



Zevra Therapeutics' President and Chief Executive Officer Issues Letter to Stockholders Highlighting Recent Key Accomplishments and Outlook for 2024

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CELEBRATION, Fla., April 29, 2024 (GLOBE NEWSWIRE) -- Zevra Therapeutics, Inc. (NasdaqGS: ZVRA) (Zevra, or the Company), a rare disease therapeutics company, today announced that Neil F. McFarlane, Zevra's President and Chief Executive Officer, has issued a Letter to Stockholders providing a review of key accomplishments and outlook for 2024.

Dear Stockholders,

It is hard for me to believe that April 2024 marks six months since the start of my tenure as Zevra's President and Chief Executive Officer in October 2023. From that time, and even prior to my official start date, I began a listening tour, seeking feedback from many of Zevra's stakeholders – stockholders, investors, employees, patients and caregivers – with an agenda to understand what we do well, where we can improve and what we should be focusing on to drive value.

The overarching conclusion from those conversations is that great promise lies at the intersection of the talent, capabilities, and opportunities that we have brought together here at Zevra. There are also many things that deserve more attention and areas where improvement is needed.

Taking that a step further, the question of "What's best for the patient?" has become the mantra of the Zevra team, guiding our decisions daily. And, I have instilled a second clear directive into the Zevra team, which is, "We must execute." Driving value for patients can best be accomplished by defining a clear strategy, creating necessary plans to reach our strategic objectives, and then executing those plans.

Our Company continues to work through a period of significant growth and transformation with the addition of meaningful new skills and capabilities from the strengths of three companies that have now come together to become *One Zevra*. Today, I am pleased to share with you a summary of our recent key accomplishments and the reasons for my optimism for 2024 and beyond.

We are Building a High-Performance Team

Our people are at the heart of everything we do. We are building a team of talented professionals committed to using science and data-driven development approaches to create and deliver new therapies to address unmet needs for those we serve.

Since we first announced our strategic objective of becoming a leading rare disease company in the first half of 2022, we have seen significant growth in the size of our team. Through our recruiting efforts, and by virtue of our acquisitions, we have grown from a team of 24 employees to a current team of 81. This includes the buildout of targeted customer-facing commercial and medical affairs teams with decades of experience in rare diseases. We also added Adrian Quartel, M.D. as Zevra's Chief Medical Officer, who brings more than 20 years of experience with a track record of success in clinical development, pharmacovigilance and medical affairs addressing the needs of the rare disease community. We anticipate there are additional key personnel that will be needed to round out our team as we plan for success and continue our evolution into a high-performing team.

Our ability to attract and retain the best talent for our mission will be paramount to reaching our full potential as an organization. Equity participation is a key component of total compensation in the biotech industry, which is why we have proposed certain amendments to our 2014 Equity Incentive Plan (the "2014 Plan") in our 2024 proxy, including the addition of shares and a three-year extension of the 2014 Plan. The significant growth in our headcount combined with executive management changes in 2023 and prior years has impacted our equity usage rate. However, our compensation philosophy is grounded in a data-driven approach, and we intend to utilize the additional shares judiciously in accordance with industry best practices over the remaining life of the 2014 Plan to provide long-term incentives that are fully aligned with stockholders' interests in the pursuit of long-term value creation.

We've Made Significant Progress Advancing our Rare Disease Portfolio

During the fourth quarter of 2023, and heading into 2024, we made demonstrable progress in executing our key strategic priorities. First, we completed our acquisition of Acer Therapeutics in November 2023, allowing us to start delivering value to patients by commercializing OLPRUVA®. Second, we resubmitted the New Drug Application (NDA) for arimocloamol. Third, we completed the Phase 2 study of KP1077 in patients with idiopathic hypersomnia (IH) and we are preparing to advance KP1077 into a potential Phase 3 trial.

Since the completion of the Acer acquisition in mid-November 2023, we have made meaningful progress towards ensuring that people who suffer from certain urea cycle disorders (UCDs) have access to, and are aware of, the benefits of OLPRUVA. I am proud of the team's execution to build our rare disease commercial capability. As a result, we initiated the full commercial launch of OLPRUVA as of the end of January 2024.

We have concentrated our initial efforts on approximately 40 metabolic treatment centers of excellence across the United States as the first part of our strategy to build awareness with physicians about the differentiation that OLPRUVA can bring to people living with UCDs that are addressed by the product. In the three months since launch, our team has been able to engage with more than 90% of our customers, which reflects the deep rare disease experience of our team. I am also proud to share that we have seen meaningful growth in reimbursement coverage, which was approximately 55% of U.S. covered lives at the time of acquisition, to now more than 70%.

The commercial footprint we have established for OLPRUVA is designed to provide scale and cost synergies to support and accelerate the launch and commercialization of arimocloamol, if approved. Our team has put forth tremendous effort to submit a comprehensive data set to the U.S. Food and Drug Administration (FDA) supporting the resubmission of the NDA for arimocloamol. In March, we announced that the FDA had extended the review period for the NDA, resulting in a revised Prescription Drug User Fee Act (PDUFA) date of September 21, 2024, and re-affirmed its intent to present the resubmission for discussion at an advisory committee meeting. While that meeting has not yet been scheduled, we welcome the opportunity for the data to be shared publicly, and even more importantly, to allow the voice of the patient to be heard by the advisory committee, the FDA and the public.

We were overwhelmed by the outpouring of support for arimocloamol which came from the NPC community shortly after we filed the resubmission. The

National Niemann-Pick Disease Foundation (NNPDF) spearheaded efforts with six other NPC advocacy and research organizations to compile a petition of nearly 1,000 signatures from NPC patients with direct experience utilizing arimoclomol, as well as caregivers and physicians. The petition can be accessed on the NNPDF website [here](#). I encourage you to read the personal stories of people living with this devastating rare disease.

Also in March, we reported positive top-line data from our Phase 2 study of KP1077 in patients with IH. We are encouraged by the results which show that KP1077 is well tolerated and demonstrates early signs of differentiated and meaningful clinical benefits. We will be presenting the results from the study at the upcoming SLEEP 2024 conference taking place June 1-5, 2024. The study successfully fulfilled the objectives of providing key information needed for the design of a potentially pivotal efficacy trial. We plan to request an end-of-Phase 2 (EOP2) meeting with the FDA to seek guidance on the Phase 3 clinical trial design and are optimistic about the potential of KP1077 to address unmet needs in sleep disorders.

We have also completed our preliminary evaluation of the celiaprolol program for the treatment of vascular Ehler-Danlos Syndrome (vEDS), which is a promising product candidate we added from the Acer acquisition. We recently restarted recruitment of the ongoing Phase 3 trial, which is a long-term event-driven trial design, and believe that celiaprolol could address significant unmet needs as there are currently no approved treatments for vEDS in the U.S.

We have a Foundation of Financial Strength

Our balance sheet remains strong and provides Zevra with capital flexibility to achieve our strategic objectives. We recently announced the refinancing of our existing debt with up to \$100 million in committed capital which has further strengthened our balance sheet and provides added capital flexibility to support our mission. This new credit facility, which was led by premier biotech investors including Perceptive Advisors and HealthCare Royalty Partners, has simplified our debt structure with an extended maturity and provides non-dilutive capital flexibility to support our strategic priorities. With the initial draw of \$60 million, we have refinanced our existing debt of approximately \$43 million and added an incremental \$14 million in net cash proceeds to the cash balance after fees and discounts.

In addition to a strong balance sheet, we also have a solid base of revenues from which we can build. We expect that reimbursements from the arimoclomol expanded access program in France will continue to provide approximately \$2.1 million in net revenue per quarter. We expect these reimbursements to continue for as long as we are eligible for the French ATU program and continue to seek approval of the product in Europe.

We also remain encouraged by the ongoing royalty and milestone contributions from the AZSTARYS® product for the treatment of ADHD in patients age six years and up, which is being commercialized by our partner, Corium, Inc. After earning the first two net sales milestones which totaled \$15 million calendar year 2023 under the AZSTARYS license, we are encouraged by the product's continuing prescription growth since the beginning of 2024, as well as the potential to reach additional cash milestones at higher net sales thresholds in the next few years.

Of course, these are steppingstones towards building a sustainable operating business with reliable cash flows from our own commercialization efforts. Achieving our strategic objectives to successfully commercialize OLPRUVA, and then upon approval, successfully launch arimoclomol, are key to reaching that seminal inflection point of value creation.

We're Committed to Governance Best Practices

From the beginning of 2023 through today, the composition of our Board of Directors has changed dramatically, bringing new skills, diversity, perspectives and core competencies needed to support Zevra's objective of becoming a leading rare disease therapeutics company. The addition of Wendy Dixon, Ph.D., John Bode, Douglas Calder and Corey Watton in the first half of last year began a period of Board refreshment, which was completed following the addition of Thomas Anderson, in August 2023, my appointment to the Board in October 2023, and the recent appointment of Alvin Shih, M.D., MBA, in January 2024. With the goal of leading Zevra into its future as a patient-focused, commercial stage, rare disease company, and under the stable leadership of our Board Chair, Tamara Favorito, we have come together with full alignment behind Zevra's mission. This positions the Board as a pillar of strength from which we can anchor our efforts and move the Company forward.

The newly composed Board immediately moved into action by affirming its commitment to employing governance best practices for a company of our size and stage in the biotech industry. The Board is looking to the future in order to prepare and inform how we improve our governance structure today, and it has already started in February 2024, making updates to the Company's bylaws which included changes that address the universal proxy rules recently adopted by the U.S. Securities and Exchange Commission, as well as updates to certain disclosure requirements in connection with stockholder nominations and proposals.

Committee membership was also adjusted in February 2024, which was made possible by completing the Board's refreshment process. We believe the new committee assignments build upon the strengths of all our directors. And with those new assignments, each standing committee of the Board is now undertaking a comprehensive review of each committee's charter, seeking to push forward in our commitment to governance best practices in every area: Audit, Compensation, and Nominating and Corporate Governance. Also, the Board will leverage feedback from its self-evaluation process, which provides an opportunity to reflect on and improve both processes and effectiveness.

Our work here is not done. The Board is committed to ongoing review and consideration of other adjustments which may be needed to enhance our ability to accomplish our objectives and to strengthen our governance framework.

We are Optimistic about Our Future

Bringing it all together, I am confident the opportunities we have in front of us have the potential to deliver meaningful stockholder value.

- We are driving to make the launch of OLPRUVA a success.
- We look forward to presenting the full data package from the completed KP1077 Phase 2 trial in IH patients at the upcoming SLEEP 2024 conference in early June.
- We are thoroughly preparing for the potential FDA advisory committee meeting to discuss the arimoclomol NDA, and we are looking forward to the PDUFA date on September 21, 2024.
- We intend to accelerate the commercial launch of arimoclomol, if approved, by leveraging our commercial capabilities that are now fully installed and look forward to receiving a Priority

Review Voucher (PRV) upon approval.

The pace of Zevra's transformation has been tremendous, and I am proud of how much progress we have made. However, there is much more to do. From the combined strength of three teams with diverse experiences and backgrounds, we have become *One Zevra*, fully focused and dedicated to our mission of bringing life-changing therapeutics to people living with rare disease.

We are grateful for you, our stockholders, and for your support in achieving our mission. We look forward to a bold future full of the potential to impact the lives of those we serve.

Sincerely,

Neil F. McFarlane
President and Chief Executive Officer
Zevra Therapeutics, Inc.

About Zevra Therapeutics

Zevra Therapeutics is a rare disease company combining science, data, and patient needs to create transformational therapies for diseases with limited or no treatment options. Our mission is to bring life-changing therapeutics to people living with rare diseases. With unique, data-driven development and commercialization strategies, the Company is overcoming complex drug development challenges to make new therapies available to the rare disease community.

Expanded access programs are made available by Zevra Therapeutics and its affiliates and are subject to the Company's Expanded Access Program (EAP) policy as published on its website at www.zevra.com. Participation in these programs is subject to the laws and regulations of each jurisdiction under which each respective program is operated. Eligibility for participation in any such program is at the treating physician's discretion.

For more information, please visit www.zevra.com or follow us on [X](#) (formerly Twitter) and [LinkedIn](#).

Cautionary Note Concerning Forward-Looking Statements

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that do not relate solely to historical or current facts, including without limitation statements regarding the potential benefits of our debt facility, our cash balance, our corporate governance objectives, potential revenues from our arimoclomol expanded access program, the potential for royalty and milestone contributions, the presentation of data at conferences, the promise and potential impact of our preclinical or clinical trial data, the initiation, timing and results of any clinical trials or readouts, the content, information used for, timing or results of any NDA submissions or resubmissions for arimoclomol or any other product candidates for any specific disease indication or at any dosage, the potential benefits of any of our products or product candidates, the potential launch or commercialization of any of product candidates or products, personnel needs and growth, including our plans to build out commercial teams for products or product candidates, and our strategic and product development objectives, including with respect to becoming a leading, commercially focused rare disease company. Forward-looking statements are based on information currently available to Zevra and its current plans or expectations. They are subject to several known and unknown uncertainties, risks, and other important factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. These and other important factors are described in detail in the "Risk Factors" section of Zevra's Annual Report on Form 10-K for the year ended December 31, 2023, and Zevra's other filings with the Securities and Exchange Commission. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we cannot assure that such expectations will prove correct. These forward-looking statements should not be relied upon as representing our views as of any date after the date of this press release.

Additional Information and Where to Find It

Zevra has filed with the Securities and Exchange Commission (the "SEC") a definitive proxy statement on Schedule 14A, with respect to its solicitation of proxies for Zevra's 2024 Annual Meeting of Stockholders. This communication is not a substitute for any proxy statement or other document that Zevra may file with the SEC in connection with any solicitation by Zevra.

INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) FILED BY ZEVRA AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC WHEN THEY BECOME AVAILABLE CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT ANY SOLICITATION.

Investors and security holders may obtain copies of these documents and other documents filed with the SEC by Zevra free of charge through the website maintained by the SEC at www.sec.gov. Copies of the documents filed by Zevra are also available free of charge by accessing Zevra's website at www.zevra.com.

Participants in the Solicitation

This communication is neither a solicitation of a proxy or consent nor a substitute for any proxy statement or other filings that may be made with the SEC. Nonetheless, Zevra, its directors and executive officers and other members of management and employees may be deemed to be participants in the solicitation of proxies with respect to a solicitation by Zevra. Information about Zevra's executive officers and directors is available in Zevra's definitive proxy statement for the 2024 Annual Meeting of Stockholders, which was filed with the SEC on April 3, 2024. The definitive proxy statement is available free of charge at the SEC's website at www.sec.gov. Copies of the documents filed by Zevra are also available free of charge by accessing Zevra's website at www.zevra.com.

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