

BioAdvance NEWS

Advancing the Business of Life Sciences

NUPATHE HARNESSES TECHNOLOGY IN CNS DRUG DISCOVERY APPROACH

“Discovery consists of seeing what everybody else has seen and thinking what nobody else has thought,” — so it is said in the acclaimed *Gulliver's Travels*. This wisdom also applies to the vision for innovation at startup NuPathe, Inc. Led by serial-entrepreneur Jane Hollingsworth (CEO) and CNS development expert Terri Sebree (President), the co-founders and their team are focused on identifying opportunities to improve disease management and developing novel product candidates that address unmet medical conditions such as migraine, Parkinson's disease (PD) and schizophrenia.

With both Hollingsworth and Sebree's experience in commercialization and business development in various therapeutic areas, the entrepreneurs made a move with NuPathe into the CNS market. They also decided that the company's strategic focus would be breakthrough delivery mechanisms that could provide significant patient benefit. Physicians are actively seeking ways to better manage these diseases. Many acknowledge the limitations of a variety of current treatments such as poor efficacy, incomplete symptom control, adverse effects, and low patient compliance and satisfaction.

NuPathe's strategy confronts such deficits and focuses on new ways to address these illnesses. One of its target products, NP101, is a novel and proprietary transdermal treatment for acute migraine. It harnesses a proprietary SmartRelief™ patch technology to deliver sumatriptan — the approved, “gold standard” migraine drug. Based on NuPathe's intellectual property position and the technology, Hollingsworth notes NP101 “is likely to be the only migraine patch for the foreseeable future.”

Technology is at the core of NP101's innovation, using the company's breakthrough iontophoretic patch — a thin, self-contained, disposable patch without bulky, expensive microprocessors or wires that were part of old iontophoretic technology. Since 80% of those with migraines suffer from nausea/vomiting or recurrence, NP101's non-oral, fast and sustained relief is aimed at providing an empowering alternative for migraine sufferers. “When the first, very good, early clinical data on NP101 was received, we knew that we had a product, not just a good idea,” said Hollingsworth. NuPathe is targeting to provide six to eight hours of consistent delivery with NP101, and they plan to initiate a Phase III clinical trial late this year.

As with any young company, a crucial milestone for NuPathe was receiving funding. In 2005 the company received BioAdvance seed funding and this investment (along with funding from Ben Franklin Technology Partners and a private investor) allowed the company to initiate its early clinical development, build out its proprietary technology position, and find a site for operations. In September 2006, the company completed a \$15 million series A financing round, which has advanced the development of NP101 and its second target product for Parkinson's disease.

In addition to NP101, technology anchors two of NuPathe's other product candidates. Hollingsworth recalls another important business milestone when in mid-2006 the company completed an in-licensing deal with the University of Pennsylvania for its LAD™ — long acting drug delivery technology. Now NuPathe's proprietary, implantable LAD is enabling the company to address important medical issues such as pharmacokinetic variability, compliance, and dosing — critical treatment needs for many diseases including PD and schizophrenia. NuPathe's NP201 (PD) and NP202 (schizophrenia) are based on this small, biodegradable technology and clinical trials for both are planned for next year.



Jane Hollingsworth
CEO, NuPathe Inc.

Hollingsworth, who also co-founded, grew, and took public the specialty pharmaceutical company Auxilium Pharmaceuticals, Inc., knows what it takes to assemble and head a successful life sciences company. With years of CRO and large pharma background, Hollingsworth believes its more efficient and effective for small companies like NuPathe to develop opportunities. She calls the NuPathe team fast, flexible, and very able. When she and Sebree decided on a new venture they saw CNS as an emerging market with many illnesses and disease areas not fully addressed. “With Terri's extensive experience in CNS and the many needs of patients, it was clearly the itch to scratch,” adds Hollingsworth.

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MARILLION'S CEO TAPS A COMPLEMENT OF BUSINESS AND SCIENTIFIC SKILLS

Funding early-stage life sciences firms in the Philadelphia region

Milestones

\$11.5 million in seed investments made to **21 startup companies** and **9 additional academic and commercial projects**

\$185 million in additional capital raised

Recent fundraisings

Avid Radiopharmaceuticals
\$26 million
Galleon Pharmaceuticals
\$10 million

Recent Exits

Acuity Pharmaceuticals

Companies in Pivotal Trials

Yaupon Therapeutics

Companies in or through Phase II Trials

Acuity
Alteris
Avid
Eagle Vision
Infrascan
NuPathe Inc.
Protez

Companies in or entering Phase I Trials

Avid
Jenrin
Galleon
Melior
Marillion
Theraquest
Yaupon

Investments in areas such as:

Addiction	Migraine
Alzheimer's Disease	Metabolic Diseases
Cancer	Pain
Cardiology	Respiratory Disorders
GI Diseases	

BioAdvance Contact

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As CEO of Marillion Pharmaceuticals — a Malvern, PA based startup — Zahed Subhan, PhD, MBA, JD is focused on building a portfolio of novel treatments for cancer. The company's lead candidate, the only vitamin D5 receptor ligand to be synthesized (MN-01), is at the IND-stage. Subhan expects the compound to enter a phase I/II clinical trial in multiple cancers this year.

“A one-man mission” aptly describes Dr. Subhan. He employs an ideal range of skills and expertise to direct R&D, secure funding, in-license new compounds, manage operations and conduct Marillion Pharmaceuticals' day-to-day business — all as a virtual company.

“The ultimate goal here is to build a strong and well-rounded product portfolio at Marillion,” says Subhan. And to do so, he taps into education and expertise he has accumulated over the past two decades. Subhan's career spans research, clinical development, marketing and business development within both established global life sciences firms and biotech startups. Launching four drugs along the way, he began fourteen years ago with life sciences firms Sanofi-Synthelabo, Glaxo Wellcome, Merck and DuPont Merck. He later moved into biotech with Boston's Gemini Genomics helping take the company public (NASDAQ) — raising \$100 million; a year later he was part of the management team when Gemini was acquired by

Sequenom. Subhan also worked with Locus Pharmaceuticals in Pennsylvania and most recently was CEO of Nuevolution A/S (Copenhagen) where he raised a \$17 million funding round.

Marillion was founded in 2005 with the goal to develop and commercialize novel therapeutics for the treatment of cancer, inflammatory and autoimmune diseases. The company received its first funding (\$500,000) from BioAdvance to help move its nanoparticle technology forward. Subhan and Marillion also attracted \$1.5 million in additional venture funding from India-based APIDC East Venture. Both investors have recently made follow-on investments totaling \$650,000.

In 2006 Subhan worked with HealthPro BioVentures who provided advisory services for a strategic licensing transaction in which Subhan obtained an exclusive worldwide license to the vitamin D5 receptor ligand to be developed (1 α -hydroxy-vitamin D5). Synthesized by Professor Robert Moriarty, Emeritus Professor of Chemistry at the University of Illinois and co-founder, OncQuest, D5 exhibits an unusually wide separation between therapeutic and calcemic actions compared with other VDR ligands synthesized. A US patent for 1 α -hydroxy-vitamin D5 was issued in March 2005. The D5 drug candidate was licensed from OncQuest Inc./University of Illinois in June 2005 and is now being developed by Marillion for various cancer indications.



Zahed Subhan, PhD, MBA
CEO, Marillion Pharmaceuticals, Inc.

In addition to the D5 drug development platform — with its nine additional analogs — Marillion has also developed a proprietary nanoparticle tumor-targeting technology. The compound (MN-06) is licensed from University of Pennsylvania and may be able to significantly reduce the severe side effects of commonly prescribed chemotherapeutic agents and could ultimately enable reduced doses and targeting to tumor cells, leaving surrounding tissues largely unaffected.

With an IND for MN-01 filed and nine additional analogs aside from the D5 platform in therapeutic areas including psoriasis, cancer and chronic kidney disease — Subhan's next step is to move MN-01 into the clinic in a Phase I/II multi-center study which will look at a variety of cancers (prostate, breast and colon). And, with that trial initiated, Subhan looks ahead to potentially raising more funds and working with the CRO who will run the trial.

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