

**BIOGRAPHICAL SKETCH**

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NAME Neal G. Simon	POSITION TITLE Chief Executive Officer Azevan Pharmaceuticals, Inc.		
eRA COMMONS USER NAME ngsimon			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
State University of New York at Binghamton	B.A.	1974	Psychology
Rutgers, The State University of New Jersey	M.S.	1977	Psychology
Rutgers, The State University of New Jersey	Ph.D.	1979	Biopsychology
Dept. of Psychiatry, SUNY at Stony Brook	PostDoctoral	1979-81	Biochem/Endocrinol

**A. Personal Statement**

I am a co-founder of Azevan Pharmaceuticals and have worked continuously on the company's vasopressin antagonist drug development programs since operations started in 2000. As the CEO and part of the core management team, I have shared principal responsibility for the development of SRX246 and other clinical candidates spanning discovery, optimization, assuring intellectual property protection, preclinical development, IND filings, two successful Phase I Clinical Trials (including both single and multiple ascending dose arms for two drugs), and a 700+ compound library.

As the company CEO, I have obtained support for Azevan's vasopressin antagonist program through multiple NIH awards (STTR Phase I and Phase II grants, SBIR Phase I, Phase II, and Competing Continuation grants, the National Toxicology Evaluation Program, the RAID Program) and Series A and Series B private venture capital investments led by Ascent Biomedical Ventures, L.P. I have been the PI or co-PI on the STTR and SBIR grants, the National Toxicology Evaluation Program Award, and the RAID grant.

I also hold an appointment as a Professor of Biological Sciences at Lehigh University and have over 30 years research experience in neurobiology. For the past decade, I have focused my research efforts in neuropharmacology and drug development. I am the author of over 150 publications and abstracts, including 5 recently co-authored papers with Azevan Scientists.

**B. Positions and Honors****Positions**

1979-1981	National Research Service Award, postdoctoral fellow, R.E. Whalen, Ph. D., and R. Green, M.D., Directors, State University of New York, Stony Brook
1981-1982	Research Scientist, Long Island Research Institute, New York State Office of Mental Hygiene, Stony Brook, New York
1982-1983	Adjunct Assistant Professor of Psychology, University of California, Riverside
1983-1988	Assistant Professor of Psychology, Lehigh University
1988-1992	Associate Professor of Psychology, Lehigh University
1992-1993	Associate Dean of Graduate Studies and Associate Professor of Psychology, Lehigh University
1992-1994	Director, Center for Molecular Biosciences and Biotechnology, and Professor (as of 1993), Departments of Psychology and Molecular Biology, Lehigh University
1993-1995	Professor, Department of Psychology and Molecular Biology, Lehigh University
1994-1995	American Council on Education Fellow, Office of the President, Lehigh University
1996	Professor Associé (1 <sup>st</sup> Class Distinguished Research Professorship), Laboratoire d'Neurobiologie et Ethologie, Université Louis Pasteur, Strasbourg, France
1995-2006	Professor and Chair, Department of Biological Sciences, Lehigh University

Principal Investigator/Program Director (Last, First, Middle): **Brownstein, Michael J.**

2006-present Professor Department of Biological Sciences, Lehigh University

1999-present CEO, Azevan Pharmaceuticals, Inc.

### **Honors and Awards**

1969-1974 New York State Regents Scholar

1979-1981 National Research Service Postdoctoral Fellowship

1988 Lehigh University Award for Outstanding Teaching by a Junior Faculty Member

1994-1995 Fellow, American Council on Education

1996 Professeur Associé (1<sup>st</sup> Class Distinguished Research Professorship), Université Louis Pasteur

### **Private Sector Activities**

Co-founder and CEO, Azevan Pharmaceuticals, Inc, 116 Research Drive, Bethlehem, Pennsylvania.

Founded in 1999, the company's mission is to develop new drugs for stress-related affective disorders, including PTSD, major depression, and impulsivity/inappropriate aggression.

### **C. Selected Publications**

#### **Highly Relevant to the Proposed Presentation**

Simon NG, Ferris CF, Lu S, et al (2011). Vasopressin 1a receptor antagonists as a novel treatment for PTSD: preclinical and phase I studies. Poster presented at: 51st Annual Meeting of the New Clinical Drug Evaluation Unit (NCDEU); July 13–16, 2011; Boca Raton, FL. <http://www.cmeinstitute.com/postersession/index2011.asp>.

Fabio, K., Guillon, Lu, S., Heindel, N., Miller, M., Ferris, C., Brownstein, M., Garripa, C., Steiner, M., Coccaro, E., Damiano, E., Koppel, G., and Simon, N. (2010). Vasopressin Antagonists as Anxiolytics and Antidepressants: Recent Developments. *Frontiers in CNS Drug Discovery*, 1, 1, 156-183

Simon, N. G. and Ferris, C.F (2009). Aversive Emotions: Hormonal Basis of Aggression. In L. Squire (ed.) *New Encyclopedia of Neuroscience*, Elsevier, 149-158.

Ferris CF, Stolberg T, Kulkarni P, Murugavel M, Blanchard R, Blanchard DC, Febo M, Brevard M, Simon NG. (2008). Imaging the neural circuitry and chemical control of aggressive motivation. *BMC Neurosci.* 13:111. **PMID: 19014547**

Simon NG, Guillon C, Fabio K, Heindel ND, Lu SF, Miller M, Ferris CF, Brownstein MJ, Garripa C, Koppel GA. (2008). Vasopressin antagonists as anxiolytics and antidepressants: recent developments. *Recent Patents CNS Drug Discov.* 3:77-93. **PMID: 18537767**

Guillon CD, Koppel GA, Brownstein MJ, Chaney MO, Ferris CF, Lu SF, Fabio KM, Miller MJ, Heindel ND, Hunden DC, Cooper RD, Kaldor SW, Skelton JJ, Dressman BA, Clay MP, Steinberg MI, Bruns RF, Simon NG. (2007). Azetidinones as vasopressin V1a antagonists. *Bioorg Med Chem.* 15:2054-80. **PMID: 17234419**

Ferris, C.F., Lu, S., Messenger, T., Miller, M., Koppel, G.A., Bruns, F.R., Simon, N.G. (2006) An orally active vasopressin V1a receptor antagonist, SRX251, selectively blocks aggressive behavior. *Pharmacol. Biochem. Behav.* 83, 169-174. **PMID: 16504276**

#### **Other Relevant Publications and Contributions to the Field**

Q Mo, S Lu, MJ. Brownstein, NG Simon (2010). Genome-wide analysis of DHEA and DHT induced gene expression in mouse hypothalamus and hippocampus. *J ster Biochem Mol Biol*, 114(3-5):135-43 **PMID: 19429443**

Mo, Q., Lu, S., Simon, N.G. (2006) Dehydroepiandrosterone and its metabolites: Differential effects on androgen receptor trafficking and transcriptional activity. *J ster. Biochem. Mol. Biol.*, 99, 50-58. **PMID: 16524719**

Simon, N., Mo, Q., Hu, S., and Lu, S. (2006). Hormonal pathways regulating intermale and interfemale aggression. *Intl. J. Neurobiol.*, 73, 99-124. **PMID: 16737902**

Simon, N. and Lu, S. (2005). Androgens and aggression. In R. Nelson(ed), *Aggressive Behavior*. Oxford Press, p 537-582.

Mo, Q., Lu, S., Hu, S., and Simon, N.G. (2004). DHEA and DHEA sulfate differentially regulate androgen receptor and its transcriptional activity. *Mol. Brain Res.* 126, 165-172. **PMID: 15249140**

Simon, N.G., Kaplan, J.R., Hu, S., Register, T.C. and Adams, M.R. (2004) Increased aggressive behavior and decreased affiliative behavior in adult male monkeys after long-term consumption of diets rich in soy protein and isoflavones. *Horm. Behav.*, 45, 278-284. **PMID: 15053944**

Lu, S., Mo, Q., Hu, S., Garippa, C. and Simon, N.G. (2003). Dehydroepiandrosterone upregulates neural androgen receptor and transcriptional activity. *J. Neurobiol.*, 57, 163-171. **PMID: 14556282**

Simon, N.G. (2002) Development and expression of hormonal systems regulating aggression. In Pfaff, D., Etgen, E. and Rubin, R. (eds). *Hormones, Brain, and Behavior*. Academic Press, San Diego, pp. 39-85

Cologer-Clifford, A., Simon, N. G., Richter, M. L., Smoluk, S. A., and Lu, S. Androgens and estrogens modulate 5-HT<sub>1A</sub> and 5-HT<sub>1B</sub> agonist effects on aggression. *Physiol. Behav.*, 65, 823-828, 1999. **PMID: 10073487**

## **D. Research Support**

### **Ongoing Research Support**

07/01/05 -12/31/12 Novel Vasopressin Antagonists for Drug Development. Ascent Biomedical Ventures, L.P. \$3,500,000 (co-PI with N.D. Heindel), 20% effort

*These funds also support the development of highly selective and specific vasopressin 1a (V1a) receptor antagonists for use in the treatment of anxiety and major depression*

4/1/10 - 3/30/14 New Drugs for Stress-related Affective Illness. National Institute of Mental Health, \$2.1 million (co-PI with M. J. Brownstein), 20% effort

*These funds also support the development of novel mixed vasopressin 1a (V1a)/vasopressin 1b (V1b)receptor antagonists for use in the treatment of stress-related mood disorders*

5/01/11- 4/30/12 Screening New Therapeutics for the Treatment of Post Traumatic Stress Disorder. National Institute of Mental Health, \$135,000 (with C. Ferris). 10% effort

*These funds support the screening of novel therapeutics for the treatment of PTSD using a new conditioned fear model and awake rodent imaging studies. A Phase II submission is in preparation.*

### **Recently Completed Projects**

Principal Investigator/Program Director (Last, First, Middle): Brownstein, Michael J.

10/01/02-8/30/11. A Potential New Drug for Depression. National Institute of Mental Health, \$3,850,000 (co-P.I. with E. Damiano), 20% effort

*The project supports the development of highly selective and specific vasopressin 1a (V1a) receptor antagonists for use in the treatment of anxiety and major depression*

09/30/09-09/30/10, A Potential New Drug for Depression. National Institute of Mental Health, \$226,385 (co-P.I. with E. Damiano), 10% effort

*This project was a supplement to the above grant issued under the American Reinvestment and Recovery Act of 2009.*

07/01/01 – 06/30/05. Treating Self-Abuse in Autism and Mental Retardation. National Institutes of Mental Health, 2R42 HD37290 (project role: principal investigator) \$600,000

*The project developed novel vasopressin antagonists for self-injurious behavior and impulsivity.*