

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 March 31, 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**  
(State or other jurisdiction of Incorporation or organization)

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

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

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

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

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 April 25, 2022 was 41,912,952.

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**PART I – FINANCIAL INFORMATION**

**Item 1. FINANCIAL STATEMENTS (Unaudited)**

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

	<u>March 31, 2022</u>	<u>December 31, 2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,736	\$ 28,024
Trade and other receivables, net	19,896	12,120
Inventories, net	4,629	4,038
Prepaid expenses and other current assets	3,324	3,077
<b>Total current assets</b>	<b>42,585</b>	<b>47,259</b>
Property and equipment, net	4,496	5,055
Right-of-use assets, net	2,524	2,725
Intangible assets, net	38	51
Other non-current assets	6,886	6,903
<b>Total assets</b>	<b>\$ 56,529</b>	<b>\$ 61,993</b>
<b>Liabilities and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 8,496	\$ 8,314
Accrued expenses	4,868	8,736
Lease liabilities, current	926	899
Deferred revenue, current	1,599	765
Liability related to the sale of future revenue, current	1,732	1,225
Loans payable, current	6,563	2,025
<b>Total current liabilities</b>	<b>24,184</b>	<b>21,964</b>
Loans payable, net	47,680	51,551
Liability related to the sale of future revenue, net	60,346	59,059
Lease liabilities	1,710	1,946
Deferred revenue	13,890	7,122
Other non-current liabilities	1,862	2,485
<b>Total liabilities</b>	<b>149,672</b>	<b>144,127</b>
<b>Contingencies (Note 19)</b>		
Stockholders' deficit:		
Common stock, \$0.001 par value. Authorized 250,000,000 shares; 41,620,388 and 41,228,736 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	41	41
Additional paid-in capital	176,833	174,621
Accumulated deficit	(270,017)	(256,796)
<b>Total stockholders' deficit</b>	<b>(93,143)</b>	<b>(82,134)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 56,529</b>	<b>\$ 61,993</b>

See accompanying notes to the condensed consolidated financial statements.

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2022</b>	<b>2021</b>
Revenues	\$ 12,270	\$ 11,122
Costs and expenses:		
Manufacture and supply	4,214	2,757
Research and development	4,773	3,659
Selling, general and administrative	13,021	13,231
Total costs and expenses	22,008	19,647
Loss from operations	(9,738)	(8,525)
Other expenses:		
Interest expense	(1,618)	(2,761)
Interest expense related to the sale of future revenue, net	(1,861)	(3,334)
Interest and other expense, net	(3)	(52)
Net loss before income taxes	(13,220)	(14,672)
Income taxes	—	—
Net loss	\$ (13,220)	\$ (14,672)
Comprehensive loss	\$ (13,220)	\$ (14,672)
Net loss per share - basic and diluted	\$ (0.32)	\$ (0.41)
Weighted-average number of common shares outstanding - basic and diluted	41,465,798	35,563,275

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	<u>41,620,388</u>	<u>41</u>	<u>176,833</u>	<u>(270,017)</u>	<u>(93,143)</u>
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	<u>36,241,358</u>	<u>36</u>	<u>149,095</u>	<u>(200,929)</u>	<u>(51,798)</u>

See accompanying notes to the condensed consolidated financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Operating activities:</b>		
Net loss	\$ (13,220)	\$ (14,672)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation, amortization, and impairment	727	755
Share-based compensation	913	1,507
Amortization of debt issuance costs and discounts	40	1,184
Interest expense related to the sale of future revenue, net	1,836	3,302
Other, net	(100)	167
Changes in operating assets and liabilities:		
Trade and other receivables, net	(7,678)	(3,374)
Inventories, net	(591)	(338)
Prepaid expenses and other assets	(230)	(535)
Accounts payable	182	(402)
Accrued expenses and other liabilities	(3,963)	(2,501)
Deferred revenue	7,602	810
Net cash used for operating activities	<u>(14,482)</u>	<u>(14,097)</u>
<b>Investing activities:</b>		
Capital expenditures	(104)	(103)
Net cash used for investing activities	<u>(104)</u>	<u>(103)</u>
<b>Financing activities:</b>		
Proceeds from issuance of common stock, net	1,298	9,891
Net cash provided by financing activities	<u>1,298</u>	<u>9,891</u>
Net decrease in cash and cash equivalents	(13,288)	(4,309)
Cash and cash equivalents at beginning of period	28,024	31,807
Cash and cash equivalents at end of period	\$ 14,736	\$ 27,498
Supplemental disclosures of cash flow information:		
Cash payments for interest	\$ 1,609	\$ 1,610

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 medicines to solve patients’ problems with current standards of care, providing transformative products to improve their lives. The Company is developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. The Company has five products on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut Syndrome. Our licensees market their products in the U.S. and around the world. 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 a late-stage proprietary product pipeline focused on treating diseases of the central nervous system, or CNS, and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. 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 of shares of 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 of shares of common stock under the ATM facility. For the three months ended March 31, 2022, the Company sold 391,652 shares which provided net proceeds of approximately \$1,298 after deducting commissions and other transaction costs of \$62. For the three months ended March 31, 2021, the Company sold 1,672,104 shares which provided net proceeds of approximately \$9,891 after deducting commissions and other transaction costs of \$306. This ATM facility has approximately \$36,043 available at March 31, 2022.

**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 March 31, 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 is currently evaluating the impact of the adoption of this guidance on its consolidated financial statements.

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

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. The accounting standard update was issued to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The new accounting guidance is effective for the Company beginning after December 15, 2022. Early adoption is permitted. The Company does not expect the new accounting guidance to have a material impact on the Company's consolidated financial statements.

### Note 3. Risks and Uncertainties

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 March 31, 2022, the Company had \$14,736 of cash and cash equivalents.

The Company has experienced a history of net losses. The Company's accumulated deficits totaled \$270,017 as of March 31, 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 March 31, 2022, the Company sold 7,873,071 shares which generated net cash proceeds of approximately \$37,131, net of commissions and other transaction costs of \$1,826. For the three months ended March 31, 2022, the Company sold 391,652 shares which provided net proceeds of approximately \$1,298, net of commissions and other transaction costs of \$62. This ATM facility has approximately \$36,043 available at March 31, 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. See Note 20 for details.

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 March 31, 2022, and December 31, 2021, such contract assets were \$1,823 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 March 31, 2022, and December 31, 2021, such contract liabilities were \$15,489 and \$7,887, respectively.

The Company's revenues were comprised of the following:

	Three Months Ended March 31,	
	2022	2021
Manufacture and supply revenue	\$ 9,171	\$ 6,511
License and royalty revenue	506	2,361
Co-development and research fees	403	438
Proprietary product sales, net	2,190	1,812
<b>Total revenues</b>	<b>\$ 12,270</b>	<b>\$ 11,122</b>

*Disaggregation of Revenue*

The following table provides disaggregated net revenue by geographic area:

	Three Months Ended March 31,	
	2022	2021
United States	\$ 11,081	\$ 9,850
Ex-United States	1,189	1,272
<b>Total revenues</b>	<b>\$ 12,270</b>	<b>\$ 11,122</b>

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:

	March 31, 2022	December 31, 2021
Trade receivables	\$ 18,619	\$ 9,678
Contract and other receivables	1,823	3,087
Less: allowance for doubtful accounts	(40)	(40)
Less: sales-related allowances	(506)	(605)
<b>Trade and other receivables, net</b>	<b>\$ 19,896</b>	<b>\$ 12,120</b>

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

	March 31, 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	—	—
<b>Allowance for doubtful accounts at end of the period</b>	<b>\$ 40</b>	<b>\$ 40</b>

*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 three months ended March 31, 2022:

	<b>Total Sales Related Allowances</b>	
Balance at December 31, 2021	\$	605
Provision		178
Payments / credits		(277)
Balance at March 31, 2022	\$	506

Total reductions of gross product sales from sales-related allowances and accruals were \$178 for the three months ended March 31, 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 \$506 and \$2,563, respectively, as of March 31, 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 three months ended March 31, 2022, Indivior exceeded the 10% threshold for revenue and represented approximately 78% of total revenue. As of March 31, 2022, Indivior and Haisco Pharmaceutical Group Co., Ltd. ("Haisco") exceeded the 10% threshold for outstanding receivables and represented 43% and 34%, respectively, of outstanding receivables. For the three months ended March 31, 2021, Indivior exceeded the 10% threshold for revenue and represented approximately 64% 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. See Note 20 for details on the Company's licensing and supply agreement with Haisco.

#### **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<sup>®</sup>, which was approved by the FDA on May 21, 2020 and commercially launched by Sunovion in September 2020. The FDA approval triggered Sunovion's obligation to remit a payment of \$4,000 which was received in September 2020 and was included in License and royalty revenues for the year ended December 31, 2020.

In consideration of the rights granted to Sunovion under the Sunovion License Agreement, the Company 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 March 31, 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 March 31, 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 Pharmaceutical Group Co., Ltd., a Chinese limited company listed on the Shenzhen Stock Exchange ("Haisco") 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 and Aquestive will serve as the exclusive sole manufacturer and supplier for Exservan in China. Under the Haisco Agreement, Haisco is obligated to pay the Company a \$7,000 upfront cash payment, regulatory milestone payments, and double-digit royalties on net sales of Exservan in China and the Company will earn manufacturing revenue upon the sale of Exservan in China, as the exclusive supplier of Exservan.

**Note 6. Financial Instruments – Fair Value Measurements**

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

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

The carrying amounts reported in the balance sheets for trade and other receivables, prepaid and other current assets, accounts payable and accrued expenses, and deferred revenue approximate their fair values based on the short-term maturity of these assets and liabilities.

The Company granted warrants to certain note holders in connection with its debt repayment and debt refinancing during 2020 and 2019, respectively. Those warrants were valued based on Level 3 inputs and their fair value was based primarily on an independent third-party appraisal prepared as of the grant date consistent with generally accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held Company Equity Securities Issued as Compensation. See Note 14 Warrants for further information on these warrants.

The Company's 12.5% Senior Secured Notes contain a repurchase offer or put option which gives holders of the option the right, but not the obligation, to require the Company to redeem on the Notes up to a capped portion of milestone payments resulting from the Monetization Agreement. This put option was valued based on Level 3 inputs and its fair value was based primarily on an independent third-party appraisal consistent with generally accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants Accounting and Valuation Guide. See Note 13 12.5% Senior Secured Notes and Loans Payable for further discussion.

**Note 7. Inventories, Net**

The components of Inventory, net are as follows:

	<b>March 31, 2022</b>	<b>December 31, 2021</b>
Raw material	\$ 1,437	\$ 1,442
Packaging material	1,192	1,414
Finished goods	2,000	1,182
Total inventory, net	<u>\$ 4,629</u>	<u>\$ 4,038</u>

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

	Useful Lives	March 31, 2022	December 31, 2021
Machinery	3-15 years	\$ 19,302	\$ 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		1,214	1,162
		45,019	44,915
Less: accumulated depreciation and amortization		(40,523)	(39,860)
Total property and equipment, net		\$ 4,496	\$ 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 \$714 and \$743 for the three-month periods ended March 31, 2022 and 2021, 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 1.0 and 4.5 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-months ended March 31, 2022, total operating lease expenses totaled \$419, including variable lease expenses such as common area maintenance and operating costs of \$96. For the three-months ended March 31, 2021, total operating lease expenses totaled \$433, including variable lease expenses such as common area maintenance and operating costs of \$119.

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

Remainder of 2022	\$	972
2023		944
2024		565
2025		565
2026		424
Total future lease payments		3,470
Less: imputed interest		(834)
Total operating lease liabilities	\$	<u>2,636</u>

**Note 10. Intangible Assets, Net**

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

	March 31, 2022	December 31, 2021
Purchased technology-based intangible	\$ 2,358	\$ 2,358
Purchased patent	509	509
	<u>2,867</u>	<u>2,867</u>
Less: accumulated amortization	(2,829)	(2,816)
Intangible assets, net	<u>38</u>	<u>51</u>

Amortization expense was \$13 and \$13 for each of the three-month periods ended March 31, 2022 and 2021. During the remaining life of the purchased patent, estimated annual amortization expense is \$50 in 2022.

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

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

	March 31, 2022	December 31, 2021
Royalty receivable	6,000	6,000
Other	886	903
Total other non-current assets	<u>\$ 6,886</u>	<u>\$ 6,903</u>

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 six 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:

	March 31, 2022	December 31, 2021
Accrued compensation	\$ 1,600	\$ 5,965
Real estate and personal property taxes	469	349
Accrued distribution expenses	2,563	2,224
Other	236	198
<b>Total accrued expenses</b>	<b>\$ 4,868</b>	<b>\$ 8,736</b>

**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 March 31, 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 March 31, 2022. Based on the valuation study, the put option was valued at \$133, of which \$33 has been recorded in Accrued expenses and \$100 has been recorded in Other non-current liabilities. The embedded put option is deemed to be a derivative under ASC 815 *Derivatives and Hedging*, which requires the recording of the embedded put option at fair value and subject to remeasurement at each reporting period. In addition, as of the closing of this transaction, the Company issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of its common stock.

On August 6, 2021, pursuant to the Third Supplemental Indenture, the holders of the 12.5% Notes extended to June 30, 2022 from December 31, 2021, the Company's ability to access, at the Company's option, \$30,000 of 12.5% Notes re-openers under the Indenture. The first \$10,000 of 12.5% Notes represents a commitment of such amount by current holders of 12.5% Notes, at the option of the Company, contingent upon FDA approval of the Company's product candidate Libervant (diazepam) Buccal Film for the management of seizure clusters. A second \$20,000 12.5% Notes re-opener represents a right, at the Company's option, to market to current holders of the Company's 12.5% Notes, and or other lenders, additional 12.5% Notes up

to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that the Company accesses these re-openers, it will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of the Company's common stock at the warrant grant date.

The 12.5% Notes provide a stated fixed interest rate of 12.5%, payable quarterly in arrears, with the initial quarterly principal repayment of 12.5% Notes due on September 30, 2021 and the final quarterly payment due at maturity on June 30, 2025. 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 March 31, 2022, the Company recorded its principal payments as Loans payable, net on its Condensed Consolidated Balance Sheet.

A debt maturity table is presented below:

Remainder of 2022	\$	—
2023		18,025
2024		21,888
2025		11,587
<b>Total</b>	<b>\$</b>	<b>51,500</b>

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

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

On October 7, 2021, the Company entered into the Fourth Supplemental Indenture by and among the Company and U.S. Bank National Association, as Trustee (the "Trustee") and collateral agent thereunder, to the Indenture, dated as of July 15, 2019 (the "Base Indenture" and, as supplemented by the First Supplemental Indenture, the Second Supplemental Indenture, and the Third Supplemental Indenture, the "Indenture"), by and between the Company and the Trustee in connection with the 12.5% Senior Secured Notes due 2025 of the Company (the "Notes"). Pursuant to the Fourth Supplemental Indenture, the amortization schedule for the 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 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 Notes (the "Consent Fee Letter"), pursuant to which the Company has agreed to pay the holders of the Notes an additional cash payment ("Consent Fee") of \$2,700 in the aggregate, payable in four quarterly payments beginning May 15, 2022. The Company has recorded the current portion of the Consent Fee as Loans payable, current, and the long-term portion of the Consent Fee as Other non-current liabilities 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 months ended March 31, 2022 were \$4, while comparative amortization expenses for the three months ended March 31, 2021 were \$1,152. Unamortized deferred debt issuance costs and deferred debt discounts totaled \$39 and \$43 as of March 31, 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 the Company's common stock at \$0.001 per share and included specified registration rights. Management estimated the fair value of the Initial Warrants to be \$6,800 and the Additional Warrants to be \$735, each based on an assessment by an independent third-party appraiser.

The fair value of the respective warrants is treated as a debt discount, amortizable over the term of the respective warrants, with the unamortized 12.5% Notes portion applied to reduce the aggregate principal amount of the 12.5% Notes in the Company's unaudited condensed balance sheet. Additionally, since the warrants issued do not provide warrant redemption or put rights within the control of the holders that could require the Company to make a payment of cash or other assets to satisfy the obligations under the warrants, except in the case of a “cash change in control”, the fair value attributed to the warrants is presented in Additional Paid-in Capital in Company's unaudited condensed balance sheet. There were no warrants exercised during the three-months ended March 31, 2022 or 2021, respectively.

#### **Note 15. Sale of Future Revenue**

On November 3, 2020, the Company entered into the Monetization Agreement with Marathon. Under the terms of the Monetization Agreement, the Company sold all of its contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the FDA on May 21, 2020. In exchange for the sale of these rights, the Company received an upfront payment of \$40,000 and an additional payment of \$10,000 through the achievement of the first milestone. The Company has received an aggregate amount of \$50,000 through March 31, 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 each of the next eight years. In connection with the Monetization Agreement, the Company performed an assessment under ASC 860, *Transfer and Servicing* to determine whether the existing receivable was transferred to Marathon and concluded that the receivable was not transferred.

As royalties are remitted to Marathon from Sunovion, the collection of the royalty receivable and balance of the liability related to the sale of future revenue will be effectively repaid over the life of the agreement. In order to determine the amortization of the liability related to the sale of future revenue, the Company is required to estimate the total amount of future royalty and milestone payments to Marathon over the life of the Monetization Agreement and contingent milestone payments from Marathon to the Company. The sum of future royalty payments less the \$50,000 in proceeds received and future contingent payments will be recorded as interest expense over the life of the Monetization Agreement. At execution, the estimate of this total interest expense resulted in an effective annual interest rate of approximately 24.9%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the life of the Monetization Agreement. The Company will periodically assess the estimated royalty and milestone payments to Marathon from Sunovion and contingent milestone payments from Marathon to the Company. To the extent the amount or timing of such payments is materially different from the original estimates, an adjustment will be recorded



prospectively to increase or decrease interest expense. There are a number of factors that could materially affect the amount and timing of royalty and milestone payments to Marathon from Sunovion, and correspondingly, the amount of interest expense recorded by the Company, most of which are not under the Company's control. Such factors include, but are not limited to, changing standards of care, the initiation of competing products, manufacturing or other delays, generic competition, intellectual property matters, adverse events that result in government health authority imposed restrictions on the use of products, significant changes in foreign exchange rates as the royalties remitted to Marathon are made in U.S. dollars (USD) while a portion of the underlying sales of KYNMOBI will be made in currencies other than USD, and other events or circumstances that are not currently foreseen. Changes to any of these factors could result in increases or decreases to both royalty revenue and interest expense related to the sale of future revenue. Based on the current forecast by Sunovion of estimated KYNMOBI sales as of March 31, 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 for the three months ended March 31, 2022:

Liability related to the sale of future revenue, net at December 31, 2021	\$	60,284
Royalties related to the sale of future revenue		(92)
Amortization of issuance costs		50
Interest expense related to the sale of future revenue		1,836
Liability related to the sale of future revenue, net (includes current portion of \$1,732)	\$	<u>62,078</u>

**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 months ended March 31, 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 March 31,	
	2022	2021
<b>Numerator:</b>		
Net loss	\$ (13,220)	\$ (14,672)
<b>Denominator:</b>		
Weighted-average number of common shares – basic	41,465,798	35,563,275
Loss per common share – basic and diluted	\$ (0.32)	\$ (0.41)

As of March 31, 2022 and 2021, respectively, the Company's potentially dilutive instruments included 5,259,847 and 3,905,192 options to purchase common shares and 166,700 and 13,491 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 March 31, 2022 and 2021, were potentially dilutive warrants for the purchase of 1,714,429 for both periods.

**Note 17. Share-Based Compensation**

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

	Three Months Ended March 31,	
	2022	2021
Manufacture and supply	\$ 48	\$ 82
Research and development	169	232
Selling, general and administrative	696	1,193
Total share-based compensation expenses	<u>\$ 913</u>	<u>\$ 1,507</u>
Share-based compensation from:		
Restricted stock units	\$ —	\$ 38
Stock options	913	1,469
Employee stock purchase plan	—	—
Total share-based compensation expenses	<u>\$ 913</u>	<u>\$ 1,507</u>

**Share-Based Compensation Equity Awards**

The following tables provide information about the Company's restricted stock unit and stock option activity during the three-month period ended March 31, 2022:

<u>Restricted Stock Unit Awards (RSUs):</u>	<u>Number of Units</u> (in thousands)	<u>Weighted Average Grant Date Fair Value</u>
Unvested as of December 31, 2021	—	\$ —
Granted	166	\$ 2.55
Vested	—	\$ —
Forfeited	—	\$ —
Unvested as of March 31, 2022	<u>166</u>	<u>\$ —</u>
Grant date fair value of shares vested during the period	\$ —	
Unrecognized compensation costs as of March 31, 2022	<u>\$ 377</u>	

<u>Stock Option Awards:</u>	<u>Number of Options</u> (in thousands)	<u>Weighted Average Exercise Price</u>
Outstanding as of December 31, 2021	4,146	\$ 7.28
Granted	1,125	\$ 2.55
Exercised, Forfeited, Expired	<u>(11)</u>	<u>\$ 4.98</u>
Outstanding as of March 31, 2022	<u>5,260</u>	<u>\$ 6.27</u>
Vested and expected to vest as of March 31, 2022	5,047	\$ 6.39
Exercisable as of March 31, 2022	2,496	\$ 9.25

The fair values of stock options granted during the three months ended March 31, 2022 were estimated using the Black-Scholes pricing model based on the following assumptions:

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

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2022 was \$2.03. During the three-month period ended March 31, 2022, stock options were granted with an exercise price of \$2.55 and

accordingly, given the Company's share price of \$2.61 at March 31, 2022, the intrinsic value provided by certain shares granted during this period was de minimus.

As of March 31, 2022, \$5,098 of unrecognized compensation expense related to non-vested stock options is expected to be recognized over a weighted average period of 2.07 years from the date of grant.

As of March 31, 2022, \$377 of unrecognized compensation expense related to unvested restricted stock units is expected to be recognized over a weighted average period of 2.94 years from the date of grant.

#### **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 March 31, 2022 and 2021, the Company recorded no income tax benefit from its pretax losses of \$13,220 and \$14,672.

The primary factor impacting the effective tax rate for the three and three months ended March 31, 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. The Company is not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or losses, if any, in this matter.

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

On February 7, 2018, the Company and Indivior initiated a lawsuit against Teva Pharmaceuticals USA, Inc. ("Teva") asserting infringement of the '221 patent. On April 3, 2018, the Company and Indivior initiated a separate lawsuit against Teva asserting infringement of the '305 patent. On May 29, 2018, the lawsuits regarding the '221 and '305 patents were consolidated which was originally initiated by Indivior against Teva asserting infringement of the '454 patent. The parties agreed that the case would be governed by the final judgment against Dr. Reddy's (described above). The Company is not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or losses, if any, in this matter.

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

On September 14, 2017, Indivior initiated a lawsuit against Alvogen Pine Brook LLC (“Alvogen”) asserting infringement of the ’454 patent. On February 7, 2018, the Company and Indivior filed an Amended Complaint, adding 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. 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 Commercial 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 will be held on May 18, 2022. No trial date has yet been set. The Company is not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

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

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

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 us and Indivior in the Eastern District of Pennsylvania alleging facts similar to those at issue in the Antitrust Case and the Suboxone MDL described above, which lawsuit was assigned to the same judge that is presiding over Antitrust Case and Suboxone MDL. Humana's Complaint alleges five causes of action against us, including conspiracy to violate the RICO Act, fraud under state law, unfair and deceptive trade practices under state law, insurance fraud, and unjust enrichment.

On September 21, 2020, Centene Corporation ("Centene") and other related insurance payors filed a similar lawsuit against us and Indivior in the Eastern District of Missouri. The counsel representing Humana is also representing Centene. On September 21, 2020, the Centene action was provisionally transferred to the Eastern District of Pennsylvania by the United States Judicial Panel on Multidistrict Litigation. 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 will be held on June 17, 2022. The Company is not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

#### Neurelis IPR 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 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. Plaintiff's opposition brief is due May 25, 2022, and the Company's reply brief is due June 27, 2022. 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 April 1 through April 30, 2022 and sold 318,156 shares which generated net proceeds of approximately \$505.

##### **Lincoln Park Purchase Agreement**

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 its common stock from time to time over the 36-month term of the Lincoln Park Purchase Agreement. Concurrently with entering into the Lincoln Park Purchase Agreement, the Company also entered into a registration rights agreement with Lincoln Park, pursuant to which the Company agreed to register the sale of the shares of its common stock that have been and may be issued to Lincoln Park under the Lincoln Park Purchase Agreement pursuant to its existing shelf registration statement on Form S-3 or a new registration statement. 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.

Since inception through April 30, 2022, the Company issued 403,982 shares which generated sale proceeds of approximately \$707 in connection with the Lincoln Park Purchase Agreement.

### **Haisco Receivable**

The Company entered into a License, Development and Supply Agreement with Haisco Pharmaceutical Group Co., Ltd., a Chinese limited company listed on the Shenzhen Stock Exchange ("Haisco") 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 and Aquestive will serve as the exclusive sole manufacturer and supplier for Exservan in China. Pursuant to the Haisco License Agreement, Haisco has been appointed to serve as Aquestive's agent for matters relating to the commercialization of Exservan in China, including obtaining approval to market and sell ("Marketing Authorization") Exservan in China. Subsequent to the execution of the Haisco Agreement in March 2022, the Chinese equivalent of the FDA (the "NMPA") raised an issue regarding the named holder of the U.S. New Drug Application (NDA) for Exservan in relation to the application for Marketing Authorization of Exservan in China. It is not clear whether the NMPA will require that Aquestive be the holder of the NDA in order to approve the Marketing Authorization for Exservan in China, or whether the NMPA will find that Aquestive's qualifications as the exclusive licensor, manufacturer and innovator of Exservan will be sufficient for the NMPA to approve Aquestive as the drug sponsor for Exservan in China and grant the Marketing Authorization for Exservan in China. Prior to entering into the Haisco Agreement, the Company had assigned the NDA for Exservan to another third-party in connection with a license agreement in the U.S. for Exservan and is not currently the named holder of the NDA. The Company is collaborating with Haisco to resolve this issue with the NMPA. As a result of this issue, the Company has not received the \$7,000 upfront payment due from Haisco under the Haisco Agreement and expects to agree with Haisco to extend the period of time under which Haisco is obligated to make said upfront payment consistent with the decision of the NMPA on this issue, or as otherwise agreed to by the Company and Haisco.

### **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 Libervant™, AQST-109 and AQST-108 through the regulatory and development pipeline; the focus on growing our commercial sales of Sympazan® and continuing to manufacture Suboxone®, Exservan® and other licensed products; the ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application ("NDA") for Libervant and obtain FDA approval of Libervant for U.S. market access; the ability to obtain approval from the NMPA of the Marketing Authorization for the sale of Exservan in China and the related risk of receiving payments under the Haisco Agreement; 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, risks associated with our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials; risk of delays in regulatory advancement through the FDA of Libervant and our other drug candidates or failure to receive approval, including the failure to receive orphan drug exclusivity; risk of our ability to demonstrate to the FDA “clinical superiority” within the meaning of the FDA regulations of Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk in obtaining market access for Libervant and our other product candidates for other reasons; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations) and the related risk of the failure to obtain such approval on our ability to access additional funding under the 12.5% Notes; risks and uncertainties 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 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; risk of failure to satisfy all financial and other debt covenants and of any default; short-term and long-term liquidity and cash requirements, cash funding and cash burn; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products including generics, risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and products candidates and product pricing, reimbursement or access therefore; risk of loss of significant customers; risks related to claims and legal proceedings including patent infringement, securities, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; the COVID-19 pandemic and its impact on our business; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting us including those described in the “Risk Factors” section and in other sections included in this Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities and Exchange Commission (SEC). Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. We assume no obligation to update forward-looking statements, or outlook or guidance after the date of this 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 medicines to solve patients’ problems with current standards of care and provide transformative products to improve their lives. We are developing orally administered products to deliver complex molecules, providing novel alternatives to invasive and inconvenient standard of care therapies. Aquestive has five commercialized products on the U.S. market, four licensed products and one stand-alone proprietary product to date, Sympazan® (clobazam) oral film for the treatment of seizures associated with Lennox-Gastaut Syndrome. Our licensees market their products in the U.S. and around the world. 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 a late-stage proprietary product pipeline focused on treating



diseases of the central nervous system, or CNS, and an earlier stage pipeline for the treatment of severe allergic reactions, including anaphylaxis. 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 and proprietary 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®.

#### *Proprietary CNS Product Portfolio*

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

- **Sympazan®** – an oral soluble film formulation of clobazam used for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut syndrome, or LGS, was approved by the FDA on November 1, 2018. We commercially launched Sympazan in December 2018. Sympazan was launched as a precursor and complement to our product candidate Libervant and continues to progress on key performance metrics including prescriber growth, repeat prescribers, quarterly growth in retail shipments and pharmacy claims reimbursements.
- **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 late September 2020, we received a complete response letter ("CRL") from the FDA focusing on doses tested in certain weight groups. At a Type A meeting with the FDA in November 2020, the FDA confirmed that the issues identified in the CRL may be addressed by utilizing modeling and simulations for an updated dosing regimen. We submitted a revised weight-based dosing regimen with modeling and simulations in December 2020. In February 2021, the FDA provided feedback on the December 2020 submission which provided clarity regarding the information that the Agency expected to see in our population pharmacokinetic ("PK") model and the presentation of safety data as it relates specifically to the patient population included in the studies. In June 2021, we resubmitted our New Drug Application ("NDA") to the FDA. In July 2021, the FDA accepted our resubmission filing of the NDA and assigned a Prescription Drug User Fee Act ("PDUFA") target goal date of December 23, 2021. In addition to responding to a number of information requests, the FDA concluded a Postmarketing Adverse Drug Experience (PADE) reporting audit, requested and received additional information about the patent coverage for the product, approved for use the trade name for Libervant, and made recommendations for changes in language related to our packaging. We also completed labeling negotiations of the prescribing information and no additional information was required by the FDA from the Company. Concurrently, we spoke with the FDA Office of Orphan Products Development ("OOPD") and provided additional information supplementing our original correspondence to OOPD. On December 20, 2021, we received notification from the FDA that it was not ready to act by the PDUFA date of December 23, 2021 for the Company's NDA for Libervant and was unable to provide an estimate of the timing of an expected action. Subsequent to the FDA notification, we have had several interactions with the Agency. The Center for Drug Evaluation and Research ("CDER") indicated in correspondence to the Company that CDER had finished its review of the NDA submission and did not require additional information from the Company at this time and that it is actively engaged with other groups in the Agency to reach a decision on the Company's NDA for Libervant based on the regulatory issues related to the approvability of the application. Based on our communications with the Agency, we believe that the regulatory issues at hand are related to orphan drug exclusivity, which are being reviewed by OOPD and the Office of Chief Counsel. The Agency did not provide a timeline or commitment for resolution but reiterated that the Agency did not require additional information from the Company at this time. We appreciate the complexity of the related issues and are prepared to respond to the Agency, if and when needed. We continue to believe that we have provided a strong set of facts supporting a decision by the FDA of clinical superiority to prior approved drugs in that Libervant represents a major contribution to patient care as compared to the device driven rectal and nasal spray alternatives. Preparations are advancing with payer and sales force planning underway for the commercial launch of Libervant, if approved by the FDA for U.S. market access, as soon as possible after approval. We anticipate that capital available within our existing debt facility will be available to support the launch of this product, if approved by the FDA for U.S. market access. However, overcoming the orphan drug marketing exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such marketing exclusivity and approve Libervant for U.S. market access. Further, there can be no assurance that a

competitor will not obtain other FDA marketing exclusivity that blocks U.S. market access for Libervant. Any failure to obtain FDA approval to demonstrate clinical superiority or obtain U.S. market access for Libervant would have a material adverse effect on our business, financial condition and results of operations in 2022 and later. 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.

### 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 beyond CNS indications.

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.

Aquestive commenced Part 3 of the EPIPHAST study for its AQST-109 in April 2022 and expects to complete Part 3 by the end of the second quarter 2022. The purpose of Part 3 is to continue to study the administration of the film under a variety of conditions and further characterize its pharmacokinetics, pharmacodynamics, and safety.

Aquestive plans to conduct one additional study with AQST-109 before its end of phase 2 meeting, anticipated later in the year, based on feedback received from the FDA to its pre-IND meeting. This study will be designed as a repeat dosing EpiPen comparative study and will be conducted during the third quarter 2022. This study will be designed to

show the direct comparison of AQST-109 to EpiPen. We expect to move forward with the manufacture of registration batches, have an additional meeting with the FDA and, based on those studies, begin pivotal studies of AQST-109 by 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 2022 and plan to disclose the indication and path forward for development, once we have received feedback from the agency.
- **AQST-305** – is a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results in the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin, is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of efficacy toward the end of the monthly treatment cycle. We are developing AQST-305 as a non-invasive, pain-free alternative to Sandostatin to reduce treatment burden, healthcare costs and the potential loss of efficacy in the treatment cycle. AQST-305 has shown promising preclinical and human proof of concept results. While we focus our efforts on Libervant, AQST-109, and AQST-108, in the short-term, we have taken the necessary steps to prepare AQST-305 for additional research trials.

#### Licensed Commercial Products and Product Candidates

Our portfolio also includes products and product candidates that we have licensed, or will seek to license, or for which we have licensed our intellectual property for commercialization. In the years ended December 31, 2021 and 2020, our licensed product portfolio generated \$42.3 million and \$40.2 million in revenue to Aquestive, respectively. Those products include:

- **Suboxone**<sup>®</sup> – 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 2.2 billion doses of Suboxone since its launch in 2010. As of March 31, 2022, Suboxone branded products retain approximately 40% film market share as generic film-based products have penetrated this market. We have filed patent infringement lawsuits against certain companies relating to generic film-based products for buprenorphine-naloxone. More details regarding these lawsuits are described in the unaudited financial statements, Note 19. Contingencies, contained herein.
- **Exservan**<sup>™</sup> (riluzole) – an oral film formulation of riluzole, has been developed 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 our exclusive license to Mitsubishi Tanabe Pharma Holdings America, Inc. ("MTHA") for the commercialization in the United States of Exservan. MTHA is a multinational pharmaceutical company with a focus on patients with ALS. Under the terms of the MTHA license agreement, upfront payments were paid to Aquestive with additional payments due upon the occurrence of certain milestone events in advance of launch. Aquestive will also be paid double-digit royalties on net sales of the product in the United States and will earn revenue pursuant to the exclusive supply agreement. The product launched in June 2021. Exservan may potentially fulfill a critical need for ALS patients, given it can be administered safely and easily, twice daily, without water.

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 Pharmaceutical Group 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. Under the Haisco Agreement, Haisco is obligated to pay Aquestive an upfront cash payment, regulatory milestone payments, and double-digit royalties on net sales of Exservan in China and Aquestive will earn manufacturing revenue on the sale of Exservan in China as the exclusive supplier of Exservan in China. See Note 20 for details.

- **KYNMOBI**<sup>®</sup> – 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. We received an aggregate amount of \$50,000 through March 31, 2022 under the Monetization Agreement. Under the Monetization Agreement, additional aggregate contingent payments of up to \$75,000 may be due us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential gross proceeds under the Monetization Agreement of \$125,000. Based on the current forecast by Sunovion of estimated KYNMOBI sales as of March 31, 2022, the Company may not receive any of the additional aggregate contingent payments under the Monetization agreement.
- **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. 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**<sup>™</sup> – 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.

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

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

There have been no material changes to our critical accounting policies and use of estimates as previously disclosed in our 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. We currently sell Sympazan through wholesalers for distribution through retail and specialty pharmacies. Revenues from sales of proprietary product are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and co-pay support redemptions, each of which are described in more detail below. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale. We include these estimated amounts in connection with the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized for such transaction will not occur, or when the uncertainty associated with the variable consideration is resolved. The calculation of some of these items requires management to make estimates based on sales data, historical return data, contracts and other related information that may become known in the future. The adequacy of these provisions is reviewed on a quarterly basis.

### *Costs and Expenses*

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

### *Manufacture and Supply Costs and Expenses*

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

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

We expect to continue to seek to rationalize and manage costs to reflect the declining production volumes of Suboxone. We reduced the cost of manufacturing and supply in late 2019 and continued throughout 2020 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 our proprietary product, Sympazan launched in December 2018. In addition to our proprietary products coming online, we may add licensee products which may need additional resources to manufacture. If such growth should occur for higher volume product opportunities such as Suboxone, we would incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from higher manufactured volumes from proprietary and licensed products.

#### *Research and Development Expenses*

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

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

We expect our research and development expenses to continue to be significant over the next several years as we continue to develop existing product candidates such as AQST-109 AQST-108, AQST-305 and others, and we identify and develop or acquire additional product candidates and technologies. We may hire or engage additional skilled colleagues or third parties to perform these activities, conduct clinical trials and ultimately seek regulatory approvals for any product candidate that successfully completes those clinical trials.

#### *Selling, General and Administrative Expenses*

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

A significant portion of selling, general and administrative expenses relates to the sale and marketing of our proprietary product, Sympazan. Sympazan is the precursor and complement to the launch of Libervant, assuming that it is approved and granted U.S. market access by the FDA. We believe there is a very high degree of overlap and correlation between prescribers of Sympazan and the likely prescribers of an approved Libervant. While Sympazan continues to grow, we will continue to rationalize its contribution to move towards profitability while continuing to introduce epilepsy prescribers and patients to Aquestive and PharmFilm® technology in advance of the anticipated launch of Libervant, assuming FDA approval

for U.S. market access, which cannot be assured. The current commercial organization would begin the launch of Libervant, subject to its approval for U.S. market access, shortly after its approval. Until a Libervant launch is certain, we do not plan to increase the costs of our commercial organization and expect to continue to improve the efficiency of the Sympazan commercial investments.

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

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

- Seeking to obtain the approval and subsequent launch of Libervant, subject to approval by the FDA for U.S. market access, which cannot be assured;
- Continuing the development of AQST-109 and AQST-108 along the 505(b)(2) pathway; and
- Growing the revenue contribution from Sympazan as a first step to position Aquestive in the epilepsy community.

#### *Interest Expense*

Interest expense consists of interest costs on our 12.5% Notes at a fixed rate of 12.5%, payable quarterly, as well as amortization of loan costs and the debt discount. The 12.5% Notes are discussed in Note 13, 12.5% Senior Secured Notes due 2025, to our consolidated financial statements. See Liquidity and Capital Resources below for further detail on our 12.5% Notes.

#### *Royalties and Interest Expense related to the Sale of Future Revenue*

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI<sup>®</sup>. 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 March 31, 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 March 31, 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 Months Ended March 31, 2022 and 2021

#### Revenues:

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

(In thousands, except %)	Three Months Ended March 31,		Change	
	2022	2021	\$	%
Manufacture and supply revenue	\$ 9,171	\$ 6,511	\$ 2,660	41 %
License and royalty revenue	506	2,361	(1,855)	(79)%
Co-development and research fees	403	438	(35)	(8)%
Proprietary product sales, net	2,190	1,812	378	21 %
<b>Total revenues</b>	<b>\$ 12,270</b>	<b>\$ 11,122</b>	<b>\$ 1,148</b>	<b>10 %</b>

For the three months ended March 31, 2022, total revenues increased 10% or \$1,148 compared to same period in the prior year. The increase was primarily due to higher manufacturing and supply revenue as well as proprietary product revenue.

Manufacture and supply revenue increased 41% or \$2,660 for the three months ended March 31, 2022 compared to the same period in the prior year. This increase was due to higher Suboxone manufacturing volume.

License and royalty revenue decreased 79% or \$1,855 for the three months ended March 31, 2022 compared to the same period in the prior year. This decrease was primarily due to the remaining deferred revenue from the terminated license and supply agreement with Fortovia Therapeutics Inc. that was recognized in 2021 and did not reoccur in 2022.

Co-development and research fees decreased 8% or \$35 for the three months period ended March 31, 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 21% or \$378 for the three months ended March 31, 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, our proprietary product.

#### Expenses and Other:

(In thousands, except %)	Three Months Ended March 31,		Change	
	2022	2021	\$	%
Manufacture and supply	\$ 4,214	\$ 2,757	\$ 1,457	53 %
Research and development	4,773	3,659	1,114	30 %
Selling, general and administrative	13,021	13,231	(210)	(2)%
Interest expense	1,618	2,761	(1,143)	(41)%
Interest expense related to the sale of future revenue, net	1,861	3,334	(1,473)	(44)%
Interest and other expense, net	3	52	(49)	(94)%

Manufacture and supply costs and expenses increased 53% or \$1,457 for the three months ended March 31, 2022 compared to the same period in the prior year. The increase in manufacture and supply costs was due to volume growth of Suboxone.

Research and development expenses increased 30% or \$1,114 for the three months ended March 31, 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 decreased 2% or \$210 for the three months ended March 31, 2022 as compared to the same period in the prior year. The decrease was driven by lower sales and marketing costs and share-based compensation expense.

Interest expense decreased 41% for the three months ended March 31, 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 \$1,861 for the three months ended March 31, 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 March 31, 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 \$49 for the three months ended March 31, 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, there is up to \$30,000 available under the existing debt facility upon approval of Libervant by the FDA for U.S. market access. We had \$14,736 in cash and cash equivalents as of March 31, 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 March 31, 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 March 31, 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, the holders of the 12.5% Notes agreed to extend to December 31, 2021 our ability to access, at our option, and additional \$30,000 of 12.5% Notes re-openers under the Indenture. The first \$10,000 12.5% Notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second \$20,000 12.5% Notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that we access these re-openers, we will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the warrant grant date. In addition, as of the closing of this transaction, we issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.

On September 30, 2021, the Company entered into a waiver agreement (the "Waiver") with the holders of the 12.5% Notes pursuant to which the principal payment due under the 12.5% Notes on September 30, 2021 was deferred in order to provide

sufficient time for the execution of the Fourth Supplemental Indenture (the “Fourth Supplemental Indenture”). On October 7, 2021, the Company entered into the Fourth Supplemental Indenture, by and among the Company and the Trustee and collateral agent thereunder, to the Indenture in connection with the 12.5% Notes. Pursuant to the Fourth Supplemental Indenture, the amortization schedule for the 12.5% Notes was amended to provide for the date of the first amortization payment to be extended to March 30, 2023. The Fourth Supplemental Indenture did not change the maturity date of the Notes or the interest payment obligation due under the Notes. In connection with the Fourth Supplemental Indenture, the Company entered into a Consent Fee Letter with the holders of the 12.5% Notes, pursuant to which the Company agreed to pay the holders of the 12.5% Notes an additional cash payment of \$2,700 in the aggregate, payable in four quarterly payments beginning May 15, 2022. See Note 20 for discussion.

In 2019, we established an “At-The-Market” (ATM) facility pursuant to which we may offer up to \$25,000 of shares of common stock. In the first quarter of 2021, we filed a prospectus supplement to offer up to an additional \$50,000 of shares of common stock under the ATM facility. Since inception to March 31, 2022, we sold 7,873,071 shares which generated net cash proceeds of approximately \$37,131, net of commissions and other transaction costs of \$1,826. For the three months ended March 31, 2022, we sold 391,652 shares which provided net proceeds of approximately \$1,298, net of commissions and other transaction costs of \$62. This ATM facility has approximately \$36,043 available at March 31, 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. Concurrently with entering into the Lincoln Park Purchase Agreement, we also entered into a registration rights agreement with Lincoln Park, pursuant to which we agreed to register the sale of the shares of our common stock that have been and may be issued to Lincoln Park under the Lincoln Park Purchase Agreement pursuant to our existing shelf registration statement on Form S-3 or a new registration statement. 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.

## Cash Flows

### Three Months Ended March 31, 2022 and 2021

<i>(in thousands)</i>	2022	2021
Net cash (used for) operating activities	\$ (14,482)	\$ (14,097)
Net cash (used for) investing activities	(104)	(103)
Net cash provided by financing activities	1,298	9,891
Net decrease in cash and cash equivalents	<u>\$ (13,288)</u>	<u>\$ (4,309)</u>

### Net Cash (Used for) Operating Activities

Net cash used for operating activities for the three months ended March 31, 2022 increased by \$385 compared to the same period in the prior year. The increase was related to lower non-cash operating expenses of \$3,499, offset by changes in operating assets and liabilities of \$1,662 and a lower net loss of \$1,452. The lower non-cash operating expenses were primarily due to increases in interest expense related to sale of future revenue (\$1,466) and amortization of debt issuance costs (\$1,144). The change in operating assets and liabilities was primarily due to timing of payments, increased deferred revenue related to a License, Development and Supply Agreement that we entered into with Haisco, offset by higher trade and other receivables due to increased revenue.

### Net Cash (Used for) Investing Activities

Net cash used for investing activities for the three months ended March 31, 2022 increased by \$1 compared to the same period in the prior year. The use of cash was related to capital expenditures.

### Net Cash (Used for) Financing Activities

Net cash provided for financing activities for the three months ended March 31, 2022 decreased by \$8,593 compared to the same period in the prior year. The decrease was due to less share purchase proceeds under the ATM facility in 2022.

## **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 approval of Libervant by the FDA for 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 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;
- FDA approval of our key new drug candidate, Libervant, for U.S. market access;
- our ability to issue up to \$30,000 in additional 12.5% Notes, which is contingent upon approval of Libervant by the FDA for U.S. market access;
- continuing review and appropriate adjustment of our cost structure consistent with our anticipated revenues and funding;
- continued growth and market penetration of Sympazan within expected commercialization cost levels for this product, including anticipated patient and physician acceptance and our ability to obtain adequate price and payment support from government agencies and other private medical insurers;
- effective commercialization within anticipated cost levels and expected ramp-up timeframes of our product candidate Libervant, if approved for U.S. market access by the FDA;
- infrastructure and administrative costs at expected levels to support operations as an FDA and highly regulated public company;
- a manageable level of costs for ongoing efforts to protect our intellectual property rights, including litigation costs in connection with seeking to enforce our rights concerning third parties' "at-risk" launch of generic products;
- continued compliance with all covenants under our 12.5% Notes;
- absence of significant unforeseen cash requirements;
- our ability to access funding through the Company's ATM facility and under the Lincoln Park Purchase Agreement; and
- our ability to collect the upfront payment due from Haisco.

We expect to continue to manage business costs to appropriately reflect the anticipated general decline in Suboxone revenue, the marketing and sales costs related to Sympazan, the proceeds from the KYNMOBI Monetization Agreement, and other external resources or factors affecting our business including, if available, any future potential issuances of additional

12.5% Notes under the Indenture, net proceeds or future equity financing, other future access to the capital markets or other potential available sources of liquidity, as well as the uncertainties associated with the coronavirus pandemic. In doing so, we plan to continue to focus on the core drivers of value for our stockholders, including, more importantly, continued investments in our ongoing product development and planned commercialization activities in support of Libervant, AQST-109 and AQST-108. Until profitability is achieved, if at all, additional capital and/or other financing or funding will be required, which could be material, to further advance the development and commercialization of Libervant, AQST-109 and AQST-108, if approved by the FDA for U.S. market access, and to meet our other cash requirements, including debt service. We plan to conservatively manage our pre-launch spending as to both timing and level relating to Libervant, including cost rationalization associated with marketing and selling Sympazan. In this regard, absent spending on launch activities for Libervant, we expect to continue to spend similar or less 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 products, our existing level of debt which is secured by substantially all of our assets, restriction under the Indenture, and general market conditions, and there can be no assurance that we will continue to be successful in raising capital or that any such needed financing will be available, available on favorable or acceptable terms or at the times, or in the amounts needed, if at all. Additionally, while the potential economic impact brought on by and the duration of the coronavirus pandemic is difficult to assess or predict, the significant impact of the coronavirus pandemic on the global financial markets, and on our own stock trading price, may reduce our ability to access additional capital, which would negatively impact our short-term and longer-term liquidity.

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

See also the risk factors below concerning the significant risks and uncertainties concerning our business, operations, financial results and capital resources associated with the impact of the global coronavirus pandemic.

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

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

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

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

### **Item 4. Controls and Procedures**

#### *Management’s Evaluation of our Disclosure Controls and Procedures*

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

As of March 31, 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 March 31, 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 March 31, 2022, we had \$14.7 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 U.S. Food and Drug Administration (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 December 31, 2021, 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 December 31, 2021. On August 6, 2021, the holders of the 12.5% Notes agreed to extend to June 30, 2022 our ability to access, at our option, an additional \$30.0 million of 12.5% Notes re-openers under the Indenture. The first \$10.0 million senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second \$20.0 million senior notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that we access these re-openers, we will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the warrant grant date. In addition, as of the closing of this transaction, 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. 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 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, 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, 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 us.

***We may not receive any payments under our License Agreement with Haisco.***

In March 2022, we announced the grant of an exclusive license (the "Haisco Agreement") to Haisco Pharmaceutical Group Co., Ltd. ("Haisco") for Haisco to develop and commercialize Exservan for the treatment of ALS in China. Under the Haisco Agreement, Haisco is obligated to pay us an upfront cash payment, regulatory milestone payments, and double-digit royalties on net sales of Exservan in China and we will earn manufacturing revenue on the sale of Exservan in China as the exclusive supplier of Exservan in China if approved for marketing and sale.

Pursuant to the Haisco Agreement, Haisco has been appointed to serve as our agent for matters relating to the commercialization of Exservan in China, including obtaining approval to market and sell ("Marketing Authorization") Exservan in China. Subsequent to the execution of the Haisco Agreement in March 2022, the Chinese equivalent of the FDA (the "NMPA") raised an issue regarding the named holder of the U.S. New Drug Application (NDA) for Exservan in relation to the application for Marketing Authorization of Exservan in China. It is not clear whether the NMPA will require that Aquestive be the holder of the NDA in order to approve the Marketing Authorization for Exservan in China, or whether the NMPA will find that Aquestive's qualifications as the exclusive licensor, manufacturer and innovator of Exservan will be sufficient for the NMPA to approve Aquestive as the drug sponsor for Exservan in China and grant the Marketing Authorization for Exservan in China. Prior to entering into the Haisco Agreement, the Company had assigned the NDA for Exservan to another third-party in connection with a license agreement in the U.S. for Exservan and is not currently the named holder of the NDA. We are collaborating with Haisco to resolve this issue with the NMPA. As a result of this issue, we have not received the \$7 million upfront payment that was due from Haisco under the Haisco Agreement and we expect to agree with Haisco to extend the period of time under which Haisco is obligated to make such upfront payment consistent with the decision of the NMPA on the issue, or as otherwise agreed to by us and Haisco. There is no assurance that we will come to an agreement with Haisco, or that

there will be any contribution to the Company of cash payment, royalties or manufacturing revenue on launch of the product in China if we are not able to come to an agreement with Haisco or resolve this issue with the NMPA.

***The sale of our common stock through our ATM sales agreement or our Lincoln Park Purchase Agreement may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our common stock to decline.***

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 (the “Purchase Agreement”), under which, from time to time, we may cause Lincoln Park to purchase shares of our common stock. Although we have the right to control whether we sell any shares, if at all, under these agreements, and we generally have the right to control the timing and amount of any such sales, we are subject to certain restrictions, including those that limit the number of shares we may sell. In particular, with respect to the Purchase Agreement, we may not sell more than 8,323,114 shares to Lincoln Park, which we refer to as the Exchange Cap, unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price per share of shares issued to Lincoln Park equals or exceeds \$2.16, and we may not sell shares to Lincoln Park if it would result in Lincoln Park beneficially owning more than 9.99% of our then outstanding shares of common stock. Accordingly, we may not be able to utilize the ATM sales agreement or the Purchase Agreement to raise additional capital when, or in the amounts, we desire.

***Our historical financial statements have been prepared under the assumption that we will continue as a going concern.***

Our historical financial statements have been prepared under the assumption that we will continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain additional financing or other capital, reduce expenditures, and, ultimately, generate revenue. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. However, if adequate funds are not available to us when we need them, we will be required to curtail our operations, which would, in turn, further raise substantial doubt about our ability to continue as a going concern.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.



**Item 6. Exhibits**

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

<b>Number</b>	<b>Description</b>
<a href="#">10.1*</a>	License, Development and Supply Agreement, dated as of March 2022, by and between Aquestive Therapeutics, Inc. and Haisco Pharmaceutical Group Co., Ltd. (filed herewith).
<a href="#">31.1</a>	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<a href="#">31.2</a>	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a), as amended, under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
<a href="#">32.1</a>	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
<a href="#">32.2</a>	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
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 redacted. 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: May 3, 2022

/s/ Keith J. Kendall

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

Date: May 3, 2022

/s/ A. Ernest Toth, Jr.

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

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. [\*\*\*] INDICATES THAT INFORMATION HAS BEEN REDACTED.

**LICENSE, DEVELOPMENT AND SUPPLY AGREEMENT**

**by and between**

**AQUESTIVE THERAPEUTICS, INC.**

**and**

**HAISCO PHARMACEUTICAL GROUP CO, LTD.**

**Dated as of March 3<sup>rd</sup>, 2022**

## LICENSE, DEVELOPMENT AND SUPPLY AGREEMENT

This LICENSE, DEVELOPMENT AND SUPPLY AGREEMENT (together with any Schedules hereto, this “Agreement”) is entered into as of March 3<sup>rd</sup>, 2022 (the “Effective Date”) by and between Aquestive Therapeutics, Inc., a Delaware corporation (“Aquestive”) having its principal place of business at 30 Technology Drive, Warren, New Jersey 07059, Haisco Pharmaceutical Group Co., Ltd. a Chinese limited company listed on the Shenzhen Stock Exchange with listing code 002653 (“Haisco”) having its principal place of business at No. 136 Baili Road CNSTP, Wenjiang District, Chengdu, Sichuan Province 611130. Aquestive and Haisco 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 including orally soluble film strips containing active pharmaceutical ingredients.

B. Haisco desires to obtain from Aquestive and Aquestive desires to grant to Haisco, an exclusive license to Develop and Commercialize the Product in the Field in the Territory, subject to the terms herein set forth.

C. In consideration of the mutual representations, warranties and covenants contained herein, the Parties agree as follows:

### 1. DEFINITIONS

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

1.1 “Abandoned Patent” has the meaning set forth in Section 14.2.2.

1.2 “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.

1.3 “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.

1.4 “Agreement” has the meaning set forth in the Preamble of this Agreement.

1.5 “API” means the active pharmaceutical ingredient riluzole.

1.6 “Applicable Anti-Bribery and Anti-Corruption Laws” means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended, or any equivalent non-U.S. regulations or standards, in each case, to the extent applicable in the relevant jurisdiction.

1.7 “Applicable Law” means all laws, rules, and regulations, including any rules, regulations, guidelines, or other requirements of Regulatory Authorities, applicable to the Development, Commercialization or Supply of the Product, as the case may be, that may be in effect from time to time in the United States or in the Territory, in each case, to the extent applicable in the relevant jurisdiction.

1.8 “Aquestive” has the meaning set forth in the Preamble to this Agreement.

1.9 “Aquestive IP” means any and all Intellectual Property owned or Controlled by Aquestive or its Affiliates as of the Effective Date or during the Term which is useful or necessary to Develop and/or Commercialize the Product in the Field in the Territory, including patents and know-how, related to the formulation and manufacturing of oral film dosage forms for delivery of active ingredients, including the Product, to humans.

1.10 “Aquestive Indemnitees” has the meaning set forth in Section 11.1.

1.11 “Aquestive Housemark” means the name and logo of Aquestive or any of its Affiliates as identified on Schedule 1A.1 attached hereto, as such schedule may be updated from time to time, and made a part hereof.

1.12 “Aquestive New IP” has the meaning set forth in Section 14.1.2.

1.13 “Aquestive Patents” means all patents and patent applications owned or Controlled by Aquestive or its Affiliates as of the Effective Date or during the Term, including any continuations, continuations-in-part, divisions, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, patents which remain valid subsequent to any post grant proceedings include Inter Parte Reviews (IPRs) and Post Grant Review Trials (PGRs) under the American Invents Act (AIA) or other such challenges which result in the patent being enforceable, renewal 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, which are useful or necessary to Develop and/or Commercialize Product in the Field in the Territory. 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, and made a part hereof.

1.14 “Bankruptcy Event” means the occurrence of any of the following with respect to a Party: (a) such Party files in any court or agency, pursuant to any statute or regulation of any state or country, a petition in 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 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.

1.15 “Business Day” means any day other than a Saturday or Sunday on which banking institutions in New York, New York, United States or Chengdu, People’s Republic of China are open for business.

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

1.17 “Certificate of Analysis” means the certificate evidencing the analytical tests conducted on a specific lot of a 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 the Product in the Territory. The Certificate of Analysis shall be in a format agreed to in writing by the Parties.

1.18 “Certificate of Compliance” means the certificate evidencing that the Product delivered to Haisco was manufactured in accordance with Applicable Law, and any applicable Regulatory Approvals. The Certificate of Compliance shall be in a format agreed to in writing by the Parties.

1.19 “Chinese Accounting Standards” means the accounting standards that are issued by the Ministry of Finance of People’s Republic of China from time to time.

1.20 “Clinical Supply” has the meaning set forth in Section 5.1.

1.21 “CMC” means chemistry, manufacturing and controls data required by Applicable Law and/or a Regulatory Authority to Develop the Product in the Field in the Territory.

1.22 “CMO” has the meaning set forth in Section 4.1.1.

1.23 “Commercial Invoice” has the meaning set forth in Section 7.4.

1.24 “Commercialization” means any and all activities directed to marketing, promoting, distributing, offering for sale, selling, and importing the Product in the Field in the Territory, including (a) sales force efforts, detailing, advertising, promotional materials, market research, market access (including list price and reimbursement activities), and appropriate medical education and information services, publication, and scientific and medical affairs; (b) order processing, handling of returns and recalls, booking of sales and transporting the Product for commercial sale; (c) registering and maintaining the information of pharmaceutical representatives of the Product with the NMPA and monitoring their academic promotion activities according to Applicable Law; (d) interacting with Regulatory Authorities regarding the foregoing; and (e) seeking and obtaining pricing approvals and reimbursement approvals (as applicable) for the Product. 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 the 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 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 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 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 profitability of the applicable products and other relevant factors, including technical, legal, scientific, medical, sales performance, and/or marketing factors.

1.26 “Competitive Infringement” has the meaning set forth in Section 14.4.1.

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 Haisco executed and delivered as of October 29, 2020.

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 8.10.

1.31 “CRO” has the meaning set forth in Section 2.9.

1.32 “Delivery Failure” has the meaning set forth in Section 7.9.

1.33 “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: the conduct of (a) 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) clinical studies (including post-Marketing Authorization human studies) and 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) regulatory filing submissions and registration; (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.

- 1.34 “Disclosing Party” has the meaning set forth in Section 10.1.
- 1.35 “Distributor” has the meaning set forth in Section 2.9.
- 1.36 “DMF” has the meaning set forth in Section 4.2.1.
- 1.37 “DMF Holder” has the meaning set forth in Section 4.2.3.
- 1.38 “Dosage Strength” means the 50mg dosage strength of the Product.
- 1.39 “Drug Product” means a chemical drug product as defined in Applicable Law for administration to human subjects.
- 1.40 “Excluded Claim” has the meaning set forth in Section 15.12.8.
- 1.41 “Effective Date” has the meaning set forth in the Preamble of this Agreement.
- 1.42 “Events” means the events set forth in Section 8.1.
- 1.43 “Executive Officer” has the meaning set forth in Section 15.12.2.
- 1.44 “Field” means administration of the Product for Amyotrophic Lateral Sclerosis.
- 1.45 “First Commercial Sale” means the first sale of the Product to a Third Party by Haisco or its Affiliates or agents within the Territory after receipt of Regulatory Approval; provided, that, the following shall not constitute a First Commercial Sale: (a) any sale to an Affiliate or sublicensee (unless the Affiliate or sublicensee is the last entity in the distribution chain of the Product); (b) any use of the Product in clinical trials or other research or Development activities; or (c) the disposal or transfer of the Product for a bona fide charitable purpose, without consideration, including for any compassionate use and/or as “named patient sales”.
- 1.46 “Force Majeure” has the meaning set forth in Section 15.7.
- 1.47 “Generic Product” means, with respect to the Product in the Field in the Territory, any Drug Product (other than the Product) that: (a) contains the API as the active pharmaceutical ingredient; and (b) is approved by the NMPA pursuant to an abbreviated application filed with the NMPA pursuant to the Applicable Law of the People’s Republic of China for which the Product is the Reference Listed Drug and which is not held in the name of Aquestive, Haisco or an Affiliate thereof, or sublicensee or subcontractor thereof.



1.48 “Governmental Authority” means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.49 “Haisco” has the meaning set forth in the Preamble to this Agreement.

1.50 “Haisco Housemark” means the name and logo of Haisco or any of its Affiliates as identified on Schedule 1A.2 attached hereto, as such schedule may be updated in writing from time to time, and made a part hereof by amendment of such Schedule.

1.51 “Haisco Indemnitees” has the meaning set forth in Section 11.2.

1.52 “Haisco New IP” has the meaning set forth in Section 14.1.2.

1.53 “ICC” has the meaning set forth in Section 15.12.3.

1.54 “ICC Rules” has the meaning set forth in Section 15.12.3.

1.55 “Indemnitee” has the meaning set forth in Section 11.3.1.

1.56 “Indemnitor” has the meaning set forth in Section 11.3.1.

1.57 “Indication” means any indication in the Field.

1.58 “Intellectual Property” means, collectively, all: (a) all patents, patent applications including provisional applications and statutory invention registrations, including reissues, divisions, continuations, continuations-in-part, and reexaminations, patents which remain valid after IPRs and PGRs and any court challenges, and all inventions disclosed 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 laws of the jurisdiction, to limit the use or disclosure thereof; (d) including 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 thereof.

1.59 “Joint New IP” has the meaning set forth in Section 14.1.3.

1.60 “Joint Patents” has the meaning set forth in Section 14.1.3.

1.61 “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.

1.62 “Marketing Authorization” means authorization from the relevant Regulatory Authorities within Mainland China for approval to market, sell or otherwise Commercialize the Product in the Field in the Territory.

1.63 “Minimum Payment Commitment” has the meaning set forth in Section 8.4.

1.64 “NDA” means the FDA-approved new drug application for the Product trade named EXSERVAN under NDA #212640, including all amendments and supplements thereto and all documentation filed with the FDA in connection therewith.

1.65 “Net Sales” means, for any period of determination, with respect to the Product sold by Haisco (or any Affiliate or sublicensee of Haisco), the aggregate amount invoiced for the sale by Haisco of the Product in the Field in the Territory to unaffiliated Third Parties (unless invoiced to an Affiliate or sublicensee which is the last entity in the distribution chain for the sale of the Product), less amounts for the following deductions:

- (a) trade, quantity or cash discounts, charge-back payments, allowances or rebates to the extent actually taken and allowed, including promotional or similar discounts or rebates and discounts or rebates to governmental or managed care organizations;
- (b) bad debts;
- (c) credits or allowances given or made with respect to the Product by reason of rejection, defects, recalls, returns, rebates, retroactive price reductions; and
- (d) 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.

Notwithstanding the foregoing, Net Sales shall not include amounts received or invoiced by Haisco or its Affiliates or sublicensees: (i) for the sale of the Product among Haisco and its Affiliates and sublicensees (unless the Affiliate or sublicensee is the last entity in the distribution chain of the Product); (ii) for academic research, preclinical, clinical, or regulatory purposes (including the use of a Product in Clinical Trials) reasonably necessary to comply with Applicable Law; (iii) in connection with charitable purposes, such as a compassionate use, “named patient” or expanded access program; or (iv) to physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary in the industry or which is reasonably proportional to the market for the Product to the extent permissible by Applicable Law).

The amounts of any deductions accrued pursuant to this Section shall be determined from books and records maintained in accordance with the Chinese Accounting Standards and shall only be deducted once and only to the extent not otherwise deducted from the aggregate amount invoiced.

If Haisco (or any of its Affiliates or sublicensees) sells the Product to a Third Party who also purchases other products or services from any such entity, and Haisco or its Affiliates or sublicensees bundle or include the Product as part of any multiple product offering or discount or price Product as part of a bundle or multiple Product offering, such discounts (or other price reductions or adjustments) shall be allocated to the Product and other products offered for sale by Haisco or its Affiliates or sublicensees to such customer in direct proportion to the gross sales price of the Product as compared to the gross sales price of the other products in the offering sold to such Third Party purchaser or a similarly situated Third Party purchaser if such products are not sold to the Third Party purchaser on a stand-alone basis (in each case, as such gross sales prices, are determined, or would be determined, as applicable, without such bundling or multiple product offering); provided however, that prior the gross sales price for the Product and the other products in the bundled or multiple product offering and the discount allocation or other price reductions or adjustments shall be disclosed to Aquestive in writing with reasonable supporting documentation.

1.66 “New IP” has the meaning set forth in Section 14.1.2.

1.67 “NMPA” means the Chinese National Medical Products Administration, agencies or departments under its supervision, and any of its successor agencies or departments.

1.68 “Notice to Abandon” has the meaning set forth in Section 14.2.2.

1.69 “Party” or “Parties” has the meaning set forth in the Preamble to this Agreement.

1.70 “Patent Term Extensions” has the meaning set forth in Section 14.3.

1.71 “Permitted Sublicensees” has the meaning set forth in Section 2.9.

1.72 “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.

1.73 “Primary Packaging” means the foil pouch that individually wraps and touches each Unit.

1.74 “Primary Packaging Design” means artwork associated with the Primary Packaging for the Product in the Territory.

1.75 “Product” means Aquestive’s Exservan™ (riluzole oral soluble film) product in the Dosage Strength.

1.76 “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.

1.77 “Product Marks” has the meaning set forth in Section 2.6.3.

1.78 “Product Transfer Price” has the meaning set forth in Section 7.2.

1.79 “Purchase Orders” has the meaning set forth in Section 7.1.

1.80 “Quality Agreement” has the meaning set forth in Section 7.12.

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

1.82 “Raw Materials Safety Stock” has the meaning set forth in Section 7.8.

1.83 “Recall” has the meaning set forth in Section 13.5.1.

1.84 “Recall Expenses” has the meaning set forth in Section 13.5.1.

1.85 “Recall Objection Notice” has the meaning set forth in Section 13.5.1.

1.86 “Receiving Party” has the meaning set forth in Section 10.1.

1.87 “Registration Batches” has the meaning set forth in Section 5.1.

1.88 “Regulatory Approval” means any approvals (including applications therefore, supplements and amendments thereto and pricing and reimbursement approvals), licenses, registrations, or authorizations of any Regulatory Authority, necessary for the Development, Commercialization, Supply, manufacture, testing, labeling, packaging, or shipping of the Product in the Territory, including the approval for clinical trials and the Marketing Authorization(s) for the Product.

1.89 “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 Territory.

1.90 “Regulatory Authority” means any national, regional, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental authority in the Territory involved in 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 the Product, including the NMPA, and any other body or any health regulatory authority(ies) in the Territory that is equivalent to the United States Food and Drug Administration (and its successor agencies or departments) and holds responsibility for granting Regulatory Approval for the Product, and any successor(s) thereto having substantially the same functions.

1.91 “Regulatory Documentation” means (i) documentation set forth on Schedule 1.91 attached hereto, (ii) documentation and information required by Regulatory Authorities for Development and Commercialization of the Product in the Field in the Territory, and (iii) such other documentation mutually agreed in writing to be required to be provided to Regulatory Authorities for Development and Commercialization of the Product in the Field in the Territory.

1.92 “Rescheduled Delivery Date” has the meaning set forth in Section 7.9.

1.93 “Royalty Period” means each quarterly period during the Term; provided that the first Royalty Period for each Product shall end on December 31 in the year in which the First Commercial Sale of the Product occurs.

1.94 “Royalty Report” has the meaning set forth in Section 8.5.

1.95 “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.

1.96 “Specifications” means the written specifications for the Product and Raw Materials mutually agreed upon by the Parties including, without limitation, the shelf life of such 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, shall be mutually agreed in writing by the Parties from time to time during the Term, and upon such mutual agreement shall be deemed to be incorporated by reference in this Agreement.

1.97 “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 a Party under this Agreement.

1.98 “Steering Committee” has the meaning set forth in Section 3.1.

1.99 “Step In Notice” has the meaning set forth in Section 14.2.2.

1.100 “Step In Rights” has the meaning set forth in Section 14.2.2.

1.101 “Supply” means the manufacture, supply, processing, storing, labeling, and packaging (as specified in this Agreement) for sale and delivery of the Product.

1.102 “Term” has the meaning set forth in Section 12.1.

1.103 “Territory” means Mainland China.

1.104 “Third Party” means any Person other than Aquestive and Haisco and their respective Affiliates.

1.105 “Third Party Claim” has the meaning set forth in Section 11.1.

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

1.107 “Validation Batches” has the meaning set forth in Section 5.1.

## 2. **RIGHTS AND OBLIGATIONS**

2.1 **Licenses Granted to Haisco.** Subject to the terms and conditions of this Agreement, Aquestive hereby grants to Haisco, and Haisco hereby accepts, an exclusive royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.9 below, under and to Aquestive IP within the Territory to Commercialize the Product in the Field, and to perform the Development activities set forth in Section 5.2.

2.2 **Covenant of Aquestive.** Aquestive hereby covenants and agrees with Haisco that during the Term, other than as expressly provided herein, Aquestive will not 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.

2.3 **Covenant of Haisco.** Haisco hereby covenants and agrees that neither Haisco, nor any of its Affiliates shall, directly, or indirectly (whether through an Affiliate, sublicensee, Third Party, or by any transfer or license rights to an Affiliate, sublicensee or Third Party), during the Term, make, use, Develop, import/export, seek Regulatory Approval for, manufacture, distribute, offer to sell, sell, market, promote, detail, or otherwise commercialize any products using non-injection or non-swallowed forms of delivery containing the API in the Field anywhere in the Territory other than pursuant to this Agreement.

2.4 **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 sublicensees to, practice any Intellectual Property licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.5 **Manufacturing Exclusivity.** Aquestive shall have the exclusive right to Supply the Product; provided, however, that, subject to Section 15.4 below, Aquestive may designate such right and obligation to one or more of its Affiliates or to a Third Party selected by Aquestive, in the case as to the designation thereof to a Third Party, upon submission of sufficient information to reasonably demonstrate the adequate financial and operational capacity to manufacture the requirements of Haisco for the Product under this Agreement. Notwithstanding the foregoing, Aquestive will remain responsible for the obligations designated to, and payment to, such Affiliates or such Third Party to the same extent it would if it had done such work itself.

### 2.6 **Trademarks.**

2.6.1 Subject to the terms and conditions of this Agreement, Aquestive hereby grants to Haisco, and Haisco accepts, a non-exclusive, non-transferable license, with the right to grant sublicenses solely in accordance with Section 2.9, to use the Aquestive Housemark in the



Territory solely in conjunction with the Product in the Field in the Territory and solely for such uses as are approved in writing by Aquestive, such approval not to be unreasonably withheld, conditioned or delayed. The following shall appear on the labeling and packaging of each Product: “Manufactured by Aquestive Therapeutics, Inc.”

2.6.2 Subject to the terms and conditions of this Agreement, Haisco hereby grants to Aquestive, and Aquestive accepts, a non-exclusive, non-transferable, non-sublicensable license to use the Haisco Housemark in the Territory solely in conjunction with the labeling and specified packaging of Product and solely as such are approved in writing by Haisco, in connection with the Supply of the Product hereunder, such approval not to be unreasonably withheld, conditioned or delayed.

2.6.3 Notwithstanding anything to the contrary, Haisco shall have the right to name and brand the Product in the Field in the Territory using trademarks, logos, and trade names it determines appropriate for such Product in the Territory (the “Product Marks”). Haisco shall own all rights in the Product Marks in the Territory and shall register and maintain the Product Marks in the Territory as it determines reasonably necessary. Aquestive shall provide reasonable assistance to Haisco, at Haisco’s sole cost and expense, in connection with registration and maintenance of the Product Marks, including without limitation, providing documents as Haisco may reasonably request.

2.7 **Packaging and Labeling.** Aquestive shall label and package the Product in accordance with the Primary Packaging Design specifications, Applicable Law, and the approved Regulatory Approval Application for the Product. Haisco 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 each Product, including the Primary Packaging Design, which shall be delivered to Aquestive as an electronic file in Adobe Illustrator format, and including the cylinder costs used by Aquestive’s vendor to print the graphics. Haisco shall be responsible for any required notifications to the applicable Regulatory Authorities regarding the labeling and packaging configurations for the Product, including any changes in labeling or packaging configurations and shall be responsible for ensuring that labeling, packaging configurations, and the Primary Packaging Design complies with Applicable Law. Haisco shall also be responsible for all secondary labeling and Secondary Packaging and the contents of package inserts or outserts, including ensuring that the foregoing comply with Applicable Law. The packaging for the Product, including the Primary Packaging and Secondary packaging, shall indicate that the Product is manufactured by Aquestive. Any changes to the Product Label shall be subject to Aquestive’s written approval; provided however, that a change concerning quantities within a package made in compliance with Applicable Law shall not be deemed a change to the Product Label and can be made at the sole discretion of Haisco.

2.8 **Aquestive Retained Rights.** Any rights of Aquestive not expressly granted to Haisco 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 and Section 2.9, 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 Haisco or obtain Haisco’s consent for such exploitation.

2.9 **Sublicensees and Subcontractors.** Haisco may grant sublicenses under this Agreement to one or more sublicensees, and may exercise its rights or perform its Development obligations under this Agreement through one or more subcontractors, provided that: (a) use of a subcontractor and/or grant of a sublicense requires the prior written approval of Aquestive, such approval not to be unreasonably withheld, conditioned or delayed; provided, however, that the prior written consent of Aquestive is hereby waived if and to the extent Haisco, upon written notice to Aquestive: (i) grants to its Affiliate(s) such sublicense or subcontract, or (ii) subcontracts certain activities related to Development of the Product to Third Party contract research organizations (each, a “CRO”) and grants such sublicense to the CRO to the extent necessary or appropriate for them to conduct the subcontracted activities, or (iii) subcontract certain activities related to Commercialization of the Product to Third Party distributors, sub-distributors or sales agents (each, a “Distributor”) and grants such sublicense to the Distributor to the extent necessary or appropriate for them to conduct the subcontracted activities (collectively, the “Permitted Sublicensees”); (b) Haisco will remain responsible for the work allocated to, and payment to, such subcontractor or sublicensee to the same extent it would if it had done such work itself; (c) each subcontractor or sublicensee other than the Permitted Sublicensees performs work on the basis of a written contract which is not inconsistent with Section 9.3.3, Section 9.3.4, Section 9.3.5 and Section 10 below; and (d) each Permitted Sublicensee agrees in writing to assign all Intellectual Property developed in the course of performing any such work in relation to the Product to Haisco (or, in the event such assignment is not feasible, a license to such Intellectual Property with the right to sublicense to Aquestive) on an exclusive, worldwide royalty-free basis.

### 3. **STEERING COMMITTEE**

3.1 **Steering Committee.** No later than one (1) month following the Effective Date, the Parties will establish a committee 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 (whom 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 meet at least two (2) times per calendar year, on a schedule and at a location to be agreed by the Parties in writing. Notwithstanding the foregoing, the Steering Committee shall be solely advisory and not have any decision-making authority. For the avoidance of doubt, Haisco shall have the sole decision-making authority regarding the Development set forth in Section 5.2 hereof and Commercialization for the Product in the Field in the Territory, except changes to the Product Label as provided in Section 2.7 and Section 5.3.1.

### 4. **TRANSFER OF INFORMATION AND DOCUMENTATION**

#### 4.1 **Certain Regulatory Documentation.**

4.1.1 Promptly following the receipt of the first milestone payment pursuant to Section 8.1 but in no case later than ten (10) Business Days thereafter, Aquestive shall deliver or make available to Haisco, at Aquestive’s sole cost and expense, copies of the Regulatory Documentation in the possession or Control of Aquestive and thereafter promptly but in no case



later than thirty (30) days following the written request of Haisco, all other existing information and data in the possession or Control of Aquestive which are necessary for obtaining or maintaining the Marketing Authorization for the Product in the Field in the Territory that was not filed with the FDA. To the extent any of the Regulatory Documentation is not in Aquestive's possession or Control, Aquestive shall use Commercially Reasonable Efforts to provide or cause the relevant Third Parties (including contract manufacturers, ("CMOs"), API suppliers or other partners for the Product outside of the Territory) to provide to Haisco, promptly but in no case later than sixty (60) days following the written request of Haisco, the existing documents and information in such Third Parties' possession or Control.

4.1.2 Aquestive will thereafter: (a) deliver or make available to Haisco copies of any other (including new or updated) Regulatory Documentation in the possession or Control of Aquestive; and (b) use Commercially Reasonable Efforts to cause the relevant Third Parties to deliver or make available to Haisco copies of any other (including new or updated) Regulatory Documentation, in each case to the extent required for the Development and/or Commercialization of the Product in the Field in the Territory.

4.1.3 In addition to the transfer of Regulatory Documentation described above, Aquestive shall use Commercially Reasonable Efforts to assist Haisco in preparing and filing Regulatory Documentation in the Territory at Haisco's sole cost and expense, including without limitation, in connection with regulatory actions, submissions, queries, actions and communications for the Product in the Field in the Territory.

#### 4.2 DMFs.

4.2.1 Within ninety (90) days after the Effective Date, Aquestive shall provide, or make available to Haisco all Drug Master Files associated with the Product (each, a "DMF") in the possession or Control of Aquestive that are required to support application for Regulatory Approval for the Product in the Territory, together with a letter of authorization substantially in the form as attached hereto as Schedule 4.2 (each, a "LOA").

4.2.2 If the DMF for the API is not in Aquestive's possession or Control, Aquestive shall instruct the Third Party API supplier to provide or make available to Haisco, within ninety (90) days after the Effective Date the DMF for the API and a LOA.

4.2.3 In the event any other DMF that is necessary for the Development activities to be conducted by Haisco or Commercialization of the Product in the Field in the Territory are Controlled by Third Party(ies) (each, a "DMF Holder"), and to the extent any such DMF is required to support application for the Regulatory Approval for the Product in the Territory, Aquestive shall use Commercially Reasonable Efforts to provide or cause all the applicable DMF Holder to provide or make available to Haisco, no later than ninety (90) days after the receipt of a written request from Haisco, complete copies of any and all such DMF and LOA(s), at Aquestive's (or such DMF Holder's) sole cost and expense.

4.2.4 Notwithstanding the foregoing, and only to the extent permitted by the Regulatory Authority in the Territory:

4.2.4.1 if any DMF Holder insists on directly filing any required DMF with such Regulatory Authority, it may directly file such DMF with such Regulatory Authority according to related requirements of such Regulatory Authority and obtain registration number(s) for such DMFs to support Regulatory Approval of the Product in the Territory, at Aquestive's (or such DMF Holder's) sole cost and expense, provided that (i) Aquestive shall notify Haisco, within twenty (20) days after the receipt of such request from Haisco or such Regulatory Authority, such DMF Holder's election to make direct filing; (ii) Aquestive shall request any such DMF Holder to make such submission and obtain, no later than ninety (90) days after the notice to Haisco in accordance with clause (i) in this Section 4.2.4.1, registration number(s) for such DMF, so as to support filing for Regulatory Approval of the Product in the Territory; and (iii) provide a LOA to Haisco (as applicable); and

4.2.4.2 if any DMF Holder is unable or unwilling to provide, make available, or file, as applicable, a DMF necessary to support the Regulatory Approval of the Product in the Territory, it may: (a) provide or make available to Haisco; or (b) directly file required documentation to such Regulatory Authority according to related requirements of such Regulatory Authority to support Regulatory Approval of the Product in the Territory at Aquestive's (or such DMF Holder's) sole cost and expense (if a direct submission to the Regulatory Authority), provided that Aquestive shall request any such DMF Holder to provide, make available, or make such submission and obtain associated registration number(s), as applicable, in each case no later than ninety (90) days after the receipt of a written request from Haisco or such Regulatory Authority, so as to support filing for Regulatory Approval for the Product in the Territory, and provide a LOA to Haisco (as applicable).

4.2.5 If a Regulatory Authority in the Territory requires, in connection with Haisco's Regulatory Approval Application in the Territory (including without limitation, clinical trial application and new drug application in the Territory), additional information and/or documents in connection with DMFs beyond that have already been provided under Sections 4.2.1 through 4.2.4, upon reasonable request by Haisco, Aquestive shall, and shall use Commercially Reasonable Efforts to cause the relevant Third Party API supplier and DMF Holders to, within the time specified by the applicable Regulatory Authority, submit directly to the applicable Regulatory Authority (to the extent permitted by the Regulatory Authority) or provide Haisco with, the information and documents in support of Development activities required by such Regulatory Authority.

4.2.6 In the event that any DMF Holder is unable to provide to Haisco or file with the Regulatory Authority any required DMF or equivalent documentation and/or information within the timeframe provided in this Section 4.2, Aquestive shall engage a new supplier that can fulfill such requirements; Haisco will reimburse the costs and expenses of Aquestive (to the extent reasonable and documented) incurred in engaging such new supplier to fulfill the requirements provided in this Section 4.2.

4.2.7 Notwithstanding anything set forth in this Agreement to the contrary, if, despite a Party's written request therefor, the applicable Third Party supplier is unable to provide, make available, or file, as applicable a DMF or other documentation necessary to support the Regulatory Approval of the Product in the Territory within the applicable time periods set forth in this Section 4.2, Haisco shall permit a reasonable extension of time (but shall

not be obligated to permit more than one extension for a period of no more than fifteen (15) days) to permit such Third Party supplier to comply with such request, provided that Haisco receives reasonable assurances that such Third Party has made and will continue to make good faith efforts to meet such request.

## 5. **DEVELOPMENT; MAINTENANCE OF REGULATORY APPROVALS**

5.1 **Development Responsibilities of Aquestive.** Aquestive shall, to the extent necessary to support the Development activities to be conducted by Haisco: (a) provide or use Commercially Reasonable Efforts to cause the relevant Third Parties to provide Haisco with such regulatory materials and other regulatory data and information related to the Product in English as set forth in Section 4; and (b) conduct additional activities including CMC and other pre-clinical or non-clinical activities in accordance with Section 5.2.2 at Haisco's sole cost and expense, in each case of (a) and (b) above, to the extent required by NMPA in connection with the Regulatory Approval or Marketing Authorization for the Product in the Field in the Territory. Aquestive shall Supply Haisco (i) such quantities of the Product required for the clinical studies ("Clinical Supply"), (ii) three (3) batches of Product for registration purposes ("Registration Batches"), and (iii) to the extent required, three (3) batches of Product for validation purposes ("Validation Batches"), in each case, necessary for Development to the extent included in a Statement of Work. The Clinical Supply and Registration Batches shall be supplied as follows: (i) up to [\*\*\*] Units of the Product at [\*\*\*] and (ii) quantities of Product in excess of [\*\*\*] Units at [\*\*\*]. The Validation Batches shall be supplied at [\*\*\*]. Notwithstanding the foregoing, if Aquestive must manufacture an entire batch to fulfill Supply obligations for clinical studies, Aquestive and Haisco shall mutually agree in writing upon the price for the Product, which in no case shall exceed the per Unit price set forth in the preceding sentence. Aquestive shall provide Clinical Supply with blank packaging. Haisco shall be solely responsible for the labeling of the Product for use in such clinical studies.

5.2 **Development Responsibilities of Haisco.** Subject to the general oversight of the Steering Committee, Haisco shall have sole responsibility for and have sole right to carry out, the performance of, and unless otherwise expressly set forth in this Agreement, the sole cost of, the Development activities described below:

5.2.1 **Clinical Studies.** Haisco shall be solely responsible for, and have sole right to perform, the Development 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 IV commitments, periodic safety reviews, annual reports, regulatory submissions, and the development and implementation of a pharmacovigilance program. Haisco shall provide Aquestive data and documents relating to such Product Development and post-approval maintenance of the Regulatory Approvals requested by Aquestive, to the extent in Haisco's possession or Control. Haisco shall have no right to develop the Product formulation itself. In the event that Regulatory Authorities require any modification to the Product formulation, Aquestive shall, at Haisco's sole cost and expense, assess the feasibility of such modifications to the Product formulation and if feasible, engage in development of the Product formulation and shall deliver the necessary information and documents to Haisco in accordance with the requirements of the Regulatory Authorities.



5.2.2 Regulatory Activities. The Marketing Authorization Holder for the Product in the Territory shall initially be Aquestive and will, if and to the extent legally permissible, be transferred and continue to be held in Haisco's name. Haisco shall be responsible for preparing and filing all regulatory applications and documents in the Territory. Haisco shall be solely responsible for the conduct of, have sole right to conduct, and shall use Commercially Reasonable Efforts to, in consultation with Aquestive, conduct: all Development activities in connection with or as a condition of seeking or obtaining and maintaining Regulatory Approval of the Product in the Territory, including without limitation, preparing and filing all regulatory applications and documents in the Territory, the meetings with Regulatory Authorities in the Territory, the submission and maintenance of each Regulatory Approval Application and preparation and submission of any supplements thereto, conducting periodic safety reviews, all submissions to the Regulatory Authorities in the Territory, any 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 in compliance with all Applicable Law. Haisco shall be responsible and pay for one hundred percent (100%) of the costs and expenses incurred in connection therewith unless otherwise specifically provided for in this Agreement, and shall reimburse Aquestive as applicable for any costs incurred by Aquestive therewith, including but not limited to regulatory related fees, annual product fees, and establishment fees. Haisco 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. At no cost to Aquestive, Haisco shall provide Aquestive with a copy of its annual report in English for safety and Adverse Events filed with the applicable Regulatory Authority, on an annual basis; provided that: (i) Aquestive and Haisco shall have entered into a pharmacovigilance agreement in form and substance mutually agreed to in writing by Aquestive and Haisco; and (ii) Aquestive shall provide Haisco with a copy of equivalent reports for safety and Adverse Events filed with the applicable Regulatory Authority outside the Territory in English, on an annual basis. Haisco shall file each Regulatory Approval Application based on the clinical studies required by the applicable Regulatory Authority in accordance with Applicable Law. Haisco shall provide the Steering Committee with reasonable advance notice of Haisco's intent to file any Regulatory Approvals for the Product. At Haisco's written request, or if a Regulatory Authority in the Territory requires in writing, in connection with the Regulatory Approval or Regulatory Approval Application for the Product in the Territory additional pre-clinical, non-clinical, clinical, and CMC Data beyond the data transferred by Aquestive pursuant to Section 4, Aquestive shall undertake defined regulatory activities within the timeframe specified by the applicable Regulatory Authority or as otherwise agreed by the Parties in writing, including without limitation, conducting additional CMC studies if required by the Regulatory Authority, meetings with Regulatory Authorities and the preparation and submission of each Regulatory Approval Application for the Product in the Territory; provided, that: (a) Aquestive will provide Haisco with reasonable cost estimates and the parties mutually agree in writing to execute a Statement of Work for these activities prior to the commencement of such work; and (b) subject to the foregoing, Haisco will pay Aquestive for the conduct of such activities in accordance with the applicable Statement of Work.

### 5.3 **Changes.**

5.3.1 Haisco shall have the right, upon prior written notice to Aquestive, to change the labeling or packaging for the Product; provided that changes to the Product Label shall be subject to Aquestive's written consent. For the avoidance of doubt, however, a change concerning quantities within a package made in compliance with Applicable Law shall not be deemed a change to the Product Label and can be made at the sole discretion of Haisco. 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 as a result of the implementation of such changes. Subject to the foregoing, such changes shall be at Haisco's sole cost and expense (including the 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 to the extent detailed in the applicable Statement of Work, in each case, to the extent reasonable or as otherwise agreed to in writing by Aquestive and Haisco). 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 Haisco. Notwithstanding the foregoing, cost and expenses incurred in connection with change(s) to cure a non-conformity of the label and package of the Product with the Primary Packaging Design specifications shall be borne by Aquestive.

5.3.2 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 subject to the approval of, the other Party and, if approved, the Parties shall agree in writing on a reasonable timeframe for implementation of such changes. If either Party proposes making any material changes in the Specifications for the Product, 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 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 Haisco 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 Haisco if Haisco agrees in a prior written consent to pay the increase in the Product Transfer Price attributable to such change.

## 6. **COMMERCIALIZATION**

6.1 **Haisco Responsibility and Control.** Except as otherwise expressly set forth herein, subject to the general oversight of the Steering Committee, Haisco shall have sole

responsibility for and the sole right to perform all Commercialization activities for the Product in the Territory, including developing strategies and tactics related to the advertising, promotion, pricing, marketing, and selling the Product. Haisco shall comply and shall use Commercially Reasonable Efforts to require all of its Third Party sublicensees, agents and contractors, if any, to comply, with all Applicable Law in Commercializing the Product in accordance with this Agreement.

6.2 **Specific Commercialization Rights and Obligations of Haisco.** Subject to any conditions or limitations set forth herein, it shall be Haisco's sole right and responsibility to perform the Commercialization activities for the Product in the Field in the Territory, which may include without limitation, the activities set forth on Schedule 6.2. For the avoidance of doubt, subject to the general oversight of the Steering Committee, Haisco shall have the sole decision-making authority regarding the activities to be performed for the Commercialization of the Product in the Field in the Territory.

6.3 **Product Launch and Market Coverage.** Haisco will use its best efforts to launch the Product within the Territory within ninety (90) days of receipt of the Marketing Authorization

6.4 **Commercialization and Marketing Expenses.** Haisco shall be responsible for and pay one hundred percent (100%) of all costs and expenses incurred in connection with the Commercialization of the Product 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.

6.5 **Annual Stability Testing.** If any annual stability testing on Product is required by any Regulatory Authority in the Territory where the Product is or has been commercially sold, Haisco shall be responsible for all costs associated with the maintenance of annual stability. Aquestive shall use Commercially Reasonable Efforts to cooperate with Haisco, at the sole cost and expense of Haisco, to provide such documentation, methodologies and other information reasonably necessary to conduct any stability testing performed by Haisco. In the event that Haisco wishes to retain Aquestive to provide any such stability testing, the Parties will negotiate a separate written Statement of Work setting forth any services to be provided and associated fees in connection therewith.

## 7. **MANUFACTURING**

7.1 **Commercial Supply Obligations.** Subject to the terms and conditions of this Agreement, during the Term, Aquestive shall exclusively Supply Haisco and Haisco's Affiliates and sublicensees with, and Haisco shall exclusively purchase from Aquestive, all of Haisco's and its Affiliates' and sublicensees' requirements of the Product for commercial sale in the Territory during the Term, pursuant to binding purchase orders delivered by Haisco or its Affiliate to Aquestive in accordance with Section 7.3 ("Purchase Orders"). Aquestive shall Supply Product to Haisco in Units (single dosage strips packaged according to Product and/or sample Specifications and bulk packed for shipment) in accordance with the terms and conditions of this Agreement, Applicable Law, and the Specifications.

7.2 **Product Transfer Price.** Aquestive shall Supply quantities of each Unit of the Product to Haisco at an initial transfer price of [\*\*\*] per Unit (as same may be adjusted under this Agreement, the “Product Transfer Price”); provided, however, that (i) for orders placed subsequent to an event where a Generic Product is launched in the Field in the Territory by a Third Party, or (ii) orders placed subsequent to an event where the Product is listed in the National Reimbursement List with a price cut required, the Transfer Price shall be reduced by [\*\*\*] per dose. Aquestive may, after notification to Haisco and good faith discussions with Haisco, increase the Product Transfer Price providing Haisco not less than sixty (60) days written notice of any such proposed increase no more than once annually: (a) by the rate of price increase (if any) indicated by the Producer Price Index applicable to pharmaceutical preparations published by the U.S. Bureau of Labor Statistics, Department of Labor (or any applicable successor index to be agreed to by the Parties in good faith in the event of the discontinuation of same) over the prior twelve (12) month period; and (b) to the extent necessary to cover actual increases in the event that the Unit cost of goods of the Product (determined based on the market price of Aquestive’s Raw Materials) increases by a percentage greater than the change in the Producer Price Index referenced in clause (a) hereof, 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. Notwithstanding the foregoing, in the event that there will not be reasonable margin for Haisco due to the increase of Product Transfer Price, at the request of Haisco, the Parties shall discuss in good faith adjustment of Product Transfer Price and actions to be taken to control the cost of goods of the Product. Aquestive shall decrease the Product Transfer Price by the rate of price decrease (if any) indicated by the Producer Price Index applicable to pharmaceutical preparations published by the U.S. Bureau of Labor Statistics, Department of Labor (or any applicable successor index to be agreed to by the Parties in writing in good faith in the event of the discontinuation of same) over the prior twelve (12) month period within sixty (60) days after the date that Haisco is eligible for such price decrease; *provided, however*, any such price decrease shall occur no more than once annually, shall apply prospectively only and shall not apply to Product subject to binding Purchase Orders. Haisco will issue purchase orders in whole batch increments or as otherwise agreed to by the Parties. In the event that the Product is listed in the National Reimbursement List with a price cut of more than [\*\*\*] of the then current price, the Parties will discuss in good faith adjustment of the Product Transfer Price.

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

7.3.1 In order to assist Aquestive in planning production, Haisco shall deliver to Aquestive in advance of each Calendar Quarter a supply forecast that includes the quantities of each Product and Primary Packaging Design (including samples) required by Haisco, its Affiliates and/or sublicensees 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 commercial launch of the Product 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 five (5) Business Days after receipt of each such forecast, notify Haisco in writing of any objections or prospective problems in meeting Haisco’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.

7.3.2 Haisco 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 Unit quantity of the Product ordered and the requested date of delivery of the Product to Haisco. Haisco shall furnish Purchase Orders by the fifth (5<sup>th</sup>) Business Day of each month and a minimum of sixty (60) days prior to the requested delivery date. Each Purchase Order shall be in whole batch increments of Units and Primary Packaging Design based on batch sizes and minimum orders as mutually 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, unless otherwise agreed by the Parties in writing. Aquestive shall accept each Purchase Order from Haisco so long as such Purchase Order is furnished in accordance with this Section 7.3.2 and makes reference that such Purchase Order is being furnished pursuant and subject to this Agreement.

7.3.3 An individual Purchase Order shall be deemed fulfilled with respect to the quantity requirements as long as no less than [\*\*\*] and no more than [\*\*\*] of the quantities are delivered against the individual Purchase Order. For any delivery that delivers less than [\*\*\*] of the quantities set forth in the applicable Purchase order, Aquestive shall deliver such quantity of conforming Product that is equal to the difference between the number of Units delivered and the number of Units ordered in the applicable Purchase Order in accordance with Section 7.8. Haisco agrees to accept delivery of up to [\*\*\*] of the requested Purchase Order. For any delivery that delivers more than one [\*\*\*] of the quantities set forth in the applicable Purchase Order, Haisco will retain such quantity of Product that is equal to the difference between the number of Units delivered and the number of Units ordered in the applicable Purchase Order at Haisco's sole cost and adjust the prospective supply forecast accordingly, provided that Aquestive shall be responsible for any material, documented, incremental, out-of-pocket storage costs incurred by Haisco as a result of delivery of Product in excess of [\*\*\*] of any Purchase Order. 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.

7.3.4 Aquestive shall deliver Product set forth in each Purchase Order Ex Works (Incoterms 2020 edition, published by the International Chamber of Commerce and any successor thereto) at the applicable manufacturing facility to Haisco's designated carrier as specified by Haisco in the applicable Purchase Order or otherwise notified in writing to Aquestive by Haisco.

7.4 **Invoice.** Aquestive shall invoice Haisco at the Product Transfer Price for all quantities of Product delivered in accordance herewith. Each invoice shall be substantially in the form attached hereto as Schedule 7.4 (a "Commercial Invoice") and shall be delivered at least three (3) days prior to each shipment of Product, and shall be accompanied by a Certificate of Analysis, Certificate of Compliance, certificate of origin and any other documentation required by the applicable Regulatory Authorities or by Applicable Law to Commercialize or import the



Product in the Territory. Payments shall be made in accordance with Section 8.5, and shall be due within forty-five (45) days after the date of a Commercial Invoice with respect to Product delivered, subject to the procedure for rejected shipments set forth in Section 7.5. In the event that any Commercial Invoice is disputed by a Party, the Parties shall meet to discuss and submit any relevant document necessary for clarifications.

7.5 **Product Not in Compliance.** Within forty-five (45) days after delivery of the Product at the applicable manufacturing facility to Haisco's designated carrier, Haisco or its agent shall perform a reasonable physical examination of the Product, the Certificates of Analysis, the Certificate of Compliance, and other documentation, if any, provided with each shipment of Product, and shall determine whether such Product meets the Specifications and the applicable Purchase Order. If Haisco does not submit written notice that the Product does not meet the Specifications and Purchase Order, including the reasons therefore, within forty-five (45) days after delivery of the Product at the applicable manufacturing facility to Haisco's designated carrier, such Product shall be deemed accepted by Haisco; provided, however, that such acceptance or deemed acceptance shall not adversely affect any claim: (i) in respect of a latent defect (whether prior to or after acceptance of the Product) discovered within two (2) years of delivery at the applicable manufacturing facility to Haisco's designated carrier; (ii) for indemnification provided in Section 11; or (iii) in respect of a defect determined by the customs authorities in the Territory or the NMPA attributable to Aquestive and not Haisco or its subcontractors, sublicensees or agents. If Haisco and Aquestive do not agree on the rejection of Product, then either Party may refer the matter for final analysis to an independent Third Party laboratory of international reputation pursuant to Section 7.6 for the purpose of determining the results.

7.6 **Independent Testing.** If Aquestive disagrees with Haisco's rejection of any shipment of the Product, then the Product shall be submitted to an independent Third Party laboratory of international reputation, mutually and reasonably acceptable to both Parties in writing, for analytical testing to determine the extent of the Product's compliance or non-compliance with the Specifications. Any determination by such Third Party laboratory will 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 laboratory's findings are made.

7.7 **Return or Destruction of Non-Conforming Product.** Notwithstanding any other provisions of this Agreement, Haisco agrees to return to Aquestive, or at Aquestive's direction, dispose of such Product (including Products with any latent defects and/or defects determined by the customs authorities in the Territory or the NMPA) as Haisco and Aquestive may agree, any Product, in any such case at Aquestive's sole cost, that: (a) does not conform with the Specifications at the time of the Product at the applicable manufacturing facility to Haisco's designated carrier; (b) is not in compliance with the Purchase Order (except as to quantity) as set forth in Section 7.5; or (c) if Haisco and Aquestive otherwise mutually agree in writing. Aquestive shall be responsible for the costs associated with the return and/or proper disposal of all such Product not in conformance with the Specifications at the time of shipment and shall, at the option of Haisco, promptly replace (at Aquestive's sole cost) such shipment of Product to conform to the applicable Specifications and Purchase Order but in no event later than

thirty (30) days after (a) notified of such non-conformity or non-compliance, or (b) the date that Haisco and Aquestive otherwise agree in writing.

7.8 **Raw Material and 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 Haisco's requirements for Products for the succeeding ninety (90) days based on Haisco's most recent quarterly forecast delivered pursuant to Section 7.3.1 ("Raw Materials Safety Stock"). Deliveries by Aquestive to Haisco of Product may use the Raw Materials Safety Stock. Aquestive shall keep Haisco 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.

7.9 **Delivery Failure.**

7.9.1 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 Haisco, 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").

7.9.2 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 Haisco or a dispute covered by Section 7.5, by written notice to Aquestive Haisco 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 Haisco; and (iii) recover any expedited shipping fees actually incurred by Haisco as a direct result of such Delivery Failure, in each only if such Delivery Failure results in Haisco can establish that it will have insufficient inventory of Product to satisfy forecasted customer orders for the succeeding sixty (60) days.

7.9.3 Notwithstanding anything in this Section 7.9 or elsewhere in this Agreement to the contrary, any delay in delivery to the extent due to Force Majeure, Haisco's requested change of a binding Purchase Order, or any gross negligence on the part of Haisco shall not be regarded as Delivery Failure.

7.10 **Inspections.** Aquestive shall, and shall cause its Affiliates and the Third Party API supplier(s) that are involved in the Supply for use in the Territory to, cooperate and allow representatives of any Regulatory Authority to inspect the relevant parts of the facility where the manufacture of the API or Product is carried out as required by Applicable Law and shall promptly notify Haisco of the scheduling of any such inspection relating to Supply, in each case, at Aquestive's sole cost and expense. Upon reasonable advance written notice during the Term, Aquestive shall, and shall use Commercially Reasonable Efforts to cause other Third Parties that are involved in the Supply for use in the Territory to, permit any Regulatory Authority to inspect the relevant parts of the facility where the manufacture and Supply of any API or Product is carried out in order to assess quality issues with any Product and Aquestive's and such Third Parties' compliance with Applicable Law, in each case, at Aquestive's sole cost and expense.

7.11 **Samples.** If Haisco desires to obtain Product to be used as samples to be distributed to prescribers for the benefit of patients in the Territory, Haisco shall order such Product samples under Purchase Orders separate from the Product for sale, as otherwise approved by the Steering Committee. Haisco agrees that it shall use and distribute Product samples in compliance with all Applicable Law, and Aquestive shall be entitled to, at Aquestive's sole cost and expense, conduct an inspection and audit of the Product sample distribution practices by Haisco in the Territory.

7.12 **Quality Agreement.** In connection with the manufacturing activities of the Product under this Agreement, Haisco and Aquestive will enter into one or more agreements that detail the quality assurance obligations of each Party with respect to the manufacture and supply of the Product by Aquestive which agreements shall be drafted in English (the "Quality Agreement"). Notwithstanding the foregoing, neither the Quality Agreement, nor the absence of a Quality Agreement, shall affect the rights and obligations of the Parties under this Agreement or limit Aquestive's ability to release batches of Product conforming to the Specifications. The Parties shall amend the Quality Agreement from time to time, as the Parties deem necessary. The Quality Agreement, as may be amended from time to time, is hereby incorporated by reference into and made part of this Agreement. In the event of conflict between terms of a Quality Agreement and the terms of this Agreement, the terms of this Agreement will govern with respect to all matters.

7.13 **Adverse Event and Safety Reporting.** Prior to the First Commercial Sale, the Parties will enter into a written Safety Data Exchange Agreement with respect to the Product which is hereby incorporated by reference into and made part of this Agreement. Notwithstanding anything to the contrary contained in this Agreement, Haisco shall be responsible for making all reports of Adverse Events to the applicable Regulatory Authority.

## 8. **PAYMENTS AND REPORTS**

8.1 **Milestone Payments.** A one-time non-refundable payment will be due from Haisco to Aquestive in consideration of the first achievement of the following events (the "Events"):

Event		Milestone Payment (U.S. Dollars)	Date Payment Due
1.	Execution of this Agreement	\$7,000,000	The earlier to occur of : (i) sixty (60) days after the Effective Date; and (ii) five (5) Business Days following the date on which tax filings with the applicable governmental authorities to release the payment has been completed
2.	Receipt of the Marketing Authorization for the Product in the Territory.	[***]	Within forty-five (45) days after the later of: (i) the achievement of the milestone; and (ii) the date on which Haisco has received the Commercial Invoice with respect thereto

8.2 **Notice; Payment.** Haisco shall deliver written notice to Aquestive of the achievement of the Event 2 set forth in Section 8.1 within Haisco’s responsibility within three (3) Business Days after the achievement of Event 2 by Haisco or its Affiliates.

8.3 **Royalties.** During the Term, and in addition to any payments set forth in Sections 7.2 and 8.1, Haisco shall pay to Aquestive a royalty payment of Net Sales of each Product in a given Royalty Period in the Territory as set forth below:

Amount of Net Sales during a Calendar Year		Royalty Rate* as Percentage of Net Sales
1.	Less than and including [***]	[***]
2.	Above US \$20,000,000 up to and including [***]	[***]
3.	Greater than [***]	[***]

For the avoidance of doubt, if the amount of Net Sales in the Territory in a given calendar year equals [\*\*\*], the royalty payment owed by Haisco to Aquestive pursuant to this Section 8.3 for such calendar year would be [\*\*\*], which is calculated as follows: [\*\*\*].

\*Once a Generic Product is for sale in the Territory (to the extent such Generic Product entry has resulted in a reduction in the commercial price of the Product in the Territory), the royalty rate in this Section 8.3 with respect to Net Sales for the Product will be adjusted to [\*\*\*] of the then current royalty rate.

8.4 **Minimum Payment Commitment.** In the event, in any full calendar year, Haisco’s annual composite payments to Aquestive (including Product Transfer Price and royalties) under this Agreement in such calendar year for the Product is less than the minimum amount set forth for such calendar year below (the “Minimum Payment Commitment”), then

unless such failure is attributable to the failure of Aquestive to supply conforming Product to Haisco under this Agreement (which amount shall be subtracted from the amount that Haisco shall pay pursuant to this Section 8.4), Haisco shall pay the differential (between actual amounts paid or payable to Aquestive in such calendar year and the Minimum Payment Commitment) within forty-five (45) days after the later of: (i) the date of the applicable Royalty Report, or (ii) the date on which Haisco has received the Commercial Invoice with respect thereto:

Event		Minimum Payment Commitment (U.S. Dollars)
1.	First Year After Marketing Authorization is Granted	[***]
2.	Second Year After Marketing Authorization is Granted	[***]
3.	Third Year After Marketing Authorization is Granted	[***]
4.	Fourth Year After Marketing Authorization is Granted	[***]
5.	Fifth Year After Marketing Authorization is Granted and Beyond	[***]

Haisco’s obligation to pay the Minimum Payment Commitment shall commence from and after the date Haisco receives the Marketing Authorization.

**8.5 Haisco Royalty Reports and Payments.** During the Term after the commercial launch of the Product in the Field in the Territory, Haisco shall submit royalty reports (each, a “Royalty Report”) to Aquestive within twenty (20) days following the end of each Royalty Period. Each Royalty Report shall cover the most recently completed Royalty Period and shall show: (a) the aggregate gross and Net Sales of the Product during the most recently completed Royalty Period, including reasonable detail with respect to the calculation of Net Sales, units sold, discounts, credits and other components in the calculation of Net Sales; (b) the royalties, in Chinese Yuan, payable with respect to such Net Sales, provided however, that with respect to the fourth Royalty Report, such royalties payable shall be adjusted based on the royalty rate applicable to the amount of Net Sales during such calendar year, and the amount of royalties paid following the issuance of the second Royalty Report. Within forty five (45) days after the later of: (i) the date upon which the second Royalty Report and the fourth Royalty Report, respectively, in a given semi-annual period in a calendar year during the Term are furnished; provided however, that with respect to the amount of payment following the second Royalty Report, (x) if the aggregate Net Sales falls within Tier 1, the aggregate amount payable shall not exceed [\*\*\*] ; (y) if the aggregate Net Sales falls within Tier 2, the aggregate amount payable shall not exceed [\*\*\*] ; and (ii) the date on which Haisco has received the electronic Commercial Invoice issued to Haisco with respect to the applicable amounts, Haisco shall pay to Aquestive a sum equal to the payment shown as due on such Royalty Reports calculated in accordance with this Agreement.

**8.6 Manner of Payment.** All sums due under this Agreement shall be payable in U.S. dollars by bank wire in immediately available funds to such bank account(s) as Aquestive shall designate in writing. All amounts due to Aquestive hereunder not paid within thirty (30)



days of the date due shall bear interest at the rate equal to [\*\*\*] per annum or at the highest rate permitted by Applicable Law, whichever is less.

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

8.8 **Taxes and Withholding.**

8.8.1 Each Party shall be responsible for its own tax liabilities arising under this Agreement and Aquestive shall be liable for all of its income taxes (including interest) imposed upon any payments made by Haisco to Aquestive under this Agreement.

8.8.2 If Haisco is required by Applicable Law to withhold taxes, Haisco will: (a) increase the amount so that the amount actually paid to Aquestive (after withholding of such taxes) equals the amount initially payable to Aquestive under this Agreement; (b) pay to the relevant authorities the full amount otherwise required to be deducted or withheld promptly upon determining that such deduction or withholding is required; and (c) forward to Aquestive an official receipt (or certified copy) or other documentation reasonably acceptable to Aquestive evidencing such payment to such authorities.

8.8.3 The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Haisco to Aquestive under this Agreement. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

8.9 **Accounting.** 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 the Chinese Accounting Standards, including the calculation of Net Sales and royalties due Aquestive hereunder; provided that when the actual results become known in accordance with the Chinese Accounting Standards relative to any accrued amount, any difference between the actual results and the accrual is 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, Haisco shall pay Aquestive the amount of such underpayment on the next date payment is due to Aquestive hereunder. To the extent that the difference between such accruals and the actual results has led to an overpayment, Aquestive shall deduct such amount from the next payment due to Aquestive under this Agreement, provided that if there are no future payments due to Aquestive under the Agreement, Aquestive shall refund such amount to Haisco within forty-five (45) days after the determination that an overpayment has been made.

8.10 **Record Keeping; Audits.** Haisco and its Affiliates shall keep books and accounts of record in connection with Net Sales of the Product in sufficient detail to permit accurate determination of all figures necessary for verification of royalties to be paid hereunder. Haisco and its Affiliates shall retain such records for a period of at least seven (7) years after the

end of the Calendar Quarter in which they were generated; provided, however, that if any records are in dispute and Haisco has received written notice from Aquestive of the records which are in dispute, then Haisco and its Affiliates shall keep such records until such dispute is resolved. No more than once in the first calendar year after the commercial launch of the Product in the Field in the Territory and no more than once per calendar year thereafter, upon reasonable advance written notice to Haisco, Aquestive will have the right to engage an internationally recognized public accounting firm chosen by Aquestive and reasonably acceptable to Haisco (which accounting firm will not be the external auditor of Aquestive, 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 Haisco to determine the correctness of the amount of royalties paid to Aquestive 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 Haisco only to the extent necessary for verification of royalties to be paid hereunder, upon thirty (30) days’ prior written notice having been given by Aquestive, during regular business hours, for the sole purpose of determining compliance with the Net Sales royalty provisions of this Agreement. Prior to any such examination taking place, the CPA Firm will enter into a confidentiality agreement reasonably acceptable to Haisco 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 Aquestive or any Third Party any information labeled by Haisco as being confidential customer information regarding pricing or other competitively sensitive proprietary information. Aquestive and Haisco will be entitled to receive a full written report of the CPA Firm with respect to its findings to the extent relevant to verification of royalties to be paid hereunder and Aquestive will provide, without condition or qualification, Haisco with a copy of the report, or other summary of findings, prepared by such CPA Firm promptly following Aquestive’s receipt of same. In the event of any dispute between Aquestive and Haisco 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 will resolve the dispute, and such accounting firm’s determination will be binding on both Parties absent manifest error by such accounting firm. All costs and expenses of such auditor incurred in connection with performing any such audit shall be paid by Aquestive unless such audit discloses an underpayment of at least ten percent (10%), in which case Haisco shall bear such costs and expenses.

8.11 **Underpayments and Overpayments.** If an audit conducted pursuant to Section 8.10 reveals that additional royalties were due to Aquestive under this Agreement, then Haisco shall pay to Aquestive the additional royalties within forty-five (45) days of the date Haisco receives the Commercial Invoice with respect to such underpayment. If an audit conducted pursuant to Section 8.10 reveals that Aquestive was paid royalties in excess of those royalties due to Aquestive under this Agreement, then Haisco shall be entitled to deduct such amount from the next royalty payment due Aquestive under this Agreement, provided that if there are no future royalty payments due to Aquestive under this Agreement, Aquestive shall refund such amount to Haisco within forty-five (45) days of the date Aquestive receives written notice of such overpayment.

8.12 **Currency Conversion.** Net Sales numbers will be converted from Chinese Yuan to US Dollars applying a weighted average exchange rate based on monthly Net Sales. This calculation shall be based on (i) the three-month period associated with the applicable Royalty Period and (ii) the published average exchange rate by the Board of Governors of the Federal Reserve System (“**Exchange Rate**”) for the month in which such sales were made. For the avoidance of doubt, the Net Sales numbers in US Dollars in a Royalty Period shall be calculated as follows: Month 1 Net Sales in Chinese Yuan / Month 1 Exchange Rate + Month 2 Net Sales in Chinese Yuan / Month 2 Exchange Rate + Month 3 Net Sales in Chinese Yuan / Month 3 Exchange Rate.

## 9. **REPRESENTATIONS, WARRANTIES AND COVENANTS**

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

9.1.1 **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.

9.1.2 **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.

9.1.3 **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.

9.1.4 **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.

9.1.5 **No Conflict with Agreement.** Each Party agrees not to engage in any action that is in violation or inconsistent with the terms and conditions of this Agreement or that interferes with the consummation of the transactions contemplated under this Agreement.

9.1.6 **Bankruptcy; Insolvency.** Neither Party is aware 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.

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

9.2.1 **Right to Grant Licenses.** Aquestive and its Affiliates owns or is the exclusive licensee of the rights, title, and interest in and to the Aquestive Patents and have the right to grant the licenses granted to Haisco herein.

9.2.2 **Aquestive Patents and Aquestive IP.** The Aquestive Patents represent all patents within Aquestive's and its Affiliates' Control relating to the Product, or the Development, Supply or Commercialization thereof, as of the Effective Date. The Aquestive IP is sufficient to enable Haisco in all material aspects to Develop in accordance with Section 5.1 and Commercialize the Product in the Field in the Territory.

9.2.3 **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 Haisco 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 Haisco's rights under this Agreement.

9.2.4 **Compliance with Applicable Law.** During the Term, Aquestive and each manufacturing facility in which the Product is manufactured, shall comply with, and maintain in force all licenses, consents, permits and authorizations necessary to perform its obligations under this Agreement.

9.2.5 **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.

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

9.3.1 **Right to Grant Licenses.** Haisco and its Affiliates have the right to grant the licenses granted to Aquestive herein.

9.3.2 **Third Party Agreements.** As of the Effective Date, neither Haisco 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.

9.3.3 **Compliance with Applicable Law.** Haisco 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.

9.3.4 Compliance with Anti-Bribery, Anti-Corruption, and Ethics Policies. Haisco and its Affiliates shall comply with, and shall use Commercially Reasonable Efforts to ensure that its sublicensees, subcontractors and agents comply with Applicable Anti Bribery and Anti-Corruption Laws. Haisco shall have and maintain in place through the Term its own policies and procedures to the extent required by and in accordance with the Applicable Law. Haisco will promptly report to Aquestive any request or demand for any undue or suspicious financial or other advantage of any kind received by Haisco in connection with the performance of this Agreement.

9.3.5 No Debarment. None of Haisco 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.

9.4 **Disclaimer.** EACH PARTY 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 LAW, INCLUDING WITH RESPECT TO THE PRODUCTS OR ANY TECHNOLOGY OR OTHER INTELLECTUAL PROPERTY LICENSED OR GRANTED UNDER THIS AGREEMENT, INCLUDING ANY WARRANTY OF NON-INFRINGEMENT, QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OR TRADE. FOR THE AVOIDANCE OF DOUBT, NOTHING CONTAINED IN THIS SECTION 9.4 SHALL OPERATE TO LIMIT OR INVALIDATE ANY EXPRESS WARRANTY CONTAINED HEREIN OR ANY IMPLIED WARRANTY OF GOOD FAITH AND/OR FAIR DEALING.

## 10. **CONFIDENTIAL INFORMATION**

10.1 **General.** Pursuant to the terms of this Agreement, each of Aquestive and Haisco (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 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 or other Governmental 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 (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.

## 11. **INDEMNIFICATION; LIMITATION OF LIABILITY**

11.1 **Indemnification by Haisco.** Haisco shall defend, indemnify and hold harmless Aquestive and its Affiliates and each of their respective officers, directors, shareholders, employees, successors and assigns (“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 Haisco (or any of its Affiliates, sublicensees, subcontractors or agents) any of its obligations under this Agreement; (b) a material breach by Haisco or any of its Affiliates, sublicensees, subcontractors or agents of any of Haisco’s representations, warranties, covenants or agreements under this Agreement; (c) the conduct of clinical studies or other Development activities related to the Product in the Field in the Territory by or on behalf of Haisco; (d) the Commercialization by or on behalf of Haisco of the Product in the Field in the Territory; or (e) violation of Applicable Law by any Haisco Indemnitee. Notwithstanding the foregoing, in all cases referred to in the preceding sentence, Haisco 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: (i) the gross negligence or willful misconduct or intentional wrongdoing of Aquestive or any of its Affiliates, subcontractors or agents; (ii) any breach by Aquestive or any of its Affiliates, subcontractors or agents of Aquestive’s representations, warranties, covenants or agreements under this Agreement; or (iii) matters for which Aquestive has an obligation to indemnify any Haisco Indemnitee pursuant to Section 11.2. For the avoidance of doubt, Aquestive shall be entitled to rely on Haisco’s sole judgment in fulfilling its obligations under Section 5.2 and Section 6.2 and such reliance shall in no way limit Aquestive’s rights or Haisco’s obligations under this Section 11.1.

11.2 **Indemnification by Aquestive.** Aquestive shall defend, indemnify and hold harmless Haisco and its Affiliates and each of their respective officers, directors, shareholders, employees, successors and assigns (“Haisco 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 its obligations under this Agreement; (b) a material breach by Aquestive or any of its Affiliates, subcontractors or agents of any of its representations, warranties, covenants or agreements under this Agreement; (c) the conduct of development activities related to the Product outside the Field or outside the Territory by or on behalf of Aquestive; (d) the manufacture or Supply of API or Product by or on behalf of Aquestive; (e) the Commercialization of the Product outside the Field or outside the Territory by or on behalf of Aquestive; or (f) 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 Haisco Indemnitee for any Losses of such Haisco Indemnitee to the extent that such Losses were caused



by: (i) the gross negligence or willful misconduct or intentional wrongdoing of Haisco or any of its Affiliates, subcontractors or agents; (ii) any breach by Haisco or any of its Affiliates, subcontractors or agents of Haisco's representations, warranties, covenants or agreements under this Agreement; or (iii) matters for which Haisco 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 other than patent claims (which are subject to the procedures set forth in Section 14.4 or Section 14.5) 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 except as set forth in Section 14.4 or Section 14.5, 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 such Indemnitee. 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 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, 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 in a manner which admits fault or negligence on the part of the Indemnitee without the prior written consent of the Indemnitee. 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.

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 will maintain, at its cost, a program of insurance or self-insurance against liability and other risks associated with its activities and obligations under this Agreement, in such amounts, subject to such deductibles and on such terms as are reasonable and customary for the activities to be conducted by it under this Agreement, in accordance with the Applicable Law. Each Party acknowledges and agrees that its liabilities under this Agreement will not be limited by the amount of such Party's insurance. Each Party shall provide notice to the other Party at least thirty (30) days prior to the cancellation of any such insurance policy or any substantial modification of the terms of such coverage under any such insurance policy. Each Party shall provide written proof of the existence of such insurance to the other Party upon written request.

#### 11.5 Limitation of Liability.

11.5.1 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR A BREACH OR ALLEGED BREACH

OF THIS AGREEMENT. THE FOREGOING SENTENCE SHALL NOT (A) APPLY IN CASES OF A PARTY'S FRAUD, GROSS NEGLIGENCE, WILLFUL MISCONDUCT, OR INTENTIONAL MISCONDUCT, (B) NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTIONS 11.1 OR 11.2, OR (C) LIMIT THE DAMAGES AVAILABLE TO A PARTY FOR A BREACH UNDER SECTION 2.2, SECTION 2.3, SECTION 2.5, OR SECTION 10.

11.5.2 FOR THE AVOIDANCE OF DOUBT, NOTHING IN THIS AGREEMENT SHALL LIMIT ANY REMEDY EITHER PARTY MAY HAVE AGAINST THE OTHER PARTY FOR CLAIMS BASED ON FRAUD, WILLFUL MISCONDUCT OR INTENTIONAL MISCONDUCT, AND NOTHING HEREIN SHALL LIMIT THE LIABILITY OF ONE PARTY TO THE OTHER PARTY FOR FRAUD, WILLFUL MISCONDUCT OR INTENTIONAL MISCONDUCT IN THE EVENT SUCH PARTY IS FINALLY DETERMINED BY AN ARBITRATOR OR COURT OF COMPETENT JURISDICTION TO HAVE COMMITTED FRAUD, WILLFUL MISCONDUCT OR INTENTIONAL MISCONDUCT AGAINST THE OTHER PARTY.

## 12. **TERM AND TERMINATION**

12.1 **Term.** The initial term shall commence as of the Effective Date and shall and run until the [\*\*\*] of the First Commercial Sale (together with any renewal term, the "**Term**"). Haisco shall have the option to renew this Agreement upon written notice delivered to Aquestive no later than one hundred eighty (180) days prior to the expiration of the then current term.

12.2 **Termination.** In addition to any other provision of this Agreement expressly providing for termination of this Agreement:

12.2.1 This Agreement may be terminated 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 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 ninety (90) days after receipt of a written notice describing the breach and requiring it to be so remedied.

12.2.2 This Agreement may be terminated (i) by Aquestive upon thirty (30) days' prior written notice if Haisco has violated Section 2.3 or the first sentence of Section 7.1; or (ii) by Haisco upon thirty (30) days' prior written notice if Aquestive has violated Section 2.2 or the first sentence of Section 7.1.

12.2.3 This Agreement may be terminated upon thirty (30) days' prior written notice by Aquestive if in or after [\*\*\*] after Marketing Authorization is granted, Haisco is permitted to make a Minimum Payment Commitment in [\*\*\*].

12.2.4 This Agreement may be terminated by Aquestive upon written notice if Haisco does not use Commercially Reasonable Efforts to execute its Development or

Commercialization responsibilities for the Product and fails to remedy such deficiency within sixty (60) days after receipt of a written notice from Aquestive describing the deficiency.

12.2.5 This Agreement may be terminated by Aquestive upon written notice, in the event: (a) Haisco and/or any of its activities are completely nationalized, expropriated, or taken over by a Governmental Authority; or (b) any Governmental Authority requires the Supply of the Product be conducted in the Territory.

12.2.6 This Agreement may be terminated by Haisco upon written notice if Aquestive does not use Commercially Reasonable Efforts to execute its Development or Supply responsibilities for the Product and Aquestive fails to remedy the same within sixty (60) days after receipt of a written notice from Haisco describing failure and requiring it to be so remedied.

12.2.7 This Agreement may be terminated by Haisco immediately upon written notice to Aquestive if, regardless whether Commercially Reasonable Efforts are used and regardless whether Aquestive has issued instruction(s) or request(s) to the relevant Third Parties, within the time period specified in Section 4 (subject to Section 4.2.4 and Section 4.2.5, inclusive), Aquestive fails to transfer or cause the Third Parties to (x) transfer to Haisco the Regulatory Documentation, or (y) transfer to Haisco (or in the alternative, directly filed with the Regulatory Authorities) the DMFs or equivalent documentation required by the Regulatory Authority to support the application for Regulatory Approval for the Product in the Territory, subject to the extension of time to comply with such requests for documentation under Section 4.2.7, and such failure has not been cured within forty-five (45) days following receipt of written notice from Haisco requesting cure of the failure.

12.2.8 In the event that (i) Marketing Authorization for the Product is withdrawn in any country or region due to safety reasons, or (ii) the Product is recalled in any country or region due to safety reasons and such recall has materially and adversely affected the reputation of such Product, the Parties shall immediately initiate a good faith discussion with respect to terminating this Agreement by mutual consent. If the Parties fail to reach a mutual agreement within sixty (60) days following the withdrawal or recall, this Agreement may be terminated by Haisco immediately upon delivery of written notice to Aquestive.

12.2.9 This Agreement may be terminated by Haisco immediately upon delivery of written notice to Aquestive in the event that [\*\*\*] Generic Products are simultaneously sold in the Territory.

12.2.10 This Agreement may be terminated by Aquestive upon written notice to Haisco in the event that Haisco fails to pay any milestone payment as and when due pursuant to Section 8.1, or any royalty or Minimum Payment Commitment and fails to remedy same within sixty (60) days of receipt of a written notice describing the failure and requiring it to be so remedied.

12.2.11 This Agreement may be terminated by either Party upon ninety (90) days written notice to the other Party if Marketing Authorization in the Field in the Territory has not been granted on the date that is [\*\*\*] after the Effective Date.



12.2.12 This Agreement may be terminated by Haisco for any reason or no reason giving six (6) months advance written notice to Aquestive. Haisco's right to terminate the Agreement under this Section 12.2.12 shall be subject to Haisco's payment of the Event 1 milestone payment set forth in Section 8.1, to the extent not already paid to Aquestive.

12.2.13 This Agreement may be terminated by Aquestive upon written notice to Haisco if Haisco, any Affiliate or Third Party acting on its behalf, challenges the validity of any licensed Aquestive IP or Joint New IP.

### 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 shall cease.

12.3.2 Disposition and Transfer of Inventory upon Termination; Royalties Due Thereon Not Affected By Termination. On the expiration or earlier termination of this Agreement: (a) all unpaid royalties for Product sold as of the effective date of termination shall remain due and payable as scheduled; (b) at Aquestive's option (or at Haisco's option terminated pursuant to Section 12.2.1(b), or Sections 12.2.6 through 12.2.9, inclusive), Aquestive shall complete all work-in-process and Haisco shall purchase at the Product Transfer Price under this Agreement, all remaining inventory of the Product and, at cost, all Raw Materials relating thereto in Aquestive's possession or control (but not to exceed a supply of Product corresponding to the first three (3) months of the most recent supply forecast delivered by Haisco in accordance with Section 7.3) and Aquestive shall use all Commercially Reasonable Efforts to mitigate the cost thereof to Haisco and to consult with Haisco in connection with such attempts to mitigate; (c) Haisco shall have the right to sell out such remaining inventory of Product for a period of up to six (6) months; and (d) Haisco shall pay to Aquestive a royalty, and subject to all of the provisions of Section 8.3, Section 8.5 through Section 8.9, and Section 8.12, on each sale of remaining inventory of Product by Haisco and/or its Affiliates when and as such Product is sold.

12.3.3 Upon the expiration or earlier termination of this Agreement for any reason other than other than for a termination by Haisco pursuant to Section 12.2.1(b), or Sections 12.2.6 through 12.2.9, inclusive, 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, and without cost, of all of Haisco's right, title and interest, if any, at the time of expiration or termination, in and to: (a) each Regulatory Approval; and (b) all data generated in support of such Regulatory Approvals, including, without limitation, from all associated clinical studies. In the event of a termination by Haisco pursuant to Section 12.2.1(b), or Sections 12.2.6 through 12.2.9, inclusive, such assignment shall be made for consideration equaling Haisco's out-of-pocket costs incurred (excluding payments made by Haisco to Aquestive in respect of same under this Agreement). In connection with any assignment contemplated by this Section 12.3.3, Haisco shall cooperate with Aquestive and execute and deliver to Aquestive any and all documents reasonably necessary to perfect its or Aquestive's designee's rights to the foregoing and, to the extent applicable, Haisco shall ensure that all such Regulatory Approvals to be assigned remain in good standing until such assignment to Haisco is complete.

12.3.4 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.

12.3.5 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, 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(c)), Sections 7.4 (survive for the sole purpose of Product ordered by Haisco prior to the termination of this Agreement), 7.5, 7.6 and 7.7, Sections 7.9, Section 8.1 (solely with respect to unpaid milestone payments which have accrued as of such termination), Section 8.3 (solely with respect to unpaid royalties which have accrued as of such termination or otherwise as set forth in Section 12.3.2(c)), Section 8.5 through Section 8.9 (solely with respect to unpaid royalties which have accrued as of such termination or otherwise as set forth in Section 12.3.2(c)), Section 8.12 (solely with respect to royalty payments due after such termination or expiration for sales prior to such termination or expiration), Sections 9.4, 10, 11, 12.3, 13.5, 14.1.1 through 14.1.5, 14.7, 14.8, and 15.

12.3.6 Return of Confidential Information. Within thirty (30) days of any expiration or termination of this Agreement: (a) Haisco shall cease to use and shall deliver to Aquestive, upon written request, all Confidential Information of Aquestive, except for any documents or records that Haisco is required to retain by Applicable Law or that are reasonable necessary for Haisco to exercise its rights under Section 12.3.2; and (b) Aquestive shall cease to use and shall deliver to Haisco, upon written request, all Confidential Information of Haisco 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.

12.3.7 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Aquestive or Haisco are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party’s

possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

### 13. **REGULATORY MATTERS**

13.1 **Regulatory Approvals in the Territory.** Haisco shall use Commercially Reasonable Efforts, in good faith, at Haisco's sole cost and expense, to conduct such research and Development activities, including clinical trials and dossier gap assessments, necessary or desirable to obtain, as promptly as reasonably Regulatory Approval for the Product in the Territory and shall take all such reasonable actions as shall be necessary or appropriate to prepare and file all documentation with the applicable Regulatory Authorities and to furnish such information to the Regulatory Authorities in connection therewith.

13.2 **Regulatory Strategies in the Territory.** Subject to the provisions of this Section 13, Haisco shall have sole control, and have authority and responsibility for, the regulatory strategies relating to the Product in the Territory prior to approval, including, without limitation: (a) the preparation of all documents filed with Regulatory Authorities and the filing of all submissions relating to Regulatory Approval for the Product; (b) all regulatory actions, communications and meetings with any Regulatory Authority with respect to the Product; and (c) applying for and obtaining Regulatory Approvals for the Product in the Territory. Haisco shall be responsible for all costs associated with filings with Regulatory Authorities and additional Development work necessary for Regulatory Approvals in the Territory. Haisco shall provide to Aquestive in a timely fashion drafts and final copies of material filings, documents, or correspondence (as the scope of which shall be agreed by the Parties in writing) to be filed with any Regulatory Authority in the Territory that pertains to the Product in Chinese with a summary in English. At Aquestive's written request and at the sole cost and expense of Aquestive, Haisco will provide Aquestive with a copy of English translation of such drafts and final copies described in this Section 13.2. Haisco shall consider in good faith the comments of Aquestive with respect to any such material filings, documents, or correspondence.

### 13.3 **Communications and Meetings with Governmental Authorities.**

13.3.1 **Communications with Regulatory Authorities.** Subject to the provisions of this Section 13, Haisco shall be solely responsible for interfacing, corresponding, and meeting with all Regulatory Authorities for Regulatory Approvals in the Territory. At all times during the Term, Haisco shall be responsible, at its expense, for reporting any and all Adverse Events to the applicable Regulatory Authorities. Immediately upon receipt of any contact with or communication from any Regulatory Authority relating to the Product or becoming aware of any Adverse Event in the Territory, each Party shall forward a copy or description of the same to the other Party and shall use Commercially Reasonable Efforts to respond to all reasonable inquiries from the other Party relating thereto.

13.3.2 **Notification by Haisco of any Regulatory Actions.** Each Party shall as soon as reasonably possible after receipt of any inspections, proposed regulatory actions,

investigations, or requests by any Regulatory Authority with respect to the Supply of Product in the Territory, as well as any corrective or other actions with Regulatory Authorities initiated by a Party with respect thereto, notify the other Party in reasonable detail with respect thereto and will provide the other Party with copies of all related documentation.

13.3.3 Approval of Labeling and Promotional Materials. Subject to the provisions of this Agreement, Haisco shall timely file with the applicable Regulatory Authorities and obtain any necessary Regulatory Authority approvals of any promotional materials, label, labeling, package inserts or outserts, monographs and packaging, in each case, to the extent required by the Applicable Law of the People's Republic of China.

#### 13.4 Regulatory Notices.

13.4.1 Notice. Each Party or its respective representative shall provide the other Party with notice, in a sufficiently timely basis but in any event within one (1) Business Day of receipt, to enable the other Party to comply in all material respects with Applicable Law, of notification or other information which it receives (directly or indirectly) from, any Regulatory Authority (and providing, as soon as reasonably possible, copies of any associated written requests) 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. Information that shall be disclosed pursuant to this Section 13.4 shall include, but not be limited to:

13.4.1.1 inspections by a Regulatory Authority of manufacturing, distribution or other related facilities concerning the Product;

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

13.4.1.3 any communication from a Regulatory Authority involving the manufacture, sale, promotion or distribution of the Product, or any other Regulatory Authority reviews or inquiries relating to any event set forth in Section 13.4.1(c);

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

13.4.1.5 any initiation of any Regulatory Authority investigation, detention, seizure, or injunction concerning the Product; and

13.4.1.6 any other regulatory action (e.g., proposed labeling or other registrational dossier changes and Recalls) which would affect the Product.

#### 13.5 Recalls or Other Corrective Action.

13.5.1 Notice of Action. Aquestive shall maintain traceability records in accordance with applicable governmental rules, necessary to permit a recall, field correction or



other notification to the field, of any Product. Aquestive agrees to notify Haisco promptly if Aquestive discovers any issue that it reasonably believes could lead to a recall of a Product. Haisco shall have the exclusive right to institute a recall, market withdrawal, field correction or field report of a Product and shall be responsible for managing the recall and communications with customers and Regulatory Authorities. As soon as reasonably possible, Haisco shall notify Aquestive of any actions to be taken by Haisco 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") prior to any such action so as to permit Aquestive a reasonable opportunity to consult with Haisco with respect thereto. Haisco agrees to consider Aquestive's consultation in good faith; provided, however, that, nothing in this Section 13.5 is intended to limit Haisco's ability to recall, withdraw or take any other corrective action relating to the Product. At Haisco's reasonable written request (except as set forth in this Section 13.5), Aquestive shall provide reasonable assistance to Haisco in conducting such Recall. The cost of any Recall, including, the costs of notifying customers and the costs associated with the shipment of the Product from customers and all reasonable credits extended to customers as a result thereof, and the costs of replacing the Product ("Recall Expenses"), occasioned or required as part of a general Recall of the products of a Party, shall be borne as provided in the following sentences: Any Recall Expenses caused by Aquestive or the failure of Aquestive to Supply the Product conforming to the Specifications or applicable Regulatory Approvals or other breach of this Agreement by Aquestive, as determined by a Regulatory Authority or as mutually agreed, shall be borne by Aquestive. Any Recall Expenses caused by Haisco or the failure of Haisco to Commercialize the Product conforming to the applicable Regulatory Approvals or other breach of this Agreement by Haisco, as determined by a Regulatory Authority or as mutually agreed, shall be borne by Haisco. In the event that there is no determination by a Regulatory Authority or the parties dispute which Party that is the cause of a Recall, either Party may send a notice of objection regarding such Recall (the "Recall Objection Notice"). The Parties agree to attempt to resolve such dispute within thirty (30) days after receipt of such notice. If Haisco and Aquestive fail within thirty (30) days after delivery 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) for analysis or review. The results of such evaluation shall be binding upon the Parties. The Party that is determined to have been the cause of such Recall 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 fault. If the fees of the independent laboratory or consultant are due in advance, Haisco 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 was the cause of the Recall shall reimburse the other Party for its fifty percent (50%) share of such fees (or if found proportionately at fault, for such Party's proportion of such fees). If the results of such evaluation are inconclusive, Haisco and Aquestive shall each pay fifty percent (50%) of the direct, out-of-pocket Recall Expenses relating to such Recall including the cost of any such evaluation and destruction of any recalled Product.

13.5.2 Recall Information Received. Each Party shall, as soon as reasonably practicable, notify the other Party of any Recall, market withdrawal or field correction of, field alert report or comparable report or complaint 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.

## 14. INTELLECTUAL PROPERTY

### 14.1 Ownership of IP.

14.1.1 Existing Intellectual Property. Each Party will own all right, title and interest in and to such Intellectual Property Controlled by such Party or its Affiliates or created by such Party or its Affiliates prior to the Effective Date or independently of this Agreement.

14.1.2 Improvements. As between Aquestive and its Affiliates, on the one hand, and Haisco and its Affiliates and sublicensees, on the other hand, any Intellectual Property conceived, reduced to practice or otherwise developed after the Effective Date in the performance of this Agreement (“New IP”) that is conceived, reduced to practice or otherwise developed solely by Aquestive or its Affiliates or their respective employees or Third Party contractors during the Term shall be owned by Aquestive (“Aquestive New IP”);. Any New IP other than Aquestive IP, Aquestive New IP or Joint New IP (as defined below) that is conceived, reduced to practice or otherwise developed solely by Haisco or its Affiliates or their respective employees or Third Party contractors during the Term shall be owned by Haisco (“Haisco New IP”).

14.1.3 Joint Intellectual Property. The Parties will jointly own all New IP, excluding any Aquestive New IP, (i) made jointly by at least one representative of each Party or (ii) conceived, reduced to practice or otherwise developed by Haisco or its Affiliates or their respective employees or Third Party contractors or jointly with Aquestive or its Affiliates or their respective employees or Third Party contractors during the Term that has applicability to the Product or that otherwise relies upon, incorporates, improves upon or otherwise requires the Aquestive IP or Aquestive New IP (collectively, “Joint New IP”). All patents claiming patentable Joint New IP will be referred to herein as “Joint Patents.” Except to the extent either Party is restricted by licenses granted to the other Party under this Agreement, either Party will be entitled to practice, grant licenses to, assign and exploit the Joint New IP and Joint Patents without the duty of seeking consent from the other Party.

14.1.4 For the avoidance of doubt, Aquestive New IP and the rights and interests of Aquestive under the Joint New IP shall be included in Aquestive IP and licensed to Haisco pursuant to this Agreement.

14.1.5 Haisco hereby grants to Aquestive (i) a perpetual, non-revocable, exclusive (even as to Haisco, its Affiliates and sublicensees), royalty-free license, with the right to grant sublicenses, under Joint New IP to Develop, Manufacture, and Commercialize Products outside the Territory or inside the Territory outside the Field, and (ii) a non-exclusive license and right of reference, with the right to grant sublicenses and further right of reference, to use the Regulatory Documentation Controlled by Haisco to Develop, Manufacture, or Commercialize

the Licensed Products outside the Territory or inside the Territory outside the Field. From and after the expiration or earlier termination of this Agreement, the foregoing license shall include the Field.

14.1.6 Haisco hereby grants to Aquestive during the Term (i) a non-revocable, exclusive (even as to Haisco, its Affiliates and sublicensees), royalty-free license, with the right to grant sublicenses, Haisco New IP to Develop, Manufacture, and Commercialize Products in the Territory in the Field.

#### 14.2 **Patent Prosecution and Maintenance.**

14.2.1 Subject to Section 14.2.1, Aquestive shall be responsible for the preparation, filing, prosecution and maintenance of the Aquestive Patents having claims which cover the Product (herein after referred to as the "Patent Actions"). The cost of such preparation, filing, prosecution and maintenance of the Aquestive Patents, shall be borne by Aquestive. Haisco shall be responsible for the preparation, filing, prosecution and maintenance of all patents and patent applications included in Haisco New IP ("Haisco Patents"). The cost of such preparation, filing, prosecution and maintenance of the Haisco Patents, shall be borne by Haisco.

14.2.2 In the event that Aquestive determines to abandon or cease prosecution of any Aquestive Patent (an "Abandoned Patent"), Aquestive will provide Haisco written notice thereof at least thirty (30) days before the applicable deadline ("Notice to Abandon") and provide to Haisco information it reasonably requests relating to such Aquestive Patent. In such case, upon Haisco's written election provided no later than thirty (30) days after such notice from Aquestive ("Step-In Notice"), Haisco shall have the right to assume the Patent Actions with respect to such Aquestive Patent at Haisco's expense ("Step In Rights"). If Haisco does not provide such Step-In Notice within thirty (30) days after receipt of a Notice to Abandon, Aquestive may, in its sole discretion, continue the Patent Actions with respect to such Aquestive Patent or discontinue the Patent Actions with respect to such Aquestive Patent.

14.2.3 If either Party decides to file a Joint Patent, such Party will notify the other Party of such determination and within fourteen (14) days of such notification, the Parties will discuss in good faith the joint preparation, filing, prosecution and maintenance of all patents and patent applications within the Joint Patents.

14.2.4 The Parties shall cooperate at the requesting Party's expense, with respect to the preparation, filing, prosecution and maintenance of any patents claiming New IP and in the obtaining and maintenance of any extensions, supplementary protection certificates and the like with respect to any patents claiming New IP. Such cooperation includes promptly informing the other Party of any matters coming to such Party's attention that may affect the any associated Patent Actions.

14.3 **Patent Term Extensions in the Territory.** The patent counsel of each Party will discuss and recommend for which, if any, of the Aquestive Patents and Joint Patents in the Territory the Parties should seek any term extensions, supplementary protection certificates, and equivalents thereof offering patent protection beyond the initial term with respect to any issued

patents (“Patent Term Extensions”) licensed to Haisco hereunder in the Territory. To the extent the Parties agree to apply for any such Patent Term Extensions in the Territory; Aquestive will cooperate fully with Haisco, at Haisco’s expense, in making such filings or taking any related actions, for example and without limitation, making available all required regulatory data and information and executing any required authorizations to apply for such Patent Term Extensions.

#### 14.4 **IP Enforcement Against Third Parties.**

14.4.1 Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of any Joint Patent (a “Competitive Infringement”) and any Aquestive Patent resulting from the making, using, selling, offering for sale, or importing of any product in or for the Territory, of which they become aware.

14.4.2 In each such instance of Competitive Infringement 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 Aquestive’s cost and expense. If Aquestive does not, within ninety (90) days after its receipt or delivery of notice under Section 14.4.1, 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) Haisco will have the right, but not the obligation, to commence such a suit or take such an action or defend against such Competitive Infringement in the Territory at Haisco’s cost and expense, to be represented in any such suit by counsel of its own choice and (ii) if Haisco exercises its right under the foregoing clause (i), Aquestive will take all reasonable and appropriate actions in order to permit Haisco 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 14.4 without the other Party’s prior written consent, which consent will not be unreasonably withheld 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.

14.4.3 Each Party shall reasonably assist the Party enforcing any such rights under this Section 14.4 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 Haisco in connection therewith, including any Aquestive-approved investigation and analysis thereof, is to be reimbursed to Haisco 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, and will reasonably consider the other Party’s comments on any such efforts.

14.4.4 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 (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts will be allocated as follows: (a) if Haisco is the



enforcing or defending Party, the remaining amounts will be retained by Haisco, however, Haisco will calculate Net Sales under this Agreement based on the remaining amounts attributed to lost sales as if Haisco had made the infringing sales directly, and will pay to Aquestive the License Royalty owed by Haisco to Aquestive pursuant to Section 8.5; and (b) if Aquestive is the enforcing or defending Party, the remaining amounts will be retained by Aquestive.

14.5 **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 Haisco or its Affiliates or sublicensees because of the exercise of the rights granted to Haisco under this Agreement with respect to the Aquestive Patents, and Aquestive or Haisco has not commenced any action to enforce Aquestive Patents against such Third Party under the terms of Section 14.4 above, each Party will give prompt notice to the other Party of any such action. Aquestive shall have the right and 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, Haisco will have the right, but not the obligation to defend against such action under its own control and at Aquestive's cost and expense. Neither Party will enter into any settlement, consent judgment or other voluntary final disposition of any action under this Section 14.5 without the other Party's prior written consent, which consent will not be unreasonably withheld 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 Haisco has commenced any action to enforce Aquestive Patents against such Third Party under the terms of Section 14.4 above, then the terms of Section 14.4 will supersede the terms of this Section 14.5.

14.6 As between the Parties, Haisco will have the sole right, but not the obligation, to bring an appropriate suit or other action against any person or entity allegedly infringing any Haisco New IP (including the Haisco New Patents) and to defend against any declaratory judgment action against any Haisco New IP (including the Haisco New Patents).

14.7 **Ownership of Haisco Housemarks; Termination of Right to Use.**

14.7.1 Haisco shall own all right, title, and interest in the Haisco Housemarks 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 Haisco Housemarks or any goodwill associated therewith.

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

14.8 **Ownership of Aquestive Housemarks; Termination of Right to Use.**

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

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

## 15. **MISCELLANEOUS**

15.1 **Independent Contractor.** Neither Aquestive nor Haisco, 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.

15.2 **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.

15.3 **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) five (5) 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 Haisco: Haisco Pharmaceutical Group Co., Ltd.  
No. 136 Baili Road CNSTP  
Wenjiang District, Chengdu  
Sichuan Province 611130  
People's Republic of China  
Attention: ZHOU Feng

With a copy to: Katten Muchin Rosenman LLP Shanghai Office  
Unit 4906 Wheelock Square, 1717 W. Nanjing Rd.  
Shanghai, 200040  
People's Republic of China  
Attention: XUE Feng

If to Aquestive: Aquestive Therapeutics, Inc.  
30 Technology Drive  
Warren, New Jersey 07059  
Attn: Daniel Barber, Senior Vice President, Chief  
Operating Officer

With a copy to: Aquestive Therapeutics, Inc.  
30 Technology Drive  
Warren, New Jersey 07059  
Attention: Lori J. Braender, General Counsel

**15.4 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 Haisco 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 equity or business to which this Agreement relates or in connection with a merger of the Party and (b) either Party may assign this Agreement and/or its rights and obligations under this Agreement to any of its Affiliates. Without the prior written consent of Haisco, Aquestive may not assign any of its rights to receive payments of royalty fees or any other amounts due under this Agreement to any of its Affiliates or any Third Party; for the avoidance of doubt, Aquestive remains obligated to Haisco for the performance of all of Aquestive's obligations under this Agreement. The assignment of only a part of a Party's rights under this Agreement in accordance with this Section 15.4 shall not in any way create a contractual or business relationship and no privity of contract or otherwise shall exist between the non-assigning Party and the Third Party being assigned such rights and such Third Party shall not have any third-party beneficiary rights in this Agreement. No assignment hereunder shall relieve the assigning Party of its responsibilities or obligations hereunder; provided, further that (i) any assignee shall agree in writing to be bound by all of the obligations of the assigning Party hereunder and (ii) upon the non-assigning Party's request, the assigning Party shall make such introductions to

assignee's management as may be necessary to ensure efficient transition of the Agreement to the assignee or successor. Any purported assignment or transfer in violation of this Section 15.4 shall be void *ab initio* and of no force or effect. This Agreement shall be binding upon and, subject to the terms of the foregoing sentence, inure to the benefit of the Parties, their permitted successors, legal representatives and assigns.

15.5 **No Implied Waivers; Rights Cumulative.** No failure on the part of Aquestive or Haisco 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.

15.6 **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.

15.7 **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 15.7, 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: fires, floods, embargoes, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any Regulatory Authority, change in law, regulation or policy promulgated by any Regulatory Authority (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.

15.8 **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.

15.9 **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.

15.10 **Publicity.** The Parties acknowledge that each of Haisco 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 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. During the Term, Aquestive will have the right to display the Haisco logo on the partnership page of its corporate website, and Haisco will have the right to display the Aquestive logo on its corporate website.

15.11 **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.

15.12 **Governing Law; Dispute Resolution.**

15.12.1 This Agreement shall be governed by and construed in accordance with the laws 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.

15.12.2 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 15.12.2. 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.

15.12.3 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 Los Angeles, California, 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.

15.12.4 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 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.

15.12.5 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. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' and any administrative fees of arbitration.

15.12.6 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.

15.12.7 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 15.12.

15.12.8 As used in this Section 15.12, 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.

15.13 **Entire Agreement.** This Agreement contains the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements, written or oral, between the Parties.

15.14 **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 Haisco 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.

15.15 **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.”

15.16 **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; at Aquestive’s written request, Haisco 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.

15.17 **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.

**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.**

**HAISCO PHARMACEUTICAL GROUP, LTD.**

By: /s/ Keith J. Kendall  
Name: Keith J. Kendall  
Title: President and Chief Executive Officer

By: /s/ Junming Wang  
Name: Junming Wang  
Title: Chairman





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

I, Keith J. Kendall, certify that:

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

Date: May 3, 2022

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

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

I, A. Ernest Toth, Jr, certify that:

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

Date: May 3, 2022

/s/ A. ERNEST TOTH, JR.  
A. Ernest Toth, Jr.  
Chief Financial Officer  
(Principal Financial Officer)

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

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

1. The Company's Quarterly Report on Form 10-Q for the period-ended March 31, 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: May 3, 2022

/s/ KEITH J. KENDALL  
\_\_\_\_\_  
Keith J. Kendall  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

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

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, 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 March 31, 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: May 3, 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.