

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 June 30, 2018

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
(State or Other Jurisdiction of Incorporation or
Organization)

30 Technology Drive, Warren, NJ 07059

82-3827296

(908) 941-1900

(I.R.S. Employer Identification Number)

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

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

Title of each class

Name of each exchange on which registered

Common Stock, par value \$0.001 per share

NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

(Title of Class)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company) Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act.

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

The number of outstanding shares of the registrant's par value \$0.001 common stock as of the close of business on August 31, 2018 was 24,941,851

FORM 10-Q – QUARTERLY REPORT
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2018

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AQUESTIVE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except unit amounts)
(Unaudited)

	June 30,	December 31,
	2018	2017
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 10,638	\$ 17,379
Accounts receivable, net	6,629	6,179
Inventories, net	4,348	4,014
Prepaid expenses and other current assets	5,034	591
Total current assets	26,649	28,163
Property and equipment, net	12,766	13,460
Intangible assets, net	229	254
Other assets	197	1,239
Total assets	\$ 39,841	\$ 43,116
LIABILITIES AND SHAREHOLDERS' / MEMBERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	\$ 21,140	\$ 14,003
Deferred revenue	1,234	1,347
Loans payable, current	1,100	-
Total current liabilities	23,474	15,350
Loans payable, net	45,330	45,507
Warrant liability	8,835	7,673
Asset retirement obligations	1,150	1,081
Total liabilities	78,789	69,611
Commitments and contingencies (Note 14)		
Redeemable preferred A-3 interests and accrued dividends	-	5,896
Redeemable preferred A-2 interests and accrued dividends	-	36,205
Shareholders' / Members' Deficit		
Preferred A interests, no par value. Authorized 100,000,000 units; 16,886,750 units issued and outstanding at December 31, 2017	-	16,887
Preferred A-1 interests, no par value. Authorized 100,000,000 units; 21,526,850 units issued and outstanding at December 31, 2017	-	21,883
Common interests, no par value. Authorized 500,000,000 units; 121,228,353 units issued and outstanding at December 31, 2017	-	12,727
Common stock, \$.001 par value. Authorized 350,000,000 shares; 15,077,647 voting and 4,922,353 non-voting (Note 15) shares issued and outstanding at June 30, 2018	20	-
Additional paid-in capital	(6,574)	-
Accumulated deficit	(32,394)	(120,093)
Total shareholders' / members' deficit	(38,948)	(68,596)
Total liabilities and shareholders' / members' deficit	\$ 39,841	\$ 43,116

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

	Three Months Ended June 30		Six months Ended June 30	
	2018	2017	2018	2017
Revenues	\$ 13,928	\$ 11,142	\$ 37,339	\$ 27,577
Cost and expenses:				
Manufacture and supply	4,973	5,141	10,609	9,325
Research and development	7,994	4,837	12,895	10,178
Selling, general and administrative	33,647	5,223	41,216	11,352
Total costs and expenses	46,614	15,201	64,720	30,855
Loss from operations	(32,686)	(4,059)	(27,381)	(3,278)
Other income (expenses):				
Interest expense	(1,927)	(1,949)	(3,854)	(3,767)
Change in fair value of warrant	(1,859)	111	(1,162)	(309)
Other, net	(21)	-	3	-
Net loss before income taxes	(36,493)	(5,897)	(32,394)	(7,354)
Income taxes	-	-	-	-
Net loss	(36,493)	(5,897)	(32,394)	(7,354)
Dividends on redeemable preferred interests	-	(615)	-	(1,228)
Net loss attributable to common shares / members' interests	(36,493)	(6,512)	(32,394)	(8,582)
Comprehensive loss	\$ (36,493)	\$ (6,512)	\$ (32,394)	\$ (8,582)
Net loss per share:				
Net loss per common share - basic and diluted	\$ (1.90)		\$ (1.89)	
Weighted-average number of common shares / membership interests outstanding - basic and diluted	19,188,624		17,144,492	

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

	Six Months Ended June 30,	
	<u>2018</u>	<u>2017</u>
Cash flows from operating activities:		
Net loss	\$ (32,394)	\$ (7,354)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation and amortization	1,705	1,853
Change in Fair value of warrant	1,162	309
Share-based compensation expenses	27,305	-
Asset retirement obligation accretion	69	59
Amortization of intangible	25	24
Amortization of debt issuance costs and discounts	923	920
Noncash interest expense	(16)	-
Bad debt provision (recovery)	31	(31)
Changes in operating assets and liabilities:		
Accounts receivable, net	(481)	3,199
Inventories	(334)	(1,465)
Prepaid expenses and other assets	(179)	33
Accounts payable and accrued expenses	3,593	(380)
Deferred revenue	(113)	439
Net cash provided by (used for) operating activities	<u>1,296</u>	<u>(2,394)</u>
Cash flows from investing activities:		
Capital expenditures	(886)	(1,547)
Net cash (used for) investing activities	<u>(886)</u>	<u>(1,547)</u>
Cash flows from financing activities:		
Proceeds from warrant exercise	-	24
Proceeds from issuance of debt	-	5,000
Payments for deferred financing costs	(1,528)	(3)
Payments for taxes on share-based compensation	(5,623)	-
Net cash (used for) provided by financing activities	<u>(7,151)</u>	<u>5,021</u>
Net (decrease) increase in cash and cash equivalents	<u>(6,741)</u>	<u>1,080</u>
Cash and cash equivalents:		
Beginning of period	17,379	9,209
End of period	<u>\$ 10,638</u>	<u>\$ 10,289</u>
Supplemental disclosures of cash flow information:		
Cash payments for interest	\$ 2,970	\$ 2,355
Net increase (decrease) in capital expenditures included in accounts payable and accrued expenses	125	(110)
Net increase in offering costs included in accounts payable and accrued expenses	1,694	-
Accrued withholding tax for share-based compensation	1,741	-
Accrued Series A-2 and A-3 preferred dividends	-	1,228

Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC)**NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(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”) was formed effective on January 1, 2018 via the conversion of MonoSol Rx, LLC to, a Delaware corporation and a simultaneous name change. Prior to that date, the business operated as MonoSol Rx, LLC, a Delaware limited liability company. The financial statement information presented from periods prior to January 1, 2018 are that of MonoSol Rx, LLC.

Aquestive is a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs and solve critical healthcare challenges. The Company has a late-stage proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS and is developing orally administered complex molecules as alternatives to more invasive therapies. Aquestive is pursuing its business objectives through both in-licensing and out-licensing arrangements. The Company’s major customer and primary commercialization partner has global operations headquartered in the United Kingdom with principal operations in the United States; other customers are principally located in the United States.

The Company conducts its production activities at facilities located in Portage, Indiana, and maintains its headquarters, sales and commercialization operations and its primary research laboratory in Warren, New Jersey.

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

MonoSol Rx, LLC was originally formed in Delaware in January 2004 and until December 31, 2017, the Company conducted its business through MonoSol Rx, LLC, a Delaware limited liability company, or MonoSol. On January 1, 2018, MonoSol converted from a Delaware LLC into a Delaware corporation pursuant to a statutory conversion and changed its name to Aquestive Therapeutics, Inc.

Reorganization

In a corporate reorganization conducted following the conversion of MonoSol into a Delaware corporation, the holders of units of MonoSol contributed their interests in MonoSol 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 the Company and became the parent and sole stockholder of the Company.

The table below depicts the number of redeemable and non-redeemable interests outstanding for each series of membership interests at December 31, 2017, which were converted to identical interests in APL on a 1:1 basis effective January 1, 2018;

	December 31, 2017
Redeemable Preferred A-3 Interests	5,055,000
Redeemable Preferred A-2 Interests	82,071,200
Nonredeemable A-1 interests	21,526,850
Nonredeemable A interests	16,886,750
Common Interests	121,228,353
	<u>246,768,153</u>

Stock Splits

In April 2018, the board approved an amendment to the Certificate of Incorporation of the Company to:

(i) increase the authorized number of capital stock from 25,000 to 350,000,000 shares,

(ii) authorize the Non-Voting Common Stock, and

(iii) affect 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.

In July 2018, the board approved an additional amendment to the Certificates of Incorporation of the Company to affect a reverse stock split of the Company's common stock, par value \$0.001 per share, such that each 12.34 shares outstanding converted into one share of common stock, par value \$0.001 per share.

For purposes of these financial statements, the net effect of these stock splits have been presented as if they had occurred on January 1, 2018.

Initial Public Offering of Common Stock

On July 27, 2018, the Company closed the initial public offering ("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 \$57,545 after deducting underwriting discounts, commissions, and offering related transaction costs of approximately \$9,955. On August 15, 2018, the Company was informed that the underwriters exercised their over-allotment option and the Company issued 425,727 additional common shares at \$15.00 per share. Upon the closing of such exercise, the Company received additional net proceeds of approximately \$5,939, after deducting underwriter discounts of approximately \$447.

Note 2. Basis of Presentation

The accompanying unaudited 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 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, 2017 included in our prospectus dated July 29, 2018 filed with the SEC, pursuant to Rule 424(b) under the Securities Act. 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 results of operations and cash flows reported in these consolidated financial statements should not be regarded as necessarily indicative of results that may be expected for the entire fiscal year.

Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted principles 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

On January 1, 2018 MonoSol Rx, LLC (which previously consolidated MonoSol Rx, Inc. in 2017) was converted from a Delaware LLC into a Delaware corporation pursuant to a statutory conversion under the laws of the State of Delaware. The resulting entity is Aquestive Therapeutics, Inc. into which is consolidated its wholly-owned subsidiary MonoSol Rx, Inc.

These consolidated financial statements presented for periods earlier than January 1, 2018 include the accounts of the MonoSol Rx, LLC. 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.

(B) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of these consolidated 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 the useful lives of fixed assets, valuation of warrants, stock compensation, and contingencies.

(C) Deferred Offering Costs

Deferred Offering costs, included as a component of Other Current Assets in the accompanying balance sheet and consisting primarily of direct incremental legal, accounting and other fees relating to the IPO, are capitalized as incurred. As of March 31, 2018, deferred offering costs were included as a component of Other Assets due to the uncertainty of an IPO. Due to the Company's closure of the IPO on July 27, 2018, the deferred offering costs were reclassified from Other Assets to Prepaids and Other Current Assets in the accompanying balance sheet. The deferred offering costs will be offset against IPO proceeds concurrent with the July 2018 consummation of the offering. As of June 30, 2018, the Company had capitalized costs totaling approximately \$4,273 that were incurred in connection with ongoing equity raising initiatives.

(D) Recent Accounting Pronouncements

As a public emerging growth company, the Company has elected to take advantage of the extended transition period afforded by 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 on the relevant dates on which adoption of such standards is required for public emerging growth companies.

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

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The standard will apply one comprehensive revenue recognition model across all contracts, entities, and sectors. The core principle of the new standard is that revenue should be recognized 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. Once effective, ASU 2014-09 will replace most of the existing revenue recognition requirements in U.S. GAAP. The FASB also issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which deferred the effective date of the standard one year. As a result, the new standard is effective for annual reporting periods beginning after December 15, 2019, including interim periods within the reporting period. The Company is currently assessing the effect that adoption of the new standard will have on its consolidated financial statements. As of part of the Company's assessment, an entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented, referred to as the full retrospective method, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings, referred to as the modified retrospective method. The Company is in the process of its initial assessment of the potential changes from adopting ASU No. 2014-09. The initial assessment consists of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on its consolidated financial statements, accounting policies, financial control, and operations. The Company has not yet completed its final review of the impact; however, the Company anticipates applying the modified retrospective method when implementing this guidance. As a result, this standard is effective for the Company for annual reporting periods beginning after December 15, 2019. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its initial conclusions.

In January 2016, the FASB issued revised guidance governing accounting and reporting of financial instruments. 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. These revised standards are effective for the Company for annual periods in fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact of these revised standards.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* which establishes a comprehensive new lease accounting model. The new standard: (i) clarifies the definition of a lease; (ii) requires a dual approach to lease classification similar to current lease classifications; and (iii) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The new standard is effective for the Company for fiscal years and interim periods beginning after December 15, 2019 and requires modified retrospective application. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

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 is effective for annual periods beginning after December 15, 2017, with early adoption permitted. Under the Company's Performance unit plans (Note 15), vested grants may not be exercised prior to either a change in control of the Company or completion of an IPO, rendering the grants contingent and requiring deferred expense recognition until either of the conditions is satisfied. Accordingly, the adoption of ASU 2016-09 had no impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU No. 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 adoption on its consolidated financial statements

In August 2016, the FASB issued ASU No. 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. 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 Consolidated Statement of Cash Flows.

The Company reviewed all other recently issued accounting pronouncements and concluded that they were either not applicable or not expected to have a material impact on the financial statements.

Note 4. Risks and Uncertainties

The Company's budgeted cash requirements for 2018 and beyond include expenses related to continuing development and clinical evaluation of its products, as well as preparing for related commercialization of our products. As of June 30, 2018 and December 31, 2017, we had working capital (current assets less current liabilities) of \$3,175 and \$12,813, respectively.

On July 27 and August 15, 2018, the Company closed the IPO of 4,500,000 and overallotment exercise of 425,727 shares of common stock, respectively, at a price of \$15.00 per share raising total net proceeds of \$63,484, net of underwriting discount and other offering expenses. As a public company, additional future liquidity needs will include costs to comply with the requirements of a public company.

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

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. During the six-month period ended June 30, 2018, Indivior, Inc. ("Indivior") represented 97% of the total revenues for the period. During 2017, Indivior represented 77% of the total revenue for the period. As of June 30, 2018 and December 31, 2017, the Company's outstanding receivable balance from Indivior represented approximately 94% and 93%, respectively, of total receivables.

As of June 30, 2018, cash and cash equivalents were maintained at one federally insured financial institution. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to any credit risk due to the financial position of the banking institution. The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Note 5. Revenue Recognition and Trade Receivables, net

Pursuant to FASB ASC Topic 605, *Revenue Recognition*, revenue is recognized when there is persuasive evidence of an agreement, title has passed or delivery has occurred, the price is fixed and determinable, and collection is reasonably assured.

Manufacture and Supply Revenue – The Company records revenues when products are shipped and title passes to the customers.

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

License and Royalty Revenue – License revenue is recognized in accordance with the terms of the license agreement. The Company’s license revenues most commonly are non-refundable once collected and are typically recognized as revenue at the time that the transferred licensed rights can be utilized for the benefit of the licensee, subject to determinable pricing, performance contingencies and collectability assessments. In the event that a licensing agreement requires the Company to meet ongoing or future performance objectives that are other than inconsequential or perfunctory, licensing revenue may be recognized ratably, or in conjunction with completion of its performance obligations, during the initial term of the license agreement. If a performance obligation, milestone, or contingency, such as a specified level of cumulative product sales or the approval of a regulatory agency, exists, revenue is deferred until such time that the contingencies are satisfied or obligations are met. Payments received in excess of amounts achieved are classified as deferred revenue until earned. Royalty revenue is recognized in accordance with contractual rates when they can be reasonably estimated based on reported sales data and when collection is reasonably assured. In the event that reasonable sales data is unavailable, revenue is recognized when royalty reports are received.

Collaborative Arrangements – A contractual arrangement falls within the scope of FASB ASC Subtopic 808-10, Collaborative Arrangements, if the arrangement requires the parties to be active participants and the arrangement exposes the parties to significant risks that are tied to the commercial success of the endeavor. Costs incurred and revenues generated on sales to third parties are reported in the consolidated statement of operations based on the guidance in FASB ASC Subtopic 605-45, *Revenue Recognition – Principal Agent Considerations*. Revenue earned from collaboration partners as of June 30, 2018 and 2017 was not material.

The Company’s revenues for the three and six months ended June 30, 2018 and 2017 consisted of the following:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Manufacture and supply revenue	\$ 8,684	\$ 10,336	\$ 20,244	\$ 20,491
License and royalty revenue	4,532	246	14,032	5,469
Co-development and research fees	712	560	3,063	1,617
Revenues	<u>\$ 13,928</u>	<u>\$ 11,142</u>	<u>\$ 37,339</u>	<u>\$ 27,577</u>

Disaggregation of Revenue

The following table provides additional information pertaining to revenues disaggregated by geographic market for the three and six months ended June 30, 2018 and 2017:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
United States	\$ 13,380	\$ 10,684	\$ 36,577	\$ 26,572
Ex-United States	548	458	762	1,005
Revenues	<u>\$ 13,928</u>	<u>\$ 11,142</u>	<u>\$ 37,339</u>	<u>\$ 27,577</u>

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

The Company's credit terms generally range from 30 to 60 days, depending on the customer and type of invoice. Trade receivables are carried at original invoice amount less an estimate of doubtful receivables based on a review of all outstanding amounts on a periodic basis. Management determines the allowance for doubtful accounts by identifying troubled accounts and, in the absence of historical experience, applies an estimate that is believed to be a reasonable indicator of future potential losses. Trade receivables are written off when deemed uncollectible. Recoveries of trade receivables previously written off are recorded when received.

Accounts Receivable, net

Accounts Receivable, net consist of the following:

	June 30, 2018	December 31, 2017
Trade receivables	\$ 6,662	\$ 6,156
Other receivables	53	78
Less: allowance for bad debts	(86)	(55)
Trade receivables, net	<u>\$ 6,629</u>	<u>\$ 6,179</u>

Other receivables consisted primarily of reimbursable costs incurred on behalf of a major customer.

The following table presents the changes in the allowance for bad debts account:

	June 30, 2018	December 31, 2017
Allowance for doubtful accounts at beginning of year	\$ 55	\$ 108
Additions charged to bad debt expense	31	-
Recoveries of amounts previously reserved	-	(53)
Allowance for doubtful accounts at end of the period	<u>\$ 86</u>	<u>\$ 55</u>

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. (the "Indivior License Agreement"). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior, Inc. ("Indivior"). Pursuant to the Indivior License Agreement, the Company agreed to manufacture and supply Indivior's requirements of Suboxone, a sublingual film formulation, both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, the Company is required to manufacture Suboxone in accordance with current Good Manufacturing Practice standards and according to the specifications and processes set forth in the related quality agreements the Company entered into with Indivior. Additionally, the Company is required to obtain Active Pharmaceutical Ingredients ("API") for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that the Company is obligated to fill and requires Indivior to provide the Company with a forecast of its requirements at various specified times throughout the year.

In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) in each of the United States and in the rest of the world subject to annual maximum amounts. In the event that Indivior has paid the Company a specified aggregate royalty amount in royalties on Suboxone sold in the United States, then it will be required to prepay to the Company, an additional agreed payment amount, after which all obligations of Indivior to pay royalties on Suboxone sold in the United States will terminate. Except as set forth in the prior sentence, Indivior's royalty obligations to the Company continue in the United States and the rest of the world until the expiration of all of the patents (either in the United States or other territories) or upon written notice by Indivior subject to Indivior being required to pay the Company a final royalty payout. Indivior exercised its right to buy out its future royalty obligations in the United States in 2012. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions for breach or in the event of bankruptcy or corporate dissolution, the intellectual property surrounding Suboxone is found to be invalid, or either party commits a material breach of the Indivior License Agreement. 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 Indivior provides the Company with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

Supplemental Agreement with Indivior

On September 24, 2017, the Company entered into an agreement with Indivior (the “Indivior Supplemental Agreement”). Pursuant to this agreement, the Company conveyed to Indivior all of its existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to Suboxone product. The Company also conveyed to Indivior the right to sublicense manufacturing and marketing capabilities to enable an Indivior licensed generic buprenorphine product to be produced and sold by parties unrelated to Indivior or the Company. Under the Indivior Supplemental Agreement, the Company is entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. Once paid, all payments made under this Agreement are non-refundable. In consideration for the rights granted to Indivior under the Indivior Supplemental Agreement, the Company received in September 2017, a non-refundable payment of \$17,000, which was recognized as revenue in 2017 in License and royalty revenue. The Company received \$4,250 and \$13,500 during the three and six month periods ended June 30, 2018, respectively, which is included in License and royalty revenue. In addition to amounts received through June 30, 2018, the Company may receive up to an additional \$44,500, consisting of (i) up to \$42,000 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 \$2,500 that may be earned through the issuance of additional process patent rights to us with the aggregate payment amounts under the Indivior Supplemental Agreement capped at \$75,000. Accordingly, the Agreement includes certain provisions that may allow Indivior to cease remitting certain payments to the Company upon the occurrence of certain events related to unlicensed generic versions of Suboxone. In the event that Indivior’s defense of its rights is ultimately successful, then, all payment obligations owed to the Company are retroactively reinstated.

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, the Company entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to an interest by Sunovion Pharmaceuticals, Inc. (“Sunovion”)) (the “Sunovion License Agreement”), pursuant to which the Company granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson’s disease patients, as well as two other fields.

Under the Sunovion License Agreement, the Company received \$0 and \$5,000 milestone payments during the six months ended June 30, 2018 and 2017, respectively, which was recognized as revenue and is presented in License and royalty revenue. The Company is eligible to receive remaining milestone payments of up to \$11,000 for certain regulatory events and up to \$20,000 for commercial milestone events that are contingent on the achievement of certain sales levels. In addition to the milestone payments, the Company is entitled to receive low single digit percentage royalty payments on global net sales of apomorphine-based products that may be commercialized by Sunovion.

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 their remaining inventory of products commercialized by Sunovion which include apomorphine as their API.

Collaboration and License Agreement with Mitsubishi Tanabe

In August 2017, the Company entered into an agreement with Mitsubishi Tanabe (“MT”) to perform feasibility studies related to Radicava, MT’s Amyotrophic Lateral Sclerosis treatment using the compound edaravone. The revenues earned pursuant to this arrangement totaled \$240 during the six months ended June 30, 2018.

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 arrangement, we have the right to receive payments, including, but not limited to, royalty payments on any license of KP415, the sale of KP415 to a third party, the commercialization of KP415 and the portion of any consideration that is attributable to value of KP415 and paid to KemPharm or its stockholders in a change of control transaction. The Company has not received payments under this arrangement during the six months ended June 30, 2018 and 2017.

Note 7. Fair Value Measurements

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

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

The Company’s Level 3 liabilities consisted of warrants totaling \$8,835 and \$7,673 at June 30, 2018 and December 31, 2017, respectively. The Company’s warrant liability is stated at fair value based primarily on an independent third-party appraisal prepared as of the reported balance sheet dates 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*.

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

Note 8. Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Inventory includes the cost of materials, production labor and overhead. The Company regularly reviews its inventories for impairment and reserves are established when necessary.

	<u>June 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Raw material	\$ 729	\$ 725
Packaging material	2,301	2,225
Finished goods	1,318	1,064
Total inventory	<u>\$ 4,348</u>	<u>\$ 4,014</u>

Note 9. Property and Equipment, net

Property and Equipment, net as of June 30, 2018 and December 31, 2017 consisted of the following:

	Useful Lives	June 30, 2018	December 31, 2017
Machinery	3-15 yrs	\$ 20,286	\$ 20,056
Furniture and fixtures	3-15 yrs	1,109	1,109
Leasehold improvements	(a)	21,275	21,271
Computer, network equipment and software	3-7 yrs	2,228	2,108
Construction in progress		1,578	921
		<u>46,476</u>	<u>45,465</u>
Less: accumulated depreciation and amortization		<u>(33,710)</u>	<u>(32,005)</u>
Total property and equipment, net		<u>\$ 12,766</u>	<u>\$ 13,460</u>

(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 approximately \$765 and \$938 for the three months ended June 30, 2018 and 2017, respectively and \$1,705 and \$1,853 for the six months ended June 30, 2018 and 2017, respectively.

Note 10. 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 corporate conversion and reorganization described in Note 1(B), there were no potentially dilutive instruments outstanding for the three and six months period ended June 30, 2018. Therefore, basic and diluted net loss per share were the same for all periods presented as reflected below.

	For the Three Months Ended June 30, 2018	For the Six Months Ended June 30, 2018
Numerator:		
Net loss	\$ (36,493)	\$ (32,394)
Denominator:		
Weighted-average number of common shares – basic and diluted	19,188,624	17,144,492
Income per common share – basic and diluted	\$ (1.90)	\$ (1.89)

The LLC interests, prior to the corporate conversion and reorganization of the Company described in Note 1(B), were complex and varied across several series of LLC equity interest conveying different economics and rights. As such, loss per share information prior to the reorganization under the prior equity structure is not comparable to earnings per share for periods presented after the reorganization.

Note 11. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	June 30, 2018	December 31, 2017
Accounts payable	\$ 16,522	\$ 9,601
Accrued salaries, performance bonuses, other compensation and benefits	2,339	3,761
Accrued withholding tax for share-based compensation	1,741	-
Real estate and personal property taxes	263	340
Other	275	301
Total accounts payable and accrued expenses	<u>\$ 21,140</u>	<u>\$ 14,003</u>

Note 12. Loans Payable

On August 16, 2016, the Company entered into a Loan Agreement and Guaranty with Perceptive Credit Opportunities Fund, LP (“Perceptive”). At closing, the Company borrowed \$45,000 from Perceptive, 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 (see Note 13).and the Company was permitted to borrow up to an additional \$5,000 within one year of the closing date based upon achievement of a defined milestone. In March 2017, the Company met its performance obligations under the terms of the credit agreement with Perceptive and submitted a formal request to draw down the remaining \$5,000 of its \$50,000 credit facility. The loan proceeds were used to pay the existing debt obligation of \$37,500 due to White Oak Global Advisors, LLC, with the balance available for general business purposes.

On May 21, 2018, the Company and Perceptive agreed to make certain amendments to the loan agreement then in effect. In the event that a qualified IPO is consummated on or before December 31, 2018, the Company and Perceptive agreed to postpone the initial loan principal payments and delay the loan maturity date to December 16, 2020 and bears interest, payable monthly, at one-month LIBOR or 2% plus 9.75%, subject to a minimum rate of 11.75%. Commencing on May 31, 2019, seven monthly loan principal payments are due in the amount of \$550. Thereafter, monthly principal payments in the amount of \$750 are due through the maturity date, at which time the full amount of the remaining outstanding loan balance is due. At June 30, 2018, \$1,100 was classified as current debt. The Company’s tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. Financial covenant requirements include (1) minimum liquidity under which a \$4,000 minimum cash balance must be maintained at all times and (2) a minimum revenue requirement under which minimum revenues for the trailing twelve consecutive months, measured at the end of each calendar quarter, must also be met. As of June 30, 2018, the Company was in compliance with all financial covenants. Also, as of that date, the Company’s carrying value of this loan payable approximated its fair market value.

The Company capitalizes legal and other third-party costs incurred in connection with obtaining debt as deferred debt issuance costs and applies the unamortized portion as a reduction of the outstanding face amount of the related loan in accordance with ASU 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*. Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its lenders, and offsets those as a direct reduction of its outstanding debt. Amortization expense arising from deferred debt issuance costs and debt discounts for the three months ended June 30, 2018 and 2017 totaled \$465 and \$463, respectively and for the six months ended June 30, 2018 and 2017 totaled \$923 and \$920, respectively.

Unamortized deferred debt issuance costs and deferred debt discounts totaled \$3,570 as of June 30, 2018 and \$4,493 as of December 31, 2017.

Note 13. Warrant Liability

The warrant issued to Perceptive in connection with the August 16, 2016 Loan Agreement expires on August 16, 2023 and has certain rights and preferences including anti-dilution adjustments so that, upon exercise, they will represent 4.5% of the Company’s fully diluted common stock on an as converted basis, subject to dilution for certain financing transactions including the issuance of shares upon termination of our Performance Unit Plans. The warrant also provides Perceptive with a put right which, if exercised under certain circumstances, would require the Company to purchase the warrant for \$3,000 within the first year of the loan or \$5,000 thereafter. These re-purchase terms may require net-cash settlement, and as a result, the appraised value of this warrant at the time of issuance of \$5,800 was classified as a liability, rather than as a component of equity, and is treated as a debt discount, with the unamortized portion applied to reduce the face amount of the loan in the accompanying Consolidated Balance Sheet. As noted in Note 17(A), these warrants were exercised in connection with the Company’s IPO in July 2018.

The Company uses a third-party valuation to assist in determining the fair value of the warrant due to the absence of available Level 1 and Level 2 inputs. The appraisals at both the date of the issuance and the balance sheet date were based on unobservable Level 3 inputs. The first step in determining the fair value of the warrant liability is to determine the value of the aggregate equity of the Company which was estimated utilizing the income and market valuation approaches. A probability weighted return model was then utilized to allocate the aggregate equity value of the Company to the underlying securities. Estimates and assumptions impacting the fair value measurement include the following factors: the progress of the Company’s pipeline products since the prior valuations, including status of clinical trials; the Company’s progress towards an IPO; discount rates of 26.5% and 24.0% for the six months ended June 30, 2018 and 2017, respectively and volatility rates of 85% for both the six month periods ended June 30, 2018 and 2017, respectively.

A roll-forward of warrant liability is as follows:

	Warrant liabilities
Balance as of December 31, 2017	\$ 7,673
Changes in fair value recognized	1,162
Closing Balance as of June 30, 2018	<u>\$ 8,835</u>

Note 14. Commitments and Contingencies

(A) Operating Leases

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

Rent expense for all leased manufacturing facilities and sales, laboratory and office space was approximately \$292 and \$323 for three months ended June 30, 2018 and 2017, respectively and \$623 and \$645 for the six months ended June 30, 2018 and 2017, respectively.

(B) Litigation and Contingencies

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of our business. Except as described below, we are not presently a party to any litigation or legal proceedings that we believe to be material and we are not aware of any pending or threatened litigation against us that we believe could have a material adverse effect on our business, operating results, financial condition or cash flows.

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., or Par, Alvogen Pine Brook, Inc., or Alvogen, Teva Pharmaceuticals USA, Inc., or Teva, Sandoz Inc., or Sandoz, and Mylan Technologies Inc. or 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. Of these, cases against two of the six generic companies have been resolved.

- *Sandoz*. By court order in August 2016, our ANDA patent litigation case against Sandoz has been dismissed without prejudice for lack of subject matter jurisdiction because Sandoz is no longer pursuing a Paragraph IV certification for its proposed generic version of Suboxone Sublingual Film, and therefore is no longer challenging the validity or infringement of our Orange Book-listed patents.
- *Mylan*. The case against Mylan was settled and the Court signed a Consent Judgment in September 2017 disposing of the entire case.

After the commencement of the above-mentioned ANDA patent litigation against Teva, Dr. Reddy's Laboratories acquired the ANDA filings for Teva's buprenorphine and naloxone sublingual film that are at issue in these trials.

Trials against Dr. Reddy's, Actavis and Par in the lawsuits involving the Orange Book and process patents occurred in November-December of 2015 and November of 2016. On June 3, 2016, the Court issued its Trial Opinion finding that the asserted claims of U.S. Patent No. 8,603,514, or the '514 patent, are valid and infringed by Actavis's and Par's ANDA Products. On August 31, 2017, the Court upheld U.S. Patent No. 8,900,497, or the '497 patent, as valid but not infringed by Par's, Actavis's or Dr. Reddy's proposed processes for making their ANDA Products. The Court also again upheld the validity of the '514 patent but held it was not infringed by Dr. Reddy's ANDA Products, and upheld the validity of U.S. Patent No. 8,017,150, or the '150 patent, but held that it was not infringed by Dr. Reddy's ANDA Products. All of these cases are consolidated on appeal to the Federal Circuit, except that the cases between Indivior and us and Par and certain affiliates have been resolved by a settlement agreement.

Trial against Alvogen was held in September, 2017. The only issue raised at trial was whether Alvogen's ANDA Products and processes infringe the '514 and '497 patents; Alvogen did not challenge the validity of the patents. In March 2018, the Court issued its opinion finding that Alvogen's ANDA products and processes would not infringe the '514 or '497 patents. We and Indivior appealed the ruling, and the appeal is currently pending before the Federal Circuit. If any company is able to obtain FDA approval for its generic version of Suboxone Sublingual Film, it may be able to launch the product prior to the expiration of any or all the applicable patents protecting our Suboxone Film, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

We are also seeking to enforce our patent rights in multiple cases against BioDelivery Sciences International, Inc., or 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 stayed pending *inter partes* review of the '832 patent and reexamination of the '080 patent.
- 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. This case was initially filed in September 2014 in the U.S. District Court for the District of New Jersey but was transferred to North Carolina. Shortly after the case was filed, BDSI filed an IPR challenging the asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding the '167 patent was not unpatentable. This case is stayed pending the outcome and final determination of the proceedings concerning the '167 patent (discussed further below).

On January 13, 2017, we also sued BDSI asserting infringement of the '167 patent by BDSI's Belbuca product. The case was originally filed in the U.S. District Court for the District of New Jersey and was later transferred to the U.S. District Court for the District of Delaware by agreement of the parties.

On November 28, 2016, after the PTAB issued its final written decisions finding that the '167 patent was not unpatentable in IPR2015-00165, IPR2015-00168 and IPR2015-00169, BDSI filed a notice of appeal of those decisions to the U.S. Court of Appeals for the Federal Circuit. The case has been fully briefed and the Court heard oral arguments on February 9, 2018. On June 19, 2018, BDSI filed a motion to terminate and remand the appeal, which the Company opposed. On July 31, 2018, the Federal Circuit granted the motion, vacating the PTAB's decisions and remanding for further proceedings before the PTAB.

In September 2017, Indivior brought suit against Alvogen for infringement of U.S. Patent No. 9,687,454, or the '454 patent, based on the filing of an ANDA seeking approval for a generic version of Suboxone Sublingual Film, in the U.S. District Court for the District of New Jersey. In February 2018, we and Indivior amended the complaint, which added us as a plaintiff and a claim for infringement of U.S. Patent No. 9,855,221, or the '221 patent.

Indivior brought suits against Dr. Reddy's and Teva in September 2017, and against Par and certain affiliates in October 2017, for infringement of the '454 patent, in the U.S. District Court for the District of New Jersey. Indivior also brought suit in September 2017 against Actavis Laboratories UT, Inc. for infringement of the '454 patent, in the U.S. District Court for the District of Utah. On March 13, 2018, the Court granted transfer of this case to the U.S. District Court for the District of Delaware.

In February 2018, we and Indivior brought suit against Actavis, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of the '221 patent. The suit against Actavis was filed in the U.S. District Court for the District of Utah, and the other three cases were filed in the U.S. District Court for the District of New Jersey.

In April 2018, we brought suit with Indivior against Actavis, Alvogen, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of U.S. Patent No. 9,931,305, or the '305 patent. The cases against Alvogen, Dr. Reddy's, Teva, and Par are pending in the U.S. District Court for the District of New Jersey, and they have each been consolidated with the actions asserting infringement of the '454 and '221 patents. Following transfer of the case asserting the '454 patent from Utah to Delaware, and by agreement of the parties, the cases against Actavis asserting infringement of the '454, '221, and '305 patents are consolidated in a single action pending in the U.S. District Court for the District of Delaware.

All matters involving Par were resolved on May 11, 2018, when we, Indivior, and Par and certain of its affiliates entered into a settlement agreement resolving patent litigation related to SUBOXONE (buprenorphine and Naloxone) Sublingual Film. As required by law, the parties submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

On June 14, 2018, Dr. Reddy's notified the U.S. District Court for the District of New Jersey that the FDA had granted final approval of its ANDAs and that it had launched generic versions of Suboxone Sublingual Film. The Company and Indivior filed a motion for a preliminary injunction and a request for a temporary restraining order, and the Court grant the request on June 15, 2018 enjoining and restraining Dr. Reddy's from offering for sale, selling or importing its generic versions of Suboxone Sublingual Film. On July 13, 2018, the Court granted the preliminary injunction, which enjoins Dr. Reddy's from launching a generic version of Suboxone during the pendency of the litigation and until further order from the Court. Dr. Reddy's appealed the preliminary injunction ruling to the Federal Circuit. Dr. Reddy's also requested a stay of the injunction pending appeal, which the Company and Indivior opposed. Both the District Judge and the Federal Circuit denied Dr. Reddy's request for a stay. The appeal is currently being briefed in the Federal Circuit on a modified schedule. Although a specific date has not been set, the Federal Circuit has indicated that oral argument on the appeal will be held in October 2018.

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. 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, and by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States’ claims on November 20, 2017. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The case will then proceed to expert discovery, which is scheduled to close May 3, 2019.

Product Litigation

On December 27, 2016, we were named as a co-defendant in product liability suit brought by Laurence and Michelle Allen, as Co-Administrators of the Estate of John Bradley Allen, in the U.S. District Court for the Northern District of New York. This suit, which also named Indivior Inc. and Indivior PLC as defendants, asserts causes of action for negligence, strict liability, and failure to warn against the defendants in connection with the manufacture and sale of Suboxone Sublingual Film. Plaintiffs allege that John Bradley Allen’s use of Suboxone Sublingual Film was a substantial contributing cause of his mental anguish and death and seek \$100 million in damages. All defendants moved to dismiss the complaint on April 10, 2017, and those motions were fully briefed on May 18, 2017. Aquestive was dismissed from the case on May 9, 2017, and the remainder of the case was closed on August 9, 2018, after the complaint was dismissed in favor of Indivior.

Note 15. Share-Based Compensation

(A) Non-Voting Common Share Issuance

The Company had two Performance Unit Plans, both of which were considered to be within the scope of FASB ASC Subtopic 718-30, *Compensation – Stock Compensation – Awards Classified as Liabilities*. Pursuant to the Plans, vested grants were not exercisable prior to either a change in control of the Company or completion of an IPO. These performance conditions rendered the grants contingent and deferred expense recognition until either of the conditions were satisfied. Neither of these conditions were satisfied as of December 31, 2017.

On April 16, 2018, the Company terminated the Performance Unit Plans. The termination was executed in accordance with the provisions of the Plans’ termination, which required both Board of Directors and the certain plan participant approval. As a result, the Company accelerated the vesting of any unvested performance units and issued non-voting common shares to compensate the performance unit holders.

In accordance with ASC 718, *Compensation — Stock Compensation*, the Company recorded a total charge to earnings of \$27,298 comprised of \$19,934 which relates to the fair market value of the non-voting shares at the date the shares were granted and \$7,364 related to withholding taxes which the Company elected to pay on behalf of the performance unit holders in the second quarter of 2018 to reflect the compensation cost associated with the issuance of 4,922,353 non-voting common shares. The compensation expense was estimated using an independent third-party valuation prepared in accordance with the American Institute of Certified Public Accountants Practice Aide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*.

The assumptions for the determination of the fair value of are provided in the following table:

Valuation assumptions:	
Discount rate for lack of marketability	34%
Volatility	90%
Weighted average cost of capital	27.5%

The discount for lack of marketability takes into consideration the illiquid nature of the security as well as other qualitative characteristics that would make it less marketable than the more senior securities. For volatility, the Company used comparable public companies as a basis for its expected volatility. The weighted average cost of capital uses comparable public companies and market interest rate data.

(B) Option Awards

Aquestive issued stock options providing rights to purchase up to 81,068 shares to three key executives and one board member in April 2018. The Company measured the value of stock option grants as of the date of grant using the Black-Scholes-Merton option pricing model. The values determined through the fair value methodology are amortized on a straight-line basis over the vesting term into manufacture and supply, research and development and/or selling, general and administrative expenses, as appropriate. These options provide a contractual term of 10 years, with a fair value at date of grant price of \$2.34 and vesting over three annual periods for approximately 94% of the total option shares and vesting over 12 quarterly periods for the remaining 6%.

The assumptions for the determination of the fair value of the options issued in April 2018 are provided in the following table:

Valuation assumptions:	
Expected dividend yield	0%
Expected volatility	90%
Expected term (years)	6.1
Risk-free interest rate	2.9%

The risk-free interest rate is the average U.S. Treasury rate with a term that most closely resembles the expected life of the award. The expected term of the award was calculated using the simplified method. For volatility, the Company uses comparable public companies as a basis for its expected volatility. The Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. A weighted average was utilized taking into account the two vesting periods to determine the expected term in years and the risk-free interest rate. The other assumptions were the same under the two vesting periods. The remaining unrecognized compensation expense is \$101 and is expected to be recognized over approximately three years.

The following table summarizes the components of share-based compensation expense in the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six month periods ended June 30, 2018:

Share-based compensation	
Manufacturing and supply	\$ 345
Research and development	2,186
General and administrative	24,774
Total share-based compensation expense	<u>\$ 27,305</u>

There was no share-based compensation recognized during the three and six months ended June 30, 2017.

Note 16. Income Taxes

From its founding through October 31, 2017, the Company was a limited liability company ("LLC") treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, the LLC elected to be taxed as a C-corporation. On January 1, 2018, MonoSol converted from a Delaware LLC into a Delaware C-corporation pursuant to a statutory conversion and changed its name to Aquestive Therapeutics, Inc.

From November 1, 2017, the Company accounts 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 credit. 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 and six months ended June 30, 2018, the Company recorded income tax benefit of \$0, on pretax losses of \$36,493 and \$32,394, respectively.

The Company's U.S. statutory rate is 21%. The primary factor impacting the effective tax rate for the six months ended June 30, 2018 is the anticipated full year losses which will be incurred by the Company's operations that have valuation allowances against their net deferred tax assets.

Note 17. Subsequent Events

In preparing the condensed consolidated financial statements as of and for the three and six months ended June 30, 2018, the Company has evaluated subsequent events for recognition and measurement purposes. The Company has concluded that the following events require disclosure in the accompanying consolidated financial statements:

(A) Perceptive Exercise of Warrants

Immediately prior to pricing of the Company's initial public offering, Perceptive received 863,400 shares of common stock issuable pursuant to the automatic exercise of warrants from APL's ownership interest at an exercise price of \$.01 per share. As a result, the warrant liability reflected on the Company's balance sheet as of June 30, 2018 will be reclassified to additional paid in capital during the third quarter of 2018.

(B) 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 \$57,545 after deducting underwriter discounts, commissions, and offering related transaction costs of approximately \$9,955. On August 15, 2018, the Company was informed that the underwriters exercised their over-allotment option and the Company issued 425,727 additional common shares at \$15.00 per share. Upon the closing of such exercise, the Company received additional net proceeds of approximately \$5,939, after deducting underwriter discounts of approximately \$447. Immediately prior to the consummation of the IPO, all of the Company's outstanding shares of non-voting common stock were automatically converted into 4,922,353 shares of voting common stock.

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, 2017 and 2016 included in our prospectus dated July 24, 2018, filed with the SEC, pursuant to Rule 424(b) under the Securities Act. As discussed in the section titled "Cautionary Note Regarding Forward-Looking Statements," the following discussion and analysis contains forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those under the caption "Risk Factors" in the aforementioned prospectus.

Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. We have a late-stage proprietary product pipeline focused on the treatment of CNS diseases. We believe that the characteristics of these patient populations and shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines. Our most advanced proprietary product candidates, which we intend to commercialize ourselves, include (i) Libervant, a buccal soluble film formulation of diazepam for the treatment of recurrent epileptic seizures, for which we expect to submit an NDA in 2018; (ii) Sympazan, an oral soluble film formulation of clobazam for the treatment of seizures associated with a rare, intractable form of epilepsy known as LGS and (iii) AQST-117, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we expect to submit an NDA in the first quarter of 2019. We have also developed a proprietary pipeline of complex molecule-based products addressing large market opportunities beyond CNS indications, which include (i) AQST-108, a sublingual soluble film formulation of epinephrine for the treatment of anaphylaxis, for which we expect to begin additional human trials in late 2018 or early 2019 and (ii) AQST-305, a sublingual soluble film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors, for which we have begun human proof of concept trials in the third quarter of 2018.

We received tentative approval for Sympazan® (clobazam) Oral Film for the treatment of Lennox-Gastaut Syndrome (LGS) from the U.S. Food and Drug Administration (FDA) in line with its assigned Prescription Drug User Fee Act (PDUFA) date of August 31, 2018. Final FDA approval for Sympazan is pending the expiration of the orphan drug exclusivity period for ONFI®, which is expected in October 2018.

In addition to these product candidates, we have a portfolio of commercialized and development-stage partnered products. These products include Suboxone, a sublingual film formulation of buprenorphine and naloxone, which is the market leader for the treatment of opioid dependence. We manufacture all of our partnered and proprietary products at our FDA- and DEA-inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 1.1 billion doses of Suboxone in the last four years and over three billion commercial doses or dose equivalents for all customers since 2008. Our products are developed using our proprietary PharmFilm technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide.

On July 27, 2018 we closed in the initial public offering ("IPO") of 4,500,000 shares of common stock at an offering price of \$15.00 per share and our common stock began trading on the Nasdaq Global Market under ticker symbol "AQST". The offering resulted in aggregate gross proceeds to Aquestive of \$67.5 million before underwriting discounts and other costs and expenses of the offering. In August 2018, the underwriters partially exercised the over-allotment option granted to them in connection with the Offering, and on August 15, 2018 the Company completed the sale of 425,727 additional shares of common stock resulting in gross proceeds to Aquestive of \$6.4 million before underwriting discounts and other costs and expenses of the offering. Total gross proceeds from this offering were \$73.9 million, and net proceeds after underwriters discounts and other costs and expenses of the offering totaled \$63.5 million.

We generated revenue of \$13.9 million and \$11.1 million for the three months ended June 30, 2018 and 2017, respectively, and \$37.3 million and \$27.6 million for the six months ended June 30, 2018 and June 30, 2017, respectively, largely from commercial products marketed by our partners that generated manufacturing and supply revenues. Total revenues also included licensing, royalty and co-development and research fees. Suboxone, which was launched in 2010, was our first partnered pharmaceutical product to be commercialized, and we have multiple other partner relationships that contribute to our revenue and future revenue opportunities from partnered products.

As of June 30, 2018, we had \$10.6 million in cash and cash equivalents. As a result of our investments in product development and recent investments in pre-launch commercialization initiatives, as of June 30, 2018, we had net shareholders' deficit of \$38.9 million. We incurred net losses of \$36.5 million and \$5.9 million for the three months ended June 30, 2018 and 2017, respectively. For the six months ended June 30, 2018 and 2017, we incurred net losses of \$32.4 million and \$7.4 million, respectively.

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

- fund commercialization investments for our epilepsy products, Libervant and Sympazan, and our ALS product, AQST-117;
- continue clinical development of our complex molecules, AQST-108 and AQST-305;
- identify 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 partnered product activities, equity investments from our stockholders and debt proceeds from our credit facilities. In addition to proceeds from our initial public offering, we may require additional financing to execute our business strategy.

Critical Accounting Policies and Use of Estimates

See Note 3, *Summary of Significant Accounting Policies*, to our condensed consolidated financial statements, included herein for a discussion of recently issued accounting pronouncements and their impact or future potential impact on our financial results, if determinable. For a discussion of critical accounting policies that affect our significant judgments and estimates used in the preparation of our consolidated financial statements, refer to our Form S-1 which became effective July 24, 2018.

JOBS Act

As an "emerging growth company" under the JOBS Act of 2012, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards on the relevant date on which adoption of such standards is required for public emerging growth companies.

Financial Operations Overview

Revenues

Our revenues to date have been earned from partnered pipeline and marketed product activities. These activities generate revenues in three primary categories: co-development and research fees, license and royalty revenue and manufacturing and supply revenue.

Co-development and Research Fees

We work with our partners 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 partner. The nature and extent of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product.

License and Royalty Revenue

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

Manufacture and Supply Revenue

Currently, we produce two partnered pharmaceutical products: Suboxone and Zuplenz. We are the exclusive manufacturer for these products. We manufacture based on receipt of purchase orders from our partners, and our partners accept delivery of these orders at shipping point. As a result, we record revenues when product is shipped and title passes to the customers. Our partners are responsible for all other aspects of commercialization of these products.

We expect future revenue from partnered activities to increase based on growing production volumes of partnered products, new product development with partners, and additional licensing of our intellectual property.

As we commercialize our proprietary CNS product candidates, beginning with Libervant and Sympazan, subject to regulatory approval, we expect to directly sell our products to consumers in the United States, resulting in an additional source of revenue which will be referred to as Product Sales, net. Additionally, we may choose to select a collaborator to commercialize our product candidates in certain markets outside of the United States. To date, we have not generated any revenues from product sales of self-developed medicines.

Costs and Expenses

Our costs and expenses are primarily the result of the following activities: generation of partnered revenues; development of our pipeline of proprietary product candidates; selling, general and administrative, including pre-launch commercialization efforts related to our CNS product candidates, intellectual property defense, development and maintenance, corporate management functions and interest on our corporate borrowings. We primarily record our costs and expenses in the following categories:

Manufacture and Supply Costs and Expenses

Manufacture and supply costs and expenses are comprised of costs and expenses related to manufacturing our proprietary dissolving film products for our marketed partnered pharmaceutical products and for clinical trial batches of our proprietary and partnered product candidates, including raw materials, direct labor and fixed overhead principally in our Portage, Indiana facilities. Our material costs include the costs of raw materials used in the production of our proprietary dissolving film and primary packaging materials. Direct labor costs consist of payroll costs (including taxes and benefits) of employees engaged in production activities. Fixed overhead principally consists of indirect payroll, facilities rent, utilities and depreciation for production machinery and equipment.

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

We expect our manufacture and supply costs and expenses to increase over the next several years as we commercialize and begin to market, following regulatory approval, our product candidates, including Libervant and Sympazan, our ALS product candidate, AQST-117, and our other product candidates. Additionally, we expect to incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from our commercialization of these products and product candidates. As such, we expect our manufacturing and supply costs and expenses to increase as our product candidates receive regulatory approval and can be commercialized both in and outside the United States.

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities, including preclinical studies and clinical trials, activities related to regulatory filings, and manufacturing development efforts. Significant expenses also included in research and development are personnel costs, which includes compensation, benefits and stock-based compensation. We expense research and development costs as they are incurred.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits, share-based compensation, and other related costs for executive, finance, selling and operational personnel. Other significant costs include facility and related costs not otherwise included in research and development expenses such as: professional fees for legal, consulting, tax and accounting services; insurance; selling; market research; advisory board and key opinion leaders; depreciation; and general corporate expenses, inclusive of IT systems related costs. Historically, our selling, general and administrative expenses have been focused primarily on partnered selling activities and corporate management functions. However, costs related to commercialization of our CNS product candidates began in the second half of 2017 as we prepare to launch our late stage epilepsy products Sympazan and Libervant in late 2018 and in 2019, respectively. As we prepare to launch Sympazan during the fourth quarter 2018, we have begun entering into contractual arrangements with a third party logistic provider (3PL) and wholesalers for distribution of our products and expect to enter into a contract for our sales force over the next few weeks. With this increased activity related to the upcoming commercial launch, we expect selling expenses to increase in the second half of 2018. In addition, our general and administrative costs will increase as a public company, including costs related to additional personnel and accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

Interest Expense

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

Other Expense

Other expense consists of changes in the fair value of the Perceptive Warrants issued to Perceptive in connection with the Loan Agreement.

Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

We recorded revenue of \$13.9 million and \$11.1 million in the three months ended June 30, 2018 and June 30, 2017, respectively, generating net losses of \$36.5 million and \$5.9 million for each of those quarters, respectively.

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

Revenues

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

<i>(In thousands, except %)</i>	Three Months Ended June 30,		Change	
	2018	2017	\$	%
Manufacture and supply revenue	\$ 8,684	\$ 10,336	\$ (1,652)	(16%)
License and royalty revenue	4,532	246	4,286	NM%
Co-development and research fees	712	560	152	27%
Revenues	<u>\$ 13,928</u>	<u>\$ 11,142</u>	<u>\$ 2,786</u>	25%

Revenues increased 25% or \$2.8 million in the three months ended June 30, 2018 to \$13.9 million as compared to \$11.1 million in the three months ended June 30, 2017.

Manufacture and supply revenue decreased approximately 16% or \$1.6 million to \$8.7 million in the three months ended June 30, 2018 as compared to \$10.3 million in the three months ended June 30, 2017 due primarily to timing of purchase volume demand attributable to Suboxone and Zuplenz product sales.

License and royalty revenue increased \$4.3 million to \$4.5 million in the three months ended June 30, 2018 as compared to \$0.2 million in the three months ended June 30, 2017. This increase was primarily related to license fees on our partnered product Suboxone and royalties on Suboxone and Zuplenz. License fees were higher in the 2018 period as a result of the timing of milestones in these agreements. License fees are milestone driven and may fluctuate significantly from quarter-to-quarter.

Co-development and research fees rose 27% or \$0.1 million in the three months ended June 30, 2018 to \$0.7 million as compared to \$0.6 million in the three months ended June 30, 2017. These fees are highly dependent on the timing of partnered product research and development activities and related milestones, which may fluctuate significantly quarter-to-quarter.

Expenses:

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

<i>(In thousands, except %)</i>	Three Months Ended		Change	
	June 30,			
	2018	2017	\$	%
Manufacturing and supply	\$ 4,973	\$ 5,141	\$ (168)	(2)%
Research and development	7,994	4,837	3,157	67%
Selling, general and administrative	33,647	5,223	28,424	544%
Interest	1,927	1,949	(22)	(1)%
Other	1,870	(111)	1,981	NM%

Manufacturing and supply costs and expenses decreased 2% or \$0.1 million to \$5.0 million in the three months ended June 30, 2018 as compared to \$5.1 million in the three months ended June 30, 2017, driven primarily by timing of purchase volume demand related to partnered product volumes offset, in part by \$0.3 million of compensation cost associated with the issuance of the non-voting common shares and related withholding taxes, which the Company elected to pay on behalf of the former performance unit holders.

Research and development expenses increased 67% or \$3.2 million to \$8.0 million in the three months ended June 30, 2018 as compared to \$4.8 million in the three months ended June 30, 2017 primarily due to timing of expenses for direct project costs primarily associated with our CNS product candidates (Libervant and AQST-117) and AQST-119 which increased approximately \$2.2 million period over period due to the progression of Phase II Libervant initiatives offset in part by lower early clinical trial activity for our complex molecule product candidate AQST-108 as compared to 2017 versus 2018. Additionally, \$2.2 million of increase is related to the compensation cost associated with the issuance of the non-voting common shares and withholding taxes.

Selling, general and administrative expenses increased by 544% or \$28.4 million to \$33.6 million in the three months ended June 30, 2018 as compared to \$5.2 million primarily due to \$24.8 million of compensation cost associated with the issuance of the non-voting common shares and related withholding taxes, which the Company elected to pay on behalf of the performance unit holders. Excluding expenses associated with share-based compensation, selling, general and administrative expenses increased 70% or \$3.6 million to \$8.8 million in the three months ended June 30, 2018 as compared to \$5.2 million in the three months ended June 30, 2017 primarily due to initial investments in our commercialization capabilities in preparation for the expected launch of Libervant, Sympazan and AQST-117. These higher costs included personnel, external consultants and other resources that enabled us to establish the key commercial functions such as sales and marketing, market access and medical affairs. We also have added additional personnel and other external resources to prepare our company for going public.

Interest expense remained essentially flat period in each of the three months ended June 30, 2018 and 2017. Our interest expense is subject to adjustment based on one-month LIBOR.

Other (income) expenses decreased, principally due to the change in fair value of warrants. We re-measure 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.

Comparison of Six Months Ended June 30, 2018 and 2017

We recorded revenue of \$37.3 million and \$27.6 million in the six months ended June 30, 2018 and 2017, respectively, generating net losses of \$32.4 million and \$7.4 million for each of those periods, respectively.

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

Revenues

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

	Six Months Ended		Change	
	June 30,		\$	%
	2018	2017		
<i>(In thousands, except %)</i>				
Manufacture and supply revenue	\$ 20,244	\$ 20,491	\$ (247)	(1)%
License and royalty revenue	14,032	5,469	8,563	157%
Co-development and research fees	3,063	1,617	1,446	89%
Revenues	<u>\$ 37,339</u>	<u>\$ 27,577</u>	<u>\$ 9,762</u>	35%

Revenues increased \$9.7 million in the six months ended June 30, 2018 to \$37.3 million as compared to \$27.6 million in the six months ended June 30, 2017. This increase came primarily from increases in license and royalty revenue, followed by an increase in co-development and research fees offset, in part, by lower manufacture and supply revenue.

Manufacture and supply revenue decreased approximately 1.0% or \$0.3 million to \$20.2 million in the six months ended June 30, 2018 as compared to \$20.5 million in the six months ended June 30, 2017 primarily due to a \$2.0 million flat fee earned in the 2017 period for certain manufacturing exclusivity rights, without a corresponding revenue item in the 2018 period. Excluding this flat fee, manufacture and supply revenue increased from \$18.5 million in the six months ended June 30, 2017 to \$20.2 million in the six months ended June 30, 2018, an increase of 9%, due to an increase in the volume of products manufactured and sold during the 2018 period.

License and royalty revenue increased 157% or \$8.5 million to \$14.0 million in the six months ended June 30, 2018 as compared to \$5.5 million in the six months ended June 30, 2017. This increase was primarily related to license fees on our partnered product Suboxone and royalties on Suboxone and Zuplenz. License fees were higher in the 2018 period as a result of the achievement of certain performance obligations specified in these agreements, and royalties rose year-over-year on higher product sales volumes flowing through our partners' sales and distribution channels. License fees are generally driven by transfers of rights, patent performance contingencies, specific FDA or other regulatory achievements, sales level achievements or other contingencies and milestones, and may fluctuate significantly from quarter-to-quarter.

Co-development and research fees rose 89% or \$1.5 million to \$3.1 million in the six months ended June 30, 2018 as compared to \$1.6 million in the six months ended June 30, 2017. The increase was driven by the timing of the achievement of research and development performance obligations on partnered products and related milestones and may fluctuate significantly quarter-to-quarter.

Expenses:

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

	Six Months Ended		Change	
	June 30,		\$	%
	2018	2017		
<i>(In thousands, except %)</i>				
Manufacturing and supply	\$ 10,609	\$ 9,325	\$ 1,284	14%
Research and development	12,895	10,178	2,717	27%
Selling, general and administrative	41,216	11,352	29,864	263%
Interest	3,854	3,767	87	2%
Other	1,159	309	850	275%

Manufacturing and supply costs and expenses increased 14% or \$1.3 million to \$10.6 million in the six months ended June 30, 2018 as compared to \$9.3 million in the six months ended June 30, 2017, driven primarily by an increase in volume, higher production costs and higher scrap costs period over period and the \$0.3 million of compensation cost associated with the issuance of the non-voting common shares and related withholding taxes, which the Company elected to pay on behalf of the former performance unit holders.

Research and development expenses increased 27% or \$2.7 million to \$12.9 million in the six months ended June 30, 2018 as compared to \$10.2 million in the six months ended June 30, 2017 primarily due to increased direct project costs primarily associated with our CNS product candidates (Libervant, Sympazan and AQST-117) and AQST-119 of which \$1.2 million increase period over period was due to the progression of Phase II initiatives for Libervant offset in part by lower early clinical trial activity for our complex molecule product candidate AQST-108 as compared to 2017 versus 2018. Further adding to the increase was the \$2.2 million of compensation cost associated with the issuance of the non-voting common shares and related withholding taxes.

Selling, general and administrative expenses increased 263% or \$29.9 million to \$41.2 million in the six months ended June 30, 2018 as compared to \$11.3 million primarily due to the \$24.8 million of compensation cost associated with the issuance of the non-voting common shares and related withholding taxes. The remaining increase of \$5.1 million is a primary result of investments in our commercialization capabilities in preparation for the expected launch of Libervant, Sympazan and AQST-117. These higher costs included personnel, external consultants and other resources that enabled us to establish the key commercial functions such as sales and marketing, market access and medical affairs. We also have added additional personnel and other external resources to prepare our company for our initial public offering. Also contributing to this increase were higher costs incurred in the state anti-trust litigation and other patent related matters.

Interest expense increased 2% or \$0.1 million to \$3.9 million in the six months ended June 30, 2018 as compared to \$3.8 million in the six months ended June 30, 2017 primarily as a result of an increase in our indebtedness of \$5.0 million incurred on March 9, 2017. Our interest expense is subject to increases based on one-month LIBOR.

Other expenses increased in the six months ended June 30, 2018 compared to the six months ended June 30, 2017, principally due to the change in fair value of warrants of \$0.9 million to \$1.2 million.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and as of June 30, 2018, we had a net shareholders' deficit of \$38.9 million. We have funded our operations primarily with equity and debt financings and milestone and royalty payments from our collaboration partners. Through June 30, 2018, we received net proceeds from debt and equity issuances of \$125.6 million as follows:

- \$50.0 million from debt facilities further described below; and
- \$75.6 million from equity financings, with most of these proceeds received in 2008 and prior years

We generate revenue from partnered products and related activities, but the costs to generate these revenues and the costs and expenses of our proprietary CNS and complex molecule development programs and related commercialization efforts have resulted in the deficit we have accumulated since our inception.

We had \$10.6 million in cash and cash equivalents as of June 30, 2018. We have no committed sources of capital and our borrowing capability under the Loan Agreement is fully drawn.

On July 27, 2018, we closed the IPO of 4,500,000 shares of common stock at an offering price of \$15.00 per share. We received net proceeds of approximately \$57.5 million, after deducting underwriting discounts, commissions, and offering related transaction costs of approximately \$10.0 million. On August 15, 2018, the underwriters exercised their over-allotment option and the Company issued 425,727 at \$15.00 per share. The Company received additional net proceeds of approximately \$5.9 million, after deducting underwriter discounts of approximately \$0.4 million. The Company received from the IPO total gross proceeds of approximately \$73.9 million and net proceeds of approximately \$63.5 million, after deducting underwriter discounts and costs and expenses of the offering.

Credit Agreement and Guaranty

On August 16, 2016, we entered into a Credit Agreement and Guarantee with Perceptive, which we amended on May 21, 2018, or, as so amended, the Loan Agreement. At closing, we borrowed \$45.0 million under the Loan Agreement and were permitted to borrow up to an additional \$5.0 million 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 \$5.0 million available to us under the Loan Agreement. Proceeds under the Loan Agreement were used to repay an existing debt obligation of \$37.5 million, with the balance available for general corporate purposes. The loan from Perceptive was originally scheduled to mature on August 16, 2020. However, upon the consummation of our initial public offering, the maturity date was extended to December 16, 2020. The loan bears interest, payable monthly, at one-month LIBOR or 2% plus 9.75%, subject to a minimum rate of 11.75%. The loan is interest-only through April 2019, as amended.

Additionally, pursuant to the Loan Agreement, commencing on May 31, 2019, seven monthly principal payments are due in the amount of \$550 thousand. Thereafter, monthly principal payments in the amount of \$750 thousand are due through the maturity date (as extended), at which time the full amount of the remaining outstanding loan balance is due. Our tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. The Loan Agreement contains certain financial covenants, which include (1) a minimum liquidity requirement pursuant to which we must maintain a monthly cash balance of \$4.0 million at all times and (2) a minimum revenue requirement pursuant to which on a quarterly basis (calculation date) we must maintain minimum revenues for the twelve consecutive trailing months ended prior to the calculation date. Further, under the Loan Agreement, as amended, we are permitted, subject to Perceptive's consent, to monetize the royalty and fees derived from sales of certain Apomorphine products and, in connection with such monetization Perceptive has agreed to release liens related to these royalties and fees.

As of June 30, 2018, we were compliant with all financial and other covenants under the Loan Agreement.

In addition, upon the closing of our initial public offering, Perceptive received 863,400 shares of common stock issuable pursuant to the automatic exercise of warrants from APL's ownership interest at an exercise price of \$.01 per share.

The Loan Agreement originally contained a requirement that we make a mandatory prepayment in the amount of 25% of the net cash proceeds to us upon consummation of our initial public offering; however, as amended, following consummation of our initial public offering, such requirement no longer applies.

Cash Flows

Six Months Ended June 30, 2018 and 2017

The following table provides information regarding our cash flows for the six months ended June 30, 2018 and 2017:

<i>(In thousands)</i>	2018	2017
Net cash provided by (used for) operating activities	\$ 1,296	\$ (2,394)
Net cash (used for) investing activities	(886)	(1,547)
Net cash (used for) provided by financing activities	(7,151)	5,021
Net (decrease) increase in cash and cash equivalents	\$ (6,741)	\$ 1,080

Net Cash Provided by (Used for) Operating Activities

Net cash provided by operating activities was \$1.3 million for the six months ended June 30, 2018 compared to net cash used in operating activities of \$2.4 million for the six months ended June 30, 2017. This increase in net cash provided by operating activities of \$3.7 million was associated with net changes in working capital of \$0.6 million, increase in net loss of \$25.0 million, which was primarily a result of an increase in share-based compensation expense of \$27.3 million related to the termination of the Company's performance unit plans and an increase of \$0.8 million in noncash charges such as depreciation, amortization, amortization of debt issuance costs and changes in warrant valuation.

Net Cash (Used for) Investing Activities

Net cash used in investing activities of \$0.9 million for the six months ended June 30, 2018 compared to \$1.5 million for the six months ended June 30, 2017 was primarily attributable to timing of capital expenditures for property and equipment purchases.

Net Cash (Used for) Provided by Financing Activities

Net cash used in financing activities was \$7.1 million for the six months ended June 30, 2018 compared to cash provided by financing activities of \$5.0 million for the six months ended June 30, 2017. The cash used in 2018 is a result of \$1.5 million in transaction costs paid as part of our initial public offering and \$5.6 million related to the payment of withholding taxes associated with the share-based compensation recorded during the quarter ended June 30, 2018. Neither of which existed in 2017, this compared to \$5.0 million of debt proceeds received in 2017 from an additional draw under the Loan Agreement.

Funding Requirements

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

The key assumptions underlying this estimate include:

- the costs necessary to successfully complete our development efforts of our proprietary product candidates;
- continued revenue from our partnered products at levels similar to or above recent years' results;
- the levels and timing of revenues and costs to commercialize our late stage CNS product candidates; and
- the infrastructure costs to support being a public company.

We have no committed sources of additional capital. We may attempt to raise additional capital due to favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. Until we become profitable, if ever, we may need to raise additional capital in the future to further the development and commercialization of our epilepsy products, Libervant and Sympazan, our ALS product, AQST-117, and our other product candidates. We may seek to obtain additional financing in the future through the issuance of our common stock, through other public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders may experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may impair our future liquidity and capital position.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, or reduce our planned commercialization efforts. We also may be required to evaluate partnering aspects of our proprietary product candidate programs that we currently plan to self-commercialize.

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

Off-Balance Sheet Arrangements

We do not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest expense from fluctuations in one-month LIBOR associated with the Loan Agreement. For each 1% increase in one-month LIBOR in excess of 2%, our annual interest expense would increase by approximately \$0.5 million.

Our cash and cash equivalents are maintained in FDIC protected accounts with no exposure to material 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. We are in the process of developing a comprehensive investment strategy for our cash and cash equivalents whose underlining premise would be to preserve principal while at the same time maximizing the income that we receive from our investments without significantly increasing risk.

Our accounts receivables are concentrated predominantly with Indivior. In the event of non-performance or non-payment by Indivior, 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 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 our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, as ours are designed to do, and we necessarily were required to apply our judgment in evaluating whether the benefits of the controls and procedures that we adopt outweigh their costs.

As required by Rule 13a-15(b) of the Exchange Act, an evaluation as of June 30, 2018 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 June 30, 2018, were effective for the purposes stated above.

Internal Control Over Financial Reporting

Due to a transition period established by SEC rules applicable to newly public companies, our management is not required to evaluate the effectiveness of our internal control over financial reporting until after the filing of our Annual Report on Form 10-K for the year ended December 31, 2018. As a result, this Quarterly Report on Form 10-Q does not address whether there have been any changes in 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 may not be detected.

Emerging Growth Company Status

In April 2012, the JOBS Act was enacted by the federal government. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are emerging growth companies.

For so long as we are an emerging growth company, we will not be required to provide an auditor's attestation report on our internal control over financial reporting in future annual reports on Form 10-K as otherwise required by Section 404(b) of the Sarbanes-Oxley Act.

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 ordinary course of our business. Except as described below, we are not presently a party to any litigation or legal proceedings that we believe to be material and we are not aware of any pending or threatened litigation against us that we believe could have a material adverse effect on our business, operating results, financial condition or cash flows.

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., or Par, Alvogen Pine Brook, Inc., or Alvogen, Teva Pharmaceuticals USA, Inc., or Teva, Sandoz Inc., or Sandoz, and Mylan Technologies Inc. or 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. Of these, cases against two of the six generic companies have been resolved.

- *Sandoz*. By court order in August 2016, our ANDA patent litigation case against Sandoz has been dismissed without prejudice for lack of subject matter jurisdiction because Sandoz is no longer pursuing a Paragraph IV certification for its proposed generic version of Suboxone Sublingual Film, and therefore is no longer challenging the validity or infringement of our Orange Book-listed patents.
- *Mylan*. The case against Mylan was settled and the Court signed a Consent Judgment in September 2017 disposing of the entire case.

After the commencement of the above-mentioned ANDA patent litigation against Teva, Dr. Reddy's Laboratories acquired the ANDA filings for Teva's buprenorphine and naloxone sublingual film that are at issue in these trials.

Trials against Dr. Reddy's, Actavis and Par in the lawsuits involving the Orange Book and process patents occurred in November-December of 2015 and November of 2016. On June 3, 2016, the Court issued its Trial Opinion finding that the asserted claims of U.S. Patent No. 8,603,514, or the '514 patent, are valid and infringed by Actavis's and Par's ANDA Products. On August 31, 2017, the Court upheld U.S. Patent No. 8,900,497, or the '497 patent, as valid but not infringed by Par's, Actavis's or Dr. Reddy's proposed processes for making their ANDA Products. The Court also again upheld the validity of the '514 patent but held it was not infringed by Dr. Reddy's ANDA Products, and upheld the validity of U.S. Patent No. 8,017,150, or the '150 patent, but held that it was not infringed by Dr. Reddy's ANDA Products. All of these cases are consolidated on appeal to the Federal Circuit, except that the cases between Indivior and us and Par and certain affiliates have been resolved by a settlement agreement.

Trial against Alvogen was held in September 2017. The only issue raised at trial was whether Alvogen's ANDA Products and processes infringe the '514 and '497 patents; Alvogen did not challenge the validity of the patents. In March 2018, the Court issued its opinion finding that Alvogen's ANDA products and processes would not infringe the '514 or '497 patents. We and Indivior appealed the ruling, and the appeal is currently pending before the Federal Circuit. If any company is able to obtain FDA approval for its generic version of Suboxone Sublingual Film, it may be able to launch the product prior to the expiration of any or all the applicable patents protecting our Suboxone Film, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

We are also seeking to enforce our patent rights in multiple cases against BioDelivery Sciences International, Inc., or 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 stayed pending *inter partes* review of the '832 patent and reexamination of the '080 patent.
- 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. This case was initially filed in September 2014 in the U.S. District Court for the District of New Jersey but was transferred to North Carolina. Shortly after the case was filed, BDSI filed an IPR challenging the asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding the '167 patent was not unpatentable. This case is stayed pending the outcome and final determination of the proceedings concerning the '167 patent, (discussed further below).

On January 13, 2017, we also sued BDSI asserting infringement of the '167 patent by BDSI's Belbuca product. The case was originally filed in the U.S. District Court for the District of New Jersey and was later transferred to the U.S. District Court for the District of Delaware by agreement of the parties.

On November 28, 2016, after the PTAB issued its final written decisions finding that the '167 patent was not unpatentable in IPR2015-00165, IPR2015-00168 and IPR2015-00169, BDSI filed a notice of appeal of those decisions to the U.S. Court of Appeals for the Federal Circuit. The case has been fully briefed and the Court heard oral arguments on February 9, 2018. On June 19, 2018, BDSI filed a motion to terminate and remand the appeal, which the Company opposed. On July 31, 2018, the Federal Circuit granted motion, vacating the PTAB's decisions and remanding for further proceedings before the PTAB.

In September 2017, Indivior brought suit against Alvogen for infringement of U.S. Patent No. 9,687,454, or the '454 patent, based on the filing of an ANDA seeking approval for a generic version of Suboxone Sublingual Film, in the U.S. District Court for the District of New Jersey. In February 2018, we and Indivior amended the complaint, which added us as a plaintiff and a claim for infringement of U.S. Patent No. 9,855,221, or the '221 patent.

Indivior brought suits against Dr. Reddy's and Teva in September 2017, and against Par and certain affiliates in October 2017, for infringement of the '454 patent, in the U.S. District Court for the District of New Jersey. Indivior also brought suit in September 2017 against Actavis Laboratories UT, Inc. for infringement of the '454 patent, in the U.S. District Court for the District of Utah. On March 13, 2018, the Court granted transfer of this case to the U.S. District Court for the District of Delaware.

In February 2018, we and Indivior brought suit against Actavis, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of the '221 patent. The suit against Actavis was filed in the U.S. District Court for the District of Utah, and the other three cases were filed in the U.S. District Court for the District of New Jersey.

In April 2018, we brought suit with Indivior against Actavis, Alvogen, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of U.S. Patent No. 9,931,305, or the '305 patent. The cases against Alvogen, Dr. Reddy's, Teva, and Par are pending in the U.S. District Court for the District of New Jersey, and they have each been consolidated with the actions asserting infringement of the '454 and '221 patents. Following transfer of the case asserting the '454 patent from Utah to Delaware, and by agreement of the parties, the cases against Actavis asserting infringement of the '454, '221, and '305 patents are consolidated in a single action pending in the U.S. District Court for the District of Delaware.

All matters involving Par were resolved on May 11, 2018, when we, Indivior, and Par and certain of its affiliates entered into a settlement agreement resolving patent litigation related to SUBOXONE (buprenorphine and Naloxone) Sublingual Film. As required by law, the parties submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

On June 14, 2018, Dr. Reddy's notified the U.S. District Court for the District of New Jersey that the FDA had granted final approval of its ANDAs and that it had launched generic versions of Suboxone Sublingual Film. The Company and Indivior filed a motion for a preliminary injunction and a request for a temporary restraining order, and the Court grant the request on June 15, 2018 enjoining and restraining Dr. Reddy's from offering for sale, selling or importing its generic versions of Suboxone Sublingual Film. On July 13, 2018, the Court granted the preliminary injunction, which enjoins Dr. Reddy's from launching a generic version of Suboxone during the pendency of the litigation and until further order from the Court. Dr. Reddy's appealed the preliminary injunction ruling to the Federal Court. Dr. Reddy's also requested a stay of the injunction pending appeal which the Company and Indivior opposed. Both the District Judge and the Federal Court denied Dr. Reddy's request for a stay. The appeal is currently being briefed in the Federal Circuit on a modified schedule. Although a specific date has not been set, the Federal Circuit has indicated that oral argument on the appeal will be held in October 2018.

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. 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, and by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States' claims on November 20, 2017. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The case will then proceed to expert discovery, which is scheduled to close May 3, 2019.

Product Litigation

On December 27, 2016, we were named as a co-defendant in product liability suit brought by Laurence and Michelle Allen, as Co-Administrators of the Estate of John Bradley Allen, in the U.S. District Court for the Northern District of New York. This suit, which also named Indivior Inc. and Indivior PLC as defendants, asserts causes of action for negligence, strict liability, and failure to warn against the defendants in connection with the manufacture and sale of Suboxone Sublingual Film. Plaintiffs allege that John Bradley Allen's use of Suboxone Sublingual Film was a substantial contributing cause of his mental anguish and death and seek \$100 million in damages. All defendants moved to dismiss the complaint on April 10, 2017, and those motions were fully briefed on May 18, 2017. Aquestive was dismissed from the case on May 9, 2017, and the remainder of the case was closed on August 9, 2018, after the complaint was dismissed in favor of Indivior.

Item 1A. RISK FACTORS

As of the date of this Quarterly Report on Form 10Q, there have been no material changes during the three months ended June 30, 2018 to the risk factors discussed in our prospectus dated July 24, 2018, filed with the SEC, pursuant to Rule 424(b) under the Securities Act.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On April 16, 2018, we terminated the Performance Unit Plan and, as a result, we accelerated the vesting of any unvested performance units and issued 4,922,353 non-voting shares of common stock to the holders of our performance units in order to compensate the such holders of record on January 1, 2018, which shares automatically converted into voting shares of common stock upon the consummation of our initial public offering, as previously described in our final prospectus filed with the SEC on July 25, 2018, pursuant to Rule 424(b) of the Securities Act. The sale of these shares was not registered under the Securities Act of 1933, as amended, in reliance on the exemptions set forth under Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Use of Proceeds

On July 27, 2018, we completed the initial public offering of 4,500,000 shares of our common stock at an offering price to the public of \$15.00 and, on July 25, 2018, our common stock began trading on the Nasdaq Global Market under ticker symbol "AQST". The offering resulted in aggregate gross proceeds to Aquestive of approximately \$67.5 million before underwriting discounts and other costs and expenses of the offering. In August 2018, the underwriters partially exercised the over-allotment option granted to them in connection with the Offering, and on August 15, 2018 the Company completed the sale of 425,727 additional shares of common stock resulting in gross proceeds to Aquestive of approximately \$6.4 million before underwriting discounts and other costs and expenses of the offering. There has been no material change in the planned use of such proceeds as described in our final prospectus filed with the SEC on July 25, 2018, pursuant to Rule 424(b) of the Securities Act. The shares were registered under the Securities Act (Registration Nos. 333-225924 and 333-226326), on a registration statement on Form S-1, which was declared effective by the SEC, on July 24, 2018.

We received net proceeds from the IPO and the exercise of the over-allotment option of approximately \$63.5 million, after deducting underwriting discounts, commissions and offering costs of approximately \$10.4 million. The underwriters for the IPO were BMO Capital Markets, RBC Capital Markets, Wedbush PacGrow and JMP Securities. There has been no material change in the planned use of such proceeds as described in our final prospectus filed with the SEC on July 25, 2018, pursuant to Rule 424(b) of the Securities Act. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliate. From the effective date of our Registration Statement on Form S-1 (File No. 333-225924) through the end of the reporting period covered by this Quarterly Report, we did not use any of the net offering proceeds, as the Registration Statement was declared effective after June 30, 2018.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

We received tentative approval for Sympazan[®] (clobazam) Oral Film for the treatment of Lennox-Gastaut Syndrome (LGS) from the U.S. Food and Drug Administration (FDA) in line with its assigned Prescription Drug User Free Act (PDUFA) date of August 31, 2018. Final FDA approval for Sympazan is pending the expiration of the orphan drug exclusivity period for ONFI[®], which is expected in October 2018.

Item 6. EXHIBITS**Exhibits Index**

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Aquestive Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. on July 27, 2018.).
3.2	Amended and Restated Bylaws of Aquestive Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. on July 27, 2018.).
10.1	Amendment No. 2 to Credit Agreement and Guaranty dated May 21, 2018, by and between Aquestive Therapeutics, Inc. and Perceptive Credit Opportunities Fund, LP. (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 (File No. 333-225924)).
10.2 +	Employment Agreement dated June 30, 2018, by and between Aquestive Therapeutics, Inc., LLC and Keith J. Kendall (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 (File No. 333-225924)).
10.3 +	Employment Agreement dated June 26, 2018, by and between Aquestive Therapeutics, Inc., LLC and Daniel Barber (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-225924)).
10.4 +	Employment Agreement dated June 26, 2018, by and between Aquestive Therapeutics, Inc., LLC and John T. Maxwell (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (File No. 333-225924)).
10.5 +	Aquestive Therapeutics, Inc., 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 (File No. 333-225924)).
10.6 +	Aquestive Therapeutics, Inc. Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1 (File No. 333-225924)).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Financial Officer 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 (filed herewith)
101.SCH	XBRL Taxonomy Extension Schema (filed herewith)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase (filed herewith)
101.DEF	XBRL Taxonomy Extension Definition Linkbase (filed herewith)
101.LAB	XBRL Taxonomy Extension Label Linkbase (filed herewith)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase (filed herewith)

+Indicates management contract or compensatory plan.

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)

Dated:	September 4, 2018	/s/ Keith J. Kendall Keith J. Kendall <i>President and Chief Executive Officer</i> <i>(Principal Executive Officer)</i>
Dated:	September 4, 2018	/s/ John T. Maxwell <hr/> John T. Maxwell <i>Chief Financial Officer</i> <i>(Principal Financial Officer)</i>

**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 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. 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
 - c. 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 the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 4, 2018

/s/ KEITH J. KENDALL

Keith J. Kendall

Chief Executive Officer

(Principal Executive Officer)

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

I, 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 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 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. 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
 - c. 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 the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 4, 2018

/s/ JOHN T. MAXWELL

John T. Maxwell

Chief Financial Officer (Principal Financial Officer)

**Certification Of
Principal Executive Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002**

In connection with the Quarterly Report of Aquestive Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keith J. Kendall, chief executive officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: September 4, 2018

/s/ KEITH J. KENDALL

Chief Executive Officer

(Principal Executive Officer)

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

**Certification Of
Principal Financial and Accounting Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002**

In connection with the Quarterly Report of Aquestive Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John T. Maxwell, chief financial officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Dated: September 4, 2018

/s/ JOHN T. MAXWELL

Chief Financial Officer (Principal Financial Officer)

This certification accompanies the Report and shall not be deemed "filed" by the Company with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.
