UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): December 22, 2023

Zevra Therapeutics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**001-36913**	**20-5894398**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
1180 Celebration Boulevard, Suite 103, Celebration, FL		**34747**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (321) 939-3416

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ZVRA	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 27, 2023, Zevra Therapeutics, Inc., a Delaware corporation, issued a press release announcing that it resubmitted its New Drug Application for arimoclomol, an investigational therapeutic candidate for the treatment of Niemann-Pick disease type C, to the U.S. Food and Drug Administration on December 22, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated December 27, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Zevra Therapeutics, Inc.

Date: December 27, 2023

By: /s/ R. LaDuane Clifton
R. LaDuane Clifton, CPA
Chief Financial Officer, Secretary and Treasurer

Zevra Therapeutics Announces Resubmission of Arimoclomol New Drug Application to the U.S. Food and Drug Administration

Celebration, FL – December 27, 2023 – Zevra Therapeutics, Inc. (NasdaqGS: ZVRA) a rare disease therapeutics company, today announced it resubmitted its New Drug Application (NDA) for arimoclomol, an investigational therapeutic candidate for the treatment of Niemann-Pick disease type C (NPC) to the U.S. Food and Drug Administration (FDA) on December 22, 2023. Based on standard NDA resubmission review timelines, an acknowledgment letter from the FDA that the resubmission is complete and setting the PDUFA date is expected within 30 days. Zevra expects the NDA to be classified as a Class II submission which would be subject to a review period by the FDA within six months from the date of submission.

"The Zevra team has worked diligently to deliver a high quality and thorough resubmission of the NDA for arimoclomol following multiple interactions with the FDA and after incorporating direction from the agency," said Neil McFarlane, President and Chief Executive Officer of Zevra. "We continue to accelerate our launch preparations in anticipation of FDA approval, and believe we are one step closer to getting arimoclomol into the hands of patients who are seeking a treatment."

"Zevra has engaged with the advocacy community, elevating the patient voice throughout arimoclomol's development process," said Daniel Gallo, Ph.D., Zevra's Senior Vice President of Medical Affairs and Advocacy. "The advocacy community's input has been instrumental in building awareness of the need for approved treatments that address the unmet needs of individuals and their caregivers living with this debilitating condition."

Zevra believes it has addressed the issues previously raised by the FDA in the complete response letter by providing additional evidence to support the use of the Niemann-Pick type C Clinical Severity Scale (NPCCSS) and, conducting additional studies used to support the potential mechanism of action. Additionally, new data included in the resubmission comes from multiple non-clinical studies, natural history comparisons, real-world data generated from the ongoing early access programs in the United States and the European Union, as well as data from the four-year open-label extension of the Phase 2/3 clinical trial (NCT02612129). Results from this open-label trial suggest that arimoclomol reduces the long-term progression of NPC.

Arimoclomol has been evaluated in a total of 21 studies across a range of Phase 1, 2 or 3 clinical trials evaluating its safety and efficacy across more than 600 subjects in NPC, other disease or healthy subjects. The primary efficacy trial evaluating arimoclomol for the treatment of NPC was a Phase 2/3 double-blind, placebo-controlled trial (CT-ORZY-NPC-002) of arimoclomol in 50 patients with NPC.

About Niemann-Pick disease type C:

Niemann-Pick disease type C (NPC) is an ultra-rare, genetic, progressive and fatal neurological disease caused by mutations in the *NPC1* or *NPC2* genes. Both genes encode proteins, located in intracellular compartments called lysosomes, which are essential in the transport and metabolism of lipids. Mutations in either of these NPC genes result in a reduced amount of *NPC1* or *NPC2* protein causing lysosomal dysfunction due to accumulation of intracellular lipids and ultimately, if unchecked, cell death. Evidence suggests that arimoclomol improves lysosomal function within the cells, reducing the accumulation of lipids to delay and prevent cell death. NPC is an inherited disorder that affects both children and adults with varying ages of onset, rate of progression and presents differently in each person. NPC is characterized by visceral (internal organs) manifestations, including enlarged liver and spleen, neurological and psychiatric manifestations. Those living with NPC lose independence due to physical and cognitive limitations. Key neurological impairments are in speech, cognition, swallowing, ambulation, and fine motor skills. Disease progression is irreversible and can be fatal within months or take years to diagnose and advance.

About Arimoclomol:
Arimoclomol, Zevra's orally-delivered, first-in-class investigational product candidate for the treatment of Niemann-Pick disease type C (NPC), has been granted orphan drug designation, Fast Track designation, Breakthrough Therapy designation and rare pediatric disease designation for NPC by the U.S. Food and Drug Administration (FDA), and orphan medicinal product designation for the treatment of NPC by the European Medicines Agency (EMA). Zevra resubmitted the NDA to the FDA in December 2023.

About Zevra Therapeutics:
Zevra Therapeutics is a rare disease company melding science, data, and patient needs to create transformational therapies for diseases with limited or no treatment options. With unique, data-driven clinical, regulatory, and commercialization strategies, the Company is overcoming complex drug development challenges to bring much-needed therapies to patients. With both regulatory and clinical stage product candidates, the Company is building its commercial capability to make new therapies available to the rare disease community.

Caution 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 promise and potential impact of our preclinical or clinical trial data, including without limitation 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 launch or commercialization of any of product candidates or products, 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, 2022, as updated in Zevra's Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

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