November 9, 2016

Aquinox Pharmaceuticals Announces Third Quarter 2016 Financial Results

VANCOUVER, British Columbia, Nov. 09, 2016 (GLOBE NEWSWIRE) -- Aquinox Pharmaceuticals, Inc. ("Aquinox") (NASDAQ:AQXP), a clinical-stage pharmaceutical company discovering and developing targeted therapeutics in disease areas of inflammation and immuno-oncology, today provided a corporate update and reported financial results for the third quarter ending September 30, 2016.

"In September we commenced enrollment in the LEADERSHIP 301 Phase 3 clinical trial with AQX-1125 in interstitial cystitis/bladder pain syndrome (IC/BPS) and we are continuing to add sites and jurisdictions to the trial as planned," said David Main, President & CEO of Aquinox. "Our objective remains to release top-line data from this first Phase 3 trial in the fourth quarter of 2017 and we will provide an enrollment update when we release year-end 2016 financial results in early 2017. Our recent financing, together with cash on-hand, positions us well to advance AQX-1125 and broaden our clinical and research activities."

The LEADERSHIP 301 Phase 3 trial is anticipated to enroll a minimum of 300 female patients, up to a maximum of 600 patients including males, at clinical research centers in Canada, the United States and Europe. LEADERSHIP 301 will be conducted as a three arm, multicenter, randomized, double-blind, placebo-controlled, Phase 3 clinical trial investigating the ability of 200 mg and 100 mg oral, once daily AQX-1125 to reduce bladder pain in patients with IC/BPS. The primary endpoint of the LEADERSHIP 301 trial is to measure the difference in the change from baseline in the maximum daily bladder pain score based on an 11-point numeric rating scale (NRS) at twelve weeks recorded by electronic diary. The trial will also include an open-label extension of up to 40 weeks affording all participating patients the opportunity for treatment with AQX-1125. Secondary endpoints will include urinary symptoms, including frequency and nighttime awakenings, as well as measures of quality of life. For more information on the LEADERSHIP 301 trial, please visit www.clinicaltrials.gov.

Business Highlights

Appointment of New Chief Medical Officer. On October 3, 2016, Aquinox announced the appointment of Dr. Barbara Troupin, M.D. as Chief Medical Officer and Vice President, Clinical Development. From Aquinox's offices in San Bruno, California, Dr. Troupin will lead overall clinical and medical affairs strategies for Aquinox's ongoing programs as well as future development and potential commercialization plans. Dr. Troupin brings extensive clinical leadership experience from previous roles with Apricus Bioscience, Inc. and VIVUS, Inc. Dr. Troupin received her Doctorate in Medicine in 1995 from the University of Pennsylvania School of Medicine where she also completed her Master's in Business Administration, with an emphasis in health care management, from the Wharton School of Business.

Closing of $75.4 Million Public Offering. On September 23, 2016, Aquinox completed an underwritten public offering of 6,152,500 shares of its common stock, including 802,500 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price to the public of $12.25 per share. The gross proceeds from the offering (inclusive of the option exercise), before underwriting discounts and commissions and offering costs, were $75.4 million. Aquinox intends to use the net proceeds from this offering to fund additional clinical development of AQX-1125 and to fund pre-commercial and market assessment activities, research and development costs to advance its pipeline of preclinical product candidates and for working capital and other general corporate purposes. Leerink Partners, Canaccord Genuity and Guggenheim Securities acted as joint book-running managers for the offering. Needham & Company acted as lead manager.

Summary of Financial Results

Cash Position. Cash, cash equivalents, short-term and long-term investments totaled $162.6 million as of September 30, 2016, compared to $112.9 million as of December 31, 2015. The increase was primarily the result of the public offering of common stock in September 2016 partly offset by the ongoing expenditures related to our LEADERSHIP 301 clinical trial in IC/BPS. Aquinox expects its cash, cash equivalents, short-term and long-term investments to be sufficient to complete the LEADERSHIP 301 trial as well as additional clinical development, manufacturing, preclinical, and pre-commercial and market assessment activities.

R&D Expenses. Research and development expenses for the third quarter of 2016 increased to $6.1 million from $3.7

million in the third quarter of 2015. This increase was primarily driven by increased clinical activities related to the initiation of our LEADERSHIP 301 clinical trial.

G&A Expenses. General and administrative expenses for the third quarter of 2016 increased to $2.1 million from $1.2 million in the third quarter of 2015. This increase was primarily driven by higher personnel related costs and the establishment of an office in San Bruno, CA.

Net Loss. Net loss for the third quarter of 2016 was $8.1 million compared to a net loss of $5.0 million for the third quarter of 2015. This increase was primarily driven by increased operating expenditures related to the initiation of our LEADERSHIP 301 clinical trial.

About Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS)

IC/BPS is a chronic inflammatory bladder disease characterized by pelvic pain and increased urinary urgency and/or frequency. For many sufferers, these symptoms are severe and adversely affect all major aspects of their lives, including overall physical and emotional health, employment, social and intimate relationships, and leisure activities. While the cause of the disease remains largely unknown, erosion of the bladder lining is thought to be a significant contributor. IC/BPS is estimated to affect millions of people in the United States and around the world. Most IC/BPS patients continue to suffer this debilitating condition, despite treatment with existing therapies. Most current therapies and those in development are focused solely on symptomatic relief of IC/BPS. Aquinox believes new and innovative therapies that target the underlying disease in order to reduce the chronic pain and urinary symptoms are needed.

About AQX-1125

AQX-1125, Aquinox's lead drug candidate, is a small molecule activator of SHIP1, which is a regulating component of the PI3K cellular signaling pathway. By increasing SHIP1 activity, AQX-1125 accelerates a natural mechanism that has evolved to maintain homeostasis of the immune system and reduce immune cell activation and migration to sites of inflammation. AQX-1125 has demonstrated preliminary safety and favorable drug properties for once daily oral administration in multiple preclinical studies and seven completed clinical trials.

About Aquinox Pharmaceuticals, Inc.

Aquinox Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company discovering and developing targeted therapeutics in disease areas of inflammation and immuno-oncology. Aquinox's lead drug candidate, AQX-1125, is a small molecule activator of SHIP1 suitable for oral, once daily dosing. With a successful Phase 2 clinical trial completed in 2015, Aquinox initiated a Phase 3 trial (LEADERSHIP 301) with AQX-1125 for treatment of IC/BPS in September of 2016. Aquinox has a broad intellectual property portfolio and pipeline of preclinical drug candidates that activate SHIP1. For more information, please visit www.aqxpharma.com.

Cautionary Note on Forward-looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, relating to the planning for, and timing of, our ongoing and planned clinical trials in IC/BPS; potential commercialization of, and market opportunities for, AQX-1125; and our projected cash position. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks and uncertainties related to: our ability to enroll patients in our clinical trials at the pace that we project; as an organization, we have never conducted a pivotal clinical trial before; the size and growth of the potential markets for AQX-1125 or any future product candidates and our ability to serve those markets; our ability to obtain and maintain regulatory approval of AQX-1125 or any future product candidates; reaching agreement on design of pivotal trials with regulatory authorities and our expectations regarding the potential safety, efficacy or clinical utility of AQX-1125 or any future product candidates. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. More information about the risks and uncertainties faced by Aquinox is contained in the company's Quarterly Report on Form 10-Q for the third quarter ended September 30, 2016 filed with the Securities and Exchange Commission. Aquinox disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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AQUINOX PHARMACEUTICALS, INC.

Condensed consolidated balance sheets
(Unaudited)
(In thousands of U.S. dollars)

	SEPTEMBER 30, 2016	DECEMBER 31, 2015
Assets		
Cash, cash equivalents, short-term and long-term investments	$ 162,602	$ 112,940
Other current assets	676	314
Other long-term assets	791	89
Total assets	$ 164,069	$ 113,343
Liabilities		
Current liabilities	$ 8,564	$ 4,792
Non-current liabilities	142	131
Total liabilities	$ 8,706	$ 4,923
Stockholders' equity	155,363	108,420
Total liabilities and stockholders' equity	$ 164,069	$ 113,343

AQUINOX PHARMACEUTICALS, INC.

Condensed consolidated statements of operations
(Unaudited)
(In thousands of U.S. dollars, except per share and share amounts)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2016	2015	2016	2015
Operating expenses				
Research and development	$ 6,134	$ 3,687	$ 20,250	$ 11,873
General and administrative	2,149	1,230	5,932	3,874
Total operating expenses	8,283	4,917	26,182	15,747
Other income (expenses)	137	(118)	424	(450)
Net loss before income taxes	(8,146)	(5,035)	(25,758)	(16,197)
Net loss	$ (8,146)	$ (5,035)	$ (25,758)	$ (16,197)
Net loss per common stock - basic and diluted	$ (0.46)	$ (0.43)	$ (1.48)	$ (1.46)
Basic and diluted weighted average number of common stock outstanding	17,690,362	11,841,147	17,372,616	11,096,369

Primary Logo

Source: Aquinox Pharmaceuticals, Inc.