

September 14, 2016

Aviragen Therapeutics Reports Fourth Quarter and Fiscal Year 2016 Financial Results

Conference Call to be Held Today at 4:30 P.M. ET

ATLANTA, Sept. 14, 2016 (GLOBE NEWSWIRE) -- Aviragen Therapeutics, Inc. (NASDAQ:AVIR) today announced its financial results for the fourth quarter and 2016 fiscal year ended June 30, 2016, and also provided an update on recent corporate and clinical developments.

"Over the last twelve months we have made significant advances with our three next generation direct-acting antivirals that address serious infections with limited therapeutic options. Enrollment is 90% complete in the SPIRITUS Phase 2b trial of vapendavir for the treatment of human rhinovirus infections in moderate and severe asthmatic patients, and we look forward to announcing top-line data from the trial around the end of the year. We also announced today comparable bioavailability results for two new formulations of vapendavir that are appropriate for pediatrics, Phase 3 and commercial scale-up," remarked Joseph M. Patti, PhD, President and Chief Executive Officer of Aviragen Therapeutics.

"For our RSV program, we were pleased to resume enrollment in the Phase 2a RSV challenge study of BTA585, a RSV fusion inhibitor, following a short delay. We anticipate that top-line viral load data will be available around the end of the year. Finally, we strengthened our balance sheet with \$20 million of non-dilutive cash from the partial monetization of our Inavir[®] royalty stream. This positions us well to aggressively advance our pipeline of clinical-stage antivirals."

Recent Corporate Highlights

Vapendavir Phase 1 Bioavailability Trial. The Company reported today that it has successfully completed a single-center, open-label, bioavailability study in healthy volunteers assessing the comparability of the vapendavir phosphate salt capsule, and two new formulations of vapendavir free base in the forms of an oral suspension and tablet. Forty-six (46) subjects completed three periods of oral dosing and the plasma pharmacokinetic results indicated that the bioavailability of the oral suspension and tablet formulation were comparable to the capsule form of vapendavir which is currently being used in the Phase 2b SPIRITUS trial. The oral suspension formulation is intended to enable the conduct of future pediatric trials, and the tablet formulation will allow an increase in manufacturing scale appropriate for Phase 3 trials and commercial development.

Resumed Enrollment in the Phase 2a Efficacy Study of BTA585 for the Treatment of Respiratory Syncytial Virus (RSV) Infections. In July 2016, the Company reported that, subsequent to receiving approval from the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), enrollment has resumed in the double-blind, placebo-controlled, Phase 2a trial that is designed to evaluate the safety, pharmacokinetics, and antiviral activity of orally-dosed BTA585 in healthy volunteers challenged intranasally with RSV. In May, the Company announced that it was voluntarily delaying enrollment in the trial to investigate an aberrant lab result from a subject that was coupled with transient ECG changes. The Company also reported in July that it expects to submit a complete response to the U.S. Food and Drug Administration (FDA) in the first quarter of calendar 2017 regarding the clinical hold of BTA585's investigational new drug (IND) application. The clinical hold was related to the aberrant lab report.

Entered into a License and Sponsored Research Agreement with Georgia State University Research Foundation (GSURF). In July 2016, the Company announced that it entered into an exclusive, worldwide license and sponsored research agreement with GSURF to jointly develop and commercialize RSV replication inhibitors discovered by Professor Richard Plemper and his team in the Institute for Biomedical Sciences (IBMS) at Georgia State University.

Financial Results for the Three Month Period Ended June 30, 2016

The Company reported net loss of \$7.0 million for the three month period ended June 30, 2016, as compared to a net loss of \$19.9 million in the same quarter of the prior fiscal year. Basic and diluted net loss per share was \$0.18 for the three month period ended June 30, 2016, as compared to a basic and diluted net loss per share of \$0.55 in the same period of 2015. The major components of net loss in both periods are as follows:

Revenue decreased to \$0.6 million for the three month period ended June 30, 2016 from \$4.1 million in the same period in 2015 due to a \$3.7 million reduction in royalty revenues resulting from lower government stockpiling sales of the flu product

Relenza[®].

Research and development expense increased to \$6.0 million for the three month period ended June 30, 2016 from \$5.2 million in the same period in 2015. The increase reflected higher clinical costs related to the initiation of a Phase 2a challenge trial investigating the use of BTA585 as a treatment for RSV, and higher expenses for producing clinical supplies of BTA074 for its Phase 2 clinical trial for the treatment of condyloma caused by human papillomavirus (HPV) types 6 and 11.

In June 2015, the Company recorded a \$17.6 million non-recurring, in-process research and development (IPR&D) expense in connection with the acquisition of Anaconda Pharma. There was no IPR&D expense recorded in 2016.

General and administrative expense was \$1.3 million for both the three month period ended June 30, 2016 and the same period in 2015, as higher consulting and professional fees were fully offset by lower employee compensation costs.

Accounting Treatment for the Sale of Royalty Interest to HealthCare Royalty Partners (HCRP):

In April 2016, Aviragen sold a portion of its interest in future royalty payments related to Inavir[®], a flu product marketed in Japan by Daiichi Sankyo, to HCRP for gross proceeds of \$20 million. As a result of a limit on the amount of royalties that HCRP can earn under the arrangement, U.S. accounting rules require Aviragen to account for this transaction under the debt accounting method. Aviragen has no obligation to pay any amounts to HCRP other than to pass through to HCRP its share of royalties as they are received from Daiichi Sankyo. In addition, although the royalty payments were sold to HCRP, the debt accounting rules require the Company to continue to recognize HCRP's share of the royalties as non-cash revenue in its Statement of Operations and to record the proceeds of \$20 million, net of expenses, as a liability on its Balance Sheet. As royalties are passed through Aviragen to HCRP under this arrangement, the liability is reduced. Non-cash implied interest expense will be recognized on the liability. In the fourth quarter of 2016, Aviragen recognized \$0.2 million of non-cash royalty revenue and \$0.3 million in non-cash interest expense related to this arrangement.

The Company held \$69.0 million in cash, cash equivalents, and short-term investments as of June 30, 2016.

Financial Results for the Fiscal Year Ended June 30, 2016

The Company reported a net loss of \$25.4 million for its fiscal year ended June 30, 2016, as compared to a net loss of \$19.1 million in the prior year. The \$6.3 million increase in net loss from the prior year was primarily due to a \$15.5 million decrease in revenues reflecting a reduction of \$7.0 million in royalty revenue, principally related to Relenza[®], and \$8.5 million in lower service revenue, due to the cancellation of the BARDA contract in 2014. The net loss comparison was also impacted by a \$6.5 million increase in research and development expense, largely related to higher costs for the Company's vapendavir and BTA585 clinical development programs. These items were partially offset by the impact of a non-recurring \$17.6 million IPR&D expense recorded in fiscal 2015 related to the acquisition of Anaconda Pharma. Basic and diluted net loss per share was \$0.66 for the fiscal year ended June 30, 2016, as compared to a basic and diluted net loss per share of \$0.54 in the prior year.

Conference Call and Webcast Information

Aviragen Therapeutics will host a conference call today to review these fourth quarter and fiscal year 2016 financial results, as well as provide a general update on the Company, via a webcast and conference call at 4:30 p.m. ET. To access the conference call, please dial (877) 312-5422 (domestic) or (253) 237-1122 (international) and refer to conference ID number 74878442. A live audio webcast of the call and the archived webcast will be available in the Investors section of the Company's website at http://www.aviragentherapeutics.com.

About Aviragen Therapeutics

Aviragen Therapeutics is focused on the discovery and development of the next generation of direct-acting antivirals to treat infections that have limited therapeutic options and affect a significant number of patients globally. The Company has three product candidates in active clinical development: These include vapendavir, an oral treatment for human rhinovirus (HRV) upper respiratory infections in moderate-to-severe asthmatics currently being evaluated in the Phase 2b SPIRITUS trial; BTA585, an oral fusion protein inhibitor that has received Fast Track designation by the U.S. FDA, in Phase 2 development for the treatment and prevention of respiratory syncytial virus (RSV) infections; and BTA074, a topical antiviral treatment in Phase 2 development for condyloma caused by human papillomavirus types 6 & 11. For additional information about the Company, please visit www.aviragentherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of

1995 that involve known and unknown risks and uncertainties concerning Aviragen Therapeutics' business, operations and financial performance. Any statements that are not of historical facts may be deemed to be forward-looking statements, including the timing of top-line data readouts on our Phase 2 HRV and RSV programs and the timing of submitting a complete response to the FDA. Various important factors could cause actual results, performance, events or achievements to materially differ from those expressed or implied by forward-looking statements, including: the Company, the U.S. Food and Drug Administration (FDA) or a similar regulatory body in another country, a data safety monitoring board, or an institutional review board delaying, limiting, suspending or terminating the clinical development of any of the Company's product candidates at any time for a lack of safety, tolerability, regulatory or manufacturing issues, or any other reason whatsoever; the Company's ability to secure, manage and retain qualified third-party clinical research, data management and contract manufacturing organizations upon which it relies to assist in the design, development, implementation and execution of the clinical development of all its product candidates and those organizations' ability to successfully execute their contracted responsibilities; the Company's ability to comply with applicable government regulations in various countries and regions in which we are conducting, or expect to conduct, clinical trials; and other cautionary statements contained elsewhere in this press release and in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission. There may be events in the future that the Company is unable to predict, or over which it has no control, and the Company's business, financial condition, results of operations and prospects may change in the future. The Company may not update these forward-looking statements more frequently than quarterly unless it has an obligation under U.S. Federal securities laws to do so.

AVIRAGEN THERAPEUTICS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in millions, except per share amounts)

	June 30, 2016		June 30, 2015	
	(au	ıdited)	(aı	udited)
ASSETS				
Current assets:				
Cash and cash equivalents	\$	49.7	\$	44.7
Short-term investments		19.3		12.9
Accounts receivable, net of allowance		0.7		12.6
Prepaid and other current assets		2.7		0.6
Total current assets		72.4		70.8
Non-current assets:				
Long-term investments		-		7.9
Property and equipment, net		0.3		0.2
Deferred tax asset			- ——	0.5
Total non-current assets		0.3		8.6
Total assets	\$	72.7	\$	79.4
Current liabilities:				
Accounts payable	\$	3.9	\$	1.9
Accrued expenses		3.6		5.4
Short term note payable		0.4		0.2
Contract payables (BARDA)		-		1.0
Liabilities related to sale of future royalties, net of deferred financing costs		1.3		-
Deferred tax liability		-		0.5
Total current liabilities		9.2		9.0
Non-current liabilities:				
Long term note payable, net of current portion		0.3		8.0
Liabilities related to sale of future royalties, net of deferred financing costs and current portion		16.8		-
Other long-term liabilities, net of current portion		0.2		0.1
Total liabilities		26.5		9.9
Stockholders' equity:				
Preferred stock, \$0.10 par value; 5,000,000 shares authorized and none issued and outstanding as of June 30, 2016 and 2015		-		-
Common stock, \$0.10 par value; 200,000,000 shares authorized 38,640,487 and 38,609,086 shares issued and				

outstanding at June 30, 2016 and June 30, 2015, respectively	3.9	3.9
Additional paid-in capital	157.6	155.6
Accumulated other comprehensive income	19.0	18.9
Accumulated deficit	(134.3)	(108.9)
Total stockholders' equity	46.2	69.5
Total liabilities and stockholders' equity	\$ 72.7	\$ 79.4

AVIRAGEN THERAPEUTICS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share amounts) (unaudited)

	Three Months Ended June 30,			Fiscal Year Ended June 30,			
		2016	2015		2016	2015	
Revenue:			-				
Royalty revenue and milestones	\$	0.4 \$	4.1	\$	9.1 \$	16.1	
Non-cash royalty revenue related to sale of future royalties		0.2	-		0.2	-	
Revenue from services		-			-	8.5	
Total revenue		0.6	4.1		9.3	24.6	
Operating expense:							
Cost of revenue		-	-		-	3.6	
Research and development		6.0	5.2		26.3	19.8	
In-process research and development (IPR&D)		-	17.6		-	17.6	
General and administrative		1.2	1.3		8.0	9.4	
Foreign exchange loss (gain)		0.1	-		0.2	(6.5)	
Loss on disposal of assets		-			-	0.2	
Total operating expense		7.3	24.1		34.5	44.1	
Loss from operations		(6.7)	(20.0)		(25.2)	(19.5)	
Non-operating income:							
Non-cash interest expense on liability related to sale of future royalties		(0.3)	-		(0.3)	-	
Interest income (expense), net		-	0.1	0.1		0.3	
Total non-operating income (expense)		(0.3)	0.1		(0.2)	0.3	
Loss before tax		(7.0)	(19.9)		(25.4)	(19.2)	
Income tax benefit		-			-	0.1	
Net loss	\$	(7.0) \$	(19.9)	\$	(25.4) \$	(19.1)	
Basic loss per share	\$	(0.18)	(0.55)	\$	(0.66) \$	(0.54)	
Diluted loss per share	\$	(0.18) \$	(0.55)	\$	(0.66) \$	(0.54)	
Basic weighted-average shares outstanding		,640,487	36,143,337			35,360,841	
Diluted weighted-average shares outstanding	38	,640,487	36,143,337		38,635,452	35,360,841	

Contacts:

Mark Colonnese

Executive Vice President and Chief Financial Officer

Aviragen Therapeutics, Inc.

(678) 221-3381

mcolonnese@aviragentherapeutics.com

Beth DelGiacco

Stern Investor Relations, Inc.

(212) 362-1200

beth@sternir.com



Source: Aviragen Therapeutics, Inc.

News Provided by Acquire Media