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): December 11, 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 7.01 Regulation FD Disclosure

Aquestive Therapeutics, Inc. is furnishing the investor presentations attached as Exhibit 99.1 and Exhibit 99.2 to this report for use at the BMO Prescriptions for Success Conference on December 12, 2018, and in other meetings with investors and analysts.

The information in this report is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for purposes of Section 17 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Business Update Investor Presentation, dated December 2018
99.2	Corporate Update Investor Presentation, dated December 2018

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: December 11, 2018

Aquestive Therapeutics, Inc.

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

Exhibit 99.1

Aquestive

Business Update

December 2018

Advancing medicines
Solving problems
Improving lives

Forward Looking Statements

Certain statements in this presentation and associated oral statements made by management may constitute "forward-looking statements." Words such as "believes", "expects", "projects", "future" and similar expressions often identify such forward-looking statements. These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risk factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, the risk of the Company completing its development work, the risks of delays in FDA approval (or failure to approve) of our drug candidates as well as the risks inherent in commercializing a new product (including technology risks, market risks, financial risks and implementation risks, and other risks and uncertainties affecting the Company including those described in our Form S-1 with the Securities and Exchange Commission ("SEC"). The Company disclaims and is not under any obligation to revise any forward-looking statements, including, without limitation, financial estimates, whether as a result of new information, future events, or otherwise, except as required by applicable law.

This presentation also contains estimates and other statistical data made by independent parties relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. By attending or receiving this presentation you acknowledge that you will be solely responsible for your own assessment of the market and our market position and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of our business.

All third-party trademarks, including names, logos and brands, referenced by us in this presentation are property of their respective owners. All references to third-party trademarks are for identification purposes only. Such use should not be construed as an endorsement of the products or services of us or this potential offering.

Business Update – December 2018

- Sympazan™ (clobazam) Oral Film launched in November; marketing and sales efforts initiated nationwide

- Libervant™ (diazepam) Buccal Film* progressing toward NDA submission, pending outcome of pre-NDA meeting

- Aquestive's PharmFilm patent portfolio not impacted by lifting of DRL Preliminary Injunction; Suboxone® Sublingual Film (CIII)** and Authorized Generic will continue to be a meaningful part of partnered revenue base

- Strong cash position from IPO to support commercialization and development plans with several non-dilutive capital options available, if needed

*Libervant™, the preliminary brand name for Diazepam Buccal Film, was conditionally accepted by the U.S. Food and Drug Administration (FDA) and will be submitted for final FDA review and approval in the Diazepam Buccal Film New Drug Application (NDA)
** SUBOXONE® and SUBUTEX® are registered trademarks of Indivior UK Limited.

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Sympazan™ (clobazam) Launch

- Received FDA approval as expected on November 1st for treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older
- Pharmacokinetic (PK) data presented at American Epilepsy Society 2018 Annual Meeting and published in *Epilepsia*[1]
- Commercial organization with 50+ experienced professionals, in markets nationwide actively meeting with prescribers and payers – first scripts written
- Engagements will help to educate key customers on value of PharmFilm technology, in advance of a potential 2019 Libervant launch
  - 90% overlap in high volume prescriber base

Key corporate milestone in Aquestive's transformation from a CDMO to a specialty pharmaceutical company

[1] "Pharmacokinetics of clobazam oral soluble film," https://onlinelibrary.wiley.com/doi/abs/10.1111/epi.14581

Libervant™ (diazepam) Buccal Film

- Completed six (6) studies to date, including pivotal Adult EMU study, in line with FDA interactions to date
  - Data presented at American Epilepsy Study (AES) meeting
  - Long-term safety study ongoing and progressing well
  - Continue to enroll patients in Pediatric EMU and safety studies
- Upcoming pre-NDA meeting with FDA will inform submission timing and strategy; Seeking to gain the FDA's alignment on following criteria:
  - Appropriate characterization of pharmacokinetic data in healthy volunteers and patients
  - Proposal for appropriate dosing regimen based on studies and population PK model
  - Proposal for providing safety data updates

Progressing toward NDA submission, pending outcome of pre-NDA meeting in mid-December

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Suboxone® Sublingual Film

- Appeals court lifted Preliminary Injunction, allowing DRL to enter market "at risk"; IP litigation continues
- No impact to Aquestive's patent portfolio, no validity or infringement decision rendered
  - Proprietary products have additional unique patents expected to extend protection into the late 2030s

- Revenues from Suboxone are tied to manufacturing volume (not price), and derived from several current and potential sources where Aquestive is the sole and exclusive provider:
  - US Branded orders from Indivior
  - Authorized Generic orders from Sandoz
  - Additional non-U.S. volume, which is growing as a percent of business

Suboxone will remain a significant revenue contributor 4+ years

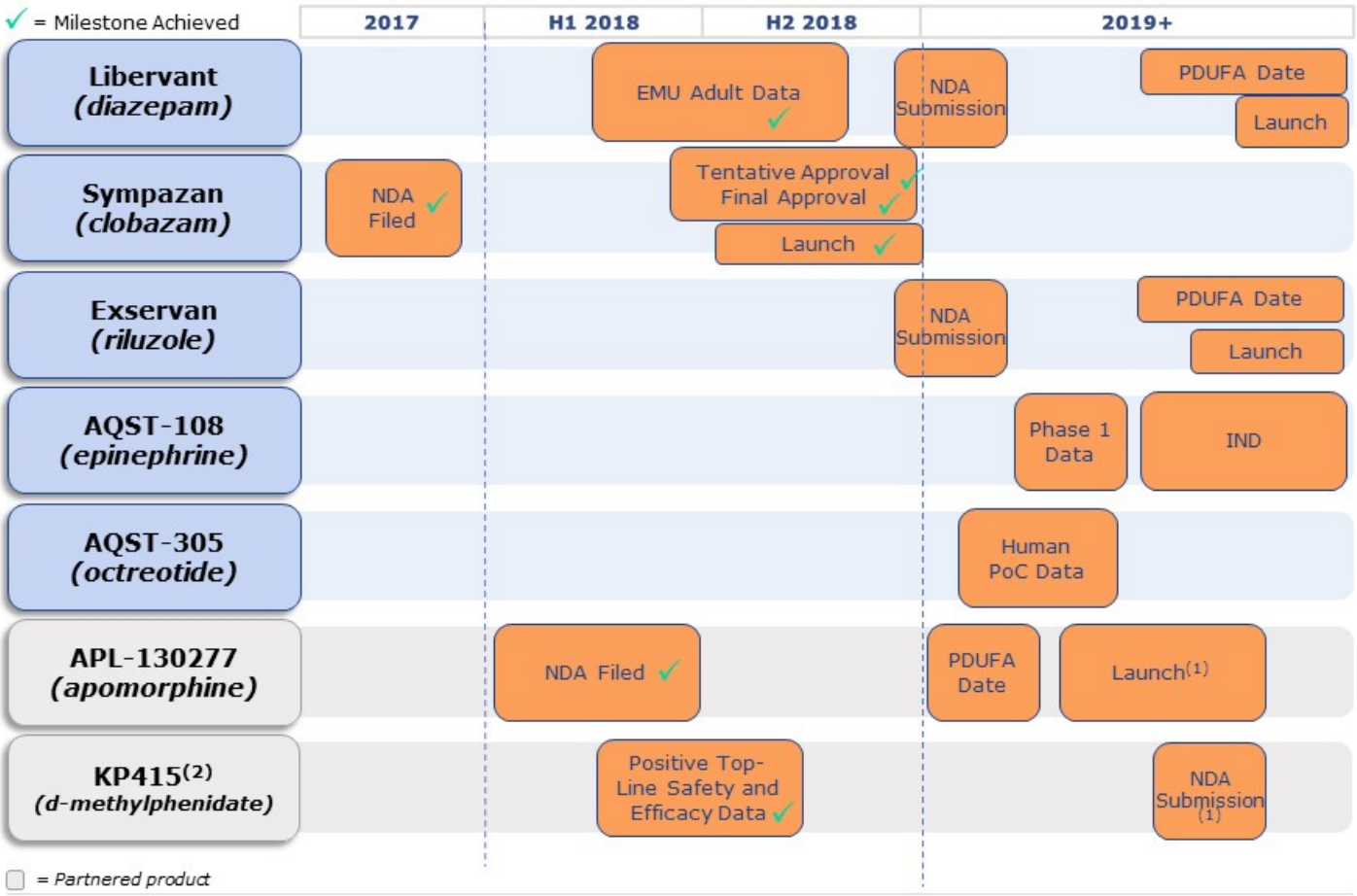
Aquestive Capital Resources

- Proceeds from July IPO positions company to commercially launch its proprietary CNS products
- Impact of Suboxone is manageable as variable cost structure will be adjusted to minimize any impact of lost revenue
- Potential monetizable royalty streams represent non-dilutive capital options
  - APL-130277 (Sunovion) - early 2019 PDUFA
  - KP-415, -484, -879 (Kempharm)
- Solid cash and balance sheet available to fund current and future programs
- Company strategy and plans were designed purposefully to shift from Suboxone/Indivior revenue base to proprietary products

Multi-dimensional business with the resources to fund growth prospects behind CNS franchise, early pipeline and diverse partner portfolio

Aquestive

Multiple Upcoming Near-Term Catalysts



1. Aquestive estimate
2. Aquestive is entitled to double digit percentages of any value generated by KP415

Aquestive

Learn more about Aquestive Therapeutics, Inc.

BMO Capital Markets®

December 12, 2018
10:40 am

2018 Prescriptions for Success Healthcare Conference

New York, New York

Online at:
investors.aquestive.com

Aquestive

Thank you

Exhibit 99.2

Aquestive

Corporate Update

December 2018

Advancing medicines
Solving problems
Improving lives

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Corporate Highlights

Broad, Late-Stage Product Pipeline

- Two late-stage CNS product candidates aimed at improving treatment paradigms
- Complex molecule product candidates in immunology and endocrinology targeting large market opportunities

Commercial-Stage, Innovative Technology & Global IP

- Received FDA approval and launched SYMAPAZAN™, adjunctive treatment of seizures associated with Lennox-Gastaut syndrome
- Commercial team with numerous product launches, including Diastat, Onfi and others in CNS space
- World-class manufacturing capabilities
- PharmFilm technology allows unmet patient needs to be addressed in novel ways
- Extensive patents or patent applications provide protection to 2037

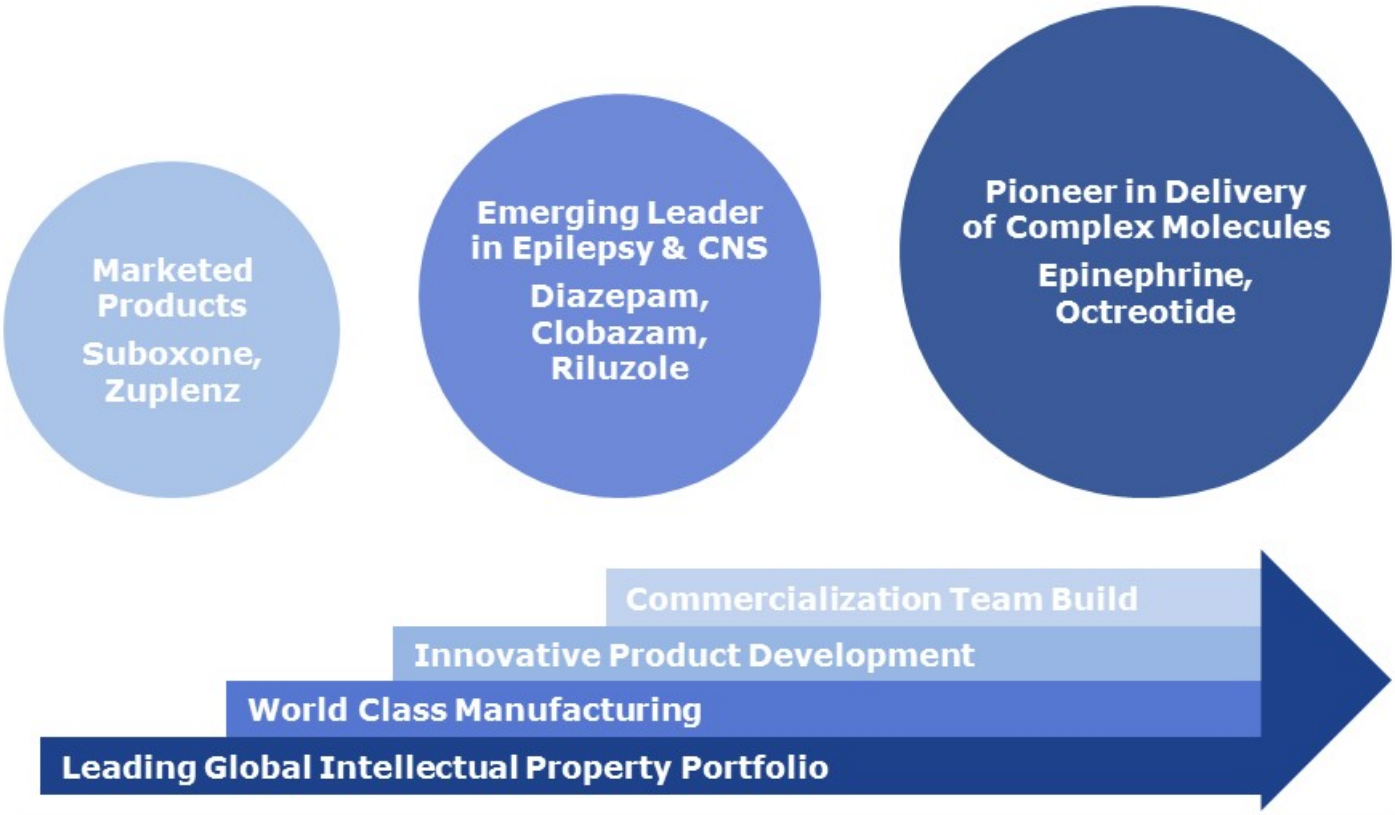
Revenue and Cash Flow from Successful Partnerships

- Multiple collaborations covering products from early-stage to commercial
- ~$50.6 million in revenue generated from licensed products and collaborations for first nine months 2018
- Cash flows re-invested in development of proprietary pipeline
- Experienced management team and board with track record of developing and commercializing pharmaceutical products

Aquestive

Strategic Evolution

Unlocking value by advancing proprietary CNS and complex molecules



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Proprietary and Partnered Pipeline Summary

Program	Molecule	Indication	Formulation	Pre-Clinical	Phase 1	Phase 2	Phase 3	Filed	Marketed	Commercial Rights	Partnered
CNS Programs											
Libervant	Diazepam	Refractory Seizures								Worldwide	
Sympazan	Clobazam	Lennox-Gastaut Syndrome								Worldwide	
Exservan	Riluzole	ALS								Worldwide	
Complex Molecule Programs											
AQST-108	Epinephrine	Anaphylaxis								Worldwide	
AQST-305	Octreotide	Acromegaly/Carcinoid Syndrome								Worldwide	
Partnered Programs											
Suboxone	Buprenorphine / Naloxone	Opioid Dependence									Indivior
Zuplenz	Ondansetron	CINV/PINV									Midatech
APL-130277	Apomorphine	Parkinson's Disease									Sunovion
AQST-119	Tadalafil	Erectile Dysfunction/BPH								Worldwide	
AQST-306	Edaravone	ALS									Mitsubishi Tanabe

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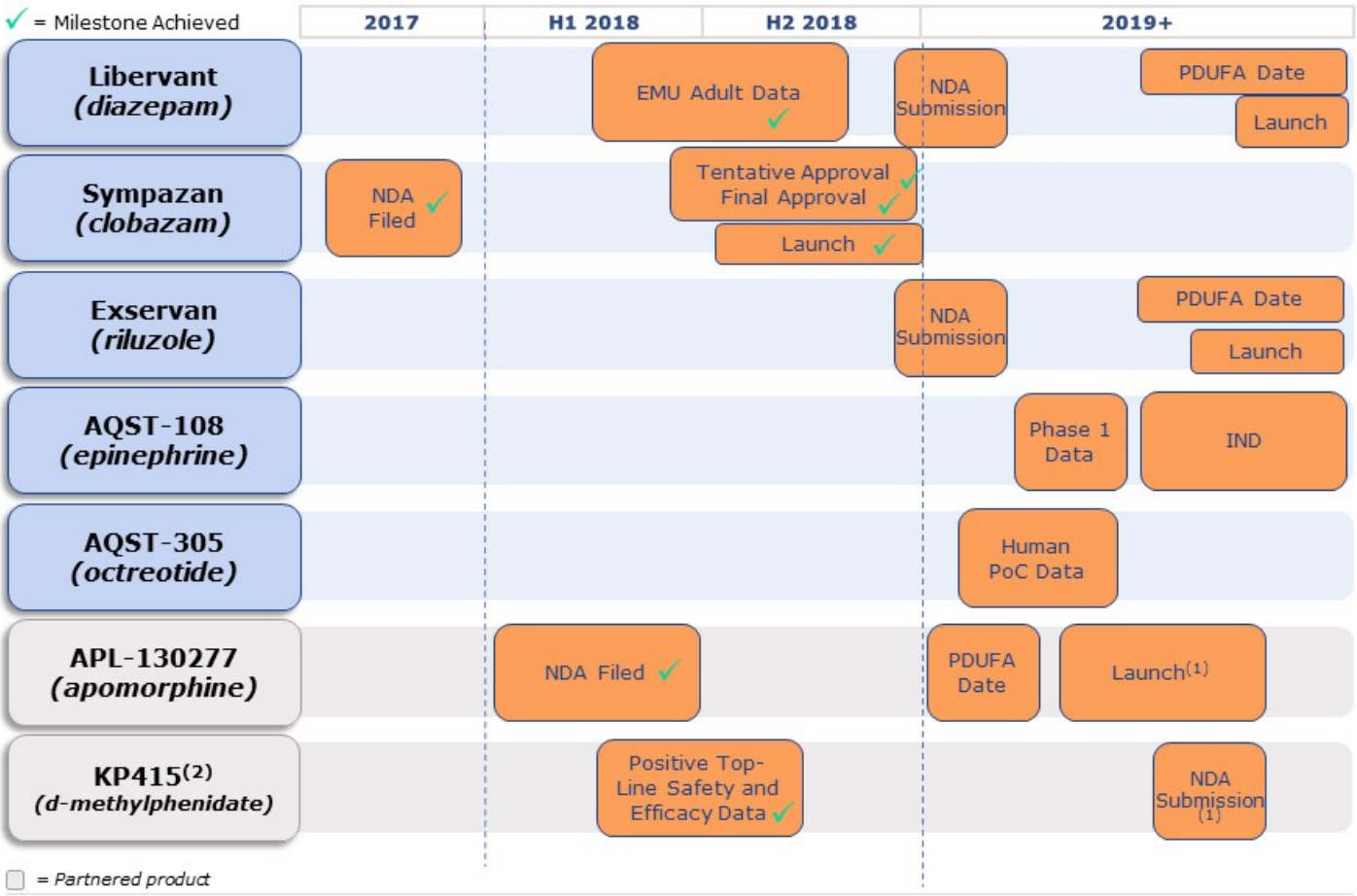
Multiple Upcoming Near-Term Catalysts



1. Aquestive estimate
2. Aquestive is entitled to double digit percentages of any value generated by KP415

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Experienced Management Team & Board of Directors

Leadership Team

Keith Kendall
President, Chief Executive Officer & Director

Dan Barber
SVP, Chief Strategy and Development Officer

Peter Boyd
SVP, Operations and Value Delivery

Lori Braender
SVP, General Counsel

Ken Marshall
Commercial Leader

John Maxwell
SVP, Chief Financial Officer

Mark Schobel
Chief Innovation & Technology Officer

Theresa Wood
SVP, Human Resources and Organizational Development

Board of Directors

Doug Bratton
Founding Partner and Chief Investment Officer, Crestline Investors / Ed Bass Group

Greg Brown, M.D.
Founding Managing Director, Healthcare Royalty Partners

John Cochran
Partner and COO, Crestline Investors / Ed Bass Group

Sandy Costa
Former President & COO, Quintiles

Nancy Lurker
CEO of EyePoint Pharmaceuticals (NASDAQ: EYPT), former CEO of PDI Corporation

James S. Scibetta
CEO of Maverick Therapeutics, former President of Pacira Pharmaceuticals

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PharmFilm Technology

- First FDA approved oral films for lingual, sublingual and combination drug delivery
- Multiple advantages versus IV, tablet and liquid formulations
- World leader in supplying oral films for prescription pharmaceutical products
  - FDA- and DEA-inspected facilities with capacity sufficient for commercial quantities of products and product candidates currently in development
- Robust intellectual property estate with at least 200 approved patents and more than 75 pending patents

PharmFilm®

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CNS Product Portfolio & Strategy

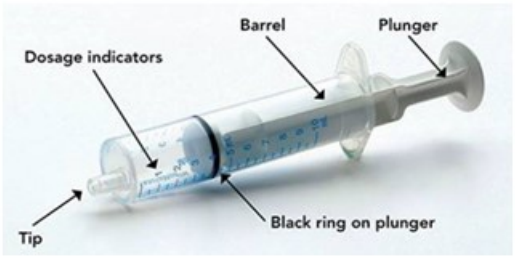
Sympazan (clobazam oral film) Launch underway

Sympazan: Positioning in LGS Treatment Paradigm

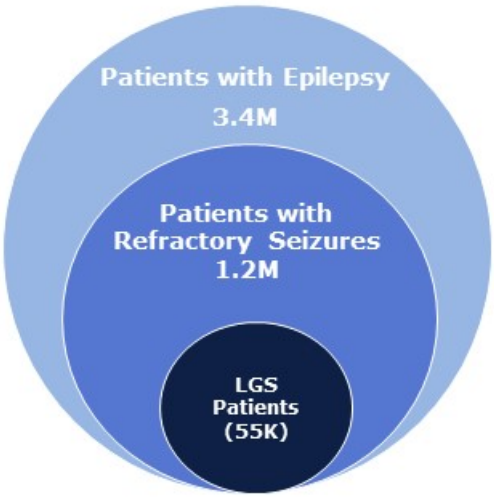
- Lennox-Gastaut syndrome (LGS) is a rare, intractable form of epilepsy affecting ~55K patients in the US
- Medication administration perceived as significant unmet need
  - Approximately 30-40% of LGS patients experience dysphagia
  - Caregivers struggle through decades of difficult treatment regimens, dosing alternatives to address this daily challenge

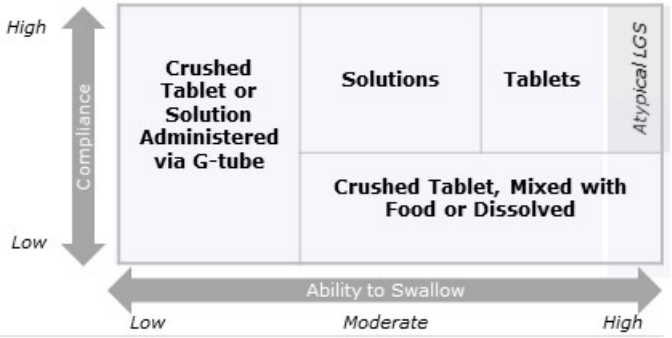
ONFI

- Approximately 500K prescriptions annually
- Available only in tablet and suspension formulations
- LGS patients often cannot, or refuse to, swallow
  - Leads to caregivers crushing tablets or using liquid formulations
  - Can result in patient receiving sub-optimal dose



Lennox-Gastaut Syndrome Market





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Commercialization Strategy

- Commercial leadership with multiple product starts, including launches of Diastat and ONFI
- 30 person sales team, led by three seasoned Regional Directors, designed to support high prescribing HCPs in epilepsy space
  - *Completed home study and live training at National Sales Meeting alongside 30 clinicians*
  - *Deployed to introduce company, educated value of PharmFilm, schedule appointments and peer programs*
  - *Estimated >90% prescribing physician overlap between Libervant and Sympazan to enable dedicated sales team to cover most of the market*
  - *Plan to expand ultimate sales team size of ~50 with 5 first line managers ahead of Libervant launch*
- Built distribution network to ensure supply in pharmacy
- US-focused commercialization strategy with option to partner ex-US

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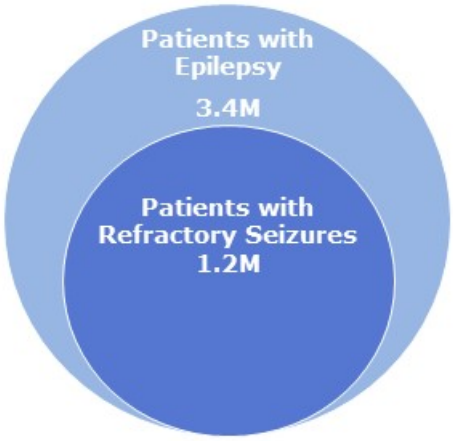
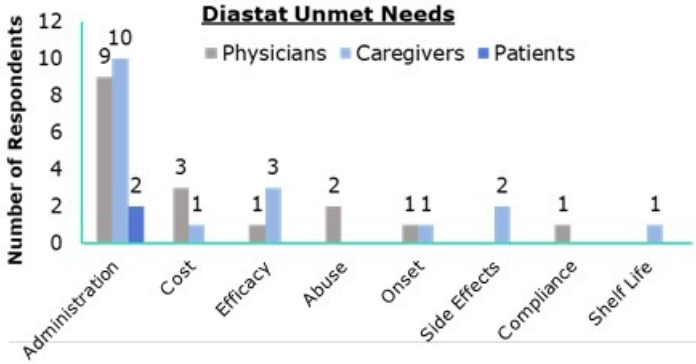
Libervant (diazepam buccal film)

Libervant: Untreated Patient Growth Opportunity

- Epileptic seizures affect ~3.4 million patients in US
  - 200K+ new diagnoses per year
- Only ~250K doses of diazepam rectal gel prescribed annually, due to:
  - 18-step administration process increases caregiver burden
  - Patient dignity and respect
  - Inaccurate dosing
  - Time to administer
- Broad label access to epilepsy at launch that includes refractory seizures
- Potential to expand rescue prescribing to ~1.2M patients with refractory seizures who are not treated or sub-optimally treated

Epileptic Seizures: Rescue Therapy Market





Diastat (diazepam rectal gel)

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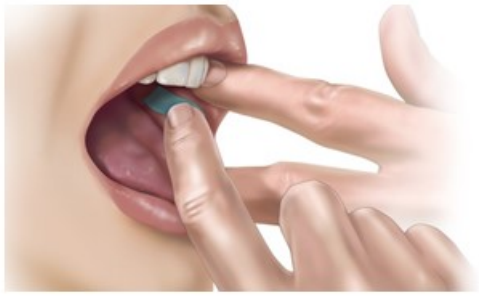
Libervant: Proprietary Formulation with Potential to Expand Patient Usage

- Buccal film administration of diazepam
- Dissolves quickly and demonstrates rapid achievement of therapeutic blood levels
- In development as rescue therapy for breakthrough epileptic seizures
- Alternative to Diastat® (diazepam rectal gel)
- Adult EMU study topline data to be presented as two late-breaking poster presentations at AES, December 2018
- Pre-NDA meeting scheduled for mid December 2018
  - Prepared to commence rolling submission before year end assume positive meeting outcome
- Granted orphan drug designation and fast track designation

Libervant™
(diazepam) buccal film



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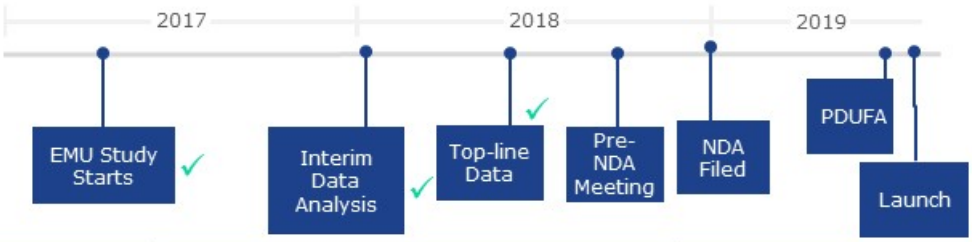
Libervant: Pivotal Trial Design and Expected Timing



Study	Patient Group	Primary Objectives	Secondary Objectives
Dose Proportionality Study (#162013)	Healthy adults	• Demonstrate dose proportional plasma levels for 5, 10 and 15mg doses	
Pivotal Bioavailability Study (#162021)	Healthy adults	• Compare pharmacokinetics and bioavailability in healthy subjects to reference product (diazepam rectal gel)	
Adult EMU Study (#160326)	Adult patients with epilepsy (n=30)	• Compare the pharmacokinetics and bioavailability in subjects with epilepsy in interictal condition, when they are not experiencing seizures, versus the ictal/peri-ictal condition, when they are experiencing seizures	• Evaluate **safety** following single-dose administration • Evaluate **usability** in the interictal and ictal/per-ictal conditions
Pediatric EMU Study (#160325)	Pediatric patients with epilepsy (n=16)		
Safety Study (#42-1703)	Children, adolescents and adults with refractory seizures (n=100)	• Safety and tolerability of chronic intermittent use of diazepam buccal film assessed by examination for any pathological changes in the oral mucosa and gustatory changes	• General safety-tolerability • Evaluate usability, including quality of life measures

Additional clinical trials include a food effect, phase one study and a label comprehension study

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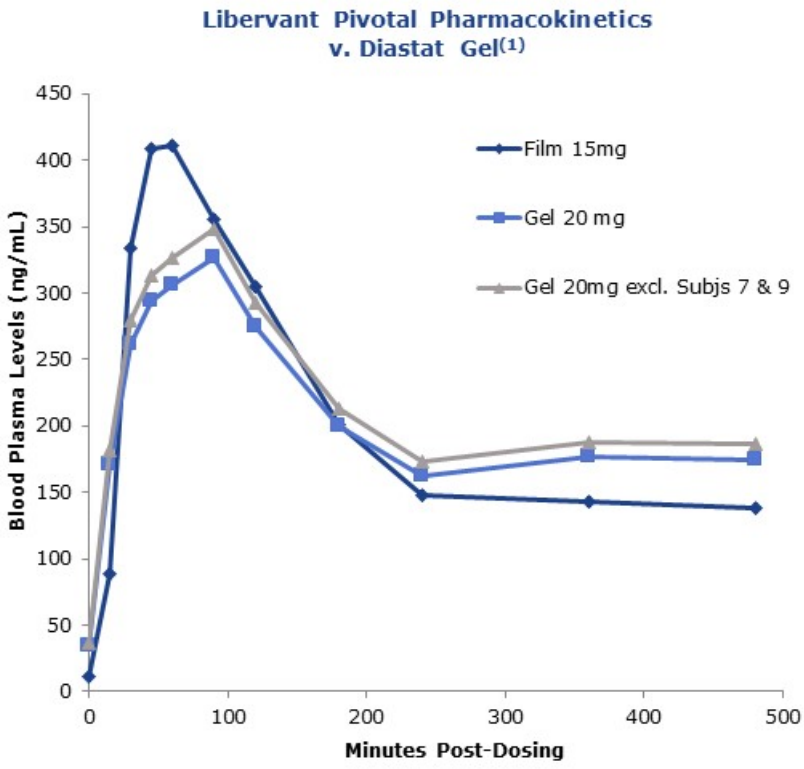
Libervant: Healthy Volunteer Pivotal PK Data

- Libervant produces peak diazepam plasma levels similar to diazepam rectal gel using lower doses of active ingredient
- Plot (right) shows 15 mg Libervant vs 20 mg Diastat
  - Less inter-subject variability compared to all doses of Diastat



1. Fasted conditions; N=29-33, Trial #162021. Subjects 7 and 9 are non-responders to Diastat.

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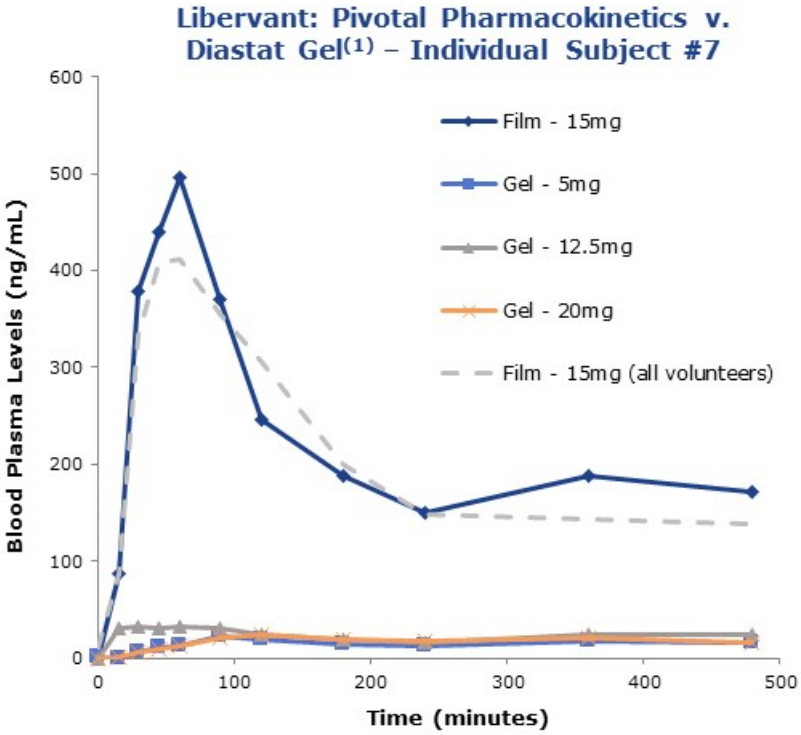
Libervant: No 'Non-Responders'

- Current standard of care (Diastat rectal gel):
  - Exhibits a population subset that does not obtain expected plasma concentrations of diazepam
- Libervant:
  - Consistent plasma concentrations
  - Even Diastat 'non-responders' received acceptable plasma concentrations with Libervant



1. Performed under fasted conditions; Trial #162021

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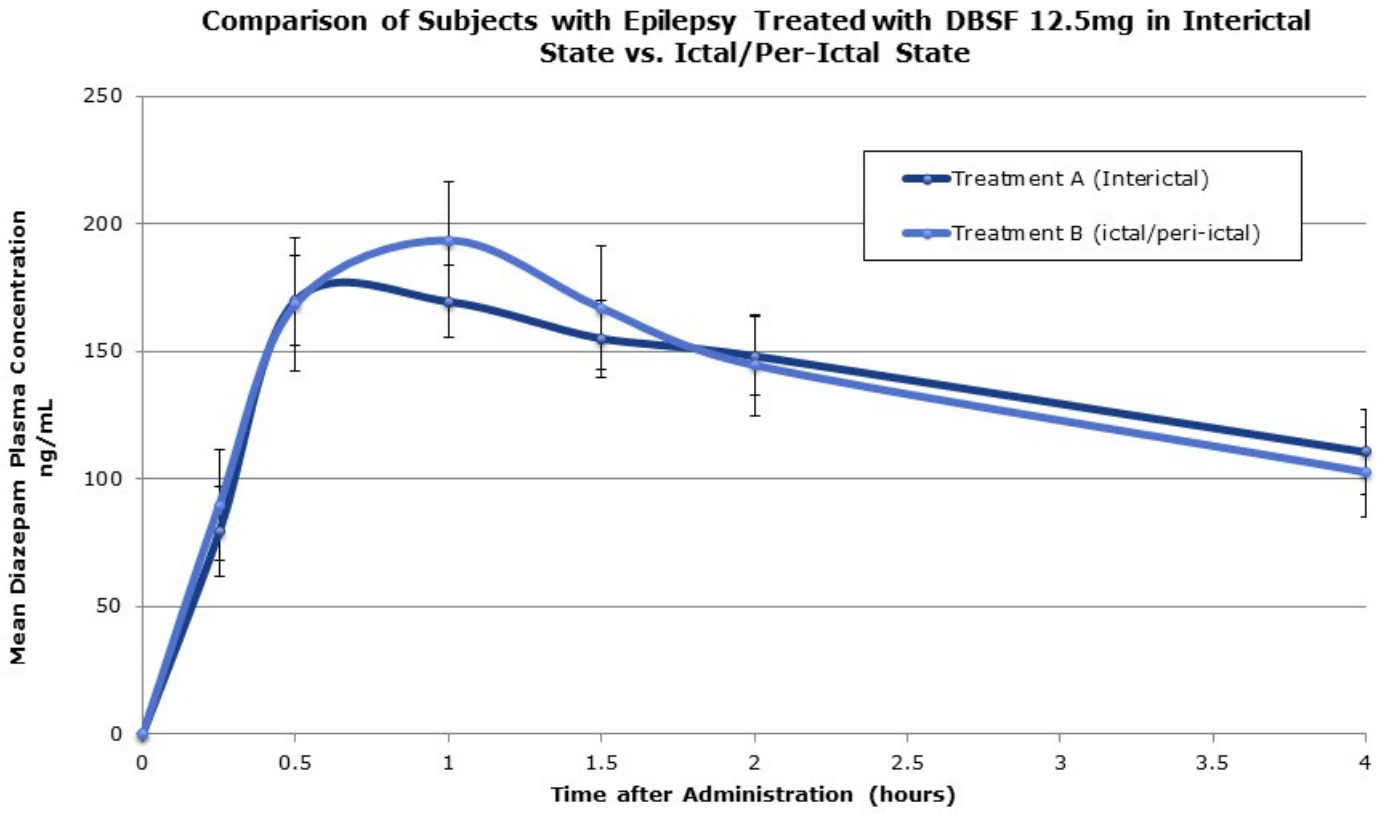
Libervant: Study Completed, Strong Results



Based on comparison of 21 subjects with valid pharmacokinetic profiles for both Treatment A and Treatment B

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Libervant: Adult EMU Safety & Tolerability

- Majority of the treatment-emergent adverse events (TEAE) in this study were classified as unrelated to study drug
- The most common adverse events that were classified as probably related to study drug were somnolence and dizziness and were relatively infrequent (overall frequency of 5.7% of subjects and 2.9% of subjects, respectively)

FREQUENCY OF PATIENTS EXPERIENCING TREATMENT-EMERGENT ADVERSE EVENTS CONSIDERED POSSIBLY OR PROBABLY RELATED TO STUDY DRUG AND NUMBER OF EVENTS - SAFETY POPULATION			
Adverse Events n (%)	Period A (N=33)	Period B (N=33)	Overall (N=35)
Somnolence	2 (6.1%)	0	2 (5.7%)
Dizziness	1 (3.0%)	0	1 (2.9%)
Hypoaesthesia	1 (3.0%)	0	1 (2.9%)
Nausea	0	1 (3.0%)	1 (2.9%)
Paraethesia oral	1 (3.0%)	1 (3.0%)	1 (2.9%)

Exservan
(riluzole oral film)

Exservan (Riluzole)

- Oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis (ALS)
- Potential to be the only formulation of riluzole that doesn't require water or liquid for swallowing
- Completed a pilot PK and pivotal PK study, as well as a food effect study
- All studies successfully shown bioequivalence to the reference listed drug, Rilutek
- Recently completed Swallowing Safety Study
  - primary objective of the study was to evaluate the effect, if any, on swallowing safety in subjects with ALS
  - study successfully met its primary objective and shows that AQST-117 has no adverse effect on swallowing safety in subjects with ALS.
- Expect to submit an NDA by 1Q19

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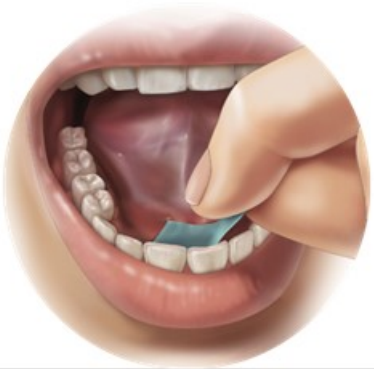
Complex Molecule Candidates & Partnered Products

AQST-108 (epinephrine): Injection to Oral

- 2017 injectable epinephrine market estimated to be approximately $1.7B and over 3.5M total prescriptions
- Potential alternative to EpiPen® intramuscular injection, the market leader in anaphylaxis treatment
- AQST-108 has the potential to:
  - Reduce treatment burden
  - Lower costs to healthcare system
  - Allow for more accurate dosing and patient compliance during times of life threatening anaphylaxis after exposure to allergens
- Expect to initiate next clinical trial in 1H 2019

Auto-injector Delivery

Sublingual Film



Source: IQVIA, IQVIA Combined Audit, 03/2018

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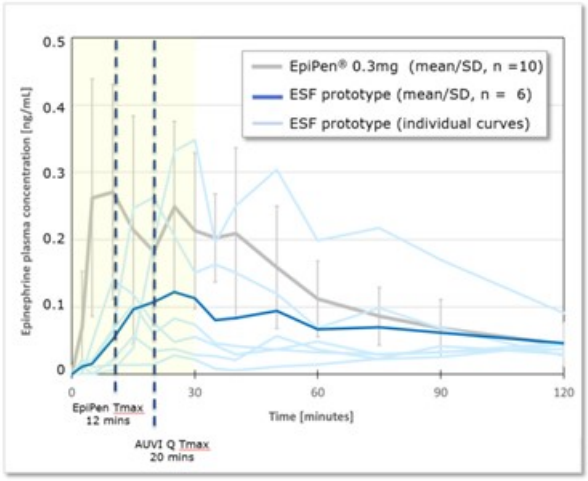
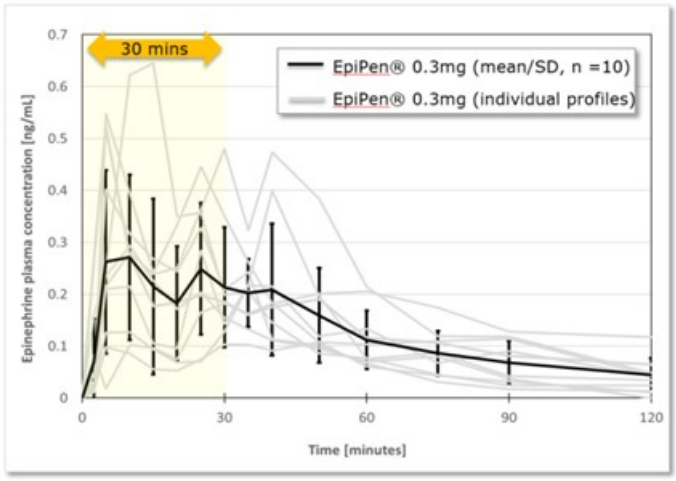
AQST-108 (epinephrine): Proof of Concept Study

- Successfully demonstrated ability to achieve significant oral absorption using PharmFilm technology
- Highlighted the variability inherent in EpiPen administration

Mean profiles for Epinephrine Sublingual Film (ESF) compared to EpiPen® in Human Crossover Study

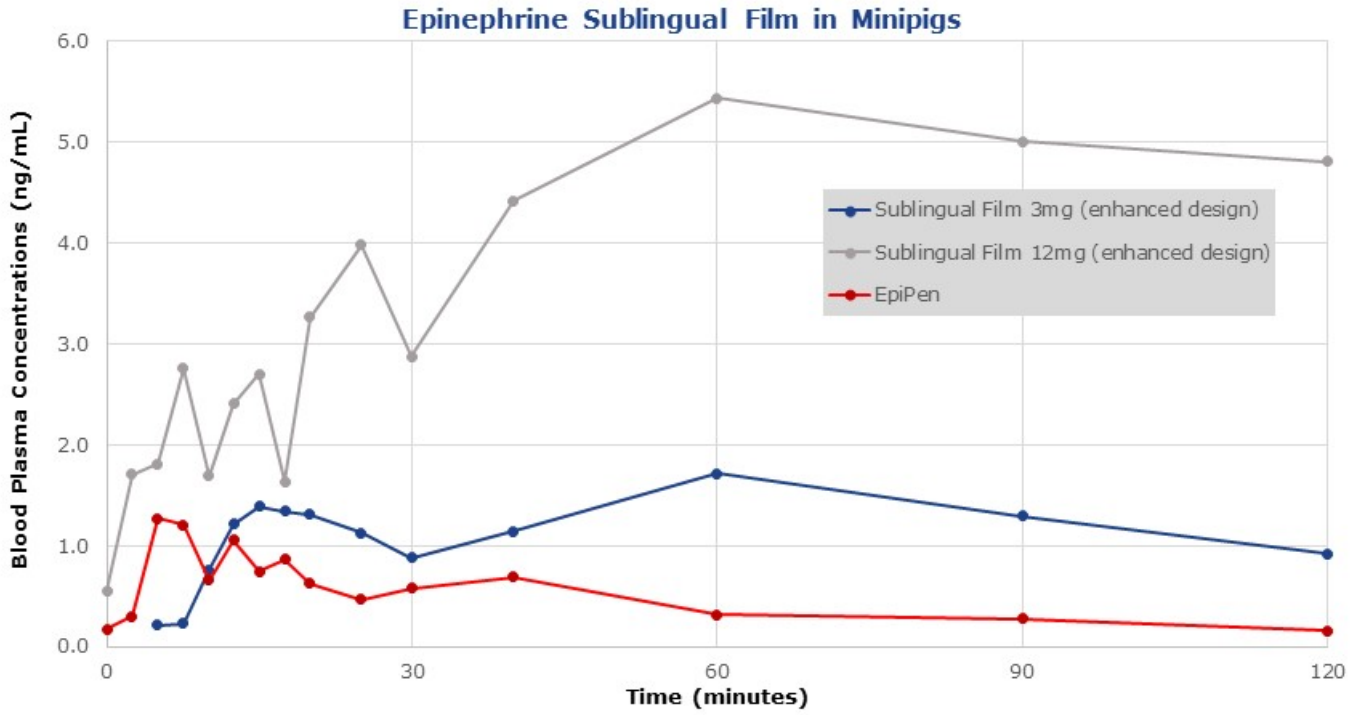


Mean profiles for EpiPen® in Human Crossover Study



Aquestive

AQST-108 (epinephrine): Optimized Formulation Appears Successful in Pig Model



Aquestive

AQST-305 (octreotide): Gateway to Peptides and Biologics via Sublingual Film

- Alternative to Sandostatin LAR®, a monthly depot injection
  - Market leader in treatment of acromegaly and neuroendocrine tumors
  - $843 million in sales in 2017[1]
- Twice daily administration of sublingual film eliminates need for monthly depot intramuscular injection
- Significant patient burden associated with Sandostatin
- Preclinical results demonstrated oral bioavailability levels of up to 10% vs. alternative technologies of <1%
- Dosed first patients in Q3 2018, with data by year-end 2018

Issues Associated with Sandostatin[2]:

- **Pain**
- **Injection Site Reactions**
- **Sub-optimal Symptom Control**
- **Emotional Impact**
- **Missed Work Days**

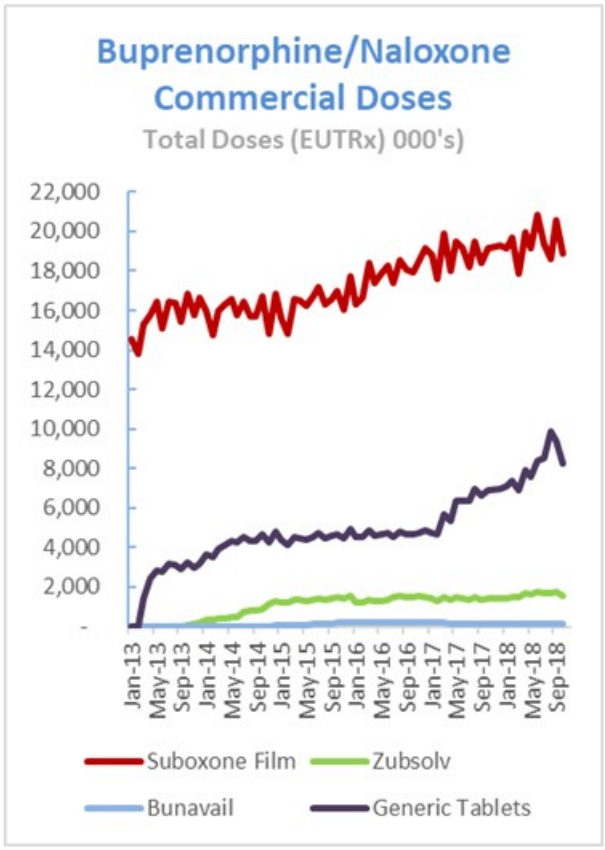
1. IQVIA, IQVIA Combined Audit, 03/2018
2. Strasburger et al, Patient reported outcomes of parenteral somatostatin analogue injections in 195 patients with acromegaly, Eur J Endocrinol, 12/18/15 EJE-15-1042

Aquestive

Validated Commercial Success of PharmFilm

Suboxone® Sublingual Film
(buprenorphine and naloxone) C

- Reduces potential for abuse and improves safety, compliance, dissolution, taste and texture
- Market leader for treatment of opioid addiction that affects more than two million people in the United States
- Over one billion doses delivered to patients
- Captured ~54% of total prescriptions in first 9 months 2018, despite 12 alternative competitors
- Aquestive is sole and exclusive worldwide developer and manufacturer of brand and authorized generic
- Aquestive volumes remain stable for 2018
- Future Aquestive volume driven by branded / CMS, authorized generic and non-US branded



Aquestive

Apomorphine (APL-130277): Late-Stage Partnership with Sunovion

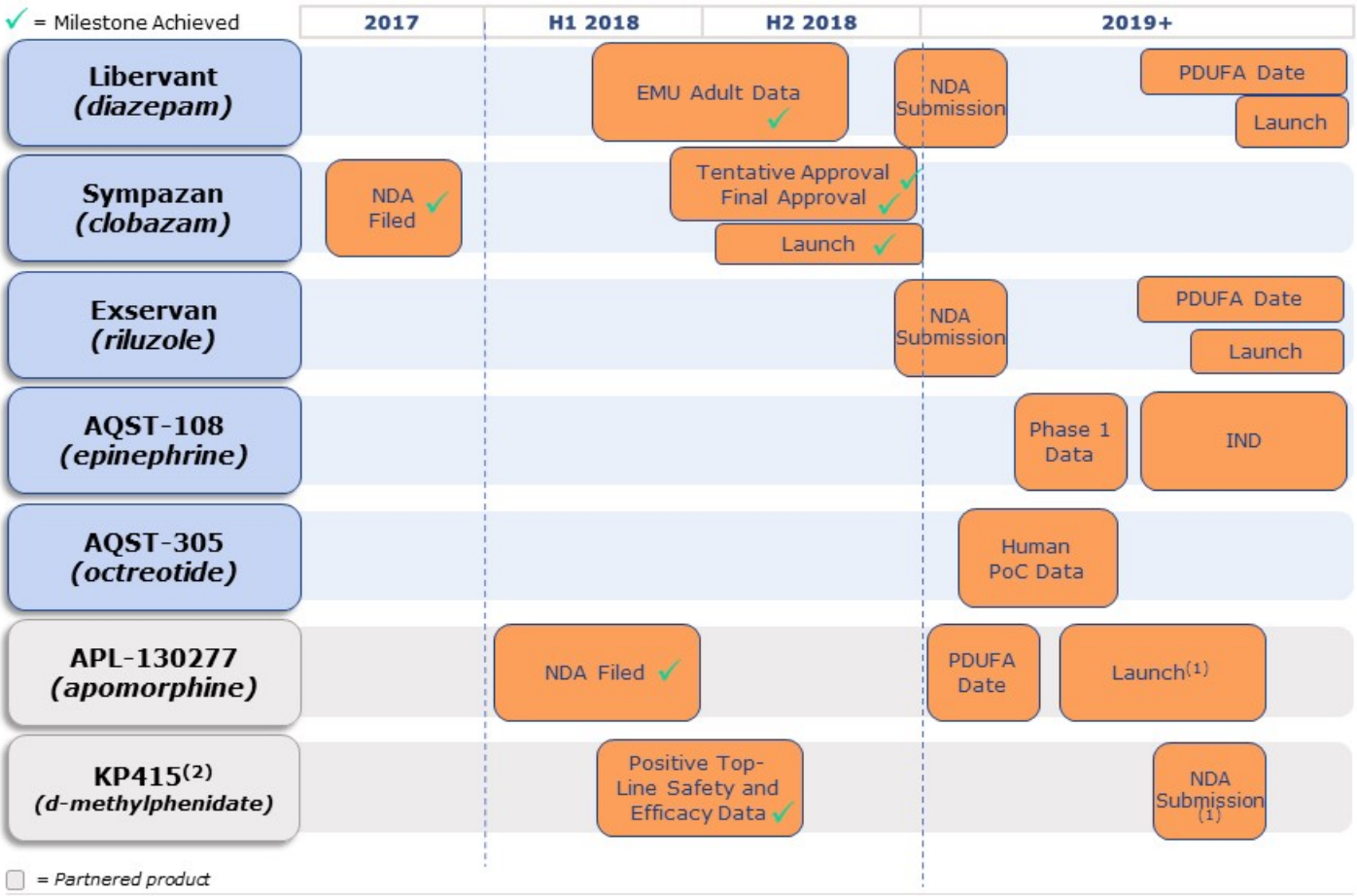
- Sunovion developed a sublingual film formulation of apomorphine utilizing Aquestive's PharmFilm technology
  - Currently delivered via injection (Apokyn Pen)
  - Aims to fulfill unmet need in patients with dysphagia
  - NDA under review for the treatment of patients with Parkinson's disease (PD) who experience motor fluctuations (OFF episodes) (affects ~500k U.S. patients)
- Reported positive top-line results from Phase 3 pivotal trial in January 2018
- PDUFA date in January 2019

Apokyn Pen: 7-Step Process[1]

Note: August 2016, Sunovion acquired Cynapsus, whose single asset is based on Aquestive technology, for $624M.

1. Source: US WorldMeds, LLC; 2014.

Multiple Upcoming Near-Term Catalysts



1. Aquestive estimate
2. Aquestive is entitled to double digit percentages of any value generated by KP415

Aquestive

Thank you