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 26, 2019

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 (17 CFR 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))

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

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 7.01 Regulation FD Disclosure.

On November 26, 2019, Aquestive Therapeutics, Inc. (the "Company") announced that data from five abstracts, including two "late-breakers", related to its therapeutic candidate, Libervant™ (diazepam) Buccal Film, will be presented at the American Epilepsy Society (AES) 2019 Annual Meeting, taking place December 6-10, 2019 in Baltimore. Copies of such abstracts are attached as Exhibits 99.1 through 99.5 to this report and incorporated into this Item 7.01 by reference.

The information in this Item 7.01 (including Exhibits 99.1 through 99.5) is being furnished pursuant to Item 7.01 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, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Abstract, dated November 26, 2019, Unreliable Absorption with Rectal Administration of Diazepam
99.2	Abstract, dated November 26, 2019, Simulation of the Pharmacokinetics of Diazepam Buccal Film in Adult Patients with Epilepsy with Weight-adjusted Dosing
99.3	Abstract, dated November 26, 2019, Patient and Caregiver Preference for Route of Administration of a Benzodiazepine for Control of Increased Seizure Activity in Stable Patients
99.4	Abstract, dated November 26, 2019, Pharmacokinetics of Diazepam Buccal Film in Adult Patients with Epilepsy: Comparison with Diazepam Rectal Gel
99.5	Abstract, dated November 26, 2019, Safety and Tolerability Associated with Chronic Intermittent Use of Diazepam Buccal Film in Pediatric, Adolescent, and Adult Patients with Epilepsy

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 26, 2019

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Unreliable Absorption With Rectal Administration of Diazepam

Gary Slatko[1], Stephen Wargacki[1], David J. Wyatt[2], Allen H. Heller[3]

[1]Aquestive Therapeutics, Warren, NJ; [2]Syneos Health Clinical Solutions Early Phase, Miami, FL; [3]Pharma Study Design, LLC, Woodbridge, CT

ABSTRACT

Rationale: Until recently, diazepam rectal gel (DRG) has been the only FDA-approved treatment for the management of selected patients with epilepsy who experience bouts of increased seizure activity. However, the route of administration for DRG is not ideal, as it may be associated with embarrassment and the need for a private setting during administration. Diazepam buccal film (DBF) is a novel formulation of diazepam under development as a therapeutic alternative to DRG. A previously reported study comparing the bioavailability of DBF and DRG in healthy adults showed high variability in pharmacokinetic parameters following administration of DRG but not DBF, with some subjects showing on multiple occasions consistently low plasma concentrations following single doses of DRG. We assessed the available published literature to identify other reported instances of low systemic exposure following rectal administration of diazepam in individual subjects.

Methods: A search of the PubMed database was conducted to identify primary studies of rectal absorption of diazepam using the following search terms: “diazepam,” “absorption,” and “rectal.” Subjects were categorized as having low rectal absorption if they had diazepam plasma levels that were either: ≥1.5 standard deviations below the group mean; ≥2 standard errors below the group mean; <20% of the group median; ≤50 ng/mL and were group outliers; or explicitly reported as low plasma levels by study investigators. Findings from these studies were compared with observed data from the previously reported study of bioavailability following administration of DBF 15 mg versus DRG 5 mg, 12.5 mg, and 20 mg.

Results: The literature search identified 10 relevant studies reporting plasma levels following rectal administration of diazepam, comprising data from 159 subjects. In 4 of these studies (including the three smallest studies, N=6), no instances of low absorption were reported. In the remaining 6 studies, the proportions of subjects with low absorption of rectal diazepam ranged from 4.2% to 18.2% **(Table)**. In the DBF versus DRG bioavailability study, 2 of 36 subjects (5.6%) consistently exhibited extremely low exposure (C_{max} and AUC_{0-t} greater than 2 standard deviations below the mean) following ≥2 DRG administrations separated by time; both subjects showed systemic exposure at or near the group mean following administration of DBF.

Conclusions: A majority of the studies identified by literature review reported subjects with low rectal absorption of diazepam; up to 18.2% of subjects showed low rectal absorption. In addition, observations from a recent comparative bioavailability study of DBF and DRG suggests that some patients may be predisposed to be non-absorbers of rectally administered diazepam.

Funding: Aquestive Therapeutics, Inc.

Table 1. Summary of Literature Search Results

Study*	Population	Formulation	Pre-dose cleansing enema?	Subjects with low plasma levels of diazepam n (%)
Agurell S, et al. *Epilepsia*. 1975;16:277-283	Children with epilepsy (N=11)	Solution	Not reported	2 (18.2)†
Mattila MAK, et al. *Br J Anaesth*. 1981;53:1269-1272	Children undergoing surgery (N=22)	Solution	No	3 (13.6)‡,§
Dhillon S, et al. *Arch Dis Child.* 1982;57:264-267	Children with epilepsy (N=13)	Solution	No	1 (11.1)§
Ivaturi V, et al. *Epilepsy Res*. 2013;103:254-261	Healthy adults (N=12)	Gel	Not reported	1 (8.3)‖
Remy C, et al. *Epilepsia*. 1992;33:353-358	Adults with epilepsy (N=39)	Solution	Not reported	2 (5.1)¶
Garnett WR, et al. *Epilepsy Res*. 2011;93:11-16	Healthy adults (N=24)	Gel	Yes	1 (4.2)¶
Cloyd JC, et al. *Epilepsia*. 1998;39:520-526	Healthy male adults (N=20)	Gel	Yes	0¶
Magnussen I, et al. *Acta Pharmacol Toxicol*. 1979;45:87-90	Adults with history of severe headache (N=6)	Solution	Not reported	0‡
Milligan N, et al. *Epilepsia*. 1982;23:323-331	Adults with epilepsy (N=6)	Solution and suppository	No	0‡
Viukari M, et al. *Acta Pharmacol Toxicol*. 1981;49:59-64	Hospitalized geriatric patients (N=6)	Solution and suppository	No	0‡

*All were single-dose studies; †Low absorption defined as diazepam plasma levels ≥2 SEs below the mean; ‡Low absorption defined as diazepam plasma levels ≥1.5 SDs below the mean; §Low absorption defined as diazepam plasma levels ≤50 ng/mL AND subject was an outlier; ‖Low absorption defined as diazepam plasma levels <20% of the median; ¶Low absorption explicitly reported by investigator.

Exhibit 99.2

FOR SUBMISSION TO AES

Simulation of the Pharmacokinetics of Diazepam Buccal Film in Adult Patients with Epilepsy with Weight-adjusted Dosing

Allen H Heller, Gary Slatko, Michael A Rogawski

Rationale: Diazepam buccal soluble film (DBF) is a novel dosage form of diazepam under development for the treatment of acute repetitive seizures (ARS). In a study reported earlier (Rogawski et al., AES Abst. 2.453, 2018), we demonstrated that pharmacokinetic (PK) performance of DBF following a single 12.5 mg dose was similar under periictal and interictal conditions. The legacy product diazepam rectal gel (Diastat) is dosed acording to a weight-based dosing scheme. This study was undertaken to compare diazepam exposures obtained with DBF when dosing according to a weight-based regimen and as a fixed dose.

Methods: Adult men and women ages 17-65 years with poorly controlled tonic clonic seizures or focal seizures with impaired awareness (N=35) were enrolled. PK profiles valid for analysis for both treatment conditions were available for 21 subjects. Most of these subjects had samples collected up to 4 hours but 3 subjects were sampled only up to 2 hours. PK profiles were simulated based on body weight and robust evidence of dose-proportionality of the DBF product from healthy volunteer studies and population PK modeling.

Results: The table shows predicted values for G_{max}, $AUC_{(0-2h)}$, and $AUC_{(0-4h)}$ (geometric means) and the ratio of the geometric means (Treatment B/Treatment A) with 90% confidence intervals. On average, predicted PK parameters were 17-18% higher compared with the 12.5-mg fixed-dose regimen, with median C_{max} 263 ng/mL (interquartile range [IQR] 197-301 ng/mL) and 247 ng/mL (IQR 152-329 ng/mL) for the interictal and ictal/periictal conditions, respectively. Weight-based dosing provided a modest reduction in inter-subject variability. As expected, predicted values for C_{max}, $AUC_{(0-2h)}$, and $AUC_{(0-4h)}$ were similar in interictal and ictal/periictal state. The figure shows the mean of the simulated plasma concentrations over time.

Conclusions: The simulated weight-based dosing regimen for administration of DBF to adults with epilepsy was associated with a higher predicted exposure than that observed with a fixed dose of 12.5 mg. These results suggest that the weight-based dosing regimen applied here (average dose 14.9 mg/kg) is associated with therapeutic diazepam plasma concentrations under both interictal and ictal/periictal conditions.

Funding: Supported by Aquestive Therapeutics Inc.

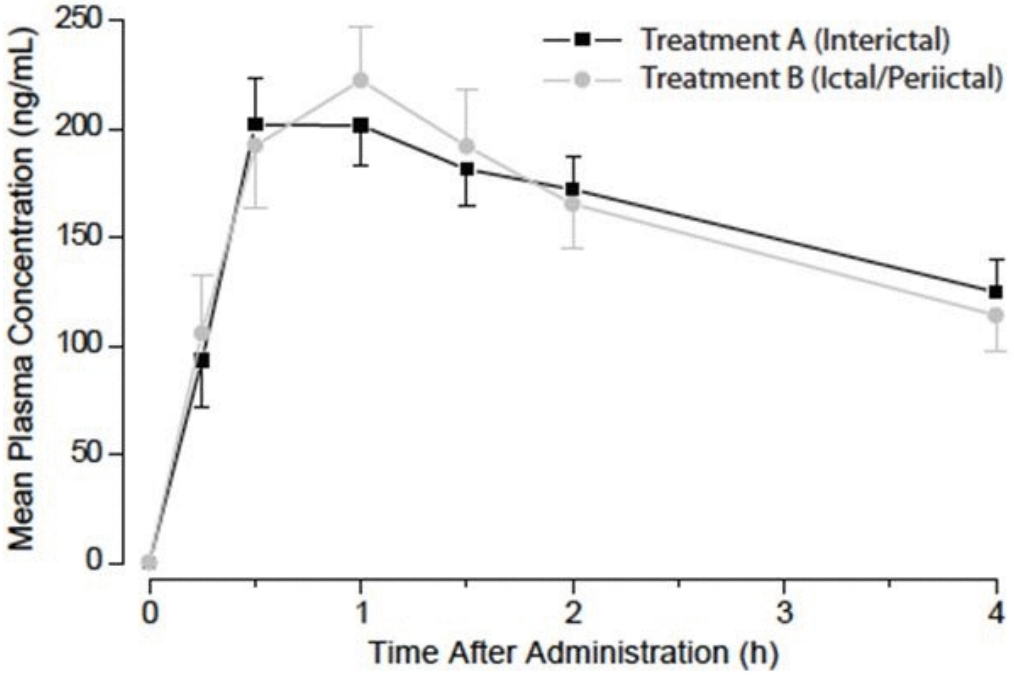
Table: Simulated Pharmacokinetic Parameters Following DBF in the Interictal and Ictal/Periictal State Using a Weight-based Regimen[1]

2-hour Profiles; N=21				
	A. Interictal	**B. Ictal/periictal**	**Ratio of Geometric Means B/A (%)[2]**	**90% CI (%)[3]**
	Geometric Mean	**Geometric Mean**		
C_{max} (ng/mL)	234.73	217.77	92.77	74.5–112.53
$AUC_{(0-2h)}$ (ng•h/mL)	321.50	301.52	93.76	73.86–119.02

4-hour Profiles; N=18				
	A. Interictal	**B. Ictal/periictal**	**Ratio B/A**	**90% CI (%)**
	Geometric Mean	**Geometric Mean**		
C_{max} (ng/mL)	224.19	211.96	95.54	73.34–121.89
$AUC_{(0-4h)}$ (ng•h/mL)	569.82	510.37	89.57	69.21–115.91

[1] Weight-based regimen: 38-50 kg: 10 mg; 51-62 kg: 12.5 mg; 63-87 kg: 15 mg; 88-111 kg: 17.5 mg.
[2] Calculated using least-squares means according to the formula: exp (difference) × 100.
[3] 90% geometric confidence interval using ln-transformed data.

Figure: Simulated Mean Diazepam Plasma Concentrations Following Administration of DBF in the Interictal or Ictal/Periictal State (N=16-21) Using a Weight-based Regimen



Predicted plasma concentrations based on data from 21 subjects with valid profiles for both Treatment A and Treatment B. Each timepoint is the mean of predicted concentrations from 16-21 subjects. Error bars are standard error of the mean.

Exhibit 99.3

AES ABSTRACT

Patient and caregiver preference for route of administration of a benzodiazepine for control of increased seizure activity in stable patients

Rationale: Patients with epilepsy on stable treatment regimens requiring intermittent use of a benzodiazepine as a rescue medication to control bouts of increased seizure activity may soon have access to diazepam or other benzodiazepines delivered through new routes of administration, such oral dissolving film or nasal spray. However, little is known regarding caregiver and patient preference for routes of administration other than the currently approved diazepam rescue medication that is administered as a rectal gel.

Methods: 29 seizure patients and caregivers prescribed intermittent use of diazepam to control bouts of increased seizure activity participated in an online survey. All participants completed a prescreen to insure they met the qualifications. Respondents were asked to identify a preference for route of administration, initially without administration instructions, and then again after reviewing instructions for administration of each product.

Results: These results represent an interim analysis of 29 respondents engaged in an on-going 60 patient survey. Of the 29 responders (15 patients and 14 caregivers) surveyed, all respondents reported 5 or more breakthrough seizures in the past 12 months and 55% had used diazepam to control episodes of seizure activity. The majority of patients (80%) and caregivers (71%) initially preferred an oral dissolving film formulation to a nasal spray formulation. Following a review of instructions for administration of each medication, 87% of patients and 86% of caregivers indicated a preference for oral dissolving film over nasal spray.

When selecting a rescue seizure medication, the most important factors identified by caregivers were effectiveness (93%) followed by immediacy of effect (71%) and ease of use (71%). Patients identified tolerability (60%), effectiveness (47%) and immediacy of effect (47%) as most important.

Overall, effectiveness (41%) and immediacy of effect (31%) were cited as the two most important considerations when choosing a route of delivery. The amount of time to access, prepare, and administer the medication should ideally be either less than one minute (52% of respondents) or 2-5 minutes (41% of respondents).

Conclusion: Most patients and caregivers chose an oral dissolving film over a nasal spray as their preferred route of administration for a benzodiazepine to control bouts of increased seizure activity based on perceived effectiveness, tolerability, and immediacy, and this preference became even more pronounced after they became more familiar with product administration.

Funding: This survey was funded by Aquestive Therapeutics

Ayanna A. Santos, PharmD
TVP Management, LLC
Succasunna, NJ

Gary Slatko, MD
Chief Medical Officer
Aquestive Therapeutics
Warren, NJ

Supporting graphics

Table A
Respondent Demographics

REGION	RESPONDENTS
WEST: AK, CA, CO, HI, ID, MT, NV, OR, UT, WA, WY	6
SOUTHWEST: AZ, NM, OK,TX	4
MIDWEST: IA, IN, IL, KS, MI, MN, MS, NE, OH, ND, SD, WI, MO	6
SOUTHEAST: AL, AR, FL, GA, NC, LA, MS, KY, TN, WV, VA	6
NORTHEAST: CT, DE, ME, MD, MA, NJ, NY, PA, RI, VT, NH	7

Patient Breakthrough Seizures (past 12 months)		
	PATIENTS	CAREGIVERS
≥ 5	11	7
6 - 25	3	4
> 25	1	3

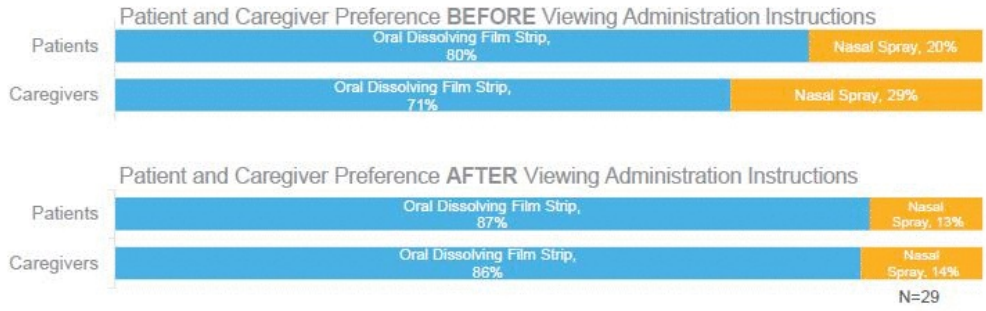
	PATIENTS		CAREGIVERS	
Gender	Male	Female	Male	Female
	5	*10*	*7*	*7*
Patient Age	18-39	40-65	2-20	21-65
	9	*6*	*7*	*7*

Avg. # of Breakthrough Seizures (past 12 months)	
PATIENTS	CAREGIVERS
9	27

SOURCE: Aquestive Patient / Caregiver Rescue Seizure Medication Preference Study, 2019

Figure B
Patient and Caregiver Preference Before and After Reviewing Rescue Seizure Medication Administration Instructions

Majority of patient and caregivers prefer oral dissolving film strip administration for rescue seizure medication



SOURCE: Aquestive Patient / Caregiver Rescue Seizure Medication Preference Study, 2019

Exhibit 99.4

TITLE

Pharmacokinetics of Diazepam Buccal Film in Adult Patients with Epilepsy: Comparison with Diazepam Rectal Gel

AUTHORS

Michael A. Rogawski[1]; Allen H. Heller[2]; Simon Farrow[3]; Cassie Jung[4]; Pavel Klein[5]; Sylvie Boudreault[6]; Gary Slatko[4]

[1]University of California, Davis, Sacramento, CA; [2]Pharma Study Design, LLC, Woodbridge, CT; [3]Clinical Research Center of Nevada, Las Vegas, NV; [4]Aquestive Therapeutics, Warren, NJ; [5]Mid-Atlantic Epilepsy and Sleep Center, Bethesda, MD; [6]Syneos Health, Quebec, CAN

Rationale: Diazepam buccal film (DBF) is a novel dosage form of diazepam under development for the management of patients with refractory epilepsy requiring intermittent use of diazepam to control increased seizure activity. We assessed the pharmacokinetic (PK) performance of DBF administered to adults with epilepsy according to a weight-based regimen (dose range 12.5–17.5 mg) compared to diazepam rectal gel (DRG) administered according to the weight-based regimen recommended in the FDA-approved label (dose range 12.5–20 mg).

Methods: Adult men and women ages 18–65 years with epilepsy on a stable regimen of ≥1 antiseizure drug (no change in the 30 days prior to receiving study drug and no change anticipated over the course of the study) were enrolled in a 2-period crossover study (NCT03953820) to receive a single dose of either DBF or DRG in randomized sequence and separated by a 28-day washout. Doses were administered within 30 min of a standardized moderate-fat meal. Subjects were confined to the clinic until 24 h after dosing. Diazepam plasma samples were obtained pre-dose and at intervals until 10 d after dosing to enable analysis of maximal plasma concentration (C_{max}), time to C_{max} (T_{max}), area under the curve to the last measurable concentration (AUC_{0-T}), and AUC extrapolated to infinity (AUC_{0-INF}). Subjects were monitored for adverse events (AE) throughout the study.

Results: Among 31 subjects enrolled, PK profiles valid for analysis for both DBF and DRG were available for 28 subjects (13 males, 15 females; mean [SD] weight 84.6±20.6 kg). Subjects were excluded from analysis if both treatments were not completed (n=2), or if predose diazepam concentrations were >5% of C_{max} (n=1). Diazepam mean (SD) dose was 15.4±1.9 mg and 17.1±3.0 mg for DBF and DRG, respectively. The **table** shows geometric means for PK parameters with ratio of geometric means (DBF/DRG) for the study population overall (N=28), and geometric means for C_{max} and corresponding ratios within each weight category. For the study population overall, geometric mean C_{max} values for DBF and DRG were 204.26 ng/mL (geometric SD [GSD] 136.12–306.49) and 211.22 ng/mL (GSD 87.71–508.63), respectively (**see figure**), indicating that C_{max} values following DBF were comparable but significantly less variable than C_{max} values following DRG (P<0.0001). Values for AUC were higher for DBF than for DRG, and median T_{max} values for DBF and DRG were 1.0 and 0.52 h, respectively (P<0.05).Three of 28 subjects following DRG dosing failed to achieve a plasma concentration ≥70 ng/mL. There were no serious AEs related to study drug.

Conclusions: These results demonstrate that a single dose of DBF administered to adults with epilepsy following a moderate-fat meal according to a weight-based regimen provides exposure to diazepam similar to DRG dosed as recommended with significantly less variability. The geometric mean values for C_{max} following DBF were consistently ≥150 ng/mL for each of the weight categories.

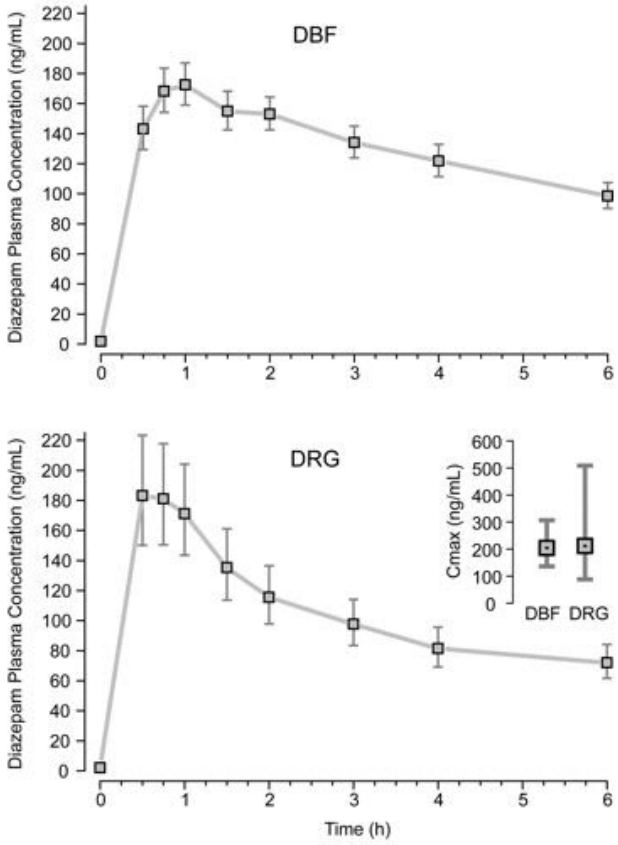
Funding: Aquestive Therapeutics, Inc.

Table: Pharmacokinetic Parameters Following DBF and DRG Administered to Adults with Epilepsy According to Body Weight Following a Moderate-Fat Meal

	DBF	DRG	Ratio of Geometric Means DBF/DRG (%)[1]	90% CI (%)[2]
	Geometric Mean	**Geometric Mean**		
Overall (N=28)				
C_{max} (ng/mL)	204.26	211.22	96.70	70.53–132.58
$AUC_{(0-T)}$ (ng•h/mL)	7290.40	5682.09	128.31	95.93–171.61
$AUC_{(0-INF)}$ (ng•h/mL)	8672.09	6880.96	126.03	103.67–153.21
	Median	Median		
T_{max} (h)	1.0	0.517	*	
C_{max} By Weight Group				
Wt 51-62 kg (n=6)				
C_{max} (ng/mL)	258.38	358.06	72.16	51.17–101.76
Dose (mg)	12.5	12.5		
Wt 63-75 kg (n=4)				
C_{max} (ng/mL)	234.45	258.88	90.56	27.89–294.12
Dose (mg)	15.0	15.0		
Wt 76-87 kg (n=7)				
C_{max} (ng/mL)	201.39	293.00	68.74	46.78–101.01
Dose (mg)	15.0	17.5		
Wt 88-111 kg (n=11)**				
C_{max} (ng/mL)	175.56	115.82	151.58	71.59–320.94
Dose (mg)	17.5	20		

[1]Calculated using least-square means according to the formula $e^{(Difference)}$ x 100.
[2]90% geometric confidence interval using ln-transformed data.
*Statistically significant, $P<0.05$.
**The highest weight category included 4 individuals with body weight 112–124.5 kg.

Figure: Geometric Mean Diazepam Plasma Concentration Following Administration of DBF and DRG to Adults with Epilepsy According to Body Weight Following a Moderate-Fat Meal (N=28)*



*Geometric mean plasma concentrations from 28 subjects with valid profiles for both DBF and DRG. Error bars are the geometric standard error. Inset shows geometric mean values for C_{max} for DBF and DRG with geometric standard deviation.

Exhibit 99.5

TITLE: Safety and Tolerability Associated With Chronic Intermittent Use of Diazepam Buccal Film in Pediatric, Adolescent, and Adult Patients With Epilepsy

AUTHORS:

Syndi Seinfeld[1]; Michael A. Gelfand[2]; Allen H. Heller[3]; Carla Buan[4]; Gary Slatko[4]

[1]Virginia Commonwealth University, Richmond, VA;[2]University of Pennsylvania, Philadelphia, PA; [3]Pharma Study Design, LLC, Woodbridge, CT; [4]Aquestive Therapeutics, Warren, NJ

ABSTRACT

Rationale: Seizure clusters occur in many patients with epilepsy, despite treatment with antiepilepsy medications. Available treatment options remain limited. Diazepam buccal film (DBF) is a novel formulation of diazepam in development for these patients; it is designed to be easily administered, with a pharmacokinetic profile comparable to rectal diazepam. The primary objective of this ongoing study (NCT03428360) is to assess the safety and tolerability of self- or caregiver-administered DBF in people with epilepsy. Interim data from patients receiving ≥1 dose of DBF as of May 2019 are reported.

Methods: Patients 2 to 65 years old with a clinical need for rescue benzodiazepine at least once monthly were included in the study. DBF was dispensed at doses ranging from 5 to 17.5 mg based on age and body weight, and then administered by patients or caregivers in their home environment as clinically needed. DBF could be administered for up to 5 seizure episodes monthly. Outcomes of interest, including adverse events (AEs) and DBF usability assessed by patients/caregivers, were collected after the first dose and then every 3 months thereafter.

Results: A total of 72 patients were enrolled to date and have used DBF at least once (adults, n=59; adolescents, n=7; pediatric, n=6). Overall occurrences of AEs, as well as AE severity and relationship to study drug, are summarized in **Table 1**. Five (6.9%) patients reported a total of 7 treatment-related AEs over a mean (SD) of 192 (97) days of follow-up, and all were mild in severity. Local buccal discomfort (mild in severity) was reported in 1 patient, and there were no reports of injury during buccal placement of DBF. No patient discontinued study participation due to an AE. Thirteen serious AEs were reported, none of which were considered treatment-related. DBF usability data were reported by 64 of the 72 (88.9%) patients, representing a total of 471 DBF use occasions with a mean (SD) of 7.4 (7.7) administrations per patient. DBF was successfully administered during a first attempt on 443 of 471 (94.1%) use occasions and during a second attempt on another 17 (3.6%) use occasions. However, all 64 patients had first-attempt success at DBF administration on at least one use occasion. Reasons for unsuccessful placement among patients with ≥1 unsuccessful attempt are summarized in **Table 2**. Patients and caregivers reported no difficulty opening either the outer or inner packaging in the majority of use occasions and almost all reported no difficulty removing DBF from the inner packaging.

Conclusions: In this observational study of chronic, intermittent administration and use, DBF was found to be safe and well tolerated by pediatric, adolescent, and adult patients with epilepsy experiencing seizure emergencies. DBF was ultimately successfully placed on 99.6% (469/471) of use occasions and readily used without difficulty when administered by patients and caregivers.

Funding: Aquestive Therapeutics, Inc.

Table 1. Summary of Adverse Events

Parameter	Pediatric (n=6)	Adolescent (n=7)	Adult (n=59)	Total (N=72)
	Number (%) of Patients, Number of Events			
Any AE	0	5 (71.4), 10	29 (49.2), 80	34 (47.2), 90
Any serious AE	0	2 (28.6), 2	7 (11.9), 11	9 (12.5), 13
Any severe AE	0	0	5 (8.5), 11	5 (6.9), 11
Any treatment-related AE*	0	1 (14.3), 1	4 (6.8), 6	5 (6.9), 7
Discontinued due to AE	0	0	0	0
Treatment-related AEs†				
Somnolence	0	0	1 (1.7), 1	1 (1.4)
Lethargy	0	0	1 (1.7), 1	1 (1.4)
Altered state of consciousness	0	0	1 (1.7), 1	1 (1.4)
Mouth swelling	0	1 (14.3), 1	0	1 (1.4)
Oral discomfort	0	0	1 (1.7), 1	1 (1.4)
Gait disturbance	0	0	1 (1.7), 1	1 (1.4)
Skin sensitization	0	0	1 (1.7), 1	1 (1.4)

*Defined as an AE categorized as having a “possible” or “probable” relationship to the study drug.
†All treatment-related AEs were mild in severity.

Table 2. Overview of Reported Reasons for Unsuccessful Placement of DBF

Reasons for Unsuccessful Insertion Attempts	Frequency (n [%]) of Unsuccessful Attempts out of 471 Use Occasions*
Excessive drooling	9 (1.9)
Clenching jaw / won't open mouth	10 (2.1)
Clenching jaw / won't open mouth / excessive drooling	1 (0.2)
Spit out before DBF adhered to buccal mucosa	7 (1.5)
Swallowed before DBF adhered to buccal mucosa	0
Other	8 (1.7)

* Respondents could choose more than 1 reason for an unsuccessful insertion attempt; 35 reasons were given for 28 unsuccessful attempts.