprox and do you have any partners that are interested?

VIVIAN LIU: Well actually we do have -- we have had fairly extensive discussions with potential partners for that product. Because Femprox, regulatory wise has certain challenges that are comparable to the ED program, the potential partners are waiting as well for the upcoming meeting with the FDA that Warner Chilcott is in the process of scheduling and that is related to the transgenic mouse issue that the FDA had expressed a concern.

We think that -- we believe at this point in time based on input from our experts and also talking with Warner Chilcott, that we believe the meeting will go well because the evidence shows in terms of additional testing that was done in other type of long-term carcinogenicity models clearly show that the mixed data generated in the transgenic mouse model was an anomaly.

So, but of course the final decision rests with the FDA and that meeting we hope will take place sometime in September. The FDA had committed to once they receive the assessment package that is being finalized by Warner Chilcott that they would schedule a meeting within 60 to 90



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So once we kind of get that obstacle out of the way in terms of the ED product which will enable Warner Chilcott to move forward on the ED program, we believe that we will then be in a position to essentially -- hopefully move forward on the ongoing discussion for Femprox.

OPERATOR: (Operator Instructions). [Bob Delucia]. (Operator Instructions). Ladies and gentlemen, there are no further requests for questions at this time. I'll turn the conference back over to Vivian Liu for closing remarks. Thank you.

VIVIAN LIU: Well, thank you for joining us this morning and I look forward to sharing new developments with you as they occur. And as always, please feel free to contact us directly if you have any additional questions. Thank you.

OPERATOR: Thank you. Ladies and gentlemen, this concludes today's teleconference. You may disconnect your lines at this time. Thank you all for your participation.

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