

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 2019**

OR

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

For the transition period from _____ to _____

Commission File Number: **001-38599**

Aquestive Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of Incorporation
or organization)

30 Technology Drive, Warren, NJ 07059
(908)-941-1900

82-3827296
(I.R.S. Employer Identification Number)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	AQST	NASDAQ Global Market

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

The number of outstanding shares of the registrant's common stock, par value of \$0.001 per share, as of the close of business on August 2, 2019 was 25,026,593.

AQUESTIVE THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2019
TABLE OF CONTENTS

	<u>Page No.</u>
PART I – FINANCIAL INFORMATION	
Item 1. Financial Statements (Unaudited)	
Condensed Consolidated Balance Sheets as of June 30, 2019 and December 31, 2018	2
Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six-month periods ended June 30, 2019 and 2018	3
Condensed Consolidated Statements of Changes in Stockholders’ Deficit for the three and six-month periods ended June 30, 2019 and 2018	4
Condensed Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2019 and 2018	5
Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	21
Item 3. Quantitative and Qualitative Disclosures about Market Risk	34
Item 4. Controls and Procedures	34
PART II – OTHER INFORMATION	
Item 1. Legal Proceedings	36
Item 1A. Risk Factors	37
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	37
Item 3. Defaults Upon Senior Securities	38
Item 4. Mine Safety Disclosures	38
Item 5. Other Information	38
Item 6. Exhibits	38
SIGNATURES	39

PART I – FINANCIAL INFORMATION**Item 1. FINANCIAL STATEMENTS (Unaudited)**

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

	<u>June 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,165	\$ 60,599
Trade and other receivables, net	10,150	6,481
Inventories, net	4,647	5,441
Prepaid expenses and other current assets	2,102	1,680
Total current assets	39,064	74,201
Property and equipment, net	10,933	12,207
Intangible assets, net	178	204
Other assets	233	239
Total assets	<u>\$ 50,408</u>	<u>\$ 86,851</u>
Liabilities and shareholders' (deficit)/equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 23,479	\$ 27,631
Deferred revenue, current	600	721
Loans payable, current	550	4,600
Total current liabilities	24,629	32,952
Loans payable, net	46,884	42,603
Deferred revenue, net of current portion	2,266	—
Asset retirement obligations	1,286	1,216
Total liabilities	<u>75,065</u>	<u>76,771</u>
Commitments and contingencies (note 17)		
Shareholders' (deficit)/equity:		
Common stock, \$.001 par value. Authorized 250,000,000 shares; 25,022,660 and 24,957,309 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	25	25
Additional paid-in capital	74,744	71,431
Accumulated deficit	<u>(99,426)</u>	<u>(61,376)</u>
Total shareholders' (deficit)/equity	<u>(24,657)</u>	<u>10,080</u>
Total liabilities and shareholders' (deficit)/equity	<u>\$ 50,408</u>	<u>\$ 86,851</u>

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues	\$ 11,129	\$ 13,928	\$ 23,772	\$ 37,339
Costs and expenses:				
Manufacture and supply	5,420	4,973	8,926	10,609
Research and development	8,151	7,994	12,454	12,895
Selling, general and administrative	16,246	33,668	34,154	41,213
Total costs and expenses	29,817	46,635	55,534	64,717
Loss from operations	(18,688)	(32,707)	(31,762)	(27,378)
Other income/(expenses):				
Interest expense	(1,937)	(1,927)	(3,863)	(3,876)
Interest income	153	-	427	22
Change in fair value of warrant	-	(1,859)	-	(1,162)
Net loss before income taxes	(20,472)	(36,493)	(35,198)	(32,394)
Income taxes	-	-	-	-
Net loss	\$ (20,472)	\$ (36,493)	\$ (35,198)	\$ (32,394)
Comprehensive loss	\$ (20,472)	\$ (36,493)	\$ (35,198)	\$ (32,394)
Net loss per share - basic and diluted	\$ (0.82)	\$ (1.90)	\$ (1.41)	\$ (1.89)
Weighted-average number of common shares outstanding - basic and diluted	24,980,861	19,188,624	24,972,280	17,144,492

See accompanying notes to the condensed consolidated financial statements.

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

	<u>Common Stock</u>		<u>Additional</u>		<u>Accumulated</u>		<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Capital</u>	<u>Deficit</u>		<u>Shareholders'</u>
							<u>Deficit</u>
For the periods ended June 30, 2018:							
Balance January 1, 2018*	5,000	\$ -	\$ (26,495)	\$ -	\$ -		\$ (26,495)
Effect of stock split	15,072,647	15	(15)				-
Net income	-	-	-		4,099		4,099
Balance, March 31, 2018	15,077,647	15	(26,510)		4,099		(22,396)
Common Stock issued to performance unit plan participants	4,922,353	5	19,929		-		19,934
Share-based compensation	-	-	7		-		7
Net loss	-	-	-		(36,493)		(36,493)
Balance, June 30, 2018	<u>20,000,000</u>	<u>\$ 20</u>	<u>\$ (6,574)</u>		<u>\$ (32,394)</u>		<u>\$ (38,948)</u>

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

For the periods ended June 30, 2019:							
Balance January 1, 2019	24,957,309	\$ 25	\$ 71,431		\$ (61,376)		\$ 10,080
Adoption of ASU 2014-09, ASU 2018-07 (note 3.C.)	-	-	20		(2,852)		(2,832)
Share-based compensation	17,830	-	1,422		-		1,422
Net loss	-	-	-		(14,726)		(14,726)
Balance, March 31, 2019	24,975,139	25	72,873		(78,954)		(6,056)
Share-based compensation	16,128	-	1,739		-		1,739
Shares issued under employee stock purchase plan	31,393	-	132		-		132
Net loss	-	-	-		(20,472)		(20,472)
Balance, June 30, 2019	<u>25,022,660</u>	<u>\$ 25</u>	<u>\$ 74,744</u>		<u>\$ (99,426)</u>		<u>\$ (24,657)</u>

See accompanying notes to the condensed consolidated financial statements.

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

	Six Months Ended	
	June 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (35,198)	\$ (32,394)
Adjustments to reconcile net loss to net cash (used for)/provided by operating activities:		
Depreciation and amortization	1,447	1,705
Change in fair value of warrant	—	1,162
Share-based compensation	3,330	27,305
Asset retirement obligation accretion	70	69
Amortization of intangible	26	25
Amortization of debt issuance costs and discounts	781	923
Non-cash interest expense	505	(16)
Bad debt provision	30	31
Other, net	(15)	—
Changes in operating assets and liabilities:		
Trade receivables and other receivables	(3,684)	(481)
Inventories, net	794	(334)
Prepaid expenses and other current assets	(416)	(179)
Accounts payable and accrued expenses	(1,829)	3,593
Deferred revenue	(687)	(113)
Net cash (used for)/provided by operating activities	<u>(34,846)</u>	<u>1,296</u>
Cash flows from investing activities:		
Capital expenditures	(486)	(886)
Net cash used for investing activities	<u>(486)</u>	<u>(886)</u>
Cash flows used for financing activities:		
Proceeds from common stock issued under employee stock purchase plan	112	—
Debt repayment	(550)	—
Payments for deferred financing costs	—	(1,528)
Payments for taxes on share-based compensation	(2,664)	(5,623)
Net cash used for financing activities	<u>(3,102)</u>	<u>(7,151)</u>
Net decrease in cash and cash equivalents	(38,434)	(6,741)
Cash and cash equivalents:		
Beginning of period	60,599	17,379
End of period	<u>\$ 22,165</u>	<u>\$ 10,638</u>
Supplemental disclosures of cash flow information:		
Cash payments for interest	\$ 2,577	\$ 2,970
Net (decrease)/increase in accrued capital expenditures	(313)	125
Net increase in financing costs included in accounts payable and accrued expenses	150	-
Net increase in offering costs included in accounts payable and accrued expenses	-	1,694
Accrued withholding tax for share based compensation	-	1,741

See accompanying notes to the condensed consolidated financial statements.

AQUESTIVE THERAPEUTICS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited, in thousands, except share and per share information)

Note 1. Corporate Organization and Company Overview

(A) Company Overview

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

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

Corporate Conversion and Reorganization

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

Stock Splits

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

- (i) increase the authorized number of shares of capital stock from 25,000 to 350,000,000 shares, and subsequently reduced that authorized total to 250,000,000,
- (ii) authorize certain non-voting common stock for use in settlement of performance incentive obligations, and
- (iii) effect a stock split of the Company’s common stock, par value \$0.001 per share, such that each share be subdivided and reclassified into 37,212 shares of voting common stock, par value \$0.001 per share. Subsequent to this split, and in connection to pricing considerations related to the Company’s initial public offering (“IPO”), a reverse split was executed such that each 12.34 shares outstanding converted into one share of common stock, par value \$0.001 per share.

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

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

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

Note 2. Basis of Presentation

The accompanying interim unaudited condensed consolidated financial statements were prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”) and with Article 10 of Regulation S-X for interim financial reporting. In compliance with those rules, certain information and footnote disclosures normally included in annual consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and related notes for the fiscal year ended December 31, 2018 included in our Annual Report on Form 10-K filed with the SEC on March 14, 2019 (the “2018 Annual Report on Form 10-K”). As included herein, the condensed consolidated balance sheet at December 31, 2018 is derived from the audited consolidated financial statements as of that date. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair statement of the results of interim periods have been included. The Company has evaluated subsequent events for disclosure through the date of issuance of the accompanying unaudited condensed financial statements.

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

Note 3. Summary of Significant Accounting Policies

(A) Principles of Consolidation

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

(B) Use of Estimates

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

(C) Recent Accounting Pronouncements

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

The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

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

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

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

[Table of Contents](#)

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

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

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

Recent Accounting Pronouncements Not Adopted as of June 30, 2019:

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

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, amending existing guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for the Company beginning after December 15, 2020. The Company is currently evaluating the impact of the adoption of this guidance on its condensed consolidated financial statements.

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

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

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

Note 4. Risks and Uncertainties

The Company's unaudited interim condensed financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company's cash requirements for 2019 and beyond include expenses related to continuing development and clinical evaluation of its products, costs of regulatory filings, patent prosecution expenses and litigation expenses, expenses related to commercialization of its products, debt service requirements, and costs to comply with the requirements of being a public company. As of June 30, 2019, working capital, including cash and cash equivalents, totaled \$14,435.

As of the date of issuance of these unaudited interim condensed financial statements, the Company expects that its revenues from licensed and proprietary products, including expected milestone payments, other co-development payments and royalties, manufacturing and sale revenues at anticipated levels, anticipated sales of its proprietary products, cash on hand, and the net proceeds from the issuance on July 15, 2019 of its 12.5% Senior Secured Notes due 2025, including possible future issuances under the Indenture (see Note 18, Subsequent Event), will be adequate to fund its expected cash requirements for at least the next twelve months.

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

Note 5. Revenues and Trade Receivables, Net

The Company's revenues to date have been earned from partnered commercialized products, research and development services provided to customers, licensing of patent-protected intellectual property and commercialization of a proprietary product. These activities generate revenues in four primary categories: manufacturing and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in the current revenue standard. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good that is distinct. When identifying our performance obligations, we consider all goods or services promised in the contract regardless of whether explicitly stated in the customer contract or implied by customary business practices. The Company's performance obligations consist mainly of transferring control of goods and services identified in the contracts, purchase orders or invoices.

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

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

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

[Table of Contents](#)

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

Contract Assets

In limited situations, certain customer contractual payment terms require billing to occur in arrears; accordingly, some portions, or all, of the Company's performance obligations are completed before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. These contract assets are reflected as a component of Trade and other receivables on the Condensed Consolidated Balance Sheet. As of June 30, 2019 and January 1, 2019, such contract assets were \$295, and \$284, respectively.

Contract Liabilities

In other limited situations, certain customer contractual payment terms allow advanced billings; accordingly, customer cash payments may be received before satisfaction of some or all contractual performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. These contract liabilities are reflected as Deferred revenue in the Consolidated Balance Sheet. As remaining performance obligations are satisfied, a portion of the deferred revenue balance is recognized in the Company's results of operations. As of June 30, 2019 and January 1, 2019, such contract liabilities were \$2,866 and \$3,762, respectively. Revenue recognized for the six-month period ended June 30, 2019 that was reflected in the deferred revenue balance as of January 1, 2019 was \$940.

The Company's revenues were comprised of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Manufacture and supply revenue	\$ 8,915	\$ 8,684	\$ 15,584	\$ 20,244
License and royalty revenue	424	4,532	5,046	14,032
Co-development and research fees	1,019	712	1,789	3,063
Proprietary product sales, net	771	-	1,353	-
Total revenues	<u>\$ 11,129</u>	<u>\$ 13,928</u>	<u>\$ 23,772</u>	<u>\$ 37,339</u>

Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
United States	\$ 10,267	\$ 13,380	\$ 22,661	\$ 36,577
Ex-United States	862	548	1,111	762
Total revenues	<u>\$ 11,129</u>	<u>\$ 13,928</u>	<u>\$ 23,772</u>	<u>\$ 37,339</u>

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

Trade and other receivables, net consist of the following:

	June 30, 2019	December 31, 2018
Trade receivables	\$ 10,036	\$ 6,610
Contract and other receivables	290	33
Less: allowance for bad debts	(88)	(58)
Less: sales-related allowances	(88)	(104)
Trade and other receivables, net	<u>\$ 10,150</u>	<u>\$ 6,481</u>

[Table of Contents](#)

Contract and other receivables totaled \$290 as of June 30, 2019, consisting primarily of contract assets related to the adoption of ASC 606 and certain reimbursable customer costs. Other receivables totaled \$33 as of December 31, 2018, consisting primarily of reimbursable costs incurred on behalf of a customer. Sales-related allowances for both periods presented are estimated in relation to revenues recognized for sales of Sympazan® beginning with the launch of this product in December 2018.

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

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
Allowance for doubtful accounts at beginning of year	\$ 58	\$ 55
Additions charged to bad debt expense	30	53
Write-downs charged against the allowance	-	(50)
Allowance for doubtful accounts at end of the period	<u>\$ 88</u>	<u>\$ 58</u>

Sales Related Allowances and Accruals

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

The following table provides a summary of activity with respect to our sales related allowances and accruals for the six months ended June 30, 2019:

	<u>Total Sales Related Allowances and Accruals</u>
Balance at December 31, 2018	\$ 585
Provision	847
Payments / credits	(535)
Balance at June 30, 2019	<u>\$ 897</u>

Total reductions of gross product sales from sales-related allowances and accruals were \$847 for the six months ended June 30, 2019. Accruals for returns allowances and prompt pay discounts are reflected as a direct reduction to trade receivables, and totaled \$88 and \$104 at June 30, 2019 and December 31, 2018, respectively. Accruals for wholesaler fees, co-pay cards and rebates are reflected as current liabilities, and totaled \$809 and \$481 at June 30, 2019 and December 31, 2018, respectively. There were no sales related allowances and accruals at June 30, 2018, as Sympazan was launched in December 2018.

Concentration of Major Customers

Customers are considered major customers when sales exceed 10% of total net sales for the period or outstanding receivable balances exceed 10% of total receivables. For the year ended December 31, 2018, Indivior, Inc. ("Indivior") provided 89% of the total revenues for the period, and as of that date, the Company's outstanding receivable balance from Indivior represented approximately 78% of gross receivables. For the six months ended June 30, 2019, revenues provided by Indivior represented approximately 86% of total revenues, and outstanding accounts receivable due from Indivior represented approximately 74% of gross receivables.

Note 6. Material Agreements

Commercial Exploitation Agreement with Indivior

In August 2008, the Company entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (with subsequent amendments, collectively, the “Indivior License Agreement”). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior, Inc. Pursuant to the Indivior License Agreement, the Company agreed to manufacture and supply Indivior’s requirements for Suboxone, a sublingual film formulation, both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, the Company is required to manufacture Suboxone in accordance with current Good Manufacturing Practice standards and according to the specifications and processes set forth in the related quality agreements the Company entered into with Indivior. Additionally, the Company is required to obtain Active Pharmaceutical Ingredients (“API”) for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a maximum annual threshold quantity of Suboxone that the Company is obligated to fill and requires Indivior to provide the Company with a forecast of its requirements at various specified times throughout the year. Additionally, in the event Indivior purchases certain large quantities of Suboxone during a specified period, Indivior will be entitled to scaled rebates on rest of the world sales only.

In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) in all countries other than the United States and subject to annual maximum amounts and limited to the life of the related United States or international patents.

The Indivior License Agreement contains customary contractual termination provisions, including those for breach, a filing for bankruptcy or corporate dissolution, an invalidation of the intellectual property surrounding Suboxone, or commission of a material breach of the Indivior License Agreement by either party. Additionally, Indivior may terminate if the U.S. Food and Drug Administration (“FDA”) or other applicable regulatory authority declares the Company’s manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. The initial term of the Indivior License Agreement was seven years from the commencement date. Thereafter, the Indivior License Agreement automatically renews for successive one-year periods, unless either party provides the other with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

Supplemental Agreement with Indivior

On September 24, 2017, the Company entered into an agreement with Indivior, or the Indivior Supplemental Agreement. Pursuant to the Indivior Supplemental Agreement, we conveyed to Indivior all of our existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to the Suboxone product. Under the Indivior Supplemental Agreement, we are entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. Once paid, all payments made under the Indivior Supplemental Agreement are non-refundable, and total payments under this agreement are capped at \$75,000. Through February 20, 2019, the at-risk launch date of the competing generic products of Dr. Reddy’s Labs and Alvogen, we received an aggregate of \$40,750 from Indivior under the Indivior Supplemental Agreement, of which \$4,250 was collected during the three months ended March 31, 2019. Further payments under the Indivior Supplemental Agreement are suspended until adjudication of related patent infringement litigation is completed. If such litigation is successful, which cannot be assured, in addition to the amounts already received as described in the foregoing, we may receive up to an additional \$34,250, consisting of (i) up to \$33,000 in the aggregate from any combination of (a) performance or event-based milestone payments and (b) single digit percentage royalties on net revenue earned by Indivior on sales of Suboxone and (ii) an additional \$1,250 that was earned through the issuance to the Company of additional process patent rights.

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

License Agreement with Sunovion Pharmaceuticals, Inc.

In April 2016, we entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion), referred to as the Sunovion License Agreement, pursuant to which we granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson’s disease patients, as well as two other fields. Our licensee, Sunovion, as sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018. According to statements by Sunovion, following the January 2019 PDUFA date, Sunovion received a Complete Response Letter from the FDA which requires additional data, but does not require additional clinical studies.

In consideration for the rights granted to Sunovion under the Sunovion License Agreement, we received aggregate payments totaling \$18,000 to date. In addition to the upfront payment of \$5,000, we have also earned an aggregate of \$13,000 in connection with specified regulatory and development milestones in the United States and Europe (the “Initial Milestone Payments”), all of which have been received to date. No payments were received during the three and six months ended June 30, 2019. We are also entitled to receive certain contingent one-time milestone payments related to product availability and regulatory approval in the United States and Europe, certain one-time milestone payments based on the achievement of specific annual net sales thresholds of APL-130277, and ongoing mid-single digit percentage royalty payments related to the net sales of APL-130277 (subject to reduction to low-single digit percentage royalty payments in certain circumstances), subject to certain minimum payments. The maximum aggregate milestone payments that may be paid to us pursuant to the Sunovion License Agreement is equal to \$45,000. With the exception of the Initial Milestone Payments, there can be no guarantee that any such milestones will in fact be met or that additional milestone payments will be payable.

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

Agreement to Terminate CLA with KemPharm

In March 2012, the Company entered into an agreement with KemPharm, Inc. (“KemPharm”) to terminate a Collaboration and License Agreement entered into in April 2011. Under this termination arrangement, we have the right to participate in any and all value that KemPharm may derive from the commercialization or any other monetization of KP 415 and KP 484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving KemPharm and collaborations, royalty arrangements, or other transactions from which KemPharm may realize value from these compounds. The Company has not received payments under this arrangement during any of the periods presented herein, and there can be no guarantee that any such payments will be made in the future.

Note 7. Financial Instruments – Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. To increase consistency and comparability in such measurements, the FASB established a three-level hierarchy which requires maximization of the use of observable inputs and minimization of the use of unobservable inputs when estimating fair value. The three levels of the fair value hierarchy include:

- Level 1 — Observable quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable prices that are based on inputs not quoted on active markets but corroborated by market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity, such as pricing models, discounted cash flow methodologies and similar techniques.

The Company’s Level 1 assets for the periods presented included cash and cash equivalents, including money market funds. The Company held no Level 2 or Level 3 assets or liabilities as of either balance sheet date presented herein. Prior to exercise in connection with the July 2018 IPO, outstanding warrants held by Perceptive Credit Opportunities Fund were categorized as Level 3 liabilities. This warrant liability was estimated at fair value based primarily on independent third-party appraisals prepared and reported periodically, consistent with generally-accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*. See Note 13 for further information on the Company’s warrants. In addition, Level 3 inputs provide the basis for estimated fair values of stock options granted during 2018 and 2019, which values were estimated using the Black-Scholes-Merton pricing model based on assumptions disclosed in Note 15.

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

Note 8. Inventories, Net

The components of Inventory, net is as follows:

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
Raw material	\$ 1,247	\$ 1,283
Packaging material	2,366	2,975
Finished goods	<u>1,034</u>	<u>1,183</u>
Total inventory, net	<u>\$ 4,647</u>	<u>\$ 5,441</u>

Note 9. Property and Equipment, Net

	<u>Useful Lives</u>	<u>June 30, 2019</u>	<u>December 31, 2018</u>
Machinery	3-15 yrs	\$ 20,905	\$ 20,681
Furniture and fixtures	3-15 yrs	1,150	1,150
Leasehold improvements	(a)	21,333	21,333
Computer, network equipment and software	3-7 yrs	2,657	2,579
Construction in progress		<u>1,526</u>	<u>1,655</u>
		47,571	47,398
Less: accumulated depreciation and amortization		<u>(36,638)</u>	<u>(35,191)</u>
Total property and equipment, net		<u>\$ 10,933</u>	<u>\$ 12,207</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 \$711 and \$765 for the three-month periods ended June 30, 2019 and 2018, respectively. For the respective six-month periods, these expenses totaled \$1,447 and 1,705.

Note 10. Intangible Assets

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

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
Purchased technology-based intangible	\$ 2,358	\$ 2,358
Purchased patent	<u>509</u>	<u>509</u>
	2,867	2,867
Less: accumulated amortization	<u>(2,689)</u>	<u>(2,663)</u>
Total intangible assets, net	<u>\$ 178</u>	<u>\$ 204</u>

Amortization expense was \$13 and \$12 for the three-month periods ended June 30, 2019 and 2018, respectively. For the corresponding six-month periods, these expenses totaled \$26 and \$25, respectively. During the remaining life of the purchased patent, estimated annual amortization expense is \$50 for each of the years from 2019 to 2022.

Note 11. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
Accounts payable	\$ 20,034	\$ 20,436
Accrued compensation	2,282	3,604
Accrued withholding tax for share-based compensation	-	2,515
Real estate and personal property taxes	176	388
Accrued distribution expenses	809	481
Other	<u>178</u>	<u>207</u>
Total accounts payable and accrued expenses	<u>\$ 23,479</u>	<u>\$ 27,631</u>

Note 12. Loans Payable

On August 16, 2016, the Company entered into a Loan Agreement and Guaranty (the "Loan Agreement") with Perceptive Credit Opportunities Fund, LP ("Perceptive"). Upon closing, the Company borrowed \$45,000 from Perceptive and was permitted to borrow up to an additional \$5,000 within one year of the closing date based upon achievement of a defined milestone which was met in March 2017 and the balance of the facility was borrowed at that time. The initial loan proceeds were used to pay the existing debt obligation of \$37,500 due to White Oak Global Advisors, LLC, with the balance available for general business purposes. On July 15, 2019, this loan from Perceptive was repaid in full as part of a refinancing transaction. See Note 18, Subsequent Events.

On May 21, 2018, the Company and Perceptive agreed to make certain amendments to the loan agreement then in effect. In the event that a qualified IPO could be consummated on or before December 31, 2018, the Company and Perceptive agreed to postpone the initial loan principal payments, delay the loan maturity date to December 16, 2020 and retain interest rate terms, payable monthly, at one-month LIBOR or approximately 2% plus 9.75%, subject to a minimum rate of 11.75%. Accordingly, commencing on May 31, 2019, seven monthly loan principal payments were due in the amount of \$550. Thereafter, monthly principal payments in the amount of \$750 were due through the maturity date, December 16, 2020, at which time the full amount of the remaining outstanding loan balance was due. At June 30, 2019 and December 31, 2018, respectively, \$550 and \$4,600 was classified as current debt. The Company's tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Further, under the Loan Agreement, as amended, the Company was permitted, subject to Perceptive's consent, to monetize the royalty and fees derived from sales of certain apomorphine products and, in connection with such monetization, Perceptive had agreed to release liens related to these royalties and fees. Other significant terms of the Loan Agreement, as amended, included financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. Financial covenant requirements included (1) minimum liquidity under which a \$4,000 minimum cash balance must be maintained at all times and (2) a minimum revenue requirement under which minimum revenues for the trailing twelve consecutive months, measured at the end of each calendar quarter. As of June 30, 2019, the Company was in compliance with all financial covenants under the Loan Agreement, as amended. Also, as of that date, the carrying value of the Company's loan payable approximated its market value. At closing of the Loan Agreement, as amended, Perceptive received a warrant to purchase senior common equity interests representing 4.5% of the fully diluted common units of the Company on an as converted basis, which was automatically exercised in full at the time of the IPO (see Note 13).

The Company capitalizes legal and other third-party costs incurred in connection with obtaining debt as deferred debt issuance costs and applies the unamortized portion as a reduction of the outstanding face amount of the related loan in accordance with ASU 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*. Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its lenders, and offsets those as a direct reduction of its outstanding debt. Amortization expense arising from deferred debt issuance costs and debt discounts for the six-month periods ended June 30, 2019 and 2018 were \$781 and \$923, respectively; for the corresponding three-month periods these expenses totaled \$392 and \$465.

Unamortized deferred debt issuance costs and deferred debt discounts totaled \$2,016 as of June 30, 2019 and \$2,797 as of December 31, 2018.

Note 13. Warrants

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

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

During interim periods, the Company used an independent third-party valuation to assist in determining the fair value of these warrants due to the absence of available Level 1 and Level 2 inputs. During the three-months and six months period June 30, 2018, as a result of an increase in the estimated fair value of this warrant liability, net losses included a non-cash loss of \$1,859 and \$1,162, respectively. No gain or loss was recognizable for any periods subsequent to the date of exercise of the warrants in July 2018. The fair values at both the date of the issuance and the dates of all interim balance sheets prior to exercise were based on unobservable Level 3 inputs. Fair value was based on the aggregate equity of the Company, which was estimated utilizing the income and market valuation approaches. A probability weighted return model was then utilized to allocate the resulting aggregate equity value of the Company to the underlying securities. Estimates and assumptions impacting the fair value measurement included the following factors: the then-current state of development of the Company's pipeline product candidates, including status of clinical trials; the Company's progress towards an IPO, including selection of investment bankers, assessment of the IPO marketplace and other funding alternatives and a discount rate of 26.5% and a volatility rate of 90%.

Note 14. Net Loss Per Share

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	\$ (20,472)	\$ (36,493)	\$ (35,198)	\$ (32,394)
Denominator:				
Weighted-average number of common shares – basic	24,980,861	19,188,624	24,972,280	17,144,492
Loss per common share - basic	\$ (0.82)	\$ (1.90)	\$ (1.41)	\$ (1.89)

As of June 30, 2019, the Company's potentially dilutive instruments included 1,983,142 options to purchase common shares and 142,852 unvested restricted stock units ("RSUs") that were excluded from the computation of diluted weighted average shares outstanding because these securities had an anti-dilutive impact due to the loss reported. No such equity securities were issued as of June 30, 2018.

Note 15. Share-Based Compensation

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

Expense classification:	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Manufacture and supply	\$ 72	\$ 345	\$ 116	\$ 345
Research and development	140	2,186	348	2,186
Selling, general and administrative	1,598	24,774	2,866	24,774
Total share-based compensation expenses	\$ 1,810	\$ 27,305	\$ 3,330	\$ 27,305
Share-based compensation from:				
Restricted stock units	\$ 467	\$ —	\$ 930	\$ —
Stock options	1,323	7	2,380	7
Non-voting common shares	—	27,298	—	27,298
Employee stock purchase plan	20	—	20	—
Total share-based compensation expenses	\$ 1,810	\$ 27,305	\$ 3,330	\$ 27,305

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

Share-Based Compensation Equity Awards

The following tables provides information about the Company's restricted stock and stock option unit activity during the six months ended June 30, 2019:

<u>Restricted stock units:</u>	<u>Number of Units</u> (in thousands)	<u>Weighted Average Grant Date Fair Value</u>
Unvested at December 31, 2018	205	\$ 14.77
Granted	—	—
Vested	(59)	15.03
Forfeited	(3)	13.00
Unvested at June 30, 2019	<u>143</u>	<u>\$ 14.70</u>
Grant date fair value of shares vested during the period	<u>\$ 896</u>	
Unrecognized compensation costs of RSU awards at June 30, 2019	<u>\$ 1,881</u>	

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

<u>Stock options:</u>	<u>Number of Options</u> (in thousands)	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 2018	1,033	\$ 14.72
Granted	975	7.51
Forfeited	(25)	7.77
Exercised, expired	—	—
Outstanding at June 30, 2019	<u>1,983</u>	<u>\$ 11.26</u>
Vested or expected to vest at June 30, 2019	<u>1,868</u>	<u>\$ 11.12</u>
Exercisable at June 30, 2019	<u>223</u>	<u>\$ 14.32</u>

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

Expected dividend yield	0%
Expected volatility	85 - 95%
Expected term (years)	5.5 - 6.1
Risk-free interest rate	1.9 - 2.6%

The weighted average grant date fair value of stock options granted during 2019 was \$7.51. During the six months ended June 30, 2019, options were granted with exercise prices ranging from \$4.38 to \$8.05, and accordingly, given Aquestive's share price of \$4.20 at the close of the Company's second quarter of 2019, these options provided no intrinsic value at that date. Similarly, options granted in 2018 provided no intrinsic value at June 30, 2019.

As of June 30, 2019, \$11,352 of total unrecognized compensation expenses related to non-vested stock options is expected to be recognized over a weighted average period of 2.3 years from the date of grant.

Employee stock purchase plan

The Company's Board of Directors adopted the Aquestive Therapeutics, Inc. Employee Stock Purchase Plan, or ESPP in June 2018, as amended and restated effective as of January 1, 2019. The Employee Stock Plan, features two six-month offering periods per year, running from January 1 to June 30 and July 1 to December 31. Under the ESPP, employees may elect to purchase the Company's common stock at the lower of 85% of the fair value of shares on either the first or last day of the offering period. During the six months ended June 30, 2019, 31,393 shares were purchased at a total discount of \$20 and were issued under the ESPP, effective as of that date.

Note 16. Income Taxes

The Company has accounted for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as net operating loss carryforwards and research and development credits. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

[Table of Contents](#)

The Company's tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items. For the three months ended June 30, 2019 and 2018, the Company recorded no income tax benefit from its pretax losses of \$20,472 and \$36,493, respectively, and similarly for the sixth months ended June 30, 2019 and 2018, the Company recorded no tax benefit from its pretax loss of \$35,198 and \$32,394, respectively, due to realization uncertainties.

The Company's U.S. Federal statutory rate is 21%. The primary factor impacting the effective tax rate for the three and six months ended June 30, 2019 is the anticipated full year operating loss which will require full valuation allowances against any associated net deferred tax assets.

Note 17. Commitments and Contingencies

(A) Operating Leases

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

Rent expense for all leased manufacturing facilities and sales, laboratory and office space totaled \$399 and \$292 for the three-month periods ended June 30, 2019 and 2018, respectively and \$771 and \$623 for the six-month periods ended June 30, 2019 and 2018, respectively.

(B) Litigation and Contingencies

From time to time, the Company has been and may again become involved in legal proceedings arising in the ordinary course of business, including product liability, intellectual property, commercial litigation, or environmental or other regulatory matters.

Patent-Related Litigation

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

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

- *Mylan* and *Sandoz* settled without a trial. *Sandoz* withdrew all challenges and became the distributor of the authorized generic.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement between the Company, Indivior, and *Par* and certain of its affiliates.
- *Actavis* was found to infringe the '514 patent and cannot enter the market until the expiration of the patent in 2024, and the Federal Circuit affirmed that ruling on July 12, 2019.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the Federal Circuit affirmed that ruling on July 12, 2019. *Teva* has agreed to be bound by all DRL adjudications.

Subsequent to the above, all potential generic competitors without a settlement agreement were also sued for infringement of two additional new patents that contain new claims not adjudicated in the original case against DRL and Alvogen. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The case(s) regarding the additional asserted patents have not been finally resolved. The case against Actavis, pending in the U.S. District Court for the District of Delaware, is scheduled for trial in December 2019. No trial date has been set in the cases against DRL and Alvogen, which are pending in the U.S. District Court for the District of New Jersey. On February 19, 2019, the Federal Circuit issued its mandate reversing the District of New Jersey's preliminary injunction against DRL. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both DRL and Alvogen. On February 19, 2019, Indivior launched the authorized generic of Suboxone Sublingual Film, which is manufactured by the Company exclusively for sale and marketing by Sandoz Inc., a sublicensee of Indivior. DRL, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by DRL and Alvogen are "at risk" because the products are the subject of the ongoing patent infringement litigations.

Table of Contents

On March 22, 2019, Aquestive and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. for infringement of the '150, '514, '454, and '305 patents, seeking an injunction and potential monetary damages. The case is pending in the Southern District of Florida, and the defendants filed their answers to the complaint, including counterclaims for non-infringement and invalidity of the asserted patents as well as two other patents that were not asserted in the original complaint.

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

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

Antitrust Litigation

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of federal and state antitrust statutes and state unfair trade and consumer protection laws relating to Indivior's launch of Suboxone Sublingual Film in 2010 and seeking an injunction, civil penalties, and disgorgement. After filing, the case was consolidated for pre-trial purposes with the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While the Company was not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that the Company participated in an antitrust conspiracy with Indivior in connection with Indivior's launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. The Company moved to dismiss the States' conspiracy claims, but by order dated October 30, 2017, the Court denied this motion to dismiss. An answer denying the States' claims was filed on November 20, 2017. The fact discovery period closed on July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions are being conducted through August 1, 2019. Summary judgement motions and *Daubert* motions relating to expert witnesses are due on September 26, 2019. At this time, management cannot determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimates, of the possible outcome or loss, if any, in this matter.

Note 18. Subsequent Event

Debt Refinancing & Warrant Issuance

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

Upon closing, the Company issued \$70 million of the principal of the Notes (the "Initial Notes") along with the Warrants and rights of first offer (the "First Offer Rights") to the lenders participating in this transaction for Notes and Warrants (the "Lenders"). Issuance of the Initial Notes, Warrants and First Offer Rights has provided net proceeds of \$66,951. In addition to the Initial Notes, the Indenture may provide access to further loans of up to \$30,000 that may become available in two tranches of Additional Notes tied to the NDA filing for and FDA approval of Libervant, an important part of our drug candidate pipeline. Provided that no events of default exist, the Company may elect, subject to majority lenders' approval, to offer to the Lenders participation in a \$10,000 additional offering of 12.5% senior secured notes (the "First Additional Offering") under terms similar to the Initial Notes, on or before March 31, 2021, upon the filing of the Libervant NDA with the FDA. A second identical funding opportunity would allow, on or before March 31, 2021, the Company to obtain an additional \$20,000 if the first option has been elected and funded, or, if not elected or funded, an additional \$30,000 may be offered for issuance following FDA approval of Libervant. There can be no assurance that any such additional financing will be consummated.

[Table of Contents](#)

Proceeds from issuance of the Initial Notes and Warrants were used to fully repay the Company's \$52,092 outstanding indebtedness to Perceptive Credit Holdings, LP, related early repayment fees and legal and other fees incurred in executing this Indenture. Remaining proceeds of \$14,859 will be used to support the advancement of Aquestive's late-stage development pipeline, ongoing proprietary product commercialization and for general corporate operations.

The Notes provide a stated fixed rate of 12.5%, payable quarterly in arrears, with the initial quarterly principal repayment of the Initial Notes due on September 30, 2021 and the final quarterly payment due at maturity on June 30, 2025. Principal payments are scheduled to increase annually from 10% of the face amount of the debt then outstanding during the first four quarters to 40% of the initial loan principal during the final four quarters. Aquestive may elect, at its option, to prepay the Notes at any time at premiums that range from 101.56% of outstanding principal if prepayment occurs on or after the 5th anniversary of the issue date of the Notes to 112.5% if redemption occurs during the third year after the issuance of the Notes. In the event that redemption occurs within the two years after the issuance of the Notes, a make-whole fee is required, based on the present value of remaining interest payments using an agreed-upon discount rate linked to the then-current U.S. Treasury rate. The Indenture also includes change of control provisions under which the Company may be required to repurchase the Notes at 101% of remaining principal plus accrued interest at the election of the lenders.

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

Affirmative and negative covenants specified in the Indenture are considered typical for loans of this nature, including, but not limited to, specifications relating to preservation of corporate existence, publicly traded status, intellectual property and business interests; limitations or prohibitions of dividend payments or other dispositions, repurchases of shares, additional debt, certain equity issuances, asset transfers or dispositions, creation or occurrence of additional liens, entering into licensing or monetization arrangements other than as permitted under the Indenture, and perfection of security interests. Events of default include various commonly specified conditions, including but not limited to, bankruptcy, insolvency, material adverse changes, failure to meet Indenture payment or other obligations, compliance with regulatory requirements and preservation of the corporate existence and business operations.

The Warrants, expiring in June 2025, entitle the Lenders to purchase two million shares of the Company's common stock, and include registration rights, specify an exercise price of \$4.25 and a term of six years.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

You should read this section in conjunction with our unaudited condensed interim consolidated financial statements and related notes included in Part I Item 1 of this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes thereto and management’s discussion and analysis of financial condition and results of operations for the years ended December 31, 2018 and 2017 included in our 2018 Annual Report on Form 10-K.

Forward-Looking Statements

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

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

Overview

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

Our most advanced proprietary investigational product candidates include:

- Libervant™, a buccal soluble film formulation of diazepam used as a rescue therapy for breakthrough epileptic seizures and an adjunctive therapy for use in recurrent convulsive seizures, for which a pre-NDA meeting was held in December 2018 with the FDA. The meeting resulted in a plan to complete a small single-dose crossover study comparing Libervant to the reference listed drug, Diastat®. This study was initiated in the first quarter of 2019, and enrollment into the study was completed in May 2019. The Company also began a rolling NDA submission process during the second quarter of 2019. Subsequent to the close of the period, the Company completed the crossover study and is evaluating the data generated.
- Exservan™, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we submitted an NDA in the first quarter of 2019; the PDUFA goal date for FDA approval is November 30, 2019.

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

- AQST-108, a sublingual soluble film formulation for the treatment of anaphylaxis and severe allergic reactions, which is intended to provide an adjunct and or alternative to injection treatments such as EpiPen. After the Company's first human proof of concept trials, a re-formulated and more advanced prototype has been developed, for which we began additional phase 1 proof of concept trials early in the second quarter of 2019; and
- AQST-305, a sublingual soluble film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors. As a result of early stage clinical proof of concept studies, re-formulation work is currently underway.

In addition to these product candidates, we have a portfolio of commercialized and development-stage licensed products. Our largest commercialized licensed product to date is Suboxone, a sublingual film formulation of buprenorphine and naloxone, for the treatment of opioid dependence. We have a sole and exclusive worldwide manufacturing agreement with Indivior to deliver both the branded Suboxone, globally through Indivior, and the authorized generic sublingual film formulation of buprenorphine and naloxone, through Sandoz for the United States market. As of July 2019, these products account for greater than 75% of the oral film products prescribed in the U.S. for recovery from opioid addiction – a market that continues to grow.

We manufacture all of our licensed and proprietary products at our FDA- and DEA-inspected facilities. There is no guarantee that proprietary or licensed products will necessarily be manufactured by the Company. We have produced over 2 billion doses of Suboxone and other commercial non-pharmaceutical products for all customers since 2006. Our products are developed using our proprietary PhamFilm® technology and know-how.

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

On July 15, 2019, we completed a private placement of \$70,000 of 12.5% Senior Secured Notes due June 2025 ("Notes") and unregistered warrants and paid off our existing credit facility. The new financing provided net proceeds of \$66,951 after expenses. The net proceeds of the financing were used to repay all outstanding obligations under the Company's prior credit facility of \$52,092. We intend to use the remaining balance of \$14,859 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes. Our Notes are discussed in Note 18, Subsequent Event, to our Consolidated Financial Statements and in Liquidity and Capital Resources.

We generated revenue of \$11,129 and \$13,928 for the three months ended June 30, 2019 and 2018, respectively, and \$23,772 and \$37,339 for the six months ended June 30, 2019 and 2018, respectively, most significantly from commercial products licensed to our marketing licensees. Total revenues included manufacturing and supply revenue, license fees, royalties, co-development and research fees and our proprietary product sales. Our revenue is subject to the normally uneven nature of the timing of co-development and licensing milestone payments, and to the volumes of product our licensees sell on the market from which we receive royalties and manufacturing revenues. Suboxone, which was launched in 2010, was our first licensed pharmaceutical product to be commercialized, and we have other licensing relationships that contribute to our revenue and future revenue opportunities. Sympazan, which was launched in December 2018, is the first proprietary pharmaceutical product commercialized directly by the Company.

As of June 30, 2019, we had \$22,165 in cash and cash equivalents. As a result of net losses incurred in the operations of the Company during the first six months of 2019, we had a net shareholders' deficit of \$24,657. We incurred net losses of \$20,472 and \$36,493 for the three months ended June 30, 2019 and 2018, respectively. For the six months ended June 30, 2019 and 2018, we incurred net losses of \$35,198 and \$32,394, respectively. Our working capital, inclusive of cash and cash equivalents, at June 30, 2019 was \$14,435.

Table of Contents

We expect to continue to incur net losses and negative operating cash flow for the foreseeable future as we pursue the development, commercialization and marketing of our proprietary product candidates. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on our research and development activities, as well as our commercialization activities. Our expenses may fluctuate substantially over time as we:

- fund commercialization investments for Sympazan (launched in December 2018) and, subject to FDA approval, Libervant, our epilepsy products;
- continue clinical development of our complex molecules, AQST-108 and AQST-305;
- identify and evaluate new pipeline candidates in CNS diseases and other indications; and
- fund working capital requirements and expected capital expenditures as a result of the launch of proprietary products and related growth.

Our business has been financed through a combination of revenue from licensed product activities, proceeds from our IPO, equity investments from our stockholders and debt proceeds from our credit facilities and issuance of our Senior Secured Notes. Our new 12.5% Senior Secured Notes due 2025 and unregistered Warrants issued on July 15, 2019, are discussed in Note 18, Subsequent Event, to our Consolidated Financial Statements and in Liquidity and Capital Resources. The Warrants include an obligation of the Company to use reasonable best efforts to register the Warrant Shares for resale with the Securities and Exchange Commission within 90 days of the closing and grant customary piggy-back rights to Warrant holders. As a result of the requirement to register the shares, we will register the warrants and affiliate shares as part of our Universal Shelf Registration that we expect to file later in the third quarter of 2019. The Shelf Registration Statement provides increased capital flexibility as we continue to execute our business plan. We do not at this time have any current plans to access the equity capital markets.

Aquestive is subject to the same risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on a very limited number of products and services and dependence on a single customer for the substantial majority of our current revenues, expected incurrence of operating losses and negative operating cash flows for the foreseeable future, reliance on future uncommitted funding sources, which cannot be assured, to satisfy short-term and longer term liquidity and cash requirements, reliance on a single manufacturing site, new technological innovations, dependence on key personnel, reliance on third-party service providers and sole source suppliers, protection of proprietary technology, compliance with government regulations, dependency on the clinical and commercial success of our drug candidates, ability to obtain regulatory approval of our drug candidates, including Libervant, uncertainty of broad adoption of the recently-launched Sympazan or other approved products, if any, by payers, physicians, and consumers, significant competition, untested manufacturing capabilities and risks related to cybersecurity.

Critical Accounting Policies and Use of Estimates

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

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other things, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we expect to comply with new or revised accounting standards no later than on the relevant dates on which adoption of such standards is required for emerging growth companies.

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

We are also a “smaller reporting company,” meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a “smaller reporting company,” and have either: (i) a public float of less than \$250 million or (ii) annual revenues of less than \$100 million during the most recently completed fiscal year and (A) no public float or (B) a public float of less than \$700 million. As a “smaller reporting company,” we are subject to reduced disclosure obligations in our SEC filings, including with respect to executive compensation in our periodic reports and proxy statements and certain reduced financial disclosures in our periodic reports.

Financial Operations Overview

Revenues

Our revenues to date have been earned from our commercialized partnered products, licensing and royalty initiatives, development initiatives for third parties and sales of self-developed medicines. These activities generate revenues in four primary categories: manufacturing and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

Manufacture and Supply Revenue

Currently, we produce two licensed pharmaceutical products: Suboxone and Zuplenz. We are the exclusive manufacturer for these products. We manufacture based on receipt of purchase orders from our licensees, and our licensees have an obligation to accept these filled orders once quality assurance validates the quality of the manufactured product. Under ASC 606, we record revenues once the manufactured product passes quality control. Our licensees are responsible for all other aspects of commercialization of these products and the Company has no role in or ability to participate in commercialization including marketing, pricing, sales and regulatory strategy.

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

Co-development and Research Fees

We work with our licensees to co-develop pharmaceutical products. In this regard, we earn fees through performance of specific tasks, activities, or completion of stages of development defined within a contractual arrangement with the relevant licensee. The nature and extent of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product.

License and Royalty Revenue

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

Proprietary Product Sales

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

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

[Table of Contents](#)

Prompt Pay Discounts

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

Wholesaler Service Fees

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

Returns Allowances

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

Rebates

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

Co-Pay Cards

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

Costs and Expenses

Our costs and expenses are primarily the result of the following activities: generation of manufacture and supply revenues; development of our pipeline of proprietary product candidates; and selling, general and administrative expenses, including pre-launch and post-launch commercialization efforts related to our CNS product candidates, intellectual property procurement, protection, prosecution and litigation expenses, corporate management functions, public company costs, share-based compensation expenses and interest on our corporate borrowings. We primarily record our costs and expenses in the following categories:

Manufacture and Supply Costs and Expenses

Manufacture and supply costs and expenses are comprised primarily of costs and expenses related to manufacturing our proprietary dissolving film products for our marketed licensed pharmaceutical products and for our newly approved proprietary products including raw materials, direct labor and fixed overhead principally in our Portage, Indiana facilities. In 2019, we expect the costs of our proprietary products manufactured to be a greater factor in these expenses, but such costs were minimal in 2018. Our material costs include the costs of raw materials, other than the API component of Suboxone, used in the production of our proprietary dissolving film and primary packaging materials. Direct labor costs consist of payroll costs (including taxes and benefits) of employees engaged in production activities. Fixed and semi-fixed overhead principally consists of indirect payroll, facilities rent, utilities and depreciation for leasehold improvements and production machinery and equipment.

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

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

[Table of Contents](#)

Research and Development Expenses

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

- employee-related expenses;
- external research and development expenses incurred under arrangements with third parties;
- the cost of acquiring, developing and manufacturing clinical study materials; and
- costs associated with preclinical and clinical activities and regulatory operations.

We expect our research and development expenses to increase over the next several years as we expand our efforts to identify and develop or acquire additional product candidates and technologies. We may hire additional skilled colleagues to perform these activities, conduct clinical trials and ultimately seek regulatory approvals for any product candidate that successfully completes those clinical trials.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits, share-based compensation, commercialization and marketing costs, and other related costs for executive, finance, selling and operational personnel. Other significant costs include facility and related costs not otherwise included in research and development expenses such as: professional fees for legal, consulting, tax and accounting services; insurance; selling; market research; advisory board and key opinion leaders; depreciation; unabsorbed factory overhead costs and general corporate expenses, inclusive of IT systems related costs.

Historically, our selling, general and administrative expenses have been focused primarily on corporate management functions along with unabsorbed factory overhead costs. However, costs related to commercialization of our CNS product candidates began in the second half of 2017 and significantly increased in 2018 as we progressed toward the launch of Sympazan in December 2018, and began initial preparations for the launch of Libervant, an additional late-stage epilepsy product currently subject to FDA approval. These costs are expected to increase in 2019, with a full year effect of Sympazan's commercialization. Incremental marketing spending in preparation for the commercial launch of Libervant is expected to be incurred prior to the PDUFA date for this product and will be accordingly planned once the PDUFA date is known. As part of the commercial launch of Sympazan, we entered into contractual arrangements with a third-party logistics provider (3PL) and wholesalers for distribution of our products. We also entered into a contract for our contracted sales force and medical affairs team and have established a market access account team. With this increased activity related to the commercial launch of Sympazan, our sales and marketing expenses have increased and are expected to continue to increase in subsequent periods as we continue to support our epilepsy franchise. We expect to be able to significantly leverage these now existing relationships for the future launch, subject to FDA approval, of Libervant. Our general and administrative costs increased as a result of becoming a public company, including costs related to additional personnel and accounting, audit, legal, regulatory, tax-related services, and other public company costs. In addition, in order to better align our selling, general and administrative expenses with expected revenue, during the second quarter we reviewed and began initiatives to reduce certain expenses in non-core functions, and we will continue to review and assess our selling, general and administrative expenses relative to planned revenues going forward.

Interest Expense

Interest expense consists of interest costs related to our debt facility, as well as amortization of loan costs and debt discount. Our interest, which under our Perceptive credit facility was subject to changes in one-month LIBOR, represents a monthly cash payment obligation. Our new 12.5% Senior Secured Notes due 2025 issued on July 15, 2019 are discussed in Note 18, Subsequent Event, to our Consolidated Financial Statements and in Liquidity and Capital Resources. Interest expense is expected to increase based on additional borrowings under such new Notes.

Interest Income

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

Change in Fair Value of Warrant

Changes in the fair value of warrants resulted from non-cash periodic revaluations of the warrants issued to Perceptive Credit Opportunities Fund in connection with the debt facility. Effective with the automatic exercise of the warrants by Perceptive prior to our IPO in July 2018, these warrants are no longer outstanding and no future related charges to earnings will be incurred. Warrants issued in conjunction with the Notes issued on July 15, 2019 will be valued at market, and revaluations will impact future periods related to the new Warrants.

For information concerning the Warrants issued in connection with our 12.5% Senior Secured Notes due 2025, see Note 18, Subsequent Event, to our Consolidated Financial Statements.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

We recorded revenue of \$11,129 and \$13,928 in the three months ended June 30, 2019 and 2018, respectively, generating a net loss of \$20,472 and \$36,493 for the three months ended June 30, 2019 and 2018, respectively.

Revenues:

<i>(In thousands, except %)</i>	Three Months Ended June 30,		Change	
	2019	2018	\$	%
Manufacture and supply revenue	\$ 8,915	\$ 8,684	\$ 231	3%
License and royalty revenue	424	4,532	(4,108)	(91%)
Co-development and research fees	1,019	712	307	43%
Proprietary product sales, net	771	-	771	100%
Total revenues	\$ 11,129	\$ 13,928	\$ (2,799)	(20%)

For the three months ended June 30, 2019, total revenues decreased 20% or \$2,799 to \$11,129 compared to revenues of \$13,928 for the same period in 2018. The change is primarily attributable to differences in license and royalty revenue that by nature are variable as to timing and magnitude. Additionally, under the Indivior Supplemental Agreement license fees are currently suspended following the “at risk” launches of several generic buprenorphine/naloxone products into the Suboxone market. These fees are recoverable in the future under certain conditions. These are offset in part by increases in manufacture and supply revenue, co-development and research fees and proprietary product sales revenue from Sympazan, launched in December 2018.

Manufacture and supply revenue increased approximately 3% or \$231 to \$8,915 for the three months ended June 30, 2019 compared to \$8,684 from the prior year period. This increase is attributable to slightly higher Suboxone product mix of higher margin dose configurations offset in part by 1.8 million fewer strips sold period over period. As of the early part of third quarter 2019, Suboxone and its authorized generic maintained a greater than 75% share in the market. While it is uncertain to predict the generic erosion effect on our Suboxone product volumes in future periods, the market for Suboxone product, including generic competitor products, continues to grow and we will continue to closely monitor these dynamics in the marketplace.

License and royalty revenue decreased 91% or \$4,108 to \$424 for the three months ended June 30, 2019 compared to revenues of \$4,532 from the prior year period. This change was primarily related to the license and new patent fees on our licensed product Suboxone. License fees totaled \$0 for the three months ended June 30, 2019 compared to \$4,250 of license fees recognized during the prior year period. Suboxone related license fees were \$4,250 lower compared to 2018, as a result of the fact that certain license fees due from Indivior have been suspended pending the outcome of litigation related to infringement claims against the generic products launched “at risk.” Royalty revenues earned on Suboxone and Zuplenz were flat year-over-year on similar product sales volumes flowing through our licensees’ sales and distribution channels. License fees are generally driven by transfer of rights, patent performance contingencies, specific FDA or other regulatory achievements, sales levels achievements or other contingencies and milestones, and will likely fluctuate significantly from quarter-to-quarter.

Co-development and research fees increased 43% or \$307 to \$1,019 for the three months ended June 30, 2019 compared to \$712 from the prior year period. The increase was driven by the timing of the achievement of research and development performance obligations on licensed products and related milestones and are normally expected to fluctuate significantly one reporting period to the next.

Product sales, net increased \$771 or 100% for the three months ended June 30, 2019 compared to the prior year period, due to the launch of our first proprietary self-developed medicine, Sympazan, in December 2018.

Expenses and Other:

	Three Months Ended		Change	
	June 30,			
(In thousands, except %)	2019	2018	\$	%
Manufacture and supply	\$ 5,420	\$ 4,973	\$ 447	9%
Research and development	8,151	7,994	157	2%
Selling, general and administrative	16,246	33,668	(17,422)	(52)%
Interest expense	1,937	1,927	10	1%
Interest income	(153)	-	153	NM
Other	-	1,859	(1,859)	NM

Manufacture and supply costs and expenses increased 9% or \$447 to \$5,420 for the three months ended June 30, 2019 compared to \$4,973 for the same period in 2018. This increase was primarily driven by lower volumes of Suboxone production and higher production costs associated with other products. Additionally, there was a \$110 increase in share-based compensation costs during the three months ended June 30, 2019 as compared to the same period in 2018. These increases were offset in part by \$345 in compensation cost associated with the issuance of the non-voting common shares and related withholding taxes allocated to manufacture and supply costs and expense during the three month period ended June 30, 2018 that did not occur during the three month period ended June 30, 2019.

Research and development expenses increased 2% or \$157 to \$8,151 for the three months ended June 30, 2019 compared to \$7,994 in the prior year period. This increase resulted from an increase of clinical trials expenses of \$1,625 along with added expenses of organizational growth that was substantially offset by a net reduction of share-based compensation expenses totaling \$2,053 that was primarily attributable to the one-time settlement in 2018 of the Company's obligations arising from its Performance Unit Plan. Clinical trial and other third party product development expenses may be expected to fluctuate based on the schedule of clinical and development activities that are conducted during any reporting period.

Selling, general and administrative expenses decreased 52% or \$17,422 to \$16,246 for the three months ended June 30, 2019 as compared to \$33,668 for the prior year period. This decrease is primarily due to \$24,767 in compensation cost associated with the issuance of the non-voting common shares and related withholding taxes allocable to selling, general and administrative expenses during the three month period ended June 30, 2018 that did not occur during the three month period ended June 30, 2019, offset in part by \$3,631 of investments in our commercialization, branding and marketing capabilities for Sympazan and in preparation for the expected launch of Libervant. These costs included those for personnel, external consultants and other resources that enabled us to establish key commercial functions such as sales and marketing, market access and medical affairs. We incurred \$535 of increased legal fees in connection with the ongoing state anti-trust litigation and other patent related matters, and \$1,589 of share-based compensation expense. Further, additional personnel and other external resources have been engaged to further assist us in operations as a public company.

Interest expense increased 1% or \$10 to \$1,937 for the three months ended June 30, 2019 compared to 1,927 for the same period in 2018. Our interest expense was subject to fluctuations based on one-month LIBOR. Our new Senior Secured Note due 2025 issued on July 15, 2019 carry a 12.5% fixed interest rate per annum.

Interest income increased 100% or \$153 for the three months ended June 30, 2019, compared to the prior year period. This increase is a result of investing the net cash proceeds from our IPO in an interest-bearing account.

Change in the fair value of warrants decreased by \$1,859 for the three months ended June 30, 2019 compared to the same period in 2018. For periods prior to our IPO, which was effective July 24, 2018, we remeasured the fair value of outstanding warrants each quarter in accordance with the AICPA Practice Aid, Valuation of Privately-Held Company Equity Securities issued as compensation. The Company had no outstanding warrants during the three months ended June 30, 2019. However, for information concerning the warrants issued in connection with our 12.5% Senior Secured Notes due 2025, issued on July 18, 2019, see Note 18, Subsequent Event, to our Consolidated Financial Statements.

Comparison of the Six Months Ended June 30, 2019 and 2018

We recorded revenue of \$23,772 and \$37,339 in the six months ended June 30, 2019 and 2018, respectively, generating a net loss of \$35,198 and \$32,394 for the six months ended June 30, 2019 and 2018, respectively.

Revenues:

	Six Months Ended June 30,		Change	
	2019	2018	\$	%
<i>(In thousands, except %)</i>				
Manufacture and supply revenue	\$ 15,584	\$ 20,244	\$ (4,660)	(23)%
License and royalty revenue	5,046	14,032	(8,986)	(64)%
Co-development and research fees	1,789	3,063	(1,274)	(42)%
Proprietary product sales, net	1,353	-	1,353	100%
Total revenues	<u>\$ 23,772</u>	<u>\$ 37,339</u>	<u>\$ (13,567)</u>	<u>(36)%</u>

For the six months ended June 30, 2019, total revenues decreased 36% or \$13,567 to \$23,772 compared to revenues of \$37,339 for the same period in 2018. The change is primarily attributable to decreases in manufacture and supply revenue, license and royalty revenue, and in co-development and research fees, offset in part by an increase in proprietary product sales revenue for Sympazan, launched in December 2018.

Manufacture and supply revenue decreased approximately 23% or \$4,660 to \$15,584 for the six months ended June 30, 2019 compared to \$20,244 from the prior year period. This decrease is attributable to lower Suboxone production volume. As of the early part of third quarter 2019, Suboxone and its authorized generic maintained a greater than 75% market share. While it is uncertain to predict the generic erosion effect on our Suboxone product volumes in future periods, the market for Suboxone product, including generic competitor products, continues to grow and we will continue to closely monitor these dynamics in the marketplace.

License and royalty revenue decreased 64% or \$8,986 to \$5,046 for the six months ended June 30, 2019 compared to revenues of \$14,032 from the prior year period. This change was primarily related to the license and new patent fees on our licensed product Suboxone. License fees totaled \$4,250 for the six months ended June 30, 2019 compared to \$13,500 of license fees recognized during the prior year period. Suboxone related license fees were \$9,250 lower compared to 2018, as a result of two factors: the uneven timing and magnitude of the various payments owed to the Company by Indivior and the fact that certain license fees due from Indivior have been suspended pending the outcome of litigation related to infringement claims against the generic products launched “at risk.” Milestones from other licensed products such as Sunovion’s APL-130277 product are likely to be earned after 2019 based on the timing of the expected PDUFA date for that product. Royalty revenues earned on Suboxone and Zuplenz remained flat year-over-year on similar product sales volumes flowing through our licensees’ sales and distribution channels. License fees are generally driven by transfer of rights, patent performance contingencies, specific FDA or other regulatory achievements, sales levels achievements or other contingencies and milestones, and will likely fluctuate significantly from quarter-to-quarter.

Co-development and research fees decreased 42% or \$1,274 to \$1,789 for the six months ended June 30, 2019 compared to \$3,063 from the prior year period. The decrease was driven by the timing of the achievement of research and development performance obligations on licensed products and related milestones, both of which are normally expected to fluctuate significantly one reporting period to the next.

Product sales, net increased \$1,353 or 100% for the six months ended June 30, 2019 compared to the prior year period, due to the launch of our first proprietary self-developed medicine, Sympazan, in December 2018.

Expenses and Other:

	Six Months Ended June 30,		Change	
	2019	2018	\$	%
<i>(In thousands, except %)</i>				
Manufacture and supply	\$ 8,926	\$ 10,609	\$ (1,683)	(16)%
Research and development	12,454	12,895	(441)	(3)%
Selling, general and administrative	34,154	41,213	(7,059)	(17)%
Interest expense	3,863	3,876	(13)	0%
Interest income	(427)	(22)	405	NM
Other	-	1,162	(1,162)	NM

Manufacture and supply costs and expenses decreased 16% or \$1,683 to \$8,926 for the six months ended June 30, 2019 compared to \$10,609 for the same period in 2018. This decrease was primarily driven by lower production costs due to the lower volume of Suboxone. Further, there was a \$110 increase in share-based compensation expenses offset by \$345 in compensation cost associated with the issuance of the non-voting common shares and related withholding taxes allocated to manufacturing and supply costs and expenses during the six month period ended June 30, 2018 that did not occur during the six month period ended June 30, 2019.

Research and development expenses decreased 3% or \$441 to \$12,454 for the six months ended June 30, 2019 compared to \$12,895 in the prior year period. This net expense reduction was the result of a net decrease of share-based compensation expenses of \$1,845 due primarily to the one-time settlement in 2018 of the Company’s obligations arising from its Performance Unit Plan, partially offset by \$1,404 of expenses arising primarily from organizational growth. Third party clinical expenses and other direct project development expenses remained stable during the two periods. Clinical trial and other third party direct product development expenses may be expected to fluctuate based on the schedule of clinical and development activities that are conducted during and reporting period.

[Table of Contents](#)

Selling, general and administrative expenses decreased 17% or \$7,059 to \$34,154 for the six months ended June 30, 2019 as compared to \$41,213 for the prior year period. This decrease is primarily due to \$24,767 in compensation cost associated with the issuance of the non-voting common shares and related withholding taxes allocable to selling, general and administrative expenses offset in part by \$7,692 of higher investments in our commercialization, branding and marketing capabilities for Sympazan and in preparation for the expected launch of Libervant. These costs included those for personnel, external consultants and other resources that enabled us to establish key commercial functions such as sales and marketing, market access and medical affairs. We incurred \$1,885 of increased legal fees in connection with the ongoing state anti-trust litigation and other patent related matters, \$2,377 of higher factory unabsorbed overhead as a result of lower production of Suboxone period over period and \$2,857 of share-based compensation expense. Further, additional personnel and other external resources have been engaged to further assist us in operations as a public company and higher factory unabsorbed overhead as a result of lower production of Suboxone period over period.

Interest expense remained flat for the six months ended June 30, 2019 compared to the same period in 2018. Our interest expense was subject to fluctuations based on one-month LIBOR. Our new Senior Secured Note due 2025 issued on July 15, 2019 carry a 12.5% fixed interest rate per annum.

Interest income increased \$405 for the six months ended June 30, 2019 compared to the same period in 2018, as a result of investing the net cash proceeds from our IPO in an interest-bearing account.

Change in the fair value of warrants decreased by \$1,162 for the six months ended June 30, 2019 compared to the same period in 2018. For periods prior to our IPO, which was effective July 24, 2018, we remeasured the fair value of outstanding warrants each quarter in accordance with the AICPA Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation. The Company had no outstanding warrants during the six months ended June 30, 2019. However, for information concerning the warrants issued in connection with our 12.5% Senior Secured Notes due 2025, issued on July 18, 2019, see Note 18, Subsequent Event, to our Consolidated Financial Statements.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and expect to incur significant operating losses and negative operating cash flow for the foreseeable future and as of June 30, 2019, we have a net stockholders' deficit of \$24,657. We have funded our operations primarily with equity and debt financings and manufacture and supply revenue as well as milestone and royalty payments from our licensees.

We had \$22,165 in cash and cash equivalents as of June 30, 2019 and working capital, including cash and cash equivalents, of \$14,435.

Credit Agreement and Guaranty

On August 16, 2016, we entered into a Credit Agreement and Guarantee with Perceptive Credit Opportunities Fund, LP, which we amended on May 21, 2018, or, as so amended, the Loan Agreement. At closing, we borrowed \$45,000 under the Loan Agreement and were permitted to borrow up to an additional \$5,000 within one year of the closing date based on achievement of a defined milestone. In March 2017, we met our performance obligations under the terms of the Loan Agreement and received the remaining \$5,000 available to us under the Loan Agreement. The loan bore interest, payable monthly, at one-month LIBOR, which at June 30, 2019 was approximately 2.75%, plus 9.75%, subject to a minimum rate of 11.75%. The loan was interest-only through April 2019, as amended. The final payments under this agreement were due December 15, 2020, and repayment began on May 31, 2019. However, the agreement and related security interests were terminated with the payoff that occurred on July 15, 2019.

As of June 30, 2019, we were compliant with all financial and other covenants under the Perceptive Loan Agreement.

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

12.5% Senior Secured Notes

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

The net proceeds from the Notes is \$66,951, after deducting the estimated expenses of the transaction. We used a portion of the net proceeds to repay an aggregate amount of approximately \$52,092, comprised of the full principal amount, all accrued and unpaid interest and applicable prepayment and end-of-term fees, owed to Perceptive under the Credit Agreement and Guaranty (described above). We will use the cash balance of approximately \$14,859 for the continued commercialization and advancement of its proprietary products and pipeline candidates, and other general corporate purposes.

The additional notes can be issued if the Company satisfies certain conditions and achieves milestones related to the filing and approval of its epilepsy product Libervant and there are available purchasers for the additional notes. Specifically, on or prior to March 31, 2021, the Company has the option to issue an additional \$10,000 aggregate principal amount of the Notes if the Company has filed a new drug application for its candidate Libervant with the FDA, provided it has obtained the written consent of the holders of a majority in aggregate principal amount of outstanding Notes (first reopener), and, on or prior to March 31, 2021, up to an additional \$30,000 (less the amount of any first additional notes issued by us) if the Company obtains approval from the FDA of its product candidate Libervant.

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

Under the agreement, the Company has the right to monetize its royalty and milestone interests in Sunovion's Apomorphine product APL-130277 once the NDA for such product is approved by the FDA. Upon any such monetization we shall offer to purchase each holder's Notes on a pro rata basis at a repurchase price in cash equal to 112.500% of the principal amount of such Notes, plus accrued interest and unpaid interest, if any, thereon to the repurchase date and such offer will be available to be exercised up to the date of the Libervant approval of the NDA by the FDA, unless exercised prior to that date. The maximum amount that can be offered for repurchase is \$40,000 or \$50,000 if the first reopener has been issued and funded. The amount of Notes repurchased will be at the discretion of the holders of the Notes.

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

Affirmative and negative covenants specified in the Indenture are considered typical for loans of this nature, including, but not limited to, specifications relating to preservation of corporate existence, publicly traded status, intellectual property and business interests; limitations or prohibitions of dividend payments or other dispositions, repurchases of shares, additional debt, certain equity issuances, asset transfers or dispositions, creation or occurrence of additional liens, entering into licensing or monetization arrangements other than as permitted under the Indenture, and perfection of security interests. Events of default include various commonly specified conditions, including but not limited to, bankruptcy, insolvency, material adverse changes, failure to meet Indenture payment or other obligations, compliance with regulatory requirements and preservation of the corporate existence and business operations of the Company.

In connection with the new financing, we agreed to issue to the new noteholders unregistered Warrants to purchase up to an aggregate of 2,000,000 shares of common stock at a price of \$4.25 per Warrant. The Warrants also contain customary change of control provisions and are exercisable on a "cashless" basis. The Warrants include an obligation for the Company to use reasonable best efforts to register the Warrant shares for resale with the Securities and Exchange Commission within 90 days of the closing and grant customary piggy-back rights to the holders of the Warrants.

Cash Flows

Six Months Ended June 30, 2019 and 2018

(In thousands)

	2019	2018
Net cash (used for) provided by operating activities	\$ (34,846)	\$ 1,296
Net cash (used for) investing activities	(486)	(886)
Net cash (used for) financing activities	(3,102)	(7,151)
Net decrease in cash and cash equivalents	\$ (38,434)	\$ (6,741)

Net Cash (Used for) Provided by Operating Activities

Net cash used for operating activities for the six months ended June 30, 2019 was \$34,846. The use of cash can be understood as represented by three main factors: (1) our net loss of \$35,198, (2) decrease in operating assets and liabilities of \$5,822, partially offset by (3) non-cash operating expenses. The non-cash operating expenses of \$6,174 primarily resulted from \$3,330 of share-based compensation expense recorded in the six months ended June 30, 2019. Other significant components included non-cash charges of \$2,844 related to depreciation, amortization and amortization of debt issuance costs.

Net cash provided by operating activities for the six months ended June 30, 2018 was \$1,296. The provision of cash can be understood as represented by three main factors: (1) non-cash operating expenses of \$31,204, which included \$27,305 related to the termination of the Company's performance unit plans and \$3,899 in non-cash charges such as depreciation, amortization, amortization of debt issuance costs and changes in warrant valuation, (2) changes in working capital accounts totaling \$2,486, primarily through collections of trade receivables and increases in trade payables as management sought to optimize our liquidity, offset in part by (3) our net loss of \$32,394.

Net Cash (Used for) Investing Activities

Net cash used for investing activities was \$486 for the six months ended June 30, 2019 compared to \$886 for the six months ended June 30, 2018. This decrease in net cash used for investing activities was primarily attributable to timing of capital expenditures for plant and equipment purchases.

Net Cash (Used for) Financing Activities

Net cash used for financing activities was \$3,102 for the six months ended June 30, 2019 compared to \$7,151 for the six months ended June 30, 2018. The cash used in 2019 is primarily the result of the payment of \$2,664 in withholding taxes associated with tax reimbursement payments from the share-based compensation recorded during 2018 and a \$550 principal payment made during May 2019 related to the Credit Agreement and Guaranty, offset in part by \$112 of proceeds derived from common stock purchased by eligible employees through the Company's employee stock purchase plan. Net cash used for financing activities in the prior year period was the result of \$1,528 transaction costs incurred related to our IPO and \$5,623 related to the payment of withholding taxes associated with the share-based compensation recorded during the quarter ended June 30, 2018.

Funding Requirements

We expect that our existing cash combined with our anticipated revenue from our licensed product activities, including expected milestone payments, other co-development payments and royalty payments, manufacturing and supply revenues at anticipated levels and anticipated sales of our proprietary product, and the net proceeds from the issuance of our 12.5% Senior Secured Notes due 2025 issued on July 15, 2019 and, assuming satisfaction of all conditions and requirements for further senior secured notes issuances of additional senior secured notes, and available purchasers thereof, additional proceeds from future issuances of up to \$30,000 of additional Senior Secured Notes, and potential future monetization of certain royalty streams or other license rights such as apomorphine (subject to conditions and requirements under the indenture), will be adequate to fund our expected cash requirements for at least the next 12 months, including investments in the commercialization of our late stage CNS product candidates and other expected costs and expenses, capital expenditures and investments in new product candidates in epilepsy and other CNS diseases. We have based this expectation on assumptions that could change, or prove to be inaccurate, and we could utilize our available financial resources sooner than we currently expect.

The key assumptions underlying this expectation include:

- continued revenue from our proprietary and licensed products at planned levels;
- cost and expense reductions consistent with our anticipated revenues, and continuing review of our cost structure;
- our ability to issue on or before March 31, 2021, and available purchasers of, additional senior secured notes in an aggregate amount up to \$30,000 principal amount under the indenture for our 12.5% Senior Secured Notes due 2025, based on satisfying certain conditions including approval of our Libervant proprietary product, and approval of the first reopener by a majority of the holders of the Senior Secured Notes, (see "12.5% Senior Secured Notes" above);
- potential monetization of royalty streams or other license or proprietary rights for our product Apomorphine at anticipated levels, which cannot be assured (and which are subject to conditions and requirements under the indenture for our new 12.5% Senior Secured Notes including note repurchase obligations at 112.500% of principal amount of such repurchased notes and accrued and unpaid interest thereon, at the option of the holders) (see "12.5% Senior Secured Notes" above);

Table of Contents

- continued funding of our commercialization costs for Sympazan, our first proprietary product launched in December 2018, and continued funding of our development and commercialization of CNS product Libervant, and our other proprietary product candidates;
- the infrastructure and administrative costs to support being a public company;
- continued compliance with all covenants under our 12.5% Senior Secured Notes; and
- absence of significant unforeseen cash requirements.

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

Management will continue to monitor the Company's cash requirements and liquidity and, if management believes operating results, including expected revenue from manufacture and supply sales and proprietary sales, expected license and milestone revenues, available proceeds from any future issuances of additional Notes under the Indenture for our Senior Secured Notes and from any monetization of royalty streams or other license rights, reductions in cash spend, other available future debt or equity financing, or other potential available sources of liquidity, are not sufficient or available for existing or projected cash requirements, management will seek to take further steps intended to improve the Company's financial position and liquidity, such as by modifying our operating plan, seeking further to reduce costs and adjusting cash spend, and evaluating and pursuing other opportunities or alternatives to obtain additional liquidity.

On July 15, 2019 we issued \$70,000 aggregate principal amount of our 12.5% Senior Secured Notes due 2025 and related Warrants, resulting in approximately \$66,951 in note proceeds, after transaction expenses. In connection with the issuance of the Senior Secured Notes, we repaid approximately \$52,092 representing all amounts outstanding or due under our Perceptive debt facility. In addition, the indenture governing the senior secured notes provides opportunity to potentially issue in the future up to an aggregate of \$30,000 of additional Senior Secured Notes based on our satisfaction of certain conditions and requirements under the indenture and having available purchasers of such additional Senior Secured Notes. The Indenture permits us, upon the continuing satisfaction of certain conditions, including that we (on a consolidated basis) have at least \$75,000 of net revenues for the most recently completed twelve calendar month period, to enter into an asset-based borrowing facility not to exceed \$10,000 (the "ABL Facility"). The ABL Facility may be collateralized by assets constituting only inventory, accounts receivable and the proceeds of the Company. See "12.5% Senior Secured Notes" above.

In the future we may attempt to pursue additional capital financing if deemed appropriate or if needed for liquidity requirements, or when strategic opportunities might become available. Until we become profitable, if ever, we expect to continue to need to raise additional capital and/or incur debt in the future to further the commercialization of Sympazan and advance the development and commercialization of our CNS products including Libervant, and of our other product candidates and to meet our other cash requirements, including debt service. Our ability to secure additional financing could be significantly impacted by numerous factors including our operating performance and prospects, timely achievement of regulatory approval of our late-stage proprietary products, our existing level of debt which is secured by substantially all of our assets, and general market conditions, and there can be no assurance that such needed capital or debt financing will be available on favorable terms or at the times or in the amounts needed. We may seek to obtain additional funding in the future through the monetization of royalty streams from our product Apomorphine, subject to our licensing agreement with Sunovion Pharmaceuticals, Inc. (and subject to the conditions and requirements under the indenture for our 12.5% Senior Secured Notes due 2025 including our note repurchase obligations at the option of the holders), but we cannot be assured of any such royalty streams or monetization. We may also seek to obtain additional funding through the issuance of our common stock, and, subject to restrictions under the indenture for the Senior Secured Notes, other public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We may not be able to raise additional capital or financing on terms acceptable to us, or at all, and any failure to raise capital or financing as and when needed for our cash requirements would likely 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. To the extent that we raise additional funds through collaborative or licensing arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future liquidity and funding position.

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

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

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

Off-Balance Sheet Arrangements

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

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

Prior to July 15, 2019, our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest expense from fluctuations in one-month LIBOR associated with our debt facility. For each 1% increase in one-month LIBOR in excess of the floor of 2%, our annual interest expense would increase by approximately \$500,000. However, our new Senior Secured Notes due 2025 issued on July 15, 2019, carry a 12.5% fixed interest rate per annum, thereby eliminating market risk due to changes in interest rates. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes. We are in the process of developing a comprehensive investment strategy for our cash and cash equivalents whose underlying premise would be to preserve principal while at the same time maximizing the income that we received from our investments without significantly increasing risk.

Our accounts receivables are concentrated predominantly with Indivior. See Quarterly Report on Form 10-Q for the period ending June 30, 2019, Part III, Item 1A, Risk Factors concerning Indivior.

With our launch of Sympazan, in December 2018, our concentration with three large national wholesalers of pharmaceutical products is not significant presently but may become so in future periods should Sympazan sales increase and should other pipeline products become approved by the FDA and become distributed through these three national, or other, wholesalers. In the event of non-performance or non-payment by either Indivior or the wholesalers, there may be a material adverse impact on our financial condition, results of operations or net cash flow.

Item 4. *Controls and Procedures.*

Evaluation of Disclosure Controls and Procedures

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

As required by Rule 13a-15(b) of the Exchange Act, an evaluation as of June 30, 2019 was conducted under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures, as of June 30, 2019, were effective for the purposes stated above.

Internal Control Over Financial Reporting

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

Inherent Limitation on Effectiveness of Controls

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we have been and may again become involved in legal proceedings arising in the course of our business.

Patent-Related Litigation

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

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

- *Mylan* and *Sandoz* settled without a trial. Sandoz withdrew all challenges and became the distributor of the authorized generic.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement between us, Indivior, and Par and certain of its affiliates.
- *Actavis* was found to infringe the ‘514 patent and cannot enter the market until the expiration of the patent in 2024, and the Federal Circuit affirmed that ruling on July 12, 2019.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the Federal Circuit affirmed that ruling on July 12, 2019. *Teva* has agreed to be bound by all DRL adjudications.

Subsequent to the above, all potential generic competitors without a settlement agreement were also sued for infringement of two additional new patents that contain new claims not adjudicated in the original case against DRL and Alvogen. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The case(s) regarding the additional asserted patents have not been finally resolved. The case against Actavis, pending in the U.S. District Court for the District of Delaware, is scheduled for trial in December 2019. No trial date has been set in the cases against DRL and Alvogen, which are pending in the U.S. District Court for the District of New Jersey. On February 19, 2019, the Federal Circuit issued its mandate reversing the District of New Jersey’s preliminary injunction against DRL. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both DRL and Alvogen. On February 19, 2019, Indivior launched the authorized generic of Suboxone Sublingual Film, which we manufacture exclusively for sale and marketing by Sandoz Inc., a sublicensee of Indivior. DRL, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by DRL and Alvogen are “at risk” because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, we and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. for infringement of the ’150, ’514, ’454, and ’305 patents, seeking an injunction and potential monetary damages. The case is pending in the Southern District of Florida, and the defendants filed their answers to the complaint, including counterclaims for non-infringement and invalidity of the asserted patents as well as two other patents that were not asserted in the original complaint.

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

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of invalidity and non-infringement of U.S. Patents Nos. 7,897,080, or the ’080 patent, 8,652,378, or the ’378 patent, and 8,475,832, or the ’832 patent. This case is stayed pending final resolution of the above-mentioned appeals on related patents.
- The second was filed by us and Indivior related to BDSI’s infringing Bunavail product, and alleges infringement of our patent, U.S. Patent No. 8,765,167, or the ’167 patent, and seeks an injunction and potential monetary damages. Shortly after the case was filed, BDSI filed four IPRs challenging the asserted ’167 patent. On March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding that all claims of the ’167 patent were valid. The case was stayed in May 2016 pending the final determination of the appeals on those decisions. Following the PTAB’s February 7, 2019 decisions on remand denying institution, we and Indivior submitted a notice to the Court on February 15, 2019 notifying the Court that the stay should be lifted as a result of the PTAB’s decisions. We are awaiting further action from the Court.

[Table of Contents](#)

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

Antitrust Litigation

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of federal and state antitrust statutes and state unfair trade and consumer protection laws relating to Indivior's launch of Suboxone Sublingual Film in 2010 and seeking an injunction, civil penalties, and disgorgement. After filing, the case was consolidated for pre-trial purposes with the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we participated in an antitrust conspiracy with Indivior in connection with Indivior's launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. We moved to dismiss the States' conspiracy claims, but by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States' claims on November 20, 2017. The fact discovery period closed on July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions are being conducted through August 1, 2019. Summary judgement motions and *Daubert* motions relating to expert witnesses are due on September 26, 2019. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimates, of the possible outcome or loss, if any, in this matter.

Item 1A. Risk Factors

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

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

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

In April 2019 the U.S. Department of Justice announced that a federal grand jury sitting in the Western District of Virginia had criminally indicted Indivior, for which we exclusively manufacture and supply Suboxone film products and license certain of our intellectual property, in connection with Indivior's allegedly deceptive and misleading marketing and distribution practices in its distribution and sale of Suboxone film products, dating back a number of years, and seeking a monetary judgement of not less than \$3 billion. Indivior has denied the claims and stated that it intends to contest the allegations vigorously. Indivior accounted for approximately 89% of our revenues for 2018 and in the future will continue to account for a substantial part of our revenues. However, there can be no assurance that the claims against Indivior could not materially and adversely affect Indivior which, if this were to occur, could impact our supply and licensing relationship with Indivior and the volume and timing of its purchases from us, which could have a material adverse financial impact on our business, liquidity and operating results. On July 11, 2019, Reckitt Benckiser Group plc, the predecessor in interest of Indivior, reached agreements with the U.S. Department of Justice and the Federal Trade Commission (FTC) to resolve their investigation into the sales and marketing of Suboxone Film by its former prescription pharmaceuticals business, now Indivior, a business that was wholly demerged from Reckitt Benckiser in 2014. Reckitt Benckiser will pay a total of up to \$1.4 billion to fully resolve all federal investigations. As of this filing, Indivior has provided no indication that it has settled this matter with the DOJ.

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

None.

Use of Proceeds

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

Number	Description
4.1	Indenture Dated as of July 15, 2019, among Aquestive Therapeutics, Inc, as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent, (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. on July 16, 2019).
4.2	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. in July 16, 2019).
10.1	Form of Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. in July 16, 2019).
10.2	Collateral Agreement dated as of July 15, 2019, among Aquestive Therapeutics, Inc., as Issuer, the Other Grantors for time to time party thereto, U.S. Bank National Association, as Trustee, and U.S. Bank National Association, as Collateral Agent (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by Aquestive Therapeutics, Inc. on July 16, 2019).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document.
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the County of Somerset, State of New Jersey.

Aquestive Therapeutics, Inc.
(REGISTRANT)

Date: August 6, 2019

/s/ Keith J. Kendall

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

Date: August 6, 2019

/s/ John T. Maxwell

John T. Maxwell
Chief Financial Officer
(Principal Financial Officer)

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

I, Keith J. Kendall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aquestive Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, consolidated results of operations and consolidated cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 6, 2019

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

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

I, John T. Maxwell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aquestive Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, consolidated results of operations and consolidated cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 6, 2019

/s/ JOHN T. MAXWELL
John T. Maxwell
Chief Financial Officer
(Principal Financial Officer)

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Keith J. Kendall, chief executive officer of Aquestive Therapeutics, Inc., (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Dated: August 6, 2019

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

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aquestive Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, John T. Maxwell, chief financial officer of Aquestive Therapeutics, Inc., (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Dated: August 6, 2019

/s/ JOHN T. MAXWELL

John T. Maxwell
Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aquestive Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.
