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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38599

Aquestive Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-3827296**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
30 Technology Drive, Warren, NJ	**07059**
(Address of Principal Executive Offices)	(Zip Code)

(908) 941-1900
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	AQST	Nasdaq Global 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 (Section 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 Securities Exchange Act of 1934.

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 to Section 13(a) of the Securities 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 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 Section 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

As of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $207.3 million based on the closing price of the registrant's common stock on such date.

The number of outstanding shares of the registrant's par value $0.001 common stock as of the close of business on March 3, 2025 was 98,871,369.

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2025 Annual Meeting of Shareholders within 120 days of the end of its fiscal year ended December 31, 2024. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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GLOSSARY OF TERMS, ABBREVIATIONS AND ACRONYMS

The following terms, abbreviations and acronyms are used to identify frequently used terms and phrases that may be used in this report:

TERM	DEFINITION
12.5% Notes	12.5% Senior Secured Notes due 2025
13.5% Notes	13.5% Senior Secured Notes
ADHD	Attention Deficit Hyperactivity Disorder
ALS	Amyotrophic Lateral Sclerosis
ANDA	Abbreviated New Drug Application
ANVISA	Brazilian Health Regulatory Agency
API	Active Pharmaceutical Ingredients
AQST	Common Stock symbol for Aquestive Therapeutics, Inc.
ARO	Asset Retirement Obligations
ASC	Accounting Standards Codification
Assertio	Assertio Holdings, Inc.
Assertio Agreement	License Agreement between Aquestive and Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings,
ASU	Accounting Standards Updates
ATM	At-The-Market facility for the purchase of AQST Common Stock
Base Indenture	Indenture for the 12.5% Notes
BBA	Bipartisan Budget Act of 2018
BDSI	BioDelivery Sciences International, Inc.
cGMP	current Good Manufacturing Practices
CMS	Centers for Medicare & Medicaid Services
CNS	Central Nervous System
Common Stock	Common Stock, par value $0.001 per share, of the Company
Common Stock Warrants	Warrants issued with private placement of up to $100,000 aggregate principal of 12.5% Notes originally due 2025
Cosmed	CosMed Industria De Cosmeticos E Medicamentos S.A
COSO	Committee of Sponsoring Organization of the Treadway Commission
CRL	Complete Response Letter (FDA)
CROs	Contract research organizations
DEA	Drug Enforcement Agency
DSCSA	Drug Supply Chain Security Act
EBIT	Earnings before interest and taxes
EMA	European Medicines Agency
EoP2	End-of-Phase 2
EPS	Earnings (loss) per share
ERTC	Employee Retention Tax Credit
ESPP	Employee Stock Purchase Plan
EU	European Union
Exchange Act	Securities Exchange Act of 1934
Existing Warrants	Common Stock Purchase Warrants with the holder of the remaining 5,000,000 warrants
FASB	Financial Accounting Standards Board
FDA	U.S. Food and Drug Administration
FDAAA	The Food and Drug Administration Amendments Act of 2007
FDCA	The Federal Food, Drug, and Cosmetic Act
FDIC	Federal Deposit Insurance Corporation
FDII	Foreign Derived Intangible Income

First Amendment	First amendment to the Sunovion License Agreement
Fortovia	Fortovia Therapeutics Inc. (previously Midatech Pharma PLC
FQHC	Federally Qualified Health Center
GAAP	Generally Accepted Accounting Principles
GLP	Good Laboratory Practice
Haisco	Haisco Pharmaceutical Group Co., Ltd.
Haisco Agreement	License, Development and Supply Agreement with Haisco, a Chinese limited company listed on the Shenzhen Stock Exchange
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act
IND	Investigational New Drug Application
Indenture Agreement	Agreement governing the 13.5% Senior Secured Notes
Indivior	Indivior Inc. (formerly, Reckitt Benckiser Pharmaceuticals Inc)
Indivior Amendment 11	Amendment No. 11 to the Indivior License Agreement
Indivior License Agreement	Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (with subsequent amendments collectively)
IRB	Institutional Review Board
Lincoln Park	Lincoln Park Capital Fund, LLC
Lincoln Park Purchase Agreement	Purchase Agreement with Lincoln Park Capital Fund, LLC
Marathon	Marathon Asset Management
Monetization Agreement	Purchase and Sale Agreement between Aquestive and Sunovion
MSSP	Managed Security Services Provider
MTHA	Mitsubishi Tanabe Pharma Holdings America, Inc.
N/M	Not Meaningful, used in percentage changes
Nasdaq	The Nasdaq Stock Market
NDA	New Drug Application
New Warrants	Warrants to purchase 2,750,000 shares of Common Stock
NIH	National Institutes of Health
ODE	Orphan Drug Exclusivity
PD	Pharmacodynamics
PDMA	The U.S. Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act
Pharmanovia	Atnahs Pharma UK Limited, a company registered in England and Wales
Pharmanovia Agreement	License and Supply Agreement with Atnahs Pharma UK Limited,
Pharmanovia Amendment	Amended License and Supply Agreement with Atnahs Pharma UK Limited as of March 27, 2023
PK	Pharmacokinetic
PPACA	Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010
PTO	United States Patent and Trademark Office
REMS	Risk Evaluation and Mitigation Strategy
Royalty Obligations	Liability related to the Royalty Rights Agreements
Royalty Rights Agreements	Royalty Rights Agreements, component of 13.5% Senior Secured Notes
RSU	Restricted Stock Unit
SEC	Securities and Exchange Commission
Securities Purchase Agreements	Securities Purchase Agreements with certain purchasers entered into on June 6, 2022

Separation Agreement	Separation Agreement, including a Consulting Agreement with Keith J. Kendall
Sunovion	Sunovion Pharmaceuticals Inc
Sunovion License Agreement	KYNMOBI Commercialization Agreement
Territory	Certain countries of the European Union, the United Kingdom, Switzerland, Norway and the Middle East and North Africa under the Pharmanovia Agreement
TGA	Australian Government Department of Health's Therapeutics Goods Administration
Zambon	Zambon S.p.A.
Zevra	Zevra Therapeutics, Inc. (formerly KemPharm, Inc.)

PART I

Forward-Looking Statements

This Annual Report on Form 10-K and certain other communications made by us include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements.

These forward-looking statements include, but are not limited to, statements regarding the advancement and related timing of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the timing of submission of supporting and pediatric clinical studies, and filing of the NDA for Anaphylm with the FDA, and the following launch of Anaphylm, if approved by the FDA; the results of the Company’s clinical studies for Anaphylm and the ability of such results to support submission of the NDA for approval of Anaphylm to the FDA; Anaphylm's potential to be the first and only oral administration of epinephrine and to be accepted as an alternative to existing standards of care, if approved by the FDA; the expected growth of the U.S. epinephrine market including in value and the opportunity such growth presents to the Company should Anaphylm be approved by the FDA; the advancement, growth and related timing of our Adrenaverse™ pipeline epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel, through clinical development and FDA regulatory approval process, including design and timing of clinical studies including those necessary to support the targeted indication of alopecia areata for AQST-108 and the following launch of AQST-108, if approved by the FDA; the potential sale or outlicensing of Anaphylm, Libervant or other product candidates; the advancement and related timing of our product candidate Libervant® (diazepam) Buccal Film for the indicated epilepsy patient population aged between 6 and 11 years through clinical development and FDA regulatory approval and the following launch of Libervant for this patient population if approved by the FDA; the approval for U.S. market access of Libervant for the epilepsy patient population aged 6 years and older and overcoming the orphan drug market exclusivity of an FDA approved nasal spray product of another company extending to January 2027 for these patients; the commercial opportunity of Libervant, Anaphylm, AQST-108 and our other product candidates, including potential revenues (including projected peak annual sales) generated from commercialization of these products, should these product candidates be approved by the FDA; the focus on continuing to manufacture Suboxone®, Emylif®, Sympazan®, Ondif® and other licensed products; the potential growth of our patent portfolio including the extension of patent protection for Anaphylm should the pending patents be approved by the U.S. Patent and Trademark Office (PTO); the potential benefits our products and product candidates could bring to patients; the achievement of clinical and commercial milestones, product orders and fulfillment; our cash requirements, cash funding and cash burn; short-term and longer term liquidity and the ability to fund our business operations; our growth and future financial and operating results and financial position, including with respect to our 2025 financial outlook; and business strategies, market opportunities, and other statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm (including for pediatric patients), AQST-108, and our other product candidates; risks associated with our distribution work for Libervant, including any delays or changes to the timing, cost and success of our distribution activities and expansion of market access to patients aged two to five for Libervant; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, for Anaphylm, AQST-108, Libervant for patients aged between 6 and 11 and other product candidates, or failure to receive FDA approval at all of any of these product candidates; risk of the Company’s ability to generate sufficient clinical data for approval of our product candidates, including with respect to our PK/PD comparability submission for FDA approval of Anaphylm; risks associated our ability to address the FDA’s comments on our future clinical trials and other concerns identified in the FDA Type C meeting minutes for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; associated with the success of any competing products, including generics; risk that we may not overcome the seven year orphan drug market exclusivity granted by the FDA for the approved nasal spray product of another company in the U.S. in order for Libervant to be granted U.S. market access for patients aged 6 years and older prior to expiration of the orphan drug market exclusivity period of the nasal spray product, which due to occur in January 2027; risk of loss of U.S. market approval of Libervant for patients aged between two to five resulting from a legal challenge relating to U.S. orphan drug market exclusivity by the owner of the approved nasal spray product with respect to the FDA’s approval for U.S. market access of Libervant for this pediatric patient population, or for other reasons; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for commercialization of our product Libervant and other product candidates, including Anaphylm and AQST-108; risks associated with the potential impact on the value of the Company of the sale or outlicensing of our product and product candidates, including Libervant and Anaphylm and other product candidates; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing, including under our ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and

other cash needs, at the times and in the amounts needed, including to fund commercialization activities relating to Libervant for patients between two to five years of age and to fund future clinical development and commercial activities for our product candidates, including Anaphylm, AQST-108 and Libervant for patients aged between 6 and 11, should these product candidates be approved by the FDA, and for Libervant patients of 6 years and older upon expiration of the orphan drug marketing exclusivity period of the nasal spray product; risk that our manufacturing capabilities will be insufficient to support demand for Libervant for patients between two to five years of age and for older patients, should Libervant receive U.S. market access for these older patients, and for demand for our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® as a sunsetting product, which accounts for a substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risks associated with the rate and degree of market acceptance in the U.S. and abroad of Libervant for epilepsy patients between two to five years of age, and for older epilepsy patients if approved for U.S. market access and after the expiration of the orphan drug market exclusivity period in January 2027; risk of the rate and degree of market acceptance in the U.S. and abroad of Libervant, Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk associated with the size and growth of our product markets; risk associated with our compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk that our patent applications for our product candidates, including for Anaphylm, will not be timely issued, or issued at all, by the PTO; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and product candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against us including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity attacks and data accessibility disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and changing interest rates; risks related to the impact of other pandemic diseases, such as COVID-19 on our business, including with respect to our clinical trials and the site initiation, patient enrollment and timing and adequacy of those clinical trials, regulatory submissions and regulatory reviews and approvals of our product candidates, availability of pharmaceutical ingredients and other raw materials used in our products and product candidates, supply chain, manufacture and distribution of our products and product candidates; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; risks related to uncertainty about presidential administration initiatives and their impact on our business; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in this Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. We assume no obligation to update forward-looking statements, or outlook or guidance after the date of this Annual Report on Form 10-K, whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely on the forward-looking statements included in this Annual Report on Form 10-K as representing our views as of any date after the date of the filing of this Annual Report on Form 10-K.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in Part I-Item 1A. Risk Factors of this Form 10-K.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to “Aquestive,” the "Company,” “we,” “us,” and “our” refer to Aquestive Therapeutics, Inc. and its subsidiaries.

Item 1. Business Overview

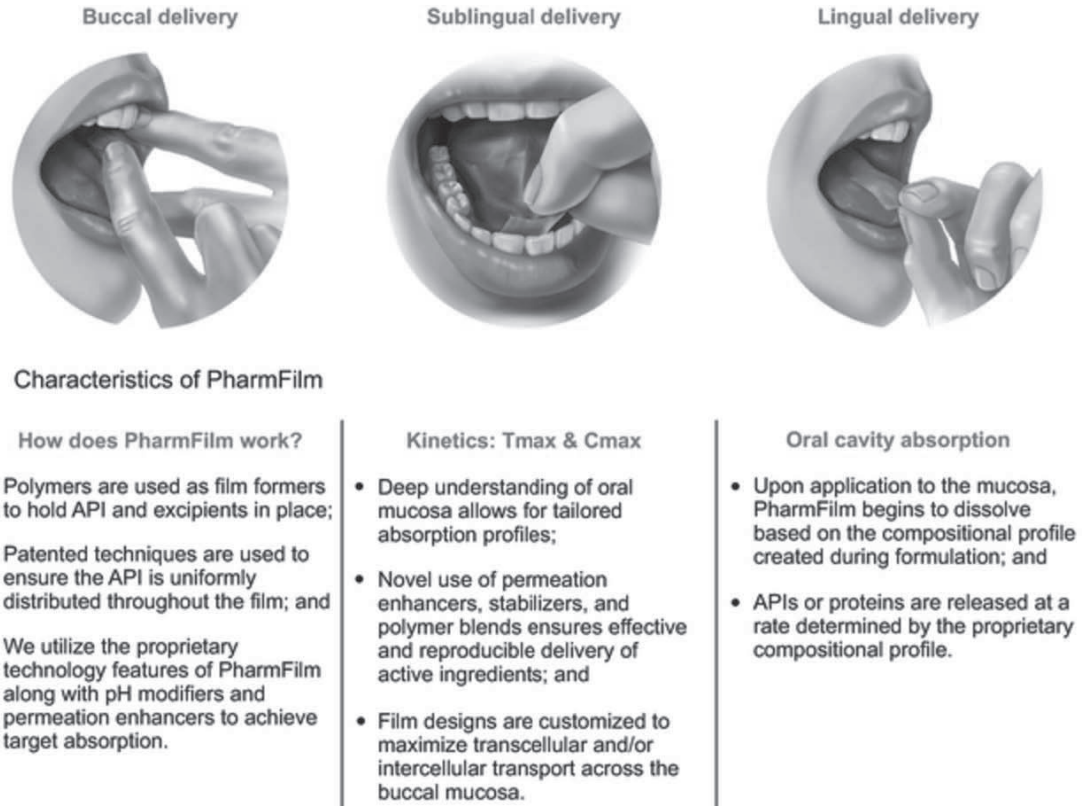
Aquestive is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing pharmaceutical products to deliver complex molecules through alternative administrations to invasive and inconvenient standard of care therapies. We have a proprietary commercial product, Libervant® (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy between two to five years of age, which was launched in April 2024. We are also advancing a product pipeline for the treatment of severe allergic reactions, including anaphylaxis, under the trade name "Anaphylm™", and our Adrenaverse epinephrine prodrug pipeline platform. We have five licensed commercialized products which are marketed by our licensees in the U.S. and around the world. We are the exclusive manufacturer of these licensed products. We also collaborate with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and have proven drug development and commercialization capabilities. Our production facilities are located in Portage, Indiana, and our corporate headquarters and primary research laboratory facilities are based in Warren, New Jersey.

We manufacture licensed products at our facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our proprietary and licensed products and product candidates currently in development. Our facilities have been inspected by the FDA, TGA, and DEA and are subject to inspection by all applicable health agencies, including ANVISA and EMA.

PharmFilm – Our Oral Film Technology

We are presently the worldwide leader in oral film drug delivery and manufacturing, having historically supplied the substantial majority of the world's oral films for prescription pharmaceutical use, and we have the capability to produce more than one billion commercial doses a year. We developed our PharmFilm technology to provide meaningful clinical and therapeutic advantages over other existing dosage forms and, in turn, to improve the lives of patients and caregivers. PharmFilm is protected by our patent portfolio, which currently includes at least 110 issued patents worldwide, of which at least 28 are U.S. patents, and more than 150 pending patent applications worldwide. Several of the patents in this intellectual property portfolio are utilized in each of our proprietary pipeline products and certain of these patent and patent application cover non-film applications (topical). We are continuing to develop additional intellectual property and know-how related to the applications and engineering of PharmFilm alone or in combination with other technologies to create product capabilities that have compelling value propositions.

PharmFilm is comprised of proprietary polymer compositions that serve as film formers to APIs and excipients in place. Proprietary and patent-protected compositions, formulations and manufacturing techniques and technology are employed to ensure that the API is distributed uniformly throughout the film and that target absorption levels are achieved. Our proprietary technology and manufacturing processes enable PharmFilm to be engineered to fit a variety of target product profiles in order to best address unmet patient needs present within specific disease states. PharmFilm, which is similar in thickness and size to a postage stamp, can be administered via buccal, sublingual or lingual oral delivery.



We believe the innovative nature of our drug delivery platform has the potential to offer a number of meaningful advantages to patients, caregivers and physicians compared to current standard of care therapies, including:

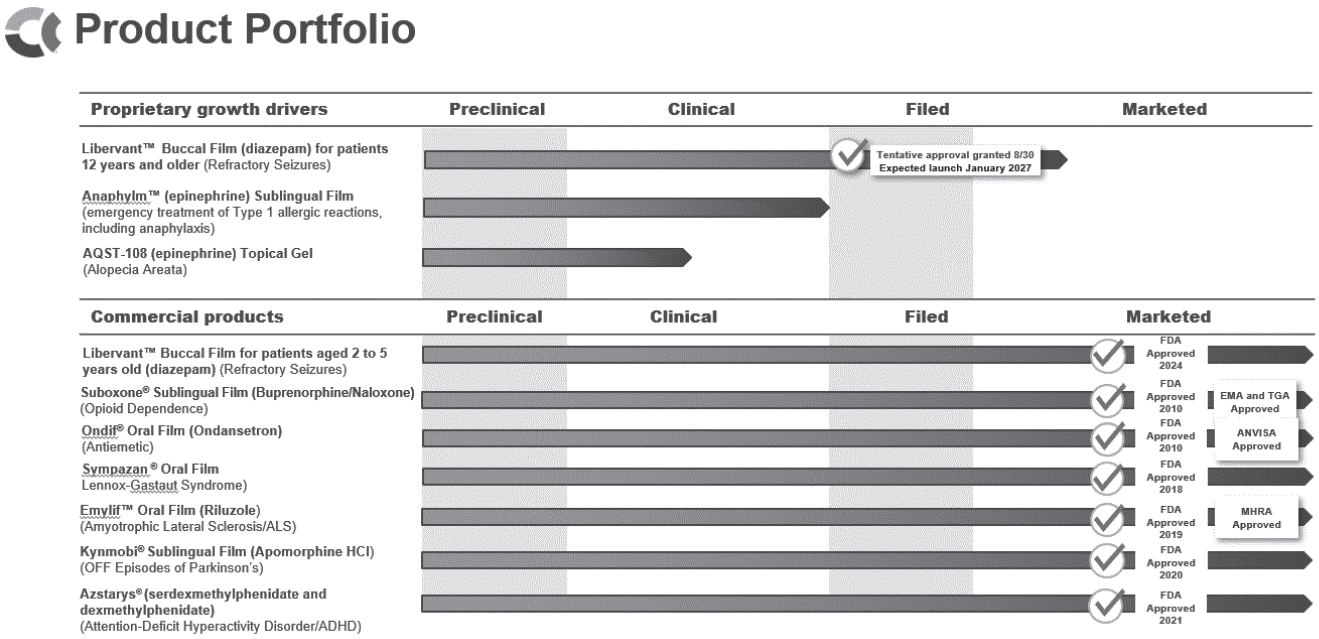
- faster, or at least equivalent, onset of action;
- ease of administration and availability (no device required);
- direct absorption into the bloodstream reducing or avoiding "first pass" effects in the liver;
- reduced gastrointestinal, or GI, side effects;
- positive dosing outcomes, especially for patients with physical (*e.g.*, dysphagia) or psychological barriers to other methods of drug administration;
- stable, durable, portable and quick dissolving (with or without water);
- customizable delivery routes for tailored PK, profiles (buccal, sublingual or lingual); and
- customizable taste profiles.

Adrenaverse™ – Our Epinephrine Prodrug Technology

Our Adrenaverse™ platform contains a library of over twenty epinephrine prodrug product candidates intended to control absorption and conversion rates across a variety of possible dosage forms and delivery sites. Epinephrine plays a critical role in immune suppression but, until now, its role has been limited due to issues in the absorption and conversion of epinephrine in the human body. We believe that our Adrenaverse platform has demonstrated the ability to harness the therapeutic potential of epinephrine through highly differentiated prodrug formulations, which can achieve absorption, provide sustained local exposure and avoid systemic exposure. The Adrenaverse platform makes it possible to deliver epinephrine locally across mucosal surfaces and the skin and, therefore, we believe that it has the potential to yield multiple product candidates focused on treating a range of diseases. The Company's pipeline includes Anaphylm™ (epinephrine) Sublingual Film and AQST-108 (epinephrine) Topical Gel, which are both product candidates emerging from the Company's Adrenaverse epinephrine prodrug platform.

Our Product Portfolio and Pipeline

The following table outlines our proprietary growth drivers and licensed products.



Libervant®, Sympazan®, PharmFilm® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

Proprietary Growth Drivers

Complex Molecule Portfolio

We have developed a proprietary pipeline of complex molecule-based product candidates as alternatives to invasively administered standard of care therapeutics addressing large market opportunities. The active programs in our complex molecule pipeline portfolio are:

- **Anaphylm** (epinephrine) Sublingual Film – the first and only non-device based, orally delivered epinephrine product candidate in development that has shown clinical results comparable to auto-injectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions, including anaphylaxis. Epinephrine is the standard of care in the treatment of anaphylaxis and is typically administered via intramuscular injection (IM), including manual auto-injectors such as EpiPen and Auvi-Q, which require patients or their caregivers to inject epinephrine into the patient's thigh during an emergency allergic reaction. As a result of this route of administration, many patients and their caregivers are reluctant to use injectable products. In August 2024, a nasal spray device was approved by the FDA for the treatment of severe allergic reactions, including anaphylaxis. However, Anaphylm would, if approved by the FDA, allow a patient to simply place a dissolvable strip, approximately the size and weight of a postage stamp, under the tongue, providing an appropriate medication where it is needed and when it is needed.

  The FDA conditionally accepted the proprietary name Anaphylm™ (pronounced "ana-film") as the proposed brand name for Anaphylm. Final approval of the Anaphylm proprietary name is conditioned on FDA approval of Anaphylm, if any.

  On February 24, 2022, following a Phase 1 clinical study conducted by the Company outside of the U.S., the FDA cleared our IND for Anaphylm, allowing for clinical investigation of Anaphylm in the U.S. The FDA confirmed that the 505(b)(2) regulatory approval pathway is acceptable for the development of Anaphylm. The FDA granted Fast Track designation of Anaphylm in March 2022.

  Throughout 2022 and 2023, we reported positive topline data from several clinical studies evaluating multiple oral film formulations and dosage strengths of Anaphylm in healthy adult subjects, including cross over studies comparing the PK and PD of epinephrine delivered via Anaphylm compared to current standards of care, EpiPen and IM injectors. These studies demonstrated that treatment with Anaphylm was well tolerated, with no serious adverse events, significant medical events, or treatment-related severe adverse events reported. The data from these clinical studies formed the basis for the EoP2 meeting with the FDA in December of 2022, which provided clarity as to the FDA's

expectations regarding key clinical program areas for design of revised dosing instructions expected for use in our pivotal clinical trial.

In the fourth quarter of 2023, we received comments from the FDA on the protocol for our pivotal clinical study for Anaphylm, which comments indicated that our proposed endpoints, sample size, and statistical analysis for the proposed pivotal clinical study were reasonable and provided clarity on PK sustainability with repeat-dose requirements. We incorporated the FDA's feedback into the pivotal clinical study design, which study commenced in in the fourth quarter of 2023.

In January 2024, we completed a Type C meeting with the FDA in which the FDA found that we had adequately addressed the FDA's previous concerns noted in the EoP2 meeting, including addressing (1) the impact of any product hold time, (2) the potential for emesis (vomiting), and (3) the impact of potential mouth conditions such as angioedema (swelling), by removing product hold time from the administration instructions and providing additional information on how to characterize emesis in our NDA submission with the FDA. Regarding mouth conditions, the FDA recommended administering Anaphylm after oral exposure to a known allergen and assessing PK performance thereunder. This study replaced our previously planned angioedema study. In those comments, the FDA did not outline any new clinical development requirements for the Anaphylm program. The FDA reserved judgement on the sufficiency of the Anaphylm clinical development program until completion of ongoing and planned studies, the results of which were presented at a pre-NDA interaction with the FDA on November 22, 2024.

In March 2024, we released topline data from our pivotal clinical study for Anaphylm. The two-part, Phase 3, single-center, open-label, randomized study was designed to compare the PK and PD of single and repeat doses of Anaphylm versus single and repeat doses of the IM injection and epinephrine autoinjectors (EpiPen® and Auvi-Q®) in healthy adult subjects. The results of this study demonstrated that the primary endpoint of epinephrine PK biocomparability of the single administration of Anaphylm to the single administration of Adrenalin (epinephrine IM injection) and epinephrine autoinjectors in healthy adult subjects was met, as well as the secondary endpoints, which included evaluating the PK sustainability of Anaphylm following repeat administration and the safety and tolerability of Anaphylm following single and repeat administrations versus epinephrine IM injection and epinephrine autoinjectors.

In June 2024, we reported positive topline PK data from the Company's temperature / pH study of Anaphylm. The single-dose, five-period, randomized crossover study was designed to compare the PK and PD of Anaphylm just after consuming normal water at different temperatures (hot, cold, and room temperature) as well as water of different pHs (acidic- lemon water, and basic- baking soda water). The most consumed beverages, such as soda, milk, coffee, and juice, have acidity between lemon water and normal water. The primary PK parameters were the maximum amount of epinephrine measured in plasma (Cmax) and exposure, or the area under the curve (AUC), at predefined time points after dosing, in 30 healthy adult subjects. Topline PK and PD data from the study showed no statistically significant difference in PK and PD results between the different groups based on temperature and pH variability in the mouth.

In July 2024, we reported positive topline data from the self-administration PK study of Anaphylm. The single-dose, three-period, randomized crossover study was designed to compare the PK and PD of Anaphylm self-administered, Anaphylm healthcare provider (HCP)-administered, and Adrenalin IM injection HCP- administered. The primary PK parameters were the Cmax and the AUC exposures, at predefined time points after dosing in 36 healthy adult subjects. The median time to maximum concentration (Tmax) was 15 minutes for both the Anaphylm self-administered and HCP-administered arms, while the median Tmax for the Adrenalin IM injection HCP-administered arm was 50 minutes post-administration. Also, there was no statistical difference between the Anaphylm self-administered and HCP- administered arms of the study based on a comparison of epinephrine exposures across the first 60 minutes post-administration. Topline PD data from the study showed no difference in the median increase in systolic blood pressure, diastolic blood pressure, and heart rate whether Anaphylm was self-administered or HCP-administered.

In October 2024, we reported positive topline data from an oral allergy syndrome challenge study (now referred to as the "OASIS" study), meeting both primary and secondary endpoints. The two-part study demonstrated that Anaphylm's PK and PD profile during allergen-induced oral physiological changes was consistent with its profile without an allergen challenge. In addition, following allergen exposure where 94% of subjects exhibited moderate to severe symptoms per the predefined oral severity score, rapid symptom resolution was observed beginning as early as 2 minutes post-administration. The median time to complete symptom resolution was 12 minutes compared to 74 minutes at screening baseline, with 50% of all symptoms across all subjects resolving by 5 minutes. The mean time of symptom resolution for edema, which affected approximately 25% of subjects, was 5 minutes after Anaphylm administration. The PK profile remained consistent, with median Tmax maintained at 12 minutes and comparable Cmax values between allergen-exposed and non-exposed cohorts. The safety profile was favorable, with all adverse events classified as mild to moderate and resolving without medical intervention.

Also in October 2024, at the ACAAI 2024 Annual Meeting in Boston, we presented results from a subsequent analysis of our pivotal study data demonstrating Anaphylm's consistent PK and PD profile regardless of variable placement or intraoral movement. The analysis showed that 87.5% of subjects maintained consistent film placement during disintegration. In the 12.5% of subjects where movement was noted, there were no significant differences in Cmax and Tmax. These findings further demonstrate that initial placement or subsequent movement of the sublingual film had no impact on epinephrine PK or PD comparability to epinephrine autoinjectors.

On November 22, 2024, we received positive pre-NDA written response feedback from the FDA prior to our planned NDA submission in the first quarter of 2025. The FDA did not indicate in those responses that any additional adult clinical trials would be necessary for submitting the NDA for Anaphylm. In addition, the FDA agreed with our planned NDA content and format for the submission, planned safety evaluation, and planned pediatric trial. The FDA also provided further guidance on additional data views to be included in the planned NDA submission and continued to emphasize its focus on PK sustainability for a single dose. In addition, the FDA requested minor modifications to the pediatric trial protocol which requested modifications were incorporated in the final pediatric trial protocol. Finally, the FDA noted that due to the new route of administration and the data supporting this route of administration, an advisory committee meeting may be necessary prior to FDA approval and we are preparing for this potential request from the FDA.

We commenced the NDA submission to the FDA in the first quarter of 2025. The pediatric study in subjects from the ages of 7 to 17 (weight greater than or equal to 30 kgs) is currently underway and the initial study results appear in line with expectations. We are planning on initiating a product launch of Anaphylm, if approved by the FDA, in the first quarter of 2026. This is based on completing the NDA submission with the FDA in the coming weeks.

- **AQST-108** (epinephrine) Topical Gel – Our product candidate, AQST-108 is composed of the prodrug dipivefrin which is enzymatically cleaved into epinephrine after administration. AQST-108, is a topically delivered adrenergic agonist prodrug, which we believe has the potential to support the re-establishment of immune privilege in the hair follicle and we are pursuing its development for the treatment of alopecia areata, which is an autoimmune disease leading to hair loss on the scalp, face and, in more severe cases, other body areas. We completed the first human clinical trial for AQST-108. The two-part trial was designed to assess the safety and local tolerability of AQST-108. Part 1 was designed as a single ascending dose escalation study to assess the safety and PK of five different dose levels. The 1.0% dose of AQST-108 was chosen based on the down selection from the highest dose to move into the Part 2 study of the development program. In Part 2, three formulations based on excipient variations were evaluated in twelve healthy subjects. In Parts 1 and 2, no serious adverse events or topical adverse events were observed. In Part 2, the calculated percentage of AQST-108 observed in the skin remained consistent across all studied formulations and zero post-dose AQST-108 concentrations in plasma were observed. We received pre-IND FDA feedback in the fourth quarter of 2024 to align on the Phase 2a clinical trial design and plan to open and IND and initiate the Phase 2a clinical trial in the second quarter of 2025.

Proprietary CNS Product

We believe the application of our proprietary PharmFilm® technology is particularly valuable and relevant to patients suffering from certain CNS disorders to meet patients' unmet medical needs and to solve patients' therapeutic problems. Our most advanced asset within our proprietary CNS portfolio, focused in epilepsy, is as follows:

- **Libervant** – a buccally, or inside of the cheek, administered soluble film formulation of diazepam, Libervant was developed as an alternative to device-dependent rescue therapies currently available to patients with refractory epilepsy, which are a rectal gel and nasal sprays.

  On April 26, 2024, the FDA approved Libervant for U.S. market access for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) (or ARS) that are distinct from a patient's usual seizure pattern in patients with epilepsy between two to five years of age. Libervant is the first and only orally administered rescue product for the treatment of seizure cluster in patients between ages two to five. The only other current FDA approved product for these ARS patients between two to five years of age is a diazepam rectal gel. In October 2024, Libervant 5mg, 7.5mg, 10mg, 12.5mg and 15 mg for ARS patients between two and five years of age became available through multiple retail distribution channels. Market access activities have broadened coverage. Libervant is available nationwide with retail distribution capabilities in place. For Medicaid patients, Libervant is available in all states. Commercial patient access to Libervant continues to expand based on health plan reviews and Pharmacy Benefit Manager agreements.

  Prior to the FDA approval of Libervant for ARS patients between two to five years, the FDA granted tentative approval in August 2022 for Libervant for the same indication in patients with epilepsy 12 years of age and older, finding that Libervant had met all required quality, safety, and efficacy standards for approval. However, due to an existing FDA regulatory grant of orphan drug market exclusivity for a diazepam nasal spray product sold by another

company for use in ARS patients 6 years of age and older, the FDA determined that Libervant was not yet eligible for marketing in the United States for this patient population of 12 years of age and older. We expect to file for FDA approval for use of Libervant for these ARS patients aged between 6 and 12 years prior to the expiration of the orphan drug marketing exclusivity block of the nasal spray product. As a result of the orphan drug marketing exclusivity granted by the FDA to the nasal spray product, the FDA cannot give final approval for U.S. market access for Libervant for any age group of 6 and above until the expiration or inapplicability of the orphan drug market exclusivity. However, overcoming the orphan drug marketing exclusivity determination is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such market exclusivity and approve Libervant for U.S. market access for this age group of 6 years and older earlier than January 2027, the scheduled date for expiration of orphan drug market exclusivity for the FDA nasal spray product. See "Licensed Commercial Products, Product Candidates and Other Products – Libervant" for a discussion of the licensing arrangement for Libervant.

In the fourth quarter of 2024 the FDA granted seven years of ODE to Libervant® (diazepam) Buccal Film for ARS patients between two to five years of age. Libervant was originally granted Orphan Drug Designation on November 10, 2016 and the ODE now granted to Libervant for patients ages two to five extends to April of 2031.

On February 14, 2025, in a lawsuit brought by Neurelis, Inc. ("Neurelis") against the FDA (Neurelis, Inc. v. Califf, for which the Company joined as a Defendant Intervenor) challenging the FDA's approval of Libervant for ARS patients aged between two and five years, the U.S. District for the District of Columbia issued a final appealable order entering a judgment in favor of Neurelis's motion for summary judgement and vacating the FDA's approval of Libervant. The District Court's ruling was not based on grounds of safety or efficacy of Libervant, but rather on the grounds that the law granting ODE to the FDA approved nasal spray Valtoco for patients aged six and older should be interpreted to extend to children aged two to five, despite that Valtoco was not approved by the FDA to treat these younger patients. The Company is appealing this ruling and has filed a motion to stay the court's ruling pending the outcome of the appeal. The Company is continuing to market and sell Libervant in the ordinary course, pending a final non-appealable ruling in this matter.

On February 24, 2025, Aquestive filed a request with the FDA that the FDA also confirms approval of Libervant for ARS patients aged between two and five years on the FDA regulatory grounds of clinical superiority over the other currently existing FDA approved ARS drugs, including confirming the FDA grant of ODE for Libervant for ARS patients aged between two and five years. FDA's orphan drug regulations define a "clinically superior" drug as "a drug shown to provide a significant therapeutic advantage over and above that provided by an approved orphan drug (that is otherwise the same drug)" in one of three ways: the basis of greater efficacy or safety, or providing a major contribution to patient care.

While the Company is not able to determine or predict the ultimate outcome of these proceedings or provide a reasonable estimate or range of estimates of the possible outcome in these matters, the Company intends to vigorously defend against any decision that jeopardizes the on-label patient access to Libervant. See Part II, Item 8. Financial Statements and Supplementary Data, Note 23, Contingencies.

Licensed Commercial Products and Product Candidates and Other Products

Our portfolio also includes other products and product candidates that we have licensed, or will seek to license, or for which we have licensed our intellectual property for commercialization. In the years ended December 31, 2024 and 2023, our licensed product portfolio generated $57,561 and $50,583 in revenue to Aquestive, respectively. Those products include:

- **Suboxone®** – a sublingual film formulation of buprenorphine and naloxone, respectively an opioid agonist and antagonist, that is marketed in the United States and internationally for the treatment of opioid dependence. Suboxone was launched by our licensee, Indivior Inc., or Indivior, in 2010. Suboxone is the most prescribed branded product in its category and was the first sublingual film product for the treatment of opioid dependence. We are the sole and exclusive supplier and manufacturer of Suboxone and have produced over 2.7 billion doses of Suboxone since its launch in 2010. As of December 31, 2024, Suboxone branded products retain approximately 27% film market share as generic film-based products have penetrated this market.
- **Emylif®** – an oral film formulation of riluzole, has been developed by Aquestive for the treatment of ALS. We believe that Emylif can bring meaningful assistance to patients who are diagnosed with ALS and face difficulties swallowing traditional forms of medication. This product was originally approved and marketed in the U.S. under the name Exservan. Exservan was approved by the FDA on November 22, 2019. We submitted a request for voluntary withdrawal of the NDA as the product is no longer marketed in the U.S. and the NDA was officially withdrawn on February 14, 2025.

During the fourth quarter of 2019, we announced the grant of a license to Zambon for the development and commercialization of Exservan in the EU for the treatment of ALS which it markets as Emylif®. Zambon is a multinational pharmaceutical company with a focus on the CNS therapeutic area. Under the terms of the license agreement with Zambon, an upfront payment was paid to Aquestive for the development and commercialization rights of Emylif in the EU, and Aquestive will be paid development and sales milestone payments and low double-digit royalties on net sales of the product in the EU. Zambon is responsible for the regulatory approval and marketing of Emylif in the countries where Zambon seeks to market the product and Aquestive is responsible for the development and manufacture of the product. During the second quarter of 2023, Aquestive received a $0.5 million milestone payment in connection with the first commercial sale in the first country in the licensed territory for Emylif pursuant to the terms of the license agreement with Zambon.

In January 2021, we announced that we granted an exclusive license to MTPA for the commercialization in the United States of Exservan. MTPA is a multinational pharmaceutical company with a focus on patients with ALS. The product was launched by MTPA in June 2021. Under the terms of the MTPA license agreement, Aquestive was the exclusive manufacturer and supplier of Exservan for MTPA in the United States. .In June 2024, the Company and MTPA mutually agreed to terminate the MTPA Licensing Agreement. See Part II Item 8. Financial Statements and Supplementary Data, Note 7, *Material Agreements* for details.

In March 2022, we announced the grant of an exclusive license to Haisco for Haisco to develop and commercialize Exservan for the treatment of ALS in China. Haisco is a China-based public pharmaceutical company. Haisco lead the regulatory and commercialization activities for Exservan in China. Aquestive was the exclusive sole manufacturer and supplier for Exservan in China. Under the terms of the license agreement with Haisco, as amended, Aquestive received a $7.0 million upfront payment in September 2022, and was to receive regulatory milestone payments, double-digit royalties on net sales of Exservan in China, and earn manufacturing revenue upon the sale of Exservan in China. In June 2024, Aquestive and Haisco mutually agreed to terminate the Haisco Agreement. See Part II Item 8. Financial Statements and Supplementary Data, Note 7, *Material Agreements* for details.

- **Ondif®** – an oral soluble film formulation of ondansetron, a 5-HT antagonist, was developed for the treatment of nausea and vomiting associated with chemotherapy and post-operative recovery. Ondansetron is available as branded and generic products as intravenous injections, intramuscular injections, orally dissolving tablets, oral solution tablets, and film. We licensed commercial rights for this product to Hypera in Brazil (which Hypera markets as Ondif). Hypera received approval to market Ondif in Brazil from ANVISA on February 21, 2022. Aquestive manufactures and supplies Ondif to Hypera. This product was originally approved and marketed in the U.S. under the name Zuplenz®. We submitted a request for voluntary withdrawal of the NDA for Zuplenz, as the product is no longer marketed in the U.S. In November 2024, the request for FDA withdrawal of the NDA for Zuplenz was completed.

- **Libervant®** – We entered into the Pharmanovia Agreement with Pharmanovia, effective as of September 26, 2022, pursuant to which we granted Pharmanovia an exclusive license to certain of our intellectual property to develop and commercialize Libervant for the treatment of prolonged or acute, convulsive seizures in all ages in certain countries of the Territory, as defined in the Pharmanovia Agreement, during the term of the Pharmanovia Agreement. Under the Pharmanovia Agreement, Pharmanovia will lead the regulatory and commercialization activities for Libervant in the Territory and Aquestive will serve as the exclusive sole manufacturer and supplier of Libervant in the Territory. We received $3.5 million upon agreement execution. Effective March 27, 2023, we amended the Pharmanovia Agreement to expand the scope of the licensed territory for Libervant to cover the rest of the world, excluding the U.S., Canada and China. Pharmanovia will be responsible for seeking appropriate regulatory approval in the expanded territories. Pursuant to the terms of the Pharmanovia Amendment, we received a non-refundable payment of $2.0 million from Pharmanovia on execution of the Pharmanovia Amendment.

- **Sympazan®** – an oral soluble film formulation of clobazam used for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut syndrome, or LGS, in patients aged two years of age or older, was approved by the FDA on November 1, 2018. We commercially launched Sympazan in December 2018. On October 26, 2022, we entered into a License Agreement with Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc., pursuant to which we granted an exclusive, worldwide license of its intellectual property for Sympazan to Assertio during the term of that agreement for an upfront payment of $9.0 million. Additionally, we subsequently received from Assertio a $6.0 million milestone payment upon its receipt of a notice of allowance from the United States Patent and Trademark Office of its patent application U.S. Serial No. 16/561,573, and payment of the related allowance fee. Aquestive is the exclusive sole manufacturer and supplier of Sympazan for Assertio and will receive manufacturing fees from Assertio for the product through the expiration of such License Agreement.

- **KYNMOBI®** – a sublingual film formulation of apomorphine, which is a dopamine agonist, was developed to treat episodic off-periods in Parkinson's disease. We licensed our intellectual property to Cynapsus Therapeutics, Inc., a company that was acquired by Sunovion for the commercialization of KYNMOBI under the Sunovion License

Agreement. KYNMOBI was approved by the FDA on May 21, 2020 and commercially launched by Sunovion in September 2020. On November 3, 2020, we entered into the Monetization Agreement. Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI. In June 2023, Sunovion announced that it had voluntarily withdrawn KYNMOBI from the U.S. and Canadian markets. See Part II Item 8. Financial Statements and Supplementary Data, Note 17, *Sale of Future Revenue* for details.

- **Azstarys®** – an FDA-approved, once-daily product for the treatment of ADHD in patients age 6 years or older. AZSTARYS consists of serdexmethylphenidate, a prodrug of d-methylphenidate (d-MPH), co-formulated with immediate release d-MPH. In March 2012, we entered into an agreement with Zevra (formerly KemPharm, Inc.) to terminate a Collaboration and License Agreement entered into by the Company and Zevra in April 2011. Under this termination arrangement, we have the right to participate in any and all value that Zevra may derive from the commercialization or any other monetization of KP-415 and KP-484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving Zevra and collaborations, royalty arrangements, or other transactions from which Zevra may realize value from these compounds, including the product Azstarys. On March 2, 2021, Zevra announced FDA approval of Azstarys for the treatment of ADHD. Pursuant to the terms of the March 2012 agreement with Zevra, we began to receive milestone and royalty revenues for Azstarys. See Part II Item 8. Financial Statements and Supplementary Data, Note 7, *Material Agreements* for details.

Market Overview

Anaphylaxis

Anaphylaxis is a severe systemic allergic reaction that can be triggered by certain foods, medications, insect stings and latex, among other allergens. Signs and symptoms of anaphylaxis typically occur within seconds or minutes of exposure and may include low blood pressure, skin rash or itching, constriction of the airway and difficulty breathing and nausea and vomiting. If not treated immediately, anaphylaxis can lead to death due to airway restriction or cardiac arrest. Anaphylaxis is a potentially life-threatening systemic allergic reaction, with an estimated incidence of 50 to 112 episodes per 100,000 people per year. An international study found that hospital admissions for anaphylaxis have increased over a 15-year study period. The most common causes of reactions that can include anaphylaxis are medications, foods (such as peanuts), and venom from insect stings. Because anaphylaxis can progress quickly, the ability to administer a reliable and accurate dose of epinephrine as quickly as possible following a reaction is critical for patient recovery and survival.

Treatment of anaphylaxis typically consists of an intramuscular injection of epinephrine administered at the earliest opportunity, followed by additional intramuscular or intravenous injections as needed. A generic form of epinephrine auto-injector (brand form EpiPen) is the leading self-administered form of epinephrine. People with known allergies and who are at risk for anaphylaxis are advised to carry two epinephrine auto-injectors with them at all times and self-administer at the first signs of an anaphylactic reaction. Auto-injectors can be inconvenient to transport and many patients and caregivers dislike injections as a delivery method. In August 2024, a non-injection-based epinephrine delivery device, *Neffy*®, was approved by the FDA and EMA for the treatment of severe allergic reactions, including anaphylaxis, and is in the early phase of its commercial launch.

Proper dosing and the ability to effectively administer epinephrine in a timely, reliable manner is critical for patients experiencing anaphylaxis. However, we believe that the inability to administer complex molecules via oral administration has limited the development of treatments that have the potential to provide significant patient benefit. We designed Anaphylm, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine, as a rescue medicine for the treatment of anaphylaxis, using Aquestive's proprietary PharmFilm technologies. We believe there is a significant market opportunity for a non-injectable, device-free, easier to administer product with a fast onset of action. A product with this profile could enable patients to conveniently and rapidly self-administer a reliable and accurate dose of epinephrine during an anaphylactic reaction, which we believe will improve patient compliance. Subject to our achieving regulatory approval of this product candidate, which we cannot assure, we believe Anaphylm has the potential to reduce the treatment burden currently associated with intramuscular injections and may lower costs to the healthcare system associated with anaphylaxis, due to inaccurate or untimely dosing.

Epilepsy

Epilepsy is a chronic CNS disorder characterized by recurrent seizure activity. There are 3.4 million people in the United States suffering from epilepsy. According to Symphony Health data, antiepileptic medications generated billions of dollars of sales in the United States in 2022. The direct (medical) and indirect (lost wages and productivity) annual costs associated with epileptic patients in the United States are significant.

Epilepsy treatment regimens typically consist of chronic and acute management therapies. Chronic medicines are used on a daily basis to suppress seizure activity. Approximately 1.1 million of those suffering from epilepsy will continue to suffer

with breakthrough seizures and may require an acute (rescue) management strategy. Patients are routinely prescribed antiepileptic drugs, or AEDs, as "maintenance" therapy to control chronic seizure activity. Most AEDs specifically target neuronal excitation or neuronal inhibitory pathways. Patients are routinely prescribed benzodiazepines as "rescue" therapy for the management of acute seizure emergencies.

Rescue therapies are administered as needed in the event of an acute seizure to rapidly terminate seizure activity. One of the most effective benzodiazepines currently available for the treatment of acute seizures is diazepam. Diazepam has historically been marketed as a product administered rectally and more recently, a nasal spray product was introduced to the market for patients ages 6 years and up. Rectal administration of this drug presents a particular challenge for patients. We developed our product candidate Libervant as an alternative to the device-dependent rescue therapies currently available to patients with refractory epilepsy and Libervant® is currently available for patients between ages two to five. See "Our Product Portfolio and Pipeline" above and "Competition" below in this Item 1. Business of this Form 10-K for additional information concerning the Libervant FDA approval process and market access issues.

There are multiple epileptic syndromes including LGS, which is a rare, intractable form of epilepsy. Patients with LGS are often drug resistant, predisposing them to recurrent seizures, and are typically prescribed a combination of antiepileptic medications, which often includes clobazam. Clobazam (branded name Onfi) is available in both a tablet and suspension formulation. Generic versions of the clobazam tablet and suspension formulation are available to patients, as well. Sympazan was developed as an alternative to these other routes of administration of clobazam.

Manufacturing and Product Supply

We operate two manufacturing and primary packaging facilities located in Portage, Indiana, where we currently manufacture our licensed products, Suboxone, Emylif, Ondif and Sympazan, and our proprietary product, Libervant for patients between two to five years of age, on an exclusive basis. These facilities are expected to have a combined capacity to accommodate the production of our proprietary product pipeline candidate and licensed products, without any current need for additional infrastructure. In 2022, we completed work to expand our manufacturing capabilities to include serialization and secondary packaging. This expansion allows us to support our existing and possible future business collaborations more broadly. With the cGMP facilities in Indiana, we will continue to explore possible additional manufacturing efficiencies in 2025. We will also continue to consider our anticipated facilities and infrastructure needs as our product development grows. We have produced over 1.0 billion doses in the last five years. The cGMP manufacturing operations in Indiana are registered with the DEA for Schedule II - V.

We are subject to various regulatory requirements, such as the regulations of the FDA, the DEA, the EU, ANVISA and other foreign health authorities such as the TGA. We are required to register our facilities and adhere to cGMP standards. These standards require manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing process. Our facilities have undergone inspections by the FDA, DEA, TGA, and several quality assurance inspections by pharmaceutical companies for cGMP compliance. In each case, the facilities have passed inspection and are subject to periodic re-inspection. Failure to comply with these and other statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Adverse events with the product or product complaints must be reported and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

We purchase our raw materials, including active pharmaceutical ingredients, from qualified, approved vendors both domestically and internationally. Whenever possible, we continue to pursue a multi-supplier strategy for critical raw materials, where available or appropriate. Our product packaging foil is supplied by a single manufacturer. Such manufacturer utilizes multiple manufacturing facilities for production of our packaging foil. We may continue to enter into more formal supply agreements in the future as production volumes increase and are more predictive.

Subject to the supervision of our internal clinical operations, we use third-party CROs to administer and conduct many aspects of our planned clinical trials including monitoring and managing data, and we will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. We intend for such CROs to play a significant role in the subsequent collection and analysis of data from such trials.

Competition

We compete with pharmaceutical and biotechnology companies that develop and commercialize therapeutics for the treatment of a broad range of disease areas and indications. Additionally, we compete with companies that utilize advanced drug administration platforms, such as oral, injectable, intranasal, transdermal patch and pulmonary delivery, to create improved therapeutics over current standards of care. This industry is highly competitive and new products and technologies evolve and come to market at a rapid pace. The companies operating in this market include multinational organizations,

established biotechnology companies, single product pharmaceutical and biotechnology companies, specialty pharmaceutical companies, and generic drug companies. Many of the larger, established organizations currently have commercialization capabilities in-house, and may have partnership or license agreements in place with smaller companies for commercialization rights. These companies may develop new drugs to treat the indications that we target or seek to have existing drugs approved for the treatment of the indications that we target.

We will compete with commercialized products in all markets for which we have approval and are seeking approval.

The biotechnology and pharmaceutical industries are characterized by rapid evolution and advancements of technologies, intense competition and strong defense of intellectual property. Any products and product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products and the ease of use and effectiveness of any companion diagnostics. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products.

Anaphylaxis

We expect that, if approved by the FDA, Anaphylm would compete with several existing products and other product candidates that target Type I allergic reactions. Among these are needle device-based treatments that have been accepted as standard of care treatment for many years, including autoinjectors such as EpiPen® marketed by Teva, and generics of EpiPen marketed by Viatris, Inc., Adrenaclick® marketed by Amneal Pharmaceuticals, LLC, and Auvi-Q® marketed by Kaleo Inc. and syringe device Symjepi® marketed by US Worldmeds. In August 2024, ARS Pharmaceuticals, Inc. announced its product *Neffy*®, a nasal spray epinephrine delivery device, was approved by the FDA and EMA for the treatment of severe allergic reactions, including anaphylaxis. Subsequently, ARS announced a licensing agreement with ALK-Abello A/S to commercialize *Neffy* in Europe, Canada and other territories outside of the United States. *Neffy* is currently marketed and available to patients in the U.S. There are other non-needle device based treatments in earlier phases of development that have not yet been approved for marketing in the United States by the FDA.

Anaphylm is the first and only orally delivered epinephrine product candidate in development to demonstrate clinical results comparable to autoinjectors such as EpiPen and Auvi-Q for the emergency treatment of allergic reactions, including anaphylaxis. We believe Anaphylm is well positioned as a non-device based treatment option for this indication, if approved by the FDA, due to its comparable efficacy to existing auto-injector and nasal spray products, easy portability and convenience of use.

Epilepsy

On January 10, 2020, a competitor of Aquestive obtained FDA approval of its diazepam nasal spray drug candidate, Valtoco, and was granted orphan-drug-exclusivity for this drug commencing as of January 10, 2020. A company that obtains FDA approval for a designated orphan drug receives orphan market exclusivity for that drug for the designated indication for a period of seven years from the grant date in the United States. This orphan drug exclusivity approval prevents a subsequent product seeking FDA approval from being marketed in the United States during the exclusivity period for the same active moiety for the same orphan drug indication except in the case where the drug candidate sponsor is able to demonstrate, and the FDA concludes, that the later drug is "clinically superior" to the approved products (*e.g.*, safer, more effective, or providing a major contribution to patient care) within the meaning of FDA regulations and guidance. In assessing whether a drug candidate sponsor has demonstrated that its drug candidate provides a "major contribution to patient care" over and above the currently approved drugs, which is evaluated by the FDA on a case by case basis, there is no single objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses, and potential for self-administration.

In August 2022, the FDA granted tentative approval for Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) (or ARS) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. The FDA concluded that Libervant had met all required quality, safety, and efficacy standards for approval. However, as a result of the orphan drug marketing exclusivity previously granted by the FDA to a nasal spray product, the FDA cannot give final approval for U.S. market access for Libervant for any age group of 6 years and above until the expiration or inapplicability of the orphan drug market exclusivity scheduled to occur in January, 2027. Due to this existing FDA regulatory grant of orphan drug market exclusivity, the FDA determined that Libervant was not yet eligible for marketing in the United States for this patient population of 12 years of age and older. We expect to file for FDA approval of these epilepsy patients aged between 6 and 12 years prior to the expiration of the orphan drug marketing exclusivity block of the nasal spray product.

In September 2023, the FDA accepted Aquestive's NDA for Libervant (diazepam) Buccal Film for ARS patients between two and five years of age. On April 26, 2024, the FDA approved Libervant for U.S. market access for ARS patients between two and five years of age. Libervant is the first and only orally administered rescue product for the treatment of ARS patients between ages two and five years. The only other current FDA approved product on the market for these epilepsy patients between two and five years of age is a diazepam rectal gel. On December 18, 2024 the FDA granted seven years of ODE to Libervant for the treatment of ARS patients between two and five years of age.

In October 2024, Libervant 5mg, 7.5mg, 10mg, 12.5mg and 15 mg for ARS patients between two and five years of age became available through multiple retail distribution channels. Market access activities have broadened coverage. Libervant is available nationwide with retail distribution capabilities in place. For Medicaid patients, Libervant is available in all states. Commercial patient access to Libervant continues to expand based on health plan reviews and Pharmacy Benefit Manager agreements.

On February 14, 2025, in a lawsuit brought by Neurelis, Inc. ("Neurelis") against the FDA (*Neurelis, Inc. v. Califf,* for which the Company joined as a Defendant Intervenor) challenging the FDA's approval of Libervant for ARS patients aged between two and five years, the U.S. District for the District of Columbia issued a final appealable order entering a judgment in favor of Neurelis's motion for summary judgement and vacating the FDA's approval of Libervant. The District Court's ruling was not based on grounds of safety or efficacy of Libervant, but rather on the grounds that the law granting ODE to the FDA approved nasal spray for ARS patients aged six and older should be interpreted to extend to children aged two to five, despite that Valtoco was not approved by the FDA to treat these younger patients. The Company is appealing this ruling and has filed a motion to stay the court's ruling pending the outcome of the appeal. The Company is continuing to market and sell Libervant in the ordinary course, pending a final non-appealable ruling in this matter. See Part II, Item 8. Financial Statements and Supplementary Data, Note 23, *Contingencies.*

Material Agreements

More details regarding material agreements are described in Part II, Item 8. Financial Statements and Supplementary Data, Note 7, *Material Agreements*.

Intellectual Property

We currently seek, and intend to continue seeking, patent protection whenever commercially reasonable for any patentable aspects of our product candidates and related technology or any new products or product candidates we acquire in the future. Where our intellectual property is not protected by patents, we may seek to protect it through other means, including maintenance of trade secrets and careful protection of our proprietary information.

Patents

Our patent portfolio currently comprises at least 110 issued patents worldwide, of which at least 28 are U.S. patents, and more than 150 pending patent applications worldwide. These issued patents and pending patent applications provide both process of making and composition of matter protection for our PharmFilm technology and products and product candidates, including Suboxone, Libervant and Anaphylm and our PharmFilm formulations of diazepam, clobazam, riluzole and epinephrine. These patents and, if issued as patents, pending patent applications will likely expire between 2024 and 2044. The pending patent applications will provide composition of matter and process of making protection for our PharmFilm dosage formulations of diazepam and epinephrine and, if issued as patents, will likely expire by 2040 and 2044, respectively. The projected expiration dates exclude any patent term adjustment or patent term extension.

PharmFilm – Our Oral Film Technology

Our PharmFilm technology is covered by at least 12 patent families. These patent families provide process, composition of matter protection for our PharmFilm technology, and comprise at least 49 issued patents worldwide, of which at least 12 are U.S. patents, and related pending patent applications worldwide. The patents and pending patent applications, if issued as patents, will likely expire between 2024 and 2044, excluding any patent term adjustment or patent term extension.

The PharmFilm technology patents and/or patent applications also generically and specifically protect the technology utilized in the products in our CNS programs, our complex molecule programs, as well as our licensee programs. For example, encompassed within our platform technology patents and/or patent applications is specific coverage directed to PharmFilm dosage formulations of CNS molecules such as diazepam. Also encompassed within our platform technology is coverage for our complex molecule program which includes molecules such as epinephrine and technology applicable to our product candidate Anaphylm. Our platform technology patents and/or patent applications further cover the products Libervant, Suboxone and Ondif, as well as our formulations of the molecules apomorphine, which is part of our licensed programs. The expiration dates for patents covering PharmFilm products and product candidates, and for pending applications if issued as patents, extend from 2024 to 2044, excluding any patent term adjustment or patent term extension.

We note that several of our issued patents are or have been involved in administrative proceedings, such as reexamination and inter partes review at the U.S. Patent and Trademark Office, or USPTO, and opposition at the European Patent Organization, or EPO.

Certain of our patents and patent applications, if granted, will be published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA or a 505(b)(2) NDA. If any of these potential generic competitors claim that their product will not infringe our listed patents, or that such patents are invalid, then they must send notice to us once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. We may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification, which would automatically prevent the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

The rest of our patent portfolio largely relates to patents and applications owned by us and directed to our product development portfolio and other product candidates and related compositions and/or manufacturing processes.

Trade Secrets and Other Proprietary Information

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our colleagues, consultants and other advisors to execute confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances, nor used outside the scope of their employment. In the case of our colleagues, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions. Further, we generally require confidentiality agreements from third parties that receive our confidential information. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Trademarks

We also rely on trademarks to develop and maintain our competitive position. Our trademarks or registered trademarks are filed in the United States and other select geographical areas.

Regulatory

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of product from the market, injunctions, fines, civil penalties and criminal prosecution.

FDA approval is required before any new drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's GLP regulations;
- submission to the FDA of an IND, application for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent IRB at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's current cGMP regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- satisfactory completion of a potential review at a public FDA Advisory Committee meeting; which is a meeting of independent outside experts that provide advice and recommendations to the FDA; and

- FDA review and approval of the NDA.

The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including current GLP. The results of preclinical testing are submitted to the FDA as part of an IND application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development. Further, an independent IRB, covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator in accordance with GCP requirements, which includes the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials.

For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

Phase 1 In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

Phase 2 Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.

Phase 3 Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and applicant under an approved NDA is also subject to an annual program fee for each prescription drug product, which beginning in Fiscal Year 2018 replaced the product and establishment fees.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under PDUFA, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system,

Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. The FDA will not approve the product unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities and possibly conducts a sponsor inspection, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The review by the FDA is two months for a Class I resubmission and six months for a Class 2 resubmission. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess whether the REMS plan is effective. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, or problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Ongoing adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs and NDA specifications after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and obtain licenses from certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs or other applicable laws, such as adverse event recordkeeping and reporting. Accordingly, manufacturers must continue to expend time, money, and training and compliance efforts in the areas of production and quality control to maintain compliance with cGMPs or other applicable laws, such as adverse event recordkeeping and reporting requirements. Regulatory authorities may require remediation, withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems or new concerns are subsequently discovered. In addition, other regulatory action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, civil penalties, and criminal prosecution may be pursued.

In addition, any distribution of prescription drug products must comply with the PDMA, a part of the FDCA. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the DSCSA has imposed new "track and trace" requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the

drug supply chain. These requirements are being phased in over a ten-year period. The DSCSA ultimately will require product identifiers (*i.e.*, serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug "pedigree" requirements under the PDMA and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes new requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by the FDA pursuant to the DSCSA. Until the FDA promulgates regulations to address the DSCSA's new national licensing standard, current state licensing requirements typically remain in effect.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Amendments established abbreviated FDA approval procedures for drugs that are shown to be equivalent to drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by submitting an ANDA to the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (i) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (ii) such patent has expired; (iii) the date on which such patent expires; or (iv) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference drug NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent related exclusivity, during which the FDA cannot review, or in some cases, approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a company may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation of a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Orphan Drug Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat rare diseases or conditions, the FDA will grant orphan designation for that product for the orphan disease indication. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation provides manufacturers with research grants, tax credits and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. If a drug designated as an orphan product receives marketing approval for an indication broader than the orphan indication for which it received the designation, it will not be entitled to orphan drug exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, we may still be subject to competition. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the United States, we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the Federal Anti-Kickback Statute, the Federal False Claims Act, and other state and federal laws and regulations. The Federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid.

The Federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent,

claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the Federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $10,000 and $25,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the Federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. In addition, private individuals can bring actions under the Federal False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

HIPAA also expanded and created several additional federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.

There are also an increasing number of state laws with requirements for manufacturers and/or marketers of pharmaceutical products. Some states require the reporting of expenses relating to the marketing and promotion of drug products and the reporting of gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the reporting of certain pricing information, including information pertaining to and justification of price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, Massachusetts and the District of Columbia require pharmaceutical companies to implement compliance programs and/or marketing codes. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives and teaching hospitals made in the previous calendar year. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

The Physician Payments Sunshine Act, implemented as the Open Payments Program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the previous calendar year and other transfers of value to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

In addition, HIPAA, and its implementing regulations impose certain obligations on entities subject to the law, such as health plans and most healthcare providers, and their business associates who provide certain services involving the use or disclosure of HIPAA protected health information on their behalf, with respect to the privacy and security of such protected health information. Further, most states have enacted laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

Compliance with such laws and regulations requires substantial resources. In addition, because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities in the past could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices did not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and individual imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Further, we may be subject to contractual damages and reputational harm as result of such non-compliance. Even if we are not determined to have

violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

International Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. In the European Union, or EU, we may seek marketing authorization under either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization issued by the European Commission following a favorable opinion by the EMA that is valid across the EU, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: the decentralized procedure and the mutual recognition procedure. Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country for medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following a national authorization, the applicant may seek further marketing authorizations from other EU countries under a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, medicinal products designated as orphan products benefit from financial incentives such as reductions in marketing authorization application fees or fee waivers and 10 years of market exclusivity following medicinal product approval. For a medicinal product to qualify as orphan: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than five in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

United States Healthcare Reform

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, PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacted the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients who have reached the “catastrophic coverage” out-of-pocket limit under the Medicare Part D prescription drug program, rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service’s 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes impacted existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Some states have elected not to expand their Medicaid programs to individuals with an income of up to 133% of the federal poverty level, as is permitted under the PPACA. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products for which we receive regulatory approval,

business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the PPACA, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. While the United States Supreme Court has generally upheld the constitutionality of the PPACA, cases challenging its legal and constitutional validity continue to be heard by the Supreme Court. Executive Orders have been issued and repealed by successive presidential Administrations, making it uncertain what fiscal burdens might be placed on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices at any given time. In each session of Congress, bills have been introduced that might significantly expand, revise or repeal the PPACA. It is unclear whether the PPACA will be overturned, repealed, replaced, or further amended.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the Inflation Reduction Act of 2022 ("IRA"), signed into law by President Biden, included a number of significant drug pricing reforms, which include the establishment of a drug price negotiation program within the HHS (beginning in 2026) that requires manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation, and a redesign of the Part D benefit, a part of which requires manufacturers to provide discounts on Part D drugs starting in 2025. Congress has further indicated that they will continue to pursue new legislative and/or administrative measures to control drug costs, including price or patient reimbursement constraints, discounts, restrictions on certain access and marketing cost disclosure and transparency measures, and, in some cases, laws designed to encourage importation from other countries and bulk purchasing.

Each recent presidential administration has enacted and repealed Executive Orders that have impacted prescription drug prices. In his first term, President Trump enacted Executive Orders directing the Secretary of HHS to eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions, ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries, allow certain low-income individuals purchase insulin and epinephrine, and implement a rulemaking plan to test a payment model, pursuant to which Medicare would receive most-favored-nation prices (*i.e.*, the lowest price) for certain pharmaceutical products. President Biden enacted Executive Orders to, among other things, reduce barriers to the PPACA marketplace, increase the affordability of the marketplace and increase eligibility for and coverage from the marketplace and Medicaid. On the first day of President Trump's second term, he revoked many of President Biden's Executive Orders, including such Orders impacting Medicaid and the PPACA. It is difficult at this time to predict what future executive or legislative initiatives may impact drug pricing.

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 and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of products for which we receive regulatory approval or to successfully commercialize our product candidates, if approved.

Coverage and Reimbursement

The commercial success of our products and product candidates, if and when approved, is partially dependent on the availability of coverage and adequate reimbursement from public (*i.e.*, federal and state government) and private (*i.e.*, commercial) payors. These third-party payors may deny coverage or reimbursement for a product or therapy, either in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors will continue to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms, and the amount of reimbursement for particular procedures or drug treatments.

As discussed above, the cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will continue to experience pricing pressures, given the trend toward managed healthcare, the increasing influence of managed care organizations, and additional regulatory and legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies, as well as healthcare legislative reforms.

Additionally, discounted pricing or rebates on purchases of pharmaceutical products must be offered under various federal and state healthcare programs, including: the Centers for Medicare & Medicaid Services' Medicaid Drug Rebate Program, Medicare Part B Program and Medicare Part D Manufacturer Discount Programs, the U.S. Department of Veterans

Affairs' Federal Supply Schedule Program, and the Health Resources and Services Administration's 340B Drug Pricing Program. Specific prices must be reported to government agencies under healthcare programs, such as the Medicaid Drug Rebate Program. The calculations necessary to determine the prices reported are complex and the failure to report prices accurately may expose us to penalties.

Some third-party payors may have cost-containment measures to be adopted or implemented in the future, including any changes to any Medicare reimbursement program, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products and product candidates will be considered medically reasonable and necessary for a specific indication, that our products and product candidates will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products and product candidates, if approved, profitably.

Additional information regarding these programs is discussed under the heading "If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered" in the "Risk Factors" section of this Annual Report on Form 10-K.

Other Regulation

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. While we believe we are in compliance with applicable environmental and other regulations, in each of these areas, as above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Human Capital

As of December 31, 2024, we employed approximately 142 colleagues. All of our colleagues were employed in the U.S. Of these colleagues, 22 are directly involved in research and development, 93 are involved in manufacturing operations, and 27 are involved in business development and general and administrative activities. Our colleagues are not represented by a labor union.

Culture and Colleagues Engagement

We believe that our colleagues are an essential element of our strategy and critical to our continued success. Our corporate values – safety, compliance, collaboration, integrity and high performance are built on the foundation that the colleagues we hire, the steps we use to engage them and the way we treat one another promote the creativity, innovation and productivity that spurs Aquestive's success.

Supporting that philosophy, our management team is responsible for ensuring that our policies and procedures reflect and reinforce our desired corporate culture including policies and procedures related to risk management, ethics and compliance.

We engage advisors to ensure that we design, plan and execute competitive compensation strategies and benefit programs to help us attract and retain a diverse workforce with the appropriate skills and talent that drive the organization's success. We also engage our colleagues in important dialogue regarding organizational performance and reward our colleagues accordingly to create a successful and attractive workplace. We are committed to creating a culture of inclusion in which all colleagues have the opportunity to be heard, make an impact and thrive.

Colleagues' Health, Wellness and Safety

The well-being of our colleagues is a top priority, and we are committed to creating a safe and healthy workplace. We provide ongoing training in support of that commitment.

Environmental Safety

We have few environmental risks but are committed to be part of the global solution. We run environmentally responsible laboratory waste collection, recycling and disposal programs. We educate and encourage our colleagues to be environmentally responsible. As of December 31, 2024, we were in compliance with government and environmental regulations.

Available Information

We file with or submit to the SEC our annual, quarterly, periodic and current reports, proxy statements and other information meeting the informational requirements of the Exchange Act. We make available, free of charge, on our website our proxy statement, annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports and other publicly filed information available as soon as reasonable practicable after we electronically file such material with, or furnish it to the SEC. Our Internet address where these documents and other information can be found is https//aquestive.com. Information contained on our website is not incorporated by reference into this Annual Report, and you should not consider that information to be part of this Annual Report. Our annual, quarterly, periodic and current reports, proxy statements and other public filings are also available free of charge on the EDGAR Database on the SEC's Internet website at www.sec.gov.

Item 1A. Risk Factors

Investing in our common stock involves significant risk and investors should carefully consider the risks described below, together with all other information included or referenced in this Annual Report on Form 10-K. There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. The risks described below are not the only ones we will face. In addition to the other information in this Annual Report on Form 10-K, any of the factors set forth below could significantly and negatively affect our business, financial condition, results of operations or prospects and the trading price of our stock. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements at the beginning of this Annual Report on Form 10-K.

Summary of Risk Factors

Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- we may need to raise substantial funds in the future to fund our operations. These funds may not be available on acceptable terms or at all and our ability to fund the execution of our business objectives cannot be assured. A failure to obtain this necessary capital when needed could force us to delay, limit, scale back or cease some or all operations.
- we have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability;
- we may fail to obtain regulatory approvals to market our products in the United States or in other countries;
- Libervant for ARS patients aged between two and five years being blocked from remaining in the U.S. market due to a competitor's orphan drug market exclusivity status;
- the development of pharmaceutical products involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product;
- if our competitors are better able to develop products for the diagnosis and treatment of diseases of the central nervous system and the treatment for anaphylaxis that are safer, more effective, less costly, easier to use or otherwise more attractive than our PharmFilm technology, our business will be adversely impacted;
- even if our product candidates are approved for commercial sale, if we are unable to develop a sales and marketing infrastructure, we may not be successful in commercializing our products in the United States;
- our ability to commercialize our product candidates will depend in part on the extent to which reimbursement will be available from government and health administration authorities, private health maintenance organizations and health insurers, and other healthcare payors;
- any delays or changes to the timing, cost and success of clinical trials for Anaphylm and our other product candidates;
- failure to generate sufficient data in our PK and PD comparability submission for FDA approval of Anaphylm;
- we have entered into, and may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues;
- we are and will be dependent on third-party CROs to conduct all of our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated and we may not be able to obtain regulatory approval for any of our product candidates;
- our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel;

- our ability to protect our intellectual property and proprietary technology is uncertain;
- we may be subject to damages resulting from claims that we, or our colleagues, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors;
- our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer;
- if we issue more shares of our Common Stock to raise capital, our current stockholders will incur substantial dilution;
- we may be subject to damages resulting from litigation matters currently pending against Aquestive;
- cybersecurity continues to affect businesses and could cause business interruption; and
- adverse developments affecting the financial services industry which could adversely affect our current and projected business operations and our financial condition and results of operations.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Some of our product candidates will require substantial additional development time and resources before we are able to receive regulatory approvals, implement commercialization infrastructure and strategies, or license product out to begin generating revenue from product sales or royalty streams. Our current product candidates are still in their early stages, and we may not generate substantial revenue from sales or royalties of our product candidates in the near term, if ever.

We have devoted most of our financial resources to product development. To date, we have financed our operations primarily through the sale of equity and debt securities, proceeds from our debt facilities, and from revenues from certain product licenses and collaborations. The extent of future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue.

The development, regulatory approval process, and commercialization of drug candidates involve significant risk and significant uncertainty, including matters over which we have no control. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses. We expect to incur substantial expenses going forward, which we expect will increase as we expand our development activities and product portfolio. Some of the expenses we expect to incur going forward include:

- conducting clinical trials of our product candidates;
- seeking regulatory approval for any of our product candidates that successfully complete clinical development;
- maintaining, expanding and protecting our intellectual property portfolio;
- acquiring or in-licensing new technologies or development-stage or approved products;
- activities related to pre-commercialization and commercialization of products;
- adding clinical, scientific, operational, financial, and management information systems personnel, including personnel to support our product development and to support our operations as a public company; and
- experiencing incremental costs due to delays or encountering any issues with any of the above, including, but not limited to, failed or not fully successful trials, complex results, safety issues or other regulatory challenges.

We expect to continue to incur net losses for at least the next few years as we pursue the development efforts and commercialization of our product candidates. Our net losses may fluctuate significantly from period to period, depending on regulatory approval developments concerning our product candidates, the timing of our planned clinical trials and expenditures on our other research and development. We expect our expenses will continue to be substantial in 2025 and future periods as we continue to:

- clinically develop Anaphylm and provide supporting data needed for market approval from the FDA, anticipated NDA submission, pre-commercialization preparations including manufacturing and regulatory inspections and commercialization activities;
- seek licensing and other transactions of our product candidates;
- engage with the FDA to overcome the present stay on Libervant entering the U.S. market due to a competitor's orphan drug market exclusivity status:
- commercialize Libervant for ARS patients between two and five years of age; and
- clinical development of our product candidate AQST-108.

We expect to continue to manage the timing and level of expenses in light of the declining Suboxone revenues, while focusing on the development and commercialization of Anaphylm.

We will need substantial additional capital to fund our operations, which may not be available on acceptable terms, if at all.

Our cash requirements for 2025 and beyond include expenses related to continuing development and clinical evaluation of our products, manufacture and supply costs, costs of regulatory filings, patent prosecution expenses and litigation expenses, expenses related to commercialization of our products, as well as costs to comply with the requirements of being a public company operating in a highly regulated industry. As of December 31, 2024, we had $71.5 million of cash and cash equivalents.

Capital may be available under our ATM facility, which we initially established in 2019, and under which, from time to time, we may offer and sell shares of our Common Stock pursuant to the Amended Equity Distribution Agreement with Piper Sandler & Co.. On April 3, 2024, we filed a new shelf registration statement on Form S-3 (the "2024 Registration Statement"), which was declared effective by the SEC on April 23, 2024. Included in the 2024 Registration Statement are: (i) a base prospectus registering the offer, issuance and sale of up to $250,000 worth of Common Stock, preferred stock, debt securities, warrants, rights and units and (ii) the $100,000 ATM facility prospectus. The remaining authorized balance of the ATM facility was $100,000 as of December 31, 2024. For additional information regarding shares sold under the ATM facility subsequent to December 31, 2024, see Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources and Part II Item 8. Financial Statements and Supplementary Data, Note 24, *Subsequent Events.*

In April 2022, we entered into a Purchase Agreement with Lincoln Park, under which, from time to time, we may cause Lincoln Park to purchase shares of our Common Stock. The Purchase Agreement with Lincoln Park has approximately an equivalent to 6,486,623 shares available for purchase at December 31, 2024. For the years ended December 31, 2024 and 2023, we did not sell shares in connection with the Lincoln Park Purchase Agreement. We have no current intent to use the Lincoln Park facility and the Lincoln Park Purchase agreement will expire on April 12, 2025.

On November 1, 2023, we reduced our debt payment obligations when we issued (the "Offering") $45,000 aggregate principal amount of our 13.5% Notes. A portion of the net proceeds from the Offering was used to redeem all of the outstanding 12.5% Notes and to pay expenses relating to the Offering, with the balance of the proceeds to be used for general corporate purposes. Interest on the 13.5% Notes accrues at a rate of 13.5% per annum and is payable quarterly in arrears on March 30, June 30, September 30 and December 30 of each year (each, a "Payment Date"). The 13.5% Notes are interest only until June 30, 2026, whereupon on such date and each Payment Date thereafter, we will also pay an installment of principal of the 13.5% Notes pursuant to a fixed amortization schedule, along with a portion of an Exit Fee determined as of the applicable date of prepayment, payment, acceleration, repurchase or redemption, as the case may be.

Until we become profitable, if ever, we expect to need to raise significant additional capital in the future through equity or debt issuances, or both, to continue to manage our expenses to extend our capital runway, in order to further the development, and regulatory approval of our products and product candidates, and to conduct our business. We have no committed sources of additional capital, and there can be no assurance that such needed capital or debt financing will be available or available on favorable terms, or at all. We may seek to obtain additional capital in the future through the issuance of our Common Stock, through other public or private equity or debt financings, through potential non-dilutive capital raising events that may result from royalty streams that may be realizable from our licensed products or licensed intellectual property, through collaborations or licensing arrangements with other companies, and through the sale of assets, including product, product candidates, plants or other tangible assets, or by other means, if available. We may not be able to raise additional capital or other funding on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders would experience dilution, and debt financings, if available (and subject to all of the existing restrictions and conditions under our debt instruments) may involve increased restrictive covenants and increased fixed payments or may otherwise further constrain our financial flexibility. We also may seek outlicensing opportunities for our proprietary products and product candidate programs that we currently plan to self-commercialize, including for Libervant and Anaphylm, or explore other potential liquidity options or strategic opportunities. Such strategic opportunities could include asset sales, outlicensing or other monetization opportunities of our proprietary products and product candidates, including Libervant and Anaphylm, although we cannot assure that any of these actions or opportunities would be available or available on available on terms acceptable to us. While an outlicensing of our proprietary products and product candidates, if approved by the FDA, could limit our exposure to the costs of commercialization of the product and provide a potential source of royalty and milestone revenues, the benefit from the potential of additional future value that could result from our independent commercialization of these products and product candidates, assuming a successful launch of our proprietary products and product candidates, if approved by the FDA, would likely be limited. To the extent that we raise additional funds through collaborative or licensing arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensees generally will depend upon our achievement of negotiated development, regulatory and sales milestones. Failure to achieve these milestones may harm our future capital position. In addition, in the event of any such asset sales or outlicensing transactions, the future growth of the Company would be

dependent on continued successful development of our early stage product candidates and/or asset acquisitions or other strategic transactions for the Company.

If adequate funds are not available for our liquidity needs and cash requirements, as and when needed, from the sources referred to above or otherwise, or at all, we would be required to engage in expense management activities such as reducing staff, delaying, significantly scaling back, or even discontinuing some or all of our current or planned research and development programs and clinical and other product development activities, or reducing our future commercialization efforts and otherwise significantly reducing our other spending and adjusting our operating plan, and we would need to seek to take other steps intended to improve our liquidity. We also may be required to evaluate additional licensing opportunities, if any become available, of our proprietary product candidate programs that we currently plan to self-commercialize or explore other potential liquidity opportunities or other alternatives or options or strategic alternatives, including asset sales, although we cannot assure that any of these actions would be available or available on reasonable terms. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing most, if not all, of their investment in Aquestive.

We may sell additional equity, incur debt or raise funds through licensing arrangements to fund our operations, which may result in dilution to our stockholders, impose restrictions on our business or require us to relinquish proprietary rights.

Aquestive has experienced a history of net losses and our accumulated deficits totaled $363.2 million as of December 31, 2024. The net losses and accumulated deficits were partially offset by gross margins from sales of commercialized licensed and proprietary products, license fees, milestone and royalty payments from commercial licensees and co-development parties.

In November 2020, we began utilizing the ATM facility. For the year ended December 31, 2024, we sold 4,557,220 shares which provided net proceeds of approximately $11.8 million, after deducting commissions and other transaction costs of $0.6 million.

On April 3, 2024, we filed the "2024 Registration Statement", which was declared effective by the SEC on April 23, 2024. Included as part of the 2024 Registration Statement are: (i) a base prospectus registering the offer, issuance and sale of up to $250,000 worth of Common Stock, preferred stock, debt securities, warrants, rights and units and (ii) the $100,000 ATM facility prospectus. The remaining authorized balance of the ATM facility was $100,000 as of December 31, 2024. For additional information regarding shares sold under the ATM facility subsequent to December 31, 2024, see Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources and Part II Item 8. Financial Statements and Supplementary Data, Note 24, *Subsequent Events*.

Until such time, if ever, that we can generate sufficient revenue to fully fund our operations, we would need to seek additional capital and cash resources through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the stockholders' existing ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financings may be coupled with an equity component, such as warrants to purchase shares of our common stock, which could also result in dilution of existing stockholders' ownership. The incurrence of additional indebtedness would result in increased fixed payment obligations and could also result in certain increased restrictive covenants (most, if not all, of which currently exist under our existing debt facilities), such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights or sell assets, and other operating restrictions that could adversely impact our ability to conduct our business and continue to result in liens being placed on all of our assets and intellectual property. If we were to default on such indebtedness, we could lose all such assets and intellectual property and our ability to operate our business.

If we raise additional funds through collaborations, or strategic alliance, marketing, distribution or licensing arrangements with third parties, we may need to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us.

Even if we can generate revenues from our operations in the future, our revenues and operating income are likely to fluctuate significantly from year-to-year or quarter-to-quarter and create volatility in our stock price.

Even if we are able to generate future revenues, our results of operations would likely continue to vary significantly from year-to-year and quarter-to-quarter. Variations may result from, among other factors:

- the timing of FDA or any other regulatory approval, delay in any FDA or other regulatory approvals, or failure to obtain any such FDA or other regulatory approvals;
- competitor's product candidates obtaining FDA or other regulatory approval, which may include orphan drug market exclusivity for seven years in the U.S., before our product has received any such regulatory approval and/or orphan drug exclusivity, or obtaining other FDA marketing exclusivity that blocks U.S. market access for our product candidates;
- the timing of process validation for particular product candidates;

- the timing of addressing any additional data required to obtain FDA approval of Anaphylm and delays as a result thereof;
- changes in the timing of and the amount we spend to research, develop, acquire, license or promote new product candidates;
- the timing, amount we spend on, and outcome of our research, development, preclinical studies and clinical trial programs;
- serious or unexpected health or safety concerns related to our products or product candidates;
- the introduction of new branded and generic products by others that render our product candidates obsolete, subject to greater competition or noncompetitive;
- our ability to maintain selling prices and gross margins on our products;
- changes in coverage and reimbursement policies of health plans and other health insurers, including changes to Medicare, Medicaid and similar government healthcare programs;
- our ability to comply with complex governmental regulations applicable to many aspects of our business;
- increases in the cost of raw materials used to manufacture our products and product candidates;
- manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications or current Good Manufacturing Practices;
- timing of revenue recognition related to our collaboration agreements;
- our ability to fund the commercialization of, commence a commercial operation, and actually commercialize our proprietary products and product candidates, if approved by the FDA;
- our ability and the significant cost to protect our intellectual property and avoid infringing the intellectual property of others and any adverse developments in any related legal proceeding or in other legal proceedings of any nature; and
- the outcome and cost of existing or possible future litigation with third parties.

Our level of indebtedness and significant debt service obligations could constrain our ability to invest in our business and make it more difficult for us to fund our operations.

We have substantial debt and substantial debt service obligations. At December 31, 2024, we had an aggregate principal amount of $45.0 million of outstanding indebtedness, represented by the 13.5% Notes. In the future, we will need to raise additional funds.

Because of our indebtedness:

- we may have difficulty satisfying our obligations with respect to our existing indebtedness including the repayment of such indebtedness;
- we may have difficulty obtaining financing in the future (and we have substantial restrictions on incurring any additional indebtedness under our current debt instruments) for working capital, capital expenditures, acquisitions or other purposes;
- we will need to use a substantial portion of our available cash flow to pay interest and principal on our debt, which will reduce the amount of money available to finance our operations and other business activities;
- we may be more vulnerable to general economic downturns and adverse industry conditions;
- if cash flow from revenues from licensed product or collaborative arrangements are insufficient to satisfy our obligations with respect to our existing indebtedness, we may be forced to seek to sell assets (subject to obtaining consent under the Indenture) or seek additional capital, which we may not be able to accomplish on favorable terms, if at all;
- we could be limited in our flexibility in planning for, or reacting to, changes in our business and in our industry in general;
- we could be placed at a competitive disadvantage compared to our competitors that have less debt, less debt restriction or less restrictive debt covenants;
- our failure to comply with the financial and other restrictive covenants in our debt instruments which, among other things, limits our ability to incur additional debt and sell or dispose of assets, could result in an event of default that, if not cured or waived, would have a material adverse effect on our business or prospects; and
- our tangible and intangible assets, including our intellectual property, are subject to first priority liens and may be used to satisfy our outstanding debt.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and potential access to other funding. However, we may not have sufficient funds, and may be unable to arrange for additional

financing, to pay the amounts due under the Indenture and 13.5% Notes or any other debt instruments we may enter into. Failure to make required debt service payments or comply with other covenants under our existing debt facilities or such other debt instruments would result in an event of default and acceleration of amounts due, which would have a material adverse effect on our business, financial condition and results of operations.

We are dependent upon the commercial success of our licensed and proprietary products and other licensing activities to generate revenue for the near future.

Although we are in the process of testing and developing proprietary product candidates and may seek to acquire rights in other approved drugs, we anticipate that our ability to generate revenue and to become profitable in the near future will depend upon the continued commercial success of Sympazan, Suboxone and Azstarys in the U.S., the continued commercial success of Ondif in Brazil and Emylif in the EU, and our ability to commercialize our product Libervant for pediatric patients between two and five years of age. Further, there is no assurance that we will become commercially successful to the extent necessary to become profitable. If our current products are not commercially successful, our ability to generate manufacturing and sale margins and licensing or royalty revenues will be impaired. Without those revenues, our ability to continue planned development initiatives and commercialization efforts would be limited. Due to our dependence on the commercial success of our products, delays or setbacks in the commercial success of any of these products would likely materially adversely affect our business, prospects, results and operations and financial consideration.

A substantial portion of our revenues is derived from a single customer and license and any loss or material reduction in revenues from such significant customer would adversely affect our business.

Historically, a substantial portion of our revenues in each quarter and year has been derived from a single customer and this trend is expected to continue while we continue to develop, seek regulatory approval of and seek to commercialize our proprietary products and product candidates. If revenues from such key customer were to decline significantly, it would materially adversely affect our business, financial condition and results of operations. Indivior accounted for approximately 62% and 80% of our revenues for 2024 and 2023, respectively, and we believe in the future will continue to account for a substantial part of our revenues.

Further, the Indivior License Agreement under which we manufacture and supply Suboxone to Indivior on an exclusive basis, may be terminated should certain causes or events occur. For example, either party to the Indivior License Agreement may terminate the relationship in connection with a material breach by the other party of its contractual obligations. Indivior may also terminate the Indivior License Agreement if the FDA or other applicable regulatory authority declares our manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. In addition, the Indivior Licensing Agreement currently has a one-year term, subject to automatic one-year renewals unless either party provides the other party with twelve months' prior notice of non-renewal. As a result, there can be no assurance that either party will not terminate the Indivior License Agreement either due to any future breach of obligation, other termination cause or event, or notice of non-renewal. Any such termination would have a material adverse impact on our business, results of operations, capital position and prospects.

Although Suboxone has continued to retain meaningful market share, we expect erosion of this sunsetting branded product over time, which will further affect our total revenues and our results from operations.

Indivior is a party to a number of lawsuits alleging Indivior engaged in deceptive and misleading marketing and distribution practices in its distribution and sale of Suboxone and seeking a monetary relief. We cannot assess whether this settlement and disposition will have a material adverse financial impact on our business, prospects, liquidity, financial condition and operating results.

Risks Related to Development and Commercialization of Our Products and Product Candidates

Our business could be adversely affected if Libervant market access for ARS patients between two and five years of age is blocked.

On August 30, 2022, the FDA provided an approvable letter for Libervant that stated that Libervant was not cleared for U.S. market access until the orphan drug market exclusivity for Valtoco, a competing nasal spray product, ends in January 2027. On April 29, 2024, we announced that the FDA approved U.S. market access for Libervant in ARS patients between two to five years of age.

In May 2024, Neurelis, Inc., the maker of Valtoco, filed a complaint in the U.S. District Court for the District of Columbia against the FDA, HHS, and certain government officials. The complaint in this matter alleges that the defendants violated the Administrative Procedure Act by approving Aquestive's NDA for Libervant® for ARS patients aged between two and five years, and asked the court to vacate that approval and enjoin the defendants from approving Libervant for this pediatric patient population until January 10, 2027, the scheduled date for the expiration of the ODE granted for Valtoco by the FDA. Aquestive intervened in the litigation to defend the approval of Libervant for this pediatric patient population. The Company's motion for a stay of the District Court's order granting Neurelis' motion for summary Judgment is pending. The Company also filed an appeal of the District Court's order with the U.S. District Court of Appeals for the District of Columbia. The Company has also submitted a request to the FDA that the FDA determines that Libervant for ARS patients between the ages of two and

five years is clinically superior to the existing FDA approved products. For greater detail, see Part II Item 8. Financial Statements and Supplementary Data, Note 23, *Contingencies* to our financial statements and in Part I Item 1. Business,

If Neurelis prevails on the appeal or the FDA does not make a determination of clinical superiority in favor of Libervant, we may be required to withdraw Libervant from the U.S. market until such time as the ODE expires for Valtoco in January 2027. This would result in significant changes to our business and delay in future revenues to the Company from Libervant.

We cannot be certain that we will be able to successfully develop our product candidates or obtain regulatory approval for our product candidates.

Prior to receiving approval to commercialize any of our drug products, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and/or other regulatory authorities in the U.S. and other countries, that our particular product candidates are both safe and effective. For each drug product, we must demonstrate its efficacy and monitor its safety throughout the process. If development within these parameters is unsuccessful, our business could be harmed, and our stock price could be adversely affected.

We currently have product candidates in preclinical and clinical development. Our business depends primarily on the successful clinical development, regulatory approval and commercialization of our product candidates. Before our product candidates can be marketed, the FDA and other comparable foreign regulatory agencies must approve our applicable NDA or comparable regulatory submissions. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is very uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Further, positive results from earlier stage clinical trials may not be predictive of later clinical trials or other regulatory developments. In addition, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials after achieving positive results in early stage development, and we cannot be certain that we will not face similar setbacks. Also, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. Even after successful completion of clinical testing, there is a risk that the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our submission. We may be asked to provide further justification and evidence to support the application for approval at an FDA Advisory Committee meeting, which requires significant time and resources to prepare. FDA staff, and the public, may also present their own analyses of the clinical trial data, and discuss other issues at an Advisory Committee meeting. FDA Advisory Committees are typically asked to comment on whether they believe there is adequate safety and effectiveness data to support approval. Advisory Committees may also recommend that FDA request additional studies before approval or suggest changes to a product's proposed labeling. Advisory Committees make nonbinding recommendations to FDA. FDA generally follows the recommendations, but is not legally bound to do so. We also face hurdles and setbacks by reason of competitors' drug candidates obtaining FDA or other regulatory approvals, including orphan drug market exclusivity, prior to our obtaining FDA or other regulatory approval of our similar drug candidate. Even if the FDA approves our NDA, we may be unable to successfully commercialize our products and product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to the numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen, and other clinical trial protocols, and the rate of dropout among clinical participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates and, correspondingly, our business and financial prospects, would be materially adversely affected.

It is also possible that the FDA will not approve an application that we may submit, or our product candidates may not obtain appropriate regulatory approvals necessary for us to commence clinical trials for our product candidates. Any delay or failure in obtaining required approvals could have a material adverse effect on our business. This process from development to commercialization can take many years and will likely require the expenditure of substantial resources beyond the proceeds we currently have on hand, without any guarantee or assurance that we will be successful with regulatory approval, or commercial success, of such product candidate.

Even if we obtain approval from the FDA and comparable foreign regulatory authorities for our current and future product candidates, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of that product candidate or any other product candidate that we may in-license, develop or acquire in the future.

If we do not obtain market exclusivity for certain of our products, including orphan drug exclusivity, our business may be harmed.

We have received orphan drug market exclusivity for our drug candidate Libervant for ARS patients aged between two and five years, and may in the future seek market exclusivity for other product candidates, including orphan drug 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, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease for seven years. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation must be requested before submitting an application for marketing approval.

A company that first obtains FDA approval for a designated orphan drug for the designated rare disease or condition receives orphan drug market exclusivity for that drug for the designated disease for a period of seven years in the United States. This orphan drug exclusivity prevents the FDA from approving another application to market a drug containing the same active moiety for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care within the meaning of FDA regulations and guidance. In addition, a designated orphan drug may not receive orphan drug market exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

Even if we receive orphan drug designation for one or more of our drug candidates, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing product candidates. If any of these other pharmaceutical companies obtains approval of an NDA before we are able to receive approval for one or more of our drug candidates with the same active moiety for the same indication, we would be barred from marketing that product in the United States during the seven-year orphan drug exclusivity period, unless we could demonstrate that such drug candidate is clinically superior to the approved products or satisfies one of the other limited exceptions to such orphan drug exclusivity.

Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition or a drug with the same active moiety can be approved for a different indication as currently permitted pursuant to FDA regulations in the United States. 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. In addition, even if we intend to seek orphan drug designation for any of our product candidates or indications, we may never receive such designations or obtain orphan drug exclusivity. See Part II, Item 8. Financial Statements and Supplementary Data, Note 23, *Contingencies.*

Also, overcoming a grant of orphan drug market exclusivity is difficult to establish, with limited precedent. In April 2024 the FDA approved Libervant® (diazepam) Buccal Film, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg, for ARS patients between the ages of two and five years. This FDA approval was recently determined to be granted in error by the U.S. District Court for the District of Columbia in a lawsuit brought by Neurelis, Inc., and there can be no assurance that the Company will be successful in its appeal of this court ruling or that the FDA will grant our current request seeking an FDA determination that Libervant for this young patient population is clinically superior to other FDA approved ARS drugs in order to maintain the exclusive approval of Libervant in this age and indication. Even if we maintain our market access approval of Libervant for this age group in this indication, if we fail to receive U.S. orphan drug market exclusivity for Libervant for this age group in this indication, our ability to prevent competitors from manufacturing, marketing and selling competing products will be materially impaired, and our results of operations and financial condition may be significantly adversely affected.

Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our product candidates.

We may experience delays in our ongoing or future preclinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule. The commencement and completion of clinical trials for our clinical product candidates may be delayed suspended or terminated as a result of many factors, including:

- the FDA disagreeing as to the design, protocol or implementation of our clinical studies;
- the delay or refusal of regulators or IRBs, to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach an agreement on acceptable terms with prospective CROs, and clinical trial sites;

- the inability to enroll or delays in enrolling a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we had expected to be promising;
- reports from preclinical testing of other similar therapies that raise safety or efficacy concerns;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays in establishing the appropriate dosage levels; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

If we experience delays in the commencement or completion of any clinical trial of our product candidates, or if any clinical trials suspended or terminated, our costs may substantially increase and the commercial prospects of our product candidates may be harmed and our ability to generate revenue from sales of any product candidate will be delayed or not realized at all. Significant preclinical study or clinical trial delays also could shorten the period during which we have exclusive rights to commercialize a product candidate or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize a product candidate.

We have limited commercialization experience and may lack the necessary expertise, personnel and resources to successfully commercialize our other product candidates that must first receive regulatory approval, either on our own or together with collaborators.

We rely on our third-party licensees to commercialize our multiple licensed products and to date have only marketed, through our own efforts and with the services of third-party outsourcing vendors, including contract sales personnel, our first self-developed product, Sympazan, launched in December 2018. With the license of Sympazan to Assertio in October 2022, we scaled back many of our commercial operations, including elimination of our sales and marketing force. However, in April 2024, we launched Libervant for ARS patients between two and five years of age. Given our limited history of direct experience in commercializing product candidates, and current limited commercial operations, we have no long-term experience upon which to measure our ability or success in commercializing future product candidates, if approved, or our ability to make predictions about financial results or prospects of any future launches of product candidates, if approved.

Our ongoing commercial strategy for our product candidates involves the development of a commercial infrastructure that spans multiple jurisdictions and is dependent upon our ability to build an infrastructure that is capable of implementing our commercial product launch strategy. The establishment and development of our commercial infrastructure will be expensive and time consuming, and we may not be able to develop our commercial infrastructure successfully or in a timely manner, or at all. Doing so will require a high degree of coordination and compliance with laws and regulations in numerous territories, including in the United States, each state, and other countries in which we do business, including restrictions on advertising practices, enforcement of intellectual property rights, restrictions on pricing or discounts, transparency laws and regulations, and unexpected changes in regulatory requirements and tariffs. If we are unable to effectively coordinate such activities or comply with such laws and regulations, our ability to commercialize our product candidates in the United States and other jurisdictions in which they are or may be available will be materially adversely affected.

We also intend to enter into strategic licenses with third parties to commercialize our product candidates. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to build our own distribution and marketing capabilities or to find suitable licensees for the commercialization of our products and product candidates, if approved, we may have difficulties generating revenue from them and our business, results of operations, financial condition and prospects and the trading price of our stock may be materially adversely affected.

Our success depends upon attaining significant market acceptance of our licensed products and proprietary products and product candidates, if approved, among patients, physicians, pharmacists and the medical community.

It is possible that we may not complete development of our product candidates or obtain regulatory approval for those product candidates. Even if we do complete development and obtain regulatory approval for our product candidates, our product candidates may not gain market acceptance among patients, physicians, nurses, pharmacists, the medical community or third-party payors, which is critical to commercial success. Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including:

- the timing of market introduction of the product candidate as well as competitive products;

- the clinical indications for which the product candidate is approved;
- the potential and perceived advantages of such product candidate over alternative treatments;
- favorable pricing and the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration;
- any negative publicity related to our or our competitors' products that include the same active ingredient;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA-approved labeling; and
- the effectiveness of sales and marketing efforts.

Even if a potential product displays a favorable efficacy and safety profile in clinical trials, market acceptance of the product will not be known until a period of time after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by patients, physicians, nurses, pharmacists, the medical community or third-party payors, we will be unable to generate significant revenues, and we may not become or remain profitable.

In addition, the potential market opportunities for our product candidates are difficult to estimate. Our estimates of the potential market opportunities are predicated on several key assumptions such as industry knowledge and publications, third-party research reports or analyses and other analytical information. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for our product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our revenue from product sales may be limited and we may be unable to achieve or maintain profitability.

Further, we may not be able to hire or contract for a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target for our product candidates in the future. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates, if approved.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and any allegations of our failure to comply with such approved indications could limit our sales efforts and have a material adverse effect on our business.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. 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 the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be materially adversely affected.

While physicians in the U.S. may choose and are generally permitted to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Promotional activities that fail to comply with the FDA's regulations or guidelines may be subject to warnings from, or enforcement action by, these authorities and may cause the FDA to issue warning letters or untitled letters, bring an enforcement actions, suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could materially harm our reputation and our business significantly.

We could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.

We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal action against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract, false or disparaging statements about another company's products or product candidates, or other legal theories. To date we have been subject to a number of claims of this nature. In defending such lawsuits, whether or not they are with or without merit or are ultimately determined in our favor, we would continue to face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our product

candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered the market, which could adversely impact our potential revenue from such product candidates. Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we can. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a product; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies.

Guidelines and recommendations published by government agencies can reduce the use of our products or product candidates.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates. Regulations and guidelines of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products or product candidates or negatively impact our ability to gain market acceptance and market share. For example, Suboxone, which treats opioid addiction, has as one of its active ingredients an opioid, buprenorphine. Revisions to regulations or guidelines suggesting the reduced use of opioid drugs such as buprenorphine could result in decreased use of Suboxone.

We face significant competition from other pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug administration technologies that are more effective than our products or product candidates. In addition, our competitors may file citizen petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2) or other filing pathways.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our products and product candidates;
- the time it takes for our product candidates to complete preclinical and clinical development and receive marketing approval;
- our ability to maintain a good relationship with regulatory authorities;
- our ability to commercialize and market any of our product candidates after receiving regulatory approval;
- the price of our products relative to pricing of branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare and Medicaid;
- our ability to protect intellectual property rights related to our products and product candidates;
- our ability to manufacture on a cost-effective basis for our products and product candidates that receive regulatory approval; and
- acceptance by physicians and other healthcare providers of any of our products and product candidates that receive regulatory approval.

If our competitors' market products that are more effective, safer or less expensive than our product candidates, or that reach the market sooner than our product candidates, our products may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

If we are unable to achieve and maintain coverage and adequate reimbursement from third-party payors for our licensed products or product candidates, if approved, their commercial success may be severely hindered.

Successful commercialization of our licensed products and product candidates, if approved, will depend in part on the extent to which coverage and adequate reimbursement are available from third-party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations, and how quickly such coverage and reimbursement can be obtained, if obtained at all. Third-party payors determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by third-party payors depend upon a number of factors, including, among other things, each third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific condition or disease;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval from third-party payors may be a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data, including results from expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, to each third-party payor. There is no guarantee that we will be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement.

Cost containment is a primary concern of the U.S. healthcare industry and elsewhere as well as for governmental authorities. Third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with third-party payor coverage policies, such as required procedures for cost-effective diagnosis methods and other conditions that must be met before the third-party payor will provide coverage for use of a product. For example, insurers may establish a "step-edit" system that requires a patient to first use a lower price alternative product prior to becoming eligible for reimbursement of a higher price product. Third-party payors also may refuse to reimburse for drugs, procedures and devices deemed to be experimental, or that are prescribed for an unapproved indication. It is also possible that a third-party payor may consider our products or product candidates as substitutable by less expensive therapies and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our products or product candidates, pricing of existing drugs may limit the amount that can be charged for our licensed products or product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on investment in product development. Further, third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Further, some third-party payors challenge the prices charged for medical products and may impose price controls or require that drug companies provide them with predetermined discounts from list prices.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is generally a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the reimbursement available for and the pricing of our product candidates, once approved, which in turn, could negatively impact the demand for our product candidates. If payors are not adequately reimbursed for our licensed products or product candidates, they may reduce or discontinue purchases of them, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition.

Our relationships with customers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any licensed products currently marketed and any product candidates for which we obtain marketing approval in the future. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated thereunder. These laws will impact, among other things, our clinical research programs and our proposed sales, marketing and educational programs for our product candidates, if approved. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. Under the PPACA a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it and action that may be customary in other industries ma unintentionally violate the Anti-Kickback Statute;
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The PPACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- HIPAA created federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.,* public or private);
- HIPAA, as amended by HITECH, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, and their respective business associates who provide services involving the creation, use or disclosure of HIPAA protected health information;
- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the PPACA, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to: (i) payments or other "transfers of value" made to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives and teaching hospitals; and (ii) certain ownership and investment interests held by physicians and their immediate family members, with such information being made publicly available through a searchable website;
- state and foreign law equivalents of each of the above federal laws; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or pricing information; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, 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, contractual damages, reputational harm and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and the provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Recently enacted and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations.

In the United States and some 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 our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. Among policymakers 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. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products. In March 2010, President Obama signed into law the PPACA. Among the provisions of the PPACA of importance to our business, including our ability to commercialize and the prices we may obtain for any of our products and product candidates that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- addition of more entity types eligible for participation in the Public Health Service 340B drug pricing program, or the 340B program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (*i.e.,* automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation, including the BBA, extended the 2% reduction, on average, to 2032, subject to additional Congressional action. Sequestration may result in additional reductions in Medicare and other healthcare funding and, if we obtain regulatory approvals, may otherwise affect the prices we may obtain for our product candidates or the frequency with which our product candidates may be prescribed or used if approved. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for

physicians under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The introduction of the Medicare quality payment program has shifted the focus of physician reimbursement from volume to value, encouraging higher quality and more cost-effective care.

Further, legislative changes to or regulatory changes under the PPACA remain possible in the U.S. Congress and under the second-term Trump administration. The nature and extent of any legislative or regulatory changes to the PPACA, including repeal and replacement initiatives, are uncertain at this time. It is possible that the PPACA repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits, including limited coverage for drugs. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 ("TCJA"), which was signed into law by President Trump during his first administration, effectively eliminated the federal "individual mandate" penalty imposed by the PPACA on individuals who failed to maintain qualifying health coverage for all or part of a year. Shortly thereafter, the BBA amended the PPACA to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." The Inflation Reduction Act of 2022, which was signed into law by President Biden, has since eliminated the coverage gap and replaced it with a $2,000 annual cap on out-of-pocket spending for covered drugs. As the second Trump presidency has commenced, we will continue to evaluate the impact of the PPACA on our business, and the potential for its further repeal or replacement.

The costs of prescription pharmaceuticals in the United States have also been the subject of considerable discussion in the United States, and members of Congress and the administration have stated that they will address such costs through new legislative and administrative measures. This focus has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In 2022, the Biden administration signed into law the Inflation Reduction Act, which included a number of significant drug pricing reforms, including the establishment of a drug price negotiation program within the HHS that, starting in 2026, will require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance; the establishment, beginning in 2023, of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation; and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs, beginning in 2025. Additionally, President Biden issued a subsequent Executive Order directing the Secretary of the HHS consider whether new payment and delivery models would lower drug costs, though, on the first day of his second term, President Trump repealed that Executive Order. 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that we may experience more rigorous coverage criteria and additional downward pricing pressure as the result of these and other healthcare reform measures that may be adopted in the future. 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 profitability, or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. Additionally, policy changes resulting from the new presidential administration may create sudden and unexpected shifts in the operations of HHS that might impact both existing and planned operations.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available product candidates. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on

Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under the current cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and visit clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we strive to manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on limited sources of supply for our thin film foil, and any disruption in the chain of supply may impact production and sales and cause delay in developing and commercializing our proprietary PharmFilm Technology product candidates.

We currently have relationships with two third parties for the manufacture of our thin film foil. Because of the unique equipment and process for manufacturing our thin film foil, transferring manufacturing activities for our foil to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching thin film foil suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of our thin film foil manufacturers breach or terminate their agreements with us, we would need to identify an alternative source for the thin film foil manufacture and supply of foil to us for the development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative thin film foil supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, or in satisfying our manufacturing and supply commitments and obligations for our licensed products, which could harm our financial position, the commercial potential for our licensed products and product candidates, and our results of operations, as well as to result in a default in our supply commitments and obligations. Any alternative thin film foil vendor would also need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our licensed products that differs from the manufacturer used for clinical development of such products. For our product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in our development and supply activities.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our approved products and product candidates, cause us to incur higher costs and prevent successful commercialization of our licensed products and product candidates, if approved. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, we would likely be in default in our supply obligations, which could result in the termination of our supply agreements, our incurring potential default damages and our loss of significant revenues.

We rely on third parties to manufacture API for our licensed products and product candidates, and we intend to rely on third parties to manufacture the API for other approved products. The commercialization of any of our licensed products and product candidates, if approved, could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of API or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

We currently rely, and expect to continue to rely, on third parties to manufacture API for our licensed products and our product candidates, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our supply of licensed products, proprietary product candidate programs and commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols or our obligations under our product supply commitments and obligations. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we will not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates and we would likely be in default in our supply commitments and obligations for our licensed products, which could result in the termination of our supply agreements, our incurring potential default damages and our loss of significant revenues.

The facilities used by us, and by our third-party API manufacturers, to manufacture our licensed products and product candidates must maintain a compliance status acceptable to the FDA or other applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If we or any of our third-party API manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, we or they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party API manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Further, as we scale up manufacturing of our product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured by us or for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our licensed products and product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, we would need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates and which could also result in default in our supply commitments and obligations for our licensed products, our incurring potential default damages and our loss of significant revenues.

More generally, we and our API manufacturers of pharmaceutical products, may often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, we and our API manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments, such as recent events in Ukraine and Russia, or other geopolitical uncertainty. If we or our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to manufacture our products, or to make our product candidates available for clinical trials and development purposes or to further commercialize any of our licensed products and product candidates in the United States, would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of significant potential revenues and could adversely affect our ability to gain market acceptance for approved products as well as a potential default of our supply commitments or obligations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved API manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and would likely result in a delay in our desired clinical and commercial timelines and disrupt our supply commitment and obligations.

The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects.

The design, development, manufacture, supply, and distribution of our licensed products and our product candidates is highly regulated and technically complex.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our products and our product candidates is highly regulated and technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities.

We, or our API and component manufacturers, must supply all necessary documentation in support of our regulatory filings for our product candidates on a timely basis and must adhere to the FDA's GLP and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by us or by our third-party API or component manufacturers to comply with cGMP or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party API and component manufacturers must also pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, inspect our manufacturing facilities or those of our third-party suppliers or contractors. If any such inspection identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third-party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales of our approved products or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third-party API or component manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending NDA for a new drug product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed resulting in a significant loss of revenues and results and resulting in a potential default in our supply commitments or obligations, which could lead to termination of our supply agreements, our incurrence of default damages and our loss of significant revenues.

We may not be successful in establishing development and commercialization collaborations, which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approvals, establishing manufacturing capabilities and marketing approved products are expensive, we continue to explore collaborations or licensing arrangements with third parties that have available resources and experience both in the United States and in territories outside of the United States. We continue to explore selective collaborations with third parties for development and commercialization of our products and candidates both in and outside of the United States. We may, however, be unable to advance the development and/or commercialization of our products and product candidates in territories outside of the United States, which may limit the market potential for certain products and product candidates outside the U.S.

In situations where we enter into a development and commercial collaborative arrangement for a product or product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaborative arrangement for such product or product candidate. There are a limited number of potential licensees, and we expect to face competition in seeking appropriate licensees. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product or product candidates and/or effectively market and sell approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

Whether we reach an 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 a number of factors. Those factors may include the likelihood of approval by the FDA or foreign regulatory authorities, the potential market for the product or product candidate, the costs and complexities of delivering such product or

product candidate to patients, competing products, and industry and market conditions generally. 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 elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain significant 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 them to market and generate product revenue.

We may not be successful in maintaining development and commercialization collaborations, and any collaborators may not devote sufficient resources to the development or commercialization of our products or product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop and successfully commercialize certain of our products and product candidates and our financial condition and operating results.

When we establish collaborative arrangements, such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we collaborate with a third-party for development and commercialization of a product or product candidate, we can expect to relinquish some or all of the control over the future success of that product or product candidate to the third-party. It is possible that a third-party collaborator may not devote sufficient resources to the development or commercialization of our product or product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product or product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our Common Stock. In some cases, we may be responsible for continuing development of a product or product candidate or research program under a collaboration, and the payment we receive from our licensee may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaborative arrangements to fail, including that:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage of ownership;
- we may be required to assume substantial actual or contingent liabilities;
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and commercialization and may substantially increase the cost of developing and commercializing our products and product candidates;
- business combinations of a strategic collaborator or significant changes in a strategic collaborator's business strategy may affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product or product candidate developed either independently or in collaboration with others, including our competitors;
- collaborators may not perform their obligations as expected;
- clinical trials conducted as part of any of these collaborations may not be successful;
- collaborators may not actively or aggressively pursue development and commercialization of any product candidates that seek to achieve, or that achieves, regulatory approval;
- we may not have access to or may be restricted from disclosing certain information regarding product candidates being developed or commercialized under a collaboration;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate; and
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

If any such collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, the development or commercialization of our products or product candidates could be delayed and our business and prospects harmed. All of the risks relating to product development, regulatory approval and commercialization apply to the activities of our existing and future collaborators.

Additionally, conflicts may arise between us and our third-party collaborators, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of

intellectual property developed during the collaboration. For example, our existing revenue streams are largely dependent on Indivior, which holds the global commercialization rights to our approved product, Suboxone. During the years ended December 31, 2024 and 2023, Indivior represented 62% and 80% of our total revenue, respectively. If any such conflicts were to arise with Indivior or any other third party collaborators, one or more of the following events could result, each of which could delay or prevent the development or commercialization of our product or product candidates and harm our business:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaborative arrangement;
- actions taken by a third-party collaborator inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration;
- unwillingness on the part of a third-party collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; and
- decision by our third-party collaborator to terminate or significantly reduce the relationship.

Risks Related to Our Business Operations and Industry

We may experience difficulties in managing growth if our business expands to meet future needs, which could disrupt our operations.

Although it is not expected to be imminent, if we need to expand our business to meet demands in growth of our manufacturing operations in connection with the continued commercialization of Libervant for ARS patients aged between two and five years, and, if granted full U.S. market access, for commercialization of Libervant for older patients, and to accommodate the potential commercialization of Anaphylm in the first quarter 2026, if approved by the FDA, or other additions to our product pipeline in the future, we would expect to expand our employee base to increase our managerial, regulatory, compliance, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants, contractors and contract employees. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our products and product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

In addition, any growth in our management team could add increased expense which we must absorb, without necessarily having commensurate growth in our revenues. Also, to date, we have only directly marketed two products in the market. If we commercialize and directly market Anaphylm, if approved for U.S. market access, this could require a significant upfront expense and create a rapid growth in our workforce. This increase in expense may negatively impact our results of operations and may add to our need for additional funds.

Our licensed products and, if approved, product candidates, may give rise to potential product liability claims or false marketing claims, and, if successful claims are brought against us, we may incur substantial liability.

As a pharmaceutical company, we operate in a market that is subject to significant risk of liability. The sales of any of our licensed products and product candidates for which we may obtain marketing approval and the use of our product candidates in clinical trials, if any, exposes us to the risk of product liability claims alleging adverse effects from such products or product candidates and false marketing claims relating to the commercialization of such products or product candidates. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies, others selling or otherwise coming into contact with our products or product candidates, or governmental agencies. Suboxone, which treats opioid addiction, has as one of its active ingredients an opioid, buprenorphine. There can be no assurance that we will not become the target of claims relating to opioid addiction as have companies that market opioids. We have been named as a defendant with Indivior in product liability claims related to dental injuries for use of Suboxone. For more detailed information regarding these claims, see Part II Item 8. Financial Statements and Supplementary Data, Note 23, *Contingencies* to our financial statements. Any product liability claims, or false marketing claims, could have a material adverse effect on our business, financial position, results of operations and future growth prospects. If we cannot successfully defend against product liability claims or false marketing claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims or false marketing claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;

- substantial costs due to litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our licensed products and product candidates; and
- decreased demand for our licensed products or product candidates, if approved for commercial sale.

We may not be able to maintain insurance coverage, and our existing or any future insurance policies or our own resources may not sufficiently cover claims for damages that we may receive in the future.

Our business exposes us to potential product liability and other liability risks that are inherent in clinical development, manufacturing, marketing, sale and use of human therapeutic products. It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical trials and any sale or use of our products. We have procured product liability insurance with respect to the sale of our licensed products and all clinical trials performed to date for which we were responsible (*i.e.,* in respect of our internal product pipeline). Further, we may seek to expand our insurance coverage for our licensed products and our marketing and commercialization of any future approved product candidates as well as other risks related to our business.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at an acceptable cost to us or in sufficient amounts to protect us against losses due to liability. The product liability claim against us with respect to Suboxone may make obtaining product liability insurance coverage at an acceptable cost more problematic. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could materially adversely affect our results of operations and business.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We have previously been the target of a phishing attack that resulted in unauthorized access to our email system. While our systems have been secured and strengthened, there can be no assurance that we will not experience cyber-attacks in the future, suffer indirect consequences from a cyber-attack on a third-party, or fail to anticipate, identify or offset threats of potential cyber-attacks or security breaches in a timely manner. This is especially so considering the nature of cyber-attack techniques, which change frequently, can be difficult to detect for extended periods of time and often are not recognized until they succeed. System failures, accidents or security breaches could cause interruptions in our operations and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

Business interruptions at our manufacturing facilities could delay us in the process of developing our product candidates.

Our headquarters are located in Warren, New Jersey and we have manufacturing facilities in Portage, Indiana. If we encounter any disruptions to our operations at these sites or one were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. Our coverage for natural disasters may be somewhat limited for floods or earthquakes and we may not carry sufficient business interruption insurance for any unexpected events to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

As a pharmaceutical company, we are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials. Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of accidental contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and U.S. federal and state or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do maintain environmental liability insurance coverage to mitigate our exposure in the event of an accident or environmental discharge. In the event that we may be held liable for any consequential damage and any resulting claims for damages, which may exceed our insured limits and financial resources, we may incur costs that may materially adversely affect our business, results of operations and prospects, and the value of our shares.

Risks Related to Government Regulation

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for each of our product candidates described in this report. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are permitted to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). We expect that our competitors could file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, cause us to suspend or discontinue clinical trials, abandon product candidates, or result in significant negative consequences following marketing approval, if any.

As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although the nature of our products or product candidates as containing active ingredients that have already been approved means that the side effects arising from the use of the active ingredient or class of drug in our products or product candidates is generally known, our products or product candidates may still cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more

restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for substantial damages for harm caused to patients; and
- our reputation may suffer.

Any of the above described events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate, significantly affect our revenues and profitability from such products, and could substantially increase the costs of commercializing our products and product candidates.

Our business is subject to extensive regulatory requirements and our approved products and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program.

The holder of an NDA is subject to payment of user fees and adherence to commitments made in the NDA. A manufacturer is also subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters asserting that we are in violation of the law;
- impose restrictions on the marketing or manufacturing of the product;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into government contracts.

Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to market our products or commercialize our product candidates and generate revenues.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market or

license our products and/or product candidates, which would materially adversely affect our ability to generate revenue and achieve or maintain profitability.

Regulatory approval is required for each of our products in each jurisdiction in which we intend to market or license such products, and the inability to obtain such approvals would limit our ability to realize their full market potential.

In order to market products outside of the United States, we or our licensees must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact the ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we or our licensees fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing products and product candidates. We may also acquire or in-license early to mid-stage new chemical entities, or NCEs. Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds, we do not have internal drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and administration methods for existing FDA-approved products and/or select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of significant resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Public concern regarding the safety of any of our drug products could result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs.

Considering widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. The FDAAA also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of this law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to provide additional clinical or preclinical data for any of our approved drug products, the indications for which that product candidate was approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize any approved product may be otherwise adversely impacted.

Uncertainty about presidential administration initiatives could negatively impact our business, financial condition and results of operations.

There is significant uncertainty with respect to legislation, regulation and government policy at the federal level, as well as the state and local levels. Recent events, including the 2024 U.S. presidential election, have created a climate of heightened uncertainty and introduced new and difficult-to-quantify macroeconomic and political risks with potentially far-reaching implications. The presidential administration's changes to U.S. policy may impact, among other things, the U.S. and global economy, international trade and relations, unemployment, immigration, taxes, healthcare, the U.S. regulatory

environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business, financial condition, operating results and cash flows. Until we know what policy changes are made and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights of any of our products and product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The issuance, scope, validity, enforceability, strength and commercial value of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own, or in-license, may fail to result in issued patents with claims that cover the products or product candidates, if approved, in the United States or in foreign countries or territories. If this were to occur, early generic competition could be expected against our products and product candidates, if approved. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

The patent prosecution process is expensive and time-consuming. We or our licensors may not be able to prepare, file and prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce or which we choose not to seek to patent, and any other elements of our drug development and reformulation processes that involve proprietary know-how, information or technology that is not covered by patents. Although we generally require all of our colleagues to assign their inventions to us, and we generally seek to have all of our colleagues, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors or other third parties. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our products or product candidates, if approved, in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement rights are not as strong as those in the United States or Europe. These products may compete with our products or product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, 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. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents or patents that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce existing patents or patents that we may obtain in the future.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We have in the past and are likely in the future to be, involved in lawsuits to protect or enforce our patents. These lawsuits are expensive and require us to expend substantial financial resources, are time consuming, may continue for many years for one or more claims and may be unsuccessful.

Competitors may infringe our patents or the patents of any potential licensors. To counter infringement or unauthorized use, we have been, and in the future may be, required to file infringement claims, which are expensive and time-consuming. In an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings invoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be significantly harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our bringing or defending litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees from our core business. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

A number of our issued patents have been involved in administrative proceedings, such as reexamination and *inter partes* review at the USPTO and opposition at the EPO. The matters are resolved, but in possible future proceedings, there can be no assurance that all claims of the challenged patents will be upheld or that the patents challenged by us will be found infringed. We may lose any of the challenged patents entirely, or we may have to amend the scope of claims to an extent which may be considered insufficient to cover our products or product candidates. If any of those scenarios were to occur, we might lose our competitive advantage in our market, and our business could be materially affected.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also 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 have a material adverse effect on the price of our common stock.

Third parties may commence legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability, and the ability of our existing and future collaborators, to develop, manufacture, market and sell our products and product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We may have been and in the future may become party to or be threatened with adversarial proceedings or litigation regarding intellectual property rights with respect to our products, product candidates and technology, which may include interference or derivation proceedings, post grant review and *inter partes* review before the USPTO or similar adversarial proceedings or litigation in any jurisdiction. Similarly, we or our licensors or collaborators have initiated, and in the future may initiate, such proceedings or litigation against third parties, which may include challenging the validity or scope of intellectual property rights controlled by third parties. Third parties have asserted and, in the future, may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that additional third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe any of those claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product or product candidates unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our technology, holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid, unenforceable or not infringed by our product or technology. In either case, such a license may not be available 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. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such event, we may be unable to

further practice our technologies or develop and commercialize any of our product candidates at issue, which could significantly harm our business.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, could involve substantial litigation expense and a substantial diversion of employee resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than we or our licensors or collaborators can. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

The patents and patent applications that we have covering our products and product candidates are limited to specific formulations and manufacturing processes, and our market opportunity for our products and product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and manufacturing processes, as well as administration methods that may be developed by competitors.

We have obtained and continue to seek to obtain patent protection for our manufacturing technology, drug administering technology and our products and product candidates, including specific formulations and manufacturing processes, which may not be as effective as composition of matter coverage in preventing work-arounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredients as our products or product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products or product candidates, subject to any regulatory exclusivity we may be able to obtain for our products.

The number of patents and patent applications covering products containing the same active ingredient as our products or product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for our products or product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our products or product candidates that are different from ours and do not infringe our issued patents covering our products or use of our products.

Suboxone, Zuplenz, Sympazan, Libervant and Emylif have been approved by the FDA, and other product candidates may be approved by the FDA in the future. As additional products of ours are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

If we or one of our licensees initiated legal proceedings against a third-party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim, and have in certain existing proceedings counterclaimed, that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, and equivalent proceedings in foreign jurisdictions (*e.g.,* opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products or product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensees to monitor the status of these fees so that we may make required payments of these fees when due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however,

in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market which could harm our business.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which will be costly and time-consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time-consuming, may divert our management's attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third-party may then initiate a lawsuit against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third-party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay.

In addition to paragraph IV litigation noted above, third-party owners of patents may generally assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods of manufacture related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation, any method or process involved in the manufacture of any of our product candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products, product candidates and methods do not or will not infringe the patents or other intellectual property rights of third parties.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, involves substantial litigation expense and could be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that

event, we would be unable to further develop and commercialize one or more of our products or product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation generally involves substantial costs and can be a distraction to management and other employees.

If we are not able to obtain adequate trademark protection or regulatory approval for our brand names, we may be required to re-brand affected products, which could cause delays in getting such product to market, substantively impact successful commercialization of any such product and substantially increasing our costs.

To protect our rights in any trademark we use or intend to use for our products or our product candidates, we may seek to register such trademarks. Trademark registration is territory-specific and we must apply for trademark registration in the United States as well as any other country where we intend to commercialize our product or product candidates. Failure to obtain trademark registrations may place our use of the trademarks at risk or make them subject to legal challenges, which could force us to choose alternative names for our product or product candidates. In addition, the FDA and other regulatory authorities outside the United States conduct independent reviews of proposed product names for pharmaceuticals, including an evaluation of the potential for confusion with other pharmaceutical product names for medications. These regulatory authorities may also object to a proposed product name if they believe the name inappropriately makes or implies a therapeutic claim. If the FDA or other regulatory authorities outside the United States object to any of our proposed product names, we may be required to adopt alternative names for our product or product candidates. If we adopt alternative names, either because of our inability to obtain a trademark registration or because of objections from regulatory authorities, we would lose the benefit of our existing trademark applications. As a result, we may be required to expend significant additional resources in an effort to adopt a new product name that would be registrable under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA and other regulatory authorities, which could adversely impact our product brand identity and successful commercialization of any product and increase our costs. Furthermore, we may not be able to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product or our product candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or any potential future licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or have exclusively licensed may not provide coverage for all aspects of our products or product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

Our quarterly operating results may fluctuate significantly, and these fluctuations could cause our stock price to decline.

We expect our operating results to continue to be subject to significant quarterly and annual fluctuations. These fluctuations could cause our stock price to decline. Our net loss and other operating results will be affected by numerous factors, including:

- whether the FDA requires us to complete additional, unanticipated studies, trials or other activities prior to approving any of our current and future product candidates, which would likely delay any such approval;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- our limited cash resources and substantial indebtedness;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- delays in obtaining, failure to obtain, or adverse developments in obtaining FDA and other regulatory approval of our product candidates;
- other regulatory developments affecting any of our other current and future product candidates, or the product candidates of our competitors;
- the costs of pre-commercialization and commercialization of any of our approved products that we market ourselves; and
- if any of our current or future product candidates receive regulatory approval, the level of underlying demand for such product candidate and wholesaler buying patterns.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our Common Stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Our largest stockholder and management own a significant percentage of our stock and may have the ability to effectively influence matters subject to stockholder approval.

As of December 31, 2024, our executive officers and directors beneficially owned approximately 6.6% of our outstanding common stock. In addition, Bratton Capital Management L.P. and its affiliates beneficially owned, directly, approximately 10.8% of our outstanding common stock as of December 31, 2024. Therefore, these stockholders may have, through their respective ownership positions, the ability to influence matters requiring stockholder approval, including elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Common Stock that you may believe are in your best interest as one of our stockholders.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses since the inception of our company and do not expect to become profitable in the near future, if ever. Under currently enacted federal income tax law, to the extent that we continue to generate taxable losses in future years, such unused losses will carry forward to offset future taxable income, if any, but our deductibility of such losses in a future year is generally limited to 80% of taxable income. Furthermore, under Section 382 of the Code, if a corporation undergoes an "ownership change," 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, such as research tax credits, to offset its post-change income may be further limited. We believe that, with our initial public offering, we may have triggered an "ownership change" limitation. In addition, we have experienced and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including an ownership change as a result of the combined effect of our initial public offering and future equity offerings. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

We do not intend to pay dividends on our Common Stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our Common Stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us, or may increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- establishing a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and of our amended and restated bylaws;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice and other requirements, including compliance with the SEC Universal Proxy Rules, for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our amended and restated bylaws or any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

Public health threats such as a global pandemic, or widespread outbreak of infectious disease, similar to the COVID-19 pandemic, may create uncertainties about our future operating results and financial conditions.

Public health threats, such as the COVID-19 or any other pandemic, may have an impact on our business, financial condition, results of operations and cash flows. Prolonged volatility or significant disruption of global financial markets due in part to a public health threat could have a negative impact on our business and overall financial position. Other factors and uncertainties include, but are not limited to, increased operational costs associated with operating during and after a pandemic; evolving macroeconomic factors, including general economic uncertainty, increased labor costs, and recessionary pressures; capital and other resources needed to respond to a pandemic; along with the severity and duration of a pandemic. These risks and their impacts are difficult to predict and could continue to otherwise disrupt and adversely affect our operations and our financial performance.

In addition, to the extent a global health crisis, epidemic or pandemic, such as theCOVID-19 pandemic, adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team and other key executives, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

Certain of our executive officers' employment agreements include covenants not to compete. These agreements prohibit our executive officers, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements or may not be able to enforce these agreements to their full extent under applicable law. If we cannot demonstrate that our interests would be harmed by such competitive behavior, we may be unable to prevent our competitors from benefiting from the expertise of our former executives and our competitiveness may be diminished.

Compliance with ever evolving federal, state, and foreign laws relating to handling of information about individuals involves significant expenditure and resources, and any failure by us or our vendors to comply may result in significant liability, negative publicity, and/or an erosion of trust, and could materially adversely affect our business, results of operations, and financial condition.

We receive, store, handle, transmit, use and otherwise process information related to individuals. We also depend on a number of third-party vendors in relation to the operation of our business, a number of which process data on our behalf. We and our vendors are subject to a variety of federal, state and foreign data privacy laws, rules, regulations, industry standards and other requirements, including those that apply generally to the handling of information about individuals, and those that are specific to certain industries, sectors, contexts, or locations. These requirements, and their application, interpretation and amendment are constantly evolving and developing.

In the United States, numerous federal and state laws, including state data breach notification laws and state health information privacy laws, govern the collection, use, and disclosure and protection of health-related and other personal information. The Federal Trade Commission and state regulators enforce a variety of data privacy issues, such as promises made in privacy policies or failures to appropriately protect information about individuals, as unfair or deceptive acts or practices in or affecting commerce in violation of the Federal Trade Commission Act or similar state laws.

We are subject to HIPAA. 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 ("protected health information," or "PHP") for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities and business associates to develop and maintain policies with respect to the protection of, use and disclosure of PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI.

Additionally, under HIPAA, covered entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach by a covered entity or its agents. Notification also must be made to the U.S. Department of Health and Human Services Office for Civil Rights, or OCR, and, in certain circumstances involving large breaches, to the media. Business associates must report breaches of unsecured PHI to covered entities within 60 days of discovery of the breach by the business associate or its agents. A non-permitted use or disclosure of PHI is presumed to be a breach under HIPAA unless the covered entity or business associate establishes that there is a low probability the information has been compromised consistent with requirements enumerated in HIPAA.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by HHS may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its

standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Member states in the European Union and other countries have also adopted data protection laws and regulations which impose significant compliance obligations. For example, in the European Union, on May 25, 2018 the EU general Data Protection Regulation (GDPR) became applicable throughout the EU and, as a regulation, has direct effect in all member states. The GDR was designed to harmonize data privacy laws across the EU and change the way organizations approach data privacy. The GDPR introduced new obligations and expanded the extraterritorial reach of the EU data protection regime. It applies to (i) organizations that process personal data in the context of an establishment in the EU (regardless of whether the processing takes place in the EU) and (ii) organizations outside the EY that offer goods or services to data subjects in the EU, or that monitor the behavior of EU data subjects. Compliance with the GDPR involves significant obligations, including requirements around accountability and transparency, contracting with service providers that process personal data, responding to data subjects' rights requests within prescribed timelines, reporting of data breaches to data subjects and. or data protection or supervisory authorities, taking account of data protection as any new services are developed, and limiting the amount of personal data collected, stores or otherwise processed. These obligations and restrictions have a significant impact on the ability to collect, analyze and transfer personal data, including in the context of health data from clinical trials.

Even though we believe we and our vendors are generally in compliance with applicable laws, rules and regulations relating to privacy and data security, these laws are in some cases relatively new and the interpretation and application of these laws are uncertain. Any failure or perceived failure by us to comply with data privacy and security laws, rules, regulations, industry standards and other requirements could result in proceedings or actions against us by individuals, consumer rights groups, government agencies, or others. We could incur significant costs in investigating and defending such claims and, if found liable, pay significant damages or fines or be required to make changes to our business. Further, these proceedings and any subsequent adverse outcomes may subject us to significant negative publicity and an erosion of trust. If any of these events were to occur, our business, results of operations, and financial condition could be materially adversely affected.

Our colleagues, principal investigators, consultants and agents may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our colleagues, principal investigators, contract sales force, consultants and agents. Misconduct by these parties could include failure to:

- comply with FDA regulations or the regulations applicable in other jurisdictions;
- provide accurate information to the FDA and other regulatory authorities;
- comply with healthcare fraud and abuse laws and regulations in the United States and abroad;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

We may be subject to claims that our colleagues, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our colleagues, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our colleagues' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other colleagues from our core business.

The market price of our Common Stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our Common Stock.

The market price of our Common Stock since our IPO has been and is likely to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your Common Stock at or above your purchase price. The market price for our Common Stock may be influenced by many factors, including:

- results of clinical trials of our current and any future product candidates or those of our competitors;
- the success or regulatory approval of competitive drugs or therapies;
- regulatory or legal developments in the United States and other countries, as to both our products and product candidates and those of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our current and any future product candidates or clinical development programs;

- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development, clinical trials or regulatory approval timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us, or our failure to achieve anticipated financial results or funding;
- market conditions in the pharmaceutical and biotechnology sectors;
- inflation and rising interest rates;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our Company, the price of our Common Stock could decline.

The trading market for our Common Stock relies, in part, on the research and reports that industry and financial analysts publish about us or our business. We currently have limited research coverage by industry and financial analysts. Should any analysts then covering our business downgrade their evaluations of our stock, the price of our stock could decline. If any analysts then covering our business cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We are a "smaller reporting company", and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our Common Stock less attractive to investors.

We are a "smaller reporting company", as defined in Rule 405 under the Securities Act which allows us to take advantage of many of the exemptions from disclosure requirements available to "emerging growth companies," as defined in the JOBS Act, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and certain reduced financial disclosures in our periodic reports, including this Annual Report on Form 10-K. We are eligible to remain a smaller reporting company for so long as we have a public float (based on our Common Stock equity) of less than $250 million measured as of the last business day of our most recently completed second fiscal quarter or a public float (based on our Common Stock equity) of less than $700 million as of such date and annual revenues of less than $100 million during the most recently completed fiscal year. We cannot predict if investors will find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result of these disclosure exemptions, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Common Stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our Common Stock.

Sales of a substantial number of shares of our Common Stock in the public market by our existing stockholders would cause our stock price to fall.

Sales of a substantial number of shares of our Common Stock by our existing stockholders, including shares issued to colleagues and directors in respect of the termination of our Performance Unit Plans, or PUP Plans, in the public market or the perception that these sales might occur, could depress the market price of our Common Stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our Common Stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act has resulted in a substantial amount of these shares becoming freely

tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our Common Stock.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial conditions and results of operation.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. Although the Department of the Treasury, the Federal Reserve and the FDIC may take action to mitigate the risk of potential losses, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalization our current projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, a critical vendor or business partner could be adversely affected by any of the liquidity or other risks that are described above as factors, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any business partner or supplier bankruptcy or insolvency, or any breach or default by a business partner or supplier, or the loss of any significant business partner or supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

Aquestive's cybersecurity program is built on four key pillars: Governance, Process, Compliance and Audit. While we face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, and results of operations, Aquestive's cybersecurity program is built upon a set of policies, procedures, and standards supported by training and awareness. In addition, cybersecurity risks are also reviewed as part of our overall Enterprise Risk Management program.

The cybersecurity team has significant experience in managing cybersecurity programs and has engaged with a MSSP to deploy state of the art cybersecurity technologies and gather threat intelligence and cyber risk trends. The cybersecurity program is executed with the MSSP, which provides active threat monitoring, risk assessment and incident response capabilities to timely assess and address any material cyber risk that could impact our business operations.

On occasion, we engage other external experts, including cybersecurity assessors, consultants, and auditors to evaluate cybersecurity measures and risk management processes, including those applicable to Aquestive. We depend on and engage various third parties, including suppliers, vendors, and service providers, to operate. We rely on the expertise of our risk management, legal, information technology, and compliance personnel, as well as our MSSP, when identifying and overseeing risks from cybersecurity threats associated with our use of such entities.

Governance

Role of Management/Board

The Senior Vice President of Information Technology (the "IT Officer"), along with the broader Information Technology function, is responsible for assessing and managing Aquestive's cybersecurity risk and informing senior management and the Audit Committee of the Board regarding cybersecurity risks and the prevention, detection, mitigation, and remediation of cybersecurity incidents. The IT Officer reports to the Chief Executive Officer and leads our cybersecurity program. Our IT Officer has been responsible for this function at Aquestive for 10 years and has over eleven years of experience in information security strategy and the management of cybersecurity risk. The internal Aquestive IT team has over fifteen years of technical experience, program management and architecture experience in managing cyber risk and information security.

The Audit Committee of the Board provides strategic oversight of Aquestive's cybersecurity matters, including risks associated with cybersecurity threats. The IT Officer briefs the Audit Committee on the effectiveness of Aquestive's cybersecurity program quarterly with a more in depth review done annually.

The potential impact of risks from cybersecurity threats on the Company are assessed on an ongoing basis, and how such risks could materially affect the Company's business strategy, operational results, and financial condition are regularly evaluated. During the reporting period, we have not identified any risks from cybersecurity threats or incidents, including as a result of previous cybersecurity incidents, that we believe have materially impacted, or are reasonably likely to materially affect, the Company, including our business strategy, operational results, and financial condition.

Item 2. Properties

We lease our 8,400-square-foot current production facility (Melton) in Portage, Indiana, which houses certain research and development offices and cGMP manufacturing operations. The lease contains an option to purchase the facility at any time during the lease term along with a right of first refusal to purchase the facility. On February 28, 2023, we extended our Melton facility lease which will expire March 31, 2028 under the same terms and conditions as the prior lease.

We also lease a 73,000-square-foot facility (Ameriplex) in Portage, Indiana, to house additional packaging, R&D and other operations. As amended, this lease has a term that extends through September 30, 2028 and contains a renewal option that could extend the lease through September 30, 2033.

We lease a 19,610-square-foot headquarters and principal laboratory in Warren, New Jersey. As amended, this lease has a term that extends our lease through August 2026 and contains a renewal option that could extend the lease through August 2029.

We do not own any real property.

Item 3. Legal Proceedings

For more information on Legal Proceedings, see Part II Item 8. Financial Statements and Supplementary Data, Note 23, *Contingencies*.

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

Market Information

Our Common stock began trading on the Nasdaq Global Select Market on July 24, 2018 and now trades on the Nasdaq Global Market under the symbol "AQST". Prior to that date there was no public market for our Common Stock.

Holders of Record

As of March 3, 2025, we had approximately 84 holders of record of our Common Stock. Certain shares are held in "street" name and, accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. 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. We currently intend to retain future earnings to fund the development and growth of our business. We do not expect to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the direction of our board of directors and will depend on then-existing conditions, including our financial conditions, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sale 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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in the Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part 1 Item 1A of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. All dollar amounts are stated in thousands.

Overview

Aquestive Therapeutics, Inc. is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. We are developing pharmaceutical products to deliver complex molecules through administrations that are alternatives to invasive and inconvenient standard of care therapies. We have a proprietary commercial product, Libervant® (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy between two and five years of age, which was launched in April 2024. We are advancing a product pipeline for the treatment of severe allergic reactions, including anaphylaxis, under the trade name "Anaphylm™", and our Adrenaverse™ epinephrine prodrug pipeline platform. We have five licensed commercialized products which are marketed by our licensees in the U.S. and around the world. We are the exclusive manufacturer of these licensed products. Aquestive also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm, and has proven drug development and commercialization capabilities. Our production facilities are located in Portage, Indiana, and our corporate headquarters and primary research laboratory facilities are based in Warren, New Jersey.

Financial Operations Overview

Revenues

We generate revenues in four primary categories: manufacture and supply revenue, license and royalty revenue, co-development and research fees, and proprietary product revenue, net.

Manufacture and Supply Revenue

We manufacture based on receipt of purchase orders from our licensees, and our licensees have an obligation to accept these orders once quality assurance validates the quality of the manufactured product with agreed upon technical specifications. In most cases. our licensees are responsible for all other aspects of commercialization of these products, and we have no role, either direct or indirect, in our customers' commercialization activities, including those related to marketing, pricing, sales, payor access and regulatory operations.

We expect future manufacture and supply revenue from licensed products to be based on volume demand for existing licensed products, and for manufacturing and supply rights under license and supply agreements for existing or new agreements for successful product development collaborations.

License and Royalty Revenue

We realize revenue from licenses of our intellectual property. For licenses that do not require further development or other ongoing activities by us, our licensee has acquired the right to use the licensed intellectual property for self-development of their product candidate, for manufacturing, commercialization or other specified purposes, upon the effective transfer of those rights, and related revenues are generally recorded at a point in time, subject to contingencies or constraints, if any. For licenses that may provide substantial value only in conjunction with other performance obligations to be provided by us, such as development services or the manufacture of specific products, revenues are generally recorded over the term of the license agreement. We also earn royalties based on our licensees' sales of products that use our intellectual property that are marketed and sold in the countries where we have patented technology rights.

Co-development and Research Fees

Co-development and research fees are earned through performance of specific tasks, activities or completion of stages of development defined within a contractual development or feasibility study agreement with a customer. The nature of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product. Accordingly, the duration of our research and development projects may range from several months to as long as three years. Although each contractual arrangement is unique, common milestones contained in these arrangements include those for the performance of efficacy and other tests, reports of findings, formulation of initial prototypes, production of stability clinical

and/or scale-up batches, and stability testing of those batches. Additional milestones may be established and linked to clinical results of the product submission and/or approval of the product by the FDA and the commercial launch of the product.

Proprietary product revenue, net

This net revenue is recognized when product is shipped and title passes to the customer, typically at time of delivery. At the time of sale, estimates for various revenue allowances are recorded based on historical trends and judgmental estimates. For sales of Libervant for patients between two to five years of age, returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates, if available, and these estimates are recorded as a reduction of receivables. Similarly determined estimates are recorded relating to wholesaler service fees, co-pay support redemptions, and other rebates, and these estimates are reflected as a component of accrued liabilities. Once all related variable considerations are resolved and uncertainties as to collectable amounts are eliminated, estimates are adjusted to actual allowance amounts. Provisions for these estimated amounts are reviewed and adjusted on no less than a quarterly basis.

Costs and Expenses

Our costs and expenses are primarily the result of the following activities: generation of manufacture and supply revenues; development of our pipeline of proprietary product candidates; and selling, general and administrative expenses, including pre-launch and post-launch commercialization efforts, intellectual property procurement, protection, prosecution and litigation expenses, corporate management functions, medical and clinical affairs administration; public company costs, share-based compensation expenses and interest on our corporate borrowings. We primarily record our costs and expenses in the following categories:

Manufacture and Supply Costs and Expenses

Manufacture and supply costs and expenses are primarily incurred from the manufacture of our commercialized licensed pharmaceutical products, including raw materials, direct labor and overhead costs principally in our Portage, Indiana facilities. Our material costs include the costs of raw materials used in the production of our proprietary dissolving film and primary packaging materials. Direct labor costs consist of payroll costs (including taxes and benefits) of employees engaged in production activities. Overhead costs principally consist of indirect payroll, facilities rent, utilities and depreciation for leasehold improvements and production machinery and equipment. These costs can increase, or decrease, based on the costs of materials, purchased at market pricing, and the amount of direct labor required to produce a product, along with the allocation of fixed overhead, which is dependent on production volume.

Our manufacture and supply costs and expenses are impacted by our customers' supply requirements. Costs of production reflect the costs of raw materials that are purchased at market prices and production efficiency (measured by the cost of a salable unit). These costs can increase, or decrease, based on the amount of direct labor and materials required to produce a product and the allocation of fixed overhead, which is dependent on the levels of production.

In addition to our proprietary products coming online, we may add licensee products which may need additional resources to manufacture. If such growth should occur for higher volume product opportunities such as Suboxone and Ondif, we would incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from higher manufactured volumes from proprietary and licensed products.

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities. Research and development expenses primarily consist of:

- employee-related expenses, including compensation, benefits, share-based compensation and travel expense;
- external research and development expenses incurred under arrangements with third parties, such as CROs, investigational sites and consultants;
- the cost of acquiring, developing and manufacturing clinical study materials; and
- costs associated with preclinical and clinical activities and regulatory operations.

We expect our research and development expenses to continue to be significant over the next several years as we continue to develop existing product candidates such as Anaphylm, AQST-108 and others, and as we identify and develop or acquire additional product candidates and technologies. We may hire or engage additional skilled colleagues or third parties to perform these activities, conduct clinical trials and ultimately seek regulatory approvals for any product candidate that successfully completes those clinical trials.

Selling, General and Administrative Expenses

Selling, General and Administrative expenses consist primarily of salaries, benefits, share-based compensation, other related costs for executive, finance, and operational personnel. Other costs include facility and related costs not otherwise included in research and development expenses such as: professional fees for patent-related and other legal expenses, regulatory fees, consulting, tax and accounting services; insurance; market research; advisory board and key opinion leaders; depreciation; and general corporate expenses, inclusive of IT systems-related costs. In addition, these expenses also include warehousing, distribution, selling and business development and other costs.

Our general and administrative costs include costs related to accounting, audit, legal regulatory, and tax-related services required to maintain compliance with exchange listing and SEC regulations, director and officer insurance costs, and investor and public relations costs. We continue to incur significant costs in seeking to protect our intellectual property rights, including significant litigation costs in connection with seeking to enforce our rights concerning third parties' at-risk launch of generic products.

We will continue to manage business costs to prepare for a potential future decline in Suboxone revenue and other external factors affecting our business, as we continue to focus on our core business:

- Continuing the development of Anaphylm and AQST-108; and
- Commercializing Libervant for after approval from the FDA on April 26, 2024 for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern in pediatric patients with epilepsy between two to five years of age.

Interest Expense

Interest expense consists of interest costs on the outstanding balances of our 12.5% Notes and 13.5% Notes at a fixed rate of 12.5% and 13.5%, respectively, payable quarterly, as well as amortization of loan costs and debt discounts. The redemption of 12.5% Notes and the issuance of 13.5% Notes are discussed in Note 15, *Long-Term Debt*, to our financial statements. In addition, see *Liquidity and Capital Resources* below for further detail on our 12.5% Notes and 13.5% Notes.

Interest Expense related to Royalty Obligations

In connection with the issuance of the 13.5% Notes, we entered into the Royalty Rights Agreements with each of the Note Holders granting the Note Holders a tiered royalty between 1.0% and 2.0% of annual worldwide net sales of Anaphylm (epinephrine) Sublingual Film for a period of eight years from the first sale of Anaphylm on a global basis. The Note Holders are also entitled to a tiered royalty between 1.0% to 2.0% of annual worldwide net sales of Libervant (diazepam) Buccal Film until the earlier of (1) the first sale of Anaphylm and (2) eight years from the first sale of Libervant. These royalty agreements are classified as debt, and the value of the $45,000 13.5% Notes has been allocated between debt and the Royalty Obligations based on their relative fair market values. The excess of future estimated royalty payments of $56,926 over the $13,856 of the allocated fair value is recognized as a discount related to the Royalty Right Agreements and is amortized as interest expense using the effective interest method. The 13.5% Notes are discussed in Part II Item 8. Financial Statements and Supplementary Data, Note 15, *Long-Term Debt.*

Interest Expense related to Sale of Future Revenue

On November 3, 2020, we entered into the Monetization Agreement with Marathon. Under the terms of the Monetization Agreement, we sold to Marathon all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, which received approval from the FDA on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment from Marathon of $40,000 and an additional payment of $10,000 through the achievement of the first milestone. We have received an aggregate amount of $50,000 through December 31, 2024 under the Monetization Agreement.

Under the Monetization Agreement, additional contingent payments of up to $75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125,000. In June 2023, Sunovion announced that it has voluntarily withdrawn KYNMOBI from the U.S. and Canadian markets, therefore, we likely will not receive any of the additional contingent payments under the Monetization agreement. We discontinued recording interest expense related to the sale of future revenue under the Monetization agreement in the fourth quarter of 2022.

During the second quarter of 2020, under the Sunovion License Agreement, we recognized $8,000 of royalty revenue and corresponding royalty receivable, related to the $1,000 annual minimum guaranteed royalty that is due in each of the subsequent eight years. In connection with the Monetization Agreement, we performed an assessment under ASC 860, *Transfer and Servicing* to determine whether the existing receivable was transferred to Marathon and concluded that the receivable was

not transferred. See Part II Item 8. Financial Statements and Supplementary Data, Note 17, *Sale of Future Revenue*, and Note 13, *Other-Non-Current Assets* for further detail.

Interest Income and other income, net

Interest income and other income, net consists of earnings derived from an interest-bearing account, investments in money market Treasury mutual funds and other miscellaneous income and expense items. The interest-bearing account and money market Treasury mutual funds have no minimum amounts to be maintained in the accounts nor any fixed length of period for which interest and dividends are earned.

Results of Operations

Comparison of Years Ended December 31, 2024 and 2023

The following discussion of our results of operations explains the material drivers of these results of operations.

Revenues

The following table sets forth our revenue data for the periods indicated.

	Year Ended December 31,		Change	
	2024	2023	$	%
(In thousands, except %)				
Manufacture and supply revenue	$ 39,976	$ 43,805	$ (3,829)	(9%)
License and royalty revenue	15,345	5,376	9,969	185%
Co-development and research fees	1,925	1,402	523	37%
Proprietary product revenue, net	315	—	315	N/M
Total revenues	$ 57,561	$ 50,583	$ 6,978	14%

Revenues increased 14% or $6,978 in 2024 compared to the same period in 2023. The increase was primarily due to certain one-time increases in license and royalty revenue and increases in co-development and research fees, partially offset by decreases in manufacture and supply revenue.

Manufacture and supply revenue decreased 9% or $3,829 for the year ended December 31, 2024 compared to the same period in 2023. This decrease was primarily due to a $4,069 decrease in Suboxone revenues mainly due to a decrease in volume and retroactive price increases in the prior period that were not present in 2024, and a $702 decrease in Sympazan revenue. These decreases were partially offset by a $586 increase in Emylif revenues from Zambon and a $368 increase in Ondif revenue which were attributable to an increase in volume. As part of the Indivior Amendment 11 to the Commercial Exploitation Agreement, we received retroactive price increases related to 2022 Suboxone purchases in the amount of $1,682 which was recognized in Manufacture and supply revenue in the year ended December 31, 2023. There were no retroactive price adjustments included in Manufacture and supply revenue for the year ended December 31, 2024.

License and royalty revenue increased 185% or $9,969 for the year ended December 31, 2024 compared to the same period in 2023. This increase was primarily due to the one-time recognition of deferred revenues of $11,544 due to the terminations of licensing and supply agreements. These increases were partially offset by a $1,500 decrease in milestone licensing revenue for Azstarys from Zevra Therapeutics recognized in the prior year.

Co-development and research fees increased 37% or $523 for the year ended December 31, 2024 compared to the same period in 2023. The increase was driven by the timing of the achievement of research and development performance obligations which are expected to fluctuate from one reporting period to the next.

Proprietary product revenue, net increased by $315 for the year ended December 31, 2024 compared to the same period in 2023 due to the launch of Libervant for patients between two to five years of age. This increase was partially offset by an additional accrual for returns allowances related to the period prior to the outlicensing to Assertio of our proprietary product, Sympazan, which is recorded as an addition to accrued distribution expenses and sales return provision.

Expenses, Interest Income and Other Income:

The following table sets forth our expense data for the periods indicated:

	Year Ended December 31,		Change	
	2024	2023	$	%
(In thousands, except %)				
Manufacture and supply	$ 17,872	$ 20,831	$ (2,959)	(14%)
Research and development	20,280	13,104	7,176	55%
Selling, general and administrative	50,180	31,750	18,430	58%
Interest expense	11,122	6,337	4,785	76%
Interest expense related to royalty obligations	5,459	905	4,554	N/M
Interest expense related to the sale of future revenue	236	220	16	7%
Interest income and other income, net	(3,437)	(16,321)	12,884	(79)%
Loss on extinguishment of debt	—	1,382	(1,382)	N/M

Manufacture and supply costs and expenses decreased 14%, or $2,959, for the year ended December 31, 2024 compared to the same period in 2023. The decrease in manufacture and supply costs was due to lower volume of strips sold, changes in product mix, and lower production costs.

Research and development expenses increased 55%, or $7,176, for the year ended December 31, 2024 compared to the same period in 2023. The increase in research and development expenses is primarily due to clinical trial costs and product research expenses associated with the continued advancement of the Anaphylm and AQST-108 programs, increases in personnel costs, and an increase in share-based compensation. The tables below provide a breakdown of the major costs included in total Research and development expenses and project costs by type of expense for each of the main clinical development projects in which we are engaged for each period presented:

	Year Ended December 31,		Change	
(In thousands)	2024	2023	$	%
Clinical Trials	$ 8,837	$ 3,597	$ 5,240	146%
Development and Manufacturing	303	664	(361)	(54%)
Product Research Expenses	1,119	678	441	65%
Total Project Costs	10,259	4,939	5,320	108%
Preclinical	987	659	328	50%
R&D personnel costs	6,509	5,775	734	13%
Consulting and Outside Services	331	323	8	2%
Share Based Compensation	1,215	456	759	166%
Depreciation/Amortization	70	91	(21)	(23%)
All Other R&D	909	861	48	6%
Total	$ 20,280	$ 13,104	$ 7,176	55%

	Year Ended December 31,											
	2024	2023		2024	2023		2024	2023		2024	2023	
	Total		% inc / dec	Anaphylm		% inc / dec	AQST-108		% inc / dec	Libervant		% inc / dec
Clinical Trials	$ 8,837	$ 3,597	146%	$ 8,231	$ 4,687	76%	$ 588	$ —	N/M	$ 18	$(1,090)	N/M
Development and Manufacturing	303	664	(54%)	310	676	(54%)	10	—	N/M	(17)	(12)	42%
Product Research Expenses	1,119	678	65%	930	463	101%	188	—	N/M	1	215	N/M
Total Project Costs	$10,259	$ 4,939	108%	$ 9,471	$ 5,826	63%	$ 786	$ —	N/M	$ 2	$ (887)	N/M

Total project expenses for Anaphylm increased 63%, or $3,645, for the year ended December 31, 2024 compared to the same period in 2023. Clinical trial expenses and product research expenses for Anaphylm increased $3,544 and $467, respectively, offset by decreases in development and manufacturing of $366 for the year ended December 31, 2024 compared to the same period in 2023. In 2024, Clinical trial expenses for Anaphylm of $8,231 were primarily due to Clinical trial costs

associated with the continued advancement of the Anaphylm program. In 2023, Clinical trial expenses for Anaphylm of $4,687 were related to the activities leading up to the Phase 3 PK Study. Total project expenses for AQST-108 increased $786 for the year ended December 31, 2024 compared to the same period in 2023 and were related to feasibility work for AQST-108. In 2023, Clinical trial expenses for Libervant of $1,090 were a credit from third party contractors upon the post completion audit of a study. In 2023, product research expenses for Libervant of $215 were primarily due to data integration and modeling work.

R&D personnel costs increased by 13%, or $734, for the year ended December 31, 2024 compared to the same period in 2023, due to additional headcount. R&D share-based compensation increased by $759, or 166%, which was primarily related to awards granted to our Chief Medical Officer upon his commencement of employment and the effect of new grants in 2024 to R&D personnel. All other R&D expenses include rent, utilities, maintenance and other expenses and fees.

Selling, general and administrative expenses increased 58%, or $18,430, for the year ended December 31, 2024 as compared to the same period in 2023. The increase primarily represents higher commercial spending of approximately $3,750, higher personnel costs of approximately $3,000, severance costs of approximately $2,900, higher share-based compensation expenses of $2,300, higher regulatory and licensing fees of approximately $1,400 related to the regulatory fee for Libervant, higher legal fees of $520, and higher expenses of $4,600 due to a change in the allocation of manufacture and supply costs compared to the prior period, partially offset by lower insurance expenses of $1,150.

Interest expense increased 76%, or $4,785, for the year ended December 31, 2024 compared to the same period in 2023. The increase was mostly driven by the increased amortization of debt issuance costs and discounts and higher interest expense on the 13.5% Notes refinanced in November 2023.

Interest expense related to amortization of the discount on the royalty obligations was $5,459 and $905 for the years ended December 31, 2024 and 2023, respectively. These amounts are due to the accounting associated with the royalty obligations as part of the 13.5% Notes issuance in November 2023. The year ended December 31, 2024 reflects 12 months of activity while the year ended December 31, 2023 reflects 2 months of activity.

Interest expense related to the sale of future revenue was $236 and $220 for the years ended December 31, 2024 and 2023. These amounts are due to the accounting associated with the sale of future revenue related to KYNMOBI royalties sold to Marathon on November 3, 2020 and do not represent or imply a monetary obligation or cash output at any time during the life of the transaction. These amounts represent amortization of issuance costs. In June 2023, Sunovion announced that it has voluntarily withdrawn KYNMOBI from the U.S. and Canadian markets, therefore, we likely will not receive any of the additional contingent payments under the Monetization agreement. As a result, we discontinued recording interest expense related to the sale of future revenue in the fourth quarter of 2022. See Part II Item 8. Financial Statements and Supplementary Data, Note 17, *Sale of Future Revenue* for details.

Interest income and other income, net was $3,437 and $16,321 for the years ended December 31, 2024 and 2023, respectively. The decrease by $12,884 is due to other income of $6,000 related to the Amendment 11 to the Indivior Commercial Exploitation Agreement, $8,500 related to the patent litigation settlement with BioDelivery Sciences International, Inc. and the receipt of the ERTC, which were recognized in the year ended December 31, 2023 and did not recur in 2024. During the year ended December 31, 2024, we recognized a gain of $1,500 on the termination of a license and supply agreement, which was partially offset by the adjustment of $1,200 to the remaining balance of the intangible asset due to the termination of the agreement. We also recognized higher interest income of $2,713 due to higher cash balances invested in interest-bearing and dividend-earning money market accounts.

For the year ended December 31, 2023, we recognized a loss on extinguishment of debt of $1,382 for prepayment penalties resulting from 12.5% Notes principal payments made in the first quarter of 2023 and fees related to the repayment of the 12.5% Notes in the fourth quarter of 2023. There was no loss on extinguishment of debt in 2024.

Liquidity and Capital Resources

Sources of Liquidity

We had $71,546 in cash and cash equivalents as of December 31, 2024. While our ability to execute our business objectives and achieve profitability over the longer term cannot be assured, our on-going business, existing cash and cash equivalents, expense management activities, potential asset sales or product outlicensing as well as access to the equity capital markets, including through our ATM facility, provide near term liquidity for us to fund our operating needs for at least the next twelve months as we continue to execute our business strategy.

On October 7, 2021, we entered into a supplemental indenture for the 12.5% Notes, pursuant to which the amortization schedule for the 12.5% Notes was amended to provide for the date of the first principal payment to be extended to March 30, 2023. The indenture did not change the maturity date of the 12.5% Notes or the interest payment obligation due under the 12.5% Notes. In connection with the indenture, we entered into a Consent Fee Letter with the holders of the 12.5% Notes,

pursuant to which we agreed to pay the holders of the 12.5% Notes an additional cash payment of $2,700 in the aggregate, payable in four quarterly payments beginning May 15, 2022. These payments were made by December 31, 2023.

In 2023, we redeemed $5,647 of our outstanding 12.5% Notes. We also made three scheduled principal payments totaling $11,463 prior to the refinancing of the 12.5% Notes on November 1, 2023. We also paid $353 in prepayment premium as result of the early retirement of debt which was reflected as a loss on extinguishment of debt in our Statements of Operations and Comprehensive Loss for the year ended December 31, 2023.

We established our first ATM facility in September 2019, and since inception to December 31, 2024, we have sold 19,857,518 shares of Common Stock which has generated net cash proceeds of approximately $60,524, net of commissions and other transactions costs of $3,119. On April 3, 2024, we filed a new shelf registration statement on Form S-3 to register the offer and sale of up to $250,000 worth of shares of Common Stock ("Registration Statement No. 333-278498" or the "2024 Registration Statement"), that was declared effective by the SEC on April 23, 2024. Included as part of the 2024 Registration Statement was a $100,000 ATM facility pursuant to the Amended Equity Distribution Agreement with Piper Sandler & Co.

For the year ended December 31, 2024, we sold 4,557,220 shares which provided net proceeds of approximately $11,821 after deducting commissions and other transaction costs of $564. For the year ended December 31, 2023, we sold 4,958,341 shares under the ATM facility which provided net proceeds of approximately $8,962 after deducting commissions and other transaction costs of $502. In the period subsequent to December 31, 2024 through March 5, 2025, we sold 7,457,627 shares under our ATM facility, which generated net proceeds of approximately $21,400 net of commissions of $605000. The remaining authorized balance of the ATM facility was $78,000,000 as of March 5, 2025.

On April 12, 2022, we entered into the Lincoln Park Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations under the Lincoln Park Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park up to $40,000 worth of shares of our Common Stock from time to time over the 36-month term of the Lincoln Park Purchase Agreement. For the years ended December 31, 2024 and 2023, we did not sell shares in connection with the Lincoln Park Purchase Agreement. We have no current intent to use the Lincoln Park facility and the Lincoln Park Purchase agreement will expire on April 12, 2025.

On June 6, 2022, we entered into the Securities Purchase Agreements with certain purchasers. The Securities Purchase Agreements provided for the sale and issuance by us of an aggregate of: (i) 4,850,000 shares of Common Stock, (ii) pre-funded warrants to purchase up to 4,000,000 shares of Common Stock and (iii) Common Stock Warrants to purchase up to 8,850,000 shares of Common Stock. The pre-funded warrants were fully exercised in 2022. In June 2023, 3,689,452 Common Stock warrants issued pursuant to the Securities Purchase Agreements were exercised with proceeds of approximately $3,542.

On August 2023, we entered into the Letter Agreement with the Exercising Holder of 5,000,000 of the remaining Common Stock Warrants. Pursuant to the Letter Agreement, the Exercising Holder and Aquestive agreed that the Exercising Holder would exercise all of its Existing Warrants at the then current exercise price of the Existing Warrants. The Exercising Holder subsequently exercised the Existing Warrants, with Aquestive receiving gross proceeds of $4,800. We also issued to the Exercising Holder New Warrants to purchase up to an aggregate of 2,750,000 shares of Common Stock. The New Warrants are exercisable after February 2, 2024, expire on February 2, 2029 and are exercisable only for cash, unless the shares of Common Stock underlying the New Warrants are not registered in accordance with the terms of the Letter Agreement, in which case the New Warrants may also be exercised by means of a "cashless exercise". The New Warrants have an exercise price of $2.60 per share.

On November 1, 2023, we issued $45,000 aggregate principal amount of its 13.5% Notes due November 1, 2028. A portion of the net proceeds from that Offering was used to redeem all of the remaining outstanding 12.5% Notes and to pay expenses relating to that Offering, with the balance of the proceeds to be used for general corporate purposes. Interest on the 13.5% Notes accrues at a rate of 13.5% per annum and is payable quarterly in arrears on March 30, June 30, September 30 and December 30 of each year commencing on December 30, 2023. The 13.5% Notes are interest-only until June 30, 2026, whereupon on such date and each payment date thereafter we will also pay an installment of principal of the 13.5% Notes pursuant to a fixed amortization schedule, along with a portion of an Exit Fee determined as of the applicable date of prepayment, payment, acceleration, repurchase or redemption, as the case may be. We accounted for this transaction as an extinguishment of debt and recognized a debt extinguishment charge of $1,029 for the year ended December 31, 2023. The debt extinguishment charge is included in Loss on the extinguishment of debt in the Company’s Statements of Operations and Comprehensive Loss.

On March 22, 2024, we completed the underwritten public offering of 16,666,667 shares of our common stock at the public offering price of $4.50 per share. In addition, pursuant to the partial exercise of the underwriters' option, on April 22, 2024, we sold an additional 559,801 shares of Common Stock. Net proceeds from the underwritten public offering, including the exercise of underwriters' option were $72,868, after deducting underwriting discounts of $4,651. In addition to the underwriting discounts related to this offering, we incurred professional fees and other costs totaling $894 as of December 31, 2024.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2024 and 2023:

(In thousands)	2024	2023
Net cash used for operating activities	$ (35,759)	$ (6,380)
Net cash used for investing activities	(159)	(995)
Net cash provided by financing activities	83,592	3,974
Net increase (decrease) in cash and cash equivalents	$ 47,674	$ (3,401)

Net Cash Used for Operating Activities

Net cash used for operating activities for the year ended December 31, 2024 increased by $29,379 compared to the same period in 2023. The increase in cash used for operating activities was primarily related to the change in net loss of $36,267 and deferred revenue of $13,809, which was mostly attributed to the recognition of deferred revenues due to the termination of license and supply agreements during the year ended December 31, 2024, and increases in trade and other receivables of $4,167. Other changes were mainly due to higher amortization of debt issuance costs and discounts of $8,742 on the 13.5% Notes refinancing in November 2023 and an increase in share-based compensation of $4,410 as compared to the year ended December 31, 2023.

Net Cash Used for Investing Activities

Net cash used for investing activities for the year ended December 31, 2024 decreased by $836 compared to the same period in 2023. The use of cash was related to capital expenditures.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 increased by $79,618 compared to the same period in 2023. The increase was primarily related to the underwritten public offering which provided net proceeds of $71,974, and higher ATM proceeds by $2,871 due to higher volumes and Common Stock prices as compared to the prior year. These increases during the year ended December 31, 2024 were also due to the absence of 12.5% Notes principal payments and premium paid to retire debt and the absence of the financing costs associated with the issuance of the 13.5% Notes, partially offset by no proceeds received from the issuance of the 13.5% Notes and the issuance of the Royalty Rights Agreements as compared to the prior year, and lower proceeds by $8,142 from the exercise of warrants.

Funding Requirements

Our on-going business, existing cash and equivalents, expense management activities as well as access to the equity capital markets, including through our ATM facility, and potential asset sales or product outlicensing potentially provide near term funding opportunities for Aquestive, see “Liquidity and Capital Resources”. On November 1, 2023, we issued $45,000 in aggregate principal amount of the 13.5% Notes due November 1, 2028. A portion of the net proceeds from the Offering were used to redeem all of the outstanding 12.5% Notes and to pay expenses relating to the Offering, with the balance of the proceeds to be used for general corporate purposes.

On March 22, 2024, we completed the Underwritten Public Offering of 16,666,667 shares of our common stock at the public offering price of $4.50 per share. In addition, pursuant to the partial exercise of the underwriters' option, on April 22, 2024, we sold an additional 559,801 shares of Common Stock. Net proceeds from the Underwritten Public Offering, including the exercise of underwriters' option were $72,868 after deducting underwriting discounts of $4,651. In addition to the underwriting discounts related to this offering, we incurred professional fees and other costs totaling $894 as of December 31, 2024.

We have used and intend to continue to use the net proceeds received from these transactions, together with the Company’s existing cash and cash equivalents, primarily to advance the development and commercialization of our product pipeline, including Anaphylm™ (epinephrine) Sublingual Film for the treatment of severe life-threatening allergic reactions, including anaphylaxis, and the continued commercial expansion of Libervant® (diazepam) Buccal Film for the treatment of ARS patients aged between two and five years, and for working capital, capital expenditures and general corporate purposes. We can provide no assurance that any of these sources of funding, either individually or in combination, will be available on reasonable terms, if at all, or sufficient to fund our business objectives. In addition, we may be required to utilize available financial resources sooner than expected. We have based our expectation on assumptions that could change or prove to be inaccurate, due to unrelated factors including factors arising in the capital markets, asset monetization markets, regulatory approval process, and regulatory oversight and other factors. Key factors and assumptions inherent in our planned continued operations and anticipated growth include, without limitation, those related to the following:

- continued ability of our customers to pay, in a timely manner, for presently contracted and future anticipated orders for our manufactured products, including effects of generics and other competitive pressures as currently envisioned;
- continued ability of our customers to pay, in a timely manner, for presently contracted and future anticipated orders for provided co-development and feasibility services, as well as regulatory support services for recently licensed products;
- access to debt or equity markets if, and at the time, needed for any necessary future funding, including our ability to access funding through our ATM facility, should we choose to access this facility;
- continuing review and appropriate adjustment of our cost structure consistent with our anticipated revenues and funding;
- continued growth and market penetration of Sympazan, including anticipated patient and physician acceptance and our licensee's ability to obtain adequate reimbursement and payment support from government agencies and other private medical insurers;
- effective commercialization within anticipated cost levels and expected ramp-up timeframes of our product Libervant for pediatric patients between two and five years of age;
- infrastructure and administrative costs at expected levels to support operations as an FDA and highly regulated public company;
- a manageable level of costs for ongoing efforts to protect our intellectual property rights and litigation matters in which we are involved;
- continued compliance with all covenants under our 13.5% Notes, including our ability to comply with our debt service obligations as required thereunder; and
- absence of significant unforeseen cash requirements.

We expect to continue to manage business costs to appropriately reflect the anticipated general decline in Suboxone revenue, and other external resources or factors affecting our business including, if available, future equity financing, other future access to the capital markets or other potential available sources of liquidity. In doing so, we plan to continue to focus on the core drivers of value for our stockholders, including, more importantly, continued investments in our ongoing product development activities in support of Anaphylm and AQST-108. Until profitability is achieved, if at all, additional capital and/or other financing or funding will be required, which could be material, to further advance the commercialization of Libervant for pediatric patients between two and five years of age and development and commercialization of Anaphylm and AQST-108, if approved by the FDA, and to meet our other cash requirements, including debt service, specifically our 13.5% Notes. We plan to conservatively manage our launch spending as to both timing and level relating to Libervant in light of the approval of Libervant by the FDA for patients between two and five years of age. Even as such, we expect to incur losses and negative cash flows for the foreseeable future and, therefore, we expect to be dependent upon external financing and funding to achieve our operating plan.

The sufficiency of our short-term and longer-term liquidity is directly impacted by our level of operating revenues and our ability to achieve our operating plan for revenues, regulatory approval in the time period planned for our product candidates and our ability to monetize other royalty streams or other licensed rights within planned timeframes, and there can be no assurance that we will be successful in any monetization transaction. Our operating revenues have fluctuated in the past and can be expected to fluctuate in the future. We expect to incur significant operating losses and negative operating cash flows for the foreseeable future, and we have a significant level of debt on which we have substantial ongoing interest payments have principal repayments related to our 13.5% Notes starting in June 2026 through the debt maturity date and royalty obligation payments projected to be made from the fourth quarter of 2024 to 2034, which are further discussed in Part II Item 8. Financial Statements and Supplementary Data, Note 15, *Long-Term Debt*. A substantial portion of our current and past revenues has been dependent upon our licensing, manufacturing and sales with one customer, Indivior, which is expected to continue, and it could take significantly longer than planned to achieve anticipated levels of cash flows to help fund our operations and cash needs.

To the extent that we raise additional funds by issuance of equity securities, our stockholders would experience further dilution and the terms of these securities could include liquidation or other preferences (if and to the extent permitted under the Indenture) that would adversely affect our stockholders' rights. Our ability to secure additional equity financing could be significantly impacted by numerous factors including our operating performance and prospects, positive or negative developments in the regulatory approval process for our product candidates, our existing level of debt which is secured by substantially all of our assets under the Indenture, and general financial market conditions, and there can be no assurance that we will continue to be successful in raising capital or that any such needed financing will be available, available on favorable or acceptable terms, if at all.

If adequate funds are not available for our short-term or longer-term liquidity needs and cash requirements as and when needed, we would be required to engage in expense management activities such as reducing staff, delaying, significantly scaling back, or even discontinuing some or all of our current or planned launch activities and research and development programs and clinical and other product development activities, and otherwise significantly reducing our other spending and adjusting our operating plan, and we would need to seek to take other steps intended to improve our liquidity. We also may seek outlicensing opportunities for our proprietary products and product candidate programs that we currently plan to self-commercialize, including for Libervant and Anaphylm, or explore other potential liquidity options or strategic opportunities. Such strategic opportunities could include asset sales, outlicensing or other monetization opportunities of our proprietary products and product candidates, including Libervant and Anaphylm, although we cannot assure that any of these actions or opportunities would be available or available on acceptable terms. While an outlicensing of our proprietary products and product candidates, if approved by the FDA, could limit our exposure to the costs of commercialization of the product and provide a potential source of royalty and milestone revenues, the benefit from the potential of additional future value that could result from our independent commercialization of these products and product candidates, assuming a successful launch of our proprietary products and product candidates, if approved by the FDA, would likely be limited. In addition, in the event of any such asset sales or outlicensing transactions, the future growth of the Company would be dependent on continued successful development or our early stage product candidates and/or asset acquisitions or other strategic transactions for the Company. There is no assurance that any such outlicensing or other strategic opportunities will be available or available on reasonable terms.

Contractual Obligations and Commitments

We have entered into various contractual agreements under which we have long term obligations. For more information regarding our commitments, see Part II, Item 8. Financial Statements and Supplementary Data, Note 23, *Contingencies.*

For more information regarding our future lease payments, see Part II, Item 8. Financial Statements and Supplementary Data, Note 11, *Right-of-Use Assets and Lease Obligations* for our minimum lease payments schedule. The expected timing of our leases may be different in future years, depending on our decision to extend lease terms and/or enter into leases in preceding years.

For more information on our payments related to the 13.5% Notes, see Part II, Item 8. Financial Statements and Supplementary Data, Note 15, *Long-Term Debt*.

Critical Accounting Policies and Use of Estimates

We have based our Management's Discussion and Analysis of our financial condition and results of operations on our Financial Statements, which have been prepared in accordance with generally accepted accounting principles, or GAAP, in the U.S. The preparation of the Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities at the date of the financial statements as well as the revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience when available and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While significant accounting policies are more fully described in Part II Item 8. Financial Statements and Supplementary Data, Note 3, *Summary of Significant Accounting Policies*, included in this filing, we believe that the following accounting policies are those that are most critical to the significant judgements and estimates used in the preparation of our Financial Statements.

Revenue Recognition

Proprietary product revenue, net - this net revenue is recognized when product is shipped and title passes to the customer, typically at time of delivery. At the time of sale, estimates for various revenue allowances are recorded based on historical trends and judgmental estimates. For sales of Libervant for patients between two to five years of age, returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates, if available, and these estimates are recorded as a reduction of receivables. Similarly determined estimates are recorded relating to wholesaler service fees, co-pay support redemptions, and other rebates, and these estimates are reflected as a component of accrued liabilities. Once all related variable considerations are resolved and uncertainties as to collectable amounts are eliminated, estimates are adjusted to actual allowance amounts. Provisions for these estimated amounts are reviewed and adjusted on no less than a quarterly basis.

License and Royalty Revenue – license revenues are determined based on an assessment of whether the license is distinct from any other performance obligations that may be included in the underlying licensing arrangement. If the customer is able to benefit from the license without provision of any other performance obligations by Aquestive and the license is

thereby viewed as a distinct or functional license, Aquestive then determines whether the customer has acquired a right to use the license or a right to access the license. For functional licenses that do not require further development or other ongoing activities by Aquestive, the customer is viewed as acquiring the right to use the license as, and when, transferred and revenues are generally recorded at a point in time, subject to contingencies or constraints. For symbolic licenses providing substantial value only in conjunction with other performance obligations to be provided by Aquestive, revenues are generally recorded over the term of the license agreement. Such other obligations provided by Aquestive generally include manufactured products, additional development services or other deliverables that are contracted to be provided during the license term. Payments received in excess of amounts ratably or otherwise earned are deferred and recognized over the term of the license or as contingencies or other performance obligations are met.

Royalty revenue is estimated and recognized when sales under supply agreements with commercial licensees are recorded, absent any contractual constraints or collectability uncertainties. Royalties based on sales of licensed products have been recorded in this manner.

Revenue recognition arising from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Milestone payments based on a non-sales metric such as a development-based milestone (*e.g.*, an NDA filing or obtaining regulatory approval) represent variable consideration and are included in the transaction price subject to any constraints. If the milestone payments relate to future development, the timing of recognition depends upon historical experience and the significance a third party has on the outcome. For milestone payments to be received upon the achievement of a sales threshold, the revenue from the milestone payments is recognized at the later of when the actual sales are incurred or the performance obligation to which the sales relate to has been satisfied.

Royalty Obligations and Interest Expense

In connection with the issuance of the 13.5% Notes, we entered into a Royalty Rights Agreement with each of the Note Holders granting the Note Holders a tiered royalty between 1.0% and 2.0% of annual worldwide net sales of Anaphylm (epinephrine) Sublingual Film for a period of eight years from the first sale of Anaphylm on a global basis. The note holders are also entitled to a tiered royalty between 1.0% to 2.0% of annual worldwide net sales of Libervant (diazepam) Buccal Film until the earlier of (1) the first sale of Anaphylm and (2) eight years from the first sale of Libervant. The Royalty Rights Agreements are classified as debt, and the value of the $45,000 13.5% Notes has been allocated between debt and the royalty obligations based on their relative fair market values. The excess of future estimated royalty payments of $56,926 over the $13,856 of allocated fair value is recognized as a discount related to the Royalty Right Agreements and is amortized over the life of the Royalty Rights Agreements. Such amortization is reflected as interest expense related to royalty obligations in the Statements of Operations and Comprehensive Loss. The 13.5% Notes are discussed in Part II Item 8. Financial Statements and Supplementary Data, Note 15, *Long-Term Debt.*

Liability and interest expense related to sale of future revenue

We treated the sale of future revenue related to KYNMOBI as debt financing in accordance with ASC 470 Debt, amortized under the effective interest rate method over the estimated life of the related expected royalty stream. The liability related to the sale of future revenue has been initially recorded at its proceeds, net of deferred cost. The liability related to the sale of future revenue and the related interest expense are based on our current estimates of future royalties expected to be paid over the life of the arrangement. We periodically assess the expected royalty payments using a combination of internal projections and forecasts from external resources. To the extent our future estimates of royalty payments are greater or less than previous estimates or the timing of such payments is materially different than its previous estimates, we will prospectively adjust the related interest expense. Amortization of debt is reflected as interest expense related to the sale of future revenue in the Statements of Operations and Comprehensive Loss. For further discussion of the sale of the future revenue, see Part II Item 8. Financial Statements and Supplementary Data, Note 17, *Sale of Future Revenue*.

Recent Accounting Pronouncements

Refer to Part II Item 8. Financial Statements and Supplementary Data, Note 3, *Summary of Significant Accounting Policies* in the accompanying Notes to our Financial Statements for a discussion of recent accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Item 7A is not applicable to us as a smaller reporting company and has been omitted.

Item 8. Financial Statements and Supplementary Data

Our financial statements, together with the report of our independent registered public accounting firm, appear in this Annual Report on Form 10-K beginning on page F-1.

Item 9. Change in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding our required disclosures.

As of December 31, 2024, our management, with the participation of our principal executive officer and 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). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate controls over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed 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. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of Aquestive Therapeutics, Inc.; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth in the *Internal Control-Integrated Framework (2013*) issued by the Committee of Sponsoring Organization of the Treadway Commission ("COSO"). Based upon its assessment and those criteria, our management has concluded that our internal control over financial reporting was effective as of December 31, 2024.

This annual report does not include an attestation report of our registered independent public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered independent public accounting firm pursuant to rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter, that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Our Chief Operating Officer Cassie Jung adopted a written sales plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act (the "Jung Plan") on December 10, 2024. The Jung Plan commences on March 11, 2025 and ends on December 31, 2025. The maximum number of shares to be sold under the Jung Plan is 108,656 shares; the actual number of shares sold will be dependent on the satisfaction of certain conditions set forth in the Jung Plan.

Our Chief Medical Officer Carl Kraus adopted a written sales plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act (the "Kraus Plan") on December 12, 2024. The Kraus Plan commences on March 17, 2025 and ends on February 27, 2026. The maximum number of shares to be sold under the Kraus Plan is 75,000. The actual number of shares sold will be dependent on the satisfaction of certain conditions set forth in the Kraus Plan.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this item will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

Item 13. Certain Relationships and Related Party Transactions and Director Independence

The information required by this item will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item will be included in our Proxy Statement to be filed with the SEC and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Item 8 hereof.

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the required information is given in the Financial Statements or Notes thereto.

(a)(3) Exhibits.

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Item 16. Form 10-K Summary

Not applicable.

Exhibit Index

The exhibits below are filed as part of this Form 10-K other than Exhibit 32.1 and Exhibit 32.2, which shall be deemed furnished.

Number	Description
3.1	Amended and Restated Certificate of Incorporation of Aquestive Therapeutics, Inc., dated as of July 27, 2018 (filed as Exhibit 3.1 to the Current Report on Form 8-K of the Company, as filed on July 27, 2018, and incorporated by reference herein).
3.2	Amended and Restated Bylaws of Aquestive Therapeutics, Inc. (filed as Exhibit 3.1 to the Current Report on Form 8-K of the Company, as filed on October 16, 2024, and incorporated by reference herein).
4.1	Form of Common Stock Certificate of Aquestive Therapeutics, Inc. (filed as Exhibit 4.1 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
4.2	Indenture dated July 15, 2019, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (filed as Exhibit 4.1 to the Current Report on Form 8-K filed on July 16, 2019, and incorporated by reference herein).
4.3	First Supplemental Indenture dated November 3, 2020, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (filed as Exhibit 4.3 to the Annual Report on Form 10-K of the Company, as filed on March 9, 2021, and incorporated by reference herein).
4.4	Second Supplemental Indenture dated November 20, 2020, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (filed as Exhibit 4.4 to the Annual Report on Form 10-K of the Company, as filed on March 9, 2021, and incorporated by reference herein).
4.5	Third Supplemental Indenture dated August 6, 2021, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (filed as Exhibit 4.1 to the Current Report on Form 8-K of the Company, as filed on August 9, 2021, and incorporated by reference herein).
4.6	Fourth Supplemental Indenture dated October 7, 2021, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (filed as Exhibit 4.1 to the Current Report on Form 8-K of the Company, as filed on August 8, 2021, and incorporated by reference herein).
4.7	Form of 2019 Warrant (filed as Exhibit 4.2 to the Current Report on Form 8-K of the Company, filed on July 16, 2019, and incorporated by reference herein).
4.8	Form of 2020 Warrant (filed as Exhibit 4.6 to the Annual Report of Form 10-K of the Company, as filed on March 9, 2021, and incorporated by reference herein).
4.9	Form of 2022 Pre-Funded Warrant (filed as Exhibit 4.1 to the Current Report on Form 8-K of the Company, as filed on June 8, 2022, and incorporated by reference herein).
4.10	Form of 2022 Common Stock Warrant (filed as Exhibit 4.2 to the Current Report on Form 8-K of the Company, as filed on June 8, 2022, and incorporated by reference herein).

4.11	Registration Rights Agreement, dated as of June 24, 2018, by and between Aquestive Partners, LLC and certain of the holders of its membership interests (filed as Exhibit 4.3 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
4.12	Description of Securities Registered under Section 12 of the Exchange Act (filed as Exhibit 4.7 to the Annual Report on Form 10-K of the Company, as filed on March 11, 2020, and incorporated by reference herein).
4.13	Fifth Supplemental Indenture, dated as of May 13, 2022, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank Trust Company, National Association, as Trustee and Collateral Agent (filed as Exhibit 4.1 to the Current Report on Form 8-K of the Company, as filed on May 17, 20222, and incorporated by reference herein).
4.14	Indenture Dated as of November 1, 2023, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto, and U.S. Bank Trust Company, National Association, as Trustee and Collateral Agent (filed as Exhibit 4.1 to the Current Report on Form 8-K of the Company, as filed on November 2, 2023, and incorporated by reference herein)
10.1	Form of Indemnification Agreement, by and between Aquestive Therapeutics, Inc and its directors and officers (filed as Exhibit 10.1 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.2	Form of Purchase Agreement in connection with the 2019 issuance of 12.5% Senior Secured Notes (filed as Exhibit 10.1 to the Current Report on Form 8-K filed on July 16, 2019, and incorporated by reference herein).
10.3	Form of 2020 Purchase Agreement in connection with the 2020 issuance of 12.5% Senior Secured Notes (filed as Exhibit 10.3 to the Annual Report of Form 10-K of the Company, as filed on March 9, 2021, and incorporated by reference herein).
10.4	Collateral Agreement in connection with issuance of 12.5% Senior Secured Notes, dated as of July 15, 2019, among Aquestive Therapeutics, Inc., as Issuer, the Other Grantors from time to time party thereto, U.S. Bank National Association, as Trustee, and U.S. Bank National Association, as Collateral Agent (filed as Exhibit 10.2 to the Current Report on Form 8-K of the Company, as filed on July 16, 2019, and incorporated by reference herein).
10.5+	Executive Employment Agreement, dated as of July 15, 2022, by and between Aquestive Therapeutics, Inc. and Daniel Barber (filed as Exhibit 10.1 to the Current Report on Form 10-Q of the Company, as filed on August 2, 2022, and incorporated by reference herein).
10.6+	Executive Employment Agreement, dated as of July 9, 2018, by and between Aquestive Therapeutics, Inc. and A. Mark Schobel (filed as Exhibit 10.8 to the Pre-Effective Amendment No. 1, as filed on July 16, 2018, to the Registration Statement on Form S-1 of the Company (File No. 333-225924), and incorporated by reference herein).
10.7†	Commercial Exploitation Agreement, by and between MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.) and Reckitt Benckiser Pharmaceuticals Inc., dated as of August 15, 2008 (as amended on August 19, 2009, November 13, 2009, March 30, 2010, October 13, 2010, December 15, 2010, December 9, 2011, December 1, 2012, October 14, 2013 (by Addendum A), July 30, 2014 (by Addendum B), and January 12, 2017) (filed as Exhibit 10.9 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.8†	Agreement, by and between MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.) and Indivior UK Limited, dated as of September 24, 2017 (filed as Exhibit 10.10 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.9†	Amendment No. 11 to Commercial Exploitation Agreement, dated as of August 15, 2008 (filed herewith).
10.10†	Agreement to Terminate CLA, by and between MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.) and KemPharm, Inc., dated as of March 20, 2012 (filed as Exhibit 10.11 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.11†	License Agreement, by and between MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.) and Cynapsus Therapeutics Inc., dated as of April 1, 2016 (filed as Exhibit 10.12 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.12†	First Amendment to License Agreement, by and between Aquestive Therapeutics, Inc. and Sunovion Pharmaceuticals, Inc., dated as of March 16, 2020 (filed as Exhibit 10.14 to the Annual Report of Form 10-K of the Company, as filed on March 9, 2021, and incorporated by reference herein).
10.13†	Second Amendment to License Agreement, by and between Aquestive Therapeutics, Inc. and Sunovion Pharmaceuticals, Inc., dated as of October 23, 2020 (filed as Exhibit 10.15 to the Annual Report of Form 10-K of the Company, as filed on March 9, 2021, and incorporated by reference herein).
10.14	Industrial Lease Agreement, by and between Ashland Northwest Partners, L.P. and MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.), dated as of October 24, 2006 (as amended on October 24, 2011 and February 8, 2018) (filed as Exhibit 10.13 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).

10.15+	Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan, as amended (filed as Exhibit 4.1 to the Registration Statement on Form S-8 of the Company (File No. 333-273857), as filed on August 9, 2023 and incorporated by reference herein).
10.16+	Aquestive Therapeutics, Inc. Employee Stock Purchase Plan as Amended (filed as Exhibit 10.18 to the Annual Report of Form 10-K of the Company, as filed on March 9, 2021, and incorporated by reference herein).
10.17+	Form of Stock Option Agreement (filed as Exhibit 10.16 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.18+	Form of Stock Option Agreement under the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.17 to the Pre-Effective Amendment No. 1, as filed on July 16, 2018, to the Registration Statement on Form S-1 of the Company (File No. 333-225924) and incorporated by reference herein).
10.19+	Form of Restricted Stock Unit Agreement under the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.18 to the Pre-Effective Amendment No. 1, as filed on July 16, 2018, to the Registration Statement on Form S-1 of the Company (File No. 333-225924) and incorporated by reference herein).
10.20+	Executive Employment Agreement, dated as of September 10, 2018, by and between Aquestive Therapeutics, Inc. and Lori J. Braender (filed as Exhibit 10.4 to the Quarterly Report on Form 10-Q of the Company, as filed on November 6, 2018, and incorporated by reference herein).
10.21	Purchase and Sale Agreement, dated as of November 3, 2020, by and between Aquestive Therapeutics, Inc. and MAM Pangolin Royalty, LLC (filed as Exhibit 10.23 to the Annual Report on Form 10-K of the Company, as filed on March 9, 2021, and incorporated by reference herein).
10.22	Amendment No.1 to Purchase Agreement, dated as of August 6, 2021, by and between Aquestive Therapeutics, Inc. and the Purchasers signatory thereto (as filed as Exhibit 10.22 to the Annual Report on Form 10-K of the Company, as filed on March 31, 2021, and incorporated by reference herein).
10.23	Amendment No. 2 to Purchase Agreement, dated as of May 13, 2022, by and between Aquestive Therapeutics, Inc. and the Purchasers signatory thereto (as filed as Exhibit 10.1 to the Current Report on Form 8-K of the Company, as filed on May 17, 2022, and incorporated by reference herein).
10.24	Consent Fee Letter, dated October 7, 2021, among Aquestive Therapeutics, Inc. and the Noteholder parties thereto (filed as Exhibit 10.1 to the Current Report on Form 8-K filed on October 8, 2021, and incorporated by reference herein).
10.25+	First Amendment to Executive Employment Agreement, dated as of June 30, 2021, by and between Aquestive Therapeutics, Inc. and Alexander Mark Schobel (as filed as Exhibit 10.25 to the Annual Report on Form 10-K of the Company, as filed on March 8, 2022, and incorporated by reference herein).
10.26+	First Amendment to Executive Employment Agreement, dated as of June 30, 2021, by and between Aquestive Therapeutics, Inc. and Keith J. Kendall (as filed as Exhibit 10.26 to the Annual Report on Form 10-K of the Company, as filed on March 8, 2022, and incorporated by reference herein).
10.27†	License and Supply Agreement, dated as of September 26, 2022, by and between Aquestive Therapeutics, Inc. and Atnahs Pharma UK Limited (filed as Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company, as filed on November 1, 2022, and incorporated by reference herein).
10.28†	License, Development and Supply Agreement, dated as of March 2022, by and between Aquestive Therapeutics, Inc. and Haisco Pharmaceutical Group Co., Ltd. (filed as Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company, as filed on May 4, 2022, and incorporated by reference herein).
10.29†	License Agreement, dated as of October 26, 2022, by and between Aquestive Therapeutics, Inc. and Otter Pharmaceuticals, LLC (filed herewith) (as filed as Exhibit 10.29 to the Annual Report on Form 10-K of the Company, as filed on March 31, 2023, and incorporated by reference herein).
10.30	Separation Agreement, dated as of May 17, 2022, by and between Aquestive Therapeutics, Inc. and Keith J. Kendall (filed as Exhibit 10.1 to the Current Report on Form 8-K of the Company, as filed on May 17, 2022, and incorporated by reference herein).
10.31	Form of Securities Purchase Agreement, dated as of June 6, 2022, by and between Aquestive Therapeutics, Inc. and the purchasers (filed as Exhibit 10.1 to the Current Report on Form 8-K of the Company, as filed on June 8, 2022, and incorporated by reference herein).
10.32	Purchase Agreement, dated as of April 12, 2022, by and between the Company and Lincoln Park (filed as Exhibit 10.1 to the Current Report on Form 8-K of the Company, as filed on April 13, 2022, and incorporated by reference herein).
10.33	Registration Rights Agreement, dated as of April 12, 2022, by and between the Company and Lincoln Park (filed as Exhibit 10.2 to the Current Report on Form 8-K of the Company, as filed on April 13, 2022, and incorporated by reference herein).

10.34	Equity Distribution Agreement, dated September 11, 2019, by and between Aquestive Therapeutics, Inc. and Piper Sandler & Co. (filed as Exhibit 1.2 to the Registration Statement on Form S-3 (333-233716) of the Company, as filed on September 11, 2019, and incorporated by reference herein)
10.35	Amendment No. 1 to the Equity Distribution Agreement, dated March 26, 2021, by and between Aquestive Therapeutics, Inc. and Piper Sandler & Co. (filed as Exhibit 10.1 to the Current Report on Form 8-K of the Company, as filed on March 26, 2021, and incorporated by reference herein)
10.36	Inducement Offer to Exercise Common Stock Purchase Warrants Letter Agreement dated August 1, 2023 (filed as Exhibit 10.1 to the Current Report on Form 8-K of the Company, as filed on August 2, 2023, and incorporated by reference herein).
10.37	Form of Purchase Agreement for the 13.5% Notes (filed as Exhibit 10.1 to the Current Report on Form 8-K of the Company, as filed on November 2, 2023, and incorporated by reference herein).
10.38	Collateral Agreement dated as of November 1, 2023 among Aquestive Therapeutics, Inc., as Issuer, the other Grantors from time to time party thereto, U.S. Bank Trust Company, National Association, as Trustee, and U.S. Bank Trust Company, National Association, as Collateral Agent (filed as Exhibit 10.2 to the Current Report on Form 8-K of the Company, as filed on November 2, 2023, and incorporated by reference herein).
10.39†	Form of Royalty Right Agreement (filed as Exhibit 10.3 to the Current Report on Form 8-K of the Company, as filed on November 2, 2023, and incorporated by reference herein).
10.40	Amendment to License and Supply Agreement between Aquestive and Atnahs Pharma UK Limited entered into March 27, 2023 (filed as Exhibit 10.40 to the Annual Report on Form 10-K of the Company, as filed on March 5, 2024, and incorporated by reference herein).
19.1	Insider Trading Policy.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm (filed herewith).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
97*	Incentive Compensation Recovery Policy (filed as Exhibit 97 to the Annual Report on Form 10-K of the Company, as filed on March 5, 2024 and incorporated by reference herein).
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 (formatted as inline XBRL and contained in Exhibit 101).

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment that has been granted by the Securities and Exchange Commission.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act and shall not be deemed to be incorporated by reference to any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

\+ Indicates a management contract or compensatory plan.

† Certain portions of this exhibit have been omitted because the omitted information is (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of the 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.

AQUESTIVE THERAPEUTICS, INC.

March 5, 2025

By: /s/ Daniel Barber

Daniel Barber
President and Chief Executive Officer
(Principal Executive Officer)

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 capabilities and on the dates indicated.

Signature	Title	Date
/s/ Daniel Barber Daniel Barber	President, Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer)	March 5, 2025
/s/ A. Ernest Toth, Jr. A. Ernest Toth, Jr.	Senior Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 5, 2025
/s/ Gregory B. Brown Gregory B. Brown, M.D.	Chairman of the Board of Directors	March 5, 2025
/s/ Abigail L. Jenkins Abigail L. Jenkins	Member of the Board of Directors	March 5, 2025
/s/ John S. Cochran John S. Cochran	Member of the Board of Directors	March 5, 2025
/s/ Julie Krop Julie Krop, M.D	Member of the Board of Directors	March 5, 2025
/s/ Marco Taglietti Marco Taglietti, M.D.	Member of the Board of Directors	March 5, 2025
/s/ Timothy Morris Timothy Morris	Member of the Board of Directors	March 5, 2025

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To the Stockholders and the Board of Directors

Aquestive Therapeutics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Aquestive Therapeutics, Inc. (the Company) as of December 31, 2024 and 2023, the related statements of operations and comprehensive loss, changes in stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2024, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, 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 these 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 a critical audit matter does not alter in any way our opinion on the 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 accounts or disclosures to which it relates.

Evaluation of the Company's ability to continue as a going concern

As discussed in Note 4 to the financial statements, the Company has experienced a history of net losses. The Company's accumulated deficit totaled $363,214 thousand as of December 31, 2024. Historically, the Company's sources of liquidity included cash and cash equivalents, equity, and debt offerings. The Company believes that its ongoing business, existing cash and equivalents, expense management activities, and access to equity capital markets through its ATM facility provide liquidity to fund its operating needs for at least twelve months from the date of issuance of these financial statements.

We identified the evaluation of the Company's assessment of its ability to continue as a going concern as a critical audit matter. A high degree of subjective auditor judgment was required to evaluate the Company's forecasted cash flows used in its going concern analysis due to uncertainty in certain assumptions, specifically forecasted expenses.

The following are the primary procedures we performed to address this critical audit matter. We compared the Company's historical forecasted cash flows to actual results to assess the Company's ability to accurately forecast. We performed sensitivity analyses over the Company's forecasted cash flows by evaluating the effect of changes to the forecasted expenses on the Company's going concern assessment. We assessed the reasonableness of the Company's forecasted expenses by comparing to management's communications to the Board of Directors and public information disseminated by the Company. We assessed the Company's disclosures related to its going concern assessment by comparing the disclosures to the audit evidence obtained.

/s/ KPMG LLP

We have served as the Company's auditor since 2006.

Short Hills, New Jersey
March 5, 2025

AQUESTIVE THERAPEUTICS, INC.
Balance Sheets
(In thousands, except per share/unit amounts)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 71,546	$ 23,872
Trade and other receivables, net	7,344	8,471
Inventories, net	6,044	6,769
Prepaid expenses and other current assets	3,286	1,854
Total current assets	88,220	40,966
Property and equipment, net	3,799	4,179
Right-of-use assets, net	5,182	5,557
Intangible assets, net	—	1,278
Other non-current assets	4,223	5,438
Total assets	$ 101,424	$ 57,418
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 10,287	$ 8,926
Accrued expenses	5,907	6,497
Lease liabilities, current	510	390
Deferred revenue, current	1,048	1,551
Liability related to the sale of future revenue, current	1,000	922
Royalty obligations, current	87	—
Loans payable, current	26	22
Total current liabilities	18,865	18,308
Notes payable, net	32,500	27,508
Royalty obligations, net	20,129	14,761
Liability related to the sale of future revenue, net	62,718	63,568
Lease liabilities	4,968	5,399
Deferred revenue, net of current portion	20,005	32,345
Other non-current liabilities	2,395	2,016
Total liabilities	161,580	163,905
Contingencies (Note 23)		
Stockholders' deficit:		
Common stock, 0.001 par value. Authorized 250,000,000 shares; 91,413,742 and 68,533,085 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	91	69
Additional paid-in capital	302,967	212,521
Accumulated deficit	(363,214)	(319,077)
Total stockholders' deficit	(60,156)	(106,487)
Total liabilities and stockholders' deficit	$ 101,424	$ 57,418

See accompanying notes to the financial statements.

AQUESTIVE THERAPEUTICS, INC.
Statements of Operations and Comprehensive Loss
(In thousands, except per share data amounts)

	Year Ended December 31,	
	2024	**2023**
Revenues	$ 57,561	$ 50,583
Costs and expenses:		
Manufacture and supply	17,872	20,831
Research and development	20,280	13,104
Selling, general and administrative	50,180	31,750
Total costs and expenses	88,332	65,685
Loss from operations	(30,771)	(15,102)
Other income (expenses):		
Interest expense	(11,122)	(6,337)
Interest expense related to royalty obligations, net	(5,459)	(905)
Interest expense related to the sale of future revenue	(236)	(220)
Interest income and other income, net	3,437	16,321
Loss on the extinguishment of debt	—	(1,382)
Net loss before income taxes	(44,151)	(7,625)
Income taxes benefit (expense)	14	(245)
Net loss	$ (44,137)	$ (7,870)
Comprehensive loss	$ (44,137)	$ (7,870)
Loss per share attributable to common stockholders:		
Basic and diluted (in dollars per share)	$ (0.51)	$ (0.13)
Weighted-average number of common shares outstanding:		
Basic and diluted (in shares)	86,726,211	61,255,864

See accompanying notes to the financial statements.

AQUESTIVE THERAPEUTICS, INC.
Statements of Changes in Stockholders' Deficit
(In thousands, except per share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance at December 31, 2022	54,827,734	$ 55	$ 192,598	$ (311,207)	$ (118,554)
Common Stock issued upon warrant exercises	8,689,452	9	8,333	—	8,342
Costs of common stock issued under private equity offering	—	—	(35)	—	(35)
Common Stock issued under public equity offering	4,958,341	5	9,459	—	9,464
Costs of common stock issued under public equity offering	—	—	(552)	—	(552)
Shares issued under employee stock purchase plan	36,168	—	66	—	66
Vested restricted stock units, net	19,515	—	(11)	—	(11)
Share-based compensation expense	—	—	2,662	—	2,662
Options exercised, net	1,875	—	1	—	1
Net loss	—	—	—	(7,870)	(7,870)
Balance at December 31, 2023	68,533,085	69	212,521	(319,077)	(106,487)
Common Stock issued under public equity offering-ATM	4,557,220	4	12,381	—	12,385
Costs of common stock issued under public equity offering-ATM	—	—	(602)	—	(602)
Common Stock issued under public equity offering	17,226,468	18	77,502	—	77,520
Costs of common stock issued under public equity offering	—	—	(5,546)	—	(5,546)
Common Stock issued upon warrant exercises	30,645	—	165	—	165
Shares issued under employee stock purchase plan	35,374	—	109	—	109
Share-based compensation expense	—	—	7,056	—	7,056
Vested restricted stock units, net	673,925	—	(1,351)	—	(1,351)
Options exercised, net	357,025	—	732	—	732
Net loss	—	—	—	(44,137)	(44,137)
Balance at December 31, 2024	91,413,742	$ 91	$ 302,967	$ (363,214)	$ (60,156)

See accompanying notes to the financial statements.

AQUESTIVE THERAPEUTICS, INC.
Statements of Cash Flows (In thousands)

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (44,137)	$ (7,870)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation, amortization, and impairment	718	1,345
Share-based compensation	7,099	2,689
Amortization of debt issuance costs and discounts	10,714	1,972
Gain on contract termination	(300)	—
Loss on the extinguishment of debt	—	1,029
Other, net	104	(204)
Changes in operating assets and liabilities:		
Trade receivables and other receivables, net	1,094	(3,073)
Inventories	725	(989)
Prepaid expenses and other assets	(223)	1,290
Accounts payable	2,782	(1,020)
Accrued expenses and other liabilities	(1,492)	(2,515)
Deferred revenue	(12,843)	966
Net cash used for operating activities	(35,759)	(6,380)
Cash flows from investing activities:		
Capital expenditures	(159)	(995)
Net cash used for investing activities	(159)	(995)
Cash flows from financing activities:		
Proceeds from issuance of common stock under public equity offering-ATM, net	11,783	8,912
Proceeds from common stock issued under public equity offering, net	71,974	—
Proceeds from exercise of warrants, net	165	8,307
Proceeds from shares issued under employee stock purchase plan	67	39
Proceeds from exercise of stock options	732	1
Proceeds from issuance of debt	—	31,144
Proceeds from issuance of Royalty Rights Agreements	—	13,856
Repayment of debt principal including lease liabilities	(23)	(51,529)
Payments for royalty obligations	(5)	—
Payments for financing costs	—	(4,643)
Premium paid to retire debt	—	(2,102)
Payments for taxes on share-based compensation	(1,101)	(11)
Net cash provided by financing activities	83,592	3,974
Net increase (decrease) in cash and cash equivalents	47,674	(3,401)
Cash and cash equivalents:		
Beginning of period	23,872	27,273
End of period	$ 71,546	$ 23,872
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 7,097	$ 4,602
Cash payments for income taxes	$ 305	$ —
Non-cash investing activities: capital expenditures in accounts payable	$ 78	$ —
Non-cash financing activities: accrued taxes on share-based compensation	$ 250	$ —

See accompanying notes to the financial statements.

Note 1. Company Overview and Equity Transactions

Company Overview

Aquestive Therapeutics, Inc. is a pharmaceutical company advancing medicines to bring meaningful improvement to patients' lives through innovative science and delivery technologies. The Company is developing pharmaceutical products to deliver complex molecules through alternative administrations to invasive and inconvenient standard of care therapies. The Company has a proprietary commercial product, Libervant® (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients between two and five years of age, which was launched in April 2024. The Company is also advancing a product pipeline for the treatment of severe allergic reactions, including anaphylaxis, under the Anaphylm™ trade name, and its Adrenaverse™ epinephrine prodrug pipeline platform. The Company has five licensed commercialized products which are marketed by its licensees in the U.S. and around the world. The Company is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. The Company's production facilities are located in Portage, Indiana, and its corporate headquarters and primary research laboratory facilities are based in Warren, New Jersey.

Equity Transactions

Equity Offering of Common Stock

The Company established its first ATM facility in September 2019, and since inception to December 31, 2024, the Company has sold 19,857,518 shares of Common Stock under its ATM Facility which has generated net cash proceeds of approximately $60,524, net of commissions and other transactions costs of $3,119. On April 3, 2024, the Company filed a new shelf registration statement on Form S-3, the 2024 Registration Statement, which was declared effective by the SEC on April 23, 2024. Included in the 2024 Registration Statement are (i) a base prospectus registering the offer, issuance and sale of up to $250,000 worth of Common Stock, preferred stock, debt securities, warrants, rights and units and (ii) a $100,000 ATM facility prospectus. For the year ended December 31, 2024, the Company sold 4,557,220 shares of common stock pursuant to the ATM prospectus and the Amended Equity Distribution Agreement with Piper Sandler & Co. (successor to Piper Jaffray & Co.), which provided net proceeds of approximately $11,821 after deducting commissions and other transaction costs of $564. For the year ended December 31, 2023, the Company sold 4,958,341 shares which provided net proceeds of approximately $8,962 after deducting commissions and other transaction costs of $502. The remaining authorized balance of the ATM facility was $100,000 as of December 31, 2024.

On April 12, 2022, the Company entered into the Lincoln Park Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations set forth in the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park up to $40,000 worth of shares of Common Stock from time to time over the 36-month term of the Lincoln Park Purchase Agreement. The Lincoln Park Purchase Agreement contains an ownership limitation such that the Company will not issue, and Lincoln Park will not purchase, shares of Common Stock if it would result in Lincoln Park's beneficial ownership exceeding 9.99% of the Company's then outstanding Common Stock. Lincoln Park has covenanted under the Lincoln Park Purchase Agreement not to cause or engage in any manner whatsoever any direct or indirect short selling or hedging of our Common Stock. For the years ended December 31, 2024 and 2023, the Company did not sell shares in connection with the Lincoln Park Purchase Agreement. The Company has no current intent to use the Lincoln Park facility and the Lincoln Park Purchase agreement will expire on April 12, 2025.

On March 22, 2024, the Company completed the underwritten public offering of 16,666,667 shares of its common stock at the public offering price of $4.50 per share. In addition, pursuant to the partial exercise of the underwriters' option, on April 22, 2024, the Company sold an additional 559,801 shares of Common Stock. Net proceeds from the underwritten public offering, including the exercise of underwriters' option were $72,868, after deducting underwriting discounts of $4,651. In addition to the underwriting discounts related to this offering, the Company incurred professional fees and other costs totaling $894 as of December 31, 2024.

Note 2. Basis of Presentation and Principles of Consolidation

These financial statements have been prepared in accordance with GAAP in the United States of America, and in accordance with the rules and regulations of the SEC. Certain reclassifications were made to conform to the current year presentation. As of March 31, 2024, the Company dissolved its subsidiaries and no longer prepares its financial statements on a consolidated basis. The dissolution of the subsidiaries did not have a material impact on the Company's financial statements as of December 31, 2024 or the consolidated financial statements as of December 31, 2023.

Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the ASC and ASU of FASB.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates and assumptions often involve assessments of matters that are inherently uncertain and accordingly actual results could differ from those estimates. Significant items subject to estimates and assumptions include those related to revenue recognition, inventory costs, allowances for rebates from proprietary product sales of Libervant for patients between two to five years of age, allowances for sales returns, the useful lives of fixed assets and the valuations of warrants issued, royalty obligations, sale of future revenues, share-based compensation, and contingencies.

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments purchased with original maturities of three months or less to be cash equivalents. At December 31, 2024 and 2023, cash and cash equivalents consisted of cash in bank accounts and money market Treasury mutual funds.

Concentration of Credit Risk

Cash and cash equivalents are held by federally insured financial institutions that management believes are of high credit quality. The Company has not experienced any losses in such accounts and such amounts may exceed federally-insured limits of $250.

Concentration of the Company's significant customers as of December 31, 2024 and 2023 is outlined in Note 6, *Revenues and Trade Receivables, Net.*

Trade Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company grants credit to customers in the normal course of business, but generally does not require collateral or any other security to support its receivables. The Company's credit terms generally range from 30 to 60 days, depending on the customer and type of invoice.

The Company maintains an allowance for credit losses on accounts receivable, which is recorded as a reduction to accounts receivable. Changes in the allowance are classified as Selling, general and administrative expenses in the Statements of Operations and Comprehensive Loss. The Company assesses collectability by reviewing accounts receivable on a collective basis where similar characteristics exist and on an individual basis when it identifies specific customers with known disputes or collectability issues. In determining the amount of the allowance for credit losses, the Company considers historical collectability based on past due status. It also considers customer-specific information, current market conditions and reasonable and supportable forecasts of future economic conditions to inform adjustments to historical loss data. On an ongoing basis, management evaluates the adequacy of these reserves. The allowance for credit losses, was $0 and $14 as of December 31, 2024 and 2023, respectively.

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost, determined by the first-in, first-out method, or net realizable value. The Company regularly reviews its inventories for impairment and reserves are established when necessary.

At each balance sheet date, the Company evaluates inventories for excess quantities, obsolescence and shelf life expiration. This evaluation includes analysis of historical sales levels by product, projections of future demand, the risk of competitive obsolescence for products, general market conditions, and a review of the shelf life expiration dates for products. To the extent that management determines there are excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products, or use them in production, prior to their expiration, the Company records allowances to adjust the carrying value to estimated net realizable value as necessary. The Company expenses inventory related to the Company's research and development activities when the Company purchases or manufactures it. Before the regulatory approval of the Company's product candidates, the Company recognizes research and development expense for the manufacture of drug products that could potentially be available to support the commercial launch of the Company's drug candidates, if approved by regulatory authorities.

Property and Equipment

Property and equipment are stated at cost net of accumulated depreciation and amortization, which is computed by the straight-line method based on the estimated useful lives of the respective assets, as discussed below. Leasehold improvements are amortized over the shorter of the lease terms or the estimated useful lives of the leased assets. Maintenance and repair costs are charged to expense as incurred, and expenditures for major renewals and improvements are capitalized. Upon disposition of property and equipment, the related cost and accumulated depreciation and amortization are removed from the accounts, and any gain or loss is reflected in the Statements of Operations and Comprehensive Loss.

Intangible Assets

Intangible assets included the costs of acquired composition and process technologies, the costs of purchased patents used in the manufacture of orally soluble film and the costs of acquired NDA. The Company amortized these assets using the straight-line method over the shorter of their legal lives or estimated useful lives. As of December 31, 2024, the balance of the Company's intangible assets was zero, see Note 12, *Intangible Assets, Net* for additional information.

Impairment of Long-Lived Assets

Long lived assets, such as property, plant, and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In these circumstances, the Company compares undiscounted cash flows expected to be generated by that asset or asset group to the corresponding carrying amounts. If this comparison is indicative of impairment, an impairment charge is recognized to the extent that the carrying amount exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered most appropriate. No impairment was recognized for the year ended December 31, 2024. The impairment charge of $216 was recognized for the year ended December 31, 2023.

Leases

Determination if an arrangement is a lease is made at inception. An arrangement is determined to contain a lease if the contract conveys the right to control the use of an identified property and equipment for a period of time in exchange for consideration. If the Company can benefit from the various underlying assets of a lease on their own or together with other resources that are readably available, or if the various underlying assets are neither highly dependent nor highly interrelated with underlying assets in the arrangements, they are considered to be a separate lease component. In the event multiple underlying assets are identified, the lease consideration is allocated to the various components based on each on the component’s relative fair value.

Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease arrangement. Operating lease assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company’s leases do not provide an implicit rate, in determining the operating lease liability, the Company uses an estimate of its incremental borrowing rate. The calculation of the operating lease assets includes any lease payments made and excludes any lease incentives. Our lease terms may include options to extend or terminate the lease and are included when it is reasonably certain that the Company will exercise the option.

The Company records operating lease assets and lease liabilities in its Balance Sheets. Lease expenses for lease payments are recognized on a straight-line bases over the lease term. Short-term leases, or leases that have a lease term of 12 months or less at consummation date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease. During the year ended December 31, 2023, the Company recognized a lease supporting its manufacturing facilities as a finance lease. Commitments under finance leases are not significant, and are included in Property and equipment, net; Loans payable, current and Notes payable, net on the Balance Sheets.

Royalty Obligations, net

On November 1, 2023, in connection with the issuance of the 13.5% Notes, the Company and the Note Holders entered into the Royalty Rights Agreements, which provide the Note Holders a tiered royalty between 1.0% and 2.0% of annual worldwide net sales of Anaphylm (epinephrine) Sublingual Film for a period of eight years from the first sale of Anaphylm on a global basis. The Note Holders are also entitled to a tiered royalty between 1.0% to 2.0% of annual worldwide net sales of Libervant (diazepam) Buccal Film until the earlier of (1) the first sale of Anaphylm and (2) eight years from the first sale of Libervant. The Royalty Rights Agreements are classified as debt, and the value of the $45,000 13.5% Notes has been allocated between debt and the royalty obligations based on their relative fair market values. The fair value of the royalty obligation is being amortized over the life of the Royalty Rights Agreements and such amortization is reflected as interest expense related to royalty obligations in the Statements of Operations and Comprehensive Loss. The 13.5% Notes are discussed in Note 15, *Long-Term Debt*, to its financial statements.

Liability Related to the Sale of Future Revenue

The Company treats the liability related to the sale of future revenue as debt financing, amortized under the effective interest rate method over the estimated life of the related expected royalty stream. The liability related to the sale of future revenue and the related interest expense are based on its current estimates of future royalties expected to be paid over the life of the arrangement. The Company periodically assesses the expected royalty payments using a combination of internal projections and forecasts from external resources. To the extent its future estimates of royalty payments are greater or less than previous estimates or the timing of such payments is materially different than its previous estimates, the Company will prospectively recognize related interest expense. Amortization of debt is reflected as interest expense related to the sale of future revenue in the Statements of Operations and Comprehensive Loss. For further discussion of the sale of the future revenue, see Note 17, *Sale of Future Revenue.*

Revenue Recognition

The Company's revenues include (i) sales of manufactured products pursuant to contracts with commercialization licensees, (ii) license and royalty revenues, (iii) co-development and research fees generally in the form of milestone payments, and (iv) sales of its proprietary CNS product, Libervant, for patients between two to five years of age. See Note 6, *Revenues and Trade Receivables, Net* for further details. The Company recognizes revenue to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To achieve this core principle, a five-step model is applied that includes (1) identifying the contract with a customer, (2) identifying the performance obligation in the contract, (3) determining the transaction price, (4) allocating the transaction price to the performance obligations, and (5) recognizing when, or as, an entity satisfies a performance obligation.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in the current revenue recognition standard. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. At contract inception, the Company assesses the goods promised in its contracts with customers and identifies a performance obligation for each promise to transfer to the customer a distinct good. When identifying performance obligations, the Company considers all goods or services promised in a contract regardless of whether explicitly stated in the contract or implied by customary business practice. The Company's performance obligations consist mainly of transferring goods and services identified in the contracts, purchase orders, invoices or statements of work.

Manufacture and supply revenue – this revenue is derived from products manufactured exclusively for specific customers according to their strictly-defined specifications, subject only to specified quality control inspections. Accordingly, at the point in time when quality control requirements are satisfied, revenue net of related discounts is recorded.

License and Royalty Revenue – license revenues are determined based on an assessment of whether the license is distinct from any other performance obligations that may be included in the underlying licensing arrangement. If the customer is able to benefit from the license without provision of any other performance obligations by the Company and the license is thereby viewed as a distinct or functional license, the Company then determines whether the customer has acquired a right to use the license or a right to access the license. For functional licenses that do not require further development or other ongoing activities by the Company, the customer is viewed as acquiring the right to use the license as, and when, transferred and revenues are generally recorded at a point in time, subject to contingencies or constraints. For symbolic licenses providing substantial value only in conjunction with other performance obligations to be provided by the Company, revenues are generally recorded over the term of the license agreement. Such other obligations provided by the Company generally include manufactured products, additional development services or other deliverables that are contracted to be provided during the license term. Payments received in excess of amounts ratably or otherwise earned are deferred and recognized over the term of the license or as contingencies or other performance obligations are met.

Royalty revenue is estimated and recognized when sales under supply agreements with commercial licensees are recorded, absent any contractual constraints or collectability uncertainties. Royalties based on sales of licensed products have been recorded in this manner.

Revenue recognition arising from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Milestone payments based on a non-sales metric such as a development-based milestone (*e.g.*, an NDA filing or obtaining regulatory approval) represent variable consideration and are included in the transaction price subject to any constraints. If the milestone payments relate to future development, the timing of recognition depends upon historical experience and the significance a third party has on the outcome. For milestone payments to be received upon the achievement of a sales threshold, the revenue from the milestone payments is recognized at the later of when the actual sales occur or the performance obligation to which the sales relate to has been satisfied.

Co-development and Research Fees – Co-development and research fees are earned through performance of specific tasks, activities or completion of stages of development defined within a contractual development or feasibility study agreement with a customer. The nature of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product. Accordingly, the duration of the Company's research and development projects may range from several months to approximately three years. Although each contractual arrangement is unique, common milestones included in these arrangements include those for the performance of efficacy and other tests, reports of findings, formulation of initial prototypes, production of stability clinical and/or scale-up batches, and stability testing of those batches. Additional milestones may be established and linked to clinical results of the product submission and/or approval of the product by the FDA and the commercial launch of the product.

Proprietary product sales, net – this net revenue is recognized when product is shipped and title passes to the customer, typically at time of delivery. At the time of sale, estimates for various revenue allowances are recorded based on historical trends and judgmental estimates. For sales of Libervant for patients between two to five years of age, returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates, if available, and these estimates are recorded as a reduction of accounts receivables. Similarly determined estimates are recorded relating to wholesaler service fees, co-pay support redemptions, and other rebates, and these estimates are reflected as a component of accrued liabilities. Once all related variable considerations are resolved and uncertainties as to collectable amounts are eliminated, estimates are adjusted to actual allowance amounts. Provisions for these estimated amounts are reviewed and adjusted on no less than a quarterly basis.

Contract Assets - in certain situations, customer contractual payment terms provide for invoicing in arrears. Accordingly, some or all performance obligations may be completely satisfied before the customer may be invoiced under such agreements. In these situations, billing occurs after revenue recognition, which results in a contract asset supported by the estimated value of the completed portion of the performance obligation. These contract assets are reflected as a component of other receivables within Trade and other receivables, net within the Balance Sheets. As of December 31, 2024 and 2023, such contract assets were $578 and $1,662, respectively, consisting primarily of products and services provided under specific contracts to customers for which earnings processes have been met prior to shipment of goods or full delivery of completed services, as well as estimated receivables from contracts with third parties.

Contract Liabilities - in certain situations, customer contractual payment terms are structured to permit invoicing in advance of delivery of a good or service. In such instances, the customer's cash payment may be received before satisfaction of some, or any, performance obligations that are specified. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. These contract liabilities are reflected as deferred revenue within the Balance Sheets. As remaining performance obligations are satisfied, an appropriate portion of the deferred revenue balance is credited to earnings. As of December 31, 2024 and 2023, such contract liabilities were $21,053 and $33,896, respectively.

Costs to obtain contracts - in certain situations, the Company may incur incremental costs of obtaining a contract with a customer. These costs, if expected to be recovered, are recognized as an asset and reflected as other assets within the Balance Sheets. The asset is amortized on a systematic basis that is consistent with the transfer to the customer of the goods or services to which the asset relates. As of December 31, 2024 and 2023, such costs to obtain contracts were $480 and $715, respectively.

Research and Development

Research and development, or R&D, expenses are recorded in accordance with ASC 730, *Research and Development* and are expensed as incurred. R&D expenses include R&D activities, services of external CROs, costs of their clinical research sites, scale-up and validation costs, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. CROs activities include preclinical laboratory experiments and clinical studies. Other activity expenses include regulatory consulting and other costs. The activities undertaken by regulatory consultants that were classified as R&D expense include assisting, communicating with, and advise its in-house staff with respect to various FDA submission processes, clinical trial processes and scientific writing matters, including preparing protocols and FDA submissions. These consulting expenses were direct costs associated with preparing, receiving and understanding work for its clinical trials and investigative drugs. Payments made to CROs based on agreed-upon terms, which may include payments in advance of a study start date. The Company expenses non-refundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when goods or services have been received rather than when payment was made. The Company reviews and accrues CROs expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion state of study as provided by CROs. Estimated CROs costs subject to revisions as such studies progress to completion. The Company charges revisions to expense in the period when the facts that give rise to the revision become known.

Income Taxes

Income taxes are recorded in accordance with FASB ASC Topic 740, *Income Taxes*, or ASC 740, which provides for deferred taxes using an asset and liability approach. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Uncertain tax positions are accounted for in accordance with the provision of ASC 740. When uncertain tax positions exist, the tax benefit is recognized to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. To date, the Company has not had any significant uncertain tax positions.

Share-Based Compensation

The Company records share-based compensation expenses for awards of stock options and RSUs under ASC 718, *Compensation — Stock Compensation*. For awards to non-employees for periods prior to the adoption of ASU 2018-07, *Compensation-Stock Compensation: Improvements to Non-employee Share-Based Payment Accounting,* on January 1, 2019, the Company had applied ASC 505-50, *Equity-based Payments to Non-Employees*. ASC 718 establishes guidance for the recognition of expenses arising from the issuance of stock-based compensation awards at their fair value at the grant date.

The Company's stock-based compensation includes grants of stock options and RSUs to employees, consultants and non-employee directors. Beginning in 2019, the Company also offered employees an opportunity to participate in an employee stock purchase plan.

The Company's estimates of the fair value of options at their grant dates are based on the Black-Scholes option valuation model and considers various variables and assumptions, including:

- the stock price at the grant date,
- exercise price,
- both the contractual and estimated expected term of the option,
- an estimate of stock price volatility based on that of an industry peer group,
- expected dividends, if any, and
- risk-free interest rate.

The Company's estimates of the fair value of RSUs at their grant or valuation dates vary based on whether the awards' vesting conditions are based on market conditions or service conditions. For awards with the vesting based on market conditions, the Company uses a Monte Carlo simulation that considers various variables and assumptions, including:

- simulated 30-day average at the end of the requisite service period,
- discount period based on the vesting term of the awards,
- an estimate of stock price volatility based on that of an industry peer group,
- expected dividends, if any, and
- risk-free interest rate.

These assumptions require estimates and judgements and changes in those inputs could impact the amount of expenses that are charged to earnings. The Company recognizes compensation expense for the fair value of RSUs and stock option awards over the requisite service period of the awards. All excess tax benefits, taxes and tax deficiencies from stock-based compensation are included in the provision for income taxes in the Company's Statements of Operations and Comprehensive Loss. As part of the Company's share-based compensation plan, shares are withheld to satisfy tax withholding obligations upon the vesting of RSUs. During the years ended December 31, 2024 and 2023, the fair value of the shares withheld was $1,351 and $11, respectively, and was recorded a reduction of Additional paid-in capital in the Statements of Changes in Stockholders' Deficit and as a financing activity in the Statements of Cash Flows. The portion of shares yet to be remitted as of 12/31/24 was $250 and is disclosed as a non-cash financing activity in the Statements of Cash Flows.

Per Share Data

Basic net loss per common share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of Common Stock outstanding during the period.

Diluted net income per common share is calculated by dividing net income available to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of shares of Common Stock and dilutive Common Stock outstanding during the period. Potentially dilutive common shares include the shares of Common Stock issuable upon the exercise of outstanding stock options and warrants, the shares of issued but unvested RSUs and the purchase of shares from the Company's employee stock purchase plan (using the treasury stock method). For all periods presented, potential common shares have been excluded from the calculation of EPS because their effect would be anti-dilutive.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that may result from transactions and economic events other than those with stockholders, such as unrealized gains or losses on investments. For the periods ended December 31, 2024 and 2023, the Company's comprehensive loss included only its net loss.

Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities. Cash and cash equivalents consisted of cash in bank accounts and money market Treasury mutual funds which are all Level 1 assets.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data. The Company currently has no Level 2 assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying amounts reported in the balance sheets for trade and other receivables, prepaid and other current assets, accounts payable, accrued expenses and deferred revenue approximate fair value based on the short-term maturity of these assets and liabilities.

The Company previously granted warrants to certain holders of the Company's the 12.5% Notes in connection with its debt repayment and debt refinancing. The Company also issued pre-funded warrants and warrants in 2022 and warrants in 2023 to purchase shares of Common Stock to certain purchasers in connection with the Securities Purchase Agreements. The warrants were valued based on the Black-Scholes valuation model performed by an independent third-party appraisal prepared as of the grant date consistent with generally-accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation.* See Note 16, *Warrants* for further information on these warrants.

The Company's 12.5% Notes contained a repurchase offer or put option which gave holders of the option the right, but not the obligation, to receive a specified amount of future royalties up to a capped amount. This put option was valued based on Level 3 inputs and its fair value was based primarily on an independent third-party appraisal consistent with generally-accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants Accounting and Valuation Guide. See Note 15, *Long-Term Debt* for further discussion.

In connection with the issuance of the 13.5% Notes on November 1, 2023, the Company and the Note Holders entered into the Royalty Right Agreements. The Royalty Right Agreements were valued based on Level 3 inputs, and their fair value is estimated by applying probability-weighted cash flows for future sales, which are then discounted to present value. Changes to fair value of the Royalty Rights Agreements can result from changes to one or a number of the aforementioned inputs. A significant change in unobservable inputs could result in a material increase or decrease to the effective interest rate of the Royalty Right Agreements liability. During 2024 and 2023, there were no material changes to the significant unobservable

inputs used to recognize the Royalty Right Agreements liability. Management has updated the projected years of payments to 2034 and the effective interest rate by 0.56%. See Note 15, *Long-Term Debt* for further discussion.

Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company manages its operations as a single segment for purposes of assessing performance and making operating decisions. For additional information regarding the adoption of ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures,* see Note 5, *Segment Reporting.*

Recent Accounting Pronouncements

The Company complies with new or revised accounting standards by the relevant dates on which adoption of such standards is required for smaller reporting companies.

From time to time, new accounting pronouncements are issued by the FASB and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Recently Adopted Accounting Pronouncements:

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ASU 2023-07, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The guidance in this update is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. The Company adopted the new disclosure requirements as of and for the years ended December 31, 2024 and December 31, 2023. Refer to Note 5, *Segment Reporting* for the required disclosure.

In August 2020, the FASB issued ASU 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)*: *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This Accounting Standards Update was issued to address the complexity in accounting for certain financial instruments with characteristics of liabilities and equity. Among other provisions, the amendments in this ASU significantly change the guidance on the issuer's accounting for convertible instruments and the guidance on the derivative scope exception for contracts in an entity's own equity such that fewer conversion features will require separate recognition, and fewer freestanding instruments, like warrants, will require liability treatment. More specifically, the ASU reduces the number of models that may be used to account for convertible instruments from five to three, amends diluted EPS calculations for convertible instruments, modifies the requirements for a contract that may be settled in an entity's own shares to be classified in equity and requires expanded disclosures intended to increase transparency. The Company adopted the new guidance on January 1, 2024. The adoption of this guidance did not have a material impact on the Company's financial statements.

In June 2022, the FASB issued ASU 2022-03, *Fair Value Measurement (Topic 820)*: *Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*. This Accounting Standards Update was issued to clarify the guidance in Topic 820, *Fair Value Measurement*, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, and to introduce new disclosure requirements for such equity securities. The Company adopted the new guidance on January 1, 2024. The adoption of this guidance did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncements Not Adopted as of December 31, 2024:

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* ASU 2024-03 will require the Company to disclose the amounts of purchases of inventory, employee compensation, depreciation and intangible asset amortization, as applicable, included in certain expense captions in the Statements of Operations, and Comprehensive Loss as well as qualitatively describe the remaining amounts included in those captions. ASU 2024-03 will also require the Company to disclose both the amount and the Company's definition of selling expenses. These disclosure requirements will be effective for the Company for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. The Company is currently evaluating the impact from the adoption of ASU 2024-03 on disclosures to its financial statements.

In December 2023, the FASB issued ASU 2023-09—*Income Taxes (Topic 740)—Improvements to Income Tax Disclosures.* This Accounting Standards Update was issued to enhance the transparency and decision usefulness of income tax

disclosures. The ASU requires that public business entities on an annual basis (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income (or loss) by the applicable statutory income tax rate). It further requires disclosure on an annual basis of the following information about income taxes paid: 1. The amount of income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign taxes 2. The amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid (net of refunds received) is equal to or greater than 5 percent of total income taxes paid (net of refunds received). Additionally, it requires the following information disclosure: 1. Income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign 2. Income tax expense (or benefit) from continuing operations disaggregated by federal (national), state, and foreign. The ASU eliminates certain current disclosure requirements. These disclosure requirements will be effective for the Company beginning January 1, 2025, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2023-09 on disclosures to its financial statements.

Note 4. Risks and Uncertainties

The Company assesses liquidity in terms of its ability to generate cash to fund its operating, investing and financing activities. The Company's cash requirements for 2025 and beyond include expenses related to continuing development and clinical evaluation of its products, manufacture and supply costs, costs of regulatory filings, patent prosecution expenses and litigation expenses, expenses related to commercialization of its products, as well as costs to comply with the requirements of being a public company operating in a highly regulated industry. As of December 31, 2024, the Company had $71,546 of cash and cash equivalents.

The Company has experienced a history of net losses. The Company's accumulated deficit totaled $363,214 as of December 31, 2024. The net losses and accumulated deficits were partially offset by gross margins from sales of commercialized licensed and proprietary products, license fees, milestone and royalty payments from commercial licensees and co-development parties. The Company's funding requirements have been met by its cash and cash equivalents, as well as its existing equity and debt offerings, including the 13.5% Senior Secured Notes, as further discussed in Note 15, *Long-Term Debt*, the ATM facility and other equity offerings, including the underwritten public offering as discussed in Note 1, *Company Overview and Equity Transactions.*

While the Company's ability to execute its business objectives and achieve profitability over the longer term cannot be assured, the Company's on-going business, existing cash and cash equivalents, expense management activities, including, but not limited to the ceasing of R&D activities, as well as access to the equity capital markets through its ATM facility, provide near term liquidity for the Company to fund its operating needs for at least the next twelve months as it continues to execute its business strategy.

Note 5. Segment Reporting

Operating segments are defined as components of an entity for which separate discrete financial information is available for evaluation by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources and in assessing performance. For the year ended December 31, 2024, the Company has identified one operating and reportable segment. The Company defines its operating segment based on internally reported financial information that is regularly reviewed by the CODM to analyze financial performance, make decisions, and allocate resources. The Company's Chief Executive Officer ("CEO") is the CODM. The Company manages its operations as a single segment for purposes of assessing performance and making operating decisions. This segment encompasses the development and advancement of a product pipeline for the treatment of severe allergic reactions, including anaphylaxis, and the Adrenaverse epinephrine prodrug pipeline platform. Additionally, the Company serves as the exclusive manufacturer for its proprietary product, Libervant, and four licensed commercialized products.

The CODM reviews the segment's profit or loss based on net loss reported on the Statements of Operations and Comprehensive Loss. The CODM also considers forecast-to-actual variances on a monthly basis for expenses deemed significant. Furthermore, the CODM reviews the segment's assets based on total assets reported on the Balance Sheets. All long-lived assets are held in the United States. While the Company generated $57,561 and $50,583 in revenues in 2024 and 2023, respectively, management expects the Company to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials, ultimately seeking regulatory approval. The CODM uses cash forecast models to guide investment decisions and assess entity-wide operating results and performance. Net loss is used to monitor budget and rolling forecasts versus actual results. The CODM views specific categories within research and development expenses, selling expenses, and general and administrative expenses as significant due to their direct correlation with cash burn and profitability.

The following table reconciles reported revenues to net loss under the significant expense principle for the years ended December 31, 2024, and 2023:

	Year Ended December 31,	
	2024	2023
Revenues	$ 57,561	$ 50,583
Costs and expenses:		
Total Manufacture and Supply Expenses	17,872	20,831
R&D Project expenses:		
Anaphylm project expenses	9,471	5,826
AQST-108 project expenses	786	—
Libervant project expenses	2	(887)
R&D other expenses:		
Personnel costs[1]	7,724	6,231
Other[2]	2,297	1,934
Total Research and Development Expenses	20,280	13,104
Selling expenses:		
Personnel costs[1]	2,382	864
Other[3]	5,164	775
Total Selling expenses	7,546	1,639
General & Administrative expenses:		
Personnel costs[1]	21,064	10,770
Other[4]	21,570	19,341
Total General and Administrative Expenses	42,634	30,111
Total Selling, General and Administrative Expenses	50,180	31,750
Total costs and expenses	88,332	65,685
Loss from operations	(30,771)	(15,102)
Other (expenses) income	(13,380)	7,477
Net loss before income taxes	(44,151)	(7,625)
Income taxes benefits (expense)	14	(245)
Net loss	$ (44,137)	$ (7,870)
Comprehensive loss	$ (44,137)	$ (7,870)

1 - Personnel costs include payroll expenses, share-based compensation expenses and severance

2 - Other Research and Development expenses include preclinical, consulting, maintenance, and testing fees

3 - Other Selling expenses include commercialization and other related expenses

4 - Other General and Administrative expenses include legal/patent fees, insurance fees, IT expenses, investor relations expenses, regulatory fees, facility and other costs

Note 6. Revenues and Trade Receivables, Net

The Company's revenue was comprised of the following:

	Year Ended December 31,	
	2024	2023
Manufacture and supply revenue	$ 39,976	$ 43,805
License and royalty revenue	15,345	5,376
Co-development and research fees	1,925	1,402
Proprietary product revenue, net	315	—
Total revenues	$ 57,561	$ 50,583

Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Year Ended December 31,	
	2024	2023
United States	$ 39,930	$ 37,104
Ex-United States	17,631	13,479
Revenues	$ 57,561	$ 50,583

For the year ended December 31, 2024, United States revenues were derived primarily from Indivior (manufacture and supply revenue, and co-development and research fees), MTPA (license and royalty revenue that was previously recorded as deferred revenue and now recognized due to the termination of the contract), and Assertio (manufacture and supply revenue, license and royalty revenue and co-development and research fees). Ex-United States revenues were derived primarily from Haisco (license and royalty revenue that was previously recorded as deferred revenue and now recognized due to the termination of the contract), Indivior (manufacture and supply revenue, license and royalty revenue and co-development and research fees), and Hypera (manufacture and supply revenue, license and royalty revenue and co-development and research fees) for revenue markets outside of the United States.

For the year ended December 31, 2023, United States revenues were derived primarily from Indivior (manufacture and supply revenue, and co-development and research fees), Assertio (manufacture and supply revenue, and license and royalty revenue), and Zevra (license and royalty revenue). Ex-United States revenues were derived primarily from Indivior (manufacture and supply revenue, license and royalty revenue and co-development and research fees) and Hypera (manufacture and supply revenue and license and royalty revenue) for revenue markets outside of the United States.

Trade and other receivable, net consist of the following:

	December 31,	
	2024	2023
Trade receivables	$ 4,919	$ 5,570
Contract and other receivables	2,473	2,915
Less: allowance for credit losses	—	(14)
Less: sales-related allowances	(48)	—
Trade and other receivables, net	$ 7,344	$ 8,471

Contract and other receivables totaled $2,473 and $2,915 as of December 31, 2024 and 2023, respectively, consisting primarily of contract assets and other receivables. Contract assets consist of products and services provided under specific contracts to customers for which earnings processes have been met prior to shipment of goods or full delivery of completed services, as well as estimated receivables from contracts with third parties. Other receivables include the current portion related to the Monetization royalty receivable and other receivables. Sales-related allowances as of December 31, 2024 were estimated in relation to revenues recognized for sales of Libervant for patients between two to five years of age.

The following table presents the changes in the allowance for credit losses:

	December 31,	
	2024	2023
Balance at beginning of the period	$ 14	$ 40
Allowance reduction	(14)	(26)
Balance at end of the period	$ —	$ 14

Sales-Related Allowances

Revenues from sales of products are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and co-pay support redemptions. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale. The Company includes these estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized for such transaction will not occur, or when the uncertainty associated with the variable consideration is resolved. The calculation of some of these items requires management to make estimates based on sales data, historical return data, contracts and other related information that may become known in the future. The adequacy of these provisions is reviewed on a quarterly basis.

The following table presents the changes in sales-related allowances:

	December 31,	
	2024	2023
Balance at beginning of period	$ —	$ 669
Provision	71	—
Payments / credits	(23)	(87)
Reclassifications	$ —	$ (582)
Balance at end of period	$ 48	$ —

Accruals for returns allowances and prompt pay discounts are reflected as a direct reduction of trade receivables, and accruals for wholesaler service fees, co-pay support redemptions and other rebates are reflected as current liabilities. The accrued balances relative to these provisions included in Trade and other receivables, net and accrued expenses were $48 and $665, respectively, as of December 31, 2024, and $0 and $645, respectively, as of December 31, 2023. See Note 14, *Accrued Expenses*.

Concentration of Major Customers

Customers are considered major customers when net revenue exceeds 10% of total revenue for the period or outstanding receivable balances exceed 10% of total receivables. For the year ended December 31, 2024, Indivor and Haisco represented approximately 62% and 12% of total revenue, including the one-time recognition of deferred revenue for Haisco, respectively. As of December 31, 2024, Indivor and Cosmed exceeded the 10% threshold for outstanding receivable balances and represented 41% and 16%, respectively, of total trade and other receivables. For the year ended December 31, 2023, Indivor represented approximately 80% of total revenue. As of December 31, 2023, Indivor and Zevra Therapeutics, Inc. exceeded the 10% threshold for outstanding receivable balances and represented 65% and 13%, respectively of total trade and other receivables.

Note 7. Material Agreements

Commercial Exploitation Agreement with Indivior

In August 2008, the Company entered into the Indivior License Agreement (with subsequent amendments) with Reckitt Benckiser Pharmaceuticals, Inc. who was later succeeded to in interest by Indivior. Pursuant to the Indivior License Agreement, the Company agreed to manufacture and supply Indivior's requirements for Suboxone, a sublingual film formulation, both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, the Company is required to manufacture Suboxone in accordance with current Good Manufacturing Practice standards and according to the specifications and processes set forth in the related quality agreements the Company entered into with Indivior. Additionally, the Company is required to obtain API for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that the Company is obligated to fill and requires Indivior to provide the Company with a forecast of its requirements at various specified times throughout the year. The Indivior License Agreement provides for payment by Indivior of an agreed upon purchase price per unit until January 1, 2025 and, thereafter, that is subject to annual adjustments based on

changes in an agreed upon price index. In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) outside of the U.S., subject to annual maximum amounts and limited to the life of the related patents.

The Indivior License Agreement contains customary contractual termination provisions, including with respect to a filing for bankruptcy or corporate dissolution, an invalidation of the intellectual property surrounding Suboxone, and commission of a material breach of the Indivior License Agreement by either party. Additionally, Indivior may terminate the Indivior License Agreement if the FDA or other applicable regulatory authority declares the Company's manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. The initial term of the Indivior License Agreement was seven years from the commencement date. Thereafter, the Indivior License Agreement automatically renewed for successive one-year periods.

Effective as of March 2, 2023, the Company and Indivior entered into the Indivior Amendment to the Indivior License Agreement. The Indivior Amendment was entered into for the primary purpose of amending the Agreement as follows: (i) extending the term of the Agreement until August 16, 2026 and thereafter providing for automatic renewal terms of successive one year periods unless Indivior delivers notice to the Company, at least twelve months prior to the expiration of the then current term, of Indivior's intent not to renew, subject to the earlier termination rights of the parties under the Agreement, and providing that the Agreement will not automatically renew for any renewal term beginning after the expiration of the last to expire of the product patents covered under the Indivior License Agreement; and (ii) agreeing to transfer pricing and payment terms for supplied product under the Indivior License Agreement. During the year ended December 31, 2023, in consideration of the agreements between the parties, the Company received a payment of $11,482 from Indivior, of which amount $5,482 represented: (a) payment of the portion of a 2022 price increase that had not been previously paid and (b) an estimated payment in 2023 for certain price increases. During the year ended December 31, 2023, the Company recognized $5,482, of which $1,682 was related to the 2022 price increases, in Manufacture and supply revenue and $6,000 in Interest income and other income, net on the Statements of Operations and Comprehensive Loss. There were no retroactive price adjustments included in Manufacture and supply revenue for year ended December 31, 2024.

Supplemental Agreement with Indivior

On September 24, 2017, the Company entered into an agreement with Indivior, or the Indivior Supplemental Agreement. Pursuant to the Indivior Supplemental Agreement, the Company conveyed to Indivior all existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to the Suboxone product. The Company also conveyed to Indivior the right to sublicense manufacturing and marketing capabilities to enable an Indivior licensed generic buprenorphine product to be produced and sold by parties unrelated to Indivior or Aquestive. Under the Indivior Supplemental Agreement, the Company was entitled to receive certain payments from Indivior commencing on the date of the Indivior Supplemental Agreement through January 1, 2023. Once paid, all payments made under the Indivior Supplemental Agreement are non-refundable. Through February 20, 2019, the at-risk launch date of the competing generic products of Dr. Reddy's Labs and Alvogen, the Company received an aggregate of $40,750 from Indivior under the Indivior Supplemental Agreement. Further payments under the Indivior Supplemental Agreement were suspended until adjudication of related patent infringement litigation was finalized. No further payments are due to the Company under the Indivior Supplemental Agreement. See Note 23, *Contingencies* for details.

All payments made by Indivior to the Company pursuant to the Indivior Supplemental Agreement were in addition to, and not in place of, any amounts owed by Indivior to the Company pursuant to the Indivior License Agreement.

License Agreement with Sunovion Pharmaceuticals, Inc.

On April 1, 2016, the Company entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion), referred to as the Sunovion License Agreement, pursuant to which Sunovion obtained an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing apomorphine for the treatment of off episodes in Parkinson's disease patients. Sunovion used this intellectual property to develop its apomorphine product KYNMOBI, which was approved by the FDA on May 21, 2020. This approval triggered Sunovion's obligation to remit a payment of $4,000, due on the earlier of: (a) the first day of product availability at a pharmacy in the United States; or (b) within six months of FDA approval of the product. This amount was received as of September 30, 2020 and was included in License and royalty revenues for the twelve months ended December 31, 2020.

Effective March 16, 2020, the Company entered into the First Amendment to the Sunovion License Agreement. The Amendment was entered into for the primary purpose of amending the Sunovion License Agreement as follows: (i) including the United Kingdom and any other country currently in the EU which later withdraws as a member country in the EU for purpose of determining the satisfaction of the condition triggering the obligation to pay the third milestone due under the Sunovion License Agreement, (ii) extending the date after which Sunovion has the right to terminate the Sunovion License Agreement for convenience from December 31, 2024 to March 31, 2028, (iii) modifying the effective inception date of the first

minimum annual royalty due from Sunovion to the Company form January 1, 2020 to April 1, 2020, and (iv) modifying the termination provision to reflect the Company's waiver of the right to terminate the Sunovion License Agreement in the event that KYNMOBI was not commercialized by January 1, 2020. This Sunovion License Agreement will continue until terminated by Sunovion in accordance with the termination provisions of the Amendment to the Sunovion License Agreement. The Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents unless earlier terminated under the termination provisions contained therein. Upon termination of the Sunovion License Agreement, all rights to intellectual property granted to Sunovion to develop and commercialize apomorphine-based products will revert to the Company.

On October 23, 2020, the Company amended the Sunovion License Agreement to clarify the parties' agreement with respect to certain provisions in the Sunovion License Agreement, specifically the date after which Sunovion has the right to terminate the Sunovion License Agreement and the rights and obligations of the parties regarding the prosecution and maintenance of the Company's patents covered under the Sunovion License Agreement.

In consideration of the rights granted to Sunovion under the Sunovion License Agreement, the Company received aggregate payments totaling $22,000 to date. In addition to the upfront payment of $5,000, the Company has also earned an aggregate of $17,000 in connection with specified regulatory and development milestones in the United States and Europe (the "Initial Milestone Payments"), all of which have been received to date. With the Monetization Agreement (defined below) entered into on November 3, 2020 relating to KYNMOBI as described in the paragraph below, the Company is no longer entitled to receive any payments under the Sunovion License Agreement.

Purchase and Sale Agreement with an affiliate of Marathon

On November 3, 2020, the Company entered into the Monetization Agreement with Marathon. Under the terms of the Monetization Agreement, the Company sold to Marathon all of its contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI. In exchange for the sale of these rights, the Company received an upfront payment from Marathon of $40,000 and an additional payment of $10,000 through the achievement of the first milestone. The Company has received an aggregate amount of $50,000 through December 31, 2024 under the Monetization Agreement.

Under the Monetization Agreement, additional contingent payments of up to $75,000 may be due to the Company upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125,000. In June 2023, Sunovion announced that it has voluntarily withdrawn KYNMOBI from the U.S. and Canadian markets, therefore, the Company likely will not receive any of the additional contingent payments under the Monetization agreement. See Note 17, *Sale of Future Revenue* for further details on the accounting for the Monetization Agreement.

Agreement to Terminate CLA with Zevra Therapeutics, Inc. (formerly KemPharm)

In March 2012, the Company entered into an agreement with Zevra to terminate a Collaboration and License Agreement entered into by the Company and Zevra in April 2011. Under this termination arrangement, the Company has the right to participate in any and all value that Zevra may derive from the commercialization or any other monetization of KP-415 and KP-484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving Zevra and collaborations, royalty arrangements, or other transactions from which Zevra may realize value from these compounds, including the product Azstarys®.

Licensing and Supply Agreement with Haisco for Exservan™ (Riluzole Oral Film) for ALS Treatment in China

The Company entered into the Haisco Agreement with Haisco, a Chinese limited company listed on the Shenzhen Stock Exchange, effective as of March 3, 2022, pursuant to which Aquestive granted Haisco an exclusive license to develop and commercialize Exservan (riluzole oral film) for the treatment of ALS in China. Under the terms of the Haisco Agreement, Aquestive was the exclusive sole manufacturer and supplier for Exservan in China. Under the Haisco Agreement, as amended, the Company received a $7,000 upfront cash payment in September 2022, and was entitled to receive regulatory milestone payments and double-digit royalties on net sales of Exservan in China, and earn manufacturing revenue upon the sale of Exservan in China. In June 2024, the Haisco Agreement was terminated, and the Company will not receive any contingent payments under the Haisco Agreement. The Company recognized previously deferred revenue of $7,000 for the upfront payment received in September 2022 on the Company's Statements of Operations and Comprehensive Loss for the year ended December 31, 2024. The termination agreement released all parties from any existing or ongoing obligations. Commissions of $134 that had been capitalized were expensed immediately in Selling, general, and administrative expenses on the Statements of Operations and Comprehensive Loss.

Compensatory Arrangements of Certain Officers

On May 17, 2022, the Company announced that Keith J. Kendall, former President and Chief Executive Officer of the Company, was leaving the Company and the Company's Board of Directors, effective May 17, 2022. In connection with his departure, Mr. Kendall and the Company entered into a Separation Agreement, including a Consulting Agreement, dated as of May 17, 2022. Under the Separation Agreement, in addition to other severance benefits already received by Mr. Kendall in 2022, Mr. Kendall received a monthly severance payment for eighteen months following the Termination Date, or November 22, 2023. By the end of December 31, 2023, all payments due to Mr. Kendall were made.

Licensing and Supply Agreement with Atnahs Pharma UK Limited

The Company entered into the Pharmanovia Agreement, effective as of September 26, 2022, pursuant to which the Company granted Pharmanovia an exclusive license to certain of the Company's intellectual property to develop and commercialize Libervant (diazepam) Buccal Film for the treatment of prolonged or acute, convulsive seizures in all ages in the Territory during the term of the Pharmanovia Agreement. Under the Pharmanovia Agreement, Pharmanovia will lead the regulatory and commercialization activities for Libervant in the Territory and the Company will serve as the exclusive sole manufacturer and supplier of Libervant in the Territory. Pursuant to the Pharmanovia Agreement, the Company received $3,500 upon agreement execution and upon the occurrence of certain conditions set forth in the Pharmanovia Agreement, will receive additional milestone payments and profit shares, as well as manufacturing fees and royalty fees through the expiration of the Pharmanovia Agreement.

Effective March 27, 2023, the Company amended the Pharmanovia Agreement to expand the scope of territory for the license of Libervant to cover the rest of the world, excluding the U.S., Canada and China. Under the Pharmanovia Amendment, Pharmanovia will be responsible for seeking applicable regulatory approval in the expanded territories, which include Latin America, Africa and Asia Pacific. Pursuant to the terms of the Pharmanovia Amendment, the Company received a non-refundable payment of $2,000 from Pharmanovia in connection with the execution of the Pharmanovia Amendment.

Licensing Agreement with Assertio Holdings, Inc.

Effective as of October 26, 2022, the Company entered into the Assertio Agreement to license Sympazan (clobazam) oral film for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients aged two years of age and older. Under the terms of the Assertio Agreement, the Company granted to Assertio an exclusive, worldwide license of its intellectual property for Sympazan to Assertio during the term of the Assertio License Agreement for an upfront payment of $9,000. In addition, Aquestive received a $6,000 milestone payment subsequent to Aquestive's receipt of a notice of allowance from the PTO of the Company's patent application U.S. Serial No. 16/561,573, and payment by the Company of the related allowance fee. The Company received the notice of allowance from the PTO and paid the related allowance fee on October 27, 2022. Further, under the Assertio Agreement, the Company will receive royalties from Assertio for the sale of the product through the expiration of the Assertio Agreement. The Company also entered into a long-term supply agreement with Assertio for Sympazan pursuant to which the Company is the exclusive sole worldwide manufacturer and supplier of the product and will receive manufacturing fees from Assertio for the product through the expiration of such supply agreement.

Licensing Agreement with Mitsubishi Tanabe Pharma America, Inc.

In January 2021, the Company announced that Aquestive granted an exclusive license to MTPA for the commercialization of Exservan in the United States. MTPA is a multinational pharmaceutical company with a focus on patients with ALS. The product was launched by MTPA in June 2021. Under the terms of the MTPA license agreement, Aquestive was the exclusive manufacturer and supplier of Exservan for MTPA in the United States. In June 2024, under the Second Amendment to the License and Supply Agreement, MTPA and the Company mutually agreed to terminate the agreement. As of June 30, 2024 and as part of the termination, the parties were released from any existing or ongoing obligations (except for certain limited non-material post-termination obligations). Upon termination, previously deferred revenue of $3,317 was recognized in the Statements of Operations and Comprehensive Loss for the year ended December 31, 2024 for milestone payments that had been received. Commissions of $57 that had been capitalized were expensed immediately in Selling, general, and administrative expenses on the Statements of Operations and Comprehensive Loss for the year ended December 31, 2024.

Note 8. Financial Instruments – Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Observable quoted prices in active markets for identical assets or liabilities.

- Level 2 — Observable prices that are based on inputs not quoted on active markets but corroborated by market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity, such as pricing models, discounted cash flow methodologies and similar techniques.

The carrying amounts reported in the balance sheets for trade and other receivables, prepaid and other current assets, accounts payable and accrued expenses, and deferred revenue approximate their fair values based on the short-term maturity of these assets and liabilities.

The Company granted warrants to certain noteholders in connection with its debt repayment and debt refinancing during 2020 and 2019, respectively. Those warrants were valued based on Level 3 inputs and their fair value was based primarily on an independent third-party appraisal prepared as of the grant date consistent with generally accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held Company Equity Securities Issued as Compensation. See Note 16*, Warrants* for further information on these warrants.

The Company's 12.5% Senior Secured Notes contained a repurchase offer or put option which gives holders of the option the right, but not the obligation, to require the Company to redeem the 12.5% Notes up to a capped portion of milestone payments resulting from the Monetization Agreement. This put option was valued based on Level 3 inputs and its fair value was based primarily on an independent third-party appraisal consistent with generally accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants Accounting and Valuation Guide. See Note 15, *Long-Term Debt* for further discussion.

In June 2022, the Company issued pre-funded warrants to purchase up to 4,000,000 shares of Common Stock and Common Stock Warrants to purchase up to 8,850,000 shares of Common Stock in connection with its Securities Purchase Agreements with certain purchasers. Those warrants were valued based on Level 3 inputs and their fair value was based primarily on an independent third-party appraisal prepared as of the grant date consistent with generally accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants' Accounting and Valuation Guide. See Note 16*, Warrants* for further information on these warrants.

On August 1, 2023, the Company entered into the Letter Agreement with the Exercising Holder of the remaining warrants to purchase 5,000,000 of the shares of Common Stock. Pursuant to the Letter Agreement, the Exercising Holder and the Company agreed that the Exercising Holder would exercise all of its Existing Warrants for shares of Common Stock underlying the Existing Warrants at $0.96 per share of Common Stock, the current exercise price of the Existing Warrants. Under the Letter Agreement, in consideration of the Exercising Holder exercising the Existing Warrants, the Company issued to the Exercising Holder new warrants to purchase up to an aggregate of 2,750,000 shares of New Warrants at $2.60 per share. Those warrants were valued based on Level 3 inputs and their fair value was based primarily on an independent third-party appraisal prepared as of the grant date consistent with generally accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants' Accounting and Valuation Guide. See Note 16*, Warrants* for further information on these warrants.

On November 1, 2023, in connection with the issuance of the 13.5% Notes, the Company and the Note Holders entered into the Royalty Right Agreements dated as of November 1, 2023, which provides the Note Holders:

a. a tiered royalty between 1.0% and 2.0% of annual worldwide net sales of Anaphylm (epinephrine) Sublingual Film for a period of eight years from the first sale of Anaphylm on a global basis, and
b. a tiered royalty between 1.0% to 2.0% of annual worldwide net sales of Libervant (diazepam) Buccal Film until the earlier of (1) the first sale of Anaphylm and (2) eight years from the first sale of Libervant.

Those Royalty Agreements were valued based on Level 3 inputs and their fair value was based primarily on internal management estimates developed based on third-party data and reflect management's judgements, current market conditions, and forecasts. The initial fair value measurement of the Royalty Right Agreements was determined based on significant unobservable inputs, including the discount rate, estimated probabilities of success, and the estimated amount of future sales of Anaphylm and Libervant. See Note 15, *Long-Term Debt* for further discussion.

Note 9. Inventories, Net

Inventory consists of the following:

	December 31,	
	2024	2023
Raw material	$ 3,266	$ 2,118
Packaging material	2,135	3,028
Finished goods	643	1,623
Total inventory	$ 6,044	$ 6,769

Note 10. Property and Equipment, Net

		December 31,	
	Useful Lives	2024	2023
Machinery	3 - 15 years	$ 20,317	$ 20,248
Furniture and fixtures	3 - 15 years	769	769
Leasehold improvements	(a)	21,419	21,386
Computer, network equipment and software	3 - 7 years	2,685	2,627
Construction in progress		2,110	2,033
		47,300	47,063
Less: accumulated depreciation and amortization		(43,501)	(42,884)
Total property and equipment, net		$ 3,799	$ 4,179

(a) Leasehold improvements are amortized over the shorter of the lease term or their estimated useful lives.

Total depreciation and amortization related to property and equipment was $640 and $1,153 for the years ended December 31, 2024 and 2023, respectively. No impairment losses were recognized for the year ended December 31, 2024. For the year ended December 31, 2023, the Company recognized a $216 impairment of an asset held in Construction in progress account that was assessed by management as no longer usable. Such impairment charge is included in the Manufacture and supply expenses on the Statements of Operations and Comprehensive Loss.

Note 11. Right-of-Use Assets and Lease Obligations

The Company leases all realty used at its production and warehouse facilities, corporate headquarters, commercialization operations center and research and laboratory facilities. None of these three leases include the characteristics specified in ASC 842, Leases, that require classification as financing leases and, accordingly, these leases are accounted for as operating leases. These leases, as amended, provide remaining terms between 3.3 years and 8.8 years, including renewal options expected to be exercised to extend the lease periods. See Part II, Properties for details.

During the year ended December 31, 2023, the Company recognized a lease supporting its manufacturing facilities as a finance lease. Commitments under finance leases are not significant, and are included in Property and equipment, net, and Notes Payable, net on the Balance Sheets.

The Company does not recognize a right-to-use asset and lease liability for short-term leases, which have terms of 12 months or less on its Balance Sheets. For longer-term lease arrangements that are recognized on the Company's Balance sheets, the right-of-use asset and lease liability is initially measured at the commencement date based upon the present value of the lease payments due under the lease. These payments represent the combination of the fixed lease and fixed non-lease components that are due under the arrangement. The costs associated with the Company’s short-term leases, as well as variable costs relating to the Company’s lease arrangements, are not material to the financial results.

The implicit interest rates of the Company’s lease arrangements are generally not readily determinable and as such, the Company applies an incremental borrowing rate, which is established based upon the information available at the lease commencement date, to determine the present value of lease payments due under an arrangement. Measurement of the operating lease liability reflects a range of an estimated discount rate of 14.8% to 15.6% applied to minimum lease payments, including expected renewals, based on the incremental borrowing rate experienced in the Company’s collateralized debt refinancing.

The Company’s lease costs are recorded in manufacture and supply, research and development and selling, general and administrative expenses in its Statements of Operations and Comprehensive Loss. For the years ended December 31, 2024 and

2023, total operating lease expenses totaled $1,814 and $1,745, respectively, including variable lease expenses such as common area maintenance and operating costs of $487 and $447, respectively.

The Company's payments due under its operating leases are as follows:

	Amount
2025	$ 1,284
2026	1,318
2027	1,346
2028	1,180
2029 and thereafter	3,915
Total lease payments	9,043
Less: imputed interest	(3,565)
Total operating lease liabilities	$ 5,478

Note 12. Intangible Assets, Net

The following table provides the components of identifiable intangible assets, all of which are finite lived.

	December 31,	
	2024	2023
Purchased intangible	$ 3,858	$ 3,858
Purchased patent	509	509
	4,367	4,367
Less: accumulated amortization	(4,367)	(3,089)
Intangible assets, net	—	1,278

Amortization expense was $78 and $157 for each of the years ended December 31, 2024 and 2023, respectively.

In June 2024, in connection with a termination of an agreement, the Company recorded a gain on termination of the contract in the amount of $1,500, which was partially offset by an adjustment to the remaining balance of $1,200 of the intangible asset. The net gain of $300 was recorded within Other income, net on the Statements of Operations and Comprehensive Loss for the year ended December 31, 2024. See Note 7, *Material Agreements.*

Note 13. Other Non-Current Assets

The following table provides the components of other non-current assets:

	December 31,	
	2024	2023
Royalty receivable	$ 3,000	$ 4,000
Other	1,223	1,438
Total other non-current assets	$ 4,223	$ 5,438

During the second quarter of 2020, under the Sunovion License Agreement, the Company recognized $8,000 of royalty revenue and corresponding royalty receivable, related to the eight $1,000 annual minimum guaranteed royalty payments that are due to the Company. In connection with the Monetization Agreement, the Company performed an assessment under ASC 860, *Transfer and Servicing* to determine whether the existing receivable was transferred to Marathon and concluded it was not transferred. As of December 31, 2024 and 2023, Royalty receivable consists of four and five, respectively, annual minimum payments due from Sunovion, the last of which is due in March, 2028. The current portion of the royalty receivable is included in Trade and other receivables, net. See Note 17, *Sale of Future Revenue* for further details on how this receivable relates to the Monetization Agreement transaction.

Non-current portion of commissions capitalized under ASC 340, *Other Assets and Deferred Costs,* is recorded within Other non-current assets on the Balance Sheets. Commissions of $191 were expensed in Selling, general, and administrative expenses on the Statements of Operations and Comprehensive Loss for the year ended December 31, 2024 due to the termination of the underlying contracts.

Note 14. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2024	2023
Accrued compensation	$ 4,732	$ 4,202
Real estate and personal property taxes	365	337
Accrued distribution expenses and sales returns provision	665	645
Interest payable	17	1,013
Other	128	300
Total accrued expenses	$ 5,907	$ 6,497

The increase in Accrued compensation is mostly related to an increase in the current portion of accrued severance as of December 31, 2024. The decrease in Interest payable is due to the timing of interest payments on the 13.5% Senior Notes. The fourth quarter 2024 interest payment on the 13.5% Senior Notes was made on December 30, 2024. As of December 31, 2023, interest payable on the 13.5% Senior Notes was due on January 2, 2024. See Note 15, *Long-Term Debt,* for discussion of 13.5% Notes and related interest payable.

Accrued distribution expenses and sales returns provision mostly represent estimated liabilities for wholesaler service fees, co-pay support redemptions and other rebates related to the proprietary product Libervant and returns related to the period prior to the outlicensing of our proprietary product, Sympazan.

Note 15. Long-Term Debt

12.5% Senior Secured Notes

On July 15, 2019, the Company completed the private placement of up to $100,000 aggregate principal of its 12.5% Notes due 2025 and issued Warrants to purchase 2,000,000 shares of Common Stock, at $0.001 par value per share.

Upon closing of the Base Indenture, the Company issued $70,000 of the 12.5% (the "Initial Notes") along with the Warrants and rights of first offer (the “First Offer Rights”) to the noteholders participating in this transaction. Issuance of the Initial Notes and Warrants provided net proceeds of $66,082.

On November 3, 2020, the Company entered into the First Supplemental Indenture (the "First Supplemental Indenture" and, together with all other subsequent supplemental indentures and the Base Indenture, collectively, the "Indenture") by and among the Company and U.S. Bank National Association, as Trustee (the "Trustee") and Collateral Agent thereunder to the Base Indenture, by and between the Company and the Trustee. Under the Second Supplemental Indenture, dated November 20, 2020, the Company repaid $22,500 of its $70,000 outstanding 12.5% Notes from the upfront proceeds received under the Monetization Agreement. Further, the Company entered into an additional Purchase Agreement with its noteholders whereby the Company issued in aggregate $4,000 of additional 12.5% Notes (the "Additional Notes") in lieu of paying a prepayment premium to two noteholders on the early repayment of the 12.5% Notes discussed above. The result of these two transactions reduced the net balance of the Company's 12.5% Senior Notes outstanding in the aggregate to $51,500 at December 31, 2020. The $4,000 principal issuance would be repaid proportionally over the same maturities as the other 12.5% Notes. The Company also paid to one of its noteholders a $2,250 premium as result of the early retirement of debt.

The Company accounted for the $22,500 debt repayment as a debt modification of the 12.5% Notes. The fees paid to the noteholders inclusive of (i) $2,250 early premium prepayment and (ii) $4,000 issuance of Additional Notes in lieu of paying a prepayment penalty were recorded as additional debt discount, amortized over the remaining life of the 12.5% Notes using the effective interest method. Loan origination costs of $220 associated with the Additional Notes were expensed as incurred. Existing deferred discounts and loan origination fees on the 12.5% Notes are amortized as an adjustment of interest expense over the remaining term of modified debt using the effective interest method.

The First Supplemental Indenture contained a provision whereby, as the Company receives any cash proceeds from the Monetization Agreement, each noteholder has the right to require the Company to redeem all or any part of such noteholder’s outstanding 12.5% Notes at a repurchase price in cash equal to 112.5% of the principal amount, plus accrued and unpaid interest. This repurchase offer was capped at 30% of the cash proceeds received by the Company as the contingent milestones were attained, if any, up through June 30, 2025. A valuation study was performed by an independent third-party appraiser and updated in June 30, 2023. Based on the valuation study, the put option was valued at $0. The resulting $45 decrease in the put option fair value was recorded in interest income and other income, net on the Statements of Operations and Comprehensive Loss for the year ended December 31, 2023. The embedded put option was deemed to be a derivative under ASC 815 *Derivatives and Hedging*, which required the recording of the embedded put option at fair value subject to remeasurement at

each reporting period. In addition, as of the closing of this transaction, the Company issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of the Company's Common Stock. As of December 31, 2023, the put option was no longer in place due to the refinancing of the 12.5% Notes.

On October 7, 2021, the Company entered into the Fourth Supplemental Indenture, pursuant to which the amortization schedule for the 12.5% Notes was amended to provide for the date of the first principal payment to be extended from September 30, 2021 to March 30, 2023. The Fourth Supplemental Indenture did not change the maturity date of the 12.5% Notes or the interest payment obligation due under the 12.5% Notes. In connection with the Fourth Supplemental Indenture, the Company entered into a Consent Fee Letter with the holders of the 12.5% Notes (the "Consent Fee Letter"), pursuant to which the Company agreed to pay the holders of the 12.5% Notes an additional cash payment ("Consent Fee") of $2,700 in the aggregate, payable in four quarterly payments beginning May 15, 2022. The last Consent Fee installment of $675 was made in February 2023.

The 12.5% Notes provided a stated fixed interest rate of 12.5%, payable quarterly in arrears, with the final quarterly principal repayment of 12.5% Notes due at maturity on June 30, 2025.

The Company could have elected, at its option, to redeem the 12.5% Notes at any time at premiums that range from 101.56% of outstanding principal if prepayment occurs on or after the fifth anniversary of the issue date of the Initial Notes to 112.50% if payment occurs during the third year after the issuance of the 12.5% Notes. The Indenture also included change of control provisions under which the Company may have been required to redeem the 12.5% Notes at 101% of the remaining principal plus accrued interest at the election of the noteholders.

During the year ended December 31, 2023, the Company redeemed $5,647 of its outstanding 12.5% Notes. The Company also paid a $353 prepayment premium as a result of the early retirement of debt which was reflected as a loss on extinguishment of debt on the Company's Statements of Operations and Comprehensive Loss for the year ended December 31, 2023. The Company also made three scheduled principal payments totaling $11,463 during the year ended December 31, 2023.

Amortization expense arising from deferred debt issuance costs and debt discounts related to the 12.5% Notes for the year ended December 31, 2023 was $13.

On November 1, 2023, the Company issued the 13.5% Notes, as described below, and used the proceeds from the issuance to repay the outstanding principal balance under the 12.5% Notes of $36,014, including accrued and unpaid interest and a redemption fee. The Company accounted for this transaction as an extinguishment of debt and recognized a debt extinguishment charge of $1,029 for the year ended December 31, 2023. The debt extinguishment charge is included in Loss on the extinguishment of debt in the Company's Statements of Operations and Comprehensive Loss.

13.5% Senior Secured Notes

On November 1, 2023, the Company entered into an Indenture Agreement with certain institutional investors (the "Note Holders") and issued $45,000 aggregate principal amount of its 13.5% Notes due 2028. The Company received net proceeds of approximately $4,326 from this transaction after the repayment of the 12.5% Notes and deduction of debt discount, and debt issuance costs.

The 13.5% Notes are senior secured obligations of the Company and mature on November 1, 2028. The 13.5% Notes bear interest at a fixed rate of 13.5% per year, payable quarterly commencing on December 30, 2023 with the first interest payment due on January 2, 2024. On each payment date commencing on June 30, 2026, the Company will pay an installment of principal of the 13.5% Notes pursuant to a fixed amortization schedule, along with the applicable Exit Fee. The Exit Fee totals $2,000.

The Company may, at its option, redeem the 13.5% Notes in full or in part:

a. if such redemption occurs prior to November 1, 2025, at a redemption price equal to 100% of the principal amount plus accrued and unpaid interest, plus the applicable Exit Fee, plus an Applicable Premium which is the greater of
    i. 1.0% of the principal redeemed; and
    ii. the amount, if any, by which the present value of the principal to be redeemed on November 1, 2025, plus all required interest due on such date, computed using a discount rate equal to the Treasury Rate, plus 100 basis points, exceeds the amount of principal to be redeemed; and
b. if such redemption occurs after November 1, 2025, the redemption price is equal to 108.50% of the principal amount plus accrued and unpaid interest, plus the applicable Exit Fee.

If the Company undergoes a change of control, the Note Holders may require the Company to repurchase for cash all or any portion of the 13.5% Notes at a change of control repurchase price equal at 108.5% plus the Exit Fee of the remaining principal, plus accrued interest at the election of the Note Holders.

The Indenture permits the Company, upon the continuing satisfaction of certain conditions, including that the Company has at least $100,000 of net revenues for the most recently completed twelve calendar month period, to enter into an ABL facility not to exceed $10,000. The ABL Facility may be collateralized only by assets of the Company constituting inventory, accounts receivable, and the proceeds thereof.

In connection with the issuance of 13.5% Notes, the Company and the Note Holders entered into the Royalty Right Agreements dated as of November 1, 2023, which provides Note Holders:

a. a tiered royalty between 1.0% and 2.0% of annual worldwide net sales of Anaphylm (epinephrine) Sublingual Film for a period of eight years from the first sale of Anaphylm on a global basis, and

b. a tiered royalty between 1.0% to 2.0% of annual worldwide net sales of Libervant (diazepam) Buccal Film until the earlier of (1) the first sale of Anaphylm and (2) eight years from the first sale of Libervant.

Both the 13.5% Notes and Royalty Right Agreements represent freestanding instruments which were issued in conjunction with each other. They are classified as debt within the scope of ASC 470, *Debt* and are subsequently measured on an amortized cost basis.

The initial fair value measurement of the Royalty Right Agreements was determined based on significant unobservable inputs, including the discount rate, estimated probabilities of success, and the estimated amount of future sales of Anaphylm and Libervant. These inputs are derived using internal management estimates developed based on third-party data and reflect management's judgements, current market conditions, and forecasts.

The Royalty Right Agreements fair value is estimated by applying probability-weighted cash flows for future sales, which are then discounted to present value. Changes to the fair value of the Royalty Rights Agreements can result from changes to one or a number of the aforementioned inputs. A significant change in unobservable inputs could result in a material increase or decrease to the effective interest rate of the Royalty Right Agreements liability.

The following table summarizes the significant unobservable inputs used in the initial fair value measurement of the Royalty Right Agreements as of December 31, 2023:

	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Royalty Right Agreements	Probability weighted income approach	Discount Rate	15%
		Probability of Success	75%
		Projected Years of Payments	2025 - 2033

As of December 31, 2024, there were no material changes to the significant unobservable inputs used to recognize the Royalty Right Agreements liability. Management has updated the projected years of payments to 2034 and the effective interest rate by 0.56%.

Since the Royalty Right Agreements were issued in connection with the 13.5% Notes, the Company allocated the proceeds to the two instruments based on their relative fair values. The Company allocated approximately $13,856 to the Royalty Right Agreements. The Company determined the allocated fair value by calculating the present value of estimated future royalties to be paid to Note Holders over the life of the arrangement.

The excess of future estimated royalty payments of $56,926 over the $13,856 of allocated fair value is recognized as a discount related to the Royalty Right Agreements and is amortized as interest expense using the effective interest method.

The allocated amounts of $13,856 when combined with the Exit Fee of $2,000, original issue discount of $1,125 and debt issuance costs of $3,517, resulted in debt discount of $20,498. The debt discount is being amortized over the term of 13.5% Notes using the effective interest method.

Amortization expense arising from the discounts related to the 13.5% Notes and Royalty Right Agreements for the year ended December 31, 2024 was 5,019 and $5,459, respectively. Amortization expense arising from the discounts related to the 13.5% Notes and Royalty Right Agreements for the year ended December 31, 2023 was $833 and $905, respectively.

Unamortized discounts totaled $12,646 for the 13.5% Notes and $36,706 for royalty obligations as of December 31, 2024. Unamortized discounts totaled $17,665 for the 13.5% Notes and $42,165 for royalty obligations as of December 31, 2023.

Long-term notes and unamortized debt discount balances are as follows:

	December 31,	
	2024	2023
Total outstanding notes	$ 45,000	$ 45,000
Unamortized discount, including Exit Fee	(12,646)	(17,665)
Notes payable, long-term	32,354	27,335
Finance lease, long-term	146	173
Notes payable, net	$ 32,500	$ 27,508

	December 31,	
	2024	2023
Royalty obligations	$ 56,922	$ 56,926
Unamortized discount	(36,706)	(42,165)
Current portion of royalty obligation	(87)	—
Royalty obligations, net	$ 20,129	$ 14,761

Scheduled principal payments on the 13.5% Notes as of December 31, 2024 are as follows:

2025	$ —
2026	9,540
2027	14,535
2028	20,925
Total	$ 45,000

Note 16. Warrants

Warrants Issued to 12.5% Senior Secured Noteholders

Warrants that were issued in conjunction with the Initial Notes (the "Initial Warrants") and Additional Notes (the "Additional Warrants") expire on June 30, 2025 and entitle the noteholders to purchase up to 2,143,000 shares of Common Stock and included specified registration rights. Management estimated the fair value of the Initial Warrants to be $6,800 and the Additional Warrants to be $735, each based on an assessment by an independent third-party appraiser. The fair value of the respective warrants was treated as a debt discount, amortizable over the term of the respective warrants, with the unamortized 12.5% Notes portion applied to reduce the aggregate principal amount of the 12.5% Notes. Additionally, since the Initial Warrants and Additional Warrants issued do not provide warrant redemption or put rights within the control of the holders that could require the Company to make a payment of cash or other assets to satisfy the obligations under the warrants, except in the case of a "cash change in control", the fair value attributed to the warrants is presented in Additional Paid-in Capital in the Company's Balance Sheets. During the year ended December 31, 2024, 30,645 of the Additional Warrants were exercised with the Company receiving proceeds of $165. There were no warrants exercised during the year ended December 31, 2023.

Warrants to purchase a total of 1,683,784 shares of Common Stock with exercise prices of $4.25 and $5.38 for 1,571,429 warrants and 112,355 warrants, respectively, remained outstanding as of December 31, 2024. Warrants to purchase a total of 1,714,429 shares of Common Stock with exercise prices of $4.25 and $5.38 for 1,571,429 warrants and 143,000 warrants, respectively, remained outstanding as of December 31, 2023 See Note 15, *Long-Term Debt.*

Warrants Issued Under Securities Purchase Agreements

In June 2022, the Company issued pre-funded warrants and Common Stock Warrants to certain purchasers in connection with the Securities Purchase Agreements. The pre-funded warrants entitled purchasers to purchase up to 4,000,000 shares of Common Stock and were exercised in full during the year ended as of December 31, 2022. The Common Stock Warrants expire on June 8, 2027 and entitle the purchasers to purchase up to 8,850,000 shares of Common Stock at a price ranging from $0.96 to $1.09 per share. Management estimated the fair value of the pre-funded warrants and Common Stock warrants to be $5,874 based on an assessment by an independent third-party appraiser. The fair value of the pre-funded and Common Stock warrants is treated as equity and is presented in Additional Paid-in Capital in the Company's Balance Sheets. On June 14, 2023, 3,689,452 Common Stock warrants issued pursuant to the Securities Purchase Agreements were exercised with proceeds of approximately $3,542.

On August 1, 2023, the Company entered into the Letter Agreement with the Exercising Holder of 5,000,000 of the remaining Common Stock Warrants. Pursuant to the Letter Agreement, the Exercising Holder and the Company agreed that the Exercising Holder would exercise all of its Existing Warrants for shares of Common Stock underlying the Existing Warrants at $0.96 per share of Common Stock, the current exercise price of the Existing Warrants. Under the Letter Agreement, in consideration of the Exercising Holder exercising the Existing Warrants, the Company issued to the Exercising Holder New Warrants to purchase up to an aggregate of 2,750,000 shares of Common Stock. The New Warrants are exercisable after February 2, 2024, expire on February 2, 2029 and are issuable only for cash, subject to exception if the shares of Common Stock underlying the New Warrants are not registered in accordance with the terms of the Letter Agreement, in which case the New Warrants may also be exercised, in whole or in part, at such time by means of a "cashless exercise". The New Warrants have an exercise price of $2.60 per share. Management estimated the fair value of the warrants to be $4,671 based on an assessment by an independent third-party appraiser. The fair value of the New warrants is treated as equity and is presented in Additional Paid-in Capital in the Company's Balance Sheets.

On August 2, 2023, 5,000,000 of the Existing Warrants were exercised pursuant to the Securities Purchase Agreement with the Exercising Holder, with the Company receiving gross proceeds therefrom of $4,800. In total, 8,689,452 Common Stock warrants issued pursuant to the Securities Purchase Agreements with proceeds of approximately $8,307 were exercised during the year ended December 31, 2023. The Company incurred $35 in relation to this transaction.

There were no warrants issued or exercised as it relates to the Warrants Issued Under Securities Purchase Agreements during the year ended December 31, 2024.

As of December 31, 2024, in addition to the warrants to purchase 2,750,000 shares of Common Stock described above, there remained outstanding warrants to purchase 160,548 shares of Common Stock at an exercise price of $0.96 and warrants to purchase 1,683,784 shares of Common Stock outstanding related to the original issuance of the 12.5% Notes prior to the debt refinancing described above in this Note 15, *Long-Term Debt*, with exercise prices of $4.25 and $5.38 for 1,571,429 warrants and 112,355 warrants, respectively.

Note 17. Sale of Future Revenue

On November 3, 2020, the Company entered into the Monetization Agreement with Marathon. Under the terms of the Monetization Agreement, the Company sold all of its contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, which received approval from the FDA on May 21, 2020. In exchange for the sale of these rights, the Company received an upfront payment of $40,000 and an additional payment of $10,000 through the achievement of the first milestone. The Company has received an aggregate amount of $50,000 through December 31, 2024 under the Monetization Agreement.

Under the Monetization Agreement, additional contingent payments of up to $75,000 may be due to the Company upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125,000.

The Company recorded the upfront proceeds of $40,000 and subsequent first milestone of $10,000, reduced by $2,909 of transaction costs, as a liability related to the sale of future revenue that will be amortized using the effective interest method over the life of the Monetization Agreement. As future contingent payments are received, they will increase the balance of the liability related to the sale of future revenue. Although the Company sold all of its rights to receive royalties and milestones, as a result of ongoing obligations related to the generation of these royalties, the Company will account for these royalties as revenue. Its ongoing obligations include the maintenance and defense of the intellectual property and to provide assistance to Marathon in executing a new license agreement for KYNMOBI in the event Sunovion terminates the Sunovion License Agreement in one or more jurisdictions of the licensed territory under the Sunovion License Agreement. The accounting liabilities, as adjusted over time, resulting from this transaction and any non-cash interest expenses associated with those liabilities do not and will not represent any obligation to pay or any potential future use of cash.

During the second quarter of 2020, under the Sunovion License Agreement, the Company recognized $8,000 of royalty revenue and corresponding royalty receivable, related to the $1,000 annual minimum guaranteed royalty that is due. In connection with the Monetization Agreement, the Company performed an assessment under ASC 860, Transfer and Servicing to determine whether the existing receivable was transferred to Marathon and concluded that the receivable was not transferred.

As royalties are remitted to Marathon from Sunovion, the collection of the royalty receivable and balance of the liability related to the sale of future revenue will be effectively repaid over the life of the agreement. In order to determine the amortization of the liability related to the sale of future revenue, the Company is required to estimate the total amount of future royalty and milestone payments to Marathon over the life of the Monetization Agreement and contingent milestone payments from Marathon to the Company. The sum of future royalty payments less the $50,000 in proceeds received and future contingent payments will be recorded as interest expense over the life of the Monetization Agreement. At execution, the

estimate of this total interest expense resulted in an effective annual interest rate of approximately 24.9%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the life of the Monetization Agreement. The Company assesses the estimated royalty and milestone payments to Marathon from Sunovion and contingent milestone payments from Marathon to the Company. To the extent the amount or timing of such payments is materially different from the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially affect the amount and timing of royalty and milestone payments to Marathon from Sunovion and, correspondingly, the amount of interest expense recorded by the Company, most of which are not under the Company's control. Such factors include, but are not limited to, changing standards of care, the initiation of competing products, manufacturing or other delays, generic competition, intellectual property matters, adverse events that result in government health authority imposed restrictions on the use of products, significant changes in foreign exchange rates as the royalties remitted to Marathon are made in U.S. dollars (USD) while a portion of the underlying sales of KYNMOBI will be made in currencies other than USD, and other events or circumstances that are not currently foreseen. Changes to any of these factors could result in increases or decreases to both royalty revenue and interest expense related to the sale of future revenue.

In June 2023, Sunovion announced that it has voluntarily withdrawn KYNMOBI from the U.S. and Canadian markets. Therefore, the Company likely will not receive any of the additional contingent payments under the Monetization agreement. Further, the Company discontinued recording interest expense related to the sale of future revenue during the fourth quarter of 2022.

The following table shows the activity of the Liability related to the sale of future revenue:

	December 31,	
	2024	2023
Liability related to the sale of future revenue, net at beginning of the period	$ 64,490	$ 65,259
Royalties related to the sale of future revenue	(1,008)	(989)
Amortization of issuance costs	236	220
Liability related to the sale of future revenue, net at end of the period (includes current portion of $1,000 and $922, respectively)	$ 63,718	$ 64,490

Note 18. Other Non-Current Liabilities

The Company's other non-current liabilities at December 31, 2024 consisted of AROs of $2,039 and severance liabilities of $356. The Company's other non-current liabilities at December 31, 2023 consisted of AROs of $2,016.

AROs consists of estimated future spending related to removing certain leasehold improvements at the Company's facilities in Portage, Indiana and Warren, New Jersey, and returning all facilities to their original condition. Depreciation expense related to the ARO assets included in overall depreciation expense for the periods ended December 31, 2024 and 2023 were $11 and $7, respectively.

Below is a schedule of activity in the Company's liability for AROs for the year ended December 31, 2024 and 2023.

Balance at December 31, 2022	$ 1,989
Additions	—
Accretion	27
Balance at December 31, 2023	2,016
Additions	—
Accretion	23
Balance at December 31, 2024	$ 2,039

Note 19. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average number of shares of Common Stock.

Diluted EPS is adjusted by the effect of dilutive securities, including options and awards under the Company's equity compensation plans, warrants and ESPP. As a result of the Company's net loss incurred for the years ended December 31, 2024 and 2023, all potentially dilutive instruments outstanding would have anti-dilutive effects on per-share calculations. Therefore, basic and diluted net loss per share are the same for the years ended December 31, 2024 and 2023 as reflected below.

	Year Ended December 31, 2024	Year Ended December 31, 2023
Numerator:		
Net loss	$ (44,137)	$ (7,870)
Denominator:		
Weighted-average number of common shares – basic and diluted	86,726,211	61,255,864
Loss per common share – basic and diluted	$ (0.51)	$ (0.13)

(a) For the years ended December 31, 2024 and 2023, outstanding stock options of 6,301,364 and 5,733,064 to purchase shares of Common Stock, respectively, were anti-dilutive.

(b) For the years ended December 31, 2024 and 2023, outstanding restricted stock units of 3,692,876 and 3,280,313 to purchase shares of Common Stock, respectively were anti-dilutive.

(c) For the years ended December 31, 2024 and 2023, outstanding warrants of 4,594,332 and 4,624,977 to purchase shares of Common Stock, respectively, were anti-dilutive.

Note 20. Share-Based Compensation

The Company provides certain employees, non-employee directors and consultants with performance incentives under the Aquestive Therapeutics, Inc. Equity Incentive Plan ("the Plan"), adopted by the Board of Directors on June 15, 2018. Under this Plan, the Company may grant restricted stock units, stock options, or other stock-based awards in order to align the long-term financial interests of selected participants with those of its stockholders, strengthen the commitment of such persons to the Company, and attract and retain competent and dedicated persons whose efforts will enhance long-term growth, profitability and share value.

The service-based restricted stock units and stock options that have been awarded are subject to graded vesting over a service period, which is typically three years. The restricted stock units with vesting based on market conditions were awarded in 2023 and vest in three years on the anniversary of the first tranche award. Compensation cost is recognized for restricted stock units, both service-based awards and market conditions vesting-based awards, on a straight line basis over the requisite service period for each award granted. Compensation cost for stock option awards is recognized based on a pro-rata basis over the requisite period for each award granted.

At December 31, 2024, there were approximately 2.0 million shares available for grant.

The Company recognized share-based compensation in its Statements of Operations and Comprehensive Loss during the periods presented as follows:

Expense classification:	Year Ended December 31, 2024	Year Ended December 31, 2023
Manufacture and supply	$ 374	$ 191
Research and development	1,215	456
Selling, general and administrative	5,510	2,042
Total share-based compensation expenses	$ 7,099	$ 2,689
Share-based compensation from:		
Restricted Stock Units	4,545	993
Stock Options	2,512	1,669
Employee Stock Purchase Plan	42	27
Total share-based compensation expenses	$ 7,099	$ 2,689

The following tables provide information about the Company's restricted stock unit and stock option activity during the year ended December 31, 2024 and 2023.

Restricted Stock Units

The following tables summarize the Company's awards of service-based and market conditions vesting-based restricted stock units for the years 2024 and 2023:

Restricted Stock Unit Awards (RSUs) - Service-based:	Number of Units	Weighted Average Grant Date Fair Value Per Share
	(In thousands)	
Unvested as of December 31, 2022	162	$ 2.38
Granted	1,874	0.91
Forfeited	(31)	2.33
Vested	(57)	2.03
Unvested as of December 31, 2023	1,948	$ 0.97
Granted	1,470	5.52
Forfeited	(43)	1.58
Vested	(765)	1.45
Unvested as of December 31, 2024	2,610	$ 3.38
Expected to vest as of December 31, 2024	2,459	$ 3.35

The Company granted 1,470,300 service-based restricted stock units during 2024. The Company granted 1,874,300 service-based restricted stock units during 2023. During 2024, the total grant date fair market value of shares vested was $1,112.

As of December 31, 2024, $5,772 of total unrecognized compensation expenses related to unvested service-based restricted stock units are expected to be recognized over a remaining weighted average period of 1.73 years. The service-based restricted stock units granted to employees are subject to a three-year graduated vesting schedule and are not subject to performance-based criteria other than continued employment.

2022 Inducement Equity Incentive Plan

In accordance with NASDAQ Listing Rule 5635(c)(4), the Company adopted the 2022 Equity Inducement Plan approved by the Compensation Committee of the Board of Directors of the Company effective as of July 29, 2022. There were no awards outstanding under this Plan as of December 31, 2024.

Restricted Stock Unit Awards (RSUs) - Market conditions vesting-based:	Number of Units	Weighted Average Grant Date Fair Value Per Share
	(In thousands)	
Unvested as of December 31, 2022	—	$ —
Granted	1,332	2.40
Forfeited	—	—
Vested	—	—
Unvested as of December 31, 2023	1,332	$ 2.40
Granted	—	—
Forfeited	—	—
Vested	(250)	2.41
Unvested as of December 31, 2024	1,082	$ 2.40
Expected to vest as of December 31, 2024	1,010	$ 2.40

There were no market conditions vesting-based restricted stock units granted in 2024. The Company granted 1,332,000 market conditions vesting-based restricted stock units during 2023.

As of December 31, 2024, $1,133 of total unrecognized compensation expenses related to unvested market conditions vesting-based restricted stock units are expected to be recognized over a remaining weighted average period of 1.34 years.

The market conditions vesting-based restricted stock units vest based on a Performance Price measured as the 30-day average of the closing prices of the Company's common stock as reported on the Nasdaq Stock Market immediately prior to and including the last calendar day of the three-year performance period (which ends on the third anniversary of the grant date). To the extent the Performance Price is less than $1.75, the Vesting Percentage will be zero. To the extent the Performance Price is $1.75, the Vesting Percentage will be 50%. To the extent the Performance Price is $1.76 or greater, but less than $2.50, the Vesting Percentage will be a prorated amount between 50.01% and 99.99%, based on straight-line interpolation. To the extent the Performance Price is $2.50, the Vesting Percentage will be 100%. To the extent the Performance Price is $2.51 or greater, but less than $3.25, the Vesting Percentage will be a prorated amount between 100.01% and 149.99%, based on straight-line interpolation. To the extent the Performance Price is $3.25 or greater, the Vesting Percentage will be 150%. In no event will the Vesting Percentage exceed 150%.

The Company's estimates of the fair value of market conditions vesting-based awards at their grant or valuation dates were based on a Monte Carlo simulation and considered various variables and assumptions, including a simulated 30-day average at the end of the Performance period including the following assumptions:

	Year Ended December 31, 2023
Expected dividend yield	0%
Expected volatility	92% - 95%
Expected term (years)	2.74 - 3.00
Risk-free interest rate	3.6% - 4.4%
Stock price at grant date	$2.01 - $2.04

Stock option awards

The following table summarizes the Company's stock option activity for the years during 2024 and 2023:

(in 000s, except share price data)	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	6,028	$ 5.48	7.50	$ 38
Granted	150	$ 2.02		
Exercised	(1)	$ 0.88		
Forfeited and Expired	(444)	$ 2.27		
Outstanding as of December 31, 2023	5,733	$ 5.58	6.41	$ 1,082
Granted	1,024	4.83		
Exercised	(357)	$ 2.05		
Forfeited and Expired	(99)	$ 3.84		
Outstanding as of December 31, 2024	6,301	$ 5.68	6.08	$ 4,009
Expected to vest as of December 31, 2024	6,234	$ 5.69	6.05	$ 3,980
Exercisable as of December 31, 2024	4,861	$ 6.24	5.33	$ 2,898

The weighted average grant date fair value of stock options granted during 2024 and 2023 was $3.98 and $1.50, respectively. During the year ended December 31, 2024, 1,023,900 stock options were granted with an exercise price of $4.83 and accordingly, given the Company's share price of $3.56 at December 31, 2024, the intrinsic value provided by certain shares granted during this period was de minimis.

The fair values of stock options granted were estimated using the Black-Scholes model based on the following assumptions:

	Year Ended December 31,	
	2024	2023
Expected dividend yield	0%	0%
Expected volatility	104% - 107%	100%
Expected term (years)	5.50 - 6.13	5.50
Risk-free interest rate	4.1% - 4.5%	4.0%
Exercise prices	$2.50 - $5.68	$2.02

The Company anticipates reinvesting earnings for the foreseeable future in product development and other avenues of share-value growth and therefore used a dividend yield of zero. The estimate of volatility was determined based on an estimate of stock price volatility using the historical trading data of the Company's publicly-traded Common Stock at the time of grant. The expected term of the award was calculated using the simplified method and weighted average was utilized taking into account the vesting periods and contractual life. The risk-free interest rates are derived from the U.S. Treasury yield curve in effect on the date of grant for instruments with a remaining term similar to the expected term of the options.

As of December 31, 2024, $2,867 of total unrecognized compensation expenses related to non-vested stock options is expected to be recognized over a remaining weighted average period of 1.35 years. These option grants provided a maximum contract term of 10 years from grant date, with a weighted average remaining contract life of 6.08 years. Options granted to senior management and key employees are subject to a 3-year graded vesting schedule while options granted to the Board of Directors are subject to a one year cliff vesting schedule. These stock options are not subject to performance-based criteria other than continued employment.

Employee Stock Purchase Plan

The Company’s Employee Stock Purchase Plan (the "ESPP"), as amended and restated effective as of January 1, 2019, features two six-month offering periods per year, running from January 1 to June 30 and July 1 to December 31. Under the ESPP, employees of the Company may elect to purchase the Company’s Common Stock at the lower of 85% of the fair value of shares on either the first or last day of the offering period. Under the ESPP, a total of 250,000 shares of Common Stock were initially reserved for issuance. During the year ended 2024 and 2023, 35,374 and 36,168 shares were purchased and issued through the ESPP at total discounts of $42 and $27, respectively.

Note 21. Employee Benefit Plans

The Company sponsors a defined-contribution 401(k) plan covering all full-time employees and makes matching employer contributions as defined by the terms of that plan. The Company may also make discretionary contributions. Total contributions made to the plan by the Company for the years ended December 31, 2024 and 2023 were $849 and $761, respectively.

Note 22. Income Taxes

The components of the provision for income taxes are as follows:

Expense classification:	Year Ended December 31,	
	2024	2023
Current		
Federal	$ (14)	$ 245
State	—	—
Total	(14)	245
Deferred		
Federal	—	—
State	—	—
Total	—	—
Provision for Income Tax	$ (14)	$ 245

The tax effect of temporary differences between the tax bases of assets and liabilities and their financial reporting amounts that give rise to the deferred tax assets and deferred tax liabilities as of December 31, 2024 and 2023 are as follows:

	December 31,	
	2024	2023
Deferred tax assets:		
Accounts receivable	$ —	$ 4
Inventory	337	345
Accrued expenses	186	73
NOL carryforwards	34,689	27,120
Interest limitation imposed by the TJCA	11,594	9,880
Stock Compensation	6,862	6,529
Deferred Revenue	5,157	7,662
Royalty Monetization	16,117	16,750
Property and Equipment	2,690	2,756
Orphan Drug and R&D Tax Credits	5,099	4,805
Intangible Assets	137	154
Section 174 R&D Capitalization	7,263	5,039
Sales of Royalty Rights	3,438	3,520
OID and Deferred Financing Cost	1,636	—
Other	143	58
	95,348	84,695
Deferred tax liabilities:		
OID and Deferred Financing Cost	—	(193)
Prepaid expenses	(795)	(449)
	(795)	(642)
Valuation Allowance	(94,553)	(84,053)
Net deferred tax asset/(liability)	$ —	$ —

At December 31, 2024 and 2023, the Company had federal net operating loss carryforwards of $128,658 and $101,029, respectively, a significant portion of which carryforward for an indefinite period. At December 31, 2024 and 2023, the Company also had state net operating loss carryforwards of $139,189 and $104,478, respectively, which begin expiring in 2034. As a result of the December 2017 U.S. Tax Cuts and Jobs Act ("TCJA"), updated regulations under section 163(j) create new limitations on deductible interest expense. For the year ended December 31, 2024, the Company's interest expense deduction under 163(j) will be limited for tax purposes based on a calculation of 30% of its EBIT on a tax basis. The Company has determined, based upon available evidence, that is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax assets. Valuation allowances of $94,553, and $84,053 have been established at December 31, 2024 and 2023, respectively. The Company may also be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code due to ownership changes. As a result, the use of NOL carry forwards from the current and prior periods are subject to annual limitations.

The TCJA requires taxpayers to capitalize and amortize R&D expenditures under section 174 for tax years beginning after December 31, 2021. For the years ended December 31, 2024 and 2023, the capitalized R&D costs were $17.3 million and $12.6 million, respectively. The Company will amortize these costs for tax purposes over five years if the R&D was performed in the U.S. and over 15 years if the R&D was performed outside the U.S.

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that there were no uncertain positions as of December 31, 2024 and 2023.

A reconciliation of income tax benefit and the amount computed by applying the statutory federal income tax rates of 21% to loss before taxes for the years ended December 31, 2024 and 2023, respectively, as follows:

	Year Ended December 31,	
	2024	2023
Income taxes at statutory rate	21.00 %	21.00 %
Increase (decrease) resulting from:		
State income tax	3.27	4.00
Permanent differences	(1.10)	(0.43)
Valuation allowance	(23.50)	(26.53)
Return to provision	1.06	(3.28)
State rate change	(0.69)	(1.78)
FDII Deductions	0.00	3.80
Other	(0.01)	—
Effective tax rate	0.03 %	(3.22)%

During the year ended December 31, 2023, the Company received an ERTC refund of $1,250, which is included in Interest income and other income, net on the Company's Statements of Operations and Comprehensive Loss.

Note 23. Contingencies

From time to time, the Company has been and may again become involved in legal proceedings arising in the course of its business, including product liability, intellectual property, securities, civil tort, and commercial litigation, and environmental or other regulatory matters.

Kentucky Litigation - Humana

Humana Inc. v. Indivior Inc, Indivior Solutions Inc., Indivior PLC, Reckitt Benckiser Group plc, Reckitt Benckiser Healthcare (UK) Ltd., and Aquestive Therapeutics, Inc.

On August 20, 2021, Humana filed a complaint in state court in Kentucky, alleging conspiracy to violate the RICO Act, fraud under state law, unfair and deceptive trade practices under state law, insurance fraud, and unjust enrichment against the Company relating to Indivior's launch of Suboxone Sublingual Film in 2010. The Humana action was stayed pending related litigation, and the stay was lifted on October 30, 2023. The parties to this case reached a settlement on November 27 2024, the terms of which are confidential. Aquestive had no obligation, cost or liability in the settlement as all were assumed by Indivior.

California Litigation

Neurelis, Inc. v. Aquestive Therapeutics, Inc.

On December 5, 2019, Neurelis, Inc. ("Neurelis") filed a lawsuit against the Company in the Superior Court of California, County of San Diego alleging the following three causes of action: (1) Unfair Competition under California Business and Professional Code § 17200 ("UCL"); (2) Defamation; and (3) Malicious Prosecution. Neurelis filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. The Company filed a Motion to Strike Neurelis's Complaint under California's anti-SLAPP ("strategic lawsuit against public participation") statute on January 31, 2020, which Neurelis opposed. On August 6, 2020, the Court issued an order granting in part and denying in part the Company's anti-SLAPP motion. The parties cross-appealed the ruling to the California Court of Appeal. The appeals court held oral argument on the appeal on October 14, 2021, and issued its ruling on November 17, 2021. Under the ruling, the court struck the entirety of the malicious prosecution claim and struck portions of the UCL and defamation claims. On April 12, 2022, Neurelis filed a Second Amended Complaint in response to the Court of Appeal's decision. The Second Amended Complaint also added a cause of action for Trade Libel. On May 3, 2022, the Company filed a "demurrer" challenge to the sufficiency of the allegations of the Second Amended Complaint. Oral argument on the Company's motion for attorney fees related to the anti-SLAPP motion and on the Second Amended Complaint and demurer challenge was held on June 17, 2022. The Court entered an order granting the Company's motion for attorney fees, awarding $156 and ordering Neurelis to pay the fees within 60 days of June 17, 2022. The Court denied the Company's demurrer and the parties proceeded with discovery on the claims in the Second Amended Complaint. The plaintiff filed a motion to file a third amended complaint. which the Court granted on November 17, 2023. The Third Amended Complaint alleges additional facts but includes the same claims as the Second Amended Complaint. Hearings on motions for summary judgement are scheduled for May 16, 2025. The trial in this matter is scheduled for July 18, 2025. The Company is not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

Neurelis FDA Lawsuit

Neurelis, Inc. v. Califf, *et al*., U.S. District Court for the District of Columbia

In May 2024, Neurelis filed a complaint in the U.S. District Court for the District of Columbia against the U.S. Food and Drug Administration, the U.S. Department of Health and Human Services, and certain government officials. The complaint in this matter alleges that the defendants violated the Administrative Procedure Act by approving Aquestive's NDA for Libervant for ARS patients aged between two and five years, and asks the Court to vacate that approval and enjoin the defendants from approving Libervant for this pediatric patient population until January 10, 2027, the scheduled date for the expiration of the U.S. orphan drug market exclusivity granted by the FDA to the Valtoco nasal spray product of Neurelis. Aquestive intervened in this litigation to defend the approval of Libervant for this ARS pediatric patient population and, on June 25, 2024, the Court entered a scheduling order governing further proceedings in the case. Pursuant to that order, Neurelis filed a motion for summary judgment on August 19, 2024; Aquestive and the federal defendants each filed their own cross-motions for summary judgment and opposed Neurelis's motion for summary judgment on September 18, 2024. Neurelis filed its combined reply brief in support of its motion for summary judgment and in opposition to the defendants' cross-motions on October 9, 2024, and Aquestive and the federal defendants filed their closing briefs on October 30, 2024. Following the FDA's award of ODE to Libervant for ARS patients between two and five years of age, Neurelis filed a motion for preliminary injunction requesting an expedited order to vacate FDA's approval and enjoining the sale of Libervant. On February 14, 2025, the Court ruled in favor of Neurelis, granting its summary judgment motion, and against the FDA's and Aquestive's cross-motions for summary judgment. In an accompanying opinion, the Court directed the FDA to vacate the approval of Libervant. Because the Court entered a final appealable judgment in favor of Neurelis, Neurelis' motion for an expedited preliminary injunction was denied as moot by the Court. On February 18, 2025, Aquestive filed an appeal of the Court's decision with the U.S. Circuit Court of Appeals for the District of Columbia (the "DC Appellate Court") and, on the same day, filed an emergency motion with the District Court to stay its order pending a decision on the appeal with the DC Appellate Court. The District Court set a scheduling order governing filings of all briefs on the motion for stay, ending on March 5, 2025. No dates have been set for arguments on the stay of the District Court's order or proceedings on the appeal at the DC Appellate Court. The Company is not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

Suboxone Product Liability Litigation

The Company was named as a defendant in a multitude of product liability lawsuits, along with Indivior and several other named defendants, in which the individual plaintiffs in those cases allege that their use of Suboxone® Sublingual Film, a prescription drug product for opioid use disorder, caused them dental injuries. On February 2, 2024, this litigation became a Multidistrict Litigation ("MDL") consolidated in the U.S District Court for the Northern District of Ohio. One case alleging the same allegations as contained in the MDL has been filed in a state court in the State of New Jersey. The parties to the MDL have agreed to a tolling of unfiled claimants in several states. Indivior has agreed to defend the Company in these litigation matters. Discovery is underway and no trial date has been set in the MDL matter. The Company's motion to dismiss the MDL matter was granted as to all claims by plaintiffs except design defect claims. The Company is not able to determine or predict the ultimate outcome of this litigation or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

The Company was named as a defendant in three proposed class action lawsuits filed in Canada, along with Indivior and several other named defendants, in which the individual plaintiffs in those cases allege that their use of Suboxone® products caused them dental injuries. two of these cases have been filed in British Columbia, and the plaintiffs in those cases are seeking assignment of a case management judge. The anticipated next step in British Columbia will involve applications by the plaintiffs to determine which of the two cases will proceed towards a certification hearing and which will be stayed. The third case has been filed in Quebec and is proceeding towards an authorization hearing, the date of which has not yet been set. The authorization and certification hearings will determine whether the Courts will allow the cases to proceed as class actions. Pre-discovery and case management proceedings are underway and no trial date has yet been set. Given the early stages of these proceedings, the Company is not able to determine or predict the ultimate outcome of this litigation or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this litigation.

Note 24. Subsequent Events

Utilization of the At-The-Market Facility

In the period subsequent to December 31, 2024 through March 5, 2025, the Company sold 7,457,627 shares under its ATM facility, which generated net proceeds of approximately $21,400 net of commissions of $605. The remaining authorized balance of the ATM facility was $78,000 as of March 5, 2025.

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