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 September 30, 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 common stock, par value of $0.001 per share, as of the close of business on November 1, 2019 was 25,042,964.

AQUESTIVE THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 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)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 20,914	$ 60,599
Trade and other receivables, net	10,316	6,481
Inventories, net	4,124	5,441
Prepaid expenses and other current assets	2,706	1,680
Total current assets	38,060	74,201
Property and equipment, net	10,351	12,207
Intangible assets, net	165	204
Other assets	242	239
Total assets	$ 48,818	$ 86,851
Liabilities and stockholders' (deficit)/equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,218	$ 27,631
Deferred revenue, current	835	721
Loans payable, current	-	4,600
Total current liabilities	20,053	32,952
Loans payable, net	59,775	42,603
Deferred revenue, net of current portion	2,127	—
Asset retirement obligations	1,322	1,216
Total liabilities	83,277	76,771
Commitments and contingencies (note 17)		
Stockholders' (deficit)/equity:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 25,042,964 and 24,957,309 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	25	25
Additional paid-in capital	83,354	71,431
Accumulated deficit	(117,838)	(61,376)
Total stockholders' (deficit)/equity	(34,459)	10,080
Total liabilities and stockholders' (deficit)/equity	$ 48,818	$ 86,851

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues	$ 12,418	$ 13,267	$ 36,190	$ 50,606
Costs and expenses:				
Manufacture and supply	4,643	5,592	13,569	16,201
Research and development	5,063	4,534	17,517	17,429
Selling, general and administrative	13,714	12,346	47,868	53,559
Total costs and expenses	23,420	22,472	78,954	87,189
Loss from operations	(11,002)	(9,205)	(42,764)	(36,583)
Other income/(expenses):				
Interest expense	(2,652)	(1,933)	(6,515)	(5,809)
Interest income	138	216	565	238
Loss on the extinguishment of debt	(4,896)	-	(4,896)	-
Change in fair value of warrant	-	(4,116)	-	(5,278)
Net loss before income taxes	(18,412)	(15,038)	(53,610)	(47,432)
Income taxes	-	-	-	-
Net loss	$ (18,412)	$ (15,038)	$ (53,610)	$ (47,432)
Comprehensive loss	$ (18,412)	$ (15,038)	$ (53,610)	$ (47,432)
Net loss per share - basic and diluted	$ (0.74)	$ (0.64)	$ (2.15)	$ (2.45)
Weighted-average number of common shares outstanding - basic and diluted	25,031,478	23,646,192	24,992,229	19,335,541

See accompanying notes to the condensed consolidated financial statements.

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

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity/ Deficit
For the periods ended September 30, 2019:					
Balance at January 1, 2019	24,957,309	$ 25	$ 71,431	$ (61,376)	$ 10,080
Adoption of ASU 2014-09, 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)
Share-based compensation	16,128	-	1,739	-	1,739
Shares issued under employee stock purchase plan	31,393	-	132	-	132
Net loss	-	-	-	(20,472)	(20,472)
Balance at June 30, 2019	25,022,660	$ 25	$ 74,744	$ (99,426)	$ (24,657)
Share-based compensation	20,304	-	1,810	-	1,810
Fair value of warrants issued	-	-	6,800	-	6,800
Net loss	-	-	-	(18,412)	(18,412)
Balance at, September 30, 2019	25,042,964	$ 25	$ 83,354	$ (117,838)	$ (34,459)
For the periods ended September 30, 2018:					
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)
Common Stock issued to performance unit plan participants	4,922,353	5	19,929	-	19,934
Share based compensation	-	-	7	-	7
Net loss	-	-	-	(36,493)	(36,493)
Balance at June 30, 2018	20,000,000	$ 20	$ (6,574)	$ (32,394)	$ (38,948)
Common Stock issued related in initial public offering	4,925,727	5	68,709	-	68,714
Issuance costs related to initial public offering	-	-	(5,230)	-	(5,230)
Reclassification of warrant liability to equity	-	-	12,951	-	12,951
Share-based compensation	16,458	-	995	-	995
Net loss	-	-	-	(15,038)	(15,038)
Balance at, September 30, 2018	24,942,185	$ 25	$ 70,851	$ (47,432)	$ 23,444

* 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.

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (53,610)	$ (47,432)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	2,143	2,438
Change in fair value of warrant	--	5,278
Share-based compensation	5,199	28,541
Asset retirement obligation accretion	106	102
Amortization of intangible	39	38
Amortization of debt issuance costs and discounts	1,338	1,297
Loss on extinguishment of debt	4,896	—
Non-cash interest expense	24	—
Bad debt provision	36	20
Other, net	16	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,887)	(1,291)
Inventories, net	1,317	(469)
Prepaid expenses and other assets	(1,029)	(889)
Accounts payable and accrued expenses	(5,632)	2,754
Deferred revenue	(591)	(566)
Net cash used for operating activities	(49,635)	(10,179)
Cash flows from investing activities:		
Capital expenditures	(577)	(1,334)
Net cash used for investing activities	(577)	(1,334)
Cash flows used for financing activities:		
Proceeds from initial offering of common stock	—	68,714
Proceeds from common stock issued via employee stock purchase plan	112	—
Proceeds from issuance of long-term debt	70,000	—
Debt repayment	(50,000)	—
Payments for loan acquisition costs	(3,918)	—
Payments for deferred offering costs	—	(4,695)
Premium paid to retire debt	(2,944)	—
Payments for taxes on share-based compensation	(2,723)	(5,903)
Net cash provided by financing activities	10,527	58,116
Net (decrease) increase in cash and cash equivalents	(39,685)	46,603
Cash and cash equivalents:		
Beginning of period	60,599	17,379
End of period	$ 20,914	$ 63,982
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 5,153	$ 4,511
Net (decrease) in capital expenditures included in accounts payable and accrued expenses	(290)	(145)
Net increase/(decrease) in offering costs included in accounts payable and accrued expenses	162	(515)
Accrued withholding tax for share based compensation	-	1,701
Deferred financing costs charged to additional paid in capital	-	5,230
Warrants issued in connection with long-term debt	6,800	-
Noncash component of warrants exercised	-	12,591

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" or the "Company") is a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs and solving 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 commercialization of self-developed proprietary products and through in-licensing and out-licensing arrangements. 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

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. The underwriter's over-allotment option was exercised in August 2018 and the Company issued 425,727 additional shares of common stock at $15.00 per share and the Company received additional net proceeds of approximately $5,939, after deducting underwriting 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 warrants issued in connection with the 12.5% Senior Secured Notes, 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 accounting 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, 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 the Company's manufacturing and supply product sales. Under the modified retrospective method of adoption, the comparative information in the consolidated financial statements has not been revised and continues to be reported under the previously applicable revenue accounting guidance, ASC 605.

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 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 September 30, 2019:

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842),* and subsequently issued clarifications and corrections to the update by issuing ASU 2018-10 in July 2018. This update requires lessees to recognize lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous authoritative guidance. Upon adoption, the lease liability will be equal to the present value of future lease payments and a right-of-use, or ROU, asset will be based on the lease liability, subject to adjustment for items such as initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating or financing. Operating leases will continue to result in straight-line expense while financing leases will result in a front-loaded expense pattern (similar to current accounting guidance by lessees for operating leases, respectively under ASC 840).

There are a number of practical expedients available to the Company at transition. The transition practical expedients are that the Company may elect to not re-assess: (i) whether its contracts contain a lease under the new definition, (ii) the classification of those leases and (iii) the accounting for any initial direct costs previously incurred. In addition, the Company may apply hindsight in determining the lease terms on its existing leases and any potential impairments that may exist on the ROU assets to be recognized on adoption, and the Company may elect to not recognize an ROU asset and lease liability for those leases with a remaining term of 12 months or less.

Upon adoption, ROU assets and lease liabilities will be recognized on the Company's consolidated balance sheets. The lease liability recognized upon adoption will be based upon the present value of the sum of the remaining minimum lease payments (as previously identified under ASC 840) and any amounts probable of being owed under the residual value guarantee (if applicable), to be determined using the discount rate then in effect. The interest rate will be based on the Company's ability to borrow on a collateralized basis over a similar remaining term and in a similar economic environment. The ROU asset to be recorded will be based on the lease liability and adjusted for any prepaid or accrued lease payments, the remaining balance of any lease incentives, the unamortized initial direct costs and impairments (if applicable).

The standard is effective for the Company beginning January 1, 2020. The Company has the option to adopt the new standard using one of two methods: retrospectively to each prior reporting period presented with a cumulative effect adjustment recognized at the beginning of the earliest comparative period presented, or the modified retrospective method, at the beginning of the period of adoption. The Company will adopt the standard using the modified retrospective method whereby the ROU assets and lease liabilities will be reflected in the Company's financial statements only for periods beginning on or after January 1, 2020.

The Company continues to evaluate the impact of ASU 2016-02 on its financial statements. The Company does not believe that recognition of lease liabilities and corresponding ROU assets will have a material impact on the Company's balance sheet. Further, the Company does not believe the adoption of this standard will have a significant impact on its statements of operations, stockholders' equity/(deficit) or cash flows. Refer to Note 17, Commitments and Contingencies, for further information on the Company's existing leases.

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 allow 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 unaudited interim condensed financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. 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, debt service requirements, and costs to comply with the requirements of being a public company. As of September 30, 2019, working capital, including cash and cash equivalents, totaled $18,007.

As of the date of issuance of these unaudited interim condensed financial statements, the Company expects that its revenues from licensed and proprietary products, including expected milestone payments, other co-development payments and royalties, manufacturing and sale revenues at anticipated levels, anticipated sales of its proprietary products, cash on hand, and the net proceeds from the issuance on July 15, 2019 of its 12.5% Senior Secured Notes due 2025, including possible future issuances under the Indenture (see Note 12), potential monetization of its out-licensed Apomorphine product candidate subject to regulatory approval thereof and if needed and available to it, which cannot be assured, access to the capital markets under its shelf registration statement filed with the SEC and effective September 17, 2019, will be adequate to fund its expected cash requirements for at least the next twelve months.

To the extent additional funds are necessary to meet liquidity or other cash needs as the Company continues to execute its business strategy, the Company will seek to satisfy such additional funding requirements through additional debt or equity financings, potential monetization of other royalty streams, the completion of a licensing transaction for one or more of the Company's pipeline assets, continuing expense reduction initiatives, or a combination of these potential sources of funds. Although the Company has been successful in raising capital in the past, there is no assurance that these sources of funding will be sufficient or available or on reasonable terms, if at all, which could adversely affect its financial condition and business prospects.

Note 5. Revenues and Trade Receivables, Net

The Company's revenues to date have been earned from licensed commercialized products, research and development services provided to customers, licensing of patent-protected intellectual property and commercialization of a proprietary product. 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 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 the 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 are recognized at a point in time when the manufactured product passes quality control testing.

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 licensees, 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 to complete the specific performance obligation identified in the related contract.

Revenues from the 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 billing to occur in arrears; accordingly, some portions, or all, of the Company's performance obligations are completed before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. These contract assets are reflected as a component of Trade and other receivables, net on the Condensed Consolidated Balance Sheet. As of September 30, 2019 and January 1, 2019, such contract assets were $760, and $284, respectively.

Contract Liabilities

In other limited situations, certain customer contractual payment terms allow advanced billings; accordingly, customer cash payments may be received before satisfaction of some or all contractual performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. These contract liabilities are reflected as Deferred revenue in the Condensed Consolidated Balance Sheet. As remaining performance obligations are satisfied, a portion of the deferred revenue balance is recognized in the Company's results of operations. As of September 30, 2019 and January 1, 2019, such contract liabilities were $2,962 and $3,762, respectively. Revenue recognized for the nine-month period ended September 30, 2019 that was reflected in the deferred revenue balance as of January 1, 2019 was $1,079.

The Company's revenues were comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Manufacture and supply revenue	$ 9,155	$ 9,005	$ 24,739	$ 29,249
License and royalty revenue	1,356	3,355	6,402	17,387
Co-development and research fees	1,073	907	2,862	3,970
Proprietary product sales, net	834	-	2,187	-
Total revenues	$ 12,418	$ 13,267	$ 36,190	$ 50,606

Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
United States	$ 11,022	$ 12,483	$ 33,683	$ 49,060
Ex-United States	1,396	784	2,507	1,546
Total revenues	$ 12,418	$ 13,267	$ 36,190	$ 50,606

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:

	September 30, 2019	December 31, 2018
Trade receivables	$ 9,687	$ 6,610
Contract and other receivables	843	33
Less: allowance for bad debts	(94)	(58)
Less: sales-related allowances	(120)	(104)
Trade and other receivables, net	$ 10,316	$ 6,481

Contract and other receivables totaled $843 as of September 30, 2019, consisting primarily of contract assets related to the adoption of ASC 606 and certain reimbursable customer costs. 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:

	September 30, 2019	December 31, 2018
Allowance for doubtful accounts at beginning of year	$ 58	$ 55
Additions charged to bad debt expense	36	53
Write-downs charged against the allowance	--	(50)
Allowance for doubtful accounts at end of the period	$ 94	$ 58

Sales Related Allowances and Accruals

Revenues from proprietary product sales are recorded net of prompt payment discounts, wholesaler service fees, return 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 nine months ended September 30, 2019:

	Total Sales Related Allowances and Accruals
Balance at December 31, 2018	$ 585
Provision	1,576
Payments / credits	(984)
Balance at September 30, 2019	$ 1,177

Total reductions of gross product sales from sales-related allowances and accruals were $1,576 for the nine months ended September 30, 2019. Accruals for return allowances and prompt pay discounts are reflected as a direct reduction to trade receivables, and totaled $120 and $104 at September 30, 2019 and December 31, 2018, respectively. Accruals for wholesaler fees, co-pay cards and rebates are reflected as current liabilities, and totaled $1,057 and $481 at September 30, 2019 and December 31, 2018, respectively. There were no sales related allowances and accruals at September 30, 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, PLC. (“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% of gross receivables. For the nine months ended September 30, 2019, revenues provided by Indivior represented approximately 83% of total revenues and outstanding accounts receivable due from Indivior represented approximately 77% 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. 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 maximum 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. Additionally, in the event Indivior purchases certain large quantities of Suboxone during a specified period, Indivior will be entitled to scaled rebates on rest of the world sales only.

In addition to the purchase price for the Suboxone supplied product, 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 all countries other than the United States and subject to annual maximum amounts and limited to the life of the related United States or international patents.

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 a supplemental 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. 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 is completed. If such litigation is successful, which cannot be assured, 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) 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 Pharmaceuticals, Inc. ("Sunovion"), referred to as the Sunovion License Agreement, pursuant to which we granted to 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 episodes in Parkinson's disease patients, as well as two other fields of disease conditions. 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 have been received to date. No payments were received during the three and nine months ended September 30, 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 are 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.

The 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. Third quarter 2019 license and royalty revenue includes $1,000 from the Company's 10% share of milestone payments paid to KemPharm during September 2019, under its licensing of KP-415 and KP-484. There can be no guarantee that any such payments will be made in the future.

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

The 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. The fair value of warrants presented in the Company's condensed consolidated statements of changes in shareholders' deficit were Level 3 and were estimated using the Black-Scholes-Merton pricing model. 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 and 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, net, 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:

	September 30, 2019	December 31, 2018
Raw material	$ 1,142	$ 1,283
Packaging material	1,729	2,975
Finished goods	1,253	1,183
Total inventory, net	$ 4,124	$ 5,441

Note 9. Property and Equipment, Net

	Useful Lives	September 30, 2019	December 31, 2018
Machinery	3-15 yrs	$ 20,927	$ 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	2,771	2,579
Construction in progress		1,503	1,655
		47,684	47,398
Less: accumulated depreciation and amortization		(37,333)	(35,191)
Total property and equipment, net		$ 10,351	$ 12,207

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

Total depreciation and amortization related to property and equipment was $695 and $733 for the three-month periods ended September 30, 2019 and 2018, respectively. For the respective nine-month periods, these expenses totaled $2,143 and $2,438.

Note 10. Intangible Assets

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

	September 30, 2019	December 31, 2018
Purchased technology-based intangible	$ 2,358	$ 2,358
Purchased patent	509	509
	2,867	2,867
Less: accumulated amortization	(2,702)	(2,663)
Total intangible assets, net	$ 165	$ 204

Amortization expense was $13 for each of the three-month periods ended September 30, 2019 and 2018, respectively. For the corresponding nine-month periods, these expenses totaled $39 and $38, respectively. 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:

	September 30, 2019	December 31, 2018
Accounts payable	$ 14,202	$ 20,436
Accrued compensation	3,480	3,604
Accrued distribution expenses	1,057	481
Real estate and personal property taxes	246	388
Accrued withholding tax for share-based compensation	49	2,515
Other	184	207
Total accounts payable and accrued expenses	$ 19,218	$ 27,631

Note 12. 12.5 % Senior Secured Notes and Loans Payable

12.5% Senior Secured Notes

On July 15, 2019, the Company completed the private placement of up to $100 million aggregate principal of its 12.5% Senior Secured Notes due 2025 (the “Notes”) and issued warrants for two million shares of common stock (the “Warrants”), $.001 per value per share, through its structuring agent, Morgan Stanley & Co., LLC, and entered into a purchase agreement and related indenture (the “Purchase Agreement” or “Indenture”) governing these Notes. The Company simultaneously entered into related agreements including a Collateral Agreement with U.S. Bank National Association as trustee and collateral agent, and a Lien Subordination and Intercreditor Agreement for the benefit of Madryn Health Partners, other institutional noteholders and U.S. Bank National Association in dual roles providing terms governing an asset-based loan facility.

Upon closing, the Company issued $70,000 of the principal of the Notes (the "Initial Notes") along with the Warrants and rights of first offer (the "First Offer Rights") to the lenders participating in this transaction for Notes and Warrants (the "Lenders"). Issuance of the Initial Notes and Warrants provided net proceeds of $66,082. In addition to the Initial Notes, the Indenture may provide access to further loans of up to $30,000 that may become available in two tranches of Additional Notes tied to the NDA filing for and FDA approval of Libervant, an important part of our drug candidate pipeline. Provided that no events of default exist, the Company may elect, subject to approval of the holder of a majority of the outstanding principal amount of the Notes, to offer to the Lenders participation in a $10,000 additional offering of 12.5% senior secured notes (the "First Additional Offering") under terms similar to the Initial Notes, on or before March 31, 2021, upon the filing of the Libervant NDA with the FDA. A second identical funding opportunity would allow, on or before March 31, 2021, the Company to obtain an additional $20,000 if the first option has been elected and funded, or, if not elected or funded, an additional $30,000 may be offered for issuance following FDA approval of Libervant. There can be no assurance that any such additional financing will be consummated.

Proceeds from issuance of the Initial Notes and Warrants were used to fully repay the Company's $52,092 outstanding indebtedness to Perceptive Credit Holdings, LP, related early repayment fees and legal and other fees incurred in executing this Indenture. Remaining proceeds of $13,990 are being used to support the advancement of Aquestive's late-stage development pipeline, ongoing proprietary product commercialization and for general corporate operations.

The Notes provide a stated fixed rate of 12.5%, payable quarterly in arrears, with the initial quarterly principal repayment of the Initial Notes due on September 30, 2021 and the final quarterly payment due at maturity on June 30, 2025. Principal payments are scheduled to increase annually from 10% of the face amount of the debt then outstanding during the first four quarters to 40% of the initial loan principal during the final four quarters.

A debt maturity table is presented below:

Remainder of 2019	$ -
2020	-
2021	3,500
2022	10,500
2023	17,500
2024 and thereafter	38,500
Total	$ 70,000

The Company may elect, at its option, to prepay the Notes at any time at premiums that range from 101.56% of outstanding principal if prepayment occurs on or after the 5th anniversary of the issue date of the Notes to 112.5% if payment occurs during the third year after the issuance of the Notes. In the event that redemption occurs within the two years after the issuance of the Notes, a make-whole fee is required, based on the present value of remaining interest payments using an agreed-upon discount rate linked to the then-current U.S. Treasury rate. The Indenture also includes change of control provisions under which the Company may be required to repurchase the Notes at 101% of the remaining principal plus accrued interest at the election of the lenders.

Collateral for the loan consists of a first priority lien on substantially all property and assets, including intellectual property, of the Company. This secured obligation provides payment rights that are senior to all existing and future subordinated indebtedness of the Company and provides Lenders with perfected security interests in substantially all of the Company's assets. In the event that asset-based loans of up to $10,000 ("ABL Facility") may be obtained, subject receivables and inventory assets will provide a second priority lien to senior secured note holders. The Company's license of its IP to a third-party drug development enterprise (specifically, Sunovion Pharmaceutical's APL-130277 product) is one of the various assets serving as collateral for this loan. The loan indenture permits the Company to monetize this asset while specifying that a portion of the proceeds, up to $40,000 if the First Additional Offering has not been elected or funded, or, $50,000 if it has been elected and funded, must be applied to prepay the Initial Notes, at 112.5% of the principal amount of the Notes being repurchased, plus accrued and unpaid interest, if any, thereon to the date of repurchase, to the extent elected by the Note holders, assuming that such monetization, up to such $40,000 or $50,000 level, as applicable, equals or exceeds those levels and if such monetization does not equal or exceed such level, such prepayment would be pro-rated among the Note holders. To the extent that Lenders do not elect repayment of the debt at the date of monetization, the amount not elected up to $40,000 (or $50,000 if an additional tranche is issued) will be held in a collateral account until approval of Libervant by the FDA, at which time this cash collateral is to be released to the Company. Proceeds in excess of $40,000 (or $50,000 if an additional tranche is issued) can be used immediately for general corporate purposes.

Affirmative and negative covenants specified in the Indenture are considered typical for loans of this nature, including, but not limited to, specifications relating to preservation of corporate existence, publicly traded status, intellectual property and business interests; limitations or prohibitions of dividend payments or other distributions, repurchases of shares, asset transfers or dispositions, creation or occurrence of additional liens, entering into licensing or monetization arrangements other than as permitted under the Indenture, and perfection of security interests. The Company was in compliance with its debt covenants under the Indenture as of September 30, 2019. Also, as of that date, the carrying value of the Company's loan payable approximated its market value.

The Indenture also restricts the incurrence of additional indebtedness except only such indebtedness as is expressly permitted under the terms of the Indenture (which includes the ABL Facility) on the terms and conditions set forth in the Indenture and such indebtedness as may be permitted under limitations set forth in the Indenture. The Indenture also restricts the issuance of any "Disqualified Stock", including, generally, mandatorily redeemable securities or securities redeemable at the option of the holder or securities convertible or exchangeable at the option of the holder for indebtedness of the Company or for other Disqualified Stock

Events of default include various commonly specified conditions, including but not limited to, bankruptcy, insolvency, material adverse changes, failure to meet Indenture payment or other obligations, compliance with regulatory requirements and preservation of corporate existence and business operations.

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 associated with its 12.5% Senior Secured Notes for the three and nine-month periods ended September 30, 2019 were $493.

Unamortized deferred debt issuance costs and deferred debt discounts totaled $10,225 as of September 30, 2019.

Perceptive Loan

On August 16, 2016, the Company entered into a Loan Agreement and Guaranty (the "Loan Agreement") with Perceptive Credit Opportunities Fund, LP ("Perceptive"). Upon closing, 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 which was met in March 2017 and the balance of the facility was borrowed at that time. The initial 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 July 15, 2019, this loan from Perceptive was repaid in full as part of a refinancing transaction.

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 were due in the amount of $550. Thereafter, monthly principal payments in the amount of $750 were due through the maturity date, December 16, 2020, at which time the full amount of the remaining outstanding loan balance was due. As noted above, on July 15, 2019, the Company fully repaid its outstanding indebtedness under the Loan Agreement, and there was no outstanding debt related to Perceptive as of September 30, 2019. At December 31, 2018, $4,600 was classified as current debt. The Company's tangible and intangible assets were subject to first priority liens to the extent of the outstanding debt. Further, under the Loan Agreement, as amended, the Company was 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 had agreed to release liens related to these royalties and fees. Other significant terms of the Loan Agreement, as amended, included financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. Financial covenant requirements included (1) minimum liquidity under which a $4,000 minimum cash balance must be maintained at all times and (2) a minimum revenue requirement for the trailing twelve consecutive months, measured at the end of each calendar quarter. As of July 15, 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 associated with the Perceptive Loan for the nine-month periods ended September 30, 2019 and 2018 were $847 and $1,297, respectively; for the corresponding three-month periods these expenses totaled $64 and $374, respectively.

The Company recorded during the three-month period ended September 30, 2019 a $4,896 loss on the extinguishment of debt associated with the early retirement of the Perceptive Loan. The $4,896 loss on the extinguishment of debt is comprised of the following: $2,944 in prepayment premiums paid to Perceptive to settle the outstanding debt and $1,952 in unamortized deferred debt issuance costs and deferred debt discounts associated with the Perceptive Loan.

There were no unamortized deferred debt issuance costs and deferred debt discounts related to the Preceptive Loan as of September 30, 2019, while unamortized deferred debt issuance costs and deferred debt discounts amounted to $2,797 as of December 31, 2018.

Note 13. Warrants

12.5% Senior Secured Notes

The Warrants issued in conjunction with the 12.5% Senior Secured Notes expire on June 30, 2025 and entitle the Lenders to purchase two million shares of the Company's common stock at $4.25 per share and include specified registration rights. Management estimated the fair value of the warrants to be approximately $6,800, assisted by an independent third-party appraiser. The fair value of these warrants is treated as a debt discount, amortizable over the term of the warrants, with the unamortized loan portion applied to reduce the face amount of the loan in the Company's balance sheet. Additionally, since the Warrants issued do not provide warrant redemption or put rights within the control of the holders that could require the Company to make a payment of cash or other assets to satisfy the obligations under the Warrants, except in the case of a "cash change in control", the fair value attributed to the Warrants is presented in additional-paid in capital in the accompanying Condensed Consolidated Balance Sheets.

Perceptive Loan

The warrants issued to Perceptive in connection with the Perceptive Loan 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 warrants also provided Perceptive with a put right which, if exercised under certain circumstances, would require the Company to purchase the warrants 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 these warrants 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 the Company's common stock $.001 par value per share issuable pursuant to the automatic exercise of warrants at a total price of $116 that was collected subsequently. 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.

A roll-forward of warrant liability is as follows:

	Warrant Liability
Balance at December 31, 2017	$ 7,673
Changes in fair value recognized	5,278
Exercise of warrants	(12,951)
Balance at September 30, 2018	$ -

Note 14. Net Loss Per Share

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

As a result of the Company's net losses incurred for the three and nine-month periods ended September 30, 2019 and September 30, 2018, respectively, all potentially dilutive instruments outstanding would have anti-dilutive effects on per-share calculations for these periods. Therefore, basic and diluted net loss per share were the same, as reflected below.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	$ (18,412)	$ (15,038)	$ (53,610)	$ (47,432)
Denominator:				
Weighted-average number of common shares – basic	25,031,478	23,646,192	24,992,229	19,335,541
Loss per common share - basic	$ (0.74)	$ (0.64)	$ (2.15)	$ (2.45)

As of September 30, 2019, the Company's potentially dilutive instruments included 2,256,092 options to purchase common shares and 107,144 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.

Note 15. Share-Based Compensation

The Company recognized share-based compensation in its Condensed Consolidated Statements of Operations and Comprehensive Loss during 2019 and 2018 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Expense classification:	2019	2018	2019	2018
Manufacture and supply	$ 60	$ 32	$ 176	$ 377
Research and development	188	192	536	2,378
Selling, general and administrative	1,622	1,102	4,480	25,786
Total share-based compensation expenses	$ 1,870	$ 1,236	$ 5,200	$ 28,541
Share-based compensation from:				
Restricted stock units	$ 473	$ 610	$ 1,403	$ 610
Stock options	1,397	626	3,777	633
Non-voting common shares	--	—	--	27,298
Employee stock purchase plan	--	—	20	—
Total share-based compensation expenses	$ 1,870	$ 1,236	$ 5,200	$ 28,541

The 2018 expense presented above also include those arising from the Company's prior incentive compensation plan ("Performance Unit Plan" (PUP)) that was terminated and settled in April 2018 through the issuance of non-voting common shares, $.001 par value per share, of the Company. Under that Plan, vested grants were not exercisable prior to a change in control or completion of an IPO and accordingly, compensation expenses for these awards were initially recognized in April 2018 upon plan participant and Board approval of the plan termination.

Share-Based Compensation Equity Awards

The following tables provide information about the Company's restricted stock and stock option unit activity during the nine months ended September 30, 2019:

Restricted stock units:	Number of Units	Weighted Average Grant Date Fair Value
	(in thousands)	
Unvested at December 31, 2018	205	$ 14.77
Granted	--	--
Vested	(95)	14.91
Forfeited	(3)	13.00
Unvested at September 30, 2019	107	$ 14.70
Grant date fair value of shares vested during the period	$ 1,421	
Unrecognized compensation costs of RSU awards at September 30, 2019	$ 1,409	

Unrecognized compensation costs related to awards of RSUs are expected to be recognized over a weighted-average period of less than three years.

Stock options:	Number of Options	Weighted Average Exercise Price
	(in thousands)	
Outstanding at December 31, 2018	1,033	$ 14.72
Granted	1,253	6.67
Forfeited	(30)	7.73
Exercised, expired	--	--
Outstanding at September 30, 2019	2,256	$ 10.34
Vested or expected to vest at September 30, 2019	2,113	$ 10.28
Exercisable at September 30, 2019	345	$ 14.79

The fair values of stock options granted during 2019 were estimated using the Black-Scholes-Merton pricing model based on the following assumptions:

Expected dividend yield	0%
Expected volatility	85 - 95%
Expected term (years)	5.5 - 6.1
Risk-free interest rate	1.5 - 2.6%

The weighted average grant date fair value of stock options granted during 2019 was $6.67. During the nine months ended September 30, 2019, stock options were granted with exercise prices ranging from $3.36 to $8.05, and accordingly, given the Company's share price of $3.18 at the close of the Company's third quarter 2019, these options provided no intrinsic value at that date. Similarly, stock options granted in 2018 provided no intrinsic value at September 30, 2019.

As of September 30, 2019, $10,679 of total unrecognized compensation expenses related to non-vested stock options is expected to be recognized over a weighted average period of 2.1 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, or ESPP, in June 2018, as amended and restated effective as of January 1, 2019. The ESPP was approved by stockholders on June 13, 2019. The ESPP features two six-month offering periods per year, running from January 1 to June 30 and July 1 to December 31. Under the ESPP, employees may elect to purchase the Company's common stock at the lower of 85% of the fair value of shares on either the first or last day of the offering period. During the nine months ended September 30, 2019, 31,393 shares were purchased at a total discount of $20 and were issued under the ESPP, effective as of that date.

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 September 30, 2019 and 2018, the Company recorded no income tax benefit from its pretax losses of $18,412 and $15,038, respectively, and similarly for the nine months ended September 30, 2019 and 2018, the Company recorded no tax benefit from its pretax loss of $53,610 and $47,432, 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 and nine months ended September 30, 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 totaled $399 and $375 for the three-month periods ended September 30, 2019 and 2018, respectively and $1,170 and $998 for the nine-month periods ended September 30, 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.

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 until the expiration of the patent in 2024, and the Federal Circuit affirmed that ruling on July 12, 2019.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the Federal Circuit affirmed that ruling on July 12, 2019. *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. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The remaining case against Actavis was dismissed in light of the infringement ruling above, which prevents Actavis from entering the market until 2024. The case(s) against the remaining defendants, regarding the additional asserted patents have not been finally resolved. A *Markman* hearing in the cases against DRL and Alvogen was held on October 17, 2019, with the court taking the claim construction issues under advisement. No trial date has been set in those cases, 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 DRL. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both DRL and Alvogen. 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. DRL, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by DRL 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 filed their answers to the complaint, including counterclaims for non-infringement and invalidity of the asserted patents as well as two other patents that were not asserted in the original complaint. On July 29, 2019, we and Indivior filed a motion to dismiss Aveva and Apotex’s counterclaim for inequitable conduct relating to Indivior’s ‘454 patent. The hearing on that motion originally scheduled for October 30, 2019, was cancelled by the Court, subject to possible rescheduling.

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 IPRs 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 a 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. On August 7, 2019 the Court granted BDSI’s motion to dismiss the Complaint without prejudice and denied BDSI’s motion to stay as moot. 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. On August 29, 2019 the Federal Circuit granted the motion to dismiss BDSI’s appeal. On September 30, 2019, BDSI filed a petition for rehearing *en banc*, and we filed our response to that petition on November 1, 2019.

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 on July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions were conducted through August 1, 2019. Summary judgment motions and *Daubert* motions relating to expert witnesses are currently stayed pending the Court’s resolution of discovery motions in the MDL case. 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. All dollar amounts are stated in thousands.

Forward-Looking Statements

This Quarterly Report on Form 10-Q and certain other communications made by us includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements about our growth and future financial and operating results and financial position, regulatory approvals and pathways, clinical trial timing and plans, the achievement of clinical and commercial milestones, product orders and fulfillment, short-term and longer term liquidity and cash requirements, cash funding and cash burn, business strategies, market opportunities, financing, and other statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials; risk of delays in FDA approval of our drug candidates or failure to receive approval; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk that a competitor obtains orphan drug exclusively and blocks our product for the same indication for the seven years; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default risk related to government claims against Indivior PLC/Inc ("Indivior") for which we license, manufacture and sell Suboxone and which accounts for the substantial part of our current operating revenues; risks associated with Indivior's announcement of its intention to cease production of its authorized generic buprenorphine-naloxone film products, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunsetting product; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our products and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; 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 risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in governmental laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in the Company's Annual Report on Form 10-K filed with the SEC on March 14, 2019 and in our quarterly reports on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which address matters only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this report whether as a result of new information, future events or otherwise, except as may be required by applicable law.

Overview

We are a specialty pharmaceutical company focused on developing and commercializing differentiated products with our proprietary PharmFilm® technology to solve patients' therapeutic problems and to meet patients' 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 central nervous system (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 Food and Drug Administration (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-new drug application (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 completed in July 2019. The Company also began a rolling NDA submission process during the second quarter of 2019 and has completed submission of two of three sections of the NDA. The submission is expected to be completed on around the end of November 30, 2019.

- Exservan™, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we submitted an NDA in the first quarter of 2019; the Prescription Drug User Fee Act (PDUFA) goal date for FDA approval is expected to be 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 adjunct and/or alternative to injection treatments such as EpiPen. After the Company's first human proof of concept trials, a re-formulated and more advanced prototype was developed, for which phase 1 proof of concept trials were completed in the third quarter of 2019. Based on the results of this proof of concept study, the Company requested scheduling a pre-NDA meeting with the FDA which we expect to be in late 2019 or early 2020.

- AQST-305, a sublingual soluble film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors. As a result of early stage clinical 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, currently, the authorized generic sublingual film formulation of buprenorphine and naloxone, through Sandoz Inc. ("Sandoz") for the United States market. As of October 2019, these products account for approximately 75% of the oral film products prescribed in the U.S. for recovery from opioid addiction. See "Financial Overview" below concerning Indivior's announced intention to cease production of the authorized generic film product.

In early 2019, certain third-party pharmaceutical companies launched, at risk, generic film products for buprenorphine-naloxone. Also, in early 2019, Indivior, through Sandoz., began to market and sell an authorized generic sublingual film product for Suboxone, which has been well received in the marketplace and which we also exclusively manufacture and supply. As of October 2019, Suboxone and the authorized generic film product continued to retain approximately 75% of the market for film treatments of opioid dependence, of which more than a majority of Indivior's retained market share was branded Suboxone and the balance was the authorized Sandoz generic. On October 15, 2019, Indivior publicly announced that, in order to mitigate the impact from the recent passage of H.R. 438 – Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, which came into effect on October 1, 2019 and which includes changes to the methodology for calculating average manufacturer price for branded drugs, Indivior had given notice to Sandoz of Indivior's intention to cease production of the authorized generic sublingual film product. Indivior has historically accounted for a substantial part of our total annual revenues and, for fiscal 2018, accounted for approximately 89% of our annual revenues. Through the 2019 third quarter, our manufacturing and supply revenues of Suboxone and the authorized generic for Suboxone accounted for 83% of our total 2019 nine-month revenues. While we continue to have a strong order book for Suboxone products and the authorized generic film for the balance of 2019, our manufacturing and supply revenue for the Sandoz authorized generic products is expected to cease in the near future, which would materially negatively affect our manufacture and supply revenues and our results of operations. In addition, although Indivior, through the branded and the authorized generic film products, has continued to date to retain substantial market share, we have continued to plan for the erosion of this sunsetting product over time, which will further affect our total revenues and our results from operations.

We manufacture all of our licensed and proprietary products at our FDA- and DEA-inspected facilities. 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 our 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.

On July 15, 2019, we completed a private placement of $70,000 of 12.5% Senior Secured Notes due June 2025 ("Notes" or "Senior Secured Notes") and unregistered warrants and paid off our existing credit facility. The new financing provided net proceeds of $66,082 after expenses. The net proceeds of the financing were used to repay all outstanding obligations under the Company's prior credit facility of $52,092. We are using the remaining net cash proceeds of $13,990 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes. Our Notes are discussed in Note 12, 12.5% Senior Secured Notes, to our Consolidated Financial Statements and in Liquidity and Capital Resources.

On September 11, 2019, we filed with the SEC a Registration Statement on Form S-3, which was declared effective on September 17, 2019 (File No. 333-233716) ("the Registration Statement"). Under the Registration Statement we may sell up to $150 million of our securities, including without limitation, common stock, preferred stock, warrants, and debt securities. Also, in connection with the Registration Statement the Company entered into an equity distribution agreement with Piper Jaffray & Co., as sales agent, providing the opportunity for an at-the-market offering of up to approximately $17,055 of our common stock from time to time. We have not offered or sold any securities under the Registration Statement as of the date hereof.

We generated revenue of $12,418 and $13,267 for the three months ended September 30, 2019 and 2018, respectively, and $36,190 and $50,606 for the nine months ended September 30, 2019 and 2018, respectively, most significantly from commercial products licensed to our marketing licensees. Total revenues included manufacturing and supply revenue, license fees, royalties, co-development and research fees and our proprietary product sales. Our 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 September 30, 2019, we had $20,914 in cash and cash equivalents. As a result of net losses incurred in the operations of the Company during the first nine months of 2019, we had a net shareholders' deficit of $34,459. We incurred net losses of $18,412 and $15,038 for the three months ended September 30, 2019 and 2018, respectively. For the nine months ended September 30, 2019 and 2018, we incurred net losses of $53,610 and $47,432, respectively. Our working capital, inclusive of cash and cash equivalents, at September 30, 2019 was $18,007.

We expect to continue to incur significant net losses and negative operating cash flows for the foreseeable future as we pursue the development, regulatory approval, licensing, commercialization and marketing of our proprietary products and product candidates. Our net losses may fluctuate significantly from period to period, depending on the timing and scope of our clinical trials and expenditures on our research and development activities, as well as our commercialization activities. Our expenses are expected to significantly increase over time and may fluctuate significantly from quarter to quarter as we:

- continue to fund the commercialization of Sympazan (launched in December 2018) and, subject to FDA approval, Libervant, our epilepsy 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 and proprietary product activities, proceeds from our IPO, equity investments from our stockholders and debt proceeds from our credit facilities and issuance of our Senior Secured Notes. Our new 12.5% Senior Secured Notes due 2025 and unregistered Warrants issued on July 15, 2019, are discussed in Note 12, 12.5% Senior Secured Notes, to our Condensed Consolidated Financial Statements and in Liquidity and Capital Resources. We registered the warrants and affiliate shares as part of our Universal Shelf Registration described above. The Shelf Registration Statement provides increased capital 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 and dependence on a single customer for the substantial portion of our current revenues, expected incurrence of significant operating losses and negative operating cash flows for the foreseeable future, reliance on future uncommitted funding sources, which cannot be assured, to satisfy short-term and longer term liquidity and cash requirements, 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, including Libervant, 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 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, as an "emerging growth company", 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 or (ii) provide all of the compensation disclosure that is 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 as to subsection (ii) either (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 commercialized partnered products, licensing and royalty initiatives, development initiatives for third parties and sales of 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 (as well as the authorized generic film product) 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 filled 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 and the Company has no role in or ability to participate in commercialization including marketing, pricing, sales and regulatory strategy.

We expect future manufacture and supply revenue from licensed products to be based on volume demand for such 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, including 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, 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 licensee to commercialize our product candidates in certain markets inside and 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, each of which are described in more detail below. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale. 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 national 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 such time that 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, Medicaid and Medicare Part D, 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 were based on 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 product sales and an increase in accrued expenses.

Co-Pay Cards

Co-pay card redemptions costs represent the costs to help offset a customer's co-pay or cover a predetermined amount of prescription costs based on the Company's rules of participation in such programs. 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 and post-launch commercialization efforts related to our CNS product candidates, intellectual property procurement, protection, prosecution and litigation expenses, corporate management functions, public company costs, share-based compensation expenses and interest on our corporate borrowings. We primarily record our costs and expenses in the following categories:

Manufacture and Supply Costs and Expenses

Manufacture and supply costs and expenses are 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. 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.

Our manufacture and supply costs and expenses may 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. Additionally, we may 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 or acquire additional product candidates and technologies. We may 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; unabsorbed factory overhead costs 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 along with unabsorbed factory overhead costs. 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. We anticipate launching in 2020 and began initial preparations for the launch of Libervant, an additional late-stage epilepsy product. These costs have increased in 2019, with a full year effect of Sympazan's commercialization. Incremental marketing spending in preparation for the commercial launch of Libervant is expected to be incurred prior to the PDUFA date for this product and will be accordingly planned once the PDUFA date is 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 medical affairs team and have established a market access account team. With this increased activity related to the commercial launch of Sympazan, our sales and marketing expenses have increased and are expected to continue to increase in subsequent periods as we continue to support our epilepsy franchise. We expect to be able to significantly leverage these now existing relationships for the future launch, subject to FDA approval, of Libervant. 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. We continue to incur significant costs in seeking to protect our intellectual property rights, including significant litigation costs in connection with seeking to enforce our rights concerning third parties' at-risk launch of generic products. In addition, in order to better align our selling, general and administrative expenses with expected revenue, during the second quarter we reviewed and began initiatives to reduce certain expenses in non-core functions, and we will continue to review and assess our selling, general and administrative expenses relative to planned revenues going forward.

Interest Expense

Interest expense consists of interest costs related to our debt facility, as well as amortization of loan costs and debt discount. Our interest cost, which under our Perceptive credit facility was subject to changes in one-month LIBOR, represents a monthly cash payment obligation. Our 12.5% Senior Secured Notes due 2025 issued on July 15, 2019 are discussed in Note 12, 12.5% Senior Secured Notes, to our Consolidated Financial Statements and in Liquidity and Capital Resources. Interest expense has increased based on additional borrowings under such new Notes.

Interest Income

Interest income consists of earnings derived from an interest-bearing account. We expect to continue generating interest 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 Perceptive Warrant

Changes in the fair value of Perceptive 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 September 30, 2019 and 2018

We recorded revenue of $12,418 and $13,267 in the three months ended September 30, 2019 and 2018, respectively, generating a net loss of $18,412 and $15,038 for the three months ended September 30, 2019 and 2018, respectively.

Revenues:

(In thousands, except %)	Three Months Ended September 30, 2019	2018	Change $	Change %
Manufacture and supply revenue	$ 9,155	$ 9,005	$ 150	2%
License and royalty revenue	1,356	3,355	(1,999)	(60%)
Co-development and research fees	1,073	907	166	18%
Proprietary product sales, net	834	-	834	100%
Total revenues	$ 12,418	$ 13,267	$ (849)	(6%)

For the three months ended September 30, 2019, total revenues decreased 6% or $849 to $12,418 compared to revenues of $13,267 for the same period in 2018. The change is primarily attributable to differences in license and royalty revenue that by nature are variable as to timing and magnitude. Additionally, under the Indivior Supplemental Agreement license fees are currently suspended following the "at risk" launches of several generic buprenorphine/naloxone products into the Suboxone market. These fees are recoverable in the future under certain conditions. These are offset in part by increases in manufacture and supply revenue, co-development and research fees and proprietary product sales revenue from Sympazan, launched in December 2018.

Manufacture and supply revenue increased approximately 2% or $150 to $9,155 for the three months ended September 30, 2019 compared to $9,005 from the prior year period. This increase is attributable to a shift to a higher - priced mix of Suboxone and authorized generic products offset by modestly lower volumes year - over - year. As of the early part of fourth quarter 2019, Suboxone and its authorized generic continued to retain approximately 75% of the market share. However, as discussed above, Indivior has announced its intention to suspend marketing of the authorized generic. If suspended, our manufacturing and supply revenue would be affected in future periods possibly as early as 2020. The branded Suboxone products have maintained more than a majority of our production for Indivior because of the branded products performance in the market.

License and royalty revenue decreased 60% or $1,999 to $1,356 for the three months ended September 30, 2019 compared to revenues of $3,355 from the prior year period. This change was primarily related to the license and new patent fees on our licensed product Suboxone. License fees totaled $1,000 for the three months ended September 30, 2019 compared to $3,000 of license fees recognized during the prior year period. Suboxone related license fees were $3,000 lower compared to 2018, as a result of the fact that certain license fees due from Indivior have been suspended pending the outcome of litigation related to infringement claims against the generic products launched "at risk." There can be no guarantee that any such payments will be made in the future. Included in the third quarter 2019 license and royalty revenue was $1,000 from our 10% share of milestone payments paid to KemPharm during September 2019, under its licensing of KP-415 and KP-484. There can be no assurance that any such payments will be made in the future. Royalty revenues earned on Suboxone and Zuplenz were 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 increased 18% or $166 to $1,073 for the three months ended September 30, 2019 compared to $907 from the prior year period. The increase 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 from one reporting period to the next.

Product sales, net increased $834 or 100% for the three months ended September 30, 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:

(In thousands, except %)	Three Months Ended September 30, 2019	2018	Change $	Change %
Manufacture and supply	$ 4,643	$ 5,592	$ (949)	(17%)
Research and development	5,063	4,534	529	12%
Selling, general and administrative	13,714	12,346	1,368	11%
Interest expense	2,652	1,933	719	37%
Interest income	(138)	(216)	(78)	36%
Loss on extinguishment of debt	4,896	-	4,896	NM
Other	-	4,116	(4,116)	NM

Manufacture and supply costs and expenses decreased 17% or $949 to $4,643 for the three months ended September 30, 2019 compared to $5,592 for the same period in 2018. The decrease was driven by lower volumes of Suboxone in the 2019 period compared to 2018 as well as the non-cash reversal of an accrual for manufacturing related costs that no longer represented an obligation of the Company, offset in part by higher costs of co-development revenue activity in the 2019 period.

Research and development expenses increased 12% or $529 to $5,063 for the three months ended September 30, 2019 compared to $4,534 in the prior year period. This increase resulted from an increase of clinical trials expenses of $646 due to the timing of primarily Libervant as compared to prior periods. Clinical trial and other third-party product development expenses may be expected to fluctuate based on the schedule of clinical and development activities that are conducted during any reporting period.

Selling, general and administrative expenses increased 11% or $1,368 to $13,714 for the three months ended September 30, 2019 as compared to $12,346 for the prior year period. The increase in expense was primarily driven by investments in our commercialization, branding and marketing capabilities for Sympazan. 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. In addition, we recognized higher legal fees in connection with the ongoing state antitrust litigation and other patent related matters, and higher insurance premiums.

Interest expense increased 37% or $719 to $2,652 for the three months ended September 30, 2019 compared to $1,933 for the same period in 2018, primarily as a result of a higher amount of debt outstanding starting in the third quarter of 2019 as compared to 2018. Prior to July 15, 2019, our interest expense was subject to fluctuations based on one-month LIBOR. Our new Senior Secured Notes due 2025 issued on July 15, 2019 carry a 12.5% fixed interest rate per annum, with an increased principal amount outstanding thereunder.

Interest income decreased 36% or $78 for the three months ended September 30, 2019, compared to the prior year period. This decrease is a result of a lower cash balance being invested in an interest-bearing account.

Loss on the extinguishment of debt increased by $4,896 for the three months ended September 30, 2019 compared to the same period in 2018. This increase is the result of the expenses associated with early extinguishment of our loans payable with Perceptive. The amount consists of $2,944 related to the prepayment premium associated with early payment of our outstanding obligations to Perceptive along with unamortized debt discount and unamortized loan acquisition costs of $1,606 and $346, respectively.

Other represents the change in the fair value of Perceptive warrants which decreased by $4,117 for the three months ended September 30, 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. For information concerning the warrants issued in connection with our 12.5% Senior Secured Notes due 2025, issued on July 18, 2019, see Note 12, 12.5% Senior Secured Notes, to our Consolidated Financial Statements.

Comparison of the Nine Months Ended September 30, 2019 and 2018

We recorded revenue of $36,190 and $50,606 in the nine months ended September 30, 2019 and 2018, respectively, generating a net loss of $53,913 and $47,432 for the nine months ended September 30, 2019 and 2018, respectively.

Revenues:

(In thousands, except %)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change $	Change %
Manufacture and supply revenue	$ 24,739	$ 29,249	$ (4,510)	(15%)
License and royalty revenue	6,402	17,387	(10,985)	(63%)
Co-development and research fees	2,862	3,970	(1,108)	(28%)
Proprietary product sales, net	2,187	-	2,187	100%
Total revenues	$ 36,190	$ 50,606	$ (14,416)	(28%)

For the nine months ended September 30, 2019, total revenues decreased 28% or $14,416 to $36,190 compared to revenues of $50,606 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 proprietary product sales revenue for Sympazan, launched in December 2018.

Manufacture and supply revenue decreased approximately 15% or $4,510 to $24,739 for the nine months ended September 30, 2019 compared to $29,249 from the prior year period. This decrease is attributable to lower Suboxone and authorized generic production volume in the first half of 2019. As of the early part of fourth quarter 2019, Suboxone and its authorized generic continued to retain approximately 75% of the market share. However, as discussed above, Indivior has announced its intention to suspend marketing of the authorized generic, and therefore manufacturing and supply revenue may be affected by this suspension in future periods, likely beginning in 2020. The branded Suboxone products have maintained more than a majority of our production for Indivior because of the branded products performance in the market.

License and royalty revenue decreased 63% or $10,985 to $6,402 for the nine months ended September 30, 2019 compared to revenues of $17,387 from the prior year period. This change was primarily related to the license and new patent fees on our licensed product Suboxone. License fees totaled $4,250 for the nine months ended September 30, 2019 compared to $16,500 of license fees recognized during the prior year period. Suboxone related license fees were $12,250 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 certain license fees due from Indivior have been suspended pending the outcome of litigation related to infringement claims against the generic products launched “at risk.” Included in the third quarter 2019 license and royalty revenue was $1,000 from our 10% share of milestone payments paid to KemPharm during September 2019, under its licensing of KP-415 and KP-484. There can be no assurance that any such payments will be made in the future. Milestones from other licensed products such as Sunovion’s APL-130277 product are likely to be earned after 2019 based on the timing of the expected PDUFA date for that product. 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 28% or $1,108 to $2,862 for the nine months ended September 30, 2019 compared to $3,970 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, both of which are normally expected to fluctuate significantly one reporting period to the next.

Product sales, net increased $2,187 or 100% for the nine months ended September 30, 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:

(In thousands, except %)	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018	Change $	Change %
Manufacture and supply	$ 13,569	$ 16,201	$ (2,632)	(16)%
Research and development	17,517	17,429	88	0%
Selling, general and administrative	47,868	53,559	(5,691)	(11)%
Interest expense	6,515	5,809	706	12%
Interest income	(565)	(238)	327	NM
Loss on extinguishment of debt	4,896	-	4,896	NM
Other	-	5,278	(5,278)	NM

Manufacture and supply costs and expenses decreased 16% or $2,632 to $13,569 for the nine months ended September 30, 2019 compared to $16,201 for the same period in 2018. The decrease was driven by lower volumes of Suboxone and authorized generic in the 2019 period compared to 2018 as well as the non-cash reversal of an accrual for manufacturing related costs that no longer represented an obligation of the Company, offset in part by higher costs of co-development revenue activity in the 2019 period. Further, there was a $201 decrease in share-based compensation expenses during the nine-month period ended September 30, 2019 compared to same period the nine-month period ended September 30, 2018.

Research and development expenses were flat for the nine months ended September 30, 2019 compared to the prior year period. There was an increase in clinical trials expense in the 2019 period driven by Libervant and AQST-108 development efforts. The increased clinical costs were offset by a decrease of share-based compensation expense of $1,842 in 2019 as compared to 2018. Clinical trial and other third-party direct product development expenses may be expected to fluctuate based on the schedule of clinical and development activities that are conducted during any reporting period.

Selling, general and administrative expenses decreased 11% or $5,691 to $47,868 for the nine months ended September 30, 2019 as compared to $53,559 for the prior year period. This decrease is primarily due to $21,297 in lower stock-based compensation expense in the 2019 period compared to 2018 offset in part by $8,093 of higher investments in our commercialization, branding and marketing capabilities for Sympazan. 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. In addition, in 2019 compared to 2018, we incurred $1,900 of increased legal fees in connection with the ongoing state antitrust litigation and other patent related matters, higher factory unabsorbed overhead as a result of lower production of Suboxone and authorized generic period over period and higher insurance premiums.

Interest expense increased 12% or $706 to $6,515 for the nine months ended September 30, 2019 compared to the same period in 2018, primarily from higher debt balances starting in the third quarter 2019. Prior to July 15, 2019, our interest expense was subject to fluctuations based on one-month LIBOR. Our new Senior Secured Notes due 2025 issued on July 15, 2019 carry a 12.5% fixed interest rate per annum, with an increased principal amount outstanding thereunder.

Interest income increased $327 for the nine months ended September 30, 2019 compared to the same period in 2018, as a result of investing the net cash proceeds from our IPO.

Loss on the extinguishment of debt increased by $4,896 for the three months ended September 30, 2019 compared to the same period in 2018. This increase is the result of the expenses associated with early extinguishment of our Loans Payable with Perceptive. The amount consists of $2,944 related to the prepayment premium associated with early payment of our outstanding obligations to Perceptive along with unamortized debt discount and unamortized loan acquisition costs of $1,606 and $346, respectively.

Other represents the change in the fair value of Perceptive warrants which decreased by $5,278 for the nine months ended September 30, 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. For information concerning the warrants issued in connection with our 12.5% Senior Secured Notes due 2025, issued on July 18, 2019, see Note 12, 12.5% Senior Secured Notes, to our Consolidated Financial Statements.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and expect to incur significant operating losses and negative operating cash flow for the foreseeable future and as of September 30, 2019, we have a net stockholders' deficit of $34,459. We have funded our operations primarily with equity and debt financings and manufacture and supply revenue as well as milestone and royalty payments from our licensees.

We had $20,914 in cash and cash equivalents as of September 30, 2019 and working capital, including cash and cash equivalents, of $18,007.

12.5% Senior Secured Notes

On July 15, 2019, we issued $70,000 aggregate principal amount of our 12.5% Senior Secured Notes due 2025 and Warrants under an Indenture. In addition, the Indenture provides opportunity to issue up to $30,000 of additional Notes under certain conditions for a total possible issuance amount of $100,000.

The net proceeds from the Notes was $66,082, after deducting the estimated expenses of the transaction. We used a portion of the net proceeds to repay an aggregate amount of approximately $52,092, comprised of the full principal amount, all accrued and unpaid interest and applicable prepayment and end-of-term fees, owed to Perceptive under the Credit Agreement and Guaranty (described below). We are using the remaining net cash proceeds of approximately $13,990 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes.

The additional Notes can be issued if we satisfy certain conditions and achieves certain milestones related to the filing and approval of our epilepsy product Libervant and there are available purchasers for the additional Notes. Specifically, on or prior to March 31, 2021, we have the option to issue an additional $10,000 aggregate principal amount of the Notes if we filed a new drug application for our candidate Libervant with the FDA, provided we have obtained the written consent of the holder of a majority in aggregate principal amount of outstanding Notes, in its discretion, which cannot be assured (the "First additional Notes"), up to an additional $30,000 (less the amount of any first additional Notes issued by us) if the Company has obtained approval from the FDA of our product candidate Libervant. There can be no assurance that any such additional financing will be consummated.

Interest on the Notes accrues at a rate of 12.5% per annum and is payable quarterly in arrears on March 30th, June 30th, September 30th and December 30th of each year commencing on September 30, 2019. On each payment date commencing on September 30, 2021, we will also pay an installment of principal of the Notes pursuant to a fixed amortization schedule. The stated maturity date of the Notes is June 30, 2025.

Collateral for the loan consists of a priority lien on substantially all property and assets, including intellectual property, of the Company.

Under the agreement, we have the right to monetize our royalty and milestone interests in Sunovion's Apomorphine product APL-130277 which would not be expected prior to FDA approval of the product. Upon any such monetization we must offer to purchase each holder's Notes on a pro rata basis at a repurchase price in cash equal to 112.5% of the principal amount of such Notes, plus accrued and unpaid interest, if any, thereon to the repurchase date, and such offer will be available to be exercised up to the date of approval of the Libervant approval of the NDA by the FDA, unless exercised prior to that date. The maximum amount that can be offered for repurchase is $40,000 (or $50,000 if the first reopener has been issued and funded). The amount of Notes repurchased will be at the discretion of the holders of the Notes. See Note 12, 12.5% Senior Secured Notes, to our Consolidated Financial Statements, subject to the above - described cap.

The Indenture permits us, upon the continuing satisfaction of certain conditions, including that the Company (on a consolidated basis) has at least $75,000 of net revenues for the most recently completed twelve calendar month period, to enter into an asset-based borrowing facility ("ABL Facility") not to exceed $10,000. The ABL Facility may be collateralized by assets constituting only inventory, accounts receivable and the proceeds thereof of the Company. The Indenture carries customary covenants and restrictions associated with Notes of this nature.

Affirmative and negative covenants and restrictions specified in the Indenture are considered typical for loans of this nature including, but not limited to, specifications relating to preservation of corporate existence, publicly traded status, intellectual property and business interests; limitations or prohibitions of dividend payments or other distributions, repurchases of shares, asset transfers or dispositions, creation or occurrence of additional liens, entering into licensing or monetization arrangements, other than as permitted under the Indenture; and perfection of security interests.

The Indenture also restricts the incurrence of additional indebtedness except only such indebtedness as is expressly permitted under the terms of the Indenture (which includes the ABL Facility) on the terms and conditions set forth in the Indenture and such indebtedness as may be permitted under limitations set forth in the Indenture. The Indenture also restricts the issuance of any "Disqualified Stock", including, generally, mandatorily redeemable securities or securities redeemable at the option of the holder or securities convertible or exchangeable at the option of the holder for indebtedness of the Company or for other Disqualified Stock.

Events of default include various commonly specified conditions including but not limited to, bankruptcy, insolvency, material adverse changes, failure to meet Indenture payment or other obligations, compliance with regulatory requirements and preservation of the corporate existence and business operations of the Company. As of September 30, 2019, the Company was compliant with all financial and other covenants under the 12.5% Senior Secured Notes Indenture.

Under the Indenture, we issued holders of the Notes unregistered Warrants to purchase up to an aggregate of 2,000,000 shares of common stock, $.001 par value per share of the Company at a price of $4.25 per Warrant. The Company registered the Warrants and affiliate shares as part of our Universal Shelf Registration described above.

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. The loan bore interest, payable monthly, at one-month LIBOR, which at June 30, 2019 was approximately 2.75%, plus 9.75%, subject to a minimum rate of 11.75%. 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. The loan was interest-only through April 2019, as amended. The final payments under this agreement were due December 15, 2020, and repayment began on May 31, 2019. However, the agreement and related security interests were terminated with the payoff that occurred on July 15, 2019.

Cash Flows

Nine Months Ended September 30, 2019 and 2018

(In thousands)	2019	2018
Net cash used for operating activities	$ (49,635)	$ (10,179)
Net cash used for investing activities	(577)	(1,334)
Net cash provided by financing activities	10,527	58,116
Net (decrease) increase in cash and cash equivalents	$ (39,685)	$ 46,603

Net Cash Used for Operating Activities

Net cash used for operating activities for the nine months ended September 30, 2019 was $49,635. The use of cash can be understood as represented by three main factors: (1) our net loss of $53,610, (2) decrease in operating assets and liabilities of $9,822, partially offset by (3) non-cash operating expenses. The non-cash operating expenses of $13,797 primarily resulted from $5,199 of share-based compensation expense and the $4,896 loss on the extinguishment of debt recorded in the nine months ended September 30, 2019. Other significant components included non-cash charges of $3,702 related to depreciation, amortization and amortization of debt issuance costs.

Net cash used for operating activities for the nine months ended September 30, 2018 was $10,179. The provision of cash can be understood as represented by three main factors: (1) our net loss of $47,432, (2) decrease in net operating liabilities of $461, partially offset by (3) non-cash operating expenses. The non-cash operating expenses of $37,314 primarily resulted from $28,541 of share-based compensation expense recorded in the nine months ended September 30, 2018. Other significant components included non-cash charges of $9,173 related to depreciation, amortization, changes in warrant valuation and amortization of debt issuance costs.

Net Cash (Used for) Investing Activities

Net cash used for investing activities was $577 for the nine months ended September 30, 2019 compared to $1,334 for the nine months ended September 30, 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 Provided by Financing Activities

Net cash provided by financing activities was $10,527 for the nine months ended September 30, 2019 compared to $58,116 for the nine months ended September 30, 2018. The net cash provided in 2019 is primarily the result of the proceeds from the issuance of our 12.5% Senior Secured Notes of $70,000 and proceeds derived from common stock purchased by eligible employees through the Company's employee stock purchase plan of $112 offset in part, by the repayment of $50,000 associated with our Perceptive Credit Agreement and Guaranty and the premium payment associated with the early retirement of that debt of $2,944 and loan acquisition cost payments associated with our 12.5% Senior Secured Notes of $3,918. Additionally, in 2019 we used $2,723 for withholding taxes associated with tax reimbursement payments from the share-based compensation recorded during 2018. Net cash provided by financing activities in the prior year period was the result of $68,714 proceeds received from our initial public offering offset in part by $4,695 in transaction costs paid as part of our initial public offering and $5,903 related to the reimbursement of withholding taxes associated with the share-based compensation recorded during the second and third quarters of 2018.

Funding Requirements

We expect that our existing cash and cash equivalents combined with our anticipated revenue from our licensed product activities, including expected milestone payments, other co-development payments and royalty payments, manufacturing and supply revenues at anticipated levels, sales of our proprietary product at anticipated levels, cash on hand, the net proceeds from the issuance of our 12.5% Senior Secured Notes due 2025 issued on July 15, 2019 and, assuming satisfaction of all conditions and requirements for further issuances and available purchasers thereof, additional proceeds from future issuances of up to $30,000 of additional Senior Secured Notes, and potential future monetization of certain royalty streams or other license rights for

Apomorphine (subject to all conditions and requirements under the Senior Secured Notes Indenture) and if needed and available to it, which cannot be assured, access to the capital markets under our shelf-registration statement filed with the SEC and declared effective September 17, 2019, will be adequate to fund our expected cash requirements for at least the next 12 months, including planned investments in the commercialization of our late stage CNS product candidates and other expected costs and expenses, capital expenditures and investments in new product candidates in epilepsy and other CNS diseases. We have based this expectation on assumptions that could change, or prove to be inaccurate, and we could utilize our available financial resources sooner than we currently expect.

The key assumptions underlying this expectation include:

- continued revenue from our proprietary and licensed products at planned levels;
- our ability to issue and assuming available purchasers of, additional Senior Secured Notes in an aggregate amount up to $30,000 principal amount under the Indenture for our 12.5% Senior Secured Notes due 2025, based on satisfying certain conditions including NDA filing and subsequent regulatory approval of our Libervant proprietary product, and approval of the first reopener in its discretion (for up to $10 million) by the holder of a majority in principal amount of the Senior Secured Notes, which approval is subject to review by such holder and cannot be assured (see "12.5% Senior Secured Notes" above);
- our ability to monetize royalty streams or other license or proprietary rights for our product Apomorphine at anticipated levels, which cannot be assured (and which is subject to conditions and requirements under the Indenture for our 12.5% Senior Secured Notes including note repurchase obligations at 112.5% of principal amount of such repurchased notes and accrued and unpaid interest thereon, at the option of the holders (see "12.5% Senior Secured Notes" above)) and which monetization would not be expected prior to FDA approval;
- access to the capital markets if and at the time needed for any necessary future funding;
- continuing to review of our cost structure and cost and expense reductions consistent with our anticipated revenues;
- continued funding of our commercialization costs for Sympazan, our first proprietary product launched in December 2018, and continued funding of our development and commercialization of CNS product Libervant and our other proprietary product candidates;
- the infrastructure and administrative costs to support being a public company;
- continued compliance with all covenants under our 12.5% Senior Secured Notes; and
- absence of significant unforeseen cash requirements.

We continue to be in the process of transitioning to a company newly commercializing its self-developed products, with our commercialization activities first beginning with regulatory approval of our first proprietary product Sympazan in December 2018. For our commercialization efforts to be successful we must continue to train, deploy and further develop an effective sales and marketing organization and infrastructure. To become and remain profitable we must continue to develop, obtain timely regulatory approval of, and successfully commercialize or otherwise out-license or monetize, those of our proprietary products and product candidates that we believe will have the most market potential and commercial success. We may encounter unforeseen expenses, difficulties and delays and the success of our commercialization efforts may take longer to achieve than planned. As a result, we are unable to determine or forecast with certainty when or if we will achieve or sustain profitability.

We expect our expenses to continue to significantly increase as we continue to devote substantial financial resources to our ongoing product development, research and development activities, pre-clinical activities, clinical trials, regulatory approval activities, and commercialization activities. We also expect to continue to incur significant losses and negative cash flows and we therefore are dependent upon external financing and funding to achieve out operating plan.

Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- Achieving regulatory approval in the time period we have anticipated of our product candidate Libervant. We hope to complete the filing of our NDA for Libervant with the FDA in the fourth quarter 2019 and thereafter we hope to achieve timely regulatory approval of Libervant during 2020, which cannot be assured, which proprietary product is expected over time to provide a significant revenue source for us through our commercialization efforts. The completion of the NDA filing for, and regulatory approval of, Libervant are also among the conditions to our opportunity to access additional financing of up to $30 million under our Senior Secured Notes Indenture (see "12.5% Senior Secured Notes" above);
- Sunovion Pharmaceuticals, Inc.'s achieving in the time period we have anticipated regulatory approval of Apomorphine, which we out-licensed to Sunovion and which, subject to regulatory approval, which cannot be assured, is expected to provide the opportunity for a significant revenue source for us;

- Our ability to achieve successful commercialization of our proprietary product Sympazan and, subject to regulatory approval, our product Libervant, and the cost and timing of our future commercialization activities for Libervant;
- Continued revenues at planned levels from our manufacture and sale of branded Suboxone to Indivior and continued market acceptance of such branded product, without the authorized generic version of Suboxone;
- Cost, timing and outcome and success of our development of and clinical trials for our complex molecule-based product AQST-108 and our other product candidates;
- Continuing significant costs in seeking to protect our intellectual property rights, including significant litigation costs in connection with seeking to enforce our rights concerning third parties' at-risk launch of generic products;
- Patient and doctor acceptance of and our ability to obtain adequate reimbursement for our products which we commercialize;
- The effect of competing products on our commercialized and licensed products, including Suboxone; and
- All other costs of executing our business plan and absence of unforeseen cash requirements.

The sufficiency of our short-term and longer-term liquidity is directly impacted by our level of operating revenues and our ability to achieve our operating plan for revenues, regulatory approval of our late-stage proprietary products and our ability to monetize in the time period planned our royalty streams or other license rights such as Apomorphine. We also are entitled to further potential milestones, royalty and other payments under our Indivior Supplemental Agreement, which are suspended and may only be reinstated if Indivior successfully adjudicates or settles the related patent infringement litigation, and there is no assurance when or if any such payments may be due. Our operating revenues have fluctuated in the past and can be expected to fluctuate in the future. We expect to incur significant operating losses and negative operating cash flows for the foreseeable future, and we have a significant level of debt on which we have ongoing debt repayment and debt service obligations. A substantial portion of our current and past revenues has been dependent upon our licensing, manufacturing and sales with one customer, Indivior, which is expected to continue while we commercialize our own proprietary products and it could take longer than planned to achieve anticipated sales levels of our proprietary products.

Management will continue to monitor the Company's cash requirements and liquidity and, if management believes operating results, including expected revenue from manufacture and supply sales and proprietary sales, expected license and milestone revenues, any available proceeds from any future issuances of additional Notes under the Indenture for our Senior Secured Notes and from any monetization of royalty streams or other license rights, reductions in cash spend, other available future equity financing, including if needed and available to it, which cannot be assured, access to the capital markets under our shelf registration statement filed with the SEC and effective September 17, 2019 or other potential available sources of liquidity, are not sufficient or available for existing or projected cash requirements, management will seek to take further steps intended to improve the Company's financial position and liquidity, such as by modifying our operating plan, adjusting the timing and scope of our development activities, seeking further to reduce costs and adjusting cash spend, and evaluating and pursuing other opportunities or alternatives to obtain additional liquidity.

On July 15, 2019 we issued $70,000 aggregate principal amount of our 12.5% Senior Secured Notes due 2025 and related Warrants, resulting in approximately $66,082 in note proceeds, after transaction expenses. In connection with the issuance of the Senior Secured Notes, we repaid approximately $52,092 representing all amounts outstanding or due under our Perceptive debt facility. In addition, the Indenture governing the Senior Secured Notes provides opportunity to potentially issue in the future up to an aggregate of $30,000 of additional Senior Secured Notes based on our satisfaction of certain conditions and requirements under the Indenture and having available purchasers of such additional Senior Secured Notes. The Indenture also permits us, upon the continuing satisfaction of certain conditions, including that we (on a consolidated basis) have at least $75,000 of net revenues for the most recently completed twelve calendar month period, to enter into an asset-based borrowing facility not to exceed $10,000 (the "ABL Facility"). The ABL Facility may be collateralized by assets constituting only inventory, accounts receivable and the proceeds of the Company. See "12.5% Senior Secured Notes" above.

On September 11, 2019, the Company filed with the SEC a Registration Statement on Form S-3, which was effective on September 17, 2019 (File No. 333-233716) ("the Registration Statement"). Under the Registration Statement the Company may sell up to $150 million of our securities, including without limitation, common stock, preferred stock, warrants, and debt securities, which in all cases would be subject to the terms of the Indenture. Also, in connection with the Registration Statement the Company entered into an equity distribution agreement with Piper Jaffray & Co., as sales agent, providing the opportunity for an at-the-market offering of up to approximately $17,055 of our common stock from time to time. No securities have been offered or sold by the Company under the Registration Statement as of the date hereof. In the event that we are or believe we may be unable to access in the time period we expect, or at all, additional indebtedness under the first reopener under our Senior Secured Notes Indenture upon the filing of the Libervant NDA or under the second reopener which is conditional on regulatory approval of Libervant, or if we are or believe we may be unable to monetize our product Apomorphine in the time period we expect or at all, then we can be expected to seek to access the capital markets at such times we deem appropriate for our cash needs, or at such other time as we may deem appropriate under the circumstances. In the event of any such sales of common stock or other securities thereunder, the Company currently would intend to use the net proceeds of any such offering primarily for working capital, capital expenditures and development costs and general corporate purposes.

Unless and until we become profitable, we expect to continue to need to raise additional capital and/or other financing or funding in the future, any of which could be material, to further the commercialization of Sympazan and advance the development and commercialization of our CNS products including Libervant, and of our other product candidates and to meet our other cash requirements, including debt service. We do not currently have any committed external sources of financing. Our ability to secure additional equity financing could be significantly impacted by numerous factors including our operating performance and prospects, timely achievement of regulatory approval of our late-stage proprietary products, our existing level of debt which is secured by substantially all of our assets, restrictions under our Senior Secured Note Indenture, and general market conditions, and there can be no assurance that such needed financing will be available, available on favorable terms or at the times or in the amounts needed. We may seek to obtain additional funding in the future through the monetization of royalty streams from our product Apomorphine, subject to regulatory approval thereof , which product candidate is licensed to Sunovion Pharmaceuticals, Inc. (and subject to the conditions and requirements under the Indenture for our 12.5% Senior Secured Notes due 2025 including our note repurchase obligations at the option of the holders), but we cannot be assured of any such royalty streams or monetization. Our ability to obtain any additional indebtedness or other debt financing is limited by the terms of the Indenture for our Senior Secured Notes and the Indenture also restricts or prohibits certain types of equity financing (see "12.5% Senior Secured Notes" above). We may also seek to obtain additional funding through 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 other funding on terms acceptable to us, or at all, and any failure to raise additional capital or other funding as and when needed for our cash requirements would have a negative impact on our financial condition and on our ability to execute and achieve our business plan and cause us to delay or curtail our operations until such funding is received.

To the extent that we raise additional funds by issuance of equity securities, our stockholders would experience dilution and the terms of these securities could include liquidation or other preferences (if and to the extent permitted under the Indenture) that would adversely affect our stockholders' rights. To the extent that we raise additional funds through collaborative, strategic alliances or licensing arrangements with third parties, it may be necessary to relinquish (subject to required consent under our Indenture for the disposition or transfer of assets other than Apomorphine) valuable rights to our intellectual property or future revenue 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 liquidity and funding position.

If adequate funds are not available for our liquidity needs and cash requirements as and when needed, we may be required to delay, reduce the scope of, or eliminate our research and development programs and clinical and other product development activities, or reduce our planned commercialization efforts and otherwise reduce our other spend and adjust our operating plan, and we would need to seek to take other steps intended to improve our liquidity. We also may be required to evaluate additional licensing opportunities, if any become available, of our proprietary product candidate programs that we currently plan to self-commercialize or explore other potential liquidity opportunities or other alternatives or options, although we cannot assure that any of these actions would be available or available on reasonable terms.

Our costs associated with operating as a new public company have increased, and we expect to incur additional costs to support the obligation of a public company to various regulatory agencies, to investors and in order to comply with certain legislation and regulations. These expenditures include the costs of additional employees with specific skills and experiences such as SEC reporting, higher insurance expense, and 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 as well as Indivior's announced notice of its intention to cease production of its authorized generic version of Suboxone. We have to date not experienced any significant reduction in purchase orders from Indivior for the manufacture and supply of Suboxone and the authorized generic film products, other than what we believe it 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***

Prior to July 15, 2019, our exposure to market risk due to changes in interest rates related 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. However, our Senior Secured Notes due 2025 issued on July 15, 2019, carry a 12.5% fixed interest rate per annum, thereby eliminating market risk due to changes in interest rates. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes.

Our accounts receivables are concentrated predominantly with Indivior. See Part II, Item 1A, Risk Factors below concerning Indivior.

With our launch of Sympazan, in December 2018, 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 the Securities Exchange Act of 1934, as amended ("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 are necessarily 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 September 30, 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 September 30, 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.

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 until the expiration of the patent in 2024, and the Federal Circuit affirmed that ruling on July 12, 2019.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the Federal Circuit affirmed that ruling on July 12, 2019. *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. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The remaining case against Actavis was dismissed in light of the infringement ruling above, which prevents Actavis from entering the market until 2024. The case(s) against the remaining defendants, regarding the additional asserted patents have not been finally resolved. A *Markman* hearing in the cases against DRL and Alvogen was held on October 17, 2019, with the court taking the claim construction issues under advisement. No trial date has been set in those cases, 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 DRL. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both DRL and Alvogen. 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. DRL, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by DRL 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 filed their answers to the complaint, including counterclaims for non-infringement and invalidity of the asserted patents as well as two other patents that were not asserted in the original complaint. On July 29, 2019, we and Indivior filed a motion to dismiss Aveva and Apotex's counterclaim for inequitable conduct relating to Indivior's '454 patent. The hearing on that motion originally scheduled for October 30, 2019, was cancelled by the Court, subject to possible rescheduling.

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 IPRs 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 a 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. On August 7, 2019 the Court granted BDSI’s motion to dismiss the Complaint without prejudice and denied BDSI’s motion to stay as moot. 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. On August 29, 2019 the Federal Circuit granted the motion to dismiss BDSI’s appeal. On September 30, 2019, BDSI filed a petition for rehearing *en banc*, and we filed our response to that petition on November 1, 2019.

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 on July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions were conducted through August 1, 2019. Summary judgement motions and *Daubert* motions relating to expert witnesses are currently stayed pending the Court’s resolution of discovery motions in the MDL case. 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 factors below.

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

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

In April 2019 the U.S. Department of Justice announced that a federal grand jury sitting in the Western District of Virginia had criminally indicted Indivior PLC, 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. 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 and our revenues from Indivior, which could have a material adverse financial impact on our business, liquidity and operating results. On July 11, 2019, Reckitt Benckiser Group plc, the predecessor in interest of Indivior, reached agreements with the U.S. Department of Justice and the Federal Trade Commission (FTC) to resolve their investigation into the sales and marketing of Suboxone Film by its former prescription pharmaceuticals business, now Indivior, a business that was wholly demerged from Reckitt Benckiser in 2014. Reckitt Benckiser will pay a total of up to $1.4 billion to fully resolve all federal investigations. As of this filing, Indivior has not disclosed any settlement or other disposition of this matter with the DOJ.

Indivior PLC recently announced that it had notified Sandoz Inc., of Indivior's intention to cease production of the Sandoz authorized generic product, which, if withdrawn from the market, would be expected to have a material impact on our manufactured product sales and revenues.

Under a Commercial Exploitation Agreement dated August 2008 (the "Indivior License Agreement") we agreed to manufacture and supply Indivior's requirements for Suboxone, a sublingual film formulation, both inside and outside the U.S., on an exclusive basis. The initial term of the Indivior License Agreement was seven years from the commencement date and thereafter 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 then renewal term.

In early 2019, certain third-party pharmaceutical companies launched, at risk, generic film products for buprenorphine-naloxone. Also, in early 2019, Indivior, through Sandoz Inc., began to market and sell an authorized generic sublingual film product for Suboxone, which has been well received in the marketplace and which we also exclusively manufacture and supply. As of October 2019, Suboxone and the authorized generic film product continued to retain approximately 75% of the market for film treatments of opioid dependence, of which more than a majority of Indivior's retained market share was branded Suboxone and the balance was the authorized Sandoz generic. On October 15, 2019, Indivior publicly announced that, in order to mitigate the impact from the recent passage of H.R. 438 – Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, which came into effect on October 1, 2019 and which includes changes to the methodology for calculating average manufacturer price for branded drugs, Indivior had given notice to Sandoz of Indivior's intention to cease production of the authorized generic sublingual film product.

Indivior has historically accounted for a substantial part of our total annual revenues and, for fiscal 2018, accounted for approximately 89% of our annual revenues. Through the 2019 third quarter, our manufacturing and supply of Suboxone and the authorized generic for Suboxone accounted for 83% of our total 2019 nine-month revenues.

While we continue to have a strong order book for Suboxone products and the authorized generic film for the balance of 2019, our manufacturing and supply revenue for the Sandoz authorized generic products will cease in the near future, which will materially negatively affect our manufacture and supply revenues and our results of operations. In addition, although Indivior, through the branded and the authorized generic film products, has continued to date to retain substantial market share, we have continued to plan for the erosion of this sunsetting product over time, which will further affect our total revenues and our results from operations.

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
4.1	Indenture dated as of July 15, 2019, among Aquestive Therapeutics, Inc, as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. on July 16, 2019).
4.2	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K files by Aquestive Therapeutics, Inc. in July 16, 2019).
10.1	Form of Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. in July 16, 2019).
10.2	Collateral Agreement dated as of July 15, 2019, among Aquestive Therapeutics, Inc., as Issuer, the Other Grantors for time to time party thereto, U.S. Bank National Association, as Trustee, and U.S. Bank National Association, as Collateral Agent (incorporated by reference to Exhibited 10.2 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. on July 16, 2019).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a), under the Securities Exchange Act of 1934, as amended, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a), under the Securities Exchange Act of 1934, as amended, 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 – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL 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: November 5, 2019

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

Date: November 5, 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 financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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: November 5, 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 financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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: November 5, 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 September 30, 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: November 5, 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 period ended September 30, 2019, to which this Certification is attached as Exhibit 32.2 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Dated: November 5, 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.