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, 2023

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 organization)	**(908) 941-1900**	(I.R.S. Employer Identification Number)

(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

Indicate by check mark whether the registrant 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 April 26, 2023 was 55,922,361.

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PART I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS *(Unaudited)*

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 26,882	$ 27,273
Trade and other receivables, net	7,551	4,704
Inventories, net	6,981	5,780
Prepaid expenses and other current assets	2,292	2,131
Total current assets	43,706	39,888
Property and equipment, net	3,814	4,085
Right-of-use assets, net	5,884	5,211
Intangible assets, net	1,396	1,435
Other non-current assets	6,485	6,451
Total assets	$ 61,285	$ 57,070
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 12,440	$ 9,946
Accrued expenses	4,508	7,967
Lease liabilities, current	328	255
Deferred revenue, current	4,765	1,513
Liability related to the sale of future revenue, current	1,147	1,147
Loans payable, current	17,195	18,700
Total current liabilities	40,383	39,528
Loans payable, net	25,196	33,448
Liability related to the sale of future revenue, net	64,137	64,112
Lease liabilities	5,706	5,085
Deferred revenue	33,039	31,417
Other non-current liabilities	2,059	2,034
Total liabilities	170,520	175,624
Contingencies (Note 19)		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 55,922,361 and 54,827,734 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	56	55
Additional paid-in capital	193,848	192,598
Accumulated deficit	(303,139)	(311,207)
Total stockholders' deficit	(109,235)	(118,554)
Total liabilities and stockholders' deficit	$ 61,285	$ 57,070

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	**2022**
Revenues	$ 11,134	$ 12,270
Costs and expenses:		
Manufacture and supply	4,737	4,214
Research and development	3,547	4,773
Selling, general and administrative	7,455	13,021
Total costs and expenses	15,739	22,008
Loss from operations	(4,605)	(9,738)
Other income/ (expenses):		
Interest expense	(1,435)	(1,618)
Interest expense related to the sale of future revenue, net	(52)	(1,861)
Interest and other income (expense), net	14,513	(3)
Loss on extinguishment of debt	(353)	—
Net income (loss) before income taxes	8,068	(13,220)
Income taxes	—	—
Net income (loss)	$ 8,068	$ (13,220)
Comprehensive income (loss)	$ 8,068	$ (13,220)
Earnings (loss) per share attributable to common stockholders:		
Basic (in dollars per share)	$ 0.15	$ (0.32)
Diluted (in dollars per share)	$ 0.11	$ (0.32)
Weighted average common shares outstanding:		
Basic (in shares)	55,631,947	41,465,798
Diluted (in shares)	73,792,886	41,465,798

See accompanying notes to the condensed consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity/Deficit
	Shares	Amount			
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	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)
Balance at December 31, 2021	41,228,736	$ 41	$ 174,621	$ (256,796)	$ (82,134)
Common Stock issued under public equity offering	391,652	—	1,360	—	1,360
Costs of common stock issued under public equity offering	—	—	(62)	—	(62)
Share-based compensation expense	—	—	913	—	913
Other	—	—	1	(1)	—
Net loss	—	—	—	(13,220)	(13,220)
Balance at March 31, 2022	41,620,388	41	176,833	(270,017)	(93,143)

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2023	**2022**
Operating activities:		
Net income (loss)	$ 8,068	$ (13,220)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation, amortization, and impairment	325	727
Share-based compensation	344	913
Amortization of debt issuance costs and discounts	56	40
Interest expense related to the sale of future revenue, net	—	1,836
Other, net	(260)	(100)
Changes in operating assets and liabilities:		
Trade and other receivables, net	(2,217)	(7,678)
Inventories, net	(1,201)	(591)
Prepaid expenses and other assets	(195)	(230)
Accounts payable	2,494	182
Accrued expenses and other liabilities	(3,472)	(3,963)
Deferred revenue	4,874	7,602
Net cash used for operating activities	8,816	(14,482)
Investing activities:		
Capital expenditures	(2)	(104)
Net cash used for investing activities	(2)	(104)
Financing activities:		
Proceeds from common stock issued under public equity offering, net	916	1,298
Repayment of debt principal	(9,086)	—
Premium paid to retire debt	(1,027)	—
Payments for taxes on share-based compensation	(8)	—
Net cash provided by financing activities	(9,205)	1,298
Net (decrease) increase in cash and cash equivalents	(391)	(13,288)
Cash and cash equivalents at beginning of period	27,273	28,024
Cash and cash equivalents at end of period	$ 26,882	$ 14,736
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 1,466	$ 1,609

See accompanying notes to the condensed consolidated financial statements.

AQUESTIVE THERAPEUTICS, INC.
Notes to Condensed Consolidated 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. (together with its subsidiary, "we", "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 central nervous system, or 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 an "At-The-Market" (ATM) facility pursuant to which the Company may offer up to $25,000 worth of shares of common stock, par value $0.001 per share, of the Company (the "Common Stock"). 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 Securities and Exchange Commission (SEC) on April 5, 2021. The Company discontinued using the 2021 Prospectus upon the filing of the prospectus supplement on September 7, 2022.

For the three months ended March 31, 2023, the Company sold 1,078,622 shares of Common Stock under the ATM which provided net proceeds of approximately $916 after deducting commissions and other transaction costs of $77. This ATM facility has approximately $32,422 worth of shares of Common Stock available at March 31, 2023. For the three months ended March 31, 2022, the Company sold 391,652 shares which provided net proceeds of approximately $1,298 after deducting commissions and other transaction costs of $62.

On April 12, 2022, the Company entered into a purchase agreement ("Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), 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 1,611,181 shares, including commitment shares, which provided proceeds of approximately $1,987 in connection with the Lincoln Park Purchase Agreement**.** On April 13, 2022, the Company filed a prospectus supplement in connection with this offering. The Company did not sell shares in connection with the Lincoln Park Purchase Agreement in the first quarter of 2023.

On June 6, 2022, the Company entered into securities purchase agreements ("Securities Purchase Agreements") with certain purchasers named therein. The Securities Purchase Agreements provided for the sale and issuance by the Company 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 Company received net proceeds of approximately $7,796, after deducting placement agent fees and expenses and estimated offering expenses payable by the Company. The Company used the net proceeds from the offering for general corporate purposes. On

June 8, 2022, the Company filed a prospectus supplement in connection with this equity offering. The pre-funded warrants were fully exercised in 2022 and no Common Stock warrants issued pursuant to the Securities Purchase Agreements were exercised during the three-months ended March 31, 2023.

(C) Nasdaq Stock Market Notifications

On December 30, 2022, the Company received a notice from the Nasdaq Stock Market ("Nasdaq") that the Company was not in compliance with Nasdaq's Listing Rule 5450(a)(1), as the minimum bid price of the Company's Common Stock had been below $1.00 per share for 30 consecutive business days (the "Minimum Bid Price Requirement"). The notification of noncompliance had no immediate effect on the listing or trading of the Company's Common Stock on The Nasdaq Global Market. The Company had 180 calendar days, or until June 28, 2023, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the minimum bid price of the Company's Common Stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during this 180-calendar day grace period. On April 13, 2023, the Company received a notice from Nasdaq informing the Company that it had regained compliance with Nasdaq's Listing Rule 5450(a)(1) for continued listing on The Nasdaq Global Market, as the minimum bid price of the Company's Common Stock had met or exceeded $1.00 per share for a minimum of ten consecutive business days during this 180-day calendar period. See Note 20, *Subsequent Events* for details.

(D) Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements were prepared in conformity with U.S. generally accepted accounting principles ("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 consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated 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, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2023 (the "2022 Annual Report on Form 10-K"). As included herein, the Condensed Consolidated Balance Sheet as of December 31, 2022 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 consolidated financial statements.

Any reference in these notes to applicable guidance refers to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Note 2. Summary of Significant Accounting Policies

(A) Recent Accounting Pronouncements

As an emerging growth company, the Company has elected to take advantage of the extended transition period afforded by the Jumpstart Our Business Startups Act for the implementation of new or revised accounting standards and, as a result, the Company will comply with new or revised accounting standards no later than the relevant dates on which adoption of such standards is required for emerging growth companies. The Company believes that the impact of recently issued accounting 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, 2023:

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326), amending existing guidance on the accounting for credit losses on financial instruments within its scope. The guidance provides for use of a forward-looking expected loss model for estimating credit losses, replacing the incurred loss model that is based on past events and current conditions. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The Company adopted the new guidance on January 1, 2023. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. The accounting standard update was issued to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The Company adopted the new guidance on January 1, 2023. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Adopted as of March 31, 2023:

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. These amendments will be effective for the Company beginning January 1, 2024, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2020-06 on its consolidated 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. These amendments will be effective for the Company beginning January 1, 2024, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2020-06 on its consolidated 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 2023 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, 2023, the Company had $26,882 of cash and cash equivalents.

The Company has experienced a history of net losses in prior periods. The Company's accumulated deficits totaled $303,139 as of March 31, 2023. The net losses and accumulated deficits were partially offset by gross margins from 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 12.5% Senior Secured Notes.

The Company began utilizing its ATM facility in November 2020. Since inception to March 31, 2023, the Company sold 11,420,579 shares of Common Stock which generated net cash proceeds of approximately $40,656, net of commissions and other transaction costs of $2,130. For the three months ended March 31, 2023, the Company sold 1,078,622 shares of Common Stock which provided net proceeds of approximately $916, net of commissions and other transaction costs of $77. This ATM facility has approximately $32,422 worth of shares of Common Stock available at March 31, 2023. The Company is subject to the SEC general instructions of Form S-3 known as the "baby shelf rules." Under these instructions, the amount of funds the Company can raise through primary public offerings of securities in any 12-month period using its registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of the Company's Common Stock held by non-affiliates. Therefore, the Company will be limited in the amount of proceeds it is able to raise by selling shares of its Common Stock using its Form S-3, including under the ATM facility and the Lincoln Park Purchase Agreement, until such time as its public float exceeds $75 million.

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, expense management activities, including, but not limited to potentially ceasing nearly all R&D activities, as well as access to the equity capital markets, including through its ATM facility and under the Lincoln Park Purchase Agreement, provide near term liquidity for the Company to fund its operating needs, including making the principal and interest payments on the 12.5% Senior Secured Notes, for at least the next twelve months as it continues to execute its business strategy. See Note 13, *12.5% Senior Secured Notes and Loans Payable* for details.

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.

Proprietary product sales, net - this net revenue is recognized when product is shipped and title passes to the customer, typically at time of delivery. At the time of sale, estimates for various revenue allowances are recorded based on historical trends and judgmental estimates. For sales of Sympazan (prior to its outlicensing by the Company to Otter Pharmaceuticals, LLC in October 2022), returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates, if available, and these estimates are recorded as a reduction of receivables. Similarly determined estimates are recorded relating to wholesaler service fees, co-pay support redemptions, Medicare, Medicaid and other rebates, and these estimates are reflected as a component of accrued liabilities. Once all related variable considerations are resolved and uncertainties as to collectable amounts are eliminated, estimates are adjusted to actual allowance amounts. Provisions for these estimated amounts are reviewed and adjusted on no less than a quarterly basis.

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

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 are incurred 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 Consolidated Balance Sheet. As of March 31, 2023, and December 31, 2022, such contract assets were $3,507 and $2,139, 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.

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 Consolidated Balance Sheet. As remaining performance obligations are satisfied, an appropriate portion of the deferred revenue balance is credited to earnings. As of March 31, 2023, and December 31, 2022, such contract liabilities were $37,804 and $32,930, respectively.

The Company's revenues were comprised of the following:

	Three Months Ended March 31,	
	2023	**2022**
Manufacture and supply revenue	$ 9,762	$ 9,171
License and royalty revenue	919	506
Co-development and research fees	453	403
Proprietary product sales, net	—	2,190
Total revenues	$ 11,134	$ 12,270

Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Three Months Ended March 31,	
	2023	2022
United States	$ 8,165	$ 11,081
Ex-United States	2,969	1,189
Total revenues	$ 11,134	$ 12,270

Ex-United States revenues are derived primarily from Hypera Pharma ("Hypera") and Indivior Inc. ("Indivior") for product manufactured for markets outside of the United States.

Trade and other receivables, net consist of the following:

	March 31, 2023	December 31, 2022
Trade receivables	$ 4,122	$ 3,274
Contract and other receivables	3,507	2,139
Less: allowance for doubtful accounts	(40)	(40)
Less: sales-related allowances	(38)	(669)
Trade and other receivables, net	$ 7,551	$ 4,704

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

	March 31, 2023	December 31, 2022
Allowance for doubtful accounts at beginning of the period	$ 40	$ 40
Additions charged to expense	—	—
Write-downs charged against the allowance	—	—
Allowance for doubtful accounts at end of the period	$ 40	$ 40

Sales-Related Allowances and Accruals

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

The following table provides a summary of activity with respect to sales-related allowances and accruals for the three months ended March 31, 2023:

	Total Sales-Related Allowances
Balance at December 31, 2022	$ 669
Provision	—
Payments / credits	(49)
Reclassifications	$ (582)
Balance at March 31, 2023	$ 38

Total reductions of gross product sales from sales-related allowances and accruals were $0 for the three months ended March 31, 2023. Accruals for returns allowances and prompt pay discounts are reflected as a direct reduction of trade receivables and accruals for wholesaler service fees, co-pay support redemptions and rebates as current liabilities. The accrued balances relative to these provisions included in Trade and other receivables, net and Accounts payable and accrued expenses were $38 and $793, respectively, as of March 31, 2023 and $669 and $1,012, respectively, as of December 31, 2022.

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, 2023, Indivior and Hypera exceeded the 10% threshold for revenue and represented approximately 77% and 14% of total revenue, respectively. As of March 31, 2023, Indivior and Hypera exceeded the 10% threshold for outstanding receivables and represented 68% and 11%, respectively, of outstanding receivables. For the three months ended March 31, 2022, Indivior exceeded the 10% threshold for revenue and represented approximately 78% of total revenue. As of December 31, 2022, Indivior exceeded the 10% threshold for outstanding receivables and represented 80% of total trade and other receivables.

Note 5. Material Agreements

Commercial Exploitation Agreement with Indivior

In August 2008, the Company entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (with subsequent amendments collectively, the “Indivior License Agreement”). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior Inc. 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 Active Pharmaceutical Ingredients ("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 a purchase price per unit that is subject to adjustment based on the Company’s ability to satisfy minimum product thresholds.

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 renews for successive one-year periods, unless either party provides the other with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

Effective as of March 2, 2023, the Company entered into Amendment No. 11 to the Indivior License Agreement (the “Indivior 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; and (ii) agreeing to transfer pricing and payment terms for supplied product.

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. As a result of the settlement and dismissal of all claims under the lawsuit with Dr. Reddy’s Labs on June 28, 2022, 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 Pharmaceuticals, Inc.), referred to as the Sunovion License Agreement, pursuant to which Sunovion obtained an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing apomorphine for the treatment of off episodes in Parkinson’s disease patients. Sunovion used this intellectual property to develop its apomorphine product KYNMOBI®, which was approved by the FDA on May 21, 2020. This approval triggered Sunovion's obligation to remit a payment of $4,000 due on the earlier of: (a) the first day of product availability at a pharmacy in the United States; or (b) within six months of FDA approval of the product. This amount was received as of September 30, 2020 and was included in License and royalty revenues for the twelve months ended December 31, 2020.

Effective March 16, 2020, the Company entered into a first amendment (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 European Union (EU) which later withdraws as a member country in the EU for purpose of determining the satisfaction of the condition triggering the obligation to pay the third milestone due under the Sunovion License Agreement, (ii) extending the date after which Sunovion has the right to terminate the Sunovion License Agreement for convenience from December 31, 2024 to March 31, 2028, (iii) modifying the effective inception date of the first minimum annual royalty due from Sunovion to the Company form January 1, 2020 to April 1, 2020, and (iv) modifying the termination provision to reflect the Company's waiver of the right to terminate the Sunovion License Agreement in the event that KYNMOBI was not commercialized by January 1, 2020. This Sunovion License Agreement will continue until terminated by Sunovion in accordance with the termination provisions of the Amendment to the Sunovion License Agreement. The Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents unless earlier terminated under the termination provisions contained therein. Upon termination of the Sunovion License Agreement, all rights to intellectual property granted to Sunovion to develop and commercialize apomorphine-based products will revert to the Company.

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

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

Purchase and Sale Agreement with an affiliate of Marathon Asset Management ("Marathon")

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("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, 2023 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. Based on the current public forecast by Sunovion of estimated KYNMOBI sales as of March 31, 2023, 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, Inc.)

In March 2012, the Company entered into an agreement with Zevra Therapeutics, Inc. (formerly KemPharm, Inc.) (“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.

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

The Company entered into a License, Development and Supply Agreement with Haisco, a Chinese limited company listed on the Shenzhen Stock Exchange, effective as of March 3, 2022 (the "Haisco Agreement"), pursuant to which Aquestive granted Haisco an exclusive license to develop and commercialize Exservan™ (riluzole oral film) for the treatment of amyotrophic lateral sclerosis, or ALS (“Exservan"), in China. Under the terms of the Haisco Agreement, Aquestive will serve as 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 will receive regulatory milestone payments, receive double-digit royalties on net sales of Exservan in China, and earn manufacturing revenue upon the sale of Exservan in China.

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 (collectively, the “Separation Agreement”) dated as of May 17, 2022. Pursuant to the Separation Agreement, Mr. Kendall’s employment with the Company ceased effective as of May 17, 2022 (the “Termination Date”). Under the Separation Agreement, Mr. Kendall received the following principal severance benefits, contingent upon Mr. Kendall's compliance with a customary release of claims entered into at the time: (i) a cash payment consisting of the sum of any previously unpaid base salary through the Termination Date and any accrued and unused vacation time for the 2022 calendar year; (ii) a cash payment consisting of his pro-rata portion of his target bonus in the amount of $280; (iii) a cash payment in the amount of $150, representing 90 days of his base pay in lieu of the required notice period under Mr. Kendall’s employment agreement; (iv) severance payments consisting of (a) a cash payment of $263, which represents an acceleration of the first three installments of Mr. Kendall’s 18-month severance he is entitled to under his employment agreement; (b) monthly severance payments of $53 per month for the first through the seventh months following the Termination Date; (c) $70 paid for the eighth month after the Termination Date; and (d) monthly severance payments of $88 for the ninth through eighteenth months following the Termination Date; (v) accelerated vesting of unvested outstanding equity awards, with options remaining exercisable for the duration of the stated

term of each award; and (vi) continuing coverage under the Company's group health and life insurance plans at the same levels and on the same terms and conditions as are provided to similarly-situated executives, for a period of 18 months. Under the terms of the Separation Agreement, Mr. Kendall served as a consultant to the Company, on an as-needed basis providing transition services, strategic planning, financial planning, merger and acquisition advice and consultation, for a period from the Separation Date to December 31, 2022. For these services, Mr. Kendall received a consulting fee of $10 per month.

Licensing and Supply Agreement with Atnahs Pharma UK Limited

The Company entered into a License and Supply Agreement with Atnahs Pharma UK Limited, a company registered in England and Wales ("Pharmanovia"), effective as of September 26, 2022 (the "Pharmanovia Agreement"), 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 certain countries of the European Union, the United Kingdom, Switzerland, Norway and the Middle East and North Africa (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 (the "Pharmanovia Amendment") to expand the scope of territory to cover the rest of the world, excluding US, Canada and China. Under the Pharmanovia Amendment, Pharmanovia will be responsible for seeking appropriate 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 Pharmanovia Amendment execution.

Licensing Agreement with Assertio Holdings, Inc.

Effective October 26, 2022, the Company entered into a License Agreement with Otter Pharmaceuticals, LLC, a subsidiary of Assertio, 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 (the "Assertio Agreement"). Under the terms of the Assertio Agreement, the Company granted an exclusive, worldwide license of its intellectual property for Sympazan to Assertio during the term of the Assertio License Agreement for an upfront payment of $9,000. In addition, Aquestive received a $6,000 milestone payment subsequent to Aquestive's receipt of a notice of allowance from the United States Patent and Trademark Office (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 contain a repurchase offer or put option which gives holders of the option the right, but not the obligation, to require the Company to redeem the 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, *12.5% Senior Secured Notes and Loans Payable* 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.

Note 7. Inventories, Net

The components of Inventory, net are as follows:

	March 31, 2023	December 31, 2022
Raw material	$ 1,699	$ 1,899
Packaging material	3,359	2,914
Finished goods	1,923	967
Total inventory, net	$ 6,981	$ 5,780

Note 8. Property and Equipment, Net

	Useful Lives	March 31, 2023	December 31, 2022
Machinery	3-15 years	$ 19,880	$ 19,810
Furniture and fixtures	3-15 years	769	769
Leasehold improvements	(a)	21,386	21,375
Computer, network equipment and software	3-7 years	2,627	2,627
Construction in progress		1,399	1,467
		46,061	46,048
Less: accumulated depreciation and amortization		(42,247)	(41,963)
Total property and equipment, net		$ 3,814	$ 4,085

(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 $286 and $714 for the three-month periods ended March 31, 2023 and 2022, respectively.

Note 9. Right-of-Use Assets and Lease Obligations

The Company leases all realty used as its production and warehouse facilities, corporate headquarters, commercialization operations center and research and laboratory facilities. None of these three leases include the characteristics specified in ASC 842, *Leases*, that require classification as financing leases and, accordingly, these leases are accounted for as operating leases. These leases, as amended, provide remaining terms between 5.0 and 10.5 years, including renewal options expected to be exercised to extend the lease periods.

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 consolidated balance sheet. For longer-term lease arrangements that are recognized on the Company's consolidated balance sheet, 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 Consolidated Statements of Operations and Comprehensive Income (Loss). 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. For the three-month period ended March 31, 2022, total operating lease expenses totaled $419, including variable lease expenses such as common area maintenance and operating costs of $96, respectively.

Maturities of the Company’s operating lease liabilities are as follows:

Remainder of 2023	$ 903
2024	1,230
2025	1,266
2026	1,300
2027 and thereafter	6,319
Total future lease payments	11,018
Less: imputed interest	(4,984)
Total operating lease liabilities	$ 6,034

Note 10. Intangible Assets, Net

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

	March 31, 2023	December 31, 2022
Purchased intangible	$ 3,858	$ 3,858
Purchased patent	509	509
	4,367	4,367
Less: accumulated amortization	(2,971)	(2,932)
Intangible assets, net	1,396	1,435

Amortization expense was $39 and $13 for each of the three-month periods ended March 31, 2023 and 2022. During the remaining life of the purchased intangible assets, estimated amortization expense is $117 in the remainder of 2023 and $156 in 2024, respectively.

Note 11. Other non-current Assets

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

	March 31, 2023	December 31, 2022
Royalty receivable	5,000	5,000
Other	1,485	1,451
Total other non-current assets	$ 6,485	$ 6,451

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 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 it was not transferred. Royalty receivable consists of five 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, 2023	December 31, 2022
Accrued compensation	$ 2,407	$ 6,389
Real estate and personal property taxes	413	322
Accrued distribution expenses and sales returns provision	793	1,012
Other	895	244
Total accrued expenses	$ 4,508	$ 7,967

Note 13. 12.5% Senior Secured Notes and Loans Payable

On July 15, 2019, the Company completed a private placement of up to $100,000 aggregate principal of its 12.5% Senior Secured Notes due 2025 (the “12.5% Notes”) and issued warrants for 2,000,000 shares of Common Stock (the “Warrants”), at $0.001 par value per share.

Upon closing of the indenture for the 12.5% Notes (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 lenders 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 lenders on the early repayment of the 12.5% Notes discussed above. The result of these two transactions reduced the net balance of the Company's 12.5% Senior Notes outstanding in the aggregate to $51,500 at December 31, 2020. The $4,000 principal issuance would be repaid proportionally over the same maturities as the other 12.5% Notes. The Company also paid one of its lenders 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 lenders inclusive of (i) $2,250 early premium prepayment and (ii) $4,000 issuance of Additional Notes in lieu of paying a

prepayment penalty were recorded as additional debt discount, amortized over the remaining life of the 12.5% Notes using the effective interest method. Loan origination costs of $220 associated with the Additional Notes were expensed as incurred. Existing deferred discounts and loan origination fees on the 12.5% Notes are amortized as an adjustment of interest expense over the remaining term of modified debt using the effective interest method.

The First Supplemental Indenture contains a provision whereby, as the Company receives any cash proceeds from the Monetization Agreement, each noteholder has the right to require the Company to redeem all or any part of such noteholder's outstanding 12.5% Notes at a repurchase price in cash equal to 112.5% of the principal amount, plus accrued and unpaid interest. This repurchase offer is capped at 30% of the cash proceeds received by the Company as the contingent milestones are attained, if any, up through June 30, 2025. 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 embedded put option is deemed to be a derivative under *ASC 815, Derivatives and Hedging*, which requires the recording of the embedded put option at fair value and subject to remeasurement at each reporting period. In addition, as of the closing of this transaction, the Company issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of its Common Stock.

On August 6, 2021, pursuant to the Third Supplemental Indenture, the holders of the 12.5% Notes extended to June 30, 2022 from December 31, 2021, the Company's ability to access, at the Company's option, $30,000 of 12.5% Notes re-openers under the Indenture. Under the Third Supplemental Indenture, the first $10,000 of 12.5% Notes re-openers represented a commitment of such amount by current holders of 12.5% Notes, at the option of the Company, contingent upon FDA approval of the Company's product candidate Libervant™ (diazepam) Buccal Film for the management of seizure clusters ("First Additional Securities"). In addition, under the Third Supplemental Indenture, a second $20,000 12.5% Notes re-opener represented a right, at the Company's option, to market to current holders of the Company's 12.5% Notes, and or other noteholders, additional 12.5% Notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access ("Second Additional Securities"). Under the Third Supplemental Indenture, the Company agreed that, if and to the extent that the Company accessed these re-openers, it would grant to the noteholders warrants to purchase up to 714,000 shares of Common Stock, with the strike price calculated based on the 30-day volume weighted average closing price of the Common Stock at the warrant grant date.

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 amortization 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. Additionally, the Company recognized a loss on the extinguishment of debt of $13,822 for fees and expenses related to the Fourth Supplemental Indenture during the fourth quarter of 2021. As of March 31, 2023, the Company completed its $2,700 Consent Fee payment to the holders of the 12.5% Notes.

On May 13, 2022, pursuant to the Fifth Supplemental Indenture, the holders of the 12.5% Notes further extended to March 31, 2023 from June 30, 2022, the Company's ability to access, at the Company's option, $30,000 of 12.5% Notes re-openers under the Indenture, subject to the full approval of Libervant by the FDA for sale in the United States, which full approval included U.S. market access for Libervant. Because full FDA approval was not obtained by March 31, 2023, the Company's option to access the re-openers expired on such date.

A debt maturity table is presented below:

Remainder of 2023	$	12,609
2024		19,487
2025		10,317
Total	$	42,413

The 12.5% Notes provide a stated fixed interest rate of 12.5%, payable quarterly in arrears, with the final quarterly principal repayment of 12.5% Notes due at maturity on June 30, 2025. As of March 31, 2023, the Company recorded its principal payments as Loans payable, current and Loans payable, net on its Condensed Consolidated Balance Sheet.

The Company may elect, 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 Notes. The Indenture also includes change of control provisions under which the Company may be 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. The prepayments along with a scheduled principal repayment in the first quarter of 2023 reduced the net balance of the 12.5% Notes outstanding in the aggregate to $42,413.

The Company capitalizes legal and other third-party costs incurred in connection with obtaining debt as deferred debt issuance costs and applies the unamortized portion as a reduction of the outstanding face amount of the related loan. Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its lenders, and offsets those as a direct reduction of its outstanding debt. Amortization expense arising from deferred debt issuance costs and debt discounts related to the 12.5% Notes for the three months ended March 31, 2023 was $4, while comparative amortization expense for the three months ended March 31, 2022 were $4. Unamortized deferred debt issuance costs and deferred debt discounts totaled $22 and $27 as of March 31, 2023 and December 31, 2022, respectively.

Collateral for the loan under the 12.5% Notes consists of a first priority lien on substantially all property and assets, including intellectual property of the Company. This secured obligation provides payment rights that are senior to all existing and future subordinated indebtedness of the Company and provides Lenders with perfected security interests in substantially all of the Company’s assets.

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 entitle the noteholders to purchase up to 2,143,000 shares of Common Stock and included specified registration rights. Management estimated the fair value of the Initial Warrants to be $6,800 and the Additional Warrants to be $735, each based on an assessment by an independent third-party appraiser. The fair value of the respective warrants was treated as a debt discount, amortizable over the term of the respective warrants, with the unamortized 12.5% Notes portion applied to reduce the aggregate principal amount of the 12.5% Notes in the Company’s unaudited Condensed Consolidated Balance Sheet. 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 Consolidated Balance Sheet. There were no warrants exercised as it relates to the Initial Warrants and the Additional Warrants during the three months ended March 31, 2023 or 2022, respectively.

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 entitle the purchasers to purchase up to 8,850,000 shares of Common Stock at a price ranging from $0.96 to $1.09 per share. Management estimated the fair value of the pre-funded warrants and Common Stock warrants to be $5,874 based on an assessment by an independent third-party appraiser. The fair value of the pre-funded and Common Stock warrants is treated as equity and presented in Additional Paid-in Capital in the Company’s unaudited Condensed Consolidated Balance Sheet. No Common Stock warrants issued pursuant to the Securities Purchase Agreements were exercised during the three months ended March 31, 2023.

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, 2023 under the Monetization Agreement.

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

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

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

As royalties are remitted to Marathon from Sunovion, the collection of the royalty receivable and balance of the liability related to the sale of future revenue will be effectively repaid over the life of the agreement. In order to determine the amortization of the liability related to the sale of future revenue, the Company is required to estimate the total amount of future royalty and milestone payments to Marathon over the life of the Monetization Agreement and contingent milestone payments from Marathon to the Company. The sum of future royalty payments less the $50,000 in proceeds received and future contingent payments will be recorded as interest expense over the life of the Monetization Agreement. At execution, the estimate of this total interest expense resulted in an effective annual interest rate of approximately 24.9%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the life of the Monetization Agreement. The Company 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 in both royalty revenue and interest expense related to the sale of future revenue. Based on the current public forecast by Sunovion of estimated KYNMOBI sales as of March 31, 2023, 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.

The following table shows the activity of the liability related to the sale of future revenue for the three months ended March 31, 2023:

Liability related to the sale of future revenue, net at December 31, 2022	$	65,259
Royalties related to the sale of future revenue		(27)
Amortization of issuance costs		52
Interest expense related to the sale of future revenue		—
Liability related to the sale of future revenue, net (includes current portion of $1,147)	$	65,284

Note 16. Net Earnings (Loss) Per Share

Basic net earnings (loss) per share is calculated by dividing net income (loss) 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, 2023. As a result of the Company's net loss incurred for the three months ended March 31, 2022, all potentially dilutive instruments outstanding would have anti-dilutive effects on per-share calculations. Therefore, basic and diluted net loss per share were the same for the three months ended March 31, 2022 as reflected below.

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net income (loss)	$ 8,068	$ (13,220)
Denominator:		
Weighted-average number of common shares – basic	55,631,947	41,465,798
Effect of dilutive stock options and warrants	18,160,939	—
Weighted-average number of common shares – diluted	73,792,886	41,465,798
Earnings per share attributable to common stockholders:		
Earnings (Loss) per common share – basic	$ 0.15	$ (0.32)
Earnings (Loss) per common share – diluted	$ 0.11	$ (0.32)

As of March 31, 2023, the Company's dilutive instruments included 5,774,772 options, 1,821,738 unvested restricted stock units, and 10,564,429 warrants to purchase common shares.

As of March 31, 2022, the Company's potentially dilutive instruments included 5,259,847 options, 166,700 unvested restricted stock units and 1,714,429 warrants to purchase common shares that were excluded from the computation of diluted weighted average shares outstanding because these securities had an antidilutive impact due to the loss reported.

Note 17. Share-Based Compensation

The Company recognized share-based compensation in its unaudited Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) during 2023 and 2022 as follows:

	Three Months Ended March 31,	
	2023	2022
Manufacture and supply	$ 41	$ 48
Research and development	72	169
Selling, general and administrative	231	696
Total share-based compensation expenses	$ 344	$ 913
Share-based compensation from:		
Restricted stock units	$ 25	$ —
Stock options	319	913
Total share-based compensation expenses	$ 344	$ 913

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, 2023:

Restricted Stock Unit Awards (RSUs):	Number of Units	Weighted Average Grant Date Fair Value
	(in thousands)	
Unvested as of December 31, 2022	162	$ 2.38
Granted	1,724	$ 0.81
Vested	(26)	$ 2.55
Forfeited	(39)	$ 2.55
Unvested as of March 31, 2023	1,821	$ 0.89
Vested and expected to vest as of March 31, 2023	1,632	$ 0.89

Stock Option Awards:	Number of Options	Weighted Average Exercise Price
	(in thousands)	
Outstanding as of December 31, 2022	6,028	$ 5.48
Granted	—	$ —
Exercised, Forfeited, Expired	(253)	$ 2.33
Outstanding as of March 31, 2023	5,775	$ 5.62
Vested and expected to vest as of March 31, 2023	5,666	$ 5.69
Exercisable as of March 31, 2023	4,089	$ 6.92

As of March 31, 2023, $1,413 of unrecognized compensation expense related to unvested restricted stock units is expected to be recognized over a weighted average period of 2.89 years from the date of grant.

As of March 31, 2023, $2,672 of unrecognized compensation expense related to non-vested stock options is expected to be recognized over a weighted average period of 1.72 years from the date of grant.

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. Under the 2022 Equity Inducement Plan, the Company granted an inducement equity of 100,000 shares of non-qualified Common Stock options award to an officer in September 2022.

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, 2023, the effective income tax rate was 0% and the Company recorded $0 from its pretax gain of $8,068. For the three months ended March 31, 2022, the Company recorded no income tax benefit from its pretax loss of $13,220.

The primary factors impacting the effective tax rate for three months ended March 31, 2023, is the anticipated full year pre-tax book loss, the expected utilization of net operating losses and research and development credits to offset any current year tax liabilities, and a full valuation allowance against any associated net deferred tax assets.

Note 19. Contingencies

Litigation and 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. Dr. Reddy's Labs. S.A. and Dr. Reddy's Labs., Inc.

On February 7, 2018, the Company and Indivior Inc. and Indivior UK Ltd. (collectively, "Indivior") initiated a lawsuit against Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") 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 Dr. Reddy's 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 which was originally initiated by Indivior against Dr. Reddy's asserting infringement of U.S. Patent No. 9,687,454 (the "'454 patent"). On June 28, 2022, pursuant to a settlement agreement between the parties, the Court entered a Stipulation and Order of Dismissal, dismissing all claims and counterclaims with prejudice in the lawsuit.

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 the '221 patent. On April 3, 2018, the Company and Indivior initiated a separate lawsuit against Teva asserting infringement of 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 the '454 patent. The parties agreed that the case would be governed by the final judgment against Dr. Reddy's Laboratories S.A., which was settled pursuant to a settlement agreement whereby the court entered a Stipulation and Order of Dismissal, dismissing all claims and counterclaims with prejudice in the lawsuit on June 28, 2022.

Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics, Inc. v. Alvogen Pine Brook LLC

On September 14, 2017, Indivior initiated a lawsuit against Alvogen Pine Brook LLC ("Alvogen") asserting infringement of the '454 patent. On February 7, 2018, the Company and Indivior filed an Amended Complaint, adding the Company as a plaintiff and asserting infringement of the'221 patent. On April 3, 2018, the Company and Indivior initiated a separate lawsuit against Alvogen asserting infringement of the '305 patent. On May 29, 2018, the cases were consolidated. On February 26, 2019, the court granted the parties' agreed stipulation to drop the '221 patent from the case. On January 9, 2020, the court entered a stipulated order of non-infringement of the '305 patent based on the court's claim construction ruling, and the Company and Indivior preserved the right to appeal the claim construction ruling.

On November 21, 2019, Alvogen filed an amended answer and counterclaims asserting monopolization, attempted monopolization, and conspiracy to monopolize against the Company and Indivior under federal and New Jersey antitrust laws. The court denied the Company's motion to dismiss Alvogen's counterclaims on August 24, 2020. On November 2, 2020, Alvogen filed a second amended answer and counterclaims, removing its allegations of monopolization and attempted monopolization against the Company and asserting only conspiracy to monopolize against the Company. Fact discovery on Alvogen's antitrust counterclaims concluded on January 29, 2021. Expert discovery concluded on October 8, 2021, and dispositive motions were filed on October 26, 2021. The court heard oral argument on the dispositive motions on August 29, 2022, and the parties are awaiting a ruling from the court. There is no trial date set. 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 losses, if any, in this matter.

Reckitt Benckiser Pharmaceuticals, Inc. and MonoSol Rx, LLC v. BioDelivery Sciences International, Inc. and Quintiles Commercials US, Inc. (BDSI 2014 Lawsuit)

On September 22, 2014, the Company and Indivior initiated a lawsuit against BDSI and Quintiles Commercial US, Inc. ("Quintiles") asserting infringement of U.S. Patent No. 8,765,167 (the "'167 patent") in the District of New Jersey (Civil Action No. 3:14-cv-5892). On July 22, 2015, the case was transferred to the United States District Court for the Eastern District of North Carolina. BDSI filed requests for inter partes review ("IPR") of the '167 patent before the Patent Trial and Appeal Board ("PTAB"), and on May 6, 2016, the Court stayed the case pending the outcome and final determination of the IPR proceedings. On March 24, 2016, the PTAB issued final written decisions finding the '167 patent was not unpatentable, and the United States Court of Appeals for the Federal Circuit ("Federal Circuit") remanded those decisions for further proceedings

before the PTAB. Following the PTAB's February 7, 2019 decision on remand denying institution, BDSI appealed that decision to the Federal Circuit. The Federal Circuit granted the Company's motion to dismiss the appeal, and denied BDSI's request for rehearing en banc. BDSI filed a petition for writ of certiorari to the Supreme Court of the United States ("Supreme Court"), which the Supreme Court denied on October 5, 2020. On April 15, 2021, the court lifted the stay of the litigation. On March 8, 2023, pursuant to a settlement agreement between the parties, the parties filed a Joint Stipulation of Dismissal, dismissing all claims and counterclaims asserted in the lawsuit.

Aquestive Therapeutics, Inc. v. BioDelivery Sciences International, Inc.

On November 11, 2019, the Company initiated a lawsuit against BDSI asserting infringement of the '167 patent in the Eastern District of North Carolina. On April 1, 2020, the Court denied BDSI's motion to stay and its motion to dismiss the complaint. On April 16, 2020, BDSI filed its Answer and Counterclaims to the complaint, including counterclaims for non-infringement, invalidity, and unenforceability of the '167 patent. On May 7, 2020, the Company filed a Motion to Dismiss BDSI's unenforceability counterclaim and a Motion to Strike BDSI's corresponding affirmative defenses. On May 28, 2020, BDSI amended its counterclaims and filed an Answer and Amended Counterclaims, which included additional allegations in support of BDSI's unenforceability counterclaim. On June 25, 2020, the Company filed a Motion to Dismiss BDSI's Amended Counterclaim for unenforceability and a Motion to Strike BDSI's corresponding affirmative defense of unenforceability, which BDSI opposed. On March 16, 2021, the court issued an order granting-in-part and denying-in-part the Company's motion to dismiss BDSI's counterclaims asserting unenforceability of the '167 patent. On March 8, 2023, pursuant to a settlement agreement between the parties, the parties filed a Joint Stipulation of Dismissal, dismissing all claims and counterclaims asserted in the lawsuit.

Antitrust Litigation

State of Wisconsin, et al. v. Indivior Inc., Reckitt Benckiser Healthcare (UK) Ltd., Indivior PLC, and MonoSol Rx, LLC

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought a lawsuit against Indivior and the Company in the U.S. District Court for the Eastern District of Pennsylvania alleging violations of federal and state antitrust statutes and state unfair trade and consumer protection laws relating to Indivior's launch of Suboxone Sublingual Film in 2010 and seeking an injunction, civil penalties, and disgorgement. After filing the lawsuit, the case was consolidated for pre-trial purposes with the In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While the Company was not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that the Company participated in an antitrust conspiracy with Indivior in connection with Indivior's launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. On March 8, 2021, Aquestive filed a motion for summary judgment, and briefing on summary judgment motions was completed on May 28, 2021. The hearing on Aquestive's motion for summary judgment was held on May 18, 2022 and, on October 19, 2022, the Court entered an order dismissing all claims against the Company in the lawsuit. The order dismissing all claims against the Company could be appealed by the plaintiffs in this case. The Company is not able to determine or predict whether the plaintiffs will appeal the order or 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.

Humana and Centene Actions

Centene Corporation, Wellcare Health Plans, Inc., New York Quality Healthcare Corporation d/b/a Fidelis Care, and Health Net, LLC v. Indivior Inc, Indivior Solutions Inc., Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., and Aquestive Therapeutics, Inc.

On September 18, 2020, Humana, Inc. ("Humana"), a health insurance payor, filed a lawsuit against the Company and Indivior in the United States District Court for the Eastern District of Pennsylvania alleging facts similar to those at issue in the Antitrust Case and the Suboxone MDL described above, which lawsuit was assigned to the same judge that is presiding over Antitrust Case and Suboxone MDL. Humana's Complaint alleges five causes of action against the Company, including conspiracy to violate the RICO Act, fraud under state law, unfair and deceptive trade practices under state law, insurance fraud, and unjust enrichment.

On September 21, 2020, Centene Corporation ("Centene") and other related insurance payors filed a similar lawsuit against the Company and Indivior in the United States District Court for the Eastern District of Missouri. The counsel representing Humana is also representing Centene. On September 21, 2020, the Centene action was provisionally transferred to the Eastern District of Pennsylvania by the United States Judicial Panel on Multidistrict Litigation. On January 15, 2021, the Company filed a motion to dismiss the Centene and Humana complaints. The court in the Eastern District of Pennsylvania dismissed all complaints against the defendants in these matters on July 22, 2021. On August 20, 2021, Centene and Humana appealed the decision to the United States Appeals Court for the Third Circuit ("Third Circuit"). Also, on August 20, 2021,

Humana filed a complaint against the Company and Indivior in state court in Kentucky, alleging the same causes of action previously filed in the federal case in the Eastern District of Pennsylvania. That state court action remains stayed pending further action from the court following resolution of the federal appeal in the Third Circuit. On December 15, 2022, the Third Circuit issued an opinion and order affirming the district court's dismissal of the Centene and Humana actions. The Company is not able to determine or predict the ultimate outcome of the Centene and Humana actions or 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 these matters.

California Litigation

Neurelis, Inc. v. Aquestive Therapeutics, Inc.

On December 5, 2019, Neurelis Inc. filed a lawsuit against us in the Superior Court of California, County of San Diego alleging the following three causes of action: (1) Unfair Competition under California Business and Professional Code § 17200 ("UCL"); (2) Defamation; and (3) Malicious Prosecution. Neurelis filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. The Company filed a Motion to Strike Neurelis's Complaint under California's anti-SLAPP ("strategic lawsuit against public participation") statute on January 31, 2020, which Neurelis opposed. On August 6, 2020, the Court issued an order granting in part and denying in part the Company's anti-SLAPP motion. The parties cross-appealed the ruling to the California Court of Appeal. The appeals court held oral argument on the appeal on October 14, 2021, and issued its ruling on November 17, 2021. Under the ruling, the court struck the entirety of the malicious prosecution claim and struck portions of the UCL and defamation claims. On April 12, 2022, Neurelis filed a Second Amended Complaint in response to the Court of Appeal's decision. The Second Amended Complaint also added a cause of action for Trade Libel. On May 3, 2022, the Company filed a "demurrer" challenge to the sufficiency of the allegations of the Second Amended Complaint. Oral argument on the Company's motion for attorney fees related to the anti-SLAPP motion and on the Second Amended Complaint and demurer challenge was held on June 17, 2022. The Court entered an order granting the Company's motion for attorney fees, awarding $156 and ordering Neurelis to pay the fees within 60 days of June 17, 2022. The Court denied the Company's demurrer and the parties are proceeding with discovery on the claims in the Second Amended Complaint. No trial date has been set. 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.

Federal Securities Class Action

Deanna Lewakowski v. Aquestive Therapeutics, Inc., et al.

On March 1, 2021, a securities class action lawsuit was filed in the United States District Court for the District of New Jersey alleging that the Company and certain of its officers engaged in violations of the federal securities laws relating to public statements made by the Company regarding the FDA approval of Libervant. Following the court's appointment of a lead plaintiff, an amended complaint was filed by the plaintiffs on June 25, 2021. Defendants filed a motion to dismiss on August 16, 2021, which became fully briefed as of November 1, 2021. On March 14, 2023, the Court entered an order granting Defendants' motion to dismiss without prejudice and permitting plaintiffs leave to file a final, Second Amended Complaint by April 14, 2023. On April 7, 2023, the parties filed a Stipulation of Voluntary Dismissal stating that plaintiffs determined not to file an amended complaint and agreed to dismiss the action as to them with prejudice. On April 10, 2023, the Court so-ordered the stipulation and terminated the lawsuit.

Shareholder Derivative Litigation

Loreen Niewenhuis v. Keith Kendall, et al.

On December 15, 2021, a purported Aquestive shareholder instituted a derivative action captioned Loreen Niewenhuis v. Keith Kendall, et al. in the United States District Court for the District of New Jersey, purportedly on behalf of the Company, against certain current and former officers and directors of the Company. The case was designated as related to the pending federal securities class action Deanna Lewakowski v. Aquestive Therapeutics, Inc., referenced above, and accepted by the same judge presiding over the securities class action. The complaint in this matter alleges claims for breach of fiduciary duty and contribution. The factual allegations that form the basis of these claims are similar to the disclosure-related allegations asserted in the class action. On April 4, 2022, the plaintiff filed an amended complaint asserting the same claims against the same defendants. The Company filed a motion to dismiss the amended complaint on April 25, 2022, which became fully briefed as of June 27, 2022. On April 20, 2023, the parties filed a Stipulation of Voluntary Dismissal stating that plaintiff agreed to dismiss the action as to her with prejudice. On April 21, 2023, the Court so-ordered the stipulation and terminated the lawsuit.

Note 20. Subsequent Events

Positive Decision in Litigation Matters

On April 10, 2023, the presiding judge in the federal securities class action, Neurelis, Inc. v. Aquestive Therapeutics, Inc., filed in the United States Court for the District of New Jersey, ordered the dismissal of the class action with prejudice pursuant to a Stipulation of Voluntary Dismissal filed by the parties in that action. On April 21, 2023, the same presiding judge ordered the dismissal with prejudice of a related shareholder derivative lawsuit, Loreen Niewenhuis v. Keith Kendall, *et al*, pursuant to a Stipulation of Voluntary Dismissal filed by the parties in that action. Refer to Note 19, *Contingencies* for details.

Nasdaq's Listing Rule 5450(a)(1) Compliance

On April 13, 2023, the Company received a notice from Nasdaq" informing the Company that it has regained compliance with Nasdaq's Listing Rule 5450(a)(1) for continued listing on The Nasdaq Global Market, as the minimum bid price of the Company's Common Stock had met or exceeded $1.00 per share for a minimum of ten consecutive business days during the applicable 180-day review period.

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 consolidated financial statements and related notes included in Part I Item 1 of this Quarterly Report on Form 10-Q and our audited consolidated 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, 2022 and 2021 included in our 2022 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 AQST-109 and our other product candidates through the regulatory and development pipeline; the focus on continuing to manufacture Suboxone®, Exservan®, Sympazan®, Ondif® and other licensed products; the likelihood that we can overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. in order for Libervant® to be granted U.S. market access; clinical trial timing and plans for AQST-109 and our other product candidates; statements regarding the potential benefits our products could bring to patients; the ability to fund our business operations; the 2023 financial outlook; statements about our growth and future financial and operating results and financial position, regulatory approvals and pathways, clinical trial timing and plans, the achievement of clinical and commercial milestones, product orders and fulfillment, short-term and longer term liquidity and cash requirements, cash funding and cash burn; and business strategies, market opportunities, financing and other statements that are not historical facts. These forward-looking statements are also subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredients and other raw materials supply chain, manufacture and distribution; sale of and demand for our products; our liquidity and availability of capital resources, customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, we are unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

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 AQST-109; risk of delays in regulatory advancement through the FDA of AQST-109 and our other drug candidates or failure to receive approval at all; the risk that we may not overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. in order for Libervant to be granted U.S. market access; risk in obtaining market access from the FDA for our other product candidates; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks and uncertainties concerning the revenue stream from the monetization of our royalty rights for the product KYNMOBI®, as well as the achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the KYNMOBI monetization transaction; risk of development of a sales and marketing capability for future commercialization of our product candidates; risk of sufficient capital and cash resources, including access to available debt and equity financing, including under the Company's ATM facility and the Lincoln Park Purchase Agreement, and revenues from operations, to satisfy all of our short-term and longer-term cash requirements and other cash needs, at the times and in the amounts needed, including near-term debt amortization schedules; risk of failure to satisfy all financial and other debt covenants and of any default; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior Inc. ("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 our product and product candidates; 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; adverse developments affecting the financial services industry; risks related to inflation and rising interest rates; uncertainties related to general economic, political, business, industry, regulatory 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 and our other Quarterly Reports on Form 10-Q and in our Current Reports on Form 8-K and our other filings with the Securities and Exchange Commission (SEC). 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 2022 Annual Report on Form 10-K filed with the SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. We assume no obligation to update forward-looking statements, or outlook or guidance after the date of this 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.

Overview

Aquestive Therapeutics, Inc. ("we", "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. We are developing pharmaceutical products to deliver complex molecules through alternative administrations 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 central nervous system, or CNS.

We manufacture licensed products at our facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. Our facilities have been inspected by the Food and Drug Administration (FDA), Australian Government Department of Health's Therapeutics Goods Administration (TGA), and Drug Enforcement Agency (DEA), and are subject to inspection by all applicable health agencies, including the Brazilian Health Regulatory Agency (ANVISA) and European Medicines Agency (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:

- **AQST-109** (epinephrine sublingual film, trade name "Anaphylm" conditionally approved by the FDA) – the first and only non-device based, orally delivered epinephrine product candidate that has shown clinical results comparable to autoinjectors (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 caregivers to inject epinephrine into their thighs 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, AQST-109 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.

  We completed a first-in-human Phase 1 clinical trial for AQST-109 in Canada. This Phase 1 randomized, single-ascending dose study was performed in order to assess the safety, tolerability, and pharmacologic profile of AQST-109. On February 25, 2022, we reported positive topline data from Part 1 of our crossover study of AQST-109, EPIPHAST, a randomized, open-label, three-part adaptive design, crossover study in healthy adult subjects comparing the pharmacokinetics (PK) and pharmacodynamics (PD) of epinephrine delivered via AQST-109 oral film compared to epinephrine IM. The EPIPHAST study was also conducted in Canada. In Part 1 of the EPIPHAST study, multiple oral film formulations and dosage strengths of AQST-109 were evaluated. The lead formulation of AQST-109 has shown clinically meaningful blood concentrations when delivered in two different physical configurations, with a

median time to maximum concentration (Tmax) of 13.5 minutes and 22.5 minutes, respectively. Part 1 also showed arithmetic mean maximum concentrations (Cmax) of 771 pg/mL and 580 pg/mL for the two configurations, or geometric mean Cmax values of 258pg/mL and 268pg/mL for the two configurations, respectively. These geometric mean Cmax and median Tmax values are consistent with those previously reported for approved injectable epinephrine devices such as EpiPen. Under the EPIPHAST study, the healthy volunteers were also exposed to a 0.5mg IM of epinephrine, allowing for a comparison with the PK, safety, and tolerability of the higher end of the approved dosage range of epinephrine, consistent with guidance received from the FDA in a written response to our Investigational New Drug Application (IND) for AQST-109. The findings show that these two configurations of the selected AQST-109 formulation can deliver clinically meaningful blood concentrations of epinephrine sooner than that observed with the higher dose of epinephrine IM injection, and in line with existing epinephrine autoinjectors. In addition, dosing with AQST-109 resulted in changes in blood pressure and heart rate that were comparable to epinephrine auto-injectors. The EPIPHAST trial indicated that treatment was well tolerated, with no serious adverse events, significant medical events, or treatment-related severe adverse events reported. On February 24, 2022, the FDA cleared our IND, allowing for clinical investigation of AQST-109 in the U.S. The FDA confirmed that the 505(b)(2) approval pathway is acceptable for the development of AQST-109. The FDA granted Fast Track designation in March 2022 to AQST-109 for the emergency treatment of allergic reactions, including anaphylaxis.

In April 2022, we reported positive topline results from Part 2 of the EPIPHAST study for AQST-109. Part 2 is a randomized, crossover design comparing AQST-109 12mg to epinephrine IM 0.3mg. Utilizing a replicate crossover design, Part 2 confirmed in a larger population of 24 healthy subjects the key PK and PD measures observed in Part 1 of the EPIPHAST study and the first-in-human PK study. The median Tmax was observed to be 15 minutes for AQST-109, compared to 50 minutes for the epinephrine IM 0.3mg.

In July 2022, we reported positive topline results from the final two arms of Part 3 of the EPIPHAST study for AQST-109. The purpose of Part 3 was to continue to study the administration of the film under a variety of conditions to further characterize its PK, PD and safety. The final two arms were designed to assess the impact of (1) administering the film sublingually two minutes after consuming a peanut butter sandwich and (2) swallowing the film whole immediately with water. Part 3 study results demonstrated consistent Tmax of 12 minutes with sublingual administration of AQST-109 epinephrine oral film, after consuming a peanut butter sandwich. Part 3 study also showed positive results with an unexpectedly high level of gastrointestinal absorption after swallowing AQST-109 whole immediately with water that was distinct from the sublingually absorbed profile.

In September 2022, we reported positive topline results from the EPIPHAST II trial for AQST-109. The EPIPHAST II trial was designed to compare single doses of AQST-109 to EpiPen 0.3mg and epinephrine IM 0.3mg, as well as repeat doses of AQST-109 to repeat doses of epinephrine IM 0.3mg. Results from the single dose administration showed AQST-109 achieved a significantly faster Tmax (12 minutes), compared to both EpiPen (22.5 minutes) and epinephrine IM 0.3mg (45 minutes). AQST-109 repeat dosing provided significantly higher drug plasma concentrations, with a Tmax of 8 minutes after administration, and extensive absorption was observed. The mean Cmax of AQST-109 was 465 pg/mL after one dose and 2,958 pg/mL after two doses. In comparison, the epinephrine IM 0.3mg Cmax was 489 pg/mL after one dose and 911 pg/mL after two doses. The single dose of EpiPen resulted in a Cmax of 869 pg/mL. Changes in systolic blood pressure and heart rate were similar after a single dose of AQST-109 when compared to a single dose of EpiPen. This data, along with the data from the completed EPIPHAST study, was the basis for our second End-of-Phase 2 (EoP2) meeting with the FDA. We received a positive written feedback from the FDA after our initial EoP2 meeting request to discuss Chemistry, Manufacturing, and Controls (CMC) for AQST-109, which we believe indicates that our approach to characterizing attributes of AQST-109 appears reasonable in the context of a potential future filing.

In late December 2022, we received the final minutes from the EoP2 meeting with the FDA which provided clarity as to the FDA's expectations regarding key program areas. In March 2023, we obtained further clarification from the FDA indicating that the Company should submit its pivotal study protocol for review once it selects its reference listed drugs (RLDs). We have completed additional studies to identify the appropriate autoinjector RLDs and continue to work on the optimal administration parameters. We expect to submit a revised pivotal trial protocol to the FDA and commence the pivotal trial immediately following alignment with the FDA.

In April 2023, the FDA conditionally accepted the proprietary name Anaphylm™ (pronounced "ana-PHYLM") as the proposed brand name for AQST-109. Final approval of the Anaphylm™ proprietary name is conditioned on FDA approval of AQST-109.

- **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 recent second 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 preclinically. Upon completion of the preclinical work, we will request a pre-IND meeting for AQST-108 with the FDA and plan to disclose the indication and path forward for development, once we have received feedback from the FDA.

Proprietary CNS Product Candidate

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. In August 2022, the FDA granted tentative approval for Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. The FDA has concluded that Libervant has met all required quality, safety, and efficacy standards for approval. Due to an existing FDA regulatory grant of orphan drug market exclusivity for Valtoco®, a diazepam nasal spray product sold by another company, Libervant is not yet eligible for marketing in the United States. As a result of the FDA determination, the FDA cannot give final approval for Libervant 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. We are actively engaging the FDA regarding its determination. We provided the FDA with additional clinical data in September 2022 and were informed that the FDA was reviewing this data. Furthermore, in October 2022, we provided the FDA with a draft protocol for a head-to-head comparative PK study of Libervant versus the competing product. We continue to believe that, particularly in the case of our submitted studies on the effect of food on the absorption of diazepam formulations, Libervant has the distinct advantage of being able to be readily administered when needed without regard to food, providing an important benefit to patients. However, overcoming the orphan drug marketing exclusivity 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 earlier than January 2027, the scheduled date for expiration of orphan drug market exclusivity, if this effort is not successful. Further, there can be no assurance that a competitor will not obtain other FDA market exclusivity that blocks U.S. market access for Libervant. More details on this product approval are described in the "Competition" section of this Item I. Business of this Form 10-K.

  In September 2022, we announced the grant of an exclusive license to Atnahs Pharma UK Limited ("Pharmanovia") for Pharmanovia to develop and commercialize Libervant for the treatment of prolonged or acute, convulsive seizures in all ages in certain countries of the European Union, the United Kingdom, Switzerland, Norway and the Middle East and North Africa (the "Territory") during the term of the Pharmanovia licensee. 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.

Licensed Commercial Products and Product Candidates

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, 2022 and 2021, our licensed product portfolio generated $40.0 million and $42.3 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 Inc., or Indivior, in 2010. Suboxone is the most prescribed branded product in its category and was the first sublingual film product for the treatment of opioid dependence. We are the sole and exclusive supplier and manufacturer of Suboxone and have produced over 2.5 billion doses of Suboxone since its launch in 2010. As of March 31, 2023, Suboxone branded products retain approximately 34% 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 amyotrophic lateral sclerosis (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 S.p.A. ("Zambon") for the development and commercialization of Exservan in the European Union (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 will be responsible for the development and manufacture of the product. During the fourth quarter of 2022, Aquestive received a $0.5 million milestone payment in connection with the receipt of regulatory approval 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 Mitsubishi Tanabe Pharma Holdings America, Inc. ("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 may 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 Pharmaceutical Group Co., Ltd. ("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 cash 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.

- **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 Pharmaceuticals Inc., or Sunovion, for the commercialization of KYNMOBI under an Agreement dated April 1, 2016, as amended (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 a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). 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 the Brazilian regulatory authority (ANVISA) on February 21, 2022. We licensed commercial rights for Zuplenz to Fortovia Therapeutics Inc. (previously Midatech Pharma PLC, "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.

- **Azstarys™** – an FDA-approved, once-daily product for the treatment of attention deficit hyperactivity disorder (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 Therapeutics, Inc. (formerly KemPharm, Inc.) (“Zevra”), to terminate a Collaboration and License Agreement entered into by the Company and Zevra in April 2011. Under this termination arrangement, the Company has the right to participate in any and all value that Zevra may derive from the commercialization or any other monetization of KP-415 and KP-484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving Zevra and collaborations, royalty arrangements, or other

transactions from which Zevra may realize value from these compounds, including the product Azstarys. On March 2, 2021, Zevra announced FDA approval of Azstarys for the treatment of ADHD.

- **Libervant™** - a buccal film formulation of diazepam tentatively approved by the FDA 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 12 years of age and older. The Company entered into a License and Supply Agreement with Atnahs Pharma UK Limited, a company registered in England and Wales ("Pharmanovia"), effective as of September 26, 2022 (the "Pharmanovia Agreement"), 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 certain countries of the European Union, the United Kingdom, Switzerland, Norway and the Middle East and North Africa (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. Effective March 27, 2023, the Company amended the Pharmanovia Agreement to expand the scope of territory 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 a License Agreement with Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. ("Assertio"), a specialty pharmaceutical company offering differentiated products to patients, 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 a $6.0 million milestone payment upon its receipt of a notice of allowance from the United States Patent and Trademark Office of its patent application U.S. Serial No. 16/561,573, and payment of the related allowance fee. 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.

Business Update Regarding COVID-19

The extent to which COVID-19 impacts our business, operations, clinical trials, regulatory approval process, capital, financial and monetization markets, financial results and financial condition, and those of our suppliers, distributors, customers and other third parties necessary to our business including those involved in the regulatory approval process, will depend on future developments, which are highly uncertain and cannot be predicted with certainty or clarity, including the duration and continuing severity of the outbreak, resurgence of the outbreak, continued or additional government actions to contain COVID-19, efficacy of vaccines, and new information that will emerge concerning the short-term and long-term impact of COVID-19.

To date, we have been able to continue to manufacture and supply our products and currently do not anticipate any significant interruption in supply, although we continue to monitor this situation closely and there is no assurance that disruptions or delay will not occur as a result of COVID-19. We are also monitoring demand for our products, which could be negatively impacted during the COVID-19 pandemic, as well as the financial condition of our customers and licensees.

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 2022 Annual Report on Form 10-K.

JOBS Act and Smaller Reporting Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act ("JOBS Act"), and a "smaller reporting company", as defined in Rule 405 under the Securities Act of 1933, as amended. For as long as we continue to be an emerging growth company, we may 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 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. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO (which is December 31, 2023), (b) in which we have total annual gross revenues of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We also qualify as 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 s 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we expect to comply with new or revised accounting standards not later than the relevant dates on which adoption of such standards is required for public emerging growth companies.

Financial Operations Overview

Revenues

Our revenues to date have been earned from our manufactured products made to order for licensees, as well as revenue from our self-developed, recently outlicensed proprietary product, Sympazan. 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 four primary categories: manufacture and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

Manufacture and Supply Revenue

We manufacture based on receipt of purchase orders from our licensees, and our licensees have an obligation to accept these orders once quality assurance validates the quality of the manufactured product with agreed upon technical specifications. 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. Royalty revenue related to the sale of future revenue is described further in this section under Critical Accounting Policies and Use of Estimates.

Proprietary Product Sales, Net

We commercialized our first proprietary CNS product, Sympazan, in December 2018. Revenues from sales of proprietary product are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and co-pay support redemptions, each of which are described in more detail below. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale. We include these estimated amounts in connection with the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized for such transaction will not occur, or when the uncertainty associated with the variable consideration is resolved. The calculation of some of these items requires management to make estimates based on sales data, historical return data, contracts and other related information that may become known in the future. The adequacy of these provisions is reviewed on a quarterly basis. In October 2022, we entered into a License Agreement (the "Assertio Agreement") with Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. (“Assertio”), a specialty pharmaceutical company offering differentiated products to patients, pursuant to which the Company granted an exclusive, worldwide license of its intellectual property for Sympazan to Assertio during the term of

that agreement. We are the exclusive sole manufacturer and supplier of Sympazan for Assertio and began recognizing Manufacture and Supply Revenue subsequent to the Assertio Agreement.

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, offset by anticipated manufacturing revenue of our proprietary and 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, we would incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from higher manufactured volumes from proprietary and licensed products.

Research and Development Expenses

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

- employee-related expenses, including compensation, benefits, share-based compensation and travel expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, 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 AQST-109, 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, 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.

A significant portion of selling, general and administrative expenses relates to the sale and marketing of our proprietary product, Sympazan prior to its outlicensing under the Assertio Agreement in October 2022. Subsequently, we have significantly reduced expenses related to the marketing and sales of Sympazan. Until Libervant receives FDA approval for U.S. market access, which cannot be assured, we do not plan to increase the size and resources dedicated to our commercial organization.

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, the manufacturing costs related to Sympazan and other external factors affecting our business, as we continue to focus on our core business:

- Continuing the development of AQST-109 and AQST-108 along the 505(b)(2) pathway; and
- Seeking to obtain the approval and subsequent launch of Libervant, subject to approval by the FDA for U.S. market access, which cannot be assured.

Interest Expense

Interest expense consists of interest costs on our 12.5% Notes at a fixed rate of 12.5%, payable quarterly, as well as amortization of loan costs and the debt discount. The 12.5% Notes are discussed in Note 13, *12.5% Senior Secured Notes and Loans Payable*, to our condensed consolidated financial statements. See Liquidity and Capital Resources below for further detail on our 12.5% Notes.

Royalties and Interest Expense related to the Sale of Future Revenue

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("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, 2023 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate 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. Based on the current public forecast by Sunovion of estimated KYNMOBI sales as of March 31, 2023, the Company likely will not receive any of the additional contingent payments under the Monetization Agreement.

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 eight $1,000 annual minimum guaranteed royalty that is due. 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 consolidated financial statements for further detail.

Interest Income and other income (expense), net

Interest income and other income (expense), 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, 2023 and 2022

Revenues:

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

	Three Months Ended March 31,		Change	
(In thousands, except %)	**2023**	**2022**	**$**	**%**
Manufacture and supply revenue	$ 9,762	$ 9,171	$ 591	6 %
License and royalty revenue	919	506	413	82 %
Co-development and research fees	453	403	50	12 %
Proprietary product sales, net	—	2,190	(2,190)	(100)%
Total revenues	$ 11,134	$ 12,270	$ (1,136)	(9)%

For the three months ended March 31, 2023, total revenues decreased 9% or $1,136 compared to same period in the prior year. The decrease was primarily due to the absence of proprietary product sales subsequent to the outlicensing agreement with Assertio in October 2022, offset by an increase in manufacturing supply revenue, and increases in license and royalty revenue as well as co-development and research fees.

Manufacture and supply revenue increased approximately 6% or $591 for the three months ended March 31, 2023 compared to the same period in the prior year. This increase was due to increased Zuplenz manufacturing revenue (marketed as Ondif), Sympazan manufacturing revenue, partially offset by a decline in Suboxone manufacturing revenue.

License and royalty revenue increased 82% or $413 for the three months ended March 31, 2023 compared to the same period in the prior year. This increase was primarily due to royalty revenue from Sympazan, Azstarys, and Exservan.

Co-development and research fees increased 12% or $50 for the three months ended March 31, 2023 compared to the same period in the prior year. The increase was driven by the timing of the achievement of research and development performance obligations and are expected to fluctuate from one reporting period to the next.

Proprietary product sales, net was not recognized for the three months ended March 31, 2023 subsequent to the outlicensing agreement with Assertio in October 2022. The Company recognized $2,190 of Proprietary product sales, for the same period in the prior year.

Expenses and Other:

	Three Months Ended March 31,		Change	
(In thousands, except %)	**2023**	**2022**	**$**	**%**
Manufacture and supply	$ 4,737	$ 4,214	$ 523	12 %
Research and development	3,547	4,773	(1,226)	(26)%
Selling, general and administrative	7,455	13,021	(5,566)	(43)%
Interest expense	1,435	1,618	(183)	(11)%
Interest expense related to the sale of future revenue, net	52	1,861	(1,809)	(97)%
Interest and other (income) expense, net	(14,513)	3	(14,516)	(100)%
Loss on extinguishment of debt	(353)	—	(353)	(100)%

Manufacture and supply costs and expenses increased 12% or $523 for the three months ended March 31, 2023 compared to the same period in the prior year. The increase was due to higher costs related to raw material and production.

Research and development expenses decreased 26% or $1,226 for the three months ended March 31, 2023 compared to the same period in the prior year. Research and development expenses are driven primarily by the timing of clinical trial and other product development activities associated with our pipeline.

Selling, general and administrative expenses decreased 43% or $5,566 for the three months ended March 31, 2023 as compared to the same period in the prior year. The decrease reflects lower administrative costs in our commercial organization subsequent to the outlicensing of Sympazan in October 2022.

Interest expense decreased 11% or $183 for the three months ended March 31, 2023 compared to the same period in the prior year. The decrease was driven by a lower principal amount of debt outstanding in 2023 subsequent to $9,086 of principal repayment in the first quarter of 2023.

Interest expense related to the sale of future revenue, net was $52 and $1,861 for the three months ended March 31, 2023 and March 31, 2022. This amount is due to the accounting associated with the sale of future revenue related to KYNMOBI royalties sold to Marathon on November 3, 2020 and does not represent or imply a monetary obligation or cash output at any time during the life of the transaction. Based on the current forecast by Sunovion of estimated KYNMOBI sales as of March 31, 2023, 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, which led to a decrease in 2023. See Note 15, *Sale of Future Revenue* for details.

Interest and other income, net was $14,513 for the three months ended March 31, 2023, as compared to interest and other expense, net of $3 for the three months ended March 31, 2022. The change reflects other 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. recognized in the first quarter of 2023.

Liquidity and Capital Resources

Sources of Liquidity

We had $26,882 in cash and cash equivalents as of March 31, 2023. 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 equivalents, expense management activities, including, but not limited to potentially ceasing nearly all R&D 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 the Company to fund its operating needs, including making the principal and interest payments on the 12.5% Notes, for at least the next twelve months as the Company continues to execute its business strategy.

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). 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®. KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson’s disease patients, received approval from the FDA on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment 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, 2023 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a timeframe, which could result in total potential proceeds of $125,000. Based on the current public forecast by Sunovion of estimated KYNMOBI sales as of March 31, 2023, the Company likely will not receive any of the additional aggregate contingent payments under the Monetization agreement.

With the upfront proceeds of the Marathon monetization, we repaid $22,500 of the 12.5% Notes, and issued $4,000 of new 12.5% Notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the aggregate principal balance of 12.5% Notes outstanding to $51,500. In addition, as of the closing of this transaction, we issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our Common Stock.

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 amortization payment to be extended to March 30, 2023. The Fourth Supplemental Indenture did not change the maturity date of the Notes or the interest payment obligation due under the Notes. In connection with the Fourth Supplemental Indenture, the Company entered into a Consent Fee Letter

with the holders of the 12.5% Notes, pursuant to which the Company 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.

In 2019, we established an “At-The-Market” (ATM) facility and currently have a prospectus supplement registering the offer and sale of up to $35,000 of shares of Common Stock pursuant under the ATM facility. Since inception to March 31, 2023, we sold 11,420,579 shares which generated net cash proceeds of approximately $40,656, net of commissions and other transaction costs of $2,130. 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. This ATM facility has approximately $32,422 available at March 31, 2023.

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, the Company sold 1,611,181 shares including commitment shares of Common Stock, which provided proceeds of approximately $1,987 in connection with the Lincoln Park Purchase Agreement. On April 13, 2022, the Company filed a prospectus supplement in connection with this offering. The Company did not sell shares in connection with the Lincoln Park Purchase Agreement in the first quarter of 2023.

On June 6, 2022, we entered into securities purchase agreements ("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. We received net proceeds of approximately $7,796, after deducting placement agent fees and expenses and estimated offering expenses payable by us. The pre-funded warrants were fully exercised in 2022 and no Common Stock warrants issued pursuant to the Securities Purchase Agreements were exercised during the three-months ended March 31, 2023.

As of the filing of the Annual Report on Form 10-K on March 31, 2023, we are subject to the SEC general instructions of Form S-3 known as the "baby shelf rules." Under these instructions, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of our Common Stock held by non-affiliates. Therefore, we are limited in the amount of proceeds we are able to raise by selling shares of our Common Stock using our Form S-3, including under the ATM facility and the Lincoln Park Purchase Agreement, until such time as our public float exceeds $75 million.

Cash Flows

Three Months Ended March 31, 2023 and 2022

(in thousands)	**2023**	**2022**
Net cash provided by (used for) operating activities	$ 8,816	$ (14,482)
Net cash (used for) investing activities	(2)	(104)
Net cash (used for) provided by financing activities	(9,205)	1,298
Net decrease in cash and cash equivalents	$ (391)	$ (13,288)

Net Cash Provided by (Used for) Operating Activities

Net cash provided by operating activities for the three months ended March 31, 2023 increased by $23,298 compared to the same period in the prior year. The increase was related to a higher net income of $21,288 and a higher trade and other receivables of $5,461, partially offset by a decrease in interest expense related to the sale of future revenue of $1,836.

Net Cash (Used for) Investing Activities

Net cash used for investing activities for the three months ended March 31, 2023 decreased by $102 compared to the same period in the prior year. The use of cash was related to capital expenditures.

Net Cash (Used for) Provided by Financing Activities

Net cash used for financing activities for the three months ended March 31, 2023 increased by $10,503 compared to the same period in the prior year. The decrease was primarily due to partial debt redemption and premium paid to retire debt, offset by ATM proceeds.

Funding Requirements

The Company's 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 the Company, subject to the limitations imposed by the baby shelf rules. 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, including the full approval of Libervant by the FDA for U.S. market access, 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:

- the effects of the COVID-19 pandemic on our operations, operations of our key suppliers and third-party clinical and other service providers, our colleagues and contractors and debt equity and other capital markets;
- 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;
- 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 price 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 candidate Libervant, if approved for U.S. market access by the FDA;
- 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 12.5% Notes, including our ability to comply with our debt service obligations as required thereunder;
- absence of significant unforeseen cash requirements; and
- our ability to access funding through the Company's ATM facility and under the Lincoln Park Purchase Agreement.

We expect to continue to manage business costs to appropriately reflect the anticipated general decline in Suboxone revenue, the unlikelihood of any proceeds from the KYNMOBI Monetization Agreement, and other external resources or factors affecting our business including, if available, net proceeds or future equity financing, other future access to the capital markets or other potential available sources of liquidity, as well as the uncertainties associated with the coronavirus pandemic. 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 AQST-109 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 development and commercialization of Libervant, AQST-109 and AQST-108, if approved by the FDA for U.S. market access, and to meet our other cash requirements, including debt service, specifically our 12.5% Notes. We plan to conservatively manage our pre-launch spending as to both timing and level relating to Libervant in light of the tentative approval of Libervant by the FDA. In this regard and in light of our out-license of Sympazan, we expect to significantly reduce our cost on commercialization in 2023 compared to 2022. 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 debt repayment and debt service obligations and have principal repayments related to our 12.5% Notes due through the debt maturity date, which is further discussed in Note 13, *12.5% Senior Secured Notes and Loans Payable* to our Condensed Consolidated 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 proprietary products, timely achievement of regulatory approval by the FDA for Libervant for U.S. market access, and there can be no assurance that we will receive such approval prior to the expiration in January 2027 of the orphan drug market exclusivity of the FDA approved nasal spray of a competitor, our existing level of debt which is secured by substantially all of our assets and associated debt repayment schedule, restriction 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. Additionally, while the potential economic impact brought on by and the duration of the coronavirus pandemic is difficult to assess or predict, the significant impact of the coronavirus pandemic on the global financial markets, and on our own stock trading price, may reduce our ability to access additional capital, which would negatively impact our short-term and longer-term liquidity.

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 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 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 entries 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, 2023, 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, 2023, 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 the Company's business prospects, financial condition, results of operations, liquidity and available capital resources set forth in Part I, Item 1A of the Company's 2022 Annual Report on Form 10-K.

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

The Company's cash requirements for 2023 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 our 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, 2023, we had $26.9 million of cash and cash equivalents.

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). 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. KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the FDA on May 21, 2020. We have received an aggregate amount of $50.0 million through March 31, 2023 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75.0 million 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 $125.0 million. Based on the current forecast of estimated KYNMOBI sales as of March 31, 2023, the Company likely will not receive any of the additional aggregate contingent payments under the Monetization Agreement.

With the upfront proceeds of the monetization, we repaid $22.5 million of the Senior Secured Notes due 2025 (the "12.5% Notes"), and issued $4.0 million of new 12.5% Notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the aggregate principal balance of 12.5% Notes outstanding to $51.5 million. In addition, as of the closing of this monetization transaction, we issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our Common Stock.

On October 7, 2021, we entered into the Fourth Supplemental Indenture in connection with the 12.5% Notes. Pursuant to the Fourth Supplemental Indenture, the amortization schedule for the 12.5% Notes has been 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 June 30, 2025 or the interest payment obligation due under the Notes.

During the first quarter of 2023, the Company redeemed $9.1 million of its outstanding 12.5% Notes. The Company also paid $0.4 million in prepayment premium as result of the early retirement of debt which was reflected as a loss on extinguishment of debt. The prepayments along with a scheduled principal repayment in the first quarter of 2023 reduced the net balance of the 12.5% Notes outstanding in the aggregate to $42.4 million.

In 2019, we established an "at-the-market" (ATM) facility, under which, from time to time, we may offer and sell shares of our Common Stock. In April 2022, we entered into a Purchase Agreement with Lincoln Park, under which, from time to time, we may cause Lincoln Park to purchase shares of our Common Stock.

We may not be able to raise additional capital or secure other funding on terms acceptable to us, or at all, and any failure to raise additional capital or other funding as and when needed for our cash requirements, including payments on our 12.5% Notes, would have a negative impact on our business, financial condition and prospects and on our ability to execute and achieve our business plan.

If adequate funds are not available for our liquidity needs and cash requirements as and when needed from the sources referred to above or otherwise, or at all, we would be required to engage in expense management activities such as reducing staff, delaying, significantly scaling back, or even discontinuing some or all of our current or planned research and development programs and clinical and other product development activities, or reducing our future commercialization efforts and otherwise

significantly reducing our other spending and adjusting our operating plan, and we would need to seek to take other steps intended to improve our liquidity. We also may be required to evaluate additional licensing opportunities, if any become available, of our proprietary product candidate programs that we currently plan to self-commercialize or explore other potential liquidity opportunities or other alternatives or options or strategic alternatives, including asset sales, although we cannot assure that any of these actions would be available or available on reasonable terms. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing most if not all of their investment in the Company.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

Number	Description
31.1*	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).
31.2*	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).
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
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.

+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been omitted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

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 2, 2023

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

Date: May 2, 2023

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

Exhibit 31.1

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 2, 2023

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

Exhibit 31.2

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 2, 2023

/s/ A. ERNEST TOTH, JR.
A. Ernest Toth, Jr.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

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, 2023, 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 2, 2023

/s/ Daniel Barber
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.

Exhibit 32.2

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, 2023, 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 2, 2023

/s/ A. ERNEST TOTH, JR
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.