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ZVRA.OQ - Q4 2022 Zevra Therapeutics Inc Earnings Call

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PRESENTATION

Operator

Good day, and welcome to the Zevra Therapeutics Fourth Quarter and Full Year 2022 Update Call. (Operator Instructions) Please be advised that today's call is being recorded.

I want to hand the call over to Zevra's Vice President of Investor Relations and Corporate Communications, Nichol Ochsner. Thank you. You may begin.

Nichol L. Ochsner - *Zevra Therapeutics, Inc. - VP of IR & Corporate Communications*

Good morning. Thank you for joining us today to review Zevra's Fourth quarter and full year 2022 clinical operational progress and financial results. A few housekeeping items before we start. I invite you to view the webcast slides and the press release, both of which were issued this morning and can be found in the Investors section of our website.

As outlined on Slide 2, during today's presentation, we will be making several forward-looking statements. These forward-looking statements include, but are not limited to, the clinical and regulatory path for arimoclomol, AZSTARYS, revenue milestones and expected revenue from the French EAP program, the planned next steps in our pipeline programs; the timing for enrollment, initiation, the completion and reporting of data from our clinical trials and the upcoming Annual Meeting of Stockholders. These statements are neither promises nor guarantees and involve risks and uncertainties and other important factors that may cause actual results to differ materially from those discussed here. Important factors that could cause actual results to differ from forward-looking statements can be found in the Risk Factors section of our annual report on Form 10-K for the full year ended December 31, 2022, expected to be filed with the SEC today.

Finally, you can view the agenda for today's call on Slide 3. I'm pleased to welcome Zevra's management team members participating in today's call. I'm joined today by our CEO, Richard Pascoe, our President and Co-Founder; Dr. Travis Mickle; our Chief Financial Officer; LaDuane Clifton, our Chief Product Development Officer and Co-Founder; Christal Mickle; and Joshua Schafer, Chief Commercial Officer and Executive Vice President, Business Development.

I will now turn the call over to Rich Pascoe.

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

Thank you, Nichol, and thank you all for joining us today to review our Q4 and full year 2022 results. Before we get into the highlights of the successful year, I want to take a step back and talk about where we are today and provide an overview of our strategic evolution over the past 18 months. A lot has happened with a new name and focus, it is important to walk our investors through how we got here and share my enthusiasm for our future. (inaudible) Zevra Therapeutics, a nimble and focused rare disease company. Our team has a successful track record of success in championing patients in need as well as tackling and overcoming challenges in drug development and regulatory approval.

We are leveraging our years of expertise and unique insights to chart a new course for drug development and forging pathways to success for promising product candidates. As we move Zevra forward, we will continue to leverage our legacy platform to target internally discovered rare disease product opportunities and extend our pipeline assets exclusivity through life cycle management. In this way, we bring transformational therapies and hope to patients with rare diseases and their families and create value for our shareholders.

Importantly, we are well positioned for success, we have a robust pipeline of promising rare disease product candidates with multiple value-creating milestones expected over the coming year. We have a world-class leadership team with the experience of numerous successful product approvals and an equally accomplished Board of Directors that align with our strategic trajectory in rare disease. Supporting it all, we have a strong balance sheet. So how did we get here? We've worked hard to evolve the company's strategy over the past 2 years, thoughtfully led by our management team in collaboration with our Board of Directors and supported by our shareholders.

After the approval, licensing and commercialization of AZSTARYS, and our actions to put the company on a firmer financial footing, the management team and Board pause to evaluate where we were and what we learned in getting AZSTARYS to the market. Our objective was to determine our best path forward to create value in a time frame and at a scale that our shareholders deserve. We concluded that we have strong capabilities and success in the scientific, development and regulatory areas. However, focusing exclusively on a pipeline of product candidates that will eventually compete in heavily generic markets and out-licensing those products as a commercial strategy would likely fail to meet our objective of delivering a significant return on investment to our shareholders.

We then work thoughtfully -- we then work to thoughtfully, set a new course for the company, focusing on bringing the organization's existing strengths together with a refined strategic focus on rare disease indications with the goal of commercializing our products in the United States. We took a series of transformative actions that align perfectly with our strategy, highlighted by the acquisition of arimoclomol an NDA-stage product candidate upon which we intend to build commercial capabilities that will allow Zevra to create value for the benefit of shareholders. This new direction capitalizes on our strengths and cash position to enable us to retain the value of our hard-earned approvals and control our commercial destiny while delivering much needed therapeutics to patients with limited or no treatment options.

It is important to note that rare disease is not an entirely new focus for us. We were already working in rare disease with our prodrug technology applied in rare sleep disorders with KP1077 for idiopathic hypersomnia. From that experience, we recognize that rare disease drug development offers several significant advantages over development in large mass market indications.

First and foremost, we have the privilege of partnering with patients, families and advocacy groups to deeply understand their needs and ensure that our therapeutic approaches are answering their biggest quality of life and disease management concerns. This ensures our products are relevant and capable of commercial success.

Rare disease drug development time lines are often shorter and involve much smaller studies than larger indications resulting in lower cost of research and development. Through the Orphan Drug Act, the company benefits from incentives, such as priority review voucher and a 6-month review window for pursuing therapeutics for rare diseases and the resulting products receive extended patent protection for longer market exclusivity.

Rare Disease products also do not experience significant generic competition once patents expire. Moreover, with a small patient population treated primarily by specialist clinicians, we can bring those products to commercialization with our own in-house commercial team.

Taking this together, we saw that rare disease drug development creates an ideal platform for maximizing value creation for patients and shareholders. This led to our decision to focus exclusively on rare disease and our strategic acquisition of arimoclomol. Through that acquisition, we acquired a high potential product candidate for Niemann-Pick disease Type C. We also onboarded an amazing European team with deep connections to the NPC patient community and significant rare disease drug development expertise. As we began focusing on rare diseases, we recognize that our name and branding is KemPharm no longer reflected who we are as a company. So we underwent a process to redefine our messaging and brand story. The outcome of that process is our new name, Zevra Therapeutics and branding to reflect our commitment to the rare disease patients we deserve.

The word Zevra is Greek for zebra, which is the internationally recognized symbol for rare disease community. Interestingly, a group of Zevra is also called (inaudible), these expressions capture our team perfectly as we are [sells] about empowering people with rare diseases. We are confident that Zevra is a name that will resonate with patients, and we envision a dazzling future for the rare disease communities that we serve.

Zevra is better positioned today than at any point in its history as we work towards our key priorities to secure regulatory approval for our pipeline assets, build top-tier commercial capabilities, and enhance our pipeline through internal and external efforts. We have two very strong product candidates with multiple value-creating milestones expected this year. We continue to explore new product opportunities both through our prodrug platform and business development activities focused on rare disease. We are a rare beast in that we already have a growing revenue stream as a development stage company, which bolsters our already strong financial position.

I am confident in the team and our strong financial foundation and diverse portfolio of multiple clinical programs and in our ability to deliver value in 2023 and beyond. Importantly, we have a fully engaged and supportive Board of Directors that has been deeply involved in our strategic evolution and can help us to advance our company. 2022 was a pivotal year for our organization and our evolution into a rare disease company with the acquisition of arimoclomol and the completion of a 4-year safety study of that product candidate in NPC. Our ongoing collaborative dialogue with the FDA around the program has been highly productive in preparing us for NDA resubmission.

We've also made tremendous headway in our KP1077 program for rare sleep disorders over the last year, including positive data from our cardiovascular trial of SDX, a primary component of KP1077 in a Phase II trial initiation in idiopathic hypersomnia. Orphan drug designation for this product candidate in IH provides the advantages I highlighted earlier, including regulatory incentives and extended market exclusivity after approval.

We continue to bolster our strong financial position, earning a onetime fee of nearly $2 million from Corium following the FDA approval of ADLARITY. Our net revenue for the full year was $10.5 million. Cash, cash equivalents and investments as of December 31, 2022, were $102.9 million. Our available capital is expected to extend our cash runway into 2026, an enviable position for any biotech company in today's capital markets.

In 2022, we began our efforts to further build our team by appointing Nichol Ochsner, as VP of Investor Relations and Corporate Communications. In addition, the Board appointed Christopher Posner as an independent director, another great addition to the team. As you can see from this slide, we've had tremendous momentum in the fourth quarter of 2022 and the beginning of 2023 on several fronts. I want to point out a few of those. Notably, a recent development in the arimoclomol program was the presentation of the data from the interim analysis of the Phase II/III 4-year safety study at the 2023 WORLDSymposium. These data, which demonstrate the clinical benefit of arimoclomol will be a cornerstone of our resubmission of a new drug application expected as early as the third quarter of this year.

Notably, the data suggests that arimoclomol may reduce the progression of NPC. This underscores our understanding that if you can improve lysosomal function, you can improve outcomes for patients. We also underwent our strategic rebrand to Zevra Therapeutics in alignment with our identity as a rare disease company and to further engage with the rare disease community we joined, the NORD Corporate Counsel.

Since the beginning of the year, we have made several additional key appointments and changes to our leadership and Board of Directors, strengthening a team that I'm confident can lead Zevra into the future with success. Shown here are our executive team and our Board of Directors, not only are we an accomplished group of decades of experience in R&D and commercialization leadership, but we are also a blend of legacy team members and new talent with skills that can take us into the future. The team is aligned with our direction and transformation into a rare disease company.

Now I'd like to turn our attention to our arimoclomol program for Niemann-Pick Disease Type C. Arimoclomol is administered orally and is formulated for ease of use in varying patient circumstances. This product candidate has been studied in 10 Phase I, 4 Phase II and 3 pivotal Phase II/III trials. Arimoclomol has received orphan drug designation for NPC in the United States and the European Union and Fast Track designation, breakthrough therapy designation and rare pediatric disease designation from the FDA for NPC. If approved in the U.S., arimoclomol would also be eligible to receive a pediatric priority review voucher.

We are on track to submit the new drug application to the FDA as early as the third quarter of this year for arimoclomol. One of the most attractive aspects of the arimoclomol program is that it should it be approved, we have the near-term opportunity to commercialize the product ourselves to retain the full market value for our shareholders.

We believe a small and nimble commercial team could fully serve the specialists and medical centers treating the NPC patient population. The benefit of a small commercial team is the lower cost of market entry. We believe that our established and new advocacy relationships in the NPC community will help support the adoption of arimoclomol, and we have already established market entry with this patient population through our U.S. and EU early access programs. Beyond our immediate focus on a successful U.S. commercial launch, we also see the commercial potential for arimoclomol outside of the U.S., in the EU, Japan, China and other geographies.

Now I will highlight our KP1077 program for rare sleep disorders, beginning with idiopathic hypersomnia, which is currently enrolling patients and dosing patients in a Phase II clinical study in the U.S. The market potential for idiopathic hypersomnia is also highly compelling with limited treatment options available for this small underserved patient segment. KP1077 has been designated by the FDA as an orphan drug as well as possible eligibility for fast-track review status and designation as a breakthrough treatment.

In addition, we believe that a differentiated from other treatment options, pricing KP1077 in between products like Teva Pharmaceuticals' PROVIGIL, which is approximately a $24,000 per year treatment at the highest dose, and Jazz Pharmaceuticals' Xywav, which is approximately $187,000 per year at the highest dose that leads to capture -- capturing significant market share. Because this is a rare indication, our intent is the commercialization of this product ourselves, which is aligned with our strategy for arimoclomol and therefore, allows us to keep a larger portion of the economic value.

We expect interim data from Phase II -- from the Phase II trial of KP1077 in idiopathic hypersomnia by the third quarter of this year and top line data by the end of 2023. Importantly, the interim data will also be an open-label titration phase, which is meaningful because it will allow us to start designing the Phase III study in IH. We are also planning a development program for KP1077 in narcolepsy. The IND filing for this additional program is expected during the second quarter of 2023.

With that, I will turn the call over to our CFO, LaDuane Clifton. LaDuane?

R. LaDuane Clifton - *Zevra Therapeutics, Inc. - CFO, Secretary & Treasurer*

Thank you, Rich, and good morning, everyone. Let's jump right into the numbers with an update on the commercial progress of AZSTARYS. Like many of you, we closely track the prescription trends for AZSTARYS and the trend line since the third quarter of last year has become more encouraging. While the early days of the launch were impacted by COVID-related challenges, and the need for greater formulary coverage with the largest PBMs, there has been a meaningful change in prescription volumes starting in July of 2022. You may recall that we had reported to you that as of Q3 2022, Corium had achieved coverage with the three largest PBMs and double the size of their field force to 175 reps.

The growth trajectory of the product since that time has continued, and we are optimistic about the possibility of reaching one or more milestones during 2023. With an improving prescription trend, the amount of the royalties realized from the license is meaningful, though modest. The table provided here shows actual royalties earned by quarter and the corresponding prescription count estimates based on publicly available data. These trends suggest that royalties will contribute more revenue in the future. Still, we realize that achieving the sales milestones may be a more significant driver of value from this license. This leads to another critical point. Our legacy model for developing an asset and then out-license for commercialization is not expected to drive strong growth for Zevra in the short or medium term.

Back in 2021, as we began thinking strategically about rebuilding our pipeline, we knew this had to be addressed. The ability to directly commercialize a product we develop and get approved became a primary criterion in evaluating where we would focus our pipeline investments.

Our decision to focus on the rare disease space positions us to field a small, nimble commercial team that can be highly effective and drive better return on capital than the results we have had to date with the out-licensed model. We see the AZSTARYS as foundational to where we are as a company but we also look forward to the potential for growth that we may be able to unlock with the direct commercialization of both arimoclomol and KP1077, if approved.

Now let's focus on the financial results for Q4 and full year 2022. In 2022, we took significant steps to improve our financial position. We continue to have a solid balance sheet and adding the arimoclomol program has begun to provide a steady revenue stream to support our ongoing regulatory and product development initiatives. For Q4, net revenue was $2.3 million, driven primarily by reimbursements from the French EAP program.

Full year net revenue was $10.5 million. We reported a Q4 net loss of $9 million or $0.26 per share, which was driven by our R&D investments and increased G&A, all associated with the KP1077 and arimoclomol programs. For the full year, net loss was $41.5 million or $1.20 per share, which includes a onetime noncash charge of $17.7 million related to the in-process R&D assets we acquired from Orphazyme.

On a non-GAAP basis, FY 2022 net loss, excluding the onetime noncash charge was $23.9 million or $0.69 per basic and diluted share. And as Rich has already noted, our cash position remains solid with $102.9 million on the balance sheet as of December 31, 2022. Looking ahead to 2023, we reiterate our guidance that our existing available capital on the balance sheet is expected to extend our cash runway into 2026. This includes the reimbursement from the French EAP, what we need for the arimoclomol NDA resubmission, the completion of the development program for KP1077 through its NDA submission and potential PDUFA as well as our preparations for the possible U.S. launch of arimoclomol if approved.

In addition, we anticipate that the prescription trend for AZSTARYS will allow us to earn at least one and possibly two of the sales milestones under that license agreement during 2023. Net revenue from the French EAP program is expected to continue at the rate of about $2 million per quarter throughout the year.

To conclude, we believe we are in a solid financial position with numerous opportunities to create value for our shareholders as we execute our business plans. And now I'll return the call back to Rich.

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

Thank you, LaDuane. As we look to 2023, I'm excited about what lies ahead as we continue to transform Zevra and work to enhance value creation for our shareholders. We continue our ongoing discussions with regulatory agencies and are preparing to refile the arimoclomol new drug application as soon as the third quarter of this year.

For the KP1077 program in rare sleep disorders, we are on track to file an IND for 1077 in narcolepsy in the second quarter of this year, and we also anticipate interim data from the Phase II trial in idiopathic hypersomnia, as early as the third quarter, with top line results in that trial by the time -- by the end of this year. Those data have the potential to not just support the advancement of KP1077 into a Phase III study in IH but also may support a Phase III trial in narcolepsy. We anticipate ongoing revenue from our arimoclomol expanded access program in France and we have the potential to realize additional sales milestones and revenue for AZSTARYS.

This provides further capital flexibility and the potential to further extend our cash runway, which already extends into 2026. In closing, I want to reiterate our commitment to creating value for our shareholders and bringing life-enhancing products to patients suffering from rare diseases.

As I look around our industry, I see small-cap biotech companies dealing with failed clinical programs, employee layoffs, toxic financings and bankruptcies among other challenges. In contrast, Zevra is financially sound with two promising late-stage assets, and we are growing the company in a thoughtful and measured fashion.

Before we open the call for questions, I want to briefly address the alternative slate of 3 director candidates proposed by 1 of our shareholders. Zevra Board believes that electing any of these candidates would diminish the overall quality of and experience represented on the Board.

By contrast, the 3 incumbent directors collectively bring decades of biotech and pharmaceutical experiences both the senior executives and as public company Board members. Their backgrounds cover a range of relevant areas, including drug development, medical, finance, business development and commercialization, all of which are essential to driving continued momentum and shareholder value as we execute our transformative growth strategy.

Your Board regularly seeks to maintain open communication with our shareholders and values constructive input. In fact, many of the changes I discussed on this call today are in direct response to feedback received from our shareholders. We heard you loud and clear that you want to change that you value revenue and that you wanted the Board and management to be bold. We heated that call. We took a hard look at our organizational strengths, we invested in a better understanding of where and how to invest the resources entrusted to us by our shareholders.

We continue to leverage the team that got us to higher ground, and we added new talent where needed. We undertook an ongoing Board refreshment program to bring new and critical thinking to the boardroom, and we focused on creating value to the commercialization of rare novel disease products in areas of significant unmet need.

I believe that today, the company is in the strongest position to succeed at any time in its history. And I'm so excited for our future as a company and what we aim to accomplish for patients and shareholders alike. Thank you for your continued support as we work to transform lives with new therapies for rare diseases with limited or no treatment options.

Please note that we will not be commenting further on the proxy matter during the Q&A, and I would appreciate it if you would keep your questions directed to our performance, results and strategy.

With that, I will now return the call to the operator for questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Sumant Kulkarni with Canaccord Genuity.

Unidentified Analyst

This is Kyle speaking for Sumant Kulkarni. Two questions from us. Has there been any specific interactions with the FDA since your last update that gives you more confidence and your ability to potentially refile the arimoclomol NDA as early as 3Q?

And then the second question, has the FDA already seeing the open-label extension data presented recently -- if not, when do you expect the agency to see that data? Would it be prior to the filing or as part of the buying packaging?

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

Kyle, it's Rich. Thanks for the question. I'm going to ask Travis Mickle to address those questions.

Travis C. Mickle - *Zevra Therapeutics, Inc. - Co-Founder, President & Director*

Yes, sure. No problem. So as far from our last update, we have not had a more formal interaction with the FDA as to the resubmission. And then which really answers the next part of your question as well, which is, no, the FDA hasn't seen the data yet. We do plan to submit the information, the ongoing clinical data, the 4-year wrap-up study as well as additional confirmatory evidence that was collected, and we will either provide that to them in a form of a formal meeting or we will actually just provide that to them and ask questions. So the format of that in our ongoing dialogue hasn't been decided yet, but we will update as soon as we have any new information.

Operator

Our next question comes from Jonathan Aschoff with ROTH MKM.

Jonathan Matthew Aschoff - *ROTH MKM Partners, LLC, Research Division - MD & Senior Research Analyst*

What sales threshold trigger that first and second AZSTARYS milestone, and I think they are $10 million and $20 million each, if I remember correctly. When in 2023, do you think you would intend to achieve those two sales thresholds that would trigger the $10 million and the $20 million?

R. LaDuane Clifton - *Zevra Therapeutics, Inc. - CFO, Secretary & Treasurer*

Yes. Jonathan, thank you for the questions. So while we've tried to provide more information today than we have in the past from publicly available data, we're still not able to give the exact sales thresholds or the actual amount of the milestones. So with that said, we do expect likely if we achieve 1 or [costly] 2 of those, it would most likely be toward the second half of 2023.

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

And Jonathan, it's Rich. I might just add, the way that deal is constructed, which is good for the company, they were lower thresholds than you might typically find in a license agreement for the achievement of certain milestones. And so we try to front-load as much of it as we could with respect to those types of outcomes. And so I think -- it's why, in large part, we're very optimistic that we'll hit one perhaps more than one this year.

Jonathan Matthew Aschoff - *ROTH MKM Partners, LLC, Research Division - MD & Senior Research Analyst*

Okay. You mentioned narcolepsy once in the press release. So will you be waiting for the outcome in IH before starting perhaps a Phase III trial in narcolepsy or are you still going to start a Phase II/III trial before getting any data in IH?

Christal M. M. Mickle - *Zevra Therapeutics, Inc. - Co-Founder & Chief Product Development Officer*

So this is Christal Mickle. We are actually -- we will look to see what data we get from this Phase II study with IH and determine whether or not we go with the parallel program with narcolepsy and IH for a Phase III study that would help with enrollment and other cost savings there. But again, we will wait for the readout with the Phase II study before we make any of those decisions.

Jonathan Matthew Aschoff - *ROTH MKM Partners, LLC, Research Division - MD & Senior Research Analyst*

Okay. And I'm guessing just briefly the arimoclomol 4Q data. I mean 4Q revenue was about $1.9 million? Or was there a bunch of other nondrug revenue in there?

R. LaDuane Clifton - *Zevra Therapeutics, Inc. - CFO, Secretary & Treasurer*

No, that's right, Jonathan. That was (inaudible). And just keep in mind that, that includes this clawback liability that we have to record. So we often talk about gross revenue of $1 million a month from that for about [EUR 1 million] a month. And then we have to clawback the liability. I think you may be familiar with that from prior quarters.

Operator

(Operator Instructions) Our next question comes from Louise Chen with Cantor Fitzgerald.

Louise Alesandra Chen - *Cantor Fitzgerald & Co., Research Division - Senior Research Analyst & MD*

Congratulations on all the progress this quarter. So I have two questions for you. I wanted to ask you about IH and the readouts that are coming, the interim and then the top line data readout later this year? And what would you consider a successful outcome that would make you competitive in the market?

And then also, the other question I have for you is when you think about expanding your rare disease pipeline, are you going to do that through M&A, internal development? What kind of resources can you put behind it? And when could we see additional products being added? I know you're very busy with what you have on your plate right now, but just kind of curious, thinking longer term?

Christal M. M. Mickle - *Zevra Therapeutics, Inc. - Co-Founder & Chief Product Development Officer*

So this is Christal Mickle to answer your first question. With the interim data, we're really looking at a number of things such as do we have the right amount of patients to power a study in a future study and really looking at what a future study would look like, dosing regimen things like that. So those are all still playing out. Obviously, we expect with our [FDA profile], looking different than saying what's on the market as far as off-label use of methylphenidate and things like that. We look to that as a differentiator with our product as we have with the start in the past.

Joshua M. Schafer - *Zevra Therapeutics, Inc. - Chief Commercial Officer & Executive VP of Business Development*

This is Joshua Schafer. I'll take the second question. We are very actively looking to add new products to the portfolio, whether that would be through internal development and leveraging our prodrug platform to bring new products into the pipeline. But we're also looking very actively at potential M&A licensing deals, any number of constructs to bring additional products into our portfolio that can really accelerates and advance our transition into a rare disease company.

Having said that, we're looking for opportunities that are synergistic with arimoclomol and where we can leverage a commercial organization and a development organization that is really focused in on the rare disease capabilities that we're building.

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

Louise, this is Rich. Just to add to all of that. I think clearly, the priorities today are the resubmission and approval and potential launch for arimoclomol followed closely by completing the Phase II program in idiopathic hypersomnia for 7 -- 1077 and advancing that into a Phase III trial.

To your question, we want to generate the necessary data in this Phase II program for 1077 to tee up Phase III pivotal program that can differentiate the product in the marketplace, and that's the goal there. Beyond that, we're always looking for good opportunities. At the same time, we understand the priorities are advancing the existing pipeline.

Operator

Our next question comes from Oren Livnat with H.C. Wainwright.

Oren Gabriel Livnat - *H.C. Wainwright & Co, LLC, Research Division - MD & Senior Healthcare Analyst*

I have a few. Actually, you mentioned actually in your press release and in the script, specifically extending exclusivity of your pipeline assets with a life cycle management, and that kind of jumped out at me. I was wondering, can you just remind us what is the current, I guess, IP landscape of your development assets? And what are we thinking about in terms of life cycle management. Is this just new IP you're working on? Or are there actual product innovations that are already in the hopper longer term? And then I have a follow-up.

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

Yes. Oren, I'll ask Travis to address specifically. But 1 of the things I'll preface it by saying 1 of the things that really excited me about these opportunities in rare diseases and looking at products like arimoclomol as we have this terrific internal capability to not only discover new assets, but to extend life cycle of those assets. And so we are very intent on doing both. And so unlike a lot of companies, I mentioned in my prepared remarks, we're a development stage company with revenue.

We're also a development stage company focusing on rare diseases with this internal capability that I'm not sure other companies can mimic. So bringing all of that to bear in terms of creating value for the future is really important to us. And so I think that's the underpinnings, if you will, behind those statements. With that, Travis, do you want to address maybe a little more specifically the mechanics of what we're doing?

Travis C. Mickle - *Zevra Therapeutics, Inc. - Co-Founder, President & Director*

Yes. As far as the IP question, Oren, arimoclomol has patents issued and pending that would run well into the 20/40s. Now those patents are not based on composition of matter like we would like to focus on. So of course, that's where Rich is alluding to our ability to expand upon IP. You're always aware too, with a rare drug in a pediatric area, it's going to be 7.5 years of orphan exclusivity. For KP1077, those patents run until 2037 and beyond. Those are, of course, composition of matter-based patents.

Oren Gabriel Livnat - *H.C. Wainwright & Co, LLC, Research Division - MD & Senior Healthcare Analyst*

Okay. Appreciate it. So we're thinking primarily about extending arimoclomol exclusivity well beyond the orphan period. is how I'm interpreting that, correct?

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

That's right.

Oren Gabriel Livnat - *H.C. Wainwright & Co, LLC, Research Division - MD & Senior Healthcare Analyst*

Right Okay. And on arimoclomol, I guess, to build upon the first question today -- regarding that confirmatory evidence and the 4-year safety data and everything you need to do for the FDA filing should I think of this 4-year data as sort of clearing the lane and in and of itself potentially addressing any FDA skepticism to the extent it might have existed at some point going forward? Or is there significantly more "confirmatory evidence" that you still need to do separate from that? And where does that stand? Can you give us any clarity on sort of progress on that front?

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

Travis, do you want to fill that?

Travis C. Mickle - *Zevra Therapeutics, Inc. - Co-Founder, President & Director*

Sure. No more clarity, unfortunately, Oren, than what we kind of stated before, what I said before. The data, I believe, from the 4-year extension arm is very helpful, especially if you look in light of the [Amylyx] approval earlier this year where they use the extension arm to show increased survivability. Here, we're looking at kind of the robustness of the effect and how it sustain kind of this lower trend of progression in the disease for a long period of time. Now of course, without a placebo in that portion.

But for the most part, that's the additional step of what's not been disclosed, the additional information that we have available to us to provide. I think that and everything that Orphazyme generated in the past as well as putting that all together an accretive story will be compelling, more compelling certainly than at the time of the CRL and certainly something that we'll at least in part, if not in its entirety discussed with the agency before the resubmission.

Oren Gabriel Livnat - *H.C. Wainwright & Co, LLC, Research Division - MD & Senior Healthcare Analyst*

Okay. And lastly on KP1077. I think you mentioned brain fog on multiple occasions as a key end points you're looking at, can you just remind us based on your interactions with the FDA or understanding of the landscape in general, what do you see as the necessary hurdle in terms of endpoints for approvability? And to what extent do you believe you need to show additional end points like brain fog or others to differentiate from off-label wakefulness or agents or stimulants?

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

Oren, it's Rich. I'll just maybe preface to comment here by stating that clearly, the brain fog and other exploratory endpoints are being looked at in this Phase II trial. We're obviously focusing on approvability, which will be driven by the primary but then enhancing the label and the commercial opportunity for the product in a competitive set or a competitive world with some of these other endpoints. I think it's perhaps too early to comment, specifically on the magnitude of effect.

But clearly, we'll assess that in this Phase II program and build whatever is appropriate into the Phase III protocol, which will then serve as a basis for approvability in a label. But fair to say that it's a little too early to call. But I want to reemphasize that as we think about the company moving forward and we think about commercializing these assets ourselves, we want to ensure that we're creating products that can be highly competitive, command premium pricing in the market. And moreover, allow us to go out and create the sort of value that we foresee for the company through that process.

Operator

Our next question comes from Sumant Kulkarni with Canaccord Genuity.

Unidentified Analyst

This is Kyle for Sumant again. A quick follow-up. On EAP gross revenue, we see that the new guidance is roughly [$2 million] annualized versus a prior estimate of $12 million. We are curious what are the factors affecting this number? And do you think this new guidance is driven more so by a function of price or a function of patient size?

R. LaDuane Clifton - *Zevra Therapeutics, Inc. - CFO, Secretary & Treasurer*

Well, thanks for the question. And really, it's actually not new guidance. I think sometimes when we spoke, we talked about gross revenue being about EUR 1 million per month, and that really is unchanged. What we tried to do in today's guidance though is to account for the around 30% or 35% clawback liability, which we always have to recognize when we put out our financial statements. So that's really the difference there is simply giving you guidance of net revenue, which is around $2 million a quarter versus the gross revenue that we've sometimes spoken about before.

Operator

Thank you. This concludes the Q&A portion of today's call. I would now like to turn the call over back to Richard Pascoe for any additional or closing remarks.

Richard W. Pascoe - *Zevra Therapeutics, Inc. - CEO & Director*

Thank you, operator. And first of all, I want to thank all of our employees and leaders, in particular, my colleagues here today around the table for their tireless efforts to bring Zevra Therapeutics into a very strong position for 2023 and beyond. It's an exciting time for us, and I appreciate their support and hard efforts to get us to where we want to be. I also want to thank all of our shareholders for your continued support and for all of those that have joined us today on the call, we appreciate your interest and your questions, and we look forward to speaking with you in the future. Thank you.

Operator

This concludes today's Zevra Therapeutics Fourth Quarter and Full Year 2022 Earnings Call and webcast. You may disconnect your line at this time, and have a wonderful day.
