

# Corporate Presentation Nasdaq: PLXP

## Forward-Looking Statements

This presentation includes or incorporates by reference statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Act of 1934, as amended. These statements relate to future events or to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These statements include, but are not limited to information or assumptions about expenses, capital and other expenditures, financing plans, capital structure, cash flow, liquidity, managements' plans, goals and objectives for future operations and growth. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential," "continue," or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases beyond our control and which could cause actual performance or results to differ materially from those expressed in or suggested by forward-looking statements.

Important factors that could cause such differences include, but are not limited to (i) our ability to bring both Vazalore™ 81 mg and Vazalore 325 mg to market-readiness; (ii) our ability to maintain regulatory approval of Vazalore 325 mg or obtain and maintain regulatory approval of Vazalore 81 mg and any future product candidates; (iii) the benefits of the use of Vazalore 325 mg and Vazalore 81 mg; (iv) our ability to successfully commercialize our Vazalore products, or any future product candidates; (v) the rate and degree of market acceptance of our Vazalore products or any future product candidates; (vi) our ability to scale up manufacturing of our Vazalore products to commercial scale; (vii) our ability to successfully build a specialty sales force and commercial infrastructure or collaborate with a firm that has these capabilities; (viii) our ability to compete with companies currently producing GI-safer technologies for NSAIDs and other analgesics; (ix) our reliance on third parties to conduct our clinical studies; (x) our reliance on third-party contract manufacturers to manufacture and supply our product candidates for us; (xi) our ability to retain and recruit key personnel, including development of a sales and marketing function; and (xii) our ability to obtain and maintain intellectual property protection for our Vazalore products or any future product candidates.

Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.



#### **Our Mission**

PLx Pharma is focused on developing & commercializing next-generation oral NSAIDs and other drugs that leverage our proprietary PLxGuard™ technology to achieve greater efficacy and improved safety. We are driven to transform the standard of care for high-risk cardiovascular patients.



### **Novel Drug Delivery Technology**

Achieves greater efficacy with improved acute GI safety Mechanism of action enables strong patent life and is applicable to a variety of APIs

#### Lead Product: Vazalore™



Clinically proven to overcome the limitations of enteric-coated aspirin with faster-acting, more reliable and predictable efficacy and improved acute GI Safety



Late-stage product opportunity: Over-the-Counter (OTC), next generation aspirin with a 325mg dose (FDA approved) and an 81mg dose both expected to launch by mid-2020



Addresses a \$12+ billion high-risk cardiovascular patient market



•World-renowned key opinion leader advisory board (including Chairman, Dr. Deepak L. Bhatt and Dr. Gabrielle Steg) that understand and advocate for our innovative solution as a new standard of care



Significant physician interest in Vazalore – WSM<sup>1</sup> research positioned Vazalore in the top 5% of all health care professional recommended or prescribed products tested in the past 20<sup>+</sup> years

1- Weinman Schnee Morais Inc.





## Targeting an Unmet Medical Need

# VAZALORE

Aspirin Capsules, 325 mg

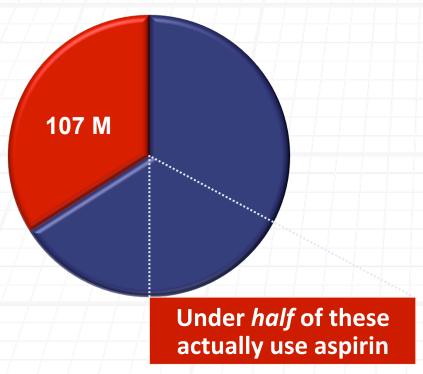
Pain Reliever/Fever Reducer (NSAID)

FIRST LIQUID-FILLED ASPIRIN CAPSULES



## **Current Aspirin Landscape**

34% of U.S. Population Falls in Categories for which Aspirin Would be Recommended 1



GI complications from NSAIDS limit compliance



50+ million people who could benefit from aspirin use are left vulnerable to cardiovascular events

1. U.S. Census Bureau estimate, September 2014



## **Current Aspirin Landscape**

#### Widespread usage

Aspirin is one of the most widely-used drugs in the world

#### Global standard of care

 Foundational drug used to treat and prevent the leading cause of death, cardiovascular disease – Highest recommendation for secondary prevention treatment guidelines

## Enteric-coated aspirin dominates the market

>90% of U.S. sales, due to the perception that it has equal efficacy (decrease in platelet aggregation) and better safety (GI) than regular aspirin – neither of which is correct

### **Treatment/Compliance limitations**

- EFFICACY: ~25% of EC aspirin treated patients have minimal absorption of aspirin
- SAFETY: Gastrointestinal (GI) upset / intolerability could limit patient compliance



## Published Studies Support Aspirin – Not Enteric-Coated Aspirin

More than 200 studies support aspirin benefits

**EVERY** important clinical study supporting cardiovascular benefit of aspirin was conducted using immediate release (regular) aspirin – not (enteric-coated).<sup>1</sup>

JAMA 2014: Study in >14,000 high-risk primary prevention subjects comparing 100mg enteric-coated aspirin vs. no aspirin stopped after 5 years, because they found no benefit for enteric-coated aspirin.<sup>2</sup>

- 1. ISIS-2 (Second International Study of Infarct Survival) Collaborative Group. Randomised trial of intravenous streptokinase, oral aspirin, both, or neither among 17187 cases of suspected acute myocardial infarction: ISIS-2. Lancet 1988; 2: 349–60
- 2. Ikeda Y *et a*l, Low-Dose Aspirin for Primary Prevention of Cardiovascular Events in Japanese Patients 60 Years or Older With Atherosclerotic Risk Factors A Randomized Clinical Trial. *JAMA*. 2014;312(23):2510-2520. doi:10.1001/jama.2014.15690



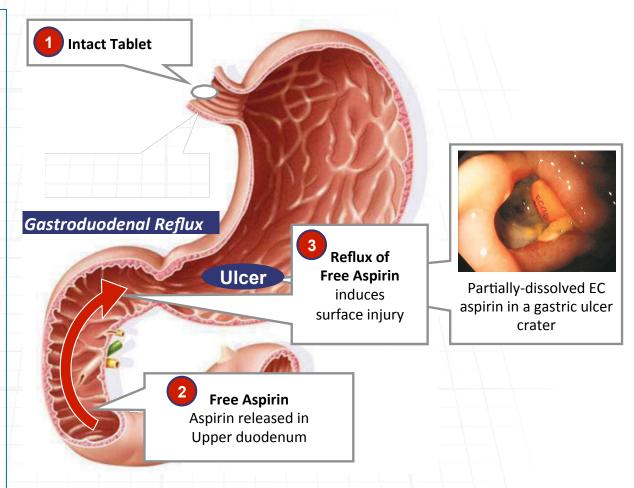
## Why Can Enteric-Coated Aspirin Still Cause Ulcers?

#### **Unidirectional Protection**

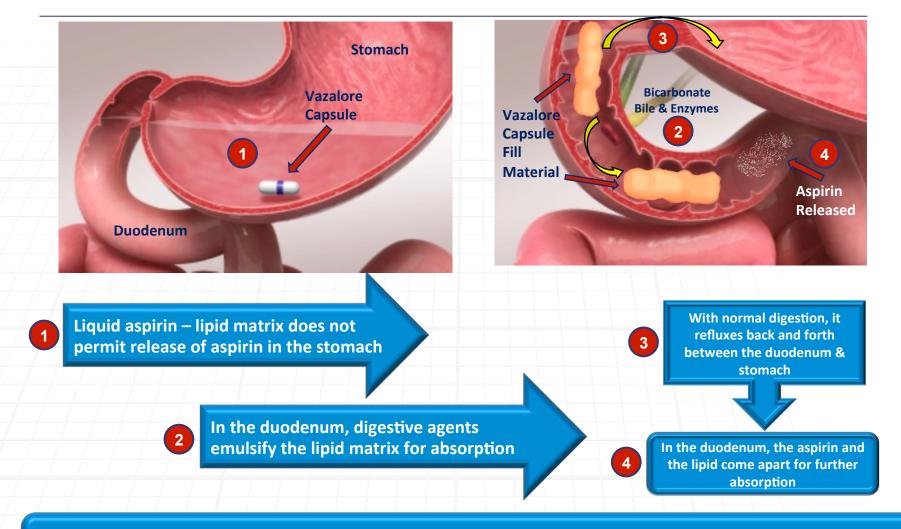
- Stomach
  EC aspirin tablet
  remains intact in
  stomach (pH 3)
- Duodenum (small intestine)

EC aspirin disintegrates in duodenum (pH 5.5)

Result
Released aspirin can
now freely reflux back
into the stomach and
induce surface injury



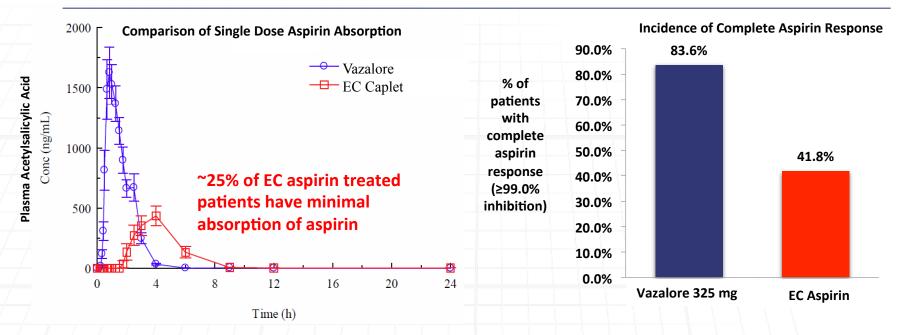
#### Vazalore's Novel Delivery System & Mechanism of Action



Vazalore selectively releases aspirin in the duodenum, which enables better and more reliable antiplatelet efficacy



## Vazalore Clinically Demonstrates Better Absorption & Antiplatelet Efficacy than Enteric-Coated (EC) Aspirin



- Single dose pharmacokinetics and thromboxane depletion in non-insulin dependent diabetics
- Two independent studies in 92 subjects
  - PL-ASA-004 published in the Journal of American College of Cardiology<sup>1</sup>
  - PL-ASA-006 study manuscript in preparation

Vazalore has fast, predictable and reliable absorption and antiplatelet activity

1. Bhatt et al Enteric Coating and Aspirin Nonresponsiveness in Patients With Type 2 Diabetes Mellitus, JACC, Jan 2017, 23269; DOI: 10.1016/j.jacc.2016.11.050



### Vazalore Has Better Acute GI Safety

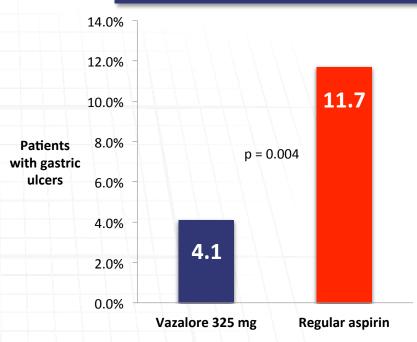
#### Aspirin's Gastric Injury

- Aspirin induces corrosive damage by direct contact with the gastric surface - manifested as ulceration and bleeding
- Endoscopy demonstrates EC aspirin is not GI safer, with no difference in ulcer risk compared to regular aspirin 1

#### **Vazalore Solution**

- Vazalore's lipid matrix release is based on pH, presence of bile, and enzymatic digestion
- Resulting in predictable and complete aspirin release in the small intestine
- Fewer gastric erosions and acute ulcers
- 1. Kelley DJ, et al. Lancet. 1996;348;1413-1416
- 2. American Journal of Gastroenterology, 2010 and unpublished PLx studies

#### 65% Fewer Acute Gastric Ulcers



Seven day endoscopy endpoints combined from two PLx clinical studies (PL-ASA-002 and PL-ASA-005) endoscopy trials with Vazalore 325 mg vs. regular 325 mg aspirin taken daily, in **441 subjects** with an age-associated risk for cardiovascular disease, demonstrated a minimum of **65% reduction** in risk for gastric ulcers 2

#### Vazalore has Better Acute GI Safety than Regular Aspirin



## Vazalore: Unleashing Aspirin's Full Potential

#### **Differentiated Marketing Claims**

- EFFICACY: 3-5 times greater chance of complete antiplatelet effect than EC aspirin
  - In head-to-head clinical trials with EC aspirin, Vazalore 325 mg provided faster acting, more reliable, predictable and sustainable antiplatelet efficacy than EC aspirin
- SAFETY: 65% lower risk of acute gastric ulceration than regular aspirin
  - EC aspirin is not in fact GI safer than regular aspirin

#### **FDA Approval**

- No aspirin product currently marketed as OTC has FDA NDA approval
- 325 mg dose approved via 505(b)(2) NDA
- 81 mg dose sNDA to be filed

#### **Addressing Significant Unmet Need**

 Market research: Most physicians interviewed have an interest in prescribing or recommending Vazalore for their high-risk patients



## Vazalore Market Opportunity: High Risk Patients

#### **Vazalore Initially Targets 4 Sizeable US Patient Populations**

4		Secondary Prevention Coronary Artery Disease	Secondary Prevention Stroke	Patients with Diabetes > 1 Risk Factor	High Risk Primary Prevention ≥ 2 or more Risk Factors
7	Addressable Patient Population	~17 million	~8 million	~7 million	~15 million
4	Total Retail Market Size	\$4.7 billion	\$2.2 billion	\$1.9 billion	\$4.1 billion

1% of this Market = ~\$125 Million Retail Revenue 5% Market Share within 5 years = ~\$625 Million in Retail Revenue

Note: CAD and Stroke assumes a 70% / 30% split between 81 mg and 325 mg while a 80% / 20% split between 81 mg and 325 mg assumed for Diabetes and Primary Prevention.



## Specialists & GPs Indicate High Intent to Prescribe Vazalore

Quantitative and Qualitative research positioned Vazalore in the top 5% of all HCP recommended or prescribed products WSM has tested in the past 20<sup>+</sup> years (over 200 tests).

	Cardiologists	Neurologists	Endocrinologists Diabetologists	GPs
Number of Physicians:	201	100	100	104
WOULD PRESCRIBE	81%	86%	80%	77%

Weinman Schnee Morais Inc.

Consumers (2,000 surveyed) were more likely to purchase specific OTC products when prescribed by a physician



#### How Doctors Would Prescribe Vazalore

	Aspirin Therapy Prescribers				
	Cardiologists	Neurologists	Endocrinologists Diabetologists	GPs	
Number of Physicians:	201	100	100	104	
Patients who have had a cardio-vascular incident/heart attack	83%	78%	87%	83%	
Patients who have had a cerebral incident/stroke	71%	88%	72%	76%	
Patients with high risk factors	69%	74%	76%	77%	
Patients with diabetes	60%	47%	71%	64%	
Patients with a family history that puts them at risk	49%	49%	57%	57%	
Patients who are overweight/large BMI/ obese	33%	35%	34%	39%	

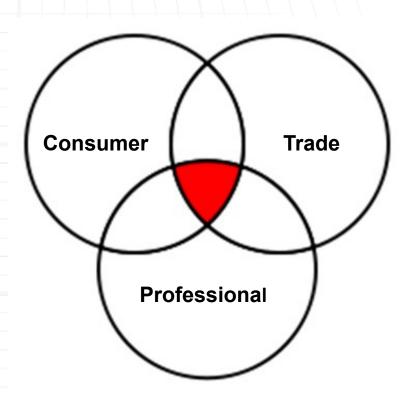


<sup>&</sup>lt;sup>1</sup> Weinman Schnee Morais Inc. (company data)

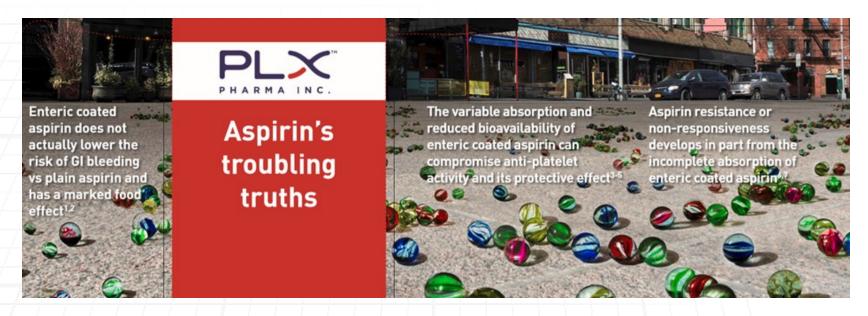
### **Brand Strategy**

#### Key Drivers

- Pre-commercial focus on Key Opinion Leaders/Professional Sales & Marketing
- Trade Sales & Marketing
- Consumer/PR
  - Drive awareness and trial via physician specialist coverage
  - Develop tools to facilitate "pharmacist intervention"
  - DTC media follows physician specialist coverage to establish the product



## Create Awareness Among HCPs: EC Aspirin's Unsettling Truth



- Condition the market (huge unmet need, patients at risk)
- Engage KOL base about current Aspirin limitations
- Transition awareness to the need for a new standard of care

References: 1. Antithrombotic Trialists' Collaboration. Collaborative meta-analysis of randomized trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. BMJ. 2002;324(7329): 71-86. 2. McQuaid KR, Laine L. Systematic review and meta-analysis of adverse events of low-dose aspirin and clopidogrel in randomized controlled trials. Am J Med. 2006;119(8):624-638. 3. FDA. US Code of Federal Regulations Title 21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=343.80. Accessed January 29, 2018. 4. Maree AO, Curtin RJ, Dooley M, et al. Platelet response to low-dose enteric-coated aspirin in patients with stable cardiovascular disease. J Am Coll Cardiol. 2005;47(7):1258-1263. 5. Cox D, Maree AO, Dooley M, et al. Effect of enteric coating on antiplatelet activity of low-dose aspirin in healthy volunteers. Stroke. 2006;37(8): 2153-2158. 6. Kelly JP, Kaufman DW, Jurgelon, et al. Risk of aspirin-associated major upper-gastrointestinal bleeding with enteric-coated or buffered product. Lancet. 1996;348(9039):1413-1416.



## Positioning Vazalore as the New Standard of Care

#### Clinical Data Support:

- Faster acting than enteric-coated aspirin
- Better antiplatelet efficacy than enteric-coated aspirin
- Better acute GI safety than regular aspirin

Potential to be bestin-class for high-risk CV patients

#### Market Segmentation:

- Vazalore targets most at risk (secondary prevention)
- PLx intends to evolve the standard of care by leveraging our clinical differentiation across the professional and consumer channels
- Market research suggests MDs indicate high intent to prescribe



## Pipeline Leverages PLxGuard Platform Technology PLxGuard Applicable to a Variety of APIs

Product Candidate	Туре	Size	Pre-Clinical	Phase 1	Phase 2	Phase 3
Vazalore Brand Extensions Chronic Pain & Other Vascular Indications*	ОТС	48MM High-Risk CVD Patients		325 mg Ap	proved	
PL1200 Ibuprofen, 200 mg* Pain, Inflammation and Fever	ОТС	25.3MM Suffer Daily Chronic Pain1				
Other NSAIDs e.g. Indomethacin**, Diclofenac**	OTC &	25.3MM Suffer Daily Chronic Pain <sub>1</sub>				
National Cancer Institute Grant PLx Formula in test with Colorectal Cancer Patients	OTC &	1.3MM Sufferers of Colorectal Cancer1				

In clinical (\*) and pre-clinical (\*\*) proof-of-concept studies, these product candidates demonstrated improved GI safety vs. the in-market drug

1. NIH - National Institutes of Health



## PLx Management Team

Name	Experience				
Michael (Mike) J. Valentino Executive Chairman of the Board	• 35+ years CEO and senior management with successful OTC and Rx brands • OTC brand, Mucinex® (~\$2.3 billion exit in 4.5 years)  Pharmacia & Upjohn  Pharmacia & Upjohn  NOVARTI				
Natasha Giordano President and CEO	• 20+ years CEO and senior management commercialization experience cegedim dendrite  Lipitor  Amodyne  Phormacouliculs, inc.  Lipitor  Amodyne  Phormacouliculs, inc.				
Rita M. O'Connor Chief Financial Officer	• 25+ years pharma and finance leadership at private & public companies  Schering-Plough				
Steven Valentino VP, Trade Sales	• 25+ years in OTC and consumer healthcare including Rx-to-OTC switches, brand management, trade sales    Officer   Officer				
Mike Dillon VP, Sales & Marketing	• Strong track record building high-performing specialty sales teams, launching/promoting blockbuster products				



### Independent Board of Directors & Advisors

Director	Experience
Gary S. Balkema	<ul> <li>Former global head of Bayer Healthcare LLC and Worldwide Consumer Care Division</li> <li>At Bayer USA, repositioned aspirin after ten year decline into a growing business</li> <li>Prior VP and General Manager for American Cyanamid Co.'s Lederle Consumer Health Division</li> </ul>
Kirk Calhoun	<ul> <li>Former audit committee chair, Adams Respiratory</li> <li>Former Partner, Ernst &amp; Young LLP</li> </ul>
Robert (Bob) Casale	<ul> <li>Former Adams Respiratory COO (Mucinex® launch, Adams' IPO and \$2.3 billion sale)</li> <li>Former senior manager at Pfizer, Warner Lambert and CEO of Scerene Healthcare</li> </ul>
John W. Hadden II	<ul> <li>Former CEO of IRX Therapeutics (private)</li> <li>Former healthcare investment banker at JP Morgan &amp; Co.</li> </ul>

#### **Scientific Advisory Board**



Deepak L. Bhatt, MD Professor of Medicine Harvard Medical School Boston, MA



Dominick Angiolillo, MD Department of Medicine Division of Cardiology University of Florida Jacksonville, FL



Gabriel Steg, MD
Professor of Cardiology at the Université
Paris - Diderot, Sorbonne-Paris Cité
Université Paris-Diderot, Sorbonne Paris
Cité
Paris, France



Todd Rosengart, MD
Professor and Chair, Department of Surgery
Baylor College of Medicine
Texas Heart Institute, Houston, TX



Byron Cryer, MD Gastroenterologist Professor of Medicine University of Texas Dallas, TX



Carey Kimmelstiel, MD
Director, Interventional Cardiology
Center; Associate Professor, Tufts
University School of Medicine
Tufts
Boston, MA



Jayne Prats, PhD Executive Consultant at ELYSIS-Med Scientific Solutions Elysis Boston, MA



Efthymios N. Deliargyris, MD, PLx Pharma Chief Medical Advisor



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**THANK YOU!**