

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AQUESTIVE THERAPEUTICS, INC.,  
Petitioner,

v.

HALE BIOPHARMA VENTURES, LLC,  
Patent Owner.

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Case IPR2019-00451  
Patent 9,763,876

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**PATENT OWNER UPDATED EXHIBIT LIST**

Exhibit No.	Description
2001	Epilepsy Fast Facts, CDC (Center for Disease Control and Preventions), CDC 24/7: Saving Lives, Protection People™, Apr. 9, 2019, pp. 1-2.
2002	Grant Fast Track – Dept. of Health and Human Services re: IND 112621; NRL-1 (diazepam intranasal solution), Dec. 27, 2016, pp 1-2.
2003	Howard LeWine, M.D., “Quick Injection Helps Stop Epileptic Seizures,” Harvard Health Blog, Feb. 23, 2012; p. 1
2004	“Managing Epilepsy Well Network and Selected Self-Management Programs; Putting Collective Wisdom to Work for People with Epilepsy,” Prevention Research Centers (PRC), CDC , Nov. 2016, pp.1-17
2005	K.M. Fiest, et al., “Prevalence and Incidence of Epilepsy, A Systematic Review and Meta-Analysis of International Studies,” NEUROLOGY 88, Jan. 17, 2017, pp.296-303
2006	SIGMA Chemical Company Catalog (1988)
2007	E. Bechgaard et al., “Solubilization of Various Benzodiazepines for Intranasal Administration, A Pilot Study,” Pharmaceutical Development and Technology 2:293-296 (1997)
2008	A. Hussain et al. “Nasal Absorption of Propranolol in Humans,” Journal of Pharmaceutical Sciences 69:1240 (1980)
2009	S. Lau and J. Slattery, “Absorption of Diazepam and Lorazepam Following Intranasal Administration,” International Journal of Pharmaceutics, 54:171-174 (1989)
2010	M. Schols-Hendriks et al., “Absorption of Clonazepam After Intranasal and Buccal Administration,” British Journal of Clinical Pharmacology 39:449-451 (1995)
2011	Dr. Nicholas Peppas Deposition Transcript, October 24, 2019.

2012	Declaration of Dr. Sveinbjorn Gizurarson, Ph.D.
2013	J. Riss et al., “Benzodiazepines in Epilepsy: Pharmacology and Pharmacokinetics,” <i>Acta Neurologica Scandinavica</i> 118:69-86 (2008)
2014	D. Wermeling, U.S. Patent No. 6,610,271, issued August 26, 2003
2015	C. Cole et al., “Community Survey of Carer’s: Individual Epilepsy Guidelines (IEG) for Rescue Medication,” <i>Seizure</i> 18:220-224 (2009)
2016	D. Terry et al., “Acceptance of the Use of Diazepam Rectal Gel in School and Day Care Settings,” <i>Journal of Child Neurology</i> 22:1135-1138 (2007)
2017	Diastat® Label (2005)
2018	“UCB announces NAYZILAM® (midazolam) nasal spray now approved by FDA to treat intermittent, stereotypic episodes of frequent seizure activity in people living with epilepsy in the U.S.,” UCB Press Release, <a href="https://www.biospace.com/article/releases/ucb-announces-nayzilam-midazolam-nasal-spray-now-approved-by-fda-to-treat-intermittent-stereotypic-episodes-of-frequent-seizure-activity-in-people-living-with-epilepsy-in-the-u-s/">https://www.biospace.com/article/releases/ucb-announces-nayzilam-midazolam-nasal-spray-now-approved-by-fda-to-treat-intermittent-stereotypic-episodes-of-frequent-seizure-activity-in-people-living-with-epilepsy-in-the-u-s/</a> (2019) (Accessed October 31, 2019)
2019	J. French and T. Pedley, “Initial Management of Epilepsy,” <i>New England Journal of Medicine</i> 359:166-176 (2008)
2020	G. Corbo et al. “Measurement of Nasal Mucociliary Clearance,” <i>Archives of Disease in Childhood</i> 64:546-550 (1989)
2021	“How does the nose work? The nasal mucosa,” <a href="https://www.fitonasal2act.com/how-does-the-nose-work/the-nasal-mucosa/">https://www.fitonasal2act.com/how-does-the-nose-work/the-nasal-mucosa/</a> (Accessed November 5, 2019)
2022	N. Mygind, “Nasal Allergy,” 9 (Blackwell Scientific Publications, 1979)

2023	“Neurelis Files New Drug Application With The FDA For VALTOCO™ (Diazepam Nasal Spray), An Investigational Treatment For Pediatric, Adolescent And Adult Epilepsy Patients,” <a href="https://www.neurelis.com/neurelis-news/neurelis-files-new-drug-application-fda-valtocotm-nasal-spray-investigational-treatment-pediatric">https://www.neurelis.com/neurelis-news/neurelis-files-new-drug-application-fda-valtocotm-nasal-spray-investigational-treatment-pediatric</a> (2018) (Accessed November 1, 2019)
2024	“Neurelis Receives FDA Orphan Drug Designation for NRL-1 in the Treatment of Acute Repetitive Seizures,” <a href="https://www.neurelis.com/neurelis-news/fda-orphan-drug-designation">https://www.neurelis.com/neurelis-news/fda-orphan-drug-designation</a> (2015) (Accessed November 1, 2019)
2025	Affidavit of Robert Cleary (Dated November 21, 2019) [SERVED BUT NOT FILED]
2026	Affidavit of Ronald Figueroa (Dated November 21, 2019) [SERVED BUT NOT FILED]
2027	Transcript of Telephone Conference on Feb. 11, 2020

Date: 13 February 2020

/Lorelei Westin/

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## CERTIFICATE OF SERVICE

I certify that this paper was served electronically on February 13, 2020, to the following addresses:

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