

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

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended September 30, 2020**

**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 November 2, 2020 was 33,619,796.

**AQUESTIVE THERAPEUTICS, INC.**  
**QUARTERLY REPORT ON FORM 10-Q**  
**FOR THE QUARTER ENDED SEPTEMBER 30, 2020**  
**TABLE OF CONTENTS**

	<u>Page No.</u>
<b>PART I – FINANCIAL INFORMATION</b>	
Item 1. <a href="#">Financial Statements (Unaudited)</a>	
<a href="#">Condensed Consolidated Balance Sheets as of September 30, 2020 and December 31, 2019</a>	3
<a href="#">Condensed Consolidated Statements of Operations and Comprehensive Loss for the three- and nine-month periods ended September 30, 2020 and 2019</a>	4
<a href="#">Condensed Consolidated Statements of Changes in Stockholders’ Deficit for the three- and nine-month periods ended September 30, 2020 and 2019</a>	5
<a href="#">Condensed Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2020 and 2019</a>	6
<a href="#">Notes to Unaudited Condensed Consolidated Financial Statements</a>	7
Item 2. <a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	25
Item 3. <a href="#">Quantitative and Qualitative Disclosures about Market Risk</a>	41
Item 4. <a href="#">Controls and Procedures</a>	42
<b>PART II – OTHER INFORMATION</b>	
Item 1. <a href="#">Legal Proceedings</a>	42
Item 1A. <a href="#">Risk Factors</a>	45
Item 2. <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	46
Item 3. <a href="#">Defaults Upon Senior Securities</a>	46
Item 4. <a href="#">Mine Safety Disclosures</a>	46
Item 5. <a href="#">Other Information</a>	46
Item 6. <a href="#">Exhibits</a>	47
<a href="#">SIGNATURES</a>	48

**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>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 17,064	\$ 49,326
Trade and other receivables, net	7,990	13,130
Inventories, net	3,242	2,859
Prepaid expenses and other current assets	3,388	2,999
Total current assets	31,684	68,314
Property and equipment, net	7,728	9,726
Right-of-use assets, net	3,609	—
Intangible assets, net and other assets	7,402	439
Total assets	\$ 50,423	\$ 78,479
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 15,237	\$ 17,749
Lease liabilities, current	664	—
Loans payable, current	1,750	—
Deferred revenue, current	722	806
Total current liabilities	18,373	18,555
Loans payable, net	60,346	60,338
Lease liabilities	3,047	—
Deferred revenue, net of current portion	3,694	4,348
Asset retirement obligations	1,482	1,360
Total liabilities	86,942	84,601
<b>Contingencies (note 18)</b>		
Stockholders' deficit:		
Common stock, \$.001 par value. Authorized 250,000,000 shares; 33,619,796 and 33,562,885 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	34	34
Additional paid-in capital	129,336	124,318
Accumulated deficit	(165,889)	(130,474)
Total stockholders' deficit	(36,519)	(6,122)
Total liabilities and stockholders' deficit	\$ 50,423	\$ 78,479

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)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Revenues	\$ 8,260	\$ 12,418	\$ 38,700	\$ 36,190
Costs and expenses:				
Manufacture and supply	2,978	4,643	10,176	13,569
Research and development	7,260	5,063	15,461	17,517
Selling, general and administrative	11,803	13,714	40,310	47,868
Total costs and expenses	<u>22,041</u>	<u>23,420</u>	<u>65,947</u>	<u>78,954</u>
Loss from operations	(13,781)	(11,002)	(27,247)	(42,764)
Other income/(expenses):				
Interest expense	(2,778)	(2,652)	(8,296)	(6,515)
Interest income	8	138	128	565
Loss on extinguishment of debt	-	(4,896)	-	(4,896)
Net loss before income taxes	<u>(16,551)</u>	<u>(18,412)</u>	<u>(35,415)</u>	<u>(53,610)</u>
Income taxes	-	-	-	-
Net loss	<u>\$ (16,551)</u>	<u>\$ (18,412)</u>	<u>\$ (35,415)</u>	<u>\$ (53,610)</u>
Comprehensive loss	<u>\$ (16,551)</u>	<u>\$ (18,412)</u>	<u>\$ (35,415)</u>	<u>\$ (53,610)</u>
Net loss per share - basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.74)</u>	<u>\$ (1.05)</u>	<u>\$ (2.15)</u>
Weighted-average number of common shares outstanding - basic and diluted	<u>33,619,379</u>	<u>25,031,478</u>	<u>33,592,846</u>	<u>24,992,229</u>

See accompanying notes to the condensed consolidated financial statements.

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

	<u>Common Stock</u>		<u>Additional</u>		<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>		<u>Deficit</u>	<u>Stockholders'</u>
			<u>Capital</u>			<u>Equity/Deficit</u>
<b>For the periods ended September 30, 2020:</b>						
Balance at January 1, 2020	33,562,885	\$ 34	\$ 124,318		\$ (130,474)	\$ (6,122)
Share-based compensation	19,811	-	1,823		-	1,823
Net loss	-	-	-		(16,530)	(16,530)
Balance at March 31, 2020	33,582,696	34	126,141		(147,004)	(20,829)
Shares issued under employee stock purchase plan	14,961	-	73		-	73
Share-based compensation	18,944	-	1,702		-	1,702
Net loss	-	-	-		(2,334)	(2,334)
Balance at June 30, 2020	33,616,601	34	127,916		(149,338)	(21,388)
Share-based compensation	3,195	-	1,420		-	1,420
Net loss	-	-	-		(16,551)	(16,551)
Balance at September 30, 2020	<u>33,619,796</u>	<u>\$ 34</u>	<u>\$ 129,336</u>		<u>\$ (165,889)</u>	<u>\$ (36,519)</u>
<b>For the periods ended September 30, 2019:</b>						
Balance at January 1, 2019	24,957,309	\$ 25	\$ 71,431		\$ (61,376)	\$ 10,080
Adoption of ASU 2014-09, ASU 2018-07 (Note 3C)	-	-	20		(2,852)	(2,832)
Share-based compensation	17,830	-	1,422		-	1,422
Net loss	-	-	-		(14,726)	(14,726)
Balance at March 31, 2019	24,975,139	25	72,873		(78,954)	(6,056)
Shares issued under employee stock purchase plan	31,393	-	132		-	132
Share-based compensation	16,128	-	1,739		-	1,739
Net loss	-	-	-		(20,472)	(20,472)
Balance at June 30, 2019	25,022,660	25	74,744		(99,426)	(24,657)
Share-based compensation	20,304	-	1,810		-	1,810
Fair value of warrants issued	-	-	6,800		-	6,800
Net loss	-	-	-		(18,412)	(18,412)
Balance at September 30, 2019	<u>25,042,964</u>	<u>\$ 25</u>	<u>\$ 83,354</u>		<u>\$ (117,838)</u>	<u>\$ (34,459)</u>

See accompanying notes to the condensed consolidated financial statements.

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

	<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>
Cash flows used for operating activities:		
Net loss	\$ (35,415)	\$ (53,610)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	2,337	2,288
Share-based compensation	5,052	5,199
Amortization of debt issuance costs and discounts	1,758	1,338
Loss on extinguishment of debt	-	4,896
All other non-cash expenses	34	76
Changes in operating assets and liabilities:		
Trade and other receivables	5,082	(3,887)
Inventories, net	(383)	1,317
Prepaid expenses and other assets	(7,101)	(1,029)
Accounts payable and accrued expenses	(2,573)	(5,632)
Deferred revenue	(738)	(591)
Net cash used for operating activities	<u>(31,947)</u>	<u>(49,635)</u>
Cash flows used for investing activities:		
Capital expenditures	(281)	(577)
Net cash used for investing activities	<u>(281)</u>	<u>(577)</u>
Cash flows used for financing activities:		
Proceeds from shares issued under employee stock purchase plan	62	112
Proceeds from issuance of long-term debt	-	70,000
Debt repayment	-	(50,000)
Payments for loan acquisition costs	-	(3,918)
Premium paid to retire debt	-	(2,944)
Payments for taxes on share-based compensation	(96)	(2,723)
Net cash (used for)/provided by financing activities	<u>(34)</u>	<u>10,527</u>
Net decrease in cash and cash equivalents	(32,262)	(39,685)
Cash and cash equivalents:		
Beginning of period	49,326	60,599
End of period	<u>\$ 17,064</u>	<u>\$ 20,914</u>
Supplemental disclosures of cash flow information:		
Cash payments for interest	\$ 6,562	\$ 5,153
Net decrease in capital expenditures included in accounts payable and accrued expenses	(152)	(290)
Net increase in offering costs included in accounts payable and accrued expenses	237	162
Warrants issued in connection with long-term debt	-	6,800

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 pharmaceutical company focused on identifying, developing and commercializing differentiated products that address patients’ unmet medical needs and solve therapeutic problems. The Company has commercialized one internally-developed proprietary product to date, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules as alternatives to more invasive therapies. Aquestive is pursuing its business objectives through both in-licensing and out-licensing arrangements, as well as the commercialization of its own products. Production facilities are in Portage, Indiana, and corporate headquarters, sales and commercialization operations and primary research laboratory facilities are based in Warren, New Jersey.

Aquestive is subject to risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on revenue from a limited number of products and customers, adequacy of existing and availability of additional operating and growth capital as and when required, uncertainty of regulatory approval for marketing its product candidates, reliance on a single manufacturing site, new technological innovations, dependence on key personnel, reliance on third-party service providers and sole source suppliers, dependence on patent-protected proprietary technology, ongoing government regulatory compliance requirements, dependence on the clinical and commercial success of its drug candidates, and uncertainty of broad adoption of its approved products, if any, by physicians and consumers. Aquestive is also subject to risks and uncertainties associated with the COVID-19 pandemic. See Note 4. Risks and Uncertainties for further discussion related to COVID-19.

#### ***(B) Equity Transaction***

##### *Equity Offering of Common Stock*

On December 17, 2019, Aquestive received net proceeds of \$37,835 after deducting underwriting discounts of \$2,415 for the sale of 8,050,000 shares of common stock, par value \$0.001 per share of the Company (“common stock”) in a public offering. Professional fees and other costs of this offering totaled \$540, in addition to the underwriting discounts.

### **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, 2019 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 11, 2020 (the “2019 Annual Report on Form 10-K”). As included herein, the condensed consolidated balance sheet as of December 31, 2019 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 accompanying financial statements reflect certain reclassifications from previously issued financial statements to conform to the current presentation. 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 and Significant Accounting Policies***

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, drug development 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.

The Company's significant accounting policies are described in the audited consolidated financial statements included in the 2019 Annual Report on Form 10-K. Subsequent to the date of those financial statements, there have been no significant changes to these policies other than those listed below.

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

#### *Recently Adopted Accounting Pronouncements:*

In February 2016, the Financial Accounting Standards Board issued ASU, 2016-02, *Leases (Topic 842)*, and issued amendments in July 2018 provided by ASU 2018-10. This ASU, as amended, requires lessees to recognize lease assets, termed "right-of-use assets" and related lease liabilities on the balance sheet that had previously been classified as operating leases under prior authoritative guidance. For income statement purposes, leases are now required to be classified as either operating or financing leases under a dual model similar to that specified by ASC 840. Operating leases continue to result in straight-line expense while financing leases result in a front-loaded expense pattern in a manner similar to recognition of capital lease expenses under ASC 840.

The Company adopted and applied ASU 2016-02 on January 1, 2020 using the modified retrospective transition provisions of ASC 842 to leases in effect as of that date of adoption and recorded right-of-use assets totaling \$4,048 and lease liabilities as adjusted for accrued lease payments, in the amount of \$4,224 based on an estimated incremental borrowing rate of 16.9%, representing the present value of remaining minimum lease payments. The assets and liabilities thus recorded were primarily those related to the Company's leased plant, laboratory and corporate administrative facilities. The Company elected to apply the ASU-specified practical expedients and accordingly did not re-assess (i) whether its contracts contained a lease under the new definition of a lease, (ii) the classification of those leases, and (iii) initial direct costs of existing leases. In addition, the Company elected not to apply the hindsight expedient in the assessment of lease renewals and resultant term of leases. The Company also elected not to recognize a right-of-use asset and lease liability for those leases with a remaining lease term of 12 months or less. The adoption of ASU 2016-02 did not require a cumulative-effect adjustment to the opening balance of the accumulated deficit at the time of adoption.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, and subsequently issued a number of amendments to this update. The new standard, as amended in Accounting Standards Codification, or ASC 606, provides a single comprehensive model to be used in accounting for revenue arising from contracts with customers and supersedes previous revenue recognition guidance. The standard's core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The Company adopted this standard effective January 1, 2019.

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 Company adopted this new guidance on January 1, 2020 without material impact on its condensed consolidated financial position or results of operations.



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 Company adopted this new guidance on January 1, 2020 without material impact on its condensed consolidated financial position or results of operations.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer for a promised good or service that is distinct within the collaborative arrangement. The guidance also precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless those transactions are directly related to third-party sales. The Company adopted this new guidance on January 1, 2020 without material impact on its condensed consolidated financial position or results of operations.

*Recent Accounting Pronouncements Not Adopted as of September 30, 2020:*

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 provides for use of a forward-looking expected loss model for estimating credit losses, replacing the incurred loss model that is based on past events and current conditions. 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, 2022. The Company is currently evaluating the impact of the adoption of this guidance on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The update provides guidance distinguishing between capitalizable service contract implementation costs and contract costs required to be expensed. In addition, the update requires that the term of the hosting arrangement is to include the non-cancelable period of the arrangement plus periods covered by (i) an option to extend the arrangement if the customer is reasonably certain to exercise that option; (ii) an option to terminate the arrangement if the customer is reasonably certain not to exercise the termination option and (iii) an option to extend (or not to terminate) the arrangement in which exercise of the option is in the control of the vendor. This standard will become effective for the Company beginning January 1, 2021. The amendments may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of ASU 2018-15 and does not expect to have a material impact on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes*, which amends accounting for income taxes during interim periods and makes changes to certain income tax classifications. The new standard allows exceptions to the use of the incremental approach for intra-period tax allocation, when there is a loss from continuing operations and income or a gain from other items, and to the general methodology for calculating income taxes in an interim period, when a year-to-date loss exceeds the anticipated loss for the year. The standard also requires franchise or similar taxes partially based on income to be reported as income tax and the effects of enacted changes in tax laws or rates to be included in the annual effective tax rate computation from the date of enactment. The standard will be effective for the Company beginning January 1, 2022, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2019-12 on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*. This Accounting Standards Update was issued to address the complexity in accounting for certain financial instruments with characteristics of liabilities and equity. Among other provisions, the amendments in this ASU significantly change the guidance on the issuer’s accounting for convertible instruments and the guidance on the derivative scope exception for contracts in an entity’s own equity such that fewer conversion features will require separate recognition, and fewer freestanding instruments, like warrants, will require liability treatment. More specifically, the ASU reduces the number of models that may be used to account for convertible instruments from five to three, amends diluted EPS calculations for convertible instruments, modifies the requirements for a contract that may be settled in an entity’s own shares to be classified in equity and requires expanded disclosures intended to increase transparency. These amendments will be effective for the Company beginning January 1, 2024, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2020-06 on its consolidated financial statements.

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



**Note 4. Risks and Uncertainties**

The Company's cash requirements for 2020 and beyond include expenses related to continuing development and clinical evaluation of its products, manufacture and supply costs, costs of regulatory filings, patent prosecution expenses and litigation expenses, expenses related to commercialization of its products, as well as costs to comply with the requirements of being a public company operating in a highly regulated industry. As of September 30, 2020, working capital totaled \$13,311, which included \$17,064 of cash and cash equivalents.

As of September 30, 2020, Aquestive has experienced a history of net losses and the Company's accumulated deficits totaled \$165,889 which have been partially funded by profits from manufacture and supply operations, licensing revenues and certain other services, with the balance of the related funding requirements met by the Company's equity and debt offerings including its 12.5% Senior Secured Notes due 2025 (the "12.5% Notes"). In 2019, the Company raised funding totaling \$52,226, consisting of net proceeds of \$13,110 from the refinancing of its debt in July 2019, \$37,295 from the public offering of 8,050,000 common shares in December 2019, and \$1,821 from the exercise of warrants issued in connection with the debt refinancing.

The characteristics described above provide indications that the Company's ability to execute its near-term business objectives and achieve profitability over the longer term cannot be assured. Further, management views the impact of COVID-19 on the economy, its industry, its customers and suppliers and its own operations as constantly evolving, the future effects of which continue to be highly uncertain and unpredictable. Due to current or future interruptions and possible disruptions in health services, operations of the United States Food and Drug Administration ("FDA"), freight and other transportation services, supply, manufacturing, workforce health, availability of acceptable capital, financial and asset monetization markets, and availability of essential human and business requirements, and unforeseeable financial difficulties of the Company's customers or vendors, the severity, rapidity of the spread, and the duration of the COVID-19 pandemic may be expected to negatively affect a great number of businesses across various industries, including Aquestive. The Company may experience financial and operational adversity in such areas as pre-clinical, clinical trials, regulatory review and approval of various product candidates, customer demand for products and services, customers' ability to pay for goods and services, supply of pharmaceutical ingredients and other raw materials from approved vendors, ongoing availability of an appropriate labor force and skilled professionals, and additional capital or other funding from capital, financial or monetization markets.

Subject to and absent any material adverse effect of these and other possible COVID-19 effects, the Company expects that its anticipated revenues from licensed and proprietary products, cash on hand, expense management initiatives, monetization of certain revenue streams for its out-licensed apomorphine product (KYNMOBI™), and access to equity markets, including under its shelf registration statement would be adequate to meet expected operating, investing, and financing needs for the next twelve months. To the extent additional funds are necessary to meet operating needs as the Company continues to execute its business strategy, additional funding requirements would be obtained through modification of the existing debt facility to extend the potential availability of the first and second re-openers, and access to appropriate financial markets for debt or equity financings, or a combination of these potential sources of funds, although management can provide no assurance that any of these sources of funding, either individually or in combination, will be available on reasonable terms, if at all. In addition, the Company may be required to utilize available financial resources sooner than expected. Management has based its expectation on assumptions that could change or prove to be inaccurate, either due to the impact of COVID-19 or to unrelated factors including factors arising in the capital markets, asset monetization markets, regulatory approval process, regulatory oversight and other factors.

**Note 5. Revenues and Trade Receivables, Net*****Revenue from Contracts with Customers***

The Company's revenues are derived from four primary sources: manufactured products made to order for licensees, including Suboxone® and Zuplenz®, manufacture and sale of its self-developed, self-commercialized proprietary product, Sympazan® (clobazam), intellectual property licensing arrangements, and product development services provided under contracts with customers.

***Revenue Recognition and Performance Obligations***

Aquestive recognizes revenue pursuant to ASC 606, *Revenue from Contracts with Customers*, to reflect amounts expected to be collectible in exchange for the transfer of contractually promised goods or services to its customers, as discussed in additional detail in the Company's 2019 Annual Report on Form 10-K. Accordingly, the value of contractually promised goods or services is assessed at contract inception to identify those that constitute distinct performance obligations. Contract revenues are allocated to those distinct performance obligations based on estimated standalone values or expected values, and these allocated revenues are recognized at the point in time, or over the period of time, that those distinct obligations are satisfied. The Company's performance obligations consist primarily of transferring control of goods, services or intellectual property that are identified in the contracts, purchase orders or invoices. Variable or contingent revenues which may become due from customers, such as milestone payments due upon acceptance of a regulatory filing, regulatory approval, or sales-based milestone payments, are not recognized until contingencies are met, the customer's obligation to meet its contractual payment commitments is fixed and collection of invoiced amounts is reasonably assured, thereby limiting any significant probability of a revenue reversal.

Revenues from the sale of products and services and from licensing arrangements and related payments are evidenced by a contract with the customer. For manufacturing and supply and proprietary product sales, invoices are generally issued upon the transfer of control. Co-development and research revenue is typically invoiced based on the contractual payment schedule, or upon completion of the service. Licensing revenue is generally invoiced at the inception of an agreement, with additional charges rendered as related contingencies, such as regulatory approvals or sales targets, are met. Invoices are typically payable 30 to 60 days after the invoice date, however some payment terms may reach 75 days depending on the customer. The Company performs a review of each specific customer's creditworthiness and ability to pay prior to acceptance as a customer, as well as periodic prospective reviews.

*Manufacture and supply revenue* – this revenue is derived from products manufactured exclusively for specific customers according to their strictly-defined specifications, subject only to specified quality control inspections. Accordingly, at the point in time when quality control requirements are satisfied, revenue net of related discounts is recorded.

*Proprietary product sales, net* – this net revenue is recognized upon delivery and transfer of control of proprietary product to the Company's customers, at which point the Company has no ongoing performance obligations and the customer has assumed all significant risks and rewards of ownership. These revenues are subject to payment discounts, wholesaler service fees, volume and prompt payment discounts, rebates and other chargebacks, which are estimated and recorded at the time the revenue is recognized. Once all related variable considerations are resolved and uncertainties as to collectible amounts are eliminated, estimates are adjusted to actual allowance amounts. Provisions for these estimated amounts are reviewed and adjusted on no less than a quarterly basis.

*License and royalty revenues* – the Company may realize revenue from functional or from symbolic licenses. For functional licenses that do not require further development or other ongoing activities by the Company, the customer is viewed as acquiring the right to use the license as, and when, transferred and revenues are generally recorded at a point in time, subject to contingencies or constraints, if any. For symbolic licenses providing substantial value only in conjunction with other performance obligations to be met by the Company, such as manufactured products or development services, revenues may be deferred when advance payment is received and recognized over the term of the license agreement. 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.

*Co-development and research fees* – this revenue is recognized as contractual services or performance obligations are performed. Invoicing for contractual services may occur in advance or arrears, may, or may not, coincide with completion of underlying performance obligations, and therefore may give rise to contract assets or contract liabilities when the value of services completed varies from amounts that may be invoiced to the customer.

### ***Contract Assets***

In limited situations, certain customer contractual payment terms provide for invoicing in arrears. Accordingly, some, or all performance obligations may be completely satisfied before the customer may be invoiced under such agreements. In these situations, billing occurs after revenue recognition, which results in a contract asset supported by the estimated value of the completed portion of the performance obligation. These contract assets are reflected as a component of other receivables within Trade and other receivables and as a component of intangible and other assets within the Condensed Consolidated Balance Sheet. As of September 30, 2020, and December 31, 2019, such current and non-current contract assets were \$8,922 and \$4,363, respectively, consisting primarily of minimum annual royalties due under a certain licensing agreement and completed but unshipped products manufactured to specific order by certain licensees.

### ***Contract Liabilities***

In other limited situations, certain customer contractual payment terms are structured to permit invoicing in advance of delivery of a good or service. In such instances, the customer's cash payment may be received before satisfaction of some, or any, performance obligations that are specified. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. These contract liabilities are reflected as deferred revenue within the Condensed Consolidated Balance Sheet. As remaining performance obligations are satisfied, an appropriate portion of the deferred revenue balance is credited to earnings. As of September 30, 2020, and December 31, 2019, such contract liabilities were \$4,416 and \$5,154, respectively.

The Company's revenues were comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Manufacture and supply revenue	\$ 5,903	\$ 9,155	\$ 20,078	\$ 24,739
License and royalty revenue	328	1,356	13,682	6,402
Co-development and research fees	341	1,073	870	2,862
Proprietary product sales, net	1,688	834	4,070	2,187
Total revenues	<u>\$ 8,260</u>	<u>\$ 12,418</u>	<u>\$ 38,700</u>	<u>\$ 36,190</u>

### Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
United States	\$ 6,567	\$ 11,022	\$ 35,496	\$ 33,683
Ex-United States	1,693	1,396	3,204	2,507
Total revenues	<u>\$ 8,260</u>	<u>\$ 12,418</u>	<u>\$ 38,700</u>	<u>\$ 36,190</u>

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

Trade and other receivables, net consist of the following:

	September 30, 2020	December 31, 2019
Trade receivables	\$ 6,659	\$ 9,094
Contract and other receivables	1,872	4,363
Less: allowance for bad debts	(264)	(124)
Less: sales-related allowances	(277)	(203)
Trade and other receivables, net	<u>\$ 7,990</u>	<u>\$ 13,130</u>

The current portion of contract and other receivables totaled \$1,872 and \$4,363 as of September 30, 2020 and December 31, 2019, respectively. The current period balance is comprised primarily of \$1,000 of minimum royalty revenue due from a licensee and the remaining balance represents reimbursable costs incurred on behalf of customers for which earnings processes have been met prior to shipment of goods or full delivery of completed services. The December 31, 2019 balance represents reimbursable costs incurred on behalf of customers for which earnings processes have been met prior to shipment of goods or full delivery of completed services. Sales-related allowances for both periods presented are estimated in relation to revenues recognized for sales of Sympazan.

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

	September 30, 2020	December 31, 2019
Allowance for doubtful accounts at beginning of year	\$ 124	\$ 58
Additions charged to bad debt expense	140	66
Write-downs charged against the allowance	—	—
Allowance for doubtful accounts at end of the period	<u>\$ 264</u>	<u>\$ 124</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 support 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 sales related allowances and accruals for the nine months ended September 30, 2020:

	<b><u>Total Sales Related Allowances and Accruals</u></b>	
Balance at December 31, 2019	\$	1,377
Provision		3,996
Payments / credits		(3,441)
Balance at September 30, 2020	\$	<u>1,932</u>

Total reductions of gross product sales from sales-related allowances and accruals were \$3,996 for the nine months ended September 30, 2020. Accruals for returns allowances and prompt pay discounts are reflected as a direct reduction of trade receivables and accruals for wholesaler service fees, co-pay support redemptions and rebates as current liabilities. The accrued balances relative to these provisions included in Trade and other receivables, net and Accounts payable and accrued expenses were \$277 and \$1,655, respectively, as of September 30, 2020 and \$203 and \$1,174, respectively, as of December 31, 2019.

### ***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, 2019, Indivior, Inc. (“Indivior”) provided 86% of the total revenues for the period, and as of that date, the Company’s outstanding receivable balance from Indivior represented approximately 80% of gross receivables. For the nine months ended September 30, 2020, there were two customers exceeding the 10% threshold for revenue while there were three customers exceeding the 10% threshold for outstanding accounts receivable. Revenues provided by Indivior, and Sunovion Pharmaceuticals, Inc. (“Sunovion”) represented approximately 54% and 31%, respectively of total revenue for the nine months ended September 30, 2020, and outstanding accounts receivable due from Indivior, Sunovion and AmerisourceBergen represented approximately 50%, 12% and 11%, respectively of gross receivables.

### **Note 6. Material Agreements**

#### ***Commercial Exploitation Agreement with Indivior***

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

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

The Indivior License Agreement provides for payment by Indivior of a purchase price per unit that is subject to adjustment based on the Company’s ability to satisfy minimum product thresholds. Additionally, in the event Indivior purchases certain large quantities of Suboxone during a specified period, Indivior will be entitled to scaled rebates on its purchases.

In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) in each of the United States and in the rest of the world subject to annual maximum amounts and limited to the life of the related United States or international patents. In 2012, Indivior exercised its right to buy out its future royalty obligations in the United States under the Indivior License Agreement. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions, including with respect to a filing for bankruptcy or corporate dissolution, an invalidation of the intellectual property surrounding Suboxone, and commission of a material breach of the Indivior License Agreement by either party. Additionally, Indivior may terminate the Indivior License Agreement if the 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, the Company conveyed to Indivior all existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to the Suboxone product. The Company also conveyed to Indivior the right to sublicense manufacturing and marketing capabilities to enable an Indivior licensed generic buprenorphine product to be produced and sold by parties unrelated to Indivior or Aquestive. Under the Indivior Supplemental Agreement, the Company is entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. Once paid, all payments made under the Indivior Supplemental Agreement are non-refundable. Through February 20, 2019, the at-risk launch date of the competing generic products of Dr. Reddy's Labs and Alvogen, the Company 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 were suspended until adjudication of related patent infringement litigation is finalized. If such litigation is successful, in addition to the amounts already received as described in the foregoing, the Company 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 of additional process patent rights to the Company. The aggregate payments under this Indivior Supplemental Agreement are capped at \$75,000.

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.***

On April 1, 2016, the Company entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion Pharmaceuticals Inc.), referred to as the Sunovion License Agreement, pursuant to which Sunovion obtained 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 apomorphine for the treatment of off episodes in Parkinson's disease patients. Sunovion used this intellectual property to develop its apomorphine product, KYNMOBI™, which was approved by the FDA on May 21, 2020. This approval triggered Sunovion's obligation to remit a payment of \$4,000 (the "FDA Approval Milestone Payment") due on the earlier of: (a) the first day of product availability at a pharmacy in the United States; or (b) within six months of the FDA approval. This amount was received as of September 30, 2020 and is included in License and royalty revenues for the nine-months ended September 30, 2020.

In consideration for the rights granted to Sunovion under the Sunovion License Agreement, the Company received aggregate payments totaling \$22,000 to date. In addition to the upfront payment of \$5,000, the Company also earned an aggregate of \$17,000 in connection with specified regulatory and development milestones in the United States and Europe (the "Initial Milestone Payments") The Company is also entitled to receive certain contingent one-time milestone payments related to product availability and regulatory approval in Europe, certain one-time milestone payments based on the achievement of specific annual net sales thresholds of KYNMOBI™, and ongoing mid-single digit percentage royalty payments related to the net sales of KYNMOBI™ (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 the Company pursuant to the Sunovion License Agreement are equal to \$45,000. There can be no guarantee that any future milestones will be met or that additional milestone payments will be payable. There are minimum annual guaranteed royalty payments under the contract. As of September 30, 2020, the Company recorded minimum royalty receivables of \$8,000 in the aggregate, of which \$1,000 is included in Trade and other receivables and \$7,000 is included in Intangibles, net and other assets, with the total reflected in License and royalty revenues for the nine- months ended September 30, 2020.

Effective March 16, 2020, the Company entered into a first amendment (the “First Amendment”) to the Sunovion License Agreement. The Amendment was entered into for the primary purpose of amending the Sunovion License Agreement as follows: (i) including the United Kingdom and any other country currently in the European Union (EU) which later withdraws as a member country in the EU for purpose of determining the satisfaction of the condition triggering the obligation to pay the third milestone due under the Sunovion License Agreement, (ii) extending the date after which Sunovion has the right to terminate the Sunovion License Agreement for convenience from December 31, 2024 to March 31, 2028, (iii) modifying the effective inception date of the first minimum annual royalty due from Sunovion to the Company from January 1, 2020 to April 1, 2020, and (iv) modifying the termination provisions to reflect the Company’s waiver of the right to terminate the Sunovion License Agreement in the event that KYNMOBI™ was not commercialized by January 1, 2020. This Sunovion License Agreement will continue until terminated by Sunovion in accordance with the termination provisions of the Amendment to the Sunovion License Agreement. The Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination of the Sunovion License Agreement, all rights to intellectual property granted to Sunovion to develop and commercialize apomorphine-based 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 apomorphine-based products.

On October 23, 2020, the Company amended the Sunovion License Agreement to clarify the parties’ agreement with respect to certain provisions in the License Agreement, specifically the date after which Sunovion has the right to terminate the License Agreement and the rights and obligations of the parties regarding the prosecution and maintenance of the Company’s patents covered under the License Agreement. See Note 19, (A), Subsequent Events. On November 3, 2020, the Company entered into a royalty monetization agreement (the “Monetization Agreement”) with an affiliate of Marathon Asset Management (“Marathon”) pursuant to which the Company conveyed to Marathon the right to all royalties and other payments due to the Company under the Sunovion License Agreement. See Note 19, (B), Subsequent Events.

### ***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 by the Company and KemPharm in April 2011. Under this termination arrangement, the Company has the right to participate in any and all value that KemPharm may derive from the commercialization or any other monetization of KemPharm’s 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. During September 2019, the Company received \$1,000 from its 10% share of milestone payments paid to KemPharm under its licensing of KP-415 and KP-484 to a third party. The Company has also received a payment of \$500 under this arrangement during June 2020, which is included in License and royalty revenues for the nine-month period ended September 30, 2020, in connection with the FDA’s acceptance of a New Drug Application (“NDA”) filing for KP-415. A Prescription Drug User Fee Act (PDUFA) target date for completion of FDA review has been scheduled for early March 2021. The Company’s share of remaining milestone payments associated with KP-415 approval and certain targeted labeling goals within timeframes ending in July 2021 may reach \$4,800. However, there can be no guarantee that approvals, goals or any such payments will be achieved or received 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 (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — 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 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 their fair values based on the short-term maturity of these assets and liabilities.



The Company granted warrants to certain holders of the 12.5% Notes in connection with its debt refinancing in July 2019. These warrants were valued based primarily on Level 3 inputs and an independent third-party appraisal prepared as of the grant date 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 Compensation. See Note 14 for further information on these warrants.

**Note 8. Inventories, Net**

The components of Inventory, net is as follows:

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Raw material	\$ 1,153	\$ 1,244
Packaging material	1,231	1,096
Finished goods	858	519
Total inventory, net	<u>\$ 3,242</u>	<u>\$ 2,859</u>

The Company manufactures Suboxone exclusively to order for its major customer subject to strict quality standards and recognizes revenue upon completion of all customary quality control evaluations, which occurs prior to actual shipment.

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

	<u>Useful Lives</u>	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Machinery	3-15 yrs	\$ 21,406	\$ 21,088
Furniture and fixtures	3-15 yrs	1,209	1,150
Leasehold improvements	(a)	21,333	21,333
Computer, network equipment and software	3-7 yrs	2,886	2,787
Construction in progress		1,065	1,412
		<u>47,899</u>	<u>47,770</u>
Less: accumulated depreciation and amortization		<u>(40,171)</u>	<u>(38,044)</u>
Total property and equipment, net		<u>\$ 7,728</u>	<u>\$ 9,726</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 \$714 and \$695 for the three-month periods ended September 30, 2020 and 2019, respectively. For the respective nine-month periods, these expenses totaled \$2,127 and \$2,143.

**Note 10. Right-of-Use Assets and Lease Obligations**

The Company leases all realty used as its production and warehouse facilities, corporate headquarters, commercialization operations center and research and laboratory facilities. None of these three leases include the characteristics specified in ASC 842, *Leases*, that require classification as financing leases and, accordingly, these leases are accounted for as operating leases. These leases provide remaining terms between 2.5 years and 6.0 years, including renewal options expected to be exercised to extend the lease periods. Measurement of the operating lease liability reflects an estimated discount rate of 16.9% applied to minimum lease payments, including expected renewals, based on the incremental borrowing rate experienced in the Company's latest collateralized debt refinancing. Right-of-use assets recorded upon adoption of ASC 842 totaled \$4,048. For the three- and nine-month periods ended September 30, 2020, total operating lease expenses under these leases totaled \$409 and \$1,228, respectively, including variable lease expenses such as common area maintenance and operating costs totaling \$89 and \$255, respectively. Total payments to these lessors during the nine-month period ended September 30, 2020 were \$1,255.

Maturities of the Company's operating lease liabilities are as follows:

Remainder of 2020	\$	266
2021		1,287
2022		1,295
2023		944
2024		565
2025		565
2026		424
Total lease payments		5,346
Less: imputed interest		(1,635)
Total operating lease liabilities	\$	<u>3,711</u>

**Note 11. Intangible Assets, Net and Other Assets**

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

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Purchased technology-based intangible	\$ 2,358	\$ 2,358
Purchased patent	509	509
	<u>2,867</u>	<u>2,867</u>
Less: accumulated amortization	(2,752)	(2,714)
Intangible assets, net	115	153
Royalty receivable	7,000	-
Other assets, primarily security deposits	287	286
Total intangible assets, net and other assets	<u>\$ 7,402</u>	<u>\$ 439</u>

Amortization expense was \$13 for each of the three-month periods ended September 30, 2020 and 2019. For the corresponding nine-month periods, these expenses totaled \$38 and \$39, respectively. During the remaining life of the purchased patent, estimated annual amortization expense is \$50 for each of the years from 2020 to 2022. Royalty receivable consists of seven annual \$1,000 minimum royalty payments due from Sunovion, the last of which is due in March 2028. See Note 6 above.

**Note 12. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses consisted of the following:

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Accounts payable	\$ 9,169	\$ 12,274
Accrued compensation	4,129	3,758
Accrued distribution expenses	1,655	1,174
Other	284	543
Total accounts payable and accrued expenses	<u>\$ 15,237</u>	<u>\$ 17,749</u>

**Note 13. 12.5 % Senior Secured Notes and Loans Payable**

**12.5% Senior Secured Notes**

On July 15, 2019, the Company completed a private placement of up to \$100 million aggregate principal of the 12.5% Notes and issued warrants for two million shares of common stock (the "Warrants"), \$.001 par value per share, through the structuring agent, Morgan Stanley & Co., LLC, and entered into a purchase agreement and 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 (the "Noteholders") and U.S. Bank National Association in dual roles providing terms and governing an asset-based loan facility.

Upon closing of the Indenture for the 12.5% Notes (“Indenture”), the Company issued \$70,000 of principal of the 12.5% 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 the 12.5% Notes and Warrants (the “Lenders”). Issuance of the Initial Notes and Warrants provided net proceeds of \$66,082. In addition to the Initial Notes, the Indenture may provide access to further loans of up to \$30,000 that may become available in two tranches of additional notes (the “Additional Notes”) tied to the NDA filing for and FDA U.S. marketing approval of Libervant™, an important part of the Company’s drug candidate pipeline. Subject to approval of the holder of a majority of the outstanding principal amount of the 12.5% Notes in its discretion, and provided that no events of default exist, the Company may offer to the Lenders participation in a \$10,000 additional offering of the 12.5% 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 funding opportunity would allow the Company to obtain, on or before March 31, 2021, 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™ for marketing in the U.S. On November 3, 2020, this Indenture was amended and will be partially repaid from proceeds resulting from the monetization transaction. See Note 19 (C), Subsequent Events. There can be no assurance that any additional financing will be consummated.

Proceeds from the issuance of the Initial Notes and Warrants were used to fully repay the Company’s \$56,340 outstanding indebtedness to Perceptive Credit Opportunities Fund, LP (the “Perceptive Loan”), related early repayment fees and legal and other fees incurred to obtain the loan.

The 12.5% 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. The Company has recorded \$1,750 as Loans Payable, Current to reflect this obligation in its Condensed Consolidated Balance Sheet at September 30, 2020. Principal payments are scheduled to increase annually from 10% of the face amount of debt then outstanding during the first four quarters to 40% of the initial loan principal during the final four quarters.

A debt maturity table is presented below:

Remainder of 2020	\$	-
2021		3,500
2022		10,500
2023		17,500
2024		24,500
2025		14,000
<b>Total</b>	<b>\$</b>	<b><u>70,000</u></b>

The Company may elect, at its option, to prepay the 12.5% Notes at any time at premiums that range from 101.56% of outstanding principal if prepayment occurs on or after the 5<sup>th</sup> anniversary of the issue date of the Initial Notes to 112.5% if payment occurs during the third year after the issuance of the Initial Notes. In the event that redemption occurs within the two years after the issuance of the 12.5% 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 a change of control provision under which the Company may be required to repurchase the 12.5% Notes at 101% of the remaining principal plus accrued interest at the election of the Lenders.

Collateral for the loan under the 12.5% Notes consists of a priority lien on substantially all property and assets, including intellectual property, of the Company. This secured obligation provides payment rights that are senior to all existing and future subordinated indebtedness of the Company and provides Lenders with perfected security interests in substantially all of the Company’s assets. In the event that asset-based loans of up to \$10,000 (“ABL Facility”) may be obtained, subject receivables and inventory assets will provide a second priority lien to senior secured Noteholders. The Company’s license of its intellectual property to a third-party drug development enterprise (specifically, Sunovion’s KYNMOBI™ product) is one of the various assets serving as collateral for the loan. The 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 12.5% Notes being repurchased, plus accrued and unpaid interest, if any, thereon, to the date of the repurchase, to the extent elected by the Noteholders, 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 Noteholders. To the extent that Lenders do not elect repayment of the debt at the date of the monetization, the amount not elected up to \$40,000 (or \$50,000 if an additional tranche is issued) will be held in a collateral account until approval of Libervant™ by the FDA for U.S. marketing, at which time this cash collateral is to be released to the Company. Proceeds of more than \$40,000 (or \$50,000 if an additional tranche is issued) can be used immediately for general corporate purposes. As of September 30, 2020, the Company complied with all of its covenants under the Indenture.

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 holders, and offsets those as a direct reduction of its outstanding debt. Amortization expenses arising from deferred debt issuance costs and debt discounts related to the 12.5% Notes were \$590 and \$1,758 for the three- and nine-month periods ended September 30, 2020, respectively. Comparative amortization expenses derived from deferred debt issuance costs and debt discounts related to the Perceptive Loan and the 12.5% Notes for the three- and nine-month periods ended September 30, 2019 were \$556 and \$1,338, respectively. Unamortized deferred debt issuance costs and deferred debt discounts totaled \$7,904 and \$9,662 as of September 30, 2020 and December 31, 2019, respectively.

*Loans Payable - Perceptive*

In August 2016, the Company entered into a Loan Agreement and Guaranty with Perceptive Credit Opportunities Fund, LP (“Perceptive”) under which the total available facility of \$50,000 had been borrowed as of March 2017. At closing, 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 Aquestive’s IPO. In July 2019, the Perceptive Loan was paid in full in connection with the completion of the sale of the Initial Notes and Warrants described above. The early extinguishment of this debt resulted in a charge to third quarter 2019 earnings of an amount of \$4,896, including an early retirement premium of \$2,944 and the remaining balances of the unamortized loan discount and loan acquisition costs.

**Note 14. Warrants Issued to 12.5% Senior Secured Noteholders**

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

Certain holders of the Initial Notes exercised Warrants for the purchase of 428,571 shares of common stock and proceeds therefor totaling \$1,821 were received on December 16, 2019. There were no Warrants exercised by the holders of the Initial Notes during the nine-month period ended September 30, 2020.

On November 3, 2020, the Indenture was amended, and additional at-the-money warrants will be issued at the time of purchase of additional Notes. See Note 19 (C), Subsequent Events.

**Note 15. Net Loss Per Share**

Basic net income or loss per share is calculated by dividing net income or loss by the weighted-average number of common shares outstanding during the periods. Diluted net income or loss per common share is similarly computed and includes the effect of any additional dilutive potential common shares outstanding during the periods. These potential common shares are excluded from the computation of net loss per share to the extent that their effects are antidilutive, and as a result of the Company’s net losses incurred for the three- and nine-month periods ended September 30, 2020 and 2019, respectively, no potentially dilutive securities have been included in the computation of diluted net loss per share for the periods presented below.

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
Numerator:				
Net loss	\$ (16,551)	\$ (18,412)	\$ (35,415)	\$ (53,610)
Denominator:				
Weighted-average number of common shares – basic	33,619,379	25,031,478	33,592,846	24,992,229
Loss per common share – basic and diluted	\$ (0.49)	\$ (0.74)	\$ (1.05)	\$ (2.15)

The following outstanding stock options, restricted stock units and warrants are antidilutive and have been excluded from the computation of the loss per common share for the periods ended September 30:

	September 30, 2020	September 30, 2019
Options on common shares outstanding	3,075,942	2,256,092
Restricted stock units unvested	13,489	107,144
Warrants on common shares outstanding	1,571,429	—
Total potentially antidilutive derivatives excluded from losses per share	<u>4,660,860</u>	<u>2,363,236</u>

**Note 16. Share-Based Compensation**

The Company recognized share-based compensation in its Condensed Consolidated Statements of Operations and Comprehensive Loss during 2020 and 2019 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Manufacture and supply	\$ 73	\$ 60	\$ 208	\$ 176
Research and development	178	188	543	536
Selling, general and administrative	1,176	1,622	4,301	4,480
Total share-based compensation expenses	<u>\$ 1,427</u>	<u>\$ 1,870</u>	<u>\$ 5,052</u>	<u>\$ 5,200</u>
Share-based compensation from:				
Restricted stock units	\$ 16	\$ 473	\$ 789	\$ 1,403
Stock options	1,411	1,397	4,252	3,777
Employee stock purchase plan	-	—	11	20
Total share-based compensation expenses	<u>\$ 1,427</u>	<u>\$ 1,870</u>	<u>\$ 5,052</u>	<u>\$ 5,200</u>

**Share-Based Compensation Equity Awards**

The following tables provide information about the Company's restricted stock unit and stock option activity during the nine-month period ended September 30, 2020:

Restricted Stock Unit Awards (RSUs):	Number of Units (in thousands)	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2019	74	\$ 14.64
Granted	4	7.54
Vested	(64)	14.88
Forfeited	—	—
Unvested as of September 30, 2020	<u>14</u>	<u>\$ 11.38</u>
Grant date fair value of shares vested during the period	<u>\$ 958</u>	
Unrecognized compensation costs as of September 30, 2020	<u>\$ 140</u>	

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

<u>Stock Option Awards:</u>	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>
	(in thousands)	
Outstanding as of December 31, 2019	2,231	\$ 10.42
Granted	981	2.68
Exercised, Forfeited, Expired	(136)	(4.39)
Outstanding as of September 30, 2020	<u>3,076</u>	<u>\$ 8.22</u>
Vested or expected to vest as of September 30, 2020	<u>2,866</u>	<u>\$ 8.22</u>
Exercisable as of September 30, 2020	<u>1,014</u>	<u>\$ 11.87</u>

The fair values of stock options granted during 2020 were estimated using the Black-Scholes-Merton pricing model based on the following assumptions:

Expected dividend yield	None
Expected volatility	100%
Expected term (years)	5.5 - 6.1
Risk-free interest rate	0.4 – 1.7%

The weighted average grant date fair value of stock options granted during 2020 was \$2.10. During the nine-month period ended September 30, 2020, stock options were granted with exercise prices ranging from \$1.54 to \$7.86, and accordingly, given the Company's share price of \$4.86 at September 30, 2020, certain shares granted during this period provided intrinsic value at that date totaling \$2,474. No intrinsic value was provided by stock options granted during the nine-month period ended September 30, 2019.

As of September 30, 2020, \$6,554 of unrecognized compensation expense related to non-vested stock options is expected to be recognized over a weighted average period of 1.8 years from the date of grant.

#### Employee Stock Purchase Plan

The Aquestive Therapeutics, Inc. Employee Stock Purchase Plan, or ESPP, as amended and restated effective as of January 1, 2019, features two six-month offering periods per year, running from January 1 to June 30 and July 1 to December 31. Under the ESPP, employees may elect to purchase the Company's common stock at the lower of 85% of the fair value of shares on either the first or last day of the offering period. During the nine-month periods ended September 30, 2020 and 2019, respectively, 14,961 and 31,393 shares were purchased and issued through the ESPP at total discounts of \$11 and \$20.

#### **Note 17. Income Taxes**

The Company has accounted for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as net operating loss carryforwards and research and development credits. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax asset will not be realized. The Company has considered the impact of the CARES Act in relation to the 2020 income tax provision. However, due to the full valuation allowance and no ability or intent to carryback the 2020 net operating loss, no impact is expected.

The Company's tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items. For the three months ended September 30, 2020 and 2019, the Company recorded no income tax benefit from its pretax losses of \$16,551 and \$18,412, respectively, and similarly for the nine months ended September 30, 2020 and 2019, the Company recorded no tax benefit from its pretax loss of \$35,415 and \$53,610, respectively, due to realization uncertainties.

The Company's U.S. Federal statutory rate is 21%. The primary factor impacting the effective tax rate for the three- and nine-month periods ended September 30, 2020 is the anticipated full year operating loss which will require full valuation allowances against any associated net deferred tax assets.

**Note 18. Contingencies**

***Litigation and Contingencies***

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

***Patent-Related Litigation***

Beginning in August 2013, the Company was informed of abbreviated new drug application (“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. Aquestive filed patent infringement lawsuits against all six generic companies in the United States District Court for the District of Delaware (the “Delaware District Court”). 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 products.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement among the Company, Indivior, and Par and certain of its affiliates.
- *Actavis* was found to infringe Patent No. 8,603,514, or the ’514 patent, and cannot enter the market until the expiration of the patent in 2024, and the United States Court of Appeals for the Federal Circuit (“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 Delaware District Court case against DRL and Alvogen. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The remaining case against Actavis was dismissed in light of the infringement ruling above, which prevents Actavis from entering the market until 2024. The case(s) against the remaining defendants regarding the additional asserted patents have not been finally resolved. A *Markman* hearing in the cases against Dr. Reddy’s and Alvogen which is pending in the United States District Court for the District of New Jersey (the “New Jersey District Court”) was held on October 17, 2019. On November 5, 2019, District Judge McNulty of the New Jersey District Court issued a *Markman* opinion construing the disputed terms of the asserted patents. On January 9, 2020, the New Jersey District Court entered a stipulated order of non-infringement of one of the patents, Patent No. 9,931,305, or the ’305 patent, based on the Federal Circuit’s claim construction ruling, and the Company and Indivior preserved available rights to appeal the claim construction ruling. On November 19, 2019, Magistrate Judge Waldor of the New Jersey District Court issued an order granting DRL and Alvogen’s requests to file amended answers to add antitrust counterclaims against Aquestive and Indivior. Aquestive and Indivior appealed the Magistrate Judge’s decision to District Judge McNulty on December 4, 2019, and DRL and Alvogen opposed the appeal. On January 17, 2020, the Company filed a motion to dismiss DRL’s and Alvogen’s antitrust counterclaims for failure to state a claim, and DRL and Alvogen opposed the motion. On August 24, 2020, Judge McNulty issued an Opinion and Order denying both the appeal of the Magistrate’s decision and Aquestive’s Motion to Dismiss. On June 3, 2020, the court issued an order setting a schedule for ongoing fact discovery, expert discovery, and dispositive motions. The schedule currently sets the close of fact discovery for October 20, 2020, with expert discovery continuing through the end of April 2021. The schedule also sets the deadline for filing dispositive motions for May 18, 2021. No trial date has been set in those cases. Management is 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.

On February 19, 2019, the Federal Circuit issued its mandate reversing the New Jersey District Court’s preliminary injunction against Dr. Reddy’s. Following issuance of the mandate, the New Jersey District Court vacated preliminary injunctions against both Dr. Reddy’s and Alvogen. Dr. Reddy’s, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by Dr. Reddy’s and Alvogen are “at risk” because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, Aquestive and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. in the United States District Court for the Southern District of Florida (the “Southern District of Florida Court”) for infringement of the Company’s U. S. Patent Nos. 8,017,150, 9,687,454, the ’514 patent and ’305 patent, seeking an injunction and potential monetary damages. Following a negotiated settlement between all parties, on December 3, 2019, the parties submitted a Notice of Settlement and a Joint Motion to Approve Consent Judgment. The Southern District of Florida Court entered an order dismissing the suit on December 18, 2019.

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

- 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, 8,652,378 and 8,475,832. This case is stayed.
- The second was filed by Aquestive and Indivior related to BDSI’s infringing Bunavail product, and alleges infringement of Aquestive’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 (4) IPR’s challenging the asserted ’167 patent. On March 24, 2016, the United States Patent Trial and Appeal Board (“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. The parties in this matter 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. On August 7, 2019, the Eastern District of North Carolina Court granted BDSI’s motion to dismiss the Complaint without prejudice and denied BDSI’s motion to stay as moot. On November 11, 2019, Aquestive filed a new Complaint against BDSI in the Eastern District of North Carolina Court. On November 27, 2019, BDSI filed a motion to stay the case pending BDSI’s appeal of the PTAB’s remand decisions, and the Company opposed this motion. The Eastern District of North Carolina Court denied BDSI’s motion to stay on April 1, 2020. BDSI’s appeal of the PTAB’s remand decisions to the United States Court of Appeals for the Federal Circuit was docketed on March 13, 2019, and on March 20, 2019, and a motion was made to dismiss this appeal for lack of jurisdiction. On August 29, 2019, the Federal Circuit granted the motion to dismiss BDSI’s appeal. On September 30, 2019, BDSI filed a petition for rehearing in the Federal Circuit *en banc*, which the Company opposed. The Federal Circuit denied BDSI’s petition for rehearing *en banc* on January 13, 2020. On June 11, 2020, BDSI filed a petition for writ of certiorari at the Supreme Court of the United States. At the request of the Supreme Court, Aquestive filed an opposition to BDSI’s petition on August 17, 2020, and BDSI filed a reply on August 27, 2010. On October 5, 2020, the Supreme Court issued an order denying BDSI’s petition. After the Federal Circuit denied BDSI’s petition, on January 13, 2020, BDSI filed with the Eastern District of North Carolina Court a motion to dismiss the Complaint, and Aquestive opposed on February 2, 2020. The Eastern District of North Carolina Court denied BDSI’s motion to dismiss and its motion to stay on April 1, 2020. On April 16, 2020, BDSI filed an Answer to the Complaint, including counterclaims for non-infringement, invalidity, and unenforceability of the ’167 patent. On May 7, 2020, Aquestive filed a motion to dismiss BDSI’s unenforceability counterclaim and a motion to strike BDSI’s corresponding affirmative defenses for failure to state a claim for inequitable conduct under the heightened pleading standard applicable to such claims and defenses. Rather than oppose Aquestive’s Motion to Dismiss, on May 28, 2020, BDSI amended its counterclaims and filed an Answer and Amended Counterclaims, which included additional allegations in support of BDSI’s unenforceability counterclaim. On June 25, 2020, Aquestive filed a Motion to Dismiss BDSI’s Amended Counterclaim for unenforceability and a Motion to Strike BDSI’s corresponding affirmative defense of unenforceability again for failure to state a claim under the applicable heightened pleading standard. BDSI’s filed its opposition to Aquestive’s Motion to Dismiss and Strike on July 16, 2020. Aquestive filed its Reply to BDSI’s Opposition on July 30, 2020. The parties are awaiting further action from the court on Aquestive’s motion.



## ***Antitrust Litigation***

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and the Company 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 suit, 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 Aquestive 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. Aquestive moved to dismiss the States' conspiracy claims, but by order dated October 30, 2017, the Court denied the motion to dismiss. An answer was filed denying the States' claims on November 20, 2017. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions were conducted through August 1, 2019. The remainder of the case schedule, including summary judgment briefing, is stayed pending resolution of Indivior's appeal of the District Court's class certification ruling in a co-pending multi-district litigation to which the Company is not a party. On July 28, 2020, the U.S. Court of Appeals for the Third Circuit issued its opinion affirming the District Court's order certifying the class. On August 27, 2020, the district court issued a scheduling order, setting the deadline for filing remaining *Daubert* challenges and summary judgment. Under the scheduling order, the remaining *Daubert* motions were filed on September 28, 2020, and oppositions are due on October 19, 2020. The court will set oral argument on the motions, but the date for oral argument is not yet known. Summary judgment motions are due January 11, 2021, and responses to summary judgment motions are due February 11, 2021. No trial date has yet been set. Management is 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.

## ***Humana and Centene Actions***

On September 18, 2020, Humana, Inc., a health insurance payer, filed a suit against Aquestive and Indivior in the Eastern District of Pennsylvania relating to Suboxone. The Humana action, which alleges facts similar to those at issue in the Antitrust Case and the Suboxone MDL described above, was assigned to the same judge that is presiding over those actions. Humana's Complaint alleges five causes of action against Aquestive, including conspiracy to violate the RICO Act, fraud under state law, unfair and deceptive trade practices under state law, insurance fraud, and unjust enrichment. On September 21, 2020, Centene Corporation and other related insurance payers filed a similar suit against Aquestive and Indivior in the Eastern District of Missouri. The counsel representing Humana is also representing Centene. On September 21, 2020, the Centene action was provisionally transferred to the Eastern District of Pennsylvania by the United States Judicial Panel on Multidistrict Litigation. No other proceedings have occurred and the schedule is not yet known. Management is not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimate, of the possible outcome or loss, if any, in this matter.

## ***California Complaint***

On December 5, 2019, Neurelis Inc. ("Neurelis") filed a complaint against Aquestive in the Superior Court of California, County of San Diego alleging Unfair Competition, Defamation, and Malicious Prosecution related to the Company's pursuit of FDA approval for Libervant™. Neurelis filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. The Company filed a Motion to Strike Neurelis's Complaint under California's anti-SLAPP ("strategic lawsuit against public participation") statute on Friday, January 31, 2020, which Neurelis is expected to oppose. Neurelis filed a motion for leave to file a Supplemental Complaint on February 5, 2020, which will be opposed. On February 5, 2020, Neurelis filed a Motion for Leave to File a Supplemental Complaint ("Motion"). On June 5, 2020, Neurelis filed a Motion for Limited Discovery related to Aquestive's anti-SLAPP motion.

The court previously scheduled a hearing on both Aquestive's anti-SLAPP Motion and on Neurelis's Motion for April 24, 2020. However, on April 3, 2020, in response to the COVID-19 pandemic, the court issued an order continuing all hearings scheduled through April 30, 2020. The court ultimately held a telephonic status conference on June 25, 2020 to determine a schedule for hearing the pending motions. During that status conference, the court set Aquestive's anti-SLAPP motion for hearing on July 24, 2020. The court also declined Neurelis's request to hear its Motion and its Motion for Limited Discovery. Neurelis filed its response to Aquestive's anti-SLAPP Motion on July 13, 2020, and we filed our reply on July 17, 2020. The court held a telephonic hearing on Aquestive's anti-SLAPP motion on July 24, 2020. On August 6, 2020, the Court issued an order granting in part and denying in part Aquestive's anti-SLAPP motion. Aquestive filed a notice of appeal to the California Court of Appeal on September 1, 2020, and Neurelis filed a notice of cross-appeal on October 5, 2020. Management is 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.

**Note 19. Subsequent Events**

***(A) Amendment to License Agreement with Sunovion Pharmaceuticals Inc.***

Effective as of October 23, 2020, the Company entered into a Second Amendment to the Sunovion License Agreement whereby the parties to the Sunovion License Agreement agreed to clarify the continued rights and obligations of the parties with respect to the prosecution and maintenance of the Company's patents covered under the Agreement and that, on and after March 31, 2028, in respect of any jurisdiction or jurisdictions covered under the License Agreement, Sunovion may terminate its rights with respect to the Licensed Patents under the License Agreement upon 180 days prior written notice to the Company.

***(B) Monetization of Certain Rights under the Sunovion License Agreement***

On November 3, 2020, the Company entered into the Monetization Agreement that will result in proceeds to the Company of up to \$125,000 in exchange for which the Company conveyed to Marathon the right to all royalties and other payments due to the Company under the Sunovion License Agreement (See Note 6). Under the terms of the Monetization Agreement, Aquestive will receive a \$40,000 cash payment within 12 business days of signing and is eligible to receive up to \$85,000 of contingent payments at various points, beginning as early as the fourth quarter of 2020, based on the achievement of worldwide royalty targets and certain other commercial milestones.

***(C) Amendment and Partial Repayment of the 12.5% Notes***

With the proceeds paid to the Company at closing under the Monetization Agreement, the Company will repay \$22,500 of the 12.5% Notes, and issue \$4,000 of new senior notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the balance of senior notes outstanding to \$51,500 in the aggregate. In addition, the holders of the 12.5% Notes have extended to December 31, 2021 the Company's ability to access, at the Company's option, \$30,000 of senior notes re-openers under the Indenture. The first \$10,000 senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at the option of the Company, contingent upon FDA approval of the Company's product candidate Libervant (diazepam) Buccal Film for the management of seizure clusters. A second \$20,000 senior notes re-opener represents a right, at the Company's option, to market to current holders of the Company's 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that the Company accesses these re-openers, the Company will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of the Company's common stock at the warrant grant date. In addition, as of the closing of this transaction, the Company will issue to the holders of the 12.5% Notes warrants to purchase 143,000 shares of the Company's common stock.

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

*You should read this section in conjunction with our unaudited condensed interim consolidated financial statements and related notes included in Part I Item 1 of this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the years ended December 31, 2019 and 2018 included in our 2019 Annual Report on Form 10-K. All dollar amounts are stated in thousands except for share data.*

**Forward-Looking Statements**

This Quarterly Report on Form 10-Q and certain other communications made by us include 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 regarding therapeutic benefits and plans and objectives for regulatory approvals of AQST-108, Libervant™; ability to cure the deficiencies identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant and obtain FDA approval of Libervant for U.S. market access; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; about our growth and future financial and operating results and financial position, regulatory approval and pathways, clinical trial timing and plans, our and our competitors' orphan drug approval and resulting drug exclusivity for our products or products of our competitors; short-term and long-term liquidity and cash requirements, cash funding and cash burn, business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are also subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredients and other raw materials; supply chain, manufacture, distribution and sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.



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 and plans; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of our drug candidate Libervant relative to FDA-approved diazepam rectal gel and nasal spray products, including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks and uncertainties concerning the royalty and other revenue stream of KYNMOBI™ (apomorphine), achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction, and of sufficiency of net proceeds of the monetization transaction after satisfaction of and compliance with the 12.5% Notes, as applicable, and for funding the Company's operations; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third-party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer-term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risk associated with Indivior's cessation of production of its authorized generic buprenorphine naloxone film product, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunset product; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks 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 actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings including patent infringement, investigative and antitrust litigation matters; changes in government 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 uncertainties affecting the Company described in the "Risk Factors" section and in other sections included in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak 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 Quarterly Report on Form 10-Q whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely on the forward-looking statements included in this Quarterly Report on Form 10-Q as representing our views as of any date after the date of the filing of this Quarterly Report on Form 10-Q.

## Overview

We are a pharmaceutical company focused on developing and commercializing differentiated products which leverage our proprietary PharmFilm® technology to meet patients' unmet medical needs and to solve patients' therapeutic problems. Following the Company's Initial Public Offering ("IPO") in July 2018, the Company's common stock trades on the Nasdaq Global Market under ticker symbol "AQST". We have three commercial products, including one proprietary product and two out-licensed products, another FDA-approved product that has been out-licensed for commercialization in European markets following applicable regulatory approvals, as well as a late-stage proprietary product pipeline focused on the treatment of central nervous system, or CNS, diseases and an earlier stage pipeline including treatment of anaphylaxis. We have also licensed certain intellectual property rights for use in development and commercialization of oral films containing apomorphine, which are used for the treatment of off episodes in patients suffering from Parkinson's disease and, having received FDA approval on May 21, 2020, was commercially launched by our licensee in September 2020. We believe that our products address the characteristics of these patient populations and the shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines.

Sympazan, an oral film for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut syndrome, or LGS, was approved by the FDA on November 1, 2018. The Company commercially launched Sympazan in December 2018. Sympazan was launched as a precursor and complement to our product candidate Libervant and continues to progress on key performance metrics including prescriber growth, repeat prescribers, quarterly growth in retail shipments, and covered lives.



Exservan® (riluzole), utilizing our proprietary PharmFilm technology, has been developed for the treatment of amyotrophic lateral sclerosis (ALS). Exservan was approved by the FDA on November 22, 2019. During the fourth quarter of 2019, we announced the granting of a license to Zambon S.p.A. for the development and commercialization of Exservan Oral Film in the European Union (EU) for treatment of ALS. Zambon is exclusively responsible for obtaining regulatory approval and marketing Exservan in the EU and we have sole and exclusive manufacturing rights for the product in the EU. We are seeking an appropriate licensee for the commercialization rights for Exservan in the United States. There can be no assurance that we will be successful in licensing Exservan in the United States.

Libervant is our most advanced proprietary investigational product candidate, which we intend to self-commercialize, subject to FDA approval for market access in the U.S. Libervant is a buccally, or inside of the cheek, administered soluble film formulation of diazepam. Aquestive is developing Libervant as an alternative to the device-dependent rescue therapies currently available to patients with refractory epilepsy, which are a rectal gel and newly approved nasal sprays. We are seeking to demonstrate that Libervant will, if approved by the FDA for U.S. market access, represent a “major contribution to patient care” within the meaning of FDA regulations and guidance, as compared to available treatment options, as the first, non-device delivered, oral diazepam-based product available to manage seizure clusters in epilepsy patients. However, overcoming the orphan drug marketing exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such marketing exclusivity and approve Libervant for U.S. market access. The Company filed an NDA for Libervant in November 2019. On September 25, 2020, the Company received a Complete Response Letter (CRL) from the FDA regarding our NDA for Libervant. The FDA issues a CRL to indicate that the review cycle for an application is complete but the application cannot be approved in its current form. In the CRL, the FDA cited that, in a study submitted by the Company with the NDA, certain weight groups showed a lower drug exposure level than desired. The Company has provided to the FDA additional information on PK modeling to demonstrate that dose adjustments will obtain the desired exposure levels. There were no other safety, clinical pharmacology/biopharmaceutics or CMC issues identified in the CRL. The FDA did cite a small number of protocol deviations in blood draws in one of the studies in the NDA. The Company believes, based on discussions with the FDA, that the Company will not need to conduct any further clinical studies in order to cure the concerns cited in the CRL. In October, we received confirmation that the FDA has agreed to have a Type A meeting for Libervant with us to be held on November 12, 2020. A Type A meeting is granted for candidate drugs on hold to discuss impeding issues and a path forward for approval. At that meeting, we expect to discuss the information submitted in the October meeting package and to seek to confirm the pathway for approval and propose the immediate resubmission of our NDA. If the FDA agrees with our proposal, we plan on resubmitting the NDA before the end of the year. Following resubmission of our NDA for Libervant, the Company plans to request a two-month review period for the NDA from the FDA, as is permissible, but we can provide no assurance that the FDA will grant this request, in which case the resubmitted NDA would be reviewed under the statutory six-month review cycle. The Agency did not include in the CRL any indication regarding approval of U.S. market access for Libervant.

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

- AQST-108, a “first of its kind” oral sublingual film formulation delivering systemic epinephrine that is in development as a rescue medication for the treatment of anaphylaxis using Aquestive’s proprietary PharmFilm technologies. Epinephrine is the standard of care for the treatment of anaphylaxis and is currently administered via subcutaneous or intramuscular injection. The current market leader is EpiPen®, a single-dose, pre-filled automatic injection device. As a result of its administration via subcutaneous or intra-muscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. The data from the previously completed Phase I dose escalation study demonstrated that AQST-108 achieved similar ranges of mean values of maximum concentration (C<sub>max</sub>) and time to reach maximum concentration (T<sub>max</sub>) to that reported for injectables EpiPen and another injection device, Auvi-Q®, provided a greater total exposure (AUC<sub>0-t</sub>; area under the curve) than that reported for EpiPen and Auvi-Q, had less interpatient variability when compared to degree of variation (CV%) data reported for EpiPen and Auvi-Q, and was well tolerated, with no study participants discontinuing participation due to an adverse event. We believe that, as a result of its sublingual administration, AQST-108 will improve patient compliance and lower the total cost of care. After a constructive face-to-face pre-IND meeting with the FDA in early February 2020, the Company submitted an IND for AQST-108, as expected, to the FDA on June 26, 2020 and our IND was subsequently accepted by the FDA on July 23, 2020. The FDA confirmed that the drug candidate will be reviewed under the 505(b)(2) regulatory approval pathway, and that no additional studies will be necessary prior to opening the IND application. We expect that this pathway will provide the means to more expedient and less costly development and filing. We completed enrollment and dosing of 28 healthy volunteers in a Phase 1 pharmacokinetic (PK) trial for AQST-108 in October 2020. The trial features a four-treatment crossover design comparing the pharmacokinetics and pharmacodynamics of AQST-108, 0.3 mg of epinephrine subcutaneous injection (subQ), 0.3 mg of epinephrine intramuscular (IM) injection, and 0.5 mg epinephrine subQ. The study includes secondary endpoints for changes in blood pressure and heart rate.

- AQST-305 is a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin®, is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of efficacy toward the end of the monthly treatment cycle. We are developing AQST-305 as a non-invasive, pain-free alternative to Sandostatin to reduce treatment burden, healthcare costs and the potential loss of efficacy of the treatment cycle. AQST-305 has shown promising preclinical and human proof of concept results. While we focus our efforts on Libervant and AQST-108 this year, limited formulation work is being done to prepare AQST-305 for additional research trials.

The COVID-19 pandemic may adversely impact the expected timelines for our clinical trials and studies and could contribute to delay in obtaining regulatory review and approval for our product candidates.

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 agreement with Indivior to manufacture Suboxone.

In early 2019, certain third-party pharmaceutical companies launched, at risk, generic film products for buprenorphine-naloxone. As of mid-October 2020, Suboxone branded products retain approximately 40% of film market share as generic film-based products have penetrated this market. Indivior accounted for 54% and 83% of our total revenues for the nine-month periods ended September 30, 2020 and 2019, respectively. Our total revenue mix is expected to shift to a higher proportionate share of proprietary product sales in future years as we continue to grow Sympazan revenues and pursue the launch of other products in our pipeline, assuming FDA approvals.

We manufacture all our licensed and proprietary products at our FDA- and DEA-inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 2 billion doses of Suboxone since 2006. Not all collaborative or licensed products of the Company that may be commercially launched in the future will necessarily be manufactured by the Company, such as KYNMOBI™. Our products are developed using our proprietary PharmFilm technology and know-how. The COVID-19 pandemic could negatively impact our continued commercialization of Sympazan, impact demand for our approved products and development and commercialization of other products in our pipeline.

On July 15, 2019, we completed a private placement of \$70,000 of 12.5% Senior Secured Notes due June 2025 (“12.5% Notes”) and warrants for the purchase of up to 2.0 million common shares, against which 428,571 common shares were issued in December 2019 upon exercise. This financing provided net proceeds of \$66,056 after all offering expenses. A portion of the net proceeds of the financing were used to repay all outstanding obligations and early repayment premiums under the Company’s prior credit facility of \$52,944. We used the remaining net cash proceeds of \$13,110 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes. The 12.5% Notes are discussed in Note 13, 12.5% Senior Secured Notes, to our condensed consolidated financial statements included herein and in Liquidity and Capital Resources.

On September 11, 2019, we filed with the SEC a Registration Statement on Form S-3, which was declared effective on September 17, 2019 (File No. 353-233716) (the “S-3 Registration Statement”). Under the S-3 Registration Statement we may sell up to \$150 million of our securities including, without limitation, common stock, preferred stock, warrants, and debt securities. On September 11, 2019, we entered into an equity distribution agreement to offer shares of our common stock from time to time in an “at-the-market” offering. We may offer and sell shares of common stock for an aggregate offering price of \$25.0 million. No shares have been sold pursuant to this “at-the-market” offering as of the date of this report. The equity distribution agreement does not have an expiration date but can be canceled by us at any time for convenience with 10 days written notice. On December 12, 2019, we sold 8,050,000 common shares for gross proceeds of \$40,250 in an underwritten public offering under the S-3 Registration Statement that netted \$37,295 after the underwriter discount and offering costs. The S-3 Registration Statement also covers the resale of up to an additional 4,222,082 shares of our common stock for sale by our stockholders and shares issuable upon the exercise of warrants held by the holders of our Noteholders, of which 428,571 shares were acquired when exercised in December 2019.

On November 3, 2020, we entered into the Monetization Agreement with Marathon, that will result in proceeds to us of up to \$125,000 in exchange for which the Company conveyed to Marathon the right to all royalties and other payments due to us under the Sunovion License Agreement (See Note 6). Under the terms of the Monetization Agreement, we will receive a \$40,000 cash payment within 12 business days of signing and we are eligible to receive up to \$85,000 of contingent payments at various points, beginning as early as the fourth quarter of 2020, based on the achievement of worldwide royalty targets and certain other commercial milestones.

With the upfront proceeds of the monetization, we will repay \$22,500 of the 12.5% Notes, and issue \$4,000 of new senior notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the balance of senior notes outstanding to \$51,500 in the aggregate. In addition, the holders of the 12.5% Notes have extended to December 31, 2021 our ability to access, at our option, \$30,000 of senior notes re-openers under the Indenture. The first \$10,000 senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second \$20,000 senior notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that we access these re-openers, we will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the warrant grant date. In addition, as of the closing of this transaction, the Company will issue to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.

We generated revenues of \$38,700 and \$36,190 for the respective nine-month periods ended September 30, 2020 and 2019. These revenues were derived primarily from manufacture and supply revenues from commercial products licensed to our collaboration or commercialization licensees. Total revenues also included licensing, royalty and co-development and research fees and our proprietary product sales. Our licensing and royalty revenue is subject to the normally uneven nature of the timing of licensing milestone payments and to the product volumes and sales revenues realized by our licensees from which we receive royalties. Suboxone, which was launched in 2010, was our first licensed pharmaceutical product to be commercialized, and we have other licensing relationships that contribute to our revenue and future revenue opportunities. Sympazan, which was launched in December 2018, is the first proprietary pharmaceutical product commercialized directly by the Company. As of September 30, 2020, we had \$17,064 in cash and cash equivalents. As a result of our investments in product development, recent investments in commercialization initiatives, share-based compensation expenses surrounding the 2018 initial public offering, among other expenses and legal and other expenses related to patent procurement, protection and prosecution and other matters, as of September 30, 2020, we had an accumulated deficit of \$165,889 resulting in a net shareholders' deficit of \$36,519 as of that date. For the nine-month periods ended September 30, 2020 and 2019, we incurred net losses of \$35,415 and \$53,610, respectively.

We expect to continue to incur net losses for at least the next few years as we pursue the development, commercialization and marketing of our proprietary product candidates. Our net losses may fluctuate significantly from period to period, depending on regulatory approval developments concerning both our late-stage and earlier stage product candidates, the timing of our planned clinical trials and expenditures on our other research and development, as well as our commercialization activities. We expect our expenses will continue to be substantial in 2020 and future periods over time as we continue to, subject to any delay as a result of the coronavirus pandemic:

- focus on the approval of Libervant for marketing in the U.S. and, subsequently, if approved, which we cannot assure, its commercialization,
- continue clinical development of AQST-108 along the 505(b)(2) pathway, having begun PK clinical trials during the third quarter of 2020, subject to any delay from the coronavirus pandemic, and
- continue to grow Sympazan revenues as a precursor and complement to an eventual launch of Libervant, if approved for U.S. market access.

We expect to continue to manage the timing and level of expenses in light of the declining Suboxone revenues, offset in part by increasing revenue contributions from Sympazan, while focusing on the development and regulatory approvals of Libervant and AQST-108 and their subsequent commercialization, if approved by the FDA for U.S. market access.

Our business has been financed through a combination of revenue from licensed product and proprietary product activities, proceeds from our IPO and other equity issuances and proceeds from our debt instruments and facilities. Significant additional funding is expected to be required in order to execute our business strategy and operations.

Until we become profitable, if ever, we expect to need to raise significant additional capital in the future through equity or debt issuances, or both, and to continue to manage our expenses to extend our capital runway, in order to further the development, regulatory approval, commercialization and marketing of our products and product candidates, and to conduct our business. We have no committed sources of additional capital and there can be no assurance that such needed capital will be available on favorable terms, or at all. We may seek to obtain additional capital in the future through the issuance of our common stock, through other public or private equity or debt financings, through potential non-dilutive capital raising events that may result from royalty streams that may be realizable from our licensed products or licensed intellectual property, and through collaborations or licensing arrangements with other companies or other means, if available. We may not be able to raise additional capital or other funding on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders would experience dilution, and other debt financings, if available (and subject to all of the existing restrictions and conditions under the Indenture for the 12.5% Notes) may involve increased restrictive covenants and increased fixed payments or may otherwise further constrain our financial flexibility. To the extent that we raise additional funds through collaborative or licensing arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position. See "Funding Requirements" below for additional information regarding Aquestive's cash needs.





## **Business Update Regarding COVID-19**

The current COVID-19 pandemic has continued to present substantial health and economic risks, uncertainties and challenges to our business, the U.S. and global economies and financial markets. It is not currently possible to predict how long the pandemic will last or the time it will take for the economy to return to prior levels. The extent to which COVID-19 impacts our business, operations, clinical trials, regulatory approval process, capital, financial and monetization markets, financial results and financial condition, and those of our suppliers, distributors, customers and other third parties necessary to our business including those involved in the regulatory approval process, will depend on future developments, which are highly uncertain and cannot be predicted with certainty or clarity, including the duration and continuing severity of the outbreak, resurgence of the outbreak, continued or additional government actions to contain COVID-19, timing or efficacy of any vaccine, and new information that will emerge concerning the short-term and long-term impact of COVID-19.

To date, we have been able to continue to manufacture and supply our products and currently do not anticipate any significant interruption in supply, although we continue to monitor this situation closely and there is no assurance that disruptions or delays may not occur as a result of COVID-19. We are also monitoring demand for our products, which could be negatively impacted during the COVID-19 pandemic, as well as the financial condition of our customers and licensees, one of whom delayed remittance of certain payments due the Company for development services provided but ultimately made such payments in later Q2 2020.

Our office-based employees have generally been working from home since mid-March 2020, while essential staffing levels in our operations remain on site, and personnel have continued in our laboratories and manufacturing locations. In Q1 2020 we suspended in-person interactions by our sales and marketing personnel and engaged remotely to support our commercialization efforts. Sales and marketing practices continue to evolve in accordance with changing local rules and regulations with predominately virtual interactions with healthcare providers. However, the landscape continues to change as new case rates are rising in certain states and localities and these jurisdictions have or are contemplating reestablishing restrictions.

For additional information on various uncertainties and risks caused by the COVID-19 pandemic, see Part II, Item 1A, Risk Factors included in this report.

### **Critical Accounting Policies and Use of Estimates**

See Note 3, *Summary of Significant Accounting Policies*, to our condensed consolidated financial statements, included herein for a discussion of recently issued accounting pronouncements and their impact or future potential impact on our financial results, if determinable. For a discussion of critical accounting policies that affect our judgments and estimates used in the preparation of our consolidated financial statements, refer to “*Critical Accounting Policies and Use of Estimates*” in our 2019 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 will comply with new or revised accounting standards not 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 contained therein and, as a result, 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, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, or (iii) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation. 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 compared to other issuers, including with respect to disclosure obligations regarding 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 manufactured products made to order for licensees, including Suboxone and Zuplenz, as well as revenue from our self-developed, self-commercialized proprietary product, Sympazan. Revenues are also earned from our product development services provided under contracts with customers, and from arrangements for the licensing of our intellectual property. 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 commercialized pharmaceutical products: Suboxone and Zuplenz. We are the exclusive manufacturer for these products. We manufacture based on receipt of purchase orders from our licensees, and our licensees have an obligation to accept these orders once quality assurance validates compliance of the manufactured product with agreed upon technical specifications. Under ASC 606, we record revenues once the manufactured product passes quality control inspections. Our licensees are responsible for all other aspects of commercialization of these products and the Company has no role, either direct or indirect, in our customers’ commercialization activities, including those related to marketing, pricing, sales and regulatory operations.

We expect future manufacture and supply revenue from licensed products to be based on volume demand for existing licensed products, and for manufacturing and supply rights under license and supply agreements for existing or new agreements for successful product development collaborations.

#### *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*

We may realize licensing revenue from transfers of our licenses. For licenses that do not require further development or other ongoing activities by us, our licensee has acquired the right to use the licensed intellectual property for self-development of their product candidate, for manufacturing, commercialization or other specified purposes upon the effective transfer of those rights, and related revenues are generally recorded at a point in time, subject to contingencies or constraints, if any. For licenses that may provide substantial value only in conjunction with other performance obligations to be provided by us, such as development services or the manufacture of specific products, revenues are generally recorded over the term of the license agreement. 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 have patented technology rights.

#### *Proprietary Product Sales, net*

As we commercialize FDA approved proprietary CNS product candidates, we may directly sell such products to distributors of wholesale medical products in the United States, resulting in an additional and growing source of revenue. We commercialized our first proprietary CNS product, Sympazan, in December 2018. We currently sell Sympazan through wholesalers for distribution through retail pharmacies. Additionally, we may choose to access non-domestic markets by contracting with a collaborator to commercialize our product candidates in certain foreign markets. 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 proprietary product are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and co-pay support redemptions, each of which are described in more detail in our 2019 Annual Report on Form 10-K. 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 records these estimated amounts in connection with 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 require adjustments in the future. The adequacy of these provisions is reviewed on a quarterly basis.

### ***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, medical and clinical affairs administration, 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 primarily incurred from the manufacture of our commercialized licensed pharmaceutical products and for our self-developed, self-commercialized approved proprietary product, including raw materials, direct labor and overhead costs, principally in our Portage, Indiana facilities. Our material costs include the costs of raw materials used in the production of our proprietary dissolving film and primary packaging materials. Direct labor costs consist of payroll costs (including taxes and benefits) of employees engaged in production activities. Overhead costs principally consist of indirect payroll, facilities rent, utilities and depreciation for leasehold improvements and production machinery and equipment. These costs can increase, or decrease based on the costs of materials, purchased at market pricing, and the amount of direct labor required to produce a product, along with the allocation of fixed overhead, which is dependent on production volume.

We expect to continue to seek to rationalize and manage costs to reflect the declining production volumes of Suboxone. Our unit production costs of manufacture and supply increased in late 2019, resulting from the declining volume of Suboxone that began in 2019 and that continues to decline in 2020. We expect our overall manufacture and supply expense levels to decrease over the next several years due to the effects of lower Suboxone volume caused by competing generic products, modestly offset by the costs to manufacture our proprietary products, which began with the launch of Sympazan in December 2018. In addition to our proprietary products coming online, we may add licensed products which may need additional resources to manufacture. If such growth should occur for higher volume product opportunities such as Suboxone, we would incur increased costs associated with hiring additional personnel to support the increased manufacture and supply costs arising from higher manufactured volumes from proprietary and licensed products.

#### *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, including compensation, benefits, share-based compensation and travel expenses;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, investigational sites and consultants, including costs associated with preclinical and clinical activities and regulatory operations;
- the cost of acquiring, developing and manufacturing clinical study materials; and
- costs associated with preclinical and clinical activities and regulatory operations and activities.

We expect our research and development expenses to continue to be significant over the next several years as we continue to seek to obtain U.S. marketing access for our Libervant product candidate and continue to develop existing product candidates such as AQST-108, AQST-305 and others, and we identify and develop or acquire additional product candidates and technologies. We may hire or engage additional skilled colleagues or third parties 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 patent-related and other legal expenses, consulting, tax and accounting services; insurance, selling, market research, advisory board and key opinion leaders, depreciation, and general corporate expenses, inclusive of IT systems related costs.

A significant portion of selling, general and administrative expenses relate to the sales and marketing of our proprietary product, at this time Sympazan. Sympazan is the precursor and compliment to the launch of Libervant, assuming that it is approved and granted U.S. marketing access. We believe there is a very high degree of overlap and correlation between prescribers of Sympazan and the likely prescribers of an approved Libervant. While Sympazan continues to grow, we will continue to rationalize its contribution to move towards profitability while continuing to introduce epilepsy prescribers and patients to Aquestive and PharmFilm technology in advance of the anticipated launch of Libervant. The current commercial organization would begin the launch of Libervant, subject to its approval for U.S. marketing access, which cannot be assured, shortly after its approval. Until any Libervant launch is certain, we do not plan to increase the costs of our commercial organization and will expect to continue to improve the efficiency of the Sympazan commercial investments.

Our general and administrative costs include costs related to accounting, audit, legal, regulatory and tax-related services required to maintain compliance with exchange listing and SEC regulations, director and officer insurance costs, and investor and public relations costs. We continue to incur significant costs in seeking to protect our intellectual property rights, including significant litigation costs in connection with seeking to enforce our rights concerning third parties' at-risk launch of generic products.

We will continue to manage our costs to appropriately reflect the declining Suboxone revenue, the marketing and sales costs related to Sympazan and other external factors affecting our business including the continuing impact of the COVID-19 pandemic, as we continue to focus on our core business:

- Seeking to obtain the approval and subsequent launch of Libervant, subject to approval by the FDA for marketing in the U.S., which cannot be assured.
- Continuing the development of AQST-108 along the 505(b)(2) pathway having begun PK clinical trials during the third quarter of 2020, subject to any delays associated with the coronavirus pandemic; and
- Growing the revenue contribution from Sympazan as a first step to position Aquestive in the epilepsy community.

## *Interest Expense*

Interest expense consists of interest costs at a fixed rate of 12.5%, payable quarterly, related to our currently outstanding debt obligation at the face amount of \$70,000, as well as amortization of related loan costs and the debt discount. The 12.5% Notes are discussed in Note 13, 12.5% Senior Secured Notes, and our planned reduction in the 12.5% Notes, resulting from the KYNMOBI™ royalty monetization, is discussed in Note 19(C), Subsequent Event, to our Consolidated Financial Statements and in Liquidity and Capital Resources. Interest expense has increased based on the additional borrowings under the 12.5% Notes period over period but in the future interest expense is expected to decrease as a result of the November 2020 debt reduction described above.

## *Interest Income*

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

## **Results of Operations**

### ***Comparison of the Three-Month Periods Ended September 30, 2020 and 2019***

We recorded revenue of \$8,260 and \$12,418 during the three-month periods ended September 30, 2020 and 2019, respectively, and incurred net losses of \$16,551 and \$18,412 for those three-month periods.

**Revenues:**

<i>(In thousands, except %)</i>	<b>Three Months Ended</b>		<b>Change</b>	
	<b>September 30,</b>		<b>\$</b>	<b>%</b>
	<b>2020</b>	<b>2019</b>		
Manufacture and supply revenue	\$ 5,903	\$ 9,155	\$ (3,252)	(36%)
License and royalty revenue	328	1,356	(1,028)	(76%)
Co-development and research fees	341	1,073	(732)	(68%)
Proprietary product sales, net	1,688	834	854	102%
<b>Total revenues</b>	<b>\$ 8,260</b>	<b>\$ 12,418</b>	<b>\$ (4,158)</b>	<b>(33%)</b>

For the three-month period ended September 30, 2020, total revenues decreased 33% or \$4,158 to \$8,260 compared to revenues of \$12,418 for the same period in 2019. The change is primarily attributable to decreases in manufacture and supply revenue, license and royalty revenue and co-development and research fees, offset in part by an increase in proprietary product sales, net.

Manufacture and supply revenue decreased 36% or \$3,252 to \$5,903 for the three-month period ended September 30, 2020 compared to \$9,155 recognized during the same period in the prior year. This decrease is attributable to lower volume in 2020 partially offset by increased pricing associated with our Suboxone product affecting the current period. We expect Suboxone to continue to experience market share erosion as generic competition continues to take more market share. We continue to plan for the further erosion of this sunsetting product over time.

License and royalty revenue decreased 76% or \$1,028 to \$328 for the three-month period ended September 30, 2020 compared to revenues of \$1,356 from the prior year period. This change was primarily related to the inclusion of \$1,000 from our 10% share of milestone payments paid to KemPharm during September 2019, under its licensing of KP-415 and KP-484. There were no milestone payments received during the three months ended September 30, 2020 and there is no assurance that any such payments will be made in the future. Royalty revenues earned on Suboxone and Zuplenz remained relatively flat year-over-year. 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 68% or \$732 to \$341 for the three-month period ended September 30, 2020 compared to \$1,073 from the prior year period. The decrease was driven by the timing of the achievement of research and development performance obligations and are normally expected to fluctuate significantly from one reporting period to the next.

Proprietary product sales, net increased 102% or \$854 to \$1,688 for the three-month period ended September 30, 2020 compared to \$834 during the prior year period due to increased Sympazan prescriptions written by CNS physicians and improved payor approval rates.

**Expenses and Other:**

<i>(In thousands, except %)</i>	<b>Three Months Ended</b>		<b>Change</b>	
	<b>September 30,</b>		<b>\$</b>	<b>%</b>
	<b>2020</b>	<b>2019</b>		
Manufacture and supply	\$ 2,978	\$ 4,643	\$ (1,665)	(36%)
Research and development	7,260	5,063	2,197	43%
Selling, general and administrative	11,803	13,714	(1,911)	(14%)
Interest expense	2,778	2,652	126	5%
Interest income	(8)	(138)	(130)	(94%)
Loss on extinguishment of debt	—	4,896	(4,896)	NM

Manufacture and supply costs and expenses decreased 36% or \$1,665 to \$2,978 for the three-month period ended September 30, 2020 compared to \$4,643 for the same period in 2019. The decrease was primarily due to lower volumes of Suboxone in the 2020 period compared to 2019.

Research and development expenses increased 43% or \$2,197 to \$7,260 for the three-month period ended September 30, 2020 compared to \$5,063 recorded during the prior year period. Research and development expenses are driven primarily by the timing of clinical trial and other product development activities associated with the Company's pipeline.

Selling, general and administrative expenses decreased 14% or \$1,911 to \$11,803 for the three-month period ended September 30, 2020 as compared to \$13,714 for the prior year period. The Company continues to tightly manage selling, general and administrative expenses to focus our investments on continued development of our key pipeline products, Libervant and AQST-108, and the continued commercial growth of Sympazan, our first commercialized proprietary product.

Interest expense increased 5% or \$126 to \$2,778 for the three-month period ended September 30, 2020 compared to \$2,652 for the same period in 2019. This was the result of \$20,000 of additional outstanding debt and related higher loan acquisition and discount costs associated with the issuance of the 12.5% Notes on July 15, 2019. Prior to July 15, 2019, our interest expense was subject to fluctuations based on one-month LIBOR under the prior Perceptive Loan and was approximately 12% to 12.5%.

Interest income decreased 94% or \$130 for the three-month period ended September 30, 2020, compared to the prior year period. This decrease is a result of lower interest rates and investing lower net cash balances during 2020 compared to the same period in 2019.

Loss on the extinguishment of debt during the three-month period ended September 30, 2019 represented the expenses incurred to prepay our loans payable to Perceptive Credit Opportunities Fund including the remaining unamortized debt discount and loan acquisition costs and a prepayment premium.

### ***Comparison of the Nine-Month Periods Ended September 30, 2020 and 2019***

We recorded revenue of \$38,700 and \$36,190 during the nine-month periods ended September 30, 2020 and 2019, respectively, and incurred net losses of \$35,415 and \$53,610 for those periods.

#### *Revenues:*

<i>(In thousands, except %)</i>	<b>Nine Months Ended</b>		<b>Change</b>	
	<b>September 30,</b>		<b>\$</b>	<b>%</b>
	<b>2020</b>	<b>2019</b>		
Manufacture and supply revenue	\$ 20,078	\$ 24,739	\$ (4,661)	(19%)
License and royalty revenue	13,682	6,402	7,280	114%
Co-development and research fees	870	2,862	(1,992)	(70%)
Proprietary product sales, net	4,070	2,187	1,883	86%
<b>Total revenues</b>	<b>\$ 38,700</b>	<b>\$ 36,190</b>	<b>\$ 2,510</b>	<b>7%</b>

For the nine-month period ended September 30, 2020, total revenues increased 7% or \$2,510 to \$38,700 compared to revenues of \$36,190 for the same period in 2019. The change is primarily attributable to increases in license and royalty revenue and proprietary product sales revenue for Sympazan, offset in part by decreases in manufacture and supply revenue and in co-development and research fees.

Manufacture and supply revenue decreased 19% or \$4,661 to \$20,078 for the nine-month period ended September 30, 2020 compared to \$24,739 recognized during the prior year period. This decrease is attributable to lower Suboxone volume in 2020 partially offset by increased pricing.

License and royalty revenue increased 114% or \$7,280 to \$13,682 for the nine-month period ended September 30, 2020 compared to revenues of \$6,402 realized during the comparable prior year period. License fees decreased \$1,250 during these periods. The 2020 period included a \$4,000 milestone payment earned upon the FDA approval, in May, and commercial launch in September of Sunovion's KYNMOBI™ product whereas the 2019 period included \$1,000 from our 10% share of milestone payments paid to KemPharm and \$4,250 in license and new patent fees derived from our licensed product Suboxone. In the 2020 period, royalty revenue increased significantly due to \$8,000 of KYNMOBI™ royalties recognized upon the approval of KYNMOBI™ while royalty revenues earned on Suboxone and Zuplenz slightly increased year-over-year. All further license fees due from Indivior related to Suboxone have been suspended pending the outcome of litigation related to infringement claims against the generic products that have launched "at risk."

Co-development and research fees decreased 70% or \$1,992 to \$870 for the nine-month period ended September 30, 2020 compared to \$2,862 during the prior year period. The decrease was driven by the timing of the achievement of research and development performance obligations, which typically fluctuate significantly from one reporting period to the next.

Proprietary product sales, net increased 86% or \$1,883 during the nine-month period ended September 30, 2020 to \$4,070, compared to the same prior year period of \$2,187. Acceptance within medical and patient communities has steadily continued to improve following Sympazan's launch in December 2018.

Expenses and Other:

(In thousands, except %)	Nine Months Ended		Change	
	September 30,		\$	%
	2020	2019		
Manufacture and supply	\$ 10,176	\$ 13,569	\$ (3,393)	(25%)
Research and development	15,461	17,517	(2,056)	(12%)
Selling, general and administrative	40,310	47,868	(7,558)	(16%)
Interest expense	8,296	6,515	1,781	27%
Interest income	(128)	(565)	(437)	(77%)
Loss on extinguishment of debt	—	4,896	(4,896)	NM

Manufacture and supply costs and expenses decreased 25% or \$3,393 to \$10,176 for the nine-month period ended September 30, 2020 compared to \$13,569 for the same period in 2019. The decrease primarily reflected lower volumes of Suboxone in the 2020 period compared to 2019.

Research and development expenses decreased 12% or \$2,056 to \$15,461 for the nine-month period ended September 30, 2020 compared to \$17,517 for the same prior year period. Research and development expenses are driven primarily by the timing of clinical trial and other product development activities associated with the Company's pipeline.

Selling, general and administrative expenses decreased 16% or \$7,558 to \$40,310 for the nine-month period ended September 30, 2020 compared to \$47,868 for the same prior year period. The decrease was driven by careful and prudent management of expenses primarily in sales and marketing as well as factory overhead costs.

Interest expense increased 27% or \$1,781 to \$8,296 for the nine-month period ended September 30, 2020 compared to \$6,515 for the same period in 2019, primarily from higher debt balances starting in the third quarter 2019. Prior to July 15, 2019, our interest expense was subject to fluctuations based on one-month LIBOR. Our 12.5% Senior Secured Notes carry a 12.5% fixed interest rate per annum, with an increased principal amount outstanding thereunder.

Interest income decreased 77% or \$437 for the nine-month period ended September 30, 2020, compared to the same prior year period. This decrease is a result of lower interest rates and investing lower net cash balances during 2020 compared to the same period in 2019.

Loss on the extinguishment of debt during the three months ended September 30, 2019 represented the expenses incurred to prepay our loans payable to Perceptive Credit Opportunities Fund including the remaining unamortized debt discount and loan acquisition costs and a prepayment premium.

## Liquidity and Capital Resources

### Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and as of September 30, 2020, we have a net stockholders' deficit of \$36,519. We have funded our operations primarily with equity and debt financings, with gross margins from sales of commercialized licensed and proprietary products, and with license fees, milestone and royalty payments from our commercial partners and co-development licensees. We had \$17,064 in cash and cash equivalents as of September 30, 2020 and working capital of \$13,311.

On November 3, 2020, we entered into the Monetization Agreement with Marathon, that will result in proceeds to us of up to \$125,000 in exchange for which we conveyed to Marathon the right to all royalties and other payments due to us under the Sunovion License Agreement (See Note 6). Under the terms of the Monetization Agreement, we will receive a \$40,000 cash payment within 12 business days of signing the Monetization Agreement and we are eligible to receive up to \$85,000 of contingent payments at various points, beginning as early as the fourth quarter of 2020, based on the achievement of worldwide royalty targets and certain other commercial milestones.

With the upfront proceeds paid to the Company under the Monetization Agreement, we will repay \$22,500 of the 12.5% Notes, and issue \$4,000 of new senior notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the balance of senior notes outstanding to \$51,500 in the aggregate. In addition, the holders of the 12.5% Notes have extended to December 31, 2021 our ability to access, at our option, \$30,000 of senior notes re-openers under the Indenture. The first \$10,000 senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second \$20,000 senior notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that we access these re-openers, we will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the warrant grant date. In addition, as of the closing of this transaction, the Company will issue to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.





We generate revenue from licensed products and proprietary product sales, certain product development and licensing agreements and related activities. We have invested the margins from product sales and our other revenue sources, as well as proceeds from debt and equity securities in the development of those marketed products as well as development of our proprietary CNS and complex molecule pipeline and in development and growth of our growing patent portfolio. We also invested those financial resources in the protection and prosecution of those patents, in developing the commercialization aspects of our organization, in bringing our first self-developed CNS product to market and in developing our organization from private ownership to publicly owned status. The costs of these initiatives and concurrent growth, along with interest expenses and other costs of funding resulted in the \$165,889 deficit we have accumulated from inception.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security (CARES) Act was signed into law as the pandemic continued to affect our nation's economy. Among the significant goals of the CARES Act was to provide increased liquidity for businesses through deferral of employer payroll taxes, a tax credit for retaining employees and other provisions. We currently expect to benefit from the provision to defer the payment of certain employer payroll taxes of approximately \$0.5 million for calendar year 2020, of which approximately \$0.3 million has been deferred as of September 30, 2020. It is currently expected that half of these deferrals will become due at each of December 31, 2021 and December 31, 2022, respectively.

## Cash Flows

### Nine-Month Periods Ended September 30, 2020 and 2019

(in thousands)

	2020	2019
Net cash (used for) operating activities	\$ (31,947)	\$ (49,635)
Net cash (used for) investing activities	(281)	(577)
Net cash (used for)/provided by financing activities	(34)	10,527
Net decrease in cash and cash equivalents	<u>\$ (32,262)</u>	<u>\$ (39,685)</u>

### Net Cash (Used for) Operating Activities

Net cash used for operating activities for the nine-month period ended September 30, 2020 was \$31,947. The use of cash can be understood as represented by three major factors: (1) our net loss of \$35,415, (2) incremented by a net decrease in operating assets and liabilities of \$5,713 partially offset by (3) non-cash operating expenses. The non-cash operating expenses of \$9,181 primarily resulted from \$5,052 of share-based compensation expense recorded in the nine months ended September 30, 2020. Other significant components included non-cash charges of \$4,129 related to depreciation and amortization of debt issuance costs.

Net cash used for operating activities for the nine-month period ended September 30, 2019 was \$49,635. The use of cash is attributable to: (1) our net loss of \$53,610, (2) a net decrease in operating assets and liabilities of \$9,822 partially offset by (3) non-cash operating expenses. The non-cash operating expenses of \$13,797 primarily resulted from \$5,199 of share-based compensation expense and a \$4,896 loss on early extinguishment of our debt to Perceptive Credit Opportunities Fund recorded during this period. Other significant components included non-cash charges of \$3,702 related to fixed asset depreciation and amortization of debt issuance costs.

Cash used by operations improved in 2020 compared to 2019 comparable periods due to management of costs and expenses in 2020 to focus on key priorities as discussed above.

### Net Cash (Used for) Investing Activities

Net cash used for investing activities was \$281 for the nine-month period ended September 30, 2020 compared to \$577 for the comparative prior year period.

## ***Net Cash (Used for)/Provided by Financing Activities***

Net cash used for financing activities was \$34 for the nine-month period ended September 30, 2020 compared to \$10,527 net cash provided during the corresponding period in 2019. The cash used in 2020 is a result of payment for withholding taxes on share-based compensation offset, in part, by proceeds received from employees participating in the Company's Employee Stock Purchase Plan. The cash provided in 2019 results primarily from the excess of proceeds received from the issuance of the 12.5% Notes, described below, of \$70,000 over cash used for the repayment of the \$50,000 loan principal repaid to Perceptive, a related early repayment premium of \$2,944 and \$3,918 of loan acquisition costs associated with the 12.5% Notes. We also paid \$2,723 for withholding taxes associated with tax reimbursements connected to certain share-based compensation incurred in 2018.

### ***12.5% Senior Secured Notes***

On July 15, 2019 we issued \$70,000 aggregate principal amount of the 12.5% Notes and Warrants under the Indenture for the 12.5% Notes ("Indenture"). In addition, the Indenture provides opportunity to issue up to \$30,000 of additional 12.5% Notes under certain conditions for a total possible issuance amount of \$100,000. Also, in July 2019, in connection with our issuance of the 12.5% Notes we repaid all outstanding amounts due under the Loan Agreement with Perceptive Credit Opportunities Fund dated August 16, 2016.

The net proceeds from the issuance of the 12.5% Notes was \$66,054, after deducting expenses of the transaction. We used a portion of the net proceeds to repay an aggregate amount of \$52,092 of existing Perceptive indebtedness, comprised of the outstanding principal amount, all accrued and unpaid interest and applicable prepayment and end-of-term fees, owed to Perceptive under the Credit Agreement and Guaranty (described below). We used the remaining net cash proceeds of approximately \$13,110 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes.

The additional 12.5% Notes can be issued if we satisfy certain conditions and achieve certain milestones related to the filing and approval of our epilepsy product candidate, Libervant, and there are available purchasers for the additional 12.5% Notes. Specifically, on or prior to March 31, 2021, we may issue an additional \$10,000 aggregate principal amount of the 12.5% Notes if we filed a new drug application for our candidate Libervant with the FDA prior to that date, provided we have obtained the written consent of the holders of a majority in aggregate principal amount outstanding under the 12.5% Notes in their discretion, which cannot be assured (first reopener) and, on or prior to March 31, 2021, up to an additional \$30,000 (less the amount of any first reopener additional 12.5% Notes issued by us) if the Company obtains FDA approval of Libervant for U.S. market access prior to that date. There can be no assurance that FDA approval will be granted or that such additional financing will be consummated.

Interest on the 12.5% Notes accrues at a rate of 12.5% per annum and is payable quarterly in arrears on March 30<sup>th</sup>, June 30<sup>th</sup>, September 30<sup>th</sup> and December 30<sup>th</sup> 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 12.5% Notes pursuant to a fixed amortization schedule. The stated maturity date of the 12.5% Note is June 30, 2025.

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

Under the original terms of the Indenture, we have the right to monetize our royalty and milestone interests derived from an IP licensing agreement with Sunovion Pharmaceuticals Inc. in its recently launched apomorphine-based product, KYNMOBI™. Upon any such monetization we are required to offer to purchase each holder's 12.5% Notes on a pro rata basis at a repurchase price in cash equal to 112.5% of the principal amount of such 12.5% Notes, plus accrued interest and unpaid interest, if any, thereon to the repurchase 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 12.5% Notes repurchased will be at the discretion of the holders of the 12.5% Notes. See Note 13, 12.5% Senior Secured Notes, to our Condensed Consolidated Financial Statements. To the extent that the holders of the Notes do not elect repayment of the debt in connection with any such monetization, the amount not elected up to \$40 million (or \$50 million if the first reopener has been funded) is required to be held in a collateral account until Libervant is approved by the FDA for U.S. market access. Certain aspects of this Indenture were modified in November 2020, as outlined below.

The Indenture permits us, upon the continuing satisfaction of certain conditions, including that we 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 ("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.

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

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

In connection with this financing, we issued Warrants to the initial holders of the 12.5% Notes. These Warrants provide rights to purchase up to an aggregate of 2,000,000 shares of common stock at a price of \$4.25 per Warrant. Warrants for 428,571 of common shares were exercised in December 2019 generating proceeds of \$1,829. The Company registered the Warrants and associated shares as part of our S-3 Registration Statement. There were no Warrants exercised in the nine-month period ended September 30, 2020.

With the upfront net proceeds paid under the Monetization Agreement, we will repay \$22,500 of the 12.5% Notes, and issue \$4,000 of new senior notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the senior notes outstanding to \$51,500 in the aggregate. In addition, the holders of the 12.5% Notes have extended to December 31, 2021 our ability to access, at our option, \$30,000 of senior notes re-openers under the Indenture. The first \$10,000 senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second \$20,000 senior notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access, which cannot be assured. If and to the extent that we access these re-openers, we will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the time warrant grant date. In addition, as of the closing of this transaction, the Company will issue to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.

### ***Equity Offering***

Our current cash balance is also incremented as a result of the December 17, 2019 completion of an equity offering of 8,050,000 shares of common stock pursuant to our S-3 Registration Statement, including exercise of the underwriter’s over-allotment option, resulting in gross proceeds of approximately \$40,250 before underwriter discounts and other costs and expenses. Net proceeds were \$37,835.

### ***Future Capital Requirements***

We believe that our existing cash and cash equivalents combined with ultimate and timely realization of expected recurring revenue streams and proceeds from potential debt or equity transactions will be adequate to fund our expected operating and capital costs and to service our debt costs for the next 12 months. We have based this expectation on an operating plan and related assumptions that depend on various forward-looking factors that could change, or prove to be inaccurate, and additionally, we could utilize our available financial resources sooner than we currently expect. Our existing cash resources are not alone sufficient to fund our expected development, commercialization and other operations and activities, and we expect to continue to require external sources of funding and capital to develop and seek regulatory approval of our product candidates and for the commercialization of our approved products. Key factors and assumptions inherent in our planned continued operations and anticipated growth include, without limitation, those related to the following:

- the effects of the COVID-19 pandemic on our operations, operations of our key suppliers and third-party clinical and other service providers, our employees and contractors and debt, equity and other capital markets;
- continued ability of our customers to pay, in a timely manner, for presently contracted and future anticipated orders for our manufactured goods, Suboxone and Sympazan, including effects of generics and other competitive pressures as currently envisioned;
- continued ability of our customers to pay, in a timely manner, for presently contracted and future anticipated orders for provided co-development and feasibility services, as well as regulatory support services for recently licensed products, such as Exservan;
- access to debt or equity capital markets if, and at the time, needed for any necessary future funding;

- FDA approval of our key new drug candidate, Libervant, for U.S. market access. We submitted the NDA filing for Libervant in the fourth quarter of 2019 and received a PDUFA date of September 27, 2020. We received a Complete Response Letter on September 25, 2020 denying approval of the NDA in its current form. We are planning to resubmit the NDA to the FDA and to seek to demonstrate that Libervant is “clinically superior” as a major contribution to patient care to gain U.S. market access. There can be no assurance that we will obtain approval of Libervant for U.S. market access;
- our ability to issue additional lender committed debt in an aggregate amount of \$10,000 of additional 12.5% Notes, which is contingent upon FDA product approval of Libervant, noted above;
- our ability to issue additional marketable debt in an aggregate amount of up to \$20,000 of additional 12.5% Notes, which is contingent upon FDA product approval of Libervant for U.S. market access, noted above;
- continuing review and appropriate adjustment of our cost structure consistent with our anticipated revenues and funding;
- continued growth and market penetration of Sympazan within expected commercialization cost levels for this product, including anticipated patient and physician acceptance and our ability to obtain adequate price and payment support from government agencies and other private medical insurers;
- effective commercialization within anticipated cost levels and expected ramp-up timeframes of our product candidate Libervant, if approved for U.S. market access by the FDA;
- infrastructure and administrative costs at expected levels to support operations as an FDA and highly regulated public company;
- a manageable level of costs for ongoing efforts to protect our intellectual property rights, including litigation costs in connection with seeking to enforce our rights concerning third parties’ at-risk launch of generic products;
- continued compliance with all covenants under our 12.5% Notes; and
- absence of significant unforeseen cash requirements.

We expect to continue to manage business costs to appropriately reflect the declining state of Suboxone revenues, the marketing and sales costs related to Sympazan, the proceeds from any KYNMOBI™ monetization and other external resources or factors affecting our business including, if available, any future potential issuances of additional 12.5% Notes under the Indenture, net proceeds of future equity financing, or other future access to the capital markets under our shelf registration statement filed with the SEC and effective September 17, 2019 or other potential available sources of liquidity, as well as the uncertainties associated with the coronavirus pandemic. In doing so, we plan to continue to focus on the core drivers of value for our stockholders, including, most importantly continued investments in our ongoing product development and planned commercialization activities in support of Libervant and AQST-108. Until profitability is achieved, if at all, additional capital and/or other financing or funding will be required, which could be material, to further advance the development and commercialization of Libervant and AQST-108, if approved by the FDA for U.S. market access, both of which are subject to regulatory approval, and to meet our other cash requirements, including debt service. We plan to conservatively manage our pre-launch spending as to both timing and level relating to Libervant, including cost rationalization associated with marketing and selling Sympazan. In this regard, absent spending on launch activities for Libervant, we expect to spend less on commercialization in 2020 compared to 2019. Even as such, we expect to continue to incur losses and negative cash flows and therefore we expect to be dependent upon external financing and funding to achieve our operating plan.

On November 3, 2020, we entered into the Monetization Agreement with Marathon, that will result in proceeds to us of up to \$125,000 in exchange for which we conveyed to Marathon the right to all royalties and other payments due to us under the Sunovion License Agreement (See Note 6). Under the terms of the Monetization Agreement, we will receive a \$40,000 cash payment within 12 business days of signing and we are eligible to receive up to \$85,000 of contingent payments at various points, beginning as early as the fourth quarter of 2020, based on the achievement of worldwide royalty targets and certain other commercial milestones.

With the upfront proceeds paid to the Company under the Monetization Agreement, we will repay \$22,500 of the 12.5% Notes, and issue \$4,000 of new senior notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, bringing senior notes outstanding down to \$51,500 in the aggregate. In addition, the holders of the 12.5% Notes have extended to December 31, 2021 our ability to access, at our option, \$30,000 of senior notes re-openers under the Indenture. The first \$10,000 senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second \$20,000 senior notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access, which cannot be assured. If and to the extent that we access these re-openers, we will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the warrant grant date. In addition, as of the closing of this transaction, the Company will issue to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.

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

To the extent we raise additional funds by issuance of equity securities, our stockholders would experience further dilution and the terms of these securities could include liquidation or other preferences (if and to the extent permitted under the Indenture) that would adversely affect our stockholders' rights. Our ability to secure additional equity financing could be significantly impacted by numerous factors including our operating performance and prospects, positive or negative developments in the regulatory approval process for our proprietary products, timely achievement of regulatory approval of our late-stage proprietary products, our existing level of debt which is secured by substantially all our assets, restriction under the Indenture, and general market conditions, and there can be no assurance that we will continue to be successful in raising capital or that any such needed financing will be available, available on favorable or acceptable terms or at the times or in the amounts needed. Additionally, while the potential economic impact brought on by and the duration of the coronavirus pandemic is difficult to assess or predict, the significant impact of the coronavirus pandemic on the global financial markets, and on our own stock trading price, may reduce our ability to access additional capital, which would negatively impact our short-term and longer-term liquidity.

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

See also Part II, Item 1A, Risk Factors below concerning the significant risks and uncertainties concerning the Company's business, operations, financial results and capital resources associated with the impact of the global coronavirus pandemic.

### **Off-Balance Sheet Arrangements**

During the period presented, we did not have any material off balance sheet arrangements, nor do we have any relationships with unconsolidated entities or financial partnerships, such as entries often referred to as structured finance or special purpose entities.

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

Prior to July 15, 2019, our exposure to market risk due to changes in interest rates related primarily to the increase or decrease in the amount of interest expense from fluctuations in one-month LIBOR associated with our debt facility. For each 1% increase in one-month LIBOR in excess of the floor of 2%, our annual interest expense would have increased by approximately \$500,000. However, our 12.5% Notes carry a 12.5% fixed interest rate per annum, thereby eliminating market risk due to changes in interest rates. Our cash and cash equivalents are maintained in FDIC protected accounts with no exposure to material changes in interest rates. At September 30, 2020, our interest rate on deposited cash was 0.18%. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes. Further, we do not invest in any common stock or debt instruments that have been affected by the global COVID-19 outbreak which has resulted in material market movements during the quarter ended September 30, 2020.

Our accounts receivables have historically been concentrated with Indivior and, as of September 30, 2020, includes significant amounts due from Sunovion for contractually specified minimum annual royalties. In addition, beginning with the launch of Sympazan in 2018, our receivables concentrations with three large national wholesalers of pharmaceutical products has been growing and now, taken together, comprise approximately 28% of gross receivables. These receivables for our proprietary product may become increasingly significant in future periods should Sympazan sales increase and should other pipeline products become approved by the FDA and become distributed through these three regional, or other, wholesalers, as anticipated. In the event of non-performance or non-payment by any of Indivior, Sunovion or said wholesalers, there may be a material adverse impact on our financial condition, results of operations or net cash flow.

**Item 4. Controls and Procedures.**

*Management's Evaluation of our Disclosure Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to our management, including to our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2020, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(b) and 13a-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

*Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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 abbreviated new drug application (“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 United States District Court for the District of Delaware (the “Delaware District Court”). 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 products.
- 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 Patent No. 6,603,514, or the '514 patent, and cannot enter the market until the expiration of the patent in 2024, and the United States Court of Appeals for the Federal Circuit ("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 Delaware District Court case against DRL and Alvogen. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The remaining case against Actavis was dismissed in light of the infringement ruling above, which prevents Actavis from entering the market until 2024. The case(s) against the remaining defendants regarding the additional asserted patents have not been finally resolved. A *Markman* hearing in the cases against Dr. Reddy's and Alvogen, which is pending in the United States District Court for the District of New Jersey (the "New Jersey District Court"), was held on October 17, 2019. On November 5, 2019, District Judge McNulty of the New Jersey District Court issued a *Markman* opinion construing the disputed terms of the asserted patents. On January 9, 2020, the New Jersey District Court entered a stipulated order of non-infringement of one of the patents, Patent No. 9,931,305, or the '305 patent, based on the Federal Circuit Court's claim construction ruling, and we and Indivior preserved our rights to appeal the claim construction ruling. On November 19, 2019, Magistrate Judge Waldor of the New Jersey District Court issued an order granting DRL and Alvogen's requests to file amended answers to add antitrust counterclaims against us and Indivior. We and Indivior appealed the Magistrate Judge's decision to District Judge McNulty on December 4, 2019, and DRL and Alvogen opposed the appeal. On January 17, 2020, we filed a motion to dismiss DRL's and Alvogen's antitrust counterclaims for failure to state a claim and DRL and Alvogen opposed the motion. On August 24, 2020, Judge McNulty issued an Opinion and Order denying both the appeal of the Magistrate's decision and our Motion to Dismiss. On June 3, 2020, the court issued an order setting a schedule for ongoing fact discovery, expert discovery, and dispositive motions. The schedule currently sets the close of fact discovery for October 20, 2020, with expert discovery continuing through the end of April 2021. The schedule also sets the deadline for filing dispositive motions for May 18, 2021. No trial date has been set in those cases. 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 losses, if any, in this matter.

On February 19, 2019, the Federal Circuit issued its mandate reversing the District of New Jersey's preliminary injunction against Dr. Reddy's. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both Dr. Reddy's and Alvogen. Dr. Reddy's, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by Dr. Reddy's and Alvogen are "at risk" because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, we and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. in the United States District Court for the Southern District of Florida (the "Southern District of Florida Court") for infringement of the Company's U.S. Patents Nos. 8,017,150, 9,687,454, the '514 patent and the '305 patent, seeking an injunction and potential monetary damages. Following a negotiated settlement between all parties, on December 3, 2019, the parties submitted a Notice of Settlement and a Joint Motion to Approve Consent Judgment. The Southern District of Florida Court entered an order dismissing the suit on December 18, 2019.

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

- 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, 8,652,378 and 8,475,832. This case is stayed.
- The second was filed by us and Indivior related to BDSI's infringing Bunavail product, and alleges infringement of our patent, U.S. Patent No. 8,765,167, or the '167 patent, and seeks an injunction and potential monetary damages. Shortly after the case was filed, BDSI filed four (4) IPR's challenging the asserted '167 patent. On March 24, 2016, the United States Patent Trial and Appeal Board (PTAB), issued a final written decision finding that all claims of the '167 patent were valid. The case was stayed in May 2016 pending the final determination of the appeals on those decisions. Following the PTAB's February 7, 2019 decisions on remand denying institution, we and Indivior submitted a notice to the Court on February 15, 2019 notifying the Court that the stay should be lifted as result of the PTAB's decisions. We are awaiting further action from the Court.



- On January 13, 2017, we also sued BDSI asserting infringement of the '167 patent by BDSI's Belbuca product and seeking an injunction and potential monetary damages. On August 7, 2019, the Eastern District of North Carolina Court granted BDSI's motion to dismiss the Complaint without prejudice and denied BDSI's motion to stay as moot. On November 11, 2019, we filed a new Complaint against BDSI in the Eastern District of North Carolina Court. On November 27, 2019, BDSI filed a motion to stay the case pending BDSI's appeal of the PTAB's remand decisions, and we opposed the motion. The Eastern District of North Carolina Court denied BDSI's motion to stay on April 1, 2020. BDSI's appeal of the PTAB's remand decisions to the United States Court of Appeals for the Federal Circuit was docketed on March 13, 2019, and on March 20, 2019, we moved to dismiss the appeal for lack of jurisdiction. On August 29, 2019, the Federal Circuit granted the motion to dismiss BDSI's appeal. On September 30, 2019, BDSI filed a petition for rehearing in the Federal Circuit *en banc*, which we opposed. The Federal Circuit denied BDSI's petition for rehearing *en banc* on January 13, 2020. On June 11, 2020, BDSI filed a petition for writ of certiorari at the Supreme Court of the United States. At the request of the Supreme Court, we filed an opposition to BDSI's petition on August 17, 2020, and BDSI filed a reply on August 27, 2010. On October 5, 2020, the Supreme Court issued an order denying BDSI's petition. After the Federal Circuit denied BDSI's petition, on January 13, 2020, BDSI filed with the Eastern District of North Carolina Court a motion to dismiss the Complaint, and we opposed the motion on February 2, 2020. The Eastern District of North Carolina Court denied BDSI's motion to dismiss and its motion to stay on April 1, 2020. On April 16, 2020, BDSI filed an Answer to the Complaint, including counterclaims for non-infringement, invalidity, and unenforceability of the '167 patent. On May 7, 2020, Aquestive filed a motion to dismiss BDSI's unenforceability counterclaim and a motion to strike BDSI's corresponding affirmative defenses for failure to state a claim for inequitable conduct under the heightened pleading standard applicable to such claims and defenses. Rather than oppose Aquestive's Motion to Dismiss, on May 28, 2020, BDSI amended its counterclaims and filed an Answer and Amended Counterclaims, which included additional allegations in support of BDSI's unenforceability counterclaim. On June 25, 2020, Aquestive filed a Motion to Dismiss BDSI's Amended Counterclaim for unenforceability and a Motion to Strike BDSI's corresponding affirmative defense of unenforceability again for failure to state a claim under the applicable heightened pleading standard. BDSI's filed its opposition to Aquestive's Motion to Dismiss and Strike on July 16, 2020. Aquestive filed its Reply to BDSI's Opposition on July 30, 2020. The parties are awaiting further action from the court on Aquestive's motion.

### ***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 suit, the case was consolidated for pre-trial purposes with the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we participated in an antitrust conspiracy with Indivior in connection with Indivior's launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. We moved to dismiss the States' conspiracy claims, but by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States' claims on November 20, 2017. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions were conducted through August 1, 2019. The remainder of the case schedule, including summary judgment briefing, is stayed pending resolution of Indivior's appeal of the District Court's class certification ruling in a co-pending multi-district litigation to which we are not a party. On July 28, 2020, the U.S. Court of Appeals for the Third Circuit issued its opinion affirming the District Court's order certifying the class. On August 27, 2020, the district court issued a scheduling order, setting the deadline for filing remaining *Daubert* challenges and summary judgment. Under the scheduling order, the remaining *Daubert* motions were filed on September 28, 2020, and oppositions are due on October 19, 2020. The court will set oral argument on the motions, but the date for oral argument is not yet known. Summary judgment motions are due January 11, 2021, and responses to summary judgment motions are due February 11, 2021. No trial date has yet been set. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimate, of the possible outcome or loss, if any, in this matter.

### ***Humana and Centene Actions***

On September 18, 2020, Humana, Inc., a health insurance payer, filed a suit against Aquestive and Indivior in the Eastern District of Pennsylvania relating to Suboxone. The Humana action, which alleges facts similar to those at issue in the Antitrust Case and the Suboxone MDL described above, was assigned to the same judge that is presiding over those actions. Humana's Complaint alleges five causes of action against Aquestive, including conspiracy to violate the RICO Act, fraud under state law, unfair and deceptive trade practices under state law, insurance fraud, and unjust enrichment. On September 21, 2020, Centene Corporation and other related insurance payers filed a similar suit against Aquestive and Indivior in the Eastern District of Missouri. The counsel representing Humana is also representing Centene. On September 21, 2020, the Centene action was provisionally transferred to the Eastern District of Pennsylvania by the United States Judicial Panel on Multidistrict Litigation. No other proceedings have occurred, and the schedule is not yet known. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimate, of the possible outcome or loss, if any, in this matter.

## California Complaint

On December 5, 2019, Neurelis Inc. (“Neurelis”) filed a complaint against Aquestive in the Superior Court of California, County of San Diego alleging Unfair Competition, Defamation, and Malicious Prosecution related to the Company’s pursuit of FDA approval for Libervant. Neurelis filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. The Company filed a Motion to Strike Neurelis’s Complaint under California’s anti-SLAPP (“strategic lawsuit against public participation”) statute on January 31, 2020, which Neurelis is expected to oppose. Neurelis filed a motion for leave to file a Supplemental Complaint on February 5, 2020, which we will oppose. On February 5, 2020, Neurelis filed a Motion for Leave to File a Supplemental Complaint (“Motion”). On June 5, 2020, Neurelis filed a Motion for Limited Discovery related to Aquestive’s anti-SLAPP motion.

The court previously scheduled a hearing on both Aquestive’s anti-SLAPP Motion and on Neurelis’s Motion for April 24, 2020. However, on April 3, 2020, in response to the COVID-19 pandemic, the court issued an order continuing all hearings scheduled through April 30, 2020. The court held ultimately a telephonic status conference on June 25, 2020 to determine a schedule for hearing the pending motions. During that status conference, the court set Aquestive’s anti-SLAPP motion for hearing on July 24, 2020. The court also declined Neurelis’s request to hear its Motion and its Motion for Limited Discovery. Neurelis filed its response to Aquestive’s anti-SLAPP Motion on July 13, 2020, and we filed our reply on July 17, 2020. The court held a telephonic hearing on Aquestive’s anti-SLAPP motion on July 24, 2020. On August 6, 2020, the Court issued an order granting in part and denying in part Aquestive’s anti-SLAPP motion. Aquestive filed a notice of appeal to the California Court of Appeal on September 1, 2020, and Neurelis filed a notice of cross-appeal on October 5, 2020. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimate, of the possible outcome or loss, if any, in this matter.

### Item 1A. Risk Factors

In light of continuing developments relating to the COVID-19 global pandemic, the Company is supplementing the risk factors previously disclosed in Item 1A of its 2019 Annual Report on Form 10-K to include the following risk factor under the heading “Risks Related to our Business Operations and Industry”:

#### ***Our business may be adversely affected by the ongoing coronavirus pandemic.***

Beginning in late 2019, the outbreak of COVID-19, has evolved into a global pandemic. Depending upon the length and severity of the pandemic or any resurgence, which cannot be predicted, we may experience disruptions that could materially and adversely impact our business including:

- Various aspects of our clinical trials, including delays or difficulties in enrolling patients in our clinical trials, in clinical trial site initiation, and in recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from clinical trials; diversion of healthcare resources away from the conduct of clinical trials; interruption of key clinical trial activities such as clinical trials site data monitoring due to limitations on travel imposed or recommended by federal or state governments; impact on employees and others or interruption of clinical trial visits or study procedures which may impact the integrity of subject data and clinical study endpoints; and interruption or delays in the operations of the U.S. FDA, and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines.
- If any third-party in our supply chain for any materials, including active pharmaceutical ingredients and other raw materials supply, which we need for our product candidates for our clinical trials and for the approved products we manufacture and distribute, are adversely impacted by restrictions resulting from the coronavirus pandemic, including staffing shortages, production slowdowns, or disruptions in freight and other transportation services and delivery distribution systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials, conduct our research, development and clinical operations, and manufacture, distribute and sell our approved products.
- We have closed our business office and requested most of our colleagues located there to work from home, restricted full-time on-site staff generally to those colleagues who must perform essential activities on-site and implemented staggered schedules for full-time on-site staff in our research and development laboratory in order to reduce risk of transmission. Our increased reliance on colleagues and other third parties on whom we rely working from home or having health issues may negatively impact productivity and has limited our in-person commercialization activities for our existing approved proprietary product and would limit commercial launch activities for any new approved product, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. Our colleagues conducting research and development activities might not be able to access our laboratory or manufacturing facilities for an extended period of time as a result of any further closure of our facilities as well as the possibility of further governmental restrictions. As a result, this could delay timely completion of pre-clinical activities, including completing Investigational New Drug (IND)/Clinical Trial Application (CTA) enabling studies or our ability to select future development candidates, and initiation of clinical or other of our development programs and production and delivery of our products.

- The FDA and comparable foreign regulatory agencies may experience disruptions, have slower response times or be under-resourced to continue to monitor our clinical trials or to conduct required activities and review of our product candidates seeking regulatory review and such disruptions could materially affect the development, timing and approval of our product candidates.
- The coronavirus pandemic may impact the requirements of our customers and growth of our approved products. For example, Indivior, our significant customer for Suboxone, had announced that it anticipated coronavirus impact on its product sales. Further, sales force expansion may not be as productive during a time when a significant number of interactions are virtual and such interactions may not be as effective as face-to-face interactions. Additionally, an increasing number of patient visits to their Healthcare Professionals have been virtual during the coronavirus pandemic which may reduce the likelihood that a change in medicine would occur which could impact Sympazan growth. We cannot accurately predict the adverse impact the coronavirus pandemic will have on orders of our approved products Suboxone and Sympazan. We also have experienced in one instance, and could in the future experience, extended customer payment cycles.
- As a result of concerns caused by the continuing effects of the coronavirus, we may face issues and investor concerns in raising capital through sales of our common stock or other securities, or in seeking to monetize our licensed royalty and milestone rights. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect the financial markets, our business, the value of our common stock and our ability to obtain on favorable terms, or at all, equity or debt financing or any potential monetization of our royalty streams.

The coronavirus pandemic continues to rapidly evolve. The ultimate impact of the coronavirus pandemic on us is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, the manufacturing, marketing, distribution and sale of our approved products, the healthcare system or the global economy. Given the uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

Please also refer to the complete Item 1A of the Company's 2019 Annual Report on Form 10-K for additional risks and uncertainties facing the Company, any of which risks and uncertainties may be further heightened by the coronavirus pandemic and have a material adverse effect on the Company's business prospects, financial condition, results of operations, liquidity and available capital resources.

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

None.

**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.

<b>Number</b>	<b>Description</b>
<a href="#">31.1</a>	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).
<a href="#">31.2</a>	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).
<a href="#">32.1</a>	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
<a href="#">32.2</a>	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document
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

\*Portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K. The omitted information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

## SIGNATURES

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

Aquestive Therapeutics, Inc.  
(REGISTRANT)

Date: November 4, 2020

/s/ Keith J. Kendall

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

Date: November 4, 2020

/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: November 4, 2020

/s/ KEITH J. KENDALL

Keith J. Kendall

*President and 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: November 4, 2020

/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, President and Chief Executive Officer of Aquestive Therapeutics, Inc. (the “Company”), hereby certify that, to the best of my knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2020, to which this Certification is attached as Exhibit 32.1 (the “Quarterly Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Dated: November 4, 2020

/s/ KEITH J. KENDALL

Keith J. Kendall

*President and 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 September 30, 2020, to which this Certification is attached as Exhibit 32.2 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Quarterly Report and the results of operations of the Company for the period covered by the Quarterly Report.

Dated: November 4, 2020

/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.

---