

15-May-2023 Zevra Therapeutics, Inc. (КМРН)

Q1 2023 Earnings Call

CORPORATE PARTICIPANTS

Nichol Ochsner

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Tamara A. Seymour Board Chair & Chair of Audit Committee, Zevra Therapeutics, Inc.

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OTHER PARTICIPANTS

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MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon and welcome to the Zevra Therapeutics' First Quarter 2023 Corporate and Financial Results Conference Call. Currently, all callers have been placed in a listen-only mode. And following management's prepared remarks, the call will be open for questions from the company's covering analysts. [Operator Instructions] Please be advised that today's call is being recorded.

I would now like to turn the call over to Nichol Ochsner, Zevra Therapeutics' Vice President, Investor Relations and Corporate Communications. Please go ahead, ma'am.

Nichol Ochsner

Vice President-Investor Relations & Corporate Communications, Zevra Therapeutics, Inc.

Good afternoon. Thank you for joining us today to review updates related to Zevra's first quarter 2023 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 afternoon and can be found in the Investors section of our website. During today's call, we will be making statements, several forward-looking statements. These forward-looking statements includes but are not limited to the clinical, regulatory and commercial path for arimoclomol, AZSTARYS, revenue, milestones and expected reimbursements from the French EAP program, the planned next steps in our pipeline program, the timing for enrollment, initiation, completion and reporting of data from our clinical trials, senior leadership and board members transition and refreshment and other corporate updates.

These statements are neither promises nor guarantees and involve risks and uncertainties and other important factors that could cause actual results to differ materially from those discussed here. Important factors that could

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cause actual results to differ from any forward-looking statements can be found in the Risk Factors section of our quarterly report on Form 10-Q for the three months ended March 31, 2023, which is expected to be filed later today with the SEC. Moving on to the agenda for today's call, I am pleased to welcome Zevra's board chair and management team members participating in today's call. I'm joined today by our Board Chair, Tamara Favorito; our Chief Development Officer and Co-Founder, Christal Mickle; our Chief Financial Officer, LaDuane Clifton; and our Chief Commercial Officer and Executive Vice President of Business Development, Josh Schafer.

I will now turn the call over to Tamara.

Tamara A. Seymour

Board Chair & Chair of Audit Committee, Zevra Therapeutics, Inc.

Thank you, Nichol, and thank you all for joining us today. Before the team reviews our first quarter 2023 progress, I'd like to share a few thoughts about where we are today and where we're headed. This has been a busy and eventful period for Zevra as Zevra continues to execute on its corporate strategy focused on developing and commercializing novel therapeutics designed to address the unmet needs of people with rare diseases. Importantly, advancing Zevra's pipeline remains the company's top priority. It's the cornerstone for value creation upon which our rare disease strategy has been built. Recently, we completed our 2023 annual meeting of stockholders, and during that process we received feedback from many of our stockholders seeking change, which culminated in the election of several new directors to our board.

We welcome them to our team and we intend to continue supporting the company's rare disease strategy unified in our mission to generate long-term value for our shareholders. This has also led to leadership changes, and I'm pleased to announce today that while we conduct the search for a new CEO, Christal Mickle, our Co-Founder and Chief Development Officer, will be taking on the role of interim President and CEO effective June 1. With her leadership and the support of the entire executive team, we take from this experience our renewed commitment to bringing desperately needed treatment to the patients we serve, and we look forward to the achievement of our shared goals.

To provide more details about the recent changes in April, Zevra's shareholders voted to elect John Bode, Douglas Calder and Corey Watton to Zevra's Board of Directors. Accordingly, Richard Pascoe, Christopher Posner and Dr. David Tierney stepped down from the company's board. Additionally, Wendy Dixon was appointed to the board to fill a vacancy. In addition to that, Matthew Plooster and Joseph Saluri have indicated that they will not stand for re-election at the company's 2024 Annual Meeting, and they intend to retire as soon as replacements are found for them. Last week, Rich Pascoe advised the board of his decision to resign from his role as CEO effective June 1. Richard's departure was a personal choice that he made in response to the outcome of our annual shareholders' meeting. As I've already mentioned, we're pleased that Christal Mickle will serve as Interim President and CEO effective June 1, while the board conducts a search for a permanent replacement.

As the newly appointed Chair of the Zevra board, I'd like to thank Rich Pascoe, Chris Posner, David Tierney and Travis Mickle for their leadership and numerous contributions through the years to help Zevra become the company it is today and their commitment to our shared vision of creating a commercially focused, rare disease therapeutics company. As we look to the future, Zevra is well-positioned for success with a strong pipeline of promising rare disease product candidates with multiple value-creating milestones expected in 2023 and beyond. We have a leadership team with the depth and experience needed to execute on our strategic goals and the priorities to guide the company through this critical period and to ensure that shareholder and patient interests are aligned.

I'll now turn the call over to Christal to provide an overview of our recent corporate and pipeline highlights. Christal?

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

Thank you, Tamara, and good afternoon, everyone.

The rebrand of our company as Zevra during the first quarter was the culmination of a series of strategic moves over the past two years to refocus the company toward rare disease therapeutics. The acquisition of arimoclomol in 2022 was a key element of the strategic growth of our company as this program complemented our in-house development program, KP1077, for the treatment of rare sleep disorder known as idiopathic hypersomnia. Our long-term strategy has been designed to build upon our expertise in drug development, which is now focused on rare disease, with the goal of commercializing our products in the US using a small best-in-class commercial team.

As we prepare for resubmission of the arimoclomol NDA, we are also in the process of building the commercial capabilities that will allow Zevra to bring a much needed therapy to patients with Niemann-Pick disease Type C, also known as NPC. We believe our successful execution of this strategy has the potential to create meaningful long-term value for shareholders. So why Zevra? Our new name is Greek for zebra, which is the internationally recognized symbol of the rare disease community. We honor the many stripes of rare disease that are reflected in our new branding, and we embrace our name as a direct commitment to the rare disease community.

To that end, we recently joined the Corporate Council of the National Organization for Rare Disease, also known as NORD. Beyond our name, we have established a rare and unique position for Zevra in the biotech marketplace as a development stage company with a growing revenue stream that reinforces our already strong financial position. Collectively, we believe that our strategy, our team, our strong financial foundation and our diverse portfolio of multiple clinical programs combine to enable us to deliver value to shareholders in 2023 and beyond. Importantly, we have a fully engaged and supportive board of directors that is positioned to help us advance our company's mission of addressing the unique unmet needs of people with rare diseases.

Zevra's new direction capitalizes on our strengths and our financial position, enabling us to retain the value of our hard earned approvals and control our commercial destiny while delivering much needed therapies to patients with limited or no treatment options. As part of our ongoing efforts to build and strengthen our teams to execute our rare disease strategy, we announced that Sven Guenther was promoted to Chief Scientific Officer during the first quarter. Sven continues to lead the Zevra's research team and leverages his impressive background in drug development and clinical research to advance our programs. In addition, Josh Schafer was added to our leadership team as our Chief Commercial Officer and Executive Vice President of Business Development. His expertise and leadership will be invaluable as we grow our commercial team. Finally, Travis Mickle continues to be fully engaged as a scientific consultant and he is laser-focused on the arimoclomol resubmission.

Shifting to our financial results, we ended the first quarter in a strong position with cash, cash equivalents and investments of \$95.3 million as of March 31. Based on our current operating forecast, our available capital is expected to extend our cash runway into 2026, placing Zevra in a fortunate position compared to many other biotech companies in today's volatile capital markets. As Tamara stated, the entire organization remains fully committed to our rare disease strategy, and we are focused on continuing to partner with key opinion leaders, patients, families and advocacy groups to ensure that our therapeutic approaches are answering their biggest quality of life and disease management concerns, upon ensuring that our products are relevant and capable of commercial success.

The first quarter of 2023 in recent months were significant for Zevra and its pipeline with new positive progress for both development programs. We'll first focus on arimoclomol. Arimoclomol is our orally-administered product candidate for NPC. It has been extensively studied in multiple clinical trials from Phase 1 to Phase 3. Currently, arimoclomol has been granted orphan drug designation for NPC in both the United States and the European Union and Fast Track Designation, Breakthrough Therapy Designation and Rare Pediatric Disease Designation from the FDA. If approved in the US, arimoclomol towards the resubmission of its new drug application to the FDA as early as the third quarter of this year.

The long-term goal for arimoclomol is that, once approved, Zevra plans to commercialize the product ourselves, retaining the full market value for our shareholders. With a small and nimble commercial team, we believe we can fully serve the specialist and medical centers treating the NPC patient population with low commercial cost. Building upon our US and EU early access programs, as well as our relationships within the NPC community, we believe we have a strong foundation to help support the adoption of arimoclomol. Beyond our immediate focus on a successful US commercial launch, we also see commercial potential for arimoclomol outside the US, including the EU and other potential geographies.

Now, let's turn our attention to KP1077, our lead program for rare sleep disorders. I'll begin with an update on our idiopathic hypersomnia indication and finish with our narcolepsy indication. Due to limited treatment options for idiopathic hypersomnia, also known as IH and its small and underserved community of approximately 37,000 patients seeking treatment in the US, KP1077 has been designated by the FDA as an orphan drug and is potentially eligible for expedited approval pathways. KP1077 could potentially provide clinical and safety benefits that will help differentiate it from current and future IH products. The KP1077 Phase 2 study is actively enrolling subjects at more than 30 sites in the US. Interim Phase 2 efficacy and safety data is expected as early as Q3 2023, with potential for top line data as early as year-end.

We expect the interim data from this trial will support the advancement of KP1077 into a pivotal Phase 3 study in IH. Importantly, the interim data will include information from an open-label titration phase, which we believe will help us in designing the Phase 3 study. At the end of last quarter, Zevra submitted an Investigational New Drug application, or IND, to the FDA for narcolepsy. Thereafter, the FDA informed Zevra we may proceed under our newly opened IND, indicating we can initiate our clinical program for KP1077 in narcolepsy, extending the potential of the KP1077 program further across the spectrum of sleep disorders. Phase 1 studies will be conducted to support our clinical data package in both narcolepsy and IH. In addition, the KP1077 Phase 2 study in IH could support the determination of whether to initiate a Phase 3 trial in narcolepsy in the future.

Now, LaDuane will provide more details about our first quarter 2023 financial results.

R. LaDuane Clifton

Chief Financial Officer, Secretary & Treasurer, Zevra Therapeutics, Inc.

Thanks, Christal, and good afternoon.

During Q1 2023, we saw the prescription trends for AZSTARYS continue as expected, with an estimated 8,669 (sic) [8,679] (14:56) prescriptions reported as of the week of May 5, 2023. The trend remains encouraging and gives us confidence to reiterate our guidance that we believe we will achieve the first and possibly second net sales milestone under the AZSTARYS license agreement during this year. As you may know, AZSTARYS was approved in March 2021 for the treatment of ADHD in patients aged six and older. It is being commercialized in the US by our partner Corium Incorporated, who has put together a great team to make this product available.

With substantial insurance coverage throughout the US and a sizeable field sales force, we believe the net sales milestones and a growing base of royalty revenue will continue to be foundational part of our business. Of course, our focus remains on our development pipeline and what future opportunities it can generate, especially with the possibility to leverage our own commercial capability in the future.

Now let's turn our attention to the financial results for Q1 2023. We have begun the year with a solid quarter, reporting net revenue of \$2.9 million as compared to \$2.3 million during Q4 2022. Ongoing reimbursements from the French Early Access Program are the primary driver of revenue, supplemented by AZSTARYS royalties.

Royalties earned during Q1 2023 were approximately \$630,000, representing a nearly 58% increase over the prior quarter. While the royalties provide a steady and growing income stream, milestones are expected to be the bigger driver of value from the AZSTARYS license for the foreseeable future. We reported a Q1 net loss of \$11.8 million, or \$0.34 per basic and diluted share, which was driven by our R&D investments and increased G&A, all associated with the activities underway for the KP1077 and arimoclomol programs. As of March 31, 2023, our cash, cash equivalents and investments were \$95.3 million, which was a decrease of \$7.6 million compared to December 31, 2022.

The change was driven by our operating activities, combined with our repurchase of 665,739 shares of the company's common stock for approximately \$3.4 million at an average price of \$5.09 per share. There is approximately \$39 million remaining under the company's share repurchase program as of March 31, 2023.

Looking towards the rest of 2023, our financial guidance remains unchanged from our last results call. Our existing available capital on the balance sheet is expected to extend our cash runway into 2026. Our operating forecast includes the reimbursements from the French EAP, what we need for the arimoclomol NDA's resubmission, the complete development program for KP1077 in IH through NDA submission and potential PDUFA, as well as our preparations for the possible US launch of arimoclomol if approved.

In addition, prescription transfer starts during Q1 2023 give us confidence that we will potentially reach at least one and possibly two of the net sales milestones under the AZSTARYS license agreement during 2023. Net revenue from the French EAP program is expected to remain steady at a rate of approximately \$2 million per quarter throughout the year. Our focus is on our execution of the product development plans for arimoclomol and KP1077, as well as in building our commercial capabilities. We believe we have the resources needed to accomplish these important goals.

And with that, I'll return the call to Christal.

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

Thanks, LaDuane. 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 resubmit the arimoclomol NDA as early as the third quarter of this year. For the KP1077 program and rare sleep disorders, we anticipate preliminary interim data from the Phase 2 trial in idiopathic hypersomnia as early as the third quarter. These data have the potential to support both advancement of KP-1077 into a Phase 3 study in IH, but may also support a Phase 3 trial in narcolepsy under the recently opened IMD.

To fuel our growth, we anticipate ongoing revenue from our arimoclomol extended access program in France to continue at approximately \$2 million per quarter, and we have the potential to realize one and possibly a second

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net sales milestone under the AZSTARYS license agreement. In addition to the growing royalty streams this year, our capital remains strong with a cash runway that extends into 2026. With that, I will ask the operator to open the call for questions. As a reminder, Zevra's Board Chair and management team members participating on this call today include, our Board Chair, Tamara Favorito; our Chief Financial Officer, LaDuane Clifton; and our Commercial Officer and EVP of Business Development, Josh Schafer.

QUESTION AND ANSWER SECTION

Operator: At this time [Operator Instructions] Our first question comes from Louise Chen, Cantor Fitzgerald.

Louise Chen

Analyst, Cantor Fitzgerald & Co.

Hi. Congratulations on the progress this quarter and thanks for taking my questions here. So I wanted to ask you a few things. Firstly, on the milestones potentially in 2023, can you give us a sense of the amount and timing that you might – when you might get these different milestones, how much they are? And then secondly, on KP1077 for narcolepsy, can you talk about what unmet need that you're addressing here in the market of narcolepsy? And then lastly, just on your data, as early as third quarter 2023 this year for IH, what would you consider a successful outcome in that internal readout? Thank you.

R. LaDuane Clifton

Chief Financial Officer, Secretary & Treasurer, Zevra Therapeutics, Inc.

Thanks, Louise. I appreciate that. This is LaDuane, and I'll start with the milestone question and then we'll go to the other two. So at this point, we have not been able to disclose publicly the milestone amounts under the license agreement for AZSTARYS. And so I still can't do that today, but I will tell you that, I think we expect – when I talk about earnings this year, I really mean, I expect we'll earn the first one, it's going to be between, it's likely sort of in the Q2 or Q3 timeframe is my expectation. And then if we're able to earn the second one, we would have earned it by the end of the year with the cash payment likely coming after the end of the year, so in the beginning of 2024. That's the way they report it, and they report it and pay the quarter in arrears. So, that's the first question. And I guess, Christal I would turn it to you with regard to the KP1077 IH question.

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

Sure. And I believe your first question, was it on the interim data or on narcolepsy?

Louise Chen

Analyst, Cantor Fitzgerald & Co.

Yeah. The first one was on narcolepsy and what unmet need that you're addressing there. And then yes, the second one was on the internal data for IH. Thank you.

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

So, regarding the unmet need, narcolepsy is very similar to idiopathic hypersomnia, and the fact that they also have the same issues with brain fog and having that wakefulness, excessive daytime sleepiness as IH. And so we do look to, there are products that are on the market that are helping to consolidate sleep, but really there are a few products that are on the market, but they do have some limitations based off of the doses that they can give

and aren't necessarily as effective as we feel like ours could be with our unique profile. So we do feel like there is some unmet need there in narcolepsy as well.

Joshua Schafer

Chief Commercial Officer & Executive Vice President-Business Development, Zevra Therapeutics, Inc.

And this is Josh Schafer, Louise, if I could also just add. One of the benefits of KP1077 is the lack of potential abuse. And with its profile, we think KP1077 would be a much safer alternative to some of the current stimulants. At the same time it's having improved clinical efficacy as well.

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

And then going to your other question about the interim data and what we're looking for there, so really, the whole point for – there's a couple of things for the Phase 2 study is, we're looking to see if we are powered it up based off of the analysis that we're looking at, and then obviously safety is also that's our primary endpoint here, so continuing to look at that. As far as for the interim, those are the things that we would be looking for, as well as where we are looking into two different dosing regimens and the potential for those and which one may be more effective with the least amount of side effects as far as if there's any insomnia or things like that that come with similar view. So those are the things that we would be looking for, and those would all help us to begin designing the first stages of the Phase 3 study as we go into the planning for that.

Louise Chen

Analyst, Cantor Fitzgerald & Co.

Okay. Thank you.

Operator: Our next question comes from Jonathan Aschoff, ROTH MKM.

Jonathan Aschoff

Analyst, ROTH Capital Partners LLC

Hi. Thanks. What kind of efficacy would you need to see with KP1077 in Phase 2 to proceed to a pivotal trial in IH? And maybe it's the same, maybe it's not, but what kind of efficacy would you have to see in Phase 2 to proceed in both a pivotal in IH and in narcolepsy?

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

So, as far as efficacy with this, we're looking at products that are similar. And so, while we don't have a particular point that we are looking at a different point differential, but on the Epworth Sleepiness Scale, I believe that there is other products out there that maybe I think the differentiation was maybe a 3-point difference or something like that. But again, those are other products. We don't have a specific point that we are looking at yet, again, that's why we are doing the Phase 2 trials to see looking at that as well.

Jonathan Aschoff

Analyst, ROTH Capital Partners LLC

Okay. By the way, just to nitpick, what was the consulting fee, what was the revenue that wasn't AZSTARYS or arimoclomol?

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R. LaDuane Clifton

Chief Financial Officer, Secretary & Treasurer, Zevra Therapeutics, Inc.

The consulting fees during Q1 were very small. It was around \$25,000. So, it's a very modest final payment.

Jonathan Aschoff

Analyst, ROTH Capital Partners LLC

Okay. So, how do we look at R&D, which kind of popped significantly in the first quarter? What's that going to look like this quarter, third quarter, fourth quarter?

R. LaDuane Clifton

Chief Financial Officer, Secretary & Treasurer, Zevra Therapeutics, Inc.

So, R&D is kind of tracking up as we have the active Phase 2 trial in KP1077. And I think that the trend we're on here during Q1 is going to be similar as we go through the year and complete the trial, but then also then begin preparing for the Phase 3 going into 2024.

Jonathan Aschoff

Analyst, ROTH Capital Partners LLC

Okay. So, at the very least, slightly up from Q1. Has about the same kind of popped in SG&A, is that your new run rate or your new low for the year?

R. LaDuane Clifton

Chief Financial Officer, Secretary & Treasurer, Zevra Therapeutics, Inc.

Currently, I expect that we'll be around flat in that area. But as we get into the resubmission process or once that's completed, I should say, and then we look forward into 2024, there could be some uptick in G&A as we think about beginning to prepare more deliberately for the commercial launch of arimoclomol. So, we're going to be very thoughtful and stage that. So, just to repeat, the G&A is going to be in a similar place where it is right now for a few more quarters, and then we'll kind of assess how it might change after the resubmission.

Jonathan Aschoff

Analyst, ROTH Capital Partners LLC

Okay. And one thing I kind of would like to know, if you don't mind stepping back and answering this is, typically when management changed this much, there's a change in what's going to happen and how it's going to be done. There really doesn't seem much in the way of any change with how you're going forward with Zevra other than the name change. So, what's different? Why the management change if you're really kind of going forward the same way you've been? It just doesn't seem to square with me.

R. LaDuane Clifton

Chief Financial Officer, Secretary & Treasurer, Zevra Therapeutics, Inc.

Yeah. I think Tamara maybe, if you're still on the call, you'd like to address that.

Tamara A. Seymour

Board Chair & Chair of Audit Committee, Zevra Therapeutics, Inc.

Yeah. I'd like to take that. Thank you, Jonathan, for asking that. And as you may be aware, we just went through a contested proxy fight and three new directors were elected to our board. And our CEO, Rich Pascoe, was not reelected. He was one of the three directors that we had put up for re-election, and because he was not re-elected by the board, he chose to resign as CEO as well. And I think, what you mentioned is very, very important for

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Zevra. Nothing is changing in terms of our strategy. And as Christal said in her comment, we have been working on this for two years, and we now have a strategy of developing rare disease drugs for the market. That's where we were going before the annual meeting and that's where we're going to go afterwards. So, we're very sorry to lose Rich, we understand what he did, and we will be looking for a new CEO, but we see no change in the company's strategy whatsoever.

Jonathan Aschoff

Analyst, ROTH Capital Partners LLC

Thank you for that. Lastly on the data that Louise was referring to, the interim data. So the Phase 2 data coming in as early as the third quarter, that's just an interim look to see primarily how the trial is?

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

So yes, that's exactly right. So the interim data is just that it's in the middle of the trial to see if there's any adjustments that we need to make, primarily in the powering of the study to see if we need to increase the numbers to get the effect or to be able to see the effects that are coming out of our molecule. And then, but again, we can also look at things like the dosing regimen and other things because we do have that open titration portion of it.

Jonathan Aschoff

Analyst, ROTH Capital Partners LLC

Okay. So what again was your intend in initial enrollment and what could that jump to if you see that you are underpowered?

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

Sure. So our initial enrollment, we're looking to enroll 48, and I don't remember what the exact number was. We do have a percentage above that, and I can go back and look at that. I don't remember exactly, but we do have that planned if it does need to go up.

Jonathan Aschoff Analyst, ROTH Capital Partners LLC

Okay. Thank you very much.

Operator: [Operator Instructions] This concludes the Q&A portion of today's call. We now like to turn the call back over to Christal Mickle for any additional or closing remarks.

Christal M.M. Mickle

Chief Development Officer & Co-Founder, Zevra Therapeutics, Inc.

Thank you very much. As we conclude today's call, I would like to leave you with a few additional thoughts. As one of the founders of the company, I have devoted a significant part of my career helping to build this company from scratch, and to a team that has been able to take not one but multiple products from discovery through development, culminating in regulatory approval, where these products are now available to patients providing for previously unmet needs. And today, our journey continues as we move forward with more opportunities to build upon our legacy of success in drug development. The addition of commercial capabilities is a natural part of





Zevra's evolution, and I'm proud to step into the role of Interim President and CEO as of June 1, with the goal of fully supporting our team as we execute on our objective to drive towards many more successes in the future.

One of the hallmarks of how our company began was through sincere dialogue with our shareholders and with all of our stakeholders. We remain committed to providing clear communication as one of our guiding principles and completing our work with integrity and excellence. The needs of the patient communities which we serve are at the forefront of what we do every day. And I know our team of scientists and business professionals is fully committed, as I am, to bring the promise of novel rare disease therapies to those who need the most. We have the tools and the resources needed to fully capitalize on the opportunities which lie ahead and the resolve to get it done. I am proud to be on this journey with the team we have built and with you, our shareholders. Thank you very much.

Operator: This concludes today's Zevra Therapeutics first quarter 2023 earnings call and webcast. You may disconnect your lines, and have a great, wonderful day.

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