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Liana Moussatos, Ph.D. (415) 263-6626

Richard Lau (415) 274-6851

NuPathe (PATH - OUTPERFORM): Recent Weakness Has Created A Compelling Buying Opportunity In Our View.

Price: \$3.80

Fair Value Estimate: \$20

- **Recent weakness in the market caused by economic fears has cut PATH in half and created a compelling buying opportunity in our view.** PATH is trading intraday around \$65 million market capitalization or about \$3.88 per share. We believe this is such a pound-the-table buying opportunity in front of the August 29, 2011 PDUFA deadline for their sumatriptan patch treatment for acute migraine called Zelrix™. We believe the clean clinical trial results established efficacy and estimate a 75% chance of first-pass approval, with at least 20% upside for PATH and the potential to double versus 20%-40% downside if approval is delayed.
- **In our view, PATH is significantly undervalued compared with our fair value of about \$20.** We calculate PATH's fair value based on a 30% annual discount and a 1x-10x premium range on our net peak annual sales estimate for each product and indication in the clinic to reflect risk. With PATH trading at a fraction of our \$300+ million peak sales potential for their lead acute migraine treatment candidate, Zelrix™, we believe NuPathe is an attractive investment.
- **We project cash runway through Zelrix™ launch.** The company ended Q1 2011 with about \$32.8 million in cash, investments, and cash equivalents and management guided to runway into H1 2012 which includes the anticipated launch of Zelrix™. Although there is potential for non-dilutive funding from one or more partnerships, we anticipate the company may conduct a financing to hire a sales force and for marketing preparation and launch of Zelrix, if approved on time.
- **NuPathe is an emerging pharmaceutical company applying proprietary drug delivery technologies to improve patient compliance.** The company's lead candidate, Zelrix™, is a proprietary patch delivery of sumatriptan for acute migraine treatment. The company is targeting patients with gastrointestinal symptoms of nausea and vomiting who have difficulty completely swallowing an oral medication.

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RISKS TO ATTAINMENT OF OUR FAIR VALUE INCLUDE:

Clinical Risk NuPathe is an early-stage company which has completed late-stage clinical development for their lead product candidate, Zelrix™, and has submitted a NDA which has been accepted for filing and is being reviewed by the FDA. Even though Zelrix™ successfully completed a pivotal Phase III clinical trial, it is still susceptible to inherent risks of failure at any stage of drug development such as the appearance of unexpected adverse events. The company has two preclinical candidates, NP201 and NP202 as potential treatments for Parkinson's and for schizophrenia, respectively. Because the company is not expected to release initial top line results from mid-to-late stage clinical candidates, we do not believe clinical risk is high in 2011. However, the company's business model involves in-licensing product candidates and its resources are limited in a competitive environment; moreover, the pipeline gap between Zelrix™ and the next clinical candidate NP201 is substantial and may not be filled in a timely manner to provide a staggered portfolio of product candidates to support consistent long-term growth.

Regulatory Risk NuPathe has never obtained marketing approval for a drug candidate but submitted a NDA for its lead product candidate, Zelrix™, on October 29, 2010 which the FDA accepted for filing and has assigned an August 29, 2011 prescription drug user fee act (PDUFA) date as a deadline for a marketing approval decision. As Zelrix™ is currently being reviewed by the FDA; regulatory risk is high as a decision is expected in 2011. Despite what we believe were positive Phase 3 results, the FDA could determine that the clinical program or the NDA was deficient or that Zelrix™ is not approvable and may require additional trials or manufacture additional validation batches. For example, the FDA could require that NuPathe conduct a second pivotal Phase 3 trial and/or a skin sensitization study despite the fact that the company believes it is not required to do so based on its discussions with the FDA. If the FDA requires additional studies or data, the resulting increased costs and delays in the marketing approval would likely increase financing risk. Even after conducting such trials and submitting new data, the FDA may find these to be insufficient or may not agree with the analysis and still may not approve the NDA. Any delay in obtaining, or an inability to obtain, marketing approvals would increase financing risk by delaying Zelrix™ commercialization as well as potential profitability. Regulatory risk can involve turnover in regulatory decision makers which can change policy and approval criteria after the trial is conducted. Agency statisticians may choose a different analytical process than was conducted in the NDA and conclude that the trials failed to achieve statistical efficacy. Changes in standard-of-care occurring while the trial is ongoing may also result in the design being found to be obsolete during regulatory review. Even if a product is approved, the designated patient population may be much smaller than expected which could limit sales potential. Post-approval clinical studies may be required as well as limits on sales and marketing practices and materials. If unexpected adverse effects emerge the drug can be withdrawn from the market. Regulatory requirements also vary among different countries and may result in requirements for additional clinical trials.

Manufacturing Risk NuPathe lacks manufacturing capability and plans to continue to rely on third parties to supply its product candidates. In addition, the company does not have any executed agreements for long-term commercial supply for its lead candidate Zelrix™, and if it executes such a contract, it is likely to be a single-source supplier. Manufacturers of product candidates must follow FDA rules relating to the FDA's current good manufacturing practice (cGMP) regulations which apply to organization of personnel, buildings, facilities, equipment, control of components, drug product containers, closures, production and process, packaging and labelling, holding and distribution, laboratory procedures, records and reports, as well as returned or salvaged products. The manufacturing facilities must pass a pre-approval inspection and will also have periodic inspections by the FDA and other regulatory authorities. Failure to comply can result in a manufacturer receiving warning letters, having products seized or recalled, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and/or criminal penalties. As it is our view that third parties are less motivated toward NuPathe's pipeline than NuPathe employees, we feel that manufacturing risk is somewhat higher than normal. The company has its lead product candidate, Zelrix™, in regulatory review which is a time when manufacturing processes have to be scaled up and inspected. Third parties may also be less motivated to have sufficient quantities of product candidates which could result in delays in commercialization. LTS manufactures Zelrix™ using sumatriptan and components purchased from third parties. Although LTS has experience manufacturing passive transdermal drug patches, it does not have experience in manufacturing active transdermal patches, such as Zelrix™. In order for LTS to produce a commercial supply of Zelrix™, there are multiple activities which need to be completed including transferring technology and production capabilities from LTS' German facility where Zelrix' clinical supply was produced to the commercial manufacturing facility in New Jersey, assemble the commercial scale manufacturing equipment for Zelrix™ using components purchased from third party suppliers, and validate the customized machinery and production process. Because the machinery must be customized for Zelrix™, NuPathe is funding its purchase. If LTS is unable to assemble, customize and validate Zelrix™ commercial scale production at its New Jersey facility, there could be shortages. Also, maintenance issues with customized equipment could result in shortages of Zelrix™ due to the extra time it may take LTS to obtain replacement parts, to finish repairs and to revalidate customized equipment and production. Other risks associated with reliance on third party manufacturers include increased risk associated with regulatory compliance and quality assurance, possible breach of manufacturing agreements, possible termination or nonrenewal of the agreements, and disruption and costs associated with changing suppliers.

Commercialization Risk NuPathe's business model is to develop and commercialize clinical candidates. As NuPathe is a small company, we view commercialization risk as somewhat higher than normal; however, this is offset by not relying on third parties for all commercial activities as we understand NuPathe plans to market Zelrix™ to headache specialists in the US. We anticipate NuPathe is likely to partner commercial activities for primary care and outside the US. We consider NuPathe's commercial plan to be optimal for leveraging potential profits from Zelrix™ sales for a small company. By having its own sales force, collaboration risks are likely to be

reduced including significant competition obtaining collaborators, implementing collaborations, obtaining optimal terms, maintaining collaborators' priority in their resources and efforts, successfully negotiating disagreements, and avoiding early terminations.

Competition Risk NuPathe is a relatively small company with limited resources which increases competition risk. Companies with relatively large budgets for sales and marketing may counter detail against NuPathe's future products and limit its sales. Given that its lead product, Zelrix™, is a novel patch delivery method for sumatriptan and triptans represent the majority of prescribed treatments in oral, nasal and injectable delivery methods, Zelrix™ is likely to have significant competition among acute migraine treatments even if approved by the FDA and launched. We believe competition risk is high, despite pursuing a novel niche—migraine patients with severe nausea and vomiting in which swallowing pills or other oral forms of delivery are not optimal. Physicians treating migraine have told us that many of their migraine patients who experience nausea and vomiting are still able to swallow but the pill may be expelled if they vomit. They also believe some of their patients would prefer a patch delivery. On the other hand, we believe competition risk is lowered by Zelrix™ incorporating sumatriptan which is frequently the first treatment prescribed by headache specialists. In 2010, sumatriptan sold over 70 million units in the U.S. which included about 10 million units of GlaxoSmithKline's (GSK:NYSE) branded Imitrex and Treximet. Maxalt from Merck (MRK:NYSE) sold about \$496 million in the U.S. in 2010 and was the top seller; however, patent exclusivity is expected to expire between 2012 and 2014 and other triptan patents are expected to expire between 2013-2017. Following expiration, inexpensive generic versions of branded triptans are likely to compete with Zelrix™, if approved. Because of lower cost, insurers are likely to promote use of a generic triptan prior to prescribing Zelrix™. Additional competition in the future may come from drug candidates in clinical development, including Merck's telcagepant and Levadex from MAP Pharmaceuticals (MAPP:Nasdaq) which are in late-stage clinical development or regulatory review, respectively. In addition to competition for Zelrix™, NuPathe's early-stage product candidates, NP201 and NP202, are likely to face competition in the future if they are approved. Specifically, NP201, a biodegradable, subcutaneous, injectable polymer implant combined with ropinirole, is likely to have competition from generic immediate-release and extended release versions of ropinirole and pramipexole, as well as from continuous delivery treatments, including a levodopa gel and an injectable apomorphine. NP202 is a biodegradable, subcutaneous, injectable polymer implant combined with an atypical antipsychotic medication and is likely to have competition from branded and generic versions of antipsychotic medications and other sustained-delivery depot formulations of atypical antipsychotics. The nature of the biopharmaceutical industry yields many breakthroughs and new and improved products and processes may be developed by outside companies at any time which could become best-in-class and limit the uptake of NuPathe's products. Due to the company's small size and limited resources, it may be unable to acquire additional product candidates or technologies from third parties as more established companies are also pursuing their acquisition. Increased competition may lead to fewer opportunities and less favorable terms.

Intellectual Property Risk Because the composition of matter patents covering the active pharmaceutical ingredients (APIs) of Zelrix™, NP201, and NP202, have expired, competitors will be able to offer and sell products with the same API so long as these competitors do not infringe upon any of NuPathe's product, formulation and method-of-use patents, or violate any marketing exclusivity period in the intellectual property (IP) estate. Since Zelrix™ is NuPathe's lead product candidate and is being reviewed by the FDA; we believe its IP risk is important. Two patents have been issued (US 6,745,071) or allowed (US 2008/0287497) and the intellectual property protecting NuPathe's current clinical pipeline shouldn't begin to expire until 2027 with the potential for extension to 2029. The issued patent was licensed by NuPathe and covers an iontophoresis drug delivery system. NuPathe and its licensors have filed US and foreign patent applications. In order to develop and commercialize Zelrix™, NuPathe must have a license for LTS's intellectual property and its development and license agreement has a provision that if LTS is the commercial manufacturer, it will be exclusive and LTS will grant NuPathe an exclusive, worldwide, royalty-free license to LTS's intellectual property for commercialization of Zelrix™. However, if commercially reasonable terms cannot be reached, NuPathe would need to develop equivalent or alternative intellectual property, which would significantly delay commercialization of Zelrix™ and involve additional cost. NuPathe is a relatively small company with limited resources so larger companies with more resources may use litigation to weaken its intellectual property position. Because NuPathe relies on third parties, like LTS, to protect the licensed intellectual property, NuPathe may not have any input or control over the filing, prosecution or enforcement of such intellectual property rights and these patents may be found to be invalid or unenforceable. Any enforcement of intellectual property rights, or defense of any claims asserting the invalidity thereof, may be subject to the cooperation of the third parties who may find that their business interests do not support enforcement of these patents. NuPathe has financial obligations associated with intellectual property licenses with third parties, such as University of Pennsylvania for their IP related to LAD technology used to develop and commercialize licensed products (e.g. NP201 and NP202) and to SurModics Pharmaceuticals for their IP for NP201. Clinical and regulatory milestones for NP201 and NP202 can trigger payments at a time of insufficient cash which could delay development and commercialization and even cause termination of the licenses. NuPathe also relies on trade secrets and proprietary know-how as part of its intellectual property. Despite requiring confidentiality agreements, the company is exposed to the potential for unauthorized disclosure which could lead to enablement of competitors to duplicate or surpass NuPathe's technology and weaken its competitive position. Although NuPathe maintains general liability and product liability insurance with limits, subject to deductibles, of \$2 million for general liability, \$1 million for umbrella liability coverage for payments that exceed the general liability limits and \$2 million for product liability, this insurance may not fully cover potential liabilities. Product liability lawsuits could reduce the commercial potential of any product candidates successfully developed. NuPathe plans to have international business relationships for the development and commercialization of its product candidates. Additional risks associated with international business relationships include different regulatory requirements for drug approvals, potentially weaker intellectual property rights, potential for parallel importing, changes in tariffs, trade barriers and regulatory requirements, economic weakness, compliance with tax, employment, immigration and labor laws for employees traveling abroad, foreign taxes, foreign currency fluctuations, labor unrest, production shortages, and interruptions resulting from geo-political actions or natural disasters.

Financing Risk NuPathe is an emerging pharmaceutical company with a lead product candidate being reviewed for market approval by the FDA and the company has not commercialized any products or generated sales. If Zelrix™ is approved by the August 29, 2011 PDUFA deadline, we project first product sales in 2012 and anticipate breakeven/profitability in 2014. The company has funded operations primarily with equity, warrants, convertible notes, and debt facilities and ended Q1 2011 with about \$32.8 million in cash, investments, and cash equivalents. Management has guided to runway into H1 2012 which includes the anticipated launch of Zelrix™. Consequently, we believe there is some financing risk in 2011. Although there is potential for non-dilutive funding from one or more partnerships, we anticipate the company may require financing to fund the hiring of a sales force and marketing preparations for Zelrix™, if approved on time, as well as additional clinical development for NP201 and NP202 and potential in-licensing of additional product candidates prior to our estimate of full-year breakeven/profitability in 2014. If approval for Zelrix™ is delayed, we anticipate the company is likely to require financing to meet any additional requirements for approval. In addition, because some of the manufacturing equipment for Zelrix™ is customized, the company is also obligated to pay for these costs. The company executed a Loan Facility in May 2010 with MidCap Funding III, LLC, and Silicon Valley Bank and received \$5 million. On June 24, 2011, a First Loan Modification Agreement was announced in which the Term B Loans were increased from \$6 million to \$10 million, \$3 million Term C Loans were provided until August 31, 2011, maintenance of at least \$3 million in unrestricted cash, and reduction of LIBOR from 8.75% to 8.5%. With the execution of this Amendment, NuPathe drew down an additional \$10 million term loan under its secured credit facility in order to prepare for the launch of Zelrix™ expected in the first half of 2012. NuPathe issued warrants to purchase 59,748 shares of PATH at \$7.95 per share. Due to restrictions in the May 2010 Loan Facility and the pledge of NuPathe's assets as collateral, there are potential limits to additional debt financing. The company's debt and contractual commitments, including an equipment funding agreement with LTS could tie up cash to pay interest and principal and reduce working capital, capital expenditures, and product development. In addition, because the May 2010 Loan Facility has variable rate interest, the company's debt is exposed to increases in the market rate of interest which could decrease cash runway. Also, the company is exposed to currency exchange fluctuations as payments under the equipment funding agreement with LTS are in Euros.

Analyst Certification

I, Liana Moussatos, Ph.D., Richard Lau, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Company	Disclosure
NuPathe	1

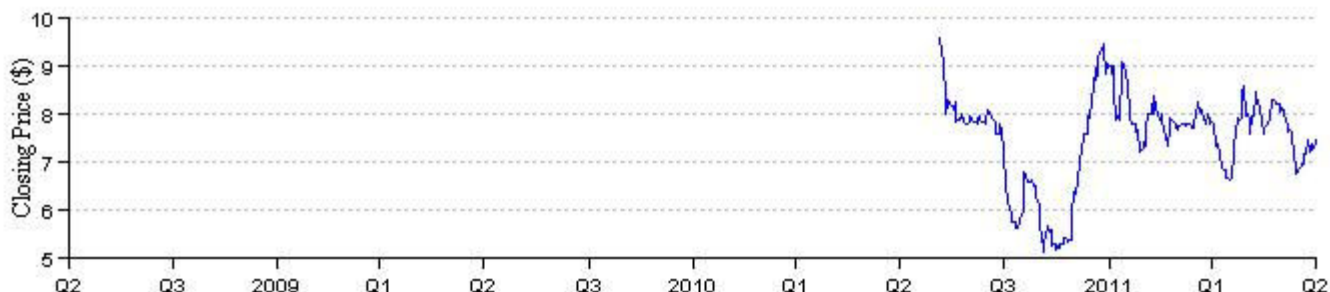
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PATH



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RESEARCH DEPT. * (213) 688-4505 * www.wedbush.com

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CORPORATE HEADQUARTERS (213) 688-8000

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EQUITY RESEARCH DEPARTMENT
(213) 688-4529

DIRECTOR OF RESEARCH
Mark D. Benson (213) 688-4435

RETAIL AND CONSUMER

Consumer Products

Rommel T. Dionisio (212) 938-9934
Kurt M. Frederick, CFA CPA (213) 688-4459

Entertainment: Toys

Edward Woo, CFA (213) 688-4382

Healthy Lifestyles

Kurt M. Frederick, CFA CPA (213) 688-4459

Specialty Retail: Hardlines

Joan L. Storms, CFA (213) 688-4537
John Garrett, CFA (213) 688-4523

Specialty Retail: Softlines

Betty Chen (415) 273-7328

RETAIL/CONSUMER MARKET RESEARCH

Gabriella Santaniello (213) 688-4557

CLEAN TECHNOLOGY AND INDUSTRIAL GROWTH

Aerospace and Defense

Kenneth Herbert (415) 274-6875
Andrew Doupé (415) 274-6876

Clean Technology

Craig Irwin (212) 938-9926
David Giesecke (212) 938-9925

Environmental Services

Al Kaschalk (213) 688-4539
Kevin Lee (213) 688-4303

Industrial Biotechnology

Liana Moussatos, Ph.D. (415) 263-6626
Christopher N. Marai, Ph.D. (415) 274-6861

Water and Renewable Energy Solutions

David Rose, CFA (213) 688-4319

TECHNOLOGY, MEDIA AND TELECOM

Communications Equipment

Rohit Chopra (212) 668-9871
Sanjit Singh (212) 938-9922

Entertainment: Retail

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Alicia Jenks (212) 938-9927

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Michael Pachter (213) 688-4474
Edward Woo, CFA (213) 688-4382
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Gil B. Luria (213) 688-4501

Internet and E-Commerce

Edward Woo, CFA (213) 688-4382

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James Dix, CFA (213) 688-4315

Movies and Entertainment

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Alicia Jenks (212) 938-9927

Semiconductors

Betsy Van Hees (415) 274-6869
Ryan Jue (415) 263-6669

Telecommunications Infrastructure

Suhail Chandy (213) 688-4380
Scott P. Sutherland, CFA (213) 688-4522

Telecommunications Software

Scott P. Sutherland, CFA (213) 688-4522
Suhail Chandy (213) 688-4380

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Scott P. Sutherland, CFA (213) 688-4522
Suhail Chandy (213) 688-4380

LIFE SCIENCES

Biotechnology/Biopharmaceuticals/BioDefense

Gregory R. Wade, Ph.D. (415) 274-6863
David M. Nierengarten, Ph.D. (415) 274-6862
Christopher N. Marai, Ph.D. (415) 274-6861

Cardiac, Hepatic and Regenerative

Duane Nash, MD JD MBA (415) 263-6650
Akiva Felt (415) 263-6648

Emerging Pharmaceuticals

Liana Moussatos, Ph.D. (415) 263-6626
Richard Lau (415) 274-6851
Christopher N. Marai, Ph.D. (415) 274-6861

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Sarah James (213) 688-4503
Daniel Patt (212) 938-9937

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1000 Wilshire Blvd., Los Angeles, CA 90017-2465
Tel: (213) 688-8000 www.wedbush.com