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RXII - Q3 2017 Rxi Pharmaceuticals Corp Earnings Call

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Caitlin Kontulis *RXi Pharmaceuticals - PAO*

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Karen Bullock *RXi Pharmaceuticals - VP Research*

CONFERENCE CALL PARTICIPANTS

Carmelo Cataudella *Aegis Capital - Analyst*

PRESENTATION

Operator

Welcome to today's webcast entitled Rxi Pharmaceuticals Third Quarter 2017 Financial Results Earning Call.

Today's call is being recorded.

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

Tamara McGrillen - *RXi Pharmaceuticals - 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, our Vice President of Research, Dr. Karen Bullock, 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-Q 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 - CEO*

Thank you, Tammy, and good afternoon, everybody.

As we have been expanding our activities in the immuno-oncology space, while, at the same time, doing an intense effort to harvest data from our clinical trials in dermatology and ophthalmology, we have seen a slight increase in our spending in Q3 of this year. Ms. Kontulis will provide you with more color around our use of cash in the past quarter and going forward.



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From a clinical point of view, we remain on track to report our clinical phase II data from the RXI-109 study in hypertrophic scars as well as from the first phase of our Samcyprone study in warts and the learnings from our study with RXI-231 in pigmentation before the end of this year.

In ophthalmology, the last patient will complete the four-month follow-up phase post-treatment at the end of December. We are targeting to have some topline data available early in the New Year.

From a research and pre-clinical point of view, our team has been concentrating on immuno-oncology both with animal studies and in vitro work. The other work is concentrating on the use of our sd-rxRNA checkpoint inhibitors against PD-1 and TIGIT with meso-CAR T cells in mice with ovarian cancer. Additional animal models looking at other solid tumors are currently ongoing.

In vitro, we are evaluating our sd-rxRNA finding various immune effector cells, including normal T cells, CART cells, natural killer cells, tumor-infiltrating lymphocytes and then dendritic cells.

We are also establishing collaborations with internationally recognized academic centers of excellence cancer research and expect to announce more details on such collaborations in the near future.

From an M&A and BD point of view, we feel that we are making good progress with several discussions with potential partners ongoing.

Finally, the question is asked quite often about our NASDAQ listing in relation to our share price. Management and the board are fully aware of the NASDAQ requirements and are keeping a close eye on the timing of the upcoming data points, the ongoing deal negotiations and the calendar for complying NASDAQ requirements to maintain the listing.

And with this, I want to hand the call over to Ms. Kontulis to provide more detail on the financial aspects.

Caitlin Kontulis - Rxi Pharmaceuticals - PAO

Thank you, Geert. Good afternoon, everyone.

Today, the Company filed its Form 10-Q for the three and nine months ended September 30, 2017 with the SEC. The filing includes detailed information on the Company's financial performance for these periods. During our call today, I'll focus on select financial highlights from the quarterly period.

Research and development expenses were \$1.5 million for the quarter ended September 30, 2017 as compared with \$1.5 million for the same period in 2016. Overall, research and development expenses were consistent quarter-over-quarter. There slight increases due to the subject fees for the second cohort of the Company's Phase 2 clinical trial with Samcyprone and pre-clinical work on our new immunotherapy program that was integrated into the company with the acquisition of MirImmune in the first quarter of this year. These increases were offset by a decrease in our stock-based compensation expense.

General and administrative expenses for the quarter ended September 30, 2017 were \$1 million as compared with \$0.8 million for the quarter ended September 30, 2016. The increase in general and administrative expenses was primarily due to payroll related expenses including severance benefits for the hire of the Company's former Chief Business Officer in connection with the acquisition of MirImmune resulting in a higher employee headcount as compared to the same period of the prior year. This was offset by a decrease in stock-based compensation expense.

Net loss was \$2.5 million for the quarter ended September 30, 2017 as compared with \$2.2 million for the same period in the prior year. The increase in net loss is primarily driven by the change general and administrative expenses, as just discussed.

On August 30, 2017, the Company entered into a purchase agreement with Lincoln Park Capital Fund, or LPC, pursuant to which we have the right to sell to LPC up to \$15 million in shares of the Company's common stock over the 30-month term of the agreement. Proceeds received from this



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agreement are expected to be used for general corporate purposes, including but not limited to the advancement of our immunotherapy program, our current and planned clinical trials and general and administrative expenses. To date, there have been no purchases under this agreement.

At September 30, 2017, the Company had cashed \$5.4 million compared with \$12.9 million at December 31, 2016. On average, the Company's quarterly cash burn is approximately \$2.5 million. Based on our operational spending rate, our cash on hand and our initial limitations under the purchase agreement with LPC, the company expects to have available cash until the third quarter of 2018. If the Company is able to access the full available funds with LPC, it would provide the company with cash until the fourth quarter of 2019.

We have not yet drawn down on the equity line with LPC but continue to be diligent in our focus on our share price in current spending needs, so that when we do utilize the funds, we are doing so in such a manner that is both beneficial to the Company and to our shareholders.

I will turn the call over to Gerrit who will provide an update on the Company's clinical trials.

Gerrit Dispersyn - *RXi Pharmaceuticals - CDO*

Thank you, Caitlin, and good afternoon, everyone.

On the R&D front, we had and continue to have a very busy quarter. In the next few minutes, I will give an overview of what is going on at the clinical development front and Dr. Karen Bullock will provide an overview of our non-clinical research and development activities.

Our clinical development programs are extremely busy, as our four clinical studies are nearing completion. This creates a significant peak workload and we have taken measures to outsource some of this work in order to keep our overall timelines intact and in line with previous announcements about their timing. Let me give you some more details from each of these studies.

RXI-109-1402 is a Phase 2 study where we are evaluating RXI-109 for the management of hypertrophic scars after a scar revision surgery. The patient participation of this study was finished in Q3. We are in the final phases of data analysis and are preparing to complete datasets for report out later in this quarter. I know that you're all anxious awaiting the results but we will have to wait for the full analysis to complete. As previously announced, a formal study analysis cannot be done piecemeal wise, so stay tuned.

RXI-109 is also being studied in a Phase 1/2 study in an ophthalmology indication namely in patients with advanced, wet age-related macular degeneration and associated retinal scarring. We are evaluating the safety and tolerability of intraocular injections of RXI-109 in these patients.

In this study, the last two patients are in the follow-up phase. As Geert mentioned, the last patient, last visit is scheduled to occur late in December. We are executing on a plan to have as much data as possible collected and locked prior to that visit so that we need only a short time between the last patient, last visit and data analysis. Therefore, we expect to announce top line data of this study early in 2018 as previously announced.

We made great progress on our consumer testing program with RXI-231 a cosmetic ingredient based on sd-rxRNA that targets the enzyme, Tyrosinase. We believe that this product may impact skin pigmentation levels, thereby improving skin appearance. After successfully completing two safety studies, RXI-231 is now being investigated in an open label, single arm, non-randomized, evaluator blinded pilot study. The study involves a one-time controlled UV exposure and test product application for up to three days prior and up to ten days after the UV exposure.

Clinical grading of skin erythema and pigmentation as well as skin color assessments using a specialized color meter are performed to assess the impact of the UV exposure in the test product applications. Subject participation in this study is completed. This is the last of the three-consumer testing studies with RXI-231 and we expect to report the results in the near future.

RXI-SCP-1502 is our Phase 2 study with Samcyprone, our proprietary formulation of the small molecule DPCP, which we are developing for the treatment of cutaneous warts. This is a multi-centered, multi-dose trial conducted in subjects with at least one cutaneous or plantar wart present for at least four weeks. Subjects are first treated with sensitization dose on the inner arm and on one or more preselected warts. Once the sensitization



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response is confirmed, subjects continue with weekly treatments for ten weeks during the main study phase. Depending on the wart clearance status, some subjects are offered to continue in a study extension phase as per protocol.

Enrolled in the second and last cohort started in early Q2 which was later than originally planned. The second cohort uses a more subject-friendly protocol, mainly a lower sensitization dose. An acceleration of the enrolment rate was the major focus over the last several months. And in September, we announced the completion of enrolment in this study. The treatment period of the main study phase for cohort 2 subjects is therefore nearing completion, so we are on track to report top line data on the main studies phase late Q4.

So, in summary, we have a few extremely interesting months ahead of us and I look forward to discussing outcomes of our studies with you in the near future.

Dr. Karen Bullock will now provide you with recent highlights of our discovery research and pre-clinical development programs. Karen?

Karen Bullock - *RXi Pharmaceuticals - VP Research*

Thank you, Gerrit, and hello, everyone.

For the past several months, our discovery and pre-clinical efforts have focused almost exclusively on developing the sd-rxRNA platform in the immuno-oncology cell therapy space. First, we are working to establish the broad applicability of our sd-rxRNA platform in this area. We have been able to show robust uptake of a fluorescently labeled sd-rxRNA in multiple relevant immune cell types, including T-cells, natural killer, or NK cells, and dendritic cells.

In each case, the uptake results in robust dose-dependent silencing of the target genes with little to no impact on cell viability. Our ability to establish feasibility with our platform in each of these cell types allows us to access and potentially improve many adoptive cell transfer platforms and treatments.

In addition, we are working to establish relationships and collaborations with key investigators in the field of ACT for immunotherapy of cancer. With this outreach, we are specifically targeting groups that are able to take a translational approach to research collaboration where positive results and pre-clinical models can result in possible clinical paths forward. These collaborations will be initially focused on existing treatment approaches using non-engineered cells such as tumor-infiltrating lymphocytes and natural killer cells.

With regards to the clinical path forward, we are happy to announce that GMP manufacturer of RXI-762, an sd-rxRNA targeting PD-1 remains on track to be delivered in the first half of next year and will be available to support perspective clinical paths we pursue as early as the end of 2018.

Considering the importance of the recent approvals of the first two CAR T-cells products, we continue our efforts to establish proof of concept for sd-rxRNA inhibition of checkpoint targets to improve the efficacy of CAR T-cells targeting solid tumors.

To do this, we are studying a previously published CAR T platform engineered to target mesothelin, which are referred to as meso-CAR T-cells. We are currently working on several in vivo studies in human cancers xenograft models in mice to evaluate meso-CAR T-cells and checkpoint targeting sd-rxRNA, including RXI-762 targeting PD-1, RXI-804 targeting TIGIT and others. We will provide updates on the result of these studies in the coming months.

Finally, we have initiated a discovery stage program to select targets and identify sd-rxRNA compounds that can be used alone or in combination to modulate T-cell differentiation and metabolism. There is much evidence and literature to suggest that when a population of T-cells used for adoptive cell transfer treatments, such as CAR T or TCR cells are more stem like. The cells have better persistence in the host and better efficacy against tumors.



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We have identified a panel of relevant targets and we are initiating and screening of sd-rxRNA against these targets. The compounds will then be evaluated in phenotypic assays in T-cells during the first half of 2018. If successful, compounds such as these should generate interest from potential business partners and collaborators developing engineering T-cells.

Outside of the immuno-oncology space, we continue collaborative efforts to develop sd-rxRNA compounds for local delivery applications. BioAxone Biosciences is a company developing therapeutics to treat spinal cord injury. They have received an SBIR Grant Award to develop and sd-rxRNA compound, BA-434, targeting P-10 for this indication.

P-10 is a protein known to be a barrier to regeneration and silencing this target may support regeneration in the adult central nervous system. As a collaborator on the grant, RXi received a sub-award to support the design and synthesis of chemically-optimized versions of the compound that BioAxone will test in pre-clinical models of spinal cord injury.

Now, with that, I will turn the call back to Tammy.

Tamara McGrillen: Thank you, Karen.

This concludes the formal presentation for today. Operator, we would like to open the call for questions, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question comes [Justin Foster]. Your line open.

Unidentified Participant

Thank you, good afternoon. [With any] part of your arrangement with Lincoln Park, is there a requirement that should remain on NASDAQ and is part of your agreement with the funding by Lincoln Park.

Geert Cauwenbergh - Rxi Pharmaceuticals - CEO

I will leave that to Caitlin.

Caitlin Kontulis - Rxi Pharmaceuticals - PAO

Can you just repeat your question, please?

Unidentified Participant

Yes, I'm sorry. As part of the agreement with Lincoln Park Capital Fund that you remain listed on the NASDAQ exchange, is that a requirement.

Caitlin Kontulis - Rxi Pharmaceuticals - PAO

-- enlisted on NASDAQ, no, but we are, [to use] best efforts, remain listed on a national exchange or the NASDAQ, NYSE or OTC markets.



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Unidentified Participant

Okay. Well, the main thing I wanted to know is whether it was required. Because as you may know, I think that the stock is being sold [shorters] because they know you're going to do a reverse split. And that if you were to be free (inaudible) of the requirement of being on NASDAQ, then you wouldn't have to do a reverse split and your stock wouldn't be sold off with hundreds of thousands of shares every day whoever these people. But I've said that before, so I just hope that you will keep that in mind when the doctor (inaudible) immediately upon your talk today, I deduce that you are under pressure for some colors to remain on NASDAQ, and I think that's a necessary requirement.

My second question has to do with Dr. Eliseev. He sold a hundred thousands of shares before his departure. Can you tell me whether his departure had something do with that that it just wasn't announced a month later or that at that time he sold his shares, he didn't know that he would be living?

Geert Cauwenbergh - Rxi Pharmaceuticals - CEO

I can probably answer that question.

Unidentified Participant

Thank you.

Geert Cauwenbergh - Rxi Pharmaceuticals - CEO

Those two things are -- no problem. Those things are actually unrelated. It is (inaudible) basically, when we acquired Mirlmmune, Dr. Eliseev was by far at the best position to know exactly what needed to be done, in terms to integrate as quickly and as eventually as possible the activities Mirlmmune into our activities. And Eliseev did a terrific job in making that happen. We have been able, in a record time, to adjust what we are doing to what Mirlmmune was bringing to the table and this rather impressive innovations that are basically coming out of the work they have done, so I hope that we will be able to benefit from that.

But relative at his own life and has been evolving venture investments and what I do, and that, at some point in time, is (inaudible) that it was probably better to leave and we certainly didn't want to keep anybody who feels that they have another mission in life.

Unidentified Participant

Understood. But just to clarify that the time that he was employed and he sold his shares, you guys were not aware that that was his plan, is that correct?

Geert Cauwenbergh - Rxi Pharmaceuticals - CEO

For instance, anybody who wants to sell shares in the company can sell shares in the company. When you're an officer, you have to go through certain processes, which he did. And I cannot judge the financial situation of individuals and they are free to do whatever they want to do as long as they do it in line with the legal requirements of SEC and other authorities which he, in this case, did.

Unidentified Participant

Okay, of course. I understand that. I just need final clarification. Thank you very much for candor, very much appreciated. His selling of those shares was not related to his departure in your opinion? In other words, you guys were -- you were probably surprised by his decision because I guess he



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didn't offer them to anybody outside the outside market inside in order to avoid selling them on the open market. So did that lead in any way to his earlier departure than otherwise would have been planned?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

I don't know what he had in mind when he joined. But I can only tell you that, yes, he continued to offer his assistance in making sure that we can make the right deals.

Operator

[Steven Felter]. Your line is open.

Unidentified Participant

All right. I am still a bit unclear as to why the RXI-231 drug is not being tested on a scale with normal pigmentation. Can you clarify?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

What do you mean by normal -- sorry, go ahead.

Unidentified Participant

Well, it's being tested on skin that has UV exposure sort of a hyper pigmentation of excess with (inaudible), and that I can -- that's a good thing to know. But what is the efficacy on a skin that has no exposure to sun (inaudible) lightening the skin?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Go ahead, Gerrit.

Gerrit Dispersyn - *RXi Pharmaceuticals - CDO*

Yes, I can answer that question. So, yes, so when you are developing a product like that, you are looking for a proof of concept study in this one. You're looking for the most controlled circumstances. And all kinds of pigmentation, whether it's existing pigmentation or a pigmentation that is induced by UV under an experimental, is the same, right? So it's an increase of the melanin in the skin. So the problem when you are selecting subjects with pre-existing pigmentation is that it's very difficult to control for it because the size and the depth of the color, et cetera, et cetera, is different. So it would require a much larger study to do so.

Also, from a pure cosmetic view point, as you may know, cosmetics are being used to essentially prevent something to be happening, right? So you have cosmetics for wrinkle prevention, et cetera, et cetera. So testing the product in circumstance that you have a control over what happens in a prevention mechanism is definitely also more aligned with the scientific question for a cosmetic being developed. So those were the two main reasons why we designed to study as it was. And quite frankly, it's a study design that we didn't come up with. It's a study design that's well described on literature as well. And it allowed us, as [ESMs] a shorter study, a quicker read-out and more alignment with what we want to know from a cosmetic treatment view point.



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Unidentified Participant

So with the further -- if the (inaudible) of this one successful, would there have to be further studies to see how it operates, how the efficacy would be on this, like I say, normal pigmentation on skin?

Geert Cauwenbergh - Rxi Pharmaceuticals - CEO

So maybe I can expand a little bit on it. Although this is (inaudible) protocol. It has been used by companies like (inaudible) when the testing the products. We also build in the possibility to look at the difference between pretreatment and acute treatment. Well, treatment, I should say, applications because it's not like if it's not a treatment. And the -- so we are analyzing as they come in, also in that (inaudible) because, for instance, when you get heavy UV exposures, you have an inflammatory response that may have different reactions and when you treat the patients or people on prophylactic basis, and that is worth knowing as well.

So it is really an early test. We really think we are learning a lot from it. And then at that point, we will have to decide if we continue the cosmetic route and probably look for a cosmetic partner, or if we continue with drug route which we could also decide to do depending on what we find there, what the findings are, and that's been a different approach. Is that an answer to your question?

Unidentified Participant

Okay, that's -- yes, you know. Now, I understand and I appreciate that.

If I can one other (inaudible). I don't know how much work has been done this year or (inaudible). But it would be -- I know you're still in the process of incurring (inaudible) a tougher component and count it to make it effective. I was just wondering if you could give us an update, you know, progress being made?

Caitlin Kontulis - Rxi Pharmaceuticals - PAO

I'm really sorry. We missed the beginning the of your question, sir.

Unidentified Participant

Okay. The -- regarding the RXI-185 product for anti-collagenase, I just want to see if there is any kind of update on it to report.

Geert Cauwenbergh - Rxi Pharmaceuticals - CEO

Right now, there is no update. The work that was done which, by the way, was promising, overall, it's very promising, that was together with a major supplier of actually one of the largest in the world, suppliers of ingredients for the cosmetic industry, they did work and it was -- and that's really positive. You can find it somewhere on the website, I'm sure. So they basically created a formulation. And they did work on human skin (inaudible), skin taken from humans. And they treated it for six days because that's about the maximum time they can keep that skin alive and biologically active.

And so they didn't find any effect with a topical administration in the first two days. But they were showing a significant reduction of collagenase activity at day four and day six, which is already, my mind, a very useful finding because you're talking a 10 [kilodalton] or 11 kilodalton but there's certainly a relatively large compound that they were able to get through human skin in a way that it had a biological effect in terms of [marking the enzyme].



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So that and hopefully the results with 231 in pigmentation will make it clear that we have topical formulations available that can deliver this kind of sized compounds through the epidermis, through the dermal, epidermal junction, or maybe into the dermis.

And by the way, just to stretch that, today, we are working with 109 with intradermal injections. If that indeed is shown in the studies with ex-vivo studies in human skin with anti-collagenase and hopefully also in the clinical study with clinical tests in volunteers with the 231, that gives us an indication that we might think of 109 for a topical formulation to be used chronically afterwards, after we've first treated initially at first scar revision surgery with intradermal, which would make it a lot more convenient for patients who undergo that kind of surgery to basically treat itself. There could be some broader interesting follow-ups as a result of this work.

Operator

Carmelo with Aegis Capital. Your line is open.

Carmelo Cataudella - Aegis Capital - Analyst

Hey, guys. Great to hear of the updates this past quarter. My question was actually on the RXI-231. Thank you, though.

Caitlin Kontulis - Rxi Pharmaceuticals - PAO

Sure. Thanks, Carmelo.

Operator

(Operator Instructions)

Bryant Speaker. Your line is open.

Unidentified Participant

Hi, yes. Thank you for taking my call. I just want to switch gears a little bit. I just wanted to kind of address the elephant in the room. I know there's many, many shareholders there with the company for quite some time has not something in touch of RXi have really taken a beating in test taken and tremendous kind of losses due to the 90% plus share price decline over the last couple of years. It's a very simple question going forward and I'm sure many shareholders would like to know. Should we as shareholders trust you with our investments going forward that you're going to be able to deliver at all of these promising elements before the end of the year as stated on the last conference call?

Geert Cauwenbergh - Rxi Pharmaceuticals - CEO

Thanks for that question. It's a very good question. Me, as a staunch buyer of RXi shares on a regular basis, don't have that same question for a simple reason that I feel that what I'm -- I repeat what I've said five-and-a-half years ago to the [HR] manager who wanted to sponsor and finance a spin-out after originally being negative about [RNA highs] because I was a small molecule person five-and-a-half years ago. After three months doing the due diligence for him on a consulting which is basically -- I thought that RNA highs were basically a [misfit]. I -- when he asked me, "Should I put my money in the [lotto]?" I said, "You would be crazy not to do it because it's gold mine, a potential goldmine. It means work but it's a potential goldmine. Anything that I said then still stands in my mind today.

So I understand the beating that has been taken and the beating that has been taken is not necessarily because of the [news flow] from the company, it has been happening. And I don't want to point things to anybody but it has been happening because of financial [machinations] road that



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happened very often with small biotech. And that is a risk of investing in small biotechs. There're forces out there that put a lot more money to pay in order to make gains. At the same time, I have not sold one share and I continue to buy because I truly believe that one day, this is going turn out as a major -- believe is not the kind of word you should be looking when you're investing. It's more than belief as certainty or so. But in my case, it is a belief I can now understand, for instance -- sorry that I go on like this but I'm sort of passionate about it. I cannot understand that -- I beg your pardon?

Unidentified Participant

No, thank you. That's good. Continue on.

Geert Cauwenbergh - Rxi Pharmaceuticals - CEO

Sorry. So I can now understand, for instance, why people are still so fascinated with antibodies, because an antibody acts -- and I'm thinking now immuno-oncology and cell therapy, okay? An antibody acts against the bad protein that has been already [fooled]. We can stop that protein from being fooled by basically making sure that the messenger on A doesn't get translated into protein.

My mom told me that prevention is better than treatment. So 20 years from now, I would not be surprised if the RNAi space, and I hope that we will give significant part of it, of course, may have taken over 50% of the antibody market. (inaudible) statement, but fortunately is forward-looking 15, 20 years. But I cannot imagine why antibodies will continue to be primadonna when you have something like RNA, we have mastered it. I'm sure there's other people who will master it and get rid of vehicles and find other ways to get into cells. And it's going to change the game. And I'm not hallucinating, trust me. I'm a pretty down to earth guy when it comes to science.

Unidentified Participant

Okay, great. Thank you for your response and your passion. I appreciate it.

Operator

There appears to be no more questions at this time.

Tamara McGrillen - Rxi Pharmaceuticals - IR

Thank you, Operator. At this point, we'd like to thank everybody for participating on our call and we may close the call.

Operator

Thank you. This does concludes today's conference. We thank you for your participation. You may disconnect your lines at this time and everyone have a great day.



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