

# SCIENCE ELEVATED BY INCENUITY

WHERE PASSION MEETS PURPOSE

**Corporate Presentation** 

CONFIDENTIAL

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 Exchange 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, management's 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 maintain regulatory approval of VAZALORE 325 mg or VAZALORE 81 mg and obtain regulatory approval for any future product candidates; (ii) the benefits of the use of VAZALORE; (iii) our ability to successfully further commercialize our VAZALORE products, or any future product candidates; (iv) the rate and degree of market acceptance of our VAZALORE products or any future product candidates; (v) our ability to successfully build and maintain a sales force and commercial infrastructure or collaborate with a firm that has these capabilities; (vi) our ability to compete with companies currently producing NSAIDs and other products; (vii) our reliance on third parties to conduct our clinical studies; (ix) 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.

Confidential





### PLx Pharma Management Team













CROSSMARK



Joanne Cotignola

Vice President

Marketing









Janet Barth

Vice President
IR & Corporate
Communications









Mayme Lou Roettig, RN, MSN Executive Medical Director









**Nicole Godino** 

National Sales Director, Professional











### OUR MISSION

PLx Pharma is focused on improving the performance of established therapeutic agents with its proprietary PLxGuard™ targeted drug delivery platform

We are driven to transform the standard of care for millions of patients





### PLx Pharma Investment Highlights

# Unique Drug Delivery Platform

#### PLxGuard for multiple APIs may have the potential to:

- Enhance delivery with optimized absorption, reducing risk of local stomach injury; extended patent life through 2032
- •Utilize the often faster and lower cost 505(b)(2) NDA regulatory path

# Commercial-Stage Lead Product VAZALORE®

#### VAZALORE, the first and only FDA-approved liquid-filled aspirin capsule:

- •Delivers fast, reliable absorption for pain relief plus the life-saving benefits of aspirin
- •Special complex inside the capsule allows for targeted release of aspirin, limiting its direct contact with the stomach

# **Large Addressable Market Opportunity**

#### \$10 billion retail market opportunity for VAZALORE:

- •Over 40 million patients at risk for vascular disease
- •Available in over 30,000 drug, grocery, mass retail and e-commerce sites in U.S.

# Financial Position & Key Catalysts

#### Positioned for growth:

- •\$69M in cash, sufficient to support VAZALORE into 2023; \$8.2 million of VAZALORE sales for the last 5 months of 2021
- •Identify screened compounds where PLxGuard is commercially viable 2022

Nasdaq: PLXP





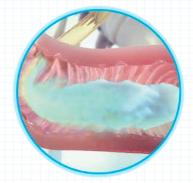
### PLxGuard™ - Innovative Drug Delivery Platform

The innovative PLxGuard drug delivery platform utilizes a pH-dependent release mechanism that relies on chemical association of lipidic excipients with APIs to selectively release them to targeted portions of the GI tract.



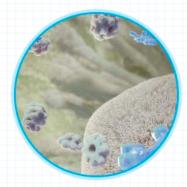
### LIMITS DIRECT CONTACT

This complex remains stable in the low pH of the stomach, limiting direct contact of the API with the gastric mucosa.



### TARGETED DELIVERY

Once the complex arrives in the duodenum, it dissociates in the higher-pH environment and the API is free to be absorbed.



### FAST, PREDICTABLE ABSORPTION

This drug delivery system is intended to predictably release the API in the duodenum to optimize absorption.



REASSEMBLES
DURING REFLUX

Even if reflux occurs and the API and lipidic excipients return to the stomach, they reassemble into the complex, limiting direct stomach contact, helping to reduce local GI injury.





### Lead Product Is FDA-approved VAZALORE®





First and only FDA-approved liquid-filled aspirin capsule for over 40 million patients at risk for another vascular event and for temporary pain relief and fever reduction with strong patent life

Fast and reliable platelet inhibition addressing the limitations of the current standard of care enteric-coated (EC) aspirin\*

**Fewer gastric erosions and ulcers** than immediate release (IR) aspirin as seen in a 7-day study of 325 mg

Large OTC opportunity with a \$10 billion retail market

World-renowned Scientific Advisory Board chaired by Drs. Deepak Bhatt & Dominick Angiolillo





## VAZALORE® Unique Aspirin Delivery System



Bioequivalence to immediate release aspirin with fast, predictable antiplatelet activity<sup>1</sup>



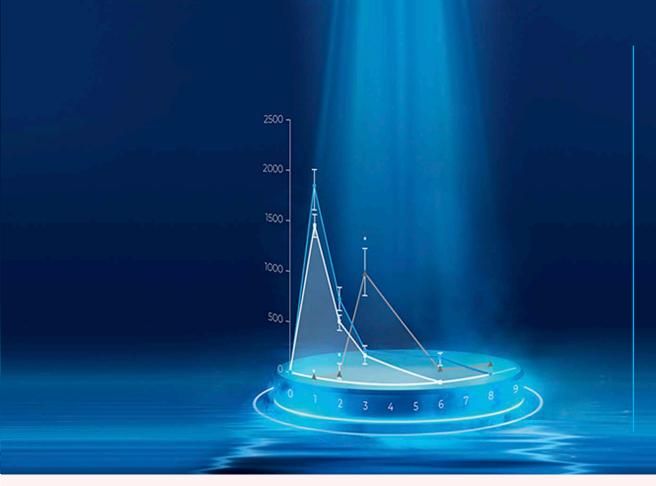
A unique, lipid-based delivery system designed to help protect the stomach



Targeted release in the duodenum to optimize absorption







## VAZALORE® CLINICAL TRIALS





# 325 mg Clinical Study—PK/PD Comparison: Plain Aspirin, VAZALORE<sup>®</sup>, Enteric Coated Aspirin<sup>1</sup>

In a single-center PK/PD study of antiplatelet activity over 3 days, in obese patients with type 2 diabetes<sup>1</sup>

#### **Objectives:**

 Determine whether formulation dependent bioavailability mediates aspirin nonresponsiveness

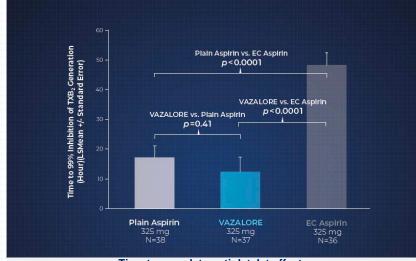
#### **Methods:**

- Randomized, blinded, triple crossover study of 40 obese patients with type 2 diabetes receiving three daily doses of:
  - Plain aspirin 325 mg
  - VAZALORE 325 mg
  - EC aspirin 325 mg

#### **Primary Endpoint:**

• Time to >99% Thromboxane B<sub>2</sub> (TXB<sub>2</sub>) inhibition

This study design cannot provide data on cardiovascular outcomes.



Time to complete antiplatelet effect:

Plain Aspirin 16.7h VAZALORE 12.5h EC aspirin 48.2h

Plain Aspirin= Immediate Release Aspirin Tablets Figure adapted with permission from Elsevier

VAZALORE 325 mg achieved 99% TXB<sub>2</sub> inhibition significantly faster (12.5 hours) than EC aspirin 325 mg (48.2 hours) (p<0.0001)<sup>1</sup>

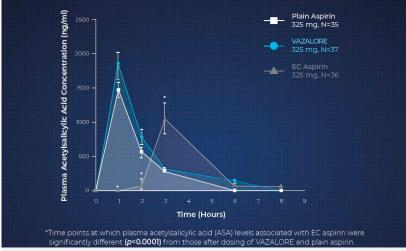






# 325 mg Clinical Study—PK/PD Comparison: Plain Aspirin, VAZALORE®, Enteric Coated Aspirin¹ (cont.)

In a single-center PK/PD study of antiplatelet activity over 3 days, in obese patients with type 2 diabetes<sup>1</sup>

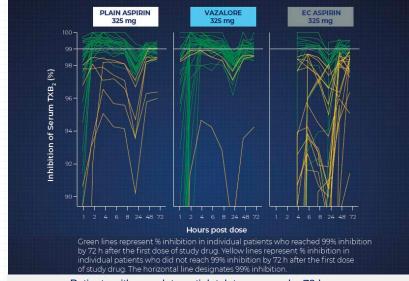


Acetylsalicylic acid AUC (ng x hr/ml):

Plain Aspirin 1964 VAZALORE 2523 EC Aspirin 456

Plain Aspirin= Immediate Release Aspirin Tablets Figure adapted with permission from Elsevier

Absorption with VAZALORE 325 mg was 5X as high as that of EC aspirin 325 mg (p<0.0001)<sup>1</sup>



Patients with complete antiplatelet response by 72 hours:

Plain aspirin 84% VAZALORE 92% EC aspirin 47%

Plain Aspirin= Immediate Release Aspirin Tablets Figure adapted with permission from Elsevier

By 72 hours, VAZALORE 325 mg provided complete antiplatelet effect (≥99% inhibition of TXB<sub>2</sub> generation) for almost twice as many patients as EC aspirin 325 mg<sup>1</sup>

This study design cannot provide data on cardiovascular outcomes.





# 325 mg Clinical Study — Upper GI Injury: Plain Aspirin vs VAZALORE®1

In an active-controlled study of upper GI damage of aspirin in healthy subjects in a 7-day study of oral 325 mg once daily<sup>1</sup>

#### **Objectives:**

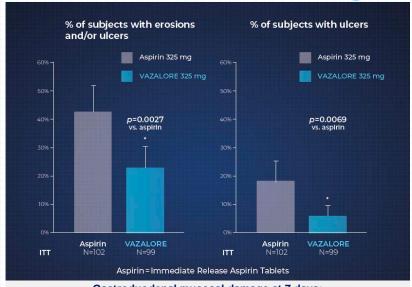
 Determine whether a novel, lipid-based aspirin formulation can reduce gastric erosions and ulcers

#### **Methods:**

- Randomized, blinded, multi-center study in 204 healthy volunteers:
  - 7 days of either aspirin or VAZALORE 325 mg
  - Endoscopy performed at Baseline and Day 7
  - Centralized, blinded endoscopic adjudication

#### **Primary Endpoint:**

• Incidence of gastroduodenal erosions or ulcers at 7 days



Gastroduodenal mucosal damage at 7 days:

(a) % of subjects with erosions and/or ulcers (b) % of subjects with ulcers

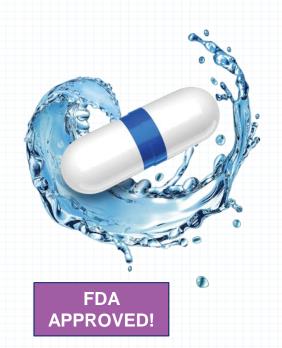
VAZALORE caused significantly fewer erosions and ulcers than IR aspirin 325 mg after 7 days of therapy<sup>1</sup>

47% lower risk of erosions or ulcers (NNT=5) 71% lower risk of ulcers (NNT=8)





# VAZALORE® 325 mg Clinical Summary



VAZALORE achieved 99% thromboxane B<sub>2</sub> inhibition significantly faster than enteric coated aspirin\*

Absorption with VAZALORE was **5X as high** as enteric coated aspirin\*

VAZALORE provided complete antiplatelet effect (99% TXB<sub>2</sub>) for **almost twice** as many patients as enteric coated aspirin\*

VAZALORE caused significantly **fewer erosions and ulcers** than immediate release aspirin as seen in a 7-day study of 325 mg in healthy subjects





## **VAZALORE®** Commercial Strategy

Healthcare Professionals (HCPs)
Top Heart/Stroke Hospitals & Affiliated
Clinical Practices





Consumers
#1 influencer is their Cardiologist/HCP
#2 influencer is BRAND familiarity

Retailers
Extensive distribution in over
30,000 retail stores

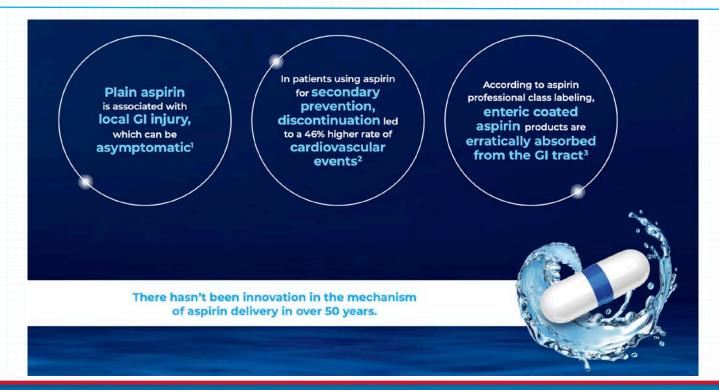








### Opportunity for Innovation in Aspirin Delivery









### Cornerstone for Healthcare Professional Plan

- Dedicated cardiovascular care specialist field force
  - Clinical Cardiologists | Top Heart & Stroke Hospitals
- World-Class Scientific Advisory Board
  - Trials | Publications | Education | Influencers
- Thought leader focus
  - Cardiovascular | Stroke | Peripheral Arterial Disease
- Medical conferences and education
  - CME Programming | Scientific Sessions | Expert Panels

Our Core Belief:

Central to everything we do is the patient!







### Scientific Advisory Board



Deepak L. Bhatt, MD, MPH, FACC, FAHA, FSCAI, FESC



Dominick J. Angiolillo, MD, PhD, FACC, FESC, FSCAI



P. Gabriel Steg, MD, FESC, FACC



Roxana Mehran, MD, FACC, FACP, FCCP, FESC, FAHA, FSCAI



Byron Cryer, MD



James M. Scheiman, MD



Mark J. Alberts, MD



Jayne Prats, PhD



Efthymios Deliargyris, MD, FACC, FESC, FSCAI



Carey Kimmelstiel, MD, FACC, FACP, FSCAI



Todd K. Rosengart, MD







### Support Pieces Keep VAZALORE® Top of Mind









325 mg Clinical Data

Professional Labeling Publications

Features and Benefits

Samples

4 Department Capacies SAMPLE ONLY NOT FOR SALE





## VAZALORE® U.S. Market Opportunity

	Vascular Patients	Diabetic Patients	TOTAL
Target Population <sup>1</sup> (millions)	27.2	15.6	42.8
Retail Market Size (billions)	\$6.4	\$3.6	\$10.0



Market Share	Factory (millions)	Retail (millions)
1%	\$70	\$100
5%	\$350	\$500
10%	\$700	\$1,000

- Vascular Patients: Patients with Atherosclerotic Cardiovascular Disease (ASCVD) defined by having a previous event such as heart attack or stroke or a previous procedure such as cardiac stent, bypass operation, carotid operation or who have imaging evidence of significant vascular disease such as ultrasound, angiogram, etc.
- Diabetic Patients: Patients with diabetes but without evidence of ASCVD who are candidates for aspirin therapy.
- Pricing around \$0.80/day to the patient, around \$25/month.







### Conversation Between HCP & Consumer

#### The VAZALORE consumer:

Most influenced by doctor and brand familiarity

- Concerned about impact of aspirin on one's stomach
- Fearful of having another event

#### Reaching the consumer:

 Generate awareness of VAZALORE as breakthrough delivery designed to help protect the stomach

 Drive trial, motivate consumers to ask doctor about VAZALORE









### Consumer Messaging











## Content for Digital/E-commerce Efforts













### **VAZALORE®** Support

### Driving Breakthrough Creative Through Strong Television Plan

#### National plan supports distribution

- Base Cable with enhanced Prime Time, Sports
- Focus on maximizing reach to build business









#### "Pinball" creative celebrates VAZALORE innovation

 The campaign visually brings to life the unique delivery mechanism of VAZALORE using a pinball machine metaphor to convey the innovative technology of a liquid-filled aspirin capsule, and the lifesaving benefits of aspirin.















### Where to Buy VAZALORE®



Available in over 30,000 retail stores & e-commerce sites in US

























### Retailer Merchandising & Education Tools

Set the Shelf





**Coming Soon Shelf Placeholders** 

**Shelf Trays** 

Create In-Store Visibility



**Displays** 

HCP Education that Drives Store Traffic





Retail Pharmacy Education Kits

Doctor Detailing Patient Education Pieces

Ready to Sell



**Open stock units** 





# VAZALORE® On-Shelf & Displays







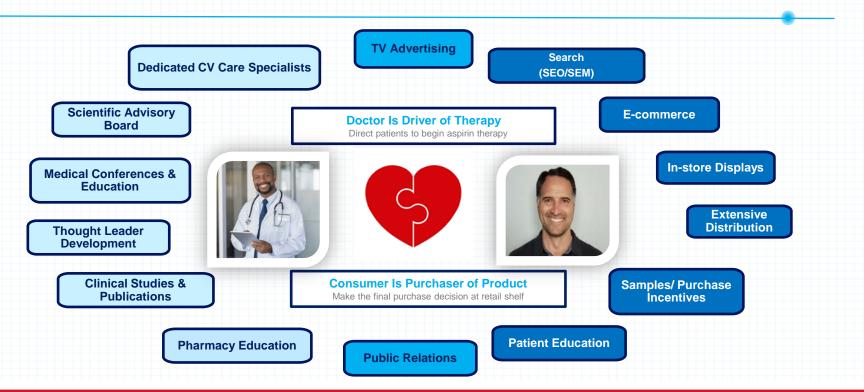








### VAZALORE® Commercial Plan Focused on HCPs, Consumer and Retail







### VAZALORE® Revenue & Manufacturing



- Revenue recognized when the product is received by the retailer; \$8.2 million recognized in the last 5 months of 2021
- Reductions to gross revenue include provisions for retailer programs, product returns, prompt pay discounts and coupon redemptions by consumers
- retail stores across the U.S., many stocking all 3 SKUs as well as displays elsewhere in the store
- Product manufactured by Thermo Fisher Scientific in the U.S.





### Financial Overview as of 12/31/21

\$69.4 million

\$8.2 million

27.5 million common shares
(44.1 million fully diluted)

Cash & Cash Equivalents (Debt free)

Net Sales VAZALORE FY2021

(Last 5 months)

Common Shares
Outstanding





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Nasdaq: PLXP





#### Follow Us

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#### • VAZALORE®

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- Phone: 1-888-842-3567

#### • PLxGuard<sup>™</sup> Drug Delivery Platform

www.plxpharma.com/our-technology/









