

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AQUESTIVE THERAPEUTICS, INC.,

Petitioner,

v.

NEURELIS, INC.,

Patent Owner.

Case IPR2019-00451

Patent 9,763,876

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,” Acta Neurologica Scandinavica 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,” Seizure 18:220-224 (2009)
2016	D. Terry et al., “Acceptance of the Use of Diazepam Rectal Gel in School and Day Care Settings,” Journal of Child Neurology 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, 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/ (2019) (Accessed October 31, 2019)
2019	J. French and T. Pedley, “Initial Management of Epilepsy,” New England Journal of Medicine 359:166-176 (2008)
2020	G. Corbo et al. “Measurement of Nasal Mucociliary Clearance,” Archives of Disease in Childhood 64:546-550 (1989)
2021	“How does the nose work? The nasal mucosa,” https://www.fitonasal2act.com/how-does-the-nose-work/the-nasal-mucosa/ (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,”

	https://www.neurelis.com/neurelis-news/neurelis-files-new-drug-application-fda-valtocoTM-nasal-spray-investigational-treatment-pediatric (2018) (Accessed November 1, 2019)
2024	“Neurelis Receives FDA Orphan Drug Designation for NRL-1 in the Treatment of Acute Repetitive Seizures,” https://www.neurelis.com/neurelis-news/fda-orphan-drug-designation (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
2028	“Intranasal Technology, Inc. Licenses Aegis Therapeutics' Intravital Drug Delivery Technology” (Business Wire) (April 13, 2005)
2029	Handbook of Pharmaceutical Excipients (Pharmaceutical Press and American Pharmacists Association, Publishers) (Fifth Edition, 2006)
2030	J. Wyse, U.S. Patent No. 9,192,570 issued November 24, 2015
2031	Daniel P. Wermeling Deposition Transcript, February 26, 2020

Dated: March 10, 2020

/Lorelei P. Westin/
Lorelei P. Westin, Ph.D., Esq., Reg. No. 52,353

CERTIFICATE OF SERVICE

I certify that this paper and exhibits 2028-2031 were served electronically on March 10, 2020, to the following addresses:

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