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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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 ☐
Non-accelerated filer ☒

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 par value $0.001 common stock as of the close of business on May 3, 2019 was 24,975,139.

AQUESTIVE THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2019
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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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 39,934	$ 60,599
Trade and other receivables, net	7,489	6,481
Inventories, net	5,137	5,441
Prepaid expenses and other current assets	3,398	1,680
Total current assets	55,958	74,201
Property and equipment, net	11,594	12,207
Intangible assets, net	191	204
Other assets	236	239
Total assets	$ 67,979	$ 86,851
Liabilities and shareholders' (deficit)/equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,088	$ 27,631
Deferred revenue, current	700	721
Loans payable, current	6,850	4,600
Total current liabilities	29,638	32,952
Loans payable, net	40,742	42,603
Deferred revenue, net of current portion	2,405	—
Asset retirement obligations	1,250	1,216
Total liabilities	74,035	76,771
Commitments and contingencies (Note 17)		
Shareholders' (deficit)/equity:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 24,975,139 and 24,957,309 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	25	25
Additional paid-in capital	72,873	71,431
Accumulated deficit	(78,954)	(61,376)
Total shareholders' (deficit)/equity	(6,056)	10,080
Total liabilities and shareholders' (deficit)/equity	$ 67,979	$ 86,851

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	2018
Revenues	$ 12,643	$ 23,411
Costs and expenses:		
Manufacture and supply	3,506	5,636
Research and development	4,303	4,901
Selling, general and administrative	17,908	7,569
Total costs and expenses	25,717	18,106
(Loss)/income from operations	(13,074)	5,305
Other income/(expenses):		
Interest expense	(1,926)	(1,927)
Interest income	274	24
Change in fair value of warrant	—	697
Net (loss)/income before income taxes	(14,726)	4,099
Income taxes	—	—
Net (loss)/income	(14,726)	4,099
Comprehensive (loss)/income	$ (14,726)	$ 4,099
Net (loss)/income per share – basic and diluted	$ (0.59)	$ 0.27
Weighted-average number of common shares outstanding - basic and diluted	24,963,603	15,077,647

See accompanying notes to the condensed consolidated financial statements.

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

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Retained Earnings/ Accumulated Deficit	Total Shareholders' Equity
Balance at January 1, 2018*	5,000	$ —	(26,495)	$ —	$ (26,495)
Effect of stock split	15,072,647	15	(15)	—	—
Net income	—	—	—	4,099	4,099
Balance at March 31, 2018	15,077,647	$ 15	$ (26,510)	$ 4,099	$ (22,396)

* Represents balances as of December 31, 2017 as adjusted for the reorganization from LLC to C corporation business structure effective at the close of business on that date.

Balance at December 31, 2018	24,957,309	$ 25	$ 71,431	$ (61,376)	$ 10,080
Adoption of ASU 2014-09 and ASU 2018-07 (Note 3.C.)	—	—	20	(2,852)	(2,832)
Share-based compensation	17,830	—	1,422	—	1,422
Net loss	—	—	—	(14,726)	(14,726)
Balance at March 31, 2019	24,975,139	$ 25	$ 72,873	$ (78,954)	$ (6,056)

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,	
	2019	2018
Cash flows from operating activities:		
Net (loss)/income	$ (14,726)	$ 4,099
Adjustments to reconcile net (loss)/income to net cash (used for)/provided by operating activities:		
Depreciation and amortization	736	940
Change in fair value of warrant	—	(697)
Share-based compensation	1,520	—
Asset retirement obligation accretion	34	34
Amortization of intangible	13	13
Amortization of debt issuance costs and discounts	389	458
Non-cash interest expense	527	(16)
Bad debt provision	6	39
Other, net	(51)	-
Changes in operating assets and liabilities:		
Trade and other receivables, net	(963)	(3,301)
Inventories, net	304	165
Prepaid expenses and other current assets	(1,715)	(51)
Accounts payable and accrued expenses	(3,306)	(721)
Deferred revenue	(448)	(177)
Net cash (used for)/provided by operating activities	(17,680)	785
Cash flows from investing activities:		
Capital expenditures	(376)	(259)
Net cash (used for) investing activities	(376)	(259)
Cash flows from financing activities:		
Payments for deferred financing costs	—	(1,417)
Payments for taxes on share-based compensation	(2,609)	—
Net cash (used for) financing activities	(2,609)	(1,417)
Net decrease in cash and cash equivalents	(20,665)	(891)
Cash and cash equivalents:		
Beginning of period	60,599	17,379
End of period	$ 39,934	$ 16,488
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 1,009	$ 1,485
Net (decrease)/increase in accrued capital expenditures	(253)	15
Net increase in financing costs included in accounts payable and accrued expenses	311	—
Accrued withholding tax for share based compensation	(4)	—

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. Corporate Organization and Company Overview

(A) Company Overview

Aquestive Therapeutics, Inc. ("Aquestive", "the Company") is a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs and solve critical healthcare challenges, having been formed effective on January 1, 2018 via the conversion of MonoSol Rx, LLC, a Delaware limited liability company, to a Delaware corporation and a simultaneous name change. The Company has a late-stage proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and is developing orally administered complex molecules as alternatives to more invasive therapies. Aquestive is pursuing its business objectives through both in-licensing and out-licensing arrangements, as well as the commercialization of its own products. Production facilities are located in Portage, Indiana, and corporate headquarters, sales, commercialization operations and primary research laboratory facilities are based in Warren, New Jersey. The Company's major customer and primary commercialization licensee has global operations headquartered in the United Kingdom with principal operations in the United States; other customers are principally located in the United States.

(B) Corporate Conversion and Reorganization, Stock Splits and IPO

Corporate Conversion and Reorganization

Effective on January 1, 2018, the Company converted from a Delaware limited liability company (LLC) into a Delaware corporation pursuant to a statutory conversion and changed its name from MonoSol Rx, LLC ("MonoSol") to Aquestive Therapeutics, Inc., having previously operated as an LLC since January 2004. At the time of the statutory conversion, the holders of membership units of MonoSol contributed all of their LLC interests to Aquestive Partners, LLC, or APL, in exchange for identical interests in APL. As a result of the exchange, APL was issued 5,000 shares of voting common stock in Aquestive Therapeutics, Inc. and became the parent and sole stockholder of the Company.

Stock Splits

During 2018, the Board of Directors approved the Amended and Restated Certificate of Incorporation of the Company to:

(i) increase the authorized number of shares of capital stock from 25,000 to 350,000,000 shares, and subsequently reduced that authorized total to 250,000,000,

(ii) authorize certain non-voting common stock for use in settlement of performance incentive obligations, and

(iii) effect a stock split of the Company's common stock, par value $0.001 per share, such that each share be subdivided and reclassified into 37,212 shares of voting common stock, par value $0.001 per share. Subsequent to this split, and in connection to pricing considerations related to the Company's initial public offering ("IPO"), a reverse split was executed such that each 12.34 shares outstanding converted into one share of common stock, par value $0.001 per share.

The net effect of these stock splits is reflected in these financial statements as if they had occurred on January 1, 2018.

Initial Public Offering of Common Stock and Authorized Number of Capital Stock

On July 27, 2018, the Company closed the IPO of 4,500,000 shares of common stock at an offering price of $15.00 per share. The Company received net proceeds of approximately $57,543 after deducting underwriting discounts, commissions, and offering-related transaction costs of approximately $9,957. On August 15, 2018, the Company was informed that the underwriters exercised their over-allotment option and the Company issued 425,727 additional shares of common stock at $15.00 per share. Upon the closing of such exercise, the Company received additional net proceeds of approximately $5,939, after deducting underwriter discounts of approximately $447. The IPO and overallotment option resulted in total net proceeds of $63,482. Immediately prior to the consummation of the IPO, all of the Company's outstanding shares of non-voting common stock were automatically converted to 4,922,353 shares of voting common stock.

Note 2. 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, 2018 included in our Annual Report on Form 10-K filed with the SEC on March 14, 2019 (the "2018 Annual Report on Form 10-K"). As included herein, the condensed consolidated balance sheet at December 31, 2018, 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 Company has evaluated subsequent events for disclosure through the date of issuance of the accompanying unaudited condensed financial statements.

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

Note 3. Summary of Significant Accounting Policies

(A) Principles of Consolidation

The interim condensed consolidated financial statements presented herein include the accounts of Aquestive Therapeutics, Inc. and its wholly owned subsidiary, MonoSol Rx, Inc. Other than corporate formation activities, MonoSol Rx, Inc. has conducted no commercial, developmental or operational activities and has no customers or vendors. The results of operations and cash flows reported in these condensed consolidated financial statements should not be regarded as necessarily indicative of results that may be expected in any other interim period or for the entire fiscal year.

(B) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to estimates and assumptions include allowances for rebates from proprietary product sales, the allowance for sales returns, the useful lives of fixed assets, valuation of share-based compensation, and contingencies.

(C) 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 standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In May 2014, the FASB, issued ASU 2014-09, *Revenue from Contracts with Customers*, and subsequently issued a number of amendments to this update. The new standard, as amended in Accounting Standards Codification, or ASC 606, provides a single comprehensive model to be used in accounting for revenue arising from contracts with customers and supersedes previous revenue recognition guidance. The standard's core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

The Company adopted this standard on January 1, 2019, using the modified retrospective method and recorded a cumulative effect adjustment of $2,832 to increase the opening balance of accumulated deficit. The impact was primarily related to deferral of a portion of the original upfront and milestone payments of its collaborative licensing arrangements resulting in a deferral of $3,100 of previously recognized revenue as of the adoption date. The cumulative adjustment also reflects $151 net acceleration of revenue related to feasibility and development arrangements with its customers and acceleration of $117 of revenue recognition of its manufacturing and supply product sales. Under the modified retrospective method of adoption, the comparative information in the consolidated financial statements have not been revised and continues to be reported under the previously applicable revenue accounting guidance, ASC 605. If ASC 605 had been applied to the first quarter of 2019, deferred revenue would have been $2,683 lower on the condensed consolidated balance sheet, with $278 lower in current portion of deferred revenue and $2,405 Deferred revenue, net of current portion.

For additional information regarding the Company's revenue, see **Note 5, Revenues and Trade Receivables, Net**

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Non-Employee Share-Based Payment Accounting,* which more closely aligns accounting for share-based payments to nonemployees to that of employees under existing guidance of Topic 718. This guidance supersedes previous guidance provided by *Subtopic 505-50, Equity – Equity-Based Payments to Non-Employees*. The Company adopted the new standard effective January 1, 2019 and recorded a cumulative effect adjustment of $20 to its Accumulated deficit upon adoption.

In January 2016, the FASB issued revised guidance governing accounting and reporting of financial instruments (ASU 2016-01) and in 2018 issued technical corrections (ASU 2018-03). This guidance requires that equity investments with readily determinable fair values that are classified as available-for-sale be measured at fair value with changes in value reflected in current earnings. This guidance also simplifies the impairment testing of equity investments without readily determinable fair values and alters certain disclosure requirements. ASU No. 2016-01, *Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, also provides guidance as to classification of the change in fair value of financial liabilities. Adoption of this standard was effective on January 1, 2019 and has had no material impact on the financial statements given the lack of any such equity investments during the period presented.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This guidance simplifies aspects of accounting for employee share-based payments, including income tax consequences, classification of awards as either equity or liabilities, and classifications within the statement of cash flows. This guidance was effective for annual periods beginning after December 15, 2017, with early adoption permitted. Under the Company's now-terminated Performance Unit Plans (PUPs), vested grants were unable to be exercised prior to either a change in control of the Company or completion of an IPO, and, as a result, expense recognition related to the settlement of these awards was deferred until the PUPs were formally terminated in April 2018. Because the Company has incurred net operating losses since its incorporation, a full valuation allowance has been provided and, accordingly, there was no financial statement impact of adopting the ASU 2016-09 provisions regarding recognition of tax effects associated with share-based compensation.

Recent Accounting Pronouncements Not Adopted as of March 31, 2019:

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842),* which establishes a comprehensive new lease accounting model. The new standard: (i) clarifies the definition of a lease, (ii) requires a dual approach to lease classification similar to current lease classifications, and (iii) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The new standard is effective for the Company for fiscal years and interim periods beginning after December 15, 2019 and requires modified retrospective application. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its condensed consolidated financial statements.

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 introduces an expected loss model for estimating credit losses, replacing the incurred loss model. 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 new guidance is effective for the Company beginning after December 15, 2020. The Company is currently evaluating the impact of the adoption of this guidance on its condensed consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,* providing guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice, including cash flows related to debt prepayment or extinguishment costs and contingent consideration that may be paid following a business combination. The guidance is effective for the Company for fiscal years beginning after December 31, 2019. Early adoption is permitted. The Company is currently evaluating the effect of the standard on its Condensed Consolidated Statement of Cash Flows.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework.* The purpose of the update is to improve the effectiveness of the fair value measurement disclosures that allows for clear communication of information that is most important to the users of financial statements. There were certain required disclosures that have been removed or modified. In addition, the update added the following disclosures: (i) changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and (ii) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The standard will become effective for the Company for its periods beginning after December 15, 2019; early adoption is permitted. The Company is currently evaluating the impact of ASU 2018-13 on its condensed consolidated financial statements.

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the condensed consolidated financial statements of the Company.

Note 4. Risks and Uncertainties

The Company's cash requirements for 2019 and beyond include expenses related to continuing development and clinical evaluation of its products, 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. As of March 31, 2019, working capital totaled $26,320.

The Company believes that its revenues from licensed products, its proprietary product and cash on hand, including remaining funds received from the July 2018 IPO, are adequate to meet its operating, investing, and financing needs for at least the next twelve months. To the extent additional funds are necessary to meet long-term liquidity needs as the Company continues to execute its business strategy, the Company anticipates that these additional funding requirements will be obtained through additional debt or equity financings, or through monetization of certain royalty streams, or via a combination of these potential sources of funds, although the Company can provide no assurance that these sources of funding will be available on reasonable terms, if at all.

Note 5. Revenues and Trade Receivables, Net

Our revenues to date have been earned from our product development pipeline, marketed product activities and self-developed medicines. These activities generate revenues in four primary categories: manufacturing and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

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 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, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good that is distinct. When identifying our performance obligations, we consider all goods or services promised in the contract regardless of whether explicitly stated in the customer contract or implied by customary business practices. The Company's performance obligations consist mainly of transferring control of goods and services identified in the contracts, purchase orders or invoices.

The Company's performance obligation with respect to its proprietary product sales is satisfied at a point in time, which transfers control upon delivery of the product to its customers. The Company considers control to have transferred upon delivery because the customer has legal title to the asset, physical possession of the asset has been transferred, the customer has significant risks and rewards of ownership of the asset and the Company has a present right to payment at that time. With respect to manufacturing and supply revenue stream, a quantity is ordered and manufactured according to customer's specifications and represents a single performance obligation. The products manufactured are exclusively for specific customers and have no alternative use. Under the customer arrangements, the Company is entitled to receive payments for progress made to date once the acceptance requirements surrounding quality control are satisfied. Thus, revenues related to this product stream is recognized at a point in time, which is when the manufactured product passes quality control.

Royalty revenues are estimated based on the provisions of contracts with customers and recognized in the same period that the royalty-based products are sold to the Company's strategic partners, as all royalties are directly attributable to the Company's manufacturing activities, and are therefore recognizable at the same time the manufacturing revenue is recognizable. In addition to usage-based royalties, licensing contracts may contain provisions for one-time payments related to certain license fees and milestone achievements. Revenue recognition of these license fees and milestone payments depend on the nature of the specific contract, typically license and milestone payments are recognized at a point in time in the period they are achieved. However, there are limited instances where upon review of the contract, it is determined that the license is non-distinct and limited in nature and does not provide benefit to the customer without purchasing the product, these upfront licensing fees are recognized over time (typically the length of the contract).

Co-development and research fee revenue is recorded over time based upon the progress of services provided in order complete the specific performance obligation identified in the related contract.

Revenues from sale of products and services and the subsequent related payments are evidenced by a contract with the customer, which includes all relevant terms of sale. For manufacturing and supply and proprietary product sales, invoices are generally issued upon the transfer of control and co-development and research revenue is typically invoiced based on the contractual payment schedule, or upon completion of the service. Invoices are typically payable 30 to 60 days after the invoice date, however some payment terms may reach 105 days depending on the customer. The Company performs a review of each specific customer's credit worthiness and ability to pay prior to acceptance as a customer. Further, the Company performs periodic reviews of its customers' creditworthiness prospectively.

Contract Assets

In limited situations, certain customer contractual payment terms require us to bill in arrears; thus, we satisfy some, or all, of our performance obligations before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. We reflect these contract assets as a component of Other receivables within Trade and other receivables on the Condensed Consolidated Balance Sheet. As of March 31, 2019, and January 1, 2019, such contract assets were $275, and $284, respectively.

Contract Liabilities

In other limited situations, certain customer contractual payment terms allow us to bill in advance; thus, we receive customer cash payment before satisfying some or all of its performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. We reflect these contract liabilities as Deferred revenue on our Consolidated Balance Sheet. As we satisfy our remaining performance obligations, we release a portion of the deferred revenue balance. As of March 31, 2019, and January 1, 2019, such contract liabilities were $3,105 and $3,762, respectively. Revenue recognized for the three-month period ended March 31, 2019 that was reflected in the deferred revenue balance as of January 1, 2019 was $657.

The Company's revenues were comprised of the following:

	Three Months Ended March 31,	
	2019	2018
Manufacture and supply revenue	$ 6,669	$ 11,560
License and royalty revenue	4,622	9,500
Co-development and research fees	770	2,351
Proprietary product sales, net	582	—
Total revenues	$ 12,643	$ 23,411

Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Three Months Ended March 31,	
	2019	2018
United States	$ 12,394	$ 23,197
Non-United States	249	214
Total revenues	$ 12,643	$ 23,411

Non-United States revenues is derived primarily from products manufactured for the Australian and Malaysian markets.

Trade and other receivables, net consist of the following:

	March 31, 2019	December 31, 2018
Trade receivables	$ 7,327	$ 6,610
Other receivables	279	33
Less: allowance for bad debt	(64)	(58)
Less: sales-related allowances	(53)	(104)
Trade and other receivables, net	$ 7,489	$ 6,481

Other receivables totaled $279 as of March 31, 2019, consisting primarily of contract assets related to the adoption of ASC 606. Other receivables totaled $33 as of December 31, 2018, consisting primarily of reimbursable costs incurred on behalf of a customer. Sales-related allowances for both periods presented are estimated in relation to revenues recognized for sales of Sympazan® beginning with the launch of this product in December 2018.

The following table presents the changes in the allowance for bad debt:

	March 31, 2019	December 31, 2018
Allowance for doubtful accounts at beginning of period	$ 58	$ 55
Additions charged to bad debt expense	6	53
Write-downs charged against the allowance	—	(50)
Allowance for doubtful accounts at end of period	$ 64	$ 58

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 card 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 our sales related allowances and accruals for the three months ended March 31, 2019:

	Total Sales Related Allowances and Accruals
Balance at December 31, 2018	585
Provision related to sales during the period	423
Reversals of prior provisions	(89)
Credits and payments	(225)
Balance at March 31, 2019	694

Total reductions of gross product sales from sale-related allowances and accruals were $423 for the three months ended March 31, 2019. Reversals of prior provisions recorded during this period totaled $89, resulting in a net effect on reported proprietary product sales of $334. Accruals for returns allowances and prompt pay discounts are reflected as a direct reduction to trade receivable and accruals for wholesaler fees, co-pay cards 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 $53 and $641, respectively, at March 31, 2019 and $104 and $481, respectively, at December 31, 2018. The were no related allowances and accruals at March 31, 2018, as Sympazan was launched in December 2018.

Concentration of Major Customers

Customers are considered major customers when sales exceed 10% of total net sales for the period or outstanding receivable balances exceed 10% of total receivables. For the year ended December 31, 2018, Indivior, Inc. ("Indivior") provided 89% of the total revenues for the period, and as of that date, the Company's outstanding receivable balance from Indivior represented approximately 78% gross receivables. For the three months ended March 31, 2019, revenues provided by Indivior represented approximately 88% of total revenue, and outstanding accounts receivable due from Indivior represented approximately 80% of gross receivables.

Note 6. 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 our ability to satisfy minimum product thresholds. Additionally, in the event Indivior purchases certain large quantities of Suboxone during a specified period, Indivior will be entitled to scaled rebates on its purchases.

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) in each of the United States and in the rest of the world subject to annual maximum amounts and limited to the life of the related United States or international patents. Indivior exercised its right to buy out its future royalty obligations in the United States under the Indivior License Agreement in 2012. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions, including those for breach, a filing for bankruptcy or corporate dissolution, an invalidation of the intellectual property surrounding Suboxone, or commission of a material breach of the Indivior License Agreement by either party. Additionally, Indivior may terminate if the U.S. Food and Drug Administration ("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.

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, we conveyed to Indivior all of our existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to the Suboxone product. We 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 us. Under the Indivior Supplemental Agreement, we are entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. Once paid, all payments made under the Indivior Supplemental Agreement are non-refundable, and total payments under this agreement are capped at $75,000. Through February 20, 2019, the at-risk launch date of the competing generic products of Dr. Reddy's Labs and Alvogen, we received an aggregate of $40,750 from Indivior under the Indivior Supplemental Agreement, of which $4,250 was collected during the three months ended March 31, 2019. Further payments under the Indivior Supplemental Agreement are suspended until adjudication of related patent infringement litigation occurs. If such litigation is successful, in addition to the amounts already received as described in the foregoing, we may receive up to an additional $34,250, consisting of (i) up to $33,000 in the aggregate from any combination of (a) performance or event-based milestone payments and (b) single digit percentage royalties on net revenue earned by Indivior on sales of Suboxone and (ii) and an additional $1,250 that was earned through the issuance to the Company of additional process patent rights.

All payments made by Indivior to the Company pursuant to the Indivior Supplemental Agreement are in addition to, and not in place of, any amounts owed by Indivior to the Company pursuant to the Indivior License Agreement. Indivior's payment obligations under the Indivior Supplemental Agreement are subject to certain factors affecting the market for Suboxone and may terminate prior to January 1, 2023 in the event certain contingencies relating to such market occur.

License Agreement with Sunovion Pharmaceuticals, Inc.

In April 2016, we entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion), referred to as the Sunovion License Agreement, pursuant to which we granted Sunovion 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 APL-130277 (apomorphine) for the treatment of off episodes in Parkinson's disease patients, as well as two other fields. Our licensee, Sunovion, as sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018. According to statements by Sunovion, following the January 2019 PDUFA date, Sunovion received a Complete Response Letter from the FDA which requires additional data, but does not require additional clinical studies.

In consideration for the rights granted to Sunovion under the Sunovion License Agreement, we received aggregate payments totaling $18,000 to date. In addition to the upfront payment of $5,000, we have also earned an aggregate of $13,000 in connection with specified regulatory and development milestones in the United States and Europe (the "Initial Milestone Payments"), all of which of which has been received to date. No payments were received during the three months ended March 31, 2019. We are also entitled to receive certain contingent one-time milestone payments related to product availability and regulatory approval in the United States and Europe, certain one-time milestone payments based on the achievement of specific annual net sales thresholds of APL-130277, and ongoing mid-single digit percentage royalty payments related to the net sales of APL-130277 (subject to reduction to low-single digit percentage royalty payments in certain circumstances), subject to certain minimum payments. The maximum aggregate milestone payments that may be paid to us pursuant to the Sunovion License Agreement is equal to $45,000. With the exception of the Initial Milestone Payments, there can be no guarantee that any such milestones will in fact be met or that additional milestone payments will be payable .

This Sunovion License Agreement will continue until terminated by us or Sunovion in accordance with the termination provisions of the Sunovion License Agreement. Absent early termination, the Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination, all rights to intellectual property granted to Sunovion to develop and commercialize products will revert to the Company and Sunovion must continue to pay royalties to the Company on each sale of Sunovion's remaining inventory of products which include apomorphine as their API.

Agreement to Terminate CLA with KemPharm

In March 2012, the Company entered into an agreement with KemPharm, Inc. ("KemPharm") to terminate a Collaboration and License Agreement entered into in April 2011. Under this termination arrangement, we have the right to participate in any and all value that KemPharm 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 KemPharm and collaborations, royalty arrangements, or other transactions from which KemPharm may realize value from these compounds. The Company has not received payments under this arrangement during any of the periods presented herein.

Note 7. 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 in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. To increase consistency and comparability in such measurements, the FASB established a three-level hierarchy which requires maximization of the use of observable inputs and minimization of the use of unobservable inputs when estimating fair value. The three levels of the fair value hierarchy include:

- Level 1 — Observable quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices) that are not quoted on active markets but that can be 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 Company's Level 1 assets for the periods presented included cash and cash equivalents, including money market funds. The Company held no Level 2 or Level 3 assets or liabilities as of either balance sheet date presented herein. Prior to exercise in connection with the July 2018 IPO, outstanding warrants held by Perceptive Credit Opportunities Fund were categorized as Level 3 liabilities. This warrant liability was estimated at fair value based primarily on independent third-party appraisals prepared an reported periodically, 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 13 for further information on the Company's warrants. In addition, Level 3 inputs provide the basis for estimated fair values of stock options granted during 2018 and 2019, which values were estimated using the Black-Scholes-Merton pricing model based on assumptions disclosed in Note 15.

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 fair value based on the short-term maturity of these assets and liabilities.

Note 8. Inventories, Net

The components of Inventory, net is as follows:

	March 31, 2019	December 31, 2018
Raw material	$ 1,431	$ 1,283
Packaging material	2,534	2,975
Finished goods	1,172	1,183
Total inventories, net	$ 5,137	$ 5,441

Note 9. Property and Equipment, Net

	Useful Lives	March 31, 2019	December 31, 2018
Machinery	3-15 yrs	$ 20,905	$ 20,681
Furniture and fixtures	3-15 yrs	1,150	1,150
Leasehold improvements	(a)	21,333	21,333
Computer, network equipment and software	3-7 yrs	2,657	2,579
Construction in progress		1,476	1,655
		47,521	47,398
Less: accumulated depreciation and amortization		(35,927)	(35,191)
Total property and equipment, net		$ 11,594	$ 12,207

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

Total depreciation and amortization related to property and equipment was $736 and $940 for the three-month periods ended March 31, 2019 and 2018, respectively.

Note 10. Intangible Assets

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

	March 31, 2019	December 31, 2018
Purchase technology-based intangible	$ 2,358	$ 2,358
Purchased patent	509	509
	2,867	2,867
Less: accumulated amortization	(2,676)	(2,663)
Intangible assets, net	$ 191	$ 204

Amortization expense was $13 for each of the three-month periods ended March 31, 2019 and 2018. During the remaining life of the purchased patent, estimated annual amortization expense is $50 for each of the years from 2019 to 2022.

Note 11. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	March 31, 2019	December 31, 2018
Accounts payable	$ 19,145	$ 20,436
Accrued compensation	1,754	3,604
Accrued withholding tax for share-based compensation	—	2,515
Real estate and personal property taxes	356	388
Accrued distribution expenses	641	481
Other	192	207
Total accounts payable and accrued expenses	$ 22,088	$ 27,631

Note 12. Loans Payable

On August 16, 2016, the Company entered into a Loan Agreement and Guaranty (the "Loan Agreement") with Perceptive Credit Opportunities Fund, LP ("Perceptive"). At closing of the Loan Agreement, as amended, the Company borrowed $45,000 from Perceptive and was permitted to borrow up to an additional $5,000 within one year of the closing date based upon achievement of a defined milestone. In March 2017, the Company met its performance obligations under the terms of the Loan Agreement with Perceptive and drew down the remaining $5,000 of its $50,000 credit facility. The loan proceeds were used to pay the existing debt obligation of $37,500 due to White Oak Global Advisors, LLC, with the balance available for general business purposes.

On May 21, 2018, the Company and Perceptive agreed to make certain amendments to the loan agreement then in effect. In the event that a qualified IPO could be consummated on or before December 31, 2018, the Company and Perceptive agreed to postpone the initial loan principal payments, delay the loan maturity date to December 16, 2020 and retain interest rate terms, payable monthly, at one-month LIBOR or approximately 2% plus 9.75%, subject to a minimum rate of 11.75%. Accordingly, commencing on May 31, 2019, seven monthly loan principal payments are due in the amount of $550. Thereafter, monthly principal payments in the amount of $750 are due through the maturity date, December 16, 2020, at which time the full amount of the remaining outstanding loan balance is due. At March 31, 2019 and December 31, 2018, respectively, $6,850 and $4,600 was classified as current debt. The Company's tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Further, under the Loan Agreement, as amended, the Company is permitted, subject to Perceptive's consent, to monetize the royalty and fees derived from sales of certain apomorphine products and, in connection with such monetization, Perceptive has agreed to release liens related to these royalties and fees. Other significant terms of the Loan Agreement, as amended, include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. Financial covenant requirements include (1) minimum liquidity under which a $4,000 minimum cash balance must be maintained at all times and (2) a minimum revenue requirement under which minimum revenues for the trailing twelve consecutive months, measured at the end of each calendar quarter, must also be met. As of March 31, 2019, the Company was in compliance with all financial covenants under the Loan Agreement, as amended. Also, as of that date, the carrying value of the Company's loan payable approximated its market value. At closing of the Loan Agreement, as amended, Perceptive received a warrant to purchase senior common equity interests representing 4.5% of the fully diluted common units of the Company on an as converted basis, which was automatically exercised in full at the time of the IPO (see Note 13).

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 in accordance with ASU 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*. 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 for the periods ended March 31, 2019 and 2018 were $389 and $458, respectively.

Unamortized deferred debt issuance costs and deferred debt discounts totaled $2,408 as of March 31, 2019 and $2,797 as of December 31, 2018.

Note 13. Warrants

The warrant issued to Perceptive in connection with the Agreement was, by its terms, set to expire on August 16, 2023 and provided certain rights and preferences including anti-dilution adjustments so that, upon exercise, they would represent 4.5% of the Company's fully diluted common stock on an as converted basis, subject to dilution for certain financing including the issuance of shares upon termination of our PUPs. The warrant also provided Perceptive with a put right which, if exercised under certain circumstances, would require the Company to purchase the warrant for $3,000 within the first year of the loan or $5,000 thereafter. Because these re-purchase terms could have required net-cash settlement, the appraised value of this warrant at the time of issuance of $5,800 was classified as a liability, rather than as a component of equity, and was treated as a debt discount, with the unamortized portion applied to reduce the face amount of the loan in the accompanying Condensed Consolidated Balance Sheet.

Immediately prior to pricing of the Company's IPO, Perceptive received 863,400 shares of common stock issuable pursuant to the automatic exercise of warrants at a total price of $116. As a result, the warrant liability of $12,951 was reclassified to Additional paid-in capital during the third quarter of 2018. A Level 1 market price of $15.00, the initial price at which the Company's common stock was publicly offered, was used in determining fair value as of the warrants' conversion date.

During interim periods, the Company used an independent third-party valuation to assist in determining the fair value of these warrants due to the absence of available Level 1 and Level 2 inputs. During the three-month period ended March 31, 2018, as a result of a decline in the estimated fair value of this warrant liability, net income included a non-cash gain of $697. No gain or loss was recognizable for any periods subsequent to the date of exercise of the warrants in July 2018. The fair values at both the date of the issuance and the dates of all interim balance sheets prior to exercise were based on unobservable Level 3 inputs. Fair value was based on the aggregate equity of the Company, which was estimated utilizing the income and market valuation approaches. A probability weighted return model was then utilized to allocate the resulting aggregate equity value of the Company to the underlying securities. Estimates and assumptions impacting the fair value measurement included the following factors: the then-current state of development of the Company's pipeline product candidates, including status of clinical trials; the Company's progress towards an IPO, including selection of investment bankers, assessment of the IPO marketplace and other funding alternatives and a discount rate of 26.5% and a volatility rate of 90%.

Note 14. Net (Loss)/Income Per Share

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

As a result of the Company's net loss incurred for the quarter ended March 31, 2019, all potentially dilutive instruments outstanding would have anti-dilutive effects on per-share calculations for this period. Therefore, basic and diluted net loss per share were the same, as reflected below.

	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Numerator:		
Net (loss) income	$ (14,726)	$ 4,099
Denominator:		
Weighted-average number of common shares – basic and diluted	24,963,603	15,077,647
Net (loss) income per common share – basic and diluted	$ (0.59)	$ 0.27

As of March 31, 2019, the Company's potentially dilutive instruments included 1,732,426 options to purchase common shares and 172,655 unvested restricted stock units ("RSUs") that were excluded from the computation of diluted weighted average shares outstanding because these securities had an anti-dilutive impact due to the loss reported. No such equity securities were issued as of March 31, 2018.

Note 15. Share-Based Compensation

The Company's share-based incentive plan costs reflected in the Condensed Consolidated Statements of Operations and Comprehensive Loss for the period ended March 31, 2019 included those related to RSU awards and stock option grants. The Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan ("the Plan") was first adopted by the Board of Directors on June 15, 2018, and accordingly, no charges to earnings were recorded in 2018 prior to the fiscal quarter ended June 30, 2018. The Company recognized share-based compensation in its Condensed Consolidated Statements of Operations and Comprehensive Loss during 2019 as follows:

Expense classification:	Three-Months Ended March 31, 2019
Manufacturing and supply	$ 44
Research and development	208
Selling, general and administrative	1,268
Total share-based compensation expenses	$ 1,520
Share-based compensation from:	
Restricted Stock Units	463
Stock Options	1,057
Total share-based compensation expenses	$ 1,520

Share-Based Compensation Equity Awards

Restricted Stock Unit Awards (RSUs)

No new RSU awards were granted during either of the three-month periods ended March 31, 2019 or 2018. The following table summarizes activity relative to the Company's awards of RSUs for the three-month period ended March 31, 2019.

	Number of Units	Weighted Average Grant Date Fair Value Per Share
	(In thousands)	
Unvested at December 31, 2018	205	$ 14.77
Granted	—	—
Vested	(30)	15.03
Forfeited	(3)	13.00
Unvested, March 31, 2019	172	$ 14.75

The total grant date fair value of shares vested in the period ended March 31, 2019 was $448. As of March 31, 2019, there was approximately $2,077 of unrecognized compensation costs related to awards of RSUs. These costs are expected to be recognized over a weighted-average period of less than three years.

Stock option awards

No stock options were granted during the three-month period ended March 31, 2018 and accordingly, the following table summarizes the Company's stock option activity only during the three-month period ended March 31, 2019:

	Number of Options	Weighted Average Exercise Price
	(In thousands)	
Outstanding at December 31, 2018	1,033	$ 14.72
Granted	845	$ 7.96
Exercised, Forfeited, Expired	—	
Outstanding at March 31, 2019	1,878	$ 11.68
Vested or expected to vest at March 31, 2019	1,745	$ 11.68
Exercisable at March 31, 2019	146	$ 15.04

The weighted average grant date fair value of stock options granted during 2019 was $5.81. The fair values of stock options granted were estimated using the Black-Scholes-Merton pricing model based on the following assumptions:

	Three Months Ended March 31, 2019
Expected dividend yield	None
Expected volatility	85%
Expected term (years)	6.1
Risk-free interest rate	2.5 - 2.6%

During the three months ended March 31, 2019, options were granted with exercise prices ranging from $7.18 to $8.05, and accordingly, given Aquestive's share price of $6.91 at the close of the Company's first quarter of 2019, these options provided no intrinsic value at that date. Certain shares granted in 2018 provided intrinsic value of $30 at March 31, 2019.

As of March 31, 2019, $12,375 of total unrecognized compensation expenses related to non-vested stock options is expected to be recognized over a weighted average period of 2.6 years from the date of grant.

Employee stock purchase plan

The Company's Board of Directors adopted the Aquestive Therapeutics, Inc. Employee Stock Purchase Plan ("ESPP") in June 2018, as amended and restated effective as of January 1, 2019. Rollout of the ESPP began in late 2018, and initial employee purchases are expected to be made in 2019. The Company may offer common stock purchase rights biannually under offerings that allow for the purchase of common stock at the lower of 85% of the fair value of shares on either the first or last day of the offering period. No purchases under the ESPP occurred in the three months ended March 31, 2019.

Note 16. 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, 2019 and 2018, the Company recorded no income tax benefit from its pretax loss of $14,726 and pretax income of $4,099, respectively, due to realization uncertainties.

The Company's U.S. Federal statutory rate is 21%. The primary factor impacting the effective tax rate for the three months ended March 31, 2019 is the anticipated full year operating loss which will require full valuation allowances against any associated net deferred tax assets.

Note 17. Commitments and Contingencies

(A) Operating Leases

The Company has entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options. Certain leases contain purchase options and require the Company to pay for taxes, maintenance and operating expenses. All of the Company's leases are classified as operating leases.

Rent expense for all leased manufacturing facilities and sales, laboratory and office space was $372 and $331 for the three-month periods ended March 31, 2019 and 2018, respectively.

(B) Litigation and Contingencies

From time to time, the Company has been and may again become involved in legal proceedings arising in the ordinary course of business, including product liability, intellectual property, commercial litigation, or environmental or other regulatory matters. Except as described below, Aquestive is not presently a party to any litigation or legal proceedings that is believed to be material.

Patent-Related Litigation

Beginning in August 2013, we were informed of ANDA filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc., or "Actavis"), Par Pharmaceutical, Inc.("Par"), Alvogen Pine Brook, Inc. ("Alvogen"), Teva Pharmaceuticals USA, Inc. ("Teva"), Sandoz Inc. ("Sandoz"), and Mylan Technologies Inc. ("Mylan"), for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. We filed patent infringement lawsuits against all six generic companies in the U.S. District Court for the District of Delaware. After the commencement of the ANDA patent litigation against Teva, Dr. Reddy's Laboratories ("DRL") acquired the ANDA filings for Teva's buprenorphine and naloxone sublingual film that are at issue in these trials.

Of these, cases against three of the six generic companies have been resolved.

- *Mylan* and *Sandoz* settled without a trial. Sandoz withdrew all challenges and became the distributor of the authorized generic.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement between us, Indivior, and Par and certain of its affiliates.
- *Actavis* was found to infringe the '514 patent and cannot enter the market. The case is on appeal.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the case is on appeal. *Teva* has agreed to be bound by all DRL adjudications.

Subsequent to the above, all potential generic competitors without a settlement agreement were also sued for infringement of two additional new patents that contain new claims not adjudicated in the original case against DRL and Alvogen. All previously decided cases are on appeal and oral arguments were heard on April 1, 2019. The case(s) regarding the additional asserted patents have not been finally resolved. The case against Actavis, pending in the U.S. District Court for the District of Delaware, is scheduled for trial in December 2019. No trial date has been set in the cases against DRL and Alvogen, which are pending in the U.S. District Court for the District of New Jersey. On February 19, 2019, the Federal Circuit issued its mandate reversing the District of New Jersey's preliminary injunction against Dr. Reddy's. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both Dr. Reddy's and Alvogen. Thereafter, on February 19, 2019, Indivior launched the authorized generic of Suboxone Sublingual Film, which we manufacture exclusively for sale and marketing by Sandoz, a sublicensee of Indivior. Dr. Reddy's, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by Dr. Reddy's and Alvogen are "at risk" because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, we and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. for infringement of the '150, '514, '454, and '305 patents, seeking an injunction and potential monetary damages. The case is pending in the Southern District of Florida, and the defendants have not yet filed their answers to the complaint.

We are also seeking to enforce our patent rights in multiple cases against BioDelivery Sciences International, Inc. ("BDSI"). Two cases are currently pending but stayed in the U.S. District Court for the Eastern District of North Carolina:

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of invalidity and non-infringement of U.S. Patents Nos. 7,897,080, or the '080 patent, 8,652,378, or the '378 patent, and 8,475,832, or the '832 patent. This case is stayed pending final resolution of the above-mentioned appeals on related patents.
- The second was filed by us and Indivior related to BDSI's infringing Bunavail product, and alleges infringement of our patent, U.S. Patent No. 8,765,167, or the '167 patent, and seeks an injunction and potential monetary damages. Shortly after the case was filed, BDSI filed four (4) IPR's challenging the asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding that all claims of the '167 patent were valid. The case was stayed in May 2016 pending the final determination of the appeals on those decisions. Following the PTAB's February 7, 2019 decisions on remand denying institution, we and Indivior submitted a notice to the Court on February 15, 2019 notifying the Court that the stay should be lifted as result of the PTAB's decisions. We are awaiting further action from the Court.
- On January 13, 2017, we also sued BDSI asserting infringement of the '167 patent by BDSI's Belbuca product and seeking an injunction and potential monetary damages. Following the PTAB's February 7, 2019 decisions on remand denying institution, the Company submitted a notice to the Court on February 15, 2019 notifying the Court that BDSI's motion to stay should be denied as moot. BDSI also sent a letter to the Court on February 13, 2019 indicating its intent to appeal the PTAB's decisions. The parties are awaiting further action from the Court. BDSI appealed the PTAB's remand decisions to the Federal Circuit, and on March 20, 2019, we moved to dismiss the appeal for lack of jurisdiction.

Antitrust Litigation

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us 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 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 we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we 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. We moved to dismiss the States' conspiracy claims but, by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States' claims on November 20, 2017. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The case is currently in the expert discovery phase, which is scheduled to close May 30, 2019. We are 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.

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, 2018 and 2017 included in our 2018 Annual Report on Form 10-K.

Forward-Looking Statements

This Quarterly Report on Form 10-Q and certain other communications made by us contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), including statements about our growth and future operating results, discovery and development of products, strategic alliances and intellectual property. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We often use the words "believe," "anticipate," "plan," "expect," "intend," "may" and similar expressions to help identify forward-looking statements. We cannot assure you that our estimates, assumptions and expectations will prove to have been correct. These forward-looking statements include, among others, statements about: the success of our sales and manufacturing efforts in support of the commercialization of any of our products or product candidates; the size and growth of the potential markets for our products or candidates and our ability to serve those markets; the Company's plans to expand the use of any of our products or candidates to additional indications and opportunities, and the timing and success of any related clinical trials; the related timing and success of United States Food and Drug Administration New Drug Applications; the outcome of any matters related to patent procurement, protection or prosecution, or matters related to infringement; the outcome of existing antitrust litigation; our plans to evaluate, develop and pursue additional product candidates; clinical trials in support of existing or potential products; our commercialization and marketing capabilities; our ability to effectively outsource certain operational and staff functions to third-parties; our expectations regarding the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory action affecting pharmaceutical product pricing, reimbursement or access; claims and concerns that may arise regarding the safety or efficacy of our products and product candidates; changes in governmental laws and regulations; loss of significant customer relationships; the impact of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements, including, without limitation, those described in our 2018 Annual Report on Form 10-K under Part I – Item 1A "Risk Factors" filed with the Securities and Exchange Commission ("SEC") on March 14, 2019, in this Quarterly Report under Part II – Item 1A "Risk Factors," and in our other filings with the SEC. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, and readers should not rely on the forward-looking statements as representing our views as of any date after the date of the filing of this Quarterly Report on Form 10-Q.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing differentiated products to address unmet medical needs. We have three commercial products on the market, including one that is proprietary and two that are out-licensed, as well as a late-stage proprietary product pipeline focused on the treatment of CNS diseases. We believe that the characteristics of these patient populations and shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines. Sympazan, an oral soluble film formulation of clobazam used as an adjunctive therapy for seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut Syndrome, LGS, was approved by the FDA on November 1, 2018. The Company commercially launched Sympazan in December 2018.

Our most advanced proprietary investigational product candidates include:

- Libervant™, a buccal soluble film formulation of diazepam used as a rescue therapy for breakthrough epileptic seizures and an adjunctive therapy for use in recurrent convulsive seizures, for which a pre-NDA meeting was held in December 2018 with the FDA. The meeting resulted in a plan to complete a small single-dose crossover study comparing Libervant to the reference listed drug, Diastat. This study was initiated in the first quarter of 2019. The Company also agreed with the FDA to begin a rolling NDA submission process during the second quarter of 2019; and

- Exservan™, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we have submitted an NDA in the first quarter of 2019; the PDUFA goal date for FDA approval is November 30, 2019.

We have also developed a proprietary pipeline of complex molecule-based products addressing market opportunities beyond CNS indications, which include:

- AQST-108, a sublingual soluble film formulation for the treatment of anaphylaxis and severe allergic reactions, which is intended to provide an alternative to injection treatments such as EpiPen. After the Company's first human proof of concept trials, a re-formulated and more advanced prototype has been developed, for which we began additional phase 1 proof of concept trials early in the second quarter of 2019; and

- AQST-305, a sublingual soluble film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors. As a result of early stage proof of concept studies re-formulation work is currently underway.

In addition to these product candidates, we have a portfolio of commercialized and development-stage licensed products. Our largest commercialized licensed product to date is Suboxone, a sublingual film formulation of buprenorphine and naloxone, for the treatment of opioid dependence. We have a sole and exclusive worldwide manufacturing agreement with Indivior to deliver both the branded Suboxone, globally through Indivior, and the authorized generic sublingual film formulation of buprenorphine and naloxone, through Sandoz for the United States market. We manufacture all of our licensed and proprietary products at our FDA- and DEA-inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. There is no guarantee that proprietary or licensed products will necessarily be manufactured by the Company. We have produced over 2 billion doses of Suboxone and other commercial non-pharmaceutical products for all customers since 2006. Our products are developed using our proprietary PharmFilm® technology and know-how.

On July 27, 2018, we closed the initial public offering ("IPO") and on August 15, 2018, the underwriter's overallotment option was exercised. A total of 4,925,727 shares of common stock were issued. On July 25, 2018, the Company began trading on the Nasdaq Global Market under ticker symbol "AQST". The offering and overallotment resulted in aggregate gross proceeds of $73,886 before underwriting discounts and other costs and expenses of the offering. Total net proceeds to Aquestive after underwriters' discounts and other costs and expenses of the IPO totaled $63,482.

We generated revenue of $12,643 and $23,411 for the three months ended March 31, 2019 and 2018, respectively, largely from commercial products licensed to our collaboration or commercialization licensees in addition to manufacturing and supply revenue. Total revenues also included licensing, royalty and co-development and research fees and our proprietary product sales. Our licensed revenue is subject to the normally uneven nature of the timing of co-development and licensing milestone payments, and to the volumes of product our licensees sell on the market from which we receive royalties and manufacturing revenues. Suboxone, which was launched in 2010, was our first licensed pharmaceutical product to be commercialized, and we have other licensing relationships that contribute to our revenue and future revenue opportunities. Sympazan, which was launched in December 2018, is the first proprietary pharmaceutical product commercialized directly by the Company. As of March 31, 2019, we had $39,934 in cash and cash equivalents. As a result of our investments in product development and recent investments in commercialization initiatives, as well as the settlement of obligations related to our MonoSol Rx, LLC Performance Unit Plan through the issuance of non-voting common stock, as of March 31, 2019, we had a net shareholders' deficit of $6,056. For the three months ended March 31, 2019, we incurred a net loss of $14,726, and for the three months ended March 31, 2018, we generated net income of $4,099.

We expect to continue to incur net losses for at least the next two years as we pursue the development, commercialization and marketing of our proprietary product candidates. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on our other research and development, as well as our commercialization activities. Our expenses may fluctuate substantially over time as we:

- fund commercialization investments for Sympazan (launched in December 2018) and, subject to FDA approval, Libervant, our epilepsy products, and Exservan, our ALS product;

- continue clinical development of our complex molecules, AQST-108 and AQST-305;

- identify and evaluate new pipeline candidates in CNS diseases and other indications; and

- fund working capital requirements and expected capital expenditures as a result of the launch of proprietary products and related growth.

Our business has been financed through a combination of revenue from licensed product activities, proceeds from our IPO, equity investments from our stockholders and debt proceeds from our credit facilities. We expect to require additional capital to finance execution of our business strategy. We expect to refinance our current debt facility later in 2019 in order to provide increased flexibility as we continue to execute our business plan.

Aquestive is subject to risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on a very limited number of products and services for the substantial majority of its revenues, reliance on a single manufacturing site, new technological innovations, dependence on key personnel, reliance on third-party service providers and sole source suppliers, protection of proprietary technology, compliance with government regulations, dependency on the clinical and commercial success of our drug candidates, ability to obtain regulatory approval of our drug candidates, uncertainty of broad adoption of the recently-launched Sympazan or other approved products, if any, by payers, physicians, and consumers, significant competition, untested manufacturing capabilities and risks related to cybersecurity.

Critical Accounting Policies and Use of Estimates

See Note 3, *Summary of Significant Accounting Policies*, to our condensed consolidated financial statements, included herein for a discussion of recently issued accounting pronouncements and their impact or future potential impact on our financial results, if determinable. For a discussion of critical accounting policies that affect our judgments and estimates used in the preparation of our consolidated financial statements, refer to "*Critical Accounting Policies and Use of Estimates*" in our 2018 Annual Report on Form 10-K.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other things, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. 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 no later than on the relevant dates on which adoption of such standards is required for emerging growth companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an "emerging growth company" we intend to rely on such exemptions, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 and (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act. These exemptions will apply for a period of five years following the consummation of our IPO or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

We are also a "smaller reporting company," meaning that 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," and have either: (i) a public float of less than $250 million or (ii) annual revenues of less than $100 million during the most recently completed fiscal year and (A) no public float or (B) a public float of less than $700 million. As a "smaller reporting company," we are subject to reduced disclosure obligations in our SEC filings, including with respect to executive compensation in our periodic reports and proxy statements and certain reduced financial disclosures in our periodic reports.

Financial Operations Overview

Revenues

Our revenues to date have been earned from our product development pipeline, marketed product activities and self-developed medicines. These activities generate revenues in four primary categories: manufacturing and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

Manufacture and Supply Revenue

Currently, we produce two licensed pharmaceutical products: Suboxone and Zuplenz. We are the exclusive manufacturer for these products. 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. Under ASC 606, we record revenues once the manufactured product passes quality control. Our licensees are responsible for all other aspects of commercialization of these products.

We expect future revenue from licensed activities to be based on volume demand for licensed products, new collaborations for product development, and additional licensing of our intellectual property.

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

Once a viable product opportunity is identified from our co-development and research activities with our licensees, we may out-license to our licensees the rights to utilize our intellectual property related to their marketing of such products. As a result, we earn revenue from license fees received under such license, development and supply agreements. We also may earn royalties based on our licensees' sales of products that use our intellectual property that are marketed and sold in the countries where we patented technology rights.

Proprietary Product Sales

As we commercialize our proprietary CNS product candidates, beginning with Sympazan, as well as Libervant and Exservan, subject to regulatory approval, we expect to directly market our products to consumers in the United States, resulting in an additional source of revenue which we refer to as Proprietary Product Sales. We commercialized our first proprietary CNS product, Sympazan, in December 2018. We currently sell Sympazan through wholesalers for distribution primarily through retail pharmacies. Additionally, we may choose to select a collaborator to commercialize our product candidates in certain markets outside of the United States. To date, the only revenue generated from our self-developed and self-commercialized pharmaceutical products is from the sale of Sympazan in the United States.

Revenues from sales of products are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and Co-pay card 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.

Prompt Pay Discounts

The prompt pay reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. We accrue discounts to wholesalers based on contractual terms of agreements. We account for these discounts at the time of sale as a reduction to gross product sales and a reduction to accounts receivable.

Wholesaler Service Fees

Our customers include major and regional wholesalers with whom we have contracted a fee for service based on a percentage of gross product sales. This fee for service is recorded as a reduction to gross product sales and an increase to accrued expenses at the time of sale and is recorded based on the contracted percentage.

Returns Allowances

We allow customers to return product that is damaged or received in error. In addition, we allow Sympazan to be returned beginning six months prior to, and twelve months following product expiration. We estimate our sales returns reserve based on industry averages until which time we have accumulated enough data to apply a historical trend analysis. The returns reserve is recorded at the time of sale as a reduction to gross product sales and accounts receivable.

Rebates

Rebates include third party Managed Care and Medicare Part D rebates, Medicaid rebates and other government rebates. Rebates are accrued based upon an estimate of claims to be paid for product sold into trade by the Company. The provisions for government rebates was based in part by contractual terms and government regulations. We monitor legislative changes to determine what impact such legislation might have on our Company. We account for these deductions as a reduction of gross products sales and an increase in accrued expenses.

Co-Pay Cards

Co-pay card redemptions costs represent the costs to buy down a customer's co-pay or cover a predetermined amount of prescription based on business rules. We account for these deductions as a reduction of gross product sales and an increase in accrued expenses.

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 commercialization efforts related to our CNS product candidates, intellectual property procurement, protection, prosecution and litigation expenses, corporate management functions 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 comprised primarily of costs and expenses related to manufacturing our proprietary dissolving film products for our marketed licensed pharmaceutical products and for our newly approved proprietary products including raw materials, direct labor and fixed overhead principally in our Portage, Indiana facilities. In 2019, we expect the costs of our proprietary products manufactured to be a greater factor in these expenses, but such costs were minimal in 2018. Our material costs include the costs of raw materials, other than the API component of Suboxone, 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. Fixed and semi-fixed overhead principally consists of indirect payroll, facilities rent, utilities and depreciation for leasehold improvements and production machinery and equipment.

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 our manufacture and supply costs and expenses to increase over the next several years due to the commercialization of Sympazan launched in December 2018 and as we commercialize and begin to market, following regulatory approval, our product candidates, including Libervant and our ALS product candidate, Exservan. Additionally, we expect to incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from our commercialization of these products and product candidates. As such, we expect our manufacturing and supply costs and expenses to increase as our product candidates receive regulatory approval and production begins.

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;
- external research and development expenses incurred under arrangements with third parties;
- 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 increase over the next several years as we expand our efforts to identify and develop additional product candidates. We will hire additional skilled colleagues 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, commercialization and marketing costs, and other related costs for executive, finance, selling and operational personnel. Other significant costs include facility and related costs not otherwise included in research and development expenses such as: professional fees for legal, consulting, tax and accounting services; insurance; selling; market research; advisory board and key opinion leaders; depreciation; and general corporate expenses, inclusive of IT systems related costs.

Historically, our selling, general and administrative expenses have been focused primarily on corporate management functions. However, costs related to commercialization of our CNS product candidates began in the second half of 2017 and significantly increased in 2018 as we progressed toward the launch of Sympazan in December 2018, and began initial preparations for the launch of Libervant, an additional late-stage epilepsy product currently subject to FDA approval. These costs are expected to increase in 2019, as we continue to support recently launched Sympazan and progress further towards Libervant's future commercial launch. Incremental marketing spending in preparation for the commercial launches of Libervant and Exservan is expected to be incurred prior to the PDUFA dates for these products and will be accordingly planned once those dates are known. As part of the commercial launch of Sympazan, we entered into contractual arrangements with a third-party logistics provider (3PL) and wholesalers for distribution of our products. We also entered into a contract for our contracted sales force and have established a market access account team. With this increased activity related to the commercial launch of Sympazan, we expect sales and marketing expenses to increase during 2019 as we continue to support our epilepsy franchise. We expect to be able to significantly leverage these now existing relationships for the future launches, subject to FDA approval, of Libervant and Exservan. In addition, our general and administrative costs increased as a result of becoming a public company, including costs related to additional personnel and accounting, audit, legal, regulatory, tax-related services, and other public company costs

Interest Expense

Interest expense consists of interest costs related to our debt facility, as well as amortization of loan costs and debt discounts. Our interest is subject to changes in one-month LIBOR and represents a monthly cash payment obligation. This debt facility is discussed in more depth in Liquidity and Capital Resources.

Interest Income

Interest income consists of earnings derived from an interest-bearing account. We expect to continue generating income in 2019 from our interest-bearing cash accounts, albeit on a declining cash balance that is expected to be applied to operating costs as needed.

Change in Fair Value of Warrant

Changes in the fair value of warrants resulted from non-cash periodic revaluations of the warrants issued to Perceptive Credit Opportunities Fund in connection with the debt facility. Effective with the automatic exercise of the warrants by Perceptive prior to our IPO in July 2018, these warrants are no longer outstanding and no future related charges to earnings will be incurred.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

We recorded revenue of $12,643 and $23,411 in the three months ended March 31, 2019 and 2018, respectively, generating a net loss of $14,726 for the three months ended March 31, 2019 and net income of $4,099 for the three months ended March 31, 2018.

Revenues

	Three Months Ended March 31,		Change	
	2019	2018	$	%
(In thousands, except %)				
Manufacture and supply revenue	$ 6,669	$ 11,560	$ (4,891)	(42%)
License and royalty revenue	4,622	9,500	(4,878)	(51%)
Co-development and research fees	770	2,351	(1,581)	(67%)
Proprietary product sales, net	582	-	582	NM
Revenues	$ 12,643	$ 23,411	$ (10,768)	(46%)

For the three months ended March 31, 2019, total revenues decreased 46% or $10,768 to $12,643 compared to revenues of $23,411 for the same period in 2018. The change is primarily attributable to decreases in manufacture and supply revenue, license and royalty revenue, and in co-development and research fees, offset in part by an increase in product sales revenue.

Manufacture and supply revenue decreased approximately 42% or $4,891 to $6,669 for the three months ended March 31, 2019 compared to $11,560 from the prior year period. This decrease is attributable to lower Suboxone production volume due primarily to the timing of purchase orders placed by Indivior for Suboxone. While our first half volume of orders is comparable on a year-over-year basis and higher than the last six months of 2018, the timing of production of these purchase orders and therefore when they are recognized for revenue shifted following the US court of appeals lifting a preliminary injunction allowing generic competitors into the US Suboxone market "at risk" while patent infringement cases against those generic manufactures are tried to conclusion.

License and royalty revenue decreased 51% or $4,878 to $4,622 for the three months ended March 31, 2019 compared to revenues of $9,500 from the prior year period. This change was primarily related to the timing of license and new patent fees on our licensed product Suboxone. License fees totaled $4,389 for the three months ended March 31, 2019 compared to $9,250 of license fees recognized during the prior year comparative period. Suboxone related license fees were $5,000 lower compared to 2018, as a result of two factors; the uneven timing and magnitude of the various payments owed to the company by Indivior and the fact that all license fees due from Indivior have been suspended pending the outcome of litigation related to infringement claims against the generic products launched "at risk." If these matters are not settled between the parties prior to a decision by the courts involved, and Indivior and the company prevail this could result in significant damages paid by the "at risk" generic manufactures sometime in the future. Royalty revenues earned on Suboxone and Zuplenz remained flat year-over-year on similar product sales volumes flowing through our licensees' sales and distribution channels. License fees are generally driven by transfer of rights, patent performance contingencies, specific FDA or other regulatory achievements, sales levels achievements or other contingencies and milestones, and will likely fluctuate significantly from quarter-to-quarter.

Co-development and research fees decreased 67% or $1,581 to $770 for the three months ended March 31, 2019 compared to $2,351 from the prior year period. The decrease was driven by the timing of the achievement of research and development performance obligations on licensed products and related milestones, and are normally expected to fluctuate significantly one reporting period to the next.

Product sales, net increased $582 or 100% for the three months ended March 31, 2019 compared to the prior year period, due to the launch of our first proprietary self-developed medicine, Sympazan, in December 2018.

Expenses and Other:

	Three Months Ended March 31,		Change	
	2019	2018	$	%
(In thousands, except %)				
Manufacturing and supply	$ 3,506	$ 5,636	$ (2,130)	(38%)
Research and development	4,303	4,901	(598)	(12%)
Selling, general and administrative	17,908	7,569	10,339	137%
Interest expense	1,926	1,927	(1)	0%
Interest income	(274)	(24)	250	NM
Change in fair value of warrants	--	(697)	697	NM

Manufacturing and supply costs and expenses decreased 38% or $2,130 to $3,506 for the three months ended March 31, 2019 compared to $5,636 for the same period in 2018. This decrease was primarily driven by lower production costs due to the lower volume of Suboxone production associated with the timing of purchase orders by Indivior for the three months ended March 31, 2019.

Research and development expenses decreased 12% or $598 to $4,303 for the three months ended March 31, 2019 compared to $4,901 in the prior year period. The change was primarily attributable to a decrease in clinical trial expenses of $1,332 due to timing of clinical trial activities, offset by an increase of $209 related to share-based compensation allocable to research and development, organizational growth, and the addition of new functional capabilities since March 31, 2018.

Selling, general and administrative expenses increased 137% or $10,339 to $17,908 for the three months ended March 31, 2019 as compared to $7,569 for the prior year period. This increase is primarily due to $4,057 of investments in our commercialization, branding and marketing capabilities for Sympazan and in preparation for the expected launches of Libervant and Exservan. These costs included those for personnel, external consultants and other resources that enabled us to establish key commercial functions such as sales and marketing, market access and medical affairs. We incurred $1,318 of increased legal fees in connection with the ongoing state anti-trust litigation and other patent related matters, and $1,268 of share-based compensation expense. Further, additional personnel and other external resources have been engaged to further assist us in operations as a public company, as well as higher unabsorbed factory overhead as a result of lower production of Suboxone period over period also contributed to the overall increase in these expenses.

Interest expense remained flat for the three months ended March 31, 2019 compared to the same period in 2018. Our interest expense is subject to fluctuations based on one-month LIBOR.

Interest income increased $250 to $274 for the three months ended March 31, 2019, compared to $24 of interest income for the same period in 2018. This increase is a result of investing the net cash proceeds from our IPO in an interest-bearing account.

Change in the fair value of warrants decreased by $697 for the three months ended March 31, 2019 compared to the same period in 2018. For periods prior to our IPO, which was effective July 24, 2018, we remeasured the fair value of outstanding warrants each quarter in accordance with the AICPA Practice Aid, Valuation of Privately-Held Company Equity Securities issued as compensation. The Company had no outstanding warrants during the three months ended March 31, 2019.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and as of March 31, 2019, we have a net stockholders' deficit of $6,056. We have funded our operations primarily with equity and debt financings and manufacture and supply revenue as well as and milestone and royalty payments from our licensees.

We had $39,934 in cash and cash equivalents as of March 31, 2019. We have no committed sources of capital and our borrowing capability under the debt facility is fully drawn. However, we expect to refinance our senior secured debt facility during 2019.

Credit Agreement and Guaranty

On August 16, 2016, we entered into a Credit Agreement and Guarantee with Perceptive Credit Opportunities Fund, LP, which we amended on May 21, 2018, or, as so amended, the Loan Agreement. At closing, we borrowed $45,000 under the Loan Agreement and were permitted to borrow up to an additional $5,000 within one year of the closing date based on achievement of a defined milestone. In March 2017, we met our performance obligations under the terms of the Loan Agreement and received the remaining $5,000 available to us under the Loan Agreement. Proceeds under the Loan Agreement were used to repay an existing debt obligation of $37,500, with the balance available for general corporate purposes. The loan from Perceptive was originally scheduled to mature on August 16, 2020. However, upon the consummation of our IPO, the maturity date of the Loan Agreement was extended to December 16, 2020. The loan bears interest, payable monthly, at one-month LIBOR, currently approximately 2.75%, plus 9.75%, subject to a minimum rate of 11.75%. The loan is interest-only through April 2019, as amended.

Additionally, pursuant to the Loan Agreement, commencing on May 31, 2019, seven monthly principal payments are due in the amount of $550. Thereafter, monthly principal payments in the amount of $750 are due through the maturity date (as extended), at which time the full amount of the remaining outstanding loan balance is due. Our tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms of the Loan Agreement include financial covenants, change of control triggers, and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. The Loan Agreement contains certain financial covenants, which include (1) a minimum liquidity requirement pursuant to which we must maintain a monthly cash balance of $4,000 at all times and (2) a minimum revenue requirement pursuant to which on a quarterly basis (calculation date) we must maintain minimum revenues for the twelve consecutive trailing months ended prior to the calculation date. Further, under the Loan Agreement, as amended, we are permitted, subject to Perceptive's consent, to monetize the royalty and fees derived from sales of certain Apomorphine products and, in connection with such monetization, Perceptive has agreed to release liens related to these royalties and fees. Further, the Loan Agreement originally contained a requirement that we make a mandatory prepayment in the amount of 25% of the net cash proceeds to us upon consummation of our IPO; however, as amended, in connection with the consummation of our IPO, such requirement did not apply.

As of March 31, 2019, we were compliant with all financial and other covenants under the Loan Agreement.

Upon the closing of our IPO, Perceptive received 863,400 shares of common stock issuable pursuant to the automatic exercise of warrants for a total exercise price of $116.

Cash Flows

Three Months Ended March 31, 2019 and 2018

(In thousands)	2019	2018
Net cash (used for) provided by operating activities	$ (17,680)	$ 785
Net cash (used for) investing activities	(376)	(259)
Net cash (used for) financing activities	(2,609)	(1,417)
Net decrease in cash and cash equivalents	$ (20,665)	$ (891)

Net Cash (Used for) Provided by Operating Activities

Net cash used for operating activities for the three months ended March 31, 2019 was $17,680. The use of cash can be understood as represented by three major factors: 1) our net loss of $14,726, 2) decrease in operating assets and liabilities of $6,128 partially offset by 3) non-cash operating expenses. The non-cash operating expenses of $3,174 primarily resulted from $1,520 of share-based compensation expense recorded in the first quarter of 2019. Other significant components included non-cash charges of $1,654 related to non-cash charges such as depreciation, amortization and amortization of debt issuance costs.

Net cash provided by operating activities for the three months ended March 31, 2018 was $785 and was attributed to $4,099 net income partially offset by non-cash charges to 2018 earnings of $771, which included depreciation and amortization of long-lived assets, amortization of debt issuance costs and changes in the fair value of the Perceptive warrants. Further offsets to the net income were provided by changes in working capital accounts totaling $4,085, primarily through collections of trade receivables and increases in trade payables as management sought to optimize our liquidity.

Net Cash (Used for) Investing Activities

Net cash used for investing activities was $376 for the three months ended March 31, 2019 compared to $259 for the three months ended March 31, 2018. This decrease in net cash used for investing activities was primarily attributable to timing of capital expenditures for plant and equipment purchases.

Net Cash (Used for) Financing Activities

Net cash used for financing activities was $2,609 for the three months ended March 31, 2019 compared to $1,417 for the three months ended March 31, 2018. The cash used in 2019 is a result of the payment of withholding taxes associated with tax reimbursement payments from the share-based compensation recorded during 2018. Net cash used for financing activities in the prior year period was primarily a result of transaction costs incurred related to our IPO.

Funding Requirements

We believe that our existing cash, including the net proceeds from our initial public offering, combined with our expected revenue from our licensed product activities and Sympazan will be sufficient to fund our operations at least through the next 12 months of operations, including our planned investments in the commercialization of our late stage CNS product candidates and other expected costs and expenses, including those related to research and development investments in our complex molecule product pipeline candidates, capital expenditures and investments in new product candidates in epilepsy and other CNS diseases. We have based this expectation on assumptions that could change, and we could utilize our available financial resources sooner than we currently expect.

The key assumptions underlying this expectation include:

- continued funding of our commercialization costs for Sympazan, our first proprietary product launched in December 2018,
- continued funding of our development and pre-launch commercialization of CNS products Libervant, Exservan and our other proprietary product candidates;
- continued revenue from our proprietary and licensed products, and;

- the infrastructure and administrative costs to support being a public company.

While we expect to pursue non-dilutive capital opportunities around our future royalty streams and our refinancing options surrounding our secured debt facility, at this time we have no committed sources of additional capital. We are currently pursuing refinancing of our debt facility in order to provide financial flexibility in executing our business plan. Additionally, we may attempt to pursue additional capital during favorable conditions, or when other strategic opportunities may become available, even if we have sufficient funds for planned operations. Until we become profitable, if ever, we expect to need to raise additional capital in the future to further the commercialization of Sympazan and advance the development and commercialization of our CNS products, Libervant and Exservan, and of our other product candidates, and there can be no assurance that such needed capital or debt financing will be available on favorable terms, or at all. We may seek to obtain additional financing in the future through the monetization of royalty streams from licensed products such as APL-130277 subject to our licensing agreement with Sunovion Pharmaceuticals, Inc., and KP-415 and KP-484, both associated with KemPharm, Inc., and/or others (but we cannot be assured of any such royalty streams or monetization of any such streams), the issuance of our common stock, other public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We may not be able to raise additional capital or financing on terms acceptable to us, or at all, and any failure to raise capital or financing as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders may experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative or licensing arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position.

If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate our research and development programs, or reduce our planned commercialization efforts. 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.

Our costs associated with operating as a new public company have increased, and we expect to incur additional costs to support the obligations of a public company to various regulatory agencies, to investors and in order to comply with certain legislation and regulations, such as the Sarbanes-Oxley Act of 2002. These expenditures include the costs of additional employees with specific skills and experiences such as SEC reporting or internal controls as well as additional costs to outside service providers such as audit, tax and legal fees.

See also Part II, Item 1A, Risk Factors below concerning Indivior and recent criminal proceedings in connection with its allegedly deceptive and misleading practices related to its marketing and distribution of its Suboxone film product, dating back a number of years. We have to date not experienced any significant reduction in purchase orders from Indivior for the manufacture and supply of Suboxone film products, other than what we believe is attributable to the entry of at-risk generics.

Off-Balance Sheet Arrangements

During the period presented, there were no material changes in our operating leases, our only off-balance sheet arrangements as defined in the rules and regulations of the SEC.

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

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest expense from fluctuations in one-month LIBOR associated with our debt facility. For each 1% increase in one-month LIBOR in excess of the floor of 2%, our annual interest expense would increase by approximately $500,000. For 2019, our interest rate received is approximately 2.3% for cash deposited in the interest-bearing account. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes. We are in the process of developing a comprehensive investment strategy for our cash and cash equivalents whose underlying premise would be to preserve principal while at the same time maximizing the income that we received from our investments without significantly increasing risk.

Our accounts receivables are concentrated predominantly with Indivior. With the recent launch of Sympazan, our concentration with three large national wholesalers of pharmaceutical products is not significant presently but may become so in future periods should Sympazan sales increase and should other pipeline products become approved by the FDA and become distributed through these three national, or other, wholesalers. In the event of non-performance or non-payment by either Indivior or the wholesalers, there may be a material adverse impact on our financial condition, results of operations or net cash flow.

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

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms, and that such information is accumulated and communicated to us, including to our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and we necessarily were required to apply our judgment in evaluating whether the benefits of the controls and procedures that we adopt outweigh their costs.

As required by Rule 13a-15(b) of the Exchange Act, an evaluation as of March 31, 2019 was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures, as of March 31, 2019, were effective for the purposes stated above.

Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on Effectiveness of Controls

Our management, including the Chief Executive Officer and Chief Financial Officer, believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, they cannot provide absolute assurance that all control issues and instances of fraud, if any, within Aquestive have been prevented or detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by unauthorized override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Accordingly, because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and many not be detected.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we have been and may again become involved in legal proceedings arising in the course of our business. Except as described below, we are not presently a party to any litigation or legal proceedings that we believe to be material.

Patent-Related Litigation

Beginning in August 2013, we were informed of ANDA filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc., or "Actavis"), Par Pharmaceutical, Inc.("Par"), Alvogen Pine Brook, Inc. ("Alvogen"), Teva Pharmaceuticals USA, Inc. ("Teva"), Sandoz Inc. ("Sandoz"), and Mylan Technologies Inc. ("Mylan"), for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. We filed patent infringement lawsuits against all six generic companies in the U.S. District Court for the District of Delaware. After the commencement of the ANDA patent litigation against Teva, Dr. Reddy's Laboratories ("DRL") acquired the ANDA filings for Teva's buprenorphine and naloxone sublingual film that are at issue in these trials.

Of these, cases against three of the six generic companies have been resolved.

- *Mylan* and *Sandoz* settled without a trial. Sandoz withdrew all challenges and became the distributor of the authorized generic.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement between us, Indivior, and Par and certain of its affiliates.
- *Actavis* was found to infringe the '514 patent and cannot enter the market. The case is on appeal.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the case is on appeal. *Teva* has agreed to be bound by all DRL adjudications.

Subsequent to the above, all potential generic competitors without a settlement agreement were also sued for infringement of two additional new patents that contain new claims not adjudicated in the original case against DRL and Alvogen. All previously decided cases are on appeal and oral arguments were heard on April 1, 2019. The case(s) regarding the additional asserted patents have not been finally resolved. The case against Actavis, pending in the U.S. District Court for the District of Delaware, is scheduled for trial in December 2019. No trial date has been set in the cases against DRL and Alvogen, which are pending in the U.S. District Court for the District of New Jersey. On February 19, 2019, the Federal Circuit issued its mandate reversing the District of New Jersey's preliminary injunction against Dr. Reddy's. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both Dr. Reddy's and Alvogen. Thereafter, on February 19, 2019, Indivior launched the authorized generic of Suboxone Sublingual Film, which we manufacture exclusively for sale and marketing by Sandoz Inc., a sublicensee of Indivior. Dr. Reddy's, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by Dr. Reddy's and Alvogen are "at risk" because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, we and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. for infringement of the '150, '514, '454, and '305 patents, seeking an injunction and potential monetary damages. The case is pending in the Southern District of Florida, and the defendants have not yet filed their answers to the complaint.

We are also seeking to enforce our patent rights in multiple cases against BioDelivery Sciences International, Inc. ("BDSI"). Two cases are currently pending but stayed in the U.S. District Court for the Eastern District of North Carolina:

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of invalidity and non-infringement of U.S. Patents Nos. 7,897,080, or the '080 patent, 8,652,378, or the '378 patent, and 8,475,832, or the '832 patent. This case is stayed pending final resolution of the above-mentioned appeals on related patents.

- The second was filed by us and Indivior related to BDSI's infringing Bunavail product, and alleges infringement of our patent, U.S. Patent No. 8,765,167, or the '167 patent, and seeks an injunction and potential monetary damages. Shortly after the case was filed, BDSI filed four (4) IPR's challenging the asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding that all claims of the '167 patent were valid. The case was stayed in May 2016 pending the final determination of the appeals on those decisions. Following the PTAB's February 7, 2019 decisions on remand denying institution, we and Indivior submitted a notice to the Court on February 15, 2019 notifying the Court that the stay should be lifted as result of the PTAB's decisions. We are awaiting further action from the Court.

- On January 13, 2017, we also sued BDSI asserting infringement of the '167 patent by BDSI's Belbuca product and seeking an injunction and potential monetary damages. Following the PTAB's February 7, 2019 decisions on remand denying institution, the Company submitted a notice to the Court on February 15, 2019 notifying the Court that BDSI's motion to stay should be denied as moot. BDSI also sent a letter to the Court on February 13, 2019 indicating its intent to appeal the PTAB's decisions. The parties are awaiting further action from the Court. BDSI appealed the PTAB's remand decisions to the Federal Circuit, and on March 20, 2019, we moved to dismiss the appeal for lack of jurisdiction.

Antitrust Litigation

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us 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 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 we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we 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. We moved to dismiss the States' conspiracy claims, but by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States' claims on November 20, 2017. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The case is currently in the expert discovery phase, which is scheduled to close May 30, 2019. We are 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.

Item 1A. Risk Factors

Our risk factors have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our 2018 Annual Report on Form 10-K except as set forth in the risk factor below.

A substantial portion of our revenues is currently derived from relatively few customers and licensees and any loss or material reduction in revenues from one or more significant customers could adversely affect our business.

Historically, a substantial portion of our revenues in each quarter and year has been derived from relatively few customers and licensees and this trend is expected to continue while we continue to develop, seek regulatory approvals of and seek to commercialize our proprietary products and product candidates. If revenues from a key customer were to decline significantly, it could materially adversely affect our business, financial condition and results of operations.

The U.S. Department of Justice recently announced that a federal grand jury sitting in the Western District of Virginia had criminally indicted Indivior, for which we exclusively manufacture and supply Suboxone film products and license certain of our intellectual property, in connection with Indivior's allegedly deceptive and misleading marketing and distribution practices in its distribution and sale of Suboxone film products, dating back a number of years, and seeking a monetary judgement of not less than $3 billion. Indivior has denied the claims and stated that it intends to contest the allegations vigorously. Indivior accounted for approximately 89% of our revenues for 2018 and in the future will continue to account for a substantial part of our revenues. We have to date not experienced any significant reduction in purchase orders from Indivior for the manufacture and supply of Suboxone film products, other than what we believe is attributable to the entry of at-risk generics. However, there can be no assurance that the claims against Indivior could not materially and adversely affect Indivior which, if this were to occur, could impact our supply and licensing relationship with Indivior and the volume and timing of its purchases from us, which could have a material adverse financial impact on our business, financial position and operating results.

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

None.

Use of Proceeds

On July 24, 2018, the SEC declared our Registration Statement on Form S-1 (Registration Nos. 333-225924 and 333-226326) for our IPO effective. There have been no material changes in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on July 25, 2018, pursuant to Rule 424(b) of the Securities Act.

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 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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, 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 8, 2019

/s/ Keith J. Kendall
Keith J. Kendall
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2019

/s/ John T. Maxwell
John T. Maxwell
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, Keith J. Kendall, 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.

Dated: May 8, 2019

/s/ KEITH J. KENDALL
Keith J. Kendall
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, John T. Maxwell, 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 annual 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.

Dated: May 8, 2019

/s/ JOHN T. MAXWELL
John T. Maxwell
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, Keith J. Kendall, 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, 2019, 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.

Dated: May 8, 2019

/s/ KEITH J. KENDALL
Keith J. Kendall
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, John T. Maxwell, 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 year ended March 31, 2019, 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.

Dated: May 8, 2019

/s/ JOHN T. MAXWELL
John T. Maxwell
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.