Filed Pursuant to Rule 433 of the Securities Act of 1933
Issuer Free Writing Prospectus dated July 29, 2016
Relating to Preliminary Prospectus dated July 28, 2016
Registration No. 333-212511

AZURRX BIOPHARMA, INC.

FREE WRITING PROSPECTUS

This free writing prospectus relates only to, and should be read together with, the preliminary prospectus dated July 28, 2016 (the "Preliminary Prospectus") included in Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-212511) (the "Registration Statement") relating to the initial public offering of common stock of AzurRx BioPharma, Inc. (the "Company").

On July 28, 2016, we filed Amendment No. 1 to the Registration Statement, which may be accessed through the following link: https://www.sec.gov/Archives/edgar/data/1604191/000141588916006616/azurrxs1a_july2016.htm

The information in this free writing prospectus is preliminary and is subject to completion or change. This free writing prospectus is only a summary of the changes to the Preliminary Prospectus and should be read together with the Preliminary Prospectus included in the Registration Statement, including the section entitled "Risk Factors" beginning on page 6 of the Preliminary Prospectus. Capitalized terms used, but not defined, herein have the meanings set forth in the Preliminary Prospectus. The following information updates and supersedes the information contained in the Preliminary Prospectus to the extent that such information is inconsistent therewith.

AzurRx BioPharma, Inc. has filed a registration statement, including the preliminary prospectus, with the Securities and Exchange Commission (the "SEC") for the offering to which this communication relates. Before you invest, you should read the preliminary prospectus in that registration statement and other documents we have filed with the SEC for more complete information about us and this offering. You may obtain these documents for free by visiting EDGAR on the SEC's website at www.sec.gov. Alternatively, you may obtain copies of the preliminary prospectus by contacting WallachBeth Capital, LLC, Attention: Capital Markets, 100 Wall Street, Suite 6600, New York, NY 10005, by telephone at 646-998-7605, or by email at cap-mkts@wallachbeth.com, or Network 1 Financial Securities, Inc., Attention: Keith Testaverde, by telephone at 800-886-7007or by mail at 2 Bridge Avenue, Suite 241, Redbank, NJ 07701.

September 2016

CORPORATE PRESENTATION

Company Disclaimer

Certain statements in this presentation constitute "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Any statements that refer to expectations or other characterizations of future events, circumstances or results are forward-looking statements. Such forward-looking statements include projections. Such projections were not prepared in accordance with public guidelines of the American Institute of Certified Public Accountants regarding projections and forecasts, nor have such projections been audited, examined or otherwise reviewed by independent auditors of the company. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements.

The views expressed are those of management and are based on currently available information. Estimates and projections contained herein have been prepared by management and involve significant elements of subjective judgment and analysis and are based on certain assumptions. No representation nor warranty, expressed or implied, is made as to the accuracy or completeness of the information contained in this document, and nothing contained herein is, or shall be relied upon, as a promise or representation, whether as to the past or the future. The projections are not intended to follow generally accepted accounting principles. Neither our accountants nor our legal counsel have compiled, audited, prepared, or contributed to the projections or the underlying assumptions. None of these parties express an opinion with respect to the projections.

You are cautioned not to place undue reliance on these forward-looking statements. Except for ongoing obligations of the company to disclose material information under the federal securities laws, the company does not undertake any obligation to release any revisions to any forward-looking statements, to report events or to report the occurrence of unanticipated events.

AzurRx BioPharma – Company description

The non-systemic therapy company focused on improving patient health in rare and infectious diseases.

Large Markets	▪ $820 MM lipase market ▪ $2B microbiome market
Strong Team	▪ Experienced US healthcare executives ▪ Strong scientific team in France
Efficient Cash	▪ 30% of lipase clinical spend reimbursed by European partner ▪ ~50% of R&D spend rebated by French government

AzurRx BioPharma Overview

- **Formed in 2008 as a developer of therapeutic protein biologics**
- **Two active biopharmaceutical development programs:**

1. ***MS1819 lipase, Phase I/IIa***
   - Non systemic, yeast derived recombinant enzyme for treatment of exocrine pancreatic insufficiency (EPI) in patients with chronic pancreatitis (CP) and cystic fibrosis (CF)
   - Large, immediately addressable EPI market ($820M in U.S., $1.5B global)
2. ***AZX1101 beta lactamases, preclinical***
   - For prevention of nosocomial (hospital acquired) bacterial infection
   - Addresses a $4.5-$11 billion medical issue

- **Experienced Management and Scientific Team**
  - Management team with 60+ years experience in healthcare at Fortune 50 companies and start-ups
  - Core scientific team with deep experience covering Hepato-Gastroenterology expertise, clinical practice, basic scientific research and translational medicine, pharmaceutical R&D and university board leadership

- **Capitalization Plan**
  - $23M invested to date
  - 2H16: IPO target $12M

→ To fund completion of MS1819 Phase 2b lipase clinical trial and IND for AZX1101 beta-lactamase

GI Therapeutic Product Pipeline

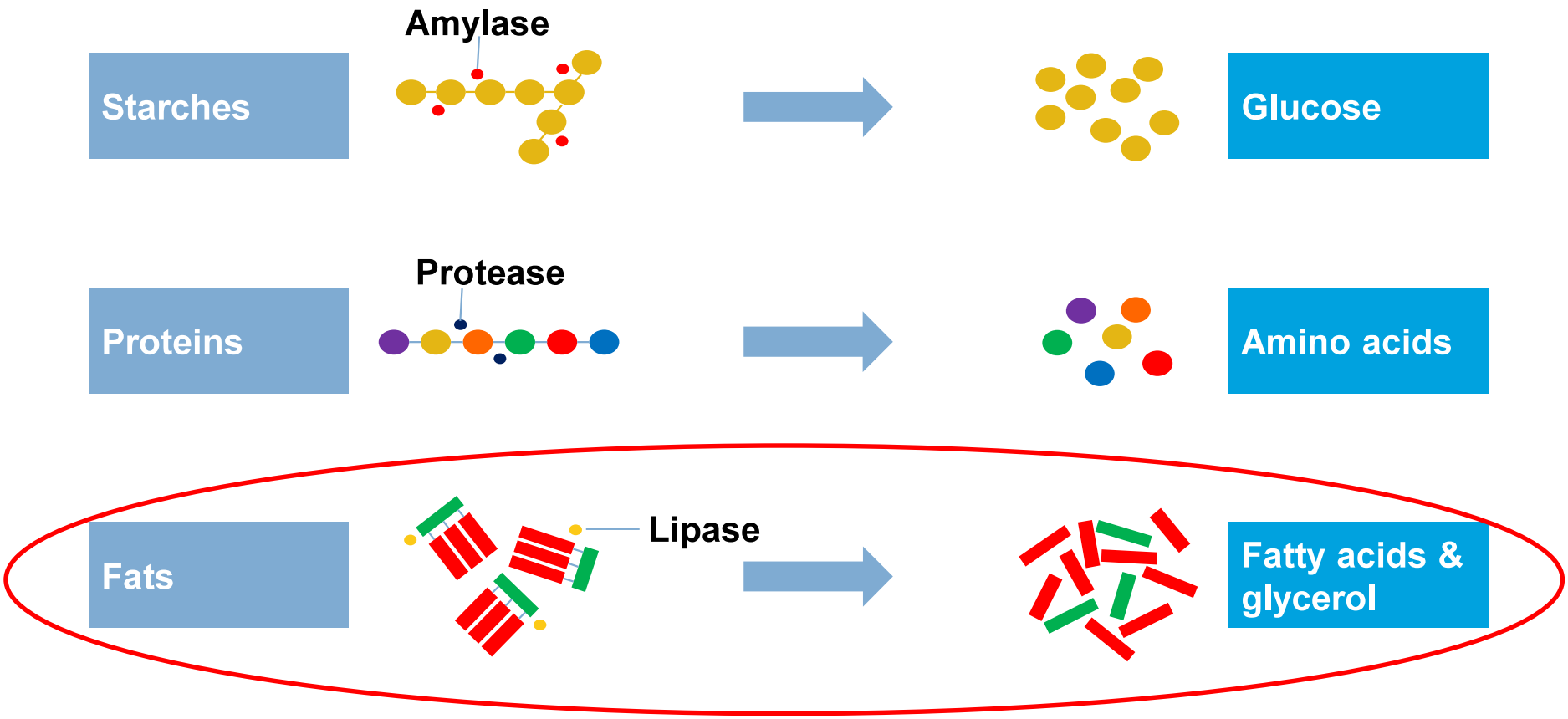
Product	Description	Indication	Development Phase					Anticipated Year to Market
			Discovery	Pre-Clinical	Phase I	Phase II	Phase III	
MS1819*	Yeast recombinant lipase (*Yarrowia lipolytica* LIP2)	Treatment of EPI in CP patients						2020
		Treatment of EPI in CF patients						2020
AZ1101	Synthetic β-Lactamase	Prevention of nosocomial infections and antibiotic associated diarrhea						2021

Expected progress through 2017

Current Status

Food Digestion Needs Enzymes, Fat Needs a Lipase

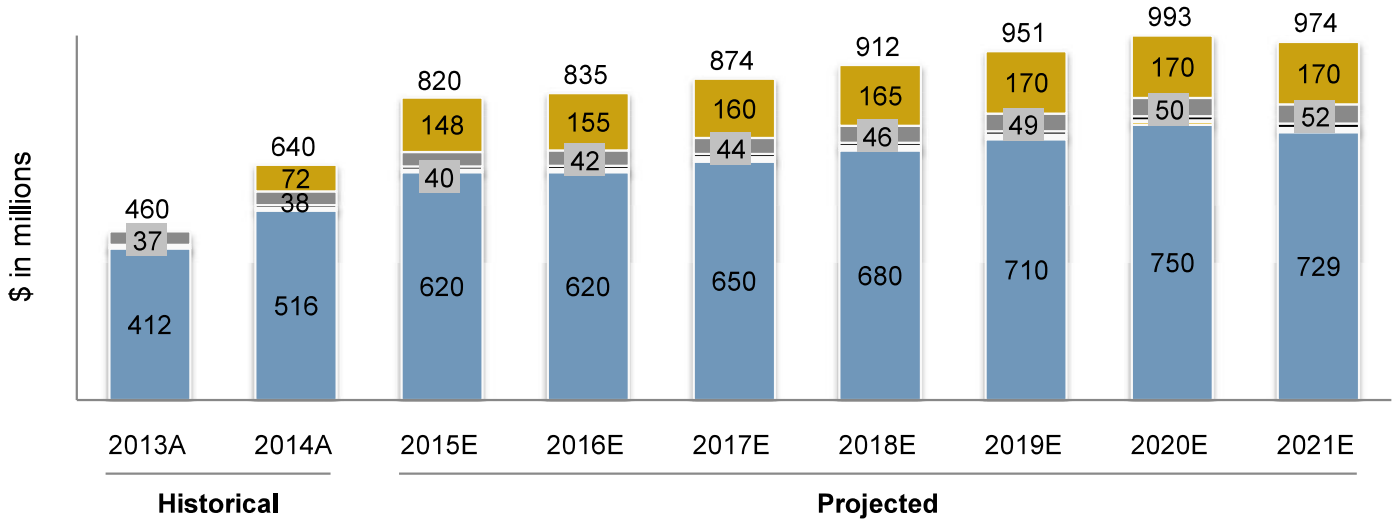
Amylases and proteases in saliva and stomach compensate in pancreatic insufficiency but no backup exists for fat digestion



- **In patients where the pancreas doesn't function, oral supplements (including porcine pancreas) must be taken to allow for fat digestion**

Large Established US Market Of $820m Growing To $1B

All lipase products are pig derived and suffer from lack of efficacy and pill burden



Growth, %									
Creon (Abbvie)[1]		25.2%	22.5%	7.3%	4.8%	4.6%	4.4%	5.6%	5.6%
Zenpep (Aptalis)[1]		-	105.4%	5.1%	3.2%	3.1%	3.0%	-	-
Pancreaze (J&J)[2]		4.0%	5.0%	5.0%	5.0%	5.0%	5.0%	3.0%	3.0%

(1) 2015E-2021E based on median or equity research projections; 2021E based on 2020E growth

(2) Equity research projections unavailable; 2013A and 2014A based on a discount of 25% to IMS data; 2015E based on compressing growth from 2014E growth.

Clear Unmet Medical Need

Current EPI Treatment Limitations

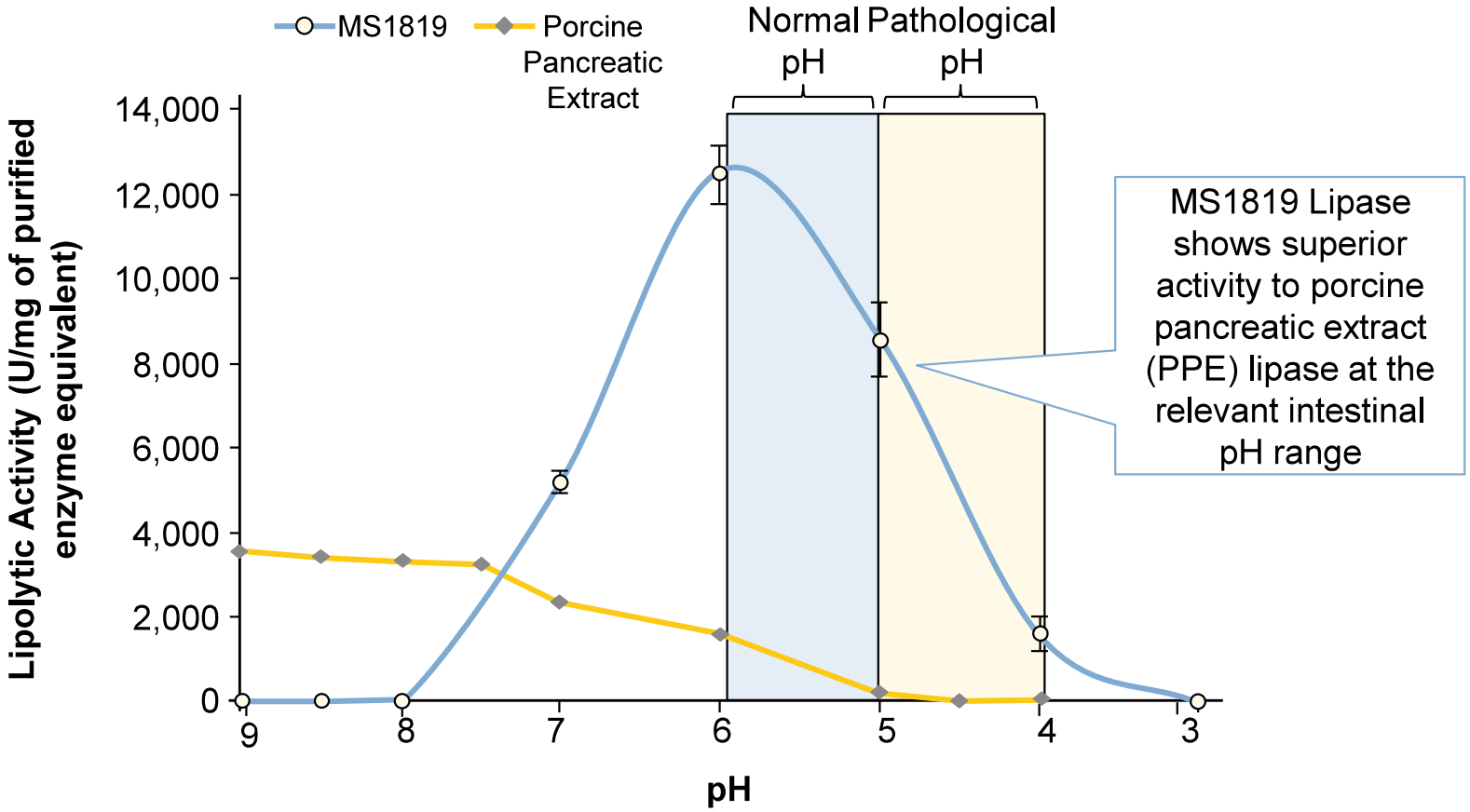
- Limited effectiveness
- Lack of stability in acidic environment
- High pill burden
  - Inconvenient for patients
  - Non-adherence
- Sourcing and supply of porcine derived pancrelipase (PPEs):
  - Subject to pig herd management
  - Risk of transmission of pathogens
  - Inconsistency of manufacturing/supply chain
- Adverse Event: fibrosing colonopathy

Opportunity
- Ability to reduce patient daily pill burden of ~25 capsules down to ~4

Daily Dose Standard of Care vs. Expected Daily Dose MS 1819

In-Vitro Activity of MS1819 at pH Range

***In vitro* lipolytic activity of the MS1819 lipase in presence bile salts in the European and US Pharmacopeia test (U/mg, Pure Enzyme)**



Note: In normal subjects, physiological pH in duodenum is between approximately 5 and 6. In CP and CF pH is lowered to a more acidic range, approximately pH 4 to 5. MS1819 not inactivated by bile salts.

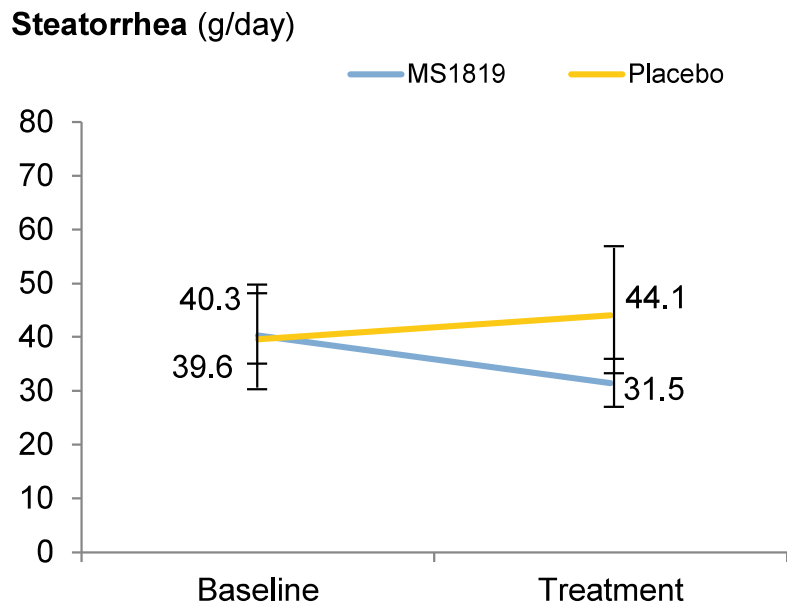
Research to Date Demonstrates Safety and Supports Efficacy

	Efficacy	Safety/Toxicity
***In vitro* – Test meal assays**	▪ Tested both by classical biochemistry assays and test-meal ▪ Conditions tested for **MS1819 in comparison to PPEs and recombinant pancreatic lipases** (pH range, length of fatty acid chains, activity in presence of bile salts, resistance to proteolysis by pepsin) ▪ In test meal assay, MS1819 specific **enzymatic activity is 133x and 224x** more active than commercial PPEs at pH4 and 6	▪ Not applicable
***In vivo* – Minipig Model**	▪ *In vivo* minipig EPI model demonstrated **efficacy comparable to PPE** - MS1819 10.5mg to 211mg showed +24% to +29% CFA; 2.5 mg milder at +15% - Similar efficacy to 100,000 U PPE - Minipig baseline CFA of 60%	▪ Absence of mutagenic potential ▪ No toxicity up to 1000mg/kg/day in rats and 250 mg/kg/day in minipigs over 3 months ▪ IgG against MS1819 can be detected in some animals (rats and minipigs) following exposure of MS1819 without detectable immunotoxicity
Flip 110 Phase Ib Clinical Study	▪ Exploratory, randomized, double-blind, placebo controlled, parallel clinical trial in 12 patients with CP or pancreatectomy and severe EPI (historical steatorrhea ≥ 7g/24h), n = 12 ▪ MS1819 treatment effect **demonstrated for the primary endpoint**, steatorrhea ▪ **Secondary endpoints also supported** the efficacy (i.e. coefficient of fat absorption (CFA), number of stools over 7 days, stool weight, Bristol scale	▪ **No significant adverse events** or SUSAR (Suspected Unexpected Serious Adverse Reactions) ▪ Possible tolerance signals of constipation, hypoglycemia (doubtful) ▪ No rise in IgG anti-MS1819 ▪ No detection of MS1819 lipase

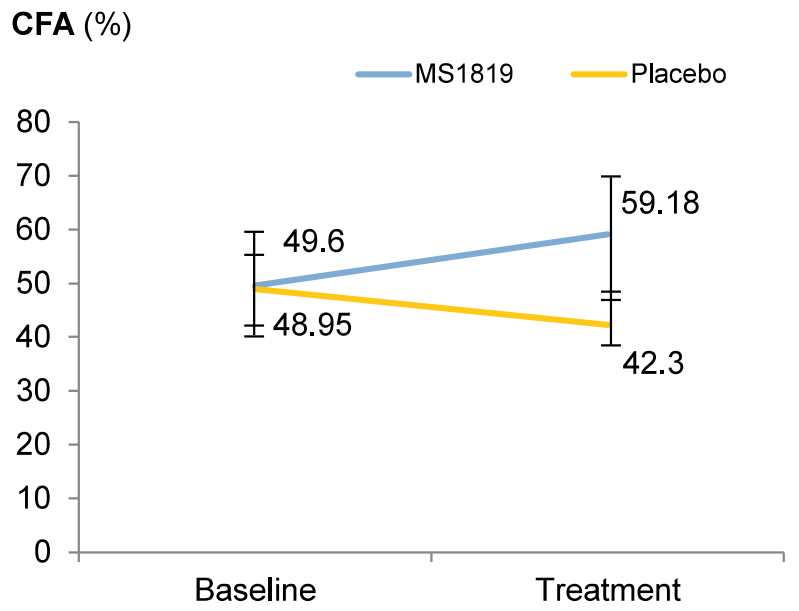
FLIP110 Study Per Protocol Efficacy Results*

MS1819 demonstrates improvement on key efficacy parameters

Steatorrhea, Per Protocol (absolute difference 12.6%)



Coefficient of Fat Absorption (CFA), Per Protocol (absolute difference 16.2%)**



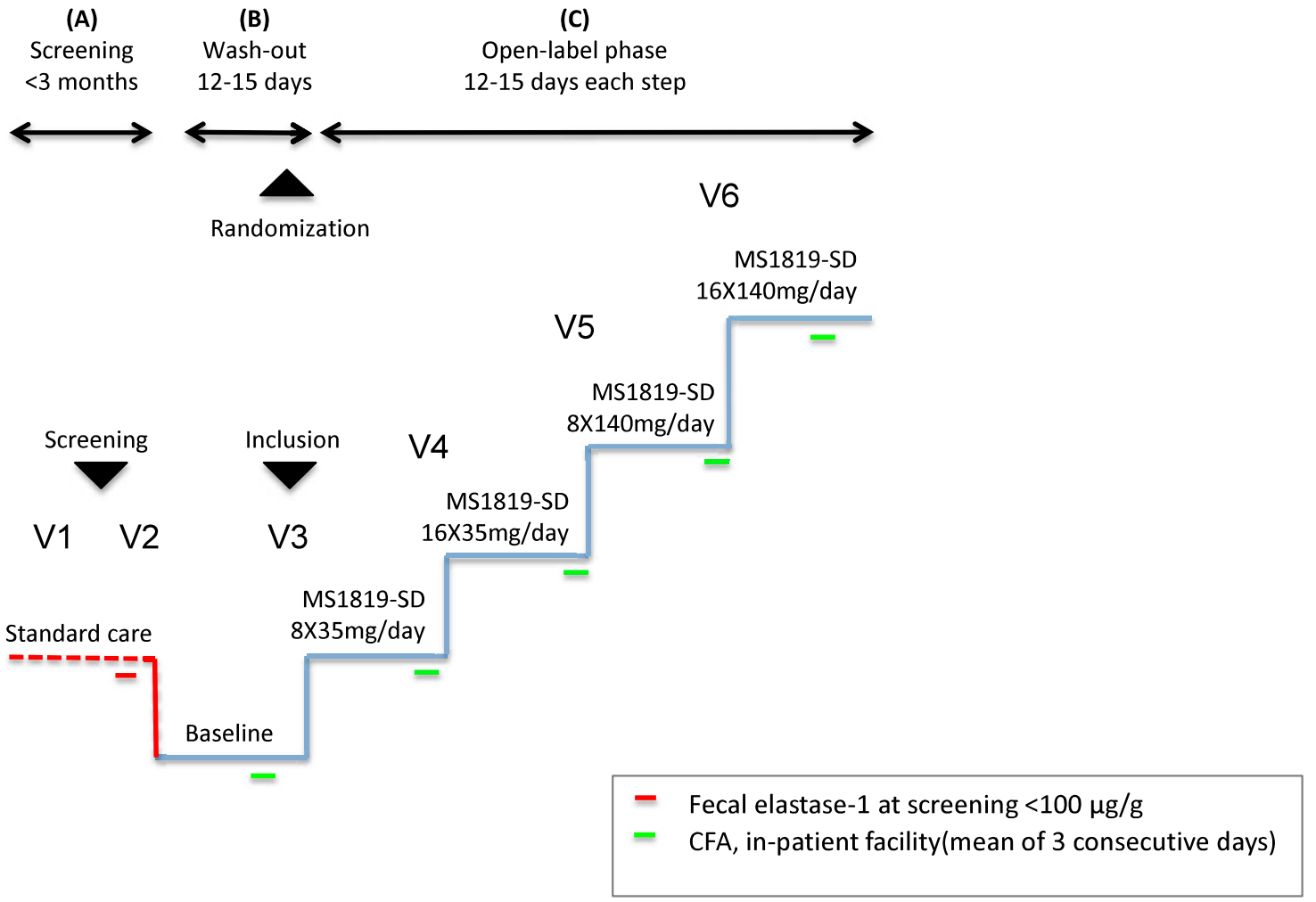
- Pilot, proof of concept study; main objective of safety with exploration of efficacy.
- Results obtained on the 2 main efficacy criteria (steatorrhea and CFA) pointed out a positive effect of MS1819 compared to a negative effect of the placebo.
- Phase IIb study aims to evaluate more patients, with demonstrated increased baseline steatorrhea and lower baseline CFA and escalation to higher doses of MS1819.

* Study not powered for statistical significance

** CFA = coefficient of fat absorption, a measure of dietary fat digestion

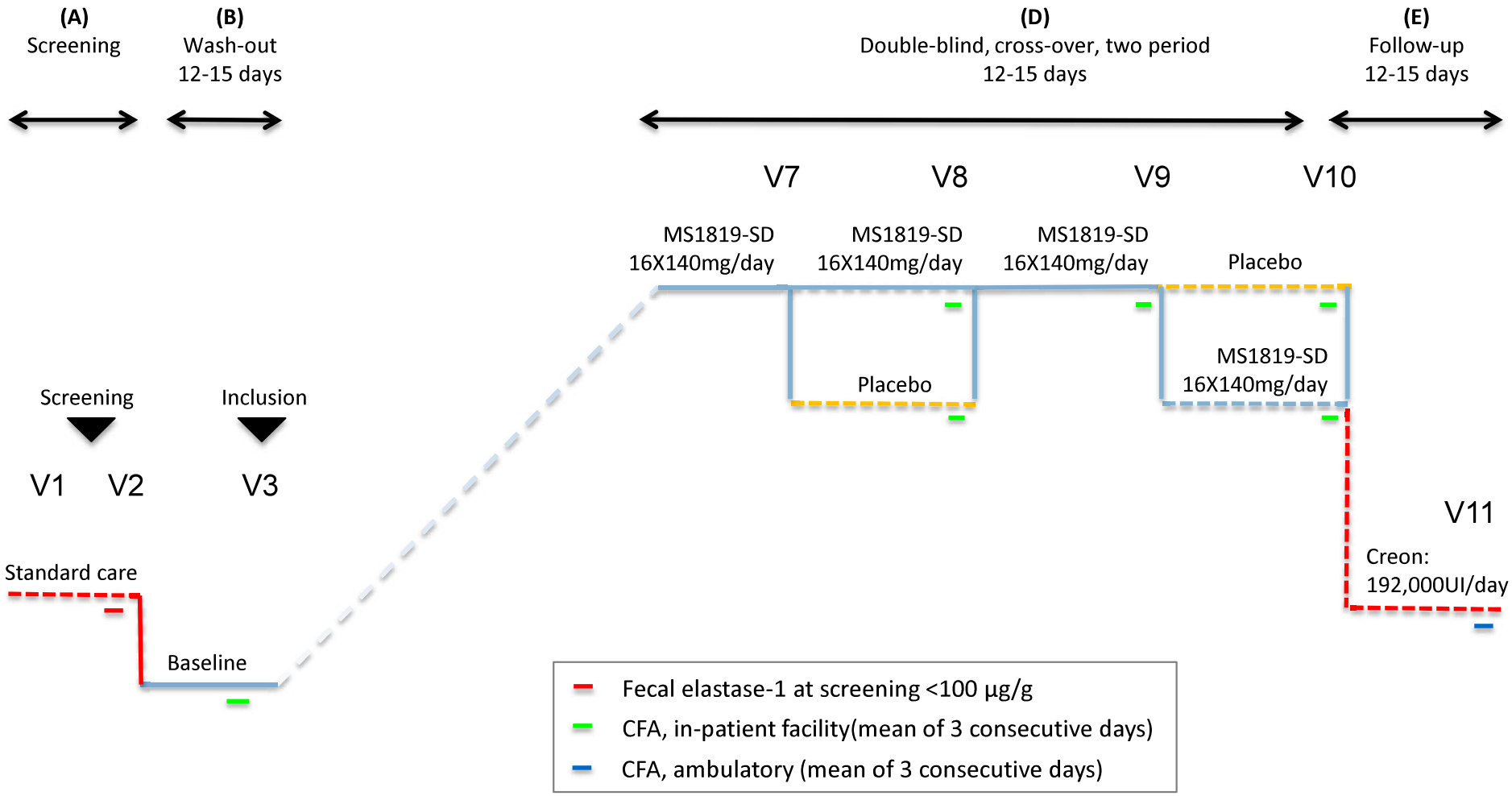
Phase IIa clinical trial in Chronic Pancreatitis

Trial is expected to start 2H2016 in Australia and New Zealand with 12-15 patients



Phase IIb clinical trial in Chronic Pancreatitis

initiation expected 1H2017 in the US, Australia and New Zealand with 30-60 patients



Intellectual Property

Patents relative to the MS1819 program

	PCT/FR1999/002079 family	PCT/FR2000/001148 family	PCT/FR2006/001352 family
Title	Method for non-homologous transformation of *Yarrowia lipolytica*[1]	Cloning and expressing an acid-resistant extracellular lipase of Yarrowia lipolytica[2]	Method for producing lipase, trans-formed *Yarrowia lipolytica* cell capable of producing said lipase and their uses[3]
Applicant	INRA, CNRS	LMS	LMS
Inventors	NICAUD, Jean-Marc GAILLARDIN, Claude PIGNEDE, Georges	SEMAN, Michel PIGNEDE, Georges FUDALEJ, Franck NICAUD, Jean-Marc GAILLARDIN, Claude	LEBLOND, Yves MOUZ, Nicolas
Abstract	The invention concerns the integration of a gene of interest into the genome of a *Yarrowia* strain devoid of zeta sequences, by transforming said strain using a vector bearing zeta sequences	The invention concerns nucleic acids coding for acid-resistant extracellular lipases, in particular C. ernobii or *Yarrowia lipolytica* yeasts and the production of said lipases in recombinant form	Method for producing *Yarrowia lipolytica* acid-resistant recombinant lipase utilizing a culture medium without any products of animal origin or non-characterized mixtures such as tryptone, peptone or lactoserum, in addition to its uses
Priority date	01.09.1998 (FR98/10900)	28.04.2000 (FR00/01148)	15.06.2006 (F026900039)

MS1819 will be covered by granted patents up to June 15th, 2026. In addition, an extension up to five years might be granted by the FDA, resulting in possible end of the protection on June 15th, 2031 and the Affordable Care Act provides for 12 years of exclusivity for novel biologics from first approval through 2032

Freedom to operate: no blocking patents have been identified so far, resulting in a complete freedom-to-operate (FTO) for the MS1819 program

Competition to date

Approved and marketed – Only PPEs[1] – A mix of lipase, protease and amylase	a. CREON®, Abbott b. ZENPEP®, VIOKASE® and ULTRESA®, Aptalis Pharma c. PANCREAZE®, Johnson and Johnson d. PERTZYE®, Digestive Care Inc.
Recombinant products under development for EPI	a. SOLPURA® aka Liprotamase®, Alnara/Eli Lilly (cross-linked bacterial lipase, protease and amylase) b. NM-BL burlulipase, Nordmark Pharma (bacterial lipase)
Terminated recombinant products for EPI	a. Dog recombinant lipase, rGL, Meristem b. Recombinant Microbial Lipase, SLV-339, Solvay Pharmaceuticals c. Human bile-salt stimulated lipase (rhBSSL), Biovitrum AB-for neonates

1 All PPE's must go through NDA approval since 4/28/2004 announcement by FDA

EPI Primary Market Research

Support for MS1819 from Physicians and Payers

87% of all diagnosed EPI patients are treated with pancreatic enzyme replacement therapy

Reducing pill burden, increasing pH stability, and providing a porcine alternative PERT is seen as a significant opportunity in meeting current unmet needs

Potential for MS1819 to capture 57% of newly diagnosed EPI patients; however there is likely limited switching opportunity for currently treated patients

Payers do not activity manage costs across PERTs, but while they have a positive view of MS1819 and do not feel that there is a pricing opportunity relative to the market leader

Source: Results of 10 gastroenterologist and 5 payer interviews conducted by an outside research firm in 8/2014

Use of Proceeds

Proceeds from the IPO are expected to fund operations for 12-18 months through several clinical milestones

$12 million
$7,500,000 to continue clinical development and testing of MS1819
$1,500,000 to advance our preclinical AZX1101 program;
$356,000 to repay convertible debt not converted in the IPO
Working Capital and General Corporate Purposes

Projected Milestones
Initiation of MS1819 dose escalation trial 2H 2016
-First patient enrolled dose escalation trial 3Q2016
-All patients enrolled dose escalation trial 4Q2016
-Open label results released as practical
Initiation of MS1819 placebo cross over study 1H2017
IND preparation for AZX1101

AzurRx clinical trial spend receives ~30% rebate from the French government

Management Team

Thijs Spoor, CEO
Mr. Spoor was the Chairman and Chief Executive Officer of FluoroPharma Medical, Inc. He was an equity research analyst at J.P. Morgan and Credit Suisse and previously worked at GE Healthcare and Amersham. Mr. Spoor holds a Nuclear Pharmacy degree from the University of Toronto as well as an M.B.A. from Columbia University.

Daniel Dupret, Chief Scientific Officer
Dr. Dupret founded Proteus SA in 1998 and served as President and CEO from 1998 to 2007. He founded Appligene SA in 1985 and served as CSO then President and CEO until 1998. From 1982 to 1985, he served as Project Leader at Transgene SA. From 2003 to 2007, he served as President of the Board of the University of Nîmes.

Philippe Jais, Director of Medical Research and Translational Medicine
Dr. Jais has 15+ years' experience in clinical development, translational medicine and hepato-gastroenterology working at LFB Biotechnology, Hoffmann-LaRoche, Solvay Pharma and Genset SA. He received his PhD in Human Molecular Genetics at University Paris VII and served as Assistant in Molecular Biology at Bichat Hospital (Paris, France). Philippe has co-founded two Biotech companies, Chiasma Laboratories in 2004, and Eukarÿs SAS in 2010.

Yves Leblond, Director Research and Development
Dr. Leblond has more than 25 years' experience in multi-national pharmaceutical companies. From 2002 to 2009, he was the R&D director for LMS Laboratories, prior experience includes head of the non-clinical drug safety for the Fournier Group, Synthelabo Group and Boerhinger Laboratories. He received his PhD. from University Paris XI.

Luc Lebreton, R&D Programs Director
Dr. Lebreton previously worked as R&D Programs Director at Eyevensys from 2013-2015. He served as Therapeutic Area Leader in occular diseeases at Abbott (formerly Solvay Pharmaceuticals) from 2007-2013 and held several roles at Laboratoires from 2001-2007. Dr. Lebreton received his PhD in pharmaco-chemistry at the University of Paris VII.

Matieu Schue, Head of Laboratory
Dr. Schué graduated as a chemical engineer at "Ecole Nationale Supérieure de Chimie de Montpellier" (ENSCM), and received his Ph.D. in molecular microbiology at the University of Birmingham in the UK with post-doc experience in recombinant protein expression and purification and enzymology

Board of Directors

Ed Borkowski, Chairman
Mr. Borkowski served as the Chief Financial Officer of ConvaTec Healthcare, CareFusion Corporation and Mylan, Inc. and in a variety of finance positions at Pharmacia, American Home Products, Cyanamid and at Arthur Andersen. Mr. Borkowski holds a Bachelor of Science in Economics and Political Science from Allegheny College and a Master in Business Administration in Finance and Accounting from Rutgers University.

Alastair Riddel MD, Director
Dr. Riddell is currently Chairman Definigen Ltd and non executive director of Silence Therapeutics plc (AIM). He was previously the CEO for Pharmagene, Paradigm Therapeutics and Stem Cell Sciences. He began his professional career as a medical doctor and Army officer with 6 years experience in a variety of hospital specialties and in general practice followed operating roles at Celltech, Centocor, and Amersham International.

Maged Shenouda, Director
Mr. Shenouda has over 25 years of experience in the pharmaceutical and securities industries. Most recently, Mr. Shenouda was the Head of Business Development and Licensing at Retrophin, Inc and as an equity analyst with Stifel Nicolaus, UBS, JP Morgan, Citigroup and Bear Stearns. Mr. Shenouda earned a B.S. in pharmacy from St. John's University and an M.B.A. from Rutgers University Graduate School of Management.

Thijs Spoor, President and CEO
Mr. Spoor was the Chairman and Chief Executive Officer of FluoroPharma Medical, Inc. He was an equity research analyst at J.P. Morgan and Credit Suisse and previously worked at GE Healthcare and Amersham. Mr. Spoor holds a Nuclear Pharmacy degree from the University of Toronto as well as an M.B.A. from Columbia University.

Capitalization

Following the IPO, the company plans to list on NASDAQ

Common Stock	6,028,928
OID Stock (As Converted)	2,642,160
Total Common and (as converted) **OID**	8,671,088
Stock Plan Options	1,081,395
Warrants	1,092,800
Total Stock Option Plan and Warrants	2,174,195
Total Common, as converted OID, Options and Warrants	10,845,283
IPO Shares ($12m at $7)	1,700,000
Fully Diluted Share Count post Offering	12,545,283


AzurRx
BioPharma

Appendix

Additional Corporate Information

Investment Highlights

- **Large, immediately addressable EPI market ($820M in U.S.) for lead compound MS1819 (Lipase) with compelling Phase IIa clinical data**
- **Large market ($2B) for prevention of nosocomial infections**
- **Highly qualified scientific and management team**
  - Successfully completed Phase IIa for MS1819 for chronic pancreatitis and has established a β-lactamase program to prevent hospital acquired infections
  - Deep gastrointestinal and enzymatic research expertise
- **Seeking investment to complete two programs:**
  - Phase IIb studies in MS1819 for chronic pancreatitis
  - Proof of concept for β-lactamase program
- **Risk adjusted NPV on MS1819 (lipase) is $140M-180M pre-Phase IIb and $270M-300M post Phase IIb**
- **Risk adjusted NPV on beta lactamase is $90M pre-clinical**

Exocrine Pancreatic Insufficiency Disease & Competitive Dossier

Treatment and Therapy Choices – Market Revenues

The PERT market exceeds $720M in the US and $1.5B globally.

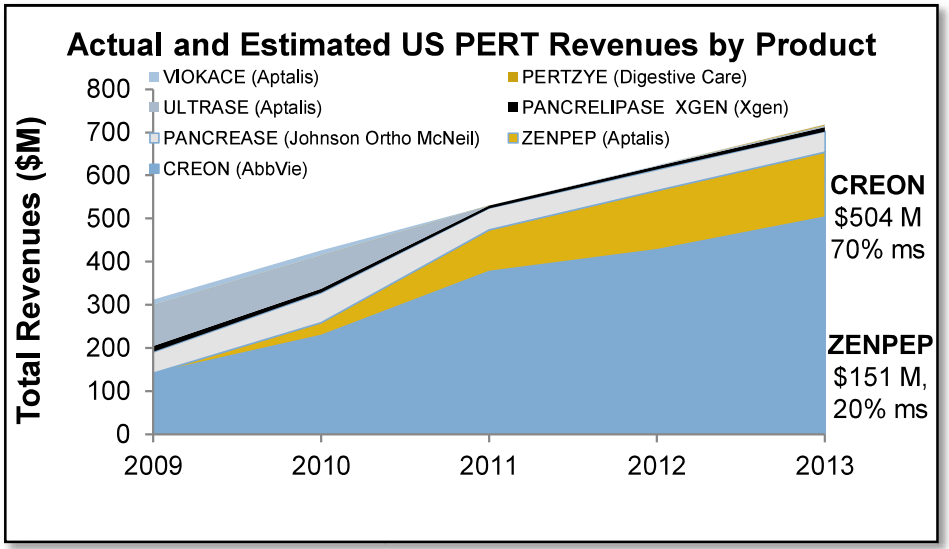
Key Points

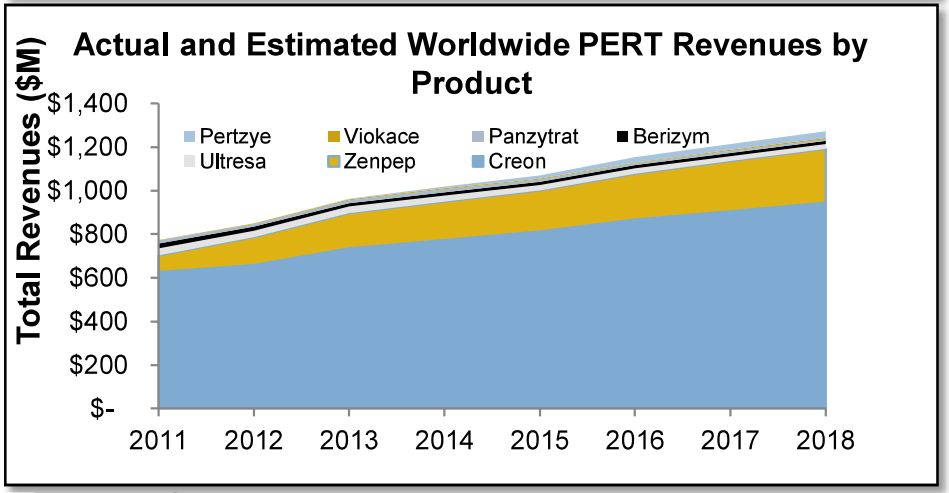
- Creon is the US and Global market leader by revenue growing at 14%
  - $500M US revenue (2013)
  - $735M Global revenue (2013)
- Overall market growth appears strong and stable with 2% growth per year since 2010
- Assuming an annual revenue of $8K - $10K per patient suggest that ~60K – 75K patients are currently treated for EPI in the US

EPI Etiologies

	% affected patients who develop EPI (U.S.)
Chronic Pancreatitis (CP)	60% (140,000)
Cystic Fibrosis (CF)	80-90% (31,000)

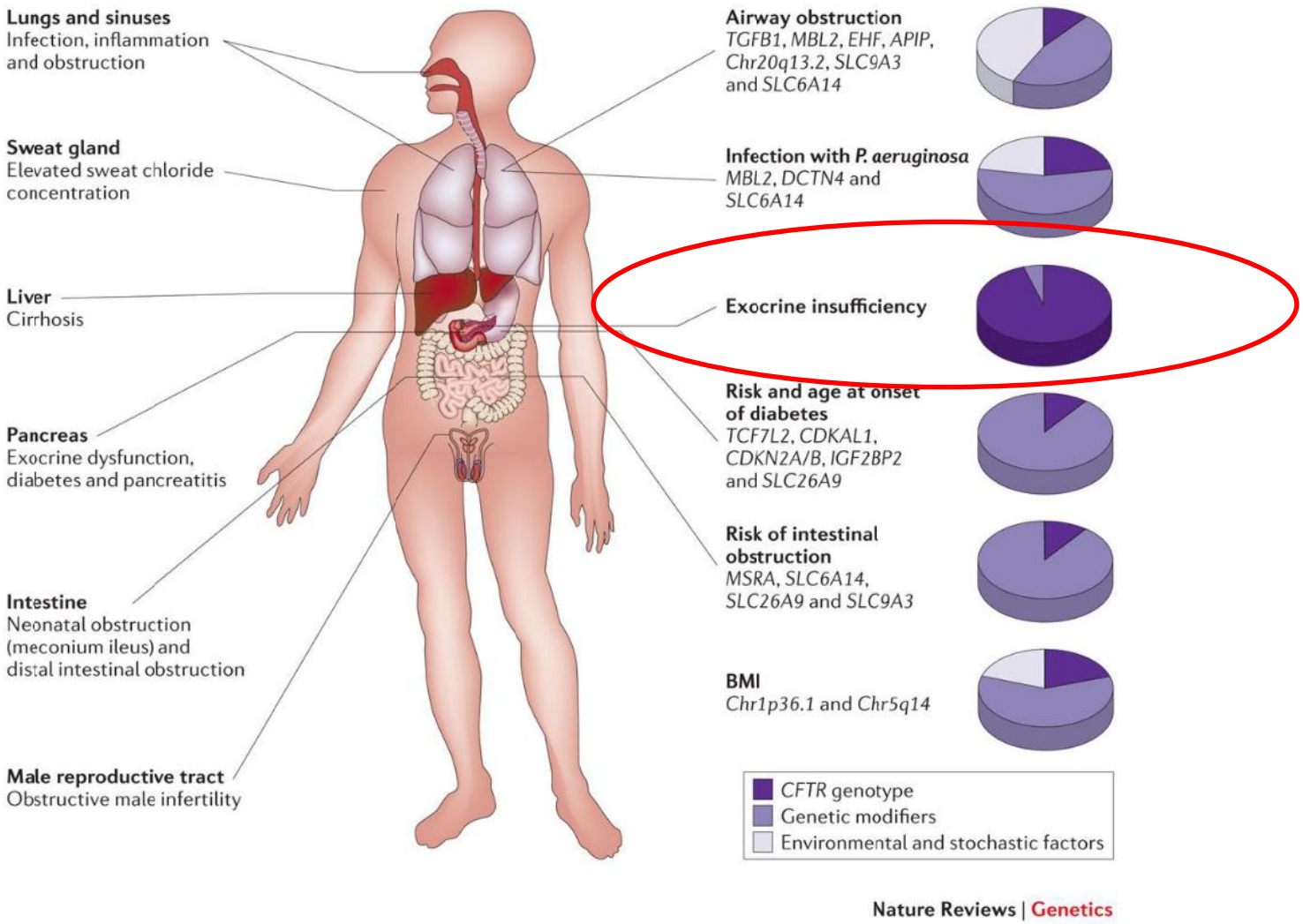
EPI Population	2013	2014	2015	2016	2017	2018	CAGR
Chronic Pancreatitis	92K	93.5K	95K	96.6K	98K	100K	1.6%
Cystic Fibrosis	27K	28K	29K	30K	31K	32K	3.2%





Source: Evaluate Pharma, 22 July, 2014 data pull, company websites, Campbell Alliance analysis; IMS data analysis

Causes of Clinical Presentations of Cystic Fibrosis



MS1819 Lipase Shows Potential to Address Key Limitations of Current EPI Treatments

EPI Disease Overview

- Exocrine Pancreatic Insufficiency (EPI) occurs when the pancreas does not secrete enough pancreatic digestive enzymes
- Clinical signs and symptoms of EPI:
  - Nutritional deficits: weight loss, delayed growth
  - Gastrointestinal symptoms: diarrhea with steatorrhea, abdominal pain, bloating, flatulence
- Commonly associated with
  - Chronic pancreatitis
  - Cystic fibrosis
  - other: pancreatectomy, genetics
- Current treatment is with prescription pancreatic enzyme replacement therapy (PERT)
  - Porcine derived pancreatic enzymes (PPEs)

Current EPI Treatment Limitations

- Limited effectiveness
- Lack of stability in acidic environment
- High pill burden
  - Inconvenient for patients
  - Non-adherence
- Sourcing and supply of porcine derived pancrelipase (PPEs):
  - Subject to pig herd management
  - Risk of transmission of pathogens
  - Inconsistency of manufacturing/supply chain
- Adverse Event: fibrosing colonopathy

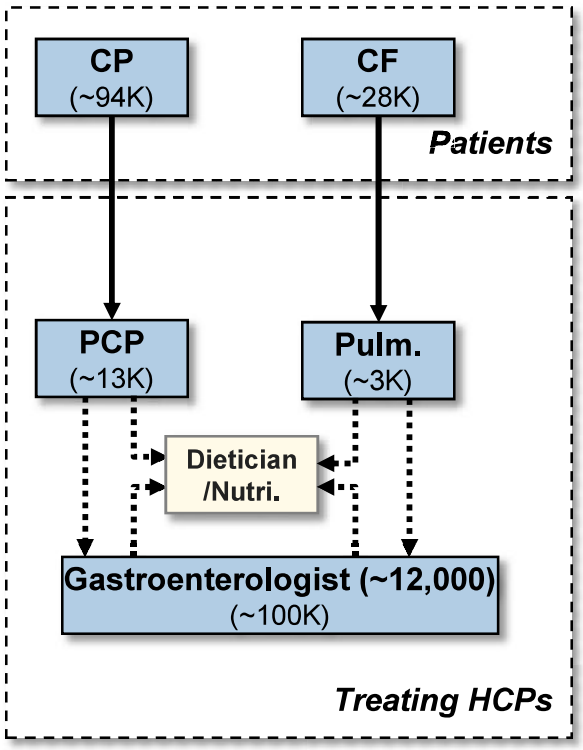
Opportunity

- Reliable and reproducible source of lipase
- Efficacy across pH range
- Lower pill burden
- Improved safety and outcomes

Commercialization Plan

Traditional specialty pharmaceutical marketing to drive awareness with Gastroenterologists

Patient Referral Pathway



Physicians treating an underlying disease may potentially prescribe PERTs prior to referring the patient to a specialist.

Payers

- Inclusion on payer formularies
- Payers do not actively manage this space due to limited cost impact of this category to their overall business
- All surveyed payers stated that they would include MS1819* in their product formularies, but believe the price should be similar to current market leaders in order to prevent access restrictions.

Approach

Pharmaceutical marketing mix:

- Field Force/Physician Detailing
- Ads (Journal, Digital)
- Congresses/Symposia
- Patient Advocacy Associations

Commercial strategy execution options (post Phase II R&D) include:

- Build
- Partner
- License
- Sell

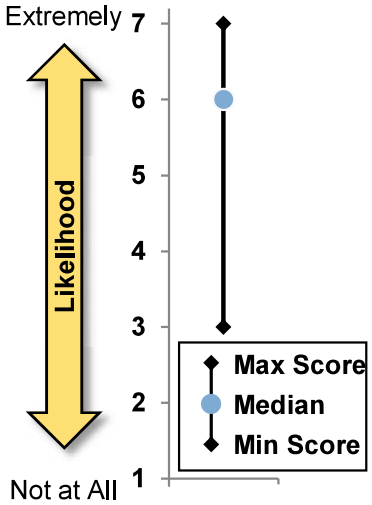
Source: http://www.ncbi.nlm.nih.gov/pubmed/24259956; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132852/; http://www.medscape.org/viewarticle/724509;

Executive Summary

EPI Primary Research – Future Prescribing Behavior

Physicians stated that they would prescribe MS1819 to ~57% of new EPI patients.

Likelihood of Physicians to Prescribe MS1819



Measured on a scale of 1 to 7

n = 10 Gastroenterologists

G.E.	EPI Patients Treated Per Year	New EPI Pts Per Year	Pts Prescribed MS1819 (%)
1	250	10%	80%
2	1,000	15%	20%
3	250	20%	20%
4	2,250	10%	75%
5	2,000	15%	70%
6	130	25%	90%
7	500	20%	50%
8	550	15%	10%
9	300	15%	70%
10	200	10%	40%

New PERT Potential & Likelihood to Prescribe

- **Gastroenterologists are willing to prescribe MS1819 to 57%* of their new adult EPI patients**
  - Physicians felt that the use of MS1819 in pediatric patients would be an effective therapy
- **Gastroenterologists would require additional data in order to support switching their therapy:**
  - Convincing clinical benefit
  - No change or lower costs for patients
  - On market product data

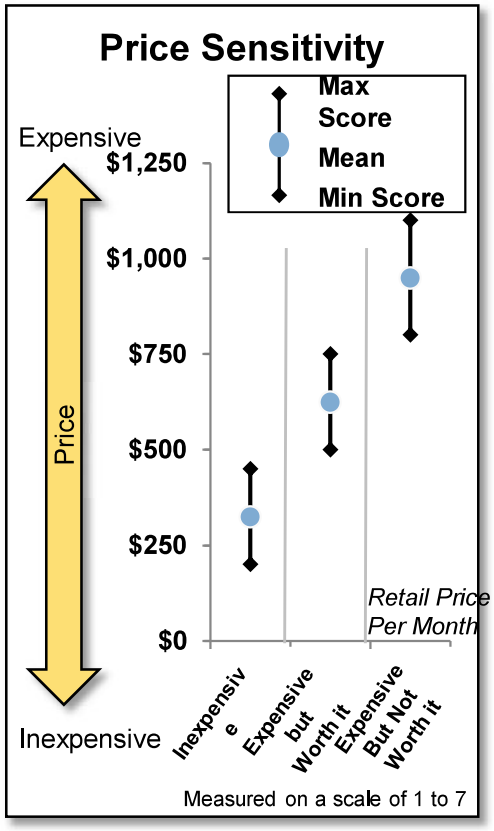
" I'll use it for new patients at first and see how it works."
—Gastroenterologist

"Lipase is the most important enzyme for fat digestion, I'm not concerned over the lack of amylase and protease – I'd prescribe this to 50% of my moderate and severe patients."
—Gastroenterologist

Abbreviations G.E. = Gastroenterologist, *% calculated as weighted average of all interviewed physicians
Source: Results of 10 gastroenterologist interviews conducted in 8/2014

EPI Primary Research – Price Expectations

All payers stated that they would include MS1819 in their product formularies, but believe the price should be similar to current market leaders in order to prevent access restrictions.



Key Points

- **MS1819 Price Sensitivity**
  - MS1819 would become inexpensive if priced under $500 per therapeutic course
  - Expensive if priced over $800
- **MS1819 Potential Formulary Position**
  - Tier 2 if priced similar or below Creon
  - Tier 3 if higher than Creon with possible step through on open formularies
  - Pricing MS1819 15% greater than Creon without evidence of significant clinical benefit and health economic data would result in non-coverage for closed formulary payers

"Conceptually this is a good product but this product must be priced competitively with the other PERTs."
—Payer

"To justify premium pricing there must be convincing clinical data and significant market demand for this product."
—Payer

"Equivalent pricing would result in similar tier positioning without restrictions."
—Payer

"Given the similar efficacy with Creon it would make sense to price this product similar to Creon or other current PERTs."
—Payer

Premium pricing of MS1819 relative to other on-market PERTS requires data supporting a clear clinical benefit in patients.

Source: Results of 5 payer interviews conducted in 8/2014

Scientific Advisory Board

Experience in Hepato-Gastroenterology and Infectious Diseases

Prof. Philip Toskes	Head of HepatoGastroenterology Dept. at the University Hospital of Florida Consultant to FDA on pancreatic enzyme replacement and clinical investigator with various PPE studies.
Dr. Fréderic Carrière	Head of UMR 7282 CNRS – IBSM (Marseilles, France) and a lipase enzyme expert and member of the expert working committee at the United States Pharmacopeia (USP) on the development of lipase monographs and testing chapters.
Prof. René Laugier	Head of the Hepato-Gastroenterology department at the University Hospital of Marseille La Timone. A recognized specialist of pancreatic disorders.
Prof. Mark Lowe	Professor of Pediatrics, University of Pittsburgh School of Medicine. A recognized expert in pediatric gastroenterology for exocrine pancreatic insufficiency in children with cystic fibrosis.

GI Therapeutic Product Pipeline

Product	Description	Indication	Development Phase					Anticipated Year to Market
			Discovery	Pre-Clinical	Phase I	Phase II	Phase III	
MS1819*	Yeast recombinant lipase (*Yarrowia lipolytica* LIP2)	Treatment of EPI in CP patients						2020
		Treatment of EPI in CF patients						2020
AZX1101	Synthetic β-Lactamase	Prevention of nosocomial infections and antibiotic associated diarrhea						2021

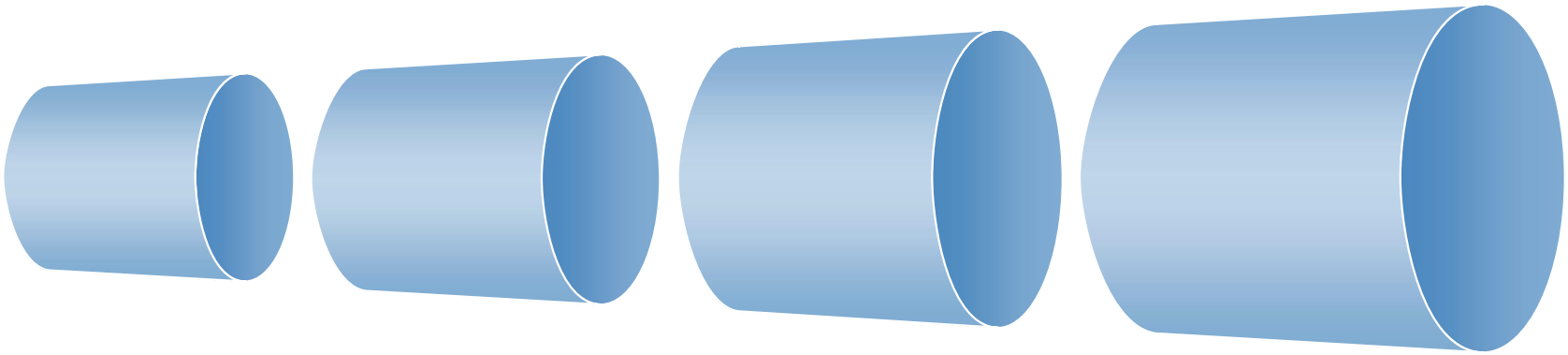
Expected progress through 2017

Current Status

C. Diff and Nosocomial Infection Prevention

AZX1101 is not a treatment for c. diff but preventative

14 M Patients	27 M Prescriptions	118 M Doses	$13 B Market



- Patients requiring IV antibiotic therapy
- Higher risk patients with multiple scripts

- 75% market
- 5 days prescription therapy
- 4 Doses per day

- $25 per prescription

CDI is a significant public health challenge in the US

- CDI represent a major public health challenge in the US and is one of key focus areas of Antimicrobial Stewardship Programs (ASP) across many hospitals[1,2]
- The number of in-patients with CDI discharge diagnosis has increased from 139000 in year 2000 to 336600 in year 2009[3]
- CDI is now considered as the most common hospital-onset , healthcare associated infection (HAI) in the US, exceeding MRSA (methicillin resistant staph aureus) infections[4]
- Mortality rate from CDI has tripled from estimated 3000/yr in 1999-2000 period to 14000/yr in the 2006-2007 period[5]
- The emergence of quinolones antibiotics resistant strain of C *difficile* known as strain 027 (by PCR-ribotyping)[6] if of great concern
- Increasingly more cases of CDI are community acquired[7]
- It is estimated that CDI causes 3 million cases of diarrhea and colitis in the US[8]

1 Khabbaz. The Lancet 2014; 384; issue 9937: 53-63.
2 Filice. VA Evidence-based Synthesis Program Reports. Sep 2013.
3 McDonald. MMWR 2012; 61:157-162.
4 Miller. Infect Control Hosp Epidemiol 2011; 32:387-90.
5 Hall. IDSA Oct 22 2011: Boston, MA.
6 Mc Donald. N Engl J Med 2005; 353:2433-2441.
7 Khanna. Am J Gastroenterol 2012; 107(1): 89-95.
8 CDC. CDC.gov/vitalsigns/Hai/stoppingCdifficile. July 2013.

AZX1101 – Opportunity Overview

Addressing nosocomial infections

- **Applications**
  - Oral, non-systemic medicine to act locally in the GI tract to prevent hospital-acquired infections by resistant bacterial strains induced by parenteral administration of β-lactam antibiotics.
  - Prevention of antibiotic-associated diarrhea (AAD).

- **Hospital-acquired (nosocomial) infections have a huge economic impact on the society and are a major public health concern contributing to increased morbidity, mortality, and cost.**
  - The Centers for Disease Control (CDC) has estimated that roughly 1.7 million hospital-associated infections (*i.e.* ~5% of the number of hospitalized patients), cause or contribute to 99,000 deaths each year in the USA, with the annual cost ranging from US $4.5 billion to $11 billion.
  - In 2010, the global market for antibiotics was ~$35 billion, with β-lactam antibiotics accounting for over 65% of this market (~$22.8B)

- **AZX1101 has the potential to address a large and growing unmet medical need for the prevention of nosocomial infections in a multi-billion dollar market.**

- **CMS has begun to penalize hospitals by not paying for "avoidable costs."**

Beta Lactamase Efficacy

Competitive Program	AZ1101 Intellectual Property
Penicillins (without *beta lactamase inhibitors*)	Penicillins (without *beta lactamase inhibitors*)
	Penicillins (with *beta lactamase inhibitors*)
3rd generation cephalosporins	3rd generation cephalosporins
	Methicillin
	Aminoglycosides
	Some fluoroquinolones
	Macrolides
	Tetracyclines
	Lincosamides


AzurRx
BioPharma