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RXII - Q4 2017 Rxi Pharmaceuticals Corp Earnings Call

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PRESENTATION

Operator

Welcome to the webcast entitled, RXi Pharmaceuticals Fourth Quarter and Year End 2017 Financial Results Earnings Call.

Today's call is being recorded.

At this time, it is my pleasure to turn the floor over to your Head of Investor Relations for RXi, Tamara McGrillen.

Tamara McGrillen - *RXi Pharmaceuticals Corporation - Head, IR*

Thank you for participating on our call today.

We are joined by our President and CEO, Dr. Geert Cauwenbergh, our Chief Development Officer, Dr. Gerrit Dispersyn, and our Principal Accounting Officer, Ms. Caitlin Kontulis.

I would like to remind listeners that this call will contain certain statements concerning RXi's future expectations, plans, and processes which constitute forward-looking statements for the purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements and as a result of various important factors including those discussed in our most recent Form 10-K filed with the SEC.

In addition, any forward-looking statements represent our views only as of the date of this recording and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligations to update such statements.

Now I would like to turn the call over to our President and CEO, Dr. Cauwenbergh.

Geert Cauwenbergh - *RXi Pharmaceuticals Corporation - President, CEO*

The acquisition of MirImmune in January of 2017 was a bold step for our Company into the field of immuno-oncology and adoptive cell therapy and has allowed us to embark on the exploration of the unique cell delivering properties of RNAi technology in this new and rapidly growing field of medicine, with major value creating opportunities while also serving major unmet needs for patients.

Dr. Dispersyn, our Chief Development Officer will provide a review and also focus on the progress we've made in recent months in this space.

Financially, we have worked to integrate MirImmune in RXi Pharmaceuticals. We, of course, ensured that we were able to continue our ongoing clinical programs in dermatology and ophthalmology during the past years, while also investing in the newly acquired therapeutic areas. This

parallel effort has moderately increased our spending over the course of 2017. Ms. Kontulis will provide you with the financial details as well as some projections going forward.

The year 2017 has allowed us to harvest most of our dermatology and ophthalmology preclinical and clinical activities. Although we had expected that we would have been able to release all data on all clinical studies, some logistical issues in data collection, while not affecting data integrity, have caused some delays, resulting in some of the final reporting activities for those studies to slip into 2018.

Having seen some of the clinical results in recent months, albeit not complete, we feel confident that our work has resulted in a solid demonstration that our sd-rxRNA approach is more than just a strong patent family.

The results offer comforting proof that our proprietary compounds are safe for use in humans even with intra-auricular injections and that they, as already indicated in the dermatology studies, can significantly alter disease processes resulting in clinically measurable improvements.

In addition, some creative topical formulation work has resulted in the capability to deliver our sd-rxRNA molecules with a molecular weight of about 10 kilodaltons through the epidermis through the level of the dermal-epidermal junction.

Of course, a very justified question has arisen from our shareholder base and from our Board of Directors. A small Company of the size of RXi cannot continue development efforts in three totally different therapeutic areas without being punished financially. For that reason, late last year, our board instructed us to make a careful analysis of our three therapeutic areas and their expected financial evolution.

The conclusion of this exercise was that the space in which RXi was most expected to generate value most rapidly for both patients and shareholders was likely immuno-oncology and cell therapy.

In depth discussions with academic thought leaders in both the US and Europe made it quite evident that the versatility of the sd-rxRNA platform could be the key to unlock therapeutic progress not only in the space of check points inhibitors but as direct therapy and when used as a complement to existing cell therapy protocols. But that our companies could also play a role in optimizing cell differentiation, which could add to the therapeutic potential of conventional cell therapy as well as CAR T-cell therapy protocols.

Also, the renewed interest in direct tumor treatments in relation to tumor proteins being expressed on the cervical tumors has brought our sd-rxRNA approach to the forefront of thinking about the potential of our approach to address this specific problem and this by the way is one of the comments and suggestions we received most from top academic groups. Therefore, we're also working on early exploratory research in that area.

The decision by our board was therefore logical and rational. We have been asked to focus 100% of the immuno-oncology and adoptive cell therapy space, while obviously trying to monetize the excellent work that our Company had done in the dermatology and ophthalmology space.

We have embarked on an extensive out-licensing effort for our dermatology and ophthalmology franchises including global exclusive access to our proprietary platform for future exploration and exploitation in those two therapeutic areas. The result of a transaction will provide us with non-dilutive cash, that allows us to further accelerate our program in the immuno-oncology and adoptive cell therapy space.

One last comment before I turn this call over to Caitlin. We are a small Company with a small number of employees. Due to their diligent, broad outreach efforts supported by our robust self-delivering RNA platform, we have attracted the attention of major academic players working in some of the largest and best-known institutions in Europe, such as the Karolinska Institute in Stockholm; the cancer center of Gustave Roussy in Paris, one of the largest in the world; and the Center of Cancer Immune Therapy or CCIT in Copenhagen, one of the leading centers in the world when it comes to autologous cell therapy.

In addition, our interactions with researchers in the Dana-Farber clinic in Boston and University of Minnesota, in Minneapolis, provides us with top quality advice from US institutions as well. Based on progress being made with our technology platform in all these places today it is our goal to enter the clinic in the next 12 to 18 months.

We will also expand our growing interactions with other companies like Medigene, working creatively on an immuno-oncology and adaptive cell therapy approach in oncological diseases.

And now, Caitlin, I'm happy to turn it over to you. You will provide a summary of our financial evolution in the past year and into 2018.

Caitlin Kontulis - *RXi Pharmaceuticals Corporation - PAO*

First, I would like to address the Company's amended interim financial statement filed today for each of the quarterly periods in 2017. In connection with the year-end audit of the Company's financial statement, an adjustment was identified based on the review of the tax related impact of the Company's acquisition of MirImmune.

Our previously reported results did not contemplate deferred taxes as a result of the different book and tax basis from the acquisition. The acquisition resulted in an increase of 1.6 million in our in-process research and development expense and a corresponding income tax benefit resulting from a reduction in the Company's valuation allowance, due to the deferred tax liability created as a result of the book and tax basis difference.

Despite being a non-cash charge, which did not affect previously reported net loss and operating cash flows have an impact on the Company's balance sheet., the Company amended these filings for our quarterly periods in 2017 to correctly present the aforementioned issue.

As a small organization, we engage and rely on third party tax accountants to provide technical expertise with respect to complex tax accounting matters and assist us in accurate recording and disclosure of tax-related matters in our financial statements.

We have begun the process of executing remediation plans to address this correction, which includes increased involvement of our third-party tax accountants on a quarterly basis and reviewing our tax accounting processes to implement enhanced tax accounting processes and controls. We believe these plans will remediate any deficiencies identified and strengthen our internal control over financial reporting.

The Company also filed its annual report on form 10-K today with the SEC. This report includes detailed information on the Company's financial performance for the year ended December 31, 2017, and I will now focus on select financial highlights for this period from this report.

In September 2017, the Company's collaborative partner BioAxone Biosciences received a grant award from the National Institute of Neurological Disorders and Stroke. BioAxone has been awarded a total of $1.8 million to fund the collaborative project over two years.

For our contribution on this grant, we will receive $129,000 in the first year, with the potential to receive an additional $120,000 in the second year, after achieving certain milestones. The grant provides funding for further development of BioAxone's preclinical candidate BA-434, a novel sd-rxRNA compound that targets PTEN for the treatment of spinal cord injury.

Revenues for the quarter and year ended December 31, 2017 were $15,000. The Company had no revenue during the quarter ended December 31, 2016, and revenues of $19,000 for the year ended December 31, 2016.

Revenues for the quarter and year ended December 31, 2017 were due to the work performed by the Company under the grant with BioAxone and revenues for the year ended December 31, 2016 were due to the Company's exclusive out-licensing agreements with MirImmune prior to its acquisition by the Company and with Thera Neuropharma.

Research and development expense for the quarter ended December 31, 2017 was $1.2 million as compared with $1.3 million for the quarter ended December 31, 2016. The decrease was due to lower spending on clinical trial-related expenses as subject visits in each of the Company's ongoing clinical trials came to an end. Research and development expense for the year ended December 31, 2017 was $5.4 million as compared with $5.4 million for the year ended December 31, 2016.

Overall, expenses were consistent year-over-year, despite an increase in direct R&D expenses due to the addition of the immuno-oncology program to the Company's development pipeline, in the first quarter of 2017 with the acquisition of MirImmune, which was offset by a decrease in non-cash stock-based compensation expense.

In January 2017, the Company acquired all of the issued and outstanding capital stock of MirImmune, a privately held biotechnology Company that was engaged in the development of cancer immunotherapy in exchange for securities of the Company.

The aggregate share value of the consideration given which included transaction costs, liabilities assumed and cancellation of notes receivable and the deferred tax impacts of the acquisition was recorded as in-process research and development.

Acquired in-process research and development expense related to the acquisition of MirImmune was $5 million for the year ended December 31, 2017. The Company did not have acquired in-process research and development expense for the three months ended December 31, 2017, 2016 and the year ended December 31, 2016.

General and administrative expense for the quarter ended December 31, 2017 was $0.8 million as compared with $1 million for the quarter ended December 31, 2016. The decrease was due to a reduction in mailing and printing-related fees for the Company's annual meeting, which was held in the December timeframe in 2016, as well as a reduction in professional fees for legal services and employee-related expenses as compared to the prior year quarter.

General and administrative expense for the year ended December 31, 2017 was $4 million, as compared with $3.6 million for the year ended December 31, 2016. The increase was primarily due to payroll related expense including severance benefits related to the Company's former Chief Business Officer and professional fees for legal related services.

The Company recognized an income tax benefit of $1.6 million for the year ended December 31, 2017 due to the tax-related impact of the Company's acquisition of MirImmune. The Company did not have such expense for the three months ended December 31, 2017 or 2016 and the year ended December 31, 2016.

Net loss applicable to common stockholders for the quarter ended December 31, 2017 was $2 million compared with $4.4 million for the quarter ended December 31, 2016, the decrease was due to the one-time charge related to the beneficial conversion feature of the Company's series B convertible preferred stock in 2016.

Net loss applicable to common stockholders for the year ended December 31, 2017, was $12.5 million compared with $11.1 million for the year ended December 31, 2016. The increase is primarily driven by acquired in process research and development expense incurred for the acquisition of MirImmune offset by the one-time charge related to the beneficial conversion feature of the Company's series B convertible preferred stock in 2016.

At December 31, 2017, the Company had cash of $3.6 million as compared with $12.9 million at December 31, 2016. In August 2017, the Company entered into a purchase agreement with Lincoln Park Capital Fund pursuant to which we have the right to sell to LPC up to $15 million in shares of our common stock over the term of the agreement. To date, the Company had sold approximately $1.2 million in shares of our common stock to LPC.

The Company's operating burn rate during 2017 was approximately $2.5 million per quarter. In 2018, as we look to out license our dermatology and ophthalmology assets, the Company expects its burn rate to decrease to approximately $2 million per quarter.

Based on the Company's cash on hand and the availability of funds from the purchase agreement with LPC, including our current NASDAQ limitations, the Company expects to have a cash run rate until Q2, Q3 2018. To address this, the Company is actively exploring multiple avenues of funding.

With that, I'll turn the call over to Gerrit.

Gerrit Dispersyn - *RXi Pharmaceuticals Corporation - CDO*

Two-thousand-seventeen has been busy and exciting for RXi's research and development team. We have been running several clinical studies in parallel and presented the positive outcomes of several of these. In addition, after the acquisition of MirImmune, we have transformed our internal R&D to fully focus on immuno-oncology and have expanded our internal and external research programs in this new and exciting area.

On the clinical fronts, we announced the results of our 1402 study showing statistically significant and clinically meaningful results for use of RXi-109 to reduce the recurrence of hypertrophic scars, post scar-revision surgery.

These results not only validate the clinical usefulness of our sd-rxRNA platform but also directly support the safety and efficacy of RXi-109 to reduce recurrence of hypertrophic scars. The significance of RXi-109 treatment was observed both by using validated detailed scoring techniques as well as simple qualitative assessments.

In addition, investigator driven data was further corroborated by an analysis of patient preferences. Treatment with RXi-109 was well tolerated in all treatment arms, there were no drug-related serious adverse events and most other treatment emergent adverse events were those commonly found with intradermal injections. The data collected therefore provides a strong piece of evidence showing that RXi-109 can confidently be moved into the next phase of clinical development.

Further validation of our sd-rxRNA platform and of a proprietary topical formulation for use of our sd-rxRNA in skin application came from the consumer testing program with RXi-231. RXi-231 is a cosmetic ingredient based on sd-rxRNA that targets the enzyme Tyrosinase. The results of this program show that RXi-231 is well tolerated and that skin application of an RXi-231-containing gel can reduce change of skin tone treated by UV as compared to vehicle gel. These results provide relevant data not only about RXi-231 for its use in managing skin tone but also about our proprietary topical formulation.

We have been working on several clinical studies in parallel and efforts are ongoing to finalize the remaining study reports. These studies are our 1501 study with RXi-109 which is a Phase 1/2 study in ophthalmology indication namely in patients with advanced wet age-related macular degeneration and associated retinal scarring.

The other remaining study is our 1502 study which is our Phase 2 study with Samcyprone, our proprietary formulation of the small molecule DPCP, and we are developing standard Samcyprone for the treatment of cutaneous warts. Even though patient participation of these two studies ended in late December and early January respectively, we were not able to finish data collection in the anticipated time frame. More specifically, we underestimated the efforts require to get the vast amount of data in an analyzable data format.

FDA guidance and regulations around data collection are very specific and therefore we take this matter very seriously. We therefore also regret that we will not be able to report on the 1501 and 1502 studies by the end of this quarter as previously promised, but we will do so later in Q2.

With that being said, based on data collected so far, we reiterate information shared previously. First, in the study 1501, the primary study endpoint namely the safety data looks very clean. Based on available data to date, there have been no serious adverse events, nor any drug-related adverse events. In addition, in study 1502, we have seen a very high level of skin sensitization with Samcyprone which is promising as such skin sensitization is a prerequisite for therapeutic activity.

We have successfully transitioned our discovery and preclinical research efforts and are now focusing almost exclusively on developing our sd-rxRNA platform in the immuno-oncology cell therapy space. Internally, we have established the broad applicability of our sd-rxRNA platform in various immune effector cells. We have been able to show a robust uptake of our sd-rxRNA compounds in multiple relevant immune cell types, including T-cells, natural killer cells or NK cells, and dendritic cells.

Furthermore, we have been optimizing the cell culture parameters that result in the biggest impact on the cell phenotype and the resulting cell efficacy. We have been focusing on targets that are involved in checkpoint inhibition, and as such are weaponizing the immune cells to remain more active even when confronted with down regulating immune checkpoint signals, by tumor cells.

In addition, we've made good progress in identifying and optimizing targets involved in new cell differentiation and cell metabolic fitness. Both of these focus areas -- immune checkpoints and cell differentiation or cell fitness focus -- are applicable for both existing cell-based therapies used in the clinic as well as for new generations of engineered immune cells such as the recently approved CAR T-cells.

All of which saw the existing cell therapies and the newly approved ones, we believe we can further improve by our sd-rxRNA compounds that we currently have in development and discovery. The wide applicability of our technology and the ease of use thereof, thanks to the self-delivering nature of the molecules, has contributed significantly to our success in expanding our extramural research.

Indeed, we were able to set up several very interesting collaborations with renowned national and international institutions and companies. For example, we have announced collaborations with leading cancer institutions such as CCIT in Denmark and Gustave Roussy in France, and with leading biotechnology companies such as Medigene, in Germany, and PCI Biotech in Norway.

Through a combination of internal and external work we are aggressively working on the critical path to get our first immuno-oncology specific sd-rxRNA compound into the clinic within a 12 to 18 months timeframe. And that will be RXi-762 targeting PD-1.

To accomplish this, we've already started the required preclinical studies such as with tumor infiltrating lymphocytes, in indications such as melanoma and ovarian cancer. This in vitro efficacy and safety data will be required for regulatory submissions and will be available later this year.

We also have secured cGMP manufacturing of our lead compound and are well underway to get our first clinical batch ready over the next two months. This batch and the preclinical study results mentioned earlier will allow us to finalize the cell manufacturing protocol. In other words, we have established a clear path and started to make good progress on the clinical development of RXi-762.

In summary, we've provided results for a number of our clinical development programs and are working diligently to finalize the data points for those remaining. In the meantime, however, our focus on internal and external research in the immuno-oncology space has us prepared for a very interesting future.

Tamara McGrillen - *RXi Pharmaceuticals Corporation - Head, IR*

This concludes the formal presentation for today.

And Operator, we would like to open the call to questions, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

John Vandermosten, Zacks Small Cap Research.

John Vandermosten - *Zacks Small Cap Research - Analyst*

The first question is on one of your competitors who has an RNAi compound in front of the EMA and the FDA right now, and what is your thought on how that might open up the space for renewed interest or increased interest if there is a positive response from those regulatory agencies?

Geert Cauwenbergh - *RXi Pharmaceuticals Corporation - President, CEO*

I think this is a great question because as you have seen with the anti-sense oligonucleotides, as you have seen with antibodies, we're seeing the same thing here.

RNAi compounds have been in development for quite a long time and everything goes with ups and downs as we've seen in the past, and with the Alnylam or Quark -- one of the two, probably Alnylam, but I am not privy to the details -- going to get this year or early next year an approval for an RNAi compound in a human disease that will basically mean that people who have been watching the biotechnology space are going to see that, hey, it has arrived.

RNAi compounds are part of the day-to-day treatment paradigm and I think in general -- not just for us, but in general -- for all RNAi companies this is going to be a good thing.

John Vandermosten - *Zacks Small Cap Research - Analyst*

And the follow-up question is on the derm and ophthalmology assets that you are putting out there, a couple of thoughts on that to see if you could provide some additional color on the process there? And then if you're using any intermediaries to help you identify a good home for those?

Geert Cauwenbergh - *RXi Pharmaceuticals Corporation - President, CEO*

Yes, we are using intermediaries. We originally started out with the process on a personal basis because some of the people in the Company, including myself, have a reasonable connection with dermatology and ophthalmology. But when we got a lot of feedback or replies from companies, we realized that for us, we're 15 people in the Company; it's not easy to make sure that we are in a professional way, just giving feedback and answering all the questions.

We have requested the assistance of a person I have known for long time -- more than 15 years -- who used to be in Citibank or Citi Group as an investment banker and that person has started their own practice and she is doing a terrific job. And, basically, I don't want to say that in a negative sense, but herding cats; that things are being done in a professional manner.

Operator

(Operator Instructions)

There appears to be no more questions at this time.

Tamara McGrillen - *RXi Pharmaceuticals Corporation - Head, IR*

I would like to thank everybody for participating on our call today. Operator, you may please close the call.

Operator

This does conclude today's conference. We thank you for your participation. You may disconnect your lines at this time.
