## UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

#### FORM 8-K

#### **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 Date of Report (Date of earliest event reported): January 9, 2017

Aviragen Therapeutics, Inc. (Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-35285 (Commission File Number) 59-1212264 (IRS Employer Identification No.)

2500 Northwinds Parkway, Suite 100 Alpharetta, GA (Address of principal executive offices)

30009 (Zip Code)

Registrant's telephone number, including area code: (678) 221-3350

Not Applicable (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 (see General Instruction A.2. below):

- ☐ 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))

#### Item 7.01 Regulation FD Disclosure

Aviragen Therapeutics, Inc. is furnishing the investor presentation attached as Exhibit 99.1 to this report, which it may use from time to time in conversations with investors, analysts, and others beginning January 9, 2017.

The information in this report is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for purposes of Section 17 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference with any filing under the Securities Act of 1933, as amended, or the Exchange Act.

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

(d) Exhibits

99.1

Investor Presentation, dated January 2017

#### **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.

Aviragen Therapeutics, Inc.

Date: January 9, 2017

/s/ Joseph M Patti

Name: Joseph M Patti

Title: Chief Executive Officer and President

(Duly Authorized Officer)

#### EXHIBIT INDEX

Exhibit Number

Description

99.1 Investor Presentation, dated January 2017



#### Safe Harbor

This presentation contains forward-looking statements about Aviragen Therapeutics, Inc. and its business, business prospects, strategy and plans, including but not limited to statements regarding anticipated preclinical and clinical drug development activities and timelines and market opportunities. All statements other than statements of historical facts included in this presentation are forward looking statements. The words "anticipates," "may," "can," "plans," "believes," "estimates," "expects," "projects," "intends," "likely," "will," "should," "to be," and any similar expressions or other words of similar meaning are intended to identify those assertions as forward-looking statements. These forward-looking statements involve substantial risks and uncertainties that could cause actual results to differ materially from those anticipated. Factors that may cause actual results to differ materially from such forwardlooking statements include those identified under the caption "Risk Factors" in the documents filed by Aviragen Therapeutics with the Securities and Exchange Commission from time to time, including its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. Except to the extent required by applicable law or regulation, Aviragen Therapeutics undertakes no obligation to update the forward-looking statements included in this presentation to reflect subsequent events or circumstances.

#### Aviragen Therapeutics Overview

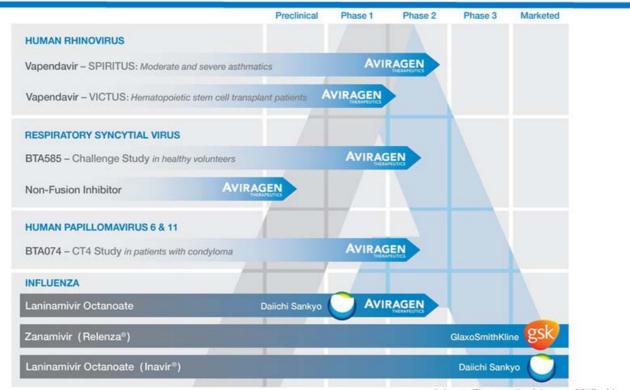
- Two Phase 2 clinical trial data readouts in next several weeks
  - ▶ BTA585 Phase 2a RSV challenge trial
  - Vapendavir Phase 2b SPIRITUS trial for rhinovirus in moderate and severe asthmatics
- Additional Phase 2 clinical programs in RV and HPV
- Strong IP portfolio
- Well capitalized

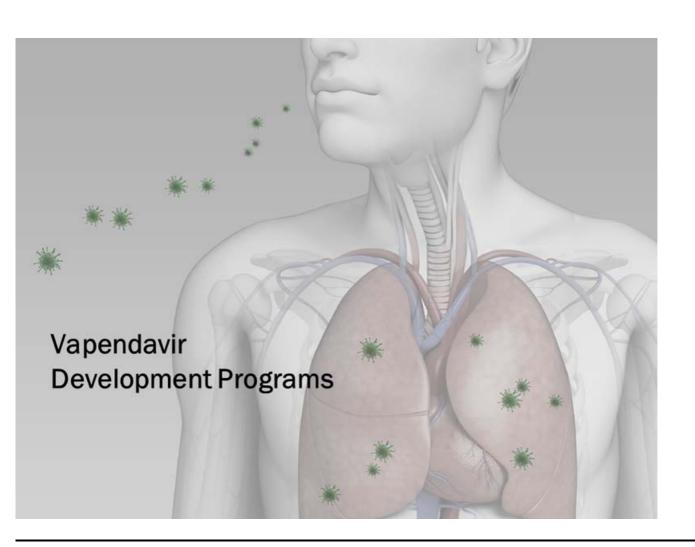
#### Developing

next generation direct-acting antivirals

to treat and prevent viral infections with limited therapeutics options

#### Advanced Pipeline of Direct-Acting Antivirals

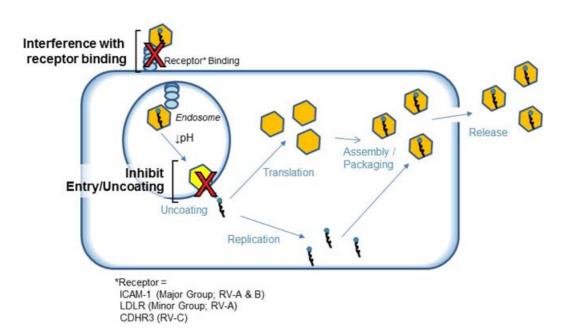




#### Vapendavir is Most Advanced Antiviral in Development for Rhinovirus (RV)

- Potent, broad spectrum, orally bioavailable picornavirus capsid binder
  - RV, EV-68, EV-71, and polio virus
- In development to treat RV upper and lower respiratory infections
- Clinical utility in multiple patient populations with clear unmet medical need
  - Moderate to severe asthmatics (adult and pediatric)
  - ► Hematopoietic stem cell transplant patients (adult and pediatric)
  - Chronic obstructive pulmonary disease (COPD) patients
- Dose dependent antiviral activity and favorable safety profile established in over 600 dosed individuals

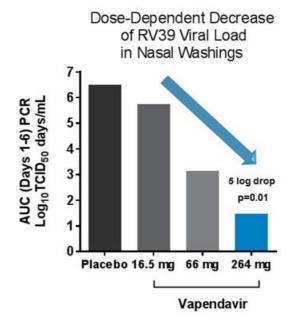
#### Antiviral Activity Through Capsid Binding



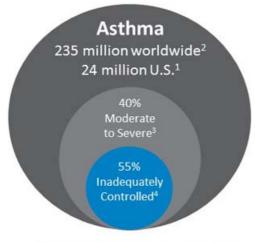
Jacobs 2013 Clin. Microbiol. Rev., 26 (1) 135 Bochkov 2015 PNAS 112 (17) 5485

#### Positive Proof-of-Concept Antiviral Data -Phase 2a RV Challenge Trial

Double-blind, placebo-controlled, randomized study in 41 healthy volunteers challenged intranasally with RV



#### RV Infections are Major Factor in the Loss of Asthma Control



\$55 billion spent annually

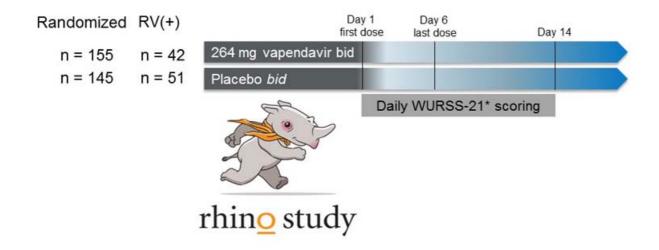
- Asthma is a major cause of morbidity and mortality in the U.S. 1,6
- 45-80% of asthma exacerbations are associated with respiratory viral infections, 60% are caused by RV 2-5
- Exacerbations are associated with 6,7:
  - ▶ 2 million emergency room visits annually
  - Progressive loss of lung function
  - ▶ Hospitalization

- 1. CDC: Asthma Fast Stats Web-Site

- 2. WHO Asthma: Fact Sheet 2013
  3. CDC Data
  4. Peters SP, et al. J Allergy Clin Immunol. 2007
  Jun;119(6):1454-61

- Dougherty RH et al. (2009) Clin Exp Allergy, 39 193-202
   Jamieson, et al. (2015) Chest Dec; 148(6):1508-16
   Kurai, et al. (2013) Front Microbiol. Oct 1;4:293
   Kistler et al (2007) JID Sept 15: 196: 817
   Khetsuriani et al. (2007) J Allergy Clin Immunol. Feb;119(2):314-21
   CDC FactSheet
   Rodrigo CG, et al. (2004) Chest; 125; 1081-1102

# Phase 2 Randomized, Double-Blind, Placebo Controlled Study in Asthmatic Adults with Symptomatic RV Infection



\* WURSS-21 = Wisconsin Upper Respiratory Symptom Survey

#### WURSS-21\* Measures Cold Severity

An illness-specific quality-of-life instrument, used to measure the severity of cold symptoms with higher scores indicating more symptoms and functional impairment

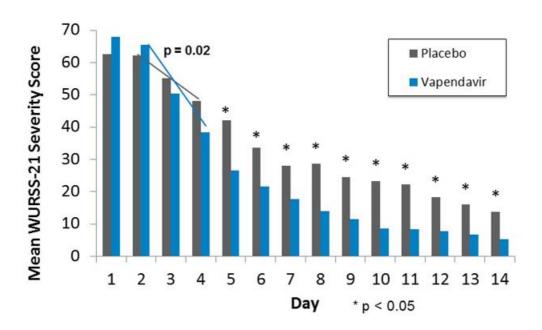
			Time	ļ.		ID:		
for each o	of the fo	llowing i	tems:					
	Not sick	Very		Mildly		Moderately		Severely
	0	1	2	3	4	5	6	7
today?	0	0	0	0	0	0	0	0
severity o	f your	cold sym	ptoms	over the I	ast 2	hours for e	ach	symptom
		Very mild		Mild		Moderate		Severe
12211111111111	0	1	2	3	4	5	6	7
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0
, how much	has yo	ur cold int					0	
	at all	mildly		Mildly		Moderately		Severe
	today? e severity c Do not this syr	Not sick 0 today? O e severity of your Do not have this symptom O O O O O O O O O O O O O O O O O O O	Not sick mildly of today? O O O O O O O O O O O O O O O O O O O	sick mildly 0 1 2 today? O O O e severity of your cold symptoms Do not have this symptom mild 0 1 2 O O O O O O O O O O O O O O O O O O O	Not   Not   Sick   Mildy   Mildy	Not sick   Very   Mildy   mi	Not sick   Well   Midly   Moderately	Not   Very   Mildly   Moderately

Wisconsin Upper Respiratory Symptom Survey - 21 --- Daily Symptom Report

	Not at all	Very mildly	Mildly		Moderately		Severely	
	0	1	2	3	4	5	6	7
Think clearly	0	0	0	0	0	0	0	0
Sleep well	0	0	0	0	0	0	0	0
Breathe easily	0	0	0	0	0	0	0	0
Walk, climb stairs, exercise	0	0	0	0	0	0	0	0
Accomplish daily activities	0	0	0	0	0	0	0	0
Work outside the home	0	0	0	0	0	0	0	0
Work inside the home	0	0	0	0	0	0	0	0
Interact with others	0	0	0	0	0	0	0	0
Live your personal life	0	0	0	0	0	0	0	0

<sup>\*</sup> Walter, MJ et al. (2008) Eur Respir J; 32: 1548-1554

#### Statistically Significant Reduction in the Severity of Cold Related Symptoms

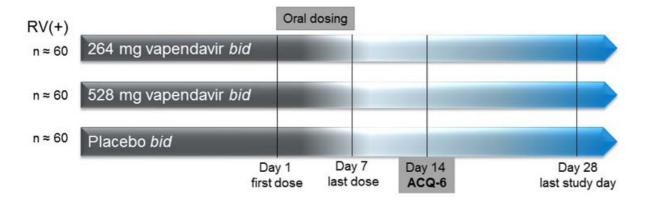


#### Favorable Results on the Primary and Secondary Endpoints

- Statistically significant reduction in the severity of cold related symptoms
  - ▶ Days 2-4 (p=0.02)\* primary endpoint
  - ▶ Days 2-14 (p=0.001)
- Strong trends on secondary endpoints
  - Change in the ACQ-5
  - Smaller decrease in FEV1
  - Reduced daily asthma reliever use
- Favorable safety profile in 263 patients
  - The most common AE was headache (≤5%)
  - No serious adverse events were reported

#### Phase 2b SPIRITUS Trial Design

Multi-center, randomized, double-blind, placebo-controlled dose-ranging study in moderate-to-severe adult asthmatics with symptomatic RV infection and a history of asthma worsening or exacerbation with a cold/upper respiratory infection



#### Asthma Control Questionnaire 6 (ACQ-6)

#### Asthma Control Questionnaire

Circle the number of the response that best describes how you have been during the past week.

1.	On average, during the past week, how often were you woken by your asthma during the night?
2.	On average, during the past week, how bad were your asthma symptoms when you woke up in the morning?
3.	In general, during the past week, how limited

- were you in your activities because of your asthma?
- 4. In general, during the past week, how much shortness of breath did you experience because of your asthma?

- Never
   Hardly Ever
   A few times
   Several times
   Many times
   A great many times
   Unable to sleep
   because of asthma
- 0 No symptoms
  1 Very mild symptoms
  2 Mild symptoms
  3 Moderate symptoms
  4 Quite severe symptoms
  5 Severe symptoms
  6 Very severe symptoms

- 0 Not limited at all
- Very slightly limited Slightly limited Moderately limited
- Very limited Extremely limited
- Totally limited
- 0 None
- 1 Avery little
- 2 A little
- 3 A moderate amount 4 Quite a lot
- 5 A great deal
- 6 Avery great deal

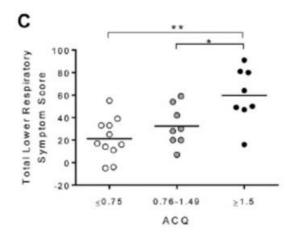
5.	In genera	I, during	the	past week,	how	much of
	the time .	Ed	done	2		

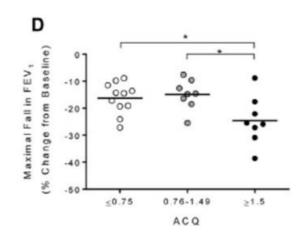
- 0 Not at all
- 1 Hardly any of the time 2 A little of the time
- 3 A moderate amount of the time
- 4 A lot of the time
- 5 Most of the time
- 6 All the time
- 6. To be completed by a member of the clinical staff:

FEV1 pre-bronchodilator:	0	>95% predicted
	1	95 - 90%
	2	89 - 80%
FEV1 predicted:	3	79 - 70%
	4	69 - 60%
	5	59 - 50%
FEV1% predicted:	6	<50% predicted

ACQ-6 score >1.5 represents asthma that is not well controlled

# Severity of Asthma Symptoms is Correlated with Asthma Control





Jackson DJ, et al. (2015) J Allergy Clin Immunol;136:497-500

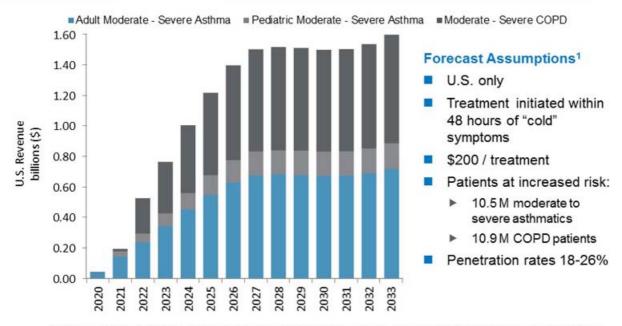
#### Primary and Secondary Endpoints

- Primary endpoint Asthma Control Questionnaire (ACQ-6)
  - Least square mean change from study day 1 to study day 14 in ACQ-6 total score
  - Primary efficacy analysis population is the intent-to-treat infected population
  - ▶ 80% power to detect a clinically meaningful difference between vapendavir treatment and placebo of 0.5 points
- Secondary endpoints
  - Lung function assessments such as FEV1
  - ▶ Incidence of moderate and severe asthma exacerbations
  - Daily β2-agonist use
- Top-line data in February

#### RV is a Common Cause of Exacerbations in Chronic Obstructive Pulmonary Disease (COPD)

- COPD is a major cause of chronic morbidity and mortality<sup>1</sup>
  - 10% of the U.S. population has COPD
  - Fourth leading cause of death
- Viruses account for 25-60% of exacerbations either alone or as copathogens<sup>2-4</sup>
- RV is the most frequently isolated virus from patients with acute exacerbation of COPD2-4
- Acute exacerbations adversely effect lung function, survival, risk of hospital admission/readmission, and quality of life5-8
- 1. Lopez AD, et al. (2006) Eur Respir J.;27(2):397-412
- Wu X, et al. (2014) Mol Biol Rep. Jul;41(7):4743-51
   Alfredo, et al. Nt (2007) J Chron Obstruct Pulmon Dis. Dec; 2(4): 477–483
- 4. Kurai, et al. (2013) Front Microbiol. Oct 1;4:293
- Seemungal TA et al. (1998) Am J Respir Crit Care Med.; 157(5 Pt 1):1418–14223
- Connors AF, et al. (1996) Am J Respir Crit Care Med.;154(4 Pt 1):959–967
   Donaldson GC, et al. (2002) Thorax.;57(10):847–852
- Almagro P, et al. (2006) Respir; Int Rev Thoracic Dis.;73(3):311–317

# Treatment of RV Infections Represents a \$1.5B+ Market Opportunity in the U.S.



<sup>1</sup>The forecasts and assumptions on this slide are from IMS Consulting Group and are estimates. Historical information is based on IMS' research of primary and secondary market sources dating between 2008 and 2015. Forecasts are based on clinical/regulatory timelines and certain other information provided by Aviragen Therapeutics. IMS expressly reserves all rights, including rights of copying, distribution and republication.

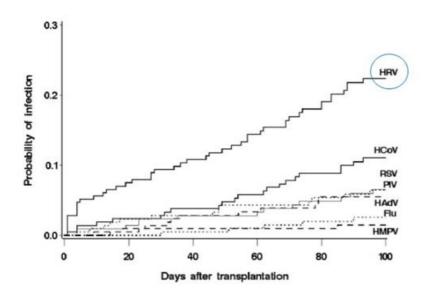
## Rhinovirus (RV) Infections in Hematopoietic Stem Cell Transplant (HSCT) Patients

#### Hematopoietic Stem Cell Transplant Patients

- Post transplant leaves patient susceptible to opportunistic infection
  - Lack of functional immunity
  - Infections are a common cause of death in HSCT patients
- 72,000 HSCT's performed per year in major markets
  - > 25 30% and growing in the U.S.
- RV is most prevalent virus leading to both upper respiratory tract infection (URTI) and lower respiratory tract infection (LRTI) among HSCT patients
  - ▶ Up to 27% of allogeneic HSCT patient will have a RV clinical episode during the first year following transplant¹
  - Duration of RV viral shedding is longest among viral pathogens in HSCT<sup>1</sup>
  - ▶ High mortality rate (similar to RSV or PIV) from LRTI of up to 40%²

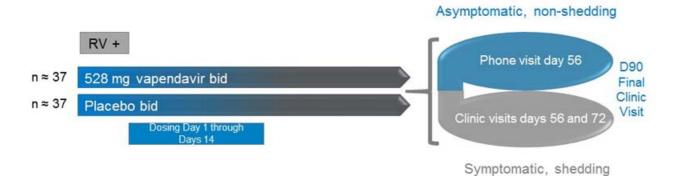
<sup>1</sup>Boeckh et al at Fred Hutchison <sup>2</sup>Seo et al at Fred Hutchison, *Biol Blood Marrow Transplant* 19 (2013) S167-S177, and Boeckh verbal report, and Jacobs et al at NY Presbyterian/Weill Cornell - unpublished manuscript

## RV is the Most Common Respiratory Viral Infection Among HSCT Patients



Milano et al, (2010) Blood, 115: 2088-94

#### Phase 2 Trial: Treatment of RV Infections in Hematopoietic Stem Cell Transplant Patients



#### Phase 2 Trial: Vapendavir Treatment of RV Infections in HSCT Patients

- Allogeneic or autologous transplant within last 6 months or HSCT patients at any timepoint post transplant with chronic graft vs host disease requiring systemic treatment
- Primary endpoint
  - Time-weighted average change from baseline (day 1) to end of treatment visit (day 14) in RV viral load (RNA log10 copies/mL)
- Secondary endpoints
  - Rate of progression of RV URTI to LRTI
  - Duration of RV shedding in HSCT subjects
  - Proportion with hospitalization and hospitalization time
  - Mortality



#### BTA585 Overview

- In development to treat potentially life-threatening RSV infections in children
  - RSV is the most common cause of acute lower respiratory tract infection
  - RSV infection in early childhood is associated with wheezing later in life
  - Current standard of care for RSV infected children is limited to supportive care
- >2.5 million children under the age of 5 require medical attention annually in the U.S. for RSV infections<sup>1,2</sup>
  - ▶ 61% of the treated children are between 2 and 5 years of age
- Potential for label expansion in the elderly and other high-risk patient populations

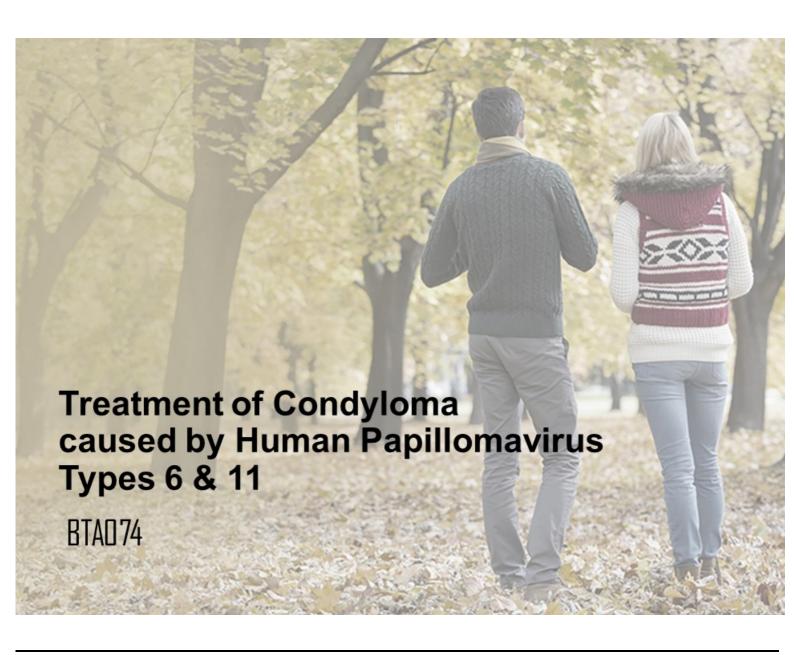
<sup>1</sup>Hall *et al.* (2009) *NEJM*;360:588-98 <sup>2</sup>http://www.childstats.gov/americaschildren/tables/pop1.asp

# Positive Phase 1a and 1b Safety and PK Results of BTA585

- Phase 1a Single ascending oral doses (50, 100, 200, 400, 500, 800 mg; 100 mg food effect)
  - ▶ 10 subjects per cohort (7 active, 3 placebo)
- Phase 1b Multiple ascending oral doses (100, 400, and 600 mg bid) for seven consecutive days
  - ▶ 12 subjects per dosing cohort (8 active, 4 placebo)
- BTA585 was generally well tolerated at all dose levels (n = 85)
  - No severe drug-related adverse events, no SAEs, no premature study terminations
  - No drug-related clinically-significant changes in ECGs or clinical laboratory values
  - Most common adverse events were headache, nausea, and chromaturia
  - Antiviral levels rapidly reached in the plasma and nasal wash fluid
- No adverse food effect on PK

#### Phase 2a RSV Challenge Study

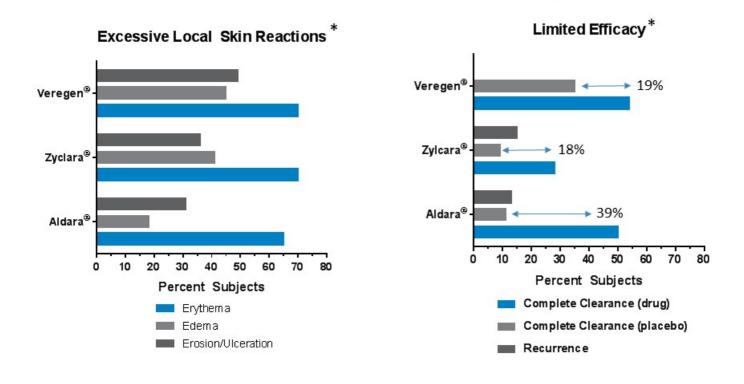
- Randomized, double-blind, placebo controlled trial to evaluate safety, PK, and antiviral activity of BTA585 in healthy adult volunteers challenged intranasally with RSV
  - 400 or 600 mg BTA585 twice daily (n = 20/cohort) for seven days
  - Placebo twice daily for seven days (n = 20)
- Primary endpoint
  - AUC of RSV-A Memphis 37b viral load as determined by RT-qPCR assay of nasal wash
- Secondary endpoints
  - Mucus weight, clinical symptoms of RSV infection, safety and tolerability
- Current regulatory status
  - ► FDA Fast Track Designation for BTA585
  - FDA placed IND on clinical hold
    - Response to clinical hold planned for Q1 2017



#### BTA074: First-in-Class Direct-Acting Antiviral Treatment for Condyloma

- HPV infection
- Most frequent sexually transmitted viral disease worldwide
- Anogenital warts are the most common clinical manifestation of HPV infection
- Highly infectious and transmitted to partner approximately 65% of the time
- Current treatments are suboptimal
  - Current therapies do not treat the HPV infection directly
  - Topical treatments exhibit significant local skin toxicities and have low clearance rates
  - Physician-applied treatments involve multiple visits and often painful procedures
- BTA074 inhibits HPV replication by binding the E2 protein
- BTA074 was safe and well tolerated in subjects treated twice daily for six weeks
  - n=14 BTA074; n=8 placebo
  - Overall response rate for BTA074 was 64% compared to 38% for placebo
  - No significant local skin toxicities

## Current Topical Treatments for Condyloma are Suboptimal

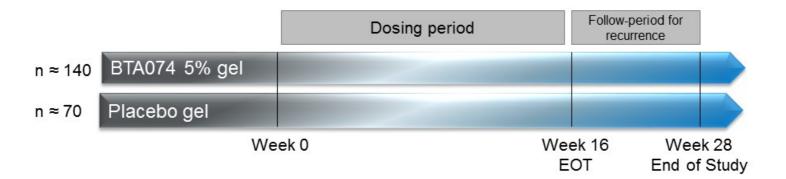


<sup>\*</sup> FDA Label (dosing up to 16 weeks)

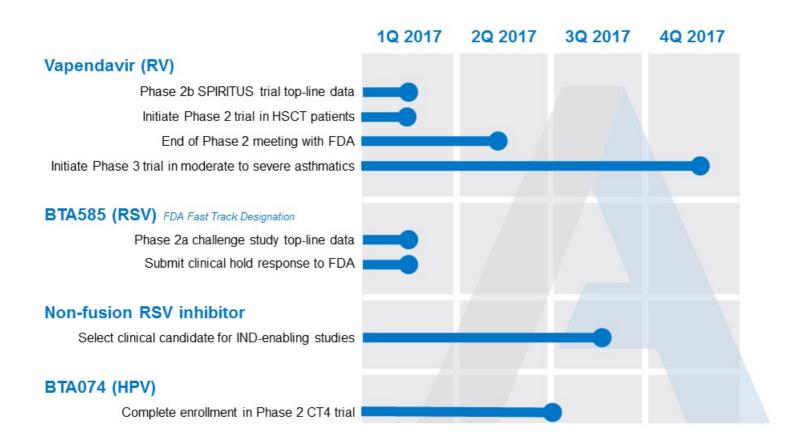
#### Phase 2 CT4 Trial

# Multi-center, randomized, double-blind, placebo-controlled trial in adult condyloma (anogenital warts) patients

- Primary Objective: Pharmacokinetics, safety and tolerability with special focus on local skin reactions
- Secondary Objective (efficacy): Complete clearance of baseline anogenital warts at end of treatment (EOT)
- Dosing: twice daily for up to 16 weeks



## **Exciting Year of Clinical Progress**



# Financial Strength for Effective Execution

	September 30, 2016
NASDAQ Symbol	AVIR
Commons Shares Outstanding (primary)	38.6 M
Cash and short-term investments	\$58.3 M

#### Aviragen Therapeutics Overview

- Two Phase 2 clinical trial data readouts in next several weeks
  - BTA585 Phase 2a RSV challenge trial
  - Vapendavir Phase 2b SPIRITUS trial for rhinovirus in moderate and severe asthmatics
- Additional Phase 2 clinical programs in RV and HPV
- Strong IP portfolio
- Well capitalized

# Developing next generation direct-acting antivirals to treat and prevent viral infections with limited therapeutics options

