

## NuPathe (PATH)

**We Estimate Zelrix Approval Delayed by About Six Months. Reiterate OUTPERFORM But Reducing Fair Value to \$17 for Delay**

August 30, 2011

Price  
**\$4.05**

Rating  
**OUTPERFORM**

Fair Value Estimate  
**\$17** (from 20)

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- **NuPathe received a complete response letter (CRL) for the Zelrix™ new drug application (NDA).** A CRL is issued when the FDA has additional questions not answered in the NDA. The company stated that the FDA believes efficacy is established but had additional questions centered around chemistry, manufacturing, and safety. The company believes it can address these questions in a short period of time without conducting more than non-clinical and/or a Phase 1 study; however, it retracted its launch guidance for H1 2012. We believe after NuPathe meets with the FDA (likely within 30-45 days), the company will be in a better position to reissue launch guidance.
- **We estimate a 6-month delay to our projected launch estimate.** We estimate that NuPathe can respond to the FDA's questions within six months and have delayed our launch estimate to September 2012. This reduces our estimates from 2012 on and shifts our full-year profitability projection to 2015 from 2014.
- **Due to our delayed launch estimate, we are reducing our fair value to \$17 from \$20 but with PATH trading at only about a \$54 million market cap, we are reiterating our OUTPERFORM rating.** 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 only a fraction of our \$300+ million peak sales potential for its lead acute migraine treatment candidate, Zelrix™, we believe NuPathe is an attractive investment.
- **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.

### Company Information

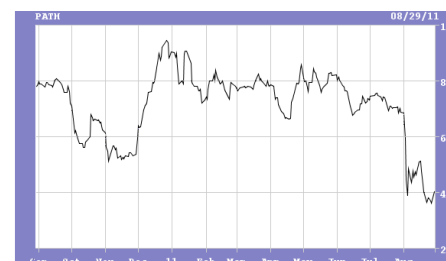
Shares Outst (M)	14.7
Market Cap (M)	\$60
52-Wk Range	\$3.30 - \$9.74
Book Value/sh	\$1.71
Cash/sh	\$1.47
Enterprise Value (M)	\$38
LT Debt/Cap %	37.30

### Company Description

NuPathe is developing novel delivery methods, including its proprietary SmartRelief and LAD for approved APIs as treatments for large unmet medical needs in acute migraine, Parkinson's disease, schizophrenia, bipolar disorder, and related CNS conditions.

FYE Dec	2010A	2011E			2012E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	\$0.0A	--	--	--	--	--
Q2 Jun	--	0.0A	--	0.0A	--	--	--
Q3 Sep	--	0.0E	--	0.0E	--	--	--
Q4 Dec	--	0.0E	--	0.0E	--	--	--
Year*	\$0.6A	\$0.0E	--	\$0.0E	\$4.9E	\$16.6E	\$19.6E
Change	--	--	--	--	--	--	--
	2010A	2011E			2012E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	(\$0.26)A	--	--	--	--	--
Q2 Jun	--	(0.44)A	--	(0.47)A	--	--	--
Q3 Sep	--	(0.58)E	--	(0.52)E	--	--	--
Q4 Dec	--	(0.76)E	--	(0.61)E	--	--	--
Year*	(\$4.39)A	(\$2.04)E	--	(\$1.83)E	(\$3.17)E	(\$2.61)E	(\$2.34)E
P/E	NMx	NMx	--	--	NMx	--	--
Change	--	--	--	--	--	--	--

Consensus estimates are from Thomson First Call.  
\* Numbers may not add up due to rounding.



Source: Thomson Reuters

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## COMPANY SUMMARY

NuPathe, located in Conshohocken, PA, is an emerging pharmaceutical company applying its proprietary delivery technology to improve patient convenience and tolerability for existing drugs. NuPathe is developing novel delivery methods including its proprietary SmartRelief and long-acting delivery (LAD) platforms using approved active pharmaceutical ingredients (APIs) as treatments for large unmet medical needs in acute migraine, Parkinson's disease, schizophrenia, bipolar disorder, and related central nervous system (CNS) conditions. We believe NuPathe's novel drug delivery systems are likely to improve patient compliance as its product candidates reduce the reasons patients have for missing a dose. The company's lead product, Zelrix™ is a sumatriptan iontophoretic patch developed using its proprietary SmartRelief technology for acute migraine with gastrointestinal symptoms and is in FDA review. With the FDA issuing a complete response letter which we estimate could delay approval and launch by about six months—offset by PATH trading at a depressed valuation in our view, we estimate 15%-20% near-term downside—which we view as transient as the FDA indicated that NuPathe established efficacy for Zelrix™. We believe approval of Zelrix™ is likely to result in one or more lucrative commercial partnerships and the company is a likely acquisition target. In addition to Zelrix™ the company is applying long-acting delivery (LAD) technology to treatments for Parkinson's disease, schizophrenia, and bipolar disorder. Patients having these conditions frequently miss a treatment when multiple daily doses are required. Physicians believe physical deterioration may accelerate from uneven control and prefer once daily dosing. The company has two preclinical candidates NP201 to treat Parkinson's disease and NP202 to treat schizophrenia and bipolar disorder.

**Figure 1. Financial Model**

NuPathe Inc. (NASDAQ: PATH)						Wedbush Pac Grow Life Sciences				
<i>Historical and Projected Income Statement</i> (In thousands except per share data)						Liana Moussatos, Ph.D. Richard Lau				
	2010A	2011E				2012E	2013E	2014E	2015E	
	FY:10A	Q1A	Q2A	Q3	Q4	FY:11E	FY:12E	FY:13E	FY:14E	FY:15E
<b>Gross Sales</b>										
Zelrix			-	-	-	-	\$ 5,807	\$ 36,658	\$ 89,578	\$ 168,373
NP201(Parkinson's Disease)			-	-	-	-	-	-	-	-
NP202 (Schizophrenia)			-	-	-	-	-	-	-	-
NP202 (Bipolar Disorder)			-	-	-	-	-	-	-	-
<b>Total Gross Sales</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 5,807</b>	<b>\$ 36,658</b>	<b>\$ 89,578</b>	<b>\$ 168,373</b>
<b>Revenues:</b>										
Net Product Sales	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 4,935	\$ 30,802	\$ 72,261	\$126,651
Zelrix	-	-	-	-	-	-	4,935	30,802	72,261	126,651
Grant Revenue	650	-	-	-	-	-	-	-	-	-
Royalty and License Revenues	-	-	-	-	-	-	-	-	632	4,195
Zelrix	-	-	-	-	-	-	-	-	632	4,195
NP201(Parkinson's Disease)	-	-	-	-	-	-	-	-	-	-
NP202 (Schizophrenia)	-	-	-	-	-	-	-	-	-	-
NP202 (Bipolar Disorder)	-	-	-	-	-	-	-	-	-	-
<b>Total Net Revenues</b>	<b>\$ 650</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 4,935</b>	<b>\$ 30,802</b>	<b>\$ 72,892</b>	<b>\$130,846</b>
<b>Cost and Expenses:</b>										
Cost of Goods	-	-	-	-	-	-	1,480	9,241	21,489	36,736
R&D	17,064	1,574	3,703	3,740	3,777	12,794	15,491	16,120	16,775	17,456
SG&A	4,772	1,970	2,530	4,305	6,848	15,654	33,161	34,507	35,908	37,366
Other	-	-	-	-	-	-	-	-	-	-
<b>Total Operating Expenses</b>	<b>\$ 21,835</b>	<b>\$ 3,544</b>	<b>\$ 6,233</b>	<b>\$ 8,045</b>	<b>\$ 10,626</b>	<b>\$ 28,448</b>	<b>\$ 50,132</b>	<b>\$ 59,868</b>	<b>\$ 74,172</b>	<b>\$ 91,558</b>
Operating Income (Loss)	(21,186)	(3,544)	(6,233)	(8,045)	(10,626)	(28,448)	(45,197)	(29,066)	(1,279)	39,288
Net Interest Income (Expense)/Other Income	(3,671)	(179)	(232)	(470)	(457)	(1,337)	(1,322)	(405)	(205)	(175)
Other Income (Expense)	-	-	-	-	-	-	-	-	-	-
<b>Income Before Income Taxes</b>	<b>\$ (24,856)</b>	<b>\$ (3,723)</b>	<b>\$ (6,465)</b>	<b>\$ (8,515)</b>	<b>\$ (11,083)</b>	<b>\$ (29,786)</b>	<b>\$ (46,520)</b>	<b>\$ (29,471)</b>	<b>\$ (1,484)</b>	<b>\$ 39,112</b>
Provision (Benefit) for Income Taxes	(500)	-	-	-	-	-	-	-	651	7,158
<b>Net Income (Loss)</b>	<b>\$ (24,356)</b>	<b>\$ (3,723)</b>	<b>\$ (6,465)</b>	<b>\$ (8,515)</b>	<b>\$ (11,083)</b>	<b>\$ (29,786)</b>	<b>\$ (46,520)</b>	<b>\$ (29,471)</b>	<b>\$ (2,135)</b>	<b>\$ 31,954</b>
<b>EPS (GAAP,Taxed,Diluted)</b>	<b>(\$4.39)</b>	<b>(\$0.26)</b>	<b>(\$0.44)</b>	<b>(\$0.58)</b>	<b>(\$0.76)</b>	<b>(\$2.04)</b>	<b>(\$3.17)</b>	<b>(\$1.99)</b>	<b>(\$0.14)</b>	<b>\$2.13</b>
Weighted Shares Outstanding (Basic and Diluted)	6,126	14,554	14,562	14,587	14,612	14,578	14,674	14,774	14,874	14,974
Cash	\$38,918	\$32,768	\$36,208	\$26,835	\$15,188	\$15,188	(\$40,263)	(\$76,675)	(\$81,637)	(\$52,608)
Net Cash per share	\$5.50	\$1.90	\$1.47	\$0.88	\$0.12	\$0.12	(\$3.11)	(\$5.19)	(\$5.49)	(\$3.51)
Annual (Burn)/Generation	\$34,992					(\$23,731)	(\$55,450)	(\$36,412)	(\$4,963)	\$29,029

Source: Wedbush Securities

**We estimate a 6-month delay to our projected launch estimate.** We estimate that NuPathe can respond to the FDA's questions within six months and have delayed our launch estimate to September 2012. This reduces our estimates from 2012 onward and shifts our full-year profitability projection to 2015 from 2014. NuPathe ended Q2 2011 with about \$36.2 million in cash, investments, and cash equivalents and management guided to runway into H1 2012. 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.

Our sales projections tend to be relatively conservative in our first two years of product launch; however, due to headache specialists' comments to us about having a group of patients who would prefer patch delivery, we become relatively bullish in year three (2015) which is our breakeven/first full year of profitability. With over 40 million migraine patients worldwide, we believe Zelrix™ sales can reach our projected peak of over \$300 million in 2018.

#### Estimated Milestones (\*our estimates)

**H2:11** NuPathe meeting with FDA for clarity on CRL requirements (late Sept-Oct)  
**2012\*** Potential partnerships for Zelrix™, NP201, NP202  
**H2:12\*** U.S. commercial launch of Zelrix™

#### We see major value drivers in 2011 and 2012.

In the near-term, we anticipate the main value drivers to include clarity on CRL requirements for potential approval of Zelrix™ in 30-45 days (late September-October) as well as a potential commercial partnership for Zelrix™ and/or development & commercial partnerships for NP201 and NP202 in 2012 and launch of Zelrix™ in H2 2012. We believe approval of Zelrix™ is likely to trigger one or more commercial partnerships.

**Figure 2: Despite the delay and resulting decreased fair value, we believe PATH is trading at an attractive valuation.**

PATH Product Pipeline Valuation		Eligible #	Pricing	Gross Peak		Revs Year	Peak	Multiple	Launch	Discount	MktCap Fair	Stock Fair
Product	Indication	Patients	\$/Patient	Sales WW	Net Peak Revs		Penetration			Rate	Value	Value
<b>Zelrix</b>	<b>Acute Migraine</b>	<b>15,000,000</b>	<b>\$1,620</b>	<b>\$307,165</b>	<b>\$198,508</b>	<b>2018</b>	<b>1%</b>	<b>8</b>	<b>9/1/2012</b>	<b>30%</b>	<b>\$252,538</b>	<b>\$17.14</b>
NP201	Parkinson's disease	3,000,000	\$2,698	\$387,359	\$102,548	2021	22%	2	11/1/2016	30%	\$14,198	\$0.96
NP202	Schizophrenia	6,600,000	\$3,854	\$491,133	\$94,733	2022	7%	1	11/1/2017	30%	\$5,045	\$0.34
NP202	Bipolar Disorder	30,000,000	\$3,854	\$468,750	\$92,656	2022	1%	1	11/1/2017	30%	\$4,934	\$0.33
We use multiples to account for clinical and regulatory risk at various stages of development.			Total Peak Revs:		\$395,789			8/30/11	Stock	MktCap	Upside Potential	
1x: in preclinical testing	6x: passed Phase 2 / in Phase 3											
2x: passed preclinical	7: positive Phase 3											
3x: IND filing accepted	8: regulatory review											
4x: Phase 1 data	9: approved											
5x: Phase 2 data	10: launched											
<b>Late Stage Products Fair Value</b>									<b>\$17.14</b>	<b>\$252,538</b>	<b>323%</b>	
<b>Current Quarter's Est Net Cash (000):</b>									<b>\$1.47</b>	<b>\$21,393</b>		
<b>Total Technology Value</b>									<b>\$18.78</b>	<b>\$276,715</b>	<b>364%</b>	
<b>Total PATH Value:</b>									<b>\$20.25</b>	<b>\$298,108</b>	<b>400%</b>	
<b>Current PATH Value:</b>									<b>\$4.05</b>	<b>\$59,671</b>		

Source: Wedbush Securities

**Due to our delayed launch estimate, we are reducing our fair value to \$17 from \$20 but with PATH trading at only about \$54 million market cap, we are reiterating our OUTPERFORM rating.** 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 only a fraction of our \$300+ million peak sales potential for its lead acute migraine treatment candidate, Zelrix™, we believe NuPathe is an attractive investment.

#### RISKS TO ATTAINMENT OF OUR FAIR VALUE INCLUDE:

**Clinical Risk** NuPathe is an early-stage company which has completed late-stage clinical development for its 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 assigned an August 29, 2011 prescription drug user fee act (PDUFA) date as a deadline for a marketing approval decision. On August 29<sup>th</sup>, the FDA issued a complete response letter (CRL) acknowledging that efficacy was established but questions remained on chemistry, manufacturing, and safety. We estimate this will cause about a six month delay to approval and launch. 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** The FDA cited questions in its review of Zelrix™ NDA remained in chemistry, manufacturing and safety. 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 in six months, we project first product sales in late 2012 and anticipate breakeven/profitability in 2015. 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.

Disclosure information regarding historical ratings and price targets is available at <http://www.wedbush.com/ResearchDisclosure/DisclosureQ211.pdf>

### Investment Rating System:

**Outperform:** Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).\*

Rating Distribution (as of June 30, 2011)	Investment Banking Relationships (as of June 30, 2011)
Outperform: 59%	Outperform: 14%
Neutral: 35%	Neutral: 2%
Underperform: 6%	Underperform: 0%

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### Wedbush Equity Research Disclosures as of August 30, 2011

Company	Disclosure
NuPathe	1

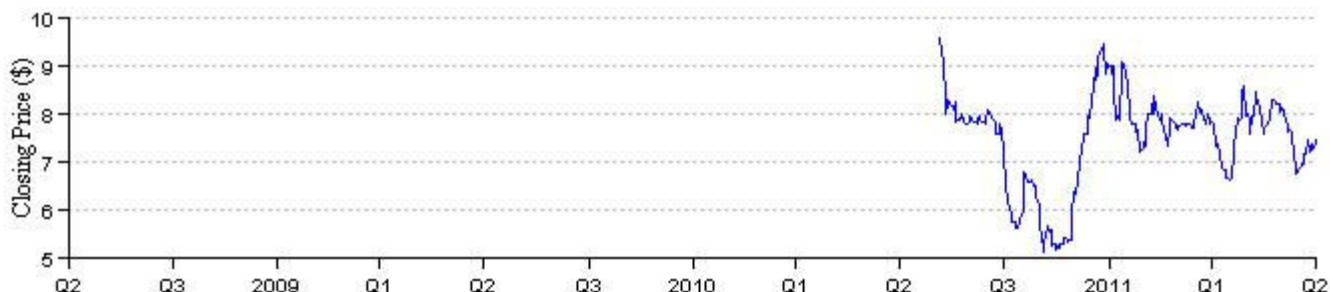
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# PATH



\* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.

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