

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

FORM 10-Q

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

For the quarterly period ended March 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 30 Technology Drive, Warren, NJ 07059 82-3827296  
(State or other jurisdiction of Incorporation or ( 908) 941-1900 (I.R.S. Employer Identification Number)  
organization)

(Address, Zip Code and Telephone Number of Registrant's Principal Executive Offices)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

The number of outstanding shares of the registrant's common stock, par value of \$0.001 per share (the "Common Stock"), as of the close of business on May 3, 2024 was 91,038,532.

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FORM 10-Q  
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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 (dollar amounts in thousands):

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
Adrenaverse™	Epinephrine prodrug platform currently comprised of Anaphylm™ and AQST-108
ALS	Amyotrophic lateral sclerosis
ANVISA	Brazilian Health Regulatory Agency
API	Active Pharmaceutical Ingredients
AQST	NASDAQ ticker symbol for Aquestive Therapeutics, Inc.
ASC	Accounting Standards Codification
Assertio	Assertio Holdings, Inc.
Assertio Agreement	License Agreement between Aquestive and Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc.
ASU	Accounting Standards Updates
ATM facility	At-The-Market facility for the purchase of AQST Common Stock
Base Indenture	Indenture for the 12.5% Notes
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
CRO	Contract research organization
EMA	European Medicines Agency
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
First Amendment	First amendment to the Sunovion License Agreement
Fortovia	Fortovia Therapeutics Inc. (previously Midatech Pharma PLC)
GAAP	Generally Accepted Accounting Principles
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
Hypera	Hypera Pharma
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)
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

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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
Offering	\$45,000 aggregate principal amount of 13.5% Notes due November 1, 2028.
PD	Pharmacodynamics
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
PTO	United States Patent and Trademark Office
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
TEVA	Teva Pharmaceuticals USA, Inc.
TGA	Australian Government Department of Health's Therapeutics Goods Administration
Underwritten Public Offering	Capital Raise of \$75,000, plus the underwriters' over-allotment proceeds of \$2,519
Zambon	Zambon S.p.A.
Zevra	Zevra Therapeutics, Inc. (formerly KemPharm, Inc.)

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**PART I – FINANCIAL INFORMATION**
**Item 1. FINANCIAL STATEMENTS (Unaudited)**

**AQUESTIVE THERAPEUTICS, INC.**  
Condensed Balance Sheets  
(In thousands, except share and per share amounts)  
(Unaudited)

	March 31, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 95,200	\$ 23,872
Trade and other receivables, net	8,324	8,471
Inventories	7,734	6,769
Prepaid expenses and other current assets	2,121	1,854
Total current assets	113,379	40,966
Property and equipment, net	4,046	4,179
Right-of-use assets, net	5,442	5,557
Intangible assets, net	1,239	1,278
Other non-current assets	5,417	5,438
Total assets	\$ 129,523	\$ 57,418
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 10,523	\$ 8,926
Accrued expenses	4,637	6,497
Lease liabilities, current	414	390
Deferred revenue, current	1,551	1,551
Liability related to the sale of future revenue, current	910	922
Loans payable, current	23	22
Total current liabilities	18,058	18,308
Notes payable, net	28,759	27,508
Royalty obligations, net	16,119	14,761
Liability related to the sale of future revenue, net	63,626	63,568
Lease liabilities	5,284	5,399
Deferred revenue, net of current portion	31,957	32,345
Other non-current liabilities	2,021	2,016
Total liabilities	165,824	163,905
<b>Contingencies (Note 19)</b>		
Stockholders' deficit:		
Common stock, \$0.001 par value. Authorized 250,000,000 shares; 90,478,731 and 68,533,085 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	90	69
Additional paid-in capital	295,514	212,521
Accumulated deficit	(331,905)	(319,077)
Total stockholders' deficit	(36,301)	(106,487)
Total liabilities and stockholders' deficit	\$ 129,523	\$ 57,418

See accompanying notes to the condensed financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Revenues	\$ 12,053	\$ 11,134
Costs and expenses:		
Manufacture and supply	4,389	4,737
Research and development	5,932	3,547
Selling, general and administrative	10,689	7,455
Total costs and expenses	21,010	15,739
Loss from operations	(8,957)	(4,605)
Other income/ (expenses):		
Interest expense	(2,784)	(1,435)
Interest expense related to royalty obligations	(1,358)	—
Interest expense related to the sale of future revenue	(58)	(52)
Interest income and other income, net	329	14,513
Loss on extinguishment of debt	—	(353)
Net (loss) income before income taxes	(12,828)	8,068
Income taxes	—	—
Net (loss) income	\$ (12,828)	\$ 8,068
Comprehensive (loss) income	\$ (12,828)	\$ 8,068
<b>(Loss) earnings per share attributable to common stockholders:</b>		
Basic (in dollars per share)	\$ (0.17)	\$ 0.15
Diluted (in dollars per share)	\$ (0.17)	\$ 0.11
<b>Weighted average common shares outstanding:</b>		
Basic (in shares)	73,614,710	55,631,947
Diluted (in shares)	73,614,710	73,792,886

See accompanying notes to the condensed financial statements.

**AQUESTIVE THERAPEUTICS, INC.**  
Condensed Statements of Changes in Stockholders' Deficit  
Three Months Ended March 31, 2024 and March 31, 2023  
(In thousands, except share amounts)  
(Unaudited)

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-in</b>	<b>Deficit</b>	<b>Stockholders'</b>
			<b>Capital</b>		<b>Deficit</b>
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	—	—	(410)	—	(410)
Common Stock issued under public equity offering	16,666,667	17	74,983	—	75,000
Costs of common stock issued under public equity offering	—	—	(5,187)	—	(5,187)
Share-based compensation expense	—	—	1,580	—	1,580
Vested restricted stock units, net	490,359	—	(893)	—	(893)
Options exercised, net	231,400	—	539	—	539
Net Loss	—	—	—	(12,828)	(12,828)
Balance at March 31, 2024	90,478,731	\$ 90	\$ 295,514	\$ (331,905)	\$ (36,301)

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-in</b>	<b>Deficit</b>	<b>Stockholders'</b>
			<b>Capital</b>		<b>Deficit</b>
Balance at December 31, 2022	54,827,734	\$ 55	\$ 192,598	\$ (311,207)	\$ (118,554)
Common Stock issued under public equity offering	1,078,622	1	992	—	993
Costs of common stock issued under public equity offering	—	—	(77)	—	(77)
Share-based compensation expense	—	—	344	—	344
Vested restricted stock units, net	16,005	—	(8)	—	(8)
Other	—	—	(1)	—	(1)
Net income	—	—	—	8,068	8,068
Balance at March 31, 2023	55,922,361	\$ 56	\$ 193,848	\$ (303,139)	\$ (109,235)

See accompanying notes to the condensed financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Operating activities:</b>		
Net (loss) income	\$ (12,828)	\$ 8,068
Adjustments to reconcile net (loss) income to net cash used for operating activities:		
Depreciation, amortization, and impairment	207	325
Share-based compensation	1,580	344
Amortization of debt issuance costs and discounts	2,673	56
Other, net	32	(260)
Changes in operating assets and liabilities:		
Trade and other receivables, net	147	(2,217)
Inventories	(965)	(1,201)
Prepaid expenses and other assets	(253)	(195)
Accounts payable	1,284	2,494
Accrued expenses and other liabilities	(1,873)	(3,472)
Deferred revenue	(388)	4,874
Net cash (used for) provided by operating activities	(10,384)	8,816
<b>Investing activities:</b>		
Capital expenditures	(29)	(2)
Net cash used for investing activities	(29)	(2)
<b>Financing activities:</b>		
Proceeds from common stock issued under public equity offering, net - ATM	11,974	916
Proceeds from common stock issued under public equity offering, net	70,126	—
Proceeds from exercise of stock options, net	539	—
Repayment of debt principal including lease liabilities	(5)	(9,086)
Premium paid to retire debt	—	(1,027)
Payments for taxes on share-based compensation	(893)	(8)
Net cash provided by (used for) financing activities	81,741	(9,205)
Net increase (decrease) in cash and cash equivalents	71,328	(391)
Cash and cash equivalents:		
Cash and cash equivalents at beginning of period	23,872	27,273
Cash and cash equivalents at end of period	<u>\$ 95,200</u>	<u>\$ 26,882</u>
<b>Supplemental disclosures of cash flow information:</b>		
Cash payments for interest	\$ 1,003	\$ 1,466
Costs associated with public offering in Accounts Payable	\$ 313	\$ —

See accompanying notes to the condensed financial statements.

**AQUESTIVE THERAPEUTICS, INC.**  
Notes to Condensed Financial Statements  
(Unaudited, in thousands, except share and per share information)

**Note 1. Company Overview and Basis of Presentation**

**(A) Company Overview**

Aquestive Therapeutics, Inc. ("Aquestive" or the "Company") is a pharmaceutical company advancing medicines to solve patients' problems with current standards of care and provide transformative products to improve their lives. The Company is developing pharmaceutical products that deliver complex molecules through alternative administrations to invasive and inconvenient standard of care therapies. 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 is advancing a product pipeline for the treatment of severe allergic reactions, including anaphylaxis. The Company has also developed a product pipeline focused on treating diseases of the CNS. 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.

**(B) Equity Transactions**

*Equity Offering of Common Stock*

On September 11, 2019, the Company established the ATM facility pursuant to which the Company could offer up to \$ 25,000 worth of shares of Common Stock, par value \$0.001 per share, of the Company. On November 20, 2020, the Company began utilizing the ATM facility. On March 26, 2021, the Company filed a prospectus supplement to offer up to an additional \$50,000 worth of shares of Common Stock under the ATM (the "2021 Prospectus"). The 2019 registration statement covering the shares under the ATM expired under its terms on September 17, 2022. On September 7, 2022, the Company filed a prospectus supplement to register the offer and sale of up to \$35,000 worth of shares of Common Stock pursuant to the Amended Equity Distribution Agreement with Piper Sandler Companies (successor to Piper Jaffray & Co.) under a shelf registration statement on Form S-3 ("Registration Statement No. 333-254775" or "the 2021 Registration Statement"), that was declared effective by the SEC on April 5, 2021. The Company discontinued using the 2021 Prospectus upon the filing of the prospectus supplement on September 7, 2022. On April 3, 2024, the Company filed a prospectus supplement to register the offer and sale of up to \$250,000 worth of shares of Common Stock pursuant to the Amended Equity Distribution Agreement under a shelf registration statement on Form S-3 (Registration Statement No. 333-278498), or the 2024 Registration Statement, which was declared effective by the SEC on April 23, 2024. The Company also established its ATM facility at \$100,000 (see Note 20, *Subsequent Events*). The Company discontinued using the 2021 Registration Statement upon the filing of the 2024 Registration Statement on April 23, 2024.

For the three months ended March 31, 2024, the Company sold 4,557,220 shares of Common Stock under the ATM which provided net proceeds of approximately \$12,012 after deducting commissions and other transaction costs of \$ 373. For the three months ended March 31, 2023, the Company sold 1,078,622 shares which provided net proceeds of approximately \$ 916 after deducting commissions and other transaction costs of \$ 77.

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 the Company's Common Stock. In 2022, the Company sold 1,600,000 shares, in addition to 236,491 commitment shares, which provided proceeds of approximately \$1,987 in connection with the Lincoln Park Purchase Agreement. The Company did not sell shares in connection with the Lincoln Park Purchase Agreement in 2023 or for three months ended March 31, 2024.

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. At closing, Aquestive received net proceeds of \$ 70,500 after deducting underwriting discounts of \$ 4,500. In addition to the underwriting discounts related to this offering, the Company's estimated incurred professional fees and other costs totaled \$687 of which \$313 remains unpaid as of March 31, 2024.

In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 2,500,000 shares of its Common Stock at the public offering price, less underwriting discounts and commissions. Subsequent to March 31, 2024,

the underwriters exercised the option by purchasing an additional 559,801 shares of Common Stock, for additional gross proceeds of \$ 2,519. See Note 20, *Subsequent Events*.

#### **(D) Basis of Presentation**

The accompanying interim unaudited condensed financial statements were prepared in conformity with U.S. GAAP and with Article 10 of Regulation S-X for interim financial reporting. In compliance with those rules, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed financial statements should be read in conjunction with the Company's audited consolidated financial statements and related notes for the fiscal year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the SEC on March 5, 2024 (the "2023 Annual Report on Form 10-K"). As included herein, the Condensed Balance Sheet as of December 31, 2023 is derived from the audited consolidated financial statements as of that date. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair statement of the results of interim periods have been included. The accompanying financial statements reflect certain reclassifications from previously issued financial statements to conform to the current presentation. The Company has evaluated subsequent events for disclosure through the date of issuance of the accompanying unaudited condensed financial statements.

Any reference in these notes to applicable guidance refers to the authoritative U.S. GAAP as found in the ASC and ASU of FASB.

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 unaudited condensed financial statements as of March 31, 2024 and the audited consolidated financial statements as of December 31, 2023.

#### **Note 2. Summary of Significant Accounting Policies**

##### **(A) Recent Accounting Pronouncements**

As of December 31, 2023, the Company is no longer an "emerging growth company," but remains a "smaller reporting company". 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.

##### *Recent Accounting Pronouncements Adopted as of March 31, 2024:*

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 condensed 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 condensed financial statements.

##### *Recent Accounting Pronouncements Not Adopted as of March 31, 2024:*

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 condensed financial statements.

### **Note 3. 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 2024 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 March 31, 2024, the Company had \$95,200 of cash and cash equivalents.

The Company has experienced a history of net losses in prior periods. The Company's accumulated deficits totaled \$ 331,905 as of March 31, 2024. The net losses and accumulated deficits were partially offset by gross margins from sales of commercialized licensed and proprietary products (prior to the licensing agreement of Sympazan with Asserio in October 2022), 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 13, *Long-Term Debt*.

The Company began utilizing its ATM facility in November 2020. Since inception to March 31, 2024, the Company sold 19,857,518 shares of Common Stock which generated net cash proceeds of approximately \$60,715, net of commissions and other transaction costs of \$ 2,928. For the three months ended March 31, 2024, the Company sold 4,557,220 shares of Common Stock which provided net proceeds of approximately \$ 12,012, net of commissions and other transaction costs of \$373. In April 2024, the Company established its ATM facility to \$ 100,000 (see Note 20, *Subsequent Events*).

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 and under the Lincoln Park Purchase Agreement, 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 4. Revenues and Trade Receivables, Net**

The Company's revenues include (i) sales of manufactured products pursuant to contracts with commercialization licensees, (ii) license and royalty revenues, and (iii) co-development and research fees generally in the form of milestone payments. 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.

#### *Performance Obligations*

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 or invoices.

*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.

*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.

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.

*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 within the Condensed Balance Sheets. As of March 31, 2024, and December 31, 2023, such contract assets were \$700 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 3rd 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 Condensed Balance Sheets. As remaining performance obligations are satisfied, an appropriate portion of the deferred revenue balance is credited to earnings. As of March 31, 2024 and December 31, 2023, such contract liabilities were \$33,508 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 Condensed 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 March 31, 2024 and December 31, 2023, such costs to obtain contracts were \$701 and \$715, respectively.

The Company's revenues were comprised of the following:

	Three Months Ended March 31,	
	2024	2023
Manufacture and supply revenue	\$ 10,518	\$ 9,762
License and royalty revenue	1,132	919
Co-development and research fees	403	453
Total revenues	<u>\$ 12,053</u>	<u>\$ 11,134</u>

#### Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Three Months Ended March 31,	
	2024	2023
United States	\$ 10,427	\$ 8,165
Ex-United States	1,626	2,969
Total revenues	<u>\$ 12,053</u>	<u>\$ 11,134</u>

Ex-United States revenues are derived primarily from Indivior (Manufacture and supply revenue, Royalties and Co-development and research fees), Zambon (primarily Manufacture and supply revenue) and Pharmanovia (Co-development and research fees) for revenue markets outside of the United States for the three months ended March 31, 2024 and from Hypera (Manufacture and supply revenue) and Indivior (Manufacture and supply revenue, Royalties and Co-development and research fees) for the three months ended March 31, 2023,

Trade and other receivables, net consist of the following:

	March 31, 2024	December 31, 2023
Trade receivables	\$ 6,703	\$ 5,570
Contract and other receivables	1,635	2,915
Less: allowance for doubtful accounts	(14)	(14)
Trade and other receivables, net	<u>\$ 8,324</u>	<u>\$ 8,471</u>

The following table presents the changes in the allowance for doubtful accounts:

	March 31, 2024	December 31, 2023
Allowance for doubtful accounts at beginning of the period	\$ 14	\$ 40
Allowance expense (reduction)	—	(26)
Allowance for doubtful accounts at end of the period	<u>\$ 14</u>	<u>\$ 14</u>

#### 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 three months ended March 31, 2024, Indivior exceeded the 10% threshold for revenue and represented approximately 84% of total revenue. As of March 31, 2024, Indivior exceeded the 10% threshold for outstanding receivable balances and represented approximately 70% of outstanding receivables. For the three months ended March 31, 2023, Indivior and Hypera exceeded the 10% threshold for revenue and represented approximately 77% and 14% of total revenue, respectively. As of December 31, 2023, Indivior and Zevra Therapeutics, Inc. represented 65% and 13% of total trade and other receivables, respectively.

#### Note 5. 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. which 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 Agreement to the Indivior License Amendment. 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 three months ended March 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 three months ended March 31, 2023, the Company recognized \$2,230, 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 Condensed Statements of Operations and Comprehensive (Loss) Income. As of December 31, 2023, the \$5,482 price increase had been fully recognized in Manufacture and supply revenue; there were no retroactive price adjustments included in Manufacture and supply revenue for the three months ended March 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 is finalized. No further payments are due to the Company under the Indivior Supplemental Agreement. See Note 19, *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 sublicense) 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 from 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 March 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 had 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 15, *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 Zevra's 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 or their derivatives.

***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 is 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 is 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. The Company has learned that Haisco announced that it intended to voluntarily withdraw the application

for approval of Exservan in China. As a result, the Company expects that the Haisco Agreement will be terminated and the Company will not receive any contingent payments under the Haisco Agreement. The expected termination may have a positive impact on the Company's 2024 financial results due to recognition of deferred revenue for the \$7.0 million upfront payment received by the Company in September 2022, but the specific impact has yet to be quantified by the Company. The expected termination of the Haisco Agreement will not have a material impact on the Company's condensed financial statements for the year end 2024.

#### ***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. During the first quarter of 2023, net severance payments made to Mr. Kendall totaled approximately \$274. 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 includes 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 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.

#### **Note 6. 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 14, *Warrants* for further information on these warrants.

The Company's 12.5% Senior Secured Notes contained a repurchase offer or put option which gave 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 13, *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 14, *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 Common Stock 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 14, *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 provided 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, the then 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 13, *Long-Term Debt* for further discussion.

#### Note 7. Inventories

The components of Inventory are as follows:

	March 31, 2024	December 31, 2023
Raw material	\$ 3,043	\$ 2,118
Packaging material	2,874	3,028
Finished goods	1,817	1,623
Total inventory	<u>\$ 7,734</u>	<u>\$ 6,769</u>

**Note 8. Property and Equipment, Net**

	Useful Lives	March 31, 2024	December 31, 2023
Machinery	3-15 years	\$ 20,248	\$ 20,248
Furniture and fixtures	3-15 years	769	769
Leasehold improvements	(a)	21,386	21,386
Computer, network equipment and software	3-7 years	2,627	2,627
Construction in progress		2,062	2,033
		47,092	47,063
Less: accumulated depreciation and amortization		(43,046)	(42,884)
Total property and equipment, net		\$ 4,046	\$ 4,179

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

Total depreciation, amortization, and impairment related to property and equipment was \$ 168 and \$286 for the three months ended March 31, 2024 and 2023, respectively.

**Note 9. 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*, which require classification as financing leases and, accordingly, these leases are accounted for as operating leases. These leases, as amended, provide remaining terms between 4.0 and 9.5 years, including renewal options expected to be exercised to extend the lease periods.

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 Condensed 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 Condensed Balance Sheets. For longer-term lease arrangements that are recognized on the Company's Condensed 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 Company's 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 Condensed Statements of Operations and Comprehensive (Loss) Income. For the three months ended March 31, 2024, total operating lease expenses totaled \$444 including variable lease expenses such as common area maintenance and operating costs of \$ 115. For the three months ended March 31, 2023, total operating lease expenses totaled \$418, including variable lease expenses such as common area maintenance and operating costs of \$108.

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

Remainder of 2024	\$ 926
2025	1,266
2026	1,300
2027	1,328
2028 and thereafter	4,990
Total future lease payments	9,810
Less: imputed interest	(4,112)
Total operating lease liabilities	\$ 5,698

**Note 10. Intangible Assets, Net**

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

	March 31, 2024	December 31, 2023
Purchased intangible	\$ 3,858	\$ 3,858
Purchased patent	509	509
	4,367	4,367
Less: accumulated amortization	(3,128)	(3,089)
Intangible assets, net	\$ 1,239	\$ 1,278

Amortization expense was \$39 for each of the three-month periods ended March 31, 2024 and 2023. During the remaining life of the purchased intangible assets, estimated amortization expense is \$118 for the remainder of 2024 and \$ 157 in 2025, respectively.

**Note 11. Other Non-current Assets**

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

	March 31, 2024	December 31, 2023
Royalty receivable	\$ 4,000	\$ 4,000
Other	1,417	1,438
Total other non-current assets	\$ 5,417	\$ 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 March 31, 2024 and December 31, 2023, Royalty receivable, non-current, consists of four 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 15, *Sale of Future Revenue* for further details on how this receivable relates to the Monetization Agreement transaction.

**Note 12. Accrued Expenses**

Accrued expenses consisted of the following:

	March 31, 2024	December 31, 2023
Accrued compensation	\$ 1,731	\$ 4,202
Real estate and personal property taxes	433	337
Accrued distribution expenses and sales returns provision	640	645
Interest payable	1,536	1,013
Other	297	300
Total accrued expenses	\$ 4,637	\$ 6,497

The reduction in Accrued compensation is mostly related to payments of accrued bonus during the three months ended March 31, 2024.

The increase in Interest payable is mostly due to the interest incurred on 13.5% Senior Notes. The 13.5% Senior Notes were issued on November 1, 2023 thus accruing only two months of interest as of December 31, 2023 while earning three months of interest as of March 31, 2024. Payments were due on January 2, 2024 and April 1, 2024, respectively. See Note 13, *Long-Term Debt*, for discussion of 13.5% Notes and related interest payable.

Accrued distribution expenses and sales returns provision represent estimated liabilities for returns and other expenses related to the proprietary product, Sympazan, prior to outlicensing to Assertio in October 2022.

## **Note 13. Long-Term Debt**

### **12.5% Senior Secured Notes**

On July 15, 2019, the Company completed a private placement of up to \$ 100,000 aggregate principal of its 12.5% Notes which were 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% Notes (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, 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% 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 noteholders inclusive of (i) a \$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 had 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. 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. Accordingly, a valuation study was performed by an independent third party appraiser and updated as of March 31, 2023. Based on the valuation study, the put option was valued at \$58 and has been recorded in Other non-current liabilities. The increase in the put option fair value by \$13 was recorded in Interest income and other income, net on the Condensed Statements of Operations and Comprehensive (Loss) Income for the three months ended March 31, 2023. 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 March 31, 2024, the put option is 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 the 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 would 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 first quarter of 2023, the Company redeemed \$9,086 of its outstanding 12.5% Notes. The Company 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 the Company's Condensed Statements of Operations and Comprehensive (Loss) Income.

Amortization expense arising from amortization of deferred debt issuance costs and debt discounts related to the 12.5% Notes for the three months ended March 31, 2023 was \$4.

On November 1, 2023, the Company issued the 13.5% Notes, as described below, and used most of 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.

### **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; the first interest payment was due and paid 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 108.5% 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 asset-based borrowing facility not to exceed \$10,000 (the "ABL Facility"). 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 8 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 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. As of March 31, 2024, there were no material changes to the significant unobservable inputs used to recognize 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:

	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

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.

At inception, 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 a 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 three-month period ended March 31, 2024 was \$1,257 and \$1,358, respectively.

Unamortized discounts totaled \$16,408 and \$17,665 for the 13.5% Notes and \$40,807 and \$42,165 for the Royalty obligations as of March 31, 2024 and December 31, 2023, respectively.

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

	March 31, 2024	December 31, 2023
Total outstanding notes	\$ 45,000	\$ 45,000
Unamortized discount, including Exit Fee	(16,408)	(17,665)
Notes payable, long-term	28,592	27,335
Finance lease	167	173
Notes payable, net	\$ 28,759	\$ 27,508
	March 31, 2024	December 31, 2023
Royalty obligations	\$ 56,926	\$ 56,926
Unamortized discount	(40,807)	(42,165)
Royalty obligations, net	\$ 16,119	\$ 14,761

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

Remainder of 2024	\$ —
2025	—
2026	9,540
2027	14,535
2028	20,925
Total	\$ 45,000

**Note 14. 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 entitled 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 unaudited Condensed Balance Sheets. There were no warrants exercised as it relates to the Initial Warrants and the Additional Warrants during the three months ended March 31, 2024 and 2023, respectively. 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, remain outstanding as of March 31, 2024 and December 31, 2023. See Note 13, *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 December 31, 2022. The Common Stock warrants expire on June 8, 2027 and entitled the purchasers to purchase up to 8,850,000 shares of Common Stock at an exercise price of \$0.96 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 presented in Additional Paid-in Capital in the Company's unaudited Condensed 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 issuance 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 Condensed 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 net 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 exercised as it relates to the Warrants Issued Under Securities Purchase Agreements during the three months ended March 31, 2024 or 2023, respectively.

In addition to the warrants to purchase 2,750,000 shares of Common Stock described above, there remain outstanding warrants to purchase 160,548 shares of Common Stock at an exercise price of \$ 0.96 and warrants to purchase 1,714,429 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 14, with exercise prices of \$ 4.25 and \$5.38 for 1,571,429 warrants and 143,000 warrants, respectively.

**Note 15. 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 March 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 has been 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 contained 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 will periodically assess 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 had 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:

	March 31, 2024	December 31, 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	(12)	(989)
Amortization of issuance costs	58	220
Liability related to the sale of future revenue, net at end of the period (includes current portion of \$ 910 and \$922, respectively)	\$ 64,536	\$ 64,490

**Note 16. Net (Loss) Earnings Per Share**

Basic net (loss) earnings per share is calculated by dividing net (loss) income by the weighted-average number of common shares.

The following table reconciles the basic to diluted weighted average shares outstanding for the three months ended March 31, 2024 and 2023. 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 three months ended March 31, 2024, 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 three months ended March 31, 2024 as reflected below.

	Three Months Ended March 31,	
	2024	2023
<b>Numerator:</b>		
Net (loss) income	\$ (12,828)	\$ 8,068
<b>Denominator:</b>		
Weighted-average number of common shares – basic	73,614,710	55,631,947
Effect of stock options <sup>(a)</sup>	—	5,774,772
Effect of restricted stock units <sup>(b)</sup>	—	1,821,738
Effect of warrants <sup>(c)</sup>	—	10,564,429
Weighted-average number of common shares – diluted	73,614,710	73,792,886
<b>(Loss) Earnings per share attributable to common stockholders:</b>		
(Loss) Earnings per common share – basic	\$ (0.17)	\$ 0.15
(Loss) Earnings per common share – diluted	\$ (0.17)	\$ 0.11

(a) For the three months ended March 31, 2024, outstanding stock options of 6,169,489 shares of Common Stock were anti-dilutive and excluded from the computation of diluted EPS.

(b) For the three months ended March 31, 2024, outstanding restricted stock units of 3,918,451 shares of Common Stock were anti-dilutive and excluded from the computation of diluted EPS.

(c) For the three months ended March 31, 2024, outstanding warrants of 4,624,977 shares of Common Stock, respectively, were anti-dilutive and excluded from the computation of diluted EPS.

(d) For the three months ended March 31, 2024 and 2023, the estimated effects of ESPP awards were not material.

**Note 17. Share-Based Compensation**

The Company recognized share-based compensation in its unaudited Condensed Statements of Operations and Comprehensive (Loss) Income during 2024 and 2023 as follows:

	Three Months Ended March 31,	
	2024	2023
Manufacture and supply	\$ 70	\$ 41
Research and development	170	72
Selling, general and administrative	1,340	231
Total share-based compensation expenses	\$ 1,580	\$ 344
Share-based compensation from:		
Restricted stock units	\$ 933	\$ 25
Stock options	647	319
Total share-based compensation expenses	\$ 1,580	\$ 344

### Share-Based Compensation Equity Awards

The following tables provide information about the Company's restricted stock unit and stock option activity during the three month period ended March 31, 2024:

	Number of Units	Weighted Average Grant Date Fair Value
	(in thousands)	
<u>Restricted Stock Unit Awards (RSUs) - Service-based:</u>		
Unvested as of December 31, 2023	1,948	\$ 0.97
Granted	1,353	\$ 5.68
Vested	(565)	\$ 0.89
Unvested as of March 31, 2024	2,736	\$ 3.32
Vested and expected to vest as of March 31, 2024	2,488	\$ 3.28

As of March 31, 2024, \$7,865 of total unrecognized compensation expenses related to unvested service-based restricted stock units are expected to be recognized over a weighted average period of 2.43 years from the date of grant. 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.

	Number of Units	Weighted Average Grant Date Fair Value
	(in thousands)	
<u>Restricted Stock Unit Awards (RSUs) - Market conditions vesting-based:</u>		
Unvested as of December 31, 2023	1,332	\$ 2.40
Vested	(150)	2.40
Forfeited	—	—
Unvested as of March 31, 2024	1,182	\$ 2.40
Vested and expected to vest as of March 31, 2024	1,061	\$ 2.40

As of March 31, 2024, \$1,858 of unrecognized compensation expense related to unvested market condition vesting based restricted stock units are expected to be recognized over a weighted average period of 2.10 years from the date of grant.

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%.

#### 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 March 31, 2024.

<u>Stock Option Awards:</u>	Number of Options	Weighted Average Exercise Price
	(in thousands)	
Outstanding as of December 31, 2023	5,733	\$ 5.58
Granted	739	5.68
Exercised	(231)	2.33
Forfeited/Expired	(72)	4.76
Outstanding as of March 31, 2024	6,169	\$ 5.72
Vested and expected to vest as of March 31, 2024	6,053	\$ 5.75
Exercisable as of March 31, 2024	4,442	\$ 6.56

The fair values of stock options granted during the three months ended March 31, 2024 were estimated using the Black-Scholes pricing model based on the following assumptions:

Expected dividend yield	—%
Expected volatility	104%
Expected term (years)	6.1
Risk-free interest rate	4.1%

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2024 was \$ 4.69. During the three months ended March 31, 2024, stock options were granted with an exercise price of \$5.68 and accordingly, given the Company's share price of \$ 4.26 at March 31, 2024, the intrinsic value provided by certain shares granted during this period was de minimis.

As of March 31, 2024, \$3,949 of unrecognized compensation expense related to non-vested stock options is expected to be recognized over a weighted average period of 1.78 years from the date of grant.

#### **Note 18. Income Taxes**

The Company has accounted for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as net operating loss carryforwards and research and development credits. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company's tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items. For the three months ended March 31, 2024, the effective income tax rate was 0%, and the Company recorded no income tax expense from its pretax loss of \$12,828. For the three months ended March 31, 2023, the Company recorded no income tax from its pretax income of \$ 8,068.

The primary factors impacting the effective tax rate for three months ended March 31, 2024 is the anticipated full year pre-tax book loss, the expected utilization of net operating losses and research and development credits to offset current year tax liabilities, and a full valuation allowance against any associated net deferred tax assets.

#### **Note 19. 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.

#### **Patent-Related Litigation**

Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.

On February 7, 2018, the Company and Indivior initiated a lawsuit against Teva Pharmaceuticals USA, Inc. ("Teva") asserting infringement of U.S. Patent No. 9,855,221 ("the '221 patent"). On April 3, 2018, the Company and Indivior initiated a separate lawsuit against Teva asserting infringement of U.S. Patent No. 9,931,305 ("the '305 patent"). On May 29, 2018, the lawsuits regarding the '221 and '305 patents were consolidated with a suit originally initiated by Indivior against Teva asserting infringement of U.S. Patent No. 9,687,454 ("the '454 patent"). The parties agreed that the case would be governed by the final judgment against Dr. Reddy's, which also involved allegations of infringement of the '221, '305, and '454 patents, which was resolved via a settlement agreement and entry of a Stipulation and Order of Dismissal on June 28, 2022. On January 31, 2024,

the Court entered a Stipulation and Order of Dismissal, dismissing all claims and counterclaims with prejudice in the lawsuit against Teva.

#### ***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. On February 23, 2024, the Company filed a motion to dismiss the Complaint. Briefing on the motion to dismiss is ongoing and is scheduled to be completed by May 23, 2024. No schedule has been set in the action and there is no trial date set. The Company is not able to determine or predict the ultimate outcome of the state court action in Kentucky by Humana, or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

#### ***California Litigation***

Neurelis, Inc. v. Aquestive Therapeutics, Inc.

On December 5, 2019, Neurelis Inc. 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 demurrer 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. Trial in this matter is scheduled for October 25, 2024. 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.

#### ***Product Liability Litigation***

As of May 1, 2024, the Company has been named as a defendant in over 350 product liability lawsuits, along with Indivior and several other named defendants. These individual plaintiffs 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 United States District Court for the Northern District of Ohio. Indivior has agreed to defend the Company in this litigation. This litigation is currently in the preliminary stages. 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.

#### **Note 20. Subsequent Events**

On April 3, 2024, the Company filed a prospectus supplement to register the offer and sale of up to \$ 250,000 worth of shares of Common Stock pursuant to the Amended Equity Distribution Agreement under a shelf registration statement on Form S-3 (Registration Statement No. 333-278498), or the 2024 Registration Statement, which was declared effective by the SEC on April 23, 2024. The Company also established an At-the-Market facility for \$100,000, which replaced the Company's previous ATM facility that expired in April 2024.

On April 22, 2024, the underwriters purchased 559,801 shares of Common Stock to cover over-allotments in the Underwritten Public Offering, bringing the total gross proceeds to the Company from the Underwritten Public Offering to approximately \$77.5 million, before deducting underwriting commissions and other offering expenses payable by the Company. All of the shares of Common Stock sold in the Underwritten Public Offering, including the over-allotment shares, were offered by the Company.

On April 26, 2024, the FDA approved the Company's NDA for its drug candidate Libervant™ (diazepam) Buccal Film for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern in patients with epilepsy between two to five years of age.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*You should read this section in conjunction with our unaudited condensed interim financial statements and related notes included in Part I Item 1 of this Quarterly Report on Form 10-Q and our audited financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the years ended December 31, 2023 and 2022 included in our 2023 Annual Report on Form 10-K. All dollar amounts are stated in thousands except for share data.*

### Forward-Looking Statements

This Quarterly Report on Form 10-Q 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 expected clinical trials and clinical trial dates, the timing of the pre-NDA meeting and Aquestive's goal of filing an NDA for Anaphylm before the end of 2024; the Company's ability to provide sufficient data in our NDA submission for Anaphylm to address FDA feedback on our proposed pivotal PK study protocol and from the End-of-Phase 2 (EOP2) meeting with the FDA; the approval for U.S. market access of Libervant™ (diazepam) Buccal Film for these epilepsy patients aged twelve years and older, and overcoming the orphan drug market exclusivity of a competing FDA approved nasal spray product extending to January 2027 for six years and above patient population; the advancement and related timing of our product candidate AQST-108 (epinephrine) sublingual film through the clinical development and regulatory process; the potential outlicensing of our product pipeline in the U.S. and abroad, including with respect to Anaphylm and Libervant; the focus on continuing to manufacture Suboxone®, Exservan®, Sympazan®, Ondif® and other licensed products; the potential benefits our products 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 2024 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 and other product candidates; risks associated with the Company's distribution work for Libervant, including any delays or changes to the timing, cost and success of its distribution activities and expansion of market access to patients between two and five years of age for Libervant; risk of litigation brought by third parties relating to overcoming their orphan drug exclusivity of an FDA approved product for these pediatric epilepsy patients; delays or changes to the timing, cost and success of the Company's product development activities and clinical trials for Anaphylm and our other product candidates; risk of delays in regulatory advancement through the FDA of Anaphylm and our other drug candidates or failure to receive FDA approval at all; risk of the Company's ability to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company's ability to address the FDA's comments on the Company's pivotal PK study protocol 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; risk of delays in or the failure to receive FDA approval of Anaphylm; risk of the success of any competing products; risk that we may not overcome the seven year orphan drug 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 ages twelve years and older; 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 future commercialization of our product candidates; risk of sufficient capital and cash resources, including sufficient access to available debt and equity financing, including under our ATM facility and the Lincoln Park Purchase Agreement, 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, including near-term debt amortization schedules; risk of failure to satisfy all financial and other debt covenants and of any default; risk of sufficient capital to fund the Company's commercialization activities relating to Libervant and to fund future clinical development activities for Anaphylm, AQST-108 and our other product candidates; risk that our manufacturing capabilities will be insufficient to support demand for Libervant; risk of eroding market share for Suboxone® and risk as a sunset product, which accounts for the substantial part of our current operating revenue; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of Libervant, Anaphylm and our other candidates and our licensed products in the U.S. and abroad; risk of the success of any competing products including generics, risk of the size and growth of our product

markets; risk of 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 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 products candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings 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 cyberattacks; 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 rising interest rates; risks related to the impact of the COVID-19 global pandemic and other pandemic diseases 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; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in this Quarterly Report on Form 10-Q. 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 the risk factors of the Company's 2023 Annual Report on Form 10-K and our other Quarterly Reports on Form 10-Q and in our Current Reports on Form 8-K and our other filings 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q as representing our views as of any date after the date of the filing of this Quarterly Report on Form 10-Q.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Aquestive," the "Company," "we," "us," and "our" refer to Aquestive Therapeutics, Inc.

## 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 administrations that are alternatives to invasive and inconvenient standard of care therapies. 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. We are advancing a product pipeline for the treatment of severe allergic reactions, including anaphylaxis. We have also developed a product pipeline focused on treating diseases of the CNS. 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 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. Not all collaborative or licensed products of the Company that may be commercially launched in the future will necessarily be manufactured by us, such as the case with KYNMOBI®.

### *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 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 currently administered via intramuscular injection (IM) including 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 currently available products. 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, when it is needed and in a form preferred by patients.

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, the FDA cleared the Company's 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 pharmacokinetics (PK) and pharmacodynamics (PD) of epinephrine delivered via Anaphylm compared to current standards of care, EpiPen® and manual intramuscular (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 End-of-Phase 2 (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 the Company's pivotal clinical trial.

In the fourth quarter of 2023, the Company received comments from the FDA on its protocol for the Company's pivotal clinical study for Anaphylm, which comments indicated that the Company's 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. The Company incorporated the FDA's feedback into the pivotal clinical study design, which study commenced in Q4 2023.

In January of 2024, the Company successfully completed a Type C meeting with the FDA in which the FDA found that the Company 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 the Company's 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 will replace the Company's previously planned angioedema study. In those comments, the FDA did not outline any new clinical development requirements for the Anaphylm program. In addition, the FDA recommended that Aquestive begin its pediatric study for Anaphylm after completion of the remaining adult studies for Anaphylm. The Company is aligned with this recommendation from the FDA. The FDA reserved judgement on the sufficiency of the Anaphylm clinical development program until completion of ongoing and planned studies, the results of which are expected to be presented at a pre-NDA meeting with the FDA, which is expected to occur in the second half of 2024.

In March 2024, the Company released topline data from the Company's 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 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.

Aquestive is conducting the additional studies for Anaphylm in line with its stated timeline. A temperature/pH study is fully enrolled and expected to be completed in the second quarter 2024. FDA feedback on the self-administration study and allergen exposure study was recently received, and the Company remains on track to complete both studies in the third quarter 2024. The pediatric study, in patients from the ages of 7 to 17 (weight greater than or equal to 30kgs), is planned to commence in the second half of 2024 based on feedback from the FDA.

The next anticipated meeting with the FDA is the pre-NDA meeting targeted for the second half of 2024. Aquestive's goal is to file the NDA with the FDA before year end 2024.

- **AQST-108** (sublingual film) – AQST-108 is composed of the prodrug dipivefrin which is enzymatically cleaved into epinephrine after administration. Dipivefrin is currently available outside of the U.S. for ophthalmic indications. A

sublingual film formulation delivering systemic epinephrine has been developed by Aquestive for the treatment of conditions other than anaphylaxis. Based on topline results of a prior Phase 1 PK trial in 28 healthy adult volunteers conducted by Aquestive, AQST-108 was generally well-tolerated, with systemic adverse events observed that are consistent with the known adverse events profile for epinephrine. Additional indications and delivery methods are currently being explored for AQST-108 under the Adrenaverse platform which contains a library of over twenty epinephrine prodrugs that can control absorption and conversion rates across a variety of dosage forms and delivery sites. Although epinephrine is a vasoconstrictor and does not penetrate well through the skin, the Company believes that AQST-108 may allow for topical absorption, thereby creating the potential treatment for a variety of dermatological conditions. Based on preclinical data, the Company has seen rapid absorption of AQST-108 across porcine tissue. The Company has completed an initial formulation of a topical product using AQST-108 and has initiated testing ascending doses of the formulation in humans. Upon completion of the preclinical and feasibility work relating to this program, the Company expects to request a pre-IND meeting for AQST-108 with the FDA and plans to disclose the indication and path forward for development, once we have received feedback from the FDA.

#### *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. We believe there remains a significant opportunity to develop additional products in the CNS market. Additionally, our know-how and proprietary position have broad application beyond CNS, and we plan to explore the applications of PharmFilm in other disease areas. 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 is our most advanced proprietary investigational product candidate. Aquestive developed Libervant 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) that are distinct from a patient's usual seizure pattern in patients with epilepsy between two and five years of age. The only other current FDA approved product for these epilepsy patients between two and five years of age is a diazepam rectal gel.

Prior to the FDA approval of Libervant for patients between two to five years old, 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 Valtoco®, a diazepam nasal spray product sold by another company for use in 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. As a result of this determination, the FDA cannot give final approval for Libervant for this age group until the expiration or inapplicability of the orphan drug market exclusivity, including, for example, by a reversal of the FDA's decision and determination that Libervant is "clinically superior" to Valtoco. 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 12 years and older earlier than January 2027, the scheduled date for expiration of orphan drug market exclusivity. Further, there can be no assurance that another company will not obtain other FDA market exclusivity that blocks U.S. market access for Libervant for this age group.

See "Licensed Commercial Products and Product Candidates and Other Products – Libervant" for a discussion of the licensing arrangement for Libervant.

#### **Licensed Commercial Products, 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, 2023 and 2022, our licensed product portfolio generated \$50.6 million and \$47.7 million in revenue to Aquestive, respectively. In the three months ended March 31, 2024 and 2023, our licensed product portfolio generated \$12.1 million and \$11.1 million 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, 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 March 31, 2024, Suboxone branded products retain approximately 29% film market share as generic film-based products have penetrated this market. We have filed patent infringement lawsuits against certain companies relating to generic film-based products for buprenorphine-naloxone. More details regarding these lawsuits are described in the unaudited financial statements, Note 19, *Contingencies*, contained herein.

- **Exservan®** – an oral film formulation of riluzole, has been developed by the Company for the treatment of ALS. We believe that Exservan can bring meaningful assistance to patients who are diagnosed with ALS and face difficulties swallowing traditional forms of medication. Exservan was approved by the FDA on November 22, 2019. 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. 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 Exservan 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 Exservan 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 Exservan pursuant to the terms of the license agreement with Zambon.

In January 2021, we announced that the Company granted an exclusive license to MTHA for the commercialization in the United States of Exservan. MTHA is a multinational pharmaceutical company with a focus on patients with ALS. The product was launched by MTHA in June 2021. Under the terms of the MTHA license agreement, Aquestive is the exclusive manufacturer and supplier of Exservan for MTHA in the United States. Exservan was developed to potentially fulfill a critical need for ALS patients, given it can be administered safely and easily, twice daily, without water.

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 will lead the regulatory and commercialization activities for Exservan in China. Aquestive will serve as the exclusive sole manufacturer and supplier for Exservan in China. Under the terms of license agreement with Haisco, as amended, Aquestive received a \$7.0 million upfront payment in September 2022, and will 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. See Note 5, *Licensing and Supply Agreement with Haisco for Exservan™ (Riluzole Oral Film) for ALS Treatment in China*, for an update on the Haisco 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.
- **Zuplenz®** – 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 Zuplenz to Hypera in Brazil (which Hypera markets as Ondif). Hypera received approval to market Zuplenz in Brazil from ANVISA on February 21, 2022. We licensed commercial rights for Zuplenz to Fortovia in the United States, Canada, and China. Fortovia launched Zuplenz in the United States in 2015. We had been the sole and exclusive manufacturer of Zuplenz for Fortovia. On August 31, 2020, Fortovia filed a Chapter 11 bankruptcy proceeding in the Bankruptcy Court for the Eastern District of North Carolina. On January 29, 2021, the Bankruptcy Court approved an agreement pursuant to which the license and supply agreement between Aquestive and Fortovia was terminated, and all rights to commercialize Zuplenz returned to us, effective January 30, 2021. The Company submitted a request for voluntary withdrawal of NDA 022524, Zuplenz, as the product is no longer marketed in the U.S. The request is being processed by FDA.
- **Azstarys™** – an FDA-approved, once-daily product for the treatment of ADHD in patients age six years or older. AZSTARYS consists of serdexmethylphenidate, a prodrug of d-methylphenidate (d-MPH), co-formulated with immediate release d-MPH. In March 2012, the Company 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, 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. On March 2, 2021, Zevra announced FDA approval of Azstarys for the treatment of ADHD. Pursuant to the terms of the March agreement with Zevra, the Company has begun to receive milestone revenues for Azstarys.

- **Libervant™** - The Company entered into the Pharmanovia Agreement with Pharmanovia, 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 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. The Company received \$3.5 million upon agreement execution. Effective March 27, 2023, the Company 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, the Company 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, the Company entered into the Assertio Agreement with pursuant to which the Company 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, the Company subsequently received from Assertio a \$6.0 million milestone payment upon the Company's 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. The Company 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 supply agreement.

#### **Critical Accounting Policies and Use of Estimates**

There have been no material changes to our critical accounting policies and use of estimates as previously disclosed in our 2023 Annual Report on Form 10-K.

#### ***JOBS Act and Smaller Reporting Company***

As of December 31, 2023, we were no longer an "emerging growth company," as defined in the United States JOBS Act. While we were an emerging growth company, we were able to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. Even though we are no longer an emerging growth company, we remain exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act pursuant to rules of the SEC.

We remain a "smaller reporting company", meaning we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a "smaller reporting company" which allows us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and certain reduced financial disclosures in our periodic reports. In addition, 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.

#### **Financial Operations Overview**

##### ***Revenues***

Our revenues to date have been earned from our manufactured products made to order for licensees. Revenues are also earned from our product development services provided under contracts with customers, and from the licensing of our

intellectual property. These activities generate revenues in three primary categories: manufacture and supply revenue, co-development and research fees, and license and royalty revenue.

#### *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. With the exception of our license of Exservan, 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. With regard to our license of Exservan to MTHA and Haisco, we continue to hold the NDA for that product and, as such, are responsible for certain regulatory obligations relating to the sale of the product so long as we are the holder of the NDA for the product.

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.

#### *Co-development and Research Fees*

We work with our licensees to co-develop pharmaceutical products. In this regard, we earn fees through performance of specific tasks, activities, or completion of stages of development defined within a contractual arrangement with the relevant licensee. The nature and extent 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.

#### *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.

#### **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.

We expect to continue to seek to rationalize and manage costs to prepare for a potential decline in Suboxone volumes as the generics in that market continue to take market share, at least partially offset by anticipated manufacturing revenue of our licensed products including Sympazan, subsequent to the Assertio Agreement in October 2022. 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 Ondansetron, we would incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from higher manufactured volumes from 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 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, engineering, 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 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 patients with epilepsy between two and 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 13, *Long-Term Debt*, to our Condensed Financial Statements. 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 Note 13, *Long-Term Debt*.

### *Interest expense related to the 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 March 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 Note 15, *Sale of Future Revenue*, to our Condensed Financial Statements for further detail.

### *Interest income and other income, net*

Interest income and other income, net consists of earnings derived from an interest-bearing account and other miscellaneous income and expense items. The interest-bearing account has no minimum amount to be maintained in the account nor any fixed length of period for which interest is earned.

## **Results of Operations**

### **Comparison of the Three Months Ended March 31, 2024 and 2023**

#### *Revenues:*

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

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
<i>(In thousands, except %)</i>				
Manufacture and supply revenue	\$ 10,518	\$ 9,762	\$ 756	8 %
License and royalty revenue	1,132	919	213	23 %
Co-development and research fees	403	453	(50)	(11)%
Total revenues	<u>\$ 12,053</u>	<u>\$ 11,134</u>	<u>\$ 919</u>	8 %

### **Three Months Ended March 31, 2024 Compared to Three Months Ended March 31, 2023**

For the three months ended March 31, 2024, total revenues increased 8% or \$919 compared to the same period in the prior year due to increases in manufacture and supply revenue, license and royalty revenue, partially offset by a decrease in co-development and research fees.

Manufacture and supply revenue increased approximately 8% or \$756 for the three months ended March 31, 2024 compared to the same period in the prior year. This increase was primarily due to a 24%, or \$1,857, increase in Suboxone manufacture and supply revenue and a 27%, or \$95, increase in Sympazan manufacture and supply revenue which was offset by a decrease in revenues from Ondif by \$1,496. 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 three months ended March 31, 2023. There were no retroactive price adjustments included in Manufacture and supply revenue for the three months ended March 31, 2024.

License and royalty revenue increased 23% or \$213 for the three months ended March 31, 2024 compared to the same period in the prior year. This increase was primarily due to an increase in royalty revenues of 158%, or \$90 for Azstarys from Zevra and an increase in royalty revenues of 28%, or \$66 for Sympazan from Assertio.

Co-development and research fees decreased 11% or \$50 for the three months ended March 31, 2024 compared to the same period in the prior year. The decrease was driven by the timing of the achievement of research and development performance obligations which are expected to fluctuate from among reporting periods.

*Expenses, Interest Income and Other Income:*

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
<i>(In thousands, except %)</i>				
Manufacture and supply	\$ 4,389	\$ 4,737	\$ (348)	(7) %
Research and development	5,932	3,547	2,385	67 %
Selling, general and administrative	10,689	7,455	3,234	43 %
Interest expense	2,784	1,435	1,349	94 %
Interest expense related to royalty obligations	1,358	—	1,358	N/M
Interest expense related to the sale of future revenue	58	52	6	12 %
Interest income and other income, net	(329)	(14,513)	14,184	98 %
Loss on extinguishment of debt	—	353	(353)	N/M

Manufacture and supply costs and expenses decreased 7% or \$348 for the three months ended March 31, 2024 compared to the same period in the prior year. The decrease was largely due to a change in product mix. In the three months ended March 31, 2023, the products we produced and sold had a much higher cost due to a more expensive API as compared to the three months ended March 31, 2024.

Research and development expenses increased 67% or \$2,385 for the three months ended March 31, 2024 compared to the same period in the prior year. The increase in Research and development expenses is primarily due to clinical trial costs associated with the continued advancement of the Anaphylm program. 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:

	Three Months Ended March 31,		Change	
	2024	2023	\$	%
<i>(In thousands)</i>				
Clinical Trials	\$ 3,578	\$ 1,396	\$ 2,182	156 %
Development and Manufacturing	134	175	\$ (41)	(23) %
Product Research Expenses	241	136	105	77 %
Total Project Expenses	3,953	1,707	2,246	132 %
Preclinical	83	9	74	N/M
R&D personnel costs	1,534	1,403	131	9 %
Consulting and outside services	5	142	(137)	(96) %
Share-based compensation	170	72	98	136 %
Depreciation/amortization	20	25	(5)	(20) %
All other R&D	167	189	(22)	(12) %
Total	\$ 5,932	\$ 3,547	\$ 2,385	67 %

	Three Months Ended March 31,											
	2024			2023			2024			2023		
			%			%			%			%
	Total		inc / dec	Anaphylm		inc / dec	AQST-108		inc / dec	Libervant		inc / dec
Clinical Trials	\$ 3,578	\$ 1,396	156 %	\$ 2,975	\$ 1,396	113 %	\$ 586	\$ —	N/M	\$ 17	\$ —	N/M
Development and Manufacturing	134	175	(23 %)	119	175	(32 %)	15	—	N/M	—	—	N/M
Product Research Expenses	241	136	77 %	53	130	(59 %)	188	—	N/M	—	6	N/M
Total Project Expenses	\$ 3,953	\$ 1,707	132 %	\$ 3,147	\$ 1,701	85 %	\$ 789	\$ —	N/M	\$ 17	\$ 6	N/M

During the three months ended March 31, 2024, total project expenses for Anaphlym increased 85%, or \$1,446 over the same period in 2023. During the three months ended March 31, 2024, clinical trial expenses for Anaphlym increased 113% or \$1,579 over the same period in 2023 offset by decreases in development and manufacturing and product research expenses of \$56 and \$77, respectively. During the three months ended March 31, 2024, clinical trial expenses for Anaphlym of \$2,975 were primarily due to clinical trial costs associated with the continued advancement of the Anaphlym program. During the three months ended March 31, 2023, clinical trial expenses for Anaphlym of \$1,396 were related to the activities leading up to the Phase 3 PK Study. During the three months ended March 31, 2024, total project expenses for AQST-108 increased \$789 over the same period in 2023 and were related to preclinical and feasibility work for AQST-108.

Preclinical expense related to activities in evaluating product candidates increased \$74 for the three months ended March 31, 2024 compared to the same period in 2023. R&D personnel costs increased by 9% or \$131, for the three months ended March 31, 2024 compared to the same period in 2023 due to additional headcount. An increase in share based compensation of \$98 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. Consulting and Outside Services decreased by \$137 for the three months ended March 31, 2024 compared to the same period in 2023.

All other R&D expenses include rent, utilities, maintenance and other expenses and fees.

Selling, general and administrative expenses increased 43% or \$3,234 for the three months ended March 31, 2024 as compared to the same period in the prior year. The increase primarily represents higher personnel costs of approximately \$1,120, one-time severance costs of approximately \$1,100, higher share-based compensation expenses of \$620, higher patent fees of \$280, higher expenses of \$950 due to a year-over-year change in the allocation of manufacture and supply costs, and higher consulting expenses of approximately \$300, partially offset by lower legal fees of \$915, and decreases in other general and administrative costs including insurance.

Interest expense increased 94% or \$1,349 for the three months ended March 31, 2024 compared to the same period in the prior year. The increase was mostly driven by the increased amortization of debt issuance costs and discounts on the 13.5% Notes refinancing in November 2023 for the three months ended March 31, 2024 compared to the three months ended March 31, 2023.

Interest expense related to royalty obligations represents amortization of the discount on the royalty obligations. It was \$1,358 for the three months ended March 31, 2024. This amount is due to the accounting associated with the royalty obligations as part of the 13.5% Notes issuance. There were no expenses related to the royalty obligations in the same period in 2023.

Interest expense related to the sale of future revenue was \$58 and \$52 for the three months ended March 31, 2024 and March 31, 2023, respectively, and represents amortization of the issuance costs. 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 outflow at any time during the life of the transaction. In June 2023, Sunovion announced that it had 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. As a result, the Company discontinued recording interest expense related to the sale of future revenue in the fourth quarter of 2022. See Note 15, *Sale of Future Revenue* for details.

Interest income and other income, net was \$329 for the three months ended March 31, 2024 which primarily represents investment income, as compared to interest income and other income, net of \$14,513 in the three months ended March 31, 2023. In three months ended March 31, 2023, we recognized income of \$6,000 related to the Amendment 11 to the Indivior Commercial Exploitation Agreement, and \$8,500 patent litigation settlement from BioDelivery Sciences International, Inc.

## **Liquidity and Capital Resources**

### ***Sources of Liquidity***

We had \$95,200 in cash and cash equivalents as of March 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, as well as access to the equity capital markets, including through the ATM facility and under the Lincoln Park Purchase Agreement, 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. As discussed below, on November 1, 2023, we issued \$45,000 in aggregate principal amount of 13.5% Notes due November 1, 2028. A portion of the net proceeds from this transaction was used to redeem all of the 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.

On October 7, 2021, we 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 amortization payment to be extended 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, 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. The last quarterly payment was made during the three months ended March 31, 2023.

During the first quarter of 2023, we redeemed \$9,086 of our outstanding 12.5% Notes. The prepayments along with the scheduled principal repayments during the first quarter of 2023 reduced the net balance of the 12.5% Notes outstanding in the aggregate to \$42,413. 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 Condensed Statements of Operations and Comprehensive (Loss) Income as of March 31, 2024.

In 2019, we established an ATM facility and, as of March 31, 2024, had a prospectus supplement registering the offer and sale of up to \$35,000 of shares of Common Stock pursuant under the ATM facility (net of what has been sold pursuant thereto). Since inception to March 31, 2024, we sold 19,857,518 shares under the ATM facility which generated net cash proceeds of approximately \$60,715, net of commissions and other transaction costs of \$2,928. For the three months ended March 31, 2024, the Company sold 4,557,220 shares of Common Stock under the ATM which provided net proceeds of approximately \$12,012 after deducting commissions and other transaction costs of \$373. For the three months ended March 31, 2023, we sold 1,078,622 shares which provided net proceeds of approximately \$916, net of commissions and other transaction costs of \$77. In April 2024, the Company established its ATM facility at \$100,000 (see Note 20, *Subsequent Events*).

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. The Lincoln Park Purchase Agreement contains an ownership limitation such that we will not issue, and Lincoln Park will not purchase, shares of Common Stock if it would result in their beneficial ownership exceeding 9.99%. 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. In 2022, we sold 1,600,000 shares in addition to 236,491 commitment shares, which provided proceeds of approximately \$1,987 in connection with the Lincoln Park Purchase Agreement. We did not sell shares in connection with the Lincoln Park Purchase Agreement in the three months ended March 31, 2024 and in the three months ended March 31, 2023.

On June 6, 2022, we entered into the Securities Purchase Agreements with certain purchasers. The Securities Purchase Agreements provide 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.

In 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 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.

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 resulting in gross proceeds of \$75,000. At closing, we received net proceeds of \$70,500 after deducting underwriting discounts of \$4,500. In addition to the underwriting discounts related to this Underwritten Public

Offering, our estimated incurred professional fees and other costs totaled \$687 of which \$313 remains unpaid as of March 31, 2024.

In addition, we granted the underwriters in the Underwritten Public Offering a 30-day option to purchase up to an additional 2,500,000 shares of our Common Stock at the public offering price, less underwriting discounts and commissions. Subsequent to March 31, 2024, the underwriters exercised the option by purchasing an additional 559,801 shares of Common Stock, for additional gross proceeds of \$2,519, before deducting underwriting commissions and other offering expenses payable by us.

### **Three Months Ended March 31, 2024 and 2023**

(in thousands)	Three Months Ended March 31,	
	2024	2023
Net cash (used for) provided by operating activities	\$ (10,384)	\$ 8,816
Net cash used for investing activities	(29)	(2)
Net cash provided by (used for) financing activities	81,741	(9,205)
Net increase (decrease) in cash and cash equivalents	\$ 71,328	\$ (391)

### **Net cash (used for) provided by operating activities**

Net cash used for operating activities for the three months ended March 31, 2024 increased by \$19,200 compared to the same period in the prior year. The increase in cash used for operating activities was primarily related to the change in net (loss) income of \$20,896 and deferred revenue of \$5,262, which was driven by payments received from our customers in the three months ended March 31, 2023, partially offset by decreases in trade and other receivables of \$2,364. Other changes were mainly due to higher amortization of debt issuance costs and discounts of \$2,617 on the 13.5% Notes refinancing in November 2023 and an increase in share-based compensation of \$1,236 as compared with the three months ended March 31, 2023.

### **Net cash used for investing activities**

Net cash used for investing activities for the three months ended March 31, 2024 increased by \$27 compared to the same period in the prior year. The use of cash was related to capital expenditures.

### **Net cash provided by (used for) financing activities**

Net cash provided by financing activities for the three months ended March 31, 2024 increased by \$90,946 compared to the same period in the prior year. The increase was primarily related to the Underwritten Public Offering which provided net proceeds of \$70,126, higher ATM proceeds of \$11,058 due to higher volumes and Common Stock prices as compared with the three months ended March 31, 2023, largely offset by the partial debt redemption and premium paid to retire debt in the three months ended March 31, 2023.

### **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 under the Lincoln Park Purchase Agreement, 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 that offering were used to redeem all of the 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.

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 resulting in gross proceeds of \$75,000. At closing, we received net proceeds of \$70,500 after deducting underwriting discounts of \$4,500. In addition to the underwriting discounts related to this offering, our estimated incurred professional fees and other costs totaled \$687 of which \$313 remains unpaid as of March 31, 2024. In addition, we have granted the underwriters a 30-day option to purchase up to an additional 2,500,000 shares of our Common Stock at the public offering price, less underwriting discounts and commissions. Subsequent to March 31, 2024, the underwriters exercised the option by purchasing an additional 559,801 shares of Common Stock, for additional gross proceeds of \$2,519, before deducting underwriting commissions and other offering expenses payable by the Company. See Note 20, *Subsequent Events*.

We intend 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 the Company's product pipeline, including Anaphylm and Libervant for the treatment of seizure clusters in epilepsy patients between two and five years of age, 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, such as Exservan;
- 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 and under the Lincoln Park Purchase Agreement;
- 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 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, including litigation costs in connection with seeking to enforce our rights concerning third parties' "at-risk" launch of generic products, and other 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 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 pre-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 2025 to 2033, which are further discussed in Note 13, *Long-Term Debt* to our Condensed Financial Statements. 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 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 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 be required to evaluate additional licensing and monetization 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, such as asset sales, although we cannot assure that any of these actions would be available or available on reasonable terms.

#### **Off-Balance Sheet Arrangements**

During the period presented, we did not have any material off-balance sheet arrangements, nor do we have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

#### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

As a "smaller reporting company" as defined by Item 10 of Regulation S-K promulgated by the SEC under the U.S. Securities Act of 1933, as amended, we are not required to provide the information required by this Item 3.

#### **Item 4. Controls and Procedures**

##### *Management's Evaluation of our Disclosure Controls and Procedures*

We maintain disclosure controls and procedures 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 to our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of March 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(b) and 13a-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 March 31, 2024, our disclosure controls and procedures were effective at a reasonable assurance level.

##### *Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting (as defined in Rule 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 are reasonably likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION****Item 1. Legal Proceedings**

For more information on Legal Proceedings, see Part I Item I. Financial Statements (Unaudited), Note 19, *Contingencies*.

**Item 1A. Risk Factors**

You should carefully review and consider the information regarding certain risks and uncertainties facing the Company that could have a material adverse effect on our business prospects, financial condition, results of operations, liquidity and available capital resources set forth in Part I, Item 1A of Aquestive's 2023 Annual Report on Form 10-K.

**Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

During the quarter ended March 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) adopted, terminated or modified a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

**Item 6. Exhibits**

The exhibits listed below are filed or furnished as part of this report.

Number	Description
<a href="#">31.1</a> *	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<a href="#">31.2</a> *	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<a href="#">32.1</a> *	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).
<a href="#">32.2</a> *	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).
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL document and contained in exhibit 101)

\* Filed herewith.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the County of Somerset, State of New Jersey.

Aquestive Therapeutics, Inc.  
(REGISTRANT)

Date: May 7, 2024

\_\_\_\_\_  
/s/ Daniel Barber  
Daniel Barber  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

Date: May 7, 2024

\_\_\_\_\_  
/s/ A. Ernest Toth, Jr.  
A. Ernest Toth, Jr.  
*Chief Financial Officer*  
*(Principal Financial Officer)*

**Certification of Principal Executive Officer of Aquestive Therapeutics, Inc.  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Daniel Barber, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aquestive Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, consolidated results of operations and consolidated cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2024

/s/ Daniel Barber

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Daniel Barber

*President and Chief Executive Officer  
(Principal Executive Officer)*

**Certification of Principal Financial and Accounting Officer of Aquestive Therapeutics, Inc.  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, A. Ernest Toth, Jr, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aquestive Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, consolidated results of operations and consolidated cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2024

/s/ A. ERNEST TOTH, JR.

A. Ernest Toth, Jr.

Chief Financial Officer  
(Principal Financial Officer)

**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**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Daniel Barber, President and Chief Executive Officer of Aquestive Therapeutics, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period-ended March 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Date: May 7, 2024

/s/ Daniel Barber

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Daniel Barber

*President and Chief Executive Officer*

*(Principal Executive Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aquestive Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.

**Certification of Principal Financial and Accounting Officer**  
**Pursuant to 18 U.S.C. Section 1350, as Adopted**  
**Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, A. Ernest Toth, Jr., Chief Financial Officer of Aquestive Therapeutics, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period-ended March 31, 2024, to which this Certification is attached as Exhibit 32.2 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Date: May 7, 2024

/s/ A. ERNEST TOTH, JR

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A. Ernest Toth, Jr.

*Chief Financial Officer*

*(Principal Financial Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aquestive Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.