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CORPORATE PARTICIPANTS

Anne Erickson *Savara Inc. - VP of IR & Corporate Communications*

David L. Lowrance *Savara Inc. - CFO & Secretary*

Jaakko Taneli Jouhikainen *Savara Inc. - President & COO*

Robert Neville *Savara Inc. - Co-Founder, Executive Chairman & CEO*

CONFERENCE CALL PARTICIPANTS

David Michael Steinberg *Jefferies LLC, Research Division - Equity Analyst*

Liisa Ann Bayko *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

PRESENTATION

Operator

Good afternoon, and welcome to the Savara Conference Call.

(Operator Instructions)

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I would like to now turn the phone over to Anne Erickson, Head of Investor Relations and Corporate Communications at Savara.

Anne Erickson - *Savara Inc. - VP of IR & Corporate Communications*

Good afternoon, and thank you everyone for joining us on today's call. A press release reporting our Second Quarter 2019 Financial Results was issued earlier today, August 8, 2019, and can be found on the Investors section of our website at Savarapharma.com. If you did not received this release or if you'd like to be added to the company's distribution list, please email me at ir@savarapharma.com.

This call is also being webcast live, and approximately one hour after the call a replay will be available on the company's website and will remain available for the next 30 days. A telephone replay will also be available through August 15. Please note that today's conference call and webcast contain forward-looking statements within the meaning of the Federal Securities Laws, including statements regarding the company's strategy, goals, product candidates, clinical studies and financing matters. Such statements are subject to significant risks and uncertainties including those described in our press release issued today, Thursday, August 8, 2019, and our recent SEC filings on Forms 8-K, 10-K and 10-Q. Actual results or performance may differ materially from the expectations indicated by our forward-looking statements due to those risks and uncertainties. We caution you to not place undue reliance on any of the forward-looking statements, which speak only as of today. As usual, we will take analyst questions at the end of the call. However, we would also like to encourage shareholders on the call to submit questions via email to ir@savarapharma.com. Time permitting, we will address these questions alongside others received by our IR team.

Joining me on the call today are Rob Neville, Chief Executive Officer, Taneli Jouhikainen, President and Chief Operating Officer, Dave Lowrance, Chief Financial Officer. I'll now turn the call over to Rob.

Robert Neville - *Savara Inc. - Co-Founder, Executive Chairman & CEO*

Thank you, Anne, and hello everybody. As always, I do appreciate you dialing into our quarterly call. This afternoon, I'll update you on next steps for the Molgradex aPAP program, Taneli will share some additional data on that program, as well as review other key clinical programs and catalysts, and Dave will then summarize our financial results.

Let me start by sharing some thoughts on the Phase 3 IMPALA top line data we announced back in June. As a reminder, IMPALA is an ongoing pivotal study evaluating Molgradex on GM-CSF for the treatment of autoimmune pulmonary alveolar proteinosis, or aPAP, and is the first investigator-sponsored randomized placebo-controlled international study for this indication. I think it's fair to assume that most of you listened to the June call and are aware that the study narrowly missed its primary endpoint. This is clearly disappointing, and serves as a permanent reminder of just how complex the drug development process can be. However, I want to make one thing clear, we believe the totality of the IMPALA data, which extend beyond the primary endpoint to include all of the secondary measures, provide a more holistic and compelling view of the efficacy results from the study, and the benefit of Molgradex for treating aPAP. The full data set underscores our confidence that there is a path forward for this program, and we remain optimistic that the drug works, and can improve the outcomes for patients.

We hold this belief for several reasons. First, while improvement in the alveolar-arterial oxygen gradient, or A-aDO2, did not reach statistical significance compared to placebo, the treatment effect of about 12-millimeter mercury in a continuous dosing arm was similar to what's been observed in previously-published studies. Moreover, the diffusing capacity of the lungs for carbon monoxide, or the DLCO, which is an independent measure of gas exchange efficiency and the predefined specified secondary endpoints, did reach statistical significance compared to a placebo, when looking at the A-a gradients and the DLCO together, we believe this demonstrates Molgradex improves gas exchange in the lungs and reduces surfactant burden as evidenced by these 2 separate measures of gas exchange. Secondly, IMPALA showed statistically significant improvement in the St. George's Respiratory Questionnaire. Secondary measure is a patient-reported quality of life tool and a clinically meaningful endpoint. It's worth noting that the improvement shown in the St. George's questionnaire was approximately twice the clinically meaningful effect that has been generally accepted for other lung diseases. Additionally, 2 other key secondary endpoints were numerically in favor of the continuous dosing on Molgradex though not statistically significant, and those being the 6-minute walk distance and the time to whole lung lavage.

And finally, the key clinical endpoint such as St. George's and the 6-minute walk and the time to whole lung lavage moved in sync with gas exchange improvements. This is critical because the FDA considers A-aDO2 secondary endpoint and as such, the agency's guidance made it clear that it needed to see consistent improvement across both the primary and secondary measures, meaning when A-aDO2 improvements were seen, FDA would expect to see improvements in some of the secondary measures as well. Improved gas exchange alone wouldn't be enough. It would need to translate into improved clinical outcomes. Impressively, this is what IMPALA demonstrated. In fact, with continuous dosing arm and the correlated improvements in either A-aDO2 or DLCO with improvements in the clinical endpoints, we see statistically significant and clear correlations across the endpoints.

So when we weigh the strength of the efficacy data from the primary and secondary endpoints, and consider the fact that virtually all 17 of the secondary endpoints either achieved [ceptive] or trended in favor of the treatment arms. We're convinced the drug has a robust treatment effect.

And with adverse events frequency similar to placebo, we are confident that Molgradex has a compelling risk-benefit profile. This is noteworthy as the U.S. Regulatory requirements for approval of drugs like Molgradex require that we show substantial evidence of the drug's effectiveness and safety for the intended use. However, when studying an orphan disease like aPAP, it's not always feasible to obtain the same kind and quantity of data as might be expected with a more common disease, such as diabetes or cancer. With a prevalence of 7 per million in the U.S., investigating treatments and confirmatory and well-controlled clinical studies in the aPAP patient population is challenging and without precedence. Therefore, scientific judgment is relied upon to determine the appropriate amounts and strength of evidence required for such a rare disease. Even though IMPALA narrowly missed statistical significance on the pre-specified primary endpoint, we believe that the overall data support the effectiveness and safety of the drug.

And so where do we go from here? All the reasons I've outlined, we believe the results of IMPALA support that treatment with Molgradex can provide clinically-meaningful outcomes and positively impact how aPAP patients feel and function. We remain optimistic that IMPALA can serve as a registrational study to support the filing of the BLA.

Accordingly, we are in the process of finalizing a briefing package for the FDA in preparation for what we now know will be a Type C meeting that will come in the form of written response this October. From this interaction, and in light of the totality of the safety and efficacy data, we hope to get a better understanding of the agency's sentiment around the strength of the secondary endpoints, as well as its view of the acceptability of the IMPALA data for submission. Additionally, given the high unmet need in aPAP and the devastating nature of the disease, we also expect to file for Breakthrough Designation in the coming months.

We remain hopeful about the Molgradex aPAP program and are working diligently to bring this important therapy to market. It remains to be seen whether that can be achieved based on the merits of the IMPALA data alone, or by generating additional data through another Phase 3 study should that be required. Regardless of the path we take, we are confident we'll get there. Fortunately for us, our pipeline provide us with multiple shots on goal, including another pivotal Phase 3 and 2 additional Phase 2a studies that provide us with several upcoming catalysts.

With a cash position of approximately $112 million, we are well financed to support our upcoming milestones.

Taneli and Dave respectively will elaborate on these points. So I'll turn the call over to Taneli now.

Jaakko Taneli Jouhikainen - *Savara Inc. - President & COO*

Good afternoon everyone, and thank you, Rob, for that update. I would like to elaborate a little more on this much talked-about concept of the totality of data that we believe is so central to our optimism for a path forward towards BLA filing of Molgradex. There are a number of key factors, in fact 7 altogether, that are important in this consideration, which I will summarize one by one in a logical sequence.

Firstly, it all starts with a thorough understanding of the disease mechanism of aPAP, which is neutralization of GM-CSF by anti-GM-CSF antibodies leading to surfactant accumulation and the resultant respiratory insufficiency and failure. Treatment of aPAP with Molgradex, an inhaled form of GM-CSF, is therefore a perfect fit mechanistically.

Second, the concept has been shown to be very promising in uncontrolled (technical difficulty) the CT scans as measured by ground-glass opacity scores with apparent dose frequency dependency. #4, the removal of surfactant was associated with a reversal of the path of physiology, that is the gas exchange impairment, as measured by 2 independent measures of gas change, the A-aDO2 and the DLCO.

#5, these changes correlated significantly with our key clinical endpoints, of which there were statistically significant and highly clinically significant treatment effects versus placebo in the SGRQ, a broadly-used patient-reported disease state assessment tool.

#6, the aforementioned changes were also associated with a reversal of a systemic physiologic response to a chronic lung disease in the form of a decrease in hemoglobin. And finally, for each of these factors, most of the observed effect were dose frequency dependent, in other words, observed more clearly in the continuous treatment arm, and less so in the intermittent dosing arm, providing further support to a true biological effect of the drug. Since our study was relatively small, not all of the observed differences were statistically significant, but the overall consistency of these results with a known biology of the disease is very convincing to us, and the sentiment is strongly shared by numerous KOLs as well as regulatory advisers.

In the upcoming months, we will be completing the 24-week open-label period of the study, which will give us an opportunity to evaluate if the improvements from baseline observed during the placebo-controlled period have continued to increase. For many of the endpoints, the effect size appeared to be increasing over time as compared to placebo, and the improvements did not appear to have plateaued at week 24. In particular, we are keenly interested to see if there has been further reduction in the frequency of whole lung lavage as treatment has continued, and if the placebo group will now flip to match or beat one or both of the active groups. We expect the last patients to have completed the open-label period in October, and to have all data analyzed and summarized by early Q1 of next year.

Wrapping up on the Molgradex aPAP program, I'm pleased to inform you that we continue to see strong enrollment into IMPALA-X our optional open-label extension study that allows patients to continue treatment for up to 3 additional years beyond the completion of the IMPALA study. At the end of Q2, 32 of 35 eligible patients had enrolled into the study. And after running now for about 1 year, I am pleased to share that there

have been no whole lung lavages reported and no drop-outs-to-date. Moving on to other parts of our pipeline, there are 2 earlier-stage clinical studies in our Molgradex franchise that are progressing in line with guidance. Both are Phase 2a open-label studies that are assessing Molgradex for the treatment of nontuberculous mycobacterial, or NTM, lung infection. The OPTIMA study, which initiated in March of 2018 and focuses on people who are not impacted by cystic fibrosis, or CF, is fully enrolled with 32 patients. We are now encouraging interim results from 14 patients last December, and continue to expect top-line results in the first quarter of 2020. The ENCORE study, which initiated earlier this year, is very similar to OPTIMA, but is enrolling people living with CF with a targeted enrollment of also approximately 30 subjects.

Now let's next move to AeroVanc, our other pivotal Phase 3 program. AeroVanc is an inhaled vancomycin for treatment of methicillin-resistant Staphylococcus aureus, or MRSA, lung infection in people living with CF. Given the intense focus on the IMPALA study over the last few months, let me take a minute to remind you of the Phase 3 AVAIL study design. In Period 1, subjects are treated for 3 consecutive cycles of twice-daily AeroVanc or placebo, a cycle being defined as 28 days of treatment followed by 28 days of rest, with the primary endpoint being mean absolute change in FEV1 at weeks 4, 12 and 20, analyzed sequentially. In Period 2, all patients receive open-label AeroVanc twice daily for an additional 3 dosing cycles to evaluate the long-term safety of the drug.

Importantly, the market opportunity with this program is quite large in the context of a rare disease. Above 30,000 people are affected by CF in the U.S. And MRSA infection has become increasingly common in CF with a prevalence of about 26%. Currently, there are no approved inhale therapies specifically targeting this infection. As of August 1, the AVAIL study had enrolled a total of 168 patients out of an initial target of 200. Enrollment of the adult population was complete already in Q3 of 2018, with 55 patients enrolled out of a target of 50. However, despite a clear improvement in enrollment rates during the past quarter, enrollment of the primary analysis population, that is subjects between 6 and 21 years of age, continues to be challenging due to the severity of the disease.

As of August 1, the study had enrolled 113 pediatric patients out of a target of 150, leaving 37 left to go. As previously indicated, we continued to see a screening failure rate of approximately 50%. This is higher than anticipated and largely due to pulmonary exacerbations occurring between the time of screening and randomization, and failure to meet the required lung function criteria. However, these high screening numbers reinforce that we are clearly reaching a large number of patients affected by MRSA. And the exacerbations prior to randomization demonstrate the high disease burden and the need for better treatment.

While we have undertaken numerous activities to boost enrollments, including bringing on additional clinical study sites, the fluctuations in enrollments feed over time has made it hard to give accurate guidance on enrollment completion. Accordingly, we are now revising enrollment completion guidance broadly to cover a range of projected enrollment rates with a new anticipated completion time for enrollment in the first half of 2020. This means top-line results are now expected in late 2020 or early '21. We continue to prioritize this program and believe that AeroVanc can significantly improve outcomes for patients with MRSA. At last year's North American Cystic Fibrosis Conference, the CF Foundation made it very clear that despite advances in the disease modifying treatments, managing chronic infection and inflammation remain key challenges in the management of CF, and high priorities for new drug development.

In fact, it is estimated that with increasing life expectancy associated with improving treatment options for CF, the absolute number of subjects with chronic infection is actually likely to increase over the years. Therefore, while the double and triple combination CF modulator therapies are clearly impactful, there is still a high need for additional treatment approaches like AeroVanc to support the CF community.

Finally, given the need to focus our attention on our later-stage programs as well as conserve our cash resources, we completed a portfolio review and made the decision to deprioritize our exploratory amikacin/fosfomycin program. We will evaluate its potential for future development when we have the resources and bandwidth to do so.

Now, I'll pass the call to Dave for a financial update.

David L. Lowrance - *Savara Inc. - CFO & Secretary*

Thanks, Taneli. Hello everyone. I'll start today with what is likely most important to you regarding our financials. As of June 30, 2019, we had cash, cash equivalents and short-term investments of $111.7 million, and approximately $25 million in debt. We've always been committed to advancing

our key clinical programs while closely managing spend, and as a result, we believe we have sufficient funds to get us into 2021. This is due in part to cost-cutting measures and reduced costs associated with our exploratory pipeline.

With respect to the P&L, Savara's net loss attributable to common stockholders for the 3 months ended June 30, 2019, was $21.9 million, or a loss of $0.57 per share, compared with a net loss attributable to common stockholders of $11.6 million, or a loss of $0.37 per share for the 3 months ended June 30, 2018. Research and development expenses were $10.5 million for the 3 months ended June 30, 2019, compared with $9.3 million for the 3 months ended June 30, 2018. The increase was primarily due to $2.2 million in development costs, associated with Molgradex and AeroVanc, which was partially offset by $1 million in expense in the form of common stock issued in connection with the purchase of the amikacin/fosfomycin asset in the second quarter of 2018. General and administrative expenses for the 3 months ended June 30, 2019, were $4.2 million, compared with $2.5 million for the 3 months ended June 30, 2018. The increase was primarily due to personnel costs and other legal accounting insurance and operating activities. During the 3 months ended June 30, 2019, we recognized $7.4 million non-cash impairment charge to the carrying value of our goodwill following the results of our IMPALA study.

To reiterate, we are tightly managing our expenses and focusing spend on only the most critical deliverables so that we can achieve our key catalysts.

And now back to you, Rob.

Robert Neville - *Savara Inc. - Co-Founder, Executive Chairman & CEO*

Thank you, Dave. And again, thanks everybody for joining the call. And just quickly in summary then, while certain aspects of the IMPALA study were clearly not in line with our expectations when we look at the totality of the [data attenuate into inadequate] detail, we are optimistic and continue to believe that Molgradex can be approved for the treatment of aPAP. Results of this landmark study, the largest placebo controlled studies for this disease ever conducted, contribute to our understanding of aPAP and the role of Molgradex to treat it. We are moving full steam ahead of the briefing package for the FDA, and continue to explore all avenues of U.S. and European regulatory bodies regarding the path for approval.

Additionally the insights from IMPALA will be used to inform further development of this program should another Phase 3 study be required. Lastly, and equally importantly, I'm grateful to be in a position where our cash balance will fund our ongoing activities into 2021, as Dave just mentioned.

As I end the call today, I want to emphasize why we are so staunchly committed to the Molgradex aPAP program. Following our announcement of the IMPALA results, we received numerous emails and calls from the aPAP community including clinicians, and advocates and patients. Their collective reaction was a strong belief (inaudible) drug works, also that it could be life changing.

Patients deserve better treatment options than an invasive whole lung lavage, and it's on their behalf that are relentless in fighting this important fight. And as always, we'll continue support in this regard, and very much appreciate it.

At the beginning of the call, Anne encouraged shareholders to submit questions via email to ir@savarapharma.com. If time permits, we'll answer these and others that have been submitted to our Investor Relations team. And so with that, I'd like to turn the call back to Anne for analyst questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Liisa Bayko with JMP Securities. Please go ahead.

Liisa Ann Bayko - *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

Can you maybe go through the timing and such for breakthrough -- achievement of breakthrough status? When will you be applying, when would you expect to hear? It'd be great thing to have.

Robert Neville - *Savara Inc. - Co-Founder, Executive Chairman & CEO*

We actually haven't fully decided what we expect to do. First is get the response from the FDA in October, the written response from the Type C meeting, and then apply for breakthrough soon thereafter, but the actual date has not been fully committed yet.

Liisa Ann Bayko - *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

And then what is your sense of your path forward for Europe? I understand with FDA, you're going to have a meeting. Will you have a similar meeting in Europe, and what kind of -- what are your expectations there?

Robert Neville - *Savara Inc. - Co-Founder, Executive Chairman & CEO*

Well, the European process has a different sequence of events. And so we will be following the customary steps ahead of European filing, that probably we anticipate doing somewhat behind an FDA filing just for resource reasons.

Operator

Our next question comes from David Steinberg with Jefferies. Please go ahead.

David Michael Steinberg - *Jefferies LLC, Research Division - Equity Analyst*

With regard to Molgradex, some experts believe that the St. George's endpoint is probably the best endpoint in terms of disease impact, but it was one of your secondary endpoints, not your primary. And I'm just curious when you do have this Type C meeting, is that one of the pathways you're going to pursue with FDA so as to perhaps not have to do any other clinical trials? And if in fact you do need to do further extensive clinical trials, I assume you are prepared to do so. And the related question is, you've got I think $112 million in cash, and for a company your size, you have quite a few programs. If you do pursue an extensive Molgradex program to see it through, what are your thoughts on conserving cash and are there some programs you would set to the side to ensure you had runway to complete that?

Jaakko Taneli Jouhikainen - *Savara Inc. - President & COO*

Let me answer the question relating to the SGRQ and the FDA, and our thoughts about the program, and then Rob can address the cash runway and the like. So you're absolutely right, the SGRQ is definitely a very well-suited endpoint for aPAP. It has 3 domains, one of which is symptoms, one is activity level, and then there's a total social impact as well. And we were able to impressively improve the total score, each of these domains improving on their own as well. So definitely this is going to have a central role in our FDA dialogue. And it is a little paradoxical to say the least that we had such a great result in an outcome measure that we were more concerned about as being affected by placebo. And what we thought to be more objective and less interfered by placebo, the A-aDO2, was not been met. But when you think about it, this is a better situation clinically speaking, because we did show clear patient impact. Patients don't care about A-aDO2 numbers, but they very much care about how they feel and what their activities are. And we hope that this is going to be also agreed upon by the FDA. But I do want to also re-emphasize the aspects of the totality of data. It is very powerful when you have so many different angles of approach, and they all fit very well to the science and the biology of the disease. And that is certainly a second key aspect that we'll be bringing forth to the FDA. Then you asked about whether or not we are ready to go ahead with another study should that be needed. The answer is yes, definitely we are. And this IMPALA study clearly has given us a lot of teaching about how to do studies in aPAP. We learned the stuff that nobody knew before. And we believe we can do a more efficient study. We

don't need to dose groups active to begin with, and we have a much better understanding of the effect size and the sample size requirements after what we've gone through.

David L. Lowrance - *Savara Inc. - CFO & Secretary*

David, this is Dave. Just to follow up on what Tenali said. Us being prepared means that we are allocating the appropriate level of resource. Molgradex for aPAP and AeroVanc Phase 3, those are clearly our key focus. Every time we get new data, though we're taking a fresh look at our forecast and what that means to us. So we'll ensure that we protect those assets and extend our longevity as long as the cash will get us.

Operator

(Operator Instructions) At this time, our question queue is clear. I'd like to hand the call back over to Anne Erickson for some email questions.

Anne Erickson - *Savara Inc. - VP of IR & Corporate Communications*

A question came in about Period 2 of IMPALA. And the question was, have you seen any whole lung lavages in the open-label period of IMPALA?

Jaakko Taneli Jouhikainen - *Savara Inc. - President & COO*

The Period 2 is the stage of this IMPALA study where everybody is on drug. And we have not yet reported anything of the open-label period. But since this question was now asked and we did address the IMPALA-X lack of lung lavages, I can tell you that it does appear that there is a reduction from what we observed during the placebo-controlled period as treatment continues. But right now, we will not go into more details until such time that all patients have completed the open-label period, and we can then have a better -- or more accurate number for you.

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Rob Neville for any closing remarks.

Robert Neville - *Savara Inc. - Co-Founder, Executive Chairman & CEO*

No, that is it. And thank you to Dave and Taneli, and Anne, and everybody that dialed in today. We do appreciate your support and we definitely -- obviously very excited about October, and we look forward to reporting back to you then. Thank you, everybody.

Operator

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.
