



**VAXXART**  
*UNLOCKING THE FULL POTENTIAL OF ORAL VACCINES*

**Needham Healthcare Conference**  
March 2018





# Safe Harbor

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# Oral Recombinant Vaccines Targeting Major Indications

Proprietary vector-adjuvant delivery system designed to generate broad immune responses

## INNOVATIVE VACCINE PLATFORM

- **Designed for wide range of recombinant antigens**
- **Broad immune responses**
  - *Systemic & mucosal*
- **Significant platform benefits**
  - *Manufacturing*
  - *Regulatory*

## TABLET OFFERS IMPORTANT ADVANTAGES

- **Ease of distribution, administration**
- **Patient acceptance**
- **Does not need to fit normal vaccine immunization schedules or “share needles”**

## VALIDATED PRODUCT CANDIDATES

- **Norovirus Vaccine**
  - *100% responders in Phase 1b*
- **Flu Phase 2 challenge study**
  - *Clinical proof of efficacy*
  - *BARDA funded (\$15.7M)*
- **First therapeutic vaccine for HPV**
  - *Preclinical proof of efficacy*



# Clinical Pipeline Focused on Antiviral Prophylactic and Therapeutic Products

Tablet Vaccine	Trials Conducted to Date or in Progress				
	Preclinical	Phase 1	Phase 2	Phase 3	Marketed
<i>Prophylactic</i>					
Norovirus <sup>1)</sup>	Progress bar				
Influenza <sup>2)</sup>	Progress bar				
RSV	Progress bar				
<i>Therapeutic</i>					
HPV Vaccine CIN-Cervical Cancer	Progress bar				
<b>Aviragen Legacy Programs</b>					
<i>Small Molecules</i>					
Teslexivir Genital Warts	Progress bar				
<i>Marketed Products</i>					
Inavir®	Progress bar				
Relenza®	Progress bar				

1) Monovalent GI.1 norovirus vaccine has completed 2 Phase 1 studies. Bivalent norovirus vaccine to enter clinic in 2018.

2) Monovalent H1 flu vaccine completed phase 2 Proof of Concept efficacy study. Flu program to be partnered.



# Veteran Management Team with Deep Experience in Vaccines and Anti-Infectives

MANAGEMENT TEAM	RELEVANT EXPERIENCE (YEARS)	COMPANIES	EXPERTISE
<b>WOUTER LATOUR, MD MBA</b> CEO	20	  	Vaccines, Oral Delivery of Biopharmaceuticals
<b>SEAN TUCKER, PHD</b> Founder and CSO	20	  	Mucosal Immunology Gene Delivery
<b>JOHN HARLAND, CPA MBA</b> CFO	25	   NEUROBIOLOGICAL TECHNOLOGIES, INC.	Biotech, Devices, Multiple Financing
<b>DAVE INGAMELLS</b> VP Manufacturing	25	    	GMP Manufacturing, Process Development Adenoviral Vectors
<b>ANNA NOVOTNEY-BARRY, MS</b> VP Clinical Development	20	    	Infectious Disease, Anti-Virals, mAbs
<b>UDAY PATEL, MA</b> VP Regulatory Affairs	20	   	Infectious and Metabolic Disease, Autoimmunity

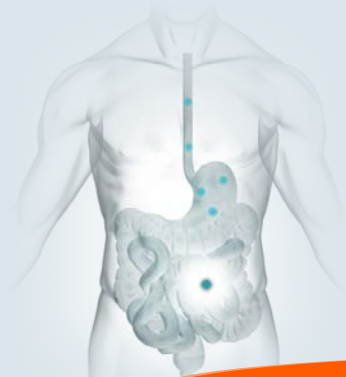


# Proprietary Oral Vaccine Platform

*Intestinal Delivery + Targeted Immune Activation*

## ENTERIC-COATED TABLETS

- Designed to Release the Vaccine in the Small Bowel



## VACCINE ANTIGEN

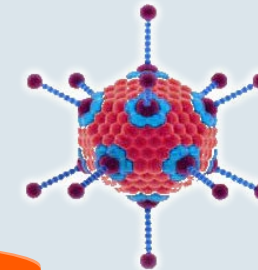
- Norovirus VP1
- Influenza HA

## TLR3 ADJUVANT

- Molecularly Expressed dsRNA

## ADENOVIRUS 5 (Ad5)

- Replication Incompetent



## THE VAXART PLATFORM

Platform Designed for  
Wide Range of  
Recombinant Antigens

Adjuvant + Antigen  
Co-expressed has Potential  
Safety, Efficacy Benefits

Manufacturing Process  
can be Used for All  
VAXART Vaccines

# Norovirus Vaccine

Phase 2 Challenge Study Initiation in 2018

Phase 1b Bivalent Study Initiation in 2018

Orally Administered Tablet Vaccine for Norovirus

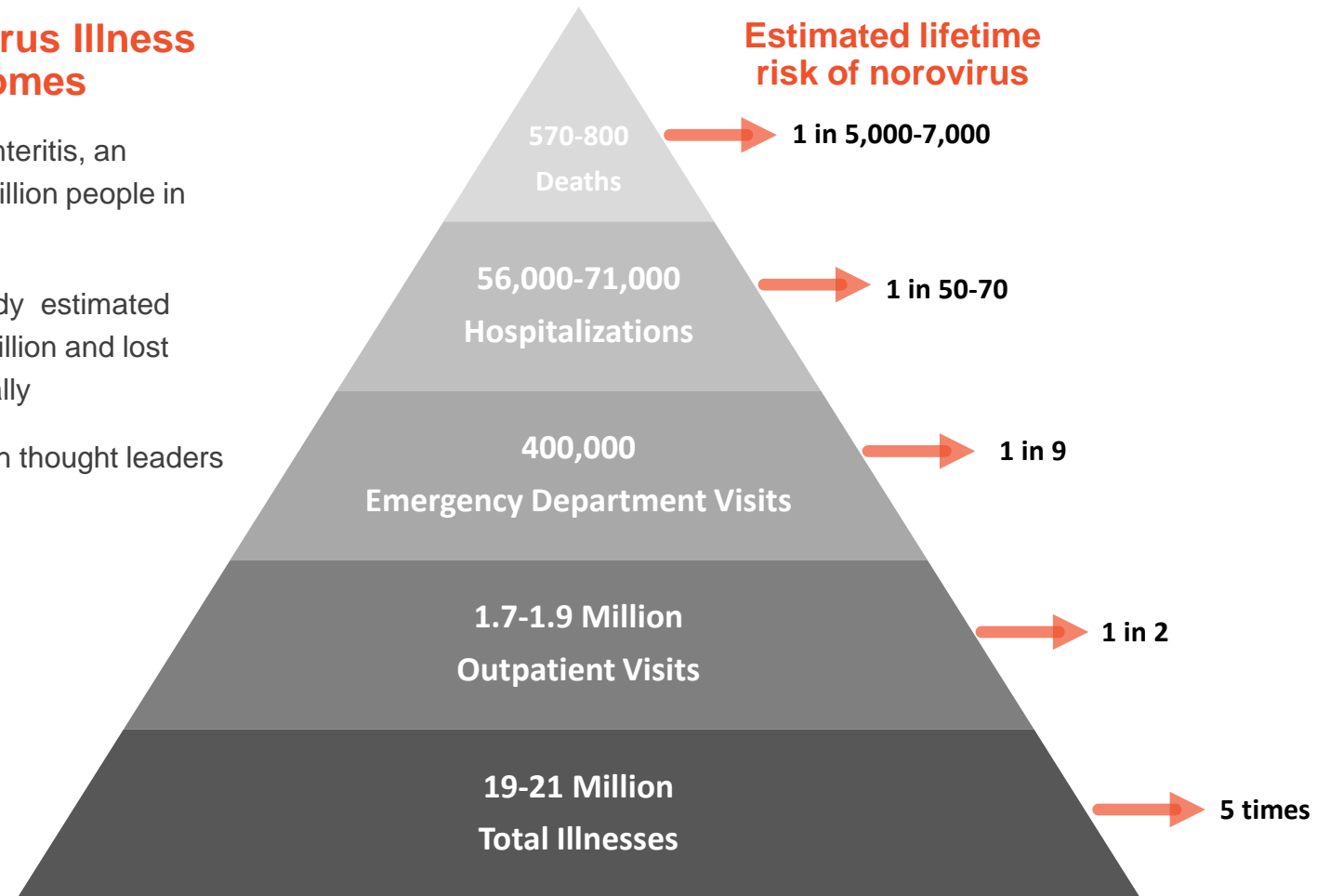




# Norovirus is a Significant Cause of Disease in the U.S.

## Annual Estimates of Norovirus Illness and Associated Outcomes

- Most common cause of acute gastroenteritis, an intestinal infection affecting 19 to 21 million people in the United States each year
- A recent Johns Hopkins University study estimated healthcare costs of norovirus at \$4.2 billion and lost productivity costs at \$56.2 billion globally
- Priority for CDC and other public health thought leaders



Source: CDC website (<https://www.cdc.gov/norovirus/php/illness-outbreaks.html>)





# Oral Tablet Norovirus Vaccine a Key Differentiator

- **Target populations**
  - Elderly and very young ~ 70M
    - Potential ACIP recommendation
  - HC workers, food industry, travel industry ~ 33M
  - Travelers: business & leisure ~ 55M
- **Vaccine Development**
  - GI and GII genotypes cause majority of NV-disease
  - Bivalent annual vaccine to cover GI.1 and GII.4 strains
  - Vaxart and Takeda only companies in clinical trials
- **Mucosal Immunity Important For Protection Against Norovirus**
  - Correlates of protection from human challenge studies: rapid induction of mucosal IgA, serum IgA (Atmar, et al, *CVI*, 2015. Ramani, et al, *PlosPathogens* 2016)



1) Sources: CDC Norovirus Illness: Key Facts



# Norovirus G1.1 – Phase 1b (Study 102)

*Open Label, Dose and Schedule Optimization Study*

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- **Study Objectives:**

- Primary: To further determine the safety of an oral tableted VXA-G1.1-NN norovirus vaccine with different dosing regimens
- Secondary: To determine the immunogenicity of a VXA-G1.1-NN norovirus vaccine at multiple dose levels and dosing schedules

- **Four cohorts receiving different dose levels and dosing regimens**

- 60 healthy adults age 18 – 49, four groups of 15 subjects each
- Three low dose cohorts
- One high dose cohort



# Phase 1 Norovirus Trial: Solicited Symptoms

*Most Events Mild in Severity (Days 0-7)*

Solicited Symptom	Low Dose			High Dose
	Cohort 1	Cohort 2	Cohort 3	Cohort 4
	(n=15)	(n=15)	(n=15)	(n=15)
<b>Number of Subjects with Solicited Symptom TEAEs</b>	<b>5 (33%)</b>	<b>8 (53%)</b>	<b>11 (73%)</b>	<b>3 (20%)</b>
<b>Gastrointestinal Disorders</b>				
Diarrhea	0	1 (7%)	5 (33%)	1 (7%)
Abdominal Pain	1 (7%)	1 (7%)	3 (20%)	1 (7%)
Nausea	1 (7%)	2 (13%)	2 (13%)	0
<b>General Disorders and Nervous System Disorders</b>				
Malaise	2 (13%)	0	2 (13%)	1 (7%)
Feeling Hot	0	1 (7%)	0	0
Headache	4 (27%)	7 (47%)	9 (60%)	1 (7%)

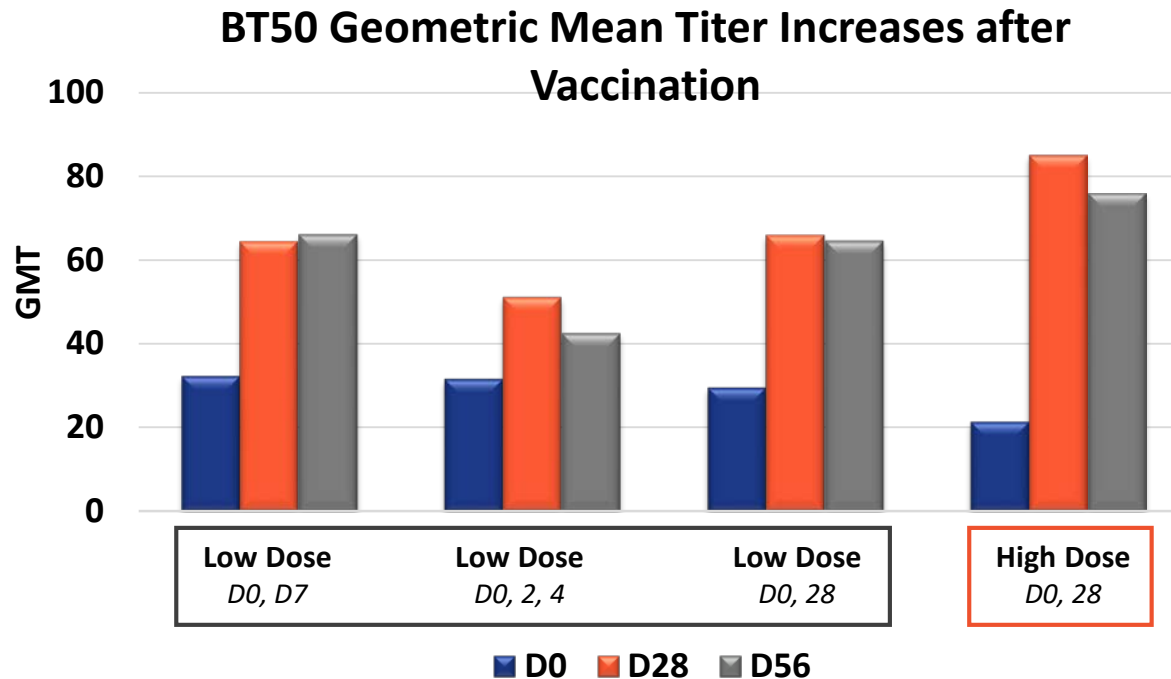
- **Unsolicited AEs (Days 0 – 28): no remarkable findings; most events mild**
- **No Serious Adverse Events**

<b>Cohort 1:</b> Low Dose, Day 0, 7	<b>Cohort 3:</b> Low Dose, Day 0, 28
<b>Cohort 2:</b> Low Dose, Day 0, 2, 4	<b>Cohort 4:</b> High Dose, Day 0, 28



# > 90% of Subjects in High Dose Group Responded by BT50<sup>1</sup>

~ 4-Fold Increase in BT50 Titers at Day 28/56



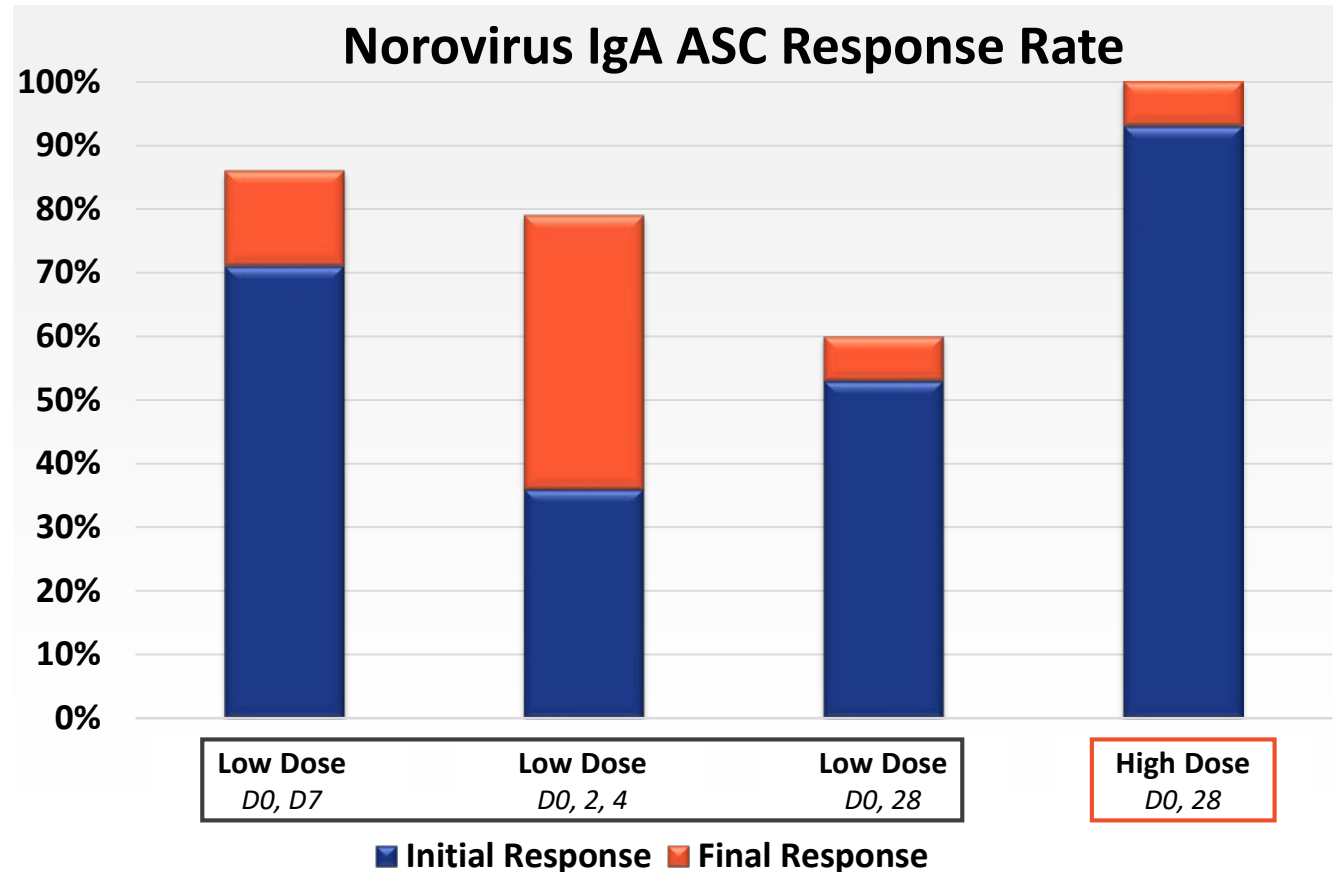
### High Dose Response Rates

D28 Response Rate (≥2X)	D56 Response Rate (≥2X)
12/15 (80%)	14/15 (93%)

<sup>1</sup> BT50, or Blocking Titer 50, measures the ability of subjects' serum to block interaction of norovirus VLPs with histo-blood group antigens. BT50 is a putative correlate of protection.



# All Subjects in High Dose Group Responded by IgA-ASC, a Marker of Mucosal Immunity



ASC = Antibody Secreting Cells

# H1 Influenza Vaccine

Orally Administered Tablet Vaccine for H1  
Influenza





# H1 Influenza Oral Vaccine

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- Initial indication chosen to demonstrate clinical proof-of-concept while targeting growing ~\$3B market
- Breakthrough trial results published in *The Lancet Infectious Diseases*\* in August 2015
  - Demonstrated protective immunity based on Hemagglutinin Inhibition Assay (HAI) four-fold or greater increase observed in more than 90% of subjects
  - Exhibited favorable safety and tolerability profile
- Identified by HHS/ASPR/BARDA\*\* as innovative approach to develop more effective influenza vaccines
  - BARDA funded the H1 Influenza Phase 2 Challenge Trial, contract no.: HHSO 100201500034C

\*) [www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099\(15\)00266-2.pdf](http://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(15)00266-2.pdf)

\*\*\*) HHS/ASPR/BARDA: U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response / Biomedical Advanced Research and Development Authority



# H1 Influenza Phase 2 Challenge Trial

*Double-Blind, Placebo-Controlled Active Comparator (QIV)*



- **A single dose administration of one of the following**
  - Arm 1: Vaxart Tablet Vaccine + placebo IM injection
  - Arm 2: QIV injection + oral placebo tablet
  - Arm 3: Placebo IM injection + oral placebo tablet
- **Challenge at Day 90-120 post-randomization**
  - Group Size (target): 60, 60, 30

## READ-OUTS

- **Primary endpoint: Reduction of PCR-confirmed influenza illness**
  - Illness is defined as subjects experiencing at least one day of one of more acute influenza symptoms per the Flu-PRO questionnaire and laboratory-confirmed infection
- **Additional post-hoc analysis: reduction of infection**
  - Detectable shedding by qRT-PCR, anytime after 36 hours post-challenge

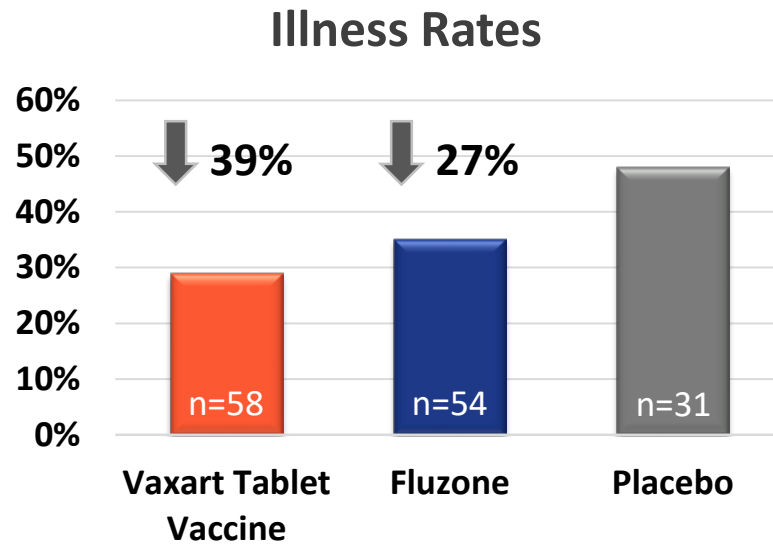




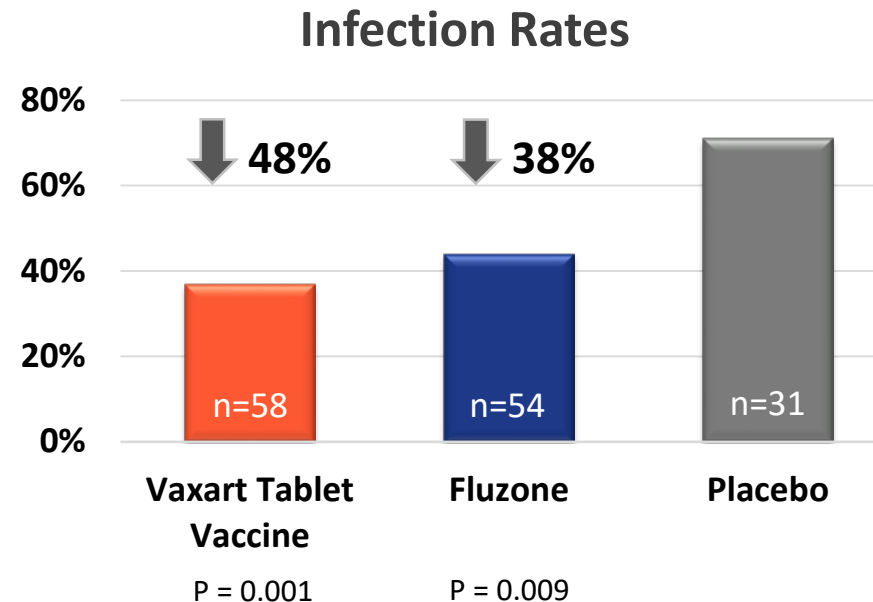
# Reduction in Illness and Infection Rates Similar to QIV

*Reduction in Infection Rates Trended Superior to QIV*

## Protection Against Illness Comparable to QIV



## Reduced Infection Rates Trending Superior to QIV





# Favorable Safety and Tolerability Profile



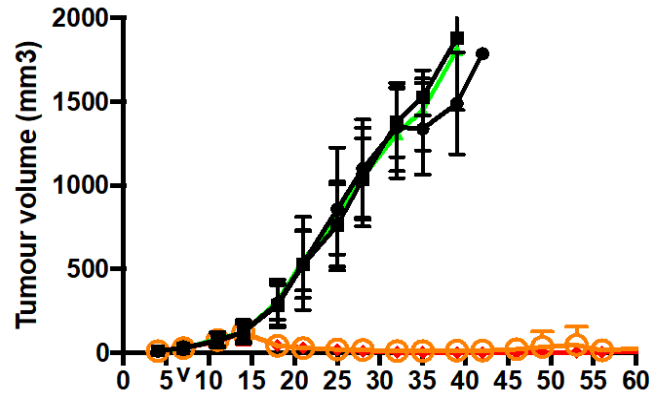
Solicited Symptom	Placebo	VXA-A1.1	QIV
	(n=36)	(n=70)	(n=72)
<b>Number of Subjects with Solicited Symptom TEAEs</b>	<b>15 (42%)</b>	<b>20 (29%)</b>	<b>26 (36%)</b>
<b>General Disorders and Nervous System Disorders</b>			
Malaise/Fatigue	5 (14%)	3 (4%)	5 (7%)
Headache	7 (19%)	5 (7%)	6 (8%)
Myalgia/body aches	1 (3%)	1 (1%)	0
Fever	0	2 (3%)	0
<b>Gastrointestinal Disorders</b>			
Diarrhea	5 (14%)	4 (6%)	0
Abdominal Pain	1 (3%)	0	1 (1%)
Nausea	1 (3%)	4 (6%)	3 (4%)
Vomiting	0	0	1 (1%)
<b>Local Symptoms</b>			
Pain at injection site	1 (2.8%)	2 (2.9%)	10 (13.9%)
Tenderness at injection site	1 (2.8%)	3 (4.3%)	19 (26.4%)



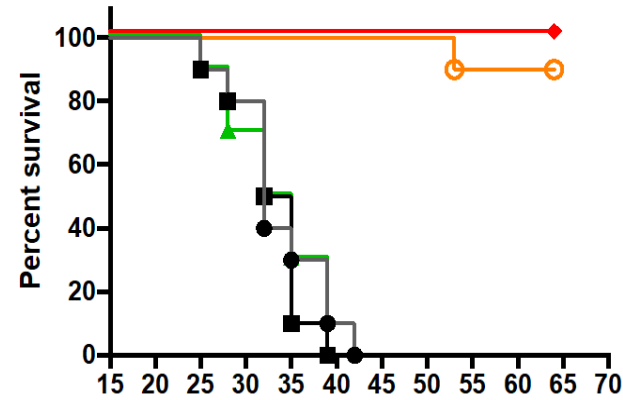
# First Immuno-Oncology Target with Strong Preclinical Data

*Efficacy in HPV-Derived Tumor Model in Mice (TC-1)*

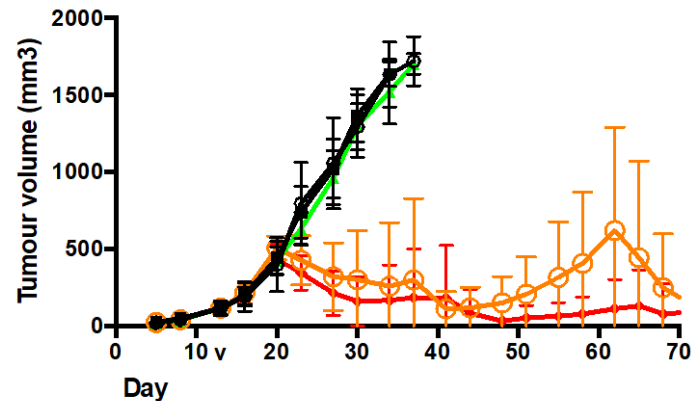
Study 1 small tumour,  
Immunize d7, 14, 21



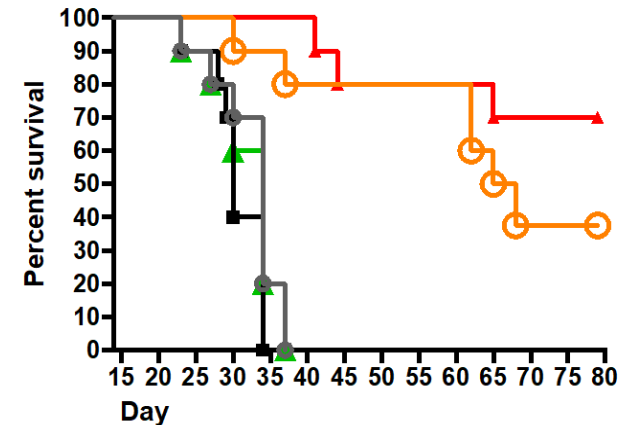
Survival Study 1



Study 2 Large tumour  
Immunize days 13, 20, 27



Survival Study 2



- G1 Untreated
- G2 Ad-nr + Isotype control Ab
- ▲ G3 Ad-nr + Anti-PD-1 Ab
- G4 Ad-HPV16 + Isotype control Ab
- ◆ G5 Ad-HPV16 + Anti-PD-1 Ab



# Validated Vaccine Platform

More than 300 Subjects Dosed to Date

## Clinical Trials

Tablet Vaccines



### Purpose:

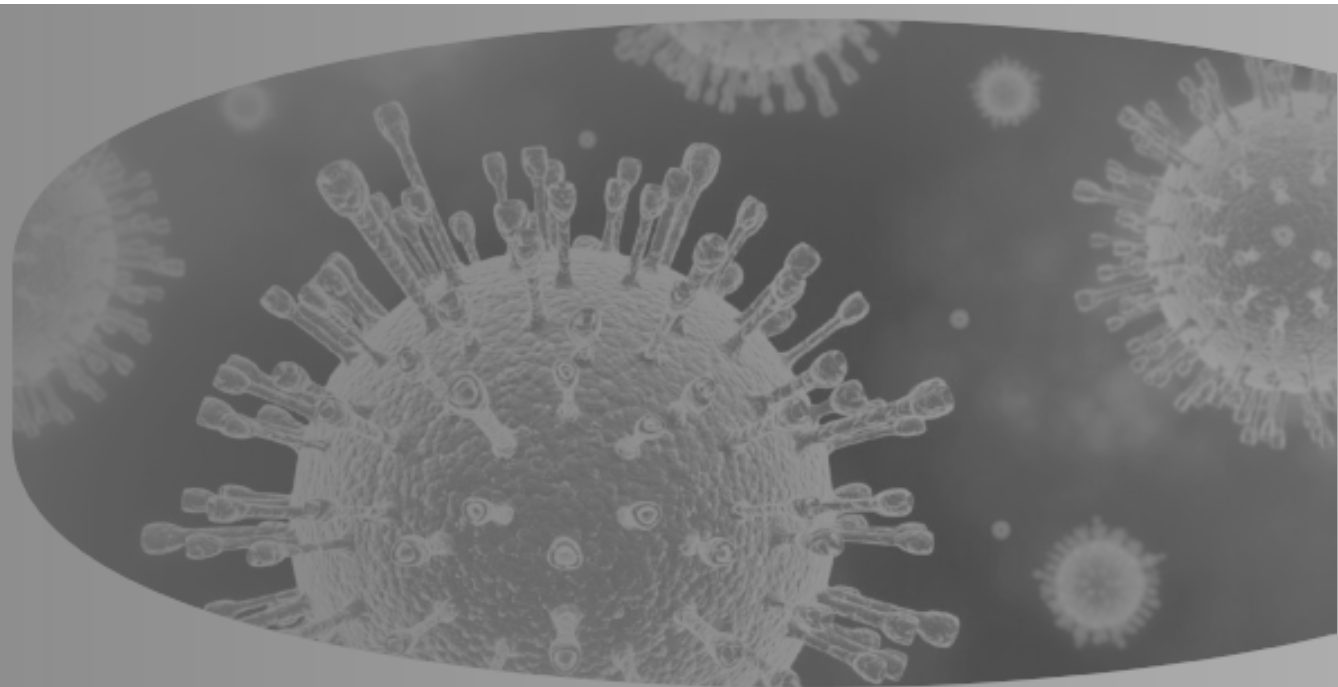
- Safety
- Immunogenicity
- Dose ranging
- Efficacy

	Flu	RSV	Norovirus
<b>SUBJECTS DOSED</b>	<b>176</b>	<b>46</b>	<b>106</b>
<b>SAFETY</b>			
Favorable safety and tolerability profile			
<b>EFFICACY</b>			
Reduction in influenza illness comparable with the leading marketed quadrivalent intramuscular influenza vaccine			
<b>BROAD IMMUNE RESPONSES</b>			
Serum neutralizing antibodies (IgG)			
Mucosal homing B cells (IgA)			
T cells			

# Aviragen Legacy Program

Teslexivir - Topline Phase 2 Data Readout in 2Q18

First-in-Class, Direct-Acting Antiviral  
Treatment for Condyloma





# Teslexivir (BTA074)

*Legacy Aviragen Program*

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- **A first-in-class, direct-acting, topical antiviral for the treatment of condyloma, or anogenital warts, caused by human papillomavirus (HPV) types 6 & 11**
- **Phase 2 CT4 Trial**
  - Multi-center, Randomized, Double-Blind, Placebo-Controlled Trial in Adult Condyloma Patients
  - 210 subjects; fully enrolled
- **Top-line Efficacy and Safety Data Expected in 2Q18**

# Financials & Milestones

A Clinical Stage Biotechnology Company Developing Oral Recombinant Vaccines Administered by Tablet rather than Injection





# Financial Highlights

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- **Reverse Merger with Aviragen completed in February 2018**
  - Cash\* as of December 31, 2017: ~\$30.0 million
  - Runway into 2H 2019
  
- **Listed on Nasdaq as VXRT**
  - 7.1 million shares outstanding

\*) Cash and cash equivalents, short term investments





# Near-Term Inflection Points

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## 1H 2018

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- Top-line efficacy results from Phase 2 CT4 trial (Teslexivir)
- Initiate norovirus titration study

## 2H 2018

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- Initiate Phase 2 norovirus challenge trial
- Initiate Phase 1 safety and immunogenicity study with bivalent norovirus vaccine

## 2019

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- File IND for HPV therapeutic vaccine
- Topline Results Phase 2 norovirus challenge trial
- Topline Results Phase 1 safety and immunogenicity study with bivalent norovirus vaccine
- Initiate Phase 1 HPV therapeutic vaccine study



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