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RXII - Q2 2017 Rxi Pharmaceuticals Corp Earnings Call

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Michael May *Walsh University - Analyst*

PRESENTATION

Operator

Welcome to today's webcast entitled RXi Pharmaceuticals Second Quarter 2017 Financial Results conference call.

Today's call is being recorded.

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

Tamara McGrillen - *RXi Pharmaceuticals - IR*

Thank you, Operator. Good afternoon, ladies and gentlemen. Thank you for participating on our call today.

We are joined by our President and CEO, Dr. Geert Cauwenbergh; our Chief Business Officer, Dr. Alexey Eliseev; our Chief Development Officer, Dr. Gerrit Dispersyn; and 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 Dr. Cauwenbergh.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Thank you very much, Tammy. Good afternoon, everybody.

As you will hear from our management team during this call, we have been working intensely in the past six months to organize the Company to absorb the activities acquired through MirImmune in an exciting and potentially transformational approach to immuno-oncology and cell therapy. Extensive reach-out to interested parties, both academic and industrial have been ongoing and several of these players understand and see the potential that our self-delivering our RNAi technology can bring to the space.

In order to have our Board to reflect this important addition to our Company, the Board members decided to invite Dr. Jonathan Freeman to become a member of the RXi Board of Directors. Dr. Freeman serves as the Chief Business Officer at Vedanta Biosciences, a privately-held company developing a class of drugs that work by modulating the human microbiome. Previously, Dr. Freeman was Senior Vice President, Head of Strategy Development and Portfolio Management at Merck AG, the German Merck. During his tenure, Jonathan was responsible for the portfolio and the strategic shift that repositioned the Merck AG as a major player in the immuno-oncology space. Prior to that role, he was the Head of Global Business Development and Licensing at Merck, executing more than 30 transactions and structured financings.

During his career Jonathan has developed a remarkable global network of valuable contacts in the biotechnology industry with special emphasis on immuno-oncology that should be able to help us to reach out to a number of potential partners for collaborative activities as well as businesses development opportunities.

Both Dr. Dispersyn and Dr. Eliseev will provide updates respectively on our internal activities to immuno-oncology research and development as well as our external business development efforts and our outreach to create an excellent partnership network of premier academic and industrial groups to help us advance swiftly in this new and highly valuable therapeutic area.

Of course, in addition to the immuno-oncology activities, we have also quite a number of very important clinical projects running in dermatology and ophthalmology. As we all know, clinical studies can be complex and time-consuming activities, especially in more chronic conditions such as scarring. It is therefore also with pleasure that I can confirm that as mentioned already in December of last year, during our annual general meeting, we expect to be able to provide a first readout of those studies later this year. Dr. Dispersyn and the whole clinical and regulatory team are doing a great job in harvesting all data and processing that information in line with required regulatory standards, and Gerrit will also provide a detailed update on those activities and expected timing of data release.

One can imagine that juggling all projects within the budget limitation of a small biotech company is not always obvious. I'm therefore also pleased to be able to say that once again, we have been able to keep our cash burn new in line with the numbers we have put forward in previous quarterly update calls. Caitlin Kontulis will provide more detailed information on our financial picture.

Along those lines, we're pleased that we have come to an agreement with Lincoln Park Capital, who has committed to provide us with a common share equity line, up to $15 million. LPC has been a loyal shareholder in our company since 2014 and has been intrigued by our entry into immuno-oncology and cell therapy, using our self-delivering RNAi platform as a versatile tool that could become a game-changer in this space. They had expressed an interest in providing a financial support in achieving our goals. And based on our past good experience with this firm, we have happily entered into that agreement. Caitlin will also provide more details as to the specifics of that agreement.

And on that note, I'm happy to hand the call over to you.

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

Thank you, Geert. Good afternoon, everyone.

Today, the Company filed its Form 10-Q for the second quarter of 2017 with the SEC. The form includes detailed information on the Company's financial performance for the three and six months ended June 30, 2017. During our call today, I'll focus on select financial highlights from the quarter.

Research and development expenses for the quarter ended June 30, 2017 were $1.3 million compared with $1.3 million for the quarter ended June 30, 2016. General, research and development expenses increased from the prior year quarter due to a ramp-up in subject enrollment rated to the second cohort in the Company's Phase 2a work trail with Samcyprone which was offset by a decrease in stock-based compensation expense. This resulted in consistent, quarter-over-quarter overall net R&D expenses.

In January 2017, the Company acquired all of the issued and outstanding capital stock of MirImmune, Inc., a privately held biotechnology company that was engaged in the development of cancer immunotherapies. In exchange, the Company issued shares of its common stock and Series C

convertible preferred stock, which were subject to a 3% holdback for any purchase price adjustments. The holdback shares were released on April 12, 2017 and the Company recorded $0.9 million of acquired in-process research and development expense for the quarter ended June 30, 2017 related to the value of these securities, subject to the holdback. The Company had no such expense in the same quarter of the prior year.

General and administrative expenses for the quarter ended June 30, 2017 were $1.1 million compared with $0.9 million for the quarter ended June 30, 2016. The increase in G&A expenses was due to an increase in employee headcount in connection with the acquisition of MirImmune as well as increases in the Company's legal and accounting fees offset by a decrease in stock-based compensation expense.

Net loss for the three months ended June 30, 2017 was $2.5 million, compared with $2.2 million for the three months ended June 30, 2016. The increase in net loss was primarily driven by the changes in acquired in-process research and development expense, and general and administrative expenses, as just discussed.

At June 30, 2017, the Company had cash of $7.7 million, compared with cash of $12.9 million at December 31, 2016. On August 8th, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC or LPC, pursuant to which the Company has the right to sell to LPC up to $15 million in shares of common stock of the Company over the 30 months term of the agreement. Under the agreement, the Company can direct LPC to purchase the 150,000 shares of common stock on any business day, which may be increased up to a maximum of 500,000 shares, depending on the market price of our common stock at the time of sale, as set forth in the agreement. In addition to these purchases, the Company may direct LPC to purchase additional amounts as accelerated purchases or as additional purchases. The purchase price of the shares will be based on the prevailing market prices of the Company's common stock at the time of each sale to LPC. This will provide the Company with the controlled method of accessing capital as the Company will be in control of the timing of any purchases. The Company believes its existing cash and the potential proceeds from the equity facility with LPC should be sufficient to fund the Company's operations for at least the next 12 months.

Lastly, on August 2nd, the Company received written notice from the NASDAQ Stock Market that the Company was granted an additional 180 calendar days to regain compliance with the minimum bid price requirements set forth in the NASDAQ listing rules. With this extension, the Company has until January 29, 2018 to regain compliance by maintaining a closing bid price of at least $1 for 10 consecutive days. The timing of the expansion with NASDAQ coincides with the expected steady news flow in the remainder of this year on all of our programs, which may help the Company to come in compliance with the listing requirements without requiring a reverse stock split. At this time, the notice has no effect on the listing of the Company's common stock.

With that, I will turn the call over to Dr. Dispersyn.

Gerrit Dispersyn - *RXi Pharmaceuticals - CDO*

Thank you, Caitlin, and hello, everyone.

Today, I'm happy to report on some significant progress of our development programs. On the clinical development front, we have been able to get all of our ongoing clinical programs on schedule, as announced this morning. Therefore, between now and the end of the year, we expect to report out key data from these studies.

As you know, RXI-109 is our sd-rxRNA reducing the expression of connective tissue growth factor or CTGF. This compound is currently being evaluated in two clinical studies, Phase 2 study in dermatology and a Phase 1/2 study in ophthalmology.

In our dermatology study, RXI-109-1402, we're evaluating RXI-109 for the management of hypertrophic scars after scar revision surgery. We have four cohorts in this study evaluating different dose levels and dose schedules. We recently announced that we finalized patient participation in the fourth and last cohort.

Since our last call, we were also able to close all investigational sites and lock the study data base. Data analysis is ongoing which is time-consuming, considering the vast amount of data. In addition, we're preparing all collected paired clinical photographs for a per protocol independent analysis. By doing this, we're preparing to complete data sets for report out. The complete data set will include conclusions based on scar evolution from

investigators and from patients, image analysis review by independent panel, safety data, demographic data and a formal comparison as to which treatment regimen resulted in the best scar outcomes. Based on this, we expect to be able to report final study outcomes by early Q4.

In ophthalmology, study 1501 is being conducted to evaluate the safety and tolerability of intraocular injections of RXI-109 in patients with advanced wet age-related macular degeneration and associate retinal scarring. This is primarily a safety study to evaluate the health of the patient and the effect on the study eye after studied dose administration. But in this study, we're also evaluating some exploratory endpoints related to efficacy, such as the impact on visual acuity and the size of the original retinal scar over time. We recently announced the important milestone of the completion of patient enrollment. This means that we're likely to finish patient follow-up before yearend, as planned and previously communicated, and in line with our corporate goal.

We will do whatever we can to accelerate wrap up of this study, but realistically since the last patient visit is scheduled to occur during the end of year holiday season, we will report top-line data early in 2018. Thus far in the study, the highest dose level of 109 has been tolerated well in all subjects receiving this dose as is also the case for the lower dose levels.

Since we last spoke, we also initiated the consumer/functional testing program with RXI-231, a cosmetic ingredient based on sd-rxRNA that targets the enzyme tyrosinase. This enzyme is located in melanocytes, which are the cells of the skin that produce a pigment called melanin. Overproduction of melanin can cause skin hyperpigmentation. Thus the cosmetic product as is tested under this program is a gel formulation designed to aid in the reduction of pigmentation and thereby improving skin appearance.

We made some great progress at the consumer testing program and have finished already two of the three studies. These two studies in healthy volunteers were designed to determine irritation and sensitization potential of the gel containing RXI-231 when applied to the skin. In the irritation study, as the pilot suggests, we investigated if the formulation with or without RXI-231 could cause any irritation in exaggerated circumstances. These exaggerated circumstances are repeated applications of the product at the same skin side for 14 days and under an occlusive dressing to maximize product penetration. This study was done in 25 volunteers. There were no adverse events reported in the study and it was shown that the product only has minimal irritation potential and resulted the same whether or not RXI-231 is added to the formulation. In other words, RXI-231 is not a skin irritant.

In the sensitization study we evaluated whether or not the formulation with or without RXI-231 would cause allergic contact dermatitis under exaggerated circumstances. In this study, the exaggerated circumstances were the repeated application of the product under occlusive dressing for five 48-hour periods followed by product exposure of 10 days later to naive skin. This study was also done in 25 volunteers and showed that the formulation with or without RXI-231 does not possess a detectable contact sensitizing potential. In other words, RXI-231 does not cause allergic contact dermatitis.

Based on these positive outcomes of the first two studies under this program, the third study is now being submitted for IRB review and expected to start early to mid-September. In this third study, we will investigate the potential of the product to improve the appearance of skin pigmentation induced by UV exposure. Considering the amount of progress we made thus far, we are well on track to report full results in Q4, as previously announced.

Lastly, I can also share some good news on our Samcyprone Phase 2 study, RXI-SCP-1502. Samcyprone is our proprietary formulation of the small molecule DPCP, which we are developing for the treatment of cutaneous warts. As mentioned in the last call, we initiated a second cohort with a more subject friendly protocol, mainly with a lower sensitization dose. Data from the first cohort showed a high rate of skin sensitization which is good because it's a prerequisite for a therapeutic response. Therefore, the second cohort will test if we can lower the sensitization dose while keeping the therapeutic efficacy. The enrollment in the second cohort started in early Q2 which was later than originally planned. However, efforts by our clinical team and by our study sites resulted in an acceleration of the enrollment rate. At this rate, our study will be back on track soon, meaning that we expect to share study data readouts before year-end, as originally planned and communicated.

You may wonder why we are not providing any more interim data from the ongoing studies at this stage. The reason is that in early phases of our Phase 1/2 or Phase 2 study, you include interim looks to make sure that a trial can be stopped if participants are being put at risk unnecessarily, and of course with the added benefit that you may get some early reads on the efficacy as well. But when you are close to the end of the study,

safety is typically no longer an issue and you focus on the formal analysis of the complete study data. Therefore, a normal clinical study protocol does not specify an interim analysis late in the study. It would also be counterproductive to spend time and resources on further incremental data reviews instead of focusing on the end goal, mainly the formal analysis of the full dataset.

On the preclinical front, we made significant progress as well. Earlier this week, we announced that we selected two sd-rxRNA compounds from our immuno-oncology pipeline for preclinical development. We also announced a related decision which is the selection of a manufacturing facility for the production of cGMP grade immuno-oncology compounds and that the manufacturing of this cGMP batch will start soon. Both these decisions are important ones, since they help with solidifying our planned timelines for moving into clinical development in immuno-oncology compounds which could occur towards the end of 2018.

Dr. Eliseev will now provide you with some further information on the preclinical immuno-oncology program, related collaborations, and business development. Alexey?

Alexey Eliseev - *RXi Pharmaceuticals - CBO*

Thank you, Gerrit, and hello, everyone.

I will highlight our progress in the area of immuno-oncology. This is still a new but an increasingly important priority area of our Company. We are continuing the develop of our sd-rxRNA platform for immune checkpoint modulation in adoptive cell transfer.

As mentioned, recently, we have designated two compounds RXI-762 and RXI-804 for preclinical development. The first compound targets PD-1 by simultaneous suspension in therapeutic adoptive transfer cell during their ex vivo treatment.

We have tested this and similar compounds, in vitro and in vivo in several therapeutic cell types including CAR T and TILs. This compound is an optimized sd-rxRNA which was generated from the lead sequence originally developed at MirImmune. The second compound targets TIGIT, an immune checkpoint that shows important synergies with PD-1 in a number of cancer indications. One of the main cell treatments in which these compounds have been tested are mesothelin targeting CAR T-cells. We are testing meso-CAR T treated by our PD-1 and TIGIT silencing compounds in several animal models starting with mouse models of ovarian cancer.

In the course of these studies, we are also optimizing the manufacturing of CAR T-cells to achieve more specific targeting to the tumors. We expect to provide an update on these studies later this year.

In parallel with the preclinical studies, we will soon initiate the manufacturing of our RXI-762 to have the GMP grade material available in early 2018.

In addition to CAR T work we are also studying RXI-762 and RXI-804 in other types of therapeutic cells through academic collaborations. This includes our continued research that underlies potential applications including sd-rxRNA stem cell transplants for the treatment of hematological cancers.

We are optimistic that one of these cell treatments enhanced by sd-rxRNA can be administered to patients by the end of 2018. It is likely that this first development program which will involve RXI-762, the PD-1 targeting compound. However, in the future we are planning to use combinations of RXI-762 and RXI-804 and potentially sd-rxRNA servicing other targets. We believe that the ability to modulate multiple checkpoints in a single cell base therapeutic treatment is a key advantage of our technology.

In the rapidly developing immuno-oncology area, it is particularly important to communicate with the industry and academia. We have been meeting with companies and academic groups active in cell-based cancer immunotherapy. Such contacts are not only important for potential deal-making but they also help shape our vision for the areas of competitive advantage of our technology. We have identified one such new area that generates a universal interest in the industry. Very briefly, this involves the application of sd-rxRNA to produce longer leading and more active

therapeutic cells with improved phenotype. We've been working with a dedicated team of opinion leaders including our SAB members to explore this opportunity.

A few more words about our business development activities. In general, we have focused our vision on several major areas, one of them is finding partners for our clinical programs in dermatology and ophthalmology. We have seen interest from a number of companies, although many of them are waiting for the completion of our ongoing studies. In the immuno-oncology area, we're looking both for early stage partnering/out-licensing deals and for potential cell-based assets that are complementary to our sd-rxRNA platform.

Now, I will turn the call back to Tammy.

Tamara McGrillen - *RXi Pharmaceuticals - IR*

Thank you Alexey. This concludes the formal presentation for today. And at this time, Operator, we would like to poll for questions, please.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Our first question comes from line of Justin Foster, private investor. Please proceed.

Unidentified Participants

Good afternoon, everybody. I have two questions for you, one is about Lincoln Park. What I don't understand is that they can purchase up to $15 million worth but cannot own more than 9.9% of outstanding shares. How is that mathematically possible unless the shares you're selling for like $6 or $7; is that what's anticipated in that statement or am I missing something?

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

Well, we have the ability to allow or to direct LPC to purchase shares over a 30-month term. So, we would like to draw down continuously over that, so that they wouldn't own that much shares, that many shares at a time. It's certainly something that we'll be cognizant of as we direct them to purchase shares. And we will keep in mind that as we go along.

Unidentified Participant

I don't understand. Are you saying they would purchase shares and then and resell them?

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

They do have the ability to do that as part of the terms of our agreement.

Unidentified Participant

I see. So, okay, thank you. Just a brief comment on reverse split. I see that that was the primary bullet point in the 8-K today, so that were significant achievement that the NASDAQ gave you six more months. My question is, as I've asked before, if that's the good think, why does the stock go down on the day that you announce that you have this extra six-month unless the Street agrees with me and some other analysts that doing a reverse split is just going to cut your stock in ten if not in five, just as it did after the previous reverse split.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Thank you. That is very good question. The bottom-line is, at this point in time, it is a non-issue, reverse split, because we're aiming at and hoping for an appreciation of our share price. And certainly the back end of the year is loaded with sufficient data points to justify such an appreciation. And as I have pointed out, I think at the pervious call, if it would be so that we are not that $1 level, then it is up to discussion in the Board, at which point we will also seek advice from additional advisors, whether it is better to make sure that we can stay on NASDAQ or that we would move to the OTC, to see.

We have been there before, as some of you may know, and it's certainly a very qualified Board to be on. So, we don't disagree with you, but that is a goal that today we do not feel that we have to make, for the simple reason that we expect the stronger data points we've lined up for the remainder of the year that we might actually drift upwards with our share price.

Unidentified Participant

Well, thank you. And this was one parting comment, I appreciate that. And of course all of your shareholders feel the same way. Given the way people are trading your stock and the dark forces out there, in my opinion you've positive data points coming, but you have always the selling into it, and that's what's going to happen in the future. And until you announce to the world that you could care less whether you're on the NASDAQ or not, and I'm not going to be desperate to do anything to get there, then your stock will start going up and will be responsive to the good data points that you promise us. And I have complete confidence in that that the data points would be there. So, that's my final plea. And I'm sorry, you have to hear from me again.

But, I plea to you not to wait five more months to announce that you'll just let the stock go where it is and if it is not on the NASDAQ, so what? If you wait five months, your stock is going to be under $1 in five months, it's going to be where it is now. But if you announce you're going to OTC, in case you have to in a few months, you're going to be liberated and those dark forces will know that they won't have 10 times the value to start playing with again, which they'll do. My profound appreciation to let me say my piece here. I know that's now what for conference calls are for. So, I thank you again for all you're doing for the Company. And I look forward to good things in the future.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

And I would like to add that I appreciate that you've been a shareholder through thick and thin like I've been myself amongst the other few others. We all want the best for the Company and for our shareholders. Thanks for being a shareholder.

Operator

Thank you. Our next question will come from the line of [Larry Kates], private investor. Please proceed.

Unidentified Participant

Thank you for taking my call. I don't have any dark forces to talk about today, but I would like to thank you for clarifying why the data on your enhanced protocol cohorts for the dermal trials has not been out yet.

My question is this, and it's a rather hard for me to know how to formulate the question properly. I realize that the immuno-oncology trials and the dermal trials are kind of independent of one another they're really on the different track, as I understand it. Just wondered, what if any relevance would the results from the dermal trails from the anti-scar trials, what relevance would they have for the immuno-oncology investigations?

In other words, if they're good, will that increase the status of the immuno-oncology trials? And contrary wise, if they should be, which I hope is not the case and I don't believe it will be the case, but if the dermal trials were not so good, what if any ramifications do you think that would have for the immuno-oncology work?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Those are very interesting questions and we can only give our views on that Mr. Kates. And first of all, the dermatology trials are supposedly going to be first time at least for the cell delivering technology in a tissue setting, in an in vivo tissue setting in humans that phenotypic changes can be -- positive phenotypic changes can be achieved with the use of the product. That is a good thing, obviously. It has little bearing, in my opinion, on the immuno-oncology space because most of the time we are talking there about treatment of cells, either in vivo or ex vivo.

And it has been shown hundreds of times now with our technology, we are highly capable of transacting about any type of cell that we expose it to, without causing damage to the cell and while having not gone over the protein. So, one and the other are not necessarily intertwined.

It is nice to have in our ongoing clinical studies the evidence that we -- results phenotypic positive change with our technology platform or compound in our technology platform vis-a-vis control.

And so, although they are independent from each other, they are relevant. The thing that will in the industry likely make a difference, I mean in the RNAi industry likely we make a difference is actually probably not us, not for RNAi, it will be the first approval by the FDA or EMA of an RNAi compound. And those who are slated to be the first, today are either Alnylam, which is well-known or a little known company that is privately hold by SoftBank in Japan that is called Quark, and it's one of those that will be the first that's maybe in 2018; I would say definitely by 2019 will get a formal approval.

And that is going to make a difference for the whole RNAi space. In the meantime, we do expect that with the outreach and the work we are doing and the positive comments we are getting from both academia and industry when we generate additional data in immuno-oncology and cell therapy that apart from the fact that it's in RNAi that this will be seen as a major tool and more to come soon, a major tool to enhance what is currently ongoing as a revolution in cell therapy. So, yes, the two are linked but they are not intertwined.

Alexey Eliseev - *RXi Pharmaceuticals - CBO*

Sorry, one small addition to Geert's response to your question. So, I agree that the outcome of derm and ophthalmology studies would probably not influence our view of the immuno-oncology. But when we are presenting the immuno-oncology platform to potential partners, we always say that this class of compounds is safe in the clinic, and this is a very strong message. So, even though we still have to validate specific compound that we use for immuno-oncology, the safety of compound of class is a big asset.

Unidentified Participant

Thank you, both. I think as my question probably reflected, I just wanted to hear which I believe I did hear that a less than satisfactory, hopefully that isn't the case, but if hypothetically, less than satisfactory phenotypical result from the dermal scarring would not be the sort of a dramatic or a drastic event with respect to the immuno-oncology work, and I think that's what I heard.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

That is exactly what we said.

Unidentified Participant

Thank you very much. Thanks a lot. That's great. And thank you for all the work you're doing and everything you're doing. I appreciate it a lot. I have a lot of this, pretty nice stake in this company and I'm glad to hear what you just told me, very glad.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

And I'm pleased that we have two long-term shareholders, apparently now three with myself. Two long-term shareholders on the call. I wish more people would participate in this because it's a great forum to interact with shareholders. Thanks for being one.

Operator

(Operator Instructions)

Our next question will come from the line of Michael May with Walsh University. Please proceed.

Michael May - *Walsh University - Analyst*

Yes. I have a two-part question for you. Is it possible at this time for you to elaborate on the strategy of the sale of the 8 million shares by the major shareholders? And in addition to that, it would appear that these major shareholders are making a tremendous sacrifice and is there a plan in the future that they would be -- maybe whole again? I appreciate if you could answer.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

I'm not sure, if I understood the question about 8 million shares. Sorry.

Michael May - *Walsh University - Analyst*

Yes. I'm sorry, sir. My question is, I assume that there is -- I guess my take -- I'm assuming something, I don't know if I'm accurately assuming it. But I'm assuming that maybe these 8 million shares might be used as an enticement or something in a partnership with partnering company. And my other part of that question is, it would appear that these major shareholders are making a tremendous sacrifice for the company and if that is so, is there a plan in the future to make them whole again?

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

Would you mind directing us to what share you're speaking of? Are these the shares related to MirImmune acquisition?

Michael May - *Walsh University - Analyst*

No. I'm talking about the shares that are in the S1 securities SEC filing, the S1 and S1A, like came on I think on August 2nd.

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

As part of the agreement with MirImmune acquisition, we agreed to register the shares related to that acquisition. So, we registered shares that were issued upon expectation of the agreement and also registered shares that should potentially be issued as milestone shares as far as milestones for the agreement are reached. We've just finished registering those with the SEC, actually went effective the other day. So, shareholders can potentially sell those shares, if any holders hold a certain amount of shares, we will see that in certain public filings that go out. And as of right now, they have not sold these shares but they're now being registered that could be something potentially happen.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

And one of the reasons why those shares were only registered recently is because we needed the approval of shareholders at the general assembly meeting in December, otherwise we would not have been able to register them and we received that approval so that's what in motion.

Michael May - *Walsh University - Analyst*

So, what you're telling me is that those shares aren't necessarily going to be actually sold by those shareholders, and if they're registered, they can be sold but they're not necessarily going to be sold, and it's not part of the plan to use as an enticement or inspiration for a partner, anything such as that?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

No, those 8 million shares are earmarked for what they're earmarked. That means if we make certain milestones as per in the agreement at the time of the acquisition MirImmune. By the way having said that, we have in theory -- no, we have I think total 100 million shares authorized. So, if we want to entice somebody in terms of becoming participant in a deal structure, we can still do that by for instance requiring or asking them to purchase shares above market -- at market or above market which then would of course also help all the other shareholders.

So, yes, shares can be used to entice people into a business development transaction but the shares that were registered are not intended for that piece. If we do it at market or above market, there's no issue to use the shares that are available to us, to use those in a business transaction.

Michael May - *Walsh University - Analyst*

So, correct me if I'm wrong in my understanding that the S1A and the S1 registered the shares, but it's not necessary that those shareholders will actually be selling those shares?

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

Correct.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Yes. Once they've the shares, it's up to them to hold them and count on appreciation, or sell them if they want to do that and need money to pay for the kids.

Michael May - *Walsh University - Analyst*

So, it was primarily put in place to give them liquidity, if they wanted it?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Correct.

Michael May - *Walsh University - Analyst*

Okay. I appreciate your answer, sir. Thanks for doing such a hard job. And I have a lot of faith in the Company, have been a shareholder for probably at least almost seven years. And I continue to be one. So, I've been talking about the Company, there's a lot of interest, and I think you'll break through one of these days.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

I'm really happy that we have questions now from shareholders that have been shareholders for long time. It makes me not feeling alone.

Michael May - *Walsh University - Analyst*

You're welcome.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Thank you for being one.

Operator

Thank you. Our next question will come from the line of [Joshua Lane], private investor. Please proceed.

Unidentified Participant

My question, I don't really understand what the next milestones are and when they might occur in the immuno-oncology oncology space. I've been very encouraged by the addition of Dr. Griffin to your advisory board and also Dr. Jonathan coming on to the Board. But I don't have a real sense of the timeline on both of -- I think both are immuno-oncology specialists or that's where their primary focus is. Can you tell me what milestones I might look for in terms of the immuno space?

Gerrit Dispersyn - *RXi Pharmaceuticals - CDO*

Yes. So, I would like to answer your question by sort of reverse engineering our plans. So, what we are hoping to do, as I mentioned is to have our first immuno-oncology program in the clinic by the end of 2018.

The compound that we are developing now will be used, at least at the initial stage, with the initial product as part of a cell therapy of adoptive cell transfer. And right now, we are testing two potentially more types of cell therapies with our first lead compounds. So, the milestone, an important milestone, for the future clinical development will be the selection of the cell therapy to go into the clinic with our lead compounds.

Again, another step back, in order to be able to move that product into the preclinical and clinical development, we need to have the compounds, PD-1 targeting compound manufactured according to the GMP standards. This is what we have started. And so the completion of that manufacturing is another important milestone, and that's something expected in the early months of 2018.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

And so, the fact that we are already taking that action of staring the GMP manufacturing for that first compound, the anti-PD-1, that should make it is clear that we are very determined to be able to get that because we're basically preparing for that step to get that product in a clinical setting in 2018. What clinical setting will be, we don't know. It can be that adoptive cell therapy; it can be also transfection of CARs, it can also be with stem cells. So, it could be with -- as part of a autologous cell [from patients] but it is certainly possible and feasible, based on what others have been able to do in this space, and look at this as a realistic timeline to have something in the clinic in 2018.

Unidentified Participant

Okay. Are there things that might be announced during the year, as you say by the end of 2018, during the year that might generate some sense of progress and excitement?

Alexey Eliseev - *RXi Pharmaceuticals - CBO*

Yes. So, we are now conducting a number of animal studies and also a number of in vitro studies to support this clinical development. We have planned between two and three animal studies this year. So, depending on the types of results that we observe, we should be able to announce some of the interim results.

Unidentified Participant

Great, okay. Thanks a lot. And I'm right that Dr. Griffin's interest is -- you have been able to peak Dr. Griffin's interest with what you've been able to show in the scar?

Alexey Eliseev - *RXi Pharmaceuticals - CBO*

Absolutely. So, Dr. Griffin has been aware of our technology since we started MirImmune and he has been a very active supporter of the technology. The way he contributes to that, I would say it's two-fold, one of them is that he can actually give some helpful ideas but as importantly, he is opening up the clinical network of Dana-Farber and other hospitals in Boston. This is extremely helpful and important for us. We've been meeting with both with the clinicians that hopefully can move our products into the clinical development and also with two cell manufacturing facilities at Dana-Farber. Both of them will be very important for us in the support of the clinical work.

Unidentified Participant

Thank you. I was looking for some reactions from -- thank you very much.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Thanks for being a shareholder as well.

Operator

Thank you. Our next question will come from line of [Steven Felter] private investor. Please proceed.

Unidentified Participant

My question is about is RXI-231 skin lightning product. You keep mentioning this for hyper pigmentation conditions. And I'm wondering whether it works also on normal pigmentation and I'm asking because in Asia there is already a significant market, cosmetics market for skin lightning...

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

So, I will briefly give some numbers in terms of the cosmetic and pigmentation market but Gerrit is definitely well-placed to answer all the other questions. You're absolutely right. And for ones the US market is not the largest market in world. The largest market -- global market for anti-pigmentation agents is $19 billion and close to $10 billion of that is Japan, the China is about at about $4 billion and India is picking up very fast. And so, the US only number five or number six in the anti-pigmentation market. So, you're absolutely right that Asian markets are really the big ones. Gerrit?

Gerrit Dispersyn - *RXi Pharmaceuticals - CDO*

So, thank you for the question. And I think I may have mentioned during the call as well that the study to show essentially the functional benefit of the RXI-231 in healthy volunteers is going to be done by exposing into UV, which is a normal pigmentation reaction of skin. So, you're absolutely correct that mechanistically that the products could be positioned in multiple ways, depending on the regulatory strategy, but it could be as a cosmetic for, any form of pigmentation whether that is hyperpigmentation, whether that is almost a morning after a sunscreen, if you want, or just a general skin lightning effect. So that's the exciting part of this program that it may open the door for multiple avenues.

Unidentified Participant

That's what I was hoping to hear. So, I guess the million dollar question is when the testing would be finished, I know you're only two months into plan, three to four months testing through, and more importantly are you getting interest from big pharma or whoever would be partners on that?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Maybe the timing.

Gerrit Dispersyn - *RXi Pharmaceuticals - CDO*

Yes, probably the timing. So, as we saw as we mentioned right, so we're really on the cusp of submitting the study protocol and inform consent form to the IRB. And so we are at a high confidence that this last study will start early to mid-September -- and really one of the reasons why we couldn't start earlier is really the fact that we also have Labor Day coming up and we need a full week -- I mean, we need full weeks essentially for study logistics, and that's not available until after the holidays. So, again, we're -- this is going to be a relatively short program. So, we should be able to report on the top line data somewhere in Q4. It's probably too early to tell exactly when, will depend also on the subject enrollment. But based upon some of the modeling work that we've done and the capacity of the center where we're running it, we're comfortable that it'll be one of the first test studies we'll be able to report out.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

And in terms of interest from third parties, based on the market numbers I've given, it's probably not a surprise to you that the usual suspects are not really all that interested, with some exclusion of companies that are in the -- more global cosmetic companies but the unusual suspects that have been broadly ended up been asking questions and want to be get up to date, tend to all be from Japan, China and South Korea.

Operator

Thank you. Our next question will come from the line of [Frank Petronas] with Prudential. Please proceed.

Unidentified Participant

My question is, you have certain amount of warrants outstanding exercisable at whatever the price. Now, the fund as they -- or as you need monies, wouldn't it be a little more beneficial to get the warrants exercised by -- as you've enough money? And what is the potential for the maximum amount of warrants being exercised? That's my first question.

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

So, right now, we have warrants outstanding from a financing we did back in 2015 and also warrants outstanding from our latest offering back in December. So, all-in, and if those were to be fully exercised, that would bring in almost $20 million from those warrants. The warrants in December are right now priced at $0.90. So, if our share price does appreciate, we think the investors that are holding those warrants start to exercise them and bring those funds in, which would be great, we would love for that to happen. And with some of the data points coming out later this year, we could start to see that.

But, the exercise is in control of the investor's hands. And so, we do have to watch our budgeting, our forecasting and always keep our eye on the financial markets and particular opportunity if we there is a good way to rate capital, and then look into that and see if that makes sense for the company.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Yes. One addition to that, so if, thanks to the good work of shareholders buying shares and us generating data, good data, the share price appreciates about certain points, we actually have the right to call the warrants.

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

Yes. We can potentially call the warrants that we issued back in December if our share price reaches a certain threshold. So, that could also be another opportunity for us to bring funds in.

Unidentified Participant

Okay. I am a late comer to your shares and to the company. I'm not familiar with the first warrant, $0.90. My question is, what is the warrant price of the one actually listed that's selling around $0.20 at this point in time?

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

So, the warrants that are -- that we listed on the NASDAQ exchange are the warrants from December that are priced or have exercise price of $0.90. The warrants that we issued in December are not trading on the national exchange and those are priced of $5.20.

Unidentified Participant

Well, where did these numbers come from? I mean, did the stock trade at those levels at some point in time?

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

Yes. The price of the warrants are based on are for using our share price at the time that we complete the financing. So, back in 2015, our share price was higher at that time; and back in December it was based on our share price at that time and using our broker and our banker, they come up with the price there.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

We had done a reverse split between the two financings.

Unidentified Participant

Okay. Last question, what is the actual float of the insider shares versus what is actually floating on the shareholder base that we shareholders own?

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

So, we have about 23 million shares outstanding currently and are non-affiliate market cap, which excludes the affiliates there is around 22 million.

Unidentified Participant

Okay, but do you have...

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

Or about 13.4, based on our current share price.

Unidentified Participant

Okay. But, you have to include the warrants as a total for your Q, your K, at the end of year or I'm saying for K at the end of the year to show how many shares would be fully exercised, if they warrants are fully exercise? Is there excess?

Caitlin Kontulis - *RXi Pharmaceuticals - PAO*

So, our outstanding shares are what is actually issued, so what people actually hold in their hands, which is about 23 million shares, and if we were to also have options and the warrants that we have outstanding be exercised, that would bring us closer to 38 million common shares outstanding.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

And so, on a fully diluted basis, it would be 38 million, but on the tradable basis at this point in time, it's 23 point something.

Unidentified Participant

Okay, great. And I do have one last question. So, now, you are getting till January to get the stocks or the stock to appreciate, based on I guess your success in the trials and so forth. But, as the purchases, or as you draw down from the money, those will be -- that monedy or those monies will be taking stock out of the marketplace to then have the stock appreciation above $1. Is that the way I read that statement?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

So, I think what you're trying to say is that if people exercise warrants, so that means that they get shares that those shares get into the market and that could depress the market -- the share price again, that's what you're saying. Correct?

Unidentified Participant

No, what I'm asking is the sentence that I read that you get one -- you get six months to get an extension to get the stock -- for the stock to appreciate $1 a share or better for 10 days, those shares that would be involved in getting that price up, would that be from the drawdown of the $15 million, the fund as you brought down the money, would you be giving them shares for the money?

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Yes, of course. The drawdown would be in exchange of shares. So, we give them shares. But that is also the reason why we emphasized that we are in control of it, so meaning that we're not going to do crazy things in terms of drawing down money if our share price is ridiculously low because that's not going to be helpful. Indeed when additional shares come into the market, you could see that there is a reduction in the price and that is exactly what we have to work with when we see our data coming out, when we see share price appreciating, then we can make sure that we stay above $1 and there is no new share that has to come into be above $1. It's...

Unidentified Participant

Okay. I'm glad that you understand the nature of my question. From the dilution factor to the warrants. So, I understand totally.

Geert Cauwenbergh - *RXi Pharmaceuticals - CEO*

Okay. Thank you very much and thank you for being one of us.

Operator

(Operator Instructions)

And I'm showing no further questions at this time.

Ladies and gentlemen, thank you for your participation on today's conference. This does conclude the program. You may all disconnect.

Everybody have a wonderful day.