

August 14, 2018



AIT Therapeutics Reports Financial Results for First Fiscal Quarter 2019

Started commercial development of ventilator compatible NO generator and delivery system -- FDA 510(k) submission expected in the first quarter of calendar 2019

Human and in-vitro Nitric Oxide (NO) data presented at the 3rd Annual World Bronchiectasis Conference

Bill Forbes, former President, Medical, Research & Development and Chief Development Officer at Salix Pharmaceuticals, joins the AIT Board of Directors

Entered into a \$20 Million Common Stock Purchase Agreement with Institutional Investor, Lincoln Park Capital Fund

Conference Call scheduled for Tuesday, August 14 at 10:30 am Eastern Time

GARDEN CITY, N.Y. and REHOVOT, Israel, Aug. 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 financial results for the fiscal first quarter ended June 30, 2018.

Recent Corporate Highlights:

- Began commercial development for its ventilator compatible proprietary NO generator and delivery system with Sparton Corporation. A 510(k) submission to the FDA for the system in the treatment of persistent pulmonary hypertension of the newborn (PPHN) is expected in the first quarter of calendar year 2019 with regulatory submissions in other global markets occurring later in 2019.
- Presented human and *in-vitro* data at the 3rd Annual World Bronchiectasis Conference. Presentations highlighted the direct killing effect of NO on *Mycobacterium abscessus* (*M. abscessus*) and *Pseudomonas aeruginosa*, as well as the use of the NO generator and delivery system as a potential therapy for *M. abscessus* complex (MABSC) lung infection.
- Appointed Bill Forbes, Pharm.D. to the Board of Directors. Dr. Forbes brings to the AIT Board more than 30 years of pharmaceutical product development experience and, working with health authorities in the US and Europe, has contributed to numerous marketing approvals spanning a diverse range of therapeutic areas. Dr. Forbes currently serves as the founder, President and Chief Executive Officer of Vivelix Pharmaceuticals, Ltd., a clinical-stage pharmaceutical company focused on gastrointestinal diseases. Prior to founding Vivelix, Dr. Forbes was at Salix Pharmaceuticals as the Chief Development Officer and also Head of Medical and

R&D. Prior to Salix, Dr. Forbes spent 15 years in Clinical Development & Regulatory Affairs and Clinical Research at a number of global pharmaceutical companies.

- Entered into a \$20 million common stock purchase agreement with Lincoln Park Capital, a Chicago-based institutional investor with an impeccable track record. This equity financing option is meant to be used strategically over its 36-month duration.
- Met with FDA to review pivotal trial design for treatment of nontuberculous mycobacteria (NTM) program for patients with *Mycobacterium abscessus* complex (MABSC).

“We held a productive meeting with the FDA on the design of a pivotal trial in patients suffering from NTM lung infections. We plan to start a pilot study in the near future that will provide data in key areas of self-administration at home, safety and efficacy at higher doses and NTM MAC (*Mycobacterium avium* complex) patients, and subsequently, provided we have the funding, begin a pivotal study before the end of calendar 2019,” said Steve Lisi, Chairman and Chief Executive Officer. “Moreover, we started commercial manufacturing development of our ventilator-compatible NO generator and delivery system with Sparton Corporation, a leading manufacturer of highly complex electromechanical devices, which will support our program in PPHN, a substantial market exceeding \$500 million annually in the U.S. alone. AIT’s differentiated generator technology positions us favorably in the hospital against the current cylinder based systems.

Mr. Lisi continued, “I would like to welcome Bill Forbes to our Board of Directors. Bill’s record speaks for itself and the AIT team looks forward to his wisdom and guidance as we move toward the commencement of pivotal studies in both bronchiolitis and NTM. Additionally, we value Lincoln Park Capital’s confidence in AIT. They have been a pleasure to work with and we look forward to a continued strong relationship.”

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

- **PPHN (and cardiac surgery outside the United States where applicable)**
 - Submit a 510(k) to the FDA in the first quarter of calendar 2019
 - Submit applications for approval in other major markets by calendar year-end 2019
 - Launch in the United States with a partner by calendar year-end 2019
- **Bronchiolitis**
 - Present more data from our pilot study at a medical conference later this fiscal year
 - Begin a registration study in the fourth quarter of calendar 2019
- **NTM**
 - Begin a pilot study in MABSC and MAC before the end of fiscal 2019 using our NO generator and delivery system at higher concentrations than 160 ppm with patients self-administering at home
 - Present new in-vitro data at medical conferences in the near and medium term
 - Begin a registration study by the end of calendar 2019

Financial results for three months ended June 30, 2018

For the three months ended June 30, 2018, the Company posted a net loss of \$3.0 million, or \$0.36 per share, compared to a net loss of \$2.9 million, or \$0.46 per share in the same

three-month period of 2017.

Research and development expenses for the three months ended June 30, 2018 were \$1.1 million, compared to \$0.6 million in the same three-month period of 2017.

General and administrative expenses for the three months ended June 30, 2018 were \$0.7 million, compared to \$2.5 million for the same three-month period of 2017.

As of June 30, 2018, the Company had Cash, Cash Equivalents, and Marketable Securities of \$6.7 million, compared to Cash, Cash Equivalents, and Marketable Securities of \$9.0 million at March 31, 2018. Management believes this cash is sufficient to fund operations through the end of June 2019.

Conference Call & Webcast

Tuesday, August 14th @ 10:30am Eastern Time

Domestic: 800-479-1004

International: 323-794-2599

Passcode: 6914488

Webcast: <http://public.viavid.com/index.php?id=130799>

Replays available through August 28th:

Domestic: 844-512-2921

International: 412-317-6671

Conference ID: 1819673

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

NTM lung 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 over one to two years. These complex, expensive and invasive regimens have a poor record in the treatment of NTM, especially MABSC. AIT's system is designed to effectively deliver up to 300 ppm NO, while NO concentrations above 150 PPM have been proven to eliminate certain bacteria, viruses, fungi and other microbes in-vitro and from the human lung and may work against antibiotic resistant bacteria.

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.

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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CONSOLIDATED BALANCE SHEETS

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

| | As of June 30, 2018 | As of March 31, 2018 |
|---|---------------------------|----------------------------|
| | <u>Unaudited</u> | |
| ASSETS: | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 386 | \$ 733 |
| Restricted cash | 16 | 6 |
| Marketable securities | 6,342 | 8,304 |
| Other accounts receivable and prepaid expenses | 116 | 59 |
| Total current assets | <u>6,860</u> | <u>9,102</u> |
| NON-CURRENT ASSETS: | | |
| Property and equipment, net | 239 | 253 |
| Total non-current assets | <u>239</u> | <u>253</u> |
| TOTAL ASSETS | <u>\$ 7,099</u> | <u>\$ 9,355</u> |
| LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY) | | |
| CURRENT LIABILITIES: | | |
| Trade payables | \$ 755 | \$ 842 |
| Other accounts payable | 726 | 1,257 |
| Loans from related parties and others | 34 | 33 |
| Total current liabilities | <u>1,515</u> | <u>2,132</u> |

| | | |
|---|-----------|-----------|
| NON-CURRENT LIABILITIES: | | |
| Liability related to warrants | 6,955 | 5,678 |
| TOTAL LIABILITIES | 8,470 | 7,810 |
| SHAREHOLDERS' EQUITY (DEFICIENCY) | | |
| Common Stock, \$0.0001 par value per share - 100,000,000 shares authorized at June 30, 2018 and March 31, 2018; 8,406,657 and 8,397,056 shares issued and outstanding at June 30, 2018 and March 31, 2018 respectively | 1 | 1 |
| Preferred Stock, \$0.0001 par value per share - 10,000,000 shares authorized at June 30, 2018 and March 31, 2018; 0 issued and outstanding shares at June 30, 2018 and March 31, 2018 | - | - |
| Accumulated other comprehensive income | 2 | (3) |
| Treasury shares | (25) | (25) |
| Additional paid- in capital | 32,221 | 32,141 |
| Deficit accumulated | (33,570) | (30,569) |
| Total shareholders' equity (deficiency) | (1,371) | 1,545 |
| TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY) | \$ 7,099 | \$ 9,355 |

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

| | For the Three months Ended June 30, | |
|-------------------------------------|--|-----------|
| | 2018 | 2017 |
| | Unaudited | Unaudited |
| Operating expenses: | | |
| Research and development expenses | \$ 1,063 | \$ 591 |
| General and administrative expenses | 693 | 2,476 |
| Operating loss | 1,756 | 3,067 |
| Financial (income) expense, net | 1,245 | (187) |
| Loss before taxes on income | 3,001 | 2,880 |
| Taxes on income | - | - |

| | | |
|--|------------------|------------------|
| Net loss | <u>\$ 3,001</u> | <u>\$ 2,880</u> |
| Net unrealized gain on available-for-sale investments | <u>5</u> | <u>-</u> |
| Total comprehensive loss | <u>\$ 2,996</u> | <u>\$ 2,880</u> |
| Net basic and diluted loss per share | <u>\$ 0.36</u> | <u>\$ 0.46</u> |
| Weighted average number of shares of Common Stock used in computing basic and diluted net loss per share | <u>8,400,327</u> | <u>6,241,942</u> |



Source: AIT Therapeutics, Inc.