## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **FORM 10-Q**

| <b>QUARTERLY REPORT PURS</b> OF 1934  | UANT TO SECT                                       | ION 13 OR 15(d) OF THE SECU                          | JRITIES EXCHANO        | GE ACT  |
|---|--|--|------------------------|---|
|   | For the qu   | arterly period ended September                       | 30, 2021               |   |
|   |  | OR   |                        |   |
| ☐ TRANSITION REPORT PURS<br>ACT OF 1934   | UANT TO SECT                                       | ION 13 OR 15(d) OF THE SEC                           | URITIES EXCHANG        | GE  |
|   | For the  | transition period from to                            |                        |   |
|   | Co   | mmission File Number: 001-3859                       | 99                     |   |
|   | _  | ve Therapeut<br>me of Registrant as Specified in its |                        |   |
| <b>Delaware</b> (State or other jurisdiction of Incorporation or organization)  |  | nnology Drive, Warren, NJ 07059<br>( 908) 941-1900   |                        | <b>82-3827296</b> Employer Identification Number) |
| (Address  | s, Zip Code and Tel                                | ephone Number of Registrant's Pr                     | incipal Executive Offi | ices)   |
| `   | •  |  | •                      | ,   |
|   | Securities re                                      | gistered pursuant to Section 12(b)                   | of the Act:            |   |
| Title of each class   |  | Trading Symbol(s)                                    | Name of each           | n exchange on which registered                    |
| Common Stock, par value \$0.001 p   | er share   | AQST   | NA                     | SDAQ Global Market                                |
| Indicate by check mark whether the registr during the preceding 12 months (or for su requirements for the past 90 days. ⊠ Yes □ | rant: (1) has filed a<br>ch shorter period<br>l No | that the registrant was required to                  | Section 13 or 15(d) o  | and (2) has been subject to such filing           |
| Indicate by check mark whether the regist Regulation S-T (§232.405 of this chapter) d Yes $\ \square$ No                        |  |  |                        |   |
| Indicate by check mark whether the regist emerging growth company. See the definition Rule 12b-2 of the Securities Exchange Ac  | ons of "large accele                               |  |                        |   |
| Large accelera<br>Non-accelerate  |  | Accelerated fil<br>Smaller reporti<br>Emerging grow  | ng company 🛛           |   |
| If an emerging growth company, indicate by revised financial accounting standards provi   |  |  |                        | n period for complying with any new or            |
| Indicate by check mark whether the registra   | nt is a shell compa                                | ny (as defined in Rule 12b-2 of the                  | Exchange Act). 🗆 Y     | es ⊠ No   |
| The number of outstanding shares of the r   | egistrant's commo                                  | n stock, par value of \$0.001 per                    | share, as of the close | of business on October 25, 2021 was               |

40,164,028.



# AQUESTIVE THERAPEUTICS, INC. FORM 10-Q TABLE OF CONTENTS

|                | _  | Page No. |
|----------------|--|----------|
| PART I – FINAN | NCIAL INFORMATION  |          |
| Item 1.        | Financial Statements (Unaudited)   |          |
| icii i.        | Condensed Consolidated Balance Sheets as of September 30, 2021 and December 31, 2020   | 3        |
|                | Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2021 and 2020 | 4        |
|                | Condensed Consolidated Statements of Changes in Stockholders' Deficit for the three and nine months ended September 30, 2021 and 2020  | 5        |
|                | Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2021 and 2020                                  | 6        |
|                | Notes to Unaudited Condensed Consolidated Financial Statements   | 7        |
| Item 2.        | Management's Discussion and Analysis of Financial Condition and Results of Operations  | 26       |
| Item 3.        | Quantitative and Qualitative Disclosures about Market Risk   | 40       |
| Item 4.        | Controls and Procedures  | 40       |
|                |  |          |
| PART II – OTHE | ER INFORMATION   |          |
|                |  |          |
| Item 1.        | <u>Legal Proceedings</u>   | 40       |
| Item 1A.       | Risk Factors   | 40       |
| Item 2.        | <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>   | 41       |
| Item 3.        | <u>Defaults Upon Senior Securities</u>   | 41       |
| Item 4.        | Mine Safety Disclosures  | 41       |
| Item 5.        | Other Information  | 41       |
| Item 6.        | <u>Exhibits</u>  | 42       |
|                |  |          |
| SIGNATURES     |  | 43       |

#### 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)

| (Ollaudited)  |    |                      |    |                      |
|---|----|----------------------|----|----------------------|
|   | S  | eptember 30,<br>2021 | ]  | December 31,<br>2020 |
| Assets  |    |                      |    |                      |
| Current assets:   |    |                      |    |                      |
| Cash and cash equivalents   | \$ | 31,164               | \$ | 31,807               |
| Trade and other receivables, net  |    | 13,643               |    | 6,955                |
| Inventories, net  |    | 2,863                |    | 2,461                |
| Prepaid expenses and other current assets   |    | 2,540                |    | 3,402                |
| Total current assets  |    | 50,210               |    | 44,625               |
| Property and equipment, net   |    | 5,197                |    | 6,873                |
| Right-of-use assets, net  |    | 2,917                |    | 3,448                |
| Intangible assets, net  |    | 64                   |    | 102                  |
| Other non-current assets  |    | 6,905                |    | 7,836                |
| Total assets  | \$ | 65,293               | \$ | 62,884               |
| Liabilities and stockholders' deficit   |    |                      |    |                      |
| Current liabilities:  |    |                      |    |                      |
| Accounts payable  | \$ | 6,215                | \$ | 7,089                |
| Accrued expenses  | Ψ  | 7,624                | Ψ  | 8,569                |
| Lease liabilities, current  |    | 860                  |    | 728                  |
| Deferred revenue, current   |    | 767                  |    | 693                  |
| Liability related to the sale of future revenue, current  |    | 1,848                |    | 1,450                |
| Loans payable, current  |    | 7,725                |    | 2,575                |
| Total current liabilities   | _  | 25,039               |    | 21,104               |
| Loans payable, net  |    | 32,673               |    | 34,329               |
| Liability related to the sale of future revenue, net  |    | 56,615               |    | 47,524               |
| Lease liabilities   |    | 2,185                |    | 2,846                |
| Deferred revenue  |    | 7,316                |    | 3,633                |
| Other non-current liabilities   |    | 1,810                |    | 1,945                |
| Total liabilities   |    | 125,638              | _  | 111,381              |
| Contingencies (Note 19)   |    |                      |    |                      |
| Stockholders' deficit:  |    |                      |    |                      |
| Common stock, \$0.001 par value. Authorized 250,000,000 shares; 40,083,245 and 34,569,254 shares issued |    |                      |    |                      |
| and outstanding at September 30, 2021 and December 31, 2020, respectively                               |    | 40                   |    | 35                   |
| Additional paid-in capital  |    | 167,466              |    | 137,725              |
| Accumulated deficit   |    | (227,851)            |    | (186,257)            |
| Total stockholders' deficit   |    | (60,345)             |    | (48,497)             |
| Total liabilities and stockholders' deficit   | \$ | 65,293               | \$ | 62,884               |

See accompanying notes to the condensed consolidated financial statements.

AQUESTIVE THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data amounts)

(Unaudited)

|  | Three Months Ended<br>September 30, |            |    |            | Nine Months Ended<br>September 30, |            |    |            |
|--|-------------------------------------|------------|----|------------|------------------------------------|------------|----|------------|
|  |                                     | 2021       |    | 2020       |                                    | 2021       |    | 2020       |
| Revenues   | \$                                  | 13,287     | \$ | 8,260      | \$                                 | 39,754     | \$ | 38,700     |
| Costs and expenses:  |                                     |            |    |            |                                    |            |    |            |
| Manufacture and supply   |                                     | 4,400      |    | 2,978      |                                    | 11,623     |    | 10,176     |
| Research and development   |                                     | 4,726      |    | 7,260      |                                    | 12,647     |    | 15,461     |
| Selling, general and administrative                                      |                                     | 12,129     |    | 11,803     |                                    | 38,494     |    | 40,310     |
| Total costs and expenses   |                                     | 21,255     |    | 22,041     |                                    | 62,764     |    | 65,947     |
| Loss from operations   | ·                                   | (7,968)    |    | (13,781)   |                                    | (23,010)   |    | (27,247)   |
| Other income/(expenses):   |                                     |            |    |            |                                    |            |    |            |
| Interest expense   |                                     | (2,787)    |    | (2,778)    |                                    | (8,305)    |    | (8,296)    |
| Interest expense related to the sale of future revenue, net              |                                     | (3,767)    |    | _          |                                    | (10,567)   |    | _          |
| Interest and other (expense) income, net                                 |                                     | (33)       |    | 8          |                                    | 288        |    | 128        |
| Net loss before income taxes   |                                     | (14,555)   |    | (16,551)   |                                    | (41,594)   |    | (35,415)   |
| Income taxes   |                                     | _          |    | _          |                                    | _          |    | _          |
| Net loss   | \$                                  | (14,555)   | \$ | (16,551)   | \$                                 | (41,594)   | \$ | (35,415)   |
| Comprehensive loss   | \$                                  | (14,555)   | \$ | (16,551)   | \$                                 | (41,594)   | \$ | (35,415)   |
| •  | ===                                 |            | -  |            |                                    |            |    |            |
| Net loss per share - basic and diluted                                   | \$                                  | (0.37)     | \$ | (0.49)     | \$                                 | (1.12)     | \$ | (1.05)     |
| Weighted-average number of common shares outstanding - basic and diluted |                                     | 39,224,863 |    | 33,619,379 |                                    | 37,297,892 |    | 33,592,846 |

See accompanying notes to the condensed consolidated financial statements.

#### AQUESTIVE THERAPEUTICS, INC.

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

|   | Common<br>Shares |    | ock<br>Amount | Additional<br>Paid-in<br>Capital |          | _  | Accumulated<br>Deficit | _  | Total<br>Stockholders'<br>Equity/Deficit |
|---|------------------|----|---------------|----------------------------------|----------|----|------------------------|----|--|
| Balance at December 31, 2020                              | 34,569,254       | \$ | 35            | \$                               | 137,725  | \$ | (186,257)              | \$ | (48,497)                                 |
| Common Stock issued under public equity offering          | 1,672,104        |    | 1             | •                                | 10,196   | •  | _                      |    | 10,197                                   |
| Costs of common stock issued under public equity offering | · · · —          |    | _             |                                  | (306)    |    | _                      |    | (306)                                    |
| Share-based compensation expense                          | _                |    | _             |                                  | 1,507    |    | _                      |    | 1,507                                    |
| Other   | _                |    | _             |                                  | (27)     |    | _                      |    | (27)                                     |
| Net loss  | _                |    | _             |                                  |          |    | (14,672)               |    | (14,672)                                 |
| Balance at March 31, 2021                                 | 36,241,358       |    | 36            |                                  | 149,095  |    | (200,929)              |    | (51,798)                                 |
| Common Stock issued under public equity offering          | 2,304,949        |    | 3             |                                  | 9,238    |    |                        |    | 9,241                                    |
| Costs of common stock issued under public equity offering | _                |    | _             |                                  | (627)    |    | _                      |    | (627)                                    |
| Shares issued under employee stock purchase plan          | 19,270           |    | _             |                                  | 76       |    | _                      |    | 76                                       |
| Share-based compensation expense                          | _                |    | _             |                                  | 1,710    |    | _                      |    | 1,710                                    |
| Vested restricted stock units                             | 2,665            |    | _             |                                  | (4)      |    | _                      |    | (4)                                      |
| Net loss  |                  |    | _             |                                  | <u> </u> |    | (12,367)               |    | (12,367)                                 |
| Balance at June 30, 2021                                  | 38,568,242       | \$ | 39            | \$                               | 159,488  | \$ | (213,296)              | \$ | (53,769)                                 |
| Common Stock issued under public equity offering          | 1,509,818        |    | 1             |                                  | 6,221    |    | _                      |    | 6,222                                    |
| Costs of common stock issued under public equity offering | _                |    | _             |                                  | (135)    |    | _                      |    | (135)                                    |
| Share-based compensation expense                          | _                |    | _             |                                  | 1,900    |    | _                      |    | 1,900                                    |
| Vested restricted stock units                             | 5,185            |    |               |                                  | (9)      |    | _                      |    | (9)                                      |
| Other   | _                |    | _             |                                  | 1        |    | _                      |    | 1  |
| Net loss  |                  |    |               |                                  |          |    | (14,555)               |    | (14,555)                                 |
| Balance at September 30, 2021                             | 40,083,245       |    | 40            |                                  | 167,466  |    | (227,851)              |    | (60,345)                                 |
|   |                  |    |               |                                  |          |    |                        |    |  |
| Balance at December 31, 2019                              | 33,562,885       | \$ | 34            | \$                               | 7        | \$ | (130,474)              | \$ | (6,122)                                  |
| Share-based compensation expense                          |                  |    | _             |                                  | 1,860    |    | _                      |    | 1,860                                    |
| Vested restricted stock units                             | 19,811           |    | _             |                                  | (37)     |    |                        |    | (37)                                     |
| 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 expense                          | _                |    | _             |                                  | 1,754    |    | _                      |    | 1,754                                    |
| Vested restricted stock units                             | 18,944           |    | _             |                                  | (52)     |    | <del>_</del>           |    | (52)                                     |
| Net loss  | <u> </u>         |    |               | _                                |          |    | (2,334)                |    | (2,334)                                  |
| Balance at June 30, 2020                                  | 33,616,601       |    | 34            |                                  | 127,916  |    | (149,338)              |    | (21,388)                                 |
| Share-based compensation expense                          | 3,195            |    | _             |                                  | 1,420    |    | _                      |    | 1,420                                    |
| Net loss  |                  |    |               |                                  |          |    | (16,551)               |    | (16,551)                                 |
| Balance at September 30, 2020                             | 33,619,796       | \$ | 34            | \$                               | 129,336  | \$ | (165,889)              | \$ | (36,519)                                 |

See accompanying notes to the condensed consolidated financial statements.

#### AQUESTIVE THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows (In thousands) (Unaudited)

|  |            | Nine Months Ended<br>September 30, |          |  |
|--|------------|------------------------------------|----------|--|
|  | 2021       |                                    | 2020     |  |
| Operating activities:  |            |                                    |          |  |
| Net loss   | \$ (41,594 | ) \$                               | (35,415) |  |
| Adjustments to reconcile net loss to net cash used for operating activities: |            |                                    |          |  |
| Depreciation, amortization, and impairment                                   | 2,233      | }                                  | 2,337    |  |
| Share-based compensation   | 5,128      | }                                  | 5,052    |  |
| Amortization of debt issuance costs and discounts                            | 3,604      | ŀ                                  | 1,758    |  |
| Interest expense related to the sale of future revenue, net                  | 10,45      | ,                                  | _        |  |
| Other, net   | (248       | )                                  | 34       |  |
| Changes in operating assets and liabilities:                                 |            |                                    |          |  |
| Trade and other receivables, net   | (6,726     | )                                  | 5,082    |  |
| Inventories, net   | (402       | .)                                 | (383)    |  |
| Prepaid expenses and other assets  | 1,793      | }                                  | (7,101)  |  |
| Accounts payable   | (874       | .)                                 | (3,189)  |  |
| Accrued expenses and other liabilities                                       | (2,046     | )                                  | 616      |  |
| Deferred revenue   | 3,752      | ,                                  | (738)    |  |
| Net cash used for operating activities                                       | (24,918    | )                                  | (31,947) |  |
| Investing activities:  |            |                                    |          |  |
| Capital expenditures   | (380       | )                                  | (281)    |  |
| Net cash used for investing activities                                       | (380       | <u> </u>                           | (281)    |  |
| Financing activities:  |            |                                    |          |  |
| Proceeds from issuance of common stock, net                                  | 24,592     | <u>,</u>                           | _        |  |
| Proceeds from shares issued under employee stock purchase plan               | 76         | ,                                  | 62       |  |
| Payments for taxes on share-based compensation                               | (13        | )                                  | (96)     |  |
| Net cash provided by/(used for) financing activities                         | 24,655     | ,                                  | (34)     |  |
| Net decrease in cash and cash equivalents                                    | (643       | <b>i)</b>                          | (32,262) |  |
| Cash and cash equivalents at beginning of period                             | 31,807     | ,                                  | 49,326   |  |
| Cash and cash equivalents at end of period                                   | \$ 31,164  | \$                                 | 17,064   |  |
| Supplemental disclosures of cash flow information:                           |            |                                    |          |  |
| Cash payments for interest   | \$ 4,828   | 3 \$                               | 6,562    |  |
| Cuon pujmento tot merest   | Ψ 7,020    | Ψ                                  | 0,502    |  |

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. Company Overview and Basis of Presentation

#### (A) Company Overview

Aquestive Therapeutics, Inc., (together with its subsidiary, "Aquestive" or "the Company") is a pharmaceutical company focused on identifying, developing and commercializing differentiated products which leverage its proprietary PharmFilm® technology to meet patients' unmet medical needs and solve patients' therapeutic problems. The Company has five products approved by the U.S. Food and Drug Administration (FDA), both proprietary and outlicensed, as well as a late-stage proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and an earlier stage pipeline including for treatment of severe allergic reactions, including anaphylaxis. The Company's licensees market their products in the U.S. and in some instances outside the U.S. The Company markets its proprietary product in the U.S. The Company believes that its proprietary and licensed products address the needs of these patient populations and the shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines. Production facilities are located in Portage, Indiana, and corporate headquarters, sales and commercialization operations and primary research laboratory facilities are based in Warren, New Jersey.

#### (B) Equity Transactions

Equity Offering of Common Stock

On September 11, 2019, the Company established an "At-The-Market" (ATM) facility pursuant to which the Company may offer up to \$25,000 of shares of common stock. On November 20, 2020, the Company began utilizing the ATM facility and through December 31, 2020 sold 930,993 shares which provided net proceeds of approximately \$6,055 after deducting commissions and other transaction costs of \$473.

On March 26, 2021, the Company filed a prospectus supplement to offer up to an additional \$50,000 of shares of common stock under the ATM facility. For the nine months ended September 30, 2021, the Company sold 5,486,871 shares which provided net proceeds of approximately \$24,592 after deducting commissions and other transaction costs of \$1,068. This ATM facility has approximately \$42,812 available at September 30, 2021.

#### **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, 2020 included in the Company's Annual Report on Form 10-K filed with the SEC on March 9, 2021 (the "2020 Annual Report on Form 10-K"). As included herein, the condensed consolidated balance sheet as of December 31, 2020 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 2. Summary of Significant Accounting Policies

#### (A) 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.

Recent Accounting Pronouncements Not Adopted as of September 30, 2021:

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-forsale 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 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.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. The accounting standard update was issued to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification

or exchange. The new accounting guidance is effective for the Company beginning after December 15, 2022. Early adoption is permitted. The Company does not expect the new accounting guidance to have a material impact on the Company's consolidated financial statements.

#### Note 3. Risks and Uncertainties

The Company assesses liquidity in terms of its ability to generate cash to fund its operating, investing and financing activities. The Company's cash requirements for 2021 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, 2021, the Company had \$31,164 of cash and cash equivalents.

The Company has experienced a history of net losses. The Company's accumulated deficits totaled \$227,851 as of September 30, 2021. The net losses and accumulated deficits were partially offset by gross margins from sales of commercialized licensed and proprietary products, license fees, milestone and royalty payments from commercial licensees and co-development parties. The Company's funding requirements are met by its cash and cash equivalents, as well as its existing equity and debt offerings, including the Senior Secured Notes due 2025 (the "12.5% Notes").

The Company began utilizing its ATM facility in November 2020. Since inception to September 30, 2021, the Company sold 6,417,804 shares which generated net cash proceeds of approximately \$30,647, net of commissions and other transaction costs of \$1,541. For the nine months ended September 30, 2021, the Company sold 5,486,871 shares which provided net proceeds of approximately \$24,592, net of commissions and other transaction costs of \$1,068. This ATM facility has approximately \$42,812 available at September 30, 2021.

While the Company's ability to execute its business objectives and achieve profitability over the longer term cannot be assured, the Company's anticipated revenues from licensed and proprietary products, available cash and cash equivalents, expense management initiatives, and access to equity markets, including through its ATM facility, under the shelf registration statement will enable the Company to fund its operating needs for at least the next twelve months as it continues to execute its business strategy.

#### Note 4. Revenues and Trade Receivables, Net

The Company's revenues include (i) sales of manufactured products pursuant to contracts with commercialization licensees, (ii) sales of its proprietary clobazam-based Sympazan oral film product, (iii) license and royalty revenues and (iv) co-development and research fees generally in the form of milestone payments. The Company recognizes revenue to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To achieve this core principle, a five-step model is applied that includes (1) identifying the contract with a customer, (2) identifying the performance obligation in the contract, (3) determining the transaction price, (4) allocating the transaction price to the performance obligations, and (5) recognizing when, or as, an entity satisfies a performance obligation.

#### Performance Obligations

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

*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 when product is shipped and title passes to the customer, typically at time of delivery. At the time of sale, estimates for various revenue allowances are recorded based on historical trends and judgmental estimates. For sales of Sympazan, returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates, if available, and these estimates are recorded as a reduction of receivables. Similarly determined estimates are recorded relating to wholesaler service fees, co-pay support redemptions, Medicare, Medicaid and other rebates, and these estimates are reflected as a component of accrued liabilities. Once all related variable considerations are resolved and uncertainties as to collectable 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 Revenue* — license revenues are determined based on an assessment of whether the license is distinct from any other performance obligations that may be included in the underlying licensing arrangement. If the customer

is able to benefit from the license without provision of any other performance obligations by the Company and the license is thereby viewed as a distinct or functional license, the Company then determines whether the customer has acquired a right to use the license or a right to access the license. 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. For symbolic licenses providing substantial value only in conjunction with other performance obligations to be provided by the Company, revenues are generally recorded over the term of the license agreement. Such other obligations provided by the Company generally include manufactured products, additional development services or other deliverables that are contracted to be provided during the license term. Payments received in excess of amounts ratably or otherwise earned are deferred and recognized over the term of the license or as contingencies or other performance obligations are met.

Royalty revenue is estimated and recognized when sales under supply agreements with commercial licensees are recorded, absent any contractual constraints or collectability uncertainties.

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

Revenue recognition arising from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Milestone payments based on a non-sales metric such as a development-based milestone (e.g., an NDA filing or obtaining regulatory approval) represent variable consideration and are included in the transaction price subject to any constraints. If the milestone payments relate to future development, the timing of recognition depends upon historical experience and the significance a third party has on the outcome. For milestone payments to be received upon the achievement of a sales threshold, the revenue from the milestone payments is recognized at the later of when the actual sales are incurred or the performance obligation to which the sales relate to has been satisfied.

Contract Assets - in certain situations, 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 within the Condensed Consolidated Balance Sheet. As of September 30, 2021, and December 31, 2020, such contract assets were \$2,637 and \$3,081, respectively, consisting primarily of products and services provided under specific contracts to customers for which earnings processes have been met prior to shipment of goods or full delivery of completed services.

Contract Liabilities - in certain situations, 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, 2021, and December 31, 2020, such contract liabilities were \$8,083 and \$4,326, respectively.

The Company's revenues were comprised of the following:

|                                  |        | nths Ended<br>nber 30, |           | nths Ended<br>aber 30, |
|----------------------------------|--------|------------------------|-----------|------------------------|
|                                  | 2021   | 2020                   | 2021      | 2020                   |
| Manufacture and supply revenue   | 10,447 | \$ 5,903               | \$ 27,623 | \$ 20,078              |
| License and royalty revenue      | 328    | 328                    | 5,000     | 13,682                 |
| Co-development and research fees | 523    | 341                    | 1,417     | 870                    |
| Proprietary product sales, net   | 1,989  | 1,688                  | 5,714     | 4,070                  |
| Total revenues                   | 13,287 | \$ 8,260               | \$ 39,754 | \$ 38,700              |

#### Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

|                  | Three Months Ended<br>September 30, |      |       |      | Ended<br>30, |      |        |
|------------------|-------------------------------------|------|-------|------|--------------|------|--------|
|                  | 2021                                | 2020 |       | 2021 |              | 2020 |        |
| United States    | \$<br>10,530                        | \$   | 6,567 | \$   | 33,487       | \$   | 35,496 |
| Ex-United States | 2,757                               |      | 1,693 |      | 6,267        |      | 3,204  |
| Total revenues   | \$<br>13,287                        | \$   | 8,260 | \$   | 39,754       | \$   | 38,700 |

Ex-United States revenues are derived primarily from Indivior for product manufactured for markets outside of the United States.

Trade and other receivables, net consist of the following:

|                                       | Septem<br>202 |        | Dec | cember 31,<br>2020 |
|---------------------------------------|---------------|--------|-----|--------------------|
| Trade receivables                     | \$            | 11,500 | \$  | 4,330              |
| Contract and other receivables        |               | 2,637  |     | 3,081              |
| Less: allowance for doubtful accounts |               | (40)   |     | (40)               |
| Less: sales-related allowances        |               | (454)  |     | (416)              |
| Trade and other receivables, net      | \$            | 13,643 | \$  | 6,955              |

The following table presents the changes in the allowance for doubtful accounts:

|  | September 30,<br>2021 | December 31,<br>2020 |
|--|-----------------------|----------------------|
| Allowance for doubtful accounts at beginning of the period | \$ 40                 | \$ 124               |
| Additions charged to expense                               | _                     | 198                  |
| Write-downs charged against the allowance                  | _                     | (282)                |
| Allowance for doubtful accounts at end of the period       | \$ 40                 | \$ 40                |

#### 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, 2021:

|                               | <br>Total Sales Related Allowances |
|-------------------------------|------------------------------------|
|                               |                                    |
| Balance at December 31, 2020  | \$<br>2,138                        |
| Provision                     | 6,769                              |
| Payments / credits            | (5,920)                            |
| Balance at September 30, 2021 | \$<br>2,987                        |

Total reductions of gross product sales from sales-related allowances and accruals were \$6,769 for the nine months ended September 30, 2021. Accruals for returns allowances and prompt pay discounts are reflected as a direct reduction of trade receivables and accruals for wholesaler service fees, copay 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 \$454 and \$2,533, respectively, as of September 30, 2021 and \$416 and \$1,722, respectively, as of December 31, 2020.

#### Concentration of Major Customers

Customers are considered major customers when net revenue exceeds 10% of total revenue for the period or outstanding receivable balances exceed 10% of total receivables. For the nine months ended September 30, 2021, Indivior Inc. ("Indivor") exceeded the 10% threshold for revenue and represented approximately 73% of total revenue. As of September 30, 2021, Indivior exceeded the 10% threshold for outstanding receivables and represented 68% of outstanding receivables. For the nine months ended September 30, 2020, Indivior and Sunovion Pharmaceuticals, Inc. ("Sunovion") represented approximately 48% and 39%, respectively of total revenue. As of December 31, 2020, Indivior, AmerisourceBergen Corporation, Sunovion, and Cardinal Health Inc. represented 53%, 14%, 13%, and 10%, respectively of outstanding receivables.

#### Note 5. 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 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. 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 (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 (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 are 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 that 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 and commercially launched by Sunovion in September 2020. The FDA approval triggered Sunovion's obligation to remit a payment of \$4,000 which was received in September 2020 and was included in License and royalty revenues for the year ended December 31, 2020.

In consideration of 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 has 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"). As a result of the Monetization Agreement, the Company is no longer entitled to receive the remaining contingent royalty or milestone payments related to net sales thresholds of KYNMOBI. During the second quarter of 2020, the Company recorded minimum royalty revenue of \$8,000 for minimum royalties which was reflected in License and royalty revenue.

Effective March 16, 2020, the Company entered into a first amendment (the "First Amendment") to the Sunovion License Agreement. The First Amendment provides for the following: (i) inclusion of the United Kingdom and any other country currently in the European Union (EU) that later withdraws as a member country of 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) extension of 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) modification of 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) modification of 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. The Sunovion License Agreement will continue until terminated by Sunovion in accordance with the termination provisions of the First Amendment. 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.

On October 23, 2020, the Company entered into a Second Amendment to the Sunovion License Agreement for the purpose of clarifying the rights and obligations of Sunovion and the Company with respect to the prosecution and maintenance of the patents covered under the Sunovion License Agreement and to provide that, on and after March 31, 2028, in respect of any jurisdiction or jurisdictions covered under the Sunovion License Agreement, Sunovion may terminate its rights to the licensed Patents under the Sunovion License Agreement upon 180 days prior written notice.

Effective as of July 23, 2021, the Company entered into a Third Amendment to the Sunovion License Agreement for the purpose of clarifying the definition of the term "Field" and certain sublicense rights and obligations of the parties under the Sunovion License Agreement, including the rights of European sublicensees upon termination of the Sunovion License Agreement.

Purchase and Sale Agreement with an affiliate of Marathon Asset Management ("Marathon")

On November 3, 2020, the Company entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, the Company sold all of its contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI, KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the FDA on May 21, 2020. In exchange for the sale of these rights, the Company received an upfront payment of \$40,000 and an additional payment of \$10,000 through the achievement of the first milestone. The Company has received an aggregate amount of \$50,000 through September 30, 2021 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to \$75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of \$125,000. See Note 15 Sale of Future Revenue for further details on the accounting for the Monetization Agreement.

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 the 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 KP-415 and KP-484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving KemPharm and collaborations, royalty arrangements, or other transactions from which KemPharm may realize value from these compounds. The Company has received payment of \$500 under this arrangement during June 2020 in connection with the FDA's acceptance of a New Drug Application ("NDA") filing for KP-415. On March 2, 2021 KemPharm announced FDA approval of KP 415 (AZTARYS<sup>TM</sup>) a new once-daily treatment for ADHD. During the second quarter of 2021, the Company received \$2,000 of milestone payments in connection with the FDA approval and other regulatory activities.

#### Note 6. 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 note holders in connection with its debt repayment and debt refinancing during 2020 and 2019, respectively. Those warrants were valued based on Level 3 inputs and their fair value was based primarily on 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 as Compensation. See Note 14 Warrants for further information on these warrants.

The Company's 12.5% Senior Secured Notes contain a repurchase offer or put option which gives holders of the option the right, but not the obligation, to require the Company to redeem on the Notes up to a capped portion of milestone payments resulting from the Monetization Agreement. This put option was valued based on Level 3 inputs and its fair value was based primarily on an independent third-party appraisal 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. See Note 13 12.5% Senior Secured Notes and Loans Payable for further discussion.

#### Note 7. Inventories, Net

The components of Inventory, net are as follows:

|                      | Se | ptember 30,<br>2021 | December 31,<br>2020 |
|----------------------|----|---------------------|----------------------|
| Raw material         | \$ | 938                 | \$<br>789            |
| Packaging material   |    | 1,195               | 1,128                |
| Finished goods       |    | 730                 | 544                  |
| Total inventory, net | \$ | 2,863               | \$<br>2,461          |

#### Note 8. Property and Equipment, Net

|   | Useful<br>Lives | Sep | otember 30,<br>2021 | ]  | December 31,<br>2020 |
|---|-----------------|-----|---------------------|----|----------------------|
| Machinery                                       | 3-15 years      | \$  | 18,900              | \$ | 21,333               |
| Furniture and fixtures                          | 3-15 years      |     | 769                 |    | 1,209                |
| Leasehold improvements                          | (a)             |     | 21,265              |    | 21,333               |
| Computer, network equipment and software        | 3-7 years       |     | 2,469               |    | 2,999                |
| Construction in progress                        |                 |     | 985                 |    | 877                  |
|   |                 |     | 44,388              |    | 47,751               |
| Less: accumulated depreciation and amortization |                 |     | (39,191)            |    | (40,878)             |
| Total property and equipment, net               |                 | \$  | 5,197               | \$ | 6,873                |

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

Total depreciation, amortization, and impairment related to property and equipment was \$724 and \$714 for the three-month periods ended September 30, 2021 and 2020, respectively. For the respective nine-month periods, these expenses totaled \$2,195 and \$2,127.

#### Note 9. 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 its 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 1.5 and 5.0 years, including renewal options expected to be exercised to extend the lease periods.

The Company does not recognize a right-to use asset and lease liability for short-term leases, which have terms of 12 months or less on its consolidated balance sheet. For longer-term lease arrangements that are recognized on the Company's consolidated balance sheet, the right-of-use asset and lease liability is initially measured at the commencement date based upon the present value of the lease payments due under the lease. These payments represent the combination of the fixed lease and fixed non-lease components that are due under the arrangement. The costs of associated with the Company's short-term leases, as well as variable costs relating to the Company's lease arrangements, are not material to the consolidated financial results.

The implicit interest rates of the Company's lease arrangements are generally not readily determinable and as such, the Company applies an incremental borrowing rate, which is established based upon the information available at the lease commencement date, to determine the present value of lease payments due under an arrangement. 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 collateralized debt refinancing.

Right-of-use assets recorded upon adoption of ASC 842 totaled \$4,048. The Company's lease costs are recorded manufacture and supply, research and development and selling, general and administrative expenses in its consolidated statements of income. For the three and nine-months ended September 30, 2021, total operating lease expenses totaled \$431 and \$1,294, respectively, including variable lease expenses such as common area maintenance and operating costs of \$117 and \$352, respectively. For the three and nine-months ended September 30, 2020, total operating lease expenses totaled \$377 and \$819, respectively, including variable lease expenses such as common area maintenance and operating costs of \$60 and \$166, respectively.

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

| Remainder of 2021                 | \$<br>322   |
|-----------------------------------|-------------|
| 2022                              | 1,294       |
| 2023                              | 944         |
| 2024                              | 565         |
| 2025                              | 565         |
| 2026                              | 424         |
| Total future lease payments       | 4,114       |
| Less: imputed interest            | (1,069)     |
| Total operating lease liabilities | \$<br>3,045 |

#### Note 10. Intangible Assets, Net

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

|                                       | September 30,<br>2021 | December 31,<br>2020 |
|---------------------------------------|-----------------------|----------------------|
| Purchased technology-based intangible | \$ 2,358              | \$ 2,358             |
| Purchased patent                      | 509                   | 509                  |
|                                       | 2,867                 | 2,867                |
| Less: accumulated amortization        | (2,803)               | (2,765)              |
| Intangible assets, net                | 64                    | 102                  |

Amortization expense was \$13 and \$13 for each of the three-month periods ended September 30, 2021 and 2020. For the corresponding nine-month periods, these expenses totaled \$38 and \$38, respectively. During the remaining life of the purchased patent, estimated annual amortization expense is \$50 for each of the years from 2021 to 2022.

#### Note 11. Other non-current Assets

The following table provides the components of other non-current assets:

|                                | ember 30,<br>)21 | D  | ecember 31,<br>2020 |
|--------------------------------|------------------|----|---------------------|
| Royalty receivable             | 6,000            |    | 7,00                |
| Other                          | 905              |    | 83                  |
| Total other non-current assets | \$<br>6,905      | \$ | 7,83                |

During the second quarter of 2020, under the Sunovion License Agreement, the Company recognized \$8,000 of royalty revenue and corresponding royalty receivable, related to the \$1,000 annual minimum guaranteed royalty that is due in each of the next eight years. In connection with the Monetization Agreement, the Company performed an assessment under ASC 860 Transfer and Servicing to determine whether the existing receivable was transferred to Marathon and concluded it was not transferred. Royalty receivable consists of seven annual minimum payments due from Sunovion, the last of which is due in March 2028. The current portion of the royalty receivable is included in Trade and other receivables, net. See Note 15 Sale of Future Revenue for further details on how this receivable relates to the Monetization Agreement transaction.

#### Note 12. Accrued Expenses

Accrued expenses consisted of the following:

|                               | September 30,<br>2021 |       |    | ecember 31,<br>2020 |
|-------------------------------|-----------------------|-------|----|---------------------|
| Accrued compensation          | \$                    | 4,596 | \$ | 6,330               |
| Accrued distribution expenses |                       | 2,533 |    | 1,722               |
| Other                         |                       | 495   |    | 517                 |
| Total accrued expenses        | \$                    | 7,624 | \$ | 8,569               |

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

#### 12.5% Senior Secured Notes

On July 15, 2019, the Company completed the private placement of up to \$100,000 aggregate principal of its 12.5% Senior Secured Notes due 2025 (the "12.5% Notes") and issued warrants for 2,000,000 shares of common stock (the "Warrants"), at \$0.001 par value per share.

Upon closing of the indenture for the 12.5% Notes (the "Base Indenture"), the Company issued \$70,000 of the 12.5% Notes (the "Initial Notes") along with the Warrants and rights of first offer (the "First Offer Rights") to the noteholders participating in this transaction. Issuance of the Initial Notes and Warrants provided net proceeds of \$66,082.

On November 3, 2020, the Company entered into the First Supplemental Indenture (the "First Supplemental Indenture" and, together with all other subsequent supplemental indentures and the Base Indenture, collectively, the "Indenture") by and among the Company and U.S. Bank National Association, as Trustee (the "Trustee") and Collateral Agent thereunder to the Base Indenture, by and between the Company and the Trustee. Under the Second Supplemental Indenture, the Company repaid \$22,500 of its \$70,000 outstanding 12.5% Notes from the upfront proceeds received under the Monetization Agreement. Further, the Company entered into an additional Purchase Agreement with its lenders whereby the Company issued in aggregate \$4,000 of additional 12.5% Notes (the "Additional Notes") in lieu of paying a prepayment premium to two lenders on the early repayment of the 12.5% Notes discussed above. The result of these two transactions reduced the net balance of the Company's 12.5% Senior Notes outstanding in the aggregate to \$51,500 at December 31, 2020, and such aggregate principal amount remains outstanding as of September 30, 2021. The \$4,000 principal issuance will be repaid proportionally over the same maturities as the other 12.5% Notes. The Company also paid to one of its lenders a \$2,250 premium as result of the early retirement of debt.

The Company accounted for the \$22,500 debt repayment as a debt modification of the 12.5% Notes. The fees paid to lenders inclusive of (i) \$2,250 early premium prepayment and (ii) \$4,000 issuance of Additional Notes in lieu of paying a prepayment penalty were recorded as additional debt discount, amortized over the remaining life of the 12.5% Notes using the effective interest method. Loan origination costs of \$220 associated with the Additional Notes were expensed as incurred. Existing deferred discounts and loan origination fees on the 12.5% Notes are amortized as an adjustment of interest expense over the remaining term of modified debt using the effective interest method.

The First Supplemental Indenture contains a provision whereby, as the Company receives any cash proceeds from the Monetization Agreement, each noteholder has the right to require the Company to redeem all or any part of such noteholder's outstanding 12.5% Notes at a repurchase price in cash equal to 112.5% of the principal amount, plus accrued and unpaid interest. This repurchase offer is capped at 30% of the cash proceeds received by the Company as the contingent milestones are attained, if any, up through June 30, 2025. A valuation study was performed by an independent third party appraiser and updated as of September 30, 2021. Based on the valuation study, the put option was valued at \$258, of which \$111 has been recorded in Accrued expenses and \$147 has been recorded in Other non-current liabilities. The embedded put option is deemed to be a derivative under *ASC 815 Derivatives and Hedging*, which requires the recording of the embedded put option at fair value and subject to remeasurement at each reporting period. In addition, as of the closing of this transaction, the Company issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of its common stock.

On August 6, 2021, pursuant to the Third Supplemental Indenture, the holders of the 12.5% Notes extended to June 30, 2022 from December 31, 2021, the Company's ability to access, at the Company's option, \$30,000 of 12.5% Notes re-openers under the Indenture. The first \$10,000 of 12.5% Notes 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 12.5% 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 12.5% 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, it 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.

The 12.5% Notes provide a stated fixed interest rate of 12.5%, payable quarterly in arrears, with the initial quarterly principal repayment of 12.5% Notes due on September 30, 2021 and the final quarterly payment due at maturity on June 30, 2025. The Company has recorded \$7,725 as Loan Payable, Current to reflect this obligation in its Consolidated Balance Sheet. Principal payments are scheduled to increase annually from 10% of the face amount of the debt then outstanding during the first four quarters to 40% of the 12.5% Notes during the final four quarters.

#### A debt maturity table is presented below:

| Remainder of 2021 | \$<br>2,575  |
|-------------------|--------------|
| 2022              | 7,725        |
| 2023              | 12,875       |
| 2024              | 18,025       |
| 2025              | 10,300       |
| Total             | \$<br>51,500 |

The Company may elect, at its option, to redeem the 12.5% Notes at any time at premiums that range from 101.56% of outstanding principal if prepayment occurs on or after the fifth anniversary of the issue date of the Initial Notes to 112.50% if payment occurs during the third year after the issuance of the Notes. The Indenture also includes change of control provisions under which the Company may be required to redeem the 12.5% Notes at 101% of the remaining principal plus accrued interest at the election of the noteholders.

On September 30, 2021, the Company entered into a waiver agreement (the "Waiver") with the holders of the 12.5% Notes pursuant to which the principal payment due under the 12.5% Notes on September 30, 2021 was deferred in order to provide sufficient time for the finalization and execution of the Fourth Supplemental Indenture (the "Fourth Supplemental Indenture") discussed in Note 20 Subsequent Events. The Fourth Supplemental Indenture was executed by the parties on October 7, 2021.

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. Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its lenders, and offsets those as a direct reduction of its outstanding debt. Amortization expense arising from deferred debt issuance costs and debt discounts related to the 12.5% Notes for the three and nine months ended September 30, 2021 were \$1,171 and \$3,488, respectively, while comparative amortization expenses for the three and nine months ended September 30, 2020 were \$590 and \$1,758,

respectively. Unamortized deferred debt issuance costs and deferred debt discounts totaled \$11,110 and \$14,596 as of September 30, 2021 and December 31, 2020, respectively.

Collateral for the loan under the 12.5% Notes consists of a first priority lien on substantially all property and assets, including intellectual property of the Company. This secured obligation provides payment rights that are senior to all existing and future subordinated indebtedness of the Company and provides Lenders with perfected security interests in substantially all of the Company's assets.

#### Note 14. Warrants

Warrants that were issued in conjunction with the Initial Notes (the "Initial Warrants") and Additional Notes (the "Additional Warrants") expire on June 30, 2025 and entitle the noteholders to purchase up to 2,143,000 shares of the Company's common stock at \$0.001 per share and included specified registration rights. Management estimated the fair value of the Initial Warrants to be \$6,800 and the Additional Warrants to be \$735, each based on an assessment by an independent third-party appraiser.

The fair value of the respective warrants is treated as a debt discount, amortizable over the term of the respective warrants, with the unamortized 12.5% Notes portion applied to reduce the aggregate principal amount of the 12.5% Notes in the Company's unaudited condensed 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 Company's unaudited condensed balance sheet. There were no warrants exercised during the nine-months ended September 30, 2021 or 2020, respectively.

#### Note 15. Sale of Future Revenue

On November 3, 2020, the Company entered into the Monetization Agreement with Marathon. Under the terms of the Monetization Agreement, the Company sold all of its contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the FDA on May 21, 2020. In exchange for the sale of these rights, the Company received an upfront payment of \$40,000 and an additional payment of \$10,000 through the achievement of the first milestone. The Company has received an aggregate amount of \$50,000 through September 30, 2021 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to \$75,000 may be due to the Company upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of \$125,000.

The Company recorded the upfront proceeds of \$40,000 and subsequent first milestone of \$10,000, reduced by \$2,909 of transaction costs, as a liability related to the sale of future revenue that will be amortized using the effective interest method over the life of the Monetization Agreement. As future contingent payments are received, they will increase the balance of the liability related to the sale of future revenue. Although the Company sold all of its rights to receive royalties and milestones, as a result of ongoing obligations related to the generation of these royalties, the Company will account for these royalties as revenue. Its ongoing obligations include the maintenance and defense of the intellectual property and to provide assistance to Marathon in executing a new license agreement for KYNMOBI in the event Sunovion terminates the Sunovion License Agreement in one or more jurisdictions of the licensed territory under the Sunovion License Agreement. The accounting liabilities, as adjusted over time, resulting from this transaction and any non-cash interest expenses associated to those liabilities do not and will not represent any obligation to pay or any potential future use of cash.

During the second quarter of 2020, under the Sunovion License Agreement, the Company recognized \$8,000 of royalty revenue and corresponding royalty receivable, related to the \$1,000 annual minimum guaranteed royalty that is due in each of the next eight years. In connection with the Monetization Agreement, the Company performed an assessment under ASC 860, *Transfer and Servicing* to determine whether the existing receivable was transferred to Marathon and concluded that the receivable was not transferred.

As royalties are remitted to Marathon from Sunovion, the collection of the royalty receivable and balance of the liability related to the sale of future revenue will be effectively repaid over the life of the agreement. In order to determine the amortization of the liability related to the sale of future revenue, the Company is required to estimate the total amount of future royalty and milestone payments to Marathon over the life of the Monetization Agreement and contingent milestone payments

from Marathon to the Company. The sum of future royalty payments less the \$50,000 in proceeds received and future contingent payments will be recorded as interest expense over the life of the Monetization Agreement. At execution, the estimate of this total interest expense resulted in an effective annual interest rate of approximately 24.9%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the life of the Monetization Agreement. The Company will periodically assess the estimated royalty and milestone payments to Marathon from Sunovion and contingent milestone payments from Marathon to the Company. To the extent the amount or timing of such payments is materially different from the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially affect the amount and timing of royalty and milestone payments to Marathon from Sunovion, and correspondingly, the amount of interest expense recorded by the Company, most of which are not under the Company's control. Such factors include, but are not limited to, changing standards of care, the initiation of competing products, manufacturing or other delays, generic competition, intellectual property matters, adverse events that result in government health authority imposed restrictions on the use of products, significant changes in foreign exchange rates as the royalties remitted to Marathon are made in U.S. dollars (USD) while a portion of the underlying sales of KYNMOBI will be made in currencies other than USD, and other events or circumstances that are not currently foreseen. Changes to any of these factors could result in increases or decreases to both royalty revenue and interest expense related to the sale of future revenue.

The following table shows the activity of the liability related to the sale of future for the nine months ended September 30, 2021:

| Liability related to the sale of future revenue, net at December 31, 2020                  | \$<br>48,974 |
|--|--------------|
| Royalties related to the sale of future revenue  | (1,077)      |
| Amortization of issuance costs   | 110          |
| Interest expense related to the sale of future revenue                                     | 10,457       |
| Liability related to the sale of future revenue, net (includes current portion of \$1,848) | \$<br>58,464 |

#### Note 16. Net Loss Per Share

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

As a result of the Company's net loss incurred for the three and nine months ended September 30, 2021 and 2020, all potentially dilutive instruments outstanding would have anti-dilutive effects on per-share calculations for the periods. Therefore, basic and diluted net loss per share were the same for all periods presented as reflected below.

|  | Three Months Ended<br>September 30, |    |            |    | Nine Months Ended<br>September 30, |    |            |  |
|--|-------------------------------------|----|------------|----|------------------------------------|----|------------|--|
|  | 2021                                |    | 2020       |    | 2021                               |    | 2020       |  |
| Numerator:                                       |                                     |    |            |    |                                    |    |            |  |
| Net loss   | \$<br>(14,555)                      | \$ | (16,551)   | \$ | (41,594)                           | \$ | (35,415)   |  |
| Denominator:                                     | <br>                                |    |            | _  |                                    |    |            |  |
| Weighted-average number of common shares – basic | 39,224,863                          |    | 33,619,379 |    | 37,297,892                         |    | 33,592,846 |  |
| Loss per common share – basic and diluted        | \$<br>(0.37)                        | \$ | (0.49)     | \$ | (1.12)                             | \$ | (1.05)     |  |

As of September 30, 2021 and 2020, respectively, the Company's potentially dilutive instruments included 4,341,967 and 3,167,192 options to purchase common shares and 0 and 14,233 unvested restricted stock units that were excluded from the computation of diluted weighted average shares outstanding because these securities had an antidilutive impact due to the losses reported. Similarly excluded as of September 30, 2021 and 2020, were potentially dilutive warrants for the purchase of 1,571,429 for both periods.

#### Note 17. Share-Based Compensation

The Company recognized share-based compensation in its Condensed Consolidated Statements of Operations and Comprehensive Loss during 2021 and 2020 as follows:

|   | Three Months Ended<br>September 30, |       |    | Nine Months End<br>September 30, |    |       |    |       |
|---|-------------------------------------|-------|----|----------------------------------|----|-------|----|-------|
|   |                                     | 2021  |    | 2020                             |    | 2021  |    | 2020  |
| Manufacture and supply                  | \$                                  | 88    | \$ | 72                               | \$ | 241   | \$ | 135   |
| Research and development                |                                     | 230   |    | 183                              |    | 670   |    | 365   |
| Selling, general and administrative     |                                     | 1,582 |    | 1,510                            |    | 4,217 |    | 3,125 |
| Total share-based compensation expenses | \$                                  | 1,900 | \$ | 1,765                            | \$ | 5,128 | \$ | 3,625 |
|   |                                     |       |    |                                  |    |       |    |       |
| Share-based compensation from:          |                                     |       |    |                                  |    |       |    |       |
| Restricted stock units                  | \$                                  | _     | \$ | 309                              | \$ | 81    | \$ | 773   |
| Stock options                           |                                     | 1,900 |    | 1,445                            |    | 5,036 |    | 2,841 |
| Employee stock purchase plan            |                                     | _     |    | 11                               |    | 11    |    | 11    |
| Total share-based compensation expenses | \$                                  | 1,900 | \$ | 1,765                            | \$ | 5,128 | \$ | 3,625 |

#### **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, 2021:

| Restricted Stock Unit Awards (RSUs):                     | Number of<br>Units | Weighted<br>Average<br>Grant Date Fair<br>Value |
|--|--------------------|---|
|  | (in thousands)     |   |
| Unvested as of December 31, 2020                         | 14                 | \$ 11.38  |
| Granted  | _                  | _   |
| Vested   | (12)               | \$ 11.14  |
| Forfeited  | (2)                | \$ 13.00  |
| Unvested as of September 30, 2021                        | <u> </u>           | \$  |
| Grant date fair value of shares vested during the period | \$ 134             |   |
| Unrecognized compensation costs as of September 30, 2021 | \$                 |   |
|  |                    |   |

| Stock Option Awards:                                 | Number of Options (in thousands) | <br>Weighted Average<br>Exercise Price |
|--|----------------------------------|--|
| Outstanding as of December 31, 2020                  | 3,259                            | \$<br>8.14                             |
| Granted  | 1,211                            | \$<br>4.73                             |
| Exercised, Forfeited, Expired                        | (128)                            | \$<br>5.11                             |
| Outstanding as of September 30, 2021                 | 4,342                            | \$<br>7.28                             |
| Vested and expected to vest as of September 30, 2021 | 4,194                            | \$<br>7.37                             |
| Exercisable as of September 30, 2021                 | 2,018                            | \$<br>10.18                            |

The fair values of stock options granted during the nine months ended September 30, 2021 were estimated using the Black-Scholes pricing model based on the following assumptions:

| Expected dividend yield | — %        |
|-------------------------|------------|
| Expected volatility     | 95% - 100% |
| Expected term (years)   | 6.1        |
| Risk-free interest rate | 1.0 %      |

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2021 was \$3.61. During the nine-month period ended September 30, 2021, stock options were granted with an exercise price ranging from \$3.76 to \$5.30 and accordingly, given the Company's share price of \$4.36 at September 30, 2021, certain shares granted during this period provided intrinsic value at that date totaling \$159.

As of September 30, 2021, \$4,691 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.

The Company did not grant restricted stock units during the nine months ended September 30, 2021. There were no unvested restricted stock units and no unrecognized compensation expense related to restricted stock units at September 30, 2021.

#### **Employee Stock Purchase Plan**

The Company's Employee Stock Purchase Plan ("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, 2021 and 2020, respectively, 19,270 and 14,961 shares were purchased and issued through the ESPP at total discounts of \$11 and \$11.

#### Note 18. 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 2021 income tax provision. However, due to the full valuation allowance and no ability or intent to carryback the 2021 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, 2021 and 2020, the Company recorded no income tax benefit from its pretax losses of \$14,555 and \$16,551. Similarly for the nine months ended September 30, 2021 and 2020, the Company recorded no income tax benefit from its pretax loss of \$41,594 and \$35,415, respectively, due to realization uncertainties.

The primary factor impacting the effective tax rate for the three and nine months ended September 30, 2021 is the anticipated full year operating loss which will require full valuation allowances against any associated net deferred tax assets.

#### Note 19. Contingencies

#### Litigation and Contingencies

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

#### Patent-Related Litigation

Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics, Inc. v. Dr. Reddy's Labs. S.A. and Dr. Reddy's Labs., Inc.,

On February 7, 2018, the Company and Indivior Inc. and Indivior UK Ltd. (collectively, "Indivior") initiated a lawsuit against Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") asserting infringement

of U.S. Patent No. 9,855,221 (the "'221 patent"). On April 3, 2018, the Company and Indivior initiated a separate lawsuit against Dr. Reddy's asserting infringement of U.S. Patent No. 9,931,305 (the "'305 patent"). On May 29, 2018, the lawsuits regarding the '221 and '305 patents were consolidated which was originally initiated by Indivior against Dr. Reddy's asserting infringement of U.S. Patent No. 9,687,454 (the "'454 patent"). On February 19, 2019, the court granted the parties' agreed stipulation to drop the '221 patent from the case. On January 8, 2020, the court entered a stipulated order of non-infringement of the '305 patent based on the court's claim construction ruling. The Company and Indivior preserved the rights to appeal the claim construction ruling. The Company 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 losses, if any, in this matter.

#### Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.,

On February 7, 2018, the Company and Indivior initiated a lawsuit against Teva Pharmaceuticals USA, Inc. ("Teva") asserting infringement of the '221 patent. On April 3, 2018, the Company and Indivior initiated a separate lawsuit against Teva asserting infringement of the '305 patent. On May 29, 2018, the lawsuits regarding the '221 and '305 patents were consolidated which was originally initiated by Indivior against Teva asserting infringement of the '454 patent. The parties agreed that the case would be governed by the final judgment against Dr. Reddy's (described above). The Company 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 losses, if any, in this matter.

#### Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics, Inc. v. Alvogen Pine Brook LLC,

On September 14, 2017, Indivior initiated a lawsuit against Alvogen Pine Brook LLC ("Alvogen") asserting infringement of the '454 patent. On February 7, 2018, the Company and Indivior filed an Amended Complaint, adding us as a plaintiff and asserting infringement of the '221 patent. On April 3, 2018, the Company and Indivior initiated a separate lawsuit against Alvogen asserting infringement of the '305 patent. On May 29, 2018, the cases were consolidated. On February 26, 2019, the court granted the parties' agreed stipulation to drop the '221 patent from the case. On January 9, 2020, the court entered a stipulated order of non-infringement of the '305 patent based on the court's claim construction ruling. The Company and Indivior preserved the rights to appeal the claim construction ruling.

On November 21, 2019, Alvogen filed an amended answer and counterclaims asserting monopolization, attempted monopolization, and conspiracy to monopolize against us and Indivior under federal and New Jersey antitrust laws. The court denied the Company's motion to dismiss Alvogen's counterclaims on August 24, 2020. On November 2, 2020, Alvogen filed a second amended answer and counterclaims, removing its allegations of monopolization and attempted monopolization against us and asserting only conspiracy to monopolize against us. Fact discovery on Alvogen's antitrust counterclaims concluded on January 29, 2021. Expert discovery concluded on October 8, 2021, and dispositive motions were filed on October 26, 2021. There is no trial date set. The Company 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 losses, if any, in this matter.

#### Reckitt Benckiser Pharmaceuticals, Inc. and MonoSol Rx, LLC v. BioDelivery Sciences International, Inc. and Quintiles Commercials US, Inc.,

On September 22, 2014, the Company and RB initiated a lawsuit against BioDelivery Sciences International, Inc. ("BDSI") and Quintiles Commercial US, Inc. ("Quintiles") asserting infringement of U.S. Patent No. 8,765,167 ("the '167 patent") in the District of New Jersey (Civil Action No. 3:14-cv-5892). On July 22, 2015, the case was transferred to the Eastern District of North Carolina (Civil Action No. 5:15-cv-00350). BDSI filed requests for *inter partes* review ("IPR") of the '167 patent before the Patent Trial and Appeal Board ("PTAB"), and on May 6, 2016, the court stayed the case pending the outcome and final determination of the IPR proceedings. On March 24, 2016, the PTAB issued final written decisions finding the '167 patent was not unpatentable, and the United States Court of Appeals for the Federal Circuit ("Federal Circuit") remanded those decisions for further proceedings before the PTAB. Following the PTAB's February 7, 2019 decision on remand denying institution, BDSI appealed that decision to the Federal Circuit. The Federal Circuit granted the Company's motion to dismiss the appeal, and denied BDSI's request for rehearing *en banc*. BDSI filed a petition for writ of certiorari to the Supreme Court of the United States ("Supreme Court"), which the Supreme Court denied on October 5, 2020. On January 4, 2021, the parties submitted a joint status report to the Eastern District of North Carolina stating their agreement that all proceedings and appeals of the IPR on the '167 patent are complete and that, as a result, the stay of the matter may be lifted. On April 15, 2021, the court lifted the stay. On April 29, 2021, BDSI filed a renewed motion to dismiss the complaint. In response, the Company and RB filed an amended complaint on May 18, 2021, which, among other things, removed Quintiles as a defendant. On June 3, 2021, BDSI filed a notice withdrawing its motion to dismiss the original complaint. On July 7, 2021, the court may schedule a claim construction hearing after the briefing

is complete, and the remainder of the schedule is dependent on the timing of the court's ruling on claim construction. The Company 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 losses, if any, in this matter.

Aquestive Therapeutics, Inc. v. BioDelivery Sciences International, Inc.,

On November 11, 2019, the Company initiated a lawsuit against BDSI asserting infringement of the '167 patent in the Eastern District of North Carolina. On April 1, 2020, the court denied BDSI's motion to stay and its motion to dismiss the complaint. On April 16, 2020, BDSI filed its Answer and Counterclaims to the complaint, including counterclaims for non-infringement, invalidity, and unenforceability of the '167 patent. On May 7, 2020, the Company filed a Motion to Dismiss BDSI's unenforceability counterclaim and a Motion to Strike BDSI's corresponding affirmative defenses. 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, the Company filed a Motion to Dismiss BDSI's Amended Counterclaim for unenforceability and a Motion to Strike BDSI's corresponding affirmative defense of unenforceability. BDSI filed its opposition to the Company's Motion to Dismiss and Strike on July 16, 2020, and the Company filed its Reply on July 30, 2020. On March 16, 2021, the court issued an order granting-in-part and denying-in-part Aquestive's motion to dismiss BDSI's counterclaims asserting unenforceability of the '167 patent. Aquestive filed its answer to the remaining portions of BDSI's counterclaims on April 6, 2021. BDSI also filed on April 6, 2021 a renewed motion to dismiss Aquestive's complaint. Aquestive filed its opposition to BDSI's renewed motion to dismiss on April 27, 2021, and BDSI filed its reply on May 11, 2021. On August 10, 2021, the court entered an order denying BDSI's motion to dismiss. On July 7, 2021, the court entered a scheduling order in the case, including the same operative dates as the court included in the scheduling order for Civil Action No. 5:15-cv-00350 described above, and the parties are proceeding under that same schedule. The Company is not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or

#### **Antitrust Litigation**

State of Wisconsin, et al. v. Indivior Inc., Reckitt Benckiser Healthcare (UK) Ltd., Indivior PLC, and MonoSol Rx, LLC,

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought a lawsuit 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 lawsuit, the case was consolidated for pre-trial purposes with the In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While the Company was not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that the Company participated in an antitrust conspiracy with Indivior in connection with Indivior's launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. The Company moved to dismiss the States' claims on Suboxone Sublingual Film and engaged in 2017, the court denied the Company's motion to dismiss. The Company filed an answer denying the States' claims on November 20, 2017. Daubert motions were filed on September 28, 2020, and oppositions were filed on October 19, 2020. On February 19, 2021, the court issued an order denying all Daubert motions. On March 8, 2021, Aquestive filed a motion for summary judgment. Briefing on summary judgment motions was completed on May 28, 2021. There is no date set for a hearing on the motions for summary judgment and no trial date has yet been set. The Company 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**

Humana Inc. v. Indivior Inc, Indivior Solutions Inc., Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., and Aquestive Therapeutics, Inc.,

<u>Centene Corporation, Wellcare Health Plans, Inc., New York Quality Healthcare Corporation d/b/a Fidelis Care, and Health Net, LLC v. Indivior Inc, Indivior Solutions Inc., Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., and Aquestive Therapeutics, Inc.,</u>

On September 18, 2020, Humana, Inc. ("Humana"), a health insurance payor, filed a lawsuit against us and Indivior in the Eastern District of Pennsylvania alleging facts similar to those at issue in the Antitrust Case and the Suboxone MDL described above, which lawsuit was assigned to the same judge that is presiding over Antitrust Case and Suboxone MDL. Humana's Complaint alleges five causes of action against us, 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 ("Centene") and other related insurance payors filed a similar lawsuit against us and Indivior in the Eastern District of Missouri. 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. On January 15, 2021, the Company filed a motion to dismiss the Centene and Humana complaints. The court held an in-person oral argument on the motions to dismiss on June 9, 2021. The court dismissed all complaints against the defendants in these matters on July 22, 2021. On August 20, 2021, Centene and Humana appealed the decision to the U.S. Appeals Court for the Third Circuit ("Third Circuit"). That state court action is stayed pending resolution of the federal appeal in the Third Circuit.

#### California Litigation

#### Neurelis, Inc. v. Aquestive Therapeutics, Inc.,

On December 5, 2019, Neurelis filed a lawsuit against us in the Superior Court of California, County of San Diego alleging the following three causes of action: (1) Unfair Competition under California Business and Professional Code § 17200; (2) Defamation; and (3) Malicious Prosecution. 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 opposed. On August 6, 2020, the court issued an order granting in part and denying in part the Company's anti-SLAPP motion. The Company 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. The Company filed its opening appeal brief on January 27, 2021, and Neurelis filed its combined opening and responsive appeal brief on March 30, 2021. Aquestive filed its combined response and reply brief on June 1, 2021 and Neurelis filed its final reply brief on July 6, 2021. Oral argument on the appeal was heard on October 14, 2021, and a ruling on the appeal is expected within 90 days of the oral argument. The trial court proceedings remain stayed while the appeal is pending. The Company 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.

#### Neurelis IPR Infringement Litigation

In the first quarter of 2019, Aquestive requested institution of three Inter Partes Reviews ("IPRs") against Neurelis' Orange Book method of treatment patent, US Patent No. 9,763,876 ('876 Patent) for nasal administration of benzodiazepines (diazepam). The PTAB denied two of the requests and instituted the third request, which challenged all claims of the Neurelis '876 Patent. On August 6, 2020, the PTAB issued its final written decision finding all challenged claims of the '876 Patent to be unpatentable. Neurelis appealed the decision to the U.S. Court of the Federal Circuit. On October 7, 2021, the Federal Circuit Court issued a *per curium* decision affirming the PTAB's final decision that the '876 Patent was unpatentable. If no appeal of the Federal Circuit Court ruling is filed by November 7, 2021, the Federal Circuit Court will issue a mandate closing the appeal period and an IPR Certificate will subsequently be issued by the United States Patent and Trademark Office. The Company 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.

#### Stockholder Class Action

#### Deanna Lewakowski v. Aquestive Therapeutics, Inc.

On March 1, 2021, a securities class action lawsuit was filed in the United States District Court of the District of New Jersey alleging that the Company and certain of its officers engaged in violations of the federal securities laws relating to public statements made by the Company regarding the FDA approval of Libervant. Following the court's appointment of a lead plaintiff, an amended complaint was filed by the plaintiffs on July 25, 2021. All dispositive motions were filed with the court on or before November 1, 2021. There is no date set for a hearing on the motions to dismiss and no trial date has yet been set. The Company 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 20. Subsequent Events

#### Continued Utilization of the At-The-Market Facility

The Company continued utilization of its At-The-Market facility from October 1 through October 31, 2021 and sold 80,783 shares which generated net proceeds of approximately \$313.

#### 12.5% Senior Secured Notes Fourth Supplemental Indenture

On October 7, 2021, the Company entered into the Fourth Supplemental Indenture, by and among the Company and the Trustee and collateral agent thereunder, to the Indenture in connection with the 12.5% Notes. Pursuant to the Fourth Supplemental Indenture, the amortization schedule for the 12.5% Notes was amended to provide for the date of the first amortization payment to be extended to March 30, 2023. The Fourth Supplemental Indenture did not change the maturity date of the Notes or the interest payment obligation due under the Notes. In connection with the Fourth Supplemental Indenture, the Company entered into a Consent Fee Letter with the noteholders, pursuant to which the Company agreed to pay the noteholders an additional cash payment of \$2.7 million in the aggregate, payable in four quarterly payments beginning May 15, 2022, in exchange to defer \$10.3 million of principal payments. The Company is currently evaluating the impact of the Fourth Supplemental Indenture on its consolidated financial statements. The amendment may result in a gain or loss on extinguishment of debt that would be reported in the statement of operations in a subsequent period.

#### 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, 2020 and 2019 included in our 2020 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 the advancement and related timing of Libervant™, AQST-109 and AQST-108 through the regulatory and development pipeline; the focus on growing our commercial sales of Sympazan® and continuing to manufacture Suboxone®. Exservan® and other licensed products; the ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application ("NDA") for Libervant and obtain FDA approval of Libervant for U.S. market access; clinical trial timing and plans for AQST-109 and AQST-108; the ability to fund our operations for the next twelve months; and 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 and distribution; 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, we are unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are also 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 our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials; risk of delays in regulatory advancement through the FDA of Libervant and our other drug candidates or failure to receive approval, including the failure to receive orphan drug exclusivity; risk of our ability to demonstrate to the FDA "clinical superiority" within the meaning of the FDA regulations of 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 in obtaining market access for Libervant and our other product candidates for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations) and the related risk of the failure to obtain such approval on our ability to access additional funding under the 12.5% Notes; risks and uncertainties concerni

commercial targets required for contingent payments under the KYNMOBI monetization transaction; risk of development of our sales and marketing capabilities; 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; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risks related to the outsourcing of certain 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; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and products candidates and product pricing, reimbursement or access therefore; risk of loss of significant customers; risks related to claims and legal proceedings including patent infringement, securities, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; the COVID-19 pandemic and its impact on our business; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting us including those described in the "Risk Factors" section and in other sections included in this 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 and Exchange Commission (SEC). Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as 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. We assume no obligation to update forward-looking statements, or outlook or guidance after the date of this Annual Report 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 whether as a result of new information, future events or otherwise, except as may be required by applicable law.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in the risk factors of our 2020 Annual Report on Form 10-K.

#### 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. We have five products approved by the U.S. Food and Drug Administration (FDA), both proprietary and out-licensed, 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. Our licensees market their products in the U.S. and in some instances outside the U.S. We market our proprietary product in the U.S. We believe that our proprietary and licensed products address the needs of these patient populations and the shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines.

#### Proprietary CNS Product Portfolio

We have initially focused our proprietary product pipeline on certain difficult to treat CNS diseases. Our two most advanced assets within our proprietary CNS portfolio, focused on epilepsy, are as follows:

- **Sympazan**® an oral soluble film formulation of clobazam used 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. We commercially launched Sympazan in December 2018. Sympazan was launched as a precursor and complement to our product candidate Libervant<sup>TM</sup> and continues to progress on key performance metrics including prescriber growth, repeat prescribers, quarterly growth in retail shipments and pharmacy claims reimbursements.
- **Libervant**<sup>TM</sup> a buccally, or inside of the cheek, administered soluble film formulation of diazepam is our most advanced proprietary investigational product candidate, which we intend to self-commercialize, subject to FDA approval for U.S. market access. Aquestive is developing Libervant as an alternative to device-dependent rescue therapies currently available to patients with refractory epilepsy, which are a rectal gel and nasal sprays. In late September 2020, we received a complete response letter ("CRL") from the FDA focusing on doses tested in certain weight groups. At a Type A meeting with the FDA in November 2020, the FDA confirmed that the issues identified in the CRL may be addressed by utilizing modeling and simulations for an updated dosing regimen. We submitted a

revised weight-based dosing regimen with modeling and simulations in December 2020. In February 2021, the FDA provided feedback on the December 2020 submission which provided clarity regarding the information that the Agency expected to see in our population pharmacokinetic ('PK") model and safety data as it relates specifically to the patient population included in the studies. In June 2021, we resubmitted our New Drug Application ("NDA") to the FDA. In July 2021, the FDA accepted our resubmission filing of the NDA and assigned a Prescription Drug User Fee Act ("PDUFA") target goal date of December 23, 2021. The Company continues to actively engage with the FDA regarding its accepted NDA for Libervant ahead of the PDUFA target goal date as the FDA completed its mid cycle review of our application in September. In addition to responding to a number of information requests, the FDA has concluded an audit of our post marketing adverse event reporting capabilities, requested and received additional information about the patent coverage for the product, approved for use the trade name for Libervant, and made recommendations for changes in language related to our packaging. Concurrently, we have spoken with the FDA Office of Orphan Products Development. We have provided additional information supplementing our original correspondence to the group and continue to believe that we have provided a strong set of facts supporting a decision by the FDA of clinical superiority to prior approved drugs for this indication to support a finding that Libervant represents a major contribution to patient care as compared to the device driven rectal and nasal spray alternatives. Preparations are advancing with payer and sales force planning underway for the commercial launch of Libervant, if approved for U.S. market access, as soon as possible after approval. We anticipate that capital available within our existing debt facility will be available, if we choose, to support the launch of this product, if approved. 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. Further, there can be no assurance that a competitor will not obtain other FDA marketing exclusivity that blocks U.S. market access for Libervant. Any failure to obtain FDA approval to demonstrate clinical superiority or get U.S. market access for Libervant would have a material adverse effect on our business, financial condition and results of operations in 2021 and later. More details on this product approval are described in the "Competition" section of Item I. Business of our 2020 Annual Report on Form 10-K.

#### Complex Molecule Portfolio

We have also developed a proprietary pipeline of complex molecule-based products as alternatives to invasively administered standard of care injectable therapeutics addressing large market opportunities beyond CNS indications.

The active programs in our complex molecule portfolio are:

• AQST-109 — is a next generation prodrug sublingual film formulation of epinephrine that is in development for the treatment of allergic reactions, including anaphylaxis. Epinephrine is the standard of care in the treatment of anaphylaxis and is currently administered via auto-injectors, such as EpiPen® and Auvi-Q®, which require patients or caregivers to inject epinephrine into their thighs during an emergency allergic reaction. As a result of this route of administration, 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. However, AQST-109 would, if approved by the FDA, allow a patient to simply place a dissolvable strip, approximately the size and weight of a postage stamp, under the tongue, providing an appropriate medication where it is needed, when it is needed and in a form preferred by patients.

The Company completed a first-in-human Phase 1 clinical trial for AQST-109 in Canada. Recently reported top line data from this study support AQST-109's potential as the first orally administered epinephrine product for the treatment for anaphylaxis with safety, tolerably, PK and pharmacodynamics (PD) measures comparable to those of the auto-injector epinephrine products. Further, we submitted a request for a pre-IND meeting for AQST-109 with the FDA and anticipate receiving a written response from the FDA by the end of 2021. We are on track to conduct a crossover study using an adaptive design for AQST-109 in Canada beginning in the fourth quarter 2021. This study will determine the final formulation and dose for AQST-109 and allow the Company to move forward to the manufacture of registration batches and a pivotal PK study in 2022.

• AQST-108 — is a sublingual film formulation delivering systemic epinephrine that is also in development by Aquestive for the treatment of certain types of allergic reactions other than anaphylaxis. AQST-108 is composed of the prodrug dipivefrin which is enzymatically cleaved systemically into epinephrine after administration. Dipivefrin is currently available outside of the U.S. for ophthalmic indications. Based on top-line results of a recent second Phase 1 PK trial in 28 healthy adult volunteers, AQST-108 was generally well-tolerated, with adverse events observed that are consistent with the known adverse events profile for epinephrine. We are on track to request a pre-IND meeting with the FDA in 2022 and plan to disclose the indication and path forward for development once we have received feedback from the agency.

• 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 in 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<sup>®</sup>, 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 in the treatment cycle. AQST-305 has shown promising preclinical and human proof of concept results. While we focus our efforts on Libervant, AQST-109, and AQST-108, in the short-term, we have taken the necessary steps to prepare AQST-305 for additional research trials.

#### **Licensed Commercial Products and Product Candidates**

Our portfolio also includes products and product candidates that we have licensed, or will seek to license, or for which we have licensed our intellectual property for commercialization. In the years ended December 31, 2020 and 2019, our licensed product portfolio generated \$40.2 million and \$49.7 million in revenue to Aquestive, respectively. Those products include:

- **Suboxone**® a sublingual film formulation of buprenorphine and naloxone, respectively an opioid agonist and antagonist, that is marketed in the United States and internationally for the treatment of opioid dependence. Suboxone Sublingual Film was launched by our licensee, Indivior Inc., or Indivior, in 2010. Suboxone Sublingual Film is the most prescribed branded product in its category and was the first sublingual film product for the treatment of opioid dependence. We are the sole and exclusive supplier and manufacturer of Suboxone Sublingual Film and have produced over 2.2 billion doses of Suboxone since its launch in 2010. As of September 30, 2021, Suboxone branded products retain approximately 38% film market share as generic film-based products have penetrated this market. We have filed patent infringement lawsuits against certain companies relating to generic film-based products for buprenorphine-naloxone. More details regarding these lawsuits are described in the unaudited financial statements, Note 19. Contingencies, contained herein.
- Exservan<sup>TM</sup> (riluzole) has been developed for the treatment of amyotrophic lateral sclerosis (ALS). We believe that Exservan, via our orally administered dosage form, can bring meaningful assistance to patients who are diagnosed with ALS and face difficulties swallowing traditional forms of medication. Exservan was approved by the FDA on November 22, 2019. During the fourth quarter of 2019, we announced the grant of a license to Zambon S.p.A. ("Zambon") for the development and commercialization of Exservan Oral Film in the European Union (EU) for the treatment of ALS. Zambon is a multinational pharmaceutical company with a focus on the CNS therapeutic area. Under the terms of the license agreement with Zambon, an upfront payment was paid to Aquestive for the development and commercialization rights of Exservan in the EU, and Aquestive will be paid development and sales milestone payments and low double-digit royalties on net sales of the product in the EU. Zambon is responsible for the regulatory approval and marketing of Exservan in the countries where Zambon seeks to market the product, and Aquestive will be responsible for the development and manufacture of the product.

In January 2021, we announced our exclusive license to Mitsubishi Tanabe Pharma Holdings America, Inc. ("MTHA") for the commercialization in the United States of Exservan. MTHA is a multinational pharmaceutical company with a focus on patients with ALS. Under the terms of the MTHA license agreement, upfront payments were paid to Aquestive with additional payments due upon the occurrence of certain milestone events in advance of launch. Aquestive will also be paid double-digit royalties on net sales of the product in the United States and will earn revenue pursuant to the exclusive supply agreement. The product launched in June 2021. Exservan may potentially fulfill a critical need for ALS patients, given it can be administered safely and easily, twice daily, without water.

• **KYNMOBI**®— a sublingual film formulation of apomorphine, which is a dopamine agonist developed to treat episodic off-periods in Parkinson's disease. We licensed our intellectual property to Cynapsus Therapeutics, Inc., a company that was acquired by Sunovion Pharmaceuticals Inc., or Sunovion, for the commercialization of KYNMOBI under an Agreement dated April 1, 2016, as amended (the "Sunovion License Agreement"). KYNMOBI was approved by the FDA on May 21, 2020 and commercially launched by Sunovion in September 2020. On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI. We received an aggregate amount of \$50,000 through September 30, 2021 under the Monetization Agreement. Under the Monetization Agreement, additional aggregate contingent payments of up to \$75.0 million may be due us upon the achievement of worldwide royalty and other

commercial targets within a specified timeframe, which could result in total potential gross proceeds under the Monetization Agreement of \$125.0 million.

• **Zuplenz** – an oral soluble film formulation of ondansetron, a 5-HT antagonist approved for the treatment of nausea and vomiting associated with chemotherapy and post-operative recovery. Ondansetron is available as branded and generic products as intravenous injections, intramuscular injections, orally dissolving tablets, oral solution tablets, and film. We licensed commercial rights for Zuplenz to Fortovia Therapeutics Inc. (previously Midatech Pharma PLC, "Fortovia") in the United States, Canada, and China. Fortovia launched Zuplenz in the United States in 2015. We had been the sole and exclusive manufacturer of Zuplenz for Fortovia. On August 31, 2020 Fortovia filed a Chapter 11 bankruptcy proceeding in the Bankruptcy Court for the Eastern District of North Carolina. On January 29, 2021, the Bankruptcy Court approved an agreement pursuant to which the license and supply agreement between Aquestive and Fortovia was terminated, and all rights to commercialize Zuplenz returned to us, effective January 30, 2021. While not expected to be a material product for us, we are seeking a new partner to commercialize Zuplenz in the United States.

#### **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 delay will 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 to us for development services provided but ultimately made such payments.

Our office-based colleagues have generally been working from home since March 2020. With additional protections and protocols, we have maintained appropriate and necessary staffing levels at both our laboratory and manufacturing sites. While we previously suspended in-person interactions by our sales and marketing personnel and engaged remotely to support our commercialization efforts, our sales and marketing practices continue to evolve in accordance with changing local rules and regulations. We believe the opportunity for in-person interactions with healthcare providers should increase as the vaccination rate continues to grow. The landscape continues to evolve as localities reestablish and or ease restrictions, as the case may be, with the rise and fall of new case rates and the pace of vaccinations.

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

There have been no material changes to our critical accounting policies and use of estimates as previously disclosed in our 2020 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 our manufactured products made to order for licensees as well as revenue from our self-developed, self-commercialized proprietary product, Sympazan<sup>®</sup>. Revenues are also earned from our product development services provided under contracts with customers, and from the licensing of our intellectual property. These activities generate revenues in four primary categories: manufacture and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

#### Manufacture and Supply Revenue

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 the quality of the manufactured product with agreed upon technical specifications. Our licensees are responsible for all other aspects of commercialization of these products and we have no role, either direct or indirect, in our customers' commercialization activities, including those related to marketing, pricing, sales, payor access 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 realize revenue from licenses of our intellectual property. 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 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. Royalty revenue related to the sale of future revenue is described further in this section under Critical Accounting Policies and Use of Estimates "Royalty Revenue and Interest Expense related to Sale of Future Revenue".

Proprietary Product Sales, Net

We commercialized our first proprietary CNS product, Sympazan, in December 2018. We currently sell Sympazan through wholesalers for distribution through retail and specialty pharmacies. 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 below. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale. We include 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 become known 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, 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.

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

We expect to continue to seek to rationalize and manage costs to reflect the declining production volumes of Suboxone. We reduced the cost of manufacturing and supply in late 2019 and continued throughout 2020 in order to recognize the declining volume of Suboxone that will continue declining in 2021. We expect our manufacture and supply costs and expenses to decrease over the next several years due to the decline in Suboxone volumes as the generics in that market continue to take market share, modestly offset by the commercialization of our proprietary products, starting with Sympazan launched in December 2018. In addition to our proprietary products coming online, we may add licensee 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 manufacturing 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 expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, investigational sites and consultants;
- the cost of acquiring, developing and manufacturing clinical study materials; and

costs associated with preclinical and clinical activities and regulatory operations.

We expect our research and development expenses to continue to be significant over the next several years as we continue to develop existing product candidates such as AQST-109 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 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 relates to the sale and marketing of our proprietary product, Sympazan. Sympazan is the precursor and complement to the launch of Libervant, assuming that it is approved and granted U.S. market access by the FDA. 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, assuming FDA approval for U.S. market access, which cannot be assured. The current commercial organization would begin the launch of Libervant, subject to its approval for U.S. market access, shortly after its approval. Until a Libervant launch is certain, we do not plan to increase the costs of our commercial organization and 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 continue to manage business costs to appropriately reflect the declining state of 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 U.S. market access, which cannot be assured;
- Continuing the development of AQST-109 and AQST-108 along the 505(b)(2) pathway; 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 on our 12.5% Notes at a fixed rate of 12.5%, payable quarterly, as well as amortization of loan costs and the debt discount. The 12.5% Notes are discussed in Note 13, 12.5% Senior Secured Notes due 2025, to our consolidated financial statements. See Liquidity and Capital Resources below for further detail on our 12.5% Notes.

Royalties and Interest Expense related to the Sale of Future Revenue

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the U.S. FDA on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of \$40,000 and an additional payment of \$10,000 through the

achievement of the first milestone, and recorded these payments as a liability related to the sale of future revenue that will be amortized using the effective interest method over the life of the Monetization Agreement.. Although we sold all of our rights to receive royalties and milestones, as a result of our ongoing obligations related to the generation of these royalties, we will account for these royalties as revenue. We have received an aggregate amount of \$50,000 through September 30, 2021 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to \$75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of \$125,000.

During the second quarter of 2020, under the Sunovion License Agreement, we recognized \$8,000 of royalty revenue and corresponding royalty receivable, related to the \$1,000 annual minimum guaranteed royalty that is due in each of the next eight years. In connection with the Monetization Agreement, we performed an assessment under ASC 860, *Transfer and Servicing* to determine whether the existing receivable was transferred to Marathon and concluded that the receivable was not transferred. See Note 15 for further detail on the sale of future revenue.

Interest Income and other income (expense), net

Interest income and other income (expense), net consists of earnings derived from an interest-bearing account and other miscellaneous income and expense items. The interest-bearing account has 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 and Nine Months Ended September 30, 2021 and 2020

Revenues:

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

|                                  | 1  | Three Months Ended<br>September 30, |    |       |    | Ch    | Nine Months Ended<br>September 30, |    |        |    | Change |    |         |       |
|----------------------------------|----|-------------------------------------|----|-------|----|-------|------------------------------------|----|--------|----|--------|----|---------|-------|
| (In thousands, except %)         |    | 2021                                |    | 2020  |    | \$    | %                                  |    | 2021   |    | 2020   |    | \$      | %     |
| Manufacture and supply revenue   | \$ | 10,447                              | \$ | 5,903 | \$ | 4,544 | 77 %                               | \$ | 27,623 | \$ | 20,078 | \$ | 7,545   | 38 %  |
| License and royalty revenue      |    | 328                                 |    | 328   |    | _     | — %                                |    | 5,000  |    | 13,682 |    | (8,682) | (63)% |
| Co-development and research fees |    | 523                                 |    | 341   |    | 182   | 53 %                               |    | 1,417  |    | 870    |    | 547     | 63 %  |
| Proprietary product sales, net   |    | 1,989                               |    | 1,688 |    | 301   | 18 %                               |    | 5,714  |    | 4,070  |    | 1,644   | 40 %  |
| Total revenues                   | \$ | 13,287                              | \$ | 8,260 | \$ | 5,027 | 61 %                               | \$ | 39,754 | \$ | 38,700 | \$ | 1,054   | 3 %   |

For the three months ended September 30, 2021, total revenues increased 61% or \$5,027 compared to same period in the prior year. The increase was primarily due to higher manufacturing and supply revenue as well as Sympazan revenue. For the nine months ended September 30, 2021, total revenues increased 3% or \$1,054 compared to the same period in the prior year. The increase was primarily due to higher Sympazan revenue and manufacture and supply revenue, offset by lower license and royalty revenue.

Manufacture and supply revenue increased 77% or \$4,544 for the three months ended September 30, 2021 compared to the same period in the prior year. Manufacture and supply revenue increased 38% or \$7,545 for the nine months ended September 30, 2021 compared to the same period in the prior year. This increase was due to higher Suboxone manufacturing volume.

License and royalty revenue remained flat for the three months ended September 30, 2021 compared to the same period in the prior year. License and royalty revenue decreased 63% or \$8,682 for the nine months ended September 30, 2021 compared to the same period in the prior year. This decrease was due to a milestone earned of \$4,000 as well as royalty revenue of \$8,000 recognized upon the FDA approval of Sunovion's KYNMOBI ™ product during the second quarter of 2020 that did not recur in 2021. This was partly offset by an increase in milestones earned from KemPharm, Inc. of \$1,500 and the recognition of remaining deferred revenue associated with the license and supply agreement with Fortovia Therapeutics Inc. which was terminated in the first quarter of 2021.

Co-development and research fees increased 53% or \$182 for the three months period ended September 30, 2021 compared to the same period in the prior year. Co-development and research fees increased 63% or \$547 for the nine months ended September 30, 2021 compared to the same period in the prior year. The increase was driven by the timing of the achievement of research and development performance obligations and are expected to fluctuate from one reporting period to the next.

Proprietary product sales, net increased 18% or \$301 for the three months ended September 30, 2021 compared to the same period in the prior year. Proprietary product sales, net increased 40% or \$1,644 for the nine months ended September 30, 2021 compared to the same period in the prior year. The increase was due to a steady rise in acceptance with the medical and patient communities over time which led to increased prescriptions and improved payor approval rates for Sympazan.

## Expenses and Other:

|   |    | Three Months Ended September 30, |    |         |    | Change  |        |    | Nine Months Ended<br>September 30, |    |         | Change |          |       |
|---|----|----------------------------------|----|---------|----|---------|--------|----|------------------------------------|----|---------|--------|----------|-------|
| (In thousands, except %)                                    |    | 2021                             |    | 2020    |    | \$      | %      |    | 2021                               |    | 2020    |        | \$       | %     |
| Manufacture and supply                                      | \$ | 4,400                            | \$ | 2,978   | \$ | 1,422   | 48 %   | \$ | 11,623                             | \$ | 10,176  | \$     | 1,447    | 14 %  |
| Research and development                                    |    | 4,726                            |    | 7,260   |    | (2,534) | (35)%  |    | 12,647                             |    | 15,461  |        | (2,814)  | (18)% |
| Selling, general and administrative                         |    | 12,129                           |    | 11,803  |    | 326     | 3 %    |    | 38,494                             |    | 40,310  |        | (1,816)  | (5)%  |
| Interest expense  |    | (2,787)                          |    | (2,778) |    | (9)     | — %    |    | (8,305)                            |    | (8,296) |        | (9)      | — %   |
| Interest expense related to the sale of future revenue, net |    | (3,767)                          |    | _       |    | (3,767) | 100 %  |    | (10,567)                           |    | _       |        | (10,567) | 100 % |
| Interest and other (expense) income, net                    |    | (33)                             |    | 8       |    | (41)    | (513)% |    | 288                                |    | 128     |        | 160      | 125 % |

Manufacture and supply costs and expenses increased 48% or \$1,422 for the three months ended September 30, 2021 compared to the same period in the prior year. Manufacture and supply costs and expenses increased 14% for the nine months ended September 30, 2021 compared to the same period in the prior year. The increase in manufacture and supply costs was due to volume growth of Suboxone.

Research and development expenses decreased 35% or \$2,534 for the three months ended September 30, 2021 compared to the same period in the prior year. Research and development expenses decreased 18% or \$2,814 for the nine months ended September 30, 2021 compared to the same period in the prior year. Research and development expenses are driven primarily by the timing of clinical trial and other product development activities associated with our pipeline.

Selling, general and administrative expenses increased 3% or \$326 for the three months ended September 30, 2021 as compared to the same period in the prior year. The increase was driven by litigation expense that arise through the course of business, partially offset by lower sales and marketing costs and share-based compensation expense. Selling, general and administrative expenses decreased 5% or \$1,816 for the nine months ended September 30, 2021 as compared to the same period in the prior year. The decrease was primarily driven by lower sales and marketing costs, patent costs and share-based compensation expense.

Interest expense remained flat for the three and nine months ended September 30, 2021 compared to the same period in the prior year.

Interest expense related to the sale of future revenue, net was \$3,767 and \$10,567 for the three and nine months ended September 30, 2021, respectively. This amount is due to the accounting associated with the sale of future revenue related to KYNMOBI® sold to Marathon on November 3, 2020 and does not represent a monetary obligation or cash outflow at any time during the life of the transaction. See note 15 for details.

Interest and other (expense) income, net decreased \$41 and increased \$160, respectively, for the three and nine months ended September 30, 2021 compared to the same periods in the prior year. This was due to the fair value adjustment of the put option related to the 12.5% Notes. See note 13 for details.

## **Liquidity and Capital Resources**

## Sources of Liquidity

We have experienced a history of net losses. Our accumulated deficits totaled \$227,851 as of September 30, 2021. The net losses and accumulated deficits were partially offset by gross margins from sales of commercialized licensed and proprietary products, license fees, milestone and royalty payments from commercial licensees and co-development parties. Our funding requirements are met by our cash and cash equivalents, as well as our existing equity and debt offerings, including the Senior Secured Notes due 2025 (the "12.5% Notes"). We had \$31,164 in cash and cash equivalents as of September 30, 2021.

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License

Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the FDA on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of \$40,000 and an additional payment of \$10,000 through the achievement of the first milestone. We have received an aggregate amount of \$50,000 through September 30, 2021 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to \$75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of \$125,000.

With the upfront proceeds of the monetization, we repaid \$22,500 of the 12.5% Notes, and issued \$4,000 of new 12.5% Notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the aggregate principal balance of 12.5% Notes outstanding to \$51,500. In addition, the holders of the 12.5% Notes agreed to extend to December 31, 2021 our ability to access, at our option, and additional \$30,000 of 12.5% Notes re-openers under the Indenture. The first \$10,000 12.5% 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 12.5% 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, we issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.

On September 30, 2021, the Company entered into a waiver agreement (the "Waiver") with the holders of the 12.5% Notes pursuant to which the principal payment due under the 12.5% Notes on September 30, 2021 was deferred in order to provide sufficient time for the execution of the Fourth Supplemental Indenture (the "Fourth Supplemental Indenture"). On October 7, 2021, the Company entered into the Fourth Supplemental Indenture, by and among the Company and the Trustee and collateral agent thereunder, to the Indenture in connection with the 12.5% Notes. Pursuant to the Fourth Supplemental Indenture, the amortization schedule for the 12.5% Notes was amended to provide for the date of the first amortization payment to be extended to March 30, 2023. The Fourth Supplemental Indenture did not change the maturity date of the Notes or the interest payment obligation due under the Notes. In connection with the Fourth Supplemental Indenture, the Company entered into a Consent Fee Letter with the holders of the 12.5% Notes, pursuant to which the Company agreed to pay the holders of the 12.5% Notes an additional cash payment of \$2.7 million in the aggregate, payable in four quarterly payments beginning May 15, 2022. See Note 20 for discussion.

In 2019, we established an "At-The-Market" (ATM) facility pursuant to which we may offer up to \$25,000,000 of shares of common stock. In the first quarter of 2021, we filed a prospectus supplement to offer up to an additional \$50,000 of shares of common stock under the ATM facility. Since inception to September 30, 2021, we sold 6,417,804 shares which generated net cash proceeds of approximately \$30,647, net of commissions and other transaction costs of \$1,541. For the nine months ended September 30, 2021, we sold 5,486,871 shares which provided net proceeds of approximately \$24,592, net of commissions and other transaction costs of \$1,068. This ATM facility has approximately \$42,812 available at September 30, 2021.

## Cash Flows

## Nine Months Ended September 30, 2021 and 2020

| (in thousands)                                       | 2021           | 2020           |
|--|----------------|----------------|
| Net cash (used for) operating activities             | \$<br>(24,918) | \$<br>(31,947) |
| Net cash (used for) investing activities             | (380)          | (281)          |
| Net cash provided (used for) by financing activities | 24,655         | (34)           |
| Net increase (decrease) in cash and cash equivalents | \$<br>(643)    | \$<br>(32,262) |

# Net Cash (Used for) Operating Activities

Net cash used for operating activities for the nine months ended September 30, 2021 decreased by \$7,029 compared to the same period in the prior year. The decrease was related to higher non-cash operating expenses of \$11,993, changes in operating assets and liabilities of \$1,215, partially offset by a higher net loss of \$6,179. The higher non-cash operating expenses were primarily due to increases in interest expense related to sale of future revenue (\$10,457) and amortization of debt issuance costs

(\$1,846). The change in operating assets and liabilities was primarily due to timing of payments, increased deferred revenue related to a \$1,250 net milestone payment received in connection with a license and supply agreement to commercialize AQST-119 Tadalafil Oral Film, offset by higher trade and other receivables due to increased revenue.

## Net Cash (Used for) Investing Activities

Net cash used for investing activities for the nine months ended September 30, 2021 increased by \$99 compared to the same period in the prior year. The use of cash was related to capital expenditures.

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

Net cash provided for financing activities for the nine months ended September 30, 2021 increased by \$24,689 compared to the same period in the prior year. The increase was primarily related to net proceeds from the sale of shares under the ATM facility in 2021.

# **Funding Requirements**

Based on our current operating plan, we believe that our existing cash and cash equivalents, revenue from our on-going business, continued business development activities, expense management actions, and our ability to access funds under our existing equity facility and debt offering will enable us to fund our expected cash requirements for the next 12 months. We 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, we may be required to utilize available financial resources sooner than expected. We have based our 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, including the approval of Libervant, and regulatory oversight and other factors. 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 colleagues 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, Sympazan and Exservan, 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 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;
- our ability to issue up to \$30,000 in additional 12.5% Notes, which is contingent upon FDA product approval and U.S. market access for Libervant:
- 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 anticipated general decline in Suboxone revenue, the marketing and sales costs related to Sympazan, the proceeds from the KYNMOBI Monetization Agreement, 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 or future equity financing, other future access to the capital markets 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, more importantly, continued investments in our ongoing product development and planned commercialization activities in support of Libervant, AQST-109 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, AQST-109 and AQST-108, if approved by the FDA for U.S. market access, 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 continue to spend less on commercialization in 2021 compared to 2020. Even as such, we expect to incur losses and negative cash flows for the foreseeable future and, therefore, we expect to be dependent upon external financing and funding to achieve our operating plan.

The sufficiency of our short-term and longer-term liquidity is directly impacted by our level of operating revenues and our ability to achieve our operating plan for revenues, regulatory approval in the time period planned for 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 suspended and may only be reinstated if Indivior successfully adjudicates or settles the related patent infringement litigation, and under the Monetization Agreement, 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 operating cash flows for the foreseeable future, and we have a significant level of debt on which we have substantial ongoing debt repayment and debt service obligations and have principal repayments related to our 12.5% Notes due through the debt maturity date, which is further discussed in Note 13. 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.

To the extent that 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 of 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, if at all. 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 would be required to engage in expense management activities such as reducing staff, delaying, significantly scaling back, or even discontinuing some or all of our current or planned research and development programs and clinical and other product development activities, or reducing our planned commercialization efforts and otherwise significantly reducing our other spending and adjusting our operating plan, and we would need to seek to take other steps intended to improve our liquidity. We also may be required to evaluate additional licensing opportunities, if any become available, of our proprietary product candidate programs that we currently plan to self-commercialize or explore other potential liquidity opportunities or other alternatives or options or strategic alternatives, although we cannot assure that any of these actions would be available or available on reasonable terms.

See also the risk factors below concerning the significant risks and uncertainties concerning our 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

As a "smaller reporting company" as defined by Item 10 of Regulation S-K promulgated by the SEC under the U.S. Securities Act of 1933, as amended, we are not required to provide the information required by this Item 3.

#### 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, 2021, 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, 2021, 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

For more information on Legal Proceedings, see Part I Item I. Financial Statements (Unaudited), Note 19. Contingencies.

## Item 1A. Risk Factors

You should carefully review and consider the information regarding certain risks and uncertainties facing the Company that could have a material adverse effect on the Company's business prospects, financial condition, results of operations, liquidity and available capital resources set forth in Part I, Item 1A of the Company's 2020 Annual Report on Form 10-K.

| Item 2. | Unregistered Sales of Equity Securities and Use of Proceeds |
|---------|---|
| None.   |   |
| Item 3. | <b>Defaults Upon Senior Securities</b>                      |
| 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.

|         | Description   |
|---------|---|
|         |   |
|         | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith). |
| 31.2    | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith). |
| 32.1    | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).   |
| 32.2    | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).   |
| 101.INS | XBRL Instance Document  |
| 101.SCH | XBRL Taxonomy Extension Schema Document   |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document  |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document   |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document  |

# **SIGNATURES**

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

## 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 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.

Date: November 2, 2021

/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, A. Ernest Toth, Jr, 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.

Date: November 2, 2021

/s/ A. ERNEST TOTH, JR.

A. Ernest Toth, Jr. Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Keith J. Kendall, 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, 2021, 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.

Date: November 2, 2021

## /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.

Exhibit 32.2

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, A. Ernest Toth, Jr., 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, 2021, 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.

Date: November 2, 2021

## /s/ A. ERNEST TOTH, JR

A. Ernest Toth, Jr. 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.