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

# FORM 10-Q

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

**For the quarterly period ended September 30, 2022**

**OR**

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

**For the transition period from _____ to _____**

**Commission File Number: 001-38599**

# Aquestive Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

| **Delaware** | **30 Technology Drive, Warren, NJ 07059** | **82-3827296** |
|---|---|---|
| (State or other jurisdiction of Incorporation or organization) | **( 908) 941-1900** | (I.R.S. Employer Identification Number) |

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

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

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

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

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☒ |

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

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

The number of outstanding shares of the registrant's common stock, par value of $0.001 per share, as of the close of business on October 24, 2022 was 54,156,014.

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

**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)

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 18,649 | $ 28,024 |
| Trade and other receivables, net | 10,737 | 12,120 |
| Inventories, net | 6,725 | 4,038 |
| Prepaid expenses and other current assets | 1,976 | 3,077 |
| Total current assets | 38,087 | 47,259 |
| Property and equipment, net | 4,284 | 5,055 |
| Right-of-use assets, net | 2,094 | 2,725 |
| Intangible assets, net | 1,487 | 51 |
| Other non-current assets | 5,893 | 6,903 |
| Total assets | $ 51,845 | $ 61,993 |
| | | |
| **Liabilities and stockholders' deficit** | | |
| Current liabilities: | | |
| Accounts payable | $ 11,072 | $ 8,314 |
| Accrued expenses | 7,733 | 8,736 |
| Lease liabilities, current | 846 | 899 |
| Deferred revenue, current | 774 | 765 |
| Liability related to the sale of future revenue, current | 1,910 | 1,225 |
| Loans payable, current | 14,225 | 2,025 |
| Total current liabilities | 36,560 | 21,964 |
| Loans payable, net | 38,675 | 51,551 |
| Liability related to the sale of future revenue, net | 63,308 | 59,059 |
| Lease liabilities | 1,340 | 1,946 |
| Deferred revenue | 17,622 | 7,122 |
| Other non-current liabilities | 2,159 | 2,485 |
| Total liabilities | 159,664 | 144,127 |
| **Contingencies (Note 19)** | | |
| | | |
| Stockholders' deficit: | | |
| Common stock, $0.001 par value. Authorized 250,000,000 shares; 53,852,126 and 41,228,736 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively | 54 | 41 |
| Additional paid-in capital | 190,982 | 174,621 |
| Accumulated deficit | (298,855) | (256,796) |
| Total stockholders' deficit | (107,819) | (82,134) |
| Total liabilities and stockholders' deficit | $ 51,845 | $ 61,993 |

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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Revenues | $ 11,463 | $ 13,287 | $ 36,998 | $ 39,754 |
| Costs and expenses: | | | | |
| Manufacture and supply | 4,625 | 4,400 | 14,081 | 11,623 |
| Research and development | 3,232 | 4,726 | 13,203 | 12,647 |
| Selling, general and administrative | 12,459 | 12,129 | 41,067 | 38,494 |
| Total costs and expenses | 20,316 | 21,255 | 68,351 | 62,764 |
| Loss from operations | (8,853) | (7,968) | (31,353) | (23,010) |
| Other income/ (expenses): | | | | |
| Interest expense | (1,649) | (2,787) | (4,902) | (8,305) |
| Interest expense related to the sale of future revenue, net | (2,039) | (3,767) | (5,837) | (10,567) |
| Interest and other income (expense), net | 5 | (33) | 34 | 288 |
| Net loss before income taxes | (12,536) | (14,555) | (42,058) | (41,594) |
| Income taxes | — | — | — | — |
| Net loss | $ (12,536) | $ (14,555) | $ (42,058) | $ (41,594) |
| Comprehensive loss | $ (12,536) | $ (14,555) | $ (42,058) | $ (41,594) |
| | | | | |
| Net loss per share - basic and diluted | $ (0.23) | $ (0.37) | $ (0.90) | $ (1.12) |
| Weighted-average number of common shares outstanding - basic and diluted | 53,424,922 | 39,224,863 | 46,828,218 | 37,297,892 |

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 Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity/Deficit |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| Balance at December 31, 2021 | 41,228,736 | $ 41 | $ 174,621 | $ (256,796) | $ (82,134) |
| Common Stock issued under public equity offering | 391,652 | — | 1,360 | — | 1,360 |
| Costs of common stock issued under public equity offering | — | — | (62) | — | (62) |
| Share-based compensation expense | — | — | 913 | — | 913 |
| Other | — | — | 1 | (1) | — |
| Net loss | — | — | — | (13,220) | (13,220) |
| Balance at March 31, 2022 | 41,620,388 | 41 | 176,833 | (270,017) | (93,143) |
| Fair value of warrants issued | — | — | 5,874 | — | 5,874 |
| Common Stock issued under private equity offering | 6,686,491 | 7 | 4,622 | — | 4,629 |
| Costs of common stock issued under private equity offering | — | — | (824) | — | (824) |
| Common Stock issued upon warrant exercises | 4,000,000 | 4 | (4) | — | — |
| Common Stock issued under public equity offering | 1,013,226 | 1 | 1,251 | — | 1,252 |
| Costs of common stock issued under public equity offering | — | — | (77) | — | (77) |
| Shares issued under employee stock purchase plan | 23,884 | — | 15 | — | 15 |
| Share-based compensation expense | — | — | 2,219 | — | 2,219 |
| Other | — | — | (1) | 1 | — |
| Net loss | — | — | — | (16,302) | (16,302) |
| Balance at June 30, 2022 | 53,343,989 | 53 | 189,908 | (286,318) | (96,357) |
| Common Stock issued under public equity offering | 501,472 | 1 | 641 | — | 642 |
| Costs of common stock issued under public equity offering | — | — | (98) | — | (98) |
| Share-based compensation expense | — | — | 535 | — | 535 |
| Vested restricted stock units | 6,665 | — | (3) | — | (3) |
| Other | — | — | (1) | (1) | (2) |
| Net loss | — | — | — | (12,536) | (12,536) |
| Balance at September 30, 2022 | 53,852,126 | $ 54 | $ 190,982 | $ (298,855) | $ (107,819) |

| | | | | | |
|---|---|---|---|---|---|
| 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 | — | — | — | (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) |

See accompanying notes to the condensed consolidated financial statements.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2022** | **2021** |
| **Operating activities:** | | |
| Net loss | $ (42,058) | $ (41,594) |
| Adjustments to reconcile net loss to net cash used for operating activities: | | |
| Depreciation, amortization, and impairment | 1,990 | 2,233 |
| Share-based compensation | 3,667 | 5,128 |
| Amortization of debt issuance costs and discounts | 157 | 3,604 |
| Interest expense related to the sale of future revenue, net | 5,683 | 10,457 |
| Other, net | 60 | (248) |
| Changes in operating assets and liabilities: | | |
| Trade and other receivables, net | 1,257 | (6,726) |
| Inventories, net | (2,687) | (402) |
| Prepaid expenses and other assets | 2,111 | 1,793 |
| Accounts payable | 2,758 | (874) |
| Accrued expenses and other liabilities | (2,357) | (2,046) |
| Deferred revenue | 10,509 | 3,757 |
| Loans payable | 675 | — |
| Net cash used for operating activities | (18,235) | (24,918) |
| **Investing activities:** | | |
| Capital expenditures | (998) | (380) |
| Additions to intangible assets | (1,500) | — |
| Net cash used for investing activities | (2,498) | (380) |
| **Financing activities:** | | |
| Proceeds from common stock issued under public equity offering, net | 3,017 | 24,592 |
| Proceeds from common stock issued under private equity offering, net | 3,805 | — |
| Proceeds from issuance and exercise of warrants | 5,874 | — |
| Proceeds from shares issued under employee stock purchase plan | 15 | 76 |
| Premium paid to retire debt | (1,350) | — |
| Payments for taxes on share-based compensation | (3) | (13) |
| Net cash provided by financing activities | 11,358 | 24,655 |
| Net (decrease) increase in cash and cash equivalents | (9,375) | (643) |
| Cash and cash equivalents at beginning of period | 28,024 | 31,807 |
| Cash and cash equivalents at end of period | $ 18,649 | $ 31,164 |
| | | |
| Supplemental disclosures of cash flow information: | | |
| Cash payments for interest | $ 1,609 | $ 4,828 |

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 advancing current standards of care to solve patients’ problems through simplifying complex delivery methods. The Company is developing pharmaceutical products to deliver complex molecules through alternative administrations to invasive and inconvenient standard of care therapies. Aquestive has five licensed commercialized products which are marketed by our licensees in the U.S. and around the world. The Company is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. The Company is advancing an early stage product pipeline for the treatment of severe allergic reactions, including anaphylaxis. The Company has also developed a product pipeline focused on treating diseases of the central nervous system, or CNS. The Company's production facilities are located in Portage, Indiana, and our 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 worth of shares of common stock, par value $0.001 per share, of the Company (the "Common Stock"). On November 20, 2020, the Company began utilizing the ATM facility. On March 26, 2021, the Company filed a prospectus supplement to offer up to an additional $50,000 worth of shares of Common Stock under the ATM . The 2019 Registration Statement expired under its terms on September 17, 2022. On September 7, 2022, the Company filed a prospectus supplement to register the offer and sale of up to $35,000 worth of shares of Common Stock pursuant to the Amended Equity Distribution Agreement under a shelf registration statement on Form S-3 (Registration Statement No. 333-254775), or the 2021 Registration Statement, that was declared effective by the Securities and Exchange Commission (SEC) on April 5, 2021. The Company discontinued using the 2021 Prospectus upon the filing of the prospectus supplement on September 7, 2022.

For the nine months ended September 30, 2022, the Company sold 1,906,350 shares of Common Stock under the ATM which provided net proceeds of approximately $3,017 after deducting commissions and other transaction costs of $237. For the nine months ended September 30, 2021, the Company sold 5,486,871 worth of shares of Common Stock under the ATM which provided net proceeds of approximately $24,592 after deducting commissions and other transaction costs of $1,068. This ATM facility has approximately $34,358 worth of shares of Common Stock available at September 30, 2022.

On April 12, 2022, the Company entered into a purchase agreement ("Lincoln Park Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which provides that, upon the terms and subject to the conditions and limitations set forth in the Lincoln Park Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park up to $40,000 worth of shares of Common Stock from time to time over the 36-month term of the Lincoln Park Purchase Agreement. The Lincoln Park Purchase Agreement contains an ownership limitation such that we will not issue, and Lincoln Park will not purchase, shares of Common Stock if it would result in their beneficial ownership exceeding 9.99%. Lincoln Park has covenanted under the Lincoln Park Purchase Agreement not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's common stock. For the nine months ended September 30, 2022, the Company sold 1,611,181 shares including commitment shares, which provided proceeds of approximately $1,987 in connection with the Lincoln Park Purchase Agreement**.** On April 13, 2022, the Company filed a prospectus supplement in connection with this offering.

On June 6, 2022, the Company entered into securities purchase agreements ("Securities Purchase Agreements") with certain purchasers. The Securities Purchase Agreements provided for the sale and issuance by the Company of an aggregate of: (i) 4,850,000 shares of Common Stock, (ii) pre-funded warrants to purchase up to 4,000,000 shares of Common Stock and (iii) Common Stock warrants to purchase up to 8,850,000 shares of Common Stock. The Company received net proceeds of approximately $7,796, after deducting placement agent fees and expenses and estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the offering for general corporate purposes. On June 8, 2022, the Company filed a prospectus supplement in connection with this equity offering.

**(C) 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, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on March 8, 2022 (the "2021 Annual Report on Form 10-K"). As included herein, the condensed consolidated balance sheet as of December 31, 2021 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, 2022:*

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, amending existing guidance on the accounting for credit losses on financial instruments within its scope. The guidance provides for use of a forward-looking expected loss model for estimating credit losses, replacing the incurred loss model that is based on past events and current conditions. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for the Company beginning after December 15, 2022. The Company does not expect the new accounting guidance to have a material impact on the Company's 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.

In June 2022, the FASB issued ASU 2022-03, *Fair Value Measurement (Topic 820)*: *Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*. This Accounting Standards Update was issued to clarify the guidance in Topic 820, Fair Value Measurement, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security, and to introduce new disclosure requirements for such equity securities. 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.

**Note 3. Risks and Uncertainties**

These consolidated financial statements have been prepared in accordance with U.S. GAAP assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, substantial doubt about the Company's ability to continue as a going concern exists.

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 2022 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, 2022, the Company had $18,649 of cash and cash equivalents.

The Company has experienced a history of net losses. The Company's accumulated deficits totaled $298,855 as of September 30, 2022. 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 have been 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"). However, the Company will require additional liquidity to continue its operations over the next 12 months.

The Company began utilizing its ATM facility in November 2020. Since inception to September 30, 2022, the Company sold 9,387,769 shares of Common Stock which generated net cash proceeds of approximately $38,850, net of commissions and other transaction costs of $2,001. For the nine months ended September 30, 2022, the Company sold 1,906,350 shares of Common Stock which provided net proceeds of approximately $3,017, net of commissions and other transaction costs of $237. This ATM facility has approximately $34,358 worth of shares of Common Stock available at September 30, 2022.

The Company's ability to execute its business objectives and achieve profitability over the longer term cannot be assured. The Company's on-going business, existing cash and equivalents, expense management activities as well as access to the equity capital markets, including through its ATM facility and under the Lincoln Park Purchase Agreement, provide near term funding opportunities for the Company. However, there can be no assurance that the Company will be able to obtain sufficient additional liquidity when needed or under acceptable terms, if at all.

The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

**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, 2022, and December 31, 2021, such contract assets were $2,150 and $3,087, 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, 2022, and December 31, 2021, such contract liabilities were $18,396 and $7,887, respectively.

The Company's revenues were comprised of the following:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Manufacture and supply revenue | $ 8,411 | $ 10,447 | $ 27,456 | $ 27,623 |
| License and royalty revenue | 376 | 328 | 1,434 | 5,000 |
| Co-development and research fees | 395 | 523 | 1,039 | 1,417 |
| Proprietary product sales, net | 2,281 | 1,989 | 7,069 | 5,714 |
| Total revenues | $ 11,463 | $ 13,287 | $ 36,998 | $ 39,754 |

*Disaggregation of Revenue*

The following table provides disaggregated net revenue by geographic area:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| United States | $ 9,078 | $ 10,530 | $ 31,416 | $ 33,487 |
| Ex-United States | 2,385 | 2,757 | 5,582 | 6,267 |
| Total revenues | $ 11,463 | $ 13,287 | $ 36,998 | $ 39,754 |

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

Trade and other receivables, net consist of the following:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Trade receivables | $ 9,358 | $ 9,678 |
| Contract and other receivables | 2,150 | 3,087 |
| Less: allowance for doubtful accounts | (40) | (40) |
| Less: sales-related allowances | (731) | (605) |
| Trade and other receivables, net | $ 10,737 | $ 12,120 |

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

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Allowance for doubtful accounts at beginning of the period | $ 40 | $ 40 |
| Additions charged to expense | — | — |
| Write-downs charged against the allowance | — | — |
| 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, 2022:

| | Total Sales Related Allowances |
|---|---|
| Balance at December 31, 2021 | $ 605 |
| Provision | 1,121 |
| Payments / credits | (995) |
| Balance at September 30, 2022 | $ 731 |

Total reductions of gross product sales from sales-related allowances and accruals were $1,121 for the nine months ended September 30, 2022. Accruals for returns allowances and prompt pay discounts are reflected as a direct reduction of trade receivables and accruals for wholesaler service fees, co-pay support redemptions and rebates as current liabilities. The accrued balances relative to these provisions included in Trade and other receivables, net and Accounts payable and accrued expenses were $731 and $2,229, respectively, as of September 30, 2022 and $605 and $2,224, respectively, as of December 31, 2021.

*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, 2022, Indivor exceeded the 10% threshold for revenue and represented approximately 75% of total revenue. As of September 30, 2022, Indivior and Cardinal Health Inc. exceeded the 10% threshold for outstanding receivables and represented 60% and 12%, respectively, of outstanding receivables. For the nine months ended September 30, 2021, Indivior exceeded the 10% threshold for revenue and represented approximately 73% of total revenue. As of December 31, 2021, two customers exceeded the 10% threshold for outstanding receivables which were Indivior and Cardinal Health Inc. which represented 51% and 12%, respectively, of total trade and other 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. Further payments 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. (the "Sunovion License Agreement"). Cynapsus Therapeutics was later succeeded to in interest by Sunovion Pharmaceuticals, Inc. ("Sunovion"). Pursuant to the Sunovion License Agreement, 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 United States Food and Drug Administration (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 has 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, 2022 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. Based on the current forecast by Sunovion of estimated KYNMOBI sales as of September 30, 2022, the Company may not receive any of the additional aggregate contingent payments under the Monetization agreement. 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 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™) 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.

*Licensing and Supply Agreement with Haisco for Exservan™ (Riluzole Oral Film) for ALS Treatment in China*

The Company entered into a License, Development and Supply Agreement with Haisco, a Chinese limited company listed on the Shenzhen Stock Exchange, effective as of March 3, 2022 ("Haisco Agreement"), pursuant to which Aquestive granted Haisco an exclusive license to develop and commercialize Exservan™ (riluzole oral film) for the treatment of amyotrophic lateral sclerosis, or ALS ("Exservan"), in China. Under the terms of the Haisco Agreement, Aquestive will serve as the exclusive sole manufacturer and supplier for Exservan in China. Under the Haisco Agreement, as amended, the Company received a $7,000 upfront cash payment, and will receive regulatory milestone payments, receive double-digit royalties on net sales of Exservan in China, and earn manufacturing revenue upon the sale of Exservan in China.

*Compensatory Arrangements of Certain Officers*

On May 17, 2022, the Company announced that Keith J. Kendall, President and Chief Executive Officer of the Company, was leaving the Company and the Company's Board of Directors, effective May 17, 2022. In connection with his departure, Mr. Kendall and the Company entered into a Separation Agreement, including a Consulting Agreement (collectively, the "Separation Agreement") dated as of May 17, 2022. Pursuant to the Separation Agreement, Mr. Kendall's employment with the Company ceased effective as of May 17, 2022 (the "Termination Date"). Under the Separation Agreement, Mr. Kendall received the following principal severance benefits, contingent upon Mr. Kendall's execution and delivery of a customary release of claims: (i) a cash payment consisting of the sum of any previously unpaid base salary through the Termination Date and any accrued and unused vacation time for the 2022 calendar year; (ii) a cash payment consisting of his pro-rata portion of his target bonus in the amount of $280; (iii) a cash payment in the amount of $150, representing 90 days of his base pay in lieu of the required notice period under Mr. Kendall's employment agreement; (iv) severance payments consisting of (a) a cash payment of $263, which represents an acceleration of the first three installments of Mr. Kendall's 18-month severance he is entitled to under his employment agreement; (b) monthly severance payments of $53 per month for the first through the seventh months following the Termination Date; (c) $70 paid for the eighth month after the Termination Date; and (d) monthly severance payments of $88 for the ninth through eighteenth months following the Termination Date; (v) accelerated vesting of unvested outstanding equity awards, with options remaining exercisable for the duration of the stated term of each award; and (vi) continuing coverage under the Company's group health and life insurance plans at the same levels and on the same terms and conditions as are provided to similarly-situated executives, for a period of 18 months. Under the terms of the Separation Agreement, Mr. Kendall will serve as a consultant to the Company, on an as-needed basis providing transition services, strategic planning, financial planning, merger and acquisition advice and consultation, for a period from the Separation Date to December 31, 2022. For these services, Mr. Kendall will receive a consulting fee of $10 per month.

*Licensing and Supply Agreement with Atnahs Pharma UK Limited*

The Company entered into a License and Supply Agreement with Atnahs Pharma UK Limited, a company registered in England and Wales ("Pharmanovia"), effective as of September 26, 2022 (the "Pharmanovia Agreement"), pursuant to which the Company granted Pharmanovia an exclusive license to certain of the Company's intellectual property to develop and commercialize Libervant™ (diazepam) Buccal Film for the treatment of prolonged or acute, convulsive seizures in all ages in certain countries of the European Union, the United Kingdom, Switzerland, Norway and the Middle East and North Africa (the "Territory") during the term of the Pharmanovia Agreement. Under the Pharmanovia Agreement, Pharmanovia will lead the regulatory and commercialization activities for Libervant in the Territory and the Company will serve as the exclusive sole manufacturer and supplier of Libervant in the Territory. Pursuant to the Pharmanovia Agreement, the Company received $3,500 upon agreement execution and will receive additional milestone payments upon the occurrence of certain conditions set forth in the Pharmanovia Agreement, additional milestone payments and profit shares, as well as manufacturing fees and royalty fees through the expiration of the Pharmanovia Agreement.

**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 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.

In June 2022, the Company issued pre-funded warrants to purchase up to 4,000,000 shares of Common Stock and Common Stock warrants to purchase up to 8,850,000 shares of Common Stock in connection with its Securities Purchase Agreements with certain purchasers. 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. See Note 14 Warrants for further information on these warrants.

**Note 7. Inventories, Net**

The components of Inventory, net are as follows:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Raw material | $ 1,734 | $ 1,442 |
| Packaging material | 2,995 | 1,414 |
| Finished goods | 1,996 | 1,182 |
| Total inventory, net | $ 6,725 | $ 4,038 |

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

| | Useful Lives | September 30, 2022 | December 31, 2021 |
|---|---|---|---|
| Machinery | 3-15 years | $ 19,412 | $ 19,250 |
| Furniture and fixtures | 3-15 years | 769 | 769 |
| Leasehold improvements | (a) | 21,265 | 21,265 |
| Computer, network equipment and software | 3-7 years | 2,469 | 2,469 |
| Construction in progress | | 1,998 | 1,162 |
| | | 45,913 | 44,915 |
| Less: accumulated depreciation and amortization | | (41,629) | (39,860) |
| Total property and equipment, net | | $ 4,284 | $ 5,055 |

(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 $557 and $724 for the three-month periods ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, these expenses totaled $1,926 and $2,195, respectively.

**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 these three leases include the characteristics specified in ASC 842, Leases, that require classification as financing leases and, accordingly, these leases are accounted for as operating leases. These leases provide remaining terms between 0.5 and 4.0 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 in 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, 2022, total operating lease expenses totaled $424 and $1,267, respectively, including variable lease expenses such as common area maintenance and operating costs of $110 and $333, respectively. 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.

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

| | |
|---|---|
| Remainder of 2022 | $ 324 |
| 2023 | 944 |
| 2024 | 565 |
| 2025 | 565 |
| 2026 | 424 |
| Total future lease payments | 2,822 |
| Less: imputed interest | (636) |
| Total operating lease liabilities | $ 2,186 |

**Note 10. Intangible Assets, Net**

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

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Purchased intangible | $ 3,858 | $ 2,358 |
| Purchased patent | 509 | 509 |
| | 4,367 | 2,867 |
| Less: accumulated amortization | (2,880) | (2,816) |
| Intangible assets, net | 1,487 | 51 |

Amortization expense was $39 and $13 for each of the three-month periods ended September 30, 2022 and 2021. For the nine months ended September 30, 2022 and 2021, these expenses totaled $64 and $38, respectively. During the remaining life of the purchased intangible assets, estimated amortization expense is $50 in the remainder of 2022 and $150 in 2023, respectively.

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

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

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Royalty receivable | 5,000 | 6,000 |
| Other | 893 | 903 |
| Total other non-current assets | $ 5,893 | $ 6,903 |

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 eight $1,000 annual minimum guaranteed royalty that is due. 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 five 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, 2022 | December 31, 2021 |
|---|---|---|
| Accrued compensation | $ 4,939 | $ 5,965 |
| Real estate and personal property taxes | 351 | 349 |
| Accrued distribution expenses | 2,229 | 2,224 |
| Other | 214 | 198 |
| Total accrued expenses | $ 7,733 | $ 8,736 |

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

***12.5% Senior Secured Notes***

On July 15, 2019, the Company completed a private placement of up to $100,000 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, 2022. 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, 2022. Based on the valuation study, the put option was valued at $108 and 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. Under the Third Supplemental Indenture, the first $10,000 of 12.5% Notes re-openers represented 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 ("First Additional Securities"). In addition, under the Third Supplemental Indenture, a second $20,000 12.5% Notes re-opener represented 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 ("Second Additional Securities"). 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 Common Stock at the warrant grant date.

On May 13, 2022, pursuant to the Fifth Supplemental Indenture, the holders of the 12.5% Notes further extended to March 31, 2023 from June 30, 2022, the Company's ability to access, at the Company's option, $30,000 of 12.5% Notes re-openers under the Indenture. The Fifth Supplemental Indenture also provided that the Company's access to the First Additional Securities and Second Additional Securities is subject to the full approval of Libervant by the FDA for sale in the United States, which full approval includes U.S. market access for Libervant. In addition, the Fifth Supplemental Indenture provides that the holders of 12.5% Notes have the right, but not the obligation, to purchase the First Additional Securities and Second Additional Securities.

A debt maturity table is presented below:

| | |
|---|---|
| Remainder of 2022 | $ — |
| 2023 | 18,025 |
| 2024 | 21,888 |
| 2025 | 11,587 |
| **Total** | $ 51,500 |

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. 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. As of September 30, 2022, the Company recorded its principal payments as Loans payable, net on its Condensed Consolidated Balance Sheet.

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 October 7, 2021, the Company entered into the Fourth Supplemental Indenture, pursuant to which the amortization schedule for the 12.5% Notes has been 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 12.5% Notes or the interest payment obligation due under the 12.5% Notes. In connection with the Fourth Supplemental Indenture, the Company entered into a Consent Fee Letter with the holders of the 12.5% Notes (the “Consent Fee Letter”), pursuant to which the Company agreed to pay the holders of the 12.5% Notes an additional cash payment ("Consent Fee") of $2,700 in the aggregate, payable in four quarterly payments beginning May 15, 2022. As of September 30, 2022, the Company recorded the Consent Fee as Loans payable, current, on its Consolidated Balance Sheet. Additionally, the Company recognized a loss on the extinguishment of debt of $13,822 for fees and expenses related to the Fourth Supplemental Indenture during the fourth quarter of 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, 2022 were $4 and $12, respectively, while comparative amortization expenses for the three and nine months ended September 30, 2021 were $1,171 and $3,488, respectively. Unamortized deferred debt issuance costs and deferred debt discounts totaled $31 and $43 as of September 30, 2022 and December 31, 2021, 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 Common Stock 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 Initial Warrants and Additional Warrants issued do not provide warrant redemption or put rights within the control of the holders that could require the Company to make a payment of cash or other assets to satisfy the obligations under the warrants, except in the case of a "cash change in control", the fair value attributed to the warrants is presented in Additional Paid-in Capital in the Company's unaudited condensed balance sheet. There were no warrants exercised as it relates to the Initial Warrants and the Additional Warrants during the nine-months ended September 30, 2022 or 2021, respectively.

In June 2022, the Company issued pre-funded warrants and Common Stock warrants to certain purchasers in connection with the Securities Purchase Agreements. The pre-funded warrants will expire when exercised in full and entitle purchasers to purchase up to 4,000,000 shares of Common Stock. The Common Stock warrants expire on June 8, 2027 and entitle the purchasers to purchase up to 8,850,000 shares of Common Stock at a price ranging from $0.96 to $1.09 per share. Management estimated the fair value of the pre-funded warrants and Common Stock warrants to be $5,874 based on an assessment by an independent third-party appraiser. The fair value of the pre-funded and Common Stock warrants is treated as equity and presented in Additional Paid-in Capital in the Company's unaudited condensed balance sheet. The pre-funded warrants were fully exercised and no Common Stock warrants issued pursuant to the Securities Purchase Agreements were exercised during the nine-months ended September 30, 2022.

**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, 2022 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 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. Based on the current forecast by Sunovion of estimated KYNMOBI sales as of September 30, 2022, the Company may not receive any of the additional aggregate contingent payments under the Monetization Agreement.

The following table shows the activity of the liability related to the sale of future revenue for the nine months ended September 30, 2022:

| | | |
|---|---|---|
| Liability related to the sale of future revenue, net at December 31, 2021 | $ | 60,284 |
| Royalties related to the sale of future revenue | | (903) |
| Amortization of issuance costs | | 154 |
| Interest expense related to the sale of future revenue | | 5,683 |
| Liability related to the sale of future revenue, net (includes current portion of $1,910) | $ | 65,218 |

**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, 2022 and 2021, 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Numerator: | | | | |
| Net loss | $ (12,536) | $ (14,555) | $ (42,058) | $ (41,594) |
| Denominator: | | | | |
| Weighted-average number of common shares – basic | 53,424,922 | 39,224,863 | 46,828,218 | 37,297,892 |
| Loss per common share – basic and diluted | $ (0.23) | $ (0.37) | $ (0.90) | $ (1.12) |

As of September 30, 2022 and 2021, respectively, the Company’s potentially dilutive instruments included 5,967,492 and 4,341,967 options to purchase common shares and 168,050 and no 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, 2022 and 2021, were potentially dilutive warrants for the purchase of 10,564,429 and 1,571,429 shares of common stock for the respective periods.

**Note 17. Share-Based Compensation**

The Company recognized share-based compensation in its Condensed Consolidated Statements of Operations and Comprehensive Loss during 2022 and 2021 as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Manufacture and supply | $ 66 | $ 88 | $ 159 | $ 241 |
| Research and development | 75 | 230 | 406 | 670 |
| Selling, general and administrative | 394 | 1,582 | 3,104 | 4,217 |
| Total share-based compensation expenses | $ 535 | $ 1,900 | $ 3,669 | $ 5,128 |
| | | | | |
| Share-based compensation from: | | | | |
| Restricted stock units | $ 58 | $ — | $ 97 | $ 81 |
| Stock options | 477 | 1,900 | 3,570 | 5,036 |
| Employee stock purchase plan | — | — | 2 | 11 |
| Total share-based compensation expenses | $ 535 | $ 1,900 | $ 3,669 | $ 5,128 |

***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, 2022:

| Restricted Stock Unit Awards (RSUs): | Number of Units | Weighted Average Grant Date Fair Value |
|---|---|---|
| | (in thousands) | |
| Unvested as of December 31, 2021 | — | $ — |
| Granted | 192 | $ 2.38 |
| Vested | (10) | $ 2.55 |
| Forfeited | (14) | $ 2.06 |
| Unvested as of September 30, 2022 | 168 | $ 2.39 |
| Vested and expected to vest as of September 30, 2022 | 154 | $ 2.39 |

| Stock Option Awards: | Number of Options | Weighted Average Exercise Price |
|---|---|---|
| | (in thousands) | |
| Outstanding as of December 31, 2021 | 4,146 | $ 7.28 |
| Granted | 1,830 | $ 1.93 |
| Exercised, Forfeited, Expired | (9) | $ 10.76 |
| Outstanding as of September 30, 2022 | 5,967 | $ 5.70 |
| Vested and expected to vest as of September 30, 2022 | 5,800 | $ 5.80 |
| Exercisable as of September 30, 2022 | 3,651 | $ 7.62 |

As of September 30, 2022, $301 of unrecognized compensation expense related to unvested restricted stock units is expected to be recognized over a weighted average period of 2.46 years from the date of grant.

The fair values of stock options granted during the nine months ended September 30, 2022 were estimated using the Black-Scholes pricing model based on the following assumptions:

| | |
|---|---|
| Expected dividend yield | —% |
| Expected volatility | 100% |
| Expected term (years) | 5.5 - 6.1 |
| Risk-free interest rate | 2.0 % - 3.4% |

The weighted average grant date fair value of stock options granted during the nine months ended September 30, 2022 was $1.54. During the nine-month period ended September 30, 2022, stock options were granted with an exercise price ranging from $0.71 to $2.55 and accordingly, given the Company's share price of $1.17 at September 30, 2022, the intrinsic value provided by certain shares granted during this period was de minimus.

As of September 30, 2022, $2,778 of unrecognized compensation expense related to non-vested stock options is expected to be recognized over a weighted average period of 2.00 years from the date of grant.

2022 Inducement Equity Incentive Plan

In accordance with Nasdaq Listing Rule 5635(c)(4), the Company adopted the 2022 Equity Inducement Plan approved by the Compensation Committee of the Board of Directors of the Company effective as of July 29, 2022. Under the 2022 Equity Inducement Plan, the Company granted an inducement equity of 100,000 shares of non-qualified Common Stock options award to an officer in September 2022.

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 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 months ended September 30, 2022 and 2021, respectively, 23,884 and 19,270 shares were purchased and issued through the ESPP at total discounts of $2 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'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, 2022 and 2021, the Company recorded no income tax benefit from its pretax losses of $12,536 and $14,555. Similarly for the nine months ended September 30, 2022 and 2021, the Company recorded no income tax benefit from its pretax losses of $42,058 and $41,594.

The primary factor impacting the effective tax rate for the three and nine months ended September 30, 2022 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, and the Company and Indivior preserved the right to appeal the claim construction ruling. On June 28, 2022, pursuant to a settlement agreement between the parties, the Court entered a Stipulation and Order of Dismissal, dismissing all claims and counterclaims with prejudice in the lawsuit.

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).

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 the Company as a plaintiff and 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 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, and the Company and Indivior preserved the right 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. The Court heard oral argument on the dispositive motions on August 29, 2022, and the parties are awaiting a ruling from the Court. 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. (BDSI 2014 Lawsuit)

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. 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 April 15, 2021, the Court lifted the stay of the litigation in the Eastern District of North Carolina. 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 entered a scheduling order in the case. Under the current scheduling order, the parties have completed their exchange of preliminary infringement and validity contentions, have completed claim construction briefing, and are proceeding with fact

discovery. The Court may schedule a claim construction hearing, 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, which BDSI opposed. 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, which Aquestive opposed. 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 the BDSI 2014 Lawsuit 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 range of estimates of the possible outcome or losses, if any, in this matter.

***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' conspiracy claims, but by order dated October 30, 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, and briefing on summary judgment motions was completed on May 28, 2021. The hearing on Aquestive's motion for summary judgment was held on May 18, 2022 and, on October 19, 2022, the Court entered an order dismissing all claims against the Company in the lawsuit. The order dismissing all claims against the Company could be appealed by the plaintiffs in this case. The Company is not able to determine or predict whether the plaintiffs will appeal the order or 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.

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.

On September 18, 2020, Humana, Inc. ("Humana"), a health insurance payor, filed a lawsuit against the Company 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 the Company, 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 the Company and Indivior in the Eastern District of Missouri. The counsel representing Humana is also representing

Centene in this matter. 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 in the Eastern District of Pennsylvania 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"). Also, on August 20, 2021, Humana filed a complaint in state court in Kentucky, alleging the same causes of action previously filed in the federal case in the Eastern District of Pennsylvania. That state court action is stayed pending resolution of the federal appeal in the Third Circuit. The Third Circuit appeal is fully briefed and oral argument was held on March 31, 2022. The parties are awaiting a ruling from the Third Circuit on the appeal. 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.

***California Litigation***

Neurelis, Inc. v. Aquestive Therapeutics, Inc.

On December 5, 2019, Neurelis Inc. 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 ("UCL"); (2) Defamation; and (3) Malicious Prosecution. Neurelis filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. The Company filed a Motion to Strike Neurelis's Complaint under California's anti-SLAPP ("strategic lawsuit against public participation") statute on January 31, 2020, which Neurelis 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 briefing on the appeal ended on July 6, 2021. The Appeals Court held oral argument on the appeal on October 14, 2021, and issued its ruling on November 17, 2021. Under the ruling, the Court struck the entirety of the malicious prosecution claim and struck portions of the UCL and defamation claims. Aquestive filed a motion for attorney fees related to the anti-SLAPP motion on February 11, 2022. On April 12, 2022, Neurelis filed a Second Amended Complaint in response to the Court of Appeal's decision. The Second Amended Complaint also added a cause of action for Trade Libel. On May 3, 2022, Aquestive filed a "demurer" challenge to the sufficiency of the allegations of the Second Amended Complaint. Oral argument on Aquestive's motion for attorney fees related to the anti-SLAPP motion and on the Second Amended Complaint and demurer challenge was held on June 17, 2022. The Court entered an order granting Aquestive's motion for attorney fees, awarding $156 and ordering Neurelis to pay the fees within 60 days of June 17, 2022. The Court denied Aquestive's demurrer and the parties are proceeding with discovery on the claims in the Second Amended Complaint. No trial date has been set. 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 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. The Federal Circuit Court issued a mandate closing the appeal period and an IPR Certificate was subsequently issued by the United States Patent and Trademark Office on January 21, 2022. No further appeals are available on this matter.

***Federal Securities Class Action***

Deanna Lewakowski v. Aquestive Therapeutics, Inc., *et al*.

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 June 25, 2021. Defendants filed a motion to dismiss on August 16, 2021, which became fully briefed as of November 1, 2021. There is no date set for a hearing on the motion 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.

***Shareholder Derivative Litigation***

Loreen Niewenhuis v. Keith Kendall, *et al*.

On December 15, 2021, a purported Aquestive shareholder instituted a derivative action captioned Loreen Niewenhuis v. Keith Kendall, et al. in the United States District Court for the District of New Jersey, purportedly on behalf of the Company, against certain current and former officers and directors of the Company. The case was designated as related to the pending federal securities class action Deanna Lewakowski v. Aquestive Therapeutics, Inc., referenced above, and accepted by the same judge presiding over the securities class action. The complaint in this matter alleges claims for breach of fiduciary duty and contribution. The factual allegations that form the basis of these claims are similar to the disclosure-related allegations asserted in the class action. On April 4, 2022, the plaintiff filed an amended complaint asserting the same claims against the same defendants. The Company filed a motion to dismiss the amended complaint on April 25, 2022, which became fully briefed as of June 27, 2022. There is no date set for a hearing on the motion 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, 2022 and sold 351,150 shares of Common Stock which generated net proceeds of approximately $355.

***Positive Decision in States' Suboxone Antitrust Lawsuit on All Claims***

The Company announced that the United States District Court for the Eastern District of Pennsylvania entered an order on October 19, 2022 dismissing all claims against the Company in the Suboxone antitrust lawsuit brought by a group of States' Attorneys General against Indivior Inc. (f/k/a Reckitt Benckiser Pharmaceuticals, Inc.) and Aquestive, Case No. 16-cv-5073.

***Licensing Agreement with Assertio Holdings, Inc.***

Effective October 26, 2022, the Company entered into a License Agreement with Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. (NASDAQ: ASRT) ("Assertio"), a specialty pharmaceutical company offering differentiated products to patients, to license Sympazan® (clobazam) oral film for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients aged two years of age or older (the "Assertio License Agreement"). Under the terms of the Assertio License Agreement, the Company granted an exclusive, worldwide license of its intellectual property for Sympazan to Assertio during the term of the Assertio License Agreement for an upfront payment of $9,000. Under the terms of the Assertio License Agreement, Aquestive will receive a $6,000 milestone payment within thirty (30) days after Aquestive's receipt of a notice of allowance from the United States Patent and Trademark Office (PTO) of the Company's patent application U.S. Serial No. 16/561,573, and payment by the Company of the related allowance fee. The Company received the notice of allowance from the PTO and paid the related allowance fee on October 27, 2022. In addition, under the Assertio License Agreement, the Company will receive royalties from Assertio for the sale of the product through the expiration of the Assertio License Agreement. The Company also entered into a long-term supply agreement with Assertio for Sympazan pursuant to which the Company is the exclusive sole worldwide manufacturer and supplier of the product and will receive manufacturing fees from Assertio for the product through the expiration of such supply agreement.

**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, 2021 and 2020 included in our 2021 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 AQST-109 and AQST-108 through the regulatory and development pipeline; the focus on continuing to manufacture Suboxone®, Exservan®, Sympazan® and other licensed products; the likelihood that we can overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. in order for Libervant® to be granted U.S. market access; clinical trial timing and plans for AQST-109 and AQST-108; the ability to fund our business operations; 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, the risk that we may not overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. in order for Libervant to be granted U.S. market access; 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 AQST-109 and our other drug candidates or failure to receive approval; the 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 our 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); the risk of the failure to obtain U.S. market access for Libervant to restrict our ability to access additional funding under the Company's 12.5% Notes; risks and uncertainties concerning the revenue stream from the monetization of our royalty rights for the product KYNMOBI®, as well as the achievement of royalty targets worldwide or in any jurisdiction and certain other 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, including under the Company's ATM facility and the Lincoln Park Purchase Agreement, 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, including near-term debt amortization schedules; 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, business torts,

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 Quarterly Report on Form 10-Q whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely on the forward-looking statements included in this Quarterly Report on Form 10-Q as representing our views as of any date after the date of the filing of this Quarterly Report on Form 10-Q 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 2021 Annual Report on Form 10-K.

**Overview**

We are a pharmaceutical company advancing current standards of care to solve patients' problems through simplifying complex delivery methods. The Company is developing pharmaceutical products to deliver complex molecules through alternative administrations to invasive and inconvenient standard of care therapies. Aquestive has five licensed commercialized products which are marketed by our licensees in the U.S. and around the world. The Company is the exclusive manufacturer of these licensed products. The Company also collaborates with pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven drug development and commercialization capabilities. The Company is advancing an early stage product pipeline for the treatment of severe allergic reactions, including anaphylaxis. The Company has also developed a product pipeline focused on treating diseases of the central nervous system, or CNS. Our production facilities are located in Portage, Indiana, and our corporate headquarters, sales and commercialization operations and primary research laboratory facilities are based in Warren, New Jersey.

We manufacture licensed products at our FDA, Australian Government Department of Health's Therapeutics Goods Administration, or TGA, and Drug Enforcement Agency, or DEA, inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. Not all collaborative or licensed products of the Company that may be commercially launched in the future will necessarily be manufactured by us, such as the case with KYNMOBI®.

*Complex Molecule Portfolio*

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

The active programs in our complex molecule pipeline portfolio are:

- **AQST-109** – the first and only orally delivered epinephrine product candidate that has shown clinical results comparable to autoinjectors (such as EpiPen® and Auvi-Q®) for the emergency treatment of allergic reactions, including anaphylaxis. Epinephrine is the standard of care in the treatment of anaphylaxis and is currently administered via intramuscular injection including 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. 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.

  We completed a first-in-human Phase 1 clinical trial for AQST-109 in Canada. This Phase 1 randomized, single-ascending dose study was performed in order to assess the safety, tolerability, and pharmacologic profile of AQST-109. On February 25, 2022, we reported positive topline data from Part 1 of our crossover study of AQST-109, EPIPHAST, a randomized, open-label, three-part adaptive design, crossover study in healthy adult subjects comparing the pharmacokinetics and pharmacodynamics of epinephrine delivered via AQST-109 oral film compared to intramuscular injection of epinephrine. The EPIPHAST study was also conducted in Canada. In Part 1 of the

EPIPHAST study, multiple oral film formulations and dosage strengths of AQST-109 were evaluated. The lead formulation of AQST-109 has shown clinically meaningful blood concentrations when delivered in two different physical configurations, with a median Tmax of 13.5 minutes and 22.5 minutes, respectively. Part 1 also showed arithmetic mean maximum concentrations (Cmax) of 771 pg/mL and 580 pg/mL for the two configurations, or geometric mean Cmax values of 258pg/mL and 268pg/mL for the two configurations, respectively. These geometric mean Cmax and median Tmax values are consistent with those previously reported for approved injectable epinephrine devices such as EpiPen®. Under the EPIPHAST study, the healthy volunteers were also exposed to a 0.5mg intramuscular injection (IM) of epinephrine, allowing for a comparison with the pharmacokinetics, safety, and tolerability of the higher end of the approved dosage range of epinephrine, consistent with guidance received from the FDA in a written response to our Investigational New Drug Application (IND) for AQST-109. The findings show that these two configurations of the selected AQST-109 formulation can deliver clinically meaningful blood concentrations of epinephrine sooner than that observed with the higher dose of epinephrine IM injection, and in line with existing epinephrine autoinjectors. In addition, dosing with AQST-109 resulted in changes in blood pressure and heart rate that were comparable to epinephrine auto-injectors. The EPIPHAST trial indicated that treatment was well tolerated, with no serious adverse events, significant medical events, or treatment-related severe adverse events reported. On February 24, 2022, the FDA cleared our IND, allowing for clinical investigation of AQST-109 in the U.S. The FDA confirmed that 505(b)(2) approval pathway is acceptable for the development of AQST-109. The FDA granted Fast Track designation in March 2022 to AQST-109 for the emergency treatment of allergic reactions, including anaphylaxis.

In April 2022, we reported positive topline results from Part 2 of the EPIPHAST study for AQST-109. Part 2 is a randomized, crossover design comparing AQST-109 12mg to epinephrine IM 0.3mg. Utilizing a replicate crossover design, Part 2 confirmed in a larger population of 24 healthy subjects the key pharmacokinetic (PK) and pharmacodynamic measures observed in Part 1 of the EPIPHAST study and the first-in-human PK study. The median time to maximum concentration (Tmax) was observed to be 15 minutes for AQST-109, compared to 50 minutes for the epinephrine 0.3mg intra-muscular (IM) injection.

In July 2022, we reported positive topline results from the final two arms of Part 3 of the EPIPHAST study for AQST-109. The purpose of Part 3 was to continue to study the administration of the film under a variety of conditions to further characterize its pharmacokinetics, pharmacodynamics, and safety. The final two arms were designed to assess the impact of (1) administering the film sublingually two minutes after consuming a peanut butter sandwich and (2) swallowing the film whole immediately with water. Part 3 study results demonstrated consistent Tmax of 12 minutes with sublingual administration of AQST-109 epinephrine oral film, after consuming a peanut butter sandwich. Part 3 study results also showed an unexpectedly high level of gastrointestinal absorption after swallowing AQST-109 whole immediately with water.

In September 2022, we reported positive topline results from the EPIPHAST II trial for AQST-109. The EPIPHAST II trial was designed to compare single doses of AQST-109 to EpiPen® 0.3mg and epinephrine 0.3mg intramuscular (IM) injection, as well as repeat doses of AQST-109 to repeat doses of epinephrine 0.3mg IM injection. Results from the single dose administration showed AQST-109 achieved a significantly faster Tmax (12 minutes), compared to both EpiPen® (22.5 minutes) and epinephrine 0.3mg IM injection (45 minutes). AQST-109 repeat dosing provided significantly higher drug plasma concentrations, with a Tmax of 8 minutes after administration, and extensive absorption was observed. The mean maximum concentration (Cmax) of AQST-109 was 465 pg/mL after one dose and 2,958 pg/mL after two doses. In comparison, the epi 0.3mg IM injection Cmax was 489 pg/mL after one dose and 911 pg/mL after two doses. The single dose of EpiPen resulted in a Cmax of 869 pg/mL. Changes in systolic blood pressure and heart rate were similar after a single dose of AQST-109 when compared to a single dose of EpiPen. This data, along with the data from the complete EPIPHAST study, will be the basis for our second End-of-Phase 2 (EoP2) meeting with the FDA. We received a positive written feedback from the FDA after our initial EoP2 meeting request to discuss Chemistry, Manufacturing, and Controls (CMC) for AQST-109, which indicates that our approach to characterizing attributes of AQST-109 appears reasonable in the context of a potential future filing. We plan to obtain guidance and or concurrence on specific questions relating to the clinical components of a potential AQST-109 filing during the EoP2 meeting. At this meeting, we also anticipate receiving feedback on our EPIPHAST study data as well as the proposed clinical development plan for AQST-109. This meeting has been granted by the FDA and is scheduled to occur prior to the end of 2022.

- **AQST-108** – is a sublingual film formulation delivering systemic epinephrine that is also in development by Aquestive for the treatment of conditions 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 systemic adverse events observed that are consistent with the known adverse events profile for epinephrine. We are on track to request a pre-IND meeting for AQST-108 with the FDA in 2023 and plan to disclose the indication and path forward for development, once we have received feedback from the FDA.

- **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, 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 AQST-109, and AQST-108, in the short-term, we have taken the necessary steps to prepare AQST-305 for additional research trials.

*CNS Products*

We initially focused the Company's proprietary product pipeline on certain difficult to treat CNS diseases, in the area of epilepsy, 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, in patients aged two years of age or older, 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. On October 26, 2022, the Company entered into a License Agreement with Otter Pharmaceuticals, LLC, a subsidiary of Assertio Holdings, Inc. (NASDAQ: ASRT) (“Assertio”), a specialty pharmaceutical company offering differentiated products to patients, pursuant to which the Company granted an exclusive, worldwide license of its intellectual property for Sympazan to Assertio during the term of that agreement. The Company is the exclusive sole manufacturer and supplier of Sympazan for Assertio.

- **Libervant™** – a buccally, or inside of the cheek, administered soluble film formulation of diazepam is our most advanced proprietary investigational product candidate. 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 August 2022, the FDA granted tentative approval for Libervant for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient’s usual seizure pattern in patients with epilepsy 12 years of age and older. The FDA has concluded that Libervant has met all required quality, safety, and efficacy standards for approval. Due to an existing FDA regulatory grant of orphan drug market exclusivity for Valtoco®, a diazepam nasal spray product sold by another company, Libervant is not yet eligible for marketing in the United States. As a result of the FDA determination, the Agency cannot give final approval for Libervant until the expiration or inapplicability of the orphan drug market exclusivity, including, for example, by a reversal of the FDA’s decision and determination that Libervant is “clinically superior” to Valtoco. We are actively engaging the FDA regarding its determination. We continue to believe that, particularly in the case of our submitted studies on the effect of food on the absorption of diazepam formulations, Libervant has the distinct advantage of being able to be readily administered when needed without regard to food, providing an important benefit to patients. However, overcoming the orphan drug marketing exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such marketing exclusivity and approve Libervant for U.S. market access. Further, there can be no assurance that a competitor will not obtain other FDA marketing exclusivity that blocks U.S. market access for Libervant. More details on this product approval are described in the “Competition” section of Item I. Business of our 2021 Annual Report on Form 10-K.

  In September 2022, we announced the grant of an exclusive license to Atnahs Pharma UK Limited ("Pharmanovia") for Pharmanovia to develop and commercialize Libervant (diazepam) Buccal Film for the treatment of prolonged or acute, convulsive seizures in all ages in certain countries of the European Union, the United Kingdom, Switzerland, Norway and the Middle East and North Africa ("Territory") during the term of the Pharmanovia Agreement. Pharmanovia will lead the regulatory and commercialization activities for Libervant in the Territory and the Company will serve as the exclusive sole manufacturer and supplier of Libervant in the Territory.

**Licensed Commercial Products and Product Candidates**

Our portfolio also includes other 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, 2021 and 2020, our

licensed product portfolio generated $42.3 million and $40.2 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 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 2.3 billion doses of Suboxone since its launch in 2010. As of September 30, 2022, Suboxone branded products retain approximately 35% 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™** (riluzole) – an oral film formulation of riluzole, has been developed by the Company for the treatment of amyotrophic lateral sclerosis (ALS). We believe that Exservan 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 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 that the Company granted an 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. The product was launched by MTHA in June 2021. Under the terms of the MTHA license agreement, Aquestive is the exclusive manufacturer and supplier of Exservan for MTHA in the United States. Exservan may potentially fulfill a critical need for ALS patients, given it can be administered safely and easily, twice daily, without water.

  In March 2022, we announced the grant of an exclusive license to Haisco Pharmaceutical Group Co., Ltd. ("Haisco") for Haisco to develop and commercialize Exservan for the treatment of ALS in China. Haisco is a China-based public pharmaceutical company. Haisco will lead the regulatory and commercialization activities for Exservan in China. Aquestive will serve as the exclusive sole manufacturer and supplier for Exservan in China.

- **KYNMOBI®**– a sublingual film formulation of apomorphine, which is a dopamine agonist, was 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.

- **Zuplenz** – an oral soluble film formulation of ondansetron, a 5-HT antagonist, was developed 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 Hypera in Brazil (which Hypera refers as to Ondif). Hypera received approval to market Zuplenz in Brazil from the Brazilian regulatory authority (ANVISA) on February 21, 2022. 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.

- **Azstarys**™ – an FDA-approved, once-daily product for the treatment of attention deficit hyperactivity disorder (ADHD) in patients age six years or older. AZSTARYS consists of serdexmethylphenidate, KemPharm's prodrug of d-methylphenidate (d-MPH), co-formulated with immediate release d-MPH. In March 2012, the Company entered into an agreement with KemPharm, Inc. ("KemPharm"), to terminate a Collaboration and License Agreement entered into by the Company and KemPharm in April 2011. Under this termination arrangement, the Company has the right to participate in any and all value that KemPharm may derive from the commercialization or any other monetization of KP-415 and KP-484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving KemPharm and collaborations, royalty arrangements, or other transactions from which KemPharm may realize value from these compounds. During September 2019, the Company received $1,000 from its 10% share of milestone payments paid to KemPharm, under its licensing of KP-415 and KP-484 to a third party. The Company also received payment of $500 under this arrangement, which was included in License and royalty revenues for the year ended December 31, 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 (AZTARYSTM) a new once-daily treatment for ADHD. For the year ended December 31, 2021, the Company received payment of $2,000 under this arrangement, which was included in License and royalty revenues.

***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.

**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 2021 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®. 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. Prior to our license of the product on October 26, 2022, we sold 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 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 and in 2021 in order to recognize the declining volume of Suboxone that will continue declining in 2022. 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 Sympazan launched in December 2018. We may add licensee products to our production line 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 and AQST-108 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 Sympazan. Sympazan was developed as the precursor and complement to the launch of Libervant, while pending approval for U.S. market access by the FDA, as we believed that there was a very high degree of overlap and correlation between prescribers of Sympazan and the likely prescribers of an approved Libervant. With the recent exclusive license of Sympazan to Assertio and the tentative approval of Libervant from the FDA withholding U.S. market access, we expect to significantly reduce the costs of our commercial organization.

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 out-license of 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; and
- Continuing the development of AQST-109 and AQST-108 along the 505(b)(2) pathway.

*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 and Loans Payable, 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®. 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, 2022 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. Based on the current forecast by Sunovion of estimated KYNMOBI sales as of September 30, 2022, the Company may not receive any of the additional aggregate contingent payments under the Monetization agreement.

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 eight $1,000 annual minimum guaranteed royalty that is due. 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, 2022 and 2021***

*Revenues*:

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

| | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|---|---|---|---|
| *(In thousands, except %)* | 2022 | 2021 | $ | % | 2022 | 2021 | $ | % |
| Manufacture and supply revenue | $ 8,411 | $ 10,447 | $ (2,036) | (19)% | $ 27,456 | $ 27,623 | $ (167) | (1)% |
| License and royalty revenue | 376 | 328 | 48 | 15 % | 1,434 | 5,000 | (3,566) | (71)% |
| Co-development and research fees | 395 | 523 | (128) | (24)% | 1,039 | 1,417 | (378) | (27)% |
| Proprietary product sales, net | 2,281 | 1,989 | 292 | 15 % | 7,069 | 5,714 | 1,355 | 24 % |
| Total revenues | $ 11,463 | $ 13,287 | $ (1,824) | (14)% | $ 36,998 | $ 39,754 | $ (2,756) | (7)% |

For the three months ended September 30, 2022, total revenues decreased 14% or $1,824 compared to same period in the prior year. The decrease was primarily due to lower revenue from co-development and research fees, as well as manufacture and supply, partially offset by an increase in proprietary product sales as well as license and royalty revenue. For the nine months ended September 30, 2022, total revenues decreased 7% or $2,756 compared to same period in the prior year. The decrease was primarily due to lower license and royalty revenue as well as co-development and research fees, partially offset by an increase in proprietary product sales revenue.

Manufacture and supply revenue decreased 19% or $2,036 for the three months ended September 30, 2022 compared to the same period in the prior year due to a decline in Suboxone manufacturing volume. Manufacture and supply revenue remained flat for the nine months ended September 30, 2022 compared to the same period in the prior year.

License and royalty revenue increased 15% or $48 for the three months ended September 30, 2022 compared to the same period in the prior year. This increase was primarily due to milestone revenue earned from Hypera. License and royalty revenue decreased 71% or $3,566 for the nine months ended September 30, 2022 compared to the same period in the prior year. The decrease was primarily due to the remaining deferred revenue of $2,098 from the terminated license and supply agreement with Fortovia Therapeutics Inc., as well as milestone revenue earned from KemPharm, Inc. of $2,000 that were recognized in 2021 and did not reoccur in 2022.

Co-development and research fees decreased 24% or $128 for the three months ended September 30, 2022 compared to the same period in the prior year. Co-development and research fees decreased 27% or $378 for the nine months ended September 30, 2022 compared to the same period in the prior year. The decrease 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 15% or $292 for the three months ended September 30, 2022 compared to the same period in the prior year. Proprietary product sales, net increased 24% or 1,355 for the nine months ended September 30, 2022 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 for Sympazan.

*Expenses and Other:*

| | Three Months Ended September 30, | | Change | | Nine Months Ended September 30, | | Change | |
|---|---|---|---|---|---|---|---|---|
| *(In thousands, except %)* | 2022 | 2021 | $ | % | 2022 | 2021 | $ | % |
| Manufacture and supply | $ 4,625 | $ 4,400 | $ 225 | 5 % | $ 14,081 | $ 11,623 | $ 2,458 | 21 % |
| Research and development | 3,232 | 4,726 | (1,494) | (32)% | 13,203 | 12,647 | 556 | 4 % |
| Selling, general and administrative | 12,459 | 12,129 | 330 | 3 % | 41,067 | 38,494 | 2,573 | 7 % |
| Interest expense | 1,649 | 2,787 | (1,138) | (41)% | 4,902 | 8,305 | (3,403) | (41)% |
| Interest expense related to the sale of future revenue, net | 2,039 | 3,767 | (1,728) | (46)% | 5,837 | 10,567 | (4,730) | (45)% |
| Interest and other (income) expense, net | (5) | 33 | (38) | (115)% | (34) | (288) | 254 | 88 % |

Manufacture and supply costs and expenses increased 5% or $225 for the three months ended September 30, 2022 compared to the same period in the prior year. Manufacture and supply costs and expenses increased 21% or $2,458 for the nine months ended September 30, 2022 compared to the same period in the prior year. The increase was due to higher costs related to raw material and production.

Research and development expenses decreased 32% or $1,494 for the three months ended September 30, 2022 compared to the same period in the prior year. Research and development expenses increased 4% or $556 for the nine months ended September 30, 2022 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 $330 for the three months ended September 30, 2022 as compared to the same period in the prior year. Selling, general and administrative expenses increased 7% or $2,573 for the nine months ended September 30, 2022 as compared to the same period in the prior year. The increase was related to severance cost and litigation expense that arose through the course of business.

Interest expense decreased 41% or $1,138 for the three months ended September 30, 2022 compared to the same period in the prior year. Interest expense decreased 41% or $3,403 for the nine months ended September 30, 2022 compared to the same period in the prior year. The decrease was driven by a loss on the extinguishment of debt that was recognized in connection with the Fourth Supplemental Indenture to the 12.5 % Senior Secured Notes during the fourth quarter of 2021, which resulted in a lower net carrying value of debt in 2022.

Interest expense related to the sale of future revenue, net was $2,039 and 5,837 for the three and nine months ended September 30, 2022. 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. Based on the current forecast by Sunovion of estimated KYNMOBI sales as of September 30, 2022, the Company may not receive any of the additional aggregate contingent payments under the Monetization agreement. This current forecast resulted in a decrease to the interest expense related to the sale of future revenue. See Note 15 for details.

Interest and other expense, net decreased $38 and increased $254 for the three and nine months ended September 30, 2022 compared to the same period 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***

The Company's on-going business, existing cash and equivalents, expense management activities as well as access to the equity capital markets, including through our ATM facility and under the Lincoln Park Purchase Agreement, potentially provide near term funding opportunities for the Company. In addition, pursuant to the Fifth Supplemental Indenture, the holders

of the 12.5% Notes extended to March 31, 2023 from June 30, 2022 our ability to access, at our option, up to $30,000 of 12.5% Notes re-openers under the Indenture, subject to the Company obtaining FDA approval of Libervant for U.S. market access, and that the holders of 12.5% Notes have the right, but not the obligation, to purchase the $30,000 12.5% Notes re-openers.

We had $18,649 in cash and cash equivalents as of September 30, 2022. However, the Company's ability to fund the execution of our business objectives cannot be assured.

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, 2022 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. Based on the current forecast by Sunovion of estimated KYNMOBI sales as of September 30, 2022, the Company may not receive any of the additional aggregate contingent payments under the Monetization agreement.

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, 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 October 7, 2021, the Company entered into the Fourth Supplemental Indenture, pursuant to which 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 $2,700 in the aggregate, payable in four quarterly payments beginning May 15, 2022.

On May 13, 2022, pursuant to the Fifth Supplemental Indenture, the holders of the 12.5% Notes further extended to March 31, 2023 from June 30, 2022, the Company's ability to access, at the Company's option, $30,000 of 12.5% Notes re-openers under the Indenture. The Fifth Supplemental Indenture also provided that the Company will only be able to access the re-openers upon FDA approval of Libervant for U.S. market access, and that the holders of 12.5% Notes have the right, but not the obligation, to purchase the re-openers. If and to the extent that we access these re-openers, we will grant warrants to the holders of the 12.5% Notes to purchase up to 714,000 shares of the Company's 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 2019, we established an "At-The-Market" (ATM) facility and currently have a prospectus supplement registering the offer and sale of up to $35,000 of shares of Common Stock pursuant under the ATM facility. Since inception to September 30, 2022, we sold 9,387,769 shares which generated net cash proceeds of approximately $38,850, net of commissions and other transaction costs of $2,001. For the nine months ended September 30, 2022, we sold 1,906,350 shares which provided net proceeds of approximately $3,017, net of commissions and other transaction costs of $237. This ATM facility has approximately $34,358 available at September 30, 2022.

On April 12, 2022, we entered into the Lincoln Park Purchase Agreement, which provides that, upon the terms and subject to the conditions and limitations under the Lincoln Park Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park up to $40,000 worth of shares of our Common Stock from time to time over the 36-month term of the Lincoln Park Purchase Agreement. The Lincoln Park Purchase Agreement contains an ownership limitation such that we will not issue, and Lincoln Park will not purchase, shares of Common Stock if it would result in their beneficial ownership exceeding 9.99%. Lincoln Park has covenanted under the Lincoln Park Purchase Agreement not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our Common Stock. For the nine months ended September 30, 2022, the Company sold 1,611,181 shares including commitment shares of Common Stock, which provided proceeds of approximately $1,987 in connection with the Lincoln Park Purchase Agreement. On April 13, 2022, the Company filed a prospectus supplement in connection with this offering.

On June 6, 2022, we entered into securities purchase agreements ("Securities Purchase Agreements") with certain purchasers. The Securities Purchase Agreements provide for the sale and issuance by us of an aggregate of: (i) 4,850,000 shares of Common Stock, (ii) pre-funded warrants to purchase up to 4,000,000 shares of Common Stock and (iii) Common Stock warrants to purchase up to 8,850,000 shares of Common Stock. We received net proceeds of approximately $7,796, after deducting placement agent fees and expenses and estimated offering expenses payable by us. The pre-funded warrants were fully exercised and no Common Stock warrants issued pursuant to the Securities Purchase Agreements were exercised during the nine-months ended September 30, 2022.

***Cash Flows***

***Nine Months Ended September 30, 2022 and 2021***

| *(in thousands)* | **2022** | **2021** |
|---|---|---|
| Net cash (used for) operating activities | $ (18,235) | $ (24,918) |
| Net cash (used for) investing activities | (2,498) | (380) |
| Net cash provided by financing activities | 11,358 | 24,655 |
| Net decrease in cash and cash equivalents | $ (9,375) | $ (643) |

***Net Cash (Used for) Operating Activities***

Net cash used for operating activities for the nine months ended September 30, 2022 decreased by $6,683 compared to the same period in the prior year. The decrease was related to changes in operating assets and liabilities of $16,764, partially offset by a higher net loss of $464 and lower non-cash operating expenses of $9,617. The change in operating assets and liabilities was primarily due to lower trade and other receivables and higher accounts payable due to timing, as well as increased deferred revenue related to License and Supply Agreements that we entered into in 2022. The lower non-cash operating expenses were primarily due to less interest expense related to sale of future revenue ($4,774), less amortization of debt issuance costs ($3,447), and less share-based compensation expense ($1,461).

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

Net cash used for investing activities for the nine months ended September 30, 2022 increased by $2,118 compared to the same period in the prior year. The use of cash was related to capital expenditures and additions to intangible assets.

***Net Cash Provided by Financing Activities***

Net cash provided for financing activities for the nine months ended September 30, 2022 decreased by $13,297 compared to the same period in the prior year. The decrease was primarily due to less share purchase proceeds under the ATM facility and premium paid to retire debt in 2022, partially offset by proceeds from issuance of common stocks and warrants under private equity offerings in 2022. See Note 1 for detail.

***Funding Requirements***

The Company's on-going business, existing cash and equivalents, expense management activities as well as access to the equity capital markets, including through our ATM facility and under the Lincoln Park Purchase Agreement, potentially provide near term funding opportunities for the Company. In addition, there is up to $30,000 available under the existing debt facility upon the full approval of Libervant by the FDA for U.S. market access. Due to to the FDA decision in August 2022, discussed above under "-Overview - Proprietary CNS Product Portfolio - Libervant," however, we must overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. in order for Libervant to be granted U.S. market access. 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, or sufficient to fund our business objectives. 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, due to unrelated factors including factors arising in the capital markets, asset monetization markets, regulatory approval process, including the full approval of Libervant by the FDA for U.S. market access, 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;

- 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 licensee's 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, and other litigation matters in which we are involved;

- continued compliance with all covenants under our 12.5% Notes, including our ability to comply with our debt service obligations as required thereunder;

- absence of significant unforeseen cash requirements;

- our ability to access funding through the Company's ATM facility and under the Lincoln Park Purchase Agreement.

We expect to continue to manage business costs to appropriately reflect the anticipated general decline in Suboxone revenue, 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 activities in support AQST-109, AQST-108 and our other pipeline products. 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, specifically our 12.5% Notes. We plan to conservatively manage our pre-launch spending as to both timing and level relating to Libervant in light of the tentative approval of Libervant by the FDA. In this regard and in light of our out-license of Sympazan, we expect to significantly reduce our cost on commercialization in 2022 compared to 2021. 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 product, our existing level of debt which is secured by substantially all of our assets, restriction under the Indenture, and general financial 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, such asset sales, 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, 2022, 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, 2022, 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 2021 Annual Report on Form 10-K.

***We will need substantial additional capital to fund our operations, which may not be available on acceptable terms, if at all.***

The Company's cash requirements for 2022 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 our 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, 2022, we had $18.6 million of cash and cash equivalents.

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. We have received an aggregate amount of $50.0 million through December 31, 2021 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75.0 million 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 $125.0 million. Based on the current forecast of estimated KYNMOBI sales as of September 30, 2022, the Company may not receive any of the additional aggregate contingent payments under the Monetization agreement.

With the upfront proceeds of the monetization, we repaid $22.5 million of the Senior Secured Notes due 2025 (the "12.5% Notes"), and issued $4.0 million 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 $51.5 million, and such aggregate principal amount remains outstanding as of September 30, 2022. In addition, the holders of the 12.5% Notes agreed to extend to March 31, 2023 from June 30, 2022, our ability to access, at our option, subject to certain conditions, an additional $30.0 million of 12.5% Notes re-openers under the Indenture. 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 monetization transaction, we issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our Common Stock.

On October 7, 2021, we entered into the Fourth Supplemental Indenture in connection with the 12.5% Notes. Pursuant to the Fourth Supplemental Indenture, the amortization schedule for the 12.5% Notes has been 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 June 30, 2025 or the interest payment obligation due under the Notes.

On May 13, 2022, pursuant to the Fifth Supplemental Indenture, the holders of the 12.5% Notes further extended to March 31, 2023 from June 30, 2022, our ability to access, at our option, $30.0 million of 12.5% Notes re-openers under the Indenture. The Fifth Supplemental Indenture also provided that the Company's access to re-openers is subject to the full approval of Libervant by the FDA for sale in the United States, which full approval includes U.S. market access for Libervant. In addition, the Fifth Supplemental Indenture provided that the holders of 12.5% Notes have the right, but not the obligation, to purchase the re-openers.

In 2019, we established an “at-the-market” (ATM) facility, under which, from time to time, we may offer and sell shares of our Common Stock. In April 2022, we entered into a Purchase Agreement with Lincoln Park, under which, from time to time, we may cause Lincoln Park to purchase shares of our Common Stock.

We may not be able to raise additional capital or secure other funding on terms acceptable to us, or at all, and any failure to raise additional capital or other funding as and when needed for our cash requirements, including payments on our 12.5% Notes, would have a negative impact on our business, financial condition and prospects and on our ability to execute and achieve our business plan.

If adequate funds are not available for our liquidity needs and cash requirements as and when needed from the sources referred to above or otherwise, or at all, 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, including asset sales, although we cannot assure that any of these actions would be available or available on reasonable terms. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing most if not all of their investment in the Company.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

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

| Number | Description |
|---|---|
| 10.1[+] | License and Supply Agreement, dated as of September 26, 2022, by and between Aquestive Therapeutics, Inc. and Atnahs Pharma UK Limited (filed herewith). |
| 31.1 | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith). |
| 31.2 | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith). |
| 32.1 | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith). |
| 32.2 | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith). |
| 101.INS | XBRL Instance Document |
| 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 |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL document and contained in exhibit 101) |

[+] Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been omitted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

**SIGNATURES**

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

Aquestive Therapeutics, Inc.
(REGISTRANT)

Date: November 1, 2022

/s/ Daniel Barber
Daniel Barber
*President and Chief Executive Officer*
*(Principal Executive Officer)*

Date: November 1, 2022

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

**THE SYMBOL "[****]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.**

# LICENSE AND SUPPLY AGREEMENT

**by and between**

**AQUESTIVE THERAPEUTICS, INC.**

**and**

**ATNAHS PHARMA UK LIMITED**

**Dated as of September 26, 2022**

**LICENSE AND SUPPLY AGREEMENT**

This LICENSE AND SUPPLY AGREEMENT (together with the Schedules hereto, this "Agreement") is entered into as of September 26, 2022 (the "Effective Date") by and between Aquestive Therapeutics, Inc., a Delaware corporation having its principal place of business at 30 Technology Drive, Warren, New Jersey 07059 ("Aquestive"), and Atnahs Pharma UK Limited, a company registered in England and Wales having its principal place of business at Suite 1, 3rd Floor 11-12 St. James' Square, London, United Kingdom, SW1Y 4LB ("Pharmanovia"). Aquestive and Pharmanovia are sometimes referred to hereinafter individually as a "Party" and collectively as the "Parties."

**RECITALS:**

A. Aquestive owns patented and trade secret proprietary technology related to film-based drug delivery systems using its PharmFilm® technologies, including orally soluble film strips containing active pharmaceutical ingredients.

B. Pharmanovia desires to obtain from Aquestive, and Aquestive desires to grant to Pharmanovia, an exclusive license to Commercialize (defined below) the Product (defined below) in the Field (defined below) in the Territory (defined below), subject to the terms of this Agreement and as set forth in the Product Schedule (defined below) which shall form a part of this Agreement.

C. The Parties desire that Aquestive shall act as the exclusive manufacturer and supplier to Pharmanovia of finished drug products as specifically described in the Product Schedule, subject to the terms of this Agreement.

D. In consideration of the foregoing and the mutual representations, warranties and covenants contained herein, the Parties, intending to be legally bound hereby, agree as follows:

1. **DEFINITIONS**

As used herein, the following terms shall have the following meanings:

1.1 "Adverse Event" means any untoward medical occurrence in a patient, clinical investigation subject, or consumer following administration of a medicine, as related to the use of the Product which requires reporting to a Regulatory Authority.

1.2 "Affiliate" of a Person means any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such first Person. As used in this definition of Affiliate, "control" and, with correlative meanings, the terms "controlled by" and "under common control with," shall mean to possess the power to direct the management or policies of a Person, whether through: (a) direct or indirect beneficial ownership of fifty percent (50%) or more of the voting interest in such entity; (b) the right to appoint fifty percent (50%) or more of the directors of such entity; or (c) by contract or otherwise.

1.3 "Agreement" has the meaning set forth in the Preamble of this Agreement.

1.4 "API" means the active pharmaceutical ingredient(s) with respect to the Product as set forth in the Product Schedule.

1.5 **"**Applicable Currency**"** means the applicable currency of a country in a Territory for the purpose of calculating amounts recognized as Net Sales under this Agreement.

1.6 "Applicable Law" means all laws, rules and regulations, or other requirements of Regulatory Authorities including, without limitation, the FCPA and Healthcare Laws, applicable to the Development, Commercialization, or Supply of the Product, as the case may be, that may be in effect from time to time during the Term.

1.7 "Aquestive" has the meaning set forth in the Preamble to this Agreement.

1.8 "Aquestive Indemnitees" has the meaning set forth in Section 11.1.

1.9 **"**Aquestive IP**"** means the Aquestive Patents, the Dossier and further any and all Intellectual Property owned or Controlled by Aquestive or its Affiliates as of the Effective Date or during the Term, including Improvements, which is useful or necessary to Commercialize the Product in the Field in the Territory.

1.10 **"**Aquestive Know-How**"** means data, knowledge, techniques, inventions, designs, drawings, health and safety information, material safety data sheets, tests (including Supply, manufacturing and batch records), reports, procedures, processes, models, manuals, formulae, systems, experiments, samples, specimens, results, statistics, research, tables of operating conditions and the like and all other know-how, in each case to the extent not in the public domain (whether proprietary or not) in connection with the Product in the Territory.

1.11 "Aquestive Marks" means, collectively, the Aquestive Housemark and the Aquestive Product Mark(s).

1.12 "Aquestive Product Mark(s)" means the Aquestive trademark(s) with respect to the Product, if any, set forth in the Product Schedule.

1.13 "Aquestive Patents" means those patents and patent applications owned or Controlled by Aquestive or its Affiliates during the Term related to the formulation, manufacturing and use of the Product in the Field in the Territory, including, without limitation, any divisionals or any substitute applications, any patent issued with respect to any such patent applications, any patents which remain valid subsequent to any post grant proceedings or other challenges which result in the patent being enforceable, any amendment or extension including any supplementary protection certificate of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing, or as applicable portions thereof or individual claims therein. A list of the Aquestive Patents as of the Effective Date is attached hereto as Schedule 1.13, which may be updated from time to time, as applicable, by amendment of such Schedule or, if specific to the Product, as set forth in the Product Schedule to this Agreement (each such Aquestive Patent specific to the Product, an **"**Aquestive Product Patent**"**).

1.14 **"**Bankruptcy Code**"** has the meaning set forth in Section 14.18.

1.15 "Bankruptcy Event" means the occurrence of any of the following with respect to a Party: (a) such Party files or has filed against it in any court or agency, pursuant to any statute or regulation of any state or country, a petition in voluntary or involuntary bankruptcy or insolvency or for reorganization and such filing is not withdrawn or dismissed within sixty (60) days after the filing thereof; (b) such Party files for, or consents to be filed against it an arrangement or for the appointment of a receiver or trustee of such Party or of its assets and such filing is not withdrawn within sixty (60) days after the filing thereof; (c) such Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within sixty (60) days after the filing thereof; or (d) the dissolution or liquidation of such Party, or such Party shall make an assignment for the benefit of its creditors or (e) such Party ceases to carry on business.

1.16 **"**Bankruptcy Supply Failure**"** means Aquestive's inability or failure to Supply Product manifested over a period of sixty (60) days or more following a Bankruptcy Event.

1.17 "Business Day" means any day other than a Saturday or Sunday on which banking institutions in New York, New York, United States and London, England are open for business.

1.18 "Calendar Quarter" means the three (3) month period in any given calendar year ending on March 31, June 30, September 30, and December 31.

1.19 "Certificate of Analysis" means the certificate evidencing the analytical tests conducted on a specific lot of the Product reflecting that such Product and any Raw Materials used therein conform to the relevant Specifications and setting forth, *inter alia*, the items tested and test results, and accompanied by all documentation required by Applicable Law and/or a Regulatory Authority to Commercialize such Product in the Territory.

1.20 "Certificate of Compliance" means the certificate evidencing that the Product delivered to Pharmanovia was manufactured in accordance with Applicable Law, and the applicable Regulatory Approval.

1.21 "Clinical Supply" has the meaning set forth in Section 4.3.1.

1.22 "CMC Data" means chemistry, manufacturing and controls data required by Applicable Law and/or a Regulatory Authority to Develop the Product in the Territory.

1.23 **"**COGS**"** means the following costs incurred by Aquestive or its Affiliates or subcontractors related to the Supply of the Product on a per Unit basis: (i) the landed cost of raw materials, including invoice price, freight and duties; (ii) reasonably allocated direct and indirect labor and overhead costs; (iii) costs in incurred in connection with quality assurance (including testing, sampling and complaint investigation); and (iii) warehousing and shipping costs, determined in accordance with GAAP, consistently applied.

1.24 Commercialization" means any and all activities directed to preparation for sale of, registration, marketing, promoting, distributing, including importing, exporting, transporting, offering for sale and selling the Product in the Field in the Territory and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, **"**Commercialize**"** means to engage in Commercialization.

1.25 "Commercially Reasonable Efforts" means, with respect to a Party and its obligations under this Agreement with respect to a Product, the level of efforts and resources (measured as of the time that such efforts and resources are required to be used under this Agreement) that are comparable to those used by a similarly situated company in the industry of a similar size and profile as such Party to develop, manufacture, supply or commercialize, as the case may be, a pharmaceutical product owned by such company or to which it has rights which is at a similar stage of research, development or commercialization (as the case may be), and with similar market potential as the applicable Product and at a similar stage in life cycle, taking into account, as applicable: that product's profile of efficacy and safety; proprietary position, including expected and actual market exclusivity (including patent and regulatory exclusivity); regulatory status, including anticipated or approved labeling and anticipated or approved post-approval requirements; present and future market and commercial potential, including the competitiveness of the marketplace; any legal and regulatory issues involved, the expected and actual profitability of that product and other relevant factors, including technical, legal, scientific, medical, sales performance, commercial and/or marketing factors.

1.26 "Competitive Infringement" has the meaning set forth in Section 13.2.1.

1.27 "Confidential Information" has the meaning set forth in Section 10.1.

1.28 "Confidentiality Agreement" means that certain Confidentiality Agreement between Aquestive and Pharmanovia executed and delivered as of December 13, 2021.

1.29 "Control" or "Controlled" means, with respect to any Intellectual Property, the possession (whether by ownership, license or sublicense, other than by a license, sublicense or other right granted (but not assignment) pursuant to this Agreement) by a Party (or its Affiliate) of the ability to assign or grant to the other Party the licenses, sublicenses or rights to access and use such Intellectual Property as provided for in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party would be required hereunder to grant such license, sublicense, or rights of access or use.

1.30 "CPA Firm" has the meaning set forth in Section 7.11.

1.31 "Delivery Failure" has the meaning set forth in Section 5.10.1.

1.32 "Development" means all development activities conducted in connection with or as a condition of seeking or obtaining and maintaining Regulatory Approval of the Product in the Field in the Territory including, among other things: (a) the conduct of all research, non-clinical, and pre-clinical activities, testing and studies of the Product; drug discovery, toxicology, pharmacokinetic, pharmacodynamic, drug-drug interaction, safety, tolerability and pharmacological studies, formulation, statistical analysis and report writing; (b) the conduct of all clinical studies (including post-Marketing Authorization human studies) and the distribution of the Product for use in clinical studies, if any; (c) preparation, filing and prosecution of any Regulatory Approval or Regulatory Approval Application for the Product; (d) responsibility for all regulatory filing submissions and registrations; (e) Raw Material testing; (f) all development activities directed to label expansion (including prescribing information) or obtaining Marketing Authorization of the Product for one or more additional indications following initial Marketing

Authorization; (g) all development activities conducted after receipt of Marketing Authorization of the Product that are required or requested in writing by a Regulatory Authority as a condition of, or in connection with, obtaining or maintaining a Marketing Authorization; (h) any pharmacoeconomic studies required for the Marketing Authorization; (i) any investigator- or institution-sponsored studies required for the Marketing Authorization; (j) pre-approvals, post-approval obligations and reporting relating to the Product in the Field in the Territory; and (j) all regulatory affairs related to any of the foregoing. When used as a verb, **"**Develop**"** means to engage in Development.

1.33 "Disclosing Party" has the meaning set forth in Section 10.1.

1.34 "Dosage Strength" means the dosage strength with respect to the Product as set forth in the Product Schedule.

1.35 "Dossier" means a copy of the documents submitted to the FDA in support of the NDA for the Product including scientific and technical data relating to the Product and other related information that may be required for Pharmanovia's submissions for Regulatory Approvals in the Territory; for the avoidance of doubt this includes but not limited to any raw technical data supporting the NDA during pre-assessment and assessment phases.

1.36 "Excluded Claim" has the meaning set forth in Section 14.12.8.

1.37 "Effective Date**"** has the meaning set forth in the Preamble of this Agreement.

1.38 **"**Exchange Rate**"** has the meaning set forth in Section 7.2.

1.39 "Executive Officer" has the meaning set forth in Section 14.12.2.

1.40 "FCPA" means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended and as may be further amended after the Effective Date, and any equivalent non-U.S. regulations or standards, if and as applicable during the Term.

1.41 "FDA" means the United States Food and Drug Administration, and any of its successor agencies or departments.

1.42 "Field" means the field with respect to the Product as set forth in the Product Schedule.

1.43 "First Commercial Sale" means with respect to a country in the Territory, the first sale of the Product to a Third Party by Pharmanovia (or any Affiliate or subcontractor of Pharmanovia authorized by Pharmanovia pursuant to this Agreement) within such country in the Territory after Regulatory Approval (and where applicable, (i) pricing or reimbursement approval in such country and (ii) labeling approval) for the Product has been obtained in such country.

1.44 "Force Majeure" has the meaning set forth in Section 14.7.

1.45 "GAAP" means generally accepted accounting principles set forth from time to time in the opinions and pronouncements of the Accounting Principles Board and the American

Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board (or agencies with similar functions of comparable stature and authority within the United States accounting profession), which are applicable to the circumstances as of the date of determination, in any case consistently applied.

1.46 "Healthcare Laws" shall mean (i) the Federal Food, Drug & Cosmetic Act (FDC Act) (21 U.S.C. §§ 301 et seq.) and the regulations promulgated thereunder, including but not limited to those related to current good manufacturing practices (cGMP) and any analogous law of any foreign country (including for the avoidance of doubt EU cGMP); (ii) any and all federal, state and local fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b), the Stark Law (42 U.S.C. § 1395nn and §1395(q)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code, the criminal health care fraud statute (18 U.S.C. § 1347), the regulations promulgated pursuant to such statutes, and any analogous law of any state or foreign country; (iii) any federal, state, or local law regulating the interactions with healthcare professionals and reporting thereof and any analogous law of any foreign country; (iv) the Controlled Substances Act and the regulations promulgated thereunder and any analogous law of any foreign country; (v) the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191) (HIPAA), the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act), the regulations promulgated under such laws, and any applicable state privacy and security laws and any analogous law of any foreign country; (vi) Medicare (Title XVIII of the Social Security Act) and the regulations promulgated thereunder; (vii) Medicaid (Title XIX of the Social Security Act) and the regulations promulgated thereunder; (viii) TRICARE (f/k/a CHAMPUS); (ix) the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173) and the regulations promulgated thereunder; (x) quality, safety and accreditation standards and requirements of all applicable state, federal, and foreign laws or regulatory bodies; (xi) requirements of law relating to the manufacturing, labeling or relabeling, packaging or repackaging, marketing, sale, or distribution of drugs or medical devices, including laws governing license requirements for any of the foregoing activities; (xii) laws related to the hiring of employees or acquisition of services or supplies from those who have been excluded from government health care programs, quality, safety, privacy, security, licensure or accreditation; and (xiii) laws and regulations promulgated by any regulatory authority equivalent to the FDA in a foreign country including but not limited to the European Medicines Agency ("EMA") and the Medicines and Healthcare Products Regulatory Agency ("MHRA") including the applicable regulations and guidances of the FDA and the EMA (and national implementations thereof) that constitute good laboratory practices, good manufacturing practices and good clinical practices).

1.47 "Housemark" means the name and logo of Aquestive or any of its Affiliates as identified in Schedule 1.47A attached hereto, and the name and logo of Pharmanovia or any of its Affiliates as identified on Schedule 1.47B attached hereto, as each such schedule may be updated from time to time, and made a part hereof by amendment of such Schedule.

1.48 "ICC" has the meaning set forth in Section 14.12.3.

1.49 "ICC Rules" has the meaning set forth in Section 14.12.3.

1.50 **"**Improvements**"** means any invention, discovery, development or modification with respect to the Product, the technology covered by the Aquestive Patents and/or the Aquestive Know-How and/or relating to the exploitation thereof, whether or not patented or patentable, including any enhancement in the efficiency, operation, Supply, ingredients, preparation, presentation, formulation, means of delivery (including the development of any delivery system or enhancement thereto) or dosage of the Product, the technology covered by the Aquestive IP, any discovery or development of any new or expanded indications for the Product, the technology covered by the Aquestive IP or any discovery or development that improves the stability, safety or efficacy of the Product, the technology covered by the Aquestive IP.

1.51 "Indemnitee" has the meaning set forth in Section 11.3.1.

1.52 "Indemnitor" has the meaning set forth in Section 11.3.1.

1.53 "Intellectual Property" means, collectively, all: (a) patents and patent applications, including, without limitation, any divisionals or any substitute applications, any patent issued with respect to any such patent applications, any patents which remain valid subsequent to any post grant proceedings or other challenges which result in the patent being enforceable, any amendment or extension including any supplementary protection certificate of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing, or as applicable portions thereof or individual claims therein; (b) copyrightable works, copyrights in works of authorship of any type, including computer software and industrial designs, registrations and applications for registration thereof; (c) trade secrets, know-how, processes, specifications, product designs, descriptions of the manufacturing process and equipment and all other manufacturing information, engineering and other manuals and drawings, standard operating procedures, flow diagrams, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, quality assurance, quality control and clinical data, technical information, data, research records, supplier lists and similar data and information, and all rights in any jurisdiction, according to the Applicable Laws of such jurisdiction, to limit the use or disclosure thereof; (d) any and all rights to extensions to any of the foregoing; (e) any and all rights of application regarding any of the foregoing; and (f) rights to sue and recover damages or obtain injunctive relief for infringement, or misappropriation of any of the foregoing.

1.54 "Losses" means any and all damages, awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including, without limitation, court costs, interest and reasonable fees of attorneys, accountants and other experts), together with all documented out-of-pocket costs and expenses incurred in complying with any judgments, orders, decrees, stipulations, investigations and injunctions that arise from or relate to a Third Party Claim.

1.55 "Marketing Authorization" means authorization from the relevant Regulatory Authority within the Territory to market, sell or otherwise Commercialize the Product in one or more countries in the Field in the Territory.

1.56 "Marketing Expenses" means all costs and expenses incurred in connection with the Commercialization of the Product in the Field in the Territory, including, without limitation:

(a) marketing, advertising, sampling, and promotional activities; (b) marketing studies; (c) primary and secondary market research; (d) promotional materials; and (e) samples.

1.57 "Milestone Payments" has the meaning set forth in Section 7.1.

1.58 "Minimum Volume Commitment" has the meaning set forth in Section 7.4.

1.59 **"**[****]**"** has the meaning set forth in Section 2.9.

1.60 "NDA" means a new drug application submitted pursuant to the requirements of the FDA under 21 U.S.C. § 355(b)(1) of the Act, in each case, with all additions, deletion or supplements thereto.

1.61 "Net Sales" means, for any period of determination, the aggregate amount invoiced for the Product by Pharmanovia (or any Affiliate, or agent of Pharmanovia) to a Third Party during such period, less amounts for the following accruals applied on a per Unit basis:

(a) credits, refunds, allowances, charge-backs, rebates, returns, distribution and other fees, reimbursements, bona fide price reductions, and similar payments provided to wholesalers, chains, mass merchandisers, group purchasing organizations and other distributors, buying groups, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, other institutions or health care organizations, any governmental, quasi-governmental or regulatory body, agency or authority in respect of any governmental programs;

(b) credits or discounts related to sales promotions, trade show discounts and stocking allowances and trade volume and cash discounts and rebates in amounts that are usual and customary, including retroactive corrections, including shelf stock or other pricing related adjustments (and corrections for billing errors or shipping errors); and

(c) any tax, tariff, duty or government charge (including any sales, value added, excise or similar tax or relevant surtax or government charge) levied on the sale, importation, exportation, transportation or delivery of the Product and borne by the seller thereof that is not reimbursed by any Third Party.

(d) costs incurred for such Product that is destroyed due to recall of goods; and

(e) any other similar and customary deductions that are consistent with International Financial Reporting Standards.

The amounts recognized as Net Sales, including any deductions accrued pursuant to clauses (a) through (d) of this Section 1.61 shall be consistent with and determined from books and records maintained in accordance with International Financial Reporting Standards and shall only be deducted once and only to the extent not otherwise deducted from the aggregate amount invoiced.

A **"**sale**"** shall not include transfers or dispositions of Product for pre-clinical or clinical purposes or as samples, in each case, without charge.

For the purposes of this definition the transfer of Product by Pharmanovia to any Affiliate shall not be considered a sale unless such Affiliate is the last entity in the distribution chain that directly sells and dispenses Product to patients, health care providers, and/or health institutions.

1.62 "Party" or "Parties" has the meaning set forth in the Preamble to this Agreement.

1.63 "Payment Period**"** means each Calendar Quarter period during the Term; commencing in the year in which the First Commercial Sale of the Product occurs.

1.64 "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other legal entity or organization, including a government or political subdivision, department, or agency of a government.

1.65 "Pharmanovia" has the meaning set forth in the Preamble to this Agreement.

1.66 "Pharmanovia Indemnitees" has the meaning set forth in Section 11.2.

1.67 **"**Pharmanovia Marks**"** means the Pharmanovia Housemark and such trade dress and trademarks as are notified to Aquestive by Pharmanovia in writing from time to time.

1.68 "Primary Packaging" means the foil pouch that individually wraps and touches each Unit.

1.69 "Primary Packaging Design" means artwork associated with the Primary Packaging for the Product in the Field in the Territory.

1.70 "Product" means the Product set forth in the Product Schedule.

1.71 "Product Label" means labels and other written material pertaining to the core label for the Product including, but not limited to, safety information, prescribing information, medication guides, and instructions for use.

1.72 "Product Requirements" has the meaning set forth in Section 5.1.

1.73 "Product Schedule" means with respect to the Product, the Product specific details concerning the Product including the Product description, the API, specific Aquestive Product Patents (if any) covering the Product, specific Aquestive Product Mark(s) (if any) covering the Product, Dosage Strength, Milestone Fees, Minimum Volume Commitment, Royalty Fees, Territory, Product Transfer Price and any other Product or Territory-specific information required for the performance of the obligations contemplated under this Agreement.

1.74 "Product Transfer Price" has the meaning set forth in Section 5.2.

1.75 **"**Profit**"** means, for any period of determination, Net Sales, less Product Transfer Price on a per Unit basis, less the following accruals applied on a per Unit basis: quality release, distribution and logistics fees, freight and insurance.

1.76 "Profit Share" has the meaning set forth in Section 5.2.

1.77 "Purchase Orders" has the meaning set forth in Section 5.1.

1.78 "Quarterly Payment Reports" has the meaning set forth in Section 7.5.

1.79 "Quality Agreement" has the meaning set forth in Section 5.11.

1.80 "Raw Materials" means raw materials, chemicals, work-in-process, and other materials used to Supply Product under this Agreement.

1.81 "Raw Materials Safety Stock" has the meaning set forth in Section 5.9.

1.82 "Recall" has the meaning set forth in Section 4.8.1.

1.83 "Recall Expenses" has the meaning set forth in Section 4.8.1.

1.84 "Recall Objection Notice" has the meaning set forth in Section 4.8.3.

1.85 "Receiving Party**"** has the meaning set forth in Section 10.1.

1.86 "Regulatory Approval" means authorization from the relevant Regulatory Authorities within the Territory for approval to Commercialize the Product in the Field in the Territory, including the Marketing Authorization for the Product.

1.87 "Regulatory Approval Application" means any filings submitted to a Regulatory Authority in the Territory, in each case, with all additions, deletion or supplements thereto, for Regulatory Approval of the Product in the Field in the Territory.

1.88 "Regulatory Authority" means any national, international, federal, regional, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, regulatory agency, department, bureau, commission, council or other regulatory or taxing authority entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, including with respect to the granting of approvals (including pricing and reimbursement approvals), licenses, registrations, or authorizations for the marketing, sale, manufacturing, testing, labeling, storage, handling, packaging, shipping or supply of the Product or granting Regulatory Approval for the Product, including the FDA, any other regulatory authority(ies) equivalent to the FDA including the EMA and the MHRA, and any successor(s) thereto having substantially the same functions, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.89 **"**Regulatory Notification**"** shall have the meaning given to it in Section 4.6.2.

1.90 "Rescheduled Delivery Date" has the meaning set forth in Section 5.10.1.

1.91 **"**[****]**"** has the meaning set forth in Section 2.9.

1.92 **"**[****]**"** has the meaning set forth in Section 2.9.

1.93 **"**[****]**"** has the meaning set forth in Section 2.9.

1.94 "Royalty Fees" has the meaning set forth in Section 7.2.

1.95 **"**Safety Data Exchange Agreement**"** has the meaning set forth in Section 5.12.

1.96 "Secondary Packaging" means the packaging that contains the Primary Packaging and which does not come in contact with the single dosage strips of the Product.

1.97 "Secondary Packaging Design" means artwork associated with the Secondary Packaging for the Product in the Field in the Territory.

1.98 "Specifications" means the written specifications for the Product and Raw Materials including, without limitation, the shelf life of the Product and Raw Materials for such Product and the specifications as set forth in the applicable Regulatory Approval for the Product. The Specifications, and any modifications or supplements thereto from time to time during the Term, shall be mutually approved in a specific written agreement by the Parties and, upon such mutual written agreement, shall be deemed to be incorporated by reference in this Agreement.

1.99 "Statement of Work" means a written document executed and delivered by the Parties that defines, as applicable, the work activities, requirements, deliverables, timeline, associated pricing and any other terms and conditions to govern given work project to be conducted by Aquestive under this Agreement.

1.100 "Steering Committee" has the meaning set forth in Section 6.

1.101 "Supply" means all activities related to the manufacture, supply, processing, storing, labeling, and packaging (as specified in this Agreement) quality control, storage release by Aquestive for sale and delivery of the Product including quality control and release.

1.102 "Technology Transfer Plan" has the meaning set forth in Section 9.2.

1.103 "Technology Transfer Partner" has the meaning set forth in Section 9.2.

1.104 "Term" has the meaning set forth in Section 12.1.

1.105 "Territory" means the territory with respect to the Product as set forth in the Product Schedule.

1.106 "Third Party" means any Person other than Aquestive and Pharmanovia and their respective Affiliates.

1.107 "Third Party Claim" has the meaning set forth in Section 11.1.

1.108 "Unit" shall mean a single dosage strip of the Product, in an individual foil pouch, for sample or sale.

## 2. CERTAIN RIGHTS AND OBLIGATIONS

2.1 **Licenses Granted to Pharmanovia**. Subject to the terms and conditions of this Agreement, Aquestive hereby grants to Pharmanovia, and Pharmanovia hereby accepts, during the Term, as to the Product in the Field in the Territory, an exclusive (including as to Aquestive and its Affiliates), royalty-bearing license under and to the Aquestive Product Patents and as to the Product in the Field in the Territory, an exclusive, royalty-bearing, license under and to the Aquestive IP to: (i) register the Product with the applicable Regulatory Authorities within the Field in the Territory and (ii) Commercialize the Product in the Field in the Territory (including but not limited to the right to sublicense to distributors the right to distribute and promote the Product in the Territory in accordance with the terms of this Agreement.

2.2 **Exclusivity**.

2.2.1 Aquestive hereby covenants and agrees with Pharmanovia that during the Term, other than as expressly provided in this Agreement, neither Aquestive or its Affiliates, nor any Person acting on behalf of Aquestive or its Affiliates, shall grant any license or right with respect to the Aquestive IP to any Affiliate or Third Party to, research, make, have made, Develop or Commercialize the Product in the Field in the Territory. Notwithstanding anything to the contrary contained in this Agreement, Aquestive shall have the sole and exclusive right to be the exclusive Developer (except for the limited Development rights of Pharmanovia set forth in Section 4.3, manufacturer and supplier of all Product Commercialized under this Agreement.

2.2.2 Pharmanovia hereby covenants and agrees that neither Pharmanovia, nor any of its Affiliates shall, directly or indirectly (whether through an Affiliate, Third Party, or by any transfer or license rights to an Affiliate or Third Party), during the Term, make, use, Develop (except for the limited Development rights of Pharmanovia set forth in Section 4.3), import/export, seek Regulatory Approval for, manufacture, supply, distribute, offer to sell, sell, market, promote, detail, or otherwise commercialize any products that contains the API as the active pharmaceutical ingredient and that is delivered in a buccal, sublingual or nasal form, in the Field in the Territory other than pursuant to this Agreement and other than to the extent such products are being commercialized by Pharmanovia as of the Effective Date.

2.3 **No Implied Licenses; Negative Covenant**. Except as set forth in this Agreement, neither Party shall acquire any license or other Intellectual Property interest, by implication or otherwise, under any Intellectual Property Controlled by the other Party or its Affiliates. Neither Party shall, nor shall it permit any of its Affiliates or subcontractors to, practice any Intellectual Property licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.4 **Use of Subcontractors**.

2.4.1 Aquestive Use of Subcontractors. Subject to the terms of the Agreement, Pharmanovia acknowledges and agrees that Aquestive may exercise its rights or perform its obligations, including Development, clinical and Supply activities, under this Agreement through

one or more subcontracts with Third Parties selected by Aquestive; provided that, Aquestive will remain fully responsible to Pharmanovia for the performance of all obligations delegated to the subcontractor including responsibility for the work allocated to, and payment to, such Third Parties to the same extent it would if it had done such work itself. Aquestive shall notify Pharmanovia in writing of all activities sub-contracted to Third Parties and the names thereof.

2.4.2 Pharmanovia Use of Subcontractors. Subject to the terms of the Agreement, Aquestive acknowledges and agrees that Pharmanovia may exercise its rights or perform its obligations including the right to Develop (as set forth in Section 4.3), Commercialize, to hold Regulatory Approvals and distribute the Product in the Territory under this Agreement through one or more subcontracts for distribution with Third Parties selected by Pharmanovia; provided that, except as set forth in this Agreement, Pharmanovia will remain fully responsible for the performance of all obligations delegated to the subcontractor including responsibility for the work allocated to, and payment to, such Third Parties to the same extent it would if it had done such work itself.

2.5 **Trademarks**.

2.5.1 Subject to the terms and conditions of this Agreement, Aquestive hereby grants to Pharmanovia, and Pharmanovia hereby accepts as to the Product in the Field in the Territory: (a) a non-exclusive, non-transferable, non-sublicensable license to use the Aquestive Marks (excluding the Aquestive Product Mark(s)); and (b) an exclusive, non-transferable, non-sublicensable license to use the Aquestive Product Mark(s), in each case, solely in conjunction with the Commercialization of the Product in the Field in the Territory and solely for such uses as are specifically approved in writing by Aquestive (which uses Aquestive hereby confirms includes use of the Aquestive Marks to identify Aquestive as the manufacturer of the Product if so required by Applicable Laws). For the avoidance of doubt there is no obligation on Pharmanovia to apply the Aquestive Marks to the Product packaging, except as required by Applicable Law.

2.5.2 Aquestive hereby confirms that Pharmanovia may apply the Pharmanovia Marks to the Product. Subject to the terms and conditions of this Agreement, Pharmanovia hereby grants to Aquestive, and Aquestive hereby accepts, a non-exclusive, non-transferable, non-sublicensable license to use the Pharmanovia Marks solely in conjunction with the labeling and specified packaging of Product for Supply in the Field in the Territory and solely as such are approved in writing by Pharmanovia.

2.5.3 Without prejudice to Section 2.5.2, Aquestive shall:

2.5.3.1 only use the Pharmanovia Marks in accordance with all written instructions (including any brand guidelines) which Pharmanovia may provide to Aquestive from time to time;

2.5.3.2 not apply to register or otherwise attempt to register (whether in its own name, or in the name of any third party), any Pharmanovia Mark or any confusingly similar trade mark as a trade mark with any governmental authority, in any jurisdiction, at any time.

2.5.4 All use of the Pharmanovia Marks by Aquestive and its Affiliates, and all goodwill generated in connection therewith, shall inure solely for and to the benefit of Pharmanovia.

2.6 **Packaging and Labeling**.

2.6.1 Packaging and Labeling. Aquestive shall label and package Product in accordance with the Primary Packaging Design Specifications and Secondary Packaging specifications that are provided by Pharmanovia from time to time. Pharmanovia shall be responsible, at its cost and expense, for developing and providing Aquestive with a copy of all graphics and artwork to be used with the Product, including the Primary Packaging Design, which shall be delivered to Aquestive as an electronic file in Adobe Illustrator format. Pharmanovia shall be responsible, at its cost and expense, for any required submissions to the applicable Regulatory Authorities in the Territory regarding the labeling and packaging configurations for the Product, including any permitted changes in labeling or packaging configurations, and shall be responsible, at its cost and expense, for ensuring that labeling, packaging configurations, and the Primary Packaging Design Specifications complies with Applicable Law. Pharmanovia shall be responsible for ensuring that all Primary Packaging and Secondary Packaging complies with Applicable Law. The packaging for the Product, including the Primary Packaging and Secondary Packaging, shall, if required by Applicable Law indicate that the Product is manufactured by Aquestive.

2.6.2 Changes.

2.6.2.1 Changes to Packaging of Product. Pharmanovia shall have the right, upon prior written notice to Aquestive, to change the Primary Packaging and Secondary Packaging of the Product consistent with Applicable Law and the terms and conditions of this Agreement. Upon delivery of such written notice, the Parties will mutually agree in good faith upon a written Statement of Work that shall include a reasonable timeframe for implementation of such changes, including without limitation, giving effect to the use of the remaining work-in-process and any Raw Materials and packaging materials in-process or held in inventory by Aquestive prior to effecting such change and a reasonable estimate of the additional costs and expenses to be reimbursed to Aquestive by Pharmanovia as a result of the implementation of such changes; provided that any such costs and expenses arising from a change of Manufacturing Site by Aquestive shall be borne by Aquestive. Subject to the foregoing, such changes shall be at Pharmanovia's sole cost and expense (including documented cost of any inventory, work-in-process, Raw Materials, documentation updates and packaging materials of Aquestive which become obsolete or unusable as a result of such request) provided that Aquestive shall use Commercially Reasonable Efforts to reallocate such inventory, work in process, Raw Materials and packaging materials. Aquestive shall not be required to make any such change if: (a) it requires any material capital investment by Aquestive; or (b) it results in any cost increases (including manpower allocations or resources) to Aquestive that is not reimbursed by Pharmanovia. For the avoidance of doubt the initial implementation of a new SKU of the Product in the Territory shall not constitute a change pursuant to this Section 2.6.2.1.

2.6.2.2 Changes to Product Specifications. Either Party shall have the right to request that a change be made to the Specifications for the Product upon prior written

notice to, and (except for changes required by Applicable Law) subject to the approval of, the other Party and, if approved, the Parties shall agree on a reasonable timeframe for implementation of such changes. If either Party proposes making any material changes to the Specifications, such Party shall give the other Party at least sixty (60) days prior written notice of the proposed change unless such change is required because of Applicable Law, regulatory requirements or product performance concerns, or the availability or quality of the Product components, in which case such notice shall be provided as soon as reasonably possible. The other Party shall promptly, but no later than within thirty (30) days after receiving such written notice, inform the notifying Party in writing of any objections to the proposed change, including any changed validation requirements necessary to accept such proposed change. In no event may any change in the Specifications of the Product be implemented except in compliance with Applicable Law. Neither Pharmanovia nor Aquestive shall refuse without good and reasonable cause implementation of a proposed change in the Specifications that is or would be otherwise allowed by Regulatory Authorities and that does not affect the Product Transfer Price or the performance of the Product and Aquestive shall not refuse the implementation of a proposed change requested by Pharmanovia subject to Aquestive and Pharmanovia agreeing in good faith in writing to such change. If a change is made under this Section 2.6.2.2, the Party requesting the change shall be liable for the costs and expenses of implementing such change (with the exception of if a change is required to comply with Applicable Law or regulatory requirements in the Territory in which case Pharmanovia shall be liable for such costs and expenses).

2.7 **Aquestive Retained Rights**. Any rights of Aquestive not expressly granted to Pharmanovia under the provisions of this Agreement shall be retained by Aquestive. In furtherance of the foregoing and not in limitation thereof, Aquestive, except as expressly set forth in Section 2.1, shall retain the right: (a) to carry-out its obligations under this Agreement; and (b) to exploit the Aquestive IP for purposes outside of the scope of the licenses granted in Section 2.1 for any and all purposes anywhere in the world, without any duty to account to Pharmanovia or obtain Pharmanovia's consent for such exploitation.

2.8 **Confirmatory Licenses.** Aquestive shall if requested to do so by Pharmanovia, enter into one or more confirmatory license agreements in such form as may be agreed by the Parties for purposes of recording the licenses granted under this Agreement with the applicable patent offices in the Territory. The Parties shall use best efforts to ensure that, subject to Applicable Law, neither this Agreement, nor the contents thereof (excepts as required by Applicable Law) shall form part of any public record.

2.9 [****]

## 3. COMMERCIALIZATION

3.1 **Pharmanovia Responsibility and Control**. Except as otherwise expressly set forth in this Agreement, Pharmanovia shall have sole responsibility for all Commercialization activities for the Product in the Field in the Territory, including developing strategies and tactics related to the advertising, promotion, pricing, marketing, and selling the Product in the Field in the Territory. Pharmanovia shall comply, and shall use Commercially Reasonable Efforts to procure that all of its Third Party agents and subcontractors, if any, to comply, with all Applicable Law in Commercializing the Product in accordance with this Agreement.

3.2 **Specific Commercialization Rights and Obligations of Pharmanovia**. Subject to any conditions or limitations set forth in this Agreement, it shall be Pharmanovia's sole right and responsibility as to the Product in the Field in the Territory to: (a) develop advertising and promotional materials related to the Product; (b) book sales for the Product; (c) handle all returns of the Product; (d) handle all aspects of order processing, Product distribution, invoicing and collection of receivables for the Product; (e) collect data regarding sales to end users of the Product; (f) monitor inventory levels of the Product; (g) provide first line customer support; (h) conduct pharmacovigilance; (i) warehouse the Product; and (j) determine the price for the Product and any discounts and rebates that may be offered thereto, including decisions relating to customer allowances and credits.

3.3 **Product Launch and Market Coverage**. Pharmanovia shall use its Commercially Reasonable Efforts to launch the Product in the applicable country in the Territory within sixty (60) days of receiving the first delivery of saleable, Product following the later of pricing reimbursement and receipt of the Regulatory Approval of such Product in such country in the Territory. Aquestive acknowledges that it shall be consistent with Commercially Reasonable Efforts for Pharmanovia to prioritize Commercialization of the Product in certain countries of the Territory and not to proceed with Commercialization of a Product in all countries of the Territory at the same planned timetable.

3.4 **Commercialization and Marketing Expenses**. Pharmanovia shall be responsible for and pay one hundred percent (100%) of all costs and expenses incurred in connection with the Commercialization of a Product in the Territory including, without limitation, all Marketing Expenses.

## 4. DEVELOPMENT AND REGULATORY MATTERS

4.1 **Transfer of Regulatory Documentation and Other Information**.

4.1.1 At no cost to Pharmanovia except as set out in the Product Schedule, Aquestive will provide Pharmanovia with the applicable Dossier (including associated CMC Data and clinical and other data referenced in the Dossier to the upon Pharmanovia's payment of the first milestone payment to Aquestive as set forth in the Product Schedule and, subject to the terms of this Agreement, will use Commercially Reasonable Efforts to provide, on an ongoing basis during the Term:

4.1.1.1 copies of all (i) applications (including all INDs), registrations, licenses, authorizations and approvals including ANDA in relation to the Product; and (ii) material correspondence and reports submitted to or received from Regulatory Authorities related to the Product and all supporting documents with respect thereto and referenced therein, including all adverse event files and complaint files;

4.1.1.2 necessary technical consultation and clinical study support by Aquestive personnel;

4.1.1.3 to the extent in Aquestive's possession or control, such further documentation related to a Regulatory Approval for the Product requested by a Regulatory Authority;

in each case in a timely manner to support Pharmanovia's efforts to obtain Regulatory Approvals for the Product in the Field in the Territory.

4.1.2 At no cost to Aquestive, Pharmanovia shall provide Aquestive with copies of: (a) data and documents submitted to Regulatory Authorities in connection with obtaining Regulatory Approvals and post-approval maintenance of the Regulatory Approvals for the Product on a quarterly basis during the Term; (b) its annual report for safety and Adverse Events filed with applicable Regulatory Authorities in English; and (c) in English other safety data received by Pharmanovia with respect to the Product on an annual basis or more frequently as required to ensure expedited safety reporting in accordance with Applicable Law or as reasonably requested by Aquestive in writing from time to time during the Term and in accordance with the Safety Data Exchange Agreement.

4.1.3 At no cost to Pharmanovia, Aquestive shall provide Pharmanovia a summary of Adverse Events reported by Aquestive to the FDA on an annual basis or more frequently as required to ensure expedited safety reporting in accordance with Applicable Law in the relevant country in the Territory or as reasonably requested by Pharmanovia in writing from time to time during the Term and in accordance with the Safety Data Exchange Agreement.

4.1.4 Aquestive will provide Pharmanovia with such documentation (including clinical trial data) in Aquestive's possession or control, and technical assistance, as is necessary or desirable for Pharmanovia to maintain the Regulatory Approvals in the Territory.

4.1.5 The documentation and support and consultation to be provided pursuant to Section 4.1.2 and Section 4.1.4 by Aquestive to Pharmanovia shall be provided at no charge except the extent that Aquestive is not in possession or control of the relevant documentation and/or further work is required to generate the documentation and/or provide the support; in these circumstances Aquestive will provide Pharmanovia with cost estimates to provide the relevant documentation and/or support and the Parties mutually agree in writing to execute a Statement of Work for these activities prior to the commencement of such work.

4.2 **Development Rights and Responsibilities of Aquestive**. Aquestive shall provide Pharmanovia, at no cost, with regulatory materials and other regulatory data and information in its possession or control related to the Product (in English), to the extent necessary to support the Development activities to be conducted by Pharmanovia under this Agreement with respect to the Product in the Field in the Territory to the extent required by a Regulatory Authority in connection with the Regulatory Approvals including to achieve Marketing Authorization for the Product in the Field in the Territory or maintenance thereof. Aquestive shall use Commercially Reasonable Efforts to cause the relevant Third Parties to provide Pharmanovia with regulatory materials and other regulatory data and information related to each Product in English to the extent required by a Regulatory Authority in connection with a Regulatory Approval including the Marketing Authorization for the Product in the Field in the Territory; in connection with this Third Party support Aquestive will provide Pharmanovia with cost estimates from these Third Parties to

provide the relevant support and the Parties mutually agree in writing to execute a Statement of Work for these activities prior to the commencement of such work. At Pharmanovia's written request in connection with a Regulatory Approval or Regulatory Approval Application or maintenance thereof for the Product in the Field in the Territory, Aquestive shall use Commercially Reasonable Efforts to provide reasonable assistance to Pharmanovia with its preparation and submission of such Regulatory Approval Application or maintenance for the Product in Field in the Territory.

4.3 **Development Rights and Responsibilities of Pharmanovia**. Subject to the general oversight of the Steering Committee, Pharmanovia shall have sole responsibility for and have sole right to carry out, the performance of, and unless otherwise expressly set forth in this Agreement, shall be responsible for the sole cost of, the Development activities described in this Section 4.3.

4.3.1 Approval and Post-Approval Activities. Pharmanovia shall be solely responsible for, and have sole right to perform, the Development activities required to obtain the Regulatory Approvals and any post-approval maintenance of Regulatory Approvals for the Product in the Field in the Territory including, without limitation, any Phase III or Phase IV commitments, periodic safety reviews, annual reports, regulatory submissions, and the development, stability testing, implementation, and maintenance of a pharmacovigilance program. Pharmanovia shall provide Aquestive data and documents relating to such Development activities and post-approval maintenance of the Regulatory Approvals: (i) as requested by Aquestive and (ii) at least thirty (30) days prior to submitting any such data or document to any Regulatory Authority. Aquestive shall Supply Pharmanovia quantities of Product required for clinical studies ("Clinical Supply"), registration purposes, and validation purposes at the Product Transfer Price, in each case, if necessary for Development of the Product in the Field in the Territory and to the extent included in a Statement of Work. Aquestive shall provide Clinical Supply with blank packaging, and Pharmanovia shall be solely responsible for the labeling of Clinical Supply.

4.3.2 No Right to Develop Product Formulation. Notwithstanding anything to the contrary contained in this Agreement or otherwise, Pharmanovia acknowledges and agrees that neither it nor any of its Affiliates, agents or subcontractors shall have any right to Develop the Product formulation itself. In the event that any Regulatory Authority requires any modification to the Product formulation, Aquestive shall, at Pharmanovia's sole cost and expense: (i) assess in good faith the feasibility of such modifications to the Product formulation and (ii) if feasible, engage in Development of the Product formulation and shall deliver the necessary information and documents to Pharmanovia in accordance with the requirements of such Regulatory Authority.

4.4 **Regulatory Activities**. Pharmanovia shall be responsible for preparing and filing all Regulatory Approval Applications and other documents in the Field in the Territory, and each Regulatory Approval relating to the Product in the Field in the Territory shall, during the Term, be owned by and held in the name of Pharmanovia or its Affiliate or nominee. Pharmanovia shall file each Regulatory Approval Application in accordance with Applicable Law. Pharmanovia shall be solely responsible for the conduct of, have sole right to conduct, and shall use Commercially Reasonable Efforts to, promptly conduct: all Development activities in connection with or as a condition of seeking or obtaining and maintaining Regulatory Approval of each Product in the Field in the Territory, including, without limitation, preparing and filing all regulatory applications

and documents in the Territory, meetings with Regulatory Authorities in the Territory, submissions and maintenance of each Regulatory Approval Application and preparation and submission of all supplements thereto, conducting periodic safety reviews, all submissions to the Regulatory Authorities in the Territory, all post-marketing obligations required by the Regulatory Authorities, and the development and implementation of a pharmacovigilance program specific to the Product in the Field in the Territory, all in compliance with all Applicable Law. Pharmanovia shall be responsible and pay for one hundred percent (100%) of the costs and expenses incurred in connection with the foregoing activities unless otherwise specifically provided for in this Agreement. Pharmanovia shall designate a regulatory liaison to report to the Steering Committee on the status of regulatory activities, including material communications with all Regulatory Authorities in the Territory, on an as-needed basis as determined by the Steering Committee. Pharmanovia shall provide the Steering Committee with reasonable advance notice, but not less than thirty (30) days' notice, of Pharmanovia's intent to file any Regulatory Approvals for the Product.

4.5 **Annual Stability Testing**. If any annual stability testing on the Product is required by any Regulatory Authority in the Territory (which is outside the scope of any annual stability testing that has already been completed by Aquestive, or if Aquestive does not already have the data required by the Regulatory Authority to prevent the need for any further annual stability testing) where the Product is commercially sold, Aquestive shall perform such stability testing pursuant to a Statement of Work, and Pharmanovia shall be responsible for all costs and expenses associated with the performance and maintenance of such stability testing. For the avoidance of doubt, at no cost to Pharmanovia, Aquestive shall share with Pharmanovia stability data in its possession or control generated from any stability data testing on the Product required by any Regulatory Authority outside the Territory.

4.6 **Communications and Meetings with Regulatory Authorities**.

4.6.1 Communications with Regulatory Authorities. Pharmanovia shall have sole control, and have authority and responsibility for, interfacing, corresponding, and meeting with all Regulatory Authorities for Regulatory Approvals in the Territory. At all times during the Term, Pharmanovia shall be responsible, at its cost and expense, for pharmacovigilance reporting to the applicable Regulatory Authorities in compliance with Applicable Law in the Territory, including, but not limited to, reporting any and all Adverse Events to the applicable Regulatory Authorities.

4.6.2 Notification by the Parties of Regulatory Actions. Each Party shall as soon as reasonably possible after receipt of any notices of inspections, proposed regulatory actions, investigations or material official written requests by any Regulatory Authority with respect to the Supply or Commercialization of Product, as well as any corrective or other actions with Regulatory Authorities initiated by a Party with respect thereto within or outside the Territory ("Regulatory Notification") so far as they relate to the Territory, provide written notice to the other Party in reasonable detail with respect thereto and will provide the other Party with copies of all related documentation.

4.7 **Regulatory Notifications**.

4.7.1 Notice. Each Party or its respective authorized representative shall provide the other Party with written notice, in a sufficiently timely basis to enable the other Party to comply in all material respects with Applicable Law in the relevant country in the Territory and in any event within three (3) Business Days of receipt of a Regulatory Notification that: (a) raises any material concerns regarding the safety or efficacy of the Product; (b) indicates or suggests a Third Party Claim arising in connection with the Product; or (c) is reasonably likely to lead to a Recall, market withdrawal or field correction of, field alert report or comparable report with respect to the Product. Examples of Regulatory Notifications shall include, but not be limited to correspondence from a Regulatory Authority relating to:

4.7.1.1 inspections by a Regulatory Authority of manufacturing, distribution or other related facilities concerning safety or efficacy issues with the Product;

4.7.1.2 inquiries by a Regulatory Authority concerning clinical investigation activities (including, without limitation, inquiries regarding investigators, clinical monitoring organizations and other related Third Parties) with respect to the Product;

4.7.1.3 any receipt of a warning letter from a Regulatory Authority relating to the Product;

4.7.1.4 any initiation of any Regulatory Authority investigation, detention, seizure, or injunction concerning the Product.

4.8 **Recalls or Other Corrective Action**.

4.8.1 Notice of Action. Aquestive shall maintain traceability records in accordance with Applicable Law, necessary to permit a recall, field correction or other notification to the field, of the Product. Pharmanovia shall have the exclusive right to institute a recall, market withdrawal, field correction or field report of the Product and shall be responsible for managing the recall and communications with customers and Regulatory Authorities. As soon as reasonably possible, Pharmanovia shall notify Aquestive of any actions to be taken by Pharmanovia or its Affiliates, subcontractors or agents with respect to any recall or market withdrawal or field correction, field alert report or comparable report or any matter which is suspected or likely to be the subject of a complaint which may require a recall, market correction or similar action relating to the Product in the Territory (a "Recall") if possible this shall be prior to any such action being taken so as to permit Aquestive a reasonable opportunity to consult with Pharmanovia with respect thereto. At Pharmanovia's written request and cost, Aquestive shall use Commercially Reasonable Efforts to provide reasonable assistance to Pharmanovia in conducting such Recall; the costs of such assistance shall be borne in the same manner as other Recall Expenses. The cost of any Recall, including, the costs of notifying customers and the costs associated with the shipment of such Product from customers and all reasonable credits extended to customers as a result thereof, and the costs of replacing the Product (collectively, "Recall Expenses"), occasioned or required as part of a general Recall of Product, shall be borne as provided in the following sentences:

4.8.1.1 Any Recall Expenses, to the extent solely caused by Aquestive its Affiliates or subcontractors, or the failure of Aquestive to Supply the Product conforming to the

Specifications or applicable Regulatory Approvals, as determined by a final non-appealable order of a Regulatory Authority or as mutually agreed in writing by the Parties, shall be borne by Aquestive.

4.8.2 Any Recall Expenses to the extent caused by Pharmanovia or any Third Party (other than Aquestive's subcontractors) or the failure of Pharmanovia or its subcontractors to Commercialize the Product conforming to the applicable Regulatory Approvals or other breach of this Agreement by Pharmanovia, as determined by a final non-appealable order of a Regulatory Authority or as mutually agreed in writing by the Parties, shall be borne by Pharmanovia.

4.8.3 Recall Objection Notice. In the event that there is no determination by a Regulatory Authority or the Parties dispute which Party is the cause of a Recall, either Party may send a written notice of objection regarding such Recall to the other Party (the "Recall Objection Notice"). The Parties agree to attempt to resolve such dispute within ten (10) days after receipt of the Recall Objection Notice. If Pharmanovia and Aquestive fail within ten (10) days after receipt of the Recall Objection Notice to agree as to the Party that is the cause of such Recall, the issue, and as applicable, any representative samples of the Product, shall be submitted to a mutually and reasonably acceptable independent Third Party laboratory of national reputation, or consultant (if not a laboratory analysis issue), as evidenced by written agreement of the Parties, for analysis or review. The results of such evaluation by such independent Third Party laboratory or consultant, as the case may be, must be in writing and shall be binding upon the Parties. If Aquestive, its Affiliates or subcontractors is determined to have been the sole cause of such Recall, Aquestive shall pay one hundred percent (100%) of the Recall Expenses including the cost of any such evaluation, or, if it is determined that both Parties are partially at fault, then the Parties shall share in the Recall Expenses in proportion to each Party's relative fault. Otherwise, Pharmanovia shall pay the Recall Expenses relating to such Recall including the cost of any such evaluation and destruction of any recalled Product. If the fees of the independent laboratory or consultant are due in advance, Pharmanovia and Aquestive shall each pay fifty percent (50%) of such fees; provided, however, that promptly after the independent Third Party laboratory or consultant completes its evaluation, the Party that is responsible for the Recall Expenses shall reimburse the other Party for its fifty percent (50%) share of such fees; and if the Parties are found to be proportionately at fault, each Party shall reimburse the other Party for such Party's proportion of such fees.

4.8.4 Recall Information Received. Each Party shall, as soon as reasonably practicable, notify the other Party in writing of any Recall, market withdrawal or field correction of, field alert report or comparable report as detailed in the Quality Agreement with respect to the Product and supply all information received by it relating thereto in sufficient detail to allow the Parties to comply with Applicable Law in the relevant country in the Territory.

## 5. SUPPLY

### 5.1 Commercial Supply Obligations.

5.1.1 Subject to the terms and conditions of this Agreement, during the Term, Aquestive shall exclusively Supply Pharmanovia and Pharmanovia's Affiliates and subcontractors with, and Pharmanovia shall, subject to Section 5.2, exclusively purchase from Aquestive, all of Pharmanovia's requirements of Pharmanovia and Pharmanovia's Affiliates and subcontractors of

the Product for commercial sale in the Field in the Territory during the Term, pursuant to binding purchase orders delivered by Pharmanovia to Aquestive in accordance with Section 5.3 (**"**Purchase Orders**"**). Aquestive shall Supply Product to Pharmanovia in Units in accordance with the terms and conditions of this Agreement, Applicable Law, the Purchase Order the Specifications and the shelf-life requirements set out in the Product Schedule (**"**Product Requirements**"**).

5.1.2 Without prejudice to any other rights that Pharmanovia may have under this Agreement, in equity or at law the restriction in Section 5.1.1 shall not apply if and to the extent a Bankruptcy Supply Failure occurs. In such an event and without prejudice to any other any other rights that Pharmanovia may have under this Agreement, in equity or at law:

5.1.2.1 Pharmanovia may immediately terminate the exclusivity of the appointment of Aquestive pursuant to Section 5.1 by written notice to Aquestive and with effect from such notification the exclusive purchase obligation pursuant to Section 5.1 shall cease to apply for the remainder of the Term; and

5.1.2.2 Aquestive shall grant to Pharmanovia, a perpetual irrevocable, non-exclusive sub-licensable license to the Aquestive Know-How and a license to Supply and/or have Supplied the Product; and

5.1.2.3 The provisions of Section 9 relating to technology transfer shall apply.

5.1.2.4 For the avoidance of doubt, Aquestive shall not be relieved of its Supply obligations by virtue of such loss of exclusivity. Following such loss of exclusivity, nothing in this Agreement shall prevent Pharmanovia or any Affiliate of Pharmanovia from purchasing and/or having manufactured the Product from or by any other manufacturer or supplier, or from manufacturing the Product itself.

5.2 **Product Transfer Price**.

5.2.1 Aquestive shall Supply quantities of each Unit of the Product to Pharmanovia at each of the initial transfer prices set forth in the Product Schedule (each a **"**Product Transfer Price**"**). The Parties agree that upon the earlier of (a) the end of Commercialization Year 3 (as defined in the Product Schedule) and (b) each time an adjustment to the Minimum Volume Commitment, if any, is made pursuant to Section 7.4, the Parties shall discuss and agree upon in good faith a revision to the Product Transfer Price. Thereafter, Aquestive may, after notification to Pharmanovia, increase the Product Transfer Price providing Pharmanovia not less than [****] days written notice of any such proposed increase no more than [****] to the extent necessary to cover actual increases in COGS, as evidenced by relevant supporting documents provided, however, any such price increase shall apply prospectively only and shall not apply to Product subject to binding Purchase Orders. The Parties acknowledge that cost reductions and Product Transfer Price may be possible by improvements in manufacturing processes and increased purchasing resulting from an increase in purchasing volume by Pharmanovia, among other reasons. In the event that Aquestive's COGS are reduced the Parties shall have a good faith discussion about a proportion reduction in the Product Transfer Price. Thereafter, Aquestive shall, after notification to Pharmanovia, reduce the Product Transfer Price providing Pharmanovia

written notice to the COGS have been reduced. In connection with the foregoing, the Parties agree to discuss in good faith potential actions to be taken to develop cost reductions, but the foregoing does not constitute a guarantee of any cost reductions.

5.2.2 Notwithstanding the foregoing, if, at any time after the end of the [****] year of this Agreement, Pharmanovia can establish by competent evidence that its Profit/Net Sales in respect of the Product on a [****] month basis has fallen below [****]% for all countries in the Territory, then at Pharmanovia's request, the Parties agree that for future Purchase Orders:

5.2.2.1 the Product Transfer Price shall be equal to COGS plus [****]%; and

5.2.2.2 no further Royalty payments shall be made by Pharmanovia and Pharmanovia shall instead pay to Aquestive a Profit Share as further set out in Section 7.3.

5.3 **Forecasts, Order and Delivery of Product**.

5.3.1 In order to assist Aquestive in planning production, Pharmanovia shall deliver to Aquestive in advance of each Calendar Quarter a supply forecast that includes the quantities of each Product and Primary Packaging (including samples) required by Pharmanovia by month for the next twelve (12) months. The first such forecast for the Product shall be delivered within a mutually agreed timeframe in writing in advance of the First Commercial Sale of such Product in the relevant country in the Territory, and thereafter on the first Business Day of each February, May, August, and November of each calendar year during the Term for the immediately succeeding Calendar Quarter. Aquestive shall, no later than [****] Business Days after receipt of each such forecast, notify Pharmanovia in writing of any objections or prospective problems in meeting Pharmavovia's forecasted requirements; provided however, that such objections or prospective problems can be raised only if and to the extent the forecasted requirements with regard to the applicable month exceeds [****]% of forecasted requirements with regard to the same month set forth in the immediately preceding supply forecast.

5.3.2 Pharmanovia shall furnish to Aquestive binding Purchase Orders on a monthly basis corresponding to the first three (3) months of the most recent supply forecast. Each such Purchase Order shall designate the quantity of the Product ordered and the requested date of delivery of such Product to Pharmanovia. Aquestive shall confirm receipt and acceptance of each conforming Purchase Order in writing within five (5) Business Days after its receipt of each Purchase Order. Pharmanovia shall furnish Purchase Orders by the fifth ($5^{th}$) Business Day of each month and a minimum of ninety (90) days prior to the requested delivery date. Each Purchase Order shall be in whole batch increments of Units and corresponding Primary Packaging based on the batch sizes and minimum orders set forth in the Product Schedule or as may otherwise be agreed in writing by the Parties. The Parties agree that no provision of any Purchase Order, invoice or of any confirmation or acknowledgement or any other documentation or forms submitted by either Party to the other Party shall be controlling to the extent it sets forth any terms or conditions that are additional to, or in conflict or inconsistent with, the terms or conditions of this Agreement.

5.3.3 In the event that any Purchase Order is more than [****]% of the amounts set forth in the most recent supply forecast, Aquestive shall use Commercially Reasonable Efforts

to Supply such excess amounts but shall not be liable for its inability to do so. If there is a shortage of any Product and/or Raw Materials, components or other materials, or capacity at the Manufacturing Facility, Aquestive shall use Commercially Reasonable Efforts to equitably apportion such Products or materials or capacity between the affected Products for supply and sale to Pharmanovia under this Agreement and those corresponding products (or other products requiring the same Raw Materials) manufactured by or on behalf of Aquestive and/or its Affiliates (whether for themselves or Third Parties) for sale in or outside the Territory. Aquestive shall inform Pharmanovia without delay of any actual or suspected capacity issues at the Manufacturing Facility and/or any supply difficulties in relation to the Products.

5.3.4 Aquestive and Pharmanovia will consider each individual Purchase Order filled as long as no less than [****]% and no more than [****]% of the quantities are delivered against the individual Purchase Order. Pharmanovia agrees to accept delivery of up to [****]% of the requested Purchase Order.

5.3.5 Aquestive shall deliver Products set forth in each Purchase Order Ex Works (Incoterms 2020 edition, published by the International Chamber of Commerce and any successor thereto) at the Manufacturing Facility to Pharmanovia's designated carrier as specified by Pharmanovia in the applicable Purchase Order or otherwise notified in writing to Aquestive by Pharmanovia at least thirty (30) days prior to the applicable delivery date set forth in such Purchase Order. Title to the Products shall pass to Pharmanovia on delivery free of any security, charge, interest, lien or other encumbrance.

5.3.6 Each batch of Product Delivered to Pharmanovia (or its nominee) under this Agreement will have a remaining shelf life at the time of delivery of no less than the minimum shelf life for such Product set out in the Product Schedule.

5.3.7 Aquestive shall not change the Manufacturing Facility for the Supply of the Product or the process, plant or equipment used in the manufacture (including packaging) of the Product, without twelve (12) months' prior written notice to Pharmanovia. Aquestive shall be responsible for all costs or expenses incurred by Pharmanovia and its Affiliates incurred as a result of any request by Aquestive to change the Manufacturing Facility.

5.4 Invoice. Aquestive shall invoice Pharmanovia at the Product Transfer Price for all quantities of the Product delivered in accordance herewith. Each invoice shall be delivered concurrently with each shipment of such Product and be accompanied by a Certificate of Analysis, Certificate of Compliance, customs invoice, packing list and at the cost and expense of Pharmanovia, any other documentation required by the applicable Regulatory Authorities or by Applicable Law to Commercialize such Product in the Field in the Territory. Payments shall be made in accordance with Section 7.7, and shall be due within [****] days after receipt of the invoice with respect thereto, subject to the procedure for rejected shipments set forth in Section 5.6. In the event that any invoice is disputed in writing by Pharmanovia, the Parties shall meet within ten (10) Business Days after Aquestive's receipt of such written dispute to discuss and submit any relevant document necessary for clarifications.

5.5 Suspension of Services. Subject to any invoice being disputed by either Party in good faith, if the payment of any sum exceeding $[****] due under this Agreement to Aquestive

is not paid or is delayed, in addition to any other rights and remedies available to Aquestive under this Agreement (including, without limitation, interest due under Section 7.77), at law or in equity, Aquestive shall have the right, with forty-five (45) days prior written notice during which time Pharmanovia may cure any default, to suspend or delay the performance of the services by Aquestive under this Agreement, provided that Aquestive shall have given Pharmanovia at least two written notices of intention to suspend or delay performance pursuant to this Section 5.5 during such forty-five (45) day notice period. In the event of suspension or discontinuation of the services due to delayed or non-payment in circumstances where Aquestive is entitled to do so pursuant to the terms hereof, Aquestive shall not be liable for any Losses (whether direct or indirect) incurred by Pharmanovia as a result of the suspension or discontinuation of services.

5.6 Product Not in Compliance with Purchase Order. If Pharmanovia does not submit written notice that the Product does not meet the Product Requirements, including the reasons therefore, within ten (10) Business Days of:

5.6.1.1 delivery of the Product if such failure to meet the Product Requirements is reasonably discoverable by visual inspection at the delivery date; and

5.6.1.2 discovery of the failure, if such failure to meet the Product Requirements is not reasonably discoverable by visual inspection at the delivery date and which renders such Product unsuitable for distribution to subjects or patients,

such Product shall be deemed accepted by Pharmanovia provided, however, that such acceptance or deemed acceptance shall not adversely affect any claim for indemnification provided in Section 11. If Pharmanovia and Aquestive do not agree on the rejection of the Product, then either Party may refer the matter for final analysis to an independent Third Party laboratory of national reputation pursuant to Section 5.7 for the purpose of determining the results thereof.

5.7 Independent Testing. If Aquestive disagrees with Pharmanovia's rejection of any shipment of the Product, then such Product shall be submitted to an independent Third Party laboratory (or other professional Third Party independent assessor) of national reputation, mutually and reasonably acceptable to both Parties in writing, for analytical testing to determine the extent of such Product's compliance or non-compliance with the Product Requirements. Any determination by such Third Party shall be in writing and shall be final and binding upon the Parties. The fees and expenses of such laboratory testing and all other related expenditure incurred as a result of the dispute shall be borne entirely by the Party against whom such Third Party's findings are made.

5.8 Return of Non-Conforming Product. Notwithstanding any other provisions of this Agreement to the contrary, Pharmanovia agrees to return to Aquestive (or at Aquestive's written direction, to its contractors) or dispose of such Product as Aquestive may direct in writing to Pharmanovia any Product, in any such case at Aquestive's sole cost, that: (a) does not conform with the Product Requirements at the time of Ex Works delivery to Pharmanovia; (b) to the extent is not in compliance with the Purchase Order as set forth in Section 5.6; or (c) if Pharmanovia and Aquestive mutually agree in writing. Aquestive shall be responsible for the costs associated with the return and proper disposal of all such Product to the extent not in conformance with the Product Requirements and Purchase Order at the time of shipment and Pharmanovia's sole remedy for such

shipment of non-conforming Product is replacement thereof by Aquestive with Product conforming to Product Requirements (at Aquestive's sole cost including shipping costs incurred by Pharmanovia). Notwithstanding the foregoing, Aquestive shall not be responsible for any costs associated with the return and proper disposal of any such Product that is in conformance with the Specifications and Purchase Order at the time of shipment including but not limited to where such non-conformance arose after the time of shipment due to any act or omission of Pharmanovia or a Third Party.

5.9 Raw Materials Safety Stock. Within sixty (60) days after the First Commercial Sale, Aquestive will establish and at all times during the term of this Agreement maintain a safety stock of Raw Materials in quantities sufficient to satisfy Pharmanovia's requirements for Products for the succeeding ninety (90) days based on Pharmanovia's most recent quarterly forecast delivered pursuant to Section 5.3.1 ("Raw Materials Safety Stock"). Deliveries by Aquestive to Pharmanovia of Product may use the Raw Materials Safety Stock. Aquestive shall keep Pharmanovia reasonably informed of the level of Raw Materials safety stock. If the Raw Materials Safety Stock drops below a ninety (90) day supply, Aquestive shall replenish the Raw Materials Safety Stock as quickly as practicable.

5.10 Delivery Failure.

5.10.1 Where the quantity of conforming Product delivered is less than [****]% of the amount required by the relevant binding Purchase Order, the Parties shall enter into good faith discussions regarding the cure of such delivery shortfall, and, unless otherwise agreed in writing by Pharmanovia, in the event of any such Product shortfall resulting in delivery of less than [****]% of the amount of Product required by a binding Purchase Order or the Product is not delivered on the delivery date set forth in such binding Purchase Order (**"**Delivery Failure**"**), Aquestive shall cure such Product shortfall as soon as reasonably practicable after the original delivery date in accordance with such delivery schedule as may be mutually agreed between the Parties and in any event no later than with the next delivery of Product as set forth in the relevant binding Purchase Order (each, a **"**Rescheduled Delivery Date**"**).

5.10.2 In the event a Delivery Failure continues after a Rescheduled Delivery Date, provided that the reason for the Delivery Failure is not due in whole or in part to any delay, fault or failure attributable to Pharmanovia or a dispute covered by Section 5.7, by written notice to Aquestive, the Parties shall discuss a resolution in good faith and Pharmanovia shall be entitled to (i) require Aquestive to prioritize its manufacturing capacity (if the Delivery Failure is a result of a deficiency in Aquestive's manufacturing capacity) to ensure the Delivery Failure is cured no later than sixty (60) days after receipt of such written notice by Aquestive; (ii) cancel such binding Purchase Order (or the relevant portions thereof) without penalty to Pharmanovia; and (iii) recover any expedited shipping fees actually incurred by Pharmanovia as a direct result of such Delivery Failure, in each case only if Pharmanovia can establish that it will have insufficient inventory of Product to satisfy forecasted customer orders for the succeeding sixty (60) days as a result of such Delivery Failure.

5.10.3 In the event of Delivery Failure continues after a Rescheduled Delivery Date on [****] or more occasions in any [****] month period Pharmanovia shall be entitled to a

[****]% percent discount per calendar month for each month a Purchase Order subject to such Delivery Failure is delivered beyond the delivery date.

5.10.4 Notwithstanding anything in this Section 5.10 or elsewhere in this Agreement to the contrary, any delay in delivery to the extent due to Force Majeure, Pharmanovia's requested change of a binding Purchase Order, or any negligence on the part of Pharmanovia shall not be regarded as Delivery Failure.

5.11 Aquestive Quality Agreement. In connection with the Supply activities of the Product under this Agreement, within ninety (90) days of the Effective Date, Pharmanovia and Aquestive will enter into a written quality assurance agreement, reasonably acceptable to both Parties, which details the obligations of each Party with respect to the Supply of the Product by Aquestive (the "Quality Agreement"). The definitive terms and conditions for such detailed quality assurance obligations shall be discussed in good faith and agreed upon between Pharmanovia and Aquestive separately in the Quality Agreement, which shall thereupon be incorporated by reference into and made a part of this Agreement. In the event of conflict between terms of the Quality Agreement and the terms of this Agreement, the terms of this Agreement will govern.

5.12 Adverse Event and Safety Reporting. Within thirty (30) days of the Effective Date, the Parties will enter into a written Safety Data Exchange Agreement with respect to the Product which shall thereupon be incorporated by reference into and made part of this Agreement (the **"**Safety Data Exchange Agreement**"**). In the event of conflict between terms of the Safety Data Exchange Agreement and the terms of this Agreement, the terms of this Agreement will govern. Notwithstanding anything to the contrary contained in this Agreement, Pharmanovia shall be responsible for making all reports of Adverse Events to the applicable Regulatory Authority.

## 6. STEERING COMMITTEE.

No later than one (1) month following the Effective Date, the Parties will establish a committee consisting of the appropriate business and/or technical leaders to provide a forum for communication between the Parties regarding Development, Supply and Commercialization activities under this Agreement (the "Steering Committee"). Each Party shall assign an alliance manager (who shall serve on the Steering Committee) to oversee the implementation of this Agreement and to organize each Steering Committee meeting and provide updates for the Product to the Steering Committee. The Steering Committee shall discuss key activities deemed critical to Regulatory Approvals and Commercialization of the Product. The Steering Committee shall meet at least two (2) times per Calendar Year, on a schedule and at a location to be agreed by the Parties. Notwithstanding the foregoing, the Steering Committee shall be solely advisory and not have any decision-making authority. For the avoidance of doubt, Pharmanovia shall have the sole decision-making authority regarding the Commercialization for the Product in the Field in the Territory and all other activities for which Pharmanovia has responsibility under this Agreement.

## 7. PAYMENTS AND REPORTS

7.1 **Milestone Payments**. Milestone payments shall be due from Pharmanovia to Aquestive in respect of a Product as set forth in the Product Schedule (**"**Milestone Payments**"**).

Each Milestone Payment shall be payable only once on the first attainment of the corresponding milestone event irrespective of (i) the number of times each milestone event is achieved; and (ii) the number of Products that achieve the milestone event or countries of the Territory in which the milestone event is achieved.

7.2 **Royalties**. During the Term, subject to the provisions of Section 5.3 and Section 7.3, Pharmanovia shall pay to Aquestive a royalty payment in each Payment Period through the termination or expiration of this Agreement as set forth the Product Schedule ("Royalty Fees"). Royalty Fees shall be paid in US Dollars (as per Section 7.7) and shall be calculated by applying a weighted average exchange rate based on monthly Net Sales. This calculation shall be based on [****].

7.3 **Profit Share.** If the conditions set out in Section 5.2.2 are met, Pharmanovia shall pay to Aquestive a Profit share in each Payment Period through the termination or expiration of this Agreement as set forth the Product Schedule ("Profit Share").

7.4 **Minimum Volume Commitment**. In the event in any year during which the exclusivity of the Supply arrangement described at Section 5.1.1 is in operation, the quantity of Product purchased by Pharmanovia from Aquestive under this Agreement is less than the minimum amount set forth for such year in the Product Schedule (the "Minimum Volume Commitment"), then unless such failure is attributable to the failure of Aquestive to supply conforming Product to Pharmanovia under this Agreement within 60 days of its due date, or due to matters outside of the control of Pharmanovia that impacts Pharmanovia's ability to sell Product, in which case the Parties shall have a good faith discussion regarding adjustment of the Minimum Volume Commitment, and unless otherwise set forth in the Product Schedule, Pharmanovia shall pay to Aquestive the price of the quantity of Product that Pharmanovia would have to purchase to meet the Minimum Volume Commitment in such year within thirty (30) days of the end of such year. For any part year during which the Minimum Volume Commitment applies, the amount of the Minimum Volume Commitment shall be pro-rated.

7.5 **Pharmanovia Reports and Payments**. During the Term, Pharmanovia shall submit Quarterly Payment Reports or quarterly Profit Share reports (as applicable) ("Quarterly Payment Reports") to Aquestive within [****] days following the end of each Calendar Quarter. Each Quarterly Payment Report shall cover the most recently completed Calendar Quarter and shall show: (a) the aggregate gross and Net Sales of each Product during the most recently completed Calendar Quarter including reasonable detail with respect to the calculation of Net Sales, Units sold, discounts, credits and other components in the calculation of Net Sales; and (b) the Royalty Fees or Profit Share (as applicable), in U.S. dollars, payable with respect to such Net Sales; and (c) in relation to the Profit Share, further deductions made to Net Sales in relation to the Profit Share calculation.

7.6 **Invoicing and Payment**. Aquestive shall invoice Pharmanovia for the Royalty Fees or Profit Share (as applicable) within [****] Business Days of receipt of each Quarterly Payment Report. Pharmanovia shall pay the Royalty Fees or Profit Share (as applicable) within [****] days of receipt of the invoice.

7.7 **Manner of Payment**. All sums due under this Agreement shall be payable in U.S. dollars by ACH in immediately available funds to such bank account(s) as Aquestive shall designate in writing. All overdue amounts due to Aquestive hereunder shall bear interest at the rate equal to one and one half percent (1.5%) per month or at the highest rate permitted by Applicable Law, whichever is less.

7.8 **Bartering Prohibited**. Pharmanovia and its Affiliates and subcontractors shall not solicit or accept any bartered goods or services in exchange for the sale or transfer of the Product.

7.9 **Taxes and Withholding**. All payments under this Agreement will be made without any deduction or withholding for or on account of any taxes, duties, levies, or other charges. Pharmanovia will: (a) pay to the relevant authorities the full amount otherwise required to be deducted or withheld under Applicable Law promptly upon determining that such deduction or withholding is required; and (b) forward to Aquestive an official receipt (or certified copy) or other documentation reasonably acceptable to Aquestive evidencing such payment to such authorities. The Parties shall use Commercially Reasonable Efforts to cooperate and coordinate with each other in completing and filing documents required under the provisions of any applicable tax laws (including tax treaties) in connection with the making of any required tax or withholding payment, in connection with a claim of exemption from, or entitlement to, a reduced or zero rate of withholding or in connection with any claim to a refund of or credit for any such payment. The Party receiving a payment pursuant to this Agreement shall provide the remitting Party appropriate certification from relevant revenue authorities that such Party is a tax resident of that jurisdiction or reduction or exemption from tax withholding, if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

7.10 **Accounting**. Except as otherwise defined in this Agreement, all financial terms and standards defined or used in this Agreement for sales or activities occurring in the Territory shall be governed by and determined in accordance with GAAP, including the calculation of Net Sales and royalties due Aquestive hereunder; provided that when the actual results become known in accordance with GAAP relative to any accrued amount, any difference between the actual results and the accrual shall be reported and accounted for in the next payment due hereunder (subject to customary processing periods). To the extent that the difference between such accruals and the actual results has led to an underpayment, Pharmanovia shall pay Aquestive the amount of such underpayment on the next date payment is due to Aquestive hereunder.

7.11 **Record Keeping; Audits**. The Parties and their Affiliates shall keep books and accounts of record in connection with Net Sales and Profit with respect to the Product (in the case of Pharmanovia) in sufficient detail to permit accurate determination of all figures necessary for verification of Royalty Fees and Profit Share to be paid hereunder and COGS (in the case of Aquestive, solely to the extent the Profit Share is in effect). The Parties and its Affiliates shall retain such records for a period of at least three (3) years after the end of the Calendar Quarter in which they were generated; provided, however, that if any records are in dispute and one Party has received written notice from the other of the records which are in dispute, then that Party and its Affiliates shall keep such records until such dispute is resolved. No more than once every calendar year, upon reasonable advance written notice to the other Party, a Party will have the right to engage a nationally recognized public accounting firm of its choice and reasonably acceptable to

the other Party (which accounting firm will not be the external auditor of the selecting Party, will not have been hired or paid on a contingency basis and will have experience auditing pharmaceutical companies) (a "CPA Firm") to conduct an audit of such books and records of the other Party and its Affiliates to determine the correctness of the amount of royalties paid to Aquestive or COGS (as applicable) under the terms of this Agreement. The CPA Firm will be given access to and will be permitted to examine such books and records of the audited Party as it will reasonably request, upon thirty (30) days' prior written notice having been given by the other Party, during regular business hours, for the sole purpose of determining compliance with the Net Sales royalty provisions, Profit Share provisions, or COGs calculations set out in this Agreement. Prior to any such examination taking place, the CPA Firm will enter into a confidentiality agreement reasonably acceptable to Pharmanovia and Aquestive with respect to the Confidential Information to which they are given access and will not contain in its report or otherwise disclose to the other Party or any Third Party any information labeled by the audited Party as being confidential customer information regarding pricing or other competitively sensitive proprietary information. Aquestive and Pharmanovia will be entitled to receive a full written report of the CPA Firm with respect to its findings and the requesting Party will provide, without condition or qualification, the audited Party with a copy of the report, or other summary of findings, prepared by such CPA Firm promptly following its receipt of same. In the event of any dispute between Aquestive and Pharmanovia regarding the findings of any such inspection or audit, the Parties will initially attempt in good faith to resolve the dispute amicably between themselves, and if the Parties are unable to resolve such dispute within thirty (30) days after delivery to both Parties of the CPA firm's report, each Party will select an internationally recognized independent certified public accounting firm (other than the CPA Firm), and the two firms chosen by the Parties will choose a third internationally recognized independent certified public accounting firm which accounting firm will not be the external auditor of either Party, will not have been hired or paid on a contingency basis and will have experience auditing pharmaceutical companies) which selected accounting firm will resolve the dispute, and such selected accounting firm's determination will be binding on both Parties absent manifest error by such selected accounting firm. All costs and expenses of such auditor incurred in connection with performing any such audit shall be paid by the requesting Party unless such audit discloses an underpayment or miscalculation of at least [****]%, in which case the audited Party shall bear such costs and expenses. In the event of the engagement of other accounting firms relating to a dispute between the Parties as referred to in this Section 7.11, all costs and expenses of such other accounting firms shall be paid by the Party found to be at fault by the final determination of the selected accounting firm.

7.12 **Underpayments and Overpayments**. If an audit conducted pursuant to Section 7.11 reveals that additional royalties were due to Aquestive under this Agreement, then Pharmanovia shall pay to Aquestive the additional royalties within [****] days of the date Pharmanovia receives written notice of such underpayment. If an audit conducted pursuant to Section 7.11 reveals that Aquestive was paid royalties in excess of those Royalty Fees or Profit Share payments, as applicable, due to Aquestive under this Agreement, or an overpayment of the Product Transfer Price by Pharmanovia then Pharmanovia shall, at its election, be entitled to: (a) a refund of such amount within [****] days of the date Aquestive receives written notice of such overpayment; or (b) deduct such amount from the next royalty or other payment due Aquestive under this Agreement.

## 8. REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 **Representations, Warranties and Covenants of Each Party**. Each Party hereby represents and warrants as of the Effective Date to the other Party as follows:

8.1.1 Corporate Existence, Power, and Authority. Such Party: (a) is duly formed and in good standing under the laws of the jurisdiction of its formation; (b) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; and (c) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder.

8.1.2 Binding Agreement. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

8.1.3 Compliance with Applicable Law. All necessary consents, approvals and authorizations of all Regulatory Authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations as of the Effective Date hereunder have been obtained.

8.1.4 No Conflict with Applicable Law. The execution and delivery of this Agreement, the performance of such Party's obligations hereunder, and any actions or omissions of such Party related to the activities contemplated hereunder and the circumstances surrounding this Agreement: (a) do not and will not conflict with or violate any Applicable Law or any provision of the articles of incorporation, bylaws or other governing charter documents of such Party; and (b) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

8.1.5 Bankruptcy; Insolvency. Neither Party is aware of any Bankruptcy Event affecting such Party or of any action or petition, pending or otherwise, for bankruptcy or insolvency of such Party or its Affiliates or subsidiaries in any state, country, or other jurisdiction, and it is not aware of any facts or circumstances that could result in such Party becoming or being declared insolvent, bankrupt or otherwise incapable of meeting its obligations under this Agreement as they become due in the ordinary course of business.

8.2 **Additional Aquestive Representations, Warranties and Covenants**. Aquestive represents, warrants, and covenants to Pharmanovia as follows:

8.2.1 Right to Grant Licenses. Aquestive and its Affiliates owns the rights, title, and interest in and to the Aquestive Patents, the Aquestive IP and the Aquestive Marks free from encumbrances, charges or liens of any kind (except such encumbrances, charges or liens granted in connection with commercial lending arrangements in the ordinary course of business) and have the right to grant the licenses granted to Pharmanovia herein.

8.2.2 Intellectual Property.

8.2.2.1 To Aquestive's knowledge, as of the Effective Date, no Third Party is infringing or making unauthorized use of any registered Aquestive IP.

8.2.2.2 No outstanding written claim or threat of action has been received by Aquestive or its Affiliates (and to Aquestive's knowledge, there are no allegations or proceedings, pending or threatened), claiming that the grant of the licenses pursuant to this Agreement, or the exploitation of the Aquestive IP or the Product (including any activities relating to the Development of the Product by Aquestive) has infringed, is infringing or would be likely to infringe, any valid and subsisting intellectual property rights of any Third Party.

8.2.2.3 Except as disclosed to Pharmanovia in writing prior to the Effective Date, , as of the Effective Date, there are no proceedings, pending or threatened in writing, or to Aquestive's knowledge, pending, which challenge Aquestive's exclusive ownership, the validity or the enforceability of the Aquestive IP.

8.2.2.4 As of the Effective Date, all registrations and filings necessary to preserve the rights in the Aquestive Patents have been made and are in good standing and all applicable fees have been paid on or before the due date for payment.

8.2.2.5 Within the three (3) years preceding the Effective Date, Aquestive has not received written notice of any claim or threatened claim from any Person (including any employee of Aquestive or any of its Affiliates) claiming compensation in respect of Aquestive's or its Affiliates' ownership, use or exploitation of any Aquestive IP.

8.2.3 Aquestive Patents. To Aquestive's knowledge, the Aquestive Patents represent all patents relating to the Supply and Commercialization of the Product in the Field in the Territory, as of the Effective Date.

8.2.4 Third Party Agreements. Except in connection with commercial lending arrangements, neither Aquestive nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that conflicts with, or limits the scope of, any of the rights or licenses granted to Pharmanovia hereunder or that will result in any Third Party obtaining any interest in, or that would give to any Third Party any right to assert any claim in or with respect to, any of Pharmanovia's rights under this Agreement.

8.2.5 Product Development.

8.2.5.1 In respect of the Product, Aquestive, its Affiliates and their contractors have gathered, generated, prepared, processed, maintained and retained all data and information that is required to be generated, maintained or retained pursuant to and in accordance with (and have conducted all development activities accordance with) with good laboratory practice and Applicable Laws; and

8.2.5.2 Aquestive has not withheld from Pharmanovia or any Regulatory Authority any material adverse information relating to the safety or efficacy of the Product, and

Aquestive is not aware of any scientific or technical facts or circumstances that would adversely affect the safety or efficacy of the Product.

8.2.6 Supply of Product.

8.2.6.1 Aquestive has the capacity and resources to Supply the Product in accordance with this Agreement.

8.2.6.2 Aquestive has and shall maintain the necessary facilities, equipment, know-how, procedures and personnel to manufacture and Supply the Product in accordance with the terms of this Agreement.

8.2.6.3 All activities required to validate Aquestive's equipment, plant, Manufacturing Facilities, and production processes necessary for the manufacture and Supply the Product have been completed.

8.2.7 Compliance with Applicable Law. Aquestive shall comply with and maintain in force all licenses, consents, permits and authorizations necessary to perform its obligations under this Agreement and shall perform its obligations under this Agreement in compliance with Applicable Law, in each case in all material respects.

8.2.8 Compliance with Anti-Bribery, Anti-Corruption, and Ethics Policies. Aquestive shall have and maintain in place through the Term its own policies and procedures to ensure compliance with Applicable Law relating to anti-bribery and anti-corruption in the Territory. Aquestive will immediately report to Pharmanovia any request or demand for any undue or suspicious financial or other advantage of any kind received by Aquestive or any of its Affiliates in connection with the performance of this Agreement.

8.2.9 No Debarment. None of Aquestive or its Affiliates have employed or otherwise used in any capacity, and will not employ or otherwise use in any capacity, the services of any Person debarred under United States law, including Section 21 U.S.C. 335a, or any foreign equivalent thereof.

8.3 **Additional Pharmanovia Representations, Warranties and Covenants**. Pharmanovia further represents, warrants, and covenants to Aquestive that:

8.3.1 Right to Grant Licenses. Pharmanovia and its Affiliates have the right to grant the licenses granted to Aquestive herein.

8.3.2 Third Party Agreements. As of the Effective Date, neither Pharmanovia nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any Third Party obtaining any interest in, or that would give to any Third Party any right to assert any claim in or with respect to, any of Aquestive's rights under this Agreement.

8.3.3 Compliance with Applicable Law. Pharmanovia shall comply with and maintain in force all licenses, consents, permits and authorizations necessary to perform its obligations under this Agreement and shall perform its obligations under this Agreement in compliance with Applicable Law in the Territory.

8.3.4 Compliance with Anti-Bribery, Anti-Corruption, and Ethics Policies. Pharmanovia shall have and maintain in place through the Term its own policies and procedures to ensure compliance with Applicable Law relating to anti-bribery and anti-corruption in the Territory. Pharmanovia will immediately report to Aquestive: (a) any request or demand for any undue or suspicious financial or other advantage of any kind received by Pharmanovia in connection with the performance of this Agreement.

8.3.5 No Debarment. None of Pharmanovia or its Affiliates have employed or otherwise used in any capacity, and will not employ or otherwise use in any capacity, the services of any Person debarred under United States law, including Section 21 U.S.C. 335a, or any foreign equivalent thereof.

8.4 **Disclaimer**. AQUESTIVE HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED HEREIN NOT EXPRESSLY MADE IN THIS AGREEMENT TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAWS, INCLUDING WITH RESPECT TO THE PRODUCT OR ANY PATENT OR OTHER INTELLECTUAL PROPERTY LICENSED OR GRANTED UNDER THIS AGREEMENT, INCLUDING ANY WARRANTY OF NON-INFRINGEMENT, QUALITY, PERFORMANCE, IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OR TRADE.

## 9. TECHNOLOGY TRANSFER

9.1 Upon the occurrence of a Bankruptcy Supply Failure, Pharmanovia shall be entitled to request that a program for transitioning the Supply of the relevant Product to Pharmanovia or its nominee is carried out by submitting a request to Aquestive. Pending such transition, Aquestive agrees to introduce Pharmanovia or its designee to, and or assist Pharmanovia or its designee to enter into agreements with, any of Aquestive's Third Party manufacturers, including, if so requested by Pharmanovia, by assigning or novating Aquestive's or its Affiliate's relevant contracts (in whole or in part as applicable) to Pharmanovia or its designee.

9.2 As soon as reasonably practicable following Aquestive's receipt of any request pursuant to Section 9.1, but in any event no later than thirty (30) days after such receipt, the Parties shall negotiate in good faith and agree a formal plan ("Technology Transfer Plan") for the transitioning of Supply of the Product to Pharmanovia or to any Affiliate of Pharmanovia or third party contract manufacturer as Pharmanovia may direct (following consultation with Aquestive) ("Technology Transfer Partner").

9.3 Aquestive shall carry out the activities allocated to it in the Technology Transfer Plan in accordance with any timelines set out therein. The methods that will be used to effect the Technology Transfer Plan will include:

9.3.1 the provision of copies of all such documentation and materials in the possession of Aquestive and/or its Affiliates which record Aquestive Know-How related to the

Supply of Products including the then-current process for the Supply of the Products, as well as any improvements or enhancements to such processes;

9.3.2 the provision of technical assistance to Pharmanovia and/or the Technology Transfer Partner to ensure timely transfer of Supply of the Product; and

9.3.3 access to employees of Aquestive and its Affiliates (and/or their third party contract manufacturer) who have knowledge of the Products and the Manufacturing process at Aquestive's (and/or its Affiliates' and/or their third party contract manufacturer's) premises and/or, where reasonably required, at Pharmanovia's or Technology Transfer Partner's premises.

## 10. CONFIDENTIAL INFORMATION

10.1 **General**. Pursuant to the terms of this Agreement, each of Aquestive and Pharmanovia (in such capacity, the "Disclosing Party") has disclosed and will be disclosing to the other Party, and to the Affiliates, officers, directors, employees, agents and/or representatives of each (in such capacity, the "Receiving Party") certain secret, confidential or proprietary data, Intellectual Property and related information, including, without limitation, technical, scientific, business and other information, data, materials and the like relating to drug applications, patent applications, products, processes, formulations, manufacturing technology, samples, operating methods and procedures, marketing, manufacturing, distribution and sales methods and systems, sales figures, pricing policies and price lists and other business information ("Confidential Information"). The terms and conditions of this Agreement shall be considered Confidential Information. Without limiting the foregoing, it is acknowledged that the Aquestive IP (other than any published Aquestive Patents) shall constitute the Confidential Information of Aquestive (subject to Section 10.3) for purposes of this Agreement. The Receiving Party shall make no use of any Confidential Information of the Disclosing Party except in the exercise of its rights and the performance of its obligations set forth in this Agreement. The Receiving Party: (a) shall keep and hold as confidential, and shall cause its officers, directors, employees, agents, and representatives to keep and hold as confidential, all Confidential Information of the Disclosing Party; and (b) shall not disclose, and shall cause its Affiliates, officers, directors, employees, agents, and representatives not to disclose, any Confidential Information of the Disclosing Party. Confidential Information disclosed by the Disclosing Party shall remain the sole and absolute property of the Disclosing Party, subject to the rights granted in this Agreement or Applicable Law.

10.2 **Prior Confidentiality Agreement**. As of the Effective Date, the terms of this Section 10 shall supersede any prior non-disclosure, secrecy, or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Confidentiality Agreement, which is hereby terminated. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

10.3 **Exceptions**. The above restrictions set forth in Section 10.1 on the use and disclosure of Confidential Information shall not apply to any information which: (a) is already known to the Receiving Party at the time of disclosure by the Disclosing Party, as demonstrated by competent proof (other than as a result of prior disclosure under any agreement between the Parties with respect to confidentiality); (b) is or becomes generally known or available to the public

other than through any act or omission of the Receiving Party in breach of this Agreement (or any other agreement between the Parties with respect to confidentiality); (c) is acquired by the Receiving Party from a Third Party who is not directly or indirectly under an obligation of confidentiality to the Disclosing Party with respect to same, or (d) is developed independently by the Receiving Party without the use, direct or indirect, of the Disclosing Party's Confidential Information. In addition, nothing in this Section 10 shall be interpreted to limit the ability of either Party to disclose its own Confidential Information to any other Person on such terms and subject to such conditions as it deems advisable or appropriate.

10.4 **Permitted Disclosures**. It shall not be a breach of Section 10.1 if a Receiving Party discloses Confidential Information of a Disclosing Party: (a) pursuant to Applicable Law, including securities laws applicable to a public company, to any Regulatory Authority or the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market, the New York Stock Exchange, or other Regulatory Authority; (b) in order to comply with its obligations under the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market or the New York Stock Exchange; or (c) in a judicial, administrative or arbitration proceeding to enforce such Party's rights under this Agreement; provided, however, that the Receiving Party: (i) provides the Disclosing Party with as much advance written notice as possible of the required disclosure; (ii) reasonably cooperates with the Disclosing Party in any attempt to prevent, limit or seek confidential treatment for the disclosure; and (iii) discloses only the minimum amount of Confidential Information necessary for compliance. The Parties may also disclose the existence of this Agreement and terms thereof to their directors, investors, officers, employees, attorneys, accountants and other advisers on a need to know basis and may, upon obtaining a written confidentiality agreement, further disclose the existence and terms of this Agreement to third Parties to whom it may be relevant in connection with financings, acquisitions, licenses and similar transactions to the extent such Third Parties are under confidentiality obligations at least as restrictive as those set forth herein.

10.5 **Equitable Remedies**. Each Party specifically recognizes that any breach by it of this Section 10 may cause irreparable injury to the other Party and that actual damages may be difficult to ascertain, and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each Party agrees that in the event of any such breach, the other Party shall be entitled to seek injunctive relief and such other legal and equitable remedies as may be available, without the necessity of securing or posting of any bond or proving actual damages.

## 11. INDEMNIFICATION; LIMITATION OF LIABILITY

11.1 **Indemnification by Pharmanovia**. Pharmanovia shall defend, indemnify and hold harmless Aquestive and its Affiliates and each of their respective successors and assigns, and each of their respective officers, directors, shareholders, employees, subcontractors, agents, and representatives ("Aquestive Indemnitees") from and against all claims, allegations, suits, actions or proceedings asserted against any Aquestive Indemnitee by any Third Parties, whether governmental or private ("Third Party Claims"), and all associated Losses, to the extent arising out of or resulting from: (a) the performance or failure to perform by Pharmanovia (or any of its Affiliates, subcontractors or agents) of any of Pharmanovia's obligations under this Agreement;

(b) a breach by Pharmanovia or any of its Affiliates, subcontractors or agents of any of Pharmanovia's obligations, representations, warranties, covenants or agreements under this Agreement; (c) the Commercialization by or on behalf of Pharmanovia of any Products in the Territory; or (d) violation of Applicable Law by any Pharmanovia Indemnitee; provided, that, in all cases referred to in this Section 11.1, Pharmanovia shall not be liable to indemnify any Aquestive Indemnitee for any Losses of such Aquestive Indemnitee to the extent that such Losses were caused by or arise out of: (i) the negligence or willful misconduct or intentional wrongdoing of Aquestive or any of its Affiliates, subcontractors or agents in the performance of Aquestive's obligations under this Agreement; (ii) any breach by Aquestive or any of its Affiliates, subcontractors or agents of Aquestive's obligations, representations, warranties, covenants or agreements under this Agreement; or (iii) matters for which Aquestive has an obligation to indemnify any Pharmanovia Indemnitee pursuant to Section 11.2.

11.2 **Indemnification by Aquestive**. Aquestive shall defend, indemnify and hold harmless Pharmanovia and its Affiliates and each of their successors and assigns, and each of their respective officers, directors, shareholders, employees, subcontractors, agents, and representatives (**"**Pharmanovia Indemnitees**"**) from and against all Third Party Claims, and all associated Losses, to the extent arising out of or resulting from: (a) the performance or failure to perform by Aquestive (or any its Affiliates, subcontractors or agents) any of Aquestive**'**s obligations under this Agreement; (b) a breach by Aquestive or any of its Affiliates, subcontractors or agents of any of Aquestive**'**s obligations, representations, warranties, covenants or agreements under this Agreement; or (c) any claim or allegation that the Aquestive Patents infringe upon the Intellectual Property Rights of a Third Party; other than any claim or demand that is directed solely to the API and the alleged infringement would have occurred from the use of the API alone; or (d) violation of Applicable Law by any Aquestive Indemnitee; provided, that, in all cases referred to in this Section 11.2, Aquestive shall not be liable to indemnify any Pharmanovia Indemnitee for any Losses of such Pharmanovia Indemnitee to the extent that such Losses were caused by or arise out of: (i) the negligence or willful misconduct or intentional wrongdoing of Pharmanovia or any of its Affiliates, subcontractors or agents in the performance of Pharmanovia**'**s obligations under this Agreement; (ii) any breach by Pharmanovia or any of its Affiliates, subcontractors or agents of Pharmanovia**'**s representations, warranties, covenants or agreements under this Agreement; or (iii) matters for which Pharmanovia has an obligation to indemnify any Aquestive Indemnitee pursuant to Section 11.1.

11.3 **Procedure for Indemnification**.

11.3.1 Notice. In the case of a Third Party Claim or demand made by any Person who is not a Party of this Agreement (or an Affiliate thereof) as to which a Party (the "Indemnitor") may be obligated to provide indemnification pursuant to this Agreement, such Party seeking indemnification hereunder ("Indemnitee") will notify the Indemnitor in writing of the Third Party Claim (and specifying in reasonable detail the factual basis for the Third Party Claim and, to the extent known, the amount of the Third Party Claim) reasonably promptly after becoming aware of such Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided hereunder except to the extent the Indemnitor shall have been actually materially prejudiced as a result of such failure.

11.3.2 Defense of Claim. If a Third Party Claim is made against an Indemnitee, then the Indemnitor will be entitled, within thirty (30) days after receipt of written notice from the Indemnitee of the commencement or assertion of any such Third Party Claim, to assume the defense thereof by providing written notice to Indemnitee of its intention to assume the defense of such Third Party Claims within such thirty (30) day period (at the expense of the Indemnitor) with counsel selected by the Indemnitor and reasonably satisfactory to the Indemnitee for so long as the Indemnitor is conducting a good faith and diligent defense. Should the Indemnitor so elect to assume the defense of such Third Party Claim, the Indemnitor will not be liable to the Indemnitee for any legal or other expenses subsequently incurred by the Indemnitee in connection with the defense thereof; provided, however, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnitor and the Indemnitee in respect of such claim, such Indemnitee shall have the right to employ separate counsel to represent such Indemnitee with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by such Indemnitor; provided, further, that the Indemnitor shall only be responsible for the reasonable fees and expenses of one separate counsel for all Indemnitees, provided that where a conflict of interest is found to exist each Indemnitee with a conflict will be entitled to separate counsel at such Indemnitees' expense. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitee shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnitor. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitor will promptly supply to the Indemnitee copies of all material correspondence and documents relating to or in connection with such Third Party Claim and keep the Indemnitee reasonably informed of developments relating to or in connection with such Third Party Claim, as may be reasonably requested in writing by the Indemnitee (including, without limitation, providing to the Indemnitee on reasonable request updates and summaries as to the status thereof). If the Indemnitor chooses to defend a Third Party Claim, all Indemnitees shall reasonably cooperate with the Indemnitor in the defense thereof (such cooperation to be at the expense, including reasonable legal fees and expenses, of the Indemnitor). If the Indemnitor does not elect to assume control by written acknowledgement of the defense of any Third Party Claim within the thirty (30) day period set forth above, or if such good faith and diligent defense is not being or ceases to be conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor (but limited to the reasonable legal fees and expenses of one counsel for all Indemnitees), after five (5) Business Days' written notice to the Indemnitor of its intent to do so, to undertake the defense of the Third Party Claim for the account of the Indemnitor (with counsel selected by the Indemnitee), and to compromise or settle such Third Party Claim, exercising reasonable business judgment.

11.3.3 Settlement of Claims. In no event may the Indemnitor compromise or settle any Third Party Claim without the prior written consent of the Indemnitee such consent not to be unreasonably withheld or delayed. Without limiting the foregoing, if the Indemnitor acknowledges in writing its obligation to indemnify the Indemnitee for a Third Party Claim, the Indemnitee will agree to any settlement, compromise or discharge of such Third Party Claim that the Indemnitor may recommend that by its terms obligates the Indemnitor to pay the full amount of Losses (whether through settlement or otherwise) in connection with such Third Party Claim and unconditionally and irrevocably releases the Indemnitee completely from all Losses in connection with such Third Party Claim; provided, however, that, without the Indemnitee's prior written consent, the Indemnitor shall not consent to any settlement, compromise or discharge (including, without limitation, the consent to entry of any judgment), that provides for injunctive

or other nonmonetary relief affecting the Indemnitee or which admits fault or negligence on the part of the Indemnitee.

11.3.4 Assumption of Defense. Notwithstanding anything to the contrary contained herein, an Indemnitee shall be entitled to assume the defense of any Third Party Claim with respect to the Indemnitee upon written notice to the Indemnitor pursuant to this Section 11.3.4, in which case, the Indemnitor shall be relieved of liability under Section 11.1 or 11.2, as applicable, solely for such Third Party Claim and related Losses.

11.4 **Insurance**. During the Term and for a period of five (5) years after the termination or expiration of this Agreement, each Party shall obtain and/or maintain, respectively, at its sole cost and expense, comprehensive general liability insurance, products liability insurance and clinical trials insurance (including any self-insured arrangements), each in amounts, respectively, which are reasonable and customary in the pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party but in no event less than Ten Million Dollars ($10,000,000) per occurrence and Ten Million Dollars ($10,000,000) annual aggregate. Each Party shall also maintain any mandatory insurance, including but not limited to workers compensation coverage, in accordance with all Applicable Law. All insurance policies reflecting such insurance shall be written on a "per occurrence" or "claims made" basis with an insurance company rated at least A-3 by Best's rating guide. Each of the Parties and their designees who have an insurable interest shall be added as an additional insured on the other Party's product liability insurance policy. If requested, each Party shall provide the other with a certificate of insurance and shall keep such policy current. Each Party shall provide at least thirty (30) calendar days' prior written notice to the other Party of the cancellation or any substantial modification of the terms of coverage. Such product liability insurance (or self-insured arrangements) shall insure against all liability, including without limitation personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Products. Each Party shall require its insurers to waive all rights of subrogation against the other Party, and its directors, officers, employees, and agents on all the foregoing coverages. Each Party shall provide written proof of the existence of such insurance to the other Party upon written request. Each Party acknowledges and agrees that its liabilities under this Agreement will not be limited by the amount of such Party's insurance.

11.5 **Limitation of Liability**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES OR LOSSES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY THE OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR A BREACH OR ALLEGED BREACH OF THIS AGREEMENT, HOWEVER ARISING WHETHER FOR BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE. THE FOREGOING SENTENCE SHALL NOT APPLY IN CASES OF A PARTY'S GROSS NEGLIGENCE, OR INTENTIONAL MISCONDUCT, FRAUD OR DEATH OR PERSONAL INJURY CAUSED BY NEGLIGENCE.

## 12. TERM AND TERMINATION

12.1 **Term**. The initial term shall commence as of the Effective Date and shall run unless terminated in accordance with the terms of this Agreement, on a country by country basis in the Territory, for a period of [****] years from the First Commercial Sale (together with any renewal term, the "Term"). Pharmanovia shall have the option to renew this Agreement for successive [****] renewal terms by providing [****] days written notice to Aquestive prior to the expiration of the then current term.

12.2 **Termination**.

12.2.1 Termination of this Agreement. In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated as follows:

12.2.1.1 By either Party immediately upon written notice: (a) upon the occurrence of a Bankruptcy Event with respect to the other Party; or (b) in addition to and not in limitation of the termination rights set forth below in this Section 12.2, if the other Party commits any material misrepresentation or breach of any of its covenants, obligations, representations or warranties under this Agreement and, in the case of a breach which is capable of remedy, such Party fails to remedy the same within sixty (60) days after receipt of a written notice describing the breach and requiring it to be so remedied.

12.2.1.2 By Aquestive upon thirty (30) days' prior written notice if Pharmanovia has violated Section 2.2.2.

12.2.1.3 By Pharmanovia on thirty (30) days' prior written notice if Aquestive has violated Section 2.2.1.

12.2.1.4 By Aquestive upon written notice to Pharmanovia in the event that Pharmanovia fails to pay as and when due: (a) any Milestone Payment;(b) any Royalty Fee; or (c) any amount required to be paid with respect to a Minimum Volume Commitment; and in the case of (a) fails to remedy same within thirty (30) days of receipt and in the case of (b) and (c) within forty five (45) days of a written notice describing the failure and requiring it to be so remedied provided that Pharmanovia's failure to pay is not due to an invoice being disputed in writing by Pharmanovia in good faith.

12.2.1.5 By either Party on no less than three (3) months' written notice of termination if Pharmanovia does not file for the first Regulatory Approval in a country in the Territory within three (3) years of the Effective Date provided that the Parties shall have had good faith discussions for at least three (3) months to discuss a resolution of this issue prior to any such notice being served.

12.2.1.6 By Pharmanovia upon written notice to Aquestive if Aquestive does not use Commercially Reasonable Efforts to execute its Supply responsibilities for the Product and Aquestive fails to remedy the same within [****] days after receipt of a written notice from Pharmanovia describing failure and requiring it to be so remedied.

12.2.1.7 By Aquestive, after the third anniversary of the Effective Date, upon written notice in respect to a specific country in the Territory if Pharmanovia does not use

Commercially Reasonable Efforts to execute its Commercialization and Development responsibilities for the Product in that specific country in the Territory and Pharmanovia fails to demonstrate in good faith an intention to Commercialize the Product in such country in the Territory within [****] days after receipt of a written notice from Aquestive describing failure and requiring it to be so remedied. For the purposes of this section, the EEA shall be considered a single country.

12.2.1.8 By Aquestive upon [****] days' prior written notice if the quantities of Units purchased by Pharmanovia from Aquestive under the Product Schedule do not meet the Minimum Volume Commitment (to the extent applicable) in any [****] consecutive [****], unless such failure is attributable to the failure of Aquestive to supply a conforming Product to Pharmanovia under this Agreement, or due to matters outside of the control of Pharmanovia that impacts Pharmanovia's ability to sell Product.

12.3 **Effects of Termination**.

12.3.1 Effect of Termination Generally. On the expiration or earlier termination of this Agreement for any reason, except as otherwise expressly provided herein, all rights and obligations of each Party hereunder or thereunder, as the case may be, shall cease.

12.3.2 Disposition and Transfer of Inventory upon Termination; Royalty Fees Due Thereon Not Affected By Termination. On the expiration or earlier termination of this Agreement: (a) all unpaid Royalty Fees for the Product sold as of the effective date of termination shall remain due and payable as scheduled; (b) on the agreement of both Parties, Aquestive shall complete all work-in-process, and Pharmanovia shall purchase at the Product Transfer Price under this Agreement, all remaining inventory of Product and, at cost, all Raw Materials relating thereto in Aquestive's possession or control but not to exceed a supply of the affected Product corresponding to the last [****] of the most recent supply forecast delivered by Pharmanovia in accordance with Section 5.3 and Aquestive shall use all Commercially Reasonable Efforts to mitigate the cost thereof to Pharmanovia and to consult with Pharmanovia in connection with such attempts to mitigate; (c) Pharmanovia shall have the right to sell out such remaining inventory of the affected Products for a period of up to [****] months; and (d) Pharmanovia shall pay to Aquestive the Royalty Fees on each sale of remaining inventory of the Product by Pharmanovia and/or its Affiliates when and as such Product is sold.

12.3.3 Accrued Rights. Termination, relinquishment, or expiration of this Agreement for any reason shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration including damages arising from any breach under this Agreement. Termination, relinquishment, or expiration of this Agreement shall not relieve either Party from any obligation which is expressly or by implication intended to survive such termination, relinquishment or expiration of this Agreement and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after, such termination, relinquishment, or expiration. Remedies for breaches under this Agreement shall also survive any termination, relinquishment, or expiration of this Agreement.

12.3.4 Intellectual Property Rights.

12.3.4.1 Upon expiration of this Agreement or termination by Pharmanovia pursuant to Sections 12.2.1.1 , 12.2.1.3, 12.2.1.5 or 12.2.1.6, all right, title and interest, in and to, with respect to each Regulatory Approval and all data generated in support of such Regulatory Approval for the Product in the Territory shall remain with Pharmanovia or its Affiliates and nominees, including without limitation, from all associated pre-clinical and clinical studies. For the avoidance of doubt, in these circumstances Pharmanovia shall have no further obligation, notwithstanding Section 12.3.2, to pay any Royalty Payments or payments associated with failure to meet the Minimum Volume Commitments pursuant to this Agreement, relating to the period after the expiry or termination date.

12.3.4.2 Upon termination of this Agreement or part thereof by Aquestive pursuant to Sections 12.2.1.1, 12.2.1.2, 12.2.1.4, 12.2.1.5, 12.2.1.7 or 12.2.1.8, Aquestive shall have the right, to be exercised at Aquestive's sole option, to receive an assignment in whole or in part, directly or to a designated sublicensee, of all of Pharmanovia's right, title and interest, in and to, with respect to the Product in the affected country in the Territory if it is a partial termination, (i) each Regulatory Approval and (ii) all data generated in support of such Regulatory Approval, including without limitation, from all associated pre-clinical and clinical studies, if a partial termination in relation to the Product in the affected country in the Territory; for the avoidance of doubt this shall not include the Pharmanovia Marks. Such assignment shall be made for consideration equaling Pharmanovia's out-of-pocket costs incurred (excluding payments made by Pharmanovia to Aquestive in respect of same under this Agreement). In connection with any assignment contemplated by this Section 12.3.4.2, Pharmanovia shall cooperate with Aquestive and execute and deliver to Aquestive any and all documents reasonably necessary to perfect its or its sublicensee's rights to the foregoing and, to the extent applicable, Pharmanovia shall ensure that the all Product-related Intellectual Property and Regulatory Approvals, if a partial termination in relation to the Product in the affected country in the Territory to be assigned remain in good standing until such assignment to Aquestive is complete. Aquestive undertakes, in these circumstances, within 3 months, to carry out the necessary variations to the Regulatory Approvals and artwork related thereto, to ensure that the Pharmanovia Marks and any other reference to Pharmanovia or its Affiliates or nominees is removed therefrom.

12.3.5 Survival. The following Sections of this Agreement, as well as any other provisions in this Agreement which specifically state they will survive termination or expiration of this Agreement or any terms of this Agreement that would reasonably be expected in the contemplation of both Parties to survive termination, shall survive expiration or termination of this Agreement for any reason: Section 1, Section 2.1 (provided that the license granted in Section 2.1 shall be non-exclusive and all such sections shall survive for the sole purpose of selling out remaining inventory of Product as set forth in Section 12.3.2 , Section 4.8, Sections 5.4, 5.46, 5.6, 5.7, 5.11 and 5.12, Section 8.1 (with respect to unpaid milestone payments which have accrued as of such termination), Section 7.2 through Section 7.12 inclusive (with respect to Royalty Fee payments and Profit Share payments due after such termination or expiration for sales prior to such termination or expiration or otherwise in respect of sales permitted pursuant to Section 12.3.2), Sections 8.4, 9, 10, 11, 12.3, 13.5.2, and 14.

12.3.6 Return of Confidential Information.

12.3.6.1 Within thirty (30) days of any expiration or termination of this Agreement: (a) Pharmanovia shall cease to use and shall deliver to Aquestive, upon written request of Aquestive, all Confidential Information of Aquestive, except for any documents or records that Pharmanovia is required to retain by Applicable Law or reasonably necessary for Pharmanovia to exercise its rights under Section 12.3.2; and (b) Aquestive shall cease to use and shall deliver to Pharmanovia, upon written request, all Confidential Information of Pharmanovia except for any documents or records that Aquestive is required to retain by Applicable Law or that are reasonable necessary for Aquestive to exercise its rights under Section 12.3.2; provided, however, that all such retained documents or records shall continue to be subject to the confidentiality obligations under this Agreement.

## 13. INTELLECTUAL PROPERTY

### 13.1 Patent Prosecution and Maintenance.

13.1.1 Aquestive shall be responsible for the preparation, filing, prosecution and maintenance (including payment of renewal fees when due) of the Aquestive Patents. The cost of such preparation, filing, prosecution and maintenance of the Aquestive Patents shall be borne by Aquestive.

13.1.2 Aquestive shall use Commercially Reasonable Efforts to procure the grant of any of the Aquestive Patents that are patent applications in each country of the Territory. Aquestive shall provide updates on the status of the Aquestive Patents to the Steering Committee on a regular basis and, if reasonably practicable, consult with Atnahs on material decisions in relation thereto.

13.1.3 In the event that Aquestive desires to abandon or cease prosecution or maintenance of any Aquestive Patent, Aquestive shall provide reasonable prior written notice to Pharmanovia of such intention to abandon (which notice shall, to the extent possible, be given no later than sixty (60) days prior to the next deadline for any action that must be taken with respect to any such Aquestive Patent in the relevant patent office). In such case, upon Pharmanovia's written election provided no later than thirty (30) days after such notice from Aquestive, Pharmanovia shall have the right to assume prosecution and maintenance of such Aquestive Patent at Pharmanovia's expense. If Pharmanovia does not provide such election within thirty (30) days after such notice from Aquestive, Aquestive may, in its sole discretion, continue prosecution and maintenance of such Aquestive Patent or discontinue prosecution and maintenance of such Aquestive Patent.

### 13.2 IP Enforcement Against Third Parties.

13.2.1 Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of any Aquestive Patent of which they become aware (a "Competitive Infringement").

13.2.2 In each such instance of Competitive Infringement of any Aquestive Patent, Aquestive shall have the right, but not the obligation, in its own name and under its own direction

and control, to institute litigation against such alleged or threatened Competitive Infringement at its cost and expense. If Aquestive does not, within ninety (90) days after its receipt or delivery of notice under Section 13.2.1 relating to infringement of any Aquestive Patent, commence a suit to enforce the applicable patent, take other action to terminate such Competitive Infringement or initiate a defense against such Competitive Infringement, then: (i) Pharmanovia will have the right, but not the obligation, including conducting infringement proceedings and settlement negotiations in its own and Aquestive's name, to commence such a suit or take such an action or defend against such Competitive Infringement in the Territory at Pharmanovia's cost and expense, to be represented in any such suit by counsel of its own choice and (ii) if Pharmanovia exercises its right under the foregoing clause (i), Aquestive will take all reasonable and appropriate actions in order to permit Pharmanovia to commence a suit or take the actions with respect to the Competitive Infringement. Neither Party will enter into any settlement, consent judgment or other voluntary final disposition of any action under this Section 13.2 without the other Party's prior written consent, which consent will not be unreasonably withheld, delayed, or conditioned unless the settlement includes any express or implied admission of liability or wrongdoing on either Party's part, in which case the right to grant or deny consent is absolute and at its sole discretion.

13.2.3 Each Party shall reasonably assist the Party enforcing any such rights under this Section 13.2 in any such action or proceeding if so requested by the enforcing Party, and will be named in or join such action or proceeding if requested by the enforcing Party, and will reasonably cooperate with the enforcing Party in such participation (including providing copies of all prior claim construction submissions and supporting documents subject to confidentiality provisions as required); provided, that if Aquestive is the enforcing Party, the reasonable, out-of-pocket costs and expenses of Pharmanovia in connection therewith, including any Aquestive-approved investigation and analysis thereof, is to be reimbursed to Pharmanovia on an as-incurred basis. The enforcing Party shall keep such other Party and/or its designated legal counsel reasonably informed as to the progress in connection with the foregoing Competitive Infringement (including any settlement discussions), and will reasonably consider the other Party's comments on any such efforts.

13.2.4 If the enforcing Party recovers monetary damages in such claim, suit or action, such recovery will be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation the remaining amounts will be retained by Pharmanovia, however, Pharmanovia will calculate Net Sales under this Agreement based on the remaining amounts attributed to lost sales as if Pharmanovia had made the infringing sales directly, and will pay to Aquestive the Royalty Fees owed by Pharmanovia to Aquestive pursuant to Section 7.2 or any Profit Share owed by Pharmanovia to Aquestive pursuant to Section 7.3.

13.3 **Action by Third Party**. In the event that any Third Party initiates a declaratory judgment action alleging the noninfringement, invalidity or unenforceability of the Aquestive Patents, or if any Third Party brings an infringement action against Pharmanovia or its Affiliates or subcontractors because of the exercise of the rights granted to Pharmanovia under this Agreement with respect to the Aquestive Patents, and Aquestive or Pharmanovia has not commenced any action to enforce Aquestive Patents against such Third Party under the terms of Section 13.2 above, each Party will give prompt notice to the other Party of any such action of which it becomes aware. Aquestive shall have the right, but not the obligation, to take any necessary actions (including the filing of pleadings required by the Applicable Law or any local

rules of court) and defend against such action under its own control and at its own expense. If Aquestive fails to defend such action, Pharmanovia will have the right, but not the obligation to defend against such action under its own control and at its own cost and expense; Aquestive will take all reasonable and appropriate actions in order to permit Pharmanovia to initiate and continue such defense and will provided all assistance reasonably requested by Pharmanovia in connection with such defense. Neither Party will enter into any settlement, consent judgment or other voluntary final disposition of any action under this Section 13.3 without the other Party's prior written consent, which consent will not be unreasonably withheld, conditioned or delayed, unless the settlement includes any express or implied admission of liability or wrongdoing on either Party's part, in which case the right to grant or deny consent is absolute and at its sole discretion. Notwithstanding the above, if Aquestive or Pharmanovia has commenced any action to enforce Aquestive Patents against such Third Party under the terms of Section 13.2 above, then the terms of Section 13.2 will supersede the terms of this Section 13.3.

13.4 **Ownership of Pharmanovia Housemarks; Termination of Right to Use**.

13.4.1 Pharmanovia shall own all right, title, and interest in the Pharmanovia Housemarks and Pharmanovia Marks in all forms of use or display in which they may appear, and any goodwill associated therewith. Notwithstanding any provision of this Agreement, Aquestive agrees that it shall not, by virtue of this Agreement, acquire any right, title, and interest in or to the Pharmanovia Housemarks or Pharmanovia Marks or any goodwill associated therewith.

13.4.2 Upon and following the termination of this Agreement, except in connection with any Supply of Product to Pharmanovia after termination or expiration of this Agreement, Aquestive shall not use the Pharmanovia Housemarks, the Pharmanovia Marks, or any other name or mark of Pharmanovia.

13.5 **Ownership of Aquestive Marks; Termination of Right to Use**.

13.5.1 Aquestive shall own all right, title, and interest in the Aquestive Marks in all forms of use or display in which they may appear, and any goodwill associated therewith. Notwithstanding any provision of this Agreement, Pharmanovia agrees that it shall not, by virtue of this Agreement, acquire any right, title, and interest in or to the Aquestive Marks or any goodwill associated therewith.

13.5.2 Upon and following the termination of this Agreement, except in connection with any Supply of Product to Pharmanovia after termination or expiration of this Agreement, Pharmanovia shall not use the Aquestive Marks or any other name or mark of Aquestive.

## 14. MISCELLANEOUS

14.1 **Independent Contractor**. Neither Aquestive nor Pharmanovia, together in each case with their respective employees and representatives, are under any circumstances to be considered as employees, partners, joint venturers, agents, or representatives of the other by virtue of this Agreement, and neither shall have the authority or power to bind the other or contract in the other's name.

14.2 **Registration and Filing of this Agreement**. To the extent, if any, that either Party concludes in good faith that it or is required to file or register this Agreement or a notification thereof with any Regulatory Authority including, without limitation, the U.S. Securities and Exchange Commission or the U.S. Federal Trade Commission, in accordance with Applicable Law, such Party shall (a) inform the other Party thereof, (b) provide copies of the proposed disclosure to the other Party reasonably in advance of such filing or other disclosure under the circumstances, (c) promptly notify the other Party in writing of such requirement and any respective timing constraints, and (d) give the other Party a reasonable time under the circumstances from the date of notice by such Party of the required disclosure to comment upon and request confidential treatment for such disclosure; provided, that, the other Party shall promptly review and provide comments regarding the proposed disclosure and the disclosing Party will in good faith consider incorporating such comments.

14.3 **Notices**. All notices or other communications required or permitted to be given under any of the provisions of this Agreement shall be in writing in the English language, and shall be deemed to have been duly given: (a) when personally received by the intended recipient; (b) when delivered by messenger or internationally recognized delivery service (with confirmation of receipt); (c) when delivered via e-mail or facsimile (and promptly confirmed by mail); or (d) three (3) Business Days after having been mailed by first class registered or certified mail, return receipt requested, postage prepaid, addressed to the applicable party at the address indicated below, or to any other address or addressee as any Party may in the future specify by notice to the other Party (with notice of change of address or addressee not being valid until actually received):

| | |
|---|---|
| If to Pharmanovia: | Atnahs Pharma UK Limited<br>Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR<br>Telephone: +44 1268 820 870<br>Attention: Dr James Burt, CEO |
| With a copy to: | Atnahs Pharma UK Limited<br>Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR<br>Telephone: +44 1268 820 870<br>Attention: General Counsel |
| If to Aquestive: | Aquestive Therapeutics, Inc.<br>30 Technology Drive<br>Warren, New Jersey 07059<br>Attn: Daniel Barber, Chief Executive Officer<br>E-mail: dbarber@aquestive.com |
| With a copy to: | Aquestive Therapeutics, Inc.<br>30 Technology Drive<br>Warren, New Jersey 07059<br>Attention: General Counsel<br>E-mail: lbraender@aquestive.com |

14.4 **Binding Effect; No Assignment**. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Except as expressly set forth in this Agreement, neither Aquestive nor Pharmanovia may assign any of its rights or delegate any of its liabilities or obligations hereunder without the prior written consent of the other Party, provided, however, that, without the prior written consent of the other Party: (a) either Party may assign this Agreement to any purchaser of all or substantially all of its assets or business to which this Agreement relates; and (b) either Party may assign this Agreement and/or its rights and obligations under this Agreement to any of its Affiliates. No assignment hereunder shall relieve the assigning Party of its responsibilities or obligations hereunder; provided, further that any assignee shall agree in writing to be bound by all of the obligations of the assigning Party hereunder. Any purported assignment or transfer in violation of this Section 13.4 will be void *ab initio* and of no force or effect. Aquestive shall not assign or otherwise transfer any right, title or interest in any of the Aquestive IP to any third party unless provision is made to ensure that the assignee's rights to such Aquestive IP remain subject to the license rights granted to Pharmanovia under this Agreement and further obligations are not imposed on Pharmanovia thereby.

14.5 **No Implied Waivers; Rights Cumulative**. No failure on the part of Aquestive or Pharmanovia to exercise and no delay in exercising any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, including the right or power to terminate this Agreement, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

14.6 **Severability**. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement shall remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree shall remain in full force and effect to the extent not held invalid or unenforceable. The Parties further agree to replace such invalid or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business, and other purposes of such invalid or unenforceable provision.

14.7 **Force Majeure**. Neither Party shall be liable for delay in delivery or nonperformance (except for any obligation for the payment of money), in whole or in part, nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 14.7, to the extent that such delay in delivery or nonperformance is caused by any of the following events that are reasonably beyond the control of such Party and without the fault or negligence of such Party: (i) strikes, lockouts or other labor disturbances; (ii) any change or effect resulting from or associated with acts of war or terrorism or changes imposed by a Regulatory Authority to address concerns associated with war or terrorism; (iii) any change or effect resulting from any acts of God, force majeure events, armed hostilities or sabotage, riots, civil commotion, insurrections, or any other weather developments or natural or man-made disasters; (iv) any change or effect resulting from any epidemics, pandemics or other public health emergencies, including COVID-19 or any worsening or variant thereof, or (vii) any change or effect resulting from conflict in the territory of Ukraine or any sanctions or restrictions related thereto, (a "Force Majeure"); provided, however, that the Party affected by such a condition shall,

as soon as it becomes aware of same (but in any event within ten (10) days of its occurrence), give written notice to the other Party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use its Commercially Reasonable Efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for a period of ninety (90) consecutive calendar days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such force majeure event, the non-affected Party may terminate this Agreement immediately by written notice to the other Party.

14.8 **Amendment**. This Agreement may not be amended, and no provision hereof may be modified or waived, except by an instrument in writing duly executed by each of the Parties hereto.

14.9 **Rules of Construction**. The Parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any law, regulation, holding or ruling of construction providing that ambiguities in an agreement or other document shall be construed against the Party drafting such agreement or document.

14.10 **Publicity**.

14.10.1 Press Releases. The Parties acknowledge that each of Pharmanovia and Aquestive intends to issue press releases and other public statement disclosing the existence of or relating to this Agreement, and each agrees to provide the other Party a copy of such release and statement and to obtain the express prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that neither Party shall be prevented from complying with any duty of disclosure it may have pursuant to Applicable Law, including securities laws applicable to a public company.

14.10.2 Use of Marks. During the Term, Aquestive will have the right to display the Pharmanovia Housemark on the partnership page of its corporate website, and Pharmanovia will have the right to display the Aquestive Marks on its corporate website.

14.11 **Expenses**. Except as expressly set forth herein, each Party shall bear all fees and expenses incurred by such Party in connection with, relating to or arising out of the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, including attorneys', accountants' and other professional fees and expenses.

14.12 **Governing Law; Dispute Resolution**.

14.12.1 This Agreement shall be governed by and construed in accordance with the laws (substantive and procedural) of the state of New York, United States without regarding to its conflict of laws principles. The Parties expressly exclude application of the United Nations Convention for the International Sale of Goods.

14.12.2 In the event of any dispute, claim, or controversy between the Parties under this Agreement, the Parties will first attempt in good faith to resolve such dispute by

negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within ten (10) days, either Party may refer the matter to the Parties' Executive Officers for attempted resolution. Each Party shall designate an "Executive Officer" of its company as the designee in the event of any dispute that has not been resolved in accordance with this Section 14.12.2. The Executive Officer shall be the President of the respective Party or his or her designee. The Executive Officers of the Parties will attempt in good faith to resolve such dispute by negotiation and consultation for a thirty (30) day period following such referral.

14.12.3 If the Executive Officers cannot reach consensus on a given matter within thirty (30) days, then, such dispute, controversy, or claim that is not an **"**Excluded Claim**"** shall be resolved by binding arbitration by the International Court of Arbitration of the International Chamber of Commerce ("ICC") in accordance with the rules of the ICC as in force on the date on which the request for arbitration is filed ("ICC Rules"). The place of arbitration shall be New York, New York, United States. Such arbitration shall be conducted by a sole arbitrator mutually selected by written agreement of the Parties. In the event that the Parties are not able to mutually select the sole arbitrator, the arbitration shall be conducted by a panel of three arbitrators, consisting of one arbitrator to be selected by the Party referring such matter to arbitration and one arbitrator to be selected by the other Party, and the third to be selected jointly by the two arbitrators selected by the Parties in accordance with the ICC Rules. The arbitration shall be conducted in English.

14.12.4 It is the intention of the Parties that discovery procedures, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrator(s) will permit such limited discovery procedures necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than thirty (30) days after selection of the arbitrator(s), the Parties and their representatives shall hold a preliminary meeting with the arbitrator(s), to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within six (6) months from such meeting. Failing any such mutual agreement, the arbitrator(s) will design and the Parties shall follow procedures to such effect. The arbitrator(s) will, in rendering its decision, apply the governing law (procedural and substantive) of the State of New York, United States without giving effect to any rules or laws relating to arbitration. Any award rendered by the arbitrator(s) will be final and binding, and judgment may be entered upon it in any court of competent jurisdiction.

14.12.5 Either Party may apply to the arbitrator(s) for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrator(s) shall have no authority to award punitive or any other non-compensatory damages. The prevailing Party shall be entitled to recover its reasonable attorneys' fees, costs and disbursements. The costs of the arbitration including without limitation, the fees of the arbitrator (but excluding each party's attorney's fees) shall be initially shared equally by the parties but may be awarded by the arbitrator as additional damages in favor of the prevailing party.

14.12.6 Except to the extent necessary to confirm or enforce an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration

be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

14.12.7 Notwithstanding anything to the contrary contained in this Agreement, each of the Parties shall have the right to bring an action or claim for interim measures, including specific performance or injunctive relief, in order to preserve its rights or enforce the obligations of the other Party under this Agreement, in any court of competent jurisdiction or having jurisdiction over any of the Parties or their respective assets, without the need to first submit such matter to arbitration under this Section 14.12.

14.12.8 As used in this Section 14.12, the term **"**Excluded Claim**"** shall mean a dispute, controversy or claim that concerns (i) the inventorship, validity, enforceability or infringement of a patent, trademark or copyright; or (ii) any antitrust, anti-monopoly, anti-corruption or competition law or regulation, whether or not statutory.

14.13 **Entire Agreement**. This Agreement, the Quality Agreement, the Safety Data Exchange Agreement and the Product Schedule contains the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements, written or oral, between the Parties.

14.14 **Third Party Beneficiaries**. None of the provisions of this Agreement, express or implied, is intended to be or shall be for the benefit of or enforceable by any Person (including, without limitation, any creditor of either Party hereto) other than Pharmanovia and Aquestive and their respective successors and permitted assigns. No such Person shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability, or obligation (or otherwise) against either Party hereto.

14.15 **Non-Recourse**. No past, present or future director, officer, employee, incorporator, member, partner, stockholder, Affiliate, agent, attorney or representative of either Party or any of their respective Affiliates shall have any liability (whether in contract or in tort) for any obligations or liabilities of such Party or applicable Affiliate arising under, in connection with or related to this Agreement or any of the transactions contemplated hereunder including for any Third Party Claim relating thereto.

14.16 **Interpretation and Construction**. The headings of Sections in this Agreement are provided for convenience only and shall not affect its construction or interpretation. All references to "Section" or "Sections" refer to the corresponding Section or Sections of this Agreement. All words used in this Agreement shall be construed to be of such gender or number as the circumstances require. Unless otherwise expressly provided in this Agreement, the word "including" does not limit the preceding words or terms and shall be deemed to be followed by the words "without limitation." Unless otherwise expressly provided in this Agreement, the terms "shall have responsibility for", "shall be responsible for" or the like, shall be deemed to be followed by "and shall be obligated to duly carry out such responsibility."

14.17 **Controlling Language**. This Agreement and the Schedules hereto are prepared and executed in the English language only, which language shall control and prevail in all respects. The English language shall be used in the interpretation and performance of this Agreement. Any

translations of this Agreement into any other language are for reference only and shall have no legal or other effect. Any notice which is required or permitted to be given by one Party to the other under this Agreement shall be in the English language and shall be in writing. All other correspondence and documentation required to be delivered to a Party under this Agreement, arising out of or connected with this Agreement, and any related purchase order(s) shall be in the English language; provided that if a document to be delivered under this Agreement is in a language other than English in its original form, it shall be delivered in its original language and at Aquestive's written request, Pharmanovia will provide Aquestive with a copy of English translation of such document the cost of which shall be borne by Aquestive. All proceedings related to this Agreement shall be conducted in the English language.

14.18 **Rights in Bankruptcy**. The Parties acknowledge that all rights and licenses granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar foreign laws (collectively, the "Bankruptcy Code"), licenses of rights to be "intellectual property" as defined under the Bankruptcy Code or such foreign laws. Pharmanovia shall have all rights, elections, and protections under the Code and all other applicable bankruptcy, insolvency, and similar laws with respect to this Agreement and the subject matter hereof. If a case is commenced during the Term by or against Aquestive or its Affiliates or their respective assets under a Bankruptcy Code or a similar proceeding then, then subject to Pharmanovia's rights of election under Section 365(n), all rights, licenses, and privileges granted to Pharmanovia under this Agreement will continue subject to the respective terms and conditions hereof, and will not be affected, even by Aquestive's rejection of this Agreement and Aquestive (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party.

14.19 **Product Schedule**. To the extent any terms and provisions of the Product Schedule conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall control, except to the extent that the Product Schedule expressly and specifically states an intent to supersede a certain provision of this Agreement on a specific matter. The Product Schedule and any amendments thereto shall be deemed to be incorporated herein by reference.

14.20 **Counterparts; Signatures**. This Agreement may be executed in multiple counterparts, all of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Signatures provided by facsimile or e-mail transmission shall be deemed to be original signatures.

[Signature page follows]

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed by their duly authorized representatives, effective as of the Effective Date.

| **AQUESTIVE THERAPEUTICS, INC.** | **ATNAHS PHARMA UK LIMITED** |
|---|---|
| By: _____ | By: _____ |
| Name: | Name: |
| Title: | Title: |

PRODUCT SCHEDULE 1

Product Schedule to the License and Supply Agreement (the "Agreement") dated as of September 26, 2022 by and between Aquestive Therapeutics, Inc. ("Aquestive") and Atnahs Pharma UK Limited ("Pharmanovia").

Capitalized terms used herein and not otherwise defined shall have the meanings given them in the Agreement.

## 1. PRODUCT, API, DOSAGE STRENGTH, FIELD, TERRITORY

1.1 **"API"** means the active pharmaceutical ingredient diazepam.

1.2 "Commercialization Year" shall mean the one year period from the First Commercial Sale, and each annual period thereafter.

1.3 **"Dosage Strength"** means the 5mg, 7.5mg, 10mg, 12.5 mg, 15mg, 17.5mg, and 20mg dosage strengths of the Product.

1.4 "Field" means the treatment of prolonged or acute, convulsive seizures in all ages, or such other definition that is consistent with the foregoing and agreed upon in good faith by the Parties in writing).

1.5 "Product" means diazepam buccal film.

1.6 **"Manufacturing Facility"** means, as of the Effective Date, Aquestive's manufacturing site located at 6465 Ameriplex Drive, Portage, Indiana (IN) 46368, United States (USA), FDA Establishment Number 3004395604.

1.7 **"Territory"** means: (i) the countries of the European Union (as of the Effective Date), Sweden, Switzerland and Norway; (ii) the United Kingdom (England, Scotland, Wales and Northern Ireland); and (iii) the Middle East and North Africa (Algeria, Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates and Yemen).

## 2. PRODUCT TRANSFER PRICE

Aquestive shall Supply quantities of each Unit of the Product to Pharmanovia at the initial Product Transfer Prices below, further to adjustment pursuant to Section 5.2 of the Agreement:

| **Dosage Strength** | **Product Transfer Price** |
|---|---|
| Low Dose (5mg, 7.5mg, 10mg) | $[****]/per Carton* |
| Medium Dose (12.5mg, 15mg) | $[****]/per Carton |
| High Dose (17.5mg, 20mg) | $[****]/per Carton |

*each Carton contains two Units.

## 3. AQUESTIVE PRODUCT MARKS

The Aquestive Product Marks are set forth below:

Libervant™

## 4. PHARMANVOIA MARKS

Valium™

## 5. PRODUCT SHELF LIFE

[****]% of approved shelf life

## 6. AQUESTIVE PRODUCT PATENTS

The Aquestive Product Patents are set forth below:

None.

## 7. PAYMENTS

6.1 Milestone Payments

Non-refundable payments will be due from Pharmanovia to Aquestive as set forth in the table below:

| **Milestone** | | **Milestone Payment (U.S. Dollars)** | **Milestone Payment Due Date** |
|---|---|---|---|
| 1. | Agreement Execution | $3,500,000 | September 30, 2022 |
| 2. | Receipt of First Ex-US Marketing Authorization | $[****] | Within [****] Business Days of receipt of the first Marketing Authorization for the Product within the Territory. |
| 3. | Pricing and Reimbursement Milestone | $[****] | Within [****] Business Days of pricing and reimbursement approval being obtained for the Product from the applicable Regulatory Authority in the first country in the Territory. |

Pharmanovia shall give Aquestive written notice of the achievement of each milestone event in respect of which a milestone payment is due (with the exception of the first milestone event). Following receipt of such notice, Aquestive shall submit an invoice to Pharmanovia, and Pharmanovia and shall pay the corresponding Milestone Payment no later than five (5) Business Days after receipt of such invoice.

5.1 Royalty Fees

Subject to Section 5.3 of the Agreement, Pharmanovia shall pay to Aquestive for each Payment Period a Royalty Fee during the Term with respect to the Product in the Territory in an amount equal to [****] of Net Sales on a quarterly basis.

5.2 Profit Share

In the event that the Profit Share is payable by Pharmanovia, Pharmanovia shall pay to Aquestive for each Payment Period [****]% of Profits on all Products sold in the Territory on a quarterly basis.

5.3 Minimum Volume Commitments

The Minimum Volume Commitment with respect to the Product is as set forth in the table below:

| **Time Period** | | **Minimum Volume Commitment** |
|---|---|---|
| 1. | Commercialization Year 1 | None |
| 2. | Commercialization Year 2 | [****] Units |
| 3. | Commercialization Year 3 | [****] Units |
| 4. | Commercialization Year 4 | [****] Units |
| 5. | Commercialization Year 5 and beyond | To be discussed in good faith by the Parties. The Parties agree if the Minimum Volume Commitment in Commercialization Year [****] is less than in Commercialization Year [****], to discuss the Product Transfer Price in good faith. |

In the event Pharmanovia fails to meet the Minimum Volume Commitment set forth above for a given time period, Pharmanovia shall have the option to make up the shortfall in the number of Units purchased by no later than June 30 following the end of the time period.

## 8. ADDITIONAL TERMS

Pharmanovia shall issue purchase orders in whole batch increments of the following number of Units:

| **Dosage Strength** | **Number of Units** |
|---|---|
| 5mg | [****] |
| 7.5mg | [****] |
| 10mg | [****] |
| 12.5mg | [****] |
| 15mg | [****] |
| 17.5mg | [****] |

| | |
|---|---|
| 20mg | [****] |

If required by Pharmanovia, Aquestive can carton up to [****] different printed cartons, or SKUs, per manufacturing film batch, for a $[****] charge for the first [****] SKUs and another $[****] for any additional SKUs and up to a maximum of [****] SKUs. The minimum secondary quantity per SKU is [****] cartons.

## Schedule 1.13

## Aquestive Patents

| Docket No. | Country | Status | Title | Appln No. | Appln Date | Publn. No. | Publn. Date |
|---|---|---|---|---|---|---|---|
| 1199-4 PCT/EPO/DIV (2) | European Patent Convention - (EP) | Filed - (F) | THIN FILM WITH NON-SELF-AGGREGATING UNIFORM HETEROGENEITY | 19169349.8 | 10/11/2002 | 3542793 | 9/25/2019 |
| 1199-26 PCT/EPO/DIV II | European Patent Convention - (EP) | Filed - (F) | POLYETHYLENE OXIDE-BASED FILMS AND DRUG DELIVERY SYSTEMS MADE THEREFROM | 17151005.0 | 5/28/2004 | 3210601 | 8/30/2017 |
| [****] | [****] | [****] | [****] | [****] | [****] | | |
| AQU-013WOEP | European Patent Convention - (EP) | Filed - (F) | PHARMACEUTICAL COMPOSITIONS WITH ENHANCED PERMEATION | 17723617.1 | 12/05/2018 | 3452024 | 03/13/2019 |
| [****] | [****] | [****] | [****] | [****] | [****] | | |
| AQU-023WOEP | European Patent Convention - (EP) | Filed - (F) | PHARMACEUTICAL COMPOSITIONS WITH ENHANCED PERMEATION | 18786591.0 | 4/16/2020 | 3687509 | 08/05/2020 |
| [****] | [****] | [****] | [****] | [****] | [****] | | |

| Docket No. | Country | Status | Exp. Date | Title | Appln. No. | Appln. Date | Publn. No. | Publn. Date | Pat. No. | Issue Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 1199-4 B/PCT/EPO/Denmark | Denmark - (DK) | Granted - (G) | 1/30/2024 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Systems Made Therefrom | 04707004.0 | 1/30/2004 | 1587504 | 10/26/2005 | 1587504 | 4/18/2012 |
| 1199-4 B/PCT/EPO/France | France - (FR) | Granted - (G) | 1/30/2024 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Systems Made Therefrom | 04707004.0 | 1/30/2004 | 1587504 | 10/26/2005 | 1587504 | 4/18/2012 |
| 1199-4 B/PCT/EPO/Germany | Germany - (DE) | Granted - (G) | 1/30/2024 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Systems Made Therefrom | 04707004.0 | 1/30/2004 | 602004037401.6 | 10/26/2005 | 1587504 | 4/18/2012 |
| 1199-4 B/PCT/EPO/Hungary | Hungary - (HU) | Granted - (G) | 1/30/2024 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Systems Made Therefrom | 04707004.0 | 1/30/2004 | 1587504 | 10/26/2005 | 1587504 | 4/18/2012 |
| 1199-4 B/PCT/EPO/Ireland | Ireland - (IE) | Granted - (G) | 1/30/2024 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Systems Made Therefrom | 04707004.0 | 1/30/2004 | 1587504 | 10/26/2005 | 1587504 | 4/18/2012 |
| 1199-4 B/PCT/EPO/Switzerland | Switzerland - (CH) | Granted - (G) | 1/30/2024 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Systems Made Therefrom | 04707004.0 | 1/30/2004 | 1587504 | 10/26/2005 | 1587504 | 4/18/2012 |
| 1199-4 B/PCT/EPO/UK | Great Britain - (GB) | Granted - (G) | 1/30/2024 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Systems Made Therefrom | 04707004.0 | 1/30/2004 | 1587504 | 10/26/2005 | 1587504 | 4/18/2012 |
| 1199-4 PCT/EPO/DIV/DE | Germany - (DE) | Granted - (G) | 10/11/2022 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Made Therefrom | 60249871.6 | 10/11/2002 | 2351557 | 8/3/2011 | 2351557 | 4/17/2019 |

| Docket No. | Country | Status | Exp. Date | Title | Appln. No. | Appln. Date | Publn. No. | Publn. Date | Pat. No. | Issue Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 1199-4 PCT/EPO/DIV/ES | Spain - (ES) | Granted - (G) | 10/11/2022 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Made Therefrom | 10182204.7 | 10/11/2002 | 2735512 | 12/19/2019 | 2351557 | 4/17/2019 |
| 1199-4 PCT/EPO/DIV/FR | France - (FR) | Granted - (G) | 10/11/2022 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Made Therefrom | 10182204.7 | 10/11/2002 | 2351557 | 8/3/2011 | 2351557 | 4/17/2019 |
| 1199-4 PCT/EPO/DIV/IE | Ireland - (IE) | Granted - (G) | 10/11/2022 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Made Therefrom | 10182204.7 | 10/11/2002 | 2351557 | 8/3/2011 | 2351557 | 4/17/2019 |
| 1199-4 PCT/EPO/DIV/IT | Italy - (IT) | Granted - (G) | 10/11/2022 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Made Therefrom | 502019000044094 | 10/11/2002 | 2351557 | 8/3/2011 | 2351557 | 4/17/2019 |
| 1199-4 PCT/EPO/DIV/UK | Great Britain - (GB) | Granted - (G) | 10/11/2022 | Thin Film With Non-Self Aggregating Uniform Heterogeneity And Drug Delivery Made Therefrom | 10182204.7 | 10/11/2002 | 2351557 | 8/3/2011 | 2351557 | 4/17/2019 |
| 1199-15 PCT/EPO/DIV/CH | Switzerland - (CH) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 11157819.1 | 10/11/2002 | 2332523 | 6/15/2011 | 2332523 | 9/11/2013 |
| 1199-15 PCT/EPO/DIV/Denmark | Denmark - (DK) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 11157819.1 | 10/11/2002 | 2332523 | 6/15/2011 | 2332523 | 9/11/2013 |

| Docket No. | Country | Status | Exp. Date | Title | Appln. No. | Appln. Date | Publn. No. | Publn. Date | Pat. No. | Issue Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 1199-15 PCT/EPO/DIV/France | France - (FR) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 11157819.1 | 10/11/2002 | 2332523 | 6/15/2011 | 2332523 | 9/11/2013 |
| 1199-15 PCT/EPO/DIV/Germany | Germany - (DE) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 11157819.1 | 10/11/2002 | 60245533.2 | 6/15/2011 | 2332523 | 9/11/2013 |
| 1199-15 PCT/EPO/DIV/Italy | Italy - (IT) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 502013902213865 | 10/11/2002 | 1115781 9.1 | 6/15/2011 | 2332523 | 9/11/2013 |
| 1199-15 PCT/EPO/DIV/Spain | Spain - (ES) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 11157819.1 | 10/11/2002 | 2332523 | 6/15/2011 | 2332523 | 9/11/2013 |
| 1199-15 PCT/EPO/DIV/Sweden | Sweden - (SE) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 11157819.1 | 10/11/2002 | 2332523 | 6/15/2011 | 2332523 | 9/11/2013 |

| Docket No. | Country | Status | Exp. Date | Title | Appln. No. | Appln. Date | Publn. No. | Publn. Date | Pat. No. | Issue Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 1199-15 PCT/EPO/DIV/U.K. | Great Britain - (GB) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 11157819.1 | 10/11/2002 | 2332523 | 6/15/2011 | 2332523 | 9/11/2013 |
| 1199-15 PCT/EPO/France | France - (FR) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 02801042.9 | 10/11/2002 | 1458367 | 4/17/2003 | 1458367 | 12/14/2011 |
| 1199-15 PCT/EPO/Germany | Germany - (DE) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 02801042.9 | 10/11/2002 | 60241767.8 | 4/17/2003 | 1458367 | 12/14/2011 |
| 1199-15 PCT/EPO/Ireland | Ireland - (IE) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 02801042.9 | 10/11/2002 | 1458367 | 4/17/2003 | 1458367 | 12/14/2011 |
| 1199-15 PCT/EPO/Switzerland | Switzerland - (CH) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 02801042.9 | 10/11/2002 | 1458367 | 4/17/2003 | 1458367 | 12/14/2011 |

| Docket No. | Country | Status | Exp. Date | Title | Appln. No. | Appln. Date | Publn. No. | Publn. Date | Pat. No. | Issue Date |
|---|---|---|---|---|---|---|---|---|---|---|
| 1199-15 PCT/EPO/UK | Great Britain - (GB) | Granted - (G) | 10/11/2022 | Uniform Films For Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions | 02801042.9 | 10/11/2002 | 1458367 | 4/17/2003 | 1458367 | 12/14/2011 |

**Schedule 1.47A**

**Aquestive Housemark**

**Schedule 1.47B**

**Pharmanovia Housemark**

**Exhibit 31.1**

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

I, Daniel Barber, 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 1, 2022

/s/ Daniel Barber
Daniel Barber
*President and Chief Executive Officer*
*(Principal Executive Officer)*

**Exhibit 31.2**

**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 1, 2022

/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, Daniel Barber, 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, 2022, 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 1, 2022

/s/ Daniel Barber
Daniel Barber
*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, 2022, 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 1, 2022

/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.