

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K/A**

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**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

**Date of Report (Date of earliest event reported): December 5, 2016**

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**XBIOTECH INC.**

(Exact name of Registrant as specified in its charter)

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**British Columbia, Canada**  
(State of Incorporation)

**001-37347**  
(Commission File Number)

**N/A**  
(I.R.S. Employer Identification No.)

**8201 E Riverside Dr. Bldg 4, Ste 100**  
**Austin, Texas**  
(Address of principal executive offices)

**78744**  
(Zip Code)

**(512) 386-2900**  
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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## EXPLANATORY NOTE

This Current Report on Form 8-K/A is being filed by XBiotech Inc. (the “Company”) solely to more accurately state information contained under Item 8.01 of the Company’s Current Report on Form 8-K with the Securities and Exchange Commission on December 5, 2016 (the “Original Report”). Specifically, the Original Report reflected the number of Patents and Patents Pending held by the Company as 120+. The more precise number of Patents and Patents Pending is 180. We have also updated the biographical information for one of our Directors.

In accordance with Rule 12b-15 of the Securities Exchange Act of 1934, as amended, the corrected presentation as Exhibit 99.1 of the Original Report, is attached hereto.

### **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

99.1 XBiotech Presentation Slides

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 5, 2016

XBIOTECH INC.

By: /s/ John Simard  
John Simard  
Chief Executive Officer and President

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**EXHIBIT INDEX**

Exhibit Number

Description

99.1 XBiotech Presentation Slides



*Creating Breakthrough Therapies from Natural Human Immunity*

NASDAQ: XBIT

Corporate Presentation

2016

# Presentation Contains Forward Looking Statements

This presentation contains forward-looking statements, including declarations regarding management's beliefs and expectations, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties are subject to the disclosures set forth in the "Risk Factors" section of certain of our SEC filings. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this presentation. Any forward-looking statements that we make in this presentation speak only as of the date of this presentation. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this presentation.

# XBiotech Facilities

**40,000 ft<sup>2</sup>  
Manufacturing,  
Quality Control  
Laboratory,  
Administrative**



**(New 48 acre  
Campus Location)**



**16,000 ft<sup>2</sup>**

**Clinical Operations, Manufacturing Filling Suite, Vivarium**



**30,000 ft<sup>2</sup>**

**R&D Laboratories, Manufacturing, Administrative**

## Snapshot December 2016

- Incorporated in 2005, IPO April 2015 (NASDAQ XBIT)
- 107 Employees
- 86,000 ft<sup>2</sup> Operations in Austin, Texas
- Operations include R&D, Manufacturing, Sales & Marketing (planned)
- Incorporated in United States, Switzerland, Germany, Japan, Canada
- Over 100 Clinical Sites in Operation in Various Indications in 20 Countries Around the World
- 180 Patents & Patents Pending

# Corporate Board



## **Dr. Daniel Vasella**

Former Chairman & CEO Novartis. Founded Novartis in merger between Ciba-Geigy and Sandoz Laboratories, creating what became the largest revenue generating Pharma in the World.



## **Dr. Fabrizio Bonanni,**

Former Executive VP Operations Amgen, Developed World's Largest Biologics Manufacturing Operation



## **Thorpe McKenzie**

Founding Partner of Tiger Fund, One of the Most Iconic Investment Funds in the History of Wall Street.



## **John Simard**

Founder CTL ImmunoTherapies, AlleCure, MannKind, XBiotech.

# XBiotech Today

## Breakthrough Medicines

Pending Marketing Authorization for First-In-Class Therapy for Colorectal Cancer

## Deep Assets

Rich Pipeline. Three Fast-Tracked Development Paths: Oncology, Cardiovascular, Infectious Disease

## Strategic

World's Leading Disposable Manufacturing Program (GMP Certified Oct. 2016)

## Value Growth

100% Ownership of Assets, \$0 Debt

# Healthy Human Volunteers with Natural Immunity to Disease



The Human Antibody Repertoire: A Remarkable Platform for Breakthrough Medicines

Program <sup>1</sup>		Pre-Clinical	Phase I	Phase II	Phase III	Pending Marketing Authorization <sup>2</sup>
Symptomatic Colorectal Cancer	Fast Tracked				✓	MAA Decision Pending
Advanced Colorectal Cancer					✓	MAA Submission 2017
Type II Diabetes				✓		
Peripheral Vascular Disease				✓		
Psoriasis	Fast Tracked			✓		
Acne				✓		
Pyoderma Gangrenosum				✓		
Hidradentitis Suppurativa				✓		
<i>S. aureus</i> Bacteremia	Fast Tracked			✓		
<i>C. difficile</i>		✓				
Influenza		✓				
Herpes Varicella Zoster (Chickenpox)		✓				
Ebola		✓				

✓ = pilot study

<sup>1</sup>All Grey Shaded Areas Involve MAbp1 Targeting Interleukin-10. Green-shaded programs have individual antibodies specific for each infectious agent.

# Anti-Inflammatory Programs

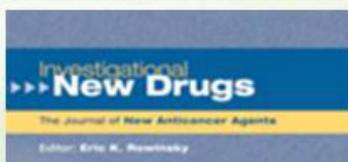
- Type II Diabetes
- Peripheral Vascular Disease
- Psoriasis
- Acne
- Pyoderma Gangrenosum
- Hidradenitis Suppurativa

# Peer-Reviewed Publications on Clinical Findings

- *MABp1, a first-in-class true human antibody targeting interleukin-1 $\alpha$  in refractory cancers: an open-label, phase 1 dose-escalation and expansion study*

THE LANCET **Oncology**

- *Xilonix, a novel true human antibody targeting the inflammatory cytokine interleukin-1 alpha, in non-small cell lung cancer*



- *Safety, pharmacokinetics, and preliminary efficacy of a specific anti-IL-1alpha therapeutic antibody (MABp1) in patients with type 2 diabetes mellitus*



## Clinical Publications (Continued)

- *Open-label trial of MABp1, a true human monoclonal antibody targeting interleukin 1 $\alpha$ , for the treatment of psoriasis*



- *An open label, phase 2 study of MABp1 monotherapy for the treatment of acne vulgaris and psychiatric comorbidity*



- *A randomized phase II study of Xilonix, a targeted therapy against interleukin 1 $\alpha$ , for the prevention of superficial femoral artery restenosis after percutaneous revascularization*



- Xilonix Monotherapy in Colorectal Cancer: Two Phase III Programs
- Pluripotent Anti-Tumor Mechanism Interrupts Tumor Growth and Augments Recovery
- Development of Novel Endpoint Radiological/Quality of Life Measure: A Direct Measure of Clinical Benefit and a Surrogate Measure of Anti-Cancer Activity
- Xilonix Suitable for Combination with Multiple Therapies

# Xilonix Therapy in Colorectal Cancer

40% of Advanced Colorectal Cancer Patients that Complete an 8 Week Treatment with Xilonix Achieve Clinical Response...

That is Nearly **Twice** as Many Compared to Placebo.

(Per Protocol Population for a Randomized Double-Blind Placebo Controlled Phase III Study. 40% of Xilonix Patients Met Primary Endpoint vs 23% on Placebo  $p= 0.0033$ )

# Achieving the Clinical Response Means:

- Twice as Likely to Have Stable Disease <sup>1</sup>
- Five Times Less Likely to Have Serious Adverse Events<sup>2</sup>

<sup>1</sup>24.1% of Patients Achieving Primary Endpoint had stable disease at 8 weeks vs 11.7% for those that did not (p=0.0062)

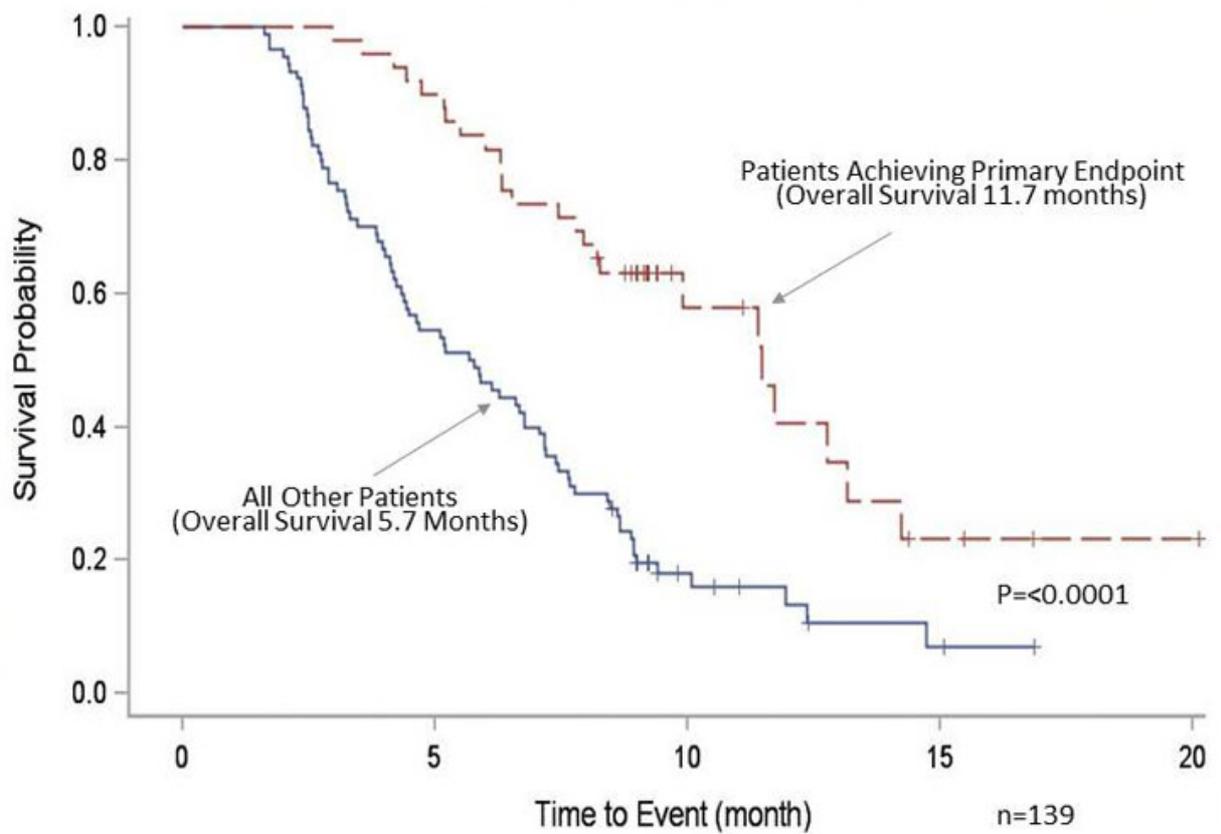
<sup>2</sup>5.7% of Patients Achieving Primary Endpoint had SAEs vs 29.3% that Failed To Achieve (p < 0.001)

# Clinical Response Associated with Wide Ranging Improvement in Health

- ✓ Increase in Lean Body Mass (1.4kg)
- ✓ Improved Global Quality of Life
- ✓ Improved Role Function
- ✓ Improved Emotional Function
- ✓ Improved Social Function
- ✓ Reduced Pain
- ✓ Reduced Fatigue
- ✓ Increased Appetite (P < 0.001 for each category)

Improvement was both statistically significant and clinically meaningful (in terms of magnitude of improvement for categories relevant to EORTC guidelines)

# Patients Achieving Clinical Response After 8 Weeks Were Nearly Twice as Likely to Live Longer



<sup>1</sup>After 8 weeks on Study 40% of Xilonix Patients Met Primary Endpoint vs 23% on Placebo ( $p < 0.0033$ )

## Summary of Patient Benefit During an 8 Week Treatment Regimen with Xilonix

- Nearly Twice as Likely to Have Increased Survival
- Twice as Likely to Have Stable Disease
- Improvement in All Life Quality Measures, Including Physical, Functional and Emotional Health
- Five Times Less Likely to have a Serious Adverse Event
  - Reduced Incidence of Hospitalization or Prolongation of Existing Hospitalization
  - Reduced Incidence of Persistent or Significant Disability/Incapacity from Disease

# EU Marketing Authorization

- Europe Represents by Far the Largest Unmet Need for Colorectal Cancer Therapy
- Discussion with European Medicines Agency for Marketing Approval is Ongoing and Decision Not Expected Until 2017
- XBiotech Plans to Sell and Market Xilonix in Europe Subject to Regulatory Approval
- European Market Authorization will Be Used to Seek Registration in Multiple Regions and Countries—Through Partnership—Around the World.

# Ongoing Global Phase III Study Under US FDA Fast-Track Program

- Double-Blind Placebo Controlled Randomized Study Involving 600+ Patients
- Overall Survival is Primary Endpoint. Subjects In Study Progressed (or intolerant) After: Oxaliplatin, Irinotecan, Flouropyrimidine, and Cetuximab or Panitumumab if KRAS wildtype
- Enrollment Completed On Schedule in November 2016 and Results of First Interim Analysis Expected in 1<sup>st</sup> Quarter 2017
- First Interim Analysis Enables Independent Data Monitoring Committee to Unblind Study to Assess Both Safety and Efficacy
- Interim Analysis Incorporates Futility Boundary

# Anti-Infective Programs

- *Staphylococcus aureus*
- *Clostridium difficile*
- Influenza Virus
- Herpes Varicella Zoster Virus (Chickenpox)
- Ebola

## CDC: Staph classified as “Serious Threat”

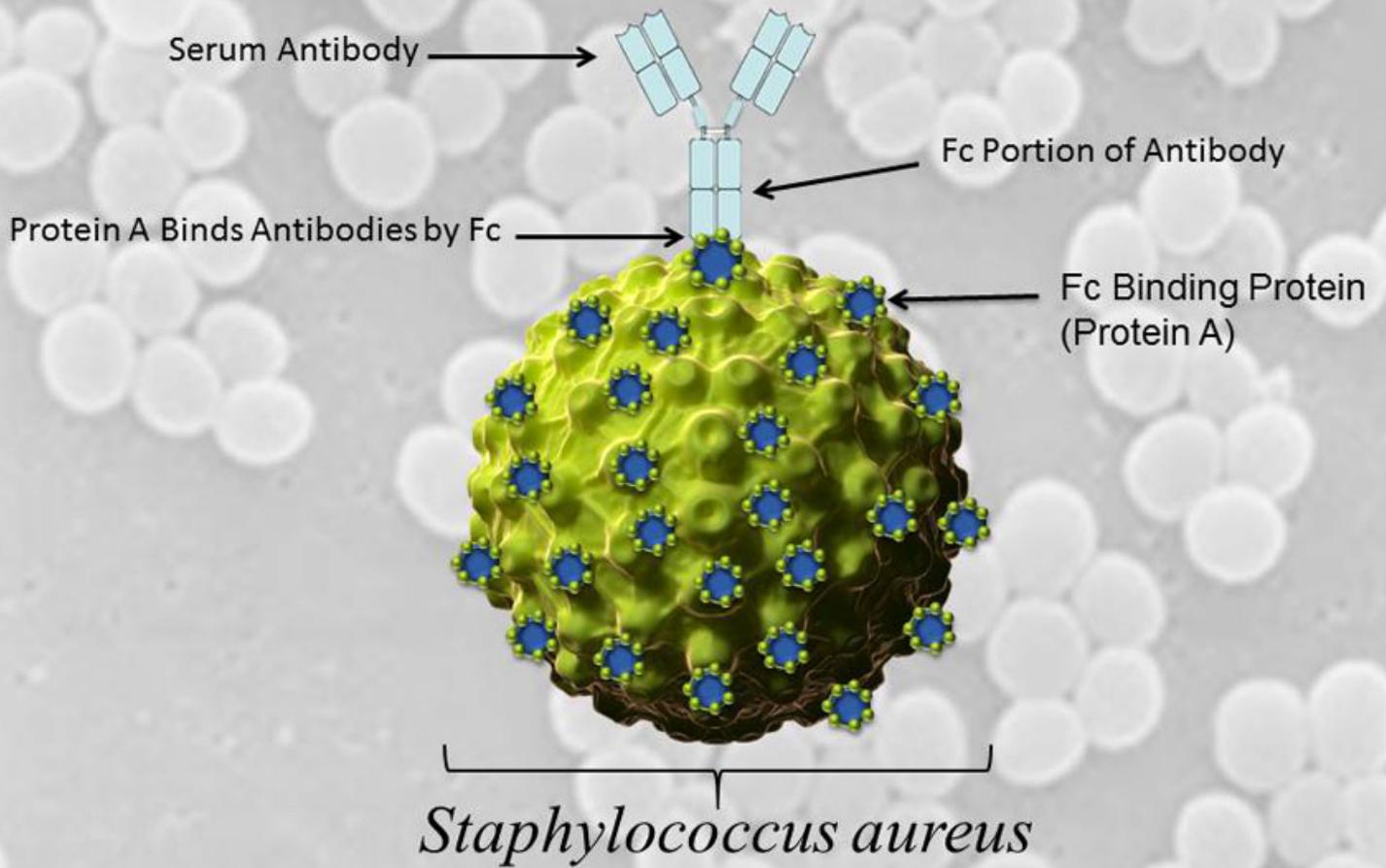
- Staph Kills an Estimated 20,000 Patients in the US Every Year<sup>1</sup>
- Antibiotic Resistance is Not Being Solved with Small Molecules
- No Effective Vaccines and Growing Consensus that Such an Approach is Difficult, if Not Impossible
- Repeated Failures Due to an Immune Evasion Mechanism

<sup>1</sup><http://mrsa-research-center.bsd.uchicago.edu/>

# FDA Fast Track 514G3 in Phase II Study

- Double-Blind, Placebo Controlled Randomized Study in 52 Patients
- A Single Dose of Antibody to Mediate Therapy
- Neutralize Immune Evasion Mechanism and Facilitate Immune Clearance
- Targets All Forms of *S. aureus* —Including MRSA, MSSA
- Enrollment Completed in December 2016
- Topline Data Readout 1<sup>st</sup> Quarter 2017

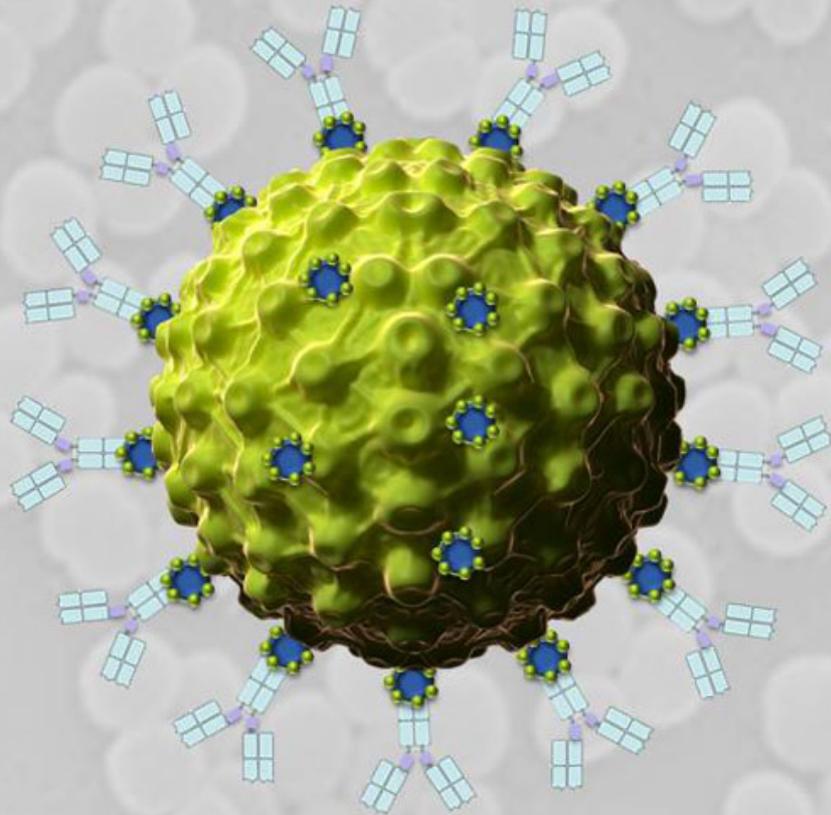
# Cartoon Depiction of *S. aureus* with Antibody Bound by Fc Region



## Serum Antibodies Bind ProA Forming Protective Coat on *S. aureus*

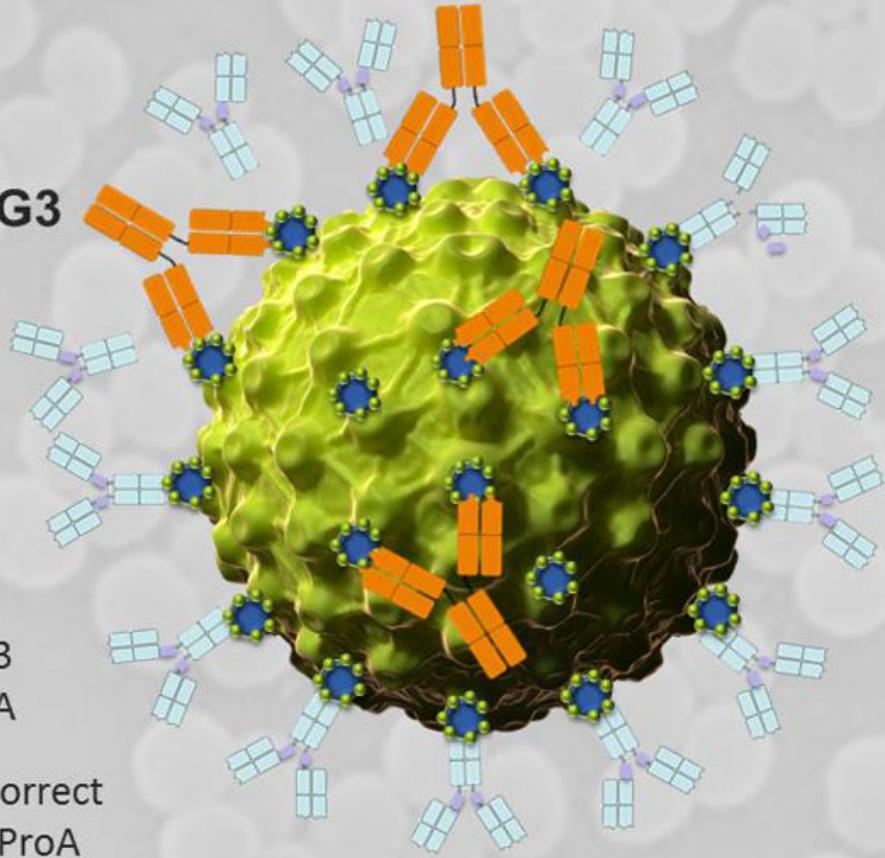
### Protect Coat Helps *S. aureus*

- Evade Detection
- Neutralize Antibodies
- Prevent Immune Control



# True Human Antibody (514G3) Binds ProA

514G3



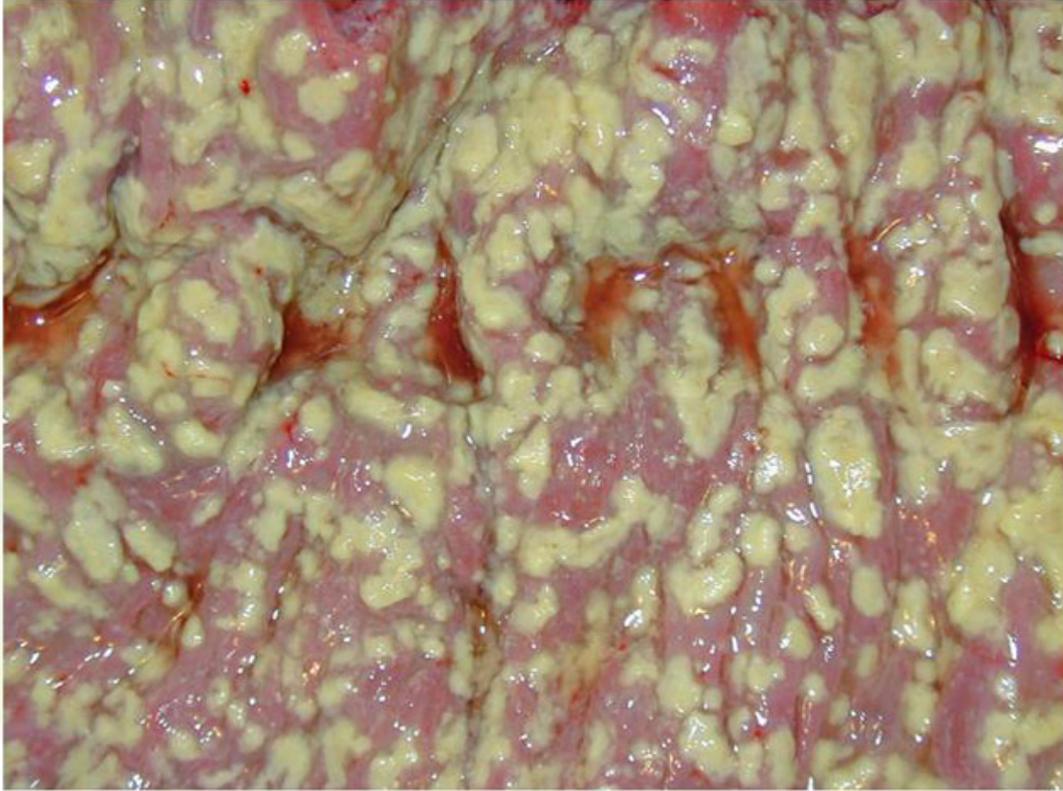
- Fc portion of 514G3 does NOT Bind ProA
- 514G3 Binds with Correct Geometry to Block ProA and Mediate Clearance

# *Clostridium difficile*

- 500,000 People in USA Contract Disease Annually
- 1/9 Persons Over 65 Years of Age Die Within 30 days of Contracting Disease
- 29,000 Deaths Annually in the US
- Currently No Means of Preventing Disease

<http://www.cdc.gov/media/releases/2015/p0225-clostridium-difficile.html>

## Best Way to Treat is to Prevent



Pathological Specimen Showing Pseudomembranous Colitis

*Image: [https://en.wikipedia.org/wiki/Clostridium\\_difficile\\_infection](https://en.wikipedia.org/wiki/Clostridium_difficile_infection)*

## Developing a Novel Therapy to Prevent Deadly *C. difficile* Infection

- FIRST Oral Delivered Monoclonal Antibody Therapy
- Safety and Tolerability Ideal for Patient Population
- Prophylaxis Therapy—Only Approach Designed to Eradicate Bacteria Rather than Target only *C. difficile* toxins
- Targeting Clinical Launch for Year End-2017

# Strategic Manufacturing—Industry Leading Disposable Platform

Unprecedented Reduction in Cost and Flexibility



Artist's Conception

## Near Term Corporate Goals



- Seek Registration for Xilonix in Europe and other markets for CRC
- Establish Sales and Marketing Capability in Key Markets of Europe
- Continue Clinical Development in Colorectal and Other Oncology Indications, Including Combination Therapies
- Develop Pivotal Study for Fast-tracked Anti-Infective Therapy for *S. aureus*
- Advance Other MABp1 Clinical Programs in Strategic Therapeutic Areas

**Thank You**