

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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 every Interactive Data File required to be submitted 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 such files).  Yes  No

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

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided 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 October 31, 2018 was 24,942,185

AQUESTIVE THERAPEUTICS, INC.

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

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

<b>Assets</b>	<b>September 30,</b>	<b>December 31,</b>
	<b>2018</b>	<b>2017</b>
Current assets:		
Cash and cash equivalents	\$ 63,982	\$ 17,379
Accounts receivable, net	7,450	6,179
Inventories, net	4,483	4,014
Prepaid expenses and other current assets	1,444	591
Total current assets	77,359	28,163
Property and equipment, net	12,211	13,460
Intangible assets, net	216	254
Other assets	224	1,239
Total assets	<u>\$ 90,010</u>	<u>\$ 43,116</u>
<b>Liabilities and Shareholders' Equity/Members' Deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 17,798	\$ 14,003
Deferred revenue	781	1,347
Loans payable, current	2,750	-
Total current liabilities	21,329	15,350
Loans payable, net	44,054	45,507
Warrant liability	-	7,673
Asset retirement obligations	1,183	1,081
Total liabilities	66,566	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 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 250,000,000 shares; 24,942,185 shares issued and outstanding at September 30, 2018 (Note 15)	25	-
Additional paid-in capital	70,851	-
Accumulated deficit	(47,432)	(120,093)
Total shareholders' equity/members' deficit	23,444	(68,596)
Total liabilities and shareholders' equity/members' deficit	<u>\$ 90,010</u>	<u>\$ 43,116</u>

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Revenues	\$ 13,267	\$ 27,146	\$ 50,606	\$ 54,723
Costs and Expenses:				
Manufacture and supply	5,592	4,880	16,201	14,205
Research and development	4,534	5,684	17,429	15,862
Selling, general and administrative	12,345	6,161	53,561	17,513
Total costs and expenses	22,471	16,725	87,191	47,580
(Loss)/income from operations	(9,204)	10,421	(36,585)	7,143
Other income (expenses):				
Interest expense	(1,933)	(1,970)	(5,809)	(5,737)
Interest income	216	-	238	-
Change in fair value of warrant	(4,116)	-	(5,278)	(309)
Other, net	(1)	-	2	-
Net (loss)/income before income taxes	(15,038)	8,451	(47,432)	1,097
Income taxes	-	-	-	-
Net (loss)/income	(15,038)	8,451	(47,432)	1,097
Dividends on redeemable preferred interests	-	(626)	-	(1,854)
Net (loss)/income attributable to common shares/members' interests	\$ (15,038)	\$ 7,825	\$ (47,432)	\$ (757)
Comprehensive net (loss)/income	\$ (15,038)	\$ 7,825	\$ (47,432)	\$ (757)
Net loss per share - basic and diluted	\$ (0.64)		\$ (2.45)	
Weighted-average number of common shares outstanding - basic and diluted	23,646,192		19,335,541	

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

	Nine Months Ended September 30,	
	<u>2018</u>	<u>2017</u>
Cash flows from operating activities:		
Net (loss)/income	\$ (47,432)	\$ 1,097
Adjustments to reconcile net (loss)/income to net cash (used for) provided by operating activities:		
Depreciation and amortization	2,438	2,797
Change in fair value of warrant	5,278	309
Share-based compensation expenses	28,541	-
Asset retirement obligation accretion	102	90
Amortization of intangible	38	37
Amortization of debt issuance costs and discounts	1,297	1,391
Noncash interest expense	-	16
Bad debt provision (recovery)	20	(38)
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,291)	3,751
Inventories, net	(469)	(1,480)
Prepaid expenses and other assets	(889)	78
Accounts payable and accrued expenses	2,754	4,219
Deferred revenue	(566)	966
Net cash (used for) provided by operating activities	<u>(10,179)</u>	<u>13,233</u>
Cash flows from investing activities:		
Capital expenditures	(1,334)	(1,980)
Net cash (used for) investing activities	<u>(1,334)</u>	<u>(1,980)</u>
Cash flows from financing activities:		
Proceeds from initial offering of common stock	68,714	-
Proceeds from warrant exercise	-	24
Proceeds from issuance of debt	-	5,000
Payments for deferred offering costs	(4,695)	(43)
Payments for taxes on share-based compensation	(5,903)	-
Net cash provided by financing activities	<u>58,116</u>	<u>4,981</u>
Net increase in cash and cash equivalents	46,603	16,234
Cash and cash equivalents:		
Beginning of period	17,379	9,209
End of period	<u>\$ 63,982</u>	<u>\$ 25,443</u>
Supplemental disclosures of cash flow information:		
Cash payments for interest	4,511	4,346
Net increase (decrease) in capital expenditures included in accounts payable and accrued expenses	(145)	13
Net (decrease) in deferred offering costs included in accounts payable and accrued expenses	(515)	-
Accrued withholding tax for share based compensation	1,701	-
Accrued Series A-2 and A-3 preferred dividends	-	1,854
Reclass of deferred offering costs charged to additional paid in capital	5,230	-
Noncash component of warrants exercised	12,591	-

**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	<u>121,228,353</u>
	<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 and Authorized Number of Capital 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. Immediately prior to the consummation of the IPO, all of the Company's outstanding shares of non-voting common stock was automatically converted to 4,922,353 shares of voting common stock.

On July 27, 2018, the board approved an amendment to the Certificate of Incorporation of the Company to decrease the authorized number of capital stock from 350,000,000 to 250,000,000 shares.

**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. We have evaluated subsequent events for disclosure through the date of issuance of the accompanying unaudited condensed financial statements.

Any reference in these notes to applicable guidance 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, consisting primarily of direct incremental legal, accounting and other fees relating to the IPO, were capitalized as incurred. As of December 31, 2017, deferred offering costs of \$1,050 were included as a component of Other Assets due to the uncertainty of an IPO. Upon the Company's closure of the IPO on July 27, 2018, the deferred offering costs of \$5,230 were reclassified from Other Assets to Additional Paid in Capital in the accompanying balance sheet.

(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 Accounting Standards Update No 2014-09, "Revenue from Contracts with Customers" (ASU 2014-09) and has subsequently issued a number of amendments to ASU 2014-09. The new standard, as amended, provides a single comprehensive model to be used in the accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry specific guidance. The standard's stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, ASU 2014-09, includes provisions within a five-step model that includes identifying the contract with a customer, identifying the performance obligation in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard will be effective for us beginning January 1, 2019 and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. We will adopt the standard using the modified retrospective method.

The Company is continuing to evaluate the impact of these updates on its consolidated financial statements. Adoption of this standard will require changes to our business processes, systems and controls to support the additional required disclosures. We are in the process of identifying and designing such changes to ensure our readiness to appropriately recognize our revenues pursuant to the new standard in 2019.

In January 2016, the FASB issued revised guidance governing accounting and reporting of financial instruments (ASU 2016-01) and in 2018 issued technical corrections (ASU 2018-03). This guidance requires that equity investments with readily determinable fair values that are classified as available-for-sale be measured at fair value with changes in value reflected in current earnings. This guidance also simplifies the impairment testing of equity investments without readily determinable fair values and alters certain disclosure requirements. ASU No. 2016-01, *Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, also provides guidance as to classification of the change in fair value of financial liabilities. 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.



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In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This guidance simplifies aspects of accounting for employee share-based payments, including income tax consequences, classification of awards as either equity or liabilities, and classifications within the statement of cash flows. This guidance was effective for annual periods beginning after December 15, 2017, with early adoption permitted. Under the Company's 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.

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

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, preparing for related commercialization of our products, as well as for the costs to comply with the requirements of being a public company. As September 30, 2018 and December 31, 2017, we had working capital (current assets less current liabilities) of \$56,030 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 discounts and other offering expenses.

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, debt or, 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 nine-month period ended September 30, 2018, Indivior, Inc. ("Indivior") represented 95% of the total revenues for the period while during the nine-month period ended September 30, 2017, Indivior represented 88% of the total revenue for the period. As of September 30, 2018, and December 31, 2017, the Company's outstanding receivable balance from Indivior represented approximately 92% and 93%, respectively, of total receivables.

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As of September 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 or 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 September 30, 2018 and 2017 was not material.

The Company's revenues for the three and nine months ended September 30, 2018 and 2017 consisted of the following:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Manufacture and supply revenue	\$ 9,005	\$ 9,020	\$ 29,249	\$ 29,511
License and royalty revenue	3,355	17,351	17,387	22,820
Co-development and research fees	907	775	3,970	2,392
Revenues	<u>\$ 13,267</u>	<u>\$ 27,146</u>	<u>\$ 50,606</u>	<u>\$ 54,723</u>

*Disaggregation of Revenue*

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
United States	\$ 12,483	\$ 26,427	\$ 49,060	\$ 52,999
Ex-United States	784	719	1,546	1,724
Revenues	<u>\$ 13,267</u>	<u>\$ 27,146</u>	<u>\$ 50,606</u>	<u>\$ 54,723</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:

	September 30, 2018	December 31, 2017
Trade receivables	\$ 7,506	\$ 6,156
Other receivables	19	78
Less: allowance for bad debts	(75)	(55)
Trade receivables, net	<u>\$ 7,450</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:

	September 30, 2018	December 31, 2017
Allowance for doubtful accounts at beginning of year	\$ 55	\$ 108
Additions charged to bad debt expense	73	-
Write-downs charged against the allowance	(53)	-
Recoveries of amounts previously reserved	-	(53)
Allowance for doubtful accounts at end of the period	<u>\$ 75</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. In 2012, Indivior exercised its right to buyout its future royalty obligations for Suboxone sales in the United States. Indivior remains obligated to pay royalties for all sales outside the United States.

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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 \$3,000 and \$16,500 during the three and nine-month periods ended September 30, 2018, respectively, which is included in License and royalty revenue. In addition to amounts received through September 30, 2018, the Company may receive up to an additional \$41,500, consisting of (i) up to \$39,000 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 nine months ended September 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 nine months ended September 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 termination arrangement, we have the right to participate in any and all value that KemPharm may derive from the commercialization or any other monetization of KP 415 and KP 484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving KemPharm and collaborations, royalty arrangements, or other transactions from which KemPharm may realize value from these compounds. The Company has not received payments under this arrangement during the nine months ended September 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. As of September 30, the Company had no Level 3 assets or liabilities.

The Company’s Level 3 liabilities at December 31, 2017 consisted of warrants totaling \$7,673. The Company’s warrant liability was 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.

	<b>September 30, 2018</b>	<b>December 31, 2017</b>
Raw material	\$ 901	\$ 725
Packaging material	2,480	2,225
Finished goods	1,102	1,064
Total inventory	<u>\$ 4,483</u>	<u>\$ 4,014</u>

**Note 9. Property and Equipment, net**

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

	<u>Useful Lives</u>	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Machinery	3-15 yrs	\$ 20,440	\$ 20,056
Furniture and fixtures	3-15 yrs	1,142	1,109
Leasehold improvements	(a)	21,314	21,271
Computer, network equipment and software	3-7 yrs	2,287	2,108
Construction in progress		1,471	921
		<u>46,654</u>	<u>45,465</u>
Less: accumulated depreciation and amortization		<u>(34,443)</u>	<u>(32,005)</u>
Total property and equipment, net		<u>\$ 12,211</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 \$733 and \$944 for the three months ended September 30, 2018 and 2017, respectively and \$2,438 and \$2,797 for the nine months ended September 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 nine months period ended September 30, 2018. Therefore, basic and diluted net loss per share were the same for all periods presented as reflected below.

	<u>For the Three Months Ended September 30, 2018</u>	<u>For the Nine Months Ended September 30, 2018</u>
Numerator:		
Net loss	\$ (15,038)	\$ (47,432)
Denominator:		
Weighted-average number of common shares – basic and diluted	23,646,192	19,335,541
Income per common share – basic and diluted	\$ (0.64)	\$ (2.45)

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 interests 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:

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Accounts payable	\$ 12,337	\$ 9,601
Accrued salaries, performance bonuses, other compensation and benefits	3,164	3,761
Accrued withholding tax for share-based compensation	1,701	-
Real estate and personal property taxes	338	340
Other	258	301
Total accounts payable and accrued expenses	<u>\$ 17,798</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, delay the loan maturity date to December 16, 2020 and retained the interest rate, payable monthly, at one-month LIBOR or approximately 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 September 30, 2018, \$2,750 was classified as current debt. The Company’s tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Further, under the Loan Agreement, as amended, the Company is permitted, subject to Perceptive’s consent, to monetize the royalty and fees derived from sales of certain Apomorphine products and, in connection with such monetization Perceptive has agreed to release liens related to these royalties and fees. Other significant terms 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 September 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 September 30, 2018 and 2017 totaled \$374 and \$471 respectively and for the nine months ended September 30, 2018 and 2017 totaled \$1,297 and \$1,391, respectively.

Unamortized deferred debt issuance costs and deferred debt discounts totaled \$3,196 as of September 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 had certain rights and preferences including anti-dilution adjustments so that, upon exercise, they would represent 4.5% of the Company’s fully diluted common stock on an as converted basis, subject to dilution for certain financing transactions including the issuance of shares upon termination of our Performance Unit Plans. The warrant also provided Perceptive with a put right which, if exercised under certain circumstances, would require the Company to purchase the warrant for \$3,000 within the first year of the loan or \$5,000 thereafter. 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.

The Company used 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 prior to the IPO date. The fair values for periods prior to the IPO date were based on unobservable Level 3 inputs. The first step in determining the fair value of the warrant liability was 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; a discount rate of 24.5% for the nine months ended September 30, 2017 and a volatility rate of 90% for the nine-month period ended September 30, 2017.

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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 a total price of \$116. As a result, the warrant liability of \$12,951 was reclassified to additional paid in capital during the third quarter of 2018. A Level 1 market pricing of \$15.00, the initial price at which the Company's common stock was offered, was used in determining fair value as of the warrants conversion date.

A roll-forward of warrant liability is as follows:

	<b>Warrant liability</b>
Balance as of December 31, 2017	\$ 7,673
Changes in fair value recognized	5,278
Exercise of warrants	(12,951)
Balance as of September 30, 2018	\$ -

**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 \$375 and \$345 for three months ended September 30, 2018 and 2017, respectively and \$998 and \$990 for the nine months ended September 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 three 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.
- *Par.* All cases against Par were resolved pursuant to a May 2018 settlement agreement between us, Indivior, and Par and certain of its affiliates.

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.



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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 October 16, 2018, the Delaware Court issued an order transferring the case to the U.S. Court District for the Eastern District of North Carolina.

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 was 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. The review proceedings remain pending 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.

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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 granted 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 Federal Circuit heard oral argument on the appeal on October 4, 2018 but has not yet issued its opinion.

### **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 is proceeding 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**

The following table summarizes the components of share-based compensation expenses, including those related to the non-voting common shares, restricted stock awards and stock option grants, reflected in the Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine-month periods ended September 30, 2018:

	<b>Periods Ended September 30, 2018</b>	
	<b>Three Months</b>	<b>Nine Months</b>
Manufacturing and supply	\$ 32	\$ 377
Research and development	192	2,378
Selling, general and administrative	1,012	25,786
Total share-based compensation expenses	<u>\$ 1,236</u>	<u>\$ 28,541</u>

The table below reflects the following share-based compensation expenses incurred during 2018:

	<b>Periods Ended September 30, 2018</b>	
	<b>Three Months</b>	<b>Nine Months</b>
Non-voting common shares (A)	\$ -	\$ 27,298
Restricted Stock Units (B)	610	610
Stock Options (B)	626	633
Total share-based compensation expenses	<u>\$ 1,236</u>	<u>\$ 28,541</u>

There were no restricted stock unit or option grants in 2017 and consequently no share-based compensation recognized during the three and nine months ended September 30, 2017.

**(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. Immediately prior to the consummation of the IPO, all of the Company's outstanding shares of non-voting common stock were automatically converted to 4,922,353 shares of voting common stock.

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 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. Volatility was based on that of comparable public companies. The weighted average cost of capital was also based on that of comparable public companies as well as market interest rate data.

**(B) Share-Based Compensation Equity Awards**

The Company provides certain employees, non-employee directors and consultants with performance incentives under its share-based compensation plans. Under these plans, the Company may grant restricted stock units and stock options in order to align the long-term financial interests of selected participants with those of its shareholders, strengthen the commitment of such persons to the Company, and attract and retain competent and dedicated persons whose efforts will enhance long-term growth, profitability and share value.

Restricted stock and option awards are subject to graded vesting over a service period, which is typically two or three years. Compensation cost is recognized for these awards on a pro-rata basis over the requisite service period for each award granted.

Restricted stock unit awards (RSUs)

During the three months ended September 30, 2018, the Company granted to certain members of senior management and key employees a total of 264,781 restricted share units having an estimated grant date fair value of \$3,926, of which 29,802 units were vested as of that date. The remaining unrecognized compensation expense of approximately \$3,043, net of estimated forfeitures, is expected to be recognized over approximately three years. The RSUs granted to senior management vest in equal quarterly installments over two years; the RSUs granted to key employees are subject to a three-year graduated vesting schedule. These RSUs are not subject to performance-based criteria other than continued employment. There were no RSU grants prior to the three months ended September 30, 2018 and there were no forfeitures during the period.

Stock option awards

During the nine months ended September 30, 2018, the Company granted 1,033,042 stock options to certain members of senior management, members of its board of directors and a consultant having an estimated grant date fair value of \$11,155, of which 28,666 options were vested as of that date. The remaining unrecognized compensation expense of \$9,770, net of estimated forfeitures, is expected to be recognized over approximately three years. These stock options were granted with exercises prices ranging from \$6.54 to \$18.67 per share with three-year vesting and a 10-year contractual term. Options granted to senior management and board members vest in equal quarterly or monthly increments over three years; options granted to key employees are subject to a three-year graduated vesting schedule. These stock options are not subject to performance-based criteria other than continued employment. There were no option grants prior to the six months ended September 30, 2018, and there were no forfeitures during the period.

The Company measured the fair value of these stock options at their grant dates using the Black-Scholes-Merton option pricing model. The assumptions for the determination of the fair value of options issued during 2018 are as follows:

Expected dividend yield	0%
Expected volatility	90%
Expected term (years)	5.8 - 6.1
Risk-free interest rate	2.8 - 2.9%

Aquestive anticipates reinvesting earnings for the foreseeable future in product development and other avenues of share-value growth and accordingly anticipates no dividend payouts. Volatility was determined based on that of comparable public companies, given the lack of any meaningful history regarding its own now-publicly-traded common stock. The expected term of the award was calculated using the simplified method. A weighted average was utilized taking into account the two vesting periods to determine the expected term in years. The risk-free interest rate is based on the average U.S. Treasury rate with a term that most closely resembles the estimated expected life of the award.

**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 credits. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

The Company’s tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items. For the three months and nine months ended September 30, 2018, the Company recorded income tax benefit of \$0, on pretax losses of \$15,038 and \$47,432, respectively.

The Company’s U.S. statutory rate is 21%. The primary factor impacting the effective tax rate for the nine months ended September 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.

**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:

- Libervant, a buccal soluble film formulation of diazepam used as a rescue therapy for breakthrough epileptic seizures and an adjunctive therapy for use in recurrent convulsive seizures, for which a pre-NDA meeting has been scheduled in December 2018 with the FDA. The Company is preparing its submission to follow the pre-NDA meeting. The Company announced top-line clinical data from its Adult EMU study on October 24, 2018, which will be presented at the American Epilepsy Society annual meeting in early December, 2018;
- Sympazan, an oral soluble film formulation of clobazam used as an adjunctive therapy for seizures associated with a rare, intractable form of epilepsy known as LGS, which was approved by the FDA on November 1, 2018. The Company has hired and trained its sales, access/reimbursement and marketing team, and is preparing to commercially launch Sympazan in November 2018, and
- 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:

- AQST-108, a sublingual soluble film formulation for the treatment of anaphylaxis intended to provide an alternative to injection treatments such as EpiPen. After the company's first human proof of concept trials, a re-formulated and more advanced prototype has been developed, for which we expect to begin additional human trials in early 2019, and
- AQST-305, a sublingual soluble film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors, for which we are undertaking human proof of concept trials at this time.

In addition to these product candidates, we have a portfolio of commercialized and development-stage products with collaboration partners. These products include Suboxone, a sublingual film formulation of buprenorphine and naloxone, which is the market leader for the treatment of opioid dependence. In addition to several other collaboration partner products in development, AQST-119, an oral soluble film formulation of tadalafil, has a Prescription Drug User Fee Act (PDUFA) date of November 18, 2018, and APL-130277, Sunovion's oral soluble film formulation of apomorphine for the treatment of off-episodes associated with Parkinson's Disease, and has a PDUFA date of January 29, 2019. We manufacture all of our currently commercialized collaboration partner products and will manufacture all of our proprietary products at our FDA- and DEA-inspected facilities. We anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. Not all collaborative products of the Company that may be commercially launched in the future will necessarily be manufactured by the Company. 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.

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On July 27, 2018 we closed 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. On July 25, 2018 began trading on the Nasdaq Global Market under ticker symbol “AQST”. The offering resulted in aggregate gross proceeds of \$67,500 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 of \$6,386 before underwriting discounts and other costs and expenses of the offering. Total net proceeds to Aquestive after underwriters discounts and other costs and expenses of the offering totaled \$63,484.

We generated revenue of \$13,267 and \$27,146 for the three months ended September 30, 2018 and 2017, respectively, and \$50,606 and \$54,723 for the nine months ended September 30, 2018 and 2017, respectively, largely from commercial products marketed by our collaboration or commercialization 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 collaboration partner pharmaceutical product to be commercialized, and we have multiple other partner relationships that contribute to our revenue and future revenue opportunities from collaboration partner products.

As of September 30, 2018, we had \$63,982 in cash and cash equivalents. As a result of our investments in product development and recent investments in pre-launch commercialization initiatives, as well as the settlement of obligations related to our MonoSol Rx, LLC Performance Unit Plan through the issuance of non-voting common stock, as of September 30, 2018, we had net shareholders’ equity of \$23,444. We incurred net losses of \$15,038 for the three months ended September 30, 2018 and net income of \$8,451 for the three months ended September 30, 2017. For the nine months ended September 30, 2018 and 2017, we incurred a net loss of \$47,432 and net income of \$1,097 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 Libervant and Sympazan, our epilepsy products and ALS product, AQST-117;
- continue clinical development of our complex molecules, AQST-108 and AQST-305;
- identify and evaluate new pipeline candidates in CNS diseases and other indications; and
- fund working capital requirements and expected capital expenditures as a result of the launch of proprietary products and related growth.

Our business has been financed through a combination of revenue from collaborative partner 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 collaborative partner 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 license fees received under such license, development and supply agreements. We also may earn royalties based on our collaborative 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 collaborative partner 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 collaborative 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 growth to be derived from partnered activities based on growing production volumes of collaborative partner products, new product development with collaborative partners, and additional licensing of our intellectual property.

As we commercialize our proprietary CNS products, beginning with Sympazan, as well as, Libervant, subject to regulatory approval, we expect to distribute our products to wholesalers in the United States, resulting in an additional source of revenue which we refer 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 collaborative partner manufacture and supply 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 collaborative partner pharmaceutical products, including raw materials, direct labor and fixed overhead principally in our Portage, Indiana facilities. Our material costs include the costs of raw materials, other than the API component of Suboxone, used in the production of our proprietary dissolving film and primary packaging materials. Direct labor costs consist of payroll costs (including taxes and benefits) of employees engaged in production activities. Fixed 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.

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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 production begins.

*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 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 entered into contractual arrangements with a third party logistic provider (3PL) and wholesalers for distribution of our products. Further we have entered into a contract for our contracted sales force and have established a market access account team. With this increased activity related to the upcoming commercial launch, we expect selling expenses to increase in the fourth quarter 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 expenses are subject to changes in one-month LIBOR and represents a monthly cash payment obligation. This debt facility is discussed in more depth in Liquidity and Capital Resources.

*Interest Income*

Interest income consists of interest income derived from an interest-bearing account which yields a fixed rate of 1.87%. There is no minimum amount to be maintained in the account nor any fixed length of period for which interest is earned.

*Change in Fair Value of Warrant*

Changes in the fair value of warrants arises from periodic revaluations of the warrants issued to Perceptive Credit Opportunities Fund in connection with the Loan Agreement.

**Results of Operations**

***Comparison of the Three Months Ended September 30, 2018 and 2017***

We recorded revenue of \$13,267 and \$27,146 in the three months ended September 30, 2018 and 2017, respectively, generating net losses of \$15,038 for the three months ended September 30, 2018 and net income of \$8,451 for the three months ended September 30, 2017.

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



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Revenues

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

	Three Months Ended September 30,		Change	
	2018	2017	\$	%
<i>(In thousands, except %)</i>				
Manufacture and supply revenue	\$ 9,005	\$ 9,020	\$ (15)	0%
License and royalty revenue	3,355	17,351	(13,996)	(81%)
Co-development and research fees	907	775	132	17%
Revenues	<u>\$ 13,267</u>	<u>\$ 27,146</u>	<u>\$ (13,879)</u>	<u>(51%)</u>

Reflecting the timing of licenses payments on collaborative partner products which were \$14,000 higher in 2017 compared to 2018, revenues decreased 51% or \$13,879 in the three months ended September 30, 2018 to \$13,267 as compared to \$27,146 in the three months ended September 30, 2017. Excluding the impact of the change in license and royalty revenue, revenues were flat year-over-year.

Manufacture and supply revenue was flat during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 due primarily to timing of purchase volume demand attributable to Suboxone and Zuplenz product sales as offset by a more advantageous mix of various higher-revenue formulations during the current period.

License and royalty revenue decreased 81% or \$13,996 to \$3,355 in the three months ended September 30, 2018 as compared to \$17,351 in the three months ended September 30, 2017. License fees from collaborative partner products in the 2018 period were \$3,000 compared to \$17,000 in the 2017 period, explaining the entirety of the decrease in license and royalty revenue. The license fees during the third quarter of both periods related to the Suboxone product, and the decrease quarter-over-quarter was driven by contractually stipulated milestones. License fees will likely continue to fluctuate significantly from quarter-to-quarter.

Co-development and research fees increased 17% or \$132 in the three months ended September 30, 2018 to \$907 as compared to \$775 in the three months ended September 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:

	Three Months Ended September 30,		Change	
	2018	2017	\$	%
<i>(In thousands, except %)</i>				
Manufacturing and supply	\$ 5,592	\$ 4,880	\$ 712	15%
Research and development	4,534	5,684	(1,150)	(20)%
Selling, general and administrative	12,345	6,161	6,184	100%
Interest expense	1,933	1,970	(37)	(2)%
Interest income	(216)	-	216	NM
Other	4,117	-	4,117	NM

Manufacturing and supply costs and expenses increased 15% or \$712 to \$5,592 in the three months ended September 30, 2018 as compared to \$4,880 in the three months ended September 30, 2017, driven primarily by increased production costs, excipients and labor and \$32 for share-based compensation that was not incurred during the three months ended September 30, 2017, offset in part by lower volume and lower scrap costs.

Research and development expenses decreased 20% or \$1,150 to \$4,534 in the three months ended September 30, 2018 as compared to \$5,684 in the three months ended September 30, 2017. This change was primarily due to timing of clinical trials activity to our proprietary products being developed during the periods. These expense reductions were offset in part by \$192 of share-based compensation that was not incurred during the three months ended September 30, 2017.

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Selling, general and administrative expenses increased 100% or \$6,184 to \$12,345 in the three months ended September 30, 2018 as compared to \$6,161 in the three months ended September 30, 2017. The increase is primarily driven by additional investments made in our commercialization, branding and marketing capabilities in preparation for the expected launch of Libervant, Sympazan and AQST-117 attributing approximately \$3,631 of the overall increase period over period. 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. Further contributing to the overall increase is \$1,012 related to share-based compensation that was not incurred during the three months ended September 30, 2017 and \$287 of patent defense expenses.

Interest expense decreased modestly primarily due to lower discount and loan acquisition cost amortization associated with extended principal payment dates period over period. Our interest expense is subject to adjustment based on one-month LIBOR.

Interest income increased 100% or \$216 in the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 as a result of investing the net cash proceeds from our IPO in an interest-bearing account.

Other expenses increased per the table above, principally due to the change in fair value of warrants. For periods prior to our IPO, we re-measured 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. Market pricing of \$15.00, the initial price at which the Company's common stock was offered, was used in determining fair value during the three months ended September 30, 2018.

**Comparison of Nine Months Ended September 30, 2018 and 2017**

We recorded revenue of \$50,606 and \$54,723 in the nine months ended September 30, 2018 and 2017, respectively, generating a net loss of \$47,432 and net income of \$1,097 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:

	Nine Months Ended September 30,		Change	
	2018	2017	\$	%
<i>(In thousands, except %)</i>				
Manufacture and supply revenue	\$ 29,249	\$ 29,511	\$ (262)	(1)%
License and royalty revenue	17,387	22,820	(5,433)	(24)%
Co-development and research fees	3,970	2,392	1,578	66%
Revenues	<u>\$ 50,606</u>	<u>\$ 54,723</u>	<u>\$ (4,117)</u>	<u>(8)%</u>

Revenues decreased 8% or \$4,117 in the nine months ended September 30, 2018 to \$50,606 as compared to \$54,723 in the nine months ended September 30, 2017. This decrease is driven primarily from decreases in license and royalty revenue, offset, in part, by higher co-development and research fees.

Manufacture and supply revenue decreased approximately 1% or \$262 to \$29,249 in the nine months ended September 30, 2018 as compared to \$29,511 in the nine months ended September 30, 2017 primarily due to a one-time \$2,000 flat fee earned in the 2017 period for certain manufacturing exclusivity rights. Excluding this flat fee, manufacture and supply revenue increased 6% on higher Suboxone volume from \$27,511 in the nine months ended September 30, 2017 to \$29,249 in the nine months ended September 30, 2018.

License and royalty revenue decreased 24% or \$5,433 to \$17,387 in the nine months ended September 30, 2018 as compared to \$22,820 in the nine months ended September 30, 2017. This decrease was primarily related to lower license fees related to Suboxone and APL-130277 (Apomorphine). License fees totaled \$16,500 in the 2018 period compared to \$22,000 of license fees recognized in the 2017 period. Suboxone related license fees were approximately even in the two periods and the decline was driven by the receipt of \$5,000 in the 2017 period related to Apomorphine for which no amount was received in the comparable 2018 period. Royalties increased modestly 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 will likely fluctuate significantly from quarter-to-quarter.

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Co-development and research fees increased 66% or \$1,578 to \$3,970 in the nine months ended September 30, 2018 as compared to \$2,392 in the nine months ended September 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:

	Nine Months Ended September 30,		Change	
	2018	2017	\$	%
<i>(In thousands, except %)</i>				
Manufacturing and supply	\$ 16,201	\$ 14,205	\$ 1,996	14%
Research and development	17,429	15,862	1,567	10%
Selling, general and administrative	53,561	17,513	36,048	206%
Interest expense	5,809	5,737	72	1%
Interest income	(238)	-	238	NM
Other	5,276	309	4,967	NM

Manufacturing and supply costs and expenses increased 14% or \$1,996 to \$16,201 in the nine months ended September 30, 2018 as compared to \$14,205 in the nine months ended September 30, 2017, driven primarily by an increase in volume, higher production costs and the \$343 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 and share based compensation of \$34, offset in part by lower scrap costs period over period.

Research and development expenses increased 10% or \$1,567 to \$17,429 in the nine months ended September 30, 2018 as compared to \$15,862 in the nine months ended September 30, 2017 primarily due to \$2,184 of compensation cost associated with the issuance of the non-voting common shares and related withholding taxes and \$194 of share-based compensation. These increases were offset in part by decreased project spend driven by the timing of clinical trial activities on our proprietary products in development.

Selling, general and administrative expenses increased 206% or \$36,048 to \$53,561 in the nine months ended September 30, 2018 as compared to \$17,513 primarily due to \$24,771 of compensation cost associated with the issuance of the non-voting common shares and related withholding taxes and \$1,015 of share-based compensation expense. The remaining increase of \$10,262 is a primary result of investments in our commercialization, branding and marketing 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 the initial public offering and operations as a public company. Also contributing to this increase were higher costs incurred in the state anti-trust litigation and other patent related matters.

Interest expense increased 1% or \$72 to \$5,809 in the nine months ended September 30, 2018 as compared to \$5,737 in the nine months ended September 30, 2017 primarily as a result of an increase in our indebtedness of \$5,000 incurred on March 9, 2017, offset in part by lower discount and loan acquisition cost amortization associated with the extended debt principal payment dates. Our interest expense is subject to increases based on one-month LIBOR.

Interest income increased to \$238 in the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 as a result of investing the net cash proceeds from our IPO in an interest-bearing account.

Other expenses per the table above increased in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017, principally due to the change in fair value of warrants to \$5,278 from \$309.

## Liquidity and Capital Resources

### Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and as a result of our IPO as of September 30, 2018, we had net shareholders' equity of \$23,444. We have funded our operations primarily with equity and debt financings and milestone and royalty payments from our collaboration partners. Through September 30, 2018, we received net proceeds from debt and equity issuances of \$189,083 as follows:

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- \$50,000 from debt facilities further described below;
- \$75,599 from pre-IPO equity financings, with most of these proceeds received in 2008 and prior years and
- \$63,484 from our IPO and the underwriters exercising their over-allotment option

We generate revenue from collaborative partner 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 \$63,982 in cash and cash equivalents as of September 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 \$57,545, after deducting underwriting discounts, commissions, and offering related transaction costs of approximately \$9,955. 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 \$5,939, after deducting underwriter discounts of approximately \$447. The Company's IPO produced total gross proceeds of approximately \$73,885 and we received net proceeds of approximately \$63,484, after deducting underwriter discounts and costs and expenses of the offering.

***Credit Agreement and Guarantee***

On August 16, 2016, we entered into a Credit Agreement and Guarantee with Perceptive Credit Opportunities Fund, which we amended on May 21, 2018, or, as so amended, the Loan Agreement. At closing, we borrowed \$45,000 under the Loan Agreement and were permitted to borrow up to an additional \$5,000 within one year of the closing date based on achievement of a defined milestone. In March 2017, we met our performance obligations under the terms of the Loan Agreement and received the remaining \$5,000 available to us under the Loan Agreement. Proceeds under the Loan Agreement were used to repay an existing debt obligation of \$37,500, with the balance available for general corporate purposes. The loan from Perceptive was originally scheduled to mature on August 16, 2020.

However, upon the consummation of our initial public offering, the maturity date was extended to December 16, 2020. The loan bears interest, payable monthly, at one-month LIBOR, currently approximately 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. Thereafter, monthly principal payments in the amount of \$750 are due through the maturity date (as extended), at which time the full amount of the remaining outstanding loan balance is due. Our tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. The Loan Agreement contains certain financial covenants, which include (1) a minimum liquidity requirement pursuant to which we must maintain a monthly cash balance of \$4,000 at all times and (2) a minimum revenue requirement pursuant to which on a quarterly basis (calculation date) we must maintain minimum revenues for the twelve consecutive trailing months ended prior to the calculation date. Further, under the Loan Agreement, as amended, we are permitted, subject to Perceptive's consent, to monetize the royalty and fees derived from sales of certain Apomorphine products and, in connection with such monetization Perceptive has agreed to release liens related to these royalties and fees.

As of September 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 for a total exercise price of \$116.

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

### Nine Months Ended September 30, 2018 and 2017

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

(In thousands)

	<b>2018</b>	<b>2017</b>
Net cash (used for) provided by operating activities	\$ (10,179)	\$ 13,233
Net cash (used for) investing activities	(1,334)	(1,980)
Net cash provided by financing activities	58,116	4,981
Net increase in cash and cash equivalents	\$ 46,603	\$ 16,234

#### Net Cash (Used for) Provided by Operating Activities

Net cash used for operating activities for the nine months ended September 30, 2018 of \$10,179 was due to a net loss of \$47,432, changes in working capital of \$461 offset in part by \$37,714 of non-cash charges, primarily derived by \$28,541 of share-based compensation which included \$27,298 related to the termination of the Company's performance unit plans in the second quarter of 2018 and \$1,243 of share-based compensation expense recorded in the second and third quarters of 2018, \$5,278 related to change in the fair value of the Perceptive warrants and \$3,895 related to other changes such as depreciation, amortization and amortization of debt issuance costs. Net cash provided by operating activities for the nine months ended September 30, 2017 of \$13,233 was due to net income of \$1,097, changes in working capital of \$7,534 and non-cash charges of \$4,602 which included primarily included depreciation, amortization and amortization of debt issuance costs.

#### Net Cash (Used for) Investing Activities

Net cash used in investing activities was \$1,334 for the nine months ended September 30, 2018 compared to \$1,980 for the nine months ended September 30, 2017. The decrease in net cash used for investing activities was primarily attributable to timing of capital expenditures for property and equipment purchases.

#### Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$58,116 for the nine months ended September 30, 2018 compared to cash provided by financing activities of \$4,981 for the nine months ended September 30, 2017. The cash provided in 2018 was a result of \$68,714 of proceeds received from our initial offering of common stock offset in part by \$4,695 in transaction costs paid as part of our initial public offering and \$5,903 related to the payment of withholding taxes associated with the share-based compensation recorded during the second and third quarters of 2018. Net cash provided by financing activities was \$4,981 for the nine months ended September 30, 2017, which was a result of \$5,000 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 assessment 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 monetization of royalty streams on collaborative partner products APL-130277 and others, 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 \$500,000.

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 September 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 September 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 three 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.
- *Par*. All cases against Par were resolved pursuant to a May 2018 settlement agreement between us, Indivior, and Par and certain of its affiliates.

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).



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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 October 16, 2018, the Delaware Court issued an order transferring the case to the U.S. Court District for the Eastern District of North Carolina.

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 was 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. The review proceedings remain pending 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 granted 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 Federal Circuit heard oral argument on the appeal on October 4, 2018 but has not yet issued its opinion.

### ***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 is proceeding 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**

*We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.*

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We have previously been the target of a phishing attack that resulted in unauthorized access to email. While our systems have been secured and strengthened, there can be no assurance that we will not experience cyber-attacks in the future, suffer indirect consequences from a cyber-attack on a third party, or fail to anticipate, identify or offset such threats of potential cyber-attacks or security breaches in a timely manner. This is especially so in light of the nature of cyber-attack techniques, which change frequently, can be difficult to detect for extended periods of time and often are not recognized until after they succeed. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

As of the date of this Quarterly Report on Form 10Q, there have been no material changes during the three months ended September 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 except as set forth above.

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

None.

**Use of Proceeds**

On July 27, 2018, we completed the initial public offering (the "IPO") of 4,500,000 shares of our common stock at an offering price to the public of \$15.00. 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 (the "Form S-1"). From the effective date of the Form S-1 through September 30, 2018, we have used the proceeds from the IPO as described in our final prospectus filed with the SEC on July 25, 2018, pursuant to Rule 424(b) of the Securities Act.

**Item 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**Item 4. MINE SAFETY DISCLOSURES**

Not applicable.

**Item 5. OTHER INFORMATION**

None.

Item 6. EXHIBITS

Exhibits Index

Exhibit Number	Exhibit Description
<a href="#">3.1</a>	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.).
<a href="#">3.2</a>	Amended and Restated Bylaws of Aquestive Therapeutics, Inc. (incorporated by reference to Exhibit 3.6 to the Registration Statement on Form S-1 (File No. 333-225924)).
<a href="#">10.1+</a>	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)).
<a href="#">10.2+</a>	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)).
<a href="#">10.3+</a>	Employment Agreement dated July 9, 2018, by and between Aquestive Therapeutics, Inc., LLC and A. Mark Schobel (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 (File No. 333-225924)).
<a href="#">10.4+</a>	Employment Agreement dated September 10, 2018, by and between Aquestive Therapeutics, Inc., LLC and Lori J. Braender.
<a href="#">31.1</a>	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002 (filed herewith).
<a href="#">31.2</a>	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002 (filed herewith).
<a href="#">32.1</a>	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 (furnished herewith).
<a href="#">32.2</a>	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document (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 compensatory plan or management contract.

**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:	November 6, 2018	/s/ Keith J. Kendall Keith J. Kendall <i>President and Chief Executive Officer</i> <i>(Principal Executive Officer)</i>
Dated:	November 6, 2018	/s/ John T. Maxwell <hr/> John T. Maxwell <i>Chief Financial Officer</i> <i>(Principal Financial Officer)</i>

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EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "Agreement") is made and entered into as of September 10, 2018 (the "Effective Date") by and between Aquestive Therapeutics, Inc. (the "Company"), and Lori Braender (the "Executive").

WITNESSETH:

**WHEREAS**, the Company desires to employ the Employee as its Senior Vice President, General Counsel; and

**WHEREAS**, the Company and the Executive desire that the terms of this Agreement begin on September 10, 2018 (the "Effective Date");

NOW, THEREFORE, in consideration of the premises and the mutual covenants herein set forth, and for other good and valuable consideration (the receipt and sufficiency of which are hereby acknowledged), the parties hereto, intending to be legally bound, hereby agree as follows:

1. Employment. During the Employment Term (as hereinafter defined), the Executive agrees to be employed by and to serve the Company as its Senior Vice President, General Counsel, and the Company agrees to employ and retain Executive in such capacity. The Executive shall report directly to the Chief Executive Officer of the Company (the "CEO"). The Executive shall: (i) devote the Executive's entire business time, energy and skill to the affairs of the Company; (ii) faithfully, loyally, and industriously perform all duties incident to the position of Senior Vice President, General Counsel, as well as any other duties consistent with the stature and responsibility of the Executive's position as may from time to time be assigned by the CEO; and (iii) comply with the Company's policies in effect from time to time. Notwithstanding any provision herein to the contrary, Executive shall not be precluded from devoting reasonable periods of time required for serving as a member of one or more advisory boards or boards of directors of companies or organizations or engaging in other minor business activities, so long as such memberships or activities do not interfere with the performance of Executive's duties hereunder and are not directly or indirectly competitive with, nor contrary to, the business or other interests of the Company, subject to prior approval by the CEO.

2. Employment Term. The term of this Agreement shall begin on the Effective Date and continue until terminated in accordance with this Agreement (the "Employment Term").

3. Compensation.

A. Base Salary. The Company shall pay Executive a base salary (the "Base Salary") at a rate of \$375,000.00 per annum, payable in accordance with the standard payroll practices of the Company. The Board of Directors of the Company (the "Board") will review Executive's Base Salary at least annually and, with recommendations from the CEO, may increase but not decrease the then current annual rate.

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B. Annual Bonus. Executive shall be eligible for a target annual performance bonus (the “Annual Bonus”) of at least Fifty Percent (50%) of Executive's Base Salary for each calendar year, provided the Company and Executive each achieves performance targets established by the Board, with recommendations from the CEO for the Company and Executive. The Annual Bonus amount, if any, for a calendar year will be determined by the Board with recommendations from the CEO and paid by the Company by March 15th of the following calendar year, unless it is administratively impracticable to determine and/or make the payment by such date. Except as otherwise provided by this Agreement, the Executive must be employed by the Company on the day any Annual Bonus payment is due and payable in order to receive said bonus payment. If the Company exceeds established performance targets, the Board may, in its sole discretion, with recommendations from the CEO, increase the amount of the Annual Bonus.

C. Stock Options. Executive shall receive an award of 85,000 stock options granted under the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan effective the first day of Executive's employment. These stock options will have an exercise price equal to the fair market value of the Company's stock on the first day of Executive's employment and will vest Twenty-five Percent (25%) on the first and second anniversaries of the grant with the remaining Fifty Percent (50%) vesting on the third anniversary of the grant. The Executive shall be eligible to participate in other employee incentive plans and equity-based compensation awards of the Company during the Employment Term at the times and in the amounts as the Board in its sole discretion, with recommendations from the CEO, shall determine.

4. Additional Benefits.

A. Executive Benefits. During the Employment Term, Executive shall be eligible to participate in such employee benefit plans as are generally available to other senior executives of the Company.

B. Paid Time Off. The Executive will be allowed to take up to four weeks of vacation each year, and shall be eligible for such sick leave and other paid time off in accordance with the Company's policies applicable to other executives generally.

C. Expense Reimbursement. The Company will pay or reimburse Executive for reasonable expenses incurred by Executive in connection with the performance of the Executive's duties and responsibilities under this Agreement, subject to presentation of vouchers and compliance with generally applicable business expense reimbursement policies of the Company.

5. Termination.

A. Termination for Cause. The Company may terminate Executive's employment for “Cause” if Executive:

(i) is convicted of or pleads nolo contendere to a felony (or its equivalent under applicable state law);

(ii) commits fraud or a material act or omission involving dishonesty with respect to the Company or any of its respective employees, customers or affiliates;

(iii) willfully and repeatedly fails or refuses to carry out the material responsibilities of Executive's employment by the Company (except where due to physical or mental incapacity);

(iv) engages in willful misconduct or a pattern of behavior which in either case has had or is reasonably likely to have a significant adverse effect on the Company;

(v) willfully engages in any act or omission which is in material violation of the Company's policy, including but not limited to engaging in insider trading transactions or disseminating inside information; or

(vi) commits a material breach of Executive's material obligations under this Agreement, including but not limited to Section 8.

A decision to terminate the Executive's employment for Cause shall be made, if at all, by the CEO, after consultation with the Board, upon reasonable notice to Executive and an opportunity for Executive, together with counsel, to be heard by the CEO, and the CEO finding that, in his good faith opinion, Executive engaged in conduct set forth above and specifying the particulars thereof in reasonable detail. If the act or omission giving rise to the termination for Cause is curable by Executive, the Company will provide thirty (30) days' written notice to Executive of the Company's intent to terminate the Executive for Cause, with an explanation of the reason(s) for the termination for Cause and, if Executive cures the act or omission within the 30-day notice period, the Company will rescind the notice of termination and Executive's employment will not be terminated for Cause at the end of the 30-day notice period. If Executive has previously been afforded the opportunity to cure particular behavior and successfully cured under this provision, the Company will have no obligation to provide Executive with notice and an opportunity to cure a recurrence of that behavior prior to a termination for Cause. For purposes of this Section 5(A), an action or inaction shall not be treated as "willful misconduct" if authorized by the CEO or the Board, or taken by Executive in the good faith belief that it was in, or not opposed to, the best interests of the Company.

B. Termination by Reason of Permanent Disability. In a manner consistent with the Americans with Disabilities Act and the Family and Medical Leave Act, this Agreement may be terminated at the Company's option immediately upon notice to Executive if Executive shall suffer a Permanent Disability. For purposes of this Agreement, the term "Permanent Disability" shall mean the Executive's inability to perform the essential functions of the Executive's job under this Agreement, with or without reasonable accommodation, for a period of 150 consecutive days or for an aggregate of 180 days, whether or not consecutive, in any twelve (12) month period, due to illness, accident or other physical or mental incapacity, as determined by a duly licensed physician mutually agreed to by both the Executive and the Company.

C. Termination by Reason of Death. In the event of the Executive's death, the Executive's employment shall be deemed to have terminated on the date of Executive's death.

D. Voluntary Resignation. Executive may terminate this Agreement at any time, subject to providing thirty (30) days' written notice to the Company. The Company may waive such notice and/or set an earlier termination date, without pay in lieu of notice.

E. Termination without Cause. The Company may terminate Executive's employment under this Agreement at any time without Cause upon thirty (30) days' prior written notice to Executive. The Company, at its sole discretion, may relieve Executive of the Executive's active duties during the notice period. Executive's termination without Cause will be effective upon the expiration of the 30-day notice period. For purposes of this Agreement, a termination of employment by the Company that purports to be for Cause, but is not in full compliance with all of the substantive and procedural requirements relating to a termination for Cause under this Agreement, shall be treated as a termination of employment without Cause.

F. Termination for Good Reason. The Executive may terminate the Executive's employment under this Agreement at any time for Good Reason upon the occurrence (or within 180 days following the occurrence, provided that the Executive furnishes the Company with written notice of the Executive's belief that grounds for a Good Reason termination by the Executive exists no later than sixty (60) days after becoming aware of the occurrence) of any one or more of the following acts or omissions which, if curable, is not cured within thirty (30) days after notice of the occurrence is provided by Executive: (1) any action by the Company which results in a material diminution in Executive's position, authority, duties or responsibilities as Senior Vice President, General Counsel of the Company (including status, offices, titles and reporting requirements contemplated by this Agreement); (2) a material breach by the Company of its obligations under this Agreement, including, without limitation, a reduction of Executive's Base Salary or target bonus opportunity in violation of this Agreement; or (3) the Company requiring the Executive to be based at any office location that is more than fifty (50) miles from its current headquarters in Warren, New Jersey, except for travel reasonably required in connection with the performance of the Executive's responsibilities hereunder. Notwithstanding the foregoing, if a "Change in Control" (as hereinafter defined) occurs, the Executive will not have "Good Reason" to terminate the Executive's employment under this Agreement merely because the Executive reports to a senior executive officer of a company that acquires the Company.

6. Obligations of the Company Upon Termination.

A. Termination for Cause. In the event that the Executive's employment under this Agreement is terminated for Cause, the Company shall have no obligation to pay the Base Salary or any other compensation provided under this Agreement, to or for the benefit of the Executive, for any period after the effective date of such termination, or to pay the Target Annual Bonus or any other bonus or incentive compensation for the fiscal year in which such termination occurs; provided, however, that the Company shall promptly provide: (i) all Base Salary earned by the Executive through the effective date of such termination; (ii) any unpaid Annual Bonus earned by the Executive for the year preceding the year in which the Executive's employment terminates; and (iii) any benefits under any plans of the Company in which the Executive is a participant, consistent with the Executive's (or the Executive's beneficiaries') rights under such plans.



B. Termination by Reason of Death or Permanent Disability. In the event that the Executive's employment under this Agreement terminates due to the Executive's death or is terminated by the Company due to the Executive's Permanent Disability, the Company shall, within five (5) business days following such termination, provide to the Executive (or the Executive's estate or other beneficiaries, as the case may be): (i) a cash payment consisting of the sum of any previously unpaid Base Salary earned by the Executive through the date on which the Executive's employment terminates, any unpaid Annual Bonus earned by the Executive for the year preceding the year in which the Executive's employment terminates, and any accrued and unused vacation pay for the year in which the Executive's employment terminates; (ii) any benefits under any plans of the Company in which the Executive is a participant, to the full extent of the Executive's (or the Executive's beneficiaries') rights under such plans; (iii) a cash payment consisting of the Executive's Target Annual Bonus for the year of termination, pro-rated for the number of days the Executive is employed during the calendar year in which the Executive's employment terminates ("Pro Rata Bonus"); and (iv) accelerated vesting of all outstanding stock options, restricted stock units ("RSUs"), stock appreciation rights ("SAR"), restricted stock ("Restricted Stock") and other equity-based compensation awards as if the Executive's employment had continued through the end of the year in which the Executive's employment terminates or, in the case of any such award that is subject to "cliff vesting," on a pro rata basis determined by a fraction the numerator of which is the number of days during such vesting period, and the denominator of which is the total number of days in the vesting period that have elapsed as of the date the Executive's employment terminates. Notwithstanding the immediately preceding sentence, with respect to any unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation that are unvested at the time of termination of employment under this Section 6(B), and which are subject to a performance condition or performance period that ends at or after the date of employment termination, such awards will be assumed to have been achieved at "target", and the Executive will be entitled to receive a pro rata share of such awards, determined by a fraction the numerator of which is the number of days during the performance period in which Executive was employed, and the denominator of which is the total number of days in the performance period. Stock options, SARs and other equity-based compensation awards that are or become vested upon termination of the Executive's employment due to death or Permanent Disability will be exercisable (if applicable) for at least one year after the date of such termination or, if earlier, until the expiration of the stated term of the award.

C. Voluntary Resignation. In the event that the Executive voluntarily resigns from the Executive's employment with the Company, the Company may, at its discretion, continue the Executive's employment with the Company for any part or the full duration of the 30-day notice period required under Section 5(D). In the event of said termination, the Company shall have no obligation to pay the Base Salary or any other compensation provided under this Agreement to or for the benefit of the Executive for any period after such termination; provided, however, that the Company shall promptly provide: (i) all Base Salary earned by the Executive through the date of such termination; (ii) any benefits under any plans of the Company in which Executive is a participant, to the full extent of the Executive's (or the Executive's beneficiaries') rights under such plans.

D. Termination by the Company Without Cause or by Executive for Good Reason--Unrelated to Change in Control. In the event that the Executive's employment under this Agreement is terminated by the Company without Cause (pursuant to Section 5(E)) or by the Executive for Good Reason (pursuant to Section 5(F)), the Company shall provide to the Executive: (i) a cash payment consisting of the sum of any previously unpaid Base Salary earned by the Executive through the date on which the Executive's employment terminates, any unpaid Annual Bonus earned by the Executive for the year preceding the year in which the Executive's employment terminates, and any accrued and unused vacation pay for the year in which the Executive's employment terminates; (ii) any benefits under any plans of the Company in which the Executive is a participant, to the full extent of the Executive's (or the Executive's beneficiaries') rights under such plans; (iii) a cash payment consisting of the Executive's Pro Rata Bonus for the year of termination; (iv) monthly payments for a period of twelve (12) months (the "Severance Period") following the termination of Executive's employment equal to 1/12 of the sum of Executive's Base Salary and Target Annual Bonus (in each case determined without regard to any reduction prior to the termination of Executive's employment); (v) continuing coverage under the Company's group health and life insurance plans in which the Executive is a participant immediately before the termination of the Executive's employment (or any successor plans), at the same levels and on the same terms and conditions as are provided to similarly situated executives during the Severance Period (or, if such coverage is not permitted by law or the applicable plan, the cash equivalent of such coverage, grossed up if and to the extent necessary to negate the tax impact of such payment and to negate the tax impact of the gross-up payment); and (vi) full and immediate vesting of outstanding unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation awards with any such stock options, SARs and other equity-based compensation awards that are or become vested upon termination of the Executive's employment by the Company without Cause or by the Executive for Good Reason remaining exercisable, as applicable, for at least one year after the date the Executive's employment terminates or, if earlier, until the expiration of the stated term of the award. Notwithstanding the immediately preceding sentence, with respect to any unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation that are unvested at the time of termination of employment under this Section 6(D), and which are subject to a performance condition or performance period that ends at or after the date of employment termination, such awards will be assumed to have been achieved at "target." The payments and benefits described in parts (iv) – (vi) of this subsection shall be conditioned upon and subject to the Executive's continuing compliance with the Executive's obligations under Section 8 of this Agreement, and the Executive's execution and delivery of a general release substantially in the form annexed hereto as Exhibit A.

E. Termination in Conjunction with a Change in Control.

(1) Severance Protection Upon Involuntary Termination. In the event that, during the period beginning one hundred and eighty (180) days before the effective date of a Change in Control and ending twelve (12) months following the effective date of a Change in Control, the Executive's employment is terminated by the Company without Cause (pursuant to Section 5(E)) or by the Executive for Good Reason (pursuant to Section 5(F)), the Executive shall be entitled to the payments and benefits described in the preceding Section 6(D) except (i) in lieu of the severance payments described in Section 6(D)(iv), Executive will be entitled to receive an immediate cash payment of an amount equal to twelve (12) months of the Executive's Base Salary and 1.0 times the Target Annual Bonus (in each case determined without regard to any reduction prior to the termination of Executive's employment); and (ii) the benefit continuation period described in Section 6(D)(v) shall commence on the date the Executive's employment terminates and expire twelve (12) months from such date of termination. The payments and benefits described in the preceding sentence and in Sections 6(D)(iv) and 6(D)(v) and the single sum severance payment described in the preceding sentence shall be conditioned upon and subject to the Executive's continuing compliance with the Executive's obligations under Section 8 of this Agreement, and the Executive's execution and delivery of a general release substantially in the form annexed hereto as Exhibit A.

(2) Definition of Change in Control. For the purposes of this Agreement, a "Change in Control" shall be deemed to have occurred if (a) any person (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended ("Exchange Act")), or group (within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code")), becomes, in any 12-month period ending on the date of the most recent acquisition of the voting securities of the Company or any successor entity by such person, persons, or group, directly or indirectly, the beneficial owner (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 40% or more of the outstanding voting securities of the Company or successor entity; (b) there shall have been consummated a consolidation, merger or reorganization of the Company or any successor entity, unless the holders of the equity interests of the Company or successor entity, immediately before such consolidation, merger or reorganization own, directly or indirectly, at least a majority of the outstanding voting securities or at least a majority of the aggregate fair market value of the corporation or other entity resulting from such consolidation, merger or reorganization; (c) a sale, transfer, liquidation or other disposition of the Company or successor entity's assets and properties representing all or substantially all of the aggregate fair market value of such assets and properties is consummated during any 12-month period; provided, however, that no "Change in Control" shall be deemed to have occurred under this Section 6(E)(2) unless such occurrence, event or condition shall constitute a change in the ownership or effective control of the Company or any successor entity or a change in the ownership of a substantial portion of the Company or successor entity's assets, each as determined under Section 409A(a)(2)(A)(v) of the Code.

F. 409A Compliance. The Company shall take all reasonable actions to ensure that none of the amounts earned or payable under this Agreement or under any Company stock purchase, compensation or other equity incentive plan will violate Section 409A of the Code. To the extent necessary to comply with the restriction in Section 409A(a)(2)(B) of the Code concerning payments to "specified employees," any amounts payable on account of the Executive's separation from service shall be paid (or commence to be paid in the case of any payments to be made in installments) on the first business day of the seventh month following the Executive's date of termination (or death, if earlier) and the first such payment shall include the cumulative amount of any payments that would have been made prior to such date if not for such restriction, together with interest at an annual rate equal to the minimum rate required by the Code in order to avoid the imputation of interest on short-term loans between employers and employees. The date of the Executive's termination of employment shall be determined in accordance with Treasury Regulation Section 1.409A-1(h). Except as otherwise provide herein, any payment required as a result of a termination of employment will be made (or, with respect to any payments to be made in installments under this Agreement, commenced) within 45 days following such event. Notwithstanding anything else herein to the contrary, to the extent that any payments due under the terms of this Agreement are conditioned upon the delivery and non-revocation of a release, and if any of those payments are determined to be nonqualified deferred compensation that is subject to the requirements of Section 409A of the Code, and if the period for consideration and revocation of such release spans two calendar years, then any such payment shall not be made until the later of (i) the end of the revocation period following delivery of the release, or (ii) the first business day of the second calendar year.

G. Value of Insurance Coverage During Severance Period. To the extent any medical or dental plan covering any post-employment period is a “self-insured medical reimbursement plan” under Section 105(h) of the Code, and such coverage would be discriminatory thereunder, the value of the insurance coverage during the post-termination coverage period (based upon premium value) shall be reported as taxable income to the Executive, and the Company shall pay the Executive promptly no later than January 15<sup>th</sup> of the year of coverage, such additional cash payments as are necessary for the Executive to receive the same net after-tax benefits (taking into account all federal, state and local income, excise and employment taxes) that the Executive would have received under such plans if the Executive had continued to receive such plan benefits while employed with the Company; provided that any such additional cash payment that would be so immediately paid shall be subject to the provisions of Section 6(F) in connection with compliance with Section 409A of the Code.

7. Section 280G.

A. Notwithstanding any other provision of this Agreement or any other plan, arrangement or agreement to the contrary, if any of the payments or benefits provided or to be provided by the Company or its affiliates or subsidiaries to the Executive or for the Executive's benefit pursuant to the terms of this Agreement or otherwise, including, without limitation, payments in connection with a Change in Control or the vesting of shares of Restricted Stock, RSUs, SARs, stock options or other equity awards or other non-cash benefits or property), whether pursuant to the terms of this Agreement or any other plan, arrangement, or agreement with the Company or any affiliated company (the “Total Payments”) (“Covered Payments”) constitute parachute payments (“Parachute Payments”) within the meaning of Section 280G of the Code and would, but for this Section 7, be subject to the excise tax imposed under Section 4999 of the Code (or any successor provision thereto) or any similar tax imposed by state or local law or any interest or penalties with respect to such taxes (collectively, the “Excise Tax”), then prior to making the Covered Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. If the amount calculated under (i) above is less than the amount under (ii) above, then the Covered Payments will be reduced or cut back by the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax (that amount, the “Reduced Amount”). “Net Benefit” shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes.

B. Any such reduction shall be made in accordance with Section 409A of the Code and the following:

(i) the Covered Payments which do not constitute nonqualified deferred compensation subject to Section 409A of the Code shall be reduced first; and

(ii) all other Covered Payments shall then be reduced as follows: (A) cash payments shall be reduced before non-cash payments; and (B) payments to be made on a later payment date shall be reduced before payments to be made on an earlier payment date.

C. Any determination required under this Section 7 shall be made in writing in good faith by an independent accounting firm selected by the Company (the "Accountants"). The Company and the Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order to make a determination under this Section 7. For purposes of making the calculations and determinations required by this Section 7, the Accountants may rely on reasonable, good faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Accountants' determinations shall be final and binding on the Company and the Executive. The Company shall be responsible for all fees and expenses incurred by the Accountants in connection with the calculations required by this Section 7.

D. It is possible that after the determinations and selections made pursuant to this Section 7 the Executive will receive Covered Payments that are in the aggregate more than the amount provided for under this Section 7 ("Overpayment") or less than the amount provided for under this Section 7 ("Underpayment").

(i) In the event that: (A) the Accountants determine, based upon the assertion of a deficiency by the Internal Revenue Service against either the Company or the Executive which the Accountants believe has a high probability of success, that an Overpayment has been made or (B) it is established pursuant to a final determination of a court or an Internal Revenue Service proceeding that has been finally and conclusively resolved that an Overpayment has been made, then the Executive shall pay any such Overpayment to the Company.

(ii) In the event that: (A) the Accountants, based upon controlling precedent or substantial authority, determine that an Underpayment has occurred or (B) a court of competent jurisdiction determines that an Underpayment has occurred, any such Underpayment, together with penalties accruing thereon, if any, plus interest at the applicable federal rate (as defined in Section 7872(f)(2) (A) of the Code) from the date the amount would have otherwise been paid to the Executive until the payment date, will be paid promptly by the Company to or for the benefit of the Executive.

E. The Company shall have the right to control all proceedings with the Internal Revenue Service that may arise in connection with the determination and assessment of any Excise Tax and, at its sole option, the Company may pursue or forgo any and all administrative appeals, proceedings, hearings, and conferences with any taxing authority in respect of such Excise Tax (including any interest or penalties thereon). Executive shall cooperate with the Company in any proceedings relating to the determination and assessment of any Excise Tax and shall not take any position or action that would materially increase the amount of any Overpayment or Underpayment.

8. Covenants of the Executive. In order to induce the Company to enter into this Agreement and continue to employ the Executive hereunder, the Executive hereby covenants and agrees as follows. For all purposes under this Section 8 herein, references to “Company” shall be deemed to include the Company’s wholly-owned subsidiaries, if any, and the Company’s “business” shall mean film based delivery systems to deliver drug actives, nutraceuticals, cosmeceuticals or flavors, and soluble film based packaging systems and such other lines of business in which the Company or its wholly-owned subsidiaries, if any, is actively engaged or actively pursuing and with respect to which Executive has oversight responsibility or is otherwise substantively involved.

A. Non-Competition. During the Employment Term, including any extensions thereof, and for a period of twelve (12) months immediately following the termination of Executive's employment under this Agreement for any reason other than death (the “Restrictive Period”), except as provided herein, Executive shall not directly or indirectly: (a) engage in or in any manner be connected or concerned, whether as an officer, director, stockholder, partner, owner, employee, advisor, creditor, or otherwise with the development, operation, management, or conduct of any business in the United States that competes with the business of the Company being conducted at the time of such termination; (b) solicit or otherwise attempt to divert business from or interfere in the Company relationship with any supplier of the Company or any customer served by the Company or and potential customer identified by the Company during the period of Executive's employment hereunder; or (c) solicit, hire or otherwise interfere with the Company relationship with any person then or previously employed by the Company; provided, however, that, after the termination of Executive's employment, Executive shall not be bound by the Covenant set forth in this subparagraph following a material breach by the Company of any of its obligations to the Executive hereunder or in the event of the cessation or dissolution of the Company business. As used herein, “cessation or dissolution” means total liquidation of the Company and does not include a cessation of business due to any Change in Control. Nothing contained herein shall prohibit Executive from owning up to 3% of the stock of a publicly traded company that competes with the business of the Company or, following the termination of the Executive's employment with the Company, prevent the Executive from being employed by or otherwise affiliated with a line of business of another company that engages in multiple lines of business so long as the Executive is not employed by, does not provide services with respect to and is not otherwise involved in the line or lines of business of such other company that compete with the Company.

B. Confidentiality. During the Employment Term, and following the termination of this Agreement for any reason for as long as the information remains confidential, Executive shall not make any use, for the Executive's own benefit or for the benefit of a business or entity other than the Company, of any verbal or written secret or confidential information. Such confidential information shall include, but not be limited to, customer lists, trade secrets, sales, marketing or consignment information, vendor lists or operational resource information, forms, processes or procedures, budget and financial statements or information, files, records, documents, compilation of data, engineering drawings, computer print-outs, or any other data of or pertaining to the Company, its business, customers and financial affairs, or its services not generally known within the Company's trade and which was acquired by the Executive during the Executive's affiliation with the Company. Executive shall not remove from the Company premises or retain without the Company's written consent any of the Company's confidential information as defined herein, or copies thereof or extracts therefrom. Executive shall hold in a fiduciary capacity for the benefit of the Company all secret or confidential information, knowledge, or data of the Company or its business or production operations obtained by Executive during the Executive's employment by the Company, which shall not be generally known to the public or recognized as standard practice (whether or not developed by Executive) and shall not, during the Executive's employment hereunder or after the termination of such employment, communicate or divulge any such information, knowledge or data to any person, firm or corporation other than the Company or persons, firms or corporations designated by the Company. Executive acknowledges that this information is treated as confidential by the Company, that the Company takes meaningful steps to protect the confidentiality of this information, and that the Company has at all times directed Executive to maintain the confidentiality of this information. Immediately upon termination of this Agreement, Executive shall return all of the Company's property to it, including any and all copies of said property. Notwithstanding this provision or any provision in this Agreement to the contrary, nothing contained in this Agreement is intended to nor shall it limit or prohibit the Executive, or waive any right on his part, to make any good faith reports to, initiate or engage in communication with, respond to any inquiry from, otherwise provide information to, participate in any investigation or proceeding that may be conducted by, or obtain any monetary recovery from, any federal or state regulatory, self-regulatory, or enforcement agency or authority, as provided for, protected under or warranted by applicable law, in all events without notice to or consent of the Company.

C. Ownership of Work Product. Executive agrees that the Company shall own all intellectual property including trade secrets, patents, patentable inventions, discoveries and improvements that relate to the Company's business that Executive conceives, develops during the period of the Executive's employment with the Company or delivers to the Company while performing services pursuant to this Agreement ("Work Product"). Executive further agrees to deliver to the Company, and that the Company shall thereafter own for all purposes, all Work Product conceived or developed by the Executive relating to the business of the Company which does not otherwise belong to Employee's former employer or to which the former employer has no legal right or claim. Executive hereby irrevocably extinguishes for the benefit of the Company and its assigns any moral right to the Work Product recognized by applicable law. All Work Product shall be considered a work made for hire by Executive and owned by the Company. If any of the Work Product may not, by operation of law, be considered work made for hire by Executive for the Company, or if ownership of all right, title and interest of the intellectual property rights therein shall not otherwise vest exclusively in the Company, Executive agrees to assign, and upon creation thereof automatically assign, without further consideration, the ownership of all trade secrets, copyrights, patentable inventions, and other intellectual property rights therein to the Company, its successors and assigns. The Company, its successors, and assigns, shall have the right to obtain and hold in its or their own name copyrights, patents, registrations and any other protection available in the foregoing. For purposes hereof, a "trade secret" shall mean any information, including, but not limited to, technical or nontechnical data, formulae, patterns, compilations, programs, devices, methods, techniques, drawings, processes, financial data, financial plans, product plans or lists of actual or potential customers or suppliers that derive economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from their disclosure or use and are the subject of efforts that are reasonable under the circumstances to maintain their secrecy. Executive agrees to perform, upon the reasonable request of the Company and at no cost to the Company (other than travel out of pocket costs where applicable), during or after the period(s) that this Agreement remains in effect, such further acts as may be necessary or desirable to transfer, perfect and defend the Company's ownership of Work Product, or to enforce the Company's Work Product against third parties. When requested, Executive shall promptly and at no cost to the Company (other than travel out of pocket costs, where applicable): (a) execute, acknowledge and deliver any requested affidavits and documents of assignment and conveyance; (b) obtain and aid in the enforcement of copyright and, if applicable, patents with respect to the Work Product in any countries; (c) provide testimony in connection with any enforcement proceeding or any proceeding affecting the right, title or interest of the Company in any Work Product; and (d) perform any other acts deemed necessary or desirable to carry out the purposes of this Agreement.

D. Inventions. All discoveries, designs, improvements, ideas and inventions, whether patentable or not, relating to (or suggested by or resulting from) products, services, or other technology of the Company or relating to (or suggested by or resulting from) methods or processes used or usable in connection with the business of the Company that have been, or may be, conceived, developed or made by Executive during the Employment Term (hereinafter "Inventions"), either solely or jointly with others, shall automatically become the sole property of the Company. Executive shall immediately disclose to the Company all such Inventions and shall, without additional compensation, execute all assignments and other documents deemed necessary by the Company to perfect the Company's title thereto, or to the patents issued thereon, or to otherwise secure and protect the Company's property rights therein. These obligations shall continue beyond the termination of Executive's employment with respect to Inventions conceived, developed or made by Executive during employment with the Company. The Company acknowledges and agrees that the provisions of this paragraph shall not apply to any invention for which no equipment, supplies, facilities or trade secret (or proprietary) information of the Company is used by Executive and which is developed entirely on Executive's own time, unless (a) such invention related to the business of the Company or to the Company's actual or demonstrably anticipated research or development; or (b) such invention results from any work performed by Executive for the Company.

E. Acknowledgment. Executive acknowledges that all of the restrictions set forth in this Section entitled "Covenants of the Executive" are reasonable in scope, both individually and in the aggregate, and essential to the preservation of the Company's business and proprietary interests and that the enforcement thereof will not in any manner preclude Executive, in the event of Executive's termination of employment with the Company for any reason, from becoming gainfully employed in such manner and to such extent as to provide a standard of living for himself, the members of the Executive's family, and those dependent upon the Executive of at least the sort and fashion to which the Executive and they have become accustomed and may expect. The Company and the Executive further agree that if any particular provision or portion of this Section 8 shall be adjudicated to be invalid or unenforceable, such adjudication shall apply only with respect to the operation of such provision in the particular jurisdiction in which such adjudication is made. The Company and Executive also agree that in the event that any restriction herein shall be found to be void or unenforceable if some part or parts thereof were deleted or the period or area of application reduced, such restriction shall apply with such modification as may be necessary to make it valid and enforceable to the fullest extent possible consonant with applicable law. In addition, pursuant to the Defend Trade Secrets Act of 2016, the parties acknowledge that (a) an individual may not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (i) is made in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney and solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding; and (b) an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the employer's trade secrets to the attorney and use the trade secret information in the court proceeding if the individual: (i) files any document containing the trade secret under seal; and (ii) does not disclose the trade secret, except pursuant to court order.



F. Representations and Warranties. Executive represents and warrants to the Company as follows: (a) Executive is under no contractual or other restriction or obligation which may conflict with or be inconsistent with the execution of this Agreement or with the performing of any duties for the Company, or any other rights of the Company; and (b) neither the Company nor any of its affiliates nor any of their respective officers, directors, employees, agents or employees has requested that Executive communicate or otherwise make available to any such parties at any time any proprietary information, data, trade secrets, or other confidential information belonging to Executive's former employers or others.

G. Severability. All of the covenants of Executive contained in this Section entitled "Covenants of the Executive" shall each be construed as an agreement independent of any other provision in this Agreement, and the existence of any claim or cause of action of Executive against the Company, whether predicated on this Agreement or otherwise, shall not constitute a defense to the enforcement by the Company of such covenants. Both parties hereby expressly agree that it is not the intention of either party to violate any public policy, statutory or common law. If any sentence, paragraph, clause or combination of the same of this Agreement is in violation of the law of any state where applicable, such sentence, paragraph, clause or combination of the same shall be void in the jurisdictions where it is unlawful, and the remainder of such paragraph and this Agreement shall remain binding on the parties to the extent that it may be lawfully done under existing applicable laws. In the event that any part of any covenant of this Agreement is determined by a court of law to be overly broad thereby making the covenant unenforceable, the parties hereto agree, and it is their desire that such court shall substitute a judicially enforceable limitation in its place, and that as so modified the covenant shall be binding upon the parties as if originally set forth herein.

H. Remedies. The Executive agrees that irreparable harm would result from any breach by Executive of the covenants of this Section 8 in particular, and this Agreement in general, and that monetary damages alone would not provide the Company adequate relief for any such breach. Accordingly, if Executive breaches any covenant in this Section 8, the parties acknowledge that equitable or injunctive relief in favor of the Company is a proper remedy, and nothing in this Agreement shall be construed as precluding the Company from seeking such equitable or injunctive relief in a court of competent jurisdiction for Executive's violations of Section 8. Any award of equitable or injunctive relief shall not preclude the Company from seeking or recovering any lawful compensatory damages that may have resulted from a breach of the covenants of this Agreement. Any waiver or failure to seek enforcement or remedy for any breach or suspected breach of any covenant of Executive in this Agreement shall not be deemed a waiver of such provision in the future. Furthermore, the existence of any claim of Executive against the Company, whether based upon this Agreement or otherwise, shall not operate as a defense to the Company enforcement of any provision of this Agreement. Proceedings seeking equitable and injunctive relief to enforce the terms of this Section 8 may be brought in any court of competent jurisdiction.

9. Indemnification. Subject to the Company by-laws, to the fullest extent allowed or permitted under any provision of applicable law, the Company shall indemnify Executive against any losses, claims, damages or liabilities, or expenses (including reasonable attorneys' fees) incurred by Executive arising out of any claim based upon acts performed or omitted to be performed by Executive in connection with the Executive's employment with the Company.

10. Attorneys' Fees. In any action brought by any party under this Agreement to enforce any of its terms, or any appeal therefrom, each party shall bear its own costs and expenses, including its own attorneys' fees; provided, however, that the Executive (or the Executive's estate or other beneficiaries, as the case may be) will be entitled to reimbursement for reasonable costs and expenses, including reasonable attorneys' fees, with respect to such action if and to the extent that the Executive (or the Executive's estate or other beneficiaries, as the case may be) is the prevailing party.

11. Cooperation. Executive agrees that, after the termination of the Executive's employment, the Executive shall cooperate on a reasonable basis in the truthful and honest prosecution and/or defense of any claim in which the Company, its affiliates and/or its subsidiaries may have an interest (subject to reasonable limitations and the Executive's other commitments concerning time and place), which may include, without limitation, making himself available on a reasonable basis to participate in any proceeding involving the Company, its affiliates and/or its subsidiaries, appearing for depositions and testimony without requiring a subpoena, and producing and/or providing any documents or names of other persons with relevant information. The Company agrees to reimburse Executive for all expenses reasonably incurred by him and to pay reasonable compensation to Executive for and in connection with services provided by the Executive pursuant to this section.

12. Travel Restrictions. As is reasonable, Executive has the right to refuse travel to destinations deemed politically unstable or otherwise hostile and/or those that may represent a danger to the Executive's health and well-being.

13. Notices. Any notices permitted or required under this Agreement shall be deemed given upon the date of personal delivery or forty-eight (48) hours after deposit in the United States mail, postage fully paid, certified mail, return receipt requested, addressed to the Company at its principal headquarters address and to the Executive at the Executive's last address on record with the Company. Either party may change the address to which notices to such party shall be delivered personally or mailed by giving notice thereof to the other party hereto in accordance with the terms of this Section 13.

14. Venue; Jurisdiction. The validity, construction, interpretation, and enforceability of this Agreement shall be determined and governed by the laws (procedural and substantive) of the State of New Jersey without giving effect to the principles of conflicts of law. For the purpose of litigating any dispute that arises under this Agreement, the parties hereby consent to exclusive jurisdiction of, and agree that such litigation shall be conducted in, any state or federal court located in the State of New Jersey.

15. Binding Effect; Assignment. Executive shall not, without the prior written consent of the Company, assign, transfer, or otherwise convey this Agreement, or any right or interest herein. This Agreement, and all rights and obligations of the Company or any of its successors, may be assigned or otherwise transferred to any of its successors and shall be binding upon and inure to the benefit of its successors. As used herein, the term "successor" shall mean any person, corporation or other entity that, by merger, consolidation, purchase of stock, assets, liquidation, voluntary or involuntary assignment, or otherwise, acquires all or a substantial part of the assets of the Company or succeeds to one or more lines of business of the Company.

16. Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements, understandings and arrangements, both oral and written, between the parties hereto with respect to such subject matter, it being understood that this Agreement shall expressly supersede any employment agreement between Executive and the Company, and any amendments thereto. This Agreement may not be modified, amended, altered or rescinded in any manner, except by written instrument signed by all of the parties hereto; provided, however, that any waiver by either party with respect to any provision hereof, or the breach of any provision hereof by the other party, need be signed only by the party waiving such provision or breach; and provided, further, that the waiver by either party hereto of a breach or compliance with any provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or compliance.

17. Severability. In case any one or more of the provisions of this Agreement shall be held by any court of competent jurisdiction to be illegal, invalid or unenforceable in any respect, the remainder of this Agreement, or the application of such provision to persons or circumstances other than those to which it is held to be illegal, invalid, or unenforceable, shall not be affected thereby.

18. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any manner the meaning or interpretation of this Agreement.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

20. Survival. The provisions of Sections 6-11 and 13-20 of this Agreement shall survive any termination of this Agreement and the termination of Executive's employment by either party for any reason.

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Agreement as of the day and year first above written.

AQUESTIVE THERAPEUTICS, INC.

EXECUTIVE

/s/ Keith J. Kendall  
Keith J. Kendall

/s/ Lori Braender  
Lori Braender

EXHIBIT A  
GENERAL RELEASE

In exchange for certain payments and benefits to be provided to me by Aquestive Therapeutics, Inc. pursuant to the Employment Agreement dated as of \_\_\_\_\_, 2018, between the undersigned executive (the "Executive") and Aquestive Therapeutics, Inc., the Executive hereby knowingly and voluntarily waives, releases and discharges Aquestive Therapeutics, Inc., its predecessors, successors, parent corporations, subsidiaries, affiliates and each of their employees, officers and directors, agents, trustees, and fiduciaries (the "Company") from any and all claims, liabilities, demands, and causes of action, which the Executive may have or claim to have against the Company, including any and all claims arising out of or relating in any way to the Executive's employment and/or separation of employment from the Company. This General Release specifically waives and releases all rights, claims, causes of action, demands, and liabilities which may arise up to and including the date the Executive signs this General Release. This General Release does not, however, waive or release any rights or claims which may arise after the date the Executive signs this General Release. This General Release of claims includes, but is not limited to:

a. all State and Federal statutory claims including, but not limited to, claims arising under Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Older Worker Benefit Protection Act, the Americans with Disabilities Act, the Family and Medical Leave Act, the Sarbanes-Oxley Act, the Employee Retirement Income Security Act, the Fair Labor Standards Act, the Worker Adjustment and Retraining Notification Act, the New Jersey Law Against Discrimination, the New Jersey Civil Rights Act, the New Jersey Civil Union Act, the New Jersey Wage and Hour Law, the New Jersey Conscientious Employee Protection Act, the New Jersey Domestic Partnership Act, and the New Jersey Family Leave Act;

b. All claims arising under the United States and New Jersey Constitutions;

c. All claims arising under any Executive Order or derived from or based upon any State or Federal regulations;

d. All common law claims including, but not limited to, claims for wrongful or constructive discharge, public policy claims, retaliation claims, claims for breach of an express or implied contract, claims for breach of an implied covenant of good faith and fair dealing, intentional infliction of emotional distress, defamation, fraud, conspiracy, loss of consortium, tortious interference with contract or prospective economic advantage, promissory estoppel and negligence;

e. All claims for any compensation including, but not limited to, back wages, front pay, overtime pay, bonuses or awards, fringe benefits, reinstatement, retroactive seniority, pension benefits, or any other form of economic loss;

f. All claims for personal injury including, but not limited to, physical injury, mental anguish, emotional distress, pain and suffering, embarrassment, humiliation, damage to name or reputation, liquidated damages, and punitive damages; and

g. All claims for costs and attorneys' fees.

The Executive hereby acknowledges that the Company is advising the Executive in writing that the Executive should consult with an attorney prior to executing this General Release. The Executive hereby states that the Executive has had the opportunity to discuss this General Release with whomever the Executive wished, including an attorney of the Executive's own choosing. The Executive further states that the Executive has had the opportunity to read, review, and consider all of the provisions of this General Release; that the Executive understands its provisions and its binding effect on him; and that the Executive is entering into this General Release freely, voluntarily, and without duress or coercion. The Executive acknowledges that the Executive has not relied upon the Company employees, officers or directors, counsel, agents or accountants for any legal, tax or other advice, and the Executive has, to the extent the Executive deems necessary, consulted with the Executive's own advisors as to these matters. The Executive represents that the Executive has not filed any grievance, charge, claim, or complaint of any kind seeking personal recovery or personal injunctive relief against the Company or any of its owners, officers, directors, employees or agents, with respect to any matter, including but not limited to, the Executive's employment with the Company and/or the separation of that employment. Nothing contained in this paragraph shall prohibit the Executive from (a) bringing any action to enforce the terms of this Agreement and General Release; (b) filing a timely charge or complaint with the Equal Employment Opportunity Commission ("EEOC") regarding the validity of this Agreement and General Release; (c) filing a timely charge or complaint with the EEOC or participating in any investigation or proceeding conducted by the EEOC regarding any claim of employment discrimination (although the Executive has waived any right to personal recovery or personal injunctive relief in connection with any such charge or complaint); (d) initiating or engaging in communication with, responding to any inquiry from, or otherwise providing information to, any other federal or state regulatory, self-regulatory or enforcement agency or authority; or (e) seeking or obtaining an award under the whistleblower provisions of the federal securities laws.

The Executive understands that the Executive has twenty-one (21) calendar days within which to consider this General Release before signing it. The Executive also understands that the Executive is free to use as much of the twenty-one (21) calendar day period as the Executive wishes or considers necessary before deciding to sign this General Release. The Executive may revoke the Executive's signature of this General Release within seven (7) calendar days of signing it by delivering written notice of revocation to the Director of Human Resources of the Company, 30 Technology Drive South, Warren, New Jersey 07059. If Executive has not revoked the Executive's signature of this General Release by written notice delivered within the seven (7) calendar day period, it becomes effective immediately thereafter.

The Executive understands that the Executive's failure or refusal to execute this General Release or the Executive's timely revocation of this General Release will result in forfeiture of any severance payments and benefits.

**BY SIGNING THIS GENERAL RELEASE, THE EXECUTIVE ACKNOWLEDGES THAT:**

**THE EXECUTIVE HAS READ IT;**

**THE EXECUTIVE UNDERSTANDS IT AND KNOWS THAT HE/SHE IS GIVING UP IMPORTANT RIGHTS;**

**THE EXECUTIVE AGREES WITH EVERYTHING IN IT;**

**THE EXECUTIVE HAS BEEN ADVISED TO CONSULT WITH AN ATTORNEY PRIOR TO EXECUTING THIS GENERAL RELEASE;**  
**AND**

**THE EXECUTIVE HAS SIGNED THIS GENERAL RELEASE KNOWINGLY AND VOLUNTARILY.**

**EXECUTIVE**

\_\_\_\_\_

**AQUESTIVE THERAPEUTICS, INC.**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**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: November 6, 2018

/s/ KEITH J. KENDALL  
Keith J. Kendall  
*Chief Executive Officer*  
*(Principal Executive Officer)*

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**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: November 6, 2018

/s/ JOHN T. MAXWELL

John T. Maxwell

*Chief Financial Officer (Principal Financial Officer)*

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**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 September 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: November 6, 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.

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**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 September 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: November 6, 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.

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