UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): August 31, 2018

Aquestive Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**001-38599**	**82-3827296**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

30 Technology Drive
Warren, NJ 07059
(908) 941-1900
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

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

Item 2.02 Results of Operations and Financial Condition

On September 4, 2018, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its second quarter ended June 30, 2018. A copy of such press release and the attached financial schedules are attached as Exhibit 99.1 to this report and incorporated into this Item 2.02 by reference.

The information in this Item 2.02 (including Exhibit 99.1) is being furnished pursuant to Item 2.02 and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 7.01 Regulation FD Disclosure.

On August 31, 2018, the Company issued a press release announcing the United States Food and Drug Administration's ("FDA") tentative approval of Sympazan® (clobazam) Oral Film (OF) for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older. A copy of such press release is attached as Exhibit 99.2 to this report and incorporated into this Item 7.01 by reference.

The information in this Item 7.01 (including Exhibit 99.2) is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01 Other Events.

On August 31, 2018, the Company announced the FDA's tentative approval of Sympazan® (clobazam) Oral Film (OF) for the treatment of for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated September 4, 2018, announcing financial results for its second quarter ended June 30, 2018
99.2	Press Release, dated August 31, 2018, announcing the FDA's tentative approval Sympazan® (clobazam) Oral Film (OF)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 4, 2018

Aquestive Therapeutics, Inc.

By: /s/ John T. Maxwell
Name: John T. Maxwell
Title: Chief Financial Officer

Exhibit 99.1

Aquestive Therapeutics Reports Second Quarter 2018 Financial Results and Recent Business Highlights, Including Tentative Approval for Sympazan™

Warren, NJ, September 4, 2018 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs, today reported financial results for the second quarter ended June 30, 2018 and provided a business update.

"Aquestive has advanced its proprietary development pipeline and continues to advance its commercial organization. With the proceeds from our recently closed IPO, we are well positioned to take our late stage CNS products, Sympazan™ and diazepam, to market as they are approved, and to continue our complex molecule development efforts," said Keith J. Kendall, Chief Executive Officer of Aquestive. "Most notably, the tentative approval for Sympazan that we received from the FDA on August 31st is a significant milestone for the company, as well as for the patients and caregivers who seek improved treatment options to manage Lennox-Gastaut Syndrome."

Pipeline Overview and Upcoming Milestones

Aquestive received tentative approval for Sympazan (clobazam) oral film for the treatment of Lennox-Gastaut Syndrome (LGS) from the U.S. Food and Drug Administration (FDA) in line with its assigned Prescription Drug User Fee Act (PDUFA) date of August 31, 2018. Final FDA approval for Sympazan is pending the expiration of the orphan drug exclusivity period for ONFI ®, which is expected in October 2018.

Aquestive completed enrollment for the adult Epilepsy Monitoring Unit (EMU) clinical study for its diazepam oral film formulation and is advancing towards an NDA filing.

Recent Business Highlights

Aquestive completed its initial public offering of common stock on July 25, 2018 at an offering price of $15.00 per share and received aggregate gross proceeds of $73.9 million, inclusive of the partial exercise of the over-allotment option by the underwriters. Net proceeds received from the offering, after deducting underwriters' discount and fees and expenses of the offering, were $63.5 million.

Aquestive's Board of Directors appointed Santo "Sandy" Costa as Chairman in line with its plan. Douglas Bratton, who served as Chairman since 2004, will continue to serve as a member of the Board of Directors. Aquestive also appointed Nancy Lurker, an experienced commercial leader in the pharmaceutical industry, to its Board of Directors.

The U.S. District Court for the District of New Jersey granted Aquestive, together with Indivior PLC (LON: INDV) and its U.S. subsidiary, Indivior Inc., a preliminary injunction against Dr. Reddy's Laboratories (DRL), mandating the restrictions of the previously entered temporary restraining order (TRO) remain in place. The preliminary injunction prevents DRL from using, selling, offering to sell, or importing its generic buprenorphine/naloxone sublingual film until further order of the district court or of the appellate court.

Second Quarter 2018 Financial Results

- Total revenues increased by 25% to $13.9 million for the second quarter of 2018, up from $11.1 million reported in the second quarter of 2017.
- Manufacturing and supply expenses decreased by 2% to $5.0 million for the second quarter of 2018 from $5.1 million in the same quarter in 2017.
- Research and development expenses increased by 67% to $8.0 million in the second quarter of 2018 from $4.8 million in the second quarter of 2017.
- Selling, general and administrative expenses increased to $33.6 million in the second quarter of 2018 from $5.2 million in the same quarter in 2017. Included in the 2018 selling, general and administrative expenses was $24.8 million of one-time compensation costs associated with the issuance of the non-voting common shares and related withholding taxes, which the company elected to pay on behalf of its former performance unit holders.

As of June 30, 2018, cash and cash equivalents were $10.6 million, as compared to $17.4 million as of December 31, 2017. After June 30, 2018, the company received net proceeds from its IPO of $63.5 million.

About Aquestive Therapeutics
Aquestive Therapeutics is a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. Aquestive Therapeutics has a late-stage proprietary product pipeline focused on the treatment of CNS diseases, and is working to advance orally-administered complex molecules that it believes can be alternatives to invasively-administered standard of care therapies. As the leader in developing and delivering drugs via its PharmFilm® technology, Aquestive Therapeutics also collaborates with pharmaceutical partners to bring new molecules to market in differentiated and highly-marketable dosage forms.

Forward-Looking Statement
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “project,” “will,” “would,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. Such statements include, but are not limited to, statements about regulatory approvals and pathways, clinical trial timing and plans, the achievement of clinical and commercial milestones, future financial and operating results, business strategies, market opportunities, financing, and other statements that are not historical facts.

These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to: risks associated with the Company’s development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials; the risks of delays in FDA approval of our drug candidates or failure to receive approval; the risks inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); development of our sales and marketing capabilities; the rate and degree of market acceptance of our product candidates; the success of any competing products; the size and growth of our product markets; the effectiveness and safety of our product candidates; risks associated with intellectual property rights and infringement; unexpected patent developments; and other risks and uncertainties affecting the Company including those described in the “Risk Factors” section included in our Registration Statement on Form S-1 declared effective by the SEC on July 24, 2018. As with any pharmaceutical product candidate under development, there are significant risks with respect to the development, regulatory approval and commercialization of new products. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. We assume no obligation to update our forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required under applicable law.

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

	Three Months Ended June 30		Six months Ended June 30	
	2018	**2017**	**2018**	**2017**
Revenues	$ 13,928	$ 11,142	$ 37,339	$ 27,577
Cost and expenses:				
Manufacture and supply	4,973	5,141	10,609	9,325
Research and development	7,994	4,837	12,895	10,178
Selling, general and administrative	33,647	5,223	41,216	11,352
Total costs and expenses	46,614	15,201	64,720	30,855
Loss from operations	(32,686)	(4,059)	(27,381)	(3,278)
Other income (expenses):				
Interest expense	(1,927)	(1,949)	(3,854)	(3,767)
Change in fair value of warrant	(1,859)	111	(1,162)	(309)
Other, net	(21)	-	3	-
Net loss before income taxes	(36,493)	(5,897)	(32,394)	(7,354)
Income taxes	-	-	-	-
Net loss	(36,493)	(5,897)	(32,394)	(7,354)
Dividends on redeemable preferred interests	-	(615)	-	(1,228)
Net loss attributable to common shares / members' interests	(36,493)	(6,512)	(32,394)	(8,582)
Comprehensive loss	$ (36,493)	$ (6,512)	$ (32,394)	$ (8,582)
Net loss per share				
Net loss per common share - basic and diluted	$ (1.90)		$ (1.89)	
Weighted-average number of common shares / membership interests outstanding - basic and diluted	19,188,624		17,144,492	

AQUESTIVE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except unit amounts)
(Unaudited)

	June 30, 2018	December 31, 2017
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 10,638	$ 17,379
Accounts receivable, net	6,629	6,179
Inventories, net	4,348	4,014
Prepaid expenses and other current assets	5,034	591
Total current assets	26,649	28,163
Property and equipment, net	12,766	13,460
Intangible assets, net	229	254
Other assets	197	1,239
Total assets	$ 39,841	$ 43,116
LIABILITIES AND SHAREHOLDERS' / MEMBERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,140	$ 14,003
Deferred revenue	1,234	1,347
Loans payable, current	1,100	-
Total current liabilities	23,474	15,350
Loans payable, net	45,330	45,507
Warrant liability	8,835	7,673
Asset retirement obligations	1,150	1,081
Total liabilities	78,789	69,611
Commitments and contingencies (Note 14)		
Redeemable preferred A-3 interests and accrued dividends	-	5,896
Redeemable preferred A-2 interests and accrued dividends	-	36,205
Shareholders' /Members' Deficit		
Preferred A interests, no par value. Authorized 100,000,000 units; 16,886,750 units issued and outstanding at December 31, 2017	-	16,887
Preferred A-1 interests, no par value. Authorized 100,000,000 units; 21,526,850 units issued and outstanding at December 31, 2017	-	21,883
Common interests, no par value. Authorized 500,000,000 units; 121,228,353 units issued and outstanding at December 31, 2017	-	12,727
Common stock, $.001 par value. Authorized 350,000,000 shares; 15,077,647 voting and 4,922,353 non-voting (Note 15) shares issued and outstanding at June 30, 2018	20	-
Additional paid-in capital	(6,574)	-
Accumulated deficit	(32,394)	(120,093)
Total shareholders'/members' deficit	(38,948)	(68,596)
Total liabilities and shareholders' / members' deficit	$ 39,841	$ 43,116

Exhibit 99.2

Aquestive Therapeutics Announces Tentative FDA Approval for Sympazan™ (clobazam) Oral Film

- *Sympazan is an oral soluble film formulation of clobazam, a benzodiazepine indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older*

- *Sympazan will be delivered via Aquestive's proprietary PharmFilm® technology*

Warren, NJ, August 31, 2018 – Aquestive Therapeutics, Inc. (NASDAQ: AQST) today announced that Sympazan™ (clobazam) oral film has received tentative approval by the U.S. Food and Drug Administration (FDA), for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older. Currently, clobazam is marketed as ONFI® and offered in two formulations - either tablet or oral suspension.

"We saw a need in the LGS community for a simpler, more consistent way to administer a full dose of clobazam - and we are now one step closer to bringing this important treatment to patients, caregivers and physicians," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. "This tentative approval for Sympazan is a key milestone for Aquestive, as it represents the first in a series of late stage proprietary products Aquestive plans to commercialize once they are approved. We believe Sympazan and our other products in development solve important therapeutic problems, and will meaningfully improve the lives of patients and their caregivers."

Lennox-Gastaut Syndrome is a severe form of epilepsy that begins in early childhood and is characterized by multiple types of seizures and intellectual disability. LGS patients often have difficulty swallowing pills and large volume suspensions due to physical limitations, behavioral or compliance issues. Challenges with treatment administration can lead to uncertain and inconsistent dosing, and increase the burden of care, particularly for patients that may be combative or resistant to treatment.

Sympazan is a proprietary formulation based on Aquestive's proven PharmFilm® technology. Multiple pharmacokinetic studies were conducted to compare Sympazan with ONFI. Based on the studies, Sympazan oral film was demonstrated to be bioequivalent to clobazam tablets and have comparable safety.

Final FDA approval for Sympazan is pending the expiration of the orphan drug exclusivity period for ONFI, which is expected in October 2018.

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