Immunic, Inc. (NASDAQ:IMUX) Q3 2023 Earnings Conference Call November 14, 2023 8:00 AM ET

Company Participants

Jessica Breu - Head of IR & Communications
Dr. Daniel Vitt - CEO and President
Glenn Whaley - CFO

Conference Call Participants

Caroline Pocher - Wedbush PacGrow
Liam Hiester - Piper Sandler
Matt Kaplan - Ladenberg Thalmann
Tom Smith - Leerink Partners
William Wood - B. Riley

Jessica Breu

Good morning, and welcome to Immunic's Third Quarter 2023 Earnings Call. My name is Jessica Breu, Head of Investor Relations and Communications at Immunic. I will also be the moderator on today's call.

Speaking on the call are Dr. Daniel Vitt, our Chief Executive Officer and President; as well as Glenn Whaley, our Chief Financial Officer. Please note that all participants will be in listen-only mode and this event is being recorded. [Operator Instructions]

Before we begin, I would like to remind you that this presentation may contain forward-looking statements. Such statements can be identified by words such as may, will, expect, anticipate, estimate, or words with similar meaning, and such statements involve a number of risks and uncertainties that could cause Immunic's actual results to differ materially from those discussed here. Please note that these forward-looking statements reflect Immunic's opinions only as of the date of this presentation, and it undertakes no obligation to revise or publicly release the results of any revision to these forward-looking statements in light of new information or future events. Please refer to Immunic's SEC filings for a more detailed description of the risk factors that may affect Immunic's results and these forward-looking statements.

I would now like to turn the call over to our CEO and President, Dr. Daniel Vitt, to begin the presentation. Daniel?

Dr. Daniel Vitt

Yes. Thank you, Jessica. I would also like to welcome everybody to today's earnings call. Earlier this morning, we announced our financial results for the third quarter ended September 30, 2023, in our press release and Form 10-Q. During the call today, we will walk through our third quarter 2023 and subsequent highlights, financial and operating results, as well as anticipated upcoming milestones. As Jessica noted, after the presentation, you will have the opportunity to ask questions.

Let's start with a review of our third quarter 2023 and subsequent highlights. I would like to begin with our vidofludimus calcium development program in multiple sclerosis. In August, we completed enrollment of our Phase 2 CALLIPER trial of vidofludimus calcium in patients with progressive multiple sclerosis or PMS. A total of 467 adult patients with primary MS or active or non-active secondary PMS were randomized to either 45 milligram daily doses of vidofludimus calcium or placebo. Patients were enrolled at more than 70 sites in North America, Western, Central and Eastern Europe.

A few months later, in October, we had reported overwhelmingly positive interim data from this Phase 2 CALLIPER trial. In total, 203 patients were included in this analysis. The overall population which includes all subtypes of PMS saw a 22.4% improvement in serum neurofilament light chain or NfL for vidofludimus calcium over placebo at week 24. We believe that this is a substantial and meaningful difference in favor of vidofludimus calcium in this SPMS population. A statistically significant difference was found for serum NfL at week 24 between vidofludimus calcium and placebo with a p value of 0.01. If you look at the subtypes of progressive MS to the right, you can appreciate that this difference in NfL at week 24 was consistently shown throughout all subtypes of progressive MS.

I would like to point out that we saw a 20% reduction for vidofludimus calcium versus placebo in SPMS, meaning the patients with no focal inflammation activity but disease progression. This subtype is a difficult to treat population with no relevant FDA approved therapies available.

This slide puts our CALLIPER interim data into the perspective of historical third-party studies and the same progressive MS subtypes. On the left, we display the data for PPMS compared to the Oratorio study for ocrelizumab which showed a spread of NfL values between active and placebo at 24 weeks of 12.4%.

In the CALLIPER trial, we observed an 18.8% improvement of active drug over placebo in PPMS at week 24. The results of this Phase 3 study led to approval of ocrelizumab for treatment of PPMS.

In the center of the slide, you see historical data for secondary progressive MS, both for non-active and active SPMS. In comparison, vidofludimus calcium was able to show a substantial reduction of NfL in both the active and non-active populations. To our knowledge, this is the first time that such a substantial effect in NfL has been shown in non-active SPMS patients, again which is the PMS subtype with the highest unmet medical need.

The right side of the slide shows comparison between our Phase 2 EMPhASIS data of vidofludimus calcium in RRMS versus our historical relapsing MS studies to complete the picture.

In summary, we believe the clear separation observed for serum NfL for vidofludimus calcium over placebo in this PMS patient population represents another major step forward for what potentially could be a first-in-class Nurr1 activator for MS. This strong signal also points to a more likely positive outcome of the overall CALLIPER trial also on clinically relevant endpoints like prevention of disability worsening.

In October, Dr. Robert J. Fox from Cleveland Clinic who is also the coordinating investigator of our ENSURE and CALLIPER programs, presented data from our Phase 2 EMPhASIS trial of vidofludimus calcium in RRMS, an e-poster at the Joint ECTRIMS-ACTRIMS Meeting. As a reminder, vidofludimus calcium showed an improvement in serum NfL in both treatment arms of 30 milligram and 45 milligram over placebo.

Just recently, we received a notice of allowance from the USPTO for patent covering the treatment of relapsing MS with a specific strength of vidofludimus calcium. This includes a daily dose of about 10 milligram to 45 milligram of vidofludimus calcium and other source as well as the free acid form of the treatment for relapsing MS, also covering the 30 milligram dosage used in our ongoing twin Phase 3 ENSURE trials. The claims are expected to provide protection into 2041, unless extended further. This patent significantly bolstered the multilayered proprietary IP position we have built around our late-stage program for patients with MS.

Moving to our IMU-856 program. In July, we hosted a Virtual Celiac Disease Expert Roundtable to discuss ongoing active celiac disease or OACD, a serious lifelong autoimmune disorder, and the substantial unmet need for therapeutic solutions. We were grateful and honored to have been joined for this event by the renowned thought leaders from Harvard Medical School, the Mayo Clinic and the Celiac Disease Foundation. During the roundtable, our Chief Medical Officer, Andreas, also provided an overview of IMU-856 program, including our positive Phase 1 trial results in celiac disease patients released earlier this year in May, which I will highlight again in just a moment.

Also in October, we presented 2 abstracts at the United European Gastroenterology Week, UEGW 2023. My colleague, Dr. Franziska Burianek, Senior Medical Director at Immunic presented data from our positive Phase 1b clinical trial of IMU-856 in patients with celiac disease during a moderated poster session. IMU-856 is an orally available and systemically acting small molecule modulator of the target SIRT6. The trial results gathered during periods of gluten-free diet and gluten challenge demonstrated positive effects for IMU-856 over placebo in 4 key dimension of celiac disease pathophysiology: protection of the gut architecture, improvement of patients' symptoms, biomarker response, and enhancement of nutrient absorption. IMU-856 was also observed to be safe and well tolerated in this trial. We believe that this highly encouraging data provides initial clinical proof-of-concept for an entirely new therapeutic approach to gastrointestinal disorders by promoting the regeneration of bowel architecture.

Additionally, Dr. Geert D'Haens from Amsterdam University Medical Center presented data from our Phase 2 CALDOSE-1 trial of vidofludimus calcium in ulcerative colitis, or UC. As a reminder, the maintenance phase results from the CALDOSE-1 trial demonstrated statistically significant activity of vidofludimus calcium compared to placebo and reaffirm the drug's favorable safety and tolerability profile. The data validated the potential of vidofludimus calcium in UC, and other inflammatory bowel disease indications.

Earlier this month, Dr. Burianek had another opportunity to present the data from our Phase 1b clinical trial of IMU-856 in patients with celiac disease and a virtual e-poster at the Association of European Celiac Societies General Assembly Conference in Athens, Greece.

That concludes our summary for the third quarter 2023 and subsequent highlights. I am very happy that the scientific and clinical advancement and progress made across our different programs has been extremely positive during this year. Immunic is leveraging this momentum now in discussions with pharmaceutical companies. For IMU-856, our goal is to identify a partner who is capable of performing several therapeutic Phase 2 clinical trials. For vidofludimus calcium, the release of our very good biomarker NfL data, has been an important trigger point for partnering discussions with global and regional pharma players.

I would now like to hand over the call to Glenn to provide financial overview. Glenn?

Glenn Whaley

Thank you, Daniel. I will now review the financial and operating results for the third quarter ended September 30, 2023. Let me start a review of our cash position. We ended the quarter with $59.7 million in cash and cash equivalents. With these funds, we expect to be able to fund operations into September of 2024.

Regarding the operating results, R&D expenses were $19.8 million for the 3 months ended September 30, 2023 as compared to $16.5 million for the 3 months ended September 30, 2022. These costs were mainly driven by external development costs related to the ongoing clinical trials of vidofludimus calcium and personnel expenses. This was partially offset by a decrease in external development costs related to the IMU-935 and IMU-856 programs.

For the 9 months ended September 30, 2023, R&D expenses were $63.9 million as compared to $50.5 million for the same period ended September 30, 2022. These costs were mainly driven by external development costs related to the ongoing clinical trials of vidofludimus calcium, IMU-856 and personnel expenses. This was partially offset by a decrease in external development costs related to the Phase 2 clinical trial of vidofludimus calcium in ulcerative colitis and IMU-935 program.

G&A expenses were $3.8 million for the 3 months ended September 30, 2023, as compared to $3.6 million for the same period ended September 30, 2022. The slight increase was spread across numerous categories. For the 9 months ended September 30, 2023, G&A expenses were $11.9 million as compared to $11.6 million for the same period ended September 30, 2022. The increase was related to an increase across numerous categories, which was partially offset by a decrease in personnel expense related to stock compensation expense.

Other income was $0.8 million for the 3 months ended September 30, 2023, as compared to negative $1.1 million for the same period ended September 30, 2022. The increase was primarily attributable to a decrease in foreign exchange losses and an increase in interest income as a result of higher interest rates. This was partially offset by a decrease in R&D tax incentives as a result of less spend for clinical trials in Australia.

For the 9 months ended September 30, 2023, other income was $3.8 million as compared to negative $1.8 million for the same period ended September 30, 2022. The increase was primarily attributable to an increase in interest income as a result of higher interest rates, a decrease in foreign exchange losses and the research allowance attributable for tax year 2021 from the German Federal Ministry of Finance that was received in 2023. The increase was partially offset by a decrease in R&D tax incentives as a result of less spend for clinical trials in Australia.

The net loss for the 3 months ended September 30, 2023 was approximately $22.8 million or $0.51 per basic and diluted share based on approximately 44.6 million weighted average common shares outstanding, compared to a net loss of approximately $21.2 million or $0.69 per basic and diluted share based on approximately 30.6 million weighted average common shares outstanding. The same period ended September 30, 2022.

Net loss for the 9 months ended September 30, 2023 was approximately $72 million or $1.63 per basic and diluted share, based on 44.2 million weighted average common shares outstanding, compared to a net loss of approximately $63.9 million or $2.16 per basic and diluted share, based on 29.7 million weighted average common shares outstanding for the same period ended September 30, 2022.

With that, I will turn the call back over to Daniel for a review of our upcoming clinical milestones. Daniel?

Dr. Daniel Vitt

Yes. Thank you. Thank you, Glenn. I would like to provide an update on the anticipated upcoming milestones for our clinical development programs.

Our current expectation is to report top line data from our Phase 2 CALLIPER trial in progressive MS in April '25. Additionally, we expect to report an interim futility analysis of our Phase 3 ENSURE program late next year to read out the first of our identical twin Phase 3 ENSURE trials in relapsing MS at the end of 2025. As stated before, based on the strong clinical activity observed so far and vidofludimus calcium solidly established safety and tolerability profile to date, we believe that the design of the Phase 3 ENSURE program will provide a straightforward path to a potential regulatory approval in relapsing MS. If top line CALLIPER data continues to show neuroprotective effects for PMS patients, we may be able to position vidofludimus calcium as the first oral treatment for non-active secondary progressive MS as well. We also expect the drug's potential first-in-class ability to activate Nurr1 to meaningfully benefit the ongoing Phase 3 ENSURE trials in relapsing MS.

With regard to our IMU-856 program as previously reported, we have begun preparing for a Phase 2 clinical trial in ongoing active celiac disease patients. We are very excited about this data and believe IMU-856 could represent an entirely new therapeutic approach for gastrointestinal disorders while promoting the regeneration of bowel architecture without the serious consequences associated with immunosuppressive therapies.

This brings us to the end of our formal presentation. Jessica, please open the call for the Q&A session.

Jessica Breu

Yes. Thank you, Daniel, and also Glenn, for walking us through the third quarter and subsequent highlights as well as our upcoming value inflection points.

Question-and-Answer Session

A - Jessica Breu

We will now begin the question-and-answer session. [Operator Instructions] And our first guest today is Caroline Pocher from Wedbush PacGrow. Caroline, please unmute yourself and go ahead.

Caroline Pocher

This is Caroline on for Andreas. Thank you for taking our questions. Just a few from us. Can you provide any insight into where you are in terms of preparing for the Phase 2 trial for 856 in celiac disease? What do you anticipate the trial design would look like and the timelines for when you think you would initiate the trial?

Dr. Daniel Vitt

Yes. I think as we have stated before, we have fully evaluated the data, done our homework on completion, the data packages. So this is work in progress right now. And maybe some thoughts on the trial design, so, likely, this will be -- should be a treatment phase of 3 months of treatment in ongoing active celiac disease patients. So a trial, which also make it possible to really conclude data for further testing down the road in pivotal trials. And more or less, that's where we are right now. We're still in the preparation process.

Caroline Pocher

And then just one follow-up from us. Can you talk about how enrollment is progressing in the ENSURE program and what your target timeline is to complete enrollment?

Dr. Daniel Vitt

Yes. I think, as you know, we usually don't give a rolling update on the recruitment status, but we keep currently our guidance of completion of enrollment in the way that we are able to read out the first of the ENSURE studies end of '25 and the second one in a couple of months later. So that's all I can say.

Jessica Breu

Our next guest is Liam Hiester from Piper Sandler.

Liam Hiester

I'm asking a question on behalf of Yasmeen Rahimi. Just 2 questions. So my first one is related to the CALLIPER trial. So what type of data are you expecting to report in April 2025, and what's the bar of success expected for the readout?

Dr. Daniel Vitt

That's a good question, because I think we have spoken a lot about this really strong NfL data. So, of course, we will also report NfL as a secondary readout from the study. But I think the most interesting endpoints will be the primary endpoint, which is, brain volume change in patients comparing active with placebo as a primary endpoint, whole brain atrophy, maybe that's the right word for that. And another and maybe the most important secondary endpoint or key secondary endpoint is, confirm disability worsening. So a change in EDSS score in a confirmed way. So that also will give us, and that's, I think, important, the ability to correlate the changes in biomarkers and clinical endpoints as well at the same time. And so that's all planned to be -- able to be released in April 25th.

Liam Hiester

And is there a specific like bar of success that you're looking for?

Dr. Daniel Vitt

Well, if you look on what's currently on the market, I think the bar is not super high here. I think we want to see a benefit on all of those endpoints. But if we more or less translate what we have seen and the NfL data set into the full data read, all that would be wonderful. And, also a meaningful medical difference in disability prevention would be maybe the best thing, best win here.

Specifically looking on those untreatable patient populations, so looking specifically on the secondary progressive patients without focal inflammation, without relapses, so the non-active secondary progressive population, I think any benefit here would be great. And I can't give you really hard numbers here at point. I think the study was designed to be powered for brain atrophy benefit. So that is something we want to achieve on a statistical readout here.

Liam Hiester

And then just one more question just to build off of the previous one, well, actually, and related to that, IMU-856. Have you spoken with the FDA at all, with Phase 2 design, or is it still just in the preliminary stage?

Dr. Daniel Vitt

This is a process which is ongoing right now. So, usually, what we do is we submit our IND filing and then you have written communication with the regulators on, for example, protocol design and so forth.

Jessica Breu

The next one here in the queue is Matt Kaplan from Ladenberg Thalmann.

Matt Kaplan

Just wanted to focus a little bit on your business development goals you mentioned during the prepared remarks. Can you talk a little bit more about that for 856 and also [858]?

Dr. Daniel Vitt

Yes. Thank you, Matt, and thank you for that question. Of course, here we have several good assets and good data. So you remember this year was full of good data readouts with the celiac data, with the CALDOSE maintenance data and now with the with the CALLIPER data. And all of these data typically are a good -- good points to intensify discussions with companies. It's difficult to really say exactly what comes first, what is the

best option. But I think what we are trying is to make sure we use the data in our active discussions to really build a level of trust and a good discussion with potential partners. And based on that, then to execute the one or the other deal.

So I think the best description would be that we are building more optionality on that and to have also access to some non-dilutive financing sources to fuel the rest of the pipeline based on that.

Matt Kaplan

And then you mentioned in terms of some new IP. What is that the new IP that was allowed? What does that get you in terms of exclusivity period?

Dr. Daniel Vitt

Yes. I think that's a good point. So that patent runs until '38. So this is a patent which covers the dose strength and the treatment of relapsing MS. And it's covered the certain dose strengths here and would protect us into '38, plus patent term extension, but there's a potential to patent term extension there, which would then protect us until '41.

No. So I mixed it up. No. I think this pattern goes toÂ…

Jessica Breu

No. '41 is correct.

Dr. Daniel Vitt

'41 is correct. Sorry. So '41 is the right number here, but we have more things in the making, so that's why.

Matt Kaplan

And then, the -- you've been characterizing the vidofludimus as well in terms of its ability to be a Nurr1 activator. What does that mean from the point of view of the drug as well?

Dr. Daniel Vitt

Yes. I'm very thankful for this question because that's maybe the elephant in the room on the MS treatment landscape, I think. The thing is that so far in MS, we have good options to treat relapses, on the one hand, and we have very good drugs on doing that and reducing inflammation.

What is maybe the missing piece is really to protect neurons from impairment from cell death by triggers and signals which are independent of focal inflammation. So something which for example, is happening, patients once they progress from relapsing MS into secondary progressive MS, where we'd have to scoop down, but still disability is there. And with the data we have obtained and in combination with literature data and what other groups have done in the scientific community, we believe that Nurr1 is a target which may give us here a signal, a protective signal for neurons in a way which is independent of that focal inflammation. And combining the Nurr1 activation now with our known and well reported DHODH inhibition, I think this drug has kind of like a double strike on the two important pieces for treating relapses -- relapsing MS here on inflammation and direct neuroprotection, whereas, it also offers now -- and this was, I think, the conclusion we draw from the NfL reduction, also offers a treatment option for those so far untreatable patients of PMS, specifically primary progressive and non-active secondary progressive in this.

Matt Kaplan

And just to be clear, this is something that's totally separate from the DHODH inhibitor -- inhibiting effects and not -- and unique to vidofludimus and not characteristic of other DHODH?

Dr. Daniel Vitt

Exactly. It's not linked to DHODH. It's something which is a property of the molecule and its binding ability to both, to DHODH on one hand and to Nurr1 on the other hand. And we have published a paper earlier this year

together with our academic collaborators around Daniel Merk showing that the drug directly binds. There's an ICT data there in this paper showing that the molecule is directly binding to Nurr1 and as a protein.

Jessica Breu

Thank you, Matt. Yes. Maybe to follow-up on Matt's question regarding BD. We received 2 questions here in writing via the Q&A tool, which go into a similar direction. And the first one, please describe your strategy for maintaining adequate liquidity to see these opportunities through to fruition? And the second one, great clinical results, what's the plan to raise cash? Maybe, Daniel, you can give your strategic thoughts here again.

Dr. Daniel Vitt

Yes. Of course, that's important piece to make sure we earn the fruits at the end of the day, and therefore, we think it's worth to follow different ways to fund the company for the next years. And as I said, one of the important pieces could be business development activity, partnering one of the assets or maybe even two or some territorial partnerships could also be an option. Another option is kind of non-dilutive financing, for example for project financing, and the third one could be any kind of equity financing. So I think we keep those options on the table, but also considering what's going on the capital markets.

Jessica Breu

Thank you, Daniel. Our next live guest here is Tom Smith from Leerink Partners.

Tom Smith

I was just wondering, there's any update on the early pipeline programs like IMU-381? And, do you have any visibility on timing for advancing this program into the clinic or, when we can expect to learn more on this asset?

Dr. Daniel Vitt

Yes. I think the program was initiated based on positive data we generated from the CALDOSE trial. But, clearly, the company is prioritizing now the clinical programs right now for the time and resource reasons. So, we have the -- all the preparation work ongoing, part of that completed. But, clearly, the resource focus and the progress of the company is focusing on performing next steps and continuing the transfer either vidofludimus calcium and for 856 right now.

Tom Smith

And if I could just follow-up on an earlier question. Just on the 856 celiac study, are there any specific gating factors, Daniel, that you would call out, I guess, in terms of getting that program off the ground and getting the IND cleared and starting to enroll patients there?

Dr. Daniel Vitt

No. As mentioned, we are preparing a trial, that means also physically preparing the trial on the material side, so production of material for the trials and so forth. And we have also stated that our priority will be celiac disease as first indication that we're trying to look at. But it's also a little bit related to the other question we have answered already today is that we also think about partnering. It could make sense to also broaden development beyond celiac disease.

So this is something which is also an important aspect to consider in any priorities, speed going forward, and so forth with the program. So, so far, this is still all in preparation, also the interaction with the regulators. And this is not just limited to the U.S. It goes also into European regulators to really make sure we have a good trial prepared. Also discussing with both our KOL network on the different aspects of having a good trial set up to make sure we read out proper data. We don't fall on our own feet here. We can learn a lot from other trials in that world of celiac disease treatment. So I think it's going forward. And as soon as we are making next steps, I think we will update the market on that.

Jessica Breu

[Operator Instructions] And we have one more here who wants to be with us live, which is Mayank Mamtani from B. Riley.

William Wood

Hi. This is actually William on for Mayank today. Congratulations on the really nice third quarter results. I think just one from us on your NfL data from CALLIPER. It looks really, really nice. You've got -- it's really nice data across all subpopulations, including this -- the broader PMS population. I'm curious slightly about the active SPMS. Got a pretty low end there. And I'm just kind of curious how we should think about the -- sort of the smaller number there. But then also when we're doing -- when we get to the final readout, will you be looking at these subpopulations and trying to figure out exactly your path forward, potentially choosing one subset over the other for then going into the Phase 3 or potentially for partnering activities? Are you really trying to keep this as a PMS, more of a broader drug? Just trying to sort of figure out your path forward there. Appreciate it.

Dr. Daniel Vitt

Thank you for the question. I think it's something important we should touch on. Because I think this is more what is the track towards any regulatory approval and how do we prioritize things.

I think we have been very excited specifically on the data for the -- as I mentioned, for the non-active population, which is really the -- one in the PPMS population and the non-active secondary and progressive populations. The active populations have responded very nicely to NfL. But I think in the U.S., in the space of the FDA regulated treatments, they fall into RMS basically. So therefore, if we focus on U.S. treatments, this is covered by our ENSURE study, basically. Therefore, if we focus on PMS, we will mainly discuss and go forward with those patients where there is little or no relapse activity remaining.

By the way, this is was data -- you mentioned the subpopulation of active patients that also reconfirms what we have seen in the EMPhASIS Phase 2 study on those patients. So I think it's also a nice confirmation of the RMS population that we have generated earlier. But if it comes to the best indication going forward, I think, we definitely need to and want to pick the best choice for regulatory approval. And I think this is more or less dictated by two things: by our data and the unmet need. And I think this clearly is in non-active secondary progressive, where there is no real treatment available right now for patients. And our data was so good there as well on the NfL side that we think it is likely the indication of choice. Of course, we first want to look on the data in April '25 to see if we see the same clinical signals as we have seen on the NfL readout.

Jessica Breu

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

Dr. Daniel Vitt

Yes. Thanks, Jessica, and thank you, today's attendees for your insightful questions. In summary, with the completion of enrollment of our Phase 2 CALLIPER trial, the positive interim data from the CALLIPER trial as well as the continuation of enrollment of the ENSURE Phase 3 trial, we have continued to make tangible progress on the clinical development of vidofludimus calcium during this past quarter. As progress is made, we also expect to provide an update on our preparations for a Phase 2 clinical trial of IMU-856 in patients with ongoing active celiac disease.

With that, I would like to close today's call. Thank you very much for joining and we are happy to answer any additional questions one-on-one.

Jessica Breu

Thank you for joining Immunic's third quarter 2023 earnings call. The call has now concluded. You may now disconnect.