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

# FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2025**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from ____ to _____**

**Commission File No. 001-36913**

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

| **Delaware** | **20-5894398** |
|---|---|
| **(State or Other Jurisdiction of Incorporation or Organization)** | **(I.R.S. Employer Identification No.)** |
| **101 Federal Street, Boston, MA 02110** | **(888) 958-1253** |
| **(Address of Principal Executive Offices and Zip Code)** | **(Registrant's Telephone Number, Including Area Code)** |

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

| Title of Each Class | Trading Symbol | Name of Each Exchange on Which Registered |
|---|---|---|
| **Common Stock, $0.0001 par value** | **ZVRA** | **The Nasdaq Stock Market LLC (Nasdaq Global Select Market)** |

**Securities registered pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or

issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $454.8 million, based upon the closing sales price for the registrant's common stock, as reported on the Nasdaq Global Select Market on June 30, 2025. The calculation of the aggregate market value of voting and non-voting common equity excludes shares of common stock the registrant held by executive officers, directors and stockholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 6, 2026, the registrant had 58,711,584 shares of common stock outstanding.

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**Documents Incorporated by Reference**

Portions of the registrant's definitive proxy statement relating to its 2026 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

**ZEVRA THERAPEUTICS, INC.**
**FORM 10-K**

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This Annual Report on Form 10-K, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as "may," "will," "would," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "assume," "potential," "continue" or other similar words or the negative of these terms. We have based these forward-looking statements largely on our current expectations about future events and financial trends that we believe may affect our business, financial condition and results of operations. The outcomes of the events described in these forward-looking statements are subject to risks, uncertainties and other factors described in "Risk Factors" and elsewhere in this report. Accordingly, you should not place undue reliance upon these forward-looking statements. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and the timing of events and circumstances and actual results could differ materially from those anticipated in the forward-looking statements. Forward-looking statements contained in this report include, but are not limited to, statements about:*

- *our ability to commercialize and the timing of commercializing our products and product candidates, if approved;*
- *the potential therapeutic benefits and effectiveness of our products and product candidates;*
- *the progress of, timing of and expected amount of expenses associated with our commercialization, research, and development activities;*
- *the size and characteristics of the markets that may be addressed by our products and product candidates;*
- *the expected timing of clinical trials for our product candidates and the availability of data and results of those trials;*
- *the progress of, outcome of, and timing of any regulatory approval for any of our product candidates;*
- *our expectations regarding federal, state and foreign tax, legal and regulatory requirements;*
- *our intention to seek to establish, and the potential benefits to us from, any strategic collaborations or partnerships for the development or sale of our products and product candidates, if approved;*
- *our expectations as to future financial performance, expense levels and liquidity sources;*
- *the sufficiency of our cash resources to fund our operating expenses and capital investment requirements for any period;*
- *our ability to raise additional funds if needed on commercially reasonable terms, or at all, in order to support our continued operations;*
- *senior leadership and board member transitions and refreshments; and*
- *other factors discussed elsewhere in this report.*

*The forward-looking statements made in this report relate only to events as of the date on which the statements are made. We have included or made reference to important factors in the cautionary statements included in this report, particularly in the section entitled "Risk Factors" that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future developments, including acquisitions, mergers, dispositions, joint ventures or investments we may make. Except as required by law, we do not assume any intent to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.*

## RISK FACTORS SUMMARY

*The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully in the section titled "Risk Factors". Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:*

**Risks Related to the Commercialization of Our Approved Products and Product Candidates**

- If we are unable to establish effective sales, marketing and distribution capabilities for our products, or if our products fail to achieve expected market acceptance, we may not be successful in commercializing such products.
- The target patient population for our rare disease products is small, so we must achieve significant market share and obtain relatively high per-patient prices to be successful.
- We may be subject to enforcement action if we engage in improper marketing or promotion of our products.
- Product liability claims could cause us to incur substantial liabilities and adversely affect commercialization of our products.
- Significant political, trade or regulatory developments, such as increased tariffs or other measures that can restrict international trade can negatively effect development and commercialization of our products and product candidates.
- We are subject to a number of risks associated with commercializing our products internationally.
- Arimoclomol is currently available to Niemann-Pick disease type C patients in select foreign jurisdictions through a global expanded access program ("EAP"), and if the EAP is terminated prior to regulatory approval of arimoclomol and commercialization in any such foreign jurisdiction, our business would be harmed.

**Risks Related to Our Business and Our Financial Position**

- We are highly dependent on MIPLYFFA (arimoclomol) for substantially all of our revenues, and any loss of revenue from this product could materially harm our business.
- We have had recurring negative net operating cash flows throughout our operating history, and we cannot guarantee or predict when we may begin to consistently generate positive net cash flows from operations, or if at all.

**Risks Related to Our Dependence on Third Parties**

- We rely on a limited number of suppliers, in some cases sole-source suppliers, and the inability of such sole-source suppliers to meet our supply requirements would materially harm our business.
- The facilities used by our third-party contract manufacturers are subject to regulatory requirements and inspections, and any failure by such third-party contract manufacturers to comply with regulatory requirements could materially harm our business.
- We rely on and expect to continue to rely on third parties to conduct our clinical trials for our product candidates, and those third parties may not perform satisfactorily.
- We have entered into a collaboration with Commave, to develop, manufacture and commercialize AZSTARYS worldwide, a party with whom we are currently in dispute, and if this collaboration is not successful, we may not be able to capitalize on the market potential of AZSTARYS.

**Risks Related to Our Intellectual Property**

- If we are unable to obtain and maintain adequate intellectual property protection for our technology and products, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our products would be impaired.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property against infringing third parties, which could be expensive, time consuming and unsuccessful.
- Third parties may initiate legal proceedings against us alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

**Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters**

- If we are not able to obtain required regulatory approvals for any of our product candidates, we will not be able to commercialize them and our ability to generate revenue or profits could be limited.
- If we experience delays or difficulties in the enrollment of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- Our approved products are, and any of our product candidates for which we obtain marketing approval will be, subject to significant post-marketing regulatory requirements and oversight.
- Current and future healthcare reform legislation or regulation in the United States and foreign jurisdictions may increase the difficulty and cost for us to obtain marketing approval of our product candidates and increase the cost to commercialize our approved products.
- We may not be able to obtain or maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.
- Our relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, and other healthcare laws and regulations, which could expose us to penalties.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and fines.

**Risks Related to Cybersecurity and Data Privacy**

- Cybersecurity breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- We are currently subject to, and may in the future become subject to additional, U.S. federal and state and international laws and regulations imposing obligations on how we collect, store and process personal information.

**Risks Related to Ownership of Our Common Stock**

- The trading price of the shares of our common stock is likely to be volatile, and purchasers of our common stock could incur substantial losses.
- Anti-takeover provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law and the terms of some or our contracts, might discourage, delay or prevent a change in control of the company or changes in our board of directors or management and, therefore, depress the price of our common stock.
- We could be negatively affected as a result of the actions of activist stockholders, which could be disruptive and costly and may conflict with or disrupt the strategic direction of our business.

## NOTE REGARDING COMPANY REFERENCE

*Unless the context otherwise requires, we use the terms "Zevra," "Company," "we," "us" and "our" in this Annual Report on Form 10-K to refer to Zevra Therapeutics, Inc. and its subsidiaries. We have proprietary rights to a number of trademarks and service marks used in this Annual Report on Form 10-K that are important to our business, including MIPLYFFA® and its related logo, OLPRUVA® and its related logo, LAT®, and the Zevra companies' logos. In addition, Zevra Therapeutics® and Zevra® are both registered trademarks of the Company. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.*

## NOTE REGARDING MARKET AND INDUSTRY DATA

*This Annual Report on Form 10-K contains statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. While we believe the industry and market data included in this Annual Report on Form 10-K is reliable and is based on reasonable assumptions, this data involves many assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the accuracy or completeness of the data contained in these industry publications and other publicly available information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" included in this Annual Report on Form 10-K.*

# PART I

## ITEM 1. BUSINESS.

### Overview

We are a commercial-stage company with a late-stage pipeline committed to redefining what is possible in bringing life-changing therapies to people living with rare diseases. We are focused on expanding patient access, progressing our pipeline toward key milestones, and delivering meaningful therapeutics. Our vision is realized through disciplined execution of our strategic plan and our core values — patient centricity, integrity, accountability, innovation, and courage — which guide our efforts to deliver long-term value. The commercialization of our lead product, marketed in the United States for Niemann-Pick disease type C (NPC), a rare, progressive neurodegenerative disease, provides a strong corporate foundation and demonstrates our ability to advance therapies from development to market.

In February 2023, we changed our name to Zevra Therapeutics, Inc. Zevra, is the Greek word for zebra, which is the internationally recognized symbol for rare disease. This name reflects our intense focus and dedication to developing transformational, patient-focused therapies for rare diseases with limited or no treatment options available, or treatment areas with significant unmet needs.

Our strategic plan is focused on transforming Zevra into a leading rare-disease company. We are prioritizing the commercialization and global expansion of our lead product, MIPLYFFA, while OLPRUVA remains commercially available. We are also advancing the development of our clinical stage asset, celiprolol, and plan to further expand our pipeline through inorganic growth. We intend to become the preferred partner for assets that we believe will allow us to leverage the expertise and infrastructure that we have built to help mitigate risk and enhance our probability of success.

In May 2022, we purchased all of the assets and operations of Orphazyme A/S (“Orphazyme”) related to arimoclomol. On September 20, 2024, the U.S. Food and Drug Administration (“FDA”) approved the New Drug Application (“NDA”) for MIPLYFFA, for use in combination with miglustat for the treatment of neurological manifestations of NPC in adult and pediatric patients 2 years of age and older, and MIPLYFFA became commercially available for dispense in the United States in November 2024. In connection with this approval, we received a transferable rare pediatric disease priority review voucher (“PRV”). On April 1, 2025, we consummated the sale of the PRV, resulting in net proceeds of $148.3 million to us. MIPLYFFA has also been granted orphan medicinal product designation for the treatment of NPC by the European Commission. We are pursuing regulatory approval in E.U. and filed a Marketing Authorization Application (“MAA”) with the European Medicines Agency (“EMA”) in July 2025; the application is currently under review.

On November 17, 2023, we completed the acquisition of Acer Therapeutics, Inc. (“Acer”), pursuant to which Acer became a wholly-owned subsidiary of Zevra. This included the acquisition of OLPRUVA (sodium phenylbutyrate) for oral suspension, which is commercially available in the U.S., for the treatment of certain urea cycle disorders (“UCDs”). In addition, we acquired Acer's pipeline of investigational product candidates, including celiprolol for the treatment of Vascular Ehlers-Danlos syndrome (VEDS) in patients with a confirmed type III collagen (COL3A1) mutation. We are actively enrolling a Phase 3 clinical trial, known as DiSCOVER, to determine whether celiprolol reduces the risk of clinical events in patients with VEDS.

### Our Product Candidates and Approved Products

We have built a diverse portfolio of products and product candidates through a combination of internal development and strategic investments through acquisition. For example, we employed our proprietary Ligand Activated Technology (LAT) platform to develop approved product AZSTARYS. Through our business development efforts, we have added commercial products (MIPLYFFA and OLPRUVA), and a clinical development candidate (celiprolol).

Current commercial products and active development assets are summarized in the table below:

**Active Zevra Commercial and Active Development Assets**

| Parent Drug | Indication | Product / Candidate | Status and IP |
|---|---|---|---|
| Arimoclomol | Niemann-Pick disease type C (NPC) | MIPLYFFA | FDA Approval: Sep. 20, 2024; Orphan Drug Exclusivity ("ODE") through 2031<br><br>Expanded Access Program ("EAP")<br><br>Marketing Authorisation Application ("MAA") under review by EMA, Submitted July 28, 2025 |
| Sodium phenylbutyrate | Urea Cycle Disorders (UCD) | OLPRUVA | FDA Approval: Dec. 22, 2022; IP through 2036 |
| Celiprolol | Vascular Ehlers Danlos Syndrome (VEDS) | Celiprolol | Clinical - Phase 3 trial ongoing; IP potential through 2038 |
| Serdexmethylphenidate | Idiopathic Hypersomnia (IH) | KP1077IH | Clinical - Phase 3 trial ready; IP potential through 2038 |
| Serdexmethylphenidate | Narcolepsy | KP1077N | Clinical - Phase 3 trial potential; IP potential through 2038 |
| Serdexmethylphenidate and dexmethylphenidate | Attention Deficit and Hyperactivity Disorder (ADHD) | AZSTARYS | FDA Approved and Partnered - Receiving royalties and milestones on net sales; IP through 2037 |

***MIPLYFFA***

NPC is an ultra-rare and progressive neurodegenerative disease characterized by an inability of the body to transport cholesterol and lipids inside of cells. Symptoms of NPC include a progressive impairment of mobility, cognition, speech, and swallowing, often culminating in premature death. The incidence of NPC is estimated to be one in 100,000 to 130,000 live births. We estimate that there are approximately 2,000 individuals with NPC in the United States and Europe combined, of which approximately 900 are in the United States and 1,100 are in Europe, where there is a mature market with an approved treatment available for NPC. Of this estimated population, approximately 300 to 350 people have been diagnosed in the United States. NPC is clinically heterogenous, with significant variability in symptom presentation and rate of progression. Although it has traditionally been considered a pediatric disease due to its genetic origins, nearly half of the people treated with MIPLYFFA are adults. Low diagnostic rates may affect the number of potential patients, and we believe that the availability of treatment options in the United States could increase awareness of the disease and assist in more accurately identifying patients.

On September 20, 2024, the FDA approved the NDA for MIPLYFFA, an orally-delivered treatment, for NPC. MIPLYFFA, the first FDA-approved treatment for NPC, is indicated for use in combination with miglustat for the treatment of neurological manifestations of NPC in adult and pediatric patients two years of age and older. In addition, we received a transferable rare pediatric disease PRV in conjunction with the approval. On April 1, 2025, we completed the sale of the PRV and received net proceeds of $148.3 million.

Effective therapies to treat NPC are desperately needed, and, for this reason, MIPLYFFA is currently being made available to NPC patients in France, Germany, and other EU member states, along with select territories outside of Europe under our global EAP. MIPLYFFA has also been granted orphan medicinal product designation for the treatment of NPC by the European Commission. In July 2025, we filed an MAA, which is under review by the EMA.

As of December 31, 2025, there were a total of 161 enrollments to receive MIPLYFFA. For MIPLYFFA, an enrollment is a prescription submitted to our specialty pharmacy, initiating the benefits investigation process to determine reimbursement and can lead to a 30-day paid dispense of MIPLYFFA. Our commercial plans focus on raising awareness among people who are living with NPC that are diagnosed and untreated, or undiagnosed.

To commercialize MIPLYFFA in the United States, we have built, or have arrangements with third parties to perform, marketing, sales, medical affairs, distribution, managerial and other non-technical capabilities. Zevra holds global rights to develop and commercialize MIPLYFFA.

MIPLYFFA summary:

- ***Demonstrated halting of disease progression.*** MIPLYFFA in combination with miglustat demonstrated a clinically significant improvement compared to placebo as early as 12 weeks and a halting of progression of the disease through 12 months of treatment. Data from the 48-month Open Label Extension study confirms the effectiveness of MIPLYFFA in halting disease progression over multiple years.

- ***Ease of flexible administration as an oral treatment.*** MIPLYFFA is administered as an oral capsule that can be swallowed whole, opened and contents mixed with foods or liquids, or delivered through a feeding tube.

- ***Extensive clinical experience with favorable safety data.*** Over 600 patients have been treated with arimoclomol across various clinical trials and indications as well as through our global EAP, with no safety findings of concern found. Further, in a pediatric sub-study of patients aged 6–24 months, arimoclomol was well tolerated following at least 12 months of treatment with no new safety concerns observed.

- ***Advantageous regulatory designations.*** MIPLYFFA has been granted orphan medicinal product designation for the treatment of NPC by the European Commission.

***OLPRUVA***

UCDs are a group of rare genetic disorders that can cause harmful ammonia to build up in the blood, potentially resulting in brain damage and neurocognitive impairments, if ammonia levels are not controlled. Any increase in ammonia over time is serious. Therefore, it is important to adhere to any dietary protein restrictions and have alternative medication options to help control ammonia levels. Approximately 1 in 100,000 people have UCD, and there are an estimated 800 patients who are actively treated with nitrogen scavenging therapy in the United States While there are therapies currently approved for the treatment of UCDs, there remain unmet needs for this community of patients. We believe that OLPRUVA offers benefits over other UCD treatments by eliminating issues with palatability, offering improved portability with its single-dose envelopes, and being provided in a dosage personalized to the patient based on weight.

OLPRUVA (sodium phenylbutyrate) for oral suspension is approved in the United States as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of UCDs involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). OLPRUVA for oral suspension is a proprietary and novel formulation of sodium phenylbutyrate powder, packaged in pre-measured single-dose envelopes, that has shown bioequivalence to existing sodium phenylbutyrate powder but with a pH-sensitive polymer coating that is designed to minimize dissolution of the coating for up to five minutes after preparation to help minimize the unpleasant taste of the sodium phenylbutyrate powder.

In the fourth quarter of 2023, we began generating revenue from the sale of OLPRUVA in the United States. Zevra has a partnership with Relief Therapeutics SA (“Relief”), which has rights to commercialize OLPRUVA in various European countries, if approved. For the year ended December 31, 2025, we had $0.8 million in revenue from sales of OLPRUVA. We have made the decision to scale back our sales and marketing efforts for OLPRUVA as we evaluate the path forward and weigh strategic alternatives.

OLPRUVA summary:

- ***OLPRUVA is available in the U.S for the treatment of certain types of UCDs.*** OLPRUVA is an adjunctive therapy for the chronic management of adults and children weighing 20kg or greater with UCD from deficiencies of CPS, OTC, or AS.

- ***OLPRUVA is differentiated from currently available forms of phenylbutyrate.*** OLPRUVA is formulated to improve palatability while providing patients with a portable and discrete pre-measured dose.

- ***Currently evaluating strategic alternatives.*** We have had limited success in commercializing OLPRUVA in the United States, and we are currently evaluating the path forward and weighing strategic alternatives.

***Celiprolol***

Ehlers-Danlos Syndrome (EDS) is a rare inherited disorder caused by mutations in the genes responsible for the structure, production, or processing of collagen, an important component of the connective tissues in the human body, or proteins that interact with collagen. VEDS is the most severe of the 13 types of EDS and causes abnormal fragility in large to medium sized arteries and hollow organs, such as the uterus and colon. This fragility can result in aneurysms, abnormal connections between blood vessels known as arteriovenous fistulas, arterial dissections, and spontaneous vascular and organ ruptures, all of which can be potentially life-threatening. The incidence of VEDS is estimated to be one in 50,000 to 200,000 people. There are approximately 7,500 patients in the United States.

We are advancing celiprolol as an investigational product candidate for the treatment of VEDS in patients with a confirmed type III collagen (COL3A1) mutation. Celiprolol is a selective adrenoceptor modulator ("SAM") that we believe would qualify as a new chemical entity ("NCE") if approved in the United States. Celiprolol is currently approved in certain EU states for the treatment of hypertension and angina.

Currently, there are no approved therapies anywhere in the world for VEDS. However, celiprolol, prescribed off label, has become the standard of care therapy for VEDS in some European countries. Medical intervention for VEDS focuses on surgery, symptomatic treatment, genetic counseling, and prophylactic measures, such as avoiding intense physical activity, scuba diving, and violent sports. Therefore, patients must adopt a "watch and wait" approach following any confirmed diagnosis. Unfortunately, many of these arterial events have high mortality associated with them; thus, a pharmacologic intervention that reduces the rate of events would be clinically meaningful.

Celiprolol received orphan drug designation from the FDA for the treatment of VEDS in 2015. In October 2018, a new celiprolol NDA was submitted to the FDA by Acer based on data obtained from the BBEST trial and was subsequently accepted by the FDA in October 2018 with priority review status. Following FDA review, Acer received a complete response letter ("CRL") from the FDA stating that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with VEDS. Subsequently, Acer appealed the FDA decision. While the FDA denied the appeal, it described possible paths forward toward approval. In a May 2021 Type B meeting with the FDA, Acer discussed the conduct of a U.S.-based prospective, randomized, double-blind, placebo-controlled, decentralized clinical trial in patients with COL3A1 positive VEDS and sought the FDA's opinion on various proposed design features of the study.

Based on the FDA's feedback during the Type B meeting, Acer adopted a decentralized (virtual) event-based clinical trial design and use of an independent centralized adjudication committee with a primary endpoint based on clinical events associated with disease outcome. In April 2022, the FDA granted celiprolol Breakthrough Therapy designation in the United States for the treatment of patients with COL3A1-positive VEDS.

In July 2022, Acer initiated enrollment in a Phase 3 long-term event-driven clinical trial designed based on the discussions from the May 2021 Type B meeting with the FDA, also known as the DiSCOVER trial. The DiSCOVER trial intends to enroll 150 VEDS patients, with 100 patients receiving celiprolol and 50 patients receiving placebo. Recruitment in the Phase-3 trial was restarted mid-2024 and the trial has 52 enrolled participants as of December 31, 2025. We believe that celiprolol could address significant unmet needs, as there are currently no approved treatments for VEDS in the U.S. We have implemented a broad recruitment drive focusing on collaborating with medical clinics where most patients are being managed. In parallel, we are engaging with the FDA to discuss regulatory options to accelerate the development program.

Celiprolol summary:

- ***Currently, no approved treatments for VEDS in the United States.*** There are currently no approved treatments for VEDS in the United States, and we believe that celiprolol, if approved, could be a significant innovation in the treatment of VEDS where current treatment options are focused primarily on surgical intervention.
- ***Unique pharmacological profile.*** Mechanism of action in VEDS patients is thought to be through vascular dilatation and smooth muscle relaxation, the effect of which is to reduce the mechanical stress on collagen fibers in the arterial wall, potentially resulting in less incidence of vascular and hollow organ ruptures.
- ***Evidence of efficacy in Europe and extensive clinical experience from multiple trials.*** Celiprolol has become the primary treatment for VEDS patients in several European countries. BBEST Clinical Trial data showed 76% reduction in risk of arterial events observed in COLA3A1+ subpopulation, with additional data from a long-term observational study in France.
- ***Regulatory designations.*** Celiprolol for VEDS has been granted Orphan Drug designation and Breakthrough Therapy designation and, we believe, would be deemed an NCE in the United States if approved before any other celiprolol product.

- ***Solid patent protection through 2038.*** Celiprolol is generally protected by U.S. patents that will expire, after utilizing all appropriate patent term adjustments but excluding possible term extensions, in 2038.

***KP1077***

Idiopathic hypersomnia ("IH") is a rare neurological sleep disorder affecting approximately 37,000 patients in the United States. The cardinal feature of IH is excessive daytime sleepiness ("EDS"), characterized by daytime lapses into sleep, or an irrepressible need to sleep that persists even with adequate or prolonged nighttime sleep. Additionally, those with IH have extreme difficulty waking, otherwise known as "sleep inertia," suffer from severe and debilitating brain fog, and may fall asleep unintentionally or at inappropriate times, also known as narcolepsy. These symptoms often further lead to reported memory problems, difficulty maintaining focus, and depression.

Narcolepsy is a rare, chronic, debilitating neurologic disorder of sleep-wake state instability that impacts up to 200,000 Americans and is primarily characterized by EDS and cataplexy (sudden loss of muscle tone while a person is awake) along with other manifestations of rapid eye movement and sleep dysregulation, which intrude into wakefulness. In most patients, narcolepsy is caused by the loss of hypocretin, a neuropeptide in the brain that supports sleep-wake state stability. Typical symptom onset occurs in adolescence or young adulthood, but it can take up to a decade to be properly diagnosed. Although there are several approved medications for narcolepsy, we believe a treatment option based on serdexmethylphenidate ("SDX"), our proprietary prodrug of d-methylphenidate ("d-MPH"), which has previously been classified as a Schedule IV controlled substance, may be beneficial.

KP1077, which utilizes SDX, our prodrug of d-MPH, as its active pharmaceutical ingredient, is being developed and evaluated for the treatment of IH and narcolepsy.

In December 2022, we announced the initiation of a double-blind, placebo-controlled, randomized-withdrawal, dose-optimizing, multicenter Phase 2 clinical trial evaluating the efficacy and safety of KP1077 for the treatment of IH. The trial concluded in March 2024 and provided meaningful information of the optimal dose and dosing regimen to inform Phase 3 trial design.

Clinically meaningful improvements were observed across all endpoints studied. The exploratory endpoints of sleep inertia and brain fog performed in-line with expectations and were stable when compared across a variety of other endpoints. Symptom improvements in patients receiving KP1077 were similar after both once-per-day and twice-per-day dosing.

KP1077 summary:

- ***No drug-to-drug interactions observed to date.*** We have not observed drug-to-drug interactions in clinical drug-drug interaction studies.

- ***Possible reduction of abuse potential as a Schedule IV controlled substance.*** All other methylphenidate-based products have been designated as Schedule II controlled substances, which indicates stricter control over the prescribing and use of such products. KP1077's sole active pharmaceutical ingredient is SDX, which has been designated a Schedule IV controlled substance.

- ***No currently approved generic equivalent product.*** KP1077 contains SDX, our proprietary prodrug of d-methylphenidate, also known as the new chemical name, serdexmethylphenidate, by the U.S. Adopted Names Council of the American Medical Association, which means that there may be no generic equivalent product for KP1077 in most states, making drug-equivalent substitution potentially difficult at the pharmacy.

- ***Orphan drug designation.*** Because the size of the IH patient population is small, the FDA has granted KP1077 orphan drug designation for the treatment of IH. We believe KP1077 may potentially be eligible for fast-track and breakthrough therapy designation, which may provide various regulatory benefits for the development program.

***AZSTARYS (partnered product)***

AZSTARYS contains d-MPH and our prodrug of d-MPH, SDX. On March 2, 2021, the FDA approved AZSTARYS as a once-daily treatment for attention deficit hyperactivity disorder (ADHD) in patients age six years and older. AZSTARYS is currently being marketed in the United States under our September 2019 collaboration and license agreement (the "AZSTARYS License Agreement") with Commave. Under the AZSTARYS License Agreement, we granted Commave an exclusive, worldwide license, to develop, manufacture, and commercialize AZSTARYS and any of our product candidates containing SDX and used to treat ADHD or any other CNS disease.

Commave has tasked its affiliate, Corium, Inc. ("Corium"), to lead all commercialization activities for AZSTARYS in the United States. Corium commercially launched AZSTARYS in the United States during the third quarter of 2021. In December 2021, Commave entered into a sublicense of commercialization rights for AZSTARYS in greater China to Shanghai Ark Biopharmaceutical Ltd.

Pursuant to the AZSTARYS License Agreement, Commave agreed to pay up to $63.0 million in milestone payments upon the occurrence of specified regulatory milestones related to AZSTARYS, including FDA approval and specified conditions with respect to the final approval label. In addition, Corium agreed to make additional payments upon the achievement of specified U.S. sales milestones of up to $420.0 million in the aggregate. Further, Commave will pay us quarterly, tiered royalty payments based on a percentage of net sales on a product-by-product basis. Corium also agreed to be responsible for and reimburse us for all of development, commercialization and regulatory expenses for any products or product candidates containing SDX, subject to certain limitations as set forth in the AZSTARYS License Agreement, including consultation fees to be paid to us for services provided to Corium in performing such activities.

In April 2021, we entered into the AZSTARYS Amendment ("AZSTARYS Amendment"), pursuant to which we and Commave agreed to modify the compensation terms of the AZSTARYS License Agreement. Commave paid us $10.0 million in connection with the execution of the AZSTARYS Amendment following the FDA approval of AZSTARYS in the United States. Corium also paid us $10.0 million following the SDX scheduling determination by the DEA, which occurred on May 7, 2021. In addition, the AZSTARYS Amendment increased the total remaining future regulatory and sales milestone payments related to AZSTARYS up to an aggregate of $590.0 million. The AZSTARYS License Agreement will continue on a product-by-product basis (i) until expiration of the royalty term for the applicable product candidate in the United States and (ii) perpetually for all other countries.

In May 2021, we announced that SDX, our proprietary prodrug of d-MPH and the primary active pharmaceutical ingredient in AZSTARYS, was classified as a Schedule IV controlled substance by the DEA. AZSTARYS is classified as a Schedule II controlled substance, as its formulation includes a 70:30 mixture of SDX (Schedule IV) and d-MPH (Schedule II), respectively.

**Our Intellectual Property**

Our intellectual property ("IP") strategy includes seeking composition-of-matter patents, among other patents, for compounds and product candidates while also protecting, where appropriate as trade secrets, our proprietary technologies. In utilizing these technologies, the resulting compounds may potentially constitute a new molecule and thus may be eligible for composition-of-matter patent protection, among other patent protections, in the United States and abroad. Beyond our internally-generated IP, we have also acquired extensive IP portfolios through our business development efforts which support the products and product candidates that we are seeking to develop and/or commercialize.

In addition to the execution of our IP strategy, we also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. We also rely on trade secret protection, assignments and confidentiality agreements to protect our interests.

As of December 31, 2025, we have been granted and maintain about 87 active patents within the United States, and about an additional 497 active foreign patents covering our selected prodrugs and product candidates. The terms of the issued U.S. patents extend to various dates ranging, for example, between at least 2029 and 2042. The term of our overall domestic and foreign patent portfolio related to our selected prodrugs and product candidates, including patent term adjustments but excluding possible patent term extensions, extend to various dates ranging, for example, between 2029 and 2044, if pending patent applications in each of our patent families are issued as patents. As of December 31, 2025, we had about 51 pending patent applications under active prosecution in the United States, and about an additional 250 pending foreign patent applications potentially covering our selected prodrugs and product candidates. Our issued and granted patents provide protection in jurisdictions that include the United States, Australia, Canada, Chile, China, European countries, Hong Kong, India, Indonesia, Israel, Japan, Kazakhstan, Malaysia, Mexico, New Zealand, Philippines, Romania, Russia, Singapore, South Africa, South Korea, and Vietnam.

***MIPLYFFA (arimoclomol)***

Pursuant to our acquisition of the Orphazyme assets, we have received method of use and method of treatment patents, and have filed related patent applications, related to the arimoclomol families in various jurisdictions, including the United States, European countries, Israel, Japan, South Korea, Canada, China, Brazil, Russia and Turkey, with anticipated patent expiration dates of 2029, excluding any potential patent term adjustments or extensions. We have filed and continue to file additional patent applications related to the arimoclomol families, including next generation of arimoclomol prodrug conjugate compounds which would have, if granted, an anticipated patent expiration date of about 2044, excluding any potential patent term adjustments or extensions. As of December 31, 2025, the MIPLYFFA related family included 13 granted U.S. patents and 38 active foreign patents, with an additional 11 pending U.S. patent applications and 73 foreign patent applications.

***OLPRUVA (sodium phenylbutyrate)***

We acquired the IP portfolio supporting OLPRUVA as part of the Merger with Acer. We have both U.S. and foreign patents with claims related to OLPRUVA. Our U.S. patents are directed to pharmaceutical compositions, including OLPRUVA's polymer coated, multi-particulate dosage formulation for oral administration and covers certain methods of use claims related to OLPRUVA. Additionally, we have patents in Europe, Israel, and Mexico related to pharmaceutical compositions, including OLPRUVA's polymer coated, multi-particulate dosage formulation for oral administration. These patents expire in 2036.

Furthermore, we have exclusive rights to certain patents and other intellectual property from Baylor College of Medicine ("BCM") for the use of sodium phenylbutyrate (NaPB) for the treatment of inborn errors of BCAA metabolism, including Maple Syrup Urine Diease ("MSUD"), with the latest patent expiring in 2032. Additionally, we have a combination therapeutic product composed of sodium phenylbutyrate or glycerol phenylbutyrate and sodium benzoate, which was exclusively licensed to Acer from BCM, which has an expiration date in June 2038. We made filings in the geographic regions that represent the largest incidence and prevalence of MSUD, including the United States, selected countries in Europe (including Turkey), and Brazil. BCM has received three patents in the United States and one in the EU with respect to OLPRUVA, each of which is exclusively licensed to us pursuant to our agreement with BCM.

***Celiprolol***

We intend to protect our commercial rights for celiprolol in the United States via multiple pathways. We believe celiprolol will be eligible for NCE exclusivity which provides upon approval as an NCE five years of marketing exclusivity, during which time the FDA will not approve another drug with the same active ingredient, regardless of the indication for use, in the United States. In January 2015, the FDA granted celiprolol Orphan Drug designation, which provides seven years of marketing exclusivity for a drug intended to treat a rare condition, if approved. During the Orphan Drug exclusivity period, the FDA cannot approve the same drug for the same indication, unless it demonstrates clinical superiority. Orphan Drug exclusivity does not prevent the FDA from approving the same drug for a different indication, or a different drug for the same indication. NCE exclusivity and Orphan Drug exclusivity periods run concurrently. Furthermore, celiprolol may qualify for an additional six months of pediatric exclusivity in the United States, which requires the submission of one or more studies in pediatric subjects that meet requirements to be specified by the FDA in a written request for pediatric studies. Pediatric exclusivity can be obtained either before or after NDA approval. Pediatric exclusivity is attached to the end of an existing exclusivity and runs consecutively. We may also consider making modifications to the formulation in order to improve the product profile and to seek additional intellectual property. While unapproved drugs may be imported into the United States under specified circumstances, such as for use in clinical studies under a valid and effective investigational new drug ("IND") or for further manufacture into an IND drug or an approved drug, we intend to aggressively assert our rights, via regulatory and legal means, to limit the importation of non-FDA approved versions of celiprolol.

We have exclusively licensed from Assistance Publique—Hôpitaux de Paris (AP-HP) a now-issued U.S. patent (US 11,523,997) titled "Method of Providing Celiprolol Therapy to a Patient," with an expiration date in November 2038, excluding any potential patent term extension, which covers certain methods for treating VEDS with celiprolol. There is also one granted patent in Mexico, and further pending applications in various jurisdictions, including the United States, Mexico, Canada, and Brazil.

***AZSTARYS and Serdexmethylphenidate (SDX)***

We have received composition-of-matter patents and also additionally filed composition-of-matter and method of treatment patent applications related to the AZSTARYS and SDX families in the United States and in Argentina, Australia, Brazil, Canada, Chile, China, Egypt, Hong Kong, European Countries, India, Israel, Indonesia, Japan, South Korea, Kazakhstan, Mexico, Malaysia, New Zealand, Philippines, Russia, Singapore, South Africa, Thailand, Ukraine, and Vietnam. We anticipate filing additional patent applications for our prodrugs and product candidates covering SDX and KP1077.

***License Agreements***

*XOMA License Agreement (MIPLYFFA)*

In May 2022, we purchased all the assets and operations of Orphazyme related to arimoclomol. Prior to this acquisition, Orphazyme had entered into an asset purchase agreement with LadRx Corporation, which was assigned to XOMA (US) LLC, a wholly-owned subsidiary of XOMA Corporation ("XOMA"), in June 2023 ("XOMA License Agreement"). Under the XOMA License Agreement, XOMA is entitled to a mid-single digit percentage royalty with respect to net sales of MIPLYFFA as well as milestone payments based on future potential sales and regulatory milestones, including a $4.0 million regulatory milestone payment upon approval in the E.U.

*Relief License Agreement (OLPRUVA)*

In connection with our acquisition of Acer, Acer and Relief entered into an exclusive license agreement on August 30, 2023 (the "Relief License Agreement"), which was assumed by Zevra. Pursuant to the Relief License Agreement, Zevra is obligated to pay royalties of 10% of U.S. net sales up to a maximum of $45.0 million, plus specified regulatory milestones, for total payments to Relief of up to $56.5 million. On April 10, 2025, the rights to this royalty were sold to Soleus Capital Management L.P.

Pursuant to the Relief License Agreement, Relief will hold exclusive development and commercialization rights for OLPRUVA in the EU, Liechtenstein, San Marino, Vatican City, Norway, Iceland, Principality of Monaco, Andorra, Gibraltar, Switzerland, United Kingdom, Albania, Bosnia, Kosovo, Montenegro, Serbia and North Macedonia ("Geographical Europe"). We have the right to receive a royalty of up to 10% of the net sales of OLPRUVA in Geographical Europe.

*Aquestive Termination Agreement (AZSTARYS)*

Under our March 2012 termination agreement with Aquestive Therapeutics ("Aquestive"), Aquestive has the right to receive a royalty amount equal to 10% of any value generated by AZSTARYS and any product candidates containing SDX. We pay Aquestive a royalty equal to 10% of the quarterly royalty payments and of the regulatory and net sales milestones we receive from Commave under the AZSTARYS License Agreement.

**Commercialization**

To support the launch of MIPLYFFA and OLPRUVA, we have built in-house capabilities including rare disease sales specialists who are working with prescribing clinicians and healthcare providers, as well as marketing, patient reimbursement services, market access and contracting, patient advocacy, and medical affairs teams. We continue to engage with commercial payers and governmental organizations to gain access for MIPLYFFA and OLPRUVA. We have established promotional programs to drive awareness and patient experience with MIPLYFFA and OLPRUVA including Quick Start, a thirty-day free trial program designed to provide patient experience, and other patient co-pay programs, reflecting our commitment to ensure access to innovative treatments to those in need.

We currently have an arrangement with a specialty pharmacy provider as the distributor for sales of our approved products. We, however, may establish additional specialty distributors or other retail pharmacies and certain medical centers or hospitals. In addition to distribution agreements, we may enter into arrangements with health care providers and payors that provide for government mandated and/or privately negotiated rebates with respect to the purchase of our products.

Commave's affiliate, Corium, is leading the commercialization of AZSTARYS in the United States under the AZSTARYS License Agreement. Corium commercially launched AZSTARYS in the United States in July 2021. In December 2021, Commave sublicensed to Shanghai Ark Biopharmaceutical Co., Ltd. the commercialization rights in Greater China, including mainland China, Hong Kong, Macau and Taiwan.

We have established a targeted commercial team which is designed to fully service the patients and prescribers within the rare disease indications for which we are successful in gaining approval for our product candidates. However, if our product candidates have large potential market opportunities that would require significant marketing resources, we may conclude that the most appropriate approach to their commercialization, if they receive regulatory approval, will involve forming a commercial collaboration or strategic relationship similar to those we have entered into with Commave, or consummating some type of strategic transaction, with a larger pharmaceutical or other marketing organization. As we get closer to potential approval of our product candidates, we will work to identify and implement the most appropriate commercialization strategies that we conclude are the most desirable with regard to each specific product candidate.

**Competition**

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We will face competition and potential competition from any number of pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, drug delivery companies and academic and research institutions. Our competitors may develop or market drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products or product candidates and these competitors may also have significantly more resources than us and be more successful than us in manufacturing and marketing their products. We anticipate facing intense and increasing competition as new products enter the market and advanced technologies become available.

***MIPLYFFA***

Soon after approval of MIPLYFFA, the FDA approved a second therapy for NPC, AQNEURSA, which is approved for the treatment of neurological manifestations of NPC in adults and pediatric patients weighing ≥15 kg and is marketed by IntraBio, Inc. While AQNEURSA has a similar indication, data included on its label has a different clinical endpoint and safety profile from MIPLYFFA. We are also aware that there are several other drug candidates in clinical development for the treatment of NPC. These include adrabetadex (Mandos), and cyclodextrin (Cyclo Therapeutics). We believe MIPLYFFA's clinical profile, mechanism of action, and development program differentiate it within the emerging NPC treatment landscape.

***OLPRUVA***

OLPRUVA competes against several currently marketed, branded and generic forms of phenylbutyrate. In particular, RAVICTI, which is marketed by Amgen Inc. (formerly Horizon Therapeutics), and PHEBURANE, which is marketed by Medunik USA. We are also aware that there are drug candidates in clinical development for the potential treatment of UCDs. In addition, authorized generics of RAVICTI, marketed by Par and Lupin, entered the market in the fourth quarter of 2025.

***Celiprolol***

We are not aware of any active ongoing clinical trials for the treatment of VEDS.

***KP1077***

If approved, we intend for KP1077 to compete against XYWAV, marketed by Jazz Pharmaceuticals, and potentially with other products that are currently in development for the treatment of IH. KP1077 could face potential competition from any products for the treatment of IH that are currently in or which may enter into clinical development.

***AZSTARYS***

AZSTARYS competes against currently marketed, branded and generic methylphenidate products for the treatment of ADHD. Some of these currently marketed products include CONCERTA, marketed by J&J Innovative Medicines (formerly Jannsen), QUELBREE, marketed by Supernus Pharmaceuticals, Inc., QUILLIVANT XR and QUILLICHEW ER, marketed by Tris Pharma, RITALIN, FOCALIN and FOCALIN XR, marketed by Novartis AG, METADATE CD, marketed by UCB SA, DAYTRANA, marketed by Noven Therapeutics, LLC, Neos Therapeutics' CONTEMPLA XR-ODT, marketed Aytu BioScience, Inc., JORNAY PM, marketed by Collegium Pharmaceutical Inc. (formerly Ironshore), and ADHANSIA XR, marketed by Adlon Therapeutics, in addition to multiple other branded and generic methylphenidate products. In addition, AZSTARYS will face potential competition from any other methylphenidate products for the treatment of ADHD that are currently in, or which may enter into clinical development.

Many of our competitors either alone or with strategic partners, have or will have substantially greater financial, technical, and human resources compared with us. Accordingly, our competitors may be more successful in developing or marketing products and technologies that are more effective, safer or less costly. Additionally, our competitors may obtain regulatory approval for their products more rapidly and may achieve more widespread market acceptance. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. There are other non-pharmaceutical therapeutic approaches that are used or may be used for our targeted indications.

**Manufacturing**

Our manufacturing strategy is to rely on contract manufacturers to produce our approved products and product candidates for clinical trials and, if approved, drug product for commercial sale. We currently have no manufacturing facilities and limited personnel in our manufacturing department. We have contracted with third parties for the manufacture, testing, and storage of our approved products and product candidates and intend to continue to do so in the future. We expect to contract with third-party manufacturers for the manufacture of all API supply needs outside the United States if and when we receive approval from regulatory authorities outside the United States.

Our current and any future third-party manufacturers, their facilities and all lots of drug substance and drug products used in our clinical trials are required to be in compliance with current good manufacturing practices ("cGMPs") and comparable foreign regulations. The cGMP and comparable foreign regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP and comparable foreign requirements and FDA and foreign regulatory authorities' satisfaction before any product is approved and we can manufacture commercial products. Our current and any future third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

Failure of third-party manufacturers to comply with statutory and regulatory requirements may subject us to possible legal or regulatory action, including refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreements to resolve allegations of non-compliance with these laws, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and individual imprisonments.

**Third-Party Payor Coverage and Reimbursement**

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governmental authorities, including those that administer the Medicare and Medicaid programs, and private managed care organizations and health insurers. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product and product candidates is and will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Each third-party payor determines whether or not it will provide coverage for a drug, what amount it will pay providers for the drug, and on what tier of its formulary the drug will be placed. These decisions are influenced by the existence of multiple drug products within a therapeutic class and the net cost to the plan, including the amount of the prescription price, if any, rebated by the drug's manufacturer. Typically, generic versions of drugs are placed in a preferred tier. The position of a drug on the formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. As a result, coverage, reimbursement and placement determinations are complex and are often the subject of extensive negotiations between the payer and the manufacturer of the drug.

Unless we enter into a strategic collaboration under which our collaborator assumes responsibility for seeking coverage and reimbursement for a given product, we will be responsible for negotiating coverage, reimbursement and placement decisions for our product candidates, if approved. Coverage, reimbursement and placement decisions for a new product are based on many factors including the coverage, reimbursement and placement of already marketed branded drugs for the same or similar indications, the safety and efficacy of the new product, availability of generics for similar indications, the clinical need for the new product and the cost-effectiveness of the product. Increasingly, both purchasers and payors are also conducting comparative clinical and cost effectiveness analyses involving application of metrics, including data on patient outcomes, provided by manufacturers.

Within the Medicare program, as self-administered drugs, our product and product candidates would be reimbursed under the expanded prescription drug benefit known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These plans develop formularies that determine which products are covered and what co-pay will apply to covered drugs. The plans have considerable discretion in establishing formularies and tiered co-pay structures, negotiating rebates with manufacturers and placing prior authorization and other restrictions on the utilization of specific products, subject to review by the Centers for Medicare & Medicaid Services ("CMS"), for discriminatory practices. These Part D plans negotiate discounts with drug manufacturers, which are passed on, in whole or in part, to each of the plan's enrollees through reduced premiums.

In order for reimbursement to be available for our products under Medicare or Medicaid, we participate in and have rebate obligations under the Medicaid Drug Rebate Program and are enrolled in the 340B drug pricing program, as well as the U.S. Department of Veterans Affairs Federal Supply Schedule pricing program. The programs we participate in, as well as our obligations under these programs, are described under the risk factor *"If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and fines."*

Third-party payers, including the U.S. government, continue to apply downward pressure on the reimbursement of pharmaceutical products. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations may result in lower reimbursement for pharmaceutical products. We expect that these trends will continue as these payors implement various proposals or regulatory policies, including various provisions of the recent health reform legislation that affect reimbursement of these products. There are currently, and we expect that there will continue to be, a number of federal, state and foreign proposals to implement controls on reimbursement and pricing, directly and indirectly.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, in the EU, pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA") which is currently governed by the national laws of the individual EU member states, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably. Historically, products launched in the EU do not follow the price structures which prevail in the United States, and generally, prices tend to be significantly lower.

**U.S. Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. The pharmaceutical products that we develop must be approved by the U.S. Food and Drug Administration ("FDA") before they may be legally marketed in the United States.

***U.S. Pharmaceutical Product Development Process***

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug and Cosmetic Act ("FDCA") and implementing regulations. Pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial enforcement. FDA noncompliance enforcement could include a refusal to review and or approve pending applications, withdrawal of an approval, a clinical study hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any regulatory enforcement action could have a material adverse effect on us.

The process required by the FDA before a non-biological pharmaceutical product may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices ("GLP"), and other applicable regulations;

- Submission of an Investigational New Drug application ("IND"), which must become effective before human clinical studies may begin;

- Conduct of adequate and well-controlled human clinical studies according to current Good Clinical Practices ("GCP"), to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;

- Submission of a New Drug Application ("NDA") for a new pharmaceutical product;

- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with s current Good Manufacturing Practice standards ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength, quality and purity;

- Potential FDA inspection of the preclinical and clinical study sites that generated the data in support of the NDA; and

- FDA review and approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any pharmaceutical product with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the pharmaceutical product candidate. These early studies are conducted using sound scientific procedures and require thorough documentation. The conduct of a single and repeat dose toxicology and toxicokinetic studies in animals must comply with federal regulations and requirements including GLP. The pharmaceutical product sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND becomes effective 30 days after receipt by the FDA, unless the FDA has concerns and notifies the sponsor. In such a case, the IND sponsor must resolve any outstanding concerns to the satisfaction of FDA before a clinical study can begin. If resolution cannot be reached within the 30-day review period, FDA can place the IND on clinical hold, or the sponsor may withdraw the application. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical studies due to safety concerns or regulatory non-compliance. Accordingly, it is not certain that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that can lead to the suspension or termination of such clinical studies.

During the development of a new drug, sponsors are given opportunities to meet with the FDA to discuss progress. These meeting may occur prior to submission of an IND, at the end of Phase 2 clinical development, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the sponsor to ask specific questions of the FDA, for the FDA to provide advice, and for the sponsor and FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical (registration) trial(s) that they believe will support approval of the new drug. A sponsor may be able to request a Special Protocol Assessment ("SPA"), the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analyses that will form the primary basis of an efficacy claim.

According to FDA guidance for industry on the SPA process, a sponsor which meets the prerequisites may make a specific request for a SPA and provide information regarding the design and size of the proposed clinical trial. The FDA's goal is to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the IND record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began.

***Conducting Clinical Trials***

Clinical trials are voluntary research studies involving the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, typically physicians independent of the clinical study sponsor's control. Clinical studies are conducted according to protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, how the results will be analyzed and presented and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical studies must be conducted in accordance with GCP requirements. Further, each clinical study must be reviewed and approved by an independent institutional review board ("IRB"), at, or servicing, each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and is tasked with considering such items as whether the safety risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB approves the informed consent that must be provided to each clinical study subject or his or her legal representative and will also monitor the clinical study to ensure patient safety until completed.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase 1* - The pharmaceutical product is initially administered to healthy volunteers and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.

- *Phase 2* - The pharmaceutical product is studied in a limited patient population with the disease or condition to evaluate its effectiveness for a particular indication or indications and to determine the common short-term side effects and risks associated with the product.

- *Phase 3* - Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit of the product and provide an adequate basis for product labeling. The studies must be well-controlled and usually include a control arm for comparison. One or two Phase 3 studies may be required by the FDA for an NDA, depending on the disease severity and other available treatment options.

- Post-approval studies, or Phase 4 clinical studies, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

- Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must include methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

***U.S. Review and Approval Processes***

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or a supplement thereof must contain data to assess the safety and effectiveness of the pharmaceutical product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any pharmaceutical product for an indication for which orphan designation has been granted. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel pharmaceutical products or pharmaceutical products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the pharmaceutical product approval process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS"), is necessary to assure the safe use of the pharmaceutical product. If the FDA concludes that a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs. If the FDA determines the application, manufacturing process or manufacturing facilities, or clinical study sites are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. In addition, the FDA will require the review and approval of product labeling.

The NDA review and approval process is lengthy and involved and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor interprets the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies.

Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess pharmaceutical product safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

***Expedited Development and Review Programs***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new pharmaceutical products that meet certain criteria. Specifically, new pharmaceutical products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. The Fast Track designation must be requested by the sponsor. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. With a Fast Track designated product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, if the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and if the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for marketing approval, including a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new pharmaceutical product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Pharmaceutical products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that the products may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a pharmaceutical product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

***Breakthrough Therapy Designation***

The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation (ODD) provides for seven years of market exclusivity, independent of patent protection, to the company with ODD that brings a particular product to market. In addition, companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing.

To gain exclusivity, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to the orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same approved use or indication within such rare disease or condition for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. Orphan drug exclusivity could block the approval of one of our product candidates for seven years if a competitor obtains approval for a drug or biologic with the same active moiety for the same approved use or indication within the rare disease or condition before we do, unless we are able to demonstrate that our product is clinically superior.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the approved use or indication within the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first, approved product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation, and only the first sponsor that obtains approval for that drug for the orphan indication will obtain market exclusivity, effectively preventing the FDA from approving products under development by competitors for a drug or biologic for the same approved use or indication, unless the competitor is able to demonstrate that the product under development is clinically superior to the approved product or the approved product is not available in sufficient quantities. To permit the FDA to end another manufacturer's orphan exclusivity period, the FDA must determine that the manufacturer has demonstrated clinical superiority by showing the later drug is safer, more effective, or otherwise makes a major contribution to patient care.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the approved use or indication within the rare disease or condition for which the product has been designated. The FDA may approve a second application for the same product for a different use or a subsequent application for a different drug for the same indication. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process..

We may plan to pursue orphan drug designation and exclusivity for some of our product candidates in the United States, European Union, and other geographies of interest for specific products. We cannot guarantee that we will obtain orphan drug designation for any products in any jurisdiction. Even if we are able to obtain orphan drug designation for a product, we cannot be sure that such product will be approved, that we will be able to obtain orphan drug exclusivity upon approval, if ever, or that we will be able to maintain any exclusivity that is granted.

***Post-Approval Requirements***

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual human prescription drug program fee requirements for approved products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort on production and quality control to maintain cGMP compliance.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act also imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and individual imprisonment. Any of these sanctions could result in adverse publicity, among other adverse consequences.

***Rare Pediatric Disease Priority Review Voucher Program***

In 2012, the U.S. Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the United States within one year following the date of approval.

For purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare diseases or conditions within the meaning of the Orphan Drug Act. Congress has only authorized the Rare Pediatric Disease Priority Review Voucher program until September 30, 2029. Consequently, unless Congress reauthorizes the program, the sponsor of a marketing application for a drug that receives Rare Pediatric Disease Designation will only be eligible to receive a voucher if the FDA grants the designation on or before September 30, 2029.

***DEA Regulation***

Our products and certain of our product candidates are, or if approved, will be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970 ("CSA"), and the DEA's implementing regulations, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are directly applicable to us and also applicable to our contract manufacturers and to distributors, prescribers and dispensers of our products and product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Schedule II drugs are those that meet the following criteria:

- the drug has a high potential for abuse;
- the drug has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and
- abuse of the drug may lead to severe psychological or physical dependence.

***Other Healthcare Regulatory Frameworks***

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education and other activities are subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the U.S. Department of Health and Human Services and its various divisions, including the CMS and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense and state and local governments. Our business activities must comply with numerous healthcare laws, including those described below. Compliance with government regulations requires the expenditure of substantial time and financial resources.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it to have committed a violation.

The federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim for payment of items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

Additionally, the federal Physician Payments Sunshine Act and its implementing regulations, require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, such providers and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members.

Depending on the circumstances, failure to comply with these laws can result in significant penalties, including criminal, civil and/or administrative penalties, damages, fines, disgorgement, debarment from government contracts, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from government programs, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our business.

***Data Privacy and Security Law***

We are subject to data privacy and security laws, regulations, and standards by foreign, federal, state and local governments that govern the collection, use, access to, confidentiality and security of health-related and other personal information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

***Healthcare Reform Measures***

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, in March 2010, the ACA was passed, which has substantially changed health care financing by both governmental and private insurers, and significantly affected the U.S. pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, expanded the 340B program which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment there have been executive, judicial and congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2032 with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional Congressional action is taken. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. On August 16, 2022, the Inflation Reduction Act ("IRA"), of 2022, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price increase reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for healthcare product candidates and services, which could result in reduced demand for our products or additional pricing pressures.

On December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022, and has been applicable since January 2025, with a phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It permits EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

***The Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

**Foreign Regulation**

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulation.

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

***EU Non-clinical Studies and Clinical Trials***

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice ("GLP") as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on Good Clinical Practices as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation ("CTR") which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application ("CTA") to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice ("GMP"). Other national and EU-wide regulatory requirements may also apply.

***EU Marketing Authorization***

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization ("MA"). To obtain regulatory approval of a product candidate under EU regulatory systems, we must submit a MA application ("MAA"). The process for this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MAs" are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") and are valid throughout the EU. The centralized procedure is compulsory for certain types of medicinal products such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products ("ATMPs") (such as gene therapy, somatic cell therapy and tissue engineered products) and (iv) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases or autoimmune diseases and other immune dysfunctions, and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the above-described procedures, in order to grant the MA, the EMA or the competent authorities of the EU member states make an assessment of the risk benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. MAs have an initial duration of five years. After these five years, the authorization may be renewed based on a reevaluation of the risk-benefit balance.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

***EU Data and Marketing Exclusivity***

In the EU, new products authorized for marketing (i.e., reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications, which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

***EU Orphan Medicinal Products***

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan designation must be requested before submitting an MAA. An EU orphan designation entitles a party to incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to ten years of market exclusivity for the approved indication, which means that the competent authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar medicinal product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan ("PIP"). No extension to any supplementary protection certificate can be granted based on pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan destination, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

***EU Pediatric Development***

In the EU, MAAs for new medicinal products must include the results of studies conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two-year extension of the orphan market exclusivity is granted.

***EU Controlled Substances***

The EU legislation does not establish different classes of narcotic or psychotropic substances. However, the United Nations ("UN") Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971 ("UN Conventions") codify internationally applicable control measures to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes. The individual EU member states are all signatories to these UN Conventions. All signatories have a dual obligation to ensure that these substances are available for medical purposes and to protect populations against abuse and dependence. The UN Conventions regulate narcotic drugs and psychotropic substances as Schedule I, II, III, IV substances with Schedule II substances presenting the lowest relative risk of abuse among such substances and Schedule I and IV substances considered to present the highest risk of abuse. The UN Conventions require signatories to require all persons manufacturing, trading (including exporting and importing) or distributing controlled substances to obtain a license from the relevant authority. Each individual export or import of a controlled substance must also be subject to an authorization. The obligations provided in the UN Conventions and additional requirements are implemented at national level and requirements may vary from one member state to another.

**Employees**

As of December 31, 2025, we employed 61 full-time employees.

**Corporate Information**

We were incorporated under the laws of the State of Iowa in October 2006 and were reincorporated under the laws of the State of Delaware in May 2014. We changed our name from KemPharm, Inc. to Zevra Therapeutics, Inc. effective as of February 21, 2023. Our website address is www.zevra.com.

## ITEM 1A. RISK FACTORS.

**Risks Related to the Commercialization of Our Approved Products and Product Candidates**

***If we are unable to establish effective sales, marketing and distribution capabilities for our approved products, including any of our product candidates that may receive marketing approval, we may not be successful in commercializing such products in the United States or any other jurisdictions.***

We currently have limited marketing and sales experience. In order to commercialize our approved products, we have added marketing, sales, medical affairs, distribution, managerial and other non-technical capabilities, or have made arrangements with third parties to perform these services. For any of our other product candidates that receive marketing approval, we may have to augment our commercial capabilities or make arrangements with third parties to perform additional services. Building and maintaining a targeted specialty sales force is expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact our commercialization efforts. We may choose to collaborate with third parties that have their own sales forces and established distribution systems, in lieu of or to augment any sales force and distribution systems we may create. If we are unable to enter into collaborations with third parties for the commercialization of approved products on acceptable terms or at all, or if any such collaborator does not devote sufficient resources to the commercialization of our products or otherwise fails in commercialization efforts, we may not be able to successfully commercialize our approved products.

***Our approved products, as well as any of our product candidates that may receive marketing approval, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.***

Our approved products, as well as any of our product candidates that may receive marketing approval, may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of our approved products will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments, including less expensive generic treatments;
- the ability to obtain differentiating claims in the labels for approved products;
- the clinical indications for which our products are approved;
- the convenience and ease of administration compared to alternative treatments;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the cost of treatment in relation to alternative treatments;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement or willingness of patients to pay out of pocket in the absence of third-party coverage; and
- the prevalence and severity of any side effects.

If our approved products do not achieve an adequate level of market acceptance, they may not generate significant product revenue and we may not become profitable.

***Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.***

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governmental authorities, including those that administer the Medicare and Medicaid programs, and private managed care organizations and health insurers. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our products and product candidates is and will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Each third-party payor determines whether or not it will provide coverage for a drug, what amount it will pay providers for the drug, and on what tier of its formulary the drug will be placed. These decisions are influenced by the existence of multiple drug products within a therapeutic class and the net cost to the plan, including the amount of the prescription price, if any, rebated by the drug's manufacturer. Typically, generic versions of drugs are placed in a preferred tier. The position of a drug on the formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. As a result, coverage, reimbursement and placement determinations are complex and are often the subject of extensive negotiations between the payer and the manufacturer of the drug. Increasingly, both purchasers and payors are also conducting comparative clinical and cost effectiveness analyses involving application of metrics, including data on patient outcomes, provided by manufacturers.

Within the Medicare program, as self-administered drugs, our product and product candidates would be reimbursed under the expanded prescription drug benefit known as Medicare Part D. This program is a voluntary Medicare benefit administered by private plans that operate under contracts with the federal government. These plans develop formularies that determine which products are covered and what co-pay will apply to covered drugs. The plans have considerable discretion in establishing formularies and tiered co-pay structures, negotiating rebates with manufacturers and placing prior authorization and other restrictions on the utilization of specific products, subject to review by the Centers for Medicare & Medicaid Services ("CMS"), for discriminatory practices. These Part D plans negotiate discounts with drug manufacturers, which are passed on, in whole or in part, to each of the plan's enrollees through reduced premiums.

In order for reimbursement to be available for our products under Medicare or Medicaid, we participate in and have rebate obligations under the Medicaid Drug Rebate Program and are enrolled in the 340B drug pricing program, as well as the U.S. Department of Veterans Affairs Federal Supply Schedule pricing program. The programs we participate in, as well as our obligations under these programs, are described under the risk factor "*If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and fines*."

Third-party payers, including the U.S. government, continue to apply downward pressure on the reimbursement of pharmaceutical products. Also, the trend towards managed health care in the United States and the concurrent growth of organizations such as health maintenance organizations may result in lower reimbursement for pharmaceutical products. We expect that these trends will continue as these payors implement various proposals or regulatory policies, including various provisions of the recent health reform legislation that affect reimbursement of these products. There are currently, and we expect that there will continue to be, a number of federal, state and foreign proposals to implement controls on reimbursement and pricing, directly and indirectly.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, in the EU, pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA") which is currently governed by the national laws of the individual EU member states, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably. Historically, products launched in the EU do not follow the price structures which prevail in the United States, and generally, prices tend to be significantly lower.

***Because the target patient population for our products and product candidates is small, we must achieve significant market share and obtain relatively high per-patient prices for our products to achieve meaningful gross margins.***

We are focused on diseases with a small patient population. A key component of the successful commercialization of an approved product for these indications includes identification of patients and a targeted prescriber base for such product. Due to small patient populations for our products and product candidates, we believe that we would need to have significant market penetration to achieve meaningful revenues and identifying patients and targeting the prescriber base are key to achieving significant market penetration. Typically, drugs for conditions with small prevalence have higher prices in order to generate a return on investment, and as a result, the per-patient prices at which we sell our products are relatively high in order for us to generate an appropriate return for the investment in these product development programs and achieve meaningful gross margins. There can be no assurance that we will be successful in achieving a sufficient degree of market penetration and/or obtaining or maintaining high per-patient prices for products for diseases with small patient populations. Further, even if we obtain significant market share for our products, because the potential target populations are very small, we may not be able to maintain profitability despite obtaining such significant market share. Additionally, patients who discontinue therapy or do not fill prescriptions are not easily replaced by new patients, given the limited patient population.

***We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.***

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We will face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic drug companies, drug delivery companies and academic and research institutions. Our competitors may develop or market drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products or product candidates, and these competitors may also have significantly more resources than us and be more successful than us in manufacturing and marketing their products.

See Part I. Item 1. "Business—Competitors" of this Annual Report on Form 10-K for additional information regarding our competitors.

***We may be subject to enforcement action if we engage in improper marketing or promotion of our products.***

The FDA and foreign regulatory bodies closely regulate promotional materials and other promotional activities. Even if the FDA initially approves product labeling, the FDA may object to our marketing claims and product advertising campaigns. Failure to comply with the FDA's promotional, marketing and advertising laws and regulations could lead to the issuance of warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences. Similar risks exist in foreign jurisdictions. Any of these consequences would harm the commercial success of our products.

Further, our promotional materials, statements and training methods must comply with regulatory prohibitions of the promotion of unapproved, or off-label, use. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's independent choice of treatment within the practice of medicine. However, if the FDA or any other federal, state or foreign enforcement authority determines that our promotional materials, statements or training constitutes promotion of an off-label use, it could request that we modify our promotional materials, statements or training methods or subject us to regulatory or enforcement actions, such as the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, disgorgement of money, operating restrictions or criminal penalties. We may also be subject to actions by other governmental entities or private parties, such as the False Claims Act, civil whistleblower or "qui tam" actions. In that event, our reputation could be damaged and adoption of the products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims.

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our approved products, or any of our product candidates that we may develop.***

We face an inherent risk of product liability exposure related to commercializing drug products and testing our product candidates in human clinical trials. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- termination of clinical trial sites or entire trial programs;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards paid to trial participants or patients;
- product recalls, withdrawals or labeling revisions and marketing or promotional restrictions; and
- loss of revenue.

Although we maintain product liability insurance coverage, we cannot be sure that our insurance coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to product liability claims, or that such coverage will continue to be available on acceptable terms at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of a large deductible or co-insurance requirements), could have an adverse effect on our business. We may need to increase our insurance coverage as products become commercially successful. Insurance coverage is increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***Significant political, trade, regulatory developments, and other circumstances beyond our control could delay, prevent or impair our development or commercialization efforts.***

Trade policies, geopolitical disputes and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures affect regions where manufacturing and product development activities take place or raw materials are sourced. The extent and duration of any tariffs and the resulting impact on general economic conditions and on our business are uncertain and depend on various factors, such as negotiations between the United States and other countries, the response of such countries, and exemptions or exclusions that may be granted. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact supply chains. As these tensions continue to rise, more targeted approaches on certain products, industries or companies could significantly impact our development and commercialization efforts. Further, such actions by the United States could result in other retaliatory actions by those countries which could impact our ability to profitably commercialize our products in those jurisdictions. As a result, our business, operations, and financial condition could be materially harmed.

***Our product candidates may be associated with serious adverse events, undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.***

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approvals by the FDA or other comparable foreign regulatory authorities. If any serious adverse events occur, clinical trials could be suspended or terminated, and our business could be seriously harmed. Regulatory authorities could order us to cease further development of or deny approval of product candidates. If we are required to delay, suspend or terminate any clinical trial, the commercial prospects of our products or product candidates may be harmed, and our ability to generate product revenues may be delayed or eliminated.

***Any side effects or adverse events caused by approved products following regulatory approval, could result in a number of potentially significant negative consequences.***

For approved products, if we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a risk evaluation and mitigation strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of approved products and could seriously harm our business.

***A variety of risks associated with marketing our approved products and any of our product candidates, if approved, internationally, could affect our business.***

We may seek regulatory approval for our approved products and any of our product candidates, if approved, outside of the United States. For example, we have submitted an MAA to the EMA for the evaluation of arimoclomol for the treatment of NPC. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries including:

- different regulatory requirements for maintaining approval of drugs in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, labor shortages, supply chain shortages, or other economic or political uncertainties or instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and
- business interruptions resulting from geo-political actions, including war and terrorism, such as the current conflict with Ukraine and Russia.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

***If our Global EAP program is terminated prior to regulatory approval and commercialization of arimoclomol in applicable foreign jurisdictions, it will have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.***

Arimoclomol is currently available to NPC patients in France, Germany, and other EU member states, as well as select territories outside of Europe through an EAP. We have submitted an MAA to the EMA for the evaluation of arimoclomol for the treatment of NPC, and the EAP is expected to remain in place until arimoclomol becomes commercially available in each of these EAP markets. If the EAP is terminated prior to commercialization of arimoclomol in an applicable foreign jurisdiction, it will have a material adverse effect on our business, results of operations, cash flows, financial condition and/or prospects.

**Risks Related to Our Business and Our Financial Position**

***We are highly dependent on one product for substantially all of our revenues, and any loss of revenue from this product could materially harm our business.***

For the year ended December 31, 2025 we derived approximately 82% of our revenues from commercial sales of MIPLYFFA® (arimoclomol), which is indicated for a rare disease with a limited patient population. We expect that MIPLYFFA® (arimoclomol) will continue to be our main source of revenue for the foreseeable future. As a result, our business, financial condition, and results of operations are highly dependent on the continued commercial success of MIPLYFFA® (arimoclomol).

Sales of MIPLYFFA® (arimoclomol) may be negatively impacted by a number of factors, including competition from third parties, changes in clinical practice or treatment guidelines, pricing and reimbursement pressures from government and private payors, heightened scrutiny of high-cost rare disease therapies, adverse safety signals, manufacturing or supply disruptions, regulatory actions or labeling changes, and challenges to or expiration of our intellectual property rights. Because the target patient population is small, even modest changes in prescribing patterns, patient identification rates, or reimbursement decisions could have a disproportionate effect on our revenues.

If MIPLYFFA® (arimoclomol) fails to increase or maintain its current level of commercial success for any reason, we may be unable to replace the lost revenues, which could materially adversely affect our business, financial condition, and results of operations.

***We have had recurring negative net operating cash flows throughout our operating history, and we cannot guarantee or predict when we may begin to consistently generate positive net cash flows from operations, or if at all.***

We incurred a *net loss* of $105.5 million for the year ended December 31, 2024. Our *net income* of $83.2 million for the year ended December 31, 2025 was primarily due to the sale of the PRV in the second quarter of 2025, which resulted in net proceeds of $148.3 million. As of December 31, 2025, we had an accumulated deficit of $422.1 million. We have had recurring negative net operating cash flows throughout our operating history, and we cannot guarantee or predict when we may begin to consistently generate positive net cash flows from operations, or if at all. Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve or maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase. Even though we generated positive net income for the year ended December 31, 2025, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, obtain product approvals, diversify our product offerings or continue our operations. A decline in our value could also cause you to lose all or part of your investment. We may incur significant losses in the future for a number of reasons, many of which are beyond our control, including the market acceptance of our products, competitive products, future product development, our market penetration and margins, as well as the other risks described in this Annual Report on Form 10-K.

***We might not be able to utilize a significant portion of our net operating loss carryforwards, which could adversely affect our profitability.***

As of December 31, 2025, we had federal net operating loss carryforwards of approximately $230.4 million, due to prior period losses, $11.1 million of which, if not utilized, will begin to expire in 2029 and $219.4 million of which have no expiration date. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our profitability. These federal net operating loss carryforwards are fully reserved under a valuation allowance in the consolidated balance sheet as of December 31, 2025. On December 22, 2017, the U.S. government enacted H.R. 1, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018” (informally titled the Tax Cuts and Jobs Act). Under the Tax Cuts and Jobs Act, U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform or continue to conform to the Tax Cuts and Jobs Act or any subsequent or newly enacted federal tax legislation. To the extent that we continue to generate taxable losses in the United States, unused losses will carry forward to offset future taxable income (subject to any applicable limitations), if any. In addition, under Section 382 and Section 383 of the Code, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We performed a Section 382 ownership change analysis through the period ending November 26, 2025 and determined that we experienced ownership changes in 2016, 2020, and 2021, which resulted in a portion of our net operating loss carryforwards being subject to an annual limitation under Section 382 for those respective tax years. No other ownership changes or limitations on our historical net operating loss carryforwards were noted through the period ending November 26, 2025. As of December 31, 2025, we maintain a full valuation allowance over our deferred tax assets for financial reporting purposes.

***We recognized an impairment charge related to intangible assets. If our remaining assets become impaired in the future, we would incur additional impairment charges, which would negatively affect our operating results.***

We recognized impairment charges of $58.7 million related to definite-lived intangible assets during the quarter ended June 30, 2025. If our remaining assets become impaired in the future, we would incur additional impairment charges, which would negatively affect our results of operations. There is significant judgment required in the analysis of a potential impairment of identified intangible assets and other long-lived assets. Impairment may result from, among other things, significant changes in the manner of use of the acquired assets, negative industry or economic trends and/or significant underperformance relative to historic or projected operating results. For additional information, see Note S of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

**Risks Related to Our Dependence on Third Parties**

***We rely on a limited number of suppliers, in some cases sole-source suppliers.***

We do not have any manufacturing facilities. We procure approved products and bulk drug substances from sole-source, third-party suppliers. We anticipate we will continue to do so for the foreseeable future. We do not currently have arrangements in place for redundant supply or a second source for these approved products or bulk drug substances. This reliance on third parties increases the risk that we will not have sufficient quantities of our approved products or product candidates, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to generate revenue or timely conduct our clinical trials or our other development or commercialization efforts. If a current contract manufacturer cannot perform as agreed, we may be required to replace such manufacturer and we may incur added costs and delays in identifying and qualifying any such replacement. Even if we are able to maintain our existing third-party relationships or establish any such agreements with other third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure by any of our suppliers to comply with applicable regulations;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- disruption, delays and costs associated with changing suppliers, including additional regulatory filings;
- the possible breach, termination or nonrenewal of the agreement by the third party;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms; and
- carrier disruptions or increased costs that are beyond our control.

Any of these events could impact our ability to successfully commercialize our products, lead to clinical trial delays, or failure to obtain regulatory approval, and have a material impact on our business.

***The facilities used by our third-party contract manufacturers to manufacture our approved products and any of our product candidates are subject to review by the FDA pursuant to inspections, and such inspections could result in findings that lead to failure to obtain FDA approval of such marketing applications.***

We are completely dependent on, our contract manufacturing partners for compliance with cGMP and similar regulatory requirements outside the United States and for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure and maintain regulatory approval of our marketing applications for the use of their manufacturing facilities for our products.

The failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including warning letters, clinical holds or termination of clinical trials, fines, injunctions, restitution, disgorgement, civil penalties, delays, suspension or withdrawal of approvals or other permits, FDA or foreign regulatory authorities refusal to approve pending applications, product detentions, FDA or DEA consent decrees placing significant restrictions on or suspending manufacturing and distribution operations, debarment, refusal to allow import or export, product detentions, adverse publicity, dear-health-care-provider letters or other warnings, license revocation, seizures or recalls of product candidates, operating restrictions, refusal of government contracts or future orders under existing contracts and civil and criminal liability, including False Claims Act liability, exclusion from participation in federal healthcare programs, and corporate integrity agreements, among other consequences, any of which could significantly and adversely affect supplies of our products.

Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements, as well as market disruption related to any necessary recalls or other corrective actions.

***We rely on a limited number of third-party distribution partners to commercialize MIPLYFFA, and the loss or inadequate performance of any of these partners could materially and adversely affect our ability to supply MIPLYFFA in key territories.***

We rely on a single specialty pharmacy to distribute MIPLYFFA in the United States. We also rely on a single distributor in the EU and another single distributor for select territories outside of Europe to distribute MIPLYFFA under our Global EAP. Because each of these geographic markets is served by only one distribution partner, our ability to commercialize our product depends heavily on the continued satisfactory performance of these third parties.

Any disruption in the services provided by these distributors—including failure to comply with regulatory requirements, breach of contractual obligations, operational failures, financial instability, changes in ownership, natural disasters or other business interruptions—could negatively impact product availability in the relevant markets. If any of these third parties were to cease providing services to us or were unable or unwilling to perform their obligations, we would be required to secure an alternative distributor. Identifying, qualifying, and contracting with a replacement distributor is often a time-consuming process that may require regulatory notifications, new logistics arrangements, and additional compliance reviews. As a result, the transition to a new distribution partner could cause significant delays in our ability to supply our approved drug in affected territories, potentially resulting in reduced revenues, customer dissatisfaction, damage to our commercial reputation, and a material adverse effect on our business.

***We rely on and expect to continue to rely on third parties to conduct our clinical trials for our product candidates, and those third parties may not perform satisfactorily.***

We rely on and expect to continue to rely on contract research organizations ("CROs"), as well as other third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct clinical trials. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and comply with regulatory standards commonly referred to as good clinical practices, or GCPs. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, investigators and trial sites. Similar requirements apply in foreign jurisdictions. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process. Failure to comply with the applicable requirements related to clinical investigations by us, our CROs or clinical trial sites can also result in clinical holds and termination of clinical trials, debarment, FDA or foreign regulatory authorities refusal to approve applications based on the clinical data, warning letters, withdrawal of marketing approval if the product has already been approved, fines and other monetary penalties, delays, adverse publicity and civil and criminal sanctions, among other consequences.

If the third parties with whom we contract do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, we may need to conduct additional trials, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed, and our business may be adversely affected.

***We have entered into a collaboration with Commave, to develop, manufacture and commercialize AZSTARYS worldwide. If this collaboration is not successful, we may not be able to capitalize on the market potential of AZSTARYS.***

We entered into the AZSTARYS License Agreement with Commave pursuant to which we granted an exclusive, worldwide license to Commave to develop, manufacture and commercialize AZSTARYS. On behalf of Commave, Corium leads all commercialization activities in the United States for AZSTARYS under the AZSTARYS License Agreement. We cannot guarantee that the AZSTARYS License Agreement will be successful or that we will receive any future payments under the AZSTARYS License Agreement. Commave has the option to terminate the AZSTARYS License Agreement, in its entirety or on a product-by-product and country-by-country basis, at their convenience. In addition, under the AZSTARYS License Agreement, we have limited control over the amount and timing of resources dedicated to the development, manufacturing or commercialization of AZSTARYS, so we cannot guarantee that we will receive any additional milestone or royalty payments. Our ability to generate revenue under the AZSTARYS License Agreement will depend on Corium's ability to successfully perform the functions assigned to it under the AZSTARYS License Agreement.

In addition, a dispute has arisen with Commave concerning the interpretation of certain provisions under the AZSTARYS License Agreement, and in September 2024, Commave filed a complaint against us in the Court of Chancery of the State of Delaware alleging breach of contract and seeking injunctive relief, specific performance, declaratory relief, and damages regarding the parties' respective rights and obligations under the AZSTARYS License Agreement. The litigation is in its early stages, and we strongly disagree with Commave's allegations and believe this lawsuit is without merit. While we intend to vigorously defend against Commave's claims, the outcome of this matter is inherently uncertain. We cannot predict with certainty the timing or ultimate outcome of this litigation or its potential impact on our business, financial condition, or results of operations. The AZSTARYS License Agreement remains in effect during this litigation, and both parties continue to perform their respective obligations thereunder. However, there can be no assurance that this dispute will not have an adverse impact on our relationship with Commave or on our business.

***We may seek to establish collaborations for certain product candidates, which may not be available on acceptable terms, or at all.***

We may seek to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of certain product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of several factors. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of product candidates, reduce or delay one or more of our development programs, delay potential commercialization of our product candidates or reduce the scope of any sales or marketing activities of our product candidates, or increase our expenditures and undertake development or commercialization activities of our product candidates at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring our product candidates to market and generate product revenue.

**Risks Related to Our Intellectual Property**

***If we are unable to obtain and maintain intellectual property protection for our technology, our approved products or our product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology, our approved products, or our product candidates if approved, may be impaired.***

Our success depends in large part on our ability to obtain and maintain trade secret protection of our proprietary technology as well as patent protection in the United States and other countries with respect to our approved products and any of our product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, we may also not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents, licensed from third parties to us. Therefore, any such patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies, generally, is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or visa-versa. Our patent position is subject to numerous additional risks, including the following:

- our pending patent applications may not result in issued patents or patents that will provide us with any meaningful protection;
- we cannot be certain that we are the first to invent the inventions covered by pending patent applications or that we are the first to file such applications and, if we are not, we may be subject to priority disputes or lose rights;
- because of the extensive time required for development, testing and regulatory review of a product candidate, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization thereby reducing, or eliminating any advantage of the patent;
- we may not be able to acquire patent term extensions or supplemental certificates of certain patents, domestic or foreign, due to regulatory delays, among others, which may affect the term of enforceability of such patents over time;

- there could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government;
- our competitors may be able to design around our owned or licensed patents by developing similar or alternative technologies or drugs without infringing on our intellectual property rights;
- third parties may develop products that have the same or similar effect as our products without infringing our patents; and
- there may be dominating or intervening patents relevant to our product candidates of which we are not aware.

Any of these factors could hurt our ability to gain full patent protection for our products. Registered trademarks and trademark applications in the United States and other countries are subject to similar risks.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

Competitors or other third parties may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products and technologies. In addition, third parties may use technology covered by patent applications, but pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

***Third parties may initiate legal proceedings against us alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.***

Our commercial success depends upon our ability, and the ability of any collaborators, to develop, manufacture, market and sell our products, product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. Although we seek to develop proprietary formulations that do not infringe the intellectual property rights of others, we may become party to, or threatened with, future adversarial proceedings or litigation, domestic or foreign, regarding intellectual property rights with respect to our products or other aspects of our technology. We cannot be certain that we have identified or will identify each and every third party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction.

Litigation regarding intellectual property rights is inherently uncertain due to the complex issues involved, and we may not be successful in defending ourselves in such matters. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our technology and drugs. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some or all of our business operations.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented show-how, know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Further, we may need to share our trade secrets and confidential know-how with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets. If any of our trade secrets were to be disclosed to a competitor, our competitive position would be harmed.

***Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.***

We expect to rely on trademarks as one means to distinguish our product candidates that are approved for marketing from the products of our competitors. We have registered trademarks, including those for LAT, Zevra, MIPLYFFA and OLPRUVA. In addition, we have solicited and applied for trademarks for the Zevra logo and several potential trade names and logos for future product candidates. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. If our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

***We may not be able to protect our intellectual property rights throughout the world.***

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our products and technologies throughout the world would be prohibitively expensive. As such, our intellectual property rights in some countries outside the United States can be less extensive than those in the United States and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products or technology and may export otherwise infringing products or technology to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in intellectual property laws of other countries. In addition, certain countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, in 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. The EU Patent Package went into effect June 1, 2023. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

**Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters**

***If we are not able to obtain required regulatory approvals for any of our product candidates, we will not be able to commercialize them and our ability to generate revenue or profits could be limited.***

The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country and change over time. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approvals in such countries. In the United States, the FDA generally requires the completion of non-clinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality and other factors before an NDA is approved. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization. Even if regulatory approval is obtained, subsequent safety, efficacy, quality or other issues can result in a product approval being suspended or withdrawn.

In order to market and sell our products in the EU and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be marketed in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application or may result in future withdrawal of approval. Failure to obtain regulatory marketing approval of our product candidates will prevent us from commercializing those product candidates, and our ability to generate revenue will be impaired.

For more detailed information regarding the regulatory requirements for approval of product candidates in the United States and EU, see "*Item 1. Business - U.S. Government Regulation and Product Approval*" and "*Item 1. Business - Foreign Regulation*" above in this Annual Report on Form 10-K.

***If we experience delays or difficulties in the enrollment of subjects in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials as may be required by the FDA or similar regulatory authorities outside the United States. Subject enrollment is affected by other factors including:

- the size and nature of the subject population specified in the trial protocol, especially in indications for rare diseases;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- ongoing trials by competitors for similar indications as our product candidates;
- severe or unexpected drug-related adverse events experienced by subjects in a clinical trial;
- the availability of drugs approved to treat the diseases or conditions under study;
- the patient referral practices of physicians;
- the severity of the disease or condition under investigation;

- the ability to obtain and maintain subject informed consent;
- the clinical trial design, including required tests, procedures and follow-up;
- the ability to monitor subjects adequately during and after treatment;
- delays in adding new, or withdrawals of existing, investigators and clinical sites; and
- the proximity and availability of clinical trial sites for prospective subjects.

Our inability to enroll a sufficient number of subjects for clinical trials would result in significant delays, increased costs and could require us to abandon one or more clinical trials altogether.

***Interim, topline, or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose topline or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. As a result, the preliminary or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Topline data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary or topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

***Our approved products are, and any of our product candidates for which we obtain marketing approval will be, subject to significant post-marketing regulatory requirements and oversight.***

Our approved products are, and any of our product candidates for which we obtain marketing approval will be, subject to significant post-marketing regulatory requirements and oversight, including the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product, significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and burdensome post-approval study or risk management requirements. For example, we are required to conduct pediatric studies related to AZSTARYS to evaluate its safety and effectiveness for the claimed indication in pediatric patients. Under the AZSTARYS License Agreement, Corium is responsible for these regulatory activities going forward, and we cannot guarantee they will be complied with.

For MIPLYFFA and any other approved products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and comparable foreign regulations and GCP for any clinical trials that we conduct post-approval. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of drugs for the pediatric population, can also result in significant financial penalties.

Our inability to maintain compliance with post-marketing regulatory requirements may inhibit our ability to commercialize our products and generate revenue, and could require us to expend significant time and resources in response and could generate negative publicity. In addition, the policies of the FDA, the EMA and other regulatory authorities may change, and additional government regulations may be enacted that could impair our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action.

For more detailed information regarding post-approval regulatory requirements, see "*Item 1. Business - U.S. Government Regulation and Product Approval - Post-Approval Requirements*" above in this Annual Report on Form 10-K.

***Our approved products are, and if marketing approval of any of our product candidates is granted, such product candidates may be, subject to limitations on the indicated uses for which the product may be marketed.***

Products may be approved with a label that limits their approved uses, including more limited subject populations, than we request, and regulatory authorities may require that contraindications, warnings or precautions be included in the product labeling, including a boxed warning, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, which could limit sales of the product. For instance, the label for AZSTARYS contains black box warnings regarding the risks of abuse and dependence. Violations of the FFDCA relating to the promotion of prescription drugs may lead to a number of actions and penalties, including warning letters, cyber letters, or untitled letters, adverse publicity, the requirement for dear-health-care-provider letters or other corrective information, fines and other monetary penalties, civil or criminal prosecution, including False Claims Act liability, restrictions on our operations and other operating requirements through consent decrees or corporate integrity agreements, debarment, exclusion from participation in federal health care programs and refusal of government contracts or future orders under existing contracts, among other consequences.

***Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of our product candidates and increase the cost to commercialize our approved products.***

In the United States and many foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect the ability to profitably sell approved products. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in 2010, the ACA was signed into law. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affects the U.S. pharmaceutical industry.

In addition, other legislative changes that have a significant impact on the pharmaceutical industry have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers, which went into effect in April 2013, and, due to subsequent legislative amendments, will stay in effect through 2032. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

On August 16, 2022, the Inflation Reduction Act of 2022 (the “IRA”) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be subject to a cap, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). The drug price negotiation program is currently subject to legal challenges, and the impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect sales of approved products or of any product candidate that we commercialize.

The current U.S. administration is pursuing a two-fold strategy to reduce drug costs in the United States. While it is unclear whether and how proposals will be implemented, these policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our products. On the one hand, the current U.S. administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the United States to the lowest price in a group of other countries. In response, multiple manufacturers have entered into confidential pricing agreements with the federal government. On the other hand, the current U.S. administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as Globe and Guard. If finalized, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the United States that is based on drug prices outside the United States would mark a drastic and unprecedented shift in the U.S. pharmaceutical market, and while the impact of the Globe and Guard proposed regulations, if finalized, cannot yet be determined, it is likely to be significant. Even proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business, for example by causing uncertainty and delaying development and commercialization efforts.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. These new laws may result in additional reductions in Medicare and other healthcare funding, which could negatively impact commercialization of approved products, and, accordingly, our financial operations.

In the EU, pharmaceutical legislation has been undergoing a complete review process in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) remain to be formally adopted by the European Parliament and Council of the EU , which is not anticipated before early 2026. The proposed changes are not expected to enter into application before 2028 and may have a significant impact on the biopharmaceutical industry in the long term.

We cannot be sure whether additional legislative changes will be enacted, or whether the FDA's or foreign regulations, guidance or interpretations will be changed. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may, among other things, result in more rigorous coverage criteria as well as additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain or maintain profitability, or commercialize our product candidates.

***We may not be able to obtain or maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.***

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan product if it is intended to treat a rare disease or condition. In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same product for the same approved use or indication within such rare disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity within the relevant approved use or indication.

In the EU, orphan designation is granted by the EC based on a scientific opinion of the EMA's Committee for Orphan Medicinal Products based on certain criteria. Orphan designation entitles a party to financial incentives such as reduction of fees, fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Moreover, upon grant of a marketing authorization and assuming the requirement for orphan designation are also met at the time the marketing authorization is granted, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan.

However, orphan drug exclusivity for a product may not effectively protect the product from competition because different drugs with different active ingredients can be approved for the same approved use or indication within the applicable rare disease or condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same approved use or indication within the relevant rare disease or condition if such regulatory authority concludes that the later drug is clinically superior because it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective.

In the EU, during the market exclusivity period, marketing authorizations may be granted to a similar medicinal product with the same orphan indication if: (i) the applicant can establish that the second medicinal product, although similar to the orphan medicinal product already authorized is safer, more effective or otherwise clinically superior to the orphan medicinal product already authorized; (ii) the marketing authorization holder for the orphan medicinal product grants its consent; or (iii) if the marketing authorization holder of the orphan medicinal product is unable to supply sufficient quantities of product.

***Our current and future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, and other healthcare laws and regulations, which could expose us to penalties.***

Healthcare providers and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of drug products. Our and our commercial partners' current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the Anti-Kickback Statute and the False Claims Act, that may constrain the business or financial arrangements and relationships through which we and our commercial partners sell, market and distribute approved products. In addition, we may be subject to transparency laws with respect to drug pricing and transfers of value made to physicians and other healthcare professionals. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute;
- federal civil and criminal false claims laws, including the False Claims Act;
- the civil monetary penalties statute;
- the Health Insurance Portability and Accountability Act, or HIPAA;
- the federal Physician Payments Sunshine Act and its implementing regulations; and
- analogous state and foreign laws and regulations.

These laws may affect our and our commercial partners' sales, marketing, and other promotional activities by imposing administrative and compliance burdens. Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, corporate integrity agreements or similar agreements to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we currently, or expect to, do business, including future collaborators, is found not to be in compliance with applicable laws, they and we may be subject to significant penalties and potential exclusion from participation in healthcare programs as a result of their non-compliance.

For more detailed information regarding applicable federal, state and foreign healthcare laws that may affect our ability to operate, see "*Item 1. Business - U.S. Government Regulation and Product Approval - Other Healthcare Regulatory Frameworks*" above in this Annual Report on Form 10-K.

***If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in which we participate, we could be subject to additional reimbursement requirements, penalties, sanctions and fines.***

Medicaid is a joint federal and state program administered by the states for low income and disabled beneficiaries. We participate in and have certain price reporting obligations under the Medicaid Drug Rebate Program (the "MDRP") as a condition of having covered outpatient drugs payable under Medicaid and, if applicable, under Medicare Part B. The MDRP requires us to pay a rebate to state Medicaid programs every quarter for each unit of our covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The rebate is based on pricing data that we must report on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services ("CMS"), the federal agency that administers the MDRP and other governmental healthcare programs. These data include the average manufacturer price (AMP) for each drug and, in the case of innovator products, the best price, which in general represents the lowest price available from the manufacturer to certain entities in the United States in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. The Medicaid rebate consists of two components, the basic rebate and the additional rebate, which is triggered if the AMP for a drug increases faster than inflation. If we become aware that our MDRP government price reporting submission for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after those data originally were due. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP. In the event that CMS terminates our rebate agreement pursuant to which we participate in the MDRP, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs. Our failure to comply with our MDRP price reporting and rebate payment obligations could negatively impact our financial results.

The IRA imposes rebates under Medicare Part B and Medicare Part D that are triggered by price increases that outpace inflation (first due in 2023), as described under the risk factor "*Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain marketing approval of our product candidates and increase the cost to commercialize our approved products*," above. The Medicare Part D rebate, if applicable, will be calculated on the basis of the AMP figures we report pursuant to the MDRP.

Federal law requires that any company that participates in the MDRP also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and, if applicable, Medicare Part B. We participate in the 340B program, which is administered by the Health Resources and Services Administration ("HRSA"), and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The ACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, but exempts "orphan drugs," from the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula based on AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes those prices to 340B covered entities. In addition, HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B-eligible drugs. HRSA has also finalized a revised regulation implementing an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. Our failure to comply with 340B program requirements could negatively impact our financial results. Any additional future changes to the definition of average manufacturer or the Medicaid rebate amount under legislation or regulation could affect our 340B ceiling price calculations and also negatively impact our financial results.

In order for approved products to be paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program. As part of this program, we are required to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price ("FCP"), to four federal agencies (VA, U.S. Department of Defense ("DOD"), Public Health Service, and U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price ("Non-FAMP"), which we must calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant civil monetary penalties for each item of false information. The FSS pricing and contracting obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we are required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our products on a Tricare Agreement in order for them to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges could result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. CMS, the Department of Health & Human Services Office of Inspector General, and other governmental agencies have pursued manufacturers that were alleged to have failed to report these data to the government in a timely or accurate manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that any submissions we are required to make under the MDRP, the 340B program, the VA/FSS program, the Tricare Retail Pharmacy Program, and other governmental drug pricing programs will not be found to be incomplete or incorrect.

**Risks Related to Cybersecurity and Data Privacy**

***Cybersecurity breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.***

In the ordinary course of our business, we may collect, process, transmit and store proprietary, confidential and sensitive information, including personal information (such as key-coded data and health information), intellectual property, trade secrets and proprietary business information owned or controlled by ourselves or other parties. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information.

There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be complied with or effective in protecting our systems and information. Despite the implementation of security measures, our information technology systems and data, and those of our CROs and other third parties on which we rely, are vulnerable to system failure, interruption, compromise, attack or damage from several sources, such as data corruption; breakdown; malicious human acts; malware (such as ransomware); misconfigurations, “bugs” or other vulnerabilities; malicious code (such as computer viruses or worms); fraudulent activity; employee misconduct, theft or error; denial-of-service attacks; public health epidemics; cyber-attacks by sophisticated nation-state and nation-state supported actors; natural disasters; terrorism; war; and telecommunication and electrical failures. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our recovery systems (and those of third parties upon whom we rely) are similarly vulnerable. Any of these events could lead to the unauthorized access, disclosure and use of proprietary, confidential, or otherwise non-public information.

The techniques used by criminal actors to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. Attacks upon information technology systems are also increasing in their levels of persistence and intensity and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques – including artificial intelligence (“AI”) – that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. As a result of the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

If we or our third-party vendors were to experience a significant cybersecurity breach of our or their information systems or data, it may result in a material adverse impact, including without limitation, fines, damages, litigation, enforcement actions, loss of trade secrets, personal information or other proprietary or sensitive information, a material disruption of our drug development programs, regulatory scrutiny or other harm to our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to mitigate, detect and remediate actual and potential vulnerabilities. The costs of maintaining or upgrading our cyber-security systems at the level commercially reasonable to keep up with our expanding operations and prevent against potential attacks are increasing, and despite our best efforts, our network security and data recovery measures and those of our vendors may still not be adequate to protect against such security breaches and disruptions.

Furthermore, federal, state and international laws and regulations can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties, fines and significant legal liability, if our information technology security efforts fail. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or confidential information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. We may also be exposed to a risk of loss or litigation and potential liability, which could materially and adversely affect our business, results of operations or financial condition. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

We cannot be sure that our insurance coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or materially adverse impacts arising out of our privacy and cybersecurity practices, processing or security breaches that we may experience, or that such coverage will continue to be available on acceptable terms at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of a large deductible or co-insurance requirements), could have an adverse effect on our business.

***We are currently subject to, and may in the future become subject to additional, U.S. federal and state and international laws and regulations imposing obligations on how we collect, store and process personal information.***

The secure processing, storage, maintenance, and transmission of sensitive personal information is vital to our operations and business. We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, governing the collection, use, disclosure, retention, and security of personal information in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, various federal and state regulators, including governmental agencies like the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international, or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the “CCPA”), requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business’s collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business’s behalf. Additional compliance investment and potential business process changes may also be required. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. These and future laws and regulations may increase our compliance costs and potential liability.

The Health Insurance Portability and Accountability Act of 1996, and regulations promulgated thereunder ("HIPAA") imposes privacy, security and breach notification obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. Among other requirements, HIPAA requires business associates to develop and maintain policies with respect to the protection of, use and disclosure of protected health information ("PHI"), including the adoption of administrative, physical and technical safeguards to protect such information, certain notification requirements in the event of a breach of unsecured PHI, and requirements to report breaches of unsecured PHI to covered entities within 60 days of discovery of the breach by the business associate or its agents. Depending on the facts and circumstances, we could be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if found to be in violation of HIPAA.

Foreign data protection laws may also apply to health-related and other personal data that we process, including personal data relating to clinical trial participants. European data protection laws impose strict obligations on the ability to process health-related and other personal data of data subjects in Europe, including standards relating to the privacy and security of personal data. For example, in Europe, the European Union General Data Protection Regulation, or the "EU GDPR", and in the United Kingdom, the United Kingdom General Data Protection Regulation and Data Protection Act 2018, or the "UK GDPR" (together with the EU GDPR, referred to as the "GDPR") imposes strict requirements for processing the personal data of individuals within the European Economic Area, or the EEA, or in the context of our activities within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance under both the EU GDPR and UK GDPR of up to €20 million/GBP 17.5 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. In addition to fines, a breach of the GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses – a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism – alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis.

On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF"), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. In relation to such cross border transfers of personal data, we expect the existing legal complexity and uncertainty regarding international personal data transfers to continue, and international transfers to the United States, China, and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; we may have to implement alternative data transfer mechanisms under the GDPR and/ or take additional compliance and operational measures; and/or it could otherwise affect the manner in which we operate our business, and could adversely affect our business, operations and financial condition. Failure, or perceived failure, to comply with foreign data protection laws and regulations, privacy policies, contracts and other data protection obligations could result in government investigations and enforcement actions (which could include civil or criminal penalties, fines, or sanctions), private litigation, a diversion of management's attention, adverse publicity and other negative effects on our operating results and business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

**Risks Related to Ownership of Our Common Stock**

***The trading price of the shares of our common stock is likely to be volatile, and purchasers of our common stock could incur substantial losses.***

Our stock price has been, and is likely to continue to be, volatile. In addition, the stock market in general and the market for pharmaceutical companies, in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated variations in our operating results;

- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry, including without limitation changes in the structure of healthcare payment systems;
- stock market price and volume fluctuations of comparable companies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- adverse regulatory announcements or determinations regarding our product candidates;
- capital commitments;
- investors' general perception of us and our business;
- global macroeconomic conditions, including inflation, tariffs, labor shortages, supply chain shortages, or other economic, political or legal changes, uncertainties or adverse developments;
- political unrest, terrorism and wars, such as the current situation with Ukraine and Russia or Israel and Hamas;
- other events or factors, including those resulting from system failures and disruptions, earthquakes, hurricanes, other natural disasters, pandemics, or responses to these events;
- recruitment, retention, or departure of key personnel; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

Many of the factors described above are not within our control and we cannot guarantee that future instances of these influencing factors will not have effects on the trading price of our common stock.

***Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law and the terms of some or our contracts, might discourage, delay or prevent a change in control of our company or changes in our board of directors or management and, therefore, depress the price of our common stock.***

Our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law contain provisions that may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock or transactions that our stockholders might otherwise deem to be in their best interests. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors or our management. Therefore, these provisions could adversely affect the price of our stock. Our corporate governance documents include provisions:

- establishing a classified board of directors with staggered three-year terms so that not all members of our board of directors are elected at one time;
- providing that directors may be removed by stockholders only for cause;
- preventing the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;
- permitting the board of directors to issue up to 10,000,000 shares of preferred stock with any rights, preferences and privileges they may designate;
- limiting the liability of, and providing indemnification to, our directors and officers;
- providing that vacancies may be filled by remaining directors;

- preventing cumulative voting; and
- providing for a supermajority requirement to amend our amended and restated bylaws.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

In addition, the provisions of our termination agreement with Aquestive Therapeutics ("Aquestive") may delay or prevent a change in control of our company. For example, if we enter into a merger, an asset sale or any other change of control transaction, then Aquestive will be entitled to a royalty equal to 10% of the price being paid to us and our stockholders in such transaction which is attributable to the value of AZSTARYS or KP1077.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law or any term of our contracts that has the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

***We could be negatively affected as a result of the actions of activist stockholders, which could be disruptive and costly and may conflict with or disrupt the strategic direction of our business.***

Activist stockholders may from time to time attempt to effect changes in our strategic direction and seek changes regarding our corporate governance or structure. Our board of directors and management team strive to maintain constructive, ongoing communications with all stockholders who wish to speak with us, including activist stockholders, and welcome their views and opinions with the goal of working together constructively to enhance value for all stockholders. Any future proxy contest with respect to election of our directors, or other activist stockholder activities, could adversely affect our business because: (1) responding to a proxy contest and other actions by activist stockholders is costly and time-consuming, disruptive to our operations and diverts the attention of management and our employees; (2) actual or perceived uncertainties as to our future direction caused by activist activities may cause or appear to cause instability or lack of continuity, resulting in the loss of potential business opportunities, and potentially making it more difficult to attract and retain qualified personnel and business partners; and (3) if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plans. Activist stockholder activities may also cause significant fluctuations in our stock price based on temporary or speculative market perceptions, or other factors that do not necessarily reflect the fundamental underlying value of our business.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.***

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of our current credit agreement precludes us from paying cash dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

## ITEM 1C. CYBERSECURITY

### Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework ("NIST CSF"). This does *not* imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Key elements of our cybersecurity risk management program include but are *not* limited to the following:

- risk assessments designed to help identify material risks from cybersecurity threats to our critical systems, and information;
- a security team principally responsible for managing (i) our cybersecurity risk assessment processes, (ii) our security controls, and (iii) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security processes;
- cybersecurity awareness training of our employees, including incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for key service providers, based on our assessment of their criticality to our operations and respective risk profile.

For more information, see "*Cybersecurity breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.*" in the "*Risk Factors*" section above.

**Cybersecurity Governance**

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee ("Committee") oversight of cybersecurity risks, including oversight of management's implementation of our cybersecurity risk management program. The Committee receives periodic reports from management on our cybersecurity risks. In addition, management updates the Committee, where it deems appropriate, regarding any cybersecurity incidents it considers to be significant or potentially significant.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from our internal security staff or external experts as part of the Board's continuing education on topics that impact public companies. Our management team, including our Chief Legal Officer, Secretary and Compliance Officer, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team includes IT staff such as a Director of IT with more than 22 years of IT-related experience in various roles including managing information security, managing privacy and data protection, evaluating cybersecurity risks, developing cybersecurity strategy, and implementing cybersecurity programs, as well as a dedicated Information Security Manager, responsible for operational IT security initiatives.

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which *may* include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment.

In addition, our management team periodically evaluates and tests the effectiveness of our cybersecurity controls and incident response capabilities through internal reviews and, where appropriate, engagement of external specialists. These efforts may include security assessments, penetration testing, resilience and recovery exercises, and employee awareness initiatives designed to enhance preparedness against evolving threats, including ransomware and social engineering.

## ITEM 2. PROPERTIES

In 2026, we changed the location of our headquarters from Celebration, Florida to Boston, Massachusetts where we sublease approximately 10,000 square feet of office space under a lease that expires in June 2028. We continue to lease approximately 6,000 square feet of office space in Celebration, Florida under a non-cancelable lease agreement that expires in August 2026, as well as office space in Copenhagen, Denmark. As we continue to grow our headquarters in Boston, we expect that we will require additional space, and we are currently negotiating with the landlord to lease additional office space.

## ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business.

In connection with the AZSTARYS License Agreement with Commave, a dispute has arisen with Commave concerning the interpretation of certain provisions under the AZSTARYS License Agreement. On September 4, 2024, Commave filed a complaint against us in the Court of Chancery of the State of Delaware (Case No. 2024-0920-LWW) alleging breach of contract and seeking injunctive relief, specific performance, declaratory relief, and damages regarding the parties' respective rights and obligations under the Agreement. On February 12, 2025, our motion to dismiss was denied and the case is now in the discovery phase. On July 17, 2025, Zevra and Commave filed cross motions for partial summary judgment as to certain of Commave's claims, and the court held oral argument on the parties' cross motions on September 22, 2025. On December 31, 2025, the court granted Commave's motion for partial summary judgment and denied our motion for partial summary judgment. Trial is currently scheduled to commence on June 8, 2026. We strongly disagree with Commave's allegations and believe this lawsuit is without merit.

The litigation is in its early stages. While we intend to vigorously defend against Commave's claims, the outcome of this matter is inherently uncertain. We cannot predict with certainty the timing or ultimate outcome of this litigation or its potential impact on our business, financial condition, or results of operations. At this time, we have not recorded any accrual for contingent liability associated with this matter. We will continue to monitor developments in this matter and will assess the potential impact on our financial statements in future periods. We expect to incur significant legal expenses in connection with this litigation, which may materially affect our results of operations in future periods.

The AZSTARYS License Agreement remains in effect during this litigation, and both parties continue to perform their respective obligations thereunder. However, there can be no assurance that this dispute will not have an adverse impact on our relationship with Commave or on our business.

Other than as disclosed herein, we believe there is no litigation pending that would reasonably be expected to, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

**Common Stock Listing**

Our common stock trades on The Nasdaq Global Select Market under the ticker symbol “ZVRA.”

**Holders of our Common Stock**

As of December 31, 2025, there were approximately 91 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock. In addition, the terms of our current credit agreement preclude us from paying cash dividends. We anticipate that we will retain all our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future.

**Securities Authorized for Issuance under Equity Compensation Plans**

Refer to the section titled “Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” of this Annual Report on Form 10-K for information regarding securities authorized for issuance under equity compensation plans.

**Recent Sales of Unregistered Securities**

None.

**Purchases of Equity Securities By the Issuer and Affiliated Purchasers**

None.

## ITEM 6. [Reserved]

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are a commercial-stage company with a late-stage pipeline committed to redefining what is possible in bringing life-changing therapeutics to people living with rare diseases. We are focused on expanding patient access, progressing our pipeline toward key milestones, and delivering meaningful therapeutics. Our vision is realized through disciplined execution of our strategic plan and our core values — patient centricity, integrity, accountability, innovation, and courage — which guide our efforts to deliver long-term value. The commercialization of our lead product, marketed in the United States for Niemann-Pick disease type C (NPC), a rare, progressive neurodegenerative disorder, provides a strong corporate foundation and demonstrates our ability to advance therapies from development to market.

In February 2023, we changed our name to Zevra Therapeutics, Inc. Zevra, is the Greek word for zebra, which is the internationally recognized symbol for rare disease. This name reflects our intense focus and dedication to developing transformational, patient-focused therapies for rare diseases with limited or no treatment options available, or treatment areas with significant unmet needs.

Our strategic plan is focused on transforming Zevra into a leading rare-disease company. We are prioritizing the commercialization and global expansion of our lead product, MIPLYFFA, while OLPRUVA remains commercially available. We are also advancing the development of our clinical stage asset, celiprolol, and plan to further expand our pipeline through inorganic growth. We intend to become the preferred partner for assets that we believe will allow us to leverage the expertise and infrastructure that we have built to help mitigate risk and enhance our probability of success.

On September 20, 2024, the U.S. Food and Drug Administration ("FDA") approved the New Drug Application ("NDA") for MIPLYFFA, for use in combination with miglustat for the treatment of neurological manifestations of NPC in adult and pediatric patients 2 years of age and older, and MIPLYFFA became commercially available for dispense in the United States in November 2024. In connection with this approval, we received a transferable rare pediatric disease priority review voucher ("PRV"). On April 1, 2025, we consummated the sale of the PRV, resulting in net proceeds of $148.3 million to us. MIPLYFFA has also been granted orphan medicinal product designation for the treatment of NPC by the European Commission. We are pursuing regulatory approval in Europe and filed a Marketing Authorization Application ("MAA") with the European Medicines Agency ("EMA") in July 2025; the application is currently under review.

On November 17, 2023, we completed the acquisition of Acer Therapeutics, Inc. ("Acer"), pursuant to which Acer became a wholly-owned subsidiary of Zevra. This included the acquisition of OLPRUVA (sodium phenylbutyrate) for oral suspension, which was approved by the FDA on December 27, 2022, for the treatment of certain urea cycle disorders ("UCDs"). In addition, we acquired Acer's pipeline of investigational product candidates, including celiprolol for the treatment of Vascular Ehlers-Danlos syndrome (VEDS) in patients with a confirmed type III collagen (COL3A1) mutation.

We have had recurring negative net operating cash flows throughout our operating history, and we cannot guarantee or predict when we may begin to consistently generate positive net cash flows from operations, or if at all. Net cash used in operating activities for the years ended December 31, 2025, and 2024, was $(1.6) million and $(69.7) million, respectively. We expect to continue to incur significant expenses and minimal positive net cash flows from operations or negative net cash flows from operations for the near future, and those expenses and losses may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will fluctuate substantially as we:

- continue building and maintaining our ongoing commercial capabilities to support the commercialization of our approved products, MIPLYFFA and OLPRUVA, in the United States;
- continue or initiate preclinical studies, clinical trials and product development activities for our pipeline of product candidates;
- seek regulatory approvals for any product candidates that may successfully complete clinical trials;

- seek to discover, license or acquire, and develop additional product candidates;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- incur additional legal, accounting and other expenses in operating as a public company; and
- add operational systems and personnel, if needed, to support any future commercialization efforts.

***License Agreements***

*XOMA License Agreement (MIPLYFFA)*

In May 2022, we purchased all the assets and operations of Orphazyme A/S ("Orphazyme") related to arimoclomol. Prior to this acquisition, Orphazyme had entered into an asset purchase agreement with LadRx Corporation, which was assigned to XOMA (US) LLC, a wholly-owned subsidiary of XOMA Corporation ("XOMA"), in June 2023 ("XOMA License Agreement"). Under the XOMA License Agreement, XOMA is entitled to a mid-single digit percentage royalty with respect to net sales of MIPLYFFA as well as milestone payments based on future potential sales and regulatory milestones, including a $4.0 million regulatory milestone payment upon approval in the E.U.

*Relief License Agreement (OLPRUVA)*

In connection with our acquisition of Acer, Acer and Relief entered into an exclusive license agreement on August 30, 2023 (the "Relief License Agreement"), which was assumed by Zevra. Pursuant to the Relief License Agreement, Zevra is obligated to pay royalties of 10% of U.S. net sales up to a maximum of $45.0 million, plus specified regulatory milestones, for total payments to Relief of up to $56.5 million. On April 10, 2025, the rights to this royalty were sold to Soleus Capital Management L.P.

Pursuant to the Relief License Agreement, Relief will hold exclusive development and commercialization rights for OLPRUVA in the EU, Liechtenstein, San Marino, Vatican City, Norway, Iceland, Principality of Monaco, Andorra, Gibraltar, Switzerland, United Kingdom, Albania, Bosnia, Kosovo, Montenegro, Serbia and North Macedonia ("Geographical Europe"). We have the right to receive a royalty of up to 10% of the net sales of OLPRUVA in Geographical Europe.

*Aquestive Termination Agreement (AZSTARYS)*

Under our March 2012 termination agreement with Aquestive Therapeutics ("Aquestive"), Aquestive has the right to receive a royalty amount equal to 10% of any value generated by AZSTARYS and any product candidates containing SDX. We pay Aquestive a royalty equal to 10% of the quarterly royalty payments and of the regulatory and net sales milestones we receive from Commave under the AZSTARYS License Agreement.

**Components of our Results of Operations**

***Revenue***

Our revenue is, and will be, primarily derived from sales of our approved products or any of our product candidates for which we obtain regulatory approval, and reimbursements under our global expanded access program ("EAP") in France, and in select territories outside Europe. We expect that our other sources of revenues will be through payments arising from our license agreements, and through any other future arrangements related to one of our product candidates.

To date, we have generated revenue from product sales of MIPLYFFA and limited sales of OLPRUVA, reimbursements received under our global EAP, royalties or net sales milestone payments generated under the AZSTARYS License Agreement, and consulting agreements. We cannot guarantee that we will continue to receive reimbursements under the global EAP or the extent of our success in commercializing MIPLYFFA or OLPRUVA. While we have received milestone payments under the AZSTARYS License Agreement, we cannot guarantee that we will earn any additional milestone or royalty payments under this agreement in the future. We also do not know when, if ever, any other product candidate will be commercially available.

***Cost of Product Revenue***

The components of cost of product revenue are royalties and expenses directly attributable to revenue. Under the Aquestive Termination Agreement, we pay Aquestive a royalty equal to 10% of the upfront license payment and all regulatory milestone and royalty payments we received from Commave under the AZSTARYS License Agreement. Under the XOMA License Agreement, we paid a $6.0 million regulatory milestone payment earned by XOMA upon the approval of MIPLYFFA on September 20, 2024. XOMA is also entitled to a mid-single digit royalty on net sales of MIPLYFFA, as well as certain net sales and regulatory milestone payments. We also owe a 10% royalty on net sales of OLPRUVA under the Relief License Agreement. Other components of cost of product revenue include $3.9 million of non-cash intangible asset amortization related to the MIPLYFFA and OLPRUVA capitalized assets and $11.7 million in inventory obsolescence reserve expense related to OLPRUVA inventory during the year ended December 31, 2025.

***Operating Expenses***

We classify our operating expenses into two categories: research and development expenses and selling, general and administrative expenses. Salaries and personnel-related costs, including benefits, bonuses and stock-based compensation expense, comprise a significant component of each of these expense categories.

*Research and Development Expense*

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop potential product candidates. This includes conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expense primarily consists of:

- salaries and personnel-related costs, including benefits and any stock-based compensation, for our scientific personnel performing research and development activities;
- costs related to executing preclinical studies and clinical trials;
- fees paid to consultants and other third parties who support our product candidate development;
- other costs in seeking regulatory approval of our products; and
- allocated facility-related costs and overhead.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs.

The following table summarizes our research and development costs for the years ended December 31, 2025 and 2024 (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Outsourced development costs directly identified to programs: | | |
| MIPLYFFA | $ 1,993 | $ 5,784 |
| OLPRUVA | 218 | 1,776 |
| KP1077 | 2 | 10,486 |
| Celiprolol | 4,498 | 2,133 |
| Other costs | 846 | 496 |
| Total outsourced development costs directly identified to programs | 7,557 | 20,675 |
| Research and development costs not directly identified to programs: | | |
| Personnel costs including cash compensation, benefits and stock-based compensation | 3,463 | 19,781 |
| Facilities costs | 96 | 51 |
| Other costs | 1,627 | 1,588 |
| Total research and development costs not directly allocated to programs | 5,186 | 21,420 |
| Total research and development expenses | $ 12,743 | $ 42,095 |

We anticipate that our research and development expenses will fluctuate in accordance with our strategic plan as we continue our efforts to advance the development of our product candidates.

The successful development of our product candidates is highly uncertain. At this time, we cannot be certain regarding the nature, timing or costs required to complete the remaining development of any product candidates. This is due to the numerous risks and uncertainties associated with the development of our products and product candidates.

*Selling, General and Administrative Expense*

We anticipate that selling expenses will vary from quarter-to-quarter in accordance with our strategic plan as we continue our efforts to commercialize MIPLYFFA and OLPRUVA. At this time, we cannot be certain regarding the nature, timing or costs required to commercialize any of our product candidates that may be approved in the future, due to the numerous risks and uncertainties associated with commercialization activities.

General and administrative expenses primarily consist of salaries and personnel-related costs, including employee benefits and any stock-based compensation, for employees performing functions other than research and development. This includes personnel in executive, finance, human resources and administrative support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, professional fees for auditing, tax and legal services, expenses associated with obtaining and maintaining patents, consulting costs and costs of our information systems.

We expect that our general and administrative expenses will fluctuate as we continue to operate as a public reporting company and continue to develop our product candidates. We believe that these fluctuations will likely include costs related to the hiring of additional personnel and fees for outside consultants, lawyers and accountants. We also expect to continue to incur costs to comply with corporate governance, internal control, investor relations, disclosure and similar requirements applicable to public reporting companies.

***Other income (expense)***

Other income (expense) consists primarily of gains generated from the sale of our PRV consummated on April 1, 2025, non-cash costs associated with fair value adjustments to our warrant and contingent value rights (“CVR”) liabilities, and amortization of debt issuance costs and debt discount to interest expense. Other income (expense) also includes interest expense incurred on our outstanding borrowings as well as interest and other income consisting primarily of interest earned on investments. These items are unrelated to our core business and thus are recognized as other income (expense) in our consolidated statements of operations.

**Results of Operations**

***Comparison of the years ended December 31, 2025, and 2024 (in thousands):***

| | Year Ended December 31, | | Period-to-Period Change |
|---|---|---|---|
| | 2025 | 2024 | |
| Revenue, net | $ 106,470 | $ 23,612 | $ 82,858 |
| Cost of product revenue (excluding $3,862 and $6,235 in intangible asset amortization for the years ended December 31, 2025, and 2024, respectively, shown separately below) | 16,482 | 7,417 | 9,065 |
| Intangible asset amortization | 3,862 | 6,235 | (2,373) |
| Impairment of intangible assets | 58,710 | — | 58,710 |
| Operating expenses: | | | |
| Research and development | 12,743 | 42,095 | (29,352) |
| Selling, general and administrative | 77,616 | 54,868 | 22,748 |
| Total operating expenses | 90,359 | 96,963 | (6,604) |
| Loss from operations | (62,943) | (87,003) | 24,060 |
| Other income (expense): | | | |
| Gain on sale of PRV | 148,325 | — | 148,325 |
| Interest expense | (7,977) | (7,351) | (626) |
| Fair value adjustment related to warrant and CVR liability | 2,178 | 2,057 | 121 |
| Fair value adjustment related to investments | 149 | (18) | 167 |
| Interest and other income, net | 6,946 | 2,175 | 4,771 |
| Total other income (expense) | 149,621 | (3,137) | 152,758 |
| Income (loss) before income taxes | 86,678 | (90,140) | 176,818 |
| Income tax expense | (3,449) | (15,371) | 11,922 |
| Net income (loss) | $ 83,229 | $ (105,511) | $ 188,740 |

*Net income (loss)*

Net income for the year ended December 31, 2025, was $83.2 million, compared to a net loss of $105.5 million for the year ended December 31, 2024, an increase to net income of $188.7 million. The increase was primarily attributable to the gain on sale of the PRV of $148.3 million, an increase of $82.9 million in revenue, and a decrease in income tax expense of $11.9 million, partially offset by $58.7 million in impairment of intangible assets.

*Revenue, net*

Revenue for the year ended December 31, 2025, was $106.5 million, compared to revenue of $23.6 million for the year ended December 31, 2024, an increase of approximately $82.9 million. The increase was primarily attributable to an increase in product sales of MIPLYFFA of $77.3 million and an increase in revenues under the global EAP of $3.9 million.

*Cost of product revenue*

Cost of product revenue for the year ended December 31, 2025, was $16.5 million, an increase of $9.1 million compared to cost of product revenue of $7.4 million for the year ended December 31, 2024. The increase was primarily due to $11.7 million in inventory obsolescence for the year ended December 31, 2025, compared to $5.7 million in inventory obsolescence for the year ended December 31, 2024, as well as royalty costs related to product sales of MIPLYFFA.

*Intangible asset amortization*

Intangible asset amortization for the year ended December 31, 2025, was $3.9 million, a decrease of approximately $2.4 million compared to intangible asset amortization of $6.2 million for the year ended December 31, 2024. The decrease was a result of not amortizing the OLPRUVA intangible asset for the full year as it was impaired in the second quarter of 2025.

*Research and development*

Research and development expenses decreased by $29.4 million, from $42.1 million for the year ended December 31, 2024, to $12.7 million for the year ended December 31, 2025. This decrease was primarily driven by a decrease in spending for the Phase 2 clinical study for KP1077 and a decrease in personnel-related costs.

*Selling, general and administrative*

Selling, general and administrative expenses increased by approximately $22.7 million, from $54.9 million for the year ended December 31, 2024, to $77.6 million for the year ended December 31, 2025. This increase was primarily related to an increase in personnel-related costs, professional fees, and other expenses as we continue to build our commercial organization.

*Other income (expense)*

Other income (expense) increased from $3.1 million of expense for the year ended December 31, 2024, to $149.6 million of income for the year ended December 31, 2025. The increase was primarily attributable to the gain on sale of the PRV of $148.3 million and an increase in interest and other income, net of $4.8 million.

*Income tax expense*

Income tax expense decreased by approximately $11.9 million, from $15.4 million for the year ended December 31, 2024, to $3.4 million for the year ended December 31, 2025, due to the periodic evaluation of our tax positions in the prior year.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Through December 31, 2025, we have funded our research and development and operating activities primarily through the issuance of debt and equity and from product sales of MIPLYFFA and OLPRUVA, reimbursements received under the global EAP, royalties or net sales milestone payments generated under the AZSTARYS License Agreement, our PRV sale consummated on April 1, 2025, and consulting agreements. As of December 31, 2025, we had cash, cash equivalents and investments of $238.9 million.

On February 26, 2025, we entered into the PRV Transfer Agreement, pursuant to which we agreed to sell the PRV to the buyer, subject to customary closing conditions. Pursuant to the PRV Transfer Agreement, the buyer agreed to pay us $150.0 million, payable in cash, upon the closing of the sale. On April 1, 2025, the asset sale was consummated, resulting in net proceeds of $148.3 million.

We have had recurring negative net operating cash flows throughout our operating history, and we cannot guarantee or predict when we may begin to consistently generate positive net cash flows from operations, or if at all. We expect that our sources of revenue will be from product sales of MIPLYFFA and OLPRUVA, product reimbursements received under the global EAP, royalties or net sales milestone payments generated under the AZSTARYS License Agreement, and any other future arrangements related to one or more of our products or product candidates.

If needed, adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

***Registration Statements on Form S-3***

On February 5, 2024, we filed a registration statement on Form S-3 (File No. 333-276856) registering an aggregate of 2,269,721 shares of our common stock for resale by certain stockholders. On April 5, 2024, we filed an amendment to such registration statement, which was declared effective on April 8, 2024.

On June 4, 2024, the Company filed a registration statement on Form S-3 (File No. 333-279941) (the “June 2024 Registration Statement”) under which we may sell securities in one or more offerings up to a total aggregate offering price of $350.0 million, $75.0 million of which was allocated to the sale of the shares of common stock issuable under the 2024 ATM Agreement (as described further below). The registration statement was declared effective on June 13, 2024.

***August 2024 Offering***

On August 8, 2024, we entered into an underwriting agreement (the "Underwriting Agreement") with Cantor Fitzgerald & Co. and William Blair & Company, L.L.C., as representatives of the several underwriters named therein (collectively, the "Underwriters"), in connection with the offering, issuance and sale by us of 9,230,770 shares of our common stock at a public offering price of $6.50 per share, pursuant to the June 2024 Registration Statement and a related prospectus supplement dated August 8, 2024 filed with the SEC (the "August 2024 Offering"). Under the terms of the Underwriting Agreement, we also granted the Underwriters an option exercisable for 30 days to purchase up to an additional 1,384,615 shares of our common stock at the public offering price, less underwriting discounts and commissions, which the Underwriters exercised in full on August 9, 2024. The August 2024 Offering closed on August 12, 2024. Total shares issued were 10,615,385. Net proceeds from the offering were approximately $64.5 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We are using the net proceeds of the offering to support the commercialization of its approved products and the continued development of its product candidates, and for other general corporate purposes.

***Entry into 2024 ATM Agreement***

On July 12, 2024, we entered into an equity distribution agreement (the "2024 ATM Agreement") with Citizens JMP Securities LLC ("Citizens JMP") under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $75.0 million through Citizens JMP as our sales agent. The issuance and sale, if any, of common stock by us under the 2024 ATM Agreement will be made pursuant to the June 2024 Registration Statement, the accompanying prospectus, and the related prospectus supplement dated July 12, 2024. Citizens JMP may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act. Citizens JMP will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Citizens JMP a commission equal to 3.0% in the aggregate of the gross sales proceeds of any common stock sold through Citizens JMP under the 2024 ATM Agreement. As of December 31, 2025, no shares have been issued or sold under the 2024 ATM Agreement.

***Term Loans***

On April 5, 2024 (the "Term Loans Closing Date"), we entered into a credit agreement (the "Credit Agreement") with HCR Stafford Fund II, L.P., HCR Potomac Fund II, L.P., and Perceptive Credit Holdings IV, LP (collectively, the "Lenders"), and Alter Domus (US) LLC, as administrative agent (the "Administrative Agent").

Under the terms of the Credit Agreement, the Lenders provided a senior secured loan facility to us in the aggregate principal amount of $100.0 million, which is divided into three tranches as follows: (i) $60.0 million, which was funded in full on the Term Loans Closing Date; (ii) $20.0 million, which was available to us in up to two drawings, each in an amount not to exceed $10.0 million, at our option until October 5, 2025; and; (iii) $20.0 million, which was available to us upon approval by the FDA of the NDA for MIPLYFFA for the treatment of NPC, at our option until December 31, 2024 (collectively, the "Term Loans"). We did not draw down the amounts described in (ii) and (iii) above prior to their applicable expiration dates.

The principal amount of the Term Loans outstanding (the "Outstanding Principal Amount") historically bore interest at a rate equal to 3-Month Term Secured Overnight Financing Rate ("SOFR") plus 7.00% per annum. As the net product sales for the calendar year ending December 31, 2025 exceeded $100.0 million, the Outstanding Principal Amount will bear interest at 3-Month Term SOFR plus 6.00% per annum beginning on January 1, 2026. In all cases, the 3-Month Term SOFR rate is subject to a floor of 4.00% per annum. Interest is payable quarterly in arrears on the last day of each calendar quarter. We have the option to pay up to 25% of the interest in-kind beginning on the Term Loans Closing Date, through and including June 30, 2026. We have recognized approximately $3.1 million and $1.4 million of interest-in-kind as of December 31, 2025, and 2024, which is included in long-term debt in the consolidated balance sheets. The Term Loans will mature on the fifth anniversary of the Term Loans Closing Date. In connection with the Credit Agreement, we incurred approximately $2.2 million of costs, which primarily consisted of underwriting, legal and other professional fees, and are included as a reduction to the carrying amount of the related debt liability and are deferred and amortized over the remaining life of the financing using the effective interest method.

The Credit Agreement contains customary affirmative and negative covenants by us, which, among other things, will require us to provide certain financial reports to the Lenders within 60 days after the end of each of the first three fiscal quarters of each fiscal year and 105 days after the end of each fiscal year, meet certain minimum net product sales amounts, meet certain minimum liquidity, and limit our ability to, among other things, incur or guarantee additional indebtedness, conduct asset sales, incur liens, make dividends or distributions, conduct transactions with affiliates, and effect a consolidation or merger without consent. Our obligations under the Credit Agreement may be accelerated upon customary events of default, including non-payment of principal, interest, fees and other amounts, covenant defaults, insolvency, material judgments, or inaccuracy of representations and warranties. The Term Loans are secured by a first priority perfected lien on, and security interest in, substantially all of our and certain of our subsidiaries' current and future assets. The proceeds of the Term Loans were used to refinance certain existing indebtedness of ourselves and our subsidiaries. We will use the remaining proceeds to pay fees and expenses related to the debt financing, to support commercialization of MIPLYFFA and OLPRUVA, and to further the development of our other product candidates.

**Cash Flows**

The following table summarizes our cash flows for the years ended December 31, 2025 and 2024 (in thousands):

| | Year Ended December 31, | | Period-to-Period Change |
|---|---|---|---|
| | 2025 | 2024 | |
| Net cash used in operating activities | $ (1,598) | $ (69,665) | $ 68,067 |
| Net cash provided by (used in) investing activities | 18,127 | (22,161) | 40,288 |
| Net cash provided by financing activities | 12,064 | 82,108 | (70,044) |
| Effect of exchange rate changes on cash and cash equivalents | 28 | 454 | (426) |
| Net increase (decrease) in cash and cash equivalents | $ 28,621 | $ (9,264) | $ 37,885 |

***Operating Activities***

For the year ended December 31, 2025, net cash used in operating activities of $1.6 million consisted of net income of $83.2 million, offset by $58.3 million in adjustments for non-cash items and changes in working capital of $26.5 million. Net income was primarily attributable to the sale of the PRV, as well as revenue received from product sales of MIPLYFFA and OLPRUVA, royalties generated under the AZSTARYS License Agreement, and reimbursements received under the global EAP, partially offset by impairment and obsolescence charges and spend on R&D programs and operating costs. The adjustments for non-cash items primarily consisted of the gain on sale of PRV of $148.3 million, partially offset by impairment of intangible assets of $58.7 million, inventory obsolescence of $11.7 million, stock-based compensation expense of $12.6 million, and $4.1 million of depreciation and amortization expense.

For the year ended December 31, 2024, net cash used in operating activities of $69.7 million consisted of a net loss of $105.5 million and $6.6 million in changes in working capital, partially offset by $42.5 million in adjustments for non-cash items. Net loss was primarily attributable to our spending on research and development programs and operating costs, partially offset by revenue received from MIPLYFFA and OLPRUVA product sales, royalties under the AZSTARYS License Agreement, and reimbursements from the global EAP. The changes in working capital consisted of $3.6 million related to a change in accounts payable and accrued expenses, $8.9 million related to a change in inventories, $2.2 million related to a change in prepaids and other assets, and $0.6 million related to operating lease liabilities, partially offset by $0.4 million related to a change in discount and rebate liabilities, $0.6 million related to a change in operating lease right of use assets, $0.8 million related to a change in other liabilities, and $6.9 million increase in accounts and other receivables. The adjustments for non-cash items primarily consisted of income tax expense of $15.4 million, stock-based compensation expense of $14.9 million, consulting fees paid in stock of $0.5 million, interest expense of $2.1 million, inventory obsolescence of $5.7 million and $5.7 million related to depreciation, amortization and other items, and a loss on disposal of $0.2 million, partially offset by a change in fair value adjustment of warrants and CVR of $2.1 million.

***Investing Activities***

For the year ended December 31, 2025, net cash provided by investing activities was $18.1 million, which was primarily attributable to proceeds from the sale of the PRV of $150.0 million and maturities of investments of $178.5 million, partially offset by $310.0 million in purchases of investments.

For the year ended December 31, 2024, net cash used in investing activities was $22.1 million, which was attributable to purchases of investments of $41.1 million and a $6.0 million regulatory milestone payment to XOMA, partially offset by maturities of investments of $25.0 million.

***Financing Activities***

For the year ended December 31, 2025, net cash provided by financing activities was $12.1 million, which was primarily attributable to proceeds from common stock warrants exercised of $8.6 million and options exercised of $3.2 million.

For the year ended December 31, 2024, net cash provided by financing activities was $82.1 million, which was primarily attributable to proceeds from the issuance of debt of $58.9 million, proceeds from insurance financing arrangements of $1.0 million and proceeds from sales of common stock under the Employee Stock Purchase Plan, or the ESPP, of $1.1 million, proceeds from issuance of common stock of $66.2 million, partially offset by repayments of debt of $42.7 million, payments of principal on insurance financing arrangements of $0.4 million, and payments of deferred offering costs of $2.0 million.

***Future Funding Requirements***

We believe our available cash and cash equivalents, together with our ability to generate operating cash flow and our access to short-term and long-term borrowings, are sufficient to fund our existing and planned capital requirements for at least the next twelve months and the foreseeable future.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of a failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position.

Potential near-term sources of additional funding include:

- any product sales of MIPLYFFA;
- any product sales of OLPRUVA;
- any reimbursements received for arimoclomol under the global EAP; and
- any royalties or net sales milestone payments generated under the AZSTARYS License Agreement.

We cannot guarantee that we will be able to generate sufficient proceeds from any of these potential sources to fund our operating expenses. We anticipate that our expenses will fluctuate substantially as we:

- continue building and maintaining our ongoing commercial capabilities to support the commercialization of our approved products, MIPLYFFA and OLPRUVA, in the United States;
- continue or initiate preclinical studies, clinical trials and product development activities for our pipeline of product candidates;
- seek regulatory approvals for any product candidates that may successfully complete clinical trials;
- seek to discover, license or acquire, and develop additional product candidates;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- incur additional legal, accounting and other expenses in operating as a public company; and
- add operational systems and personnel, if needed, to support any future commercialization efforts.

We have based our estimates of our cash needs and cash runway on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. In addition, we cannot guarantee that we will be able to generate sufficient proceeds from product sales of MIPLYFFA and OLPRUVA, reimbursements received under the global EAP, royalties or net sales milestone payments generated under the AZSTARYS License Agreement, or other funding transactions to fund our operating expenses. To meet any additional cash requirements, we may seek to sell additional equity or convertible securities that may result in dilution to our stockholders, issue additional debt or seek other third-party funding, including potential strategic transactions, such as licensing or collaboration arrangements. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates and products, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the commercialization and development of our partnered product or product candidates, should they obtain regulatory approval.

Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or debt, the terms of these securities may restrict our ability to operate. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs and/or commercialization efforts.

**Critical Accounting Estimates**

This management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of our financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note B to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to the process of making significant estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

***Acquisition of Intangible Assets***

We record all assets and liabilities acquired in business acquisitions at fair value, including goodwill and other intangible assets. The initial recognition of goodwill and other intangible assets requires management to make subjective judgments concerning estimates of how the acquired assets will perform in the future using valuation methods including discounted cash flow analysis. Inherent in the determination of fair value of the reporting units are certain estimates and judgments, including the interpretation of current economic indicators and market valuations, as well as management's strategic plans with regard to our operations. When utilizing a quantitative assessment, we determine fair value at the reporting unit level based on a combination of an income approach and market approach. The income approach is based on estimated future cash flows discounted at a rate that approximates the cost of capital of a market participant, while the market approach is based on sales and/or earnings multiples of similar companies. These approaches use significant estimates and assumptions, including projected future cash flows and the timing of those cash flows, discount rates reflecting risks inherent in future cash flows, perpetual growth rates, and determination of appropriate market comparables.

***Goodwill and Definite-Lived Intangible Assets***

Goodwill represents the excess of the purchase price of an acquired business over the fair value assigned to the assets purchased and liabilities assumed. Goodwill is not amortized but is evaluated for impairment within our single reporting unit on an annual basis, during the fourth quarter, or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of our reporting unit below its carrying amount. Our estimates associated with the annual test of goodwill for impairment, as well as the as-needed assessment of the recoverability of definite-lived intangible assets, are considered critical due to the amount of these assets recorded on our consolidated balance sheets and the judgment required.

With respect to definite-lived intangible assets, we periodically evaluate whether events and circumstances have occurred that may affect the estimated useful life or the recoverability of the remaining balance of such assets. If such events or circumstances indicate that the carrying amount of these assets may not be recoverable, management would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) were less than the carrying amount of the asset group, we would recognize an impairment charge to reduce such assets to their fair value.

***Revenue Recognition***

We recognize revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers* ("ASC 606") and, as a result, follows the five-step model when recognizing revenue: 1) identifying a contract; 2) identifying the performance obligations; 3) determining the transaction price; 4) allocating the price to the performance obligations; and 5) recognizing revenue when the performance obligations have been fulfilled.

Net revenues from product sales are recognized at the transaction price when the customer obtains control of our product, which occurs at a point in time, typically upon receipt of the product by the customer. Our current single customer for product sales of MIPLYFFA and OLPRUVA is a specialty pharmacy provider.

Our net revenues represent total revenues adjusted for discounts and allowances, including estimated cash discounts, chargebacks, rebates, returns, copay assistance, data fees and wholesaler fees for services. These adjustments represent variable consideration under ASC 606 and are recorded as a reduction of revenue. These adjustments are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Adjustments for variable consideration are determined based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products.

***Accrued Research and Development Expenses***

We enter into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. We record liabilities under these contractual commitments when an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include:

- fees paid to CROs in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of our raw materials, drug substance and product candidates; and
- professional fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of these costs, our actual expenses could differ from our estimates.

***Stock-Based Compensation***

We record the fair value of stock options issued as of the grant date as compensation expense. We recognize compensation expense over the requisite service period, which is equal to the vesting period. Stock-based compensation expense has been reported in our statements of operations as follows (in thousands):

| | Year ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Research and development | $ 841 | $ 5,819 |
| Selling, general and administrative | 11,793 | 9,087 |
| Total stock-based compensation expense | $ 12,634 | $ 14,906 |

*Determination of the Fair Value of Stock-Based Compensation Grants*

We calculate the fair value of stock-based compensation arrangements using the Black-Scholes-Merton ("BSM") option pricing model. The BSM option pricing model requires the use of subjective assumptions, including the expected volatility of our common stock, the assumed dividend yield, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and the fair value of the underlying common stock on the date of grant. In applying these assumptions, we considered the following factors:

- historically we have not had sufficient experience to estimate the volatility of our common stock. As such, we calculated the expected volatility based on reported data for selected similar publicly traded companies for which the historical information is available, or peer volatility, and blended it with our historical volatility, or leverage-adjusted peer volatility. For the purpose of identifying peer companies, we consider characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. We utilized this leverage-adjusted peer volatility for grants prior to the initial public offering, as well as grants within the two-year period immediately following the initial public offering. For grants after the second anniversary of the initial public offering we utilized our historical volatility to determine the expected volatility;

- the assumed dividend yield is based on our expectation of not paying dividends for the foreseeable future;

- we determine the average expected life of "plain vanilla" stock options based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110 due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected term of the stock options. For options that are not considered "plain vanilla," such as those with exercise prices in excess of the fair market value of the underlying stock, we use an expected life equal to the contractual term of the option;

- we determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant; and

- we estimate forfeitures based on our historical analysis of actual stock option forfeitures.

We account for stock-based compensation arrangements with directors and consultants that contain only service conditions for vesting using a fair value approach. The grant date fair value of these options is measured using the BSM option pricing model reflecting the same assumptions as applied to employee options in each of the reported periods, other than the expected life, which is assumed to be the remaining contractual life of the option.

The following summarizes the assumptions used for estimating the fair value of stock options granted to employees for the periods indicated:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Risk-free interest rate | 3.70% - 4.39% | 3.82% - 4.50% |
| Expected term (in years) | 5.50 - 6.25 | 5.50 - 6.25 |
| Expected volatility | 81.54% - 87.31% | 89.85% - 91.32% |
| Expected dividend yield | 0 | 0 |

***Income Taxes***

We are subject to taxation in the United States and the Kingdom of Denmark. Tax liabilities may arise from interpretations and judgments made with regard to transfer pricing in the application of the relevant statutes, regulations, tax rulings and case law across the various jurisdictions. We use significant judgment in (1) determining whether the technical merits of tax positions taken in the various jurisdictions are more-likely-than-not to be sustained based on applicable tax law and (2) measuring the related amount of tax liability that qualifies for recognition.

***Utilization of Net Operating Loss Carryforwards and Research and Development Credits***

As of December 31, 2025, we had federal net operating loss, or NOL, carryforwards of approximately $230.4 million, $11.1 million of which, if not utilized, will begin to expire in 2029 and $219.4 million of which have no expiration date. We also have certain state net operating loss carryforwards totaling $312.2 million, which, if not utilized, will begin to expire in 2029.

We recorded refundable research and development tax credits as interest and other income, net and not income tax under ASC 740 in the consolidated statements of operations for the year ended December 31, 2025. These refundable tax credits are a result of increased qualified research and development spending in certain jurisdictions which allow for a refundable credit even when a company has no current period income tax expense.

In accordance with Section 382 of the Code, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on a company's ability to utilize its NOL carryforwards created during the tax periods prior to the change in ownership. We performed a Section 382 ownership change analysis through the period ending November 26, 2025 and determined that we experienced ownership changes in 2016, 2020, and 2021 which resulted in a portion of our net operating loss carryforwards being subject to an annual limitation under Section 382 for those respective tax years. No other ownership changes or limitations on our historical net operating loss carryforwards were noted through the period ending November 26, 2025.

***Warrants***

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and FASB ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to our own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital on the consolidated statements of changes in stockholders' equity at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as a liability at their initial fair value on the date of issuance, and on each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss in other expense, net, on the consolidated statements of operations. The fair value of the warrants was estimated using the BSM option pricing model.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item 8 are set forth beginning in Item 15 of this report and are incorporated herein by reference.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

***Limitations on effectiveness of controls and procedures***

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our chief executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2025. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our chief executive officer and our principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

***Management's Report on Internal Control over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our chief executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "*Internal Control – Integrated Framework (2013)*" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

Our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. For as long as we remain a non-accelerated filer, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during our fiscal quarter ended December 31, 2025, that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

**(a) Disclosure in lieu of reporting on a Current Report on Form 8-K.**

None.

**(b) Insider Trading Arrangements and Policies.**

During the three-months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

## ITEM 9C. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2025 and is incorporated into this Annual Report on Form 10-K by reference.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2025 and is incorporated into this Annual Report on Form 10-K by reference.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2025 and is incorporated into this Annual Report on Form 10-K by reference.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2025 and is incorporated into this Annual Report on Form 10-K by reference.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item will be set forth in our Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2025 and is incorporated into this Annual Report on Form 10-K by reference.

## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) *Index list to Financial Statements:*



(2) *Financial Statement Schedules*

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) *Exhibits*

The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this report.

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Zevra Therapeutics, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Zevra Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income (loss), changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

**Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosures to which it relates.

***Current Portion of Income Tax Payable***

*Description of the Matter*

As disclosed in Notes B and O to the consolidated financial statements, the Company is subject to taxation in the United States and the Kingdom of Denmark. Tax liabilities may arise from interpretations and judgments made by the Company with regard to transfer pricing in the application of the relevant statutes, regulations, tax rulings and case law across the various jurisdictions. The Company uses significant judgment in (1) determining whether the technical merits of tax positions taken in the various jurisdictions are more-likely-than-not to be sustained based on applicable tax law and (2) measuring the related amount of tax liability that qualifies for recognition. The current portion of income tax payable includes $11.1 million attributable to the PRV sale, which included transfer pricing considerations.

Auditing the current portion of income tax payable related to the PRV sale was challenging because the measurement of the recognized tax payable is judgmental with regard to transfer pricing and is based on interpretations of statutes, regulations, tax rulings and case law in the various jurisdictions.

*How We Addressed the Matter in Our Audit*

To test the measurement of current portion of income tax payable related to the PRV sale, our audit procedures included, among others, involving our tax professionals to assist in assessing the technical merits of the Company's tax position through using our knowledge of and experience with the application of income tax laws by the relevant tax authorities and developing independent analyses in order to evaluate the amount recognized. We also assessed the Company's data used to measure the amount of current portion of income tax payable related to the PRV sale and tested the clerical accuracy of the calculations.

/S/ Ernst & Young LLP

We have served as the Company's auditor since 2022.

Orlando, Florida

March 9, 2026

**ZEVRA THERAPEUTICS, INC.**
**CONSOLIDATED BALANCE SHEETS**
**(in thousands, except share and par value amounts)**

| | December 31, | |
|---|---|---|
| | **2025** | **2024** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 62,406 | $ 33,785 |
| Securities at fair value, current | 128,605 | 35,711 |
| Accounts and other receivables | 23,258 | 10,509 |
| Prepaid expenses and other current assets | 6,998 | 4,052 |
| Inventories, current | 1,740 | 1,970 |
| Total current assets | 223,007 | 86,027 |
| Securities at fair value, noncurrent | 47,879 | 6,010 |
| Inventories, noncurrent | 879 | 10,999 |
| Property and equipment, net | 489 | 356 |
| Operating lease right-of-use assets | 1,212 | 657 |
| Goodwill | 4,701 | 4,701 |
| Intangible assets, net | 6,421 | 68,993 |
| Other long-term assets | 143 | 384 |
| Total assets | $ 284,731 | $ 178,127 |
| | | |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 11,598 | $ 25,456 |
| Current portion of operating lease liabilities | 419 | 420 |
| Current portion of discount and rebate liabilities | 12,188 | 5,929 |
| Current portion of income tax payable | 13,710 | — |
| Other current liabilities | 1,362 | 2,260 |
| Total current liabilities | 39,277 | 34,065 |
| Long-term debt | 61,928 | 59,504 |
| Warrant liability | 9,575 | 17,804 |
| Income tax payable | 7,029 | 14,431 |
| Operating lease liabilities, less current portion | 859 | 372 |
| Discount and rebate liabilities, less current portion | 9,693 | 7,655 |
| Other long-term liabilities | 1,713 | 4,630 |
| Total liabilities | 130,074 | 138,461 |
| | | |
| Commitments and contingencies (Note K) | | |
| | | |
| Stockholders' equity: | | |
| Preferred stock: | | |
| Undesignated preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of December 31, 2025 or December 31, 2024 | — | — |
| Common stock, $0.0001 par value, 250,000,000 shares authorized, 58,338,319 shares issued and 56,854,781 shares outstanding as of December 31, 2025; 55,246,401 shares issued and 53,670,709 shares outstanding as of December 31, 2024 | 6 | 5 |
| Additional paid-in capital | 588,458 | 555,302 |
| Treasury stock, at cost | (10,983) | (10,983) |
| Accumulated deficit | (422,060) | (505,289) |
| Accumulated other comprehensive (loss) income | (764) | 631 |
| Total stockholders' equity | 154,657 | 39,666 |
| Total liabilities and stockholders' equity | $ 284,731 | $ 178,127 |

*See accompanying notes to consolidated financial statements*

**ZEVRA THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(in thousands, except share and per share amounts)**

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Revenue, net | $ 106,470 | $ 23,612 |
| Cost of product revenue (excluding $3,862 and $6,235 in intangible asset amortization for the years ended December 31, 2025, and 2024, respectively, shown separately below) | 16,482 | 7,417 |
| Intangible asset amortization | 3,862 | 6,235 |
| Impairment of intangible assets | 58,710 | — |
| Operating expenses: | | |
| Research and development | 12,743 | 42,095 |
| Selling, general and administrative | 77,616 | 54,868 |
| Total operating expenses | 90,359 | 96,963 |
| Loss from operations | (62,943) | (87,003) |
| Other income (expense): | | |
| Gain on sale of PRV | 148,325 | — |
| Interest expense | (7,977) | (7,351) |
| Fair value adjustment related to warrant and CVR liability | 2,178 | 2,057 |
| Fair value adjustment related to investments | 149 | (18) |
| Interest and other income, net | 6,946 | 2,175 |
| Total other income (expense) | 149,621 | (3,137) |
| Income (loss) before income taxes | 86,678 | (90,140) |
| Income tax expense | (3,449) | (15,371) |
| Net income (loss) | $ 83,229 | $ (105,511) |
| | | |
| Net income (loss) per share of common stock: | | |
| Basic | $ 1.40 | $ (2.28) |
| Diluted | $ 1.35 | $ (2.28) |
| | | |
| Weighted-average shares of common stock outstanding: | | |
| Basic | 55,311,308 | 46,251,239 |
| Diluted | 57,262,715 | 46,251,239 |

*See accompanying notes to consolidated financial statements*

**ZEVRA THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**
**(in thousands)**

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Net income (loss) | $ 83,229 | $ (105,511) |
| Other comprehensive (loss) income: | | |
| Foreign currency translation adjustment | (1,395) | 674 |
| Other comprehensive (loss) income | (1,395) | 674 |
| Comprehensive income (loss) | $ 81,834 | $ (104,837) |

*See accompanying notes to consolidated financial statements*

**ZEVRA THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**
**(in thousands)**

| | Common Stock | Additional Paid-in Capital | Treasury Stock | Accumulated Deficit | Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| Balance as of January 1, 2024 | $ 4 | $ 472,664 | $ (10,983) | $ (399,778) | $ (43) | $ 61,864 |
| Net loss | — | — | — | (105,511) | — | (105,511) |
| Stock-based compensation expense | — | 14,906 | — | — | — | 14,906 |
| Issuance of common stock in public offering (Note A) | 1 | 64,516 | — | — | — | 64,517 |
| Issuance of common stock in exchange for consulting services | — | 474 | — | — | — | 474 |
| Issuance of common stock as part of the Employee Stock Purchase Plan | — | 1,058 | — | — | — | 1,058 |
| Issuance of common stock for options exercised | — | 1,684 | — | — | — | 1,684 |
| Other comprehensive income | — | — | — | — | 674 | 674 |
| Balance as of December 31, 2024 | $ 5 | $ 555,302 | $ (10,983) | $ (505,289) | $ 631 | $ 39,666 |
| Net income | — | — | — | 83,229 | — | 83,229 |
| Stock-based compensation expense | — | 12,634 | — | — | — | 12,634 |
| Issuance of common stock in exchange for consulting services | | 75 | | | | 75 |
| Issuance of common stock as part of the Employee Stock Purchase Plan | — | 615 | — | — | — | 615 |
| Issuance of common stock for options exercised or RSUs vested | 1 | 3,182 | — | — | — | 3,183 |
| Issuance of common stock for warrants exercised | — | 16,650 | — | — | — | 16,650 |
| Other comprehensive loss | — | — | — | — | (1,395) | (1,395) |
| Balance as of December 31, 2025 | $ 6 | $ 588,458 | $ (10,983) | $ (422,060) | $ (764) | $ 154,657 |

*See accompanying notes to consolidated financial statements*

**ZEVRA THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(in thousands)**

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Cash flows from operating activities:** | | |
| Net income (loss) | $ 83,229 | $ (105,511) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Stock-based compensation expense | 12,634 | 14,906 |
| Impairment of intangible assets | 58,710 | — |
| Inventory obsolescence charge | 11,681 | 5,746 |
| Income tax expense | 3,449 | 15,374 |
| Depreciation and amortization expense | 4,054 | 6,389 |
| Non-cash interest expense | 2,649 | 2,089 |
| Non-cash lease expense | 602 | 552 |
| Fair value adjustment related to warrant and CVR liabilities | (2,178) | (2,057) |
| Accretion on investments | (3,128) | (890) |
| Fair value adjustment related to investments | (149) | 18 |
| Loss on sublease and disposal of property and equipment | 63 | 218 |
| Consulting fees paid in common stock | 75 | 474 |
| Loss on foreign currency exchange rates | 1,548 | 219 |
| Gain on sale of PRV | (148,325) | — |
| Change in assets and liabilities: | | |
| Accounts and other receivables | (11,977) | 6,868 |
| Prepaid expenses and other current assets | (2,943) | (2,228) |
| Inventories | (1,305) | (8,874) |
| Other long-term assets | 451 | — |
| Accounts payable and accrued expenses | (15,587) | (3,598) |
| Discount and rebate liabilities | 6,683 | 431 |
| Operating lease liabilities | (675) | (626) |
| Other liabilities | (1,159) | 835 |
| Net cash used in operating activities | (1,598) | (69,665) |
| | | |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (835) | — |
| Disposals of property and equipment | 448 | — |
| Purchases of investments | (309,986) | (41,161) |
| Maturities of investments | 178,500 | 25,000 |
| Proceeds from sale of PRV | 150,000 | — |
| Payment of royalty to XOMA | — | (6,000) |
| Net cash provided by (used in) investing activities | 18,127 | (22,161) |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of debt, net of lender fees | — | 58,990 |
| Repayment of debt | — | (42,700) |
| Proceeds from insurance financing arrangements | — | 1,082 |
| Proceeds from Employee Stock Purchase Plan | 615 | 1,058 |
| Proceeds from issuance of stock | — | 64,516 |
| Proceeds from issuance of common stock for options exercised | 3,182 | 1,684 |
| Proceeds from issuance of common stock for warrants exercised | 8,639 | — |
| Payments of principal on insurance financing arrangements | (372) | (431) |
| Payment of deferred financing costs | — | (2,091) |
| Net cash provided by financing activities | 12,064 | 82,108 |
| Effect of exchange rate changes on cash and cash equivalents | 28 | 454 |
| Net increase (decrease) in cash and cash equivalents | 28,621 | (9,264) |
| Cash and cash equivalents, beginning of period | 33,785 | 43,049 |
| Cash and cash equivalents, end of period | $ 62,406 | $ 33,785 |
| | | |
| **Supplemental cash flow information:** | | |
| Cash paid for interest | $ 5,329 | $ 5,262 |
| Right-of-use assets obtained in exchange for lease liabilities | 1,115 | 419 |

*See accompanying notes to consolidated financial statements*

**ZEVRA THERAPEUTICS, INC.**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## A. Description of Business, Basis of Presentation, and Significant Transactions

### *Organization*

Zevra Therapeutics, Inc. (the "Company" or "Zevra") is a commercial-stage company with a late-stage pipeline committed to bringing life-changing therapeutics to people living with rare diseases. The Company is focused on expanding patient access, progressing our pipeline toward key milestones, and delivering meaningful outcomes for patients with significant unmet needs.

On September 20, 2024, the U.S. Food and Drug Administration ("FDA") approved the New Drug Application ("NDA") for MIPLYFFA® (arimoclomol), an orally-delivered treatment for Niemann-Pick disease type C ("NPC"), which is an ultra-rare and progressive neurodegenerative disease. MIPLYFFA, the first FDA-approved treatment for NPC, is indicated for use in combination with miglustat for the treatment of neurological manifestations of NPC in adult and pediatric patients two years of age and older. MIPLYFFA has also been granted orphan medicinal product designation for the treatment of NPC by the European Commission. The Company's other commercial stage asset, OLPRUVA® (sodium phenylbutyrate) for oral suspension, is approved by the FDA for the treatment of certain urea cycle disorders ("UCDs").

Additionally, the Company has a pipeline of investigational product candidates, including celiprolol for the treatment of Vascular Ehlers-Danlos syndrome ("VEDS") in patients with a confirmed type III collagen mutation and KP1077, the Company's clinical development product candidate being developed to treat idiopathic hypersomnia ("IH"), a rare neurological sleep disorder, and narcolepsy. The sole active pharmaceutical ingredient of KP1077 is serdexmethylphenidate ("SDX"), the Company's proprietary prodrug of d-methylphenidate ("d-MPH"). The FDA has granted KP1077 orphan drug designation for the treatment of IH.

### *Basis of Presentation*

The Company prepared the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") and, in the Company's opinion, reflect all adjustments, including normal recurring items that are necessary. All significant intercompany accounts and transactions have been eliminated in consolidation.

### *Registration Statements on Form S-3*

On February 5, 2024, Zevra filed a registration statement on Form S-3 (File No. 333-276856) registering an aggregate of 2,269,721 shares of Zevra's common stock. On April 5, 2024, the Company filed an amendment to such registration statement, which was declared effective on April 8, 2024.

On June 4, 2024, the Company filed a registration statement on Form S-3 (File No. 333-279941) (the "June 2024 Registration Statement") under which the Company may sell securities, including as may be issuable upon conversion, redemption, repurchase, exchange or exercise of securities, in one or more offerings up to a total aggregate offering price of $350.0 million, $75.0 million of which was allocated to the sale of the shares of common stock issuable under the 2024 ATM Agreement (as described further below). The registration statement was declared effective on June 13, 2024.

### *August 2024 Offering*

On August 8, 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cantor Fitzgerald & Co. and William Blair & Company, L.L.C., as representatives of the several underwriters named therein (collectively, the "Underwriters"), in connection with the offering, issuance and sale by the Company of 9,230,770 shares of the Company's common stock at a public offering price of $6.50 per share, pursuant to the June 2024 Registration Statement and a related prospectus supplement dated August 8, 2024, filed with the SEC (the "August 2024 Offering"). Under the terms of the Underwriting Agreement, the Company also granted the Underwriters an option exercisable for 30 days to purchase up to an additional 1,384,615 shares of its common stock at the public offering price, less underwriting discounts and commissions, which the Underwriters exercised in full on August 9, 2024. The August 2024 Offering closed on August 12, 2024. Total shares issued were 10,615,385. Net proceeds from the offering were approximately $64.5 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The Company is using the net proceeds of the offering to support the commercialization of its approved products and the continued development of its product candidates, and for other general corporate purposes.

***Entry into 2024 ATM Agreement***

On July 12, 2024, the Company entered into an equity distribution agreement (the "2024 ATM Agreement") with Citizens JMP Securities LLC ("Citizens JMP") under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $75.0 million through Citizens JMP as its sales agent. The issuance and sale, if any, of common stock by the Company under the 2024 ATM Agreement will be made pursuant to the June 2024 Registration Statement, the accompanying prospectus, and the related prospectus supplement dated July 12, 2024. Citizens JMP may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act. Citizens JMP will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay Citizens JMP a commission equal to 3.0% in the aggregate of the gross sales proceeds of any common stock sold through Citizens JMP under the 2024 ATM Agreement. As of December 31, 2025, no shares have been issued or sold under the 2024 ATM Agreement.

***Reclassifications***

Certain reclassifications were made to the 2024 consolidated financial statements to conform to the classifications used in 2025. These reclassifications had no impact on the consolidated net income (loss), changes in stockholder's equity, or cash flows previously reported.

**B. Summary of Significant Accounting Policies**

***Use of Estimates***

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to revenue recognition, the useful lives of property and equipment, the recoverability of long-lived assets, the incremental borrowing rate for leases, and assumptions used for purposes of determining stock-based compensation, income taxes, the fair value of the warrant liability and discount and rebate liabilities, among others. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities.

***Concentration of Credit Risk***

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash on deposit and investments with multiple financial institutions, the balances of which frequently exceed insured limits, and accounts receivable, which are concentrated amongst a limited number of customers.

***Cash and Cash Equivalents***

The Company considers any highly liquid investments with an original maturity of three months or less to be cash equivalents.

***Investments***

The Company maintains investment securities that are classified as available-for-sale securities for which the Company has elected the fair value option under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 825, *Financial Instruments*. As such, these securities are carried at fair value with unrealized gains and losses included in fair value adjustment related to investments on the consolidated statements of operations. The securities primarily consist of U.S. Treasury securities and corporate bonds and are included in securities at fair value in the consolidated balance sheets. As of December 31, 2025, and 2024, the Company held securities with an aggregate fair value of $176.5 million and $41.7 million, respectively, that contained an aggregate unrealized gain of approximately $149,000 and an aggregate unrealized loss of approximately $18,000, respectively. For securities held at December 31, 2025, $128.6 million mature within one year and $47.9 million mature in one to three years. Applying fair value accounting to these debt securities more accurately represents the Company's investment strategy due to the fact that excess cash is currently being invested for the purpose of funding future operations. Interest income is recognized as earned using an effective yield method giving effect to the amortization of premium and accretion of discount and is based on the economic life of the securities. Interest income is included in interest and other income, net, in the consolidated statements of operations.

***Variable Interest Entities***

The primary beneficiary of a variable interest entity ("VIE") is required to consolidate the assets and liabilities of the VIE. When the Company obtains a variable interest in another entity, it assesses at the inception of the relationship and upon occurrence of certain significant events whether the entity is a VIE, and if so, whether the Company is the primary beneficiary of the VIE based on its power to direct the activities of the VIE that most significantly impact the VIE's economic performance and the Company's obligation to absorb losses or the rights to receive benefits from the VIE that could potentially be significant to the VIE.

To assess whether the Company has the power to direct the activities of the VIE that most significantly impact the VIE's economic performance, the Company considers all the facts and circumstances, including the Company's role in establishing the VIE and the Company's ongoing rights and responsibilities. The assessment includes identifying the activities that most significantly impact the VIE's economic performance and identifying which party, if any, has the power to direct those activities. In general, the parties that make the most significant decisions affecting the VIE (management and members of the Board of Directors) are deemed to have the power to direct the activities of a VIE.

To assess whether the Company has the obligation to absorb losses of the VIE or the rights to receive benefits from the VIE that could potentially be significant to the VIE, the Company considers all of its economic interests that are deemed to be variable interests in the VIE.

This assessment requires judgment in determining whether these interests, in the aggregate, are considered potentially significant to the VIE. As of December 31, 2025, and 2024, the Company identified Acer Therapeutics, Inc. ("Acer") to be the Company's sole interest in a VIE. As Zevra is the final decision maker for all of Acer's research, development, and commercialization of drug candidates that it is producing, the Company directs the activities of Acer that most significantly impact its performance. Therefore, the Company is the primary beneficiary of this VIE for accounting purposes and consolidates the assets and liabilities of the VIE.

***Goodwill and Intangible Assets***

Goodwill represents the excess of the consideration transferred over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. Goodwill is not amortized but is evaluated for impairment within the Company's single reporting unit on an annual basis, during the fourth quarter, or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's reporting unit below its carrying amount. The Company establishes its reporting units based on the organizational structure and has determined it has one reporting unit. In performing its analysis, in accordance with ASC 350, the Company has the option to first assess qualitatively whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill. In performing qualitative assessments, the Company considers, among other factors, macroeconomic conditions, the Company's overall financial performance (including, but not limited to, comparisons to prior periods, current period internal expectations, and comparable peer companies), broader industry and market considerations, and the trading price performance of the Company's common stock.

The Company's goodwill balance was $4.7 million as of December 31, 2025, and 2024. As of December 31, 2025, and 2024, the Company completed its annual qualitative assessment under ASC 350 to determine whether the existence of events or circumstances indicated that it was more likely than not that the fair value of its reporting unit was less than its respective carrying value. The Company concluded that based on the relevant events and circumstances, it was more likely than not that the reporting unit's fair value exceeded its related carrying value and therefore no quantitative assessment was required. No goodwill impairment charges were recorded for the years ended December 31, 2025, or 2024.

Acquired in-process research and development ("IPR&D") that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each IPR&D project, the Company will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated and begin amortization. The Company evaluates IPR&D for impairment on an annual basis, during the fourth quarter, or more frequently if impairment indicators exist. The Company's IPR&D balance was $2.0 million as of December 31, 2025, and 2024. No IPR&D impairment charges were recognized for the years ended December 31, 2025, or 2024.

As of December 31, 2025, and 2024, the Company had a definite-lived intangible asset, net related to the acquisition of OLPRUVA of $0 and $61.3 million, respectively. The Company recorded an intangible asset impairment charge in the consolidated statements of operations for the year ended December 31, 2025 as a result of a triggering event indicating the asset's carrying amount may not be recoverable (see Note S). Prior to the impairment, this asset was amortized on a straight-line basis over the OLPRUVA useful life of thirteen years. The Company reviews the estimated useful lives of its intangible assets on an ongoing basis. Amortization expense is recorded as intangible asset amortization in the consolidated statements of operations and was $2.6 million and $5.9 million for the years ended December 31, 2025, and 2024, respectively.

In connection with the XOMA License Agreement, the Company paid XOMA a regulatory milestone payment of $6.0 million upon approval of MIPLYFFA in September 2024, which is included in intangible assets, net in the consolidated balance sheets. This definite-lived intangible asset is amortized on a straight-line basis over the MIPLYFFA patent life of approximately five years and is reviewed periodically for impairment. Amortization expense is recorded as intangible asset amortization in the consolidated statements of operations and was $1.3 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively.

***Property and Equipment***

The Company records property and equipment at cost less accumulated depreciation and amortization. Costs of renewals and improvements that extend the useful lives of the assets are capitalized. Maintenance and repairs are expensed as incurred. Depreciation is determined on a straight-line basis over the estimated useful lives of the assets, which generally range from three to ten years. Leasehold improvements are amortized over the shorter of the useful life of the asset or the term of the related lease. Upon retirement or disposition of assets, the costs and related accumulated depreciation and amortization are removed from the accounts with the resulting gains or losses, if any, reflected in the consolidated statements of operations.

***Impairment of Long-Lived Assets***

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset group may not be recoverable. When such events occur, the Company compares the carrying amount of the asset group to the undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying value, an impairment loss is recorded for the difference between the carrying value and fair value of the asset group. Beyond the definite-lived intangible asset impairment disclosed in Note S, no other impairment occurred for the years ended December 31, 2025, or 2024.

***Gain on Sale of PRV***

The Company received a transferable rare priority review voucher (“PRV”) in conjunction with the FDA approval of MIPLYFFA. On February 26, 2025, the Company and its subsidiary, Zevra Denmark A/S, entered into an asset purchase agreement with a buyer, pursuant to which the Company agreed to sell the PRV to the buyer for aggregate proceeds of $150.0 million, payable in cash, upon the closing of the sale. On April 1, 2025, the asset sale was consummated and title of the PRV transferred to the buyer, resulting in net proceeds of $148.3 million to the Company. The PRV did not have a carrying value at the time of sale. In accordance with ASC 610-20, *Gains and Losses from the Derecognition of Nonfinancial Assets,* the net proceeds from the sale were recorded as a gain on sale of PRV in the Company's consolidated statements of operations for the year ended December 31, 2025.

***Revenue Recognition***

The Company recognizes revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers* (“ASC 606”) and, as a result, follows the five-step model when recognizing revenue: 1) identifying a contract; 2) identifying the performance obligations; 3) determining the transaction price; 4) allocating the price to the performance obligations; and 5) recognizing revenue when the performance obligations have been fulfilled.

**Product Revenues, net**

Net revenues from product sales are recognized at the transaction price when the customer obtains control of the Company's product, which occurs at a point in time, typically upon receipt of the product by the customer. The Company's current single customer for product sales of MIPLYFFA and OLPRUVA is a specialty pharmacy provider.

In accordance with ASC 606, the Company recognizes revenue when fulfilling its performance obligation by transferring control of promised goods or services to its customer, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. In determining when the customer obtains control of the product, the Company considers certain indicators, including whether the Company has a present right to payment from the customer, whether title and/or significant risks and rewards of ownership have transferred to the customer and whether customer acceptance has been received. The Company's net revenues represent total revenues adjusted for discounts and allowances, including estimated cash discounts, chargebacks, rebates, returns, copay assistance, data fees and wholesaler fees for services. These adjustments represent variable consideration under ASC 606 and are recorded as a reduction of revenue. These adjustments are established by management as its best estimate based on available information and will be adjusted to reflect known changes in the factors that impact such allowances. Adjustments for variable consideration are determined based on the contractual terms with customers, historical trends, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for the product and anticipated introduction of competitive products. All estimated reserve liabilities related to commercial products are recorded within the current portion of discount and rebate liabilities in the consolidated balance sheets.

**Expanded Access Program**

Net revenue includes revenue from the sale of arimoclomol for the treatment of NPC under an expanded access program (“EAP”) in France, and in select territories outside Europe. An EAP is a program giving specific patients access to a drug that is not yet approved for commercial sale. Only drugs targeting serious or rare indications and for which there is currently no appropriate treatment are considered for expanded access programs. Further, to be considered for the expanded access program, the drug must have proven efficacy and safety and must either be undergoing price negotiations or seeking marketing approval.

In accordance with ASC 606, the Company recognizes revenue when fulfilling its performance obligation under the global EAP by transferring control of promised goods or services to its customer, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. In determining when the customer obtains control of the product, the Company considers certain indicators, including whether the Company has a present right to payment from the customer, whether title and/or significant risks and rewards of ownership have transferred to the customer and whether customer acceptance has been received. Revenue is recognized net of sales deductions, including discounts, rebates, applicable distributor fees, and revenue-based taxes.

The French Health Authorities and the manufacturer have agreed to a price for sales under the EAP in France, but the final price depends on the terms and conditions negotiated with the French Health Authorities, following market authorization. Any excess in the price charged by the manufacturer compared to the price agreed with the health authorities once the medicinal product is authorized in France must be repaid. The repayment is considered in the clawback liability. An estimate of net revenue and clawback liability are recognized using the ‘expected value’ method. Accounting for net revenue and clawback liability requires determination of the most appropriate method for estimating the expected final price. This estimate also requires assumptions with respect to inputs into the method, including current pricing of comparable marketed products within the rare disease area in France. Management has considered the expected final sales price as well as the price of similar medicinal products. The Company is operating within a rare disease therapeutic area where there is unmet treatment need and hence a limited number of comparable commercialized medicinal products. The limited available relevant market information for directly comparable commercialized medicines within rare disease increases the uncertainty in management's estimate.

**Licensing Agreements**

The terms of the Company’s licensing agreements typically include one or more of the following: (i) upfront fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Each of these payments may result in licensing revenues.

As part of the accounting for these agreements, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. Generally, the estimation of the stand-alone selling price may include such estimates as independent evidence of market price, forecasted revenues or costs, development timelines, discount rates, and probability of regulatory success. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time, and it measures the services delivered to the licensee, which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore, revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

*Upfront Fees*: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

*Milestone Payments*: At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or the licensee's control, such as operational developmental milestones and any related constraint, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative licensing revenues and earnings in the period of adjustment.

***Acquired IPR&D and Milestones Expenses***

In an asset acquisition, payments incurred prior to regulatory approval to acquire rights to IPR&D projects are expensed as acquired IPR&D and milestones expense in the consolidated statements of operations unless the project has an alternative future use. These costs include upfront and development milestone payments related to R&D collaborations, licensing arrangements, or other asset acquisitions that provide rights to develop, manufacture and/or sell pharmaceutical products. Where contingent development milestone payments are due to third parties, prior to regulatory approval, the payment obligations are expensed when the milestone results are achieved. Regulatory and commercial milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized to intangible asset amortization over the remaining useful life of the related product.

***Inventories***

The value of inventories is recorded at net realizable value. The Company determines the cost of its inventories, which include amounts related to materials and manufacturing overhead, on a first-in, first-out basis. Inventories that are not expected to be sold within 12 months are classified as inventories, noncurrent.

The Company may scale-up and make commercial quantities of its product candidates prior to the date it anticipates that such product will receive final regulatory approval. The scale-up and commercial production of pre-launch inventory involves the risk that such products may not be approved for marketing on a timely basis, or ever. This risk notwithstanding, the Company may scale-up and build pre-launch inventory of products that have not received final regulatory approval when the Company believes such action is appropriate in relation to the commercial value of the product launch opportunity. We capitalize inventory costs associated with our products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval. The Company had no pre-approval inventory on our consolidated balance sheets as of December 31, 2025, or 2024. Inventory used in clinical trials is also expensed as research and development expense, when selected for such use. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in a clinical manufacturing campaign. The cost of finished goods inventory that is shipped to a customer to support the Company's patient assistance programs is expensed when those shipments take place. As of December 31, 2025, and 2024, the Company did not have pre-launch inventory that qualified for capitalization.

The Company performs an assessment of the recoverability of capitalized inventory during each reporting period and writes down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of product revenue in the consolidated statements of operations. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write downs of inventory may be required. Additionally, the Company's products are subject to strict quality control and monitoring, which is performed throughout the manufacturing process. In the event that certain batches or units of product do not meet quality specifications, the Company will record a charge to cost of product revenue, to write down any unsaleable inventory to its estimated net realizable value. For the years ended December 31, 2025, and 2024, the Company recognized charges of approximately $11.7 million and $5.7 million, respectively, related to write-downs for unsaleable inventory.

***Cost of Product Revenue***

The components of cost of product revenue are royalties and expenses directly attributable to revenue. To date, the Company has generated revenue from product sales of MIPLYFFA and OLPRUVA, reimbursements received under the global EAP, royalties or net sales milestone payments generated under the Collaboration and License Agreement with Commave Therapeutics SA (the "AZSTARYS® License Agreement"), and consulting agreements.

Prior to our acquisition of the assets of Orphazyme A/S ("Orphazyme") in May 2022, Orphazyme had entered into an asset purchase agreement with LadRx Corporation, which was assigned to XOMA (US) LLC, a wholly-owned subsidiary of XOMA Corporation ("XOMA"), in June 2023 ("XOMA License Agreement"). Under the XOMA License Agreement, XOMA is entitled to a mid-single digit percentage royalty with respect to net sales of MIPLYFFA as well as milestone payments based on future potential sales and regulatory milestones. On August 30, 2023, Acer and Relief Therapeutics SA ("Relief") entered into an exclusive license agreement (the "Relief License Agreement"). Pursuant to the Relief License Agreement, Zevra was obligated to pay royalties of 10% of U.S. net sales of OLPRUVA up to a maximum of $45.0 million, plus specified regulatory milestones, for total payments to Relief of up to $56.5 million. On April 10, 2025, the rights to this royalty were sold to Soleus Capital Management L.P.

In connection with the AZSTARYS License Agreement, the Company pays Aquestive Therapeutics, Inc. ("Aquestive") a royalty equal to 10% of all regulatory milestone and royalty payments.

***Accounts and Other Receivables***

Accounts and other receivables consist of receivables from MIPLYFFA and OLPRUVA product sales, receivables under the AZSTARYS License Agreement, the global EAP, and income tax receivables and other receivables due to the Company. Receivables under the AZSTARYS License Agreement are recorded for amounts due to the Company related to reimbursable third-party costs as well as milestones and royalties on product sales. Receivables under the global EAP are recorded for product sales of MIPLYFFA in France and select territories outside of Europe. The Company provides reserves against receivables for estimated losses that may result from a customer's inability to pay. Receivables are evaluated to determine if any reserve or allowance should be recorded based on consideration of the current economic environment, expectations of future economic conditions, specific circumstances and the Company's own historical collection experience. Amounts determined to be uncollectible are charged or written-off against the reserve.

***Research and Development***

Major components of research and development costs include cash compensation, stock-based compensation, depreciation and amortization expense on research and development property and equipment, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf. Costs incurred in research and development are expensed as incurred.

The Company records nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the consolidated statements of operations as the Company receives the related goods or services.

The Company enters into contractual agreements with third-party vendors who provide research and development, manufacturing, and other services in the ordinary course of business. Some of these contracts are subject to milestone-based invoicing and services are completed over an extended period of time. The Company records liabilities under these contractual commitments when an obligation has been incurred. This accrual process involves reviewing open contracts and purchase orders, communicating with the applicable personnel to identify services that have been performed and estimating the level of service performed and the associated cost when the Company has not yet been invoiced or otherwise notified of actual cost. The majority of the service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of the accrued expenses as of each balance sheet date based on the facts and circumstances known. The Company periodically confirms the accuracy of the estimates with the service providers and make adjustments, if necessary.

***Patent Costs***

Patent costs, including related legal costs, are expensed as incurred and recorded within general and administrative expenses on the consolidated statements of operations.

***Income Taxes***

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax basis of assets and liabilities, as well as for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the tax rates that are expected to apply to taxable income for the years in which those tax assets and liabilities are expected to be realized or settled. Valuation allowances are recorded to reduce deferred tax assets to the amount the Company believes is more likely than not to be realized.

The Company is subject to taxation in the United States (including federal, state, and local jurisdictions) and the Kingdom of Denmark. Generally, the Company is subject to examination by tax jurisdictions from 2021 to 2024 tax years as the statute of limitation (excluding net operating loss carryforwards) are 3 to 4 years in the United States and Kingdom of Denmark. Tax liabilities may arise from interpretations and judgments made by the Company with regard to transfer pricing in the application of the relevant statutes, regulations, tax rulings and case law across the various jurisdictions. The Company uses significant judgment in (1) determining whether the technical merits of tax positions taken in the various jurisdictions are more-likely-than-not to be sustained based on applicable tax law and (2) measuring the related amount of tax liability that qualifies for recognition. The United States federal and state tax jurisdictions can audit the net operating loss carryforwards from the tax years in which the statute of limitation has expired but can only adjust the net operating loss carryforwards. No income tax returns are currently under examination by taxing authorities.

Uncertain tax positions are recognized only when the Company believes it is more likely than not that the tax position will be upheld on examination by the taxing authorities based on the merits of the position. The Company recognizes interest and penalties, if any, related to unrecognized income tax uncertainties in income tax expense.

On December 22, 2017, the U.S. government enacted H.R. 1, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018” (“Tax Act”). Effective January 1, 2018, the Tax Act provides for a new global intangible low-taxed income (“GILTI”) provision. Under the GILTI provision, certain foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary’s tangible assets are included in U.S. taxable income. The Company has not recorded any deferred taxes for future GILTI inclusions as any future inclusions are expected to be treated as a period expense and offset by net operating loss carryforwards in the United States.

***Stock-Based Compensation***

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, officers and directors based on the estimated fair values of the awards as of the grant date. The Company records the value of the portion of the award that is ultimately expected to vest as expense over the requisite service period. The Company also accounts for equity instruments issued to non-employees using a fair value approach under ASC subtopic 505-50. The Company values equity instruments and stock options granted using the Black-Scholes-Merton (“BSM”) option pricing model.

***Earnings per Share***

The Company uses the two-class method to compute net income (loss) per common share because the Company has issued securities, other than common stock, that contractually entitle the holders to participate in dividends and earnings of the Company. The two-class method requires earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive distributed and undistributed earnings. Holders of each series of the Company’s convertible preferred stock and select warrants are entitled to participate in distributions, when and if declared by the board of directors, that are made to common stockholders and, as a result, are considered participating securities.

***Segment and Geographic Information***

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) for which discrete financial information is available and regularly reviewed by the chief operating decision maker (“CODM”) in deciding how to allocate resources and in assessing performance. The Company’s CODM is its Chief Executive Officer. The Company views its operations and manages its business as a single operating and reporting segment. See Note C for further information.

***Foreign Currency***

Assets and liabilities are translated into the reporting currency using the exchange rates in effect on the balance sheet dates. Equity accounts are translated at historical rates, except for the change in retained earnings during the year, which is the result of the income statement translation process. Revenue and expense accounts are translated using the weighted average exchange rate during the period. The cumulative translation adjustments associated with the net assets of foreign subsidiaries are recorded in accumulated other comprehensive income (loss) in the accompanying consolidated statements of stockholders' equity.

***Debt Issuance Costs***

Debt issuance costs incurred in connection with financing arrangements are recorded as a reduction of the related debt on the consolidated balance sheets and amortized over the life of the respective financing arrangement using the effective interest method.

***Warrants***

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and FASB ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the issuing company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital on the consolidated statements of changes in stockholders' equity at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and on each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss in other expense, net, on the consolidated statements of operations. The fair value of the warrants was estimated using the BSM option pricing model.

***New Accounting Pronouncements Recently Adopted***

In December 2023, the FASB issued Accounting Standards Update ("ASU") No. 2023-09, Income Taxes ("Topic 740"): *Improvements to Income Tax Disclosures*. ASU 2023-09 establishes new income tax disclosure requirements in addition to modifying and eliminating certain existing requirements. Under the new guidance, entities must consistently categorize and provide greater disaggregation of information in the reconciliation of the effective tax rate to the statutory tax rate and must also further disaggregate income taxes paid. The Company adopted ASU 2023-09 for the year ended December 31, 2025 using a retrospective approach and included the required disclosures in the Notes to the Consolidated Financial Statements for income taxes. This standard update did not affect the Company's results of operations.

***New Accounting Pronouncements Not Yet Adopted***

In November 2024, the FASB issued ASU No. 2024-03, Income Statement: Reporting Comprehensive Income-Expense Disaggregation Disclosures ("Subtopic 220-40"): *Disaggregation of Income Statement Expenses*. The new standard requires disclosure of specified information about certain costs and expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

**C. Segment Information**

Zevra manages its business activities on a consolidated basis and operates as a single operating segment dedicated to the research and development, manufacturing, commercialization and sale of innovative medicines and therapies. The Company primarily derives its revenue from MIPLYFFA and OLPRUVA product sales, reimbursements received under the global EAP, and royalties or net sales milestone payments generated under the AZSTARYS License Agreement. The accounting policies of the segment are the same as those described in Note B.

Zevra's CODM is the Company's Chief Executive Officer, Neil F. McFarlane. The CODM uses net income (loss), as reported in the Company's consolidated statements of operations, in evaluating performance of its segment and determining how to allocate resources of the Company as a whole, including investing in its research and development, commercialization efforts, and acquisition strategy. The CODM does not review assets in evaluating the results of the segment, and, therefore, such information is not presented.

The following table presents the operating results of the Company's segment for the years ended December 31, 2025 and 2024:

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Total revenues | $ 106,470 | $ 23,612 |
| Less significant segment expenses: | | |
| Research and development directly identified to programs | 7,710 | 22,532 |
| Research and development not directly identified to programs | 5,033 | 19,562 |
| Selling, general and administrative directly identified to programs | 26,755 | 18,094 |
| Selling, general and administrative not directly identified to programs | 50,861 | 36,775 |
| Other segment items: | | |
| Impairment of intangible assets | 58,710 | — |
| Income tax expense | 3,449 | 15,371 |
| Interest income | (7,573) | (3,159) |
| Depreciation and amortization expense | 4,054 | 6,389 |
| Interest expense | 7,977 | 7,351 |
| Other (income) expense, net (a) | (133,735) | 6,208 |
| Segment net income (loss) | $ 83,229 | $ (105,511) |

(a) Other (income) expense, net included in segment net income (loss) includes the gain on the sale of the PRV in the current year, foreign currency exchange gains and losses, cost of product revenue (excluding intangible asset amortization), fair value adjustments related to warrant and contingent value right ("CVR") liabilities, fair value adjustment related to investments, and other overhead expenses.

The Company holds long-lived assets in the United States of $2.2 million and $13.4 million as of December 31, 2025 and 2024, respectively. The Company holds long-lived assets in Europe of $0.4 million and $0.5 million as of December 31, 2025 and 2024, respectively.

**D. Inventories**

The components of inventory are summarized as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Raw materials | $ 7 | $ 7,928 |
| Work in progress | 1,780 | 3,260 |
| Finished goods | 832 | 1,781 |
| Total inventories | $ 2,619 | $ 12,969 |

**E. Accounts and Other Receivables**

Accounts and other receivables consist of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Commercial accounts receivable | $ 9,876 | $ 4,010 |
| Receivables related to product reimbursements | 10,998 | 5,380 |
| Royalties accounts receivable | 1,786 | 786 |
| Other receivables | 598 | 333 |
| Total accounts and other receivables | $ 23,258 | $ 10,509 |

As of December 31, 2025, and 2024, no reserve or allowance for doubtful accounts had been established.

**F. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Prepaid insurance | $ 946 | $ 1,037 |
| Other prepaid expenses and current assets | 6,052 | 3,015 |
| Total prepaid expenses and other current assets | $ 6,998 | $ 4,052 |

**G. Property and Equipment**

Property and equipment consists of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Laboratory equipment | $ — | $ 463 |
| Furniture and office equipment | 222 | 200 |
| Computers and hardware | 439 | 701 |
| Leasehold improvements | 139 | 710 |
| Finance lease right-of-use assets | 3 | 8 |
| Total property and equipment | 803 | 2,082 |
| Less: accumulated depreciation and amortization | (314) | (1,726) |
| Property and equipment, net | $ 489 | $ 356 |

The estimated useful lives of property and equipment are as follows:

| Asset Category | Useful Life (in years) |
|---|---|
| Furniture and office equipment | 5-10 |
| Computers and hardware | 3-7 |
| Leasehold improvements | 15 years or remaining lease term |

Depreciation and amortization expense related to property and equipment was $0.2 million for both years ended December 31, 2025 and 2024.

**H. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses consist of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Accrued payroll | $ 4,700 | $ 6,126 |
| Accrued professional fees | 826 | 863 |
| Accounts payable | 2,478 | 13,075 |
| Other accrued expenses | 3,594 | 5,392 |
| Total accounts payable and accrued expenses | $ 11,598 | $ 25,456 |

**I. Debt Obligations**

**Secured Promissory Note**

On August 30, 2023, the Company and Nantahala Capital Management, LLC ("NCM"), certain of its affiliates and certain other parties (collectively with NCM, "Nantahala"), entered into a secured promissory note payable by Zevra to Nantahala in the original principal amount of $5.0 million (the "Nantahala Note"). The Nantahala Note initially bore interest at 9.0% per annum, payable quarterly in arrears in cash. The interest rate increased to 12.0% per annum effective March 1, 2024, as the Nantahala Note remained unpaid six months from its issue date. The additional 3.0% interest would have been paid in shares of Zevra's common stock based on the volume weighted average trading price of Zevra's common stock during the twenty consecutive trading days ending on the date before such interest payment date. Beginning on the first interest payment date following the second anniversary of the Nantahala Note, and on each interest payment date thereafter, Zevra was required to make $0.6 million amortization payments on the Nantahala Note until it was paid in full. All principal and unpaid interest on the Nantahala Note would have been due on August 30, 2026, the third anniversary of the Nantahala Note. Zevra was entitled to prepay the Nantahala Note at any time without penalty.

The Nantahala Note was secured by Zevra's interest in Acer's assets. The Company used the proceeds from the Nantahala Note, along with $12.0 million in cash and 98,683 shares of Zevra's common stock, to acquire Acer's term loans. In April 2024, the Nantahala Note was repaid in full and terminated. At the time of repayment, Nantahala elected to receive a cash payment in lieu of shares of Zevra's common stock in exchange for the additional 3.0% interest accrued for the period from March 1, 2024 through April 5, 2024.

**Margin Account**

On January 26, 2023, the Company and Wells Fargo, as lender, entered into a revolving margin account agreement. The Company's investments were used as collateral for the loan and the amount the Company was able to borrow was limited to 80-90% of its outstanding investment balance held with Wells Fargo. The margin account bore interest at the Prime rate minus 225 basis-points. In April 2024, the Company repaid the outstanding balance under the margin account with Wells Fargo, and upon such repayment, the margin capabilities were removed from the account.

**Term Loans**

On April 5, 2024 (the "Term Loans Closing Date"), the Company entered into a credit agreement (the "Credit Agreement") with HCR Stafford Fund II, L.P., HCR Potomac Fund II, L.P., and Perceptive Credit Holdings IV, LP (collectively, the "Lenders"), and Alter Domus (US) LLC, as administrative agent (the "Administrative Agent").

Under the terms of the Credit Agreement, the Lenders provided a senior secured loan facility to the Company in the aggregate principal amount of $100.0 million, which is divided into three tranches as follows: (i) $60.0 million, which was funded in full on the Term Loans Closing Date; (ii) $20.0 million, which was available to the Company in up to two drawings, each in an amount not to exceed $10.0 million, at the Company's option until October 5, 2025; and; (iii) $20.0 million, which was available to the Company upon approval by the FDA of the NDA for MIPLYFFA for the treatment of NPC, at the Company's option until December 31, 2024 (collectively, the "Term Loans"). The Company did not draw down the amounts described in (ii) and (iii) above prior to their applicable expiration dates.

The principal amount of the Term Loans outstanding (the "Outstanding Principal Amount") historically bore interest at a rate equal to 3-Month Term Secured Overnight Financing Rate ("SOFR") plus 7.00% per annum. As the net product sales for the calendar year ending December 31, 2025 exceeded $100.0 million, the Outstanding Principal Amount will bear interest at 3-Month Term SOFR plus 6.00% per annum beginning on January 1, 2026. In all cases, the 3-Month Term SOFR rate is subject to a floor of 4.00% per annum. Interest is payable quarterly in arrears on the last day of each calendar quarter. The Company has the option to pay up to 25% of the interest in-kind beginning on the Term Loans Closing Date, through and including June 30, 2026. The Company has recognized approximately $3.1 million and $1.4 million of interest-in-kind as of December 31, 2025, and 2024, which is included in long-term debt in the consolidated balance sheets. The Term Loans will mature on the fifth anniversary of the Term Loans Closing Date. In connection with the Credit Agreement, the Company incurred approximately $2.2 million of costs, which primarily consisted of underwriting, legal and other professional fees, and are included as a reduction to the carrying amount of the related debt liability and are deferred and amortized over the remaining life of the financing using the effective interest method.

The Credit Agreement contains customary affirmative and negative covenants by the Company, which, among other things, will require the Company to provide certain financial reports to the Lenders within 60 days after the end of each of the first three fiscal quarters of each fiscal year and 105 days after the end of each fiscal year, meet certain minimum net product sales amounts, meet certain minimum liquidity, and limit the ability of the Company to, among other things, incur or guarantee additional indebtedness, conduct asset sales, incur liens, make dividends or distributions, conduct transactions with affiliates, and effect a consolidation or merger without consent. The obligations of the Company under the Credit Agreement may be accelerated upon customary events of default, including non-payment of principal, interest, fees and other amounts, covenant defaults, insolvency, material judgments, or inaccuracy of representations and warranties. The Term Loans are secured by a first priority perfected lien on, and security interest in, substantially all current and future assets of the Company and certain subsidiaries of the Company that are guarantors thereunder. The proceeds of the Term Loans were used to refinance certain existing indebtedness of the Company and its subsidiaries. The Company will use the remaining proceeds to pay fees and expenses related to the debt financing and commercialization of MIPLYFFA and OLPRUVA, and to further the development of its other product candidates.

Long-term debt consisted of the following (in thousands):

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| Notes payable | $ 63,608 | $ 61,552 |
| Unamortized original issue discount | (755) | (921) |
| Less: debt issuance costs | (925) | (1,127) |
| | $ 61,928 | $ 59,504 |

Future minimum principal payments under the Term Loans as of December 31, 2025, are as follows (in thousands):

| Year Ending December 31, | |
|---|---|
| 2026 | $ — |
| 2027 | — |
| 2028 | — |
| 2029 | 63,608 |
| Total minimum payments | 63,608 |
| Less: unamortized debt discount, debt issuance costs and paid in kind interest | (1,680) |
| Long-term debt | $ 61,928 |

**J. Revenue, net**

For the years ended December 31, 2025, and 2024, the Company recorded $106.5 million and $23.6 million, respectively, of revenue. Included in revenue for the year ended December 31, 2025 is a de minimis amount related to the licensing of certain IP.

**Product Revenues, net**

On December 27, 2022, the FDA approved OLPRUVA (sodium phenylbutyrate), a prescription medicine used along with certain therapy, including changes in diet, for the chronic management of adults and children with certain UCDs. For the years ended December 31, 2025, and 2024, sales of OLPRUVA were $0.8 million and $0.1 million.

On September 20, 2024, the FDA approved MIPLYFFA (arimoclomol), an orally-delivered treatment for NPC, which is an ultra-rare and progressive neurodegenerative disease, for treatment in combination with miglustat. For the years ended December 31, 2025, and 2024, net sales of MIPLYFFA were $87.4 million and $10.1 million, respectively.

The Company currently utilizes a single specialty pharmacy provider as its sole distributor for both MIPLYFFA and OLPRUVA. The Company also enters into arrangements with health care providers and payors that provide for government mandated and/or privately negotiated rebates with respect to the purchase of its products. All estimated reserve liabilities related to commercial products are recorded within the current portion of discount and rebate liabilities in the consolidated balance sheets. To commercialize MIPLYFFA and OLPRUVA in the United States, the Company has built marketing, sales, medical affairs, distribution, managerial and other non-technical capabilities or has made arrangements with third parties to perform these services. All revenues derived from sales of MIPLYFFA and OLPRUVA are in the United States.

**Expanded Access Program**

For the years ended December 31, 2025, and 2024, the Company recognized revenue related to the global EAP of $13.0 million and $9.1 million, respectively, net of a clawback liability of $6.1 million and $5.7 million, respectively, and other gross to net adjustments.

The total estimated reserve liability as of December 31, 2025, and 2024, was $15.3 million and $12.6 million, respectively. As of December 31, 2025, and 2024, this estimated reserve liability is recorded as discount and rebate liabilities in the consolidated balance sheets and is separated into current and long-term based upon the timing of the expected payment to the French regulators.

**AZSTARYS License Agreement**

The Company entered into a Collaboration and License Agreement (the "AZSTARYS License Agreement") with Commave Therapeutics SA (formerly known as Boston Pharmaceuticals Holdings SA) ("Commave"), an affiliate of Gurnet Point Capital, L.P., dated September 3, 2019. Under the AZSTARYS License Agreement, as amended, the Company granted to Commave an exclusive, worldwide license to develop, manufacture and commercialize the Company's product candidates containing SDX and d-MPH, including AZSTARYS, or any other product candidates containing SDX and developed to treat ADHD or any other central nervous system disorder. Corium Inc. was tasked by Commave to lead all commercialization activities for AZSTARYS under the AZSTARYS License Agreement. Pursuant to the AZSTARYS License Agreement, Commave agreed to pay milestone payments up to an aggregate of $590.0 million upon the occurrence of specified regulatory milestones related to AZSTARYS, additional fixed payments upon the achievement of specified U.S. sales milestones, and quarterly, tiered royalty payments based on a range of percentages of net sales (as defined in the AZSTARYS License Agreement). Commave is obligated to make such royalty payments on a product-by-product basis until expiration of the royalty term for the applicable product.

The Company concluded that these regulatory milestones, sales milestones and royalty payments each contain a significant uncertainty associated with a future event. As such, these milestone and royalty payments are constrained at contract inception and are not included in the transaction price, as the Company could not conclude that it is probable a significant reversal in the amount of cumulative revenue recognized will not occur surrounding these milestone payments. At the end of each reporting period, the Company updates its assessment of whether the milestone and royalty payments are constrained by considering both the likelihood and magnitude of the potential revenue reversal. For the years ended December 31, 2025, and 2024, the Company recognized revenue under the AZSTARYS License Agreement of $5.0 million and $4.3 million, respectively. There was no deferred revenue related to this agreement as of December 31, 2025, and 2024. All revenues recognized under this agreement were derived in the United States.

The AZSTARYS License Agreement is within the scope of ASC 606, as the transaction represents a contract with a customer where the participants function in a customer/vendor relationship and are not exposed equally to the risks and rewards of the activities contemplated under the AZSTARYS License Agreement.

**Relief Exclusive License Agreement**

Pursuant to the Relief License Agreement, Relief will hold exclusive development and commercialization rights for OLPRUVA in the EU, Liechtenstein, San Marino, Vatican City, Norway, Iceland, Principality of Monaco, Andorra, Gibraltar, Switzerland, United Kingdom, Albania, Bosnia, Kosovo, Montenegro, Serbia and North Macedonia ("Geographical Europe"). The Company has the right to receive a royalty of up to 10% of the net sales of OLPRUVA in Geographical Europe. For the years ended December 31, 2025, and 2024, the Company did not recognize any revenue under the Relief License Agreement. There was no deferred revenue related to this agreement as of December 31, 2025, and 2024.

## K. Commitments and Contingencies

***Legal Matters***

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable, or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates.

*Litigation Related to the AZSTARYS License Agreement*

In September 2024, the Company became engaged in a legal dispute regarding the AZSTARYS License Agreement. The litigation is currently in the discovery phase. The Company cannot predict with certainty the timing or ultimate outcome of this litigation or its potential impact on the Company's business, financial condition, or results of operations. At this time, the Company has not recorded any accrual for contingent liability associated with this matter. The AZSTARYS License Agreement remains in effect during this litigation, and both parties continue to perform their respective obligations thereunder. However, there can be no assurance that this dispute will not have an adverse impact on the Company's relationship with Commave or on the Company's business. The Company will continue to monitor developments in this matter and will assess the potential impact on the Company's financial statements in future periods. The Company expects to incur significant legal expenses in connection with this litigation, which may materially affect its results of operations in future periods.

As of December 31, 2025, and 2024, no accruals were made related to commitments and contingencies.

## L. Stock and Warrants

***Authorized, Issued, and Outstanding Common Shares***

As of December 31, 2025, and 2024, the Company had authorized shares of common stock of 250,000,000 shares. Of the authorized shares, 58,338,319 and 55,246,401 shares of common stock were issued as of December 31, 2025, and 2024, respectively, and 56,854,781 and 53,670,709 shares of common stock were outstanding as of December 31, 2025, and 2024, respectively.

As of December 31, 2025, and 2024, the Company had reserved authorized shares of common stock for future issuance as follows:

| | December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Outstanding awards under equity incentive plans | 7,060,457 | 7,789,658 |
| Outstanding common stock warrants | 4,024,157 | 5,483,537 |
| Possible future issuances under equity incentive plans | 6,327,569 | 5,383,165 |
| Possible future issuances under employee stock purchase plan | 1,011,962 | 1,148,012 |
| Total common shares reserved for future issuance | 18,424,145 | 19,804,372 |

***Common Stock Activity***

The following table summarizes common stock activity for the years ended December 31, 2025 and 2024:

| | Shares of Common Stock |
|---|---|
| Balance as of January 1, 2024 | 41,534,668 |
| Common stock issued in connection with a public offering (Note A) | 10,615,385 |
| Common stock issued in connection with restricted stock units | 218,000 |
| Common stock issued as compensation to third parties | 92,988 |
| Common stock issued in connection with vesting of performance-based awards | 547,945 |
| Common stock issued as a result of stock options exercised | 469,563 |
| Common stock issued as a result of the Employee Stock Purchase Plan | 192,160 |
| Balance as of December 31, 2024 | 53,670,709 |
| Common stock issued as compensation to third parties | 9,306 |
| Common stock issued as a result of stock options exercised or RSUs vested | 1,579,336 |
| Common stock issued as a result of stock warrants exercised | 1,459,380 |
| Common stock issued as a result of the Employee Stock Purchase Plan | 136,050 |
| Balance as of December 31, 2025 | 56,854,781 |

***Authorized, Issued, and Outstanding Preferred Stock***

As of December 31, 2025, and 2024, the Company had 10,000,000 shares of authorized, unallocated preferred stock, As of December 31, 2025, and 2024, no shares of preferred stock were designated, issued, or outstanding.

***Warrants to Purchase Common Stock***

The Company has issued warrants to purchase common stock to various third parties, of which 4,024,157 remain outstanding as of December 31, 2025, and are immediately exercisable. These warrants qualify as participating securities under ASC Topic 260, *Earnings per Share*, and are treated as such in the net income (loss) per share calculation (Note P). The Company may be required to redeem these warrants for a cash amount equal to the BSM value of the portion of the warrants to be redeemed.

While the warrants are outstanding (but unexercised), the warrant holders will participate in any dividend or other distribution of the Company's assets to its common stockholders by way of return of capital or otherwise. As of December 31, 2025, 1,459,380 of the warrants had been exercised. No warrants had been exercised as of December 31, 2024. The warrants have been evaluated to determine the appropriate accounting and classification pursuant to ASC 480 and ASC 815. Generally, freestanding warrants should be classified as (i) liabilities if the warrant terms allow settlement of the warrant exercise in cash and (ii) equity if the warrant terms only allow settlement in shares of common stock.

The Company determined that its outstanding warrants should be recorded as a liability and stated at fair value at each reporting period. Changes to the fair value of the warrant liability are recorded through the consolidated statements of operations as a fair value adjustment related to warrant and CVR liability. As of December 31, 2025, and 2024, the fair value of the liability associated with these warrants was approximately $9.6 million and $17.8 million, respectively. The fair value adjustment related to these warrants was $0.2 million of income and $1.7 million of loss for the years ended December 31, 2025, and 2024, respectively.

**M. Stock-Based Compensation**

In November 2014, the Board of Directors of the Company ("the Board"), and in April 2015, the Company's stockholders, approved the Company's 2014 Equity Incentive Plan (the "2014 Plan"), which became effective in April 2015. The 2014 Plan provides for the grant of stock options, other forms of equity compensation, and performance cash awards. In June 2021, the Company's stockholders approved an Amended and Restated 2014 Equity Incentive Plan (the "A&R 2014 Plan"), following its adoption by the Board in April 2021, which, among other things, added 4,900,000 shares to the maximum number of shares of common stock to be issued under the plan and extended the annual automatic increases (discussed further below) until January 1, 2031 and eliminated individual grant limits that applied under the 2014 Plan to awards that were intended to comply with the exemption for "performance-based compensation" under Code Section 162(m). The maximum number of shares of common stock that may be issued under the A&R 2014 Plan was 12,079,711 as of December 31, 2025. The number of shares of common stock reserved for issuance under the A&R 2014 Plan automatically increases on January 1 of each year, beginning on January 1, 2016, and ending on and including January 1, 2031, by 4% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Board. Pursuant to the terms of the A&R 2014 Plan, on January 1, 2026, the common stock reserved for issuance under the A&R 2014 Plan automatically increased by 2,274,191 shares.

During the years ended December 31, 2025, and 2024, 1,193,883 and 1,177,545 stock options were exercised, respectively.

In June 2021, the Company's stockholders approved an Employee Stock Purchase Plan (the "ESPP"), following its adoption by the Board in April 2021. The maximum number of shares of common stock that may be issued under the ESPP is 1,500,000. The first offering period under the ESPP began on October 1, 2021, and the first purchase date occurred on May 31, 2022. As of December 31, 2025, 488,038 shares have been issued under the ESPP.

In January 2023, the Board approved the 2023 Employment Inducement Award Plan (as amended, the "2023 Plan"). The maximum number of shares of common stock that may be issued under the 2023 Plan was 4,500,000 as of December 31, 2025.

In February 2025, the Board approved the Tenth Amended and Restated Non-Employee Director Compensation Policy (the "Non-Employee Director Compensation Policy"). The equity compensation granted pursuant to the Non-Employee Director Compensation Policy is granted under the A&R 2014 Plan.

Stock-based compensation expense recorded under the A&R 2014 Plan, ESPP and 2023 Plan is included in the following line items in the accompanying consolidated statements of operations (in thousands):

| | Year ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Research and development | $ 841 | $ 5,819 |
| Selling, general and administrative | 11,793 | 9,087 |
| Total stock-based compensation expense | $ 12,634 | $ 14,906 |

There was $0.2 million stock-based compensation expense related to performance-based awards recognized during the year ended December 31, 2025 resulting from the transition agreements entered into with certain former employees as noted below. There was $2.5 million stock-based compensation expense related to performance-based awards recognized during the year ended December 31, 2024.

As a result of transition agreements entered into with certain former employees and directors, the vesting for certain stock options, restricted stock units, and performance stock units was accelerated, resulting in a net increase in stock-based compensation expense of $1.5 million for the year ended December 31, 2025. The effects of this accelerated vesting are reflected in the table above within selling, general and administrative expenses. For the year ended December 31, 2024, similar transition agreements with certain former employees resulted in a net increase in stock-based compensation expense of $2.4 million which is reflected in the table above within research and development expenses.

***Stock Option Awards***

The Company estimates the fair value of stock options using the BSM option pricing model, which requires the use of subjective assumptions, including the expected term of the option, the expected stock price volatility, expected dividend yield and the risk-free interest rate for the expected term of the option. The expected term represents the period of time the stock options are expected to be outstanding. Due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected term of the stock options, the Company uses the simplified method to estimate the expected term for its "plain vanilla" stock options. Under the simplified method, the expected term of an option is presumed to be the mid-point between the vesting date and the end of the contractual term. Some options, for example those that have exercise prices in excess of the fair value of the underlying stock, are not considered "plain vanilla" stock options. For these options, the Company uses an expected term equal to the contractual term of the option. Expected volatility is based on the Company's historical volatility over the estimated expected term of the stock options. The Company assumes no dividend yield because dividends are not expected to be paid in the near future, which is consistent with the Company's history of not paying dividends.

The Company recognizes compensation expense related to stock-based payment transactions upon satisfaction of the requisite service or vesting requirements. Forfeitures are estimated at the time of grant and revised based on actual forfeitures, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Using the BSM option-pricing model, the weighted-average fair value of awards granted during the years ended December 31, 2025, and 2024, was $8.21 and $5.74 per share, respectively. The assumptions used to estimate fair value are as follows:

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Risk-free interest rate | 3.70% - 4.39% | 3.82% - 4.50% |
| Expected term (in years) | 5.50 - 6.25 | 5.50 - 6.25 |
| Expected volatility | 81.54% - 87.31% | 89.85% - 91.32% |
| Expected dividend yield | 0 | 0 |

The activity under the A&R 2014 Plan and 2023 Plan for the year ended December 31, 2025, is summarized as follows:

| | **Number of Options** | **Weighted Average Exercise Price** | **Weighted Average Remaining Contractual Term** | **Aggregate Intrinsic Value** |
|---|---|---|---|---|
| Outstanding balance at January 1, 2025 | 5,951,400 | $ 7.25 | 6.79 | $ 17,448 |
| Granted | 1,459,750 | $ 8.21 | — | — |
| Exercised or released | 1,193,883 | $ 5.14 | — | $ 3,829 |
| Canceled or forfeited | 371,801 | $ 5.81 | — | — |
| Expired | 381,199 | $ 25.58 | — | — |
| Outstanding balance at December 31, 2025 | 5,464,267 | $ 6.80 | 6.63 | $ 15,709 |
| Exercisable at December 31, 2025 | 2,701,924 | $ 6.97 | 4.90 | $ 8,999 |
| Vested and expected to vest at December 31, 2025 | 5,264,367 | | 6.55 | $ 15,312 |

Information regarding currently outstanding and exercisable options as of December 31, 2025, is as follows:

| | Options Outstanding | | Options Exercisable | |
|---|---|---|---|---|
| Exercise Price | Number of Shares | Weighted Average Remaining Contractual Term | Number of Shares | Weighted Average Remaining Contractual Term |
| $2.85 to $10.00 | 5,270,954 | 6.60 | 2,648,611 | 4.97 |
| $10.01 to $30.00 | 141,875 | 9.71 | 1,875 | 3.31 |
| $30.01 to $50.00 | 20,593 | 0.00 | 20,593 | 1.72 |
| $50.01 to $70.00 | 12,021 | 0.73 | 12,021 | 0.73 |
| $70.01 to $327.20 | 18,824 | 1.00 | 18,824 | 1.00 |
| | 5,464,267 | | 2,701,924 | |

The total fair value of stock options vested during the years ended December 31, 2025 and 2024, was $7.6 million and $8.1 million, respectively.

Unvested stock options as of December 31, 2025 and 2024, were as follows:

| | Number of Unvested Shares | |
|---|---|---|
| | December 31, | |
| Exercise Price | 2025 | 2024 |
| $2.85 to $10.00 | 2,622,343 | 3,552,095 |
| $10.01 to $30.00 | 140,000 | — |
| Total number of unvested stock options | 2,762,343 | 3,552,095 |

As of December 31, 2025, there was $9.0 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the A&R 2014 Plan and 2023 Plan.

***Restricted stock units***

The following table summarizes the restricted stock unit activity under the A&R 2014 and 2023 Plan:

| | Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Unvested balance at January 1, 2025 | 1,838,258 | $ 5.32 |
| Granted | 679,876 | 7.79 |
| Vested | 758,421 | 5.57 |
| Forfeited | 163,524 | 6.55 |
| Unvested balance at December 31, 2025 | 1,596,189 | $ 6.13 |

As of December 31, 2025 there was $5.3 million of total unrecognized compensation cost related to restricted stock units.

**N. Fair Value of Financial Instruments**

The accounting standard for fair value measurements provides a framework for measuring fair value and requires disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on the Company's principal or, in absence of a principal, most advantageous market for the specific asset or liability.

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs, when available, and to minimize the use of unobservable inputs when determining fair value. The three tiers are defined as follows:

- Level 1: Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2: Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3: Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The carrying amounts of certain financial instruments, including cash and cash equivalents, accounts and other receivables, and accounts payable and accrued expenses approximate their respective fair values due to the short-term nature of such instruments.

***Assets and Liabilities Measured at Fair Value on a Recurring Basis***

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments to be made. The following table summarizes the conclusions reached regarding fair value measurements as of December 31, 2025, and 2024 (in thousands):

| | Balance at December 31, 2025 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| CVR liability | $ 1,540 | $ — | $ — | $ 1,540 |
| Warrant liabilities | 9,575 | — | — | 9,575 |
| Total liabilities | $ 11,115 | $ — | $ — | $ 11,115 |
| | | | | |
| Securities: | | | | |
| U.S. Treasury securities | $ 97,132 | $ 97,132 | $ — | $ — |
| Corporate bonds | 79,352 | — | 79,352 | — |
| Total assets | $ 176,484 | $ 97,132 | $ 79,352 | $ — |

| | Balance at December 31, 2024 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| CVR liability | $ 3,500 | $ — | $ — | $ 3,500 |
| Warrant liabilities | 17,804 | — | — | 17,804 |
| Total liabilities | $ 21,304 | $ — | $ — | $ 21,304 |
| | | | | |
| Securities: | | | | |
| U.S. Treasury securities | $ 35,711 | $ 35,711 | $ — | $ — |
| Corporate bonds | 6,010 | | 6,010 | |
| Total assets | $ 41,721 | $ 35,711 | $ 6,010 | $ — |

***Warrants***

The common stock warrant liabilities were recorded at fair value using the BSM option pricing model. The following assumptions were used in determining the fair value of the warrant liabilities valued using the BSM option pricing model as of December 31, 2025, and 2024:

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| Risk-free interest rate | 3.42% - 3.67% | 4.08% - 4.23% |
| Volatility | 57.28% - 66.70% | 62.14% - 68.68% |
| Dividend yield | —% | —% |
| Expected term (years) | 0.02 - 2.89 | 1.02 - 3.89 |
| Weighted average fair value | $ 2.38 | $ 3.25 |

The following table is a reconciliation for the common stock warrant liabilities measured at fair value using Level 3 unobservable inputs (in thousands):

| | |
|---|---|
| Balance as of December 31, 2024 | $ 17,804 |
| Change in fair value measurement of warrant liabilities | (218) |
| Warrants exercised | (8,011) |
| Balance as of December 31, 2025 | $ 9,575 |

For the year ended December 31, 2025, the changes in fair value of the warrant liabilities primarily resulted from the volatility of the Company's common stock.

***Contingent Consideration***

Contingent consideration liabilities relate to the Company's liabilities arising in connection with the CVRs. The contingent consideration is classified as Level 3 in the fair value hierarchy. The fair value is measured based on a Monte Carlo simulation or a scenario-based method, depending on the earn-out achievement objectives, utilizing projections about future performance. Significant inputs include volatility and projected financial information, including projections representative of a market participant's view of the expected cash payments associated with the agreed upon regulatory milestones based on probabilities of technical success, timing of the potential milestone events for the compounds, and estimated discount rates.

The following table provides a reconciliation of the beginning and ending balances related to the contingent consideration liabilities for the CVRs (dollars in thousands):

| | |
|---|---|
| Balance as of December 31, 2024 | $ 3,500 |
| Change in fair value measurement of contingent consideration liabilities | (1,960) |
| Balance as of December 31, 2025 | $ 1,540 |

For the year ended December 31, 2025, the changes in fair value of contingent consideration primarily resulted from changes in the discount rates.

**O. Income Taxes**

For the tax years ended December 31, 2025 and 2024, income from continuing operations before taxes consists of the following:

| | Year ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| U.S. operations | $ 27,140 | $ (86,269) |
| Foreign operations | 59,538 | (3,871) |
| Total pretax income (loss) | $ 86,678 | $ (90,140) |

***Income tax expense (benefit)***

Income tax expense (benefit) attributable to income from continuing operations consists of:

| | Year ended December 31, 2025 | | |
|---|---|---|---|
| | Current | Deferred | Total |
| U.S. federal | $ 2,108 | $ — | $ 2,108 |
| Foreign | 11,187 | (9,858) | 1,329 |
| State and local | — | 12 | 12 |
| | $ 13,295 | $ (9,846) | $ 3,449 |

| | Year ended December 31, 2024 | | |
|---|---|---|---|
| | Current | Deferred | Total |
| U.S. federal | $ — | $ — | $ — |
| Foreign | — | 15,373 | 15,373 |
| State and local | — | (2) | (2) |
| | $ — | $ 15,371 | $ 15,371 |

***Rate reconciliation***

Income tax expense attributable to income from continuing operations for the years ended December 31, 2025 and 2024 differed from the amounts computed by applying the statutory U.S. Federal income tax rate of 21 percent to pretax income from continuing operations as a result of the following (in thousands, except amounts pertaining to rate which are shown as a percentage):

| | Year ended December 31, | | | |
|---|---|---|---|---|
| | 2025 | | 2024 | |
| **U.S. Federal Statutory Income Tax Rate** | **$ 18,202** | **21.00 %** | **$ (18,929)** | **21.00 %** |
| **Domestic state and local income taxes, net of federal effect(a)** | 45 | 0.05 % | (635) | 0.70 % |
| **Foreign tax** | | | | |
| Denmark | | | | |
| Changes in valuation allowance | 2,390 | 2.76 % | (3,879) | 4.30 % |
| Changes to deferred tax asset/liability due to adjustment or true-up | (3,108) | (3.59) % | 3,989 | (4.42) % |
| Other | 421 | 0.49 % | (39) | 0.04 % |
| **Effect of cross-border tax laws** | | | | |
| Subpart F inclusions | 10,752 | 12.40 % | — | 0.00 % |
| Other | — | — % | 20 | (0.02) % |
| **Tax credits** | | | | |
| Research credits | 18,212 | 21.01 % | 1,517 | (1.68) % |
| **Changes in valuation allowance** | (51,390) | (59.28) % | 10,236 | (11.36) % |
| **Nontaxable or nondeductible items** | 396 | 0.46 % | 353 | (0.39) % |
| **Changes in unrecognized tax benefits** | (10,659) | (12.30) % | 16,115 | (17.87) % |
| **Changes to deferred tax asset/liability due to adjustment or true-up** | | | | |
| Net operating losses | 18,636 | 21.50 % | 6,783 | (7.53) % |
| Other | (448) | (0.52) % | (160) | 0.18 % |
| **Total** | **$ 3,449** | **3.98 %** | **$ 15,371** | **(17.05)%** |

(a) State taxes in Michigan for 2024 and in Michigan and Florida for 2025 made up the majority (greater than 50%) of the tax effect in this category.

***Deferred tax asset (liabilities)***

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2025 and 2024 are presented below (in thousands):

| | December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Deferred tax assets | | |
| Allowance for bad debts | $ 340 | $ 320 |
| Accrued expenses | 2,977 | 1,461 |
| Reserve expenses | 1,648 | 1,288 |
| Stock compensation | 6,352 | 5,711 |
| Operating lease liabilities | 339 | 108 |
| Section 174 | 14,601 | 33,941 |
| Plant and equipment | 34 | 79 |
| Intangibles | 1,140 | — |
| Net operating loss carryforwards | 63,256 | 100,552 |
| Credits | 941 | 19,153 |
| Other | 57 | 583 |
| Total deferred tax assets | 91,685 | 163,196 |
| Less: valuation allowance | (91,498) | (146,359) |
| Deferred tax assets, net of valuation allowance | 187 | 16,837 |
| | | |
| Deferred tax liabilities | | |
| Intangibles | — | (17,859) |
| Operating lease assets | (325) | (82) |
| Other | (35) | — |
| Total deferred tax liabilities | (360) | (17,941) |
| | | |
| Net deferred tax liabilities | $ (173) | $ (1,104) |

The valuation allowance for deferred tax assets as of December 31, 2025 and 2024 was $91.5 million and $146.4 million, respectively. The net change in the total valuation allowance for each of the years ended December 31, 2025 and 2024 was a decrease of $54.9 million and an increase of $11.9 million, respectively. The valuation allowance for both years was primarily related to U.S. domestic, state, and foreign net operating loss carryforwards as well as credit carryforwards that, in the judgment of management, are not more likely than not to be realized. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the periods in which those temporary differences are deductible.

At December 31, 2025, Zevra has $230.4 million in carryforwards for federal income tax purposes, which are available to reduce future federal taxable income. Of the total $230.4 million net operating loss carryforwards, $11.1 million, if not utilized, will begin to expire in 2029 and $219.4 million have no expiration date. The Company also has $312.2 million state net operating loss carryforwards which, if not utilized, will begin to expire in 2029.

***Unrecognized tax benefits***

A reconciliation of the beginning and ending amounts of total unrecognized tax benefits for the years ended December 31, 2025 and 2024 are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Balance, beginning of year | $ 16,115 | $ — |
| Increase related to prior year tax positions | — | — |
| Decrease related to prior year tax positions | (9,086) | — |
| Increases related to current year tax positions | — | 16,115 |
| Settlements | — | — |
| Lapse of Statute | — | — |
| Balance, end of year | $ 7,029 | $ 16,115 |

Included in the balance of unrecognized tax benefits at December 31, 2025 is a potential benefit of $7.0 million that, if recognized, would affect the effective tax rate on income from continuing operations.

The Company files income tax returns in the United States for federal and various state jurisdictions. Generally, the statute of limitations for income tax examinations is 3 to 4 years. As such, the Company is no longer subject to U.S. federal and state and local income tax examinations for years prior to 2021, although carryforwards that were generated prior to 2021 may still be adjusted upon examination by the Internal Revenue Service or a state tax department. The Company's Denmark subsidiary files a Denmark income tax return. The Denmark statute of limitations is 3 years and, as such, it is no longer subject to Denmark tax examinations for years prior to 2022. The Company is not under income tax examination in any material jurisdiction to date.

***Current portion of income tax payable***

The current portion of income tax payable of $13.7 million includes approximately $11.1 million attributable to the recognized tax impact of the sale of the PRV, which included transfer pricing considerations. The remainder of the current portion of income tax payable consists of $2.6 million.

**P. Net Income (Loss) Per Share**

The two-class method requires earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive distributed and undistributed earnings. Under the two-class method, for periods with net income attributable to common stockholders, basic net income attributable to common stockholders per share of common stock is computed by dividing the net income attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Undistributed net income attributable to common stockholders is computed by subtracting from net income the portion of current period earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the period’s earnings been distributed. No such adjustment to earnings is made during periods with a net loss as the holders of the participating securities have no obligation to fund losses. Diluted net income attributable to common stockholders per share of common stock is computed under the two-class method by using the weighted average number of shares of common stock outstanding plus the potential dilutive effects of stock options and warrants. In addition to analyzing under the two-class method, the Company analyzes the potential dilutive effect of stock options and warrants under the treasury-stock method when calculating diluted income (loss) attributable to common stockholders per share of common stock, in which it is assumed that the stock options and warrants convert into common stock at the beginning of the period or date of issuance, if the stock option or warrant was issued during the period. The Company reports the more dilutive of the approaches (two-class or treasury-stock/if-converted) as its diluted net income (loss) attributable to common stockholders per share of common stock during the period.

Diluted net loss per share of common stock is the same as basic net loss per share of common stock for the year ended December 31, 2024, because the effects of potentially dilutive items were anti-dilutive for the respective periods. The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted-average number of shares of common stock outstanding because their effect is anti-dilutive:

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Awards under equity incentive plans | 1,571,228 | 1,148,012 |
| Common stock warrants | — | 5,483,537 |
| Total securities excluded from the calculation of weighted average number of shares of common stock outstanding | 1,571,228 | 6,631,549 |

A reconciliation from net income (loss) to basic net income (loss) attributable to common stockholders per share of common stock and diluted net income (loss) attributable to common stockholders per share of common stock for the years ended December 31, 2025, and 2024, is as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Basic net income (loss) per share of common stock:** | | |
| Net income (loss) | $ 83,229 | $ (105,511) |
| Earnings allocated to participating securities | (5,644) | — |
| **Net income (loss) attributable to shares of common stock** | **77,585** | **(105,511)** |
| Less: Dividends declared or accumulated | — | — |
| **Undistributed net income (loss) attributable to shares of common stock, basic** | **77,585** | **(105,511)** |
| Weighted-average shares of common stock outstanding | 55,311 | 46,251 |
| **Basic net income (loss) per share of common stock** | **$ 1.40** | **$ (2.28)** |
| | | |
| **Diluted net income (loss) per share of common stock:** | | |
| Net income (loss) attributable to shares of common stock | $ 77,585 | $ (105,511) |
| Less: Fair value adjustment income related to warrant liability | — | — |
| **Net income (loss) attributable to shares of common stock, diluted** | **77,585** | **(105,511)** |
| Weighted-average number of shares of common stock outstanding | 55,311 | 46,251 |
| Dilutive effect of outstanding stock options (as converted to common stock) | 1,952 | — |
| **Weighted-average shares of common stock outstanding, diluted** | **57,263** | **46,251** |
| **Diluted net income (loss) per share of common stock** | **$ 1.35** | **$ (2.28)** |

**Q. Leases**

The Company has operating leases for office space and determines if an arrangement is a lease at contract inception. Lease assets and lease liabilities are recognized based on the present value of lease payments over the lease term at the commencement date. The Company does not separate lease and non-lease components. Leases with a term of 12 months or less at commencement are not recorded on the consolidated balance sheets. Lease expense for these arrangements is recognized on a straight-line bases over the lease term. The Company's leases have remaining lease terms of less than one year and up to approximately three years, and some which include options to terminate the leases within one year.

The components of operating lease expense were as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Operating lease cost | $ 747 | $ 330 |
| Short-term lease cost | 127 | 177 |
| Variable lease cost | 36 | 39 |
| Less: sublease income | (144) | (128) |
| Total lease costs | $ 766 | $ 418 |

Supplemental cash flow information related to leases was as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows from operating leases | $ 860 | $ 405 |
| Operating cash flows from short-term leases | 127 | 225 |
| Operating cash flows from variable lease costs | 36 | 39 |
| | | |
| Right-of-use assets obtained in exchange for lease liabilities: | | |
| Operating leases | 1,115 | 419 |

Supplemental balance sheet information related to operating leases was as follows (in thousands, except weighted average remaining lease term and weighted average discount rate):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Operating lease right-of-use assets | $ 1,212 | $ 657 |
| Total operating lease right-of-use assets | $ 1,212 | $ 657 |
| | | |
| Current portion of operating lease liabilities | $ 419 | $ 420 |
| Operating lease liabilities, less current portion | 859 | 372 |
| Total operating lease liabilities | $ 1,278 | $ 792 |
| | | |
| Weighted average remaining lease term | 3 | 3 |
| | | |
| Weighted average discount rate | 13.0 % | 9.9 % |

Maturities on lease liabilities were as follows (in thousands):

| Year Ending December 31, | |
|---|---|
| 2026 | $ 552 |
| 2027 | 542 |
| 2028 | 393 |
| 2029 | 39 |
| Total lease payments | 1,526 |
| Less: future interest expense | (248) |
| Lease liabilities | $ 1,278 |

**R. Employee Benefit Plan**

The Company has a 401(k) retirement plan (the "401(k) Plan") that covers substantially all employees. The Company may provide a discretionary match with a maximum amount of 4% of the participant's compensation, which vests immediately. The Company made matching contributions under the 401(k) Plan of approximately $0.3 million and $0.5 million for the years ended December 31, 2025, and 2024, respectively.

The Company has a discretionary profit-sharing plan (the "Profit Sharing Plan") that covers all employees. Employees become eligible participants in the Profit Sharing Plan once they have provided three years of service to the Company. The Company made no contributions to the Profit Sharing Plan in 2025 or 2024.

**S. Goodwill & Intangible Assets**

The Company's goodwill balance was $4.7 million as of December 31, 2025, and 2024. As of December 31, 2025, and 2024, the Company completed its annual qualitative assessment under ASC 350 to determine whether the existence of events or circumstances indicated that it was more likely than not that the fair value of its reporting unit was less than its respective carrying value. The Company concluded that based on the relevant events and circumstances, it was more likely than not that the reporting unit's fair value exceeded its related carrying value and therefore no quantitative assessment was required. No goodwill impairment charges were recorded for the years ended December 31, 2025, or 2024.

The definite-lived intangible assets that are subject to amortization have been reviewed for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable. In the second quarter of 2025, the Company assessed the results of its refined commercial efforts related to OLPRUVA. This was determined to be a triggering event that could result in a decrease in future expected cash flows, and thus indicated the carrying amount of the OLPRUVA asset group may not be fully recoverable. The Company performed an undiscounted cash flow analysis over the OLPRUVA asset group and determined that the carrying value of the asset group is not recoverable. Future cash flows specific to OLPRUVA, which most significantly includes an estimate of forecasted revenues, are based on reasonable and supportable assumptions regarding the cash flows expected to result from the use of the asset and its eventual disposition. The Company then estimated the fair value of the asset group to measure the impairment loss for the period. The fair value measurement was based on Level 3 inputs including projected sales driven by market share and product sales price estimates, associated expenses, growth rates, and the discount rate used to measure the fair value of the net cash flows associated with this asset group. The Company recorded an intangible asset impairment charge of $58.7 million in the consolidated statements of operations for the year ended December 31, 2025. As of December 31, 2024, the Company had a definite-lived intangible asset, net, related to the acquisition of OLPRUVA of $61.3 million. There was no comparable impairment in the year ended December 31, 2024.

Prior to the impairment discussed above, the OLPRUVA definite-lived intangible asset was being amortized on a straight-line basis over the OLPRUVA patent life of 13 years. Amortization expense is recorded as intangible asset amortization in the consolidated statements of operations and was $2.6 million and $5.9 million for the years ended December 31, 2025, and 2024, respectively.

In connection with the XOMA License Agreement, a regulatory milestone payment of $6.0 million was due to XOMA upon approval of MIPLYFFA in the United States, which the Company paid in October 2024. This definite-lived intangible asset is amortized on a straight-line basis over the MIPLYFFA patent life of approximately five years and is reviewed periodically for impairment. Amortization expense is recorded as intangible asset amortization in the consolidated statements of operations and was $1.3 million and $0.3 million for the years ended December 31, 2025, and 2024, respectively.

For intangible assets subject to amortization, estimated amortization expense for the five fiscal years subsequent to December 31, 2025, is expected to be as follows:

| | | |
|---|---|---|
| 2026 | $ | 1,263 |
| 2027 | | 1,263 |
| 2028 | | 1,263 |
| 2029 | | 632 |
| 2030 | | — |

As of December 31, 2025, and 2024, non-amortizable intangible assets include in-process research and development of $2.0 million.

**T. Subsequent Events**

The Company evaluated events and transactions occurring subsequent to December 31, 2025, through March 9, 2026, the date the accompanying financial statements were issued.

During this period, there were no subsequent events that required recognition in the accompanying consolidated financial statements, nor were there any additional non-recognized subsequent events that required disclosure.

## EXHIBITS

| Exhibit No. | Description |
|---|---|
| 2.1*** | Agreement and Plan of Merger dated as of August 30, 2023, by and among the Company Aspen Z Merger Sub, Inc., and Acer Therapeutics Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on August 31, 2023). |
| 2.2† | Asset Purchase Agreement by and among the Registrant, Zevra Denmark A/S and Orphazyme A/S, in restructuring, dated May 15, 2022 (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on May 16, 2022). |
| 2.3+† | Asset Purchase Agreement dated February 26, 2025 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 13, 2025). |
| 3.1* | Restated Certificate of Incorporation of Zevra Therapeutics, Inc. |
| 3.2 | Amended and Restated Bylaws, as currently in effect, of Zevra Therapeutics, Inc. (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on February 28, 2024). |
| 4.1 | Specimen stock certificate evidencing shares of Common Stock (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 12, 2021). |
| 4.2 | Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 12, 2025). |
| 4.3 | Form of Common Stock Purchase Warrant (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on November 20, 2023). |
| 10.1# | Amended and Restated 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2021). |
| 10.1.1# | Form of Stock Option Grant Notice and Stock Option Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 File No. 333-202660) as filed with the SEC on March 11, 2015). |
| 10.1.2# | Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 File No. 333-202660) as filed with the SEC on March 11, 2015). |
| 10.1.3# | Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under 2014 Equity Incentive Plan (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 14, 2019). |
| 10.2# | 2021 Employee Stock Purchase Plan (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2021). |
| 10.3# | 2023 Employment Inducement Award Plan and forms of award agreements thereunder (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on April 1, 2024). |
| 10.4# | Tenth Amended and Restated Non-Employee Director Compensation Policy effective February 15, 2025 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 13, 2025). |
| 10.5# | Form of Indemnification Agreement with the Registrant's directors and executive officers (incorporated herein by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202660) as filed with the SEC on March 11, 2015). |
| 10.6# | Amended and Restated Employment Agreement by and between the Registrant and R. LaDuane Clifton, dated as of June 25, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 14, 2015). |
| 10.6.1# | Amendment to Amended and Restated Employment Agreement by and between the Registrant and R. LaDuane Clifton, dated as of October 13, 2015 (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 13, 2015). |
| 10.6.2#* | Separation of Employment Agreement and General Release by and between the Registrant and R. LaDuane Clifton, dated November 19, 2025. |

**EXHIBITS, CONTINUED**

| Exhibit No. | Description |
|---|---|
| 10.7# | Employment Agreement by and between the Registrant and Adrian Quartel, dated as of January 3, 2024 (incorporated by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 12, 2025). |
| 10.8# | Employment Agreement by and between the Registrant and Joshua Schafer, dated as of January 6, 2023 (incorporated by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 12, 2025). |
| 10.9# | Employment Agreement by and between the Registrant and Rahsaan Thompson, dated as of June 20, 2024 (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 14, 2024). |
| 10.10# | Employment Agreement, effective as of October 10, 2023, between the Registrant and Neil F. McFarlane (incorporated herein by reference to the Registrant's Current Report on 8-K as filed with the SEC on October 10, 2023). |
| 10.10.1# | Amendment to the Employment Agreement by and between the Registrant and Neil F. McFarlane, dated as of May 7, 2024 (incorporated by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 12, 2025). |
| 10.11 | Lease Agreement, by and between the Registrant and BRE/COH FL LLC, dated as of November 3, 2014 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 10, 2017). |
| 10.11.1 | First Amendment to the Lease Agreement, by and between the Registrant and BRE/COH FL LLC, dated as of April 21, 2015 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 10, 2017). |
| 10.11.2 | Second Amendment to the Lease Agreement, by and between the Registrant and BRE/COH FL LLC, dated as of December 22, 2015 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 10, 2017). |
| 10.11.3 | Third Amendment to the Lease Agreement, by and between the Registrant and BRE/COH FL LLC, dated as of July 15, 2016 (incorporated herein by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 10, 2017). |
| 10.11.4 | Fourth Amendment to the Lease Agreement by and between the Registrant and BRE/COH FL LLC, dated as of September 4, 2025 (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on November 5, 2025). |
| 10.12+ | Collaboration and License Agreement, dated as of September 3, 2019, by and between the Registrant and Boston Pharmaceuticals Holdings SA (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on September 4, 2019). |
| 10.12.1+ | Amendment No. 1 to Collaboration and License Agreement, effective as of April 8, 2021, by and between the Company and Commave Therapeutics SA (formerly known as Boston Pharmaceuticals Holdings SA) (incorporated herein by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on August 13, 2021). |
| 10.13 | Equity Distribution Agreement, dated July 12, 2024, by and among the Company and Citizens JMP Securities LLC (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on July 12, 2024). |
| 10.14 | Registration Rights Agreement dated as of August 30, 2023, by and among the Registrant and each of the sellers party thereto (incorporated herein by reference to the Registrant's Current Report on Form 8-K as filed with the SEC on August 31, 2023). |
| 10.15 | Contingent Value Rights Agreement, dated as of November 17, 2023, by and among Zevra Therapeutics, Inc., Computershare, Inc., and Computershare Trust Company, N.A. (incorporated by reference to the Registrant's Current Report on 8-K as filed with the SEC on November 20, 2023). |
| 10.16†+ | Credit Agreement dated as of April 5, 2024, by and among Zevra Therapeutics, Inc. and HCR Stafford Fund II, L.P., HCR Potomac Fund II, L.P., and Perceptive Credit Holdings IV, LP (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q as filed with the SEC on May 9, 2024). |
| 10.17#* | Amended and Restated Employment Agreement by and between the Registrant and Timothy Sangiovanni, effective as of February 13, 2017. |
| 10.18†+* | Sublease Agreement, dated December 20, 2024, by and between Brownmed, Inc. and the Company. |

**EXHIBITS, CONTINUED**

| Exhibit No. | Description |
|---|---|
| 19 | Zevra Therapeutics, Inc. Amended and Restated Insider Trading and Window Period Policy (incorporated by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on March 12, 2025). |
| 21.1 | Subsidiaries of the Company. |
| 23.1* | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. |
| 24.1* | Power of Attorney (included on signature page). |
| 31.1* | Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended. |
| 31.2* | Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended. |
| 32.1** | Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2** | Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 97.1# | Zevra Therapeutics, Inc. Policy for Recovery of Erroneously Awarded Compensation, Effective October 2, 2023 (incorporated by reference to the Registrant's Annual Report on Form 10-K as filed with the SEC on April 1, 2024). |
| 101.INS* | Inline XBRL Instance Document. |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document. |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101) |

| | |
|---|---|
| * | Filed herewith |
| ** | Furnished herewith |
| *** | Pursuant to Item 601(b)(2) of Regulation S-K, schedules and similar attachments have been omitted. The registrant hereby agrees to furnish a copy of any omitted schedule or similar attachment to the SEC upon request. |
| # | Indicates management contract or compensatory plan. |
| + | Certain portions of the exhibit, identified by the mark, "[*]", have been omitted because such portions contained information that is both (i) not material and (ii) the type that the Registrant treats as private or confidential. |
| † | Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule will be furnished to the Securities and Exchange Commission upon request; provided, however, that the parties may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any document so furnished. |

## ITEM 16. FORM 10-K SUMMARY

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Zevra Therapeutics, Inc.

Dated: March 9, 2026

By: /s/ Neil F. McFarlane

Neil F. McFarlane

President and Chief Executive Officer
(Principal Executive Officer)

Dated: March 9, 2026

By: /s/ Timothy J. Sangiovanni

Timothy J. Sangiovanni, CPA

Senior Vice President, Finance and Corporate Controller
(Principal Financial and Accounting Officer)

**POWER OF ATTORNEY**

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitute and appoint Neil F. McFarlane and Timothy J. Sangiovanni, and each of them (with full power to each of them to act alone), as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Neil F. McFarlane<br>Neil F. McFarlane | President and Chief Executive Officer<br>(Principal Executive Officer) | March 9, 2026 |
| /s/ Timothy J. Sangiovanni<br>Timothy J. Sangiovanni, CPA | Senior Vice President, Finance and Corporate Controller<br>(Principal Financial and Accounting Officer) | March 9, 2026 |
| /s/ Thomas D. Anderson<br>Thomas D. Anderson | Director | March 9, 2026 |
| /s/ John B. Bode<br>John B. Bode | Director | March 9, 2026 |
| /s/ Douglas W. Calder<br>Douglas W. Calder | Director | March 9, 2026 |
| /s/ Tamara A. Favorito<br>Tamara A. Favorito | Director | March 9, 2026 |
| /s/Alicia Secor<br>Alicia Secor | Director | March 9, 2026 |
| /s/ Alvin Shih<br>Alvin Shih, M.D. | Director | March 9, 2026 |
| /s/ Corey Watton<br>Corey Watton | Director | March 9, 2026 |

**ZEVRA THERAPEUTICS, INC.**

**RESTATED**

**CERTIFICATE OF INCORPORATION**

(Pursuant to Section 245 of the General

Corporation Law of the State of Delaware)

**ZEVRA THERAPEUTICS, INC.**, a corporation organized and existing under the laws of the State of Delaware (the "***Company***"), does hereby certify as follows:

**FIRST:** The name of the Company is Zevra Therapeutics, Inc.

**SECOND:** The Company was originally incorporated as KemPharm, Inc. under the General Corporation Law of the State of Delaware on May 28, 2014, pursuant to the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware, which Certificate of Incorporation has been amended from time to time thereafter.

**THIRD:** This Restated Certificate of Incorporation restates, integrates and consolidates the provisions of the Certificate of Incorporation of the Company, as heretofore amended or supplemented, and contains only provisions that are in effect as of the date hereof. There is no discrepancy between those provisions and the provisions of the Restated Certificate. This Restated Certificate of Incorporation does not effect any further amendment to the Certificate of Incorporation of the Company as previously amended or supplemented.

**FOURTH:** This Restated Certificate of Incorporation has been duly adopted by the Board of Directors of the Company in accordance with Section 245 of the General Corporation Law of the State of Delaware, and no vote of the stockholders of the Company was required for its adoption.

**FIFTH:** The Restated Certificate of Incorporation so adopted reads in full as set forth in Exhibit A attached hereto and is incorporated herein by reference in its entirety.

**IN WITNESS WHEREOF**, Zevra Therapeutics, Inc. has caused this Restated Certificate of Incorporation to be signed by its Chief Legal Officer and Secretary on this 12th day of February, 2026.

ZEVRA THEREAPEUTICS, INC.

By: /s/ Rahsaan Thompson

Rahsaan Thompson

Chief Legal Officer and Secretary

**Exhibit A**

**ZEVRA THERAPEUTICS, INC.**

**RESTATED**

**CERTIFICATE OF INCORPORATION**

**I.**

The name of this corporation is Zevra Therapeutics, Inc. (the "***Company***").

**II.**

The address of the registered office of the Company in the State of Delaware is 251 Little Falls Drive, City of Wilmington, County of New Castle, Delaware, Zip code 19808, and the name of the registered agent of the Company in the State of Delaware at such address is Corporation Service Company.

**III.**

The purpose of the Company is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law ("***DGCL***").

**IV.**

**A.** The Company is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares of all classes of capital stock which the Company shall have authority to issue is Two Hundred Sixty Million (260,000,000) shares, of which Two Hundred Fifty Million (250,000,000) shares shall be Common Stock (the "***Common Stock***"), each having a par value of one-hundredth of one cent ($0.0001), and Ten Million (10,000,000) shares shall be Preferred Stock (the "***Preferred Stock***"), each having a par value of one-hundredth of one cent ($0.0001).

**B.** The Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Company (the "***Board***") is hereby expressly authorized to provide for the issue of the shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board providing for the issuance of such shares and as may be permitted by the DGCL. The Board is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof

then outstanding) by the affirmative vote of the holders of a majority of the voting power of the stock of the Company entitled to vote thereon, without a separate vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of Preferred Stock.

**C.** Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Company for their vote; *provided, however*, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock).

**V.**

For the management of the business and for the conduct of the affairs of the Company, and in further definition, limitation and regulation of the powers of the Company, of its directors and of its stockholders or any class thereof, as the case may be, it is further provided that:

**A. MANAGEMENT OF BUSINESS.** The management of the business and the conduct of the affairs of the Company shall be vested in its Board.

**B. BOARD OF DIRECTORS.**

**1. Number.** The number of directors that shall constitute the Board shall be fixed exclusively by resolutions adopted by a majority of the authorized number of directors constituting the Board.

**2. Term.** Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided into three classes designated as Class I, Class II and Class III, respectively. Directors shall be elected for staggered terms of three (3) years, such that the term of office of one class of directors shall expire at each annual meeting of stockholders. At each annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting. Notwithstanding the foregoing provisions of this section, each director shall serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. No decrease in the number of directors constituting the Board shall shorten the term of any incumbent director.

**3. Removal.**

**a.** Subject to the rights of any series of Preferred Stock to elect additional directors under specified circumstances, neither the Board nor any individual director may be removed without cause.

**b.** Subject to any limitation imposed by law, any individual director or directors may be removed with cause by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 ⅔%) of the voting power of all then-outstanding shares of capital stock of the Company entitled to vote generally at an election of directors.

**4. Vacancies.** Subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board resulting from death, resignation, disqualification, removal or other causes, and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders, except as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

**C. BYLAW AMENDMENTS.** The Board is expressly empowered to adopt, amend or repeal the Bylaws of the Company. Any adoption, amendment or repeal of the Bylaws of the Company by the Board shall require the approval of a majority of the authorized number of directors. The stockholders shall also have power to adopt, amend or repeal the Bylaws of the Company; *provided, however,* that, in addition to any vote of the holders of any class or series of stock of the Company required by law or by this Amended and Restated Certificate of Incorporation, such action by stockholders shall require the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 ⅔%) of the voting power of all of the then-outstanding shares of the capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class.

**D. WRITTEN BALLOTS.** The directors of the Company need not be elected by written ballot unless the Bylaws so provide.

**E. ACTION BY STOCKHOLDERS.** No action shall be taken by the stockholders of the Company except at an annual or special meeting of stockholders called in accordance with the Bylaws and no action shall be taken by the stockholders by written consent or electronic transmission.

**F. ADVANCE NOTICE.** Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Company shall be given in the manner provided in the Bylaws of the Company.

**VI.**

**A.** The liability of the directors for monetary damages shall be eliminated to the fullest extent under applicable law. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Company shall be eliminated to the fullest extent permitted by the DGCL, as so amended.

**B.** Any repeal or modification of this Article VI shall be prospective and shall not affect the rights under this Article VI in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

**VII.**

Unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company; (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders; (iii) any action asserting a claim against the Company arising pursuant to any provision of the General Corporation Law, the Amended and Restated Certificate of Incorporation or the Bylaws of the Company; or (iv) any action asserting a claim against the Company governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Company shall be deemed to have notice of and to have consented to the provisions of this Article VII.

**VIII.**

**A.** The Company reserves the right to amend, alter, change or repeal any provision contained in this Amended and Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute, except as provided in paragraph B. of this Article VIII, and all rights conferred upon the stockholders herein are granted subject to this reservation.

**B.** Notwithstanding any other provisions of this Amended and Restated Certificate of Incorporation or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the Company required by law or by this Amended and Restated Certificate of Incorporation or any certificate of designation filed with respect to a series of Preferred Stock that may be designated from time to time, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 ⅔%) of the voting power of all of the then-outstanding shares of capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Articles V, VI, VII and VIII.

*** * * ***

**Exhibit 10.6.2**

**Separation of Employment Agreement and General Release**

THIS SEPARATION OF EMPLOYMENT AGREEMENT AND GENERAL RELEASE (the "Agreement") is made as of this day of November 19, 2025, by and between R. LaDuane Clifton ("Executive") and Zevra Therapeutics, Inc. (the "Company").

WHEREAS, Executive is employed by Company as its Chief Financial Officer and Treasurer;

WHEREAS, Executive and Company entered into an Amended and Restated Employment Agreement, dated as of June 25, 2015, as amended on October 13, 2015 (the "Employment Agreement");

WHEREAS, Executive and Company desire that Executive's employment with Company will terminate effective as of the Termination Date (as defined below); and

WHEREAS, in connection with the termination of Executive's employment, the parties have agreed to a separation package and the resolution of any and all disputes between them.

NOW, THEREFORE, IT IS HEREBY AGREED by and between Executive and Company as follows:

1. Executive's employment with Company shall terminate, and Executive will cease to be employed with Company, effective as of December 31, 2025 ((the "Termination Date"). Executive's employment with Company will at all times remain terminable by either Executive or Company at-will and nothing in this Agreement confers upon Executive any right to continue to serve as an employee or other service provider of Company or interferes with or restricts the rights of Company to discharge or terminate the services of Executive at any time for any or no reason, with or without cause. Effective as of the Termination Date, Executive shall cease to hold any position (whether as an officer, director, manager, employee, trustee, fiduciary, or otherwise) with, and shall cease to exercise or convey any authority (actual, apparent, or otherwise) on behalf of, Company or any of its subsidiaries or affiliates. Executive shall execute any additional documents or instruments reasonably requested by Company to effectuate the matters described in this Section 1.

2. Release of Claims.

(a) Executive, for and in consideration of the commitments of Company as set forth in Section 5 of this Agreement, and intending to be legally bound, does hereby REMISE, RELEASE AND FOREVER DISCHARGE Company, its stockholders, and its present and past affiliates, subsidiaries and parents, its and their respective officers, directors, investors, employees, and agents, and its and their respective predecessors, successors and assigns, heirs, executors, and administrators (collectively, "Releasees"), subject to the exceptions of Sections 2(b), 2(c), 2(d) and 13 of this Agreement, from all causes of action, suits, debts, claims and demands whatsoever in law or in equity, which Executive ever had, now has, or hereafter may have, whether known or unknown, or which Executive's heirs, executors, or administrators

may have, by reason of any matter, cause or thing whatsoever, from the beginning of time to the date of this Agreement, to the extent arising from or relating in any way to Executive's employment relationship with Company, the terms and conditions of that employment relationship, and/or the termination of that employment relationship, including, but not limited to, (i) any and all claims for monetary damages or other relief arising under Title VII of The Civil Rights Act of 1964 or the Americans with Disabilities Act, each as amended; (ii) any and all claims arising under the Family and Medical Leave Act of 1993 or the Employee Retirement Income Security Act of 1974, each as amended; (iii) any and all claims arising under any applicable federal, state or local fair employment practice laws or wage and hour laws; (iv) any and all other claims under any federal, state or local common law, statute, or regulatory provision, now or hereafter recognized, including, without limitation, the Florida Civil Rights Act, the Florida Whistleblower Protection Act, the Florida Minimum Wage Act, and the Florida Constitution, Article X, Section 24, each as amended; (v) any and all claims for breach of contract, including the Employment Agreement, and (vi) any and all claims for attorneys' fees and costs (individually, a "Claim" and collectively, "Claims").

(b) The foregoing Section 2(a) shall in no event apply to (i) enforcement by Executive of Executive's rights under this Agreement, (ii) Executive's rights as a stockholder in Company or any of its affiliates, (iii) Executive's rights to indemnifications under any separate contract or insurance policy, (iv) Executive's right to seek unemployment insurance benefits, (v) Executive's right to seek workers' compensation benefits, (vi) any rights Executive has to indemnification for service as an officer of Company, or (vii) any claims that, as a matter of applicable law, are not waivable. This Agreement is effective without regard to the legal nature of the claims raised and without regard to whether any such claims are based upon tort, equity, implied or express contract or discrimination of any sort.

(c) Executive and Company agree that nothing in this Agreement prevents or prohibits Executive from: (i) making any disclosure of relevant and necessary information or documents in connection with any charge, action, investigation, or proceeding relating to this Agreement, or as required by law or legal process; (ii) participating, cooperating, or testifying in any charge, action, investigation, or proceeding with, or providing information to, any self-regulatory organization, governmental agency or legislative body, and/or pursuant to the Sarbanes-Oxley Act, including the Securities Exchange Commission and the Department of Justice, without notifying Company; (iii) testifying in, participating in or otherwise assisting in a proceeding relating to an alleged violation of any federal, state or municipal law relating to fraud, or any rule or regulation of the Securities and Exchange Commission or any self-regulatory organization; (iv) exercising any rights Executive may have under Section 7 of the National Labor Relations Act; or (v) filing a charge with the Equal Employment Opportunity Commission, the National Labor Relations Board, or any similar state or local agency, provided, however, to the fullest extent provided by law, Executive acknowledges and agrees Executive is waiving any right to recover monetary damages and other relief in connection with any such filing, but not the right to recover a whistleblower award, which Executive retains. To the extent permitted by law, upon receipt of any subpoena, court order or other legal process compelling the disclosure of any such information or documents, Executive agrees to give prompt written notice to Company so as to permit Company to protect its interests in confidentiality to the fullest

extent possible. Further, nothing in this Agreement is intended to or shall restrict Executive from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that Executive has reason to believe is unlawful.

(d) Executive and Company further agree that the Equal Employment Opportunity Commission ("EEOC") and comparable state or local agencies have the authority to carry out their statutory duties by investigating charges, issuing determinations, and filing lawsuits in Federal or state court in their own name, or taking any action authorized by the EEOC or comparable state or local agencies. Executive retains the right to file and participate in any such action. Executive retains the right to communicate with the EEOC and comparable state or local agencies and such communication can be initiated by Executive or in response to the government and such right is not limited by anything herein. Executive and Company agree that communication with employees plays a critical role in the EEOC's enforcement process because employees inform the agency of employer practices that might violate the law. For this reason, the right to communicate with the EEOC is a right that is protected by federal law and this Agreement does not prohibit or interfere with those rights. Notwithstanding the foregoing, Executive agrees to waive Executive's right to recover monetary damages or other relief in any charge, complaint or lawsuit filed by Executive or by anyone else on Executive's behalf, but does not waive Executive's right to recover whistleblower rewards.

3. Executive further agrees and recognizes that, upon the Termination Date, Executive shall have permanently and irrevocably severed Executive's employment relationship with Company, that Executive shall not seek employment with Company or any affiliated entity at any time in the future, and that neither Company nor any affiliate has any obligation to employ Executive in the future.

4. Executive and Company mutually agree that, subject to Sections 2(b), 2(c), 2(d) and 13 herein, neither party will disparage or subvert the other party or any of the other Releasees, or make any statement reflecting negatively on the other party or any of the other Releasees, including, but not limited to, any matters relating to the operation or management of Company, Executive's employment and the termination of Executive's employment, irrespective of the truthfulness or falsity of such statement.

5. Subject to (i) Executive's execution and delivery of this Agreement to Company within seven days following receipt of the Agreement, (ii) Executive's continued employment with Company through the Termination Date, (iii) Executive's execution of the Updated Release of Claims attached to this Agreement as Exhibit A and made a part of this Agreement (the "Updated Release") on or within three (3) calendar days after the Termination Date and non-revocation of the Updated Release, and (iv) Executive's continued compliance with this Agreement, the Updated Release, and the Restrictive Covenants (as defined below), and in consideration for Executive's agreement as set forth herein, Company agrees to pay or provide to Executive (as applicable) the following severance payments and benefits ("Severance Benefits"): (1) an amount in cash equal to $480,000 (which represents 12 months of Executive's base salary), minus applicable withholdings and deductions which shall be paid by Company in substantially equal installments over the twelve month period following the 60th day following

the Termination Date according to Company's customary payroll practice, with the first payment made on the second regularly scheduled pay day immediately following the expiration of the Revocation Period (as defined in the Updated Release), with no revocation, and such first payment including any installment payments that would have been payable for the period between the Termination Date and the second payroll date on which the Severance Benefits begin; (2) an amount in cash equal to $192,000, which represents the pro rata bonus award payment for the year in which the Termination Date occurs, computed in accordance with Section 4(E)(1)(b) of the Employment Agreement; (3) provided Executive timely elects continued health care coverage under Section 4980(B) of the Internal Revenue Code of 1986, as amended, ("COBRA"), Company will reimburse Executive for the monthly COBRA cost of continued health coverage in accordance with Section 4(E)(1)(c) of the Employment Agreement; and (4) accelerated vesting of each outstanding equity award granted to Executive in accordance with Section 4(E)(1)(d) of the Employment Agreement. Executive also shall be entitled to receive the Accrued Benefits (as defined in Section 4(B) of the Employment Agreement) regardless of Executive's execution and delivery of this Agreement or the Updated Release. Executive agrees that, with the Accrued Benefits, Executive has been paid all wages, payments, benefits and other compensation owed to Executive, and Executive is not entitled to receive, and shall not receive, any wages, payments, benefits, severance payments or other compensation (including any severance payments pursuant to the Employment Agreement), except to the extent expressly set forth in this Section 5. For the avoidance of doubt, if Executive terminates Executive's employment with Company prior to the Termination Date, Executive shall not be eligible to receive the Severance Benefits or any other severance or termination payments from Company or any of its affiliates. Except as otherwise provided under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or as specifically provided in this Agreement, all of Executive's rights to salary, benefits and other amounts (if any) shall cease on the Termination Date. Executive understands and agrees that the payments, benefits and agreements provided in this Agreement are being provided to Executive in consideration for Executive's acceptance and execution of, and in reliance upon Executive's representations in, this Agreement.

6. Executive acknowledges and agrees that Company previously has satisfied any and all obligations owed to Executive under any employment agreement or offer letter Executive has with Company or any other Releasee and, further, that this Agreement supersedes any and all prior agreements or understandings, whether written or oral, between the parties, excluding only the Restrictive Covenants (defined below), Executive's vested rights under any outstanding equity grants in accordance with the terms of the applicable grant agreements, any obligations relating to the securities of Company or any of its affiliates and Company's obligations under this Agreement to pay or provide the Severance Benefits and Accrued Benefits, all of which shall remain in full force and effect to the extent not inconsistent with this Agreement, and further, that, except as set forth expressly herein, no promises or representations have been made to Executive in connection with the termination of Executive's employment or the terms of this Agreement.

7. Except as may be necessary to obtain approval or authorization to fulfill Executive's or Company's obligations hereunder or as required by applicable law and subject to

the exceptions of Section 2(b), 2(c), 2(d) and 13 of this Agreement, (a) Executive agrees not to disclose the terms of this Agreement to anyone, except Executive's spouse, attorney and, as necessary, tax/financial advisor, and (b) Company agrees that the terms of this Agreement will not be disclosed, except (i) to those involved in the discussions relating to or negotiations of this Agreement and/or Executive's separation from Company, (ii) to Company's attorneys, tax advisors, and auditors, (iii) as required by applicable law, including the rules and regulations of the Securities and Exchange Commission, (iv) in any action relating to a violation of this Agreement or any other agreement between the Executive and Company or any other Releasee, and (v) in any other action involving the Executive and Company or any other Releasees; provided, however, the exceptions in Sections 2(c) and 2(d) shall also apply to Company, its employees and agents. It is expressly understood that any violation of the confidentiality obligation imposed hereunder constitutes a material breach of this Agreement.

8. Executive hereby acknowledges and agrees that Executive is subject to certain non-solicitation, non-disparagement, confidentiality and other restrictive covenants (the "Restrictive Covenants"), including, without limitation, the non-competition, non-solicitation, confidentiality and other covenants set forth in Sections 6, 7, 8 and 9 of the Employment Agreement, and Executive hereby acknowledges and agrees that Executive continues to be bound by and subject to such Restrictive Covenants, and that such Restrictive Covenants will survive the termination of Executive's employment and the Termination Date. The Restrictive Covenants are incorporated herein by reference and shall be considered a part of this Agreement as if set forth fully herein.

9. Executive represents that Executive will promptly return to Company, no later than the Termination Date or earlier upon Company's request, records and business documents, whether on computer or hard copy, and other materials (including but not limited to computer disks and tapes, computer programs and software, office keys, correspondence, files, customer lists, technical information, customer information, pricing information, business strategies and plans, sales records and all copies thereof) in Executive's possession provided by Company and/or its predecessors, parents, subsidiaries or affiliates or obtained as a result of Executive's employment with Company and/or its predecessors, parents, subsidiaries or affiliates, or created by Executive while employed by or rendering services to Company and/or its predecessors, parents, subsidiaries or affiliates (collectively, the "Corporate Records"). Executive acknowledges that all such Corporate Records are the property of Company. In addition, Executive shall promptly return in good condition, no later than the Termination Date, any and all Company owned equipment or property, including, but not limited to, automobiles, personal data assistants, facsimile machines, copy machines, pagers, credit cards, cellular telephone equipment, business cards, laptops and computers. As of the Termination Date or earlier as determined by Company in its sole discretion, Company will make arrangements to remove, terminate or transfer any and all business communication lines including network access, cellular phone, fax line and other business numbers.

10. Subject to the exceptions of Sections 2(b), 2(c), 2(d) and 13 of the Agreement, Executive expressly waives all rights afforded by any statute which expressly limits the effect of a release with respect to unknown claims. Executive acknowledges the significance of this

release of unknown claims and the waiver of statutory protection against a release of unknown claims which provides that a general release does not extend to claims which a creditor does not know or suspect to exist in the creditor's favor at the time of executing the release, which if known by it would have affected its settlement with the debtor.

11. The parties agree and acknowledge that the agreements by Company and Executive described herein, including the settlement and termination of any asserted or unasserted claims against the Releasees, are not and shall not be construed to be an admission of any violation of any federal, state or local statute or regulation, or of any duty owed by any of the Releasees to Executive.

12. Executive agrees and recognizes that should Executive breach any of the obligations or covenants set forth in this Agreement, Company will have no further obligation to provide Executive with the consideration set forth herein, and will have the right to seek repayment of all consideration paid up to the time of any such breach. Further, Executive acknowledges in the event of a breach of this Agreement, Releasees may seek any and all appropriate relief for any such breach, including equitable relief and/or money damages.

13. In accordance with 18 U.S.C. §1833, notwithstanding anything to the contrary in this Agreement or any other agreement between Executive and Company in effect as of the date Executive receives this Agreement (together, the "Subject Documents"): (a) Executive will not be in breach of any Subject Document, and shall not be held criminally or civilly liable under any federal or state trade secret law (i) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (b) if Executive files a lawsuit for retaliation by Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order. Furthermore, the parties agree that nothing in the Subject Documents prohibits Executive from reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation or releases or restrains Executive's right to receive an award for information provided to any such government agencies.

14. This Agreement and the obligations of the parties hereunder shall be construed, interpreted and enforced in accordance with the laws of the State of Florida. This Agreement shall inure to the benefit of Company, Executive and each of the other Releasees.

15. Executive certifies and acknowledges as follows:

(a) That Executive has read the terms of this Agreement, and that Executive understands its terms and effects, including the fact that Executive has agreed, subject to

Sections 2(b), 2(c), 2(d) and 13 herein, to RELEASE AND FOREVER DISCHARGE Company and each of the Releasees from any legal action arising out of Executive's employment relationship with Company and the termination of that employment relationship;

(b) That Executive has signed this Agreement voluntarily and knowingly in exchange for the consideration described herein, which Executive acknowledges is adequate and satisfactory to Executive and which Executive acknowledges is in addition to any other benefits to which Executive is otherwise entitled;

(c) That Executive has been and is hereby advised in writing to consult with an attorney prior to signing this Agreement;

(d) That Executive does not waive rights or claims that may arise after the date this Agreement is executed;

[SIGNATURE PAGE TO FOLLOW]

Intending to be legally bound hereby, Executive and Company executed the foregoing Separation of Employment Agreement and General Release this 19 day of November, 2025.

| **ZEVRA THERAPEUTICS, INC.** | **EXECUTIVE** |
|---|---|
| By: /s/ Neil F. McFarlane | /s/ R. LaDuane Clifton |
| Name: Neil F. McFarlane | R. LaDuane Clifton |
| Title: CEO | |
| Dated: November 19, 2025 | Dated: November 19, 2025 |

**Exhibit A**

**Updated Release of Claims**

*(To be signed and returned to Company on or within twenty-one (21) days after the Termination Date, and in no event before the Termination Date)*

Zevra Therapeutics, Inc. (the "***Company***") and R. LaDuane Clifton (the "***Executive***") entered into a Separation of Employment Agreement and General Release dated November 19, 2025 (the "***Agreement***"). The parties to that Agreement hereby further agree as follows:

1. A blank copy of this Updated Release of Claims ("***Updated Release***") was attached to the Agreement as **Exhibit A** and the parties agree that it is part of the Agreement.

2. In consideration of the payment of the Severance Benefits (as defined in the Agreement), Executive hereby (i) extends the release of claims in Section 2 of the Agreement to any Claims that arose through the date Executive signs this Updated Release and (ii) confirms that Executive has complied with Executive's obligations in Section 9 of the Agreement through the date Executive signs this Updated Release.

3. Executive is hereby advised to consult with an attorney of Executive's choosing prior to signing this Updated Release.

4. Executive also hereby extends the release of claims in Section 2 of the Agreement to any and all Claims under the federal Age Discrimination in Employment Act, as amended, including the Older Workers Benefit Protection Act ("***ADEA***"). Executive acknowledges that Executive is knowingly and voluntarily waiving and releasing any rights Executive may have under the ADEA and that the consideration given for this Updated Release is in addition to anything of value to which Executive was already entitled. Executive further acknowledges and agrees that: (a) this Updated Release does not apply to any rights or claims that arise after the date Executive signs this Updated Release; (b) Executive should consult with an attorney prior to signing this Updated Release; (c) Executive has been given up to twenty-one (21) calendar days to consider this Updated Release (although Executive may choose to voluntarily execute this Updated Release earlier, though not earlier than the Termination Date (as defined in the Agreement)); (d) Executive has seven (7) calendar days following the date Executive signs this Updated Release to revoke it ("***Revocation Period***"); (e) this Updated Release will not be effective until the date upon which the Revocation Period following a timely execution of this Updated Release has expired without revocation (the "***Effective Date***"), which will be the eighth (8th) calendar day after Executive timely signs it; and (f) Executive is signing this Updated Release voluntarily, knowingly, and without any duress. For the avoidance of doubt, Executive understands and agrees that the Executive may not execute this Updated Release on or before Executive's Termination Date. To be eligible to receive the Severance Benefits, Executive must execute this Updated Release on or within the three (3) days after Executive's last day of employment with Company.

4. The parties agree that this Updated Release is a part of the Agreement.

**Understood, Accepted and Agreed:**

**ZEVRA THERAPEUTICS, INC.** **EXECUTIVE**

By: /s/ Rahsaan Thompson /s/ R. LaDuane Clifton
Name: Rahsaan Thompson R. LaDuane Clifton
Title: Chief Legal Officer, Secretary and Compliance Officer

Dated: December 31, 2025 Dated: December 31, 2025

KemPharm, Inc.

# Amended and Restated Employment Agreement Timothy Sangiovanni

Effective as of
February 13, 2017

KemPharm, Inc.
Amended and Restated Employment Agreement

This Amended and Restated Employment Agreement ("Agreement") is made and entered into effective as of February 13, 2017, by and between KemPharm, Inc., a Delaware corporation (the "Company") and Timothy Sangiovanni ("Executive") (each being a "Party" hereto and together constituting the "Parties").

Background

A. The Company and Executive previously entered into that certain Employment Agreement dated as of August 17, 2015 (the "Employment Agreement")

B. Pursuant to Section 15.E of the Employment Agreement, the Employment Agreement may be amended by a written instrument between the Company and the Executive; and

C. The Company and the Executive desire to amend the Employment Agreement as provided herein.

Whereas, the Company desires to employ the Executive as its Vice President, Corporate Controller under the terms and conditions set forth below.

Now, Therefore, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the receipt, adequacy and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1. Employment.

A. Employment. Company hereby desires to employ Executive and Executive hereby accepts such employment with Company as its Vice President, Corporate Controller or in such other capacities as Company shall reasonably determine from time to time, upon the terms and conditions set forth in this Agreement.

B. Effective Date and Term. Company's employment of Executive under this Agreement shall commence effective as of February 13, 2017, (the "Effective Date"), and continue until the Date of Termination (defined in Section 4(A)) (hereinafter such period of time from the commencement until termination of employment shall be referred to as the "Employment Term").

C. Duties of Executive. During the Employment Term, all of the following shall apply: Executive shall carry out, perform and comply with such reasonable and lawful orders, directions, and written rules and policies (including those rules and policies memorialized in meeting minutes) as are assigned or set by Company's Chief Financial Officer (the "CFO") from time to time. Executive shall report to, receive directions from and be reviewed by the CFO. Executive's duties shall include the duties and responsibilities commonly associated with and are appropriate for an individual of Executive's or a similar position of a company similar to Company. Subject to the limitations of Section 4(E)(3)(iv), the CFO retains the right to modify Executive's job title and responsibilities pursuant to the legitimate business needs of Company.

D. Duty of Loyalty. During the Employment Term, Executive shall not, without the prior written consent of the CEO, accept other employment or render or perform other services for compensation. Executive shall devote Executive's full business time and attention and Executive's best efforts to the faithful performance of Executive's duties as an officer and employee of Company. Executive's expenditure of reasonable amounts of time for teaching, personal business, or on behalf of charitable or professional organizations shall not be deemed a breach of this Agreement, provided such activities do not materially interfere with the performance of Executive's duties and responsibilities hereunder.

E. Place of Performance. Executive's principal place of employment during the Employment Term will be at the Company's offices in the Orlando, FL area. Notwithstanding the foregoing, Executive understands and agrees that Executive's presence may be required at other Company worksites, or Executive may be required to travel for business, in each case, in accordance with Executive's duties and responsibilities under this Agreement, as business needs require or may change over time and as reasonably requested by the CFO.

2. Compensation and Benefits. In consideration of the services to be rendered by Executive pursuant to this Agreement, as well as Executive's covenants set forth in this Agreement, Company shall pay to Executive the following compensation, which shall be the entire and exclusive compensation for all of Executive's services rendered and other obligations taken on Company's behalf:

A. Annual Base Salary. During the Employment Term, Company shall pay to Executive an annualized base salary of $180,000.00 (the "Base Salary"). For calendar years in which Executive is employed for less than the full year, the Base Salary shall be prorated and accrue on a per diem basis for only those days on which Executive was employed during the Employment Term. The Base Salary will be paid by Company in equal installments according to Company's customary payroll practices, but in any event not less frequently than monthly, and shall be subject to all mandatory and voluntary payroll deductions. Executive's Base Salary shall be reviewed periodically by the Company's Board of Directors ("Board of Directors") or the Compensation Committee of the Board of Directors (the "Compensation Committee") if so designated and may be appropriately increased from time to time in the sole discretion of Board of Directors or the Compensation Committee, as applicable.

B. Incentive Compensation. During the Employment Term, Executive shall be entitled to participate in all short-term and long-term incentive programs established by Company, at such levels as the Board of Directors or Compensation Committee determines. Executive's annual short-term incentive opportunity target shall be no less than 30% of the Base Salary, as such percentage may be increased from time to time (the "Target Annual Bonus"). The actual amount of such annual incentive compensation shall be determined in accordance with the applicable plans based on achievement of individual and Company performance objectives established in advance by the Board of Directors or the Compensation Committee, taking into account input from the CEO, and such actual annual short term incentive compensation amount may be more or less than the target amount. No minimum incentive is guaranteed.

C. Equity Compensation. Upon the terms and conditions set forth in the following subsection, and subject to the approval of the Board of Directors or Compensation Committee, the Company shall grant to Executive an option to purchase shares of Company's common stock ("Common Stock") pursuant to and in accordance with the terms and conditions of Company's 2014 Equity Incentive Plan, or a successor plan (the "Plan") and Company's form of option or stock grant agreement, as applicable. On or after the Effective Date, Company shall grant Executive stock options to purchase 22,000 shares of Common Stock (the "Option"). The Option shall have an exercise price equal to the fair market value of the Common Stock as of the grant date of the Option. The Option shall vest in equal shares over a four-year period commencing from the date of grant and, with 25% of the options vesting on the one-year anniversary of the Effective Date, and then the remainder of unvested options vesting on an annual basis thereafter until such time that all such shares are fully vested and exercisable, *provided*, that the Option, and each other outstanding equity award granted to Executive, shall accelerate so as to be fully vested and immediately exercisable immediately prior to any Change in Control (as defined in the Plan) of the Company.

C. Retirement, Welfare and Other Benefit Plans and Programs. During the Employment Term, Executive shall be entitled to participate in the employee retirement and welfare benefit plans and programs made available to Company's other senior level executives as a group, as such retirement and welfare plans may be in effect from time to time and subject to the eligibility requirements of such plans, including but not limited to, life, health and disability plans, and a 401(k) retirement plan and similar or other plans. During the Employment Term, Executive shall be eligible for vacation, sick leave and holidays in accordance with Company's vacation, sick and holiday and other pay for time not worked policies. Nothing in this Agreement or otherwise shall prevent Company from amending or terminating after the Effective Date any retirement, welfare or other

employee benefit plans, programs, policies or perquisites from time to time as Company deems appropriate, and Executive's participation in any such plan, program, policy and perquisite shall be subject to the terms, provisions, rules and regulations thereof.

D. Reimbursement of Expenses. During the Employment Term, Company shall reimburse Executive for all reasonable and necessary business expenses that Executive incurs while performing Executive's duties under this Agreement in accordance with Company's general policies of expense reimbursement in effect from time to time.

3. Company Policies and Procedures. Executive agrees to observe and comply with the reasonable and lawful policies and procedures of Company as adopted by the Board of Directors in writing or reflected in the formal minutes of the Board of Directors or committee thereof, respecting performance of Executive's duties and to carry out and to perform the reasonable and lawful orders and directions stated by Company to Executive, from time to time, either orally or in writing.

4. Termination.

A. Notice of Termination and Date of Termination. Each Party must give written notice to the other of the intent to terminate this Agreement and Executive's employment hereunder ("Notice of Termination"). The Notice of Termination must specify a date of termination of employment, which shall incorporate any period of notice required by this Section 4 ("Date of Termination"). Executive may terminate Executive's employment at any time by giving the Company Notice of Termination at least 30 days prior to the Date of Termination designated by Executive. Company may terminate Executive's employment at any time by giving Executive a Notice of Termination at least 30 days prior to the Date of Termination designated by the Company.

B. Executive's Death or Total Disability. Executive's employment under this Agreement shall terminate upon the date of Executive's death. Additionally, if, during the Employment Term, Executive suffers a Total Disability (as defined in Section 4(E)(3)(iii)), then Company may terminate Executive's employment under this Agreement by giving Executive a Notice of Termination specifying the Date of Termination. Upon such termination due to death or Total Disability, Company shall pay to Executive or Executive's estate (i) any Base Salary that has fully accrued but not been paid as of the effective date of such termination, as well as any vested and accrued employment benefits subject to the terms of any applicable employment benefit arrangements and applicable law ("Accrued Benefits") and (ii) a prorated bonus for the year in which Executive's death or Disability occurs, which bonus shall be calculated and paid in the same manner as set forth below in Section 4(E)(1)(b). All other rights and benefits of Executive and Executive's dependents hereunder shall terminate upon such termination, except for any right to the continuation of benefits otherwise provided by law.

C. By Company with Cause. Company may terminate with Cause (as defined in Section 4(E)(3)(i)) Executive's employment hereunder at any time. In order to terminate Executive's employment hereunder with Cause, Company must give Notice of Termination to Executive specifying the Cause and the Date of Termination (as defined in Section 4(A)). Upon termination with Cause, Company shall pay to Executive all Accrued Benefits. All other rights and benefits of Executive hereunder shall terminate upon such termination, except for any right to the continuation of benefits otherwise provided by law.

D. By Executive without Good Reason or by Mutual Agreement. Executive may terminate Executive's employment without Good Reason (as defined in Section 4(E)(3)(iv)) at any time by giving Company Notice of Termination at least 30 days prior to the Date of Termination designated by Executive. In addition, this Agreement may be terminated at any time by written mutual agreement of the Parties with or without notice. Upon termination of Executive's employment by Executive without Good Reason or termination by mutual agreement of the parties, Company shall pay to Executive all Accrued Benefits. All other rights and benefits of Executive hereunder shall terminate upon such termination, except for any right to the continuation of benefits otherwise provided by law.

E. Without Cause by Company or For Good Reason by Executive. Company may terminate Executive's employment at any time without Cause by giving Executive a Notice of Termination at least one day prior to the Date of Termination, and Executive may terminate Executive's employment for Good Reason by giving Company a Notice of Termination in accordance with Section 4(A). Upon termination of Executive's employment without Cause by Company or for Good Reason by Executive, Company will pay Executive (1) all Accrued Benefits and (2) the severance compensation payable under Section 4(E)(1) hereof, to the extent applicable. All other rights and benefits of Executive hereunder shall terminate upon such termination, except for any right to the continuation of benefits otherwise provided by law.

(1) In the event that Company terminates Executive's employment without Cause or Executive terminates his employment for Good Reason, and contingent upon the Executive's execution of a release of claims in the form attached hereto as Exhibit A, then Company shall pay to Executive as severance compensation, the following:

(a) Executive's Base Salary (at the rate payable at the time of such termination) for a period of twelve (12) months following the Date of Termination. Such severance compensation shall be paid by Company in equal installments according to Company's customary payroll practices, with the first payment made on the first regularly scheduled pay day immediately following the effective date of termination, but in any event payments shall be made not less frequently than monthly; provided, however, that (a) Company shall pay such severance in a lump sum on the first regularly scheduled pay day immediately following the effective date of termination if such termination of employment occurs upon or within one year following a Sale, and the Sale constitutes a "change in control event" as defined under Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), to the extent required to comply with Section 409A of the Code; and (b) notwithstanding the preceding clause (a), if the Sale is not a "change in control event" as defined under Section 409A of the Code and penalty taxes may result under Section 409A if such severance compensation is paid in a lump sum, then the severance compensation will be paid in equal installments according to Company's customary payroll practices, with the first payment made on the first regularly scheduled pay day immediately following the effective date of termination, but in any event payments shall be made not less frequently than monthly.

(b) To the extent Executive has an annual incentive compensation award for the year of termination in which the Date of Termination occurs, Executive shall receive a pro rata Target Annual Bonus award payment for the year in which the Date of Termination occurs (measured at the target level, identified "goal" target or other similar target, without taking into account any incentive override for above goal performance, or any project-specific or other non-standard incentives), which shall be paid on the first regularly scheduled pay day immediately following the Date of Termination. The pro rata amount shall be determined as the Target Annual Bonus in effect for the year in which the Date of Termination occurs, multiplied by a fraction, the numerator of which is the number of days in which Executive was employed by Company during the year in which the Date of Termination occurs, including the Date of Termination, and the denominator of which is 365.

(c) During the 12 month period following the Date of Termination, if Executive timely elects continued coverage under Section 4980B of the Code ("COBRA"), Company will reimburse Executive for the monthly COBRA cost of continued health coverage under the health plans of Company paid by Executive for Executive, and, if applicable, Executive's spouse and dependents, less the amount that Executive would be required to contribute for health coverage if Executive were an active employee of Company; provided that such reimbursements shall not continue beyond the first to occur of (x) the date on which Executive fails to pay the COBRA cost of continuation coverage under the health plans of Company and (y) the date on which Executive is eligible for substantially similar coverage from a subsequent employer. These reimbursements will commence on the first regularly scheduled pay day immediately following the Date of Termination and will be paid on the first regularly scheduled pay day of each month, provided that Executive demonstrates proof of payment of the applicable premiums prior to the applicable reimbursement payment date.

(d) The vesting of each outstanding equity award granted to Executive will accelerate so that such awards will be fully vested as of the Date of Termination. If any equity awards vest based on the attainment of performance goals, the performance goals will be deemed to have met as of the Date of Termination, unless such greater amount of vesting is provided for in the applicable award agreements.

(2) Payment of the severance compensation shall be subject to all mandatory and voluntary payroll deductions. In the event that Executive materially breaches any of his post-employment covenants or obligations set forth in this Agreement and fails to cure such breach within fifteen (15) calendar days following receipt from Company of notice to cure such breach, then the payment of severance compensation pursuant to this section shall terminate immediately and permanently. During the period that Executive is paid the foregoing severance compensation, Executive shall not further accrue any other benefits under any benefit plans of which Executive was a participant while employed by Company, except as otherwise required by applicable federal or state law, by the express terms of this Agreement, or by the express terms of such benefit plans.

(3) For purposes of this Agreement:

(i) Executive's employment will be deemed to have been terminated by Company "with Cause" if the termination arises from or relates to a determination by the Board of Directors that (a) Executive performed an act or acts of willful and material malfeasance or misconduct with respect to the performance of Executive's duties and responsibilities as an employee and officer of Company or under this Agreement that results in material harm to Company that remains uncorrected for fifteen (15) days after receipt of written notice by Company to Executive; or (b) except as otherwise provided in Section 1(D), Executive's continued failure to devote his full business time and attention and his best efforts to the faithful performance of his material duties and responsibilities (other than a failure resulting from Executive becoming disabled) that remains uncorrected for fifteen (15) days after receipt of written notice by Company to Executive; or (c) Executive's material breach of any material provision of this Agreement that remains uncorrected for fifteen (15) days after receipt of written notice by Company to Executive; or (d) Executive commits an act of fraud, embezzlement, misappropriation, or personal dishonesty against Company (which, if proven, would constitute a felony); or (e) the conviction, or plea of *nolo contendere*, of Executive to a crime constituting a felony.

(ii) Executive's employment shall be deemed to have been terminated by Company "without Cause" if such termination does not arise from or relate to any of acts or omissions constituting "Cause" as set forth in clauses (a) through (e) of the immediately preceding subsection, and such termination is not the result of Executive's death or Executive suffering a Total Disability.

(iii) Executive shall be deemed to have suffered a "Total Disability" if (a) Executive is granted long-term disability benefits or (b) Executive becomes physically or mentally disabled so that Executive is unable to perform the essential functions of Executive's job, with or without reasonable accommodation in accordance with the Americans with Disabilities Act and its amendments, for a period of one hundred eighty (180) consecutive days.

(iv) Executive shall be deemed to have terminated his employment for "Good Reason" if Executive terminates his employment on account of the occurrence of one or more of the following without Executive's consent:

(a) A material diminution by Company of Executive's authority, duties or responsibilities the duration of which is greater than fifteen (15) days and which is not the result of Executive's acts or omissions which constitute "Cause" as set forth in clauses (a) through (e) of subsection 4(E)(3)(i);

(b) A material change in the geographic location at which Executive must perform services under this Agreement (which, for purposes of this Agreement, means the requirement that Executive work from at a location more than fifty (50) miles from the location at which Executive performs services immediately prior to the relocation);

(c) A material diminution in the Executive's Base Salary which is not the result of Executive's acts or omissions which constitute "Cause" as set forth in clauses (a) through (e) of subsection 4(E)(3)(i); or

(d) Any action or inaction that constitutes a material breach by Company of this Agreement, including the failure of Company to pay any amounts due under Section 2 or the failure of Company to obtain from its successors the express assumption and agreement required under Section 16(A).

Executive must provide Notice of Termination (as defined below) for Good Reason to Company within sixty (60) days after the event constituting Good Reason. Company shall have a period of thirty (30) days in which it may correct the act or failure to act that constitutes the grounds for Good Reason as set forth in Executive's Notice of Termination. If Company does not correct the act or failure to act, then, in order for the termination to be considered a Good Reason termination, Executive must terminate his or her employment for Good Reason by giving Notice of Termination with a Date of Termination designated by Executive which is at least thirty (30) days after the date on which the Notice of Termination is given but not more than ninety (90) days after the end of the cure period.

(4) In the event Company terminates Executive's employment with Cause, Executive voluntarily terminates his employment with Company other than for Good Reason, or such employment is terminated by mutual agreement or as the result of Executive's death or Total Disability, Executive shall not be entitled to payment of any severance compensation under this Agreement.

D. Cooperation after Notice of Termination. Following any Notice of Termination by either Company or Executive, Executive, if requested by Company, shall reasonably cooperate with Company in all matters relating to the winding up of Executive's pending work on behalf of Company and the orderly transfer of any such pending work to other employees of Company as may be reasonably designated by Company following the Notice of Termination. Executive shall not receive any additional compensation during the Employment Term, other than Executive's Base Salary, for any services that Executive renders as provided in this Section 4(F), provided that, if Executive is not receiving any severance compensation pursuant to this Section 4, for each day that Executive performs services under this Section 4(F) after the Employment Term, Executive shall be reimbursed for his reasonable out-of-pocket expenses and Company shall pay Executive a per diem cash amount equal to 130% of Executive's Base Salary rate on the Date of Termination.

E. Surrender of Records and Property. Upon termination of employment, Executive shall promptly turn-over or deliver to Company at Company's expense all property of Company in Executive's possession, custody, or control, including without limitation thereto: records (paper and electronic), files (paper and electronic), documents (paper and electronic), electronic mail (e-mail) on Company accounts, letters, financial information, memorandum, notes, notebooks, contracts, project manuals, specifications, reports, data, tables, calculations, data, electronic information, and computer disks, in all cases whether or not such property constitutes Confidential Information (as defined below), and all copies thereof; all keys to motor vehicles, offices or other property of Company; and all computers, cellular phones and other property of Company. If any of the foregoing property of Company is electronically stored on a computer or other storage medium owned by Executive or a friend, family member or agent of Executive, such information shall be copied onto a computer disk

to be delivered to Company together with a written statement of Executive that the information has been deleted from such person's computer or other storage medium.

5. Section 280G of the Code.

F. The following terms shall have the meanings set forth below for purposes of this Section 5:

(1) "Accounting Firm" means a certified public accounting firm chosen by the Company.

(2) "After-Tax" means after taking into account all applicable Taxes and Excise Tax.

(3) "Excise Tax" means the excise tax imposed by Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(4) "Safe Harbor Amount" means 2.99 times Executive's "base amount," within the meaning of Section 280G(b)(3) of the Code.

(5) "Taxes" means all federal, state, local and foreign income, excise, social security and other taxes, other than the Excise Tax, and any associated interest and penalties.

G. If any payment, individually or in the aggregate, due to Executive under this Agreement (a "Payment") is subject to the Excise Tax, then such Payment shall be adjusted, if necessary, to equal the greater of (x) the Safe Harbor Amount or (y) the Payment, whichever results in such Executive's receipt, After-Tax, of the greatest amount of the Payment. The reduction of Executive's Payments pursuant to this Section 5.B., if applicable, shall be made by first reducing the acceleration of Executive's stock option vesting (if any), the acceleration of the vesting of Executive's other equity securities (if any), and then by reducing any cash payments owed to the Executive, in that order.

A. All determinations required to be made under this Section 5, including whether and in what manner any Payments are to be reduced pursuant to the second sentence of Section 5.B., and the assumptions to be utilized in arriving at such determinations, shall be made by the Accounting Firm, and shall be binding upon the Company and Executive, except to the extent the Internal Revenue Service or a court of competent jurisdiction makes an inconsistent final and binding determination. The Accounting Firm shall provide detailed supporting calculations both to the Company and Executive within fifteen (15) business days after receiving notice from Executive that there has been a Payment or such earlier time as may be requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company.

6. Intellectual Property.

A. Work Product. During the Employment Term, Executive will be expected to perform duties which may lead to and include the discovery, creation, development, or expression of inventions, discoveries, developments, modifications, procedures, ideas, innovations, systems, programs, know-how, literary properties, chemical or biological data, computer software, improvements, processes, methods, formulas, systems, creative works and techniques (collectively, hereinafter "Work Product").

B. Assignment. Executive hereby assigns and transfers to Company, and agrees that Company shall be the sole owner of all Work Product conceived, developed or made by Executive (alone or with others), whether during working hours or at any other time, in whole or in part during Executive's employment with Company (including prior to, during and after the Employment Term), whether at the request or upon the suggestion of Company or otherwise, which are useful in, or directly or indirectly related to Company's business or any contemplated business of Company or which relate to, or are conceived, developed, or made in the course of, Executive's employment or which are developed or made from, or by reason of knowledge gained from, such employment.

C. Work for Hire. Executive hereby agrees that all work or other material containing or reflecting any Work Product shall be deemed a work made for hire under the U.S. Copyright Act. To

the extent any such Work Product is determined that it is not a work made for hire, Executive hereby assigns to Company all of Executive's right, title and interest, including all rights of copyright, patent, trade secret and other intellectual property rights, in, to and under the Work Product.

D. Continuing Obligations. Executive agrees to disclose promptly all Work Product conceived or made by Executive (alone or with others) to which Company is entitled to as provided herein, and agrees not to disclose such Work Product to others except as required by law or as is reasonably necessary or appropriate in connection with the performance of Executive's duties as an employee and officer of Company, without the express written consent of Company. Executive further agrees that during the Employment Term and at any time thereafter, Executive will, upon request by Company, provide all assistance reasonably required to protect, perfect and use the Work Product, including execution of proper assignments to Company of any and all such Work Product to which Company is entitled, execution of all papers and performance all other lawful acts which Company may deem necessary or advisable for the preparation, prosecution, procurement and maintenance of trademarks, copyrights and or patent applications, and execution of any and all proper documents as shall be required or necessary to vest title in Company to such Work Product. It is understood that all expenses in connection with such trademarks, copyrights or patents, and all applications related thereto, shall be borne by Company, however Company is under no obligation to protect such Work Product, except at its own discretion and to such extent as Company shall deem desirable. Executive shall not receive any additional compensation during the Employment Term, other than Executive's Base Salary, for any services that Executive renders as herein provided. For each day that Executive performs services under this Section 6(D) after the Employment Term, Executive shall be reimbursed for his reasonable out-of-pocket expenses and Company shall pay Executive a per diem cash amount equal to 130% of Executive's Base Salary rate on the Date of Termination.

7. Confidential Information.

A. Confidential Information. The term "Confidential Information" means all information related to Company's business, which exists or is developed at any time while Executive is an employee, officer and/or director of Company (including prior to, during and after the Employment Term), including without limitation: (i) strategic and development plans, financial information, equity investors, business plans, co-developer identities, business relationships, business records, project records, market reports, information relating to processes and techniques, technology, research, data, development, trade secrets, know-how, discoveries, ideas, concepts, specifications, diagrams, inventions, technical and statistical data, designs, drawings, models, flow charts, engineering, products, invention disclosures, patent applications, chemical and molecular structures, synthetic pathways, biological data, safety data, clinical data, developmental data, development route, manufacturing processes, synthetic techniques, analytical data, Work Product, and any and all other proprietary and sensitive information, disclosed or learned, whether oral, written, graphic or machine-readable, whether or not marked confidential or proprietary, whether or not patentable, whether or not copyrightable, including the manner and results in which any such Confidential Information may be combined with other information or synthesized or used by Company, which could prove beneficial in enabling a competitor to compete with Company; or (ii) information that satisfies the definition of a "trade secret" as that term is defined in the Iowa Uniform Trade Secrets Act, IA Code Chpt. 550, as amended from time to time; provided, however, that information that is in the public domain (other than as a result of a breach by Executive of this Section 7), approved for release by Company, or lawfully obtained from a third party who is not known by Executive (after Executive's reasonable inquiry) to be bound by a confidentiality agreement with Company is not Confidential Information.

B. Acknowledgements. Executive acknowledges and agrees that: (1) Executive's position with Company is one of high trust and confidence, (2) the Confidential Information constitutes a valuable, special and unique asset which Company uses to obtain a competitive advantage over its competitors, (3) Executive's protection of such Confidential Information against unauthorized use or disclosure is critically important to Company in maintaining its competitive advantage, (4) all Confidential Information is the property of Company, and (5) Executive shall acquire no right, title or interest in, to or under any such Confidential Information.

C. Nondisclosure. Executive promises that, unless legally compelled to do so, Executive will never (before, during or after the Employment Term): (1) disclose any Confidential Information to any person other than (i) an officer or director of Company; or (ii) any other person who is bound by nondisclosure restrictive covenants to Company and to whom disclosure of such Confidential Information is reasonably necessary or appropriate in connection with performance by Executive of Executive's duties as an employee and officer of Company; or (2) use any Confidential Information except to the extent it is reasonably necessary or appropriate in connection with performance by Executive of Executive's duties as an employee and officer of Company. Executive promises to take all reasonable precautions to prevent the inadvertent or accidental disclosure or misuse of any Confidential Information. In the event Executive receives a request to disclose all or any part of the Confidential Information under the terms of a subpoena or order issued by a court or governmental body, Executive promises, to the extent permissible by law, to (a) notify Company immediately of the existence, terms and circumstances surrounding such request, (b) consult with Company on the advisability of taking legally available steps to resist or narrow such request, (c) if disclosure is required, furnish only such portion of the Confidential Information as Executive is legally compelled to disclose; and (e) exercise Executive's best efforts to obtain an order or other reliable assurance that confidential treatment will be accorded to the disclosed Confidential Information.

8. Noncompetition.

A. Restricted Period. As used in this Agreement, the term "Restricted Period" means throughout the Employment Term and continuing until the end of the twelve month period following the date on which Executive's employment with Company is terminated for any reason (whether voluntary or involuntary).

B. Prohibition on Competition. Executive hereby covenants and agrees that, until the expiration of the Restricted Period, Executive will not serve as an officer, director, employee, independent contractor, consultant or agent of, or have any ownership interest in, any business entity which engages in any activities anywhere in the world that are materially similar to or competitive with Company's pharmaceutical prodrug development and Commercialization (as defined below) activities in the fields of (i) opioid products for the treatment of pain, (ii) stimulant products for the treatment of ADHD, and/or (iii) such other products which Company is actively and demonstrably developing and/or Commercializing at the time Executive's employment is terminated. If a court of competent jurisdiction finds this non-competition provision invalid or unenforceable due to unreasonableness in time, geographic scope, or scope of Company's business, then Executive agrees that such court shall interpret and enforce this provision to the maximum extent that such court deems reasonable. For purposes of this Agreement, "Commercialize" or "Commercialization" means the sales and marketing phase with regard to a specific drug candidate in a specific country or region following the regulatory approval of said drug candidate in the applicable country or region.

C. Exceptions. Executive's ownership of less than 5% of the stock of a company that is competitive with the activities of Company as described in Section 8(B) and listed on a national securities exchange shall not be deemed to violate the prohibitions of Section 8(B). Also, Executive shall not be considered to have violated Section 8(B) with respect to the purchasing entity if there is a Sale and Executive becomes an employee, officer, director or shareholder of the purchasing entity. The term "Sale" means the sale of more than 50% of the equity of Company, a merger of Company with an entity the equity of which after the merger the stockholders of Company immediately prior to such merger own less than 50%, or the sale of all or substantially all of the assets of Company, in any case to a person or entity not affiliated with Company. Neither a recapitalization nor change of form of Company shall be considered a Sale. Additionally, a "Sale" shall not be deemed to have occurred as a result of a lender exercising any of its remedies in connection with the occurrence or continuation of an event of default under that certain Facility Agreement, to be dated as of or around May 30, 2014, by and between Company and Deerfield Private Design Fund III, L.P or any other indebtedness of the Company.

9. Nonsolicitation of Employees. Until the expiration of the Restricted Period, Executive shall not, directly or indirectly, either on Executive's own account or for any other person or entity: (a) employ, solicit, induce, advise, or otherwise convince, interfere with Company's employment of, or offer employment to, any employee of Company; (b) employ or otherwise interfere with Company's engagement with, or offer employment to, any consultant of Company; or (c) induce or attempt to induce any such employee or consultant to breach their employment agreement or relationship or consulting agreement or relationship with Company; provided, however, that Executive shall not be in breach of this provision if any such employee or consultant, without inducement or solicitation by Executive, applies for employment at Executive's subsequent employer in response to a general advertisement soliciting employment.

10. Reasonableness Of Restrictions; Remedies. Executive has carefully read and considered the restrictive covenants set forth in Sections 7 – 9 hereof, and understands Executive's obligations thereunder, the limitations such obligations will impose upon Executive after termination of Executive's employment with Company, and that the Restricted Period extends for 12 months after the termination of Executive's employment. Executive has had full opportunity to review with Executive's personal attorney this Agreement, including Sections 7 – 9, before executing the Agreement. Executive agrees that, as a result of Executive's position with Company, the length of the Restricted Period and each restriction set forth in Sections 7, 8 and 9 herein are (1) fair and reasonable, (2) reasonably required for the protection of the legitimate business interests and goodwill established by Company, and (3) not overly broad or unduly burdensome to Executive. Executive acknowledges that Executive's compliance with Executive's obligations and restrictive covenants set forth in this Agreement is necessary to protect the business and goodwill of Company. Executive agrees that Executive's breach of Executive's obligations and/or restrictive covenants under this Agreement may irreparably and continually damage Company, for which money damages may not be adequate. Consequently, Executive agrees that in the event that Executive breaches or threatens to breach any of the covenants or agreements contained herein, Company shall be entitled to: (a) seek injunctive relief to prevent or halt Executive from breaching this Agreement; and (b) money damages as determined appropriate by a court of competent jurisdiction. Executive hereby agrees that injunctive relief may be granted by a court of competent jurisdiction without the necessity of Company to post bond, or if required to post bond, Executive agrees that the lowest amount permitted shall be adequate. Nothing in this Agreement shall be construed to prohibit Company from pursuing any other remedy available or from seeking to enforce any restrictive covenants to a lesser extent than set forth herein. The Parties agree that all remedies shall be cumulative.

11. No Prior Restrictions. Executive hereby represents and warrants to Company that the execution, delivery, and performance by Executive of Executive's duties under this Agreement do not violate any provision of any agreement or restrictive covenant which Executive has with any former employer or any other entity. Executive further agrees to honor and inform Company of any and all post-employment obligations Executive has to any former employer or any other entity with which Executive has or had a business relationship.

12. Notices. Any notice or communication required or permitted to be given hereunder may be delivered by hand, deposited with an overnight courier, sent by confirmed email, confirmed facsimile, or mailed by registered or certified mail, return receipt requested, postage prepaid, in the case of Company, addressed to Company's principal office marked attention to Company's president, and in the case of Executive, addressed to Executive's personal address as appearing in Company's payroll records, and in each case to such other mail address, e-mail address, or facsimile number as may hereafter be furnished in writing by either Party to the other Party. Such notice will be deemed to have been given as of the date it is hand delivered, emailed, faxed or three days after deposit in the U.S. mail.

13. Likeness. Executive hereby grants to Company a license to use, without further compensation or approval from Executive, Executive's name, image, portrait, voice, likeness and all other rights of publicity, or any derivative or modification thereto that Company may create, in any and all mediums, now known or hereafter developed, provided that such use is in relation to Company's business and consistent with professional business standards, and does not disparage or denigrate Executive. Provided, however, if written notice is provided to Company by Executive following termination of Executive's employment requesting that Company cease using Executive's likeness, Company has 30 days to cease using Executive's likeness in the manner set forth in the notice.

14. Section 409A; Section 162(m).

A. This Agreement is intended to comply with Section 409A of the Code and its corresponding regulations, or an exemption, and payments may only be made under this Agreement upon an event and in a manner permitted by Section 409A of the Code, to the extent applicable. Notwithstanding anything in this Agreement to the contrary, if required by Section 409A of the Code, if Executive is considered a "specified employee" for purposes of Section 409A and if payment of any amounts under this Agreement is required to be delayed for a period of six months after separation from service pursuant to Section 409A of the Code, payment of such amounts shall be delayed as required by Section 409A of the Code, and the accumulated amounts shall be paid in a lump sum payment within 10 days after the end of the six month period. If Executive dies during the postponement period prior to the payment of benefits, the amounts withheld on account of Section 409A of the Code shall be paid to the personal representative of Executive's estate within 60 days after the day of Executive's death. The Parties agree that this Section 14 shall not be construed in a manner so as to accelerate any payments due under this Agreement.

B. All payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" under Section 409A of the Code. For purposes of Section 409A of the Code, each payment hereunder shall be treated as a separate payment and the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. In no event may Executive, directly or indirectly, designate the calendar year of a payment. All reimbursements and in-kind benefits provided under the Agreement shall be made or provided in accordance with the requirements of Section 409A of the Code.

C. Executive agrees that if the stock of the Company becomes publicly traded, Executive will make any amendments to the Agreement that the Company deems necessary to allow performance-based compensation to qualify for the "qualified performance-based compensation" exception to Section 162(m) of the Code.

15. INDEMNIFICATION; LIABILITY INSURANCE. Company shall indemnify and hold Executive harmless to the fullest extent permitted by the laws of Company's state of organization or incorporation in effect at the time against and in respect of any and all actions, suits, proceedings, claims, demands, judgments, costs, expenses (including advancement of reasonable attorney's fees), losses, and damages resulting from Executive's performance of Executive's duties and obligations with Company. Executive will be entitled to be covered, both during and, while potential liability exists, by any insurance policies the Employer may elect to maintain generally for the benefit of officers and directors of the Employer against all costs, charges and expenses incurred in connection with any action, suit or proceeding to which Executive may be made a party by reason of being an officer or director of Company in the same amount and to the same extent as Company covers its other officers and directors. These obligations shall survive the termination of Executive's employment with Company.

16. General Provisions.

A. Successors and Assigns. The rights and obligations under this Agreement shall survive the termination of Executive's services to Company in any capacity and shall inure to the benefit and shall be binding upon Executive's heirs and personal representatives. Executive's duties and obligations are personal in nature and Executive may not assign or delegate any duties under this Agreement without Company's prior written approval. Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation, reorganization or otherwise) to all or substantially all of the business or assets of Company, within 15 days of such succession, expressly to assume and agree to perform this Agreement in the same manner and to the same extent as Company would be required to perform if no such succession had taken place and Executive acknowledges that in such event the obligations of Executive hereunder will continue to apply in favor of the successor. As used in this Agreement, "Company" shall mean Company and any such successor which assumes and agrees to perform the duties and obligations of Company under this Agreement by operation of law or otherwise.

B. Survival of Certain Terms. The terms, conditions and covenants set forth in this Agreement which specifically relate to periods, activities or obligations upon or subsequent to the

termination of Executive's employment, including, without limitation, the restrictive covenants contained in Sections 7 – 9, shall survive the termination of this Agreement and Company's employment of Executive hereunder, and the Parties shall remain bound by such terms, conditions and covenants.

C. Governing Law; Jurisdiction. This Agreement shall be governed by and construed and enforced in accordance with the procedural and substantive laws of the State of Iowa, without regard to its conflicts of laws provisions. The litigation of any disputes arising out of this Agreement shall take place in the appropriate federal or state court located in Johnson County, Iowa. The parties, to the extent they can legally do so, hereby consent to service of process, and to be sued in the State of Iowa and consent to the exclusive jurisdiction of the courts of the State of Iowa and the United States District Court for the Southern District of Iowa, as well as to the jurisdiction of all courts to which an appeal may be taken from such courts, for the purpose of any suit, action or other proceeding arising out of any of their obligations hereunder or with respect to the transactions contemplated hereby, and expressly waive any and all objections they may have to venue in such courts. Notwithstanding the foregoing, should Executive refuse to comply with an order or judgment of such court, then Company may enforce this Agreement and the order or judgment of such court in any jurisdiction it deems appropriate.

D. Severability, Reform. If any provision of this Agreement is determined to be void, invalid or unenforceable, the remainder shall be unaffected and shall be enforceable as if the void, invalid or unenforceable part was not a provision of the Agreement.

E. Entire Agreement. This Agreement and its attached exhibits, which by this reference are hereby incorporated into and made a part of this Agreement as if set forth herein verbatim, contain the entire understanding of the parties to this Agreement and supersede and replace all former agreements or understandings, oral or written, between Company and Executive, including any offer letter sent to Executive, regarding the subject matter hereof. Upon the effectiveness of this Agreement, the Prior Agreement shall be deemed amended and restated and superseded and replaced in its entirety by this Agreement, and shall be of no further force or effect.

F. Modification and Waiver. This Agreement may not be amended except by a written instrument signed by both Parties which specifically refers to the particular provision or provisions being amended. No provision of this Agreement may be waived except in a written instrument that specifically refers to the particular provision or provisions being waived and is signed by the Party against whom the waiver is being asserted. No waiver by any Party of any right, power or privilege hereunder shall constitute a waiver of any other right, power or privilege hereunder, and no waiver by any party of any breach of a provision hereunder shall constitute a waiver of any other breach of that or any other provision of this Agreement.

G. Taxes; Withholding. All compensation and benefits payable to Executive under this Agreement shall be subject to all income and other employment tax withholding and reporting required by federal, state or local law with respect to compensation, benefits and reimbursable expenses paid by a corporation to an employee. Executive shall be responsible for all taxes applicable to amounts payable under this Agreement.

H. Assistance in Litigation. Executive shall reasonably cooperate with Company in the defense or prosecution of any claims or actions now in existence or that may be brought in the future against or on behalf of Company that relate to events or occurrences that transpired while Executive was employed by Company. Executive's cooperation in connection with such claims or actions shall include being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of Company at mutually convenient times. Executive also shall cooperate fully with Company in connection with any investigation or review by any federal, state or local regulatory authority as any such investigation or review relates, to events or occurrences that transpired while Executive was employed by Company. Notwithstanding anything to the contrary in this Section 16(H), unless otherwise mutually agreed between Executive and Company in writing and, for each day that Executive performs services under this Section 16(H) after the final payment by Company of any and all severance compensation due to Executive under Section 4(E)(1), Executive shall be

reimbursed for his reasonable out-of-pocket expenses and Company shall pay Executive a per diem cash amount equal to 130% of Executive's Base Salary rate on the Date of Termination.

I. Beneficiaries; References. Executive shall be entitled to select (and change to the extent permitted under any applicable law) a beneficiary or beneficiaries to receive any compensation or benefit payable hereunder following Executive's death, and may change such election, in either case by giving Company written notice thereof. In the event of Executive's death or a judicial determination of Executive's incompetence, reference in this Agreement to Executive shall be deemed, where appropriate, to refer to Executive's beneficiary, estate or other legal representative. Any reference to any gender in this Agreement shall include, where appropriate, the other gender.

J. Voluntary Agreement. Each Party to this Agreement has read and fully understands the terms and provisions hereof, has had an opportunity to review this Agreement with legal counsel, has executed this Agreement based upon such party's own judgment and advice of counsel, and knowingly, voluntarily and without duress, agrees to all of the terms set forth in this Agreement. The Parties have participated jointly in the negotiation and drafting of this Agreement. If an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring any party because of authorship of any provision of this Agreement. Except as expressly set forth in this Agreement, neither the Parties nor their affiliates, advisors and/or their attorneys have made any representation or warranty, express or implied, at law or in equity with respect of the subject matter contained herein. Without limiting the generality of the previous sentence, Company, its affiliates, advisors and/or attorneys have made no representation or warranty to Executive concerning the state or federal tax consequences to Executive regarding the transactions contemplated by this Agreement.

K. Effect of Headings. Headings to sections and paragraphs of this Agreement are for reference only, and do not form a part of this Agreement, or effect the interpretation of this Agreement.

L. Counterparts. This Agreement may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages, each of which shall for all purposes are deemed to be an original and all of which shall constitute on instrument. All signatures of the parties transmitted by facsimile or PDF shall be deemed to be their original signatures for all purposes.

[SIGNATURE PAGE FOLLOWS]

Signature Page
Of
Amended and Revised Employment Agreement

In Witness Whereof, Company has caused this Agreement to be duly executed and delivered by its duly authorized officer, and Executive has duly executed and delivered this Agreement, effective as of the date first written on page 1 of this Agreement.

**KemPharm, Inc. ("Company"):**

By /s/ R. LaDuane Clifton
**R. LaDuane Clifton**
**Chief Financial Officer**

**Timothy Sangiovanni:**

/s/ Timothy Sangiovanni

**Exhibit A**

**Form of Release of Claims**

## Separation of Employment Agreement and General Release

THIS SEPARATION OF EMPLOYMENT AGREEMENT AND GENERAL RELEASE (the "Agreement") is made as of this ___ day of _____, ____, by and between Timothy Sangiovanni ("Executive") and KemPharm, Inc. (the "Company").

WHEREAS, Executive is employed by Company as Vice President, Corporate Controller;

WHEREAS, Executive and Company entered into an Employment Agreement, date _____ __, 2016, (the "Employment Agreement") which provides for certain benefits in the event that Executive's employment is terminated on account of a reason set forth in the Employment Agreement;

WHEREAS, Executive's employment with Company will terminate effective _____ (the "Termination Date"); and

WHEREAS, in connection with the termination of Executive's employment, the parties have agreed to a separation package and the resolution of any and all disputes between them.

NOW, THEREFORE, IT IS HEREBY AGREED by and between Executive and Company as follows:

1. Executive, for and in consideration of the commitments of Company as set forth in paragraph 6 of this Agreement, and intending to be legally bound, does hereby REMISE, RELEASE AND FOREVER DISCHARGE Company, its stockholders, its present and past affiliates, subsidiaries and parents, their respective officers, directors, investors, employees, and agents, and their respective predecessors, successors and assigns, heirs, executors, and administrators (collectively, "Releasees"), subject to the exceptions of Section 2 of the Agreement, from all causes of action, suits, debts, claims and demands whatsoever in law or in equity, which Executive ever had, now has, or hereafter may have, whether known or unknown, or which Executive's heirs, executors, or administrators may have, by reason of any matter, cause or thing whatsoever, from the beginning of time to the date of this Agreement, to the extent arising from or relating in any way to Executive's employment relationship with Company, the terms and conditions of that employment relationship, and/or the termination of that employment relationship, including, but not limited to, (i) any claims for monetary damages arising under the Age Discrimination in Employment Act ("ADEA"), the Older Workers Benefit Protection Act ("OWBPA"), Title VII of The Civil Rights Act of 1964, the Americans with Disabilities Act; (ii) any and all claims arising under the Family and Medical Leave Act of 1993, the Employee Retirement Income Security Act of 1974, as amended; (iii) any and all claims arising under any applicable state and local fair employment practice laws and wage and hour laws; (iv) any other claims under any federal, state or local common law, statutory, or regulatory provision, now or hereafter recognized; and (v) any claims for attorneys' fees and costs.

2. The foregoing shall in no event apply to (i) enforcement by Executive of Executive's rights under this Agreement, (ii) Executive's rights as a stockholder in Company or any of its affiliates, (iii) Executive's rights to indemnifications under any separate contract or insurance policy, (iv) Executive's right to seek unemployment insurance benefits, (v) Executive's right to seek workers' compensation benefits, (vi) any rights Executive has to indemnification for service as an officer of Company, or (vii) any claims that, as a matter of applicable law, are not waivable. This Agreement is effective without regard to the legal nature of the claims raised and without regard to whether any such claims are based upon tort, equity, implied or express contract or discrimination of any sort.

Executive and Company agree that nothing in this Agreement prevents or prohibits Executive from (i) making any disclosure of relevant and necessary information or documents in connection with any charge, action, investigation, or proceeding relating to this Agreement, or as required by law or legal process; (ii) participating, cooperating, or testifying in any charge, action, investigation, or proceeding with, or providing information to, any

self-regulatory organization, governmental agency or legislative body, and/or pursuant to the Sarbanes-Oxley Act, (iii) filing, testifying, participating in or otherwise assisting in a proceeding relating to an alleged violation of any federal, state or municipal law relating to fraud, or any rule or regulation of the Securities and Exchange Commission or any self-regulatory organization or (iv) challenging the knowing and voluntary nature of the release of ADEA claims pursuant to the OWBPA. To the extent permitted by law, upon receipt of any subpoena, court order or other legal process compelling the disclosure of any such information or documents, Executive agrees to give prompt written notice to Company so as to permit Company to protect its interests in confidentiality to the fullest extent possible. To the fullest extent provided by law, Executive acknowledges and agrees, however, Executive is waiving any right to recover monetary damages in connection with any such charge, action, investigation or proceeding. To the extent Executive receives any monetary relief in connection with any such charge, action, investigation or proceeding, Company will be entitled to an offset for the benefits made pursuant to this Agreement, to the fullest extent provided by law.

Executive and Company further agree that the Equal Employment Opportunity Commission ("EEOC") and comparable state or local agencies have the authority to carry out their statutory duties by investigating charges, issuing determinations, and filing lawsuits in Federal or state court in their own name, or taking any action authorized by the EEOC or comparable state or local agencies. Executive retains the right to participate in any such action and to seek any appropriate non-monetary relief. Executive retains the right to communicate with the EEOC and comparable state or local agencies and such communication can be initiated by Executive or in response to the government and such right is not limited by any non-disparagement claims. Executive and Company agree that communication with employees plays a critical role in the EEOC's enforcement process because employees inform the agency of employer practices that might violate the law. For this reason, the right to communicate with the EEOC is a right that is protected by federal law and this Agreement does not prohibit or interfere with those rights. Notwithstanding the foregoing, Executive agrees to waive Executive's right to recover monetary damages in any charge, complaint or lawsuit filed by Executive or by anyone else on Executive's behalf.

3. In consideration of Executive's agreement to comply with the covenants described in Section 7-9 of the Employment Agreement, Company agrees as set forth in paragraph 6 herein.

4. Executive further agrees and recognizes that Executive has permanently and irrevocably severed Executive's employment relationship with Company, that Executive shall not seek employment with Company or any affiliated entity at any time in the future, and that neither Company nor any affiliate has any obligation to employ Executive in the future.

5. Executive agrees that Executive will not disparage or subvert Company or the Releasees, or make any statement reflecting negatively on Company or the Releasees, including, but not limited to, any matters relating to the operation or management of Company, Executive's employment and the termination of Executive's employment, irrespective of the truthfulness or falsity of such statement.

6. In consideration for Executive's agreement as set forth herein, Company agrees to pay and provide Executive with the severance benefits described in Section 4(E)(1) of Executive's Employment Agreement. Executive agrees that Executive is not entitled to any payments, benefits, severance payments or other compensation beyond that expressly provided in Section 4(E)(1) of Executive's Employment Agreement and the Accrued Benefits (as defined in Section 4(B) of the Employment Agreement).

7. Executive understands and agrees that the payments, benefits and agreements provided in this Agreement are being provided to Executive in consideration for Executive's acceptance and execution of, and in reliance upon Executive's representations in, this Agreement. Executive acknowledges that if Executive had not executed this Agreement containing a release of all claims against Company and the Releasees, Executive would only have been entitled to the payments provided in Company's standard severance pay plan for employees.

8. Executive acknowledges and agrees that Company previously has satisfied any and all obligations owed to Executive under any employment agreement or offer letter Executive has with Company or a Releasee and, further, that this Agreement supersedes any and all prior agreements or understandings, whether written or oral,

between the parties, excluding only Executive's and Company's post-termination obligations under Executive's Employment Agreement, Executive's rights under any outstanding equity grants in accordance with the terms of the applicable grant agreements, any obligations relating to the securities of Company or any of its affiliates and Company's obligations under Section 4(E)(1) of Executive's Employment Agreement and to pay or provide the Accrued Benefits (as defined in Section 4(B) of the Employment Agreement), all of which shall remain in full force and effect to the extent not inconsistent with this Agreement, and further, that, except as set forth expressly herein, no promises or representations have been made to Executive in connection with the termination of Executive's Employment Agreement or the terms of this Agreement.

9. Except as may be necessary to obtain approval or authorization to fulfill Executive's or its obligations hereunder or as required by applicable law and subject to the exceptions of Section 2 of the Agreement, (a) Executive agrees not to disclose the terms of this Agreement to anyone, except Executive's spouse, attorney and, as necessary, tax/financial advisor, and (b) Company agrees that the terms of this Agreement will not be disclosed. It is expressly understood that any violation of the confidentiality obligation imposed hereunder constitutes a material breach of this Agreement.

10. Executive represents that Executive does not presently have in Executive's possession any records and business documents, whether on computer or hard copy, and other materials (including but not limited to computer disks and tapes, computer programs and software, office keys, correspondence, files, customer lists, technical information, customer information, pricing information, business strategies and plans, sales records and all copies thereof) (collectively, the "Corporate Records") provided by Company and/or its predecessors, parents, subsidiaries or affiliates or obtained as a result of Executive's employment with Company and/or its predecessors, parents, subsidiaries or affiliates, or created by Executive while employed by or rendering services to Company and/or its predecessors, parents, subsidiaries or affiliates. Executive acknowledges that all such Corporate Records are the property of Company. In addition, Executive shall promptly return in good condition any and all Company owned equipment or property, including, but not limited to, automobiles, personal data assistants, facsimile machines, copy machines, pagers, credit cards, cellular telephone equipment, business cards, laptops and computers. As of the Termination Date, Company will make arrangements to remove, terminate or transfer any and all business communication lines including network access, cellular phone, fax line and other business numbers.

11. Subject to the exceptions of Section 2 of the Agreement, Executive expressly waives all rights afforded by any statute which expressly limits the effect of a release with respect to unknown claims. Executive acknowledges the significance of this release of unknown claims and the waiver of statutory protection against a release of unknown claims which provides that a general release does not extend to claims which the creditor does not know or suspect to exist in Executive's favor at the time of executing the release, which if known by it must have materially affected its settlement with the debtor.

12. The parties agree and acknowledge that the agreements by Company described herein, and the settlement and termination of any asserted or unasserted claims against the Releasees, are not and shall not be construed to be an admission of any violation of any federal, state or local statute or regulation, or of any duty owed by any of the Releasees to Executive.

13. Executive agrees and recognizes that should Executive breach any of the obligations or covenants set forth in this Agreement, Company will have no further obligation to provide Executive with the consideration set forth herein, and will have the right to seek repayment of all consideration paid up to the time of any such breach. Further, Executive acknowledges in the event of a breach of this Agreement, Releasees may seek any and all appropriate relief for any such breach, including equitable relief and/or money damages.

14. This Agreement and the obligations of the parties hereunder shall be construed, interpreted and enforced in accordance with the laws of the State of Iowa.

15. Executive certifies and acknowledges as follows:

(a) That Executive has read the terms of this Agreement, and that Executive understands its terms and effects, including the fact that Executive has agreed to RELEASE AND FOREVER DISCHARGE Company and each of the Releasees from any legal action arising out of Executive's employment relationship with Company and the termination of that employment relationship;

(b) That Executive has signed this Agreement voluntarily and knowingly in exchange for the consideration described herein, which Executive acknowledges is adequate and satisfactory to Executive and which Executive acknowledges is in addition to any other benefits to which Executive is otherwise entitled;

(c) That Executive has been and is hereby advised in writing to consult with an attorney prior to signing this Agreement;

(d) That Executive does not waive rights or claims that may arise after the date this Agreement is executed;

(e) That Company has provided Executive with a period of [**twenty-one (21)**] or [**forty-five (45)**] days within which to consider this Agreement, and that Executive has signed on the date indicated below after concluding that this Separation of Employment Agreement and General Release is satisfactory to Executive; and

[***Note: The applicable time period will depend on whether the termination is part of a reduction in force (45 days) or not (21 days). In addition, if the termination is in connection with a reduction in force, certain disclosures will need to be made to Executive to comply with the requirements of the ADEA if Executive is at least age 40.***]

(f) Executive acknowledges that this Agreement may be revoked by Executive within seven (7) days after execution, and it shall not become effective until the expiration of such seven (7) day revocation period. In the event of a timely revocation by Executive, this Agreement will be deemed null and void and Company will have no obligations hereunder. Revocation may be achieved only by delivering a letter to **[NAME, TITLE, ADDRESS]**, clearly evidencing a decision to revoke within the seven day revocation period.

Intending to be legally bound hereby, Executive and Company executed the foregoing Separation of Employment Agreement and General Release this _____ day of _____, ____.

_____ Witness:_____

KemPharm, Inc.

By: _____ Witness:_____
Name:
Title:

**Exhibit 10.6.2**

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH INFORMATION HAS BEEN OMITTED BECAUSE (i) IT IS NOT MATERIAL, AND (ii) IT WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

# SUBLEASE AGREEMENT

This SUBLEASE AGREEMENT ("Sublease"), dated as of December 20, 2024, is made by and between Brownmed, Inc., a Massachusetts corporation ("Sublandlord") and Zevra Therapeutics, Inc., a Delaware corporation ("Subtenant"), collectively referred herein as the "Parties" and individually as a "Party".

## RECITALS

A. Sublandlord, as tenant, leases the Master Lease Premises from Master Landlord under the Master Lease for the Master Lease Term (as such terms are defined below).

B. Subtenant desires to sublease from Sublandlord, and Sublandlord desires to sublease to Subtenant, the Sublease Premises (which is the same as the Master Lease Premises).

NOW, THEREFORE, in consideration of the recitals above and the promises below, the Parties hereto agree as follows:

## ARTICLE 1
## BASIC SUBLEASE PROVISIONS

**Property Location:** 101 Federal Street, Boston, Massachusetts 02210

**Sublandlord:** Brownmed, Inc., a Massachusetts corporation

**Sublandlord's Address:** (prior to the Sublease Commencement Date)
101 Federal Street, 29th Floor
Boston, MA 02110

(Following the Sublease Commencement Date)
1300 Lundberg Drive West
Spirit Lake, IA 51360

**Subtenant:** Zevra Therapeutics, Inc., a Delaware corporation

**Subtenant's Address:** (prior to the Sublease Commencement Date)
1180 Celebration Blvd., Suite 103
Celebration, FL 34747

(following the Sublease Commencement Date)
101 Federal Street, 29th Floor
Boston, Massachusetts 02210

**Sublease Premises:** Approximately 10,484 rentable square feet of the Building, consisting of a portion of the twenty-ninth (29th) floor, as more particularly shown on the attached Exhibit A.

**Base Rent:** During the Sublease Term, Base Rent shall be as follows: The Annual Base Rent Per Rentable Square Foot initially shall be $[***] (initial Annual Base Rent of $[***], and initial Monthly Base Rent of $[***]); provided, however, that on each anniversary of the Sublease Commencement Date during the Sublease Term, the Annual Base Rent Per Rentable Square Foot shall increase by $[***]; provided, further, that Subtenant shall not be required to pay the Base Rent for the first month following the Sublease Commencement Date.

**Additional Rent:** In addition to Base Rent, Sublandlord and Subtenant hereby acknowledge that Subtenant shall be obligated to pay all additional "Rent" that is due under the Master Lease for Tenant's Proportionate Share of the Tax Excess, Tenant's Proportionate Share of the Operating Costs Excess, and the Electricity Additional Rent (as all such terms are defined in the Master Lease, and all such rent shall be referred to herein as "Additional Rent"); provided, however, that for purposes of calculating Tenant's Proportionate Share of the Tax Excess, for purposes of this Sublease, the "Base Tax Amount" (as defined in the Master Lease) shall be deemed to be the "Taxes" (as defined in the Master Lease) assessed for fiscal year 2025 (i.e., July 1, 2024 through June 30, 2025), and for purposes of calculating Tenant's Proportionate Share of Operating Costs Excess for purposes of this Sublease, the "Base Operating Costs" (as defined in the Master Lease) shall be deemed to be the "Operating Costs" (as defined in the Master Lease) for calendar year 2025.

**Sublease Commencement Date:** The "Sublease Commencement Date" shall be on the date that is fourteen (14) days after both of the following events have occurred: (1) both Parties have executed and delivered this Sublease; and (2) the Master Landlord has provided written consent to this Sublease.

**Sublease Term:** The "Sublease Term" shall commence on the Sublease Commencement Date) and shall terminate on June 30, 2028, or any such earlier termination of the Sublease or the Master Lease as provided for herein.

**Building:** The building, in which the Sublease Premises are located (the "Building"), located on that certain parcel of real estate having an address of 101 Federal Street, Boston, Massachusetts 02210 (the "Property").

**Building Hours:** 8:00 a.m. to 6:00 p.m. on all Business Days (as defined in the Master Lease), and 8:00 a.m. to 1:00 p.m. on Saturdays.

**Building Access:** Subtenant shall have access to the Building on a twenty-four (24) hour basis, seven (7) days per week.

**Master Landlord:** 75-101 FED OWNER, L.L.C., a Delaware limited liability company

**Master Lease:** Lease, with an Effective Date of November 28, 2017, by and between Master Landlord and Sublandlord, a true, accurate and complete (other than certain agreed upon redactions) copy of which is attached hereto as Exhibit B (the "Original Lease"), as amended by that certain First Amendment to Lease, dated as of December 20, 2017, by and between Master Landlord and Sublandlord, a true, accurate and complete (other than certain agreed upon redactions) copy of which is attached hereto as Exhibit C (the "First Amendment").

**Master Lease Premises:** Same as the Sublease Premises.

**Permitted Use:** First-class business office use and lawful uses ancillary thereto, and for no other purposes.

**Nightly Cleaning:** Master Landlord to provide nightly cleaning of the Sublease Premises in accordance with Section 9.3 of the Master Lease.

**Security Deposit:** $[***]

## Article 2
## INCORPORATION OF MASTER LEASE

2.01 Incorporation of Master Lease. The PAarties agree that this Sublease is subject and subordinate to the Master Lease. Sublandlord represents and warrants that the Master Lease attached hereto as Exhibit B and Exhibit C, collectively, is a true, complete and accurate copy of the Master Lease as of the date hereof. Sublandlord further represents to Subtenant that the Master Lease is in full force and effect, that the Master Lease has not been amended subsequent to the execution and delivery of the First Amendment, and, to the knowledge of Sublandlord, that

no notices of default have been sent or received by Sublandlord with respect to the Master Lease, nor has any event or condition occurred which, with the passing of time and/or the giving of notice, would result in a default by Sublandlord under the Master Lease, and that Sublandlord is not aware of any default by Master Landlord under the Master Lease. In addition, the Parties agree that the Master Lease attached hereto is incorporated herein by reference, except as herein otherwise expressly provided, and except those provisions which by their nature or import are inapplicable to the subleasing of the Sublease Premises or are inconsistent with or modified by any of the terms, covenants or conditions of this Sublease; and such rights and obligations as are contained in the Master Lease are hereby imposed upon the respective Parties hereto with the same force and effect as if: (a) references in the Master Lease to the "Lease" and the "Premises" were references, respectively, to this "Sublease" and the "Sublease Premises"; (b) references in the Master Lease to "Landlord" and "Tenant" were references, respectively, to "Sublandlord" and to "Subtenant"; and (c) references in the Master Lease to "Term" is a reference to the "Sublease Term". Subtenant agrees that it shall, at all times during the Sublease Term, keep, observe, and perform the obligations to be performed by Sublandlord as "Tenant" under the Master Lease with respect to the Sublease Premises, except as otherwise herein provided. As between Sublandlord and Subtenant only, all provisions of the Master Lease are subject to the express provisions of this Sublease, and any inconsistency between a provision of this Sublease and a provision of the Master Lease shall be resolved by reference to this Sublease unless otherwise stated. Whenever the Master Lease requires the consent of Master Landlord for an act or omission, then Sublandlord's separate consent also shall be required, which consent by Sublandlord shall not be unreasonably withheld, conditioned or delayed. Notwithstanding anything in this Sublease to the contrary, Sublandlord and Subtenant expressly agree that the following terms, covenants and conditions of the Master Lease are expressly excluded from this Sublease and are inapplicable to Subtenant: Section 3.3, Section 3.6, Section 8.2, Section 9.1(a), Section 9.2, Section 9.3, Section 9.4, Section 9.5, the second paragraph of Section 10.1, Section 11.3, Article XII, Article XIII, Section 14.2, Section 17.15, Article XVIII and Article XIX (provided that Sublandlord shall, upon the written request of Subtenant notifying Sublandlord that Master Landlord has breached any of its obligations under Section 8.2, Section 9.1(a), Section 9.2, Section 9.3, Section 9.4, Section 9.5, the second paragraph of Section 10.1, Section 11.3, Article XII, Article XIII, or Section 14.2, use commercially reasonable efforts to cause Master Landlord to perform its obligations under such Section(s), subsection(s) or Article(s)).

2.02 Binding Effect of Master Lease. Subtenant agrees, for the benefit of Sublandlord and Master Landlord, to abide by and perform during the Sublease Term all of the terms and provisions set forth in the Master Lease pertaining to the Sublease Premises, except as otherwise expressly provided by this Sublease. Subtenant shall neither commit nor permit to be committed on the Sublease Premises any act or omission that in any way violates any term or condition of the Master Lease.

2.03 Maintenance of Master Lease. Sublandlord agrees to maintain the Master Lease in full force and effect during the Sublease Term, subject however to any earlier termination of all

or any part of the Master Lease permitted under the terms of the Master Lease without Sublandlord's consent. Furthermore, Sublandlord will not agree to any amendment to the Master Lease or to waive any obligation of Master Landlord under the Master Lease without Subtenant's consent, which consent by Subtenant shall not be unreasonably withheld, conditioned or delayed. If Sublandlord receives any notice or demand from Master Landlord relating to the Sublease Premises, Sublandlord shall promptly provide a copy thereof to Subtenant. If the Master Lease is terminated for any reason, then (a) this Sublease shall terminate as, when and to the extent the Master Lease is terminated, (b) Sublandlord shall immediately notify Subtenant thereof, and (c) Sublandlord shall promptly return to Subtenant any prepaid rent and the Security Deposit in accordance with the terms of this Sublease.

2.04 Obligations of Master Landlord. Subtenant agrees that no failure or delay on the part of Master Landlord to supply any service, make any repair or take any action required under the Master Lease shall constitute a default by Sublandlord under this Sublease, constitute a constructive eviction, give rise to a claim against Sublandlord for damages or otherwise constitute a breach of this Sublease by Sublandlord. If and to the extent that Master Landlord fails to perform its obligations under the Master Lease, Sublandlord shall not be obligated to perform such obligations; provided, however, that so long as no Default (defined below) exists under this Sublease, Sublandlord agrees to use commercially reasonable efforts and reasonably cooperate with Subtenant, at Subtenant's sole cost and expense, to enforce the terms and conditions of the Master Lease for the benefit of Subtenant. Notwithstanding the immediately preceding sentence, Sublandlord shall have no obligation whatsoever to commence any litigation or arbitration proceeding to enforce the terms and conditions of the Master Lease.

## ARTICLE 3
## SUBLEASE PREMISES

3.01 Sublease Premises. Sublandlord hereby subleases to Subtenant, and Subtenant hereby subleases from Sublandlord, the Sublease Premises, subject to the terms and conditions herein contained.

3.02 Condition of Sublease Premises. On the date that is four (4) days prior to the Sublease Commencement Date, Sublandlord shall deliver, and Subtenant shall accept possession of, the Sublease Premises in "as-is" "where-is" condition, provided that the condition of the Sublease Premises is in substantially the same condition as of the date of execution of this Sublease and Sublandlord has left the Sublease Premises in broom clean condition free of all personal property except for the list of furniture described below in this Section. Sublandlord makes no representations or warranties with respect to the condition of the Sublease Premises. Notwithstanding the above, all of the furniture and equipment located in the Sublease Premises as of the date of this Sublease is being made available for Subtenant's use during the Sublease Term (the "Available Furniture"); provided, however, that Sublandlord shall be responsible, at Sublandlord's sole cost and prior to the Sublease Commencement Date, for the removal of any Available Furniture located in the Sublease Premises that Subtenant elects not to use and which

is specified by Subtenant on a written notice delivered to Sublandlord at least five (5) days prior to the Sublease Commencement Date (the "Rejected Furniture"). Any Available Furniture that is not Rejected Furniture (collectively, the "Purchased Furniture") shall be purchased by Subtenant for $[***], such purchase to be made on the date that is four (4) days prior to the Sublease Commencement Date by the tender by Subtenant of $[***] to Sublandlord, and Sublandlord shall deliver to Subtenant an executed Bill of Sale and Assignment substantially in the form attached hereto as Exhibit D (with the "List of Purchased Furniture" to be purchased properly completed to list all of the Purchased Furniture).

3.03 Building Common Areas. Subtenant shall have the right, in common with others, to reasonable use of the common facilities included in the Building, as and to the extent permitted, and subject to the rules and regulations imposed, by Master Landlord under the Master Lease.

3.04 Signage. Subtenant will have the right, at Subtenant's sole cost and expense and subject to receipt of the prior written approval of the Master Landlord in accordance with the Master Lease, to install signage on the door to the Sublease Premises and within the Sublease Premises in accordance with Section 5.6 of the Master Lease. Additionally, Landlord shall install the following signage, in accordance with Section 5.6 of the Master Lease except as modified herein, identifying Subtenant as an occupant of the Building: (i) a listing in the Building directory located in the lobby of the Building; and (ii) at Subtenant's sole cost and expense, a Building standard sign located in the elevator lobby of the floor of the Building on which the Sublease Premises are located.

## ARTICLE 4
## TERM

4.01 Term. The Sublease Term shall commence on the Sublease Commencement Date and shall expire on June 30, 2028 (the "Sublease Expiration Date"), unless this Sublease or the Master Lease is sooner terminated as provided herein or in the Master Lease. Notwithstanding the foregoing, Subtenant shall be permitted to access the Sublease Premises, without payment of Rent, during the four (4) days immediately prior to the Sublease Commencement Date for purposes of installing Subtenant's furniture, equipment and telephone and data systems, subject in each instance to coordination with both the Master Landlord and Sublandlord and to Subtenant's full compliance with all of the terms, conditions and policies set forth in this Sublease and in the Master Lease.

4.02 Master Landlord Consent to Sublease. Pursuant to Article VII of the Master Lease, the Master Landlord's prior written consent is required for this Sublease. Accordingly, this Sublease shall be of no force and effect unless and until Master Landlord consents in writing. In addition, Subtenant hereby agrees to provide any and all information, documents and financial reports required by Master Tenant pursuant to Section 7.3 of the Master Lease in connection with Sublandlord's request for Master Tenant's consent to this Sublease. Notwithstanding anything

herein to the contrary, in the event that Master Landlord's written consent has not been obtained by January 5, 2025, then Subtenant shall have the right to terminate this Sublease and any payments made by Subtenant to Sublandlord shall be immediately returned and neither party shall have any further obligations under this Sublease.

4.03 No Renewal Option. Sublandlord and Subtenant hereby acknowledge that this Sublease shall terminate on the Sublease Expiration Date without any express or implied option of Subtenant to renew the Sublease Term or otherwise extend the Sublease Term.

## ARTICLE 5
## RENT

5.01 Base Rent. Subtenant covenants and agrees to pay to Sublandlord an annual base rent ("Base Rent") in the amounts set forth in Article 1 hereof, payable in monthly installments, in advance, as specified below in Section 5.03.

5.02 Additional Rent. Subtenant also shall be obligated to pay all additional Rent that is payable pursuant to Section 4.1 of the Master Lease. Pursuant to Section 9.7 of the Master Lease, Subtenant shall be obligated to pay for telephone, cable, data transmission and other utilities and services furnished to or consumed in the Sublease Premises.

5.03 Payment of Rent. The term "Rent" as used in this Sublease, unless otherwise stated, shall mean the Base Rent set forth in this Section 5.01, plus all Additional Rent payable under this Sublease as set forth in Section 5.02. The monthly installments of Base Rent shall be due in advance on the first (1st) day of each calendar month beginning on the Sublease Commencement Date (as set forth in Article 1 hereof). In the event the Sublease Commencement Date is a day other than the first (1st) day of a calendar month or the Sublease Expiration Date is a day other than the last day of a calendar month, then in any such event the monthly installment of Base Rent payable hereunder for the applicable calendar month shall be prorated based on the number of days actually elapsed during the Sublease Term during such calendar month. All Rent due under this Sublease shall be payable on the date due without demand, setoff, abatement or deduction, except as otherwise expressly provided herein, and shall be payable to Sublandlord in lawful money of the United States at the address stated in this Sublease (or at such other place as Sublandlord may designate in writing).

5.04 Security Deposit. Concurrent with its execution of this Sublease, Subtenant shall deliver to Sublandlord, as security for Subtenant's faithful payment of Rent and performance of all Subtenant's other obligations hereunder, the Security Deposit. Sublandlord shall not be required to pay any interest on the Security Deposit. Sublandlord shall return the Security Deposit (less any amounts used or applied as permitted herein that have not been restored by Subtenant in accordance with the immediately preceding sentence) to Subtenant within thirty (30) days after the later to occur of (a) the expiration or earlier termination of this Sublease and (b) Subtenant's surrender of the Sublease Premises in the condition required under this Sublease.

5.05 Late Payments. In the event any Rent payment or any other payment due from Subtenant hereunder is not paid within five (5) days of the date that such payment is due, Subtenant shall owe to Sublandlord the late charge(s) specified in Section 4.1(d) of the Master Lease. The Parties agree that the amount of said late charge represents a reasonable estimate of the cost and expense that would be incurred by Sublandlord in processing each delinquent payment of Rent by Subtenant and that such late charge shall be paid to Sublandlord as liquidated damages for each delinquent payment. The aforesaid late charges and interest are intended to compensate Sublandlord for its costs arising by reason of any such late payment, and are not intended to constitute a waiver by Sublandlord of any other right or remedy available to Sublandlord arising by reason of Subtenant's failure to timely perform its monetary obligations hereunder. Notwithstanding the foregoing, no late payment or interest shall be due or payable with respect to the first late payment in any consecutive twenty-four month period if Subtenant makes payment within five (5) days after notice from Sublandlord (which notice may be by telephone or e-mail).

## ARTICLE 6
## SERVICES

6.01 Services. Sublandlord and Subtenant hereby acknowledge that Electricity Additional Rent shall be payable by Subtenant for the utilities and services currently furnished to the Sublease Premises, as set forth in Section 9.2 of the Master Lease. Notwithstanding any term to the contrary contained herein, Sublandlord shall not be obligated to pay for Subtenant's electricity consumption at any time during the Sublease Term. Should Subtenant desire additional telecommunications services, it shall make all arrangements for and pay for all such additional hookups and may only make application for them with Sublandlord's and Master Landlord's prior written consent. Except to the extent expressly provided otherwise in the Master Lease, neither Sublandlord nor Master Landlord shall be liable to Subtenant, in damages or otherwise, for any interruption in the service of any utility or service serving the Sublease Premises.

6.02 Building Access. Subtenant shall have access to the Sublease Premises and the Building in accordance with Section 1 of this Sublease.

## ARTICLE 7
## MAINTENANCE AND REPAIRS

7.01 Maintenance and Repairs. During the Sublease Term, Subtenant shall assume all of Sublandlord's obligations under the Master Lease in relation to maintenance and repair of the Sublease Premises, payment of taxes relating to Subtenant's business and compliance with all laws, ordinances, rules and regulations related to Subtenant's use of the Sublease Premises.

7.02 Conduct of Repairs. Subtenant shall notify Sublandlord of all material repairs required to the Sublease Premises prior to conducting such repairs. At the option of Sublandlord

or Master Landlord, all repairs to the Sublease Premises that are Subtenant's responsibility as provided in this Sublease may be performed or constructed, at Subtenant's expense, by Sublandlord or Master Landlord or such other person as Sublandlord or Master Landlord may designate.

7.03 Surrender of Sublease Premises. At the expiration or sooner termination of the Sublease Term, Subtenant shall surrender the Sublease Premises in accordance with Section 5.5(c) of the Master Lease.

## ARTICLE 8
## USE OF SUBLEASE PREMISES

8.01 Use. Subtenant shall use the Sublease Premises only for the purpose of first-class business office use and no other use or uses unless with the prior written consent of Sublandlord and Master Landlord, and shall comply with all laws, rules and requirements applicable to Subtenant's conduct of its business at and use of the Sublease Premises. Subtenant shall not conduct any activities in the Sublease Premises that would materially increase Sublandlord's risks, liabilities (in relation to Hazardous Materials (as defined in the Master Lease) or otherwise) or insurance rates, without first obtaining Sublandlord's prior written consent, and shall neither commit nor permit waste or nuisance on or about the Sublease Premises.

8.02 Condition of Sublease Premises. Sublandlord shall provide the Sublease Premises to Subtenant at the Sublease Commencement Date, and, subject to Section 3.02 hereof, Subtenant otherwise accepts the Sublease Premises, in the "as-is, where-is" condition existing as of the Sublease Commencement Date. Subtenant acknowledges that it has inspected the Building and the Sublease Premises and neither Sublandlord nor any agent of Sublandlord has made any representations or warranties, except as otherwise expressly provided in this Sublease, with respect to the Sublease Premises including, without limitation, any representation or warranty with respect to the suitability or fitness of the Sublease Premises or the Building for the conduct of Subtenant's business, or the condition, safety, repair or habitability of the Sublease Premises and acknowledges further that Sublandlord is under no obligation to construct or install any alterations or improvements in or to the Sublease Premises or provide any labor or materials or provide any allowances. Subtenant's taking possession of the Sublease Premises or occupying the Sublease Premises shall be conclusive evidence that Subtenant accepts the Sublease Premises as suitable for the purposes for which they are leased.

8.03 Compliance with Laws Regarding Use. Subtenant shall, at its own expense, comply with Sublandlord's obligations as Tenant under Section 5.2 of the Master Lease during the Sublease Term. Subtenant shall be solely responsible for obtaining or maintaining any and all permits, licenses and/or approvals necessary to the conduct of its business in the Sublease Premises. Subtenant shall neither use nor permit the use of the Sublease Premises in any manner that will or reasonably could be expected to violate any applicable Requirements (as defined in the Master Lease) or the provisions of the Master Lease.

8.04 Modification of Sublease Premises. Subtenant shall not make any Alterations (as defined in the Master Lease) of any kind in the Sublease Premises or in the Building without compliance with the terms and conditions of Article VI of the Master Lease. Any such Alterations made by Subtenant shall be made in accordance with the Master Lease and at Subtenant's sole expense. If and to the extent that Sublandlord or Master Landlord indicated to Subtenant at the time of approval of Alterations that such Alterations must be removed at the expiration or earlier termination of this Sublease, Subtenant shall restore the Sublease Premises to the same condition they were in on the Sublease Commencement Date, except for reasonable wear and tear and damage by fire, condemnation or other casualty, or damage caused by Sublandlord or Master Landlord or any agent, employee, contractor or invitee of Sublandlord or Master Landlord, by removing any Alterations made to the Sublease Premises during the Term of this Sublease prior to Subtenant's surrender of the Sublease Premises. Notwithstanding the foregoing, the prior consent of Sublandlord shall not be required for decorative Alterations (such as painting, wall coverings and carpeting) which satisfy the conditions of clauses (i), (ii), (iii) and (iv) of Section 6.1(a) of the Master Lease and cost less than $[***] in the aggregate provided that Subtenant provides Sublandlord with notice prior to undertaking such decorative Alterations.

8.05 Right of Entry. Subtenant shall permit Master Landlord and Sublandlord or their respective representatives to enter the Sublease Premises in accordance with the terms and conditions of Section 15.1 of the Master Lease.

8.06 Covenants of Subtenant. Subtenant agrees to pay the Rent herein reserved, to abide by, observe and perform all of the terms, covenants and conditions of this Sublease (including all of the applicable terms and conditions of the Master Lease), and to surrender the Sublease Premises to Sublandlord on the expiration or sooner termination of this Sublease in the condition required hereunder. Subtenant shall abide by the provisions of the Master Lease as applicable, and by the rules and regulations established from time to time by Master Landlord in accordance with the terms and conditions.

## ARTICLE 9
## INSURANCE; INDEMNIFICATION

9.01. Subtenant's Insurance. Subtenant shall be required to comply in all respects with the obligations of Tenant set forth in Section 11 of the Master Lease, and the terms and conditions of Section 11 of the Master Lease shall apply to Subtenant and this Sublease as if Subtenant were the Tenant under the Master Lease.

9.02 Indemnification.

(a) Sublandlord, its officers and directors, shall not be liable to Subtenant for any loss, injury or other damage to Subtenant or to Subtenant's property in or about the Sublease Premises, Building and/or Property at any time (including defects in the Sublease Premises,

Building and/or Property or in any equipment located therein or thereon; fire, explosion or other casualty; bursting, rupture, leakage or overflow of any plumbing or other pipes or lines, sprinklers, tanks, drains, drinking fountains or washstands in, above, or about the Sublease Premises, Building and/or the Property; or acts of other tenants in the Building or on the Property) not arising from or out of or as a direct result of the grossly negligent or willful acts or omissions of Sublandlord, its officers and directors. Except for claims expressly excluded from the operation of the indemnity set forth in Section 9.02(d), Subtenant hereby waives all claims against Sublandlord, its officers and directors, for any such loss, injury or damage to Subtenant or Subtenant's property, and the cost and expense of defending against claims relating thereto.

(b) Notwithstanding any other provision of this Sublease to the contrary, Sublandlord shall not be liable to Subtenant for any damages to Subtenant or Subtenant's property or business that results, directly or indirectly from, any issue relating to access to the Property and the Sublease Premises by means of any access roads to the Property, it being acknowledged and agreed that said access roads, and the use, repair and maintenance of same, are under the control of and the sole responsibility of the City of Boston, Massachusetts.

(c) Subtenant shall indemnify, defend and hold Sublandlord harmless from all losses, liabilities, costs, and expenses of third-party claims arising from (i) Subtenant's use of the Sublease Premises or the conduct of its business or any activity, work, or thing done, permitted or suffered by Subtenant in or about the Sublease Premises; and (ii) any act, neglect, fault or omission of Subtenant or of its agents or employees, guests or invitees in violation or breach of this Sublease; and (iii) all reasonable costs, attorneys' fees, expenses and liabilities incurred in or about such claims or any action or proceeding brought thereon. In case any action or proceeding shall be brought against Sublandlord by reason of any such claim, Subtenant upon reasonable notice from Sublandlord shall defend the same at Subtenant's sole expense by counsel approved in writing by Sublandlord. Subtenant, as a material part of the consideration to Sublandlord, hereby assumes all risk of and waives all claims against Sublandlord with respect to damage to property or injury to persons in, upon or about the Sublease Premises from any cause whatsoever except that which is caused by the willful misconduct or grossly negligent acts or omissions of Sublandlord or its authorized representatives.

(d) Sublandlord shall indemnify, defend and hold Subtenant harmless from all losses, liabilities, costs, and expenses of third-party claims arising from (i) any act, neglect, fault or omission of Sublandlord or of its agents or employees, guests or invitees in violation or breach of this Sublease; and (ii) all reasonable costs, attorneys' fees, expenses and liabilities incurred in or about such claims or any action or proceeding brought thereon. In case any action or proceeding shall be brought against Subtenant by reason of any such claim, Sublandlord upon reasonable notice from Subtenant shall defend the same at Sublandlord's sole expense by counsel approved in writing by Subtenant.

(e) The obligations of Subtenant under this Article 9 shall survive the expiration or termination of the Sublease.

## ARTICLE 10
## DEFAULTS

10.01 Subtenant Default. Subtenant shall be in default under this Sublease ("Default") if, subject to applicable notice and cure periods set forth in the Master Lease, Subtenant's actions or omissions cause a Default of Tenant to occur under the Master Lease.

10.02 Remedies for Subtenant Default. In the case of Default by Subtenant, Sublandlord may upon the occurrence of any one or more Defaults, Sublandlord may exercise any remedy against, and recover such amounts from, Subtenant as Master Landlord may exercise or be entitled to for default by Tenant under the Master Lease, which provisions of the Master Lease are hereby incorporated herein by reference.

10.03 Holding Over. If Subtenant fails to surrender the Sublease Premises upon the expiration or sooner termination of the Sublease Term, this Sublease shall nevertheless terminate as of the expiration or termination date, and Subtenant shall become a tenant at sufferance and shall be subject to the terms and conditions of Section 17.11 of the Master Lease. Notwithstanding the foregoing, as between Master Landlord and Sublandlord, Sublandlord hereby acknowledges that, to the extent required by the Master Lease, Sublandlord shall remain liable to Master Landlord for all damages incurred by Master Landlord on account of Subtenant's failure to surrender the Sublease Premises in accordance with the terms and conditions of the Master Lease.

## ARTICLE 11
## OTHER PROVISIONS

11.01 Sublandlord's Rights Under Master Lease. Any options or rights to renew or extend the Master Lease or expand or contract the Master Lease Premises, and any rights of first offer or refusal or any other such options or rights granted to Sublandlord in the Master Lease are for the sole benefit of Sublandlord, and Sublandlord shall have no obligation to exercise or decline any such right or option for the benefit of Subtenant or otherwise.

11.02 Notices. Any notice or demand required or permitted to be given hereunder shall be in writing and shall be sent by hand delivery, or by nationally recognized overnight express carrier or by registered or certified mail, postage prepaid, return receipt requested, addressed to the respective Parties at the respective addresses noted in Article 1 hereof.

However, no such notice to or demand upon Sublandlord shall be effective unless a true and complete copy thereof is also served upon its counsel, Gesmer Updegrove, LLP, 40 Broad Street, Third Floor, Boston, Massachusetts, Attention: Justin M. Nesbit, Esquire, or at such other

address as such counsel may hereafter specify in writing, and no such notice to or demand upon Subtenant shall be effective unless a true and complete copy thereof is also served upon its counsel: Levenfeld Pearlstein, LLC, 120 S. Riverside Plaza, Suite 1800, Chicago, Illinois 60606, Attention: Kevin E. Slaughter, Esq. Any such notice shall be deemed to be delivered upon actual receipt (or refusal to accept delivery) thereof. Either Party may, by notice in writing so delivered to the other, specify a different address for notice purposes.

11.03 Transfers. (a) Subtenant shall not assign or sub-sublet the whole or any part of the Sublease Premises without Master Landlord's prior written consent, which shall be granted or withheld by Master Landlord in accordance with the terms and conditions of the Master Lease, and Sublandlord's prior written consent, which shall not be unreasonably withheld, delayed or conditioned by Sublandlord; provided, however, that Sublandlord and Master Landlord shall have the right (i) to receive and approve (in Sublandlord's and Master Landlord's reasonable discretion) the information specified in subsections (i) through (vi) of Section 7.3 of the Master Lease, and (ii) evidence that the proposed use is a permitted use under the Master Lease and is consistent with the existing other tenants in the Building, all prior to granting of Sublandlord's and Master Landlord's consent. Notwithstanding such consent as described above, Subtenant shall be required to share with Sublandlord [***] of the amount that "Tenant" under the Master Lease is permitted to retain under Section 7.6 of the Master Lease (and Sublandlord and Subtenant shall be required to pay to Master Landlord all amounts due and payable under Section 7.6 of the Master Lease), and Subtenant shall remain liable to Sublandlord for the payment of all Rent and other amounts payable by Subtenant under this Sublease, and for the full performance of the covenants and conditions contained in this Sublease unless otherwise agreed in writing by Sublandlord in Sublandlord's sole discretion. The granting of consent to an assignment or a sub-subletting of the Sublease Premises in one instance does not automatically grant Subtenant the right to assign or sub-sublet the Sublease Premises in another instance. Subtenant shall reimburse Sublandlord, promptly upon request, for any amount that Sublandlord is required to reimburse to Master Landlord, pursuant to Article VII of the Master Lease, for Master Landlord's reasonable attorney's fees for review and approval of this Sublease and any other subsequent assignment or sublease, up to a maximum of $[***] per request.

(b) Notwithstanding anything to the contrary contained in this Sublease, Subtenant may, without Sublandlord's prior written consent, but upon prior written notice to Sublandlord (which notice shall be no later than thirty (30) days prior to the effective date of any such transaction, including copies of all applicable documentation, assign or sub-sublet all or any portion of the Sublease Premises and Subtenant's interest in this Sublease to: (a) any related entity, parent, subsidiary, or affiliate of Subtenant; (b) any entity that directly or indirectly controls, is controlled by or is under common control with Subtenant; or (c) any corporation or other entity that succeeds to all or substantially all of the assets and business of Subtenant.

11.04 Attorney's Fees. If there is any legal or arbitration action or proceeding between Sublandlord and Subtenant to enforce any provision of this Sublease or to protect or establish

any right or remedy of either Sublandlord or Subtenant hereunder, then the unsuccessful Party to such action or proceeding shall pay to the prevailing Party all reasonable, actual out-of-pocket costs and expenses paid or payable to third parties, including reasonable attorneys' fees incurred by such prevailing Party in such action or proceeding and in any appeal in connection therewith, and, if such prevailing Party recovers a judgment in any such action, proceeding or appeal, then such costs, expenses and attorneys' fees will be determined by the court or arbitration panel handling the proceeding and will be included in and as a part of such judgment.

11.05 Time of Essence. Time is of the essence with respect to each and every provision of this Sublease.

11.06 Quiet Enjoyment. Sublandlord represents that the Master Lease is in full force and effect and that, to Sublandlord's knowledge, there are no defaults on Sublandlord's part under the Master Lease as of the date first set forth above. Sublandlord covenants that, subject to the provisions of this Sublease and the Master Lease, so long as there exists no uncured Default, Subtenant shall quietly enjoy the Sublease Premises for the Sublease Term.

11.07 Waiver. The waiver by a Party of a breach of any term in this Sublease shall not be deemed to be a waiver of any subsequent breach of the same or any other term of this Sublease. The subsequent acceptance of Rent by Sublandlord shall not be deemed to be a waiver of any preceding breach by Subtenant of any term of this Sublease, other than the failure of Subtenant to pay the particular rental so accepted, regardless of Sublandlord's knowledge of such preceding breach at the time Sublandlord accepts such rent.

11.08 Brokers' Fees. Sublandlord and Subtenant represent and warrant to each other that they have not dealt with any real estate brokers, finders or other persons in connection with this Sublease except for Avison Young ("Sublandlord's Broker") and Cushman & Wakefield ("Subtenant's Broker"; and the Parties acknowledge and agree that Sublandlord has agreed, pursuant to a separate written agreement, to pay Subtenant's Broker a fee upon execution of this Sublease), and the Parties shall indemnify and hold each other harmless from and against any and all liability, loss, damage, expense, claim, action, demand, suit, or obligation, including but not limited to reasonable attorneys' fees, arising out of or relating to a respective breach of this representation. Upon receipt of Master Landlord's written consent to this Sublease, Sublandlord agrees to pay to each of the above-named Sublandlord's Broker and Subtenant's Broker a market commission fee for professional services rendered pursuant to a separate brokerage agreement between Sublandlord and Broker.

11.09 Entire Agreement. This Sublease, including all exhibits hereto, contains the entire agreement between the Parties with respect to the subject matter herein, and no representations, inducements, promises or agreements, oral or otherwise, not expressly stated herein shall be of any force or effect.

11.10 Submission. Submission of this instrument for examination or signature by Sublandlord shall not be construed as an offer and shall not be effective as a Sublease or otherwise until executed by both Subtenant and Sublandlord, and a fully-executed original delivered to Sublandlord.

11.11 Authority and Counterparts. Each Party represents and warrants that its respective signatory is duly authorized to execute and deliver this Sublease, and to bind the person for which such signatory signs. This Sublease may be signed in counterparts, each of which shall be equivalent to a signed original, and which together shall form one and the same instrument. Facsimile transmissions, or electronic transmissions in .pdf format, of any executed original of this Sublease and/or retransmission of any executed facsimile or .pdf transmission shall be deemed to be the same as the delivery of an executed original.

11.12 Successors and Assigns. Each provision hereof shall be binding on and inure to the benefit of the Parties and their respective agents, employees, successors and permitted assigns, provided that, except as expressly provided otherwise in Section 11.03, this Sublease shall not inure to the benefit of any assignee or transferee of Subtenant except with Sublandlord's and Master Landlord's prior written consent.

11.13 Governing Law and Jurisdiction. This Sublease shall be governed by the laws of the Commonwealth of Massachusetts (without regard to conflicts of laws principles).

11.14 Fire and other Casualty; Condemnation. In the event of any taking by eminent domain or deed in lieu thereof or damage by fire or other casualty to the Sublease Premises thereby rendering the Sublease Premises wholly or in part untenantable, Subtenant shall acquiesce in and be bound by any action taken by or agreement entered into between Master Landlord and Sublandlord with respect thereto. If, pursuant to the Master Lease, there is an abatement of rent due under the Master Lease for any period, the rent due and payable under this Sublease shall also abate under this Sublease if and to the extent that the affected portion of the Demised Premises includes the Sublease Premises or a portion thereof.

11.15 Consequential Damages. In no event shall either Sublandlord or Subtenant (except with respect to the indemnification obligations pursuant to Sections 9.02(c) and 9.02(d) of this Sublease) be liable to the other Party for any punitive or consequential damages in connection with this Sublease.

*[Remainder of Page Intentionally Left Blank; Signature Page To Follow]*

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH INFORMATION HAS BEEN OMITTED BECAUSE (i) IT IS NOT MATERIAL, AND (ii) IT WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Sublease Agreement to be executed on the date first written above.

| SUBLANDLORD | SUBTENANT |
|---|---|
| **BROWNMED, INC.**, | **ZEVRA THERAPEUTICS, INC.**, |
| a Massachusetts corporation | a Delaware corporation |
| By: /s/ Chris Kissane | By: /s/ LaDuane Clifton |
| Name: Chris Kissane | Name: LaDuane Clifton |
| Title: President | Title: CFO |

LIST OF EXHIBITS

Exhibit A – Sublease Premises

Exhibit B – Master Lease

Exhibit C – Form of Bill of Sale and Assignment

**Exhibit 21.1**

**Subsidiaries of Zevra Therapeutics, Inc.**

The following companies are direct or indirect wholly owned subsidiaries of Zevra Therapeutics, Inc.:

| **Name** | **Jurisdiction** |
| --- | --- |
| Acer Therapeutics Inc. | Delaware |
| Zevra Denmark A/S | Denmark |

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-252078, 333-252903, 333-257433, 333-276856 and 333-279941) of Zevra Therapeutics, Inc.,

(2) Registration Statement (Form S-8 No. 333-203703) pertaining to the Incentive Stock Plan, as amended, and the 2014 Equity Incentive Plan of Zevra Therapeutics, Inc.,

(3) Registration Statements (Form S-8 Nos. 333-210369, 333-216858, 333-224062, 333-230041, 333-236794 and 333-252743) pertaining to the 2014 Equity Incentive Plan of Zevra Therapeutics, Inc.,

(4) Registration Statement (Form S-8 No. 333-257429) pertaining to the Amended and Restated 2014 Equity Incentive Plan, and the 2021 Employee Stock Purchase Plan of Zevra Therapeutics, Inc.,

(5) Registration Statement (Form S-8 No. 333-270341) pertaining to the 2023 Employment Inducement Award Plan of Zevra Therapeutics, Inc.,

(6) Registration Statement (Form S-8 No. 333-278445) pertaining to the Amended and Restated 2023 Employment Inducement Award Plan of Zevra Therapeutics, Inc., and

(7) Registration Statements (Form S-8 Nos. 333-270340, 333-278444 and 333-285760) pertaining to the Amended and Restated 2014 Equity Incentive Plan of Zevra Therapeutics, Inc.;

of our report dated March 9, 2026, with respect to the consolidated financial statements of Zevra Therapeutics, Inc. included in this Annual Report (Form 10-K) of Zevra Therapeutics, Inc. for the year ended December 31, 2025.

/S/ Ernst & Young LLP

Orlando, Florida
March 9, 2026

**Exhibit 31.1**

**CERTIFICATION**

I, Neil F. McFarlane, certify that:

1. I have reviewed this Annual Report on Form 10-K of Zevra Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 9, 2026

/s/ Neil F. McFarlane

Name: Neil F. McFarlane

Title: President and Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION**

I, Timothy J. Sangiovanni, certify that:

1. I have reviewed this Annual Report on Form 10-K of Zevra Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 9, 2026

/s/ Timothy J. Sangiovanni

Name: Timothy J. Sangiovanni, CPA

Title: Senior Vice President, Finance and Corporate Controller
(Principal Financial and Accounting Officer)

**Exhibit 32.1**

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER**
**PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Zevra Therapeutics, Inc., (the "Company") for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Neil F. McFarlane, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 9, 2026

/s/ Neil F. McFarlane

Name: Neil F. McFarlane

Title: President and Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

**Exhibit 32.2**

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER**
**PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Zevra Therapeutics, Inc., (the "Company") for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy J. Sangiovanni, Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 9, 2026

/s/ Timothy J. Sangiovanni

Name: Timothy J. Sangiovanni, CPA

Title: Senior Vice President, Finance and Corporate Controller
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, is not being "filed" by the Company as part of the Report or as a separate disclosure document and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.