November 14, 2018

AIT Therapeutics Reports Financial Results for Fiscal Second Quarter 2019

PMA filing for treatment of PPHN expected in calendar second quarter 2019

Pivotal Bronchiolitis trial to initiate in calendar fourth quarter 2019 in the US

Positive clinical and pre-clinical data presented at several scientific conferences

Pilot "at-home" NTM trial to initiate in calendar 2019 in the US

Enhanced team with appointment of Douglas J. Beck as CFO and others in key operational areas

Conference Call scheduled for Wednesday, November 14 at 4:30 pm Eastern Time

GARDEN CITY, N.Y. and REHOVOT, Israel, Nov. 14, 2018 (GLOBE NEWSWIRE) -- AIT Therapeutics, Inc. (OTC: AITB), a clinical-stage medical device and biopharmaceutical company focused on developing inhaled Nitric Oxide (NO) for the treatment of patients with respiratory conditions including serious lung infections and pulmonary hypertension, today announced its financial results for its second fiscal quarter ended September 30, 2018.

Recent Corporate Highlights:

- Presented the full data set of its NO-BRO study in infants under 12 months of age hospitalized with bronchiolitis at the European Respiratory Society (ERS) in September in Paris, France, which showed a 23-hour reduction in the hospital length-of-stay in patients treated with NO + standard-of-care (SOC) versus SOC alone (59.2 vs. 82.2 hours, respectively, p=0.085: Welch's t-test). The study was a multicenter, randomized, double-blind, placebo-controlled study comparing the efficacy of intermittent 160 ppm NO (five 30-minute treatments per day for up to 5 days) plus standard-of-care (SOC) (typically oxygen and hydration) against SOC alone. The study evaluated 67 infants diagnosed with bronchiolitis and admitted to 6 hospitals across Israel. In addition to the positive primary endpoint results, the study achieved positive secondary endpoint results and demonstrated a clean safety profile, with no serious adverse events associated with NO therapy.

- Presented in vitro results of high-dose gaseous NO as an antibacterial agent in the treatment of Mycobacterium abscessus complex (MABSC) at both the ERS and at the North American Cystic Fibrosis Conference. The study investigated several multidrug-resistant clinical isolates of *M. abscessus* to determine the sensitivity to NO, which was delivered using a custom designed NO delivery system at specific concentrations. Several multidrug-resistant clinical isolates of *M. abscessus* showed significant susceptibility to NO treatment at 250 ppm. The Company plans future studies to assess NO activity in combination with commonly used antibiotics for NTM lung

infection.

- Continued positive discussions with the FDA on the potential regulatory pathway for approval for the Company's NO generator and delivery system in the treatment of persistent pulmonary hypertension of the newborn (PPHN). The Company will move forward with a Premarket Approval (PMA) filing with a planned submission to the FDA in the second calendar quarter of 2019. Typically, the FDA responds within 180 days to a PMA submission.

- Strengthened management team with the appointment of Douglas J. Beck as Chief Financial Officer. Mr. Beck joins AIT with decades of experience having served as CFO for several companies, including publicly-traded biotechnology companies. The Company also added executives in the key operational areas of device development and clinical operations.

- Increased the Company's financial flexibility by entering into a $20 million common stock purchase agreement with Lincoln Park Capital ("Lincoln Park"), a well-known institutional investment fund.

"We have made tremendous progress on all fronts this quarter. We have taken the guidance of FDA and will submit a PMA for our proprietary NO generator and delivery system for the treatment of PPHN in the second calendar quarter of 2019. PPHN is a substantial market, exceeding $525 million annually in the U.S alone," said Steve Lisi, Chairman and Chief Executive Officer. "Also, on the clinical front, we expect to complete a pivotal study in bronchiolitis over the 2019/2020 winter in the United States and begin an at-home study in nontuberculous mycobacteria (NTM) in calendar 2019."

Mr. Lisi continued, "On the operational front, we strengthened our leadership team with the hiring of a Chief Financial Officer, a head of clinical operations with over 25 years of experience, and a medical device electrical engineer with over 15 years of experience with NO delivery systems. We warmly welcome all our new team members as we reinforce our operational foundation and position AIT for continued success. On the scientific front, we have presented, and will continue to present, our data and demonstrate our system at medical conferences and will continue building on our body of evidence supporting the use of NO delivered at high concentrations."

AIT Goals for its programs over the next 18 months include:

- **PPHN (and cardiac surgery outside the United States)**
  - º Submit a PMA to the FDA in the second quarter of calendar 2019
  - º Submit applications for approval in other major geographic regions, including in PPHN and cardiac surgery, where applicable
  - º Approval and launch in the US with a partner

- **Bronchiolitis**
  - º Begin a registration study in the fourth quarter of calendar 2019

- **NTM**
  - º Complete a US multi-center pilot study in NTM, in both MABSC and mycobacterium

avium complex (MAC), patients treated over a 12-week period using our NO generator and delivery system at concentrations higher than 160 ppm with patients self-administering at home

- Present new in-vitro NO data, including in combination with antibiotics, at medical and/or scientific conferences

Financial results for three months ended September 30, 2018
For the three months ended September 30, 2018, the Company had a net loss of $4.5 million, or $0.53 per share, compared to a net loss of $7.1 million, or $1.18 per share in the same three-month period of 2017.

Research and development expenses for the three months ended September 30, 2018 were $0.6 million, compared to $1.2 million in the same three-month period of 2017.

General and administrative expenses for the three months ended September 30, 2018 were $1.8 million, compared to $0.9 million for the same three-month period of 2017.

Financial results for six months ended September 30, 2018
For the six months ended September 30, 2018, the Company had a net loss of $7.5 million, or $0.89 per share, compared to a net loss of $10.0 million, or $1.63 per share in the same six-month period of 2017.

Research and development expenses for the six months ended September 30, 2018 were $1.7 million, compared to $1.8 million in the same six-month period of 2017.

General and administrative expenses for the six months ended September 30, 2018 were $2.5 million, compared to $3.3 million for the same six-month period of 2017.

As of September 30, 2018, the Company had cash, cash equivalents, restricted cash and marketable securities of $4.9 million, compared to $9.0 million at March 31, 2018. This cash is sufficient to fund operations through the end of June 2019.

Conference Call & Webcast
Wednesday, November 14th @ 4:30 pm Eastern Time

Domestic:	800-949-2175
International:	323-994-2131
Passcode:	2733200
Webcast:	http://public.viavid.com/index.php?id=131848

Replays available through November 28:

Domestic:	844-512-2921
International:	412-317-6671
Conference ID:	2733200

About AIT Therapeutics Inc.
AIT Therapeutics Inc. is a clinical-stage medical device and biopharmaceutical company using nitric oxide (NO) to treat respiratory and other diseases. The Company is currently applying its therapeutic expertise to treat lower respiratory tract infections that are not effectively addressed with current standards of care, as well as pulmonary hypertension, in various settings. AIT is currently advancing its revolutionary NO Generator and Delivery

System in clinical trials for the treatment of bronchiolitis and severe lung infections such as nontuberculous mycobacteria (NTM). For more information, visit www.AIT-Pharm.com.

About Nitric Oxide (NO)
Nitric Oxide (NO) is a powerful molecule proven to play a critical role in a broad array of biological functions. In the airways, NO is believed to play a key role in the innate immune system at concentrations of approximately 200 ppm. In vitro studies suggest that NO possesses anti-microbial activity not only against common bacteria, both gram-positive and gram-negative, but also against other diverse organisms including mycobacteria, fungi, yeast and parasites, and has the potential to eliminate multi-drug resistant strains.

About PPHN
Persistent pulmonary hypertension of the newborn (PPHN) is a lethal condition and a secondary to failure of normal circulatory transition at birth. It is a syndrome characterized by elevated pulmonary vascular resistance (PVR) that causes labile hypoxemia due to decreased pulmonary blood flow and right-to-left shunting of blood. Its incidence has been reported as 1.9 per 1000 live births (0.4–6.8/1000 live births) with mortality rate ranging between 4–33%. This syndrome complicates the course of about 10% of infants with respiratory failure and remains a source of considerable morbidity and mortality. NO gas is a vasodilator, is approved in dozens of countries to improve oxygenation and reduces the need for extracorporeal membrane oxygenation (EMO) in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents.

About Bronchiolitis
The majority of hospital admissions of infants with bronchiolitis are caused by respiratory syncytial virus (RSV). RSV is a common and highly transmissible virus that infects the respiratory tract of most children before their second birthday. While most infants with RSV present with minor respiratory symptoms, a small percentage develop serious lower airway infections, termed bronchiolitis, which can become life-threatening. The absence of treatment options for bronchiolitis limits the care of these sick infants to largely supportive measures. AIT's system is designed to effectively deliver 160 ppm NO, which has been proven to eliminate bacteria, viruses, fungi and other microbes from the lungs.

About NTM
Nontuberculous mycobacteria (NTM) infection is a rare and serious condition causing debilitating pulmonary disease associated with increased morbidity and mortality. NTM is an emerging public health concern worldwide because of its multi-drug antibiotic resistance. Current treatment guidelines suggest a combination of multiple antibiotics delivered continually for as long as two years. These complex, expensive and invasive regimens have a poor record in the treatment of mycobacterium abscessus complex (MABSC) and refractory mycobacterium avium complex (MAC). AIT's system is designed to effectively deliver 160 - 400 ppm NO to the lung. This range of NO concentration has been demonstrated to eliminate bacteria, viruses, fungi and other microbes from the lungs and may work against antibiotic resistant bacteria.

Forward-Looking Statement
This press release contains "forward-looking statements." Forward-looking statements include statements about our expectations, beliefs, or intentions regarding our product

offerings, business, financial condition, results of operations, strategies or prospects. You can identify such forward-looking statements by the words “expects,” “intends,” “plans,” “projects,” “believes,” “estimates,” “likely,” “goal,” “assumes,” “targets” and similar expressions and/or the use of future tense or conditional constructions (such as “will,” “may,” “could,” “should” and the like) and by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including risks related to: our approach to discover and develop novel drugs, which is unproven and may never lead to marketable products; our ability to fund and the results of further pre-clinical and clinical trials; obtaining, maintaining and protecting intellectual property utilized by our products; our ability to enforce our patents against infringers and to defend our patent portfolio against challenges from third parties; our ability to obtain additional funding to support our business activities; our dependence on third parties for development, manufacture, marketing, sales, and distribution of products; the successful development of our product candidates, all of which are in early stages of development; obtaining regulatory approval for products; competition from others using technology similar to ours and others developing products for similar uses; our dependence on collaborators; and our short operating history. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements, except as required by applicable law.

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CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands, except share and per share data

	As of September 30, 2018 Unaudited	As of March 31, 2018
ASSETS:		
CURRENT ASSETS:		

Cash and cash equivalents	$ 316	$ 733
Restricted cash	17	6
Marketable securities	4,549	8,304
Other accounts receivable and prepaid expenses	124	59
Total current assets	5,006	9,102
NON-CURRENT ASSETS:		
Property and equipment, net	259	253
TOTAL ASSETS	$ 5,265	$ 9,355
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payables	$ 862	$ 842
Accrued expenses	347	1,257
Loans from related parties and others	34	33
Total current liabilities	1,243	2,132
NON-CURRENT LIABILITIES:		
Liability related to warrants	9,029	5,678
TOTAL LIABILITIES	10,272	7,810
SHAREHOLDERS' (DEFICIT) EQUITY		
Common Stock, $0.0001 par value per share - 100,000,000 shares authorized at September 30, 2018 and March 31, 2018; 8,523,657 and 8,397,056 shares issued and outstanding at September 30, 2018 and March 31, 2018 respectively	2	1
Preferred Stock, $0.0001 par value per share - 10,000,000 shares authorized at September 30, 2018 and March 31, 2018; 0 issued and outstanding shares at September 30, 2018 and March 31, 2018	-	-
Accumulated other comprehensive income	5	(3)
Treasury stock	(25)	(25)
Additional paid- in capital	33,044	32,141
Accumulated deficit	(38,033)	(30,569)
Total shareholders' (deficit) equity	(5,007)	1,545
TOTAL LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY	$ 5,265	$ 9,355

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S. dollars in thousands, except share and per share data

	For the Three months Ended September 30,	
	2018	**2017**
	Unaudited	**Unaudited**
Operating expenses:		

Research and development	$ 648	$ 1,193
General and administrative	1,765	864
Operating loss	2,413	2,057
Financial expense, net	2,050	5,092
Net loss	4,463	7,149
Net unrealized gain on available-for-sale investments	3	-
Total comprehensive loss	$ 4,460	$ 7,149
Net basic and diluted loss per share	$ 0.53	$ 1.18
Weighted average number of shares of common stock used in computing basic and diluted net loss per share	8,440,457	6,045,515

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S. dollars in thousands, except share and per share data

	For the Six months Ended September 30,	
	2018	**2017**
	Unaudited	**Unaudited**
Operating expenses:		
Research and development	$ 1,711	$ 1,784
General and administrative	2,458	3,340
Operating loss	4,169	5,124
Financial expense, net	3,295	4,905
Net loss	7,464	10,029
Net unrealized gain on available-for-sale investments	8	-
Total comprehensive loss	$ 7,456	$ 10,029
Net basic and diluted loss per share	$ 0.89	$ 1.63

Weighted average number of shares of common stock used in computing basic and diluted net loss per share	8,420,281	6,143,579

Source: AIT Therapeutics, Inc.