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): November 2, 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 November 6, 2018, Aquestive Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its third quarter ended September 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 November 2, 2018, the Company issued a press release announcing the United States Food and Drug Administration's ("FDA") 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 November 2, 2018, the Company announced the FDA's 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 November 6, 2018, announcing financial results for its third quarter ended September 30, 2018
99.2	Press Release, dated November 2, 2018, announcing the FDA's 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: November 6, 2018

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Aquestive Therapeutics Reports Third Quarter 2018 Financial Results and Recent Business Highlights

- Completed adult epilepsy monitoring study demonstrating that Libervant™ provides comparable bioavailability
- Received FDA approval for SYMAPAZAN™ for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS)
- Hosts investment community conference

Warren, NJ, November 6, 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 third quarter ended September 30, 2018 and provided a business update.

"Aquestive is the worldwide leader in delivering therapeutics on oral film with our PharmFilm® technology. Over the past quarter, we have met a number of key business milestones that position us well to achieve our long-term vision for growth," said Keith J. Kendall, Chief Executive Officer of Aquestive. "We are excited to continue advancing our pipeline and building our CNS commercial franchise with the launch of SYMPAZAN™. Late stage development of Libervant is also advancing with the recent completion of the adult EMU study."

Pipeline Overview, Upcoming Milestones and Business Update

Aquestive received U.S. FDA approval for SYMPAZAN (clobazam) oral film for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older. SYMPAZAN previously received tentative FDA approval on August 31, 2018 and has now been approved based on the expiration of the orphan drug exclusivity period for ONFI®.

Aquestive completed a pharmacokinetic adult epilepsy monitoring unit (EMU) study demonstrating that its investigational diazepam buccal film (DBF) product candidate, tentatively named Libervant, provides comparable bioavailability whether administered between seizures (interictal) or during and shortly after seizures (ictal/peri-ictal) in adult patients with poorly controlled tonic-clonic seizures or focal seizures with impaired awareness. DBF, a novel formulation of diazepam as a small, thin film strip placed inside the cheek, is under development for the management of selected patients with refractory epilepsy who require intermittent use of diazepam to control episodes of increased seizure activity.

The topline data from the adult EMU study will be presented as two late-breaking poster presentations at the American Epilepsy Society's Annual Meeting, being held from November 30 to December 4, 2018.

Aquestive recently reached agreement with the FDA to end the swallowing study for AQST-117 (riluzole), an oral soluble film formulation for the treatment of Amyotrophic Lateral Sclerosis, the third late-stage CNS asset in its proprietary portfolio, sooner than previously planned based on an analysis of the study's interim data. Topline results are expected to be reported in late 2018 and an NDA submission is expected in the first quarter of 2019.

Aquestive continues to make progress on its early stage complex molecule development programs for anaphylaxis and acromegaly. The Company expects to commence a Phase 1 proof of concept study during 2019 for AQST-108, its sublingual film formulation of epinephrine in development for the treatment of anaphylaxis. During the third quarter 2018, Aquestive commenced a Phase 1 human proof of concept study for AQST-305, the Company's sublingual formulation of octreotide in development for the treatment of acromegaly.

Aquestive's collaborative partnership development activities continue to advance, and its year-to-date Suboxone volume produced and shipped has risen by 5%. In addition, AQST-119, an oral soluble film formulation of tadalafil, a vasodilator that is used to treat erectile dysfunction, or ED, has its Prescription Drug User Fee Act (PDUFA) date on November 18, 2018 for tentative approval.

Third Quarter 2018 Financials

As of September 30, 2018, Aquestive's cash and cash equivalents were $64.0 million, as compared to $17.4 million as of December 31, 2017. In July 2018, Aquestive received net proceeds from its IPO of $63.5 million.

Aquestive's comprehensive net loss for the third quarter 2018 was $15.0 million, or $0.64 loss per share. The comprehensive net income for the third quarter 2017 was $7.8 million. The increase in net loss in the third quarter 2018 was driven in part by lower revenue in the 2018 compared to 2017 due to a $14 million reduction in contractually stipulated collaborative partner license payments. The loss in the third quarter of 2018 period was also impacted by increased total expenses compared to 2017, including from selling, general and administrative expenses that were primarily driven by investments in SYMPAZAN commercialization.

Investment Community Conference Call
Aquestive will host an investment community conference call at 4:30 p.m. ET on Tuesday, November 6, 2018. Investors and analysts may participate in the conference call by dialing (866) 417-5886 from the U.S. and (409) 217-8235 internationally, followed by the conference ID: 3248427. There will also be a simultaneous, live webcast available on the Investors section of the Company's website at https://investors.aquestive.com/events-and-presentations. The webcast will be archived for 30 days.

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 and our other filings with the Securities and Exchange Commission. 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.

Media inquiries:
Christopher Hippolyte
christopher.hippolyte@syneoshealth.com
212-364-0458

Investor inquiries:
Stephanie Carrington
stephanie.carrington@icrinc.com
646-277-1282

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

Assets	September 30, 2018	December 31, 2017
Current assets:		
Cash and cash equivalents	$ 63,982	$ 17,379
Accounts receivable, net	7,450	6,179
Inventories, net	4,483	4,014
Prepaid expenses and other current assets	1,444	591
Total current assets	77,359	28,163
Property and equipment, net	12,211	13,460
Intangible assets, net	216	254
Other assets	224	1,239
Total assets	$ 90,010	$ 43,116
Liabilities and Shareholders' Equity/Members' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 17,798	$ 14,003
Deferred revenue	781	1,347
Loans payable, current	2,750	-
Total current liabilities	21,329	15,350
Loans payable, net	44,054	45,507
Warrant liability	-	7,673
Asset retirement obligations	1,183	1,081
Total liabilities	66,566	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 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 250,000,000 shares;		
24,942,185 shares issued and outstanding at September 30, 2018 (Note 15)	25	-
Additional paid-in capital	70,851	-
Accumulated deficit	(47,432)	(120,093)
Total shareholders' equity/members' deficit	23,444	(68,596)
Total liabilities and shareholders' equity/members' deficit	$ 90,010	$ 43,116

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenues	$ 13,267	$ 27,146	$ 50,606	$ 54,723
Costs and Expenses:				
Manufacture and supply	5,592	4,880	16,201	14,205
Research and development	4,534	5,684	17,429	15,862
Selling, general and administrative	12,345	6,161	53,561	17,513
Total costs and expenses	22,471	16,725	87,191	47,580
(Loss)/ income from operations	(9,204)	10,421	(36,585)	7,143
Other income (expenses):				
Interest expense	(1,933)	(1,970)	(5,809)	(5,737)
Interest income	216	-	238	-
Change in fair value of warrant	(4,116)	-	(5,278)	(309)
Other, net	(1)	-	2	-
Net (loss)/income before income taxes	(15,038)	8,451	(47,432)	1,097
Income taxes	-	-	-	-
Net (loss)/income	(15,038)	8,451	(47,432)	1,097
Dividends on redeemable preferred interests	-	(626)	-	(1,854)
Net (loss)/income attributable to common shares/members' interests	$ (15,038)	$ 7,825	$ (47,432)	$ (757)
Comprehensive net (loss)/income	$ (15,038)	$ 7,825	$ (47,432)	$ (757)
Net loss per share - basic and diluted	$ (0.64)		$ (2.45)	
Weighted-average number of common shares outstanding - basic and diluted	23,646,192		19,335,541	

Exhibit 99.2

Aquestive Therapeutics Announces U.S. Food and Drug Administration (FDA) Approval for SYMPAZAN™ (clobazam) Oral Film

- *SYMPAZAN is the first and only FDA-approved oral film formulation of clobazam, a benzodiazepine approved for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older[1]*
- *SYMPAZAN is delivered via Aquestive's proprietary PharmFilm® technology*
- *Aquestive is on track to launch SYMPAZAN in November 2018*

Warren, NJ, November 2, 2018 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) approved SYMPAZAN™ (clobazam) oral film for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.[1] SYMPAZAN is the first and only oral film FDA-approved to treat seizures associated with LGS. Previously, clobazam was marketed as ONFI® and offered in two formulations – either tablet or oral suspension.[2]

"Aquestive Therapeutics is pleased to bring SYMPAZAN to the LGS community," said Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics. "Treating LGS can be difficult; patients may have a hard time swallowing oral medications. We're optimistic SYMPAZAN can help address unmet medical needs and be an important treatment option for this patient population."

LGS is a severe form of epilepsy that begins in early childhood and is characterized by multiple types of seizures and intellectual disability.[3] LGS patients often have difficulty swallowing pills and large volume suspensions due to physical limitations, behavioral or cognitive impact.[4,5] 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. [5-8]

Since FDA approval in 2011, clobazam tablets and oral suspension (brand name ONFI®) have been a trusted adjunctive treatment for LGS. In a Phase 3, randomized, double-blind, placebo-controlled study of 238 LGS patients, clobazam tablets significantly reduced the frequency of drop seizures (which involve falls) compared to baseline by 41 percent (low dose) to 68 percent (high dose) vs. 12 percent for placebo ($p<0.05$ for all doses vs. placebo).[2,9] Please see more Important Safety Information below, including the Boxed Warning on the risks associated with concomitant use of opioids.

"Many LGS patients have a hard time swallowing pills and suspensions. This can make administering medication hard for caregivers," says Christina SanInocencio, Executive Director of the LGS Foundation. "We believe SYMPAZAN will be welcomed by patients and caregivers impacted by LGS and searching for treatment solutions."

SYMPAZAN is a 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 profiles.[1] Aquestive's clinical development of SYMPAZAN followed the 505(b)(2) regulatory pathway.

“SYMPAZAN is the beginning of a meaningful CNS franchise for Aquestive,” Kendall says. “We are actively working to advance more redesigned, proprietary treatments that can offer meaningful improvements for patients and caregivers who live with epilepsy and other complex conditions.”

Aquestive plans to commercialize SYMPAZAN in November, and has engaged Ashfield Healthcare, a company specializing in commercialization services, to build and train a highly qualified, national sales force. The sales force will focus on pediatric neurologists and epileptologists.

SYMPAZAN oral film is berry flavored and offered in 5 mg, 10 mg, and 20 mg dosages to meet a range of LGS patient and caregiver needs.[1]

About Aquestive Therapeutics
Aquestive Therapeutics is a specialty pharmaceutical company committed to 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.

IMPORTANT SAFETY INFORMATION
BOXED WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS
Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

CONTRAINDICATIONS
SYMPAZAN is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients. Hypersensitivity reactions have included serious dermatological reactions.

WARNINGS AND PRECAUTIONS
Potentiation of Sedation from Concomitant Use with Central Nervous System (CNS) Depressants
SYMPAZAN has a CNS depressant effect. Caution patients and/or caregivers against simultaneous use with other CNS depressants or alcohol as the effects of other CNS depressants or alcohol may be potentiated.

Somnolence or Sedation
SYMPAZAN causes dose-related somnolence and sedation, which generally begins within the first month of treatment and may diminish with continued treatment. Monitor patients for somnolence and sedation, particularly with concomitant use of other CNS depressants. Caution patients against engaging in hazardous activities requiring mental alertness, i.e., operating dangerous machinery or motor vehicles, until the effect of SYMPAZAN is known.

Withdrawal Symptoms
Abrupt discontinuation of SYMPAZAN should be avoided. The risk of withdrawal symptoms is greater with higher doses. Withdraw SYMPAZAN gradually to minimize the risk of precipitating seizures, seizure exacerbation, or status epilepticus.

Serious Dermatological Reactions
Serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported with clobazam in both children and adults. Discontinue SYMPAZAN at the first sign of rash, unless the rash is clearly not drug-related.

Physical and Psychological Dependence
Patients with a history of substance abuse should be under careful surveillance when receiving SYMPAZAN.

Suicidal Behavior and Ideation
AEDs, including SYMPAZAN, increase the risk of suicidal thoughts or behavior in patients. Patients treated with SYMPAZAN should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Inform patients, their caregivers, and families of the increased risk of suicidal thoughts and behaviors. Advise them to be alert for and report immediately to healthcare providers any emergence or worsening signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm.

ADVERSE REACTIONS
Adverse reactions (≥10% and more frequently than placebo) included constipation, somnolence or sedation, pyrexia, lethargy, and drooling.

DRUG INTERACTIONS
The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression. Limit dosage and duration of concomitant use of benzodiazepines and opioids and follow patients closely for respiratory depression and sedation. Concomitant use of SYMPAZAN with other CNS depressants, including alcohol, may increase the risk of sedation and somnolence. Caution patients and/or caregivers against simultaneous use with other CNS depressants or alcohol, as effects of other CNS depressants or alcohol may be potentiated.

Hormonal contraceptives that are metabolized by CYP3A4; effectiveness may be diminished when given with SYMPAZAN. Additional non-hormonal forms of contraception are recommended when using SYMPAZAN. Dose adjustment may be necessary of drugs metabolized by CYP2D6 and of SYMPAZAN when co-administered with strong CYP2C19 inhibitors (e.g., fluconazole, fluvoxamine, ticlopidine).

USE IN SPECIFIC POPULATIONS
Pregnancy and Lactation: SYMPAZAN may cause fetal harm and should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have taken benzodiazepines during the later stages of pregnancy can develop dependence, withdrawal syndrome and symptoms suggestive of floppy infant syndrome. SYMPAZAN is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from SYMPAZAN, discontinue nursing or discontinue the drug. Encourage patients to call the toll-free number 1-888-233-2334 to enroll in the Pregnancy Registry or visit http://www.aedpregnancyregistry.org/.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please click here to see full Prescribing Information, including Boxed Warning.

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.

Media inquiries:
Christopher Hippolyte
christopher.hippolyte@syneoshealth.com
212-364-0458

Investor inquiries:
Stephanie Carrington
stephanie.carrington@icrinc.com
646-277-1282

References:

1. Aquestive Data on File. [SYMPAZAN Prescribing Information]. Warren, NJ: Aquestive Therapeutics Inc; 2018.
2. ONFI [package insert]. Deerfield, IL: Lundbeck; 2011.
3. Lennox-Gastaut syndrome. National Institutes of Health. https://ghr.nlm.nih.gov/condition/lennox-gastaut-syndrome. Published 2018. Accessed November 1, 2018.
4. Ogawa K, Kanemoto K, Ishii Y, Koyama M, Sirasaka Y, Kawasaki J, Yamasaki S. Long-term follow-up study of Lennox–Gastaut syndrome in patients with severe motor and intellectual disabilities: with special reference to the problem of dysphagia. *Seizure*. 2001; 10:197-202.
5. LGS Foundation. About Lennox-Gastaut Syndrome. Available at: http://www.lgsfoundation.org/aboutlgs. Accessed November 1, 2018.
6. Clobazam. Medline Plus. https://medlineplus.gov/druginfo/meds/a612008.html. Accessed October 25, 2018.
7. Living with LGS. About Lennox-Gastaut Syndrome. Available at: http://www.lgsfoundation.org/livingwithlgs. Accessed November 1, 2018.
8. Verrotti A., Coppola G., Fiordaliso L., D'Egidio C., Loiacono G., Chiarelli F. New antiepileptic drugs in the treatment of Lennox-Gastaut syndrome. *Journal of Pediatric Sciences*. 2009;1:e16.
9. Ng YT, Conry JA, Drummond R, Stolle J, Weinberg MA; OV-1012 Study Investigators. Randomized, phase III study results of clobazam in Lennox-Gastaut syndrome. *Neurology*. 2011 Oct 11;77(15):1473-81.