VIAVID
communications simplified.

Arcturus Therapeutics

Third Quarter 2020 Earnings Call

November 9, 2020

CORPORATE PARTICIPANTS

Neda Safarzadeh, *Director, Head of Investor Relations/Public Relations and Marketing*

Joseph Payne, *President and Chief Executive Officer*

Dr. Steve Hughes, *Chief Development Officer*

Andrew Sassine, *Chief Financial Officer*

Pad Chivukula, PhD., *Chief Scientific Officer and Chief Operating officer*

CONFERENCE CALL PARTICIPANTS

Seamus Fernandez, *Guggenheim Partners*

Madhu Kumar, *Baird*

Yasmeen Rahimi, *Piper Sandler*

Yigal Nochomovitz, *Citigroup*

Gena Wang, *Barclays*

Steve Seedhouse, *Raymond James*

PRESENTATION

Operator

Greetings and welcome to the Arcturus Therapeutics Third Quarter 2020 Earnings Call.

At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. If anyone should require Operator assistance during the conference, please press star, zero on your telephone keypad. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Neda Safarzadeh, Head of Investor Relations/Public Relations and Marketing. Thank you. You may begin.

Neda Safarzadeh

Thank you, Operator, and good afternoon, everyone.

We are joined today by Joseph Payne, President and CEO; Andy Sassine, CFO; Dr. Pad Chivukula, CSO and COO; and Dr. Steve Hughes, our Chief Development Officer.

Before we begin, I would like to remind everyone that except for statements of historical facts, the statements made by Management and any responses to questions on this conference call constitute forward-looking statements that involve substantial risks and uncertainties for purposes of the Safe Harbor provided by the Private Securities Litigation Reform Act of 1995.

Any statements other than the statements of historical facts included in this communication, including those regarding the Company's supply agreements and potential supply agreements, the Company's future manufacturing and other operations, the status and results of clinical development programs, the planned initiation, design or completion of clinical trials, the likelihood of the success of the Company's coronavirus COVID-19 vaccine candidates or other candidates, and the Company's current and future cash and financial position are, forward-looking statements.

Actual results and performance could differ materially from those projected in any forward-looking statements as a result of many factors, including without limitations an inability to develop and market product candidates, unexpected clinical results, and general market conditions that may prevent such achievements or performance. Such statements are based on Management's current expectations and involve risks and uncertainties, including those discussed under the heading Risk Factors in Arcturus' Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020, and in subsequent filings with our submissions over to the SEC. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events, or circumstances or otherwise.

Now, it is my pleasure to pass the call to Joe Payne, President and CEO. Joe, please go ahead.

Joseph Payne

Hi, thank you, Neda. Good afternoon to all.

Thank you for joining Arcturus' quarterly call today. To begin, right off the bat, I'd like to congratulate Pfizer and BioNTech for the significant milestone announced earlier today. Congratulations to them, their scientists, and their team for this accomplishment. We believe this is exceptional validation of messenger RNA therapeutics and vaccines and Arcturus is very fortunate to be part of this messenger RNA therapeutics community, especially since we're all working together in this global effort to vaccinate and protect just each of us from COVID-19. Thanks to our partners in Israel and Singapore in supporting us.

Arcturus has made substantial recent pipeline progress, highlighted by our two most advanced clinical programs. ARCT-021 is our COVID-19 self-transcribing and replicating RNA, our STARR mRNA Vaccine Candidate and ARCT-810, our therapeutic candidate for OTC deficiency, or ornithine transcarbamylase deficiency. We're very pleased today to announce encouraging initial clinical results from both of these programs. We've also made strong progress advancing our earlier stage pipelines, including our CF program, or cystic fibrosis.

I'll begin with ARCT-021, which is also known as LUNAR-COV19, or COV19. To remind you, ARCT-021 is being developed in collaboration with the Duke NUS Medical School, and development activities are being performed in Singapore. Today we're excited to report for the first time, preliminary clinical results from our ongoing Phase I/II clinical study. The objectives of the study are to evaluate safety and tolerability and the humoral and cellular immune response, and to determine the dose and administration regimens to be evaluated in further clinical development. Our encouraging Phase I/II results, to which Steve will detail in a

few minutes, our Chief Development Officer, they provide further support to suggest that our self-replicating mRNA based investigational vaccine; that this approach, using our proprietary STARR mRNA technology, may produce protective immunity at low mRNA doses, and potentially with only a single administration.

Now, based on our interim clinical data, we plan to advance a low single-dose of 7.5 micrograms, along with prime-boost regimens. We saw 100% seroconversion of IgG binding antibodies in younger adults. One out of five older adult participants has not yet seroconverted. The observed geometric mean titers in all of these cohorts exceeded 2,500. The 7.5 microgram dose level that's been selected, focusing in on that specific dose, our GMT or geometric mean titer for this group, or the GMT was exceeded 15,000 for younger adults and exceeded 2,000 in older adults, at this dose.

The IgG binding antibodies continued to increase over time in humans. This is in a similar manner to what we observed in preclinical animal models. We consider that encouraging. The data is still evolving, we remind all that the time course for STARR mRNA technology is extended and different from conventional messenger RNA, which is one of the reasons why we're seeing activity at such low dose levels. The data that we've collected will be published at the time of study completion.

We believe that ARCT-021 could be an important addition in the global fight against COVID-19. We look forward to advancing ARCT-021 into later stage clinical studies, as quickly as possible. In parallel with our clinical development activities, we've also made progress with our manufacturing activities of our vaccine. With the support of Catalent and Recipharm and other manufacturing partners, Arcturus remains on track to manufacture substantial numbers of doses.

Arcturus announced earlier today an agreement with the Singapore Economic Development Board to support our manufacturing efforts, and Andy is going to be providing more details on that in a few minutes.

In August, we signed a binding term sheet with the Israeli Ministry of Health to supply ARCT-021. We consider this a core or an important part of the country's vaccination strategy. Israel is the second country in addition to Singapore to preserve supply of Arcturus' COVID-19 vaccine, and we also continue to have constructive discussions with additional countries pertaining to stockpiling and supply agreements.

Now shifting focus to the ARCT-810 for OTC deficiency. We continue to make great progress with our LUNAR OTC program. We've completed dose escalation of all cohorts, 0.1, 0.2, 0.3, and now including the top dose of 0.4 milligrams per kilogram, in our Phase I study. We're pleased to report that steroid pretreatment was not necessary, even for the top dose cohort, and we've commenced enrollment of a Phase Ib study here in the United States in OTC deficient patients, and our first subject has initiated screening.

There's a lot there to report in one quarter for Arcturus. I now pass the call to Steve to review and provide more detail pertaining to the ARCT-021 Phase I/II study results, as well as new phase one data from our ARCT-810 Ornithine Transcarbamylase deficiency program.

Steve?

Dr. Steve Hughes

Thanks, Joe.

I'm pleased to report that the ARCT-021 Phase I/II study is now fully enrolled with 106 adult subjects, including cohorts of older participants. Before discussing the data, I would like to go over the study's design in some detail.

The study is evaluating both a single injection of ARCT-021 and prime-boost regimens. The subjects received either placebo or ARCT-021, in a double-blind randomized fashion. In this study, we have single-dose cohorts at 1, 5, 7.5 and 10 micrograms in younger adults, and the 7.5 micrograms single-dose cohort in older adults. We're also testing two dose priming regimens of 3 micrograms, and 5 micrograms, in both younger and older adults. Younger adults are in the range of 21 to 55 years, and older adults are greater than 55 years of age.

To date, 78 subjects have received at least one injection of ARCT-021, 36 subjects have received two injections, and 28 subjects have received placebo. Our interim analysis includes preliminary results from all single-dose cohorts, including the older adult cohort. For the two dose cohorts, although all subjects have now received at least one dose of vaccine, data are currently only available for the younger adult cohort at the 5 microgram dose.

These results include safety up to at these 28 days after vaccination, and immunogenicity up to the Day 43 time point, although not all subjects have immunogenicity data at a later time points. For the single-dose cohorts the neutralizing antibody data only goes up to Day 29 at this point in time. Further data is anticipated. Based on the study results. A robust anti spiked protein IgG immune response was observed with 100% seroconversion at all doses evaluated in the young adult cohorts. Only one subject that has not yet seroconverted in the older adult cohort. GMT titers for the IgG antibodies were greater than 2,300 in all cohorts.

We have selected the 7.5 micrograms, single-dose and 5 microgram two dose regimens to take forward into further studies. At the 7.5 micrograms single-dose, the geometric mean titer was greater than 15,000 in younger adults and greater than 2,300 in older adults. In the 5 microgram two dose cohort, the GMT was greater than 16,500. The GMT for neutralizing antibodies in the PRNT 50 assay was within the range of titers observed in the COVID-19 patient convalescent plasma tested in the same laboratory. However, as this is an ongoing study, the data is still evolving, and not all subjects in the cohorts evaluated have complete results for this assay at a later time points, as it has to be performed in a BSL-3 lab and therefore takes a few weeks to get the samples processed.

For example, the single-dose cohorts only have neutralizing antibody data up to Day 29. The IgG results indicate that titers continue to rise through Day 43. These later time points are important. Additionally, we do not yet have the neutralizing antibody results from the micro neutralization tests that we will be using for our Phase III study. This will be performed over the next few weeks. We will therefore share more data on the neutralizing antibody titers in the coming weeks as these data mature.

Turning now to T-cell responses. Cytokines dining in LA spot tests showed that T-cell responses existed to multiple peptide pools spanning the full length of the SARS-COV-2 spike protein. The CD-four response was TH one dominant. The CD-eight responses were seen to peptide pools that include those from the receptor binding domain. ARCT-021 was generally well tolerated and had a favorable local and systemic adverse event profile. The majority of adverse events were mild on and there have been no severe injection site reactions or fever at the doses that we plan to take forward to later stage clinical trials.

No subjects have withdrawn from the study, and there have been no serious adverse events deemed to be treatment-related. There has been one serious adverse events observed. This was an event of cellulitis from an insect bite and was judged by the investigator to be unrelated to study drug. We continues to collect and analyze data from this study, and we intend to discuss the data with regulatory authorities in the coming weeks as we move towards pivotal trials.

Moving now to our ARCT-810 program. ARCT-810 is being developed for ornithine transcarbamylase deficiency, a serious disease with limited treatment options. ARCT-810 utilizes Arcturus' LUNAR lipid mediated delivery platform to deliver OTC messenger RNA to the liver. Expression (inaudible)

transcarbamylase enzyme in the liver of patients with OTC deficiency is expected to restore normal (inaudible) and potentially prevent neurological damage and the need for liver transplantation in these patients.

We have recently completed our ARCT-810 Phase I study, a double-blind placebo-controlled dose escalation trial in healthy volunteers. The study included four cohorts in total with doses tested between 0.1 milligram per kilogram and 0.4 milligrams per kilogram. Subjects were randomized two to one, active to placebo, and all doses were in the anticipated therapeutic range. All subjects have completed all dosing and we'll study visits. The study is designed to evaluate safety and tolerability, as well as pharmacokinetics as primarily and secondary endpoints respectively. In the study of ARCT-810 was generally safe and well-tolerated. Most adverse events were mild in severity and there were no severe adverse events. No subjects were withdrew early for the study and there were no SAEs.

ARCT-810 also demonstrated a favorable pharmacokinetic profile, and our preliminary data has shown no up ARCT-810 lipid was detectable in the plasma beyond 48 hours following drug administration. Finally, the Phase I/II study of ARCT-810 in OTC deficient patients, which is being conducted in the United States under I&D (phon), has commenced enrollment and the first patient is currently in screening.

I'll now pass the call on to Andy.

Andrew Sassine

Thank you, Steve.

Good afternoon, everyone. The press release issued earlier today includes financial statements for the third quarter of Fiscal Year 2020, which I will briefly summarize.

Arcturus' primary source of revenue is currently from license fees and collaborative payments received from research and development arrangements with our pharmaceutical and biotech partner. For the third quarter, the Company reported revenues of $2.3 million compared with $3.3 million in the third quarter in 2019. The decline in collaboration revenues primarily relates to a decrease in reimbursements from cure back associated with the OTC collaboration that ended in the third quarter of 2019.

Total operating expenses in Q3 were $23.3 million compared with $10.9 million for the same period of 2019. The current quarter operating expenses were partially offset with $3.7 million of funds earned under the Singapore vaccine grants and $0.7 million in funds awarded by the Cystic Fibrosis Foundation. Research and development expenses increased approximately $10 million sequentially from the June 30, 2020 quarter, driven primarily by an approximate increase of $4 million in each of our LUNAR OTC, ARCT-810, and LUNAR-COV19 ARCT-021 program, mostly due to clinical and manufacturing expenses. The remaining $2 million was driven by increased personnel expenses and cost of our two new pipeline programs, LUNAR flu and LUNAR cardiovascular.

Earlier today, Arcturus announced an important manufacturing and vaccine supply agreement with the Singapore Economic Development Board for up to $220 million in additional financial commitment. The EDB will provide a limited recourse loan of $45 million within 60 days contingent on the delivery of certain documentation. The proceeds will be used for the purchase of equipment, material, and services related to the manufacturer of our vaccine. Under the terms of the agreement the loan will be repaid through royalties on future ARCT-021 commercial sales. If ARCT-021 development does not succeed or obtain regulatory approval, the loan will be forgiven. Additionally, Arcturus and EDB have entered into a supply agreement for the right to purchase up to $175 million of ARCT-021 vaccine at pre-negotiated prices, with shipments expected in the first quarter of 2021.

These funds provide the Company with additional resources to support our efforts to continue to rapidly scale up ARCT-021 manufacturing to support our existing Israeli and Singapore agreement, as well as other potential supply deals in 2021. Along with our global manufacturing partners, we have laid the foundation to produce hundreds of millions of doses of ARCT-021 over the next 18 months and we believe the Company has an opportunity to positively impact the global COVID-19 pandemic.

Our cash balance totaled $307.1 million as of the end of Q3, compared to cash and cash equivalents of $71.5 million at December 31 2019. The increase in cash and cash equivalents and investments is primarily due to successfully raising approximately $262 million in net proceeds through two public equity offerings in 2020. Based on our current pipeline, the Company's cash position is expected to be sufficient to support operations for more than two years.

I'll now pass the call back to Joe.

Joseph Payne

Thanks Andy.

It's certainly been a period of a strong clinical development progress for Arcturus. Looking ahead, we anticipate an eventful period of further clinical progress updates. We're highly encouraged with the ARCT-021 data that we've obtained. We believe the program has enormous potential to play an important role in the global COVID-19 vaccine response. In the coming weeks, we anticipate to obtain additional ARCT-021 Phase I/II study data, and together with the regulatory authorities, we will finalize our plans for further clinical development. Advancing this program forward as quickly as possible is our top corporate priority.

With respect to the ARCT-810 program, we also anticipate obtaining initial clinical results in OTC patients. In addition to our clinical development stage programs, we're making steady progress applying our powerful mRNA platform to develop medicines in a number of promising earlier stage programs and we look forward to providing you with updates on those in the next year.

At this point we can go ahead and open the line for questions. Operator, please proceed.

Operator

Thank you. We will now be conducting a question-and-answer session. If you would like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. We ask that you please limit yourself to one question and one follow-up question. One moment, please, while we poll for your questions.

Our first question is coming from the line of Seamus Fernandez with Guggenheim. Please proceed with your question.

Seamus Fernandez

Great. Thanks for the question.

Few here, just trying to get a little bit more specifics, and thanks for the additional specifics that you guys provided on the call. Just in terms of the convalescent plasma levels, can you just give us a sense of the titers that you saw with the convalescent plasma or neutralizing antibodies in IgG? Also, the types of patients that made up the convalescent plasma, were these predominantly hospitalized patients? Just trying

to get a better sense of how the convalescent plasma comparison metrics up against the different data that you've provided.

The second question is on just the young adult patient population, again, relative to the convalescent serum. Can you give us a sense of the percentage of the young adult population that exceeded the neutralizing antibody titers for convalescent serum, as well as the IgG titers? Then finally, just in terms of the older adults, if you could provide us that same information, that will be great. Thank you.

Joseph Payne

Sure, Steve, go ahead.

Dr. Steve Hughes

Okay. Thank you for the question. I can address some parts of the question, but not all of the parts at this point in time.

For the convalescent plasma that we got, it's had a geometric mean titer for neutralizing antibodies of 147. Those ranged from around 10 to 20, up into several hundreds from the graph that we have. We don't have at this point the IgG finding antibodies for those convalescent plasma. We need to process those. It was the neutralizing antibodies that we felt were most important for that comparison.

Within the convalescent plasma, it includes both younger and older subjects. Subjects range in age from 24 to 83 years of age. There's a range of collection time from a couple of weeks to several weeks after onset of the illness. The convalescent plasma includes subjects that have both mild, moderate, and severe disease, with the majority of subjects actually in the mild-to-moderate category as characterization.

Would you mind just repeating the last part of the question that you had?

Seamus Fernandez

Yes. If it's possible to share the percentage of young adults and older adults that exceeded or at least met or exceeded the convalescent serum levels. I think in your press release this morning, there was some commentary in that regard, but it wasn't specific.

Dr. Steve Hughes

At this point, the data that we have is still maturing. This is an interim analysis, part of an ongoing study, and it's primarily to inform our regulatory submission. Our purpose for doing this type of graph is so that we can advance by rapidly from this study to the next study. Not all subjects have completed the later analysis time points for the neutralizing antibody assay, just because it takes some time to actually get those tests processed. We're in the queue with other people and it has to be performed in the BSL-3 lab. Actually taking the sample to get the test process, takes several weeks. For that reason, we don't have full data yet on the neutralizing antibody titers.

The other thing to consider is that for our technology, the later time points are actually quite important because what we see is our antibody titers continuing to rise over time. We're not really in a position to provide further color on the neutralizing antibody titers. At this point, we should be sharing that information over the coming weeks.

Seamus Fernandez

Got it. If I can ask a separate question. Obviously, the Pfizer and BioNTech data came in, delivered certainly an impressive result. I think you guys know what their data looks like, you know what the threshold might likely be to predict a single-dose type efficacy. I was just hoping you might give us a general sense of what you think is achievable in that context with the single-dose vaccination, in part, because I think there is a little bit of concern from investors that the single-dose vaccination, if it doesn't have exactly the same threshold of data, what the bar is going to be from the Agency.

Does the Pfizer and BioNTech data, should it shift the bar upward from the 50% to 60% threshold to 70% to 80%? What's your confidence that you could meet—if that were moving bar that you can meet that with the single-dose vaccination, and when will we see the data to support that?

Joseph Payne

Well I have one comment, if the team wants to add, feel free to do so.

I think to rephrase your question is, what's the likelihood of a regulatory agency allowing us to proceed and advance this therapeutic, given the data that we've collected so far, and I think that that's reasonably high. I think that's fair to say. We're going to continue to be able to evaluate this technology and mature it. I think that will be the metric that I'd like to refer to. I think the likelihood of us succeeding in advancing this is high to very high.

Dr. Steve Hughes

Yes. I'd just like to also add that at this point in time, there isn't a call protection that's actually established. It's important to consider that subjects with mild disease that have recovered universally, for the most part, have considerably lower antibody titers than subjects with severe disease. But we're not seeing subjects with mild disease falling over with COVID re-infection over and over again. There's only been a handful of cases of COVID re-infection around the world. I think what is clear is that sky-high levels of neutralizing antibody titers aren’t required for protection.

The other important point to bear in mind is T-cells. Nobody knows whether for this disease, T-cells are more important than antibody titers than as a color of protection of disease. I think it's premature to speculate what's the most important characteristic to see in terms of protection from the vaccine, the experts that we've talked to are very confident moving forward, that our data looks exciting, it looks promising as a single-dose, and we're going to be in conversations with regulatory authorities this week to discuss our data in more detail and about moving forward with a single-dose regimen into the next stages of clinical development.

We remain very confident and very excited about our program and confident that we'll be advancing single-doses further in clinical development.

Seamus Fernandez

Okay, great. I will jump back in the queue. Thank you guys.

Joseph Payne

Thank you.

Operator

Thank you. Our next question is come from the line of Madhu Kumar of Baird. Please proceed with your questions.

Madhu Kumar

Hi, everyone. Thanks for taking our questions.

Our first one relates to ARCT-021 as well. Is there additional data that the Singapore Economic Development Board had related to ARCT-021 Phase I/II trial that influenced their decision to set up the arrangement you guys announced today? Or is the data you put out both this morning, and this afternoon, the basis that for their decision making?

Joseph Payne

Yes. I think the short answer is yes. The Singapore Duke NUS Medical School is very well aware of our data. They're running the study and managing and overseeing many of the development activities. That's where a lot of the positive energy that we get in the feedback we get as this continues to develop. But to what extent that information is shared it outside of Duke NUS, I can't comment on that.

Madhu Kumar

Although as you are aware, there is a news article that came out overnight suggesting there's Phase III (inaudible) could start as early as by year-end. Does that seem like consistent with your perspective on things or how are you doing with the timing for pivotal studies for ARCT-021?

Joseph Payne

We're in discussions at the moment with the Singapore regulators and we've had a discussion already with the FDA as part of a pre-IND package. Both of those discussions have included design for our Phase III program. We're continuing our discussions with the regulators, we'll be having a conversation with Singapore regulator this week. Very shortly will also be reengaging with FDA to discuss our Phase III program. Until we've actually concluded those discussions, I don't think we can really make any further comment on what comes next or the timing.

Madhu Kumar

One last one on 810 and OTC deficiency, given that you've been able the dose escalate with no obvious safety concerns, is there a reason to not want to look to dose higher? The PK you've seen so far, the exposure you have seen so far, do you feel like you've hit the sweet spot in terms of how much OTC you can get in there? Or do you think that this has potential to expand further given the relatively mild conditions you seem to have seen so far?

Dr. Steve Hughes

The study that has completed is a healthy volunteer study, so we've really dosed as high in the healthy volunteers as we think that we need to go. We also have the patient study ongoing and we can dose higher in the patients. We will be using the data from the healthy volunteer study to enable subsequent multiple-dose studies as well where we can evaluate these things in more detail. The short answer is really we didn't feel that we needed to dose higher in healthy volunteers. It's best as of now to advance the program as quickly as we can in patients to include more doses and higher doses.

Joseph Payne

Just to help convert the units for people on the call, you know, 0.4 mcgs per kilogram is tens of thousands of micrograms of dosing. This is a substantial amount of messenger RNA that we've administered systemically or through intravenous application of mRNA.

Madhu Kumar

One thing based on what Steve just said, is there a reason to think you would need to go to higher doses in OTC patients, relative to healthy volunteers? Is there any mechanistic rationale why you would need to dose higher?

Dr. Steve Hughes

No, not at all. Based upon our animal data, we've seen great efficacy in the animals at doses greater than 0.1 milligram per kilogram. Our doses in the healthy volunteers are well within the therapeutic range. We've looked at multiple different biomarker endpoints and also looked at mortality in the animal models. We see at doses of 0.1 milligram per kilogram or greater in the animals, efficacy, so we're very confident that the dose range that we've tested already in the healthy volunteers is well into the therapeutic range that we'll need to test in patients.

Madhu Kumar

Excellent. Thank you so much, everyone.

Joseph Payne

Thanks, Madhu.

Operator

Thank you. Our next question has come from the line of Yasmeen Rahimi of Piper Sandler. Please proceed with your questions.

Yasmeen Rahimi

Hi, team. Congrats on the great progress that you're making. A number of questions. All of them are quick clarification questions.

The first one, the percentage of seroconversion that you just put out in your 4 o'clock press release, does it refer to a single or is this a combination of single and boost? Then I have a number of other little questions.

Dr. Steve Hughes

I believe the seroconversion data that we just press released, that we just discussed, relates to all doses and all cohorts. For the binding antibodies titers, and for the binding antibodies titers we have pretty much full data there. What we see is a 100% seroconversion in the two-dose cohort which was in younger adults. We also see a 100% seroconversion in all of the younger adults single-dose cohorts. In the older adult single-dose cohort, we've seen a seroconversion in all except one subject.

But for the older adult cohorts, we don't yet have the later time points and we know that as time goes on, we see more seroconversion. We're confident that the seroconversion will continue to increase in older adult cohort.

Yasmeen Rahimi

Thank you, Steve. The second question is—thank you for giving us that GMT also in the 4 o'clock press release and thank you for pointing out that it's over 15,000 for the younger adults and 2,300 for the older.

Can you give us another time point for that single 7.5 microgram dose group, so that our investors just feel comfortable that we're continuing to see an increased response over time?

Joseph Payne

Can I rephrase the question for Steve? Are you asking that if the IgG antibody GMT, if those increased going from Day 29 to Day 43, for example?

I can only refer to what we've already mentioned. I can refer to the script while Steve collects maybe his thoughts as well, but we're very comfortable in saying that, just reviewing my script, that the IgG binding antibodies continue to increase over time in humans in a similar manner to what we observed in pre-clinical animal models.

To refresh your memory, where we were with animal models, this particular data continued to increase to approximately Day 50. We did not take a Day 50 time point in humans but we mentioned Day 43, so that's why we use approximate and it's still continuing on.

But yes, we can assure people that with respect to IgG binding antibodies, that they continue to increase in humans over time

Dr. Steve Hughes

And we don't have the data time point yet in any adult cohort.

Joseph Payne

For some of these cohorts, as Steve mentioned, we don't have the complete data package, so this data continues to evolve.

Yasmeen Rahimi

Thank you, Joe. I guess I was just thinking if you have something at Day 15 or earlier and you could share that, that way we could actually compare it to the time point that you just referenced. That was the thought process.

Dr. Steve Hughes

At Day 15, the geometric mean titer for the older adults was about 20% to 25% of the geometric mean titer of what we saw at Day 29. At Day 8, it was about one-third of what it was at Day 15. From Day 8 to Day 15, it increased about three-fold. From Day 15 to Day 30—no, sorry, to Day 36, it increased in the range of two- to three-fold. It is continuing to rise.

Yasmeen Rahimi

Thank you. Then one last question. I know that, as you pointed out, 36 of the patients received two doses, so can you maybe comment on moving forward? What percentage of the population may require a boost

shot in two doses, to the extent you can comment on based on the data that you've seen so far? Then thank you again for taking my questions.

Joseph Payne

Right, what populations respond to the single administration versus the double administration? Some people have speculated that the elderly population have weakened immune response, so that may end up being the case with Arcturus, but we don't have that data yet.

Steve, I think—

Dr. Steve Hughes

Based upon the single-shot data, we've seen very robust binding antibodies data across all of the cohorts. The older adult cohorts, like with all of the other vaccines, have a slightly lower geometric mean titer than the younger adult cohorts. But even for the older adult cohorts, we've seen that the geometric mean titer is over 2,300, so the robust binding antibody titers that we're seeing across all age groups and all cohorts. For the neutralizing antibody titers, we don't have the later time points yet. That data is still evolving and we will be able to provide more color as time goes on. But the data that we do have show that mean titers are within the range of what we see for subjects that have had COVID-19 and in the convalescent phase.

Joseph Payne

If we're not—if there is a sub-population that doesn't respond as well as others, we utilize a non-viral delivery technology that is multi-dose, so that's one of the features of this product.

Yasmeen Rahimi

Thank you for taking my questions, and thank you for the answer.

Joseph Payne

Thanks, Yasmeen.

Operator

Thank you. Our next question comes from Yigal Nochomovitz of Citigroup. Please proceed with your questions.

Yigal Nochomovitz

Yes. Hi. Thanks for taking the questions.

Just another one on the single-dose versus the prime-boost, you've talked about both. Could you just give us a little bit more understanding as to how you're going to take both of those forward, or are you going to make a decision to only take one forward? Could you just provide a little bit more context as far as whether you're going to commercialize both single-dose and the prime-boost, or make a decision to only go forward with one of them?

Dr. Steve Hughes

At this point in time, we're advancing both single-dose and prime-boost regimens forward into the next stage of clinical development, where we will evaluate further in several hundred subjects, and then we will rapidly advance one of those regimens into late stage or into a registration study. In our registration study we'll just take one forward. We still have confidence in the single-dose regimen, which is why we're advancing that for the next stage of development.

But we're also testing two doses in that next study, and then we'll very rapidly move to Phase III with just a single regimen. At this point, we can't say that it will definitely be a single-dose regimen, although we're confident that the single-dose has adequate immunogenicity to be protective in humans.

Yigal Nochomovitz

Okay. Thanks. Do you plan on publishing the results of this study in the near future?

Dr. Steve Hughes

As Joe indicated a little while ago, we're planning to publish the results of the study when the study is complete. The study will complete in the first quarter of next year. Then we will summarize the results and publish them thereafter. The issue that we have at the moment is that this is an ongoing study so the data is evolving, so trying to publish the data based upon data that could shift is a little premature.

Yigal Nochomovitz

Thank you.

Operator

Thank you. Our next questions come from the line of Gena Wang with Barclays. Please proceed with your questions.

Gena Wang

Thank you for taking my question, but I have a few.

First, just wanted to confirm, Steve, you mentioned that GMT has a 147 for convalescent serum. Just want to confirm those are the PRNT50 and the 147 is the mean or median.

Dr. Steve Hughes

It is the PRNT50, and 147 is a geometric mean, which is what's usually used (inaudible).

Gena Wang

Okay, perfect. Then what is the upper end of those PRNT50 full convalescent serum? What is the highest, the number?

Dr. Steve Hughes

The upper end is for subjects that have severe disease. I don't have the numbers right in front of me, but it's several hundred at least.

Gena Wang

Okay. When you come and PRNT50 GMT within range of the titers in the convalescent serum, are you referring to the upper end, overlapping with the upper end of the convalescent serum from those single-dose and two-dose profile?

Dr. Steve Hughes

We're referring to the range.

Gena Wang

Okay. Then any differences between single-dose 7.5 microgram versus the prime-boost 5 microgram in terms of a PRNT50?

Dr. Steve Hughes

It's not possible for us to make that determination at the moment. It's because we don't have the full data set from the single-doses. As I mentioned, we don't have the later time points. For our vaccine technology, the antigen levels, it continues to increase over time. We see increasing titers over time. It's going to be a few weeks yet before we're able to make the comparison between the single-dose and the two-dose regimens for any of the doses. However, we do see very robust antibody titers in the 5 microgram single-dose cohort as we do in the 5 microgram two-dose cohorts.

Gena Wang

Okay. Just a comment. All the others, they're principally all neutralizing antibody actually for the 14 days after use. Just wondering based on the Day 29 of what data could be look like compared to any differences, do you see between single-dose versus boost? Then the related question is, since we moved forward, next step, 7.5 microgram single-dose and the two doses. Just want to confirm those two doses is 7.5 microgram prime-boost. Then made you decide to choose 7.5 microgram over 5 microgram you did so far?

Dr. Steve Hughes

Yes. Actually in the next study we'll be taking 7.5 single-dose, 5 microgram two-dose, and 7.5 two-dose regimens forward. We're evaluating three different dose regimens in both younger and older adult cohorts. The reason for selecting 7.5 to move forward is that, the 7.5 microgram dose was as equally well-tolerated to the 5 microgram dose. So it made sense to move forward with the higher dose than the lower dose, given that at this point we're not able to make a determination as to whether a single-dose or two-doses (inaudible), they're both effective.

We don't have the later time points for the single-doses but in order to advance the program quickly, we need to make decisions with incomplete information. So we're taking 7.5 forward, that was very well tolerated. It was as well tolerated, if not better tolerated than the 5 microgram dose, and we're also taking 5 and 7.5 forward as a two-dose regimen.

Gena Wang

Okay. Thank you.

Operator

Thank you. Our next questions come from the line of Steve Seedhouse with Raymond James. Please proceed with your question.

Steve Seedhouse

Good afternoon. Thanks for taking the question.

I guess I'm just confused through this conversation. Did you end up actually dosing people with 10 micrograms? And if you did, what went into the decision ultimately to advance 7.5 in both the single- and double-dose regimens?

Dr. Steve Hughes

We did dose at 10 micrograms. We dosed a single-dose cohort at 10 micrograms. At the 10 microgram dose, we saw some Grade-3 tolerability events. We chose to move forward with the 7.5 dose as opposed to 10 micrograms because 7.5 was extremely well-tolerated with zero Grade-3 events. We don't believe that we're going to see any trade-off, based upon the immunogenicity results that we're seeing by going with the slightly lower dose.

Steve Seedhouse

Yes, make sense. Could you maybe just elaborate: where those things like fever, chills, muscle aches, muscle pain, that have been seen with other COVID vaccines? Or what were those?

Dr. Steve Hughes

We haven't seen any fevers that are Grade-3, in fact, we haven't seen any fevers that are more than mild at any dose levels in the study. I can't, honestly, remember off top of my head what the Grade-3 events were in the study. I can't really comment specifically. They just were Grade-3 tolerability events that were within the vaccine grading scale for those events.

Steve Seedhouse

Okay, fair enough. Then maybe on manufacturing—last question. At what scale on a dose basis—maybe this is an unfair question, it could be too early, but I know others, particularly with mRNA vaccines threw out some estimates pretty early. What scale do you think you can manufacturer the vaccine in let's just say 2021?

Joseph Payne

In 2021? I think Andy mentioned some—provided some guidance there, that we have the foundation to do very large manufacturing campaigns. But we're in the scale right now that's sufficient to supply for Israel and Singapore, and we have a process that's scalable for both the process to make the messenger RNA construct and to formulate it, and to still finished (inaudible) it. We have the partners that help us with this capacity like we mentioned, Catalent and Recipharm, and others, that are helping us here. Our manufacturing horizon is very promising. Our technology is validated and tech transferred, and we're in good shape there.

Pad, do you have an extra comment?

Pad Chivukula

Yes, just this one other comment as Andy mentioned, we did receive an additional $45 million for procurement of raw materials for our manufacturing efforts. With that additional funds, we're getting ready to get a lot of the key raw materials up to a kilograms scale, and get that order, so that we can be very nimble in manufacturing for next year.

Steve Seedhouse

Yes. Thank you.

Operator

That is all the time we have for questions today. I would like to turn the floor back over to President and CEO, Joseph Payne, for any closing comments.

Joseph Payne

Thanks to everyone for listening. It looks at this point we are going to close the call, but feel free to reach out as always if you have any follow-up questions. We will be as efficient as we can in our responses.

Bye for now.

Operator

Thank you. This does conclude tonight's call. You may disconnect your lines at this time. Thank you for your participation, and have a great day.