

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended December 31, 2018

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: **000-55759**

**AIT Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**825 East Gate Boulevard, Suite 320  
Garden City, NY**  
(Address of principal executive offices)

**47-3812456**

(I.R.S. Employer  
Identification No.)

**11530**  
(Zip Code)

**516-665-8200**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer   
Non-accelerated filer

Accelerated Filer   
Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of February 14, 2019, there were 8,598,657 shares of common stock, par value \$0.0001 per share, outstanding.

---

---

AIT THERAPEUTICS, INC.  
INDEX TO FORM 10-Q FILING  
FOR THE PERIOD ENDED DECEMBER 31, 2018

Table of Contents

	<u>Page</u>
<a href="#">PART I FINANCIAL INFORMATION</a>	3
<a href="#">ITEM 1. Condensed Consolidated Financial Statements.</a>	3
<a href="#">ITEM 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.</a>	21
<a href="#">ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</a>	26
<a href="#">ITEM 4. Controls and Procedures</a>	26
<a href="#">PART II OTHER INFORMATION</a>	27
<a href="#">ITEM 6. Exhibits.</a>	27
<a href="#">SIGNATURES</a>	28

PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements.

CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

INDEX

	<u>Page</u>
<a href="#"><u>Condensed Consolidated Balance Sheets</u></a>	4
<a href="#"><u>Condensed Consolidated Statements of Comprehensive Income (Loss)</u></a>	5
<a href="#"><u>Condensed Consolidated Statements of Changes in Shareholders' Equity</u></a>	6
<a href="#"><u>Condensed Consolidated Statements of Cash Flows</u></a>	7
<a href="#"><u>Notes to Condensed Consolidated Financial Statements</u></a>	8 - 20

**AIT THERAPEUTICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>As of</u> <u>December 31, 2018</u> <u>Unaudited</u>	<u>As of</u> <u>March 31, 2018</u>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 479,700	\$ 732,542
Restricted cash	15,912	5,692
Marketable securities	2,573,605	8,304,392
Other current assets and prepaid expenses	85,710	59,249
<b>Total current assets</b>	<b>3,154,927</b>	<b>9,101,875</b>
Licensing right to use technology	495,000	-
Property and equipment, net	259,221	253,184
<b>TOTAL ASSETS</b>	<b>\$ 3,909,148</b>	<b>\$ 9,355,059</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payables	\$ 833,732	\$ 842,039
Accrued expenses	324,599	1,290,886
Options to be issued to NitricGen	295,000	-
<b>Total current liabilities</b>	<b>1,453,331</b>	<b>2,132,925</b>
Liabilities related to warrants	-	5,677,934
Long-term liabilities	1,453,331	7,810,859
Commitments and contingencies		
Shareholders' equity		
Preferred Stock, \$0.0001 par value per share: 10,000,000 shares authorized, 0 shares issued and outstanding as of December 31, 2018 and March 31, 2018, respectively	-	-
Common Stock, \$0.0001 par value per share: 100,000,000 shares authorized, 8,533,657 and 8,397,056 shares issued and outstanding as of December 31, 2018 and March 31, 2018, respectively	853	840
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	40,056,458	32,141,110
Accumulated deficit	(37,586,650)	(30,569,764)
Accumulated other comprehensive income (loss)	10,156	(2,986)
<b>Total shareholders' equity</b>	<b>2,455,817</b>	<b>1,544,200</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>\$ 3,909,148</b>	<b>\$ 9,355,059</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**AIT THERAPEUTICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (UNAUDITED)**

	For the Three Months Ended December		For the Nine Months Ended December	
	31,		31,	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Operating expenses				
Research and development	\$ 586,696	\$ 1,211,596	\$ 2,299,267	\$ 2,929,678
General and administrative	1,817,543	1,166,435	4,272,799	4,578,007
Operating loss	<u>(2,404,239)</u>	<u>(2,378,031)</u>	<u>(6,572,066)</u>	<u>(7,507,685)</u>
Other income (loss)				
Change in fair value of warrant liabilities	3,351,232	647,789	-	(4,287,737)
Dividend income	13,737	-	74,723	-
Foreign exchange gain (loss)	(1,246)	(1,098)	(288)	28,043
Other expense	(1,903)	(2,242)	(2,897)	3,837
Total other income (loss)	<u>3,361,820</u>	<u>644,449</u>	<u>71,538</u>	<u>(4,255,857)</u>
Net income (loss)	<u>\$ 957,581</u>	<u>\$ (1,733,582)</u>	<u>\$ (6,500,528)</u>	<u>\$ (11,763,542)</u>
Unrealized gain on marketable securities	4,365	-	13,142	-
Total comprehensive income (loss)	<u>\$ 961,946</u>	<u>\$ (1,733,582)</u>	<u>\$ (6,487,386)</u>	<u>\$ (11,763,542)</u>
Net income (loss) per share - basic	<u>\$ 0.11</u>	<u>\$ (0.28)</u>	<u>\$ (0.77)</u>	<u>\$ (1.92)</u>
Net income (loss) per share – diluted	<u>\$ 0.11</u>	<u>\$ (0.28)</u>	<u>\$ (0.77)</u>	<u>\$ (1.92)</u>
Weighted average number of common shares outstanding - basic	<u>8,530,580</u>	<u>6,097,254</u>	<u>8,466,243</u>	<u>6,127,225</u>
Weighted average number of common shares outstanding - diluted	<u>8,554,320</u>	<u>6,097,254</u>	<u>8,466,243</u>	<u>6,127,255</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

**AIT THERAPEUTICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**  
**FOR THE NINE MONTHS ENDED DECEMBER 31, 2018 (UNAUDITED)**

	Common Stock		Treasury Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (loss)	Total Shareholders' Equity
	Number	Amount					
Balance as of April 1, 2018	8,397,056	\$ 840	\$ (25,000)	\$ 32,141,110	\$ (30,569,764)	\$ (2,986)	\$ 1,544,200
Adjustment due to the adoption of ASU- 2017-11 (1)				6,194,292	(516,358)		5,677,934
Issuance of common stock to Lincoln Park Financial Corporation pursuant to Stock Purchase Agreement, net of offering costs	127,000	12	-	27,158	-	-	27,170
Issuance of common stock upon exercise of options	9,601	1	-	(1)	-	-	-
Stock-based compensation	-	-	-	1,693,899	-	-	1,693,899
Change in unrealized gains available-for-sale marketable securities	-	-	-	-	-	13,142	13,142
Net loss	-	-	-	-	(6,500,528)	-	(6,500,528)
Balance as of December 31, 2018	<u>8,533,657</u>	<u>\$ 853</u>	<u>\$ (25,000)</u>	<u>\$ 40,056,458</u>	<u>\$ (37,586,650)</u>	<u>\$ 10,156</u>	<u>\$ 2,455,817</u>

(1) The Company elected to adopt Accounting Standards Update 2017-11 retrospective to outstanding financial instruments with down round feature by means of cumulative-effect adjustment to the beginning additional paid-in capital of \$6,194,292 and accumulated deficit of \$(516,358) as of April 1, 2018.

The accompanying notes are an integral part of these condensed consolidated financial statements.

**AIT THERAPEUTICS, INC. AND ITS SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

	For the Nine Months Ended December 31,	
	2018	2017
<b>Cash flows from operating activities</b>		
Net loss	\$ (6,500,528)	\$ (11,763,542)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	46,222	31,932
Stock-based compensation	1,693,899	2,508,909
Imputed interest on loans due to former owners	1,466	2,933
Change in fair value of warrant liabilities		4,287,737
Unrealized gain on marketable securities	13,142	-
Changes in:		
Other current assets and prepaid expenses	(26,460)	67,738
Accounts payable	(7,770)	121,504
Accrued expenses	(968,286)	(163,857)
Net cash used in operating activities	(5,748,315)	(4,906,646)
<b>Cash flows from investing activities</b>		
Licensing right to use technology	(200,000)	-
Investment in marketable securities	-	(603,857)
Proceeds from redemption of marketable securities	5,730,782	-
Purchase of property and equipment	(52,259)	(219,255)
Net cash provided by (used in) investing activities	5,478,523	(823,112)
<b>Cash flows from financing activities</b>		
Issuance of common stock, net of offering cost	27,170	-
Payment of loan and interest to former owners	-	(176,805)
Payment of line of credit	-	(28,000)
Exercise of options	-	1,005
Net cash provided by (used in) financing activities	27,170	(203,800)
Decrease in cash, cash equivalents and restricted cash	(242,622)	(5,933,558)
Cash, cash equivalents and restricted cash at beginning of period	738,234	7,140,904
Cash, cash equivalents and restricted cash at end of period	\$ 495,612	\$ 1,207,346

Supplemental disclosure of non-cash investing activities:

Fair market value of options to be issued to NitricGen for the licensing right to use technology	\$ 295,000	\$ -
--	------------	------

The accompanying notes are an integral part of these condensed consolidated financial statements.

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
**(Unaudited)**

**NOTE 1 ORGANIZATION AND BUSINESS**

AIT Therapeutics, Inc. (“AITT” or the “Company”) was incorporated on April 24, 2015 as KokiCare, Inc. under the laws of the State of Delaware. On January 9, 2017, the name of the Company was changed to AIT Therapeutics, Inc.

Advanced Inhalation Therapies (AIT) Ltd. (“AIT”) was incorporated in Israel on May 1, 2011 and commenced its operations in May 2012. On August 29, 2014, AIT established a wholly-owned subsidiary, Advanced Inhalation Therapies (AIT) Inc. (“Inc.”), a Delaware corporation. In December 2016, through a merger transaction, AIT became a wholly-owned subsidiary of the Company.

The Company is an emerging medical device company that is developing a Nitric Oxide (“NO”) delivery system that generates NO from ambient air.

**Prior to Consummation of the Merger**

The Company received a \$320,000 cash purchase price from AIT and used the cash to (i) pay off all the liabilities of the Company as of the closing of the merger, (ii) issue a cash dividend of \$2.50 per share to its stockholders immediately prior to the closing of the merger, and (iii) acquire 90,000 shares of its common stock, par value \$0.0001 per share from the company’s prior sole officer and director, for \$25,000.

KokiCare Inc. adopted its amended and restated certificate of incorporation to (i) change its name from KokiCare Inc. to AIT Therapeutics Inc., (ii) increase its capitalization to provide for the issuance of up to 100,000,000 shares of its common stock and up to 10,000,000 shares of Preferred Stock, par value \$0.0001 per share; and (iii) effect a one-for-100 reverse stock split of the common stock. In connection with the closing of the merger, all outstanding ordinary shares, warrants and options of AIT were converted into the rights to receive equivalent shares of AITT’s common stock, options and warrants at a ratio of 1:1.

**Reverse Merger**

On December 29, 2016, KokiCare Inc. entered into an Agreement and Plan of Merger (as subsequently amended, the “Merger Agreement”), together with Red Maple Ltd., a wholly owned subsidiary of KokiCare Inc., (“Merger Sub”), and AIT. The Merger Agreement provided for (i) the merger of Merger Sub with and into AIT pursuant to the laws of the State of Israel (the “Israeli Merger”), and (ii) the conversion of the ordinary shares and other outstanding securities of AIT into the right to receive shares and other applicable securities of AITT, with AIT surviving as a wholly owned subsidiary of AITT (the “Merger”). The Israeli Merger became effective on December 29, 2016 and the Merger closed on January 13, 2017 (the “Closing”).

The Merger was accounted for as a reverse recapitalization which is outside the scope of Accounting Standards Codification “ASC” 805, “Business Combinations”. Under reverse capitalization accounting, AIT is considered the acquirer for accounting and financial reporting purposes and acquired the assets and assumed the liabilities of the Company. Assets acquired and liabilities assumed are reported at their historical amounts. Consequently, the consolidated financial statements of the Company reflect the operations of the acquirer for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of the legal acquirer and a recapitalization of the equity of the accounting acquirer. These condensed consolidated financial statements include the accounts of the Company since the effective date of the reverse capitalization and the accounts of AIT since inception.

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
**(Unaudited)**

**NOTE 1 ORGANIZATION AND BUSINESS (continued)**

**Liquidity**

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of \$5,748,315 for the nine months ended December 31, 2018 and accumulated losses of \$37,586,650 since inception through December 31, 2018. The Company has cash equivalent and marketable securities of \$3,069,217 as of December 31, 2018. The Company estimates that it has enough cash to operate its business through March 31, 2020.

The Company will need to raise additional funds in order to continue our clinical trials. Insufficient funds may cause us to delay, reduce the scope of or eliminate one or more of our development programs. The Company's future capital needs and the adequacy of its available funds will depend on many factors, including the cost of clinical studies and other actions needed to obtain regulatory approval of our medical devices in development. Management plans to raise additional funds through sale of equity or debt securities or through strategic collaboration and/or licensing agreements, to fund operations until the Company is able to generate enough revenues to cover operating costs. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional equity financing, if available, may be dilutive to our shareholders. In addition, the Company may never be able to generate sufficient revenue if any from its potential medical devices. On August 10, 2018, the Company entered into a \$20 million stock purchase agreement and a registration rights agreement with Lincoln Park Capital Fund, LLC ("LPC"), providing for the issuance of up to \$20 million of the Company's common stock over 36 months at the Company's discretion, see Note 5. On January 23, 2019, the Company entered into an agreement for the commercial rights to conditions treated with  $\leq 80$  ppm of nitric oxide in the hospital setting with Circassia Pharmaceuticals plc in the United States and China, see Note 10.

In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable. The Company is subject to risks common to companies in the medical device industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with the FDA and other governmental regulations and approval requirements.

**NOTE 2 SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("US GAAP") for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying condensed consolidated financial statements reflect all adjustments (consisting only of normal recurring items) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented. The accompanying condensed consolidated Balance Sheet as of March 31, 2018 has been derived from the audited consolidated financial statements included in our Transitional Report on Form 10-KT for the three months ended March 31, 2018 and for the year then ended December 31, 2017, respectively. The condensed consolidated financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited consolidated financial statements and the related notes thereto included in the Transitional Report on Form 10-KT for the three months ended March 31, 2018 and for year ended December 31, 2017, respectively, which was filed with the United States Securities and Exchange Commission, ("SEC"), on June 15, 2018.

AIT THERAPEUTICS, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2018  
(Unaudited)

**NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Principles of Consolidation**

These condensed consolidated financial statements include the accounts of the Company since the effective date of the reverse capitalization and the accounts of AIT since inception. All intercompany balances and transactions have been eliminated in the accompanying condensed financial statements.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. The Company's significant estimates are warrant liabilities valuation, valuation of option liability, and valuation of deferred taxes.

**Cash and Cash Equivalents**

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less at acquisition.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, restricted cash and marketable securities. Cash and cash equivalents are invested in major banks in Israel and U.S. Management believes that the financial institutions that hold the Company's investments are financially sound and, accordingly, minimal credit risk exists with respect to these investments. At times, such amounts may exceed federally insured limits.

The Company has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

**Restricted Cash**

Restricted cash accounts are invested in bank deposit. These deposits serve as collateral for the Company's vehicle lease.

AIT THERAPEUTICS, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2018  
(Unaudited)

**NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Research and Development**

Research and development expenses are charged to the statement of comprehensive loss as incurred. Research and development expenses include salaries, costs incurred by outside laboratories, manufacturer's, consultants, accredited facilities in connection with clinical trials and preclinical studies and stock based-compensation.

**Foreign Exchange Transactions**

AIT's operations are in Israel and AITT's operations are in the United States. The Company's management believes that the U.S. dollar is the currency of the primary economic environment in which the Company operates and expects to continue to operate in the foreseeable future. Thus, the functional and reporting currency of the Company is the U.S. dollar. The Company's transactions and balances denominated in U.S. dollars are presented at their original amounts. Non-dollar transactions and balances have been re-measured to U.S. dollars in accordance with the Accounting Standards Board (ASC) 830, "Foreign Currency Matter".

**Stock-Based Compensation**

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award - the requisite service period. The grant-date fair value of employee share options is estimated using the Black-Scholes option pricing model. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the expected term of the equity instruments. The expected dividend yield was assumed to be zero as the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. The expected volatility was based upon its peer group. The Company routinely reviews its calculation of volatility changes in future volatility, the Company's life cycle, its peer group, and other factors. The Company uses the simplified method for share-based compensation to estimate the expected term for employee option awards for share-based compensation in its option-pricing model. The Company uses the contractual term for non-employee options to estimate the expected term, for share-based compensation in its option-pricing model. Compensation expense for warrants granted to non-employees is determined by the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured, and is recognized over the service period. The expense is subsequently adjusted to fair value at the end of each reporting period until such warrants vest, and the fair value of such instruments, as adjusted, is expensed over the related vesting period. Adjustments to fair value at each reporting date may result in income or expense, depending upon the estimate of fair value and the amount of expense recorded prior to the adjustment. The Company reviews its agreements and the future performance obligation with respect to the unvested warrants for its vendors or consultants. When appropriate, the Company will expense the unvested warrants at the time when management deems the service obligation for future services has ceased.

**Investment in Marketable Securities**

Investments in marketable securities classified available for sale are carried at fair value with the changes in unrealized gains and losses recognized in the Company's results of operations as other comprehensive income (loss) at each measurement date. Realized gains and (loss) from the sale of marketable securities are recognized in the statement of comprehensive loss using the specific identification method on a trade date basis.

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
**(Unaudited)**

**NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Property and Equipment**

Property and equipment are stated at cost less accumulated depreciation and accumulated amortization. Depreciation and amortization is calculated using the straight-line method over the estimated useful life of the assets as follows:

Computers equipment	Three years
Furniture and fixtures	Seven years
Clinical and medical equipment	Fifteen years
Leasehold improvements	Shorter of term of lease or estimated useful life of the asset

**Licensing right to use technology**

Licensing right to use technology is an intangible asset resulting from the NitricGen transaction. The intangible asset was valued based upon the fair value of the options owed to NitricGen and the cash paid for this transaction. Intangible assets are considered to have an indefinite life until the completion or abandonment of the associated research and development project.

**Income Taxes**

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. As of December 31, 2018, and March 31, 2018, the Company recorded a valuation allowance to the full extent of our net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold. On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Act. The Tax Act reduces the federal corporate income tax rate from 35% to 21%, effective January 1, 2018, which the Company expects will positively impact its future effective tax rate and after-tax earnings in the United States. The Company recognized a decrease related to its federal deferred tax assets and deferred tax liabilities, before the valuation allowance. Because a change in the valuation allowance completely offsets the change in deferred taxes, there was no impact on the condensed consolidated financial statements related to the rate change.

The Company files a U.S. Federal, various state, and International income tax returns. Uncertain tax positions are reviewed on an ongoing basis and are adjusted in light of changing facts and circumstances. Such adjustment is reflected in the tax provision when appropriate. The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in income taxes in the statements of comprehensive loss. The Company has recorded a liability in accrued expenses of \$154,300 for an uncertain tax position as of December 31, 2018 and March 31, 2018, respectively.

**Net Income (Loss) Per Share**

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of shares of common stock and potentially dilutive common stock outstanding during the period. The dilutive effect of outstanding options, warrants, restricted stock and stock-based compensation awards is reflected in diluted net income (loss) per share by application of the treasury stock method. The calculation of diluted net income (loss) per share excludes all anti-dilutive common shares. For periods in which the Company has reported net losses, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, because dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

**Recently Issued and Adopted Accounting Standards**

In January 2017, the Financial Accounting Standards Board (“FASB”) FASB released Accounting Standards Update “ASU” 2017-01, Business Combinations: Clarifying the Definition of a Business, which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The amendments in this ASU should be applied prospectively and are effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. No disclosures are required at transition. The Company adopted this standard during the third quarter December 31, 2018 and this standard did not have a material impact on our condensed consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting. This standard provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, Compensation—Stock Compensation, to a change to the terms or conditions of a share-based payment award. The Company adopted the standard commencing April 1, 2018. The impact of the adoption had no effect to the Company’s condensed consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features. II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. This ASU affects all entities that issue financial instruments (for example, warrants or convertible instruments) that include down round features. Part I of this ASU relates to the recognition, measurement, and earnings per share of certain freestanding equity-classified financial instruments that include down round features affect entities that present earnings per share in accordance with the guidance in Topic 260, Earnings Per Share, while in Part II does not have an accounting effect. The Company elected to adopt Accounting Standards Update 2017-11 during the third quarter of 2018, retrospective to outstanding financial instruments with down round feature by means of cumulative-effect adjustment by increasing beginning additional paid-in capital by \$6,194,292 and decreasing accumulated deficit by \$516,358 as of April 1, 2018.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted the standard commencing January 1, 2018. The impact of the adoption was immaterial to the Company’s condensed consolidated financial statements.

AIT THERAPEUTICS, INC.  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
DECEMBER 31, 2018  
(Unaudited)

**NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)**

**Recently Issued and not Adopted Accounting Standards**

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* (ASU 2016-02), which generally requires companies to recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet. This update is effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods. The Company is evaluating the effect that this guidance will have on the Company's condensed consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, *Stock-based Compensation: Improvements to Nonemployee Share-based Payment Accounting* which amends the existing accounting standards for share-based payments to nonemployees. This ASU aligns much of the guidance on measuring and classifying nonemployee awards with that of awards to employees. Under the new guidance, the measurement of nonemployee equity awards is fixed on the grant date. This ASU becomes effective for fiscal years beginning after December 15, 2018 and early adoption is permitted but no earlier than an entity's adoption date of Topic 606. Entities will apply the ASU by recognizing a cumulative-effect adjustment to retained earnings as of the beginning of the annual period of adoption. The Company is evaluating the impact of this accounting standard update on the Company's condensed consolidated financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, "Disclosure Update and Simplification," amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company is evaluating the impact of this guidance on its condensed financial statements. The Company anticipates its first presentation of changes in stockholders' equity will be included in its Form 10-Q for the quarter ended June 30, 2019.

In August 2018, the FASB issued Accounting Standards Update ("ASU") 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The guidance is effective for the Company's interim and annual reporting periods beginning with the Company's fiscal year ended March 31, 2021, and early adoption is permitted. The Company is evaluating the impact of this accounting standard update on the Company's condensed consolidated financial statements.

**NOTE 3 FAIR VALUE MEASUREMENT**

The Company's financial instruments primarily include cash, cash equivalents, restricted cash, marketable securities and accounts payable. Due to the short-term nature of cash, cash equivalent, restricted cash, marketable securities and accounts payable, the carrying amounts of these assets and liabilities approximate their fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
**(Unaudited)**

**NOTE 3 FAIR VALUE MEASUREMENT (continued)**

Level 1 - quoted prices in active markets for identical assets or liabilities;

Level 2 - inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

Level 3 - unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company accounted for the warrants issued to accredited shareholders included, among others, down round protective provisions as a non-current liability according to provisions of ASC 815. The Company had measured the warrants at fair value in each reporting period until they are exercised or expired, with changes in the fair value being recognized in the Company's statement of comprehensive loss. Under ASC 820, the warrants and option liability are classified as Level 3 and cash, cash equivalents, restricted cash and marketable securities invested in mutual funds are classified as Level 1. There has been no transfer between any levels during the period. During the third quarter of 2018, the Company adopted ASU 2017-11 retrospectively to outstanding financial instruments with a down round feature by means of cumulative-effect adjustment. The balance as of April 1, 2018 for additional paid-in capital was increased by \$6,194,292 and accumulated deficit was decreased by \$516,358.

	<b>As of March 31, 2018</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Cash and cash equivalents	\$ 732,542	\$ -	\$ -	\$ 732,542
Restricted cash	5,692	-	-	5,692
Marketable securities -	-	-	-	-
Mutual funds	8,304,392	-	-	8,304,392
	\$ 9,042,626	\$ -	\$ -	\$ 9,042,626

	<b>As of March 31, 2018</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Liabilities</b>				
Liabilities related to warrants	\$ -	\$ -	\$ 5,677,934	\$ 5,677,934

	<b>As of December 31, 2018</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets</b>				
Cash and cash equivalents	\$ 479,700	\$ -	\$ -	\$ 479,700
Restricted cash	15,912	-	-	15,912
Marketable securities -	-	-	-	-
Mutual funds	2,573,605	-	-	2,573,605
	\$ 3,069,217	\$ -	\$ -	\$ 3,069,217

	<b>As of December 31, 2018</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Liabilities</b>				
Liabilities related to warrants	\$ -	\$ -	\$ -	\$ -
Options to be issued to NitricGen	-	-	295,000	295,000
	\$ -	\$ -	\$ 295,000	\$ 295,000

The following is a summary of the warrant and option liabilities from March 31, 2018 to December 31, 2018.

Balance, March 31, 2018	\$ 5,677,934
Fair market value of options to be issued to NitricGen	295,000
Reclassification of warrant liabilities to stockholders' equity upon adoption of ASU-2017-11	(5,677,934)
Balance, December 31, 2018	\$ 295,000

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
**(Unaudited)**

**NOTE 4 PROPERTY AND EQUIPMENT**

Property and equipment consist of the following as of December 31, 2018 and March 31, 2018, respectively:

	<u>As of</u> <u>December 31, 2018</u>	<u>As of</u> <u>March 31, 2018</u>
Clinical and medical equipment	\$ 357,795	\$ 357,795
Computer equipment	40,283	28,727
Furniture and fixtures	39,747	1,889
Leasehold improvements	5,336	2,491
	<u>443,161</u>	<u>390,902</u>
Accumulated depreciation and amortization	(183,940)	(137,718)
	<u>\$ 259,221</u>	<u>\$ 253,184</u>

Depreciation and amortization expense for the three months ended December 31, 2018 and 2017 was \$15,638 and \$14,487, respectively. Depreciation and amortization expense for the nine months ended December 31, 2018 and 2017 was \$46,222 and \$31,932, respectively.

**NOTE 5 SHAREHOLDER'S EQUITY**

On February 16, 2018, the Company entered into a Securities Purchase Agreement with several accredited shareholders. The Company issued warrants to purchase 4,599,604 shares of its common stock, par value \$0.0001 per share at a purchase price of \$0.01 per underlying warrant share. The warrants are comprised of an aggregate of (i) 2,299,802 Tranche A Warrants to purchase shares of common stock at an exercise price of \$4.25 per share exercisable within three days from the issue date of the Tranche A Warrants and (ii) an equal amount of Tranche B Warrants to purchase shares of common stock at an exercise price of \$4.25 per share for the Tranche B Warrant, exercisable within three years from the issue date of the warrants. In connection with the February 2018 stock offering, the Company's Board of Directors approved the issuance of warrants to purchase common stock with an exercise price of \$4.25 per share. Immediately following the closing, all the shareholders in this offering exercised the full amount of their Tranche A Warrants resulting in net proceeds of \$8,734,320.

In February 2018, the Board of Directors repriced outstanding options to purchase common stock issued in 2017 to \$4.25 per share. The Company accounted for the change in option exercise price as a modification pursuant to ASC 718. Accordingly, additional stock-based compensation of \$59,507 was recorded over the remaining vesting period based upon the incremental fair value of the modified award and the fair value of the original award on the modification date.

On August 10, 2018, the Company entered into a \$20 million Stock Purchase Agreement (commonly known as At The Market Offering, or ATM) with LPC. Pursuant to the terms of the Stock Purchase Agreement, the Company may sell and issue LPC and LPC is obligated to purchase up to \$20 million in value of shares of common stock from time to time over three years. The Company also entered into a registration rights agreement with LPC whereby the Company agreed to file a registration statement with the SEC and the shares of the Company's common stock that may be issued to LPC under the terms of the Stock Purchase Agreement. The Company may direct LPC, at its sole discretion, and subject to certain conditions, to purchase up to 10,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase. The amount of a purchase may be increased under certain circumstances provided, however that LPC cannot make any single purchase that exceeds \$750,000. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the Stock Purchase Agreement. The Company filed a registration statement with the SEC and it was accepted on October 12, 2018.

From the execution of the Stock Purchase Agreement on August 10, 2018 to December 31, 2018, the Company issued and sold to LPC 127,000 shares of common stock at an average price of \$4.51 per shares for net proceeds of \$27,170 and incurred offering costs of \$545,000 that was charged to additional paid in capital. On January 17, 2019 through January 23, 2019, the Company issued and sold to LPC 65,000 shares of common stock for proceeds of \$279,265 at an average price of \$4.30 per share. There is \$19,148,565 remaining on the Stock Purchase Agreement.

**Issuance of Restricted Shares**

In January 2017, the Company issued 492,624 restricted shares to a director of the Company which 246,312 vested in July 2017. The unvested 246,312 restricted shares were cancelled in June 2017 and the Company recorded stock-based compensation expenses related to these restricted shares for the nine months ended December 31, 2018 and 2017 of \$0 and \$2,063,791. There was no stock-based compensation expense for the three months ended December 31, 2018 and 2017, respectively.

**Stock Option Plan**

The Company has an amended and restated Incentive Option Plan (the "2013 Plan"), that grants options, restricted stock units and restricted shares to officers, directors, employees, and non-employees for shares of the Company's stock. The options vesting terms are generally between two to four years and expire up to ten years after the grant date. Certain options will be accelerated upon fulfillment of certain conditions. On August 2, 2018, the Board of Directors authorized the increase of an additional 1,033,324 shares to a total of 1,500,000 shares for issuance under the 2013 Plan. On December 26, 2018, the Board of Directors authorized the increase of an additional 600,000 shares to a total of 2,100,000 shares for issuance under the 2013 Plan. As of December 31, 2018, 188,527 options are available for future grants.

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
**(Unaudited)**

**NOTE 5 SHAREHOLDERS' EQUITY (continued)**

A summary of the Company's options for the nine months ended December 31, 2018 is as follows:

	<u>Number Of Options</u>	<u>Weighted Average Exercise price</u>	<u>Weighted Average Remaining Contractual Life</u>
Options outstanding as of April 1, 2018	510,904	\$ 4.32	9.0
Granted	1,381,000	4.25	
Exercised	(9,601)	4.25	
Forfeited	(33,333)	4.25	
Options outstanding as of December 31, 2018	<u>1,848,970</u>	<u>\$ 4.29</u>	<u>8.9</u>
Options exercisable as of December 31, 2018	<u>761,896</u>	<u>\$ 4.29</u>	<u>8.6</u>

As of December 31, 2018, the aggregate intrinsic value of outstanding and exercisable options was and \$623,900 and \$343,800, respectively. The aggregate intrinsic value of options exercised during the period was \$27,300. As of December 31, 2018, the Company has unrecognized stock-based compensation expense of approximately \$1,434,100 related to unvested stock options over the weighted average remaining service period of 1.8 years. The weighted average fair value of options granted during the nine months ended December 31, 2018 and 2017 was approximately \$2.79 per share and \$2.23 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumption:

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Risk -free interest rate	2.5% - 3.2%	2.1% - 3.5%
Expect volatility	80.7% - 83%	75.2%
Expected terms (in years)	5-9.9	5.5-7.5
Dividend yield	0%	0%

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
(Unaudited)

**NOTE 5 SHAREHOLDER'S EQUITY (continued)**

**Stock-based Compensation**

The following summarizes the components of stock-based compensation expense which includes common stock, stock options, warrants and restricted stock in the condensed consolidated statements of comprehensive income (loss) for the three and nine months ended December 31, 2018 and 2017, respectively

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2018	2017	2018	2017
Research and development	\$ 88,830	\$ 44,430	\$ 187,103	\$ 117,597
General and administrative	676,949	178,195	1,506,796	2,391,312
Total stock-based compensation expense	<u>\$ 765,779</u>	<u>\$ 222,625</u>	<u>\$ 1,693,899</u>	<u>\$ 2,508,909</u>

In August 2018 and November 2018, the Board of Directors granted to the Directors and Officers, 810,000 options to purchase common stock. For the three and nine months ended, the stock-based compensation expense was \$462,339 and \$666,565, respectively related to these issuances.

**Warrants**

On September 7, 2016, the Company entered into an Option Agreement (the "Option Agreement") with a third party whereby the Company acquired the Option to purchase certain intellectual property assets and rights (the "Option") for \$25,000. The Company exercised the Option in January 2017 and paid \$500,000. On January 13, 2017 the Company issued to the third party a fully vested warrant (the "Third Party Warrant") to purchase up to 178,570 common stock of the Company at an exercise price of \$4.80 per share for each share of common stock. On May 10, 2018, the Company issued to the same third-party additional fully vested warrants to purchase up to 29,763 common stock of the Company at an exercise price of \$4.80 per share. The warrant expires in January 2024. For the nine months ended December 31, 2018 and 2017, the Company recorded stock-based compensation expense of \$55,900 and \$0 to research and development expenses, respectively and is included in the table above. There was no stock stock-based compensation expense for the three months ended December 31, 2018 and 2017, respectively, see Note 8, commitments and contingencies.

A summary of the Company's outstanding warrants as of December 31, 2018 are as follows:

Warrant Holders	Number Of Warrants	Exercise Price	Date Of Expiration
January 2017 offering - investors	1,701,616	\$ 4.25	January 2022(a)
January 2017 offering - investors	1,701,616	\$ 4.25	February 2022(a)
March 2017 offering - investors	220,988	\$ 4.25	March 2021
March 2017 offering - placement agent	11,050	\$ 4.25	March 2021
February 2018 offering - investors	2,299,802	\$ 4.25	March 2022
Third-party	208,333	\$ 4.80	January 2024
Total	<u>6,143,405</u>		

(a) These warrants have down round protection.

**NOTE 6 ACCRUED EXPENSES**

A summary of the accrued expenses as of December 31, 2018 and March 31, 2018 is as follows:

	As of December 31, 2018	As of March 31, 2018
Vendors - clinical trials	\$ -	\$ 497,577
Professional fees	67,420	492,250
Income taxes payable	154,300	154,300
Employee salaries and benefits	34,337	104,110
Due to former owners, related to acquisition	34,268	33,124
Other	34,274	9,525
	<u>\$ 324,599</u>	<u>\$ 1,290,886</u>

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
(Unaudited)

**NOTE 7 BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE**

The computation of net loss per common share, basic and diluted, for the three and nine months ended December 31, 2018 and 2017 is as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Net income (loss)	\$ 957,581	\$ (1,733,582)	\$ (6,500,528)	\$ (11,763,542)
Net income (loss) - basic	\$ 0.11	\$ (0.28)	\$ (0.77)	\$ (1.92)
Net income loss – diluted	\$ 0.11	\$ (0.28)	\$ (0.77)	\$ (1.92)
Weighted average number of common shares outstanding – basic	8,530,580	6,097,225	8,466,243	6,127,225
Weighted average number of common shares outstanding - diluted	8,554,320	6,097,225	8,466,243	6,127,225

The following potentially dilutive securities were not included in the calculation of diluted net income (loss) per share attributable to common stockholders because their effect would have been anti-dilutive for the periods presented:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
Common stock warrants	6,143,405	3,813,840	6,143,405	3,813,840
Common stock options	1,521,230	548,721	1,544,970	548,721
Restricted shares	304,000	246,312	304,000	246,312
Total	<u>7,968,635</u>	<u>4,608,873</u>	<u>7,992,375</u>	<u>4,608,873</u>

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
**(Unaudited)**

**NOTE 8 COMMITMENTS AND CONTINGENCIES**

On October 22, 2013, The Company entered into a patent license agreement with a third party, pursuant to which AIT agreed to pay to the third party a non-refundable upfront fee of \$150,000 and is obligated to pay 5% royalties of any licensed product revenues, but at least \$50,000 per annum during the royalty period as defined in the agreement. As of December 31, 2018, the Company did not record any revenues and therefore no royalties were paid or accrued.

On September 7, 2016, AIT entered into an Option Agreement (the "Option Agreement") with a third party whereby AIT acquired the Option to purchase certain intellectual property assets and rights (the "Option") for \$25,000 AIT issued to the third party a warrant (the "Third Party Warrant") to purchase up to 178,570 ordinary shares of AIT at an exercise price of \$4.80 for each share. This warrant was exchanged for a warrant to acquire the same number of shares of the Company's common stock upon consummation of the merger. On May 10, 2018, the Company issued to the third-party additional warrants to purchase up to 29,763 shares of the Company at an exercise price of \$4.80 per share for each share of common stock. The warrant expires in January 2024. Additionally, AIT is required to make certain one-time development and sales milestone payments to the third party, starting from the date on which the Company receives regulatory approval for the commercial sale of its first product candidate.

On January 31, 2018 the Company entered into an agreement ("Agreement") with NitricGen, Inc. ("NitricGen") acquire a global, exclusive, transferable license and associated assets including intellectual property, know-how, trade secrets and confidential information from NitricGen related to NO delivery systems ("Delivery System"). The Company acquired the licensing right to use the technology and agreed to pay NitricGen a total of \$2,000,000 in future payments based upon achieving certain milestones, as defined in the Agreement, and royalties on sales of the Delivery System. The Company paid NitricGen \$100,000 upon the execution agreement, \$100,000 upon achieving the next milestone and has an obligation to issue 100,000 options to purchase the Company's stock upon executing the agreement. The term of the options is five year and has an exercise price of \$6.90 per share. A liability of \$295,000 has been recorded for the fair market value of the options that have not been issued using the black-scholes option pricing model. The Company used a volatility rate of 79.9% and risk-free interest rate of 2.5%. The Company recorded the milestone payments and the fair market value of the options as a licensing right to use the technology which is an intangible asset, aggregating \$495,000. During the three months ended December 31, 2018, the Company recorded an adjustment of \$495,000 to intangible assets to correct an error of which \$200,000 was previously recorded to research and development during the three months ended March 31, 2018. The effect of this correction to the balance sheet as of December 31, 2018 was an increase to the assets by \$495,000, an increase to the liability by \$295,000 and a decrease in research and development of \$200,000. The effect of this correction to the statement of comprehensive income (loss) for the three and nine months ended December 31, 2018 was \$200,000 of income.

On March 16, 2018, Empery Asset Master, Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, (collectively, "Empery"), filed a complaint in the Supreme Court of the State of New York, relating to the notice of adjustment of both the exercise price of and the number of warrant shares issuable under warrants issued to Empery in January 2017. The Empery Suit alleges that, as a result of certain circumstances in connection with the February 2018 Offering, the January 2017 Warrants issued to Empery provide for adjustments to both the exercise price of the warrants and the number of warrant shares issuable upon such exercise. Empery seeks monetary damages and declaratory relief under theories of breach of contract or contract reformation predicated on mutual mistake. The Company intends to vigorously defend all claims.

Given the early stage of the litigation, it is not possible to determine or assess the probability of any particular outcome.

Certain officer agreements contain a change of control provision for payment of severance arrangements.

In March and April, 2018, the Company entered into two new office lease agreements, which will expire on April 2021 and June 2023, respectively. Future minimum commitments for each of the fiscal years ending March 31, are as follows:

<b>Year Ended March 31,</b>	<b>Operating Leases</b>
2019	\$ 33,500
2020	87,900
2021	90,100
2022	65,400
2023	64,700
2024	16,300
<b>Total</b>	<b>\$ 357,900</b>

Rent expense for the three months ended December 31, 2018 and 2017 was \$34,716 and \$47,672, respectively. Rent expense for the nine months ended December 31, 2018 and 2017 was \$84,261 and \$68,066, respectively

**AIT THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2018**  
(Unaudited)

**NOTE 9 RECLASSIFICATION OF PRIOR PERIOD PRESENTATION**

Certain amounts from the prior period condensed financial statements have been reclassified to conform with the current period presentation. The following has been reclassified.

	<u>Three Months Ended</u> <u>December 31, 2017</u>			<u>Nine Months Ended</u> <u>December 31, 2017</u>		
	<u>As</u> <u>Previously</u> <u>Reported</u>	<u>Reclassified</u>	<u>Adjusted</u>	<u>As</u> <u>Previously</u> <u>Reported</u>	<u>Reclassified</u>	<u>Adjusted</u>
	Research and development	\$ 1,214,268	\$ (2,672)	\$ 1,211,596	\$ 2,999,627	\$ (69,949)
General and administrative	1,169,763	(3,328)	1,166,435	4,509,075	68,932	4,578,007
Other income (loss)	644,449	-	644,449	(4,250,874)	(4,983)	(4,255,857)
Income tax (benefit)	(6,000)	6,000	-	(6,000)	6,000	-
	<u>\$ 3,022,480</u>	<u>\$ -</u>	<u>\$ 3,022,480</u>	<u>\$ 3,251,828</u>	<u>\$ -</u>	<u>\$ 3,251,828</u>

**NOTE 10 SUBSEQUENT EVENTS**

On January 23, 2019, the Company entered into an agreement for commercial rights (“the License Agreement”) with Circassia Pharmaceuticals plc, (located in the United Kingdom) for persistent pulmonary hypertension of the newborn (PPHN) and future related indications at concentrations of  $\leq 80$  ppm in the hospital setting in the United States and China. The Company may receive payments up to \$32.5 million in up front and regulatory milestones, of which \$31.5 million is associated with the U.S. market. The Company met the first two milestones which resulted in the payment of \$10.5 million in Circassia’s ordinary shares. The ordinary share price was predetermined as subject to a volume weighted average price that was defined in the Licensing Agreement. The Company will receive future royalties from 15-20% based upon gross profit, which is defined in the License Agreement.

From January 17, 2019 through January 23, 2019, the Company issued and sold 65,000 shares of common stock for proceeds of \$279,265 at an average price of \$4.30 per share to LPC. See note 5.

## **ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

### **Note Regarding Forward-Looking Statements**

*This Quarterly Report on Form 10-Q 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 such statements 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. Many factors could cause our actual activities or results to differ materially and results anticipated in 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. 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. Please see Item 1A "Risk Factors" contained in our most recently filed Transitional Report on Form 10-KT, and in this Quarterly Report on Form 10-Q for important factors that could cause actual results to differ materially from those in the forward-looking statements.*

### **Management's Discussion and Analysis of Financial Condition and Results of Operations**

#### **Introduction**

We are an emerging medical device and biopharmaceutical company developing a nitric oxide (NO) generator and delivery system, or the AIT NO Generator and Delivery System, that is capable of generating NO from ambient air. The AIT NO Generator and Delivery System can generate up to 400 parts per million ("ppm") for delivery to a patient's lung. The AIT NO Generator and Delivery System can deliver NO either continuously or for a fixed amount of time and has the ability to either titrate dose on demand or maintain a constant dose. We believe that there is a high unmet medical need for patients suffering from certain severe lung infections for which our system can be used. Our current product candidates, if approved, will be marketed as medical devices and will be subject to premarket reviews and approvals by the U.S. Food and Drug Administration, or the FDA and equivalent organizations in other countries/territories.

In contrast to approved NO delivery systems, our novel AIT NO Generator and Delivery System is designed to deliver not only low concentrations of NO, but also high concentrations of NO to the lungs, which we believe has the potential to eliminate microbial infections, including bacteria, fungi and viruses. Current FDA approved NO delivery systems are approved for persistent pulmonary hypertension of the newborn, or PPHN, which requires a NO concentration of 20 ppm and is not intended to treat microbial infections. The body produces NO naturally as an innate immunity mechanism. Based on our clinical studies, we believe that 160 ppm NO is the minimum therapeutic dose to achieve the desired pulmonary effect in those with microbial lung infections. To date, the FDA has not approved any NO formulation and/or delivery system for the delivery of 160 ppm or higher to the lungs.

Our first proposed indication is for PPHN in the United States and other subsequent countries. Our System differs from current approved NO delivery systems in the US and globally in that our System does not require hazardous cylinders containing nitrogen and nitric oxide gases. Our System generates NO from ambient air. We believe this is a major transformative change that will benefit patients, caregivers and hospitals. We anticipate our pre-market approval (PMA) submission to the FDA to take place in the second quarter of 2019. We have obtained a commercial partner for the United States and China markets for PPHN and related indications in the hospital. This partner, Circassia Pharmaceuticals, plc, is a respiratory focused specialty pharmaceutical company with presence in US hospitals and experience with NO.

We were incorporated in Delaware on April 24, 2015 under the name “KokiCare, Inc.” and operated as a healthcare software company prior to the Merger (as defined below). Concurrent with the closing of the Merger, we abandoned our pre-Merger business plan in the healthcare software industry and we are now solely pursuing our business in the medical device industry.

To date, we have not generated revenue from the sale of any product, and we do not expect to generate revenue unless and until we obtain marketing approval of, and commercialize, our product candidates. As of December 31, 2018, we had an accumulated deficit of \$37,586,650. Our financing activities are described below under “Liquidity and Capital Resources.”

#### **Critical Accounting Policies**

The accounting policies followed in the preparation of our condensed consolidated financial statements appearing at the beginning of this Quarterly Report on Form 10-Q are consistent in all material respects with those included in Note 2 of our Annual Report on the Form 10-KT for the three-month ended March 31, 2018 and for the year ended December 31, 2017. The unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States (“US GAAP”) for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying condensed consolidated financial statements reflect all adjustments (consisting only of normal recurring items) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented. The accompanying condensed consolidated Balance Sheet as of March 31, 2018 has been derived from the audited consolidated financial statements included in our Transitional Report on Form 10-KT for the three months March 31, 2018 and for the year then ended December 31, 2017, respectively. The condensed consolidated financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited consolidated financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto included in the Transitional Report on Form 10-KT for the three months ended March 31, 2018 and for year ended December 31, 2017, respectively, which was filed with the United States Securities and Exchange Commission, (“SEC”), on June 15, 2018.

## Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission.

## Results of Operations

Below are the results of operations for the three and nine months ended December 31, 2018 and 2017:

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2018	2017	2018	2017
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Operating expenses				
Research and development	\$ 586,696	\$ 1,211,596	\$ 2,299,267	\$ 2,929,678
General and administrative	1,817,543	1,166,435	4,272,799	4,578,007
Operating loss	<u>(2,404,239)</u>	<u>(2,378,031)</u>	<u>(6,572,066)</u>	<u>(7,507,685)</u>
Other income (loss)				
Change in fair value of warrant liabilities	3,351,232	647,789	-	(4,287,737)
Dividend income	13,737	-	74,723	-
Foreign exchange gain (loss)	(1,246)	(1,098)	(288)	28,043
Other expense	(1,903)	(2,242)	(2,897)	3,837
Total other income (loss)	<u>3,361,820</u>	<u>644,449</u>	<u>71,538</u>	<u>(4,255,857)</u>
Net income (loss)	<u>\$ 957,581</u>	<u>\$ (1,733,582)</u>	<u>\$ (6,500,528)</u>	<u>\$ (11,763,542)</u>
Unrealized gain on marketable securities	<u>4,365</u>	<u>-</u>	<u>13,142</u>	<u>-</u>
Total comprehensive income (loss)	<u>\$ 961,946</u>	<u>\$ (1,733,582)</u>	<u>\$ (6,487,386)</u>	<u>\$ (11,763,542)</u>
Net income (loss) per share - basic	<u>\$ 0.11</u>	<u>\$ (0.28)</u>	<u>\$ (0.77)</u>	<u>\$ (1.92)</u>
Net income (loss) per share – diluted	<u>\$ 0.11</u>	<u>\$ (0.28)</u>	<u>\$ (0.77)</u>	<u>\$ (1.92)</u>
Weighted average number of common shares outstanding - basic	<u>8,530,580</u>	<u>6,097,254</u>	<u>8,466,243</u>	<u>6,127,225</u>
Weighted average number of common shares outstanding - diluted	<u>8,554,320</u>	<u>6,097,254</u>	<u>8,466,243</u>	<u>6,127,255</u>

## Comparison of Three Months Ended December 31, 2018 with Three Months Ended December 31, 2017

### Research and development expenses

Research and development expenses for the three months ended December 31, 2018 was \$586,700 as compared to \$1,211,600 for December 31, 2017. The decrease of \$624,900 was primarily attributed to ending of a compassionate trial during the three months ended December 31, 2017 of \$496,600 offset by an increase in non-cash stock-based compensation expense of \$44,400 for the three months ended December 31, 2018. For the three months ended December 31, 2018, the Company continues to develop its NO Generator and Delivery System. For the three months ended December 31, 2018, the Company recorded an intangible asset to correct a previous error which reduced research and development expense by \$200,000.

### General and administrative expenses

General and administrative expense for the three months ended December 31, 2018 was \$1,817,500 as compared to the three months December 31, 2017 was \$1,166,400. The difference of \$651,100 was primarily attributed to non-cash stock-based compensation expense of \$538,800 for the three months ended December 31, 2018. In August 2018 and November 2018, the Board of Directors granted to the Directors and Officers, 810,000 options to purchase common stock. Non-cash stock-based compensation for the three months ended December 31, 2018 was \$676,900, which \$462,300 related to aforementioned August 2018 and November 2018 option grants. In additions for the three months ended December 31, 2018, the Company had an increase in professional fees of \$37,100 and an increase in salaries and benefits of \$360,000 due to the hiring of additional employees.

**Other income (loss)**

The primary category in other income (loss) is the change in fair value of warrant liabilities. Other income (loss) for the three months ended December 31, 2018 was a non-cash gain of \$3,351,200 as compared to the three months ended December 31, 2017. The warrant liabilities are primarily affected by the Company's stock price. Generally, when the Company's stock price is rising at the end of a reporting period, a non-cash expense is recorded and when the stock price is decreasing, a non-cash gain is recorded. The Company adopted ASU-2017-11 during the three months ended December 31, 2018 and the non-cash gain resulted from the reversal of the non-cash expense that was recorded the six months ended September 30, 2018.

***Comparison of Nine Months Ended December 31, 2018 with Nine Months Ended December 31, 2017*****Research and development expenses**

Research and development expenses for the nine months ended December 31, 2018 was \$2,299,300 as compared to \$2,929,700 for December 31, 2017. The decrease of \$630,400 was primarily attributed to ending of a compassionate trial during the nine months ended December 31, 2017 of \$874,100. This was offset by an increase in non-cash stock-based compensation expense of \$69,500. During the nine months ended December 31, 2018, The Company continues to develop its NO Generator and Delivery System. For the nine months ended December 31, 2018, the Company recorded an asset to correct a previous error which reduced research and development expense by \$200,000.

**General and administrative expenses**

General and administrative expense for the nine months ended December 31, 2018 was \$4,272,800 as compared to the nine months ended December 31, 2017 was \$4,578,000. The decrease of \$305,200 was to was primarily related to due higher non-stock-based compensation expense for the nine months ended December 31, 2017 of \$884,500. There were increases in salaries and benefits and professional fees for the nine months ended December 31, 2018 as compared to December 31, 2017 of \$972,400 and \$201,800, respectively. This was due to the hiring of additional employees. For the nine months ended December 31, 2017, the Company issued 492,624 restricted shares to a director, which 246,312 vested on July 13, 2017. The unvested 246,312 restricted shares were cancelled on June 12, 2017 and the Company recorded a non-cash stock-based compensation expenses of \$2,063,800. In August 2018 and November 2018, the Board of Directors granted to the Directors and Officers, 810,000 options to purchase common stock. Non-cash stock- based compensation for the nine months ended December 31, 2018 was \$1,540,800, of which \$666,500 related to aforementioned August 2018 and November 2018 option grants.

**Other income (loss)**

The primary category in other income (loss) is the change in fair value of warrant liabilities. Other income (loss) for the nine months ended December 31, 2018 was \$0 as compared to the nine months December 31, 2017 was a non-cash expense of \$4,287,700. The warrant liabilities are primarily affected by the Company's stock price. Generally, when the Company's stock price is rising at the end of a reporting period, a non-cash expense is recorded and when the stock price is decreasing, a non-cash gain is recorded. The Company adopted ASU-2017-11 during the three months ended December 31, 2018 and no gain or loss was recorded for the nine months ended December 31, 2018.

## Cash Flows

Below is a summary of the Company's cash flows activities for the nine months ended December 31, 2018 and 2017:

	Nine Months Ended	
	December 31,	
	2018	2017
Net cash provided by (used in):		
Operating activities	\$ (5,748,300)	\$ (4,906,700)
Investing activities	5,478,500	(823,100)
Financing activities	27,200	(203,800)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (242,600)</u>	<u>\$ (5,933,600)</u>

### Operating Activities

Net cash used in operating activities for the nine months ended December 31, 2018 and 2017 was \$5,748,300 and 4,906,700, respectively. This was primarily to support operations and continued research and development. The net loss for the nine months ended December 31, 2018 and 2017 was \$6,500,500 and 11,763,500, respectively. In addition, there was non-cash stock-based compensation expense and change in the fair value of the warrant liabilities of \$1,693,900 and \$6,796,600 for the nine months ended December 31, 2018 and 2017, respectively.

### Investing Activities

For the nine months ended December 31, 2018 net cash provided by investing activities was \$5,478,500 and for the nine months ended December 31, 2017 net cash used in investing activities was \$823,100. The primary source of cash for the nine months ended December 31, 2018 was from the proceeds of \$5,730,800 from the sale of marketable securities and paid \$200,000 for the license right to use technology. The use of cash for the nine months ended December 31, 2017 was from the purchases of \$603,900 of marketable securities and the purchase of property and equipment of \$219,300.

### Financing Activities

Net cash provided by financing activities for the nine months ended December 31, 2018 was \$27,200 and was from the net proceeds from the issuance of common stock. Net cash used in financing activities for the nine months ended December 31, 2017 was \$203,800 which was primarily from the payment of \$176,800 to the former owners of the Company.

### Liquidity and Capital Resources

#### Overview

We have incurred losses and generated negative cash flows from operations since inception. To date, we have not generated any revenue from the sale of products, and we do not expect to generate revenue from sale of our products in the next several years. Since the Company has been public through December 31, 2018, we have funded our operations principally through the issuance of equity securities aggregating \$21,250,700. We have devoted substantially all of our efforts to business planning and research and development. For the nine months ended December 31, 2018, we have incurred a net loss of \$6,500,500 and had negative cash flow from operations of \$5,7948,300. As of December 31, 2018, we have an accumulated deficit of \$37,586,700 and, and cash, cash equivalents, and marketable securities of \$3,069,200. We expect to have cash, cash equivalents and marketable securities to fund the Company's operations through March 31, 2020.

In August 2018, the Company entered into a Stock Purchase Agreement with Lincoln Park Corporation for \$20 million. The Company may sell and issue LPC and LPC is obligated to purchase up to \$20 million in value of shares of common stock from time to time over three years. The Company may direct LPC, at its sole discretion, and subject to certain conditions, to purchase up to 10,000 to 30,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase. The amount of a purchase may be increased under certain circumstances provided, however that LPC cannot make any single purchase that exceeds \$750,000. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the Stock Purchase Agreement. From the date of the Stock Purchase Agreement to January 23, 2019, the Company received proceeds of \$851,400 from the sale of 192,000 shares of the Company's common stock. The Company has \$19,148,600 remaining on the Stock Purchase Agreement.

On January 23, 2019, the Company entered into an agreement for commercial rights ("the License Agreement") with Circassia (located in the United Kingdom) for persistent pulmonary hypertension of the newborn (PPHN) and future related indications at concentrations of  $\leq 80$  ppm in the hospital setting in the United States and China. The Company may receive payments up to \$32.5 million in up front and regulatory milestones, of which \$31.5 million is associated with the U.S. market. The Company met the first two milestones which resulted in the payment of \$10.5 million in Circassia's ordinary shares. The ordinary share price was predetermined as subject to a volume weighted average price that was defined in the Licensing Agreement. The Company will receive future royalties from 15-20% based upon gross profit, which is defined in the License Agreement.

Our ability to continue to operate is dependent upon raising additional funds to finance our activities. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our product candidates. The Company's ability to continue to operate is dependent upon raising additional funds to finance its activities.

We have based these assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our NO delivery system, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidate.

Our future capital requirements will depend on many factors, including:

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the costs and timing of obtaining regulatory approval for our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of, and timing for, strengthening our manufacturing agreements for production of sufficient clinical quantities of our product candidate;
- the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally;
- the costs of acquiring or undertaking the development and commercialization efforts for additional, future therapeutic applications of our product candidate;
- the magnitude of our general and administrative expenses; and
- any cost that we may incur under current and future in-and out-licensing arrangements relating to our product candidate.

#### **Foreign Currency Exchange Risk**

Our results of operations and cash flow are subject to fluctuations due to changes in foreign currency exchange rates. Certain of our expenses are denominated in New Israeli Shekels (“NIS”). Our results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. We do not hedge our foreign currency exchange risk. In the future, we may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from significant changes in such fluctuations.

If we receive Circassia Shares as payment, the price will be converted into US dollars for purposes of calculating our payment. As a result, our payment will be exposed to currency exchange rate risk with respect to British Pounds. Our net payment will depend on the extent to which British Pounds strengthens or weakens against the U.S. dollar and the relative weight of Circassia Shares we receive as payment. If, taking into account such weighting, the U.S. dollar strengthens against British Pounds, the price of Circassia Shares will be adversely affected and our payment may be reduced.

#### **ITEM 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of foreign currency exchange rates.

#### **ITEM 4. Controls and Procedures**

##### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2018.

##### **Management’s Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in “Internal Control - Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

##### **Changes in Internal Control Over Financial Reporting**

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II OTHER INFORMATION

### Item 1. Legal Proceedings

See Note 8 to our condensed consolidated financial statements.

### ITEM 1A. RISK FACTORS

In addition to the other information set forth in this report, including the important information in the section entitled "Private Securities Litigation Reform Act," you should carefully consider the "Risk Factors" discussed in our Transitional Report on Form 10-KT for the three months March 31, 2018 and for the year ended December 31, 2017, respectively, filed with the SEC on June 15, 2018 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in this report and materially adversely affect our financial condition or future results. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results.

#### *The value of our share of Circassia is volatile*

We granted Circassia an exclusive royalty-bearing license to distribute, market and sell certain rights and licenses held by the Company. Circassia shall pay the Company an aggregate of \$32.55 milestone payments and a significant amount of royalties. The milestone payments shall be in cash or Circassia Shares, at Circassia's option. Royalty payments shall be made in cash. Circassia Shares are traded on the AIM (a sub-market of the London Stock Exchange). The trading price of Circassia Shares could be volatile and could fluctuate widely in response to a variety of factors, many of which are beyond our control. If we receive Circassia Shares as the payment, we may lose significant amount of value in this stock as its market price decreases.

#### *If we receive Circassia Shares as payment, we will be subject to currency exchange risk.*

If we receive Circassia Shares as payment, the price will be converted into US dollars for purposes of calculating our payment. As a result, our payment will be exposed to currency exchange rate risk with respect to British Pounds. Our net payment will depend on the extent to which British Pounds strengthens or weakens against the U.S. dollar and the relative weight of Circassia Shares we receive as payment. If, taking into account such weighting, the U.S. dollar strengthens against British Pounds, the price of Circassia Shares will be adversely affected and our payment may be reduced.

### ITEM 6. Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
10.1	<a href="#">License, Development and Commercialization Agreement, dated January 23, 2019, by and between AIT Therapeutics, Inc. and Circassia Limited ****</a>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
32.2	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

\*\*\*\* Confidential treatment has been requested for portions of this exhibit

**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 thereunto duly authorized.

AIT THERAPEUTICS, INC.

Date: February 14, 2019

*/s/ Steven Lisi*

---

Steven Lisi  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: February 14, 2019

*/s/ Douglas Beck*

---

Douglas Beck  
Chief Financial Officer  
(Principal Financial and Accounting Officer)



CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS AGREEMENT. THE COPY FILED HERewith OMITs THE INFORMATION SUBJECT TO THE CONFIDENTIALITY REQUEST. A COMPLETE VERSION OF THIS AGREEMENT HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

BETWEEN

AIT THERAPEUTICS, INC.

AND

CIRCASSIA LIMITED

---

## TABLE OF CONTENTS

	<u>Page</u>
1. Definitions.	1
2. Licenses.	9
3. Milestone and Royalty Payments.	11
4. Management; Joint Steering Committee.	15
5. Development.	16
6. Regulatory Matters.	17
7. Export Controls, Modern Slavery and Corruption	19
8. Commercialization.	20
9. Reports; Records.	21
10. Representations, Warranties and Covenants; Disclaimer.	23
11. Intellectual Property.	26
12. Confidentiality/Publications.	31
13. Term and Termination.	33
14. Effects of Termination or Expiration.	34
15. Announcement.	36
16. Governing Law.	36
17. Dispute Resolution.	36
18. Notices.	37
19. Force Majeure.	38
20. Indemnification and Insurance.	38
21. Non-assignability.	40
22. Language.	41
23. Entire Agreement.	41
24. Severability.	41
25. Independent Contractors; No Partnership.	41
26. Amendment and Waiver.	42
27. Counterparts.	42
28. Further Assurances.	42
EXHIBIT 1.7 - AIT THERAPEUTICS PATENTS	
EXHIBIT 1.71 - [*]	
EXHIBIT 3.2 - [*]	
EXHIBIT 5.1 - [*]	
EXHIBIT 8.7 - [*]	
EXHIBIT 15 - ANNOUNCEMENTS	

THIS LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (this "Agreement") is made and entered into effective as of January 23, 2019 (the "Effective Date"), by and between AIT Therapeutics, Inc., a Delaware corporation having its principal place of business at 825 East Gate Blvd. Garden City, NY 11530 ("AIT Therapeutics"), and Circassia Limited, a company registered in England and Wales, Company number 03689966, with a registered office at The Magdalen Centre, Robert Robinson Avenue, Science Park, Oxford OX4 4GA, United Kingdom ("Circassia"). Each of AIT Therapeutics and Circassia is sometimes referred to herein as a "Party" and collectively, as the "Parties."

WHEREAS, AIT Therapeutics has developed certain intellectual property relating to the use of a nitric oxide generator and its related nitrogen dioxide filters for the treatment of certain respiratory disorders;

WHEREAS, Circassia has substantial expertise in the development, distribution, sales and marketing of pharmaceutical and medical device products in the Territories; and

WHEREAS, AIT Therapeutics desires to grant to Circassia, and Circassia desires to obtain from AIT Therapeutics, the right to distribute, market and sell the Products in the Field in the Territories, all on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties hereto agree as follows:

**1. Definitions.**

1.1 "Adverse Event" shall have the meaning ascribed such term in Section 6.2(b).

1.2 "Adverse Event Agreement" shall have the meaning ascribed such term in Section 6.2(a).

1.3 "Affiliate" means any corporation, firm, partnership, limited liability company or other entity that controls, is controlled by or is under common control with a Party to this Agreement. For purposes of this definition, any entity will be regarded as in "control" of another entity if (a) it directly or indirectly owns more than fifty percent (50%) of the voting stock of the other entity or such lesser maximum percentage permitted in those jurisdictions where majority ownership by foreign entities is prohibited, (b) it owns or has a right to own more than fifty percent (50%) of the net assets of an entity without voting securities, or (c) it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the entity, whether through contract or otherwise.

1.4 "Agreement" means this License, Development and Commercialization Agreement, as set forth in the preamble above.

1.5 "AIT Therapeutics" shall have the meaning set forth in the preamble to this Agreement.

1.6 "AIT Therapeutics Indemnitees" shall have the meaning ascribed such term in Section 20.2.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

1.7 “AIT Therapeutics Patent” means any Patent that (a) is Controlled by AIT Therapeutics or its Affiliates as of the Effective Date or at any time during the term, and (b) claims the apparatus, composition of matter, use (including any claimed methods) or Manufacture of a Product or any component thereof in the Field. A list of AIT Therapeutics Patents in existence as of the Effective Date is attached hereto as Exhibit 1.7 and AIT Therapeutics shall update such list from time to time to include additional AIT Therapeutics Patents, including patents issuing from any listed application or claiming priority thereto or otherwise continuing therefrom.

For the avoidance of doubt, AIT Therapeutics Patents shall

[\*]

1.8 “AIT Therapeutics Agreement Revenue” means the aggregate total of Milestone Payments plus Royalty Payments actually received by AIT Therapeutics during the term of this Agreement.

1.9 “AIT Therapeutics Technology” means, collectively, the AIT Therapeutics Patents and the AIT Therapeutics Trade Secrets.

1.10 “AIT Therapeutics Trade Secret” means any Information (a) that is Controlled by AIT Therapeutics or its Affiliates on the Effective Date or during the term, (b) that constitutes a trade secret under the Delaware Uniform Trade Secrets Act, 6 Dela. Laws, Chapter 20, § 2001 *et seq.*, and (c) that (i) is or was used in the Development or Manufacture of Products, or any component thereof, (ii) is or was embodied in Products, or any component thereof, or (iii) is necessary or useful in order to use or to Commercialize the Products in the Field in the Territories.

1.11 “Alliance Manager” shall have the meaning ascribed such term in Section 4.1.

1.12 “Bankruptcy Event” means, with respect to a Party, that such Party files in any court or agency pursuant to any statute or regulation pertaining to bankruptcy, solvency, or payment of debts, of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if such other Party shall be a party to its dissolution or liquidation, or if such other Party shall make an assignment for the benefit of creditors.

1.13 “China” means the People’s Republic of China and its territories and possessions (including, without limitation, Hong Kong and Macau).

1.14 “China Regulatory License” shall have the meaning ascribed such term in Section 6.1(a) hereof.

1.15 “Circassia” shall have the meaning set forth in the preamble to this Agreement.

1.16 “Circassia Indemnitees” shall have the meaning ascribed such term in Section 20.1.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

1.17 "Circassia Pharmaceuticals plc" means Circassia Pharmaceuticals plc, a company registered under the laws of England and Wales, Company number 05822706, and which is an Affiliate of Circassia.

1.18 "Circassia Agreement Revenue" means Gross Profits actually collected during the term of the Agreement, less all Milestone Payments and Royalty Payments actually paid to AIT Therapeutics during the term of the Agreement.

1.19 "Circassia Shares" means ordinary shares, 0.08 pence each, of Circassia Pharmaceuticals plc.

1.20 "Clinic" shall mean an outpatient healthcare facility, annexed or in close proximity to a hospital, and which does not provide for typical patient-physician follow-up care. For the avoidance of doubt, the term "Clinic" does not include any mobile healthcare facility.

1.21 "Combination Product" shall mean the Product sold in combination with one or more other products or services not constituting the Product or as part of a bundle with other unrelated products or services.

1.22 "Commercially Reasonable Efforts" means the expenditure of those efforts normally used by reputable medical device organizations for medical devices (a) which are of similar market potential, and (b) which are at a similar stage in its development or product life cycle, as the Product, in each case, taking into account all Relevant Factors in effect at the time such efforts are to be expended. Further, to the extent that the performance of Circassia's obligations hereunder is adversely affected by AIT Therapeutics' material failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining the extent to which Circassia has used Commercially Reasonable Efforts to perform any such affected obligations. Notwithstanding anything herein to the contrary, Commercially Reasonable Efforts shall not preclude the suspension or discontinuance of Circassia's research, Commercialization or sale of any Products, if exercised pursuant to the terms of this Agreement, based on the exercise of Commercially Reasonable Efforts.

1.23 "Commercialization" with a correlative meaning for "Commercialize" and "Commercializing", means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-Launch, Launch, promotion, detailing, medical education and medical liaison activities, marketing, pricing, reimbursement, sale, and distribution of the Product, including: (a) strategic marketing, sales force detailing, advertising, medical education and liaison, and market and Product support; (b) any postmarketing clinical studies for use in generating data to be submitted to Regulatory Authorities (and all associated reporting requirements); and (c) all customer support, Product distribution, invoicing and sales activities.

1.24 "Commercialization Plan" shall have the meaning ascribed such term in Section 8.2.

1.25 "Confidential Information" means, with respect to a Party, all reports and other Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, electronic or other form. All Confidential Information (as defined in the Mutual CDA) disclosed by either Party pursuant to the Mutual CDA shall be deemed to be such Party's Confidential Information disclosed hereunder.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

1.26 “Control” or “Controlled” means, with respect to any material, Information, or intellectual property right, that a Party owns or has a license to such material, Information, or intellectual property right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

1.27 “Cost of Goods” means money paid, accrued or in accounts payable by Circassia to AIT Therapeutics for the purchase of a new Product and/or Filter, the price of which shall be AIT Therapeutics’ actual cost, as evidenced by its purchase price of the new Filter and/or Product from a third party supplier, plus the applicable mark-up, as specified in the Supply Agreement.

1.28 “Develop” or “Development” means all activities relating to preparing for Regulatory Approval with respect to the Product and/or Filter, together with the Manufacturing of the Product and/or Filter for the purpose of conducting the foregoing activities.

1.29 “Disclosing Party” shall have the meaning ascribed such term in Section 12.1.

1.30 “Dispute” shall have the meaning ascribed such term in Section 17.1.

1.31 “Dollar” means a U.S. dollar, and “\$” shall be interpreted accordingly.

1.32 “Effective Date” shall have the meaning ascribed such term in the preamble to this Agreement.

1.33 “Escrow Agent” shall have the meaning ascribed such term in Section 5.4.

1.34 “Escrow Agreement” shall have the meaning ascribed such term in Section 5.4.

1.35 “FDA” means the United States Food and Drug Administration and any successors thereof.

1.36 “Field” means the use of nitric oxide in hospital and Clinic settings at concentrations of 80 ppm or less for the treatment of (a) persistent pulmonary hypertension of the newborn, and (b) any other condition approved by a Regulatory Authority in a country in the Territory.

1.37 “Filing Party” shall meaning ascribed such term in Section 11.4(a).

1.38 “Filter” means a nitrogen dioxide filter as further described on Exhibit 1.70, attached hereto and incorporated herein by reference.

1.39 “First Commercial Sale” means the first sale to a Third Party of a Product in a country of the Territories after Regulatory Approval has been obtained in such country.

1.40 “Force Majeure” shall have the meaning ascribed such term in Section 19.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

1.41 "Governmental Authority" means any multi-national, federal, state, local, municipal, provincial or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.42 "Gross Profit" means Net Sales minus Cost of Goods.

1.43 "Gross Sales" means the contract price charged to a Third Party by Circassia or its Affiliate, as applicable, for a Product and/or Filter which is sold, leased or otherwise Commercialized by or for Circassia or its Affiliate and any Product- or Filter-related revenue, as applicable. For the avoidance of doubt, Gross Sales will be the price in the contract for each individual hospital or Clinic. Gross Sales for a Combination Product will be calculated by multiplying the Gross Sales of the Combination Product by the fraction,  $A/(A+B)$  where A is the weighted (by sales volume) average sale price in the relevant country of the Product, and B is the weighted average sale price (by sales volume) in that country of the other product or service (in finished form) in the Combination Product. If the weighted average sale price cannot be determined for the Product or other products or services in the Combination Product, the calculation of Gross Sales for Combination Products will be agreed by the Parties based on the relative value contributed by each component (each Party's agreement not to be unreasonably withheld or delayed).

1.44 "HSBC" means HSBC Bank plc.

1.45 "Improvement Patent" shall have the meaning ascribed such term in Section 11.3.

1.46 "Improvements" means any and all ideas, discoveries, improvements, modifications or variations of the Product, methods for manufacture of a Product and/or methods of using a Product, whether or not patentable or otherwise protectable as intellectual property, which is discovered, developed, reduced to practice, or created by a Party or its Affiliates, alone, jointly or with others.

1.47 "Indemnitee" shall have the meaning ascribed such term in Section 20.2.

1.48 "Indemnitor" shall have the meaning ascribed such term in Section 20.3.

1.49 "Information" means any data, results, technology, business information and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.

1.50 "Invalidation Proceeding" shall have the meaning ascribed such term in Section 11.8.

1.51 "Inventory" shall have the meaning ascribed such term in Section 14.4.

1.52 “Joint Product” shall have the meaning ascribed such term in Section 11.4(a).

1.53 “Joint Steering Committee” or “JSC” shall have the meaning ascribed such term in Section 4.2.

1.54 “Launch” in relation to a country in the Territories means the first commercial sale of Filters in that country.

1.55 “Laws” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign, including any regulatory agency policy or informal regulatory agency guidance, including, but not limited to, those related to medical device marketing, labeling and sales, foreign corrupt practices, import and export controls.

1.56 “Lead Party” shall have the meaning ascribed such term in Section 11.5(c).

1.57 “Letter of Intent” means that certain Letter of Intent by and between AIT Therapeutics and Circassia Pharmaceuticals plc, dated November 2, 2018.

1.58 “LIBOR” means the overnight LIBOR rate for Great Britain Pounds Sterling, as published by HSBC.

1.59 “License” means the licenses granted to Circassia pursuant to Section 2.1.

1.60 “Litigation Expenses” means all damages awarded or settlement payments actually paid to Third Parties, reasonable attorneys’ fees and expenses, expert witness fees and expenses, investigative expenses, court costs and other customary expenses actually incurred in connection with the claim, or litigation and settlement.

1.61 “Losses” shall have the meaning ascribed such term in Section 20.1.

1.62 “Manufacture” with a correlative meaning for “Manufacturing,” means all activities related to the manufacturing the Product and/or Filters in finished form for Development, manufacturing the finished Product and/or Filters for Commercialization, packaging, in-process and finished product testing for the Product and/or Filters, release of the Product and/or Filters, quality assurance activities related to manufacturing and release of the Product and/or Filters, ongoing batch tests and other FDA post-PMA approval requirements under 21 C.F.R. § 814.82 and 21 C.F.R. § 814.80 and regulatory activities related to any of the foregoing.

1.63 “Mutual CDA” means that certain Mutual Confidentiality Agreement by and between AIT Therapeutics and Circassia Pharmaceuticals plc, dated March 5, 2018.

1.64 “Net Sales” means the Gross Sales less, on an actual basis, (a) documented discounts (including customary trade, quantity, cash, etc.), charge-backs and rebates to managed health care organizations or to federal, state and local governments, their agencies, and purchasers and reimbursers or to trade customers; (b) credits for returns and other customary allowances actually given; (c) any value added taxes or governmental taxes levied; and (d) [\*]

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

1.65 “NitricGen License Agreement” means that certain License Agreement, dated January 30, 2018 by and between NitricGen, Inc., a Delaware corporation (“NitricGen”), and AIT Therapeutics, a certified copy of which is provided to Circassia by AIT Therapeutics at the time of signing this Agreement.

1.66 “NO Generator” means a nitric oxide generator [\*] and any Improvements thereof.

1.67 “Non-Filing Party” shall have the meaning ascribed such term in Section 11.4(a).

1.68 “Party” and “Parties” shall have the meaning ascribed such terms in the preamble to this Agreement.

1.69 “Patent” means (a) pending patent applications (and patents issuing therefrom), issued patents, utility models and designs; and (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any patents, patent applications, utility models or designs, in each case being enforceable within the applicable countries of the Territories as permitted by applicable Laws.

1.70 “PMA” means the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

1.71 “Product” means the NO Generator and delivery system, including, without limitation, the Nitric Oxide Delivery Module, the backup delivery system, the Filters and the Gas Monitoring Module, together with, in each case, all Improvements, [\*].

1.72 “Product Infringement” shall have the meaning ascribed such term in Section 11.5(b).

1.73 “Product Marks” shall have the meaning ascribed such term in Section 8.5.

1.74 “Receiving Party” shall have the meaning ascribed such term in Section 12.1.

1.75 “Regulatory Approval” means, with respect to a Product and/or Filter in any country or jurisdiction, all approvals (including, where required, pricing and reimbursement approvals), registrations, licenses or authorizations from the relevant Regulatory Authority in a country or jurisdiction that is specific to such Product and/or Filter, and necessary to market and sell such Product and/or Filter in such country or jurisdiction. Regulatory Approval in the United States includes, by way of example, a PMA.

1.76 “Regulatory Authority” means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the extent required in such country or regulatory jurisdiction, pricing or reimbursement approval of a Product and/or Filter in such country or regulatory jurisdiction, including, but not limited to the FDA.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

1.77 “Regulatory Documentation” means all Regulatory Filings, registrations, filings, applications, licenses, authorizations and approvals (including Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authorities), and all clinical studies, data and supporting documents contained therein, in each case relating to a Product and/or Filter, and all data contained in any of the foregoing (including advertising and promotional and marketing documents, adverse event files, periodic safety update reports (PSURs), medical event reports, complaint files and the like).

1.78 “Regulatory Filings” means, with respect to a Product and/or Filter, any submission to a Regulatory Authority of any appropriate regulatory application specific to such Product and/or Filter, and shall include, without limitation, any submission to a regulatory advisory board and any supplement or amendment thereto.

1.79 “Reporting Period” shall have the meaning ascribed such term in Section 9.1.

1.80 “Retained Territories” means all countries and territories in the world other than the Territories.

1.81 “Royalty Year” shall mean each twelve-month period commencing January 1 and ending December 31 during the Term. For the initial calendar year in which this Agreement is in effect, the Royalty Year shall be the period of time between the Effective Date and December 31. The final Royalty Year shall be the period of time between January 1 and the expiration or termination date of this Agreement.

1.82 “SEC” shall have the meaning ascribed such term in Section 12.2(d).

1.83 “SOPs” shall have the meaning ascribed such term in Section 6.5.

1.84 “Sales Report” shall have the meaning ascribed such term in Section 9.1.

1.85 “Step-In Rights Event” means the occurrence of one or more of the following events: (a) AIT Therapeutics is acquired by a third-party that sells, or plans to sell in the Territories (i) nitric oxide gas, or (ii) any device capable of generating and/or delivering nitric oxide gas; (b) AIT Therapeutics is the subject of a Bankruptcy Event; (c) AIT Therapeutics commits a material breach of this Agreement and such material breach is not cured within the applicable cure period as set forth in Section 15.2(a) hereof; or (d) AIT Therapeutics commits a material breach of [\*] and such material breach is not cured within the applicable cure period as set forth therein.

1.86 “Supply Agreement” shall have the meaning ascribed such term in Section 8.7.

1.87 “Supporting Party” shall have the meaning ascribed such term in Section 11.5(c).

1.88 “Territories” means the United States and China.

1.89 “Third Party” means any party other than a Party to this Agreement and such Party’s Affiliates.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

1.90 "Total Litigation Expenses" means the sum of all Litigation Expenses actually incurred by AIT Therapeutics and all Litigation Expenses actually incurred by Circassia in connection with the investigation of any Third-Party infringement of any AIT Therapeutics Patent(s), Improvement Patent(s) or Joint Patents, or pursuing any infringement claim, litigation, proceeding and/or settlement (if any) against such Third Party, or the defense of any product infringement or misappropriation claim asserted by a Third Party, or in connection with any Invalidation Proceeding.

1.91 "Transition Assistance Period" shall have the meaning ascribed such term in Section 14.2.

1.92 "Transition Assistance Services" shall have the meaning ascribed such term in Section 14.2.

1.93 "United States" means the United States of America and its territories and possessions.

1.94 "USPTO" means the United States Patent and Trademark Office, or any successor agency.

1.95 "US Regulatory License" shall have the meaning ascribed such term in Section 6.1(a) hereof.

1.96 "Valid Claim" means any claim contained in any AIT Therapeutics Patent or Improvement Patent in the Territories which has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency or competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise.

1.97 "VWAP" shall have the meaning ascribed such term in Section 3.3(d) hereof.

## **2. Licenses.**

### **2.1 License to Circassia.**

(a) Subject to the terms and conditions of this Agreement, AIT Therapeutics hereby grants to Circassia an exclusive (even as to AIT Therapeutics), royalty-bearing license, without the right to sublicense, under the AIT Therapeutics Technology, to: (i) use, have used, (ii) sell, have sold, offer for sale, have offered for sale, (iii) distribute, have distributed, (iv) import, have imported, and otherwise Commercialize the Products and Filters in the Field in the Territories.

(b) Subject to the terms and conditions of this Agreement (including, without limitation, Section 2.2 below), AIT Therapeutics hereby grants to Circassia upon the occurrence of a Step-In Rights Event a non-exclusive license, under the AIT Therapeutics Technology: (i) to conduct research; (ii) to Develop and have Developed; and (iii) to Manufacture or have Manufactured, in each case the Product and the Filters in the Field in the Territories or (to the extent that the Product and/or the Filters are Manufactured in the Retained Territories) in the Retained Territories.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(c) Notwithstanding the rights granted to Circassia in Section 2.1 and without limiting the generality of Section 2.2, AIT Therapeutics retains the following: (i) the right to conduct or have conducted clinical trials and other studies in the Territories for the generation of data in support of any regulatory submissions to any Regulatory Authority in the Retained Territories; and (ii) the right to Manufacture or have Manufactured the Product anywhere in the Territories, in each case together with the right to import and export the Product in such territories for such purposes.

**2.2 Negative Covenant: No Implied License** Circassia covenants and warrants that (a) it will not exercise any of the non-exclusive licenses granted to it under Section 2.1(b) unless and until a Step-In Rights Event occurs, and (b) it will not use or practice any of the AIT Therapeutics' intellectual property rights licensed to Circassia under this Section 2 except for the purposes expressly permitted in the applicable license grant. Except as explicitly set forth in this Agreement, AIT Therapeutics does not grant any license, express or implied, under its intellectual property rights to Circassia.

### 2.3 Diversion.

(a) Circassia hereby covenants and agrees that it will not, and will ensure that its Affiliates and Third Party contractors will not, either directly or indirectly, promote, market, distribute, import, sell or have sold Products, including via the Internet or mail order, to any Third Party, address or Internet Protocol ("IP") address in the Retained Territories. As to such countries in the Retained Territories: (i) Circassia shall refrain from establishing or maintaining any branch, warehouse or distribution facility for the Product in such countries; (ii) Circassia shall not engage in any advertising or promotional activities relating to the Product directed primarily to customers or other buyers or users of the Product located in such countries; and (iii) Circassia shall not solicit orders from any prospective purchaser located in such countries. If Circassia receives any order from a prospective purchaser located in a country in the Retained Territories, Circassia shall promptly refer that order to AIT Therapeutics. Notwithstanding the foregoing, Circassia shall have the right to store inventory of the Product and Filters in the Retained Territories, provided that Circassia shall only sell or offer for sale such Product or Filters in the Territories. For the sake of clarity, Section 2.3(a)(ii) shall not restrict Circassia's ability to discuss the Product and/or Filters for corporate purposes (including, without limitation, as part as an investor presentation or on a Circassia website).

(b) If any Product is diverted by an identifiable customer or distributor for use in the Retained Territories, then, upon the request of AIT Therapeutics, Circassia shall suspend further shipments of the Product to such customer or distributor until such customer or distributor provides reasonable assurances to Circassia and AIT Therapeutics that such customer or distributor has implemented reasonable precautions to prevent any further such diversions of Product.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

2.4 Exclusivity.

[\*]

2.5 Registration of License. Circassia shall have the right to record or register the License granted hereunder with any Governmental Authority in the Territories. At Circassia's request, AIT Therapeutics shall execute all documents and give all declarations regarding the License and reasonably cooperate with Circassia at the costs of Circassia to the extent such documents, declarations and/or cooperation are permitted or required for such recordation or registration of the License for the benefit of Circassia.

**3. Milestone and Royalty Payments.**

3.1 Milestone Payments. In consideration of the rights and Licenses granted to Circassia by AIT Therapeutics hereunder, Circassia shall pay, or cause Circassia Pharmaceuticals plc to pay, to AIT Therapeutics the following milestone amounts:

<b>Event</b>	<b>Payment (U.S. Dollars or Circassia Shares)</b>
1. Upon signing of this Agreement by both Parties	\$ 7,350,000
2. Within five (5) business days following completion of a pre-submission meeting with the FDA, in which the FDA [*] the results of which the FDA will require to approve the Product in the Field and that the FDA confirms that no additional clinical data will be required	\$ 3,150,000
3. On the sooner of the launch of the Product in the Field in the United States, or ninety (90) calendar days following the approval of a Product by the FDA, provided that [*]	\$ 12,600,000
4. Within five (5) business days following the approval by the FDA of the Product in the Field for use in cardiac surgery	\$ 8,400,000
5. Within five (5) business days following the approval by the Food and Drug Administration equivalent in China for the marketing and sale of the Product in the Field in China for any indication	\$ 1,050,000
<b>TOTAL PAYMENTS</b>	<b>\$ 32,550,000</b>

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

### 3.2 Royalty Payments.

(a) In consideration of the rights and licenses granted to Circassia by AIT Therapeutics hereunder, Circassia shall pay to AIT Therapeutics the following royalty amounts:

	<u>Payment (U.S. Dollars)</u>
1. First cumulative \$50 Million in Gross Profit in the United States	5%
2. First cumulative \$20 Million in Gross Profit in China	5%
Thereafter, Circassia shall pay to AIT Therapeutics running royalty amounts "Running Royalties" per Royalty Year as follows:	
3. Annual Gross Profit up to and including \$100 Million	15%
4. Annual Gross Profit exceeding \$100 Million	20%

[\*].

(b) Upon expiration of the last Patent in the Patents, the Royalty payments in Section 3.2(a) shall terminate. In consideration of Circassia's continued use of the AIT Therapeutics Technology other than the Patents for Commercialization of the Product in accordance with the terms of this Agreement, Circassia shall pay AIT Therapeutics the following royalty rates:

	<u>Payment (U.S. Dollars)</u>
3. Annual Gross Profit up to and including \$100 Million	14%
4. Annual Gross Profit exceeding \$100 Million	19%

### 3.3 Payment.

(a) Except as provided under Section 3.3(b), below, payments under Section 3.1 shall be in U.S. Dollars or Circassia Shares, at Circassia's option. In addition, the milestones will apply to sales of the Product by Circassia and its Affiliates.

(b) With respect to the second milestone payment under Section 3.1, AIT Therapeutics shall have the right to insist that this milestone payment is paid by issue of Circassia Shares.

(c) For clarity, milestone events 4 and 5 under Section 3.1 may occur during the same calendar year, in which event each of the accompanying milestone payments shall become due.

(d) With respect to the first 2 milestone payments under Section 3.1, Circassia Shares shall be priced at a 5% discount to the lower of the one-week Volume Weighted Average Price ("VWAP") or the 1 month VWAP over the previous week or month, as applicable, prior to the signing of the Agreement by both Parties. [\*]

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(e) With respect to the third milestone payment under Section 3.1, Circassia Shares shall be priced at a 5% discount to the lower of the one-week VWAP, the 1-month VWAP or the 3-month VWAP over the previous week, month or 3 months as applicable, prior to the sooner of the first commercial shipment of Product or ninety (90) calendar days following Regulatory Approval of the Product by the FDA. [\*]

(f) With respect to the fourth milestone payment under Section 3.1, Circassia Shares shall be priced at a 5% discount to the lower of the one-week VWAP, the 1-month VWAP or the 3-month VWAP over the previous week, month or 3 months as applicable, prior to the occurrence of the stated milestone related event. [\*]

(g) If Circassia chooses to make a Milestone Payment by the issue of Circassia Shares, then such Circassia Shares shall be issued as soon as reasonably practicable following the date upon which the Milestone Payment is payable. In the case of Milestones 3, 4 and 5, if there is a delay of more than 24 (twenty four) hours between the Milestone Payment becoming payable and the issue to AIT Therapeutics of the Circassia Shares and, during such period of delay, there is a downwards movement in the market price of Circassia Shares, then Circassia shall make such additional payment to AIT Therapeutics as is necessary to ensure that AIT Therapeutics receives the full value of the Milestone Payment.

(h) If Circassia chooses to make a Milestone Payment in cash, then Circassia shall make such Milestone Payment into such bank account as AIT Therapeutics shall from time to time notify to Circassia.

(i) With respect to the milestone payments under Section 3.1, payment in cash shall result in a reduction of the milestone amount by 4.7619%, with amounts as follows:

<b>Event</b>	<b>Payment (U.S. Dollars)</b>
1. Upon signing of this Agreement by both Parties	\$ 7,000,000
2. Within five (5) business days following completion of a pre-submission meeting with the FDA, in which the FDA [*] will require to approve the Product in the Field and that the FDA confirms that no additional clinical data will be required	\$ 3,000,000
3. On the sooner of the launch of the Product in the Field in the United States, or ninety (90) calendar days following the approval of a Product by the FDA, provided that [*]	\$ 12,000,000
4. Within five (5) business days following the approval by the FDA of the Product for use in cardiac surgery	\$ 8,000,000
5. Within five (5) business days following the approval by the Food and Drug Administration equivalent in China for the marketing and sale of the Product in China for any indication	\$ 1,000,000
<b>TOTAL PAYMENTS</b>	<b>\$ 31,000,000</b>

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

3.4 Other Payment Obligations. With each Sales Report, Circassia shall pay to AIT Therapeutics the royalties due and payable under this Agreement. If no royalties shall be due, Circassia shall so report. Royalties shall be due and payable on a quarterly basis, with respect to each calendar quarter (or portion thereof) of Circassia, forty-five (45) calendar days after the end of the applicable calendar quarter, in accordance with the time period set forth above.

3.5 Non-Refundable. Any royalty payments made by Circassia in accordance with Section 3.2 hereof shall, once they are paid, not be refundable nor creditable for any reason whatsoever, unless otherwise expressly provided herein. For the avoidance of doubt, nothing in this Section shall be construed as limiting or prohibiting any remedies available to Circassia at law or equity (including, without limitation, a refund or restitution of any Milestone Payments paid by Circassia pursuant to Section 3.1 or Section 3.3) upon any material breach of this Agreement by AIT Therapeutics.

3.6 Royalty Stacking. If Circassia determines in good faith that, in order to avoid infringement of a Third Party Patent that is necessary to use, have used, research, Develop, have Developed, Manufacture, have Manufactured, sell, have sold, offer for sale, have offered for sale, import, have imported, or otherwise Commercialize a Product and/or Filter in the Field in a particular country of the Territories in accordance with this Agreement, Circassia shall promptly notify AIT Therapeutics in writing. The Parties shall discuss in good faith the necessity and/or advisability of procuring a license to practice under such Third Party Patent, and provided the Parties mutually agree that such a license is necessary, then Circassia shall be permitted (i) to obtain a license from such Third Party in order to use, have used, research, Develop, have Developed, Manufacture, have Manufactured, sell, have sold, offer for sale, have offered for sale, distribute, have distributed, import, have imported, or otherwise Commercialize such Product and/or Filter in such country, (ii) to pay a royalty or other consideration under such license to such Third Party, and (iii) subject to the remaining provisions of this Section, to reduce the royalties payable by Circassia to AIT Therapeutics pursuant to this Agreement by fifty percent (50%) of the amount(s) of all such royalties or other consideration paid or payable to such Third Party by or on behalf of Circassia; provided, however, in no event shall the royalties due to AIT Therapeutics on Gross Profits from the Commercialization of such Product in any country in the Territories be reduced hereunder by more than fifty percent (50%) of the applicable running royalty percent under Section 3.2(1), 3.2(2), 3.2(3) or 3.2(4), above.

3.7 No Multiple Royalties. No multiple royalties on Gross Profits shall be payable to AIT Therapeutics on a single Product based on the fact that such Product practices more than one Valid Claim.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

3.8 Late Payments. In the event milestone or royalty payments are not received by AIT Therapeutics when due hereunder, Circassia shall pay to AIT Therapeutics interest charges that will accrue interest from the date due until paid at a rate equal to one and one-half percent (1.5%) per month (or the maximum allowed by Law, if less).

#### **4. Management; Joint Steering Committee**

4.1 Alliance Managers. Within thirty (30) days following the Effective Date, each Party will appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications including a general understanding of medical device Development, Manufacture and Commercialization issues to act as its alliance manager under this Agreement (each, an "Alliance Manager"). The Alliance Managers will serve as the primary contact points between the Parties for the purpose of providing each Party with information on the progress of the other Party's Development, Manufacture and Commercialization of the Product, as applicable. The Alliance Managers will also be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties, providing single point communication for seeking consensus both internally within each Party's respective organization, including facilitating review of external corporate communications, and raising cross-Party and/or cross-functional disputes in a timely manner. Each Party may replace its Alliance Manager with another appropriately qualified designee on written notice to the other Party.

#### **4.2 Joint Steering Committee.**

(a) Within thirty (30) days after the Effective Date, the Parties will establish a joint steering committee (the "Joint Steering Committee" or "JSC") to plan, administer, evaluate and carry out all aspects of the Development, Manufacture, regulatory and Commercialization activities with respect to the Product in the Territories.

(b) The JSC will consist of a maximum of three (3) representatives from each of AIT Therapeutics and Circassia. The representatives may be from various functional groups (e.g., clinical development, regulatory, medical affairs, commercial and manufacturing). The Chairperson for the JSC shall be selected by AIT Therapeutics during the Development phase (i.e., prior to PMA approval) and by Circassia during the Commercialization phase (i.e., following PMA approval). [\*]

(c) The Parties shall schedule the quarterly JSC meetings and agree to such schedule at least quarterly in advance. Either Party may call additional ad hoc meetings of the JSC as the needs arise with reasonable advance notice to the other Party, and such ad hoc meetings shall be conducted at times that are mutually agreed upon by the Parties. All meetings and other communications of the JSC shall be conducted in English. No later than five (5) business days prior to any regularly scheduled meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting and, as soon as practicable, all materials, documents and information for the meeting for distribution to both Parties; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. The JSC may meet in person, by videoconference or by teleconference. The chairperson of the JSC will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to the Circassia members and the AIT Therapeutics members of the JSC for review, comment and approval within ten (10) business days after each JSC meeting. Such minutes will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within ten (10) business days of receipt. In addition to the regularly scheduled meetings, AIT Therapeutics shall call additional ad hoc meetings of the JSC prior to making any major decisions in the Development and Manufacture of the Product in the Territories. The Parties shall also maintain regular, frequent and informal communications for AIT Therapeutics to obtain updates from Circassia and for the Parties to discuss the progress of the Commercialization of the Products in the Territories.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(d) The JSC shall strive to seek consensus in its actions and decision-making process. In the event of a disagreement between the AIT Therapeutics members and Circassia members of the JSC, either Party may refer the matter to one senior executive of each Party (i.e., the Chief Executive Officer or Managing Director of such Party or an executive of such Party who reports directly to the Chief Executive Officer or Managing Director) for resolution. [\*]

4.3 Costs of Governance. The Parties agree that the costs incurred by each Party in connection with its participation at any meetings under this Section 4 shall be borne solely by such Party.

#### **5. Development.**

5.1 AIT Therapeutics Development Activities. In accordance with the Development Plan, [\*] AIT Therapeutics shall be responsible for, and shall use Commercially Reasonable Efforts in, Developing, and seeking Regulatory Approval in the US for, the Product in the Field to permit Circassia to perform its obligations hereunder. AIT Therapeutics shall establish and maintain a continuous program for improvements of the NO Generator and the Filters. As part of the Development of the Product, AIT Therapeutics shall conduct continuing reliability testing of the Product as required by Law. Without limiting the generality of the foregoing, AIT Therapeutics shall (a) ensure that all NO Generators, Filters and/or Products are Developed in accordance with FDA Quality System Regulation, 21 C.F.R. § 820 and ISO 13485, and (b) use Commercially Reasonable Efforts to ensure that all NO Generators, Filters and/or Products Developed and Manufactured for Commercialization in China comply with ISO 13485 and such other regulatory requirements imposed by Law or any Regulatory Authority in China as shall be notified by Circassia to AIT from time to time.

5.2 Development Costs. As between the Parties, AIT Therapeutics shall bear all Development Costs for the Development, including, without limitation, what is necessary for the initial FDA approval for persistent pulmonary hypertension of the newborn (PPHN).

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

5.3 Step-in Rights. Upon the occurrence of any Step-In Rights Event and subject to Circassia being in material compliance with the terms of this Agreement and the Supply Agreement, Circassia shall have the following rights (each, a “Step-In Right”): (a) [\*]; and (b) to file Circassia’s own PMA with the FDA and/or the corresponding Regulatory Authority in China (or any corresponding application for Commercialization of the Product in the applicable country of the Territories) for the Regulatory Approval of the Product in the Territories, with a right to (i) reproduce, use and include in Circassia’s PMA application(s) (or any corresponding Regulatory Approval application(s) in China) all information, clinical data, and manufacturing information and data (including, without limitation, the Design File History and the Master File) from AIT Therapeutics’ PMA application and/or any approved PMA (or any corresponding application or Regulatory Approval in China) for the Product, and (ii) reference any or all such information, clinical data, and manufacturing information and data described in clause (b)(i) of this Section 5.3, in each case as required by the applicable Regulatory Authority for Circassia to file the PMA or corresponding application for Commercialization of the Product, as applicable. [\*]

5.4 [\*]

5.5 [\*]

## **6. Regulatory Matters.**

### 6.1 Regulatory Responsibilities.

(a) AIT Therapeutics shall be responsible for all Regulatory matters with regards to the Product in the US and Circassia shall be responsible for all regulatory matters with regards to the Product in China, including Regulatory Filings and Regulatory Approvals. AIT Therapeutics shall own all Regulatory Filings and Regulatory Approvals for the Product in the United States and China, subject in each case to Circassia’s Step-In Rights as set forth in Section 5.3. AIT Therapeutics shall file for all Regulatory Filings and shall maintain all Regulatory Approvals for the Product in the U.S. To the extent required by Applicable Law, AIT Therapeutics shall designate Circassia as its agent and Circassia shall file for all Regulatory Filings and shall maintain all Regulatory Approvals for the Product in China. Without limiting the generality of the foregoing, AIT Therapeutics shall submit annual establishment registration, maintain registration and list updates in the United States. Each Party (i) shall cooperate in good faith with the other Party to support each Party’s respective rights and obligations respecting Regulatory Filings and Regulatory Approvals for the Product in the Territories, and (ii) in the absence of any Step-In Rights Event, neither Party shall withdraw, modify, amend, compromise, cancel, surrender or terminate any Regulatory Filing or Regulatory Approval for the Product resulting therefrom, without the prior written consent of the other Party.

(b) The Parties shall keep each other informed of regulatory developments specific to Product throughout the Territories, and Circassia shall have the right to contribute to the regulatory plans and strategies for the Products in the Field for use in the Territories.

(c) [\*]

### 6.2 Adverse Events.

(a) Within one (1) year prior to the planned first Regulatory Approval of the Products in the Territories, the Parties shall discuss in good faith and enter into an adverse event reporting agreement setting forth the worldwide procedures for the Parties with respect to the Products, such as safety data sharing, adverse events reporting and events monitoring (the “Adverse Event Agreement”). Such Adverse Event Agreement shall govern the global procedures to be agreed upon by Circassia and AIT Therapeutics.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(b) Prior to the execution of such Adverse Event Agreement, Circassia shall submit to AIT Therapeutics all safety information and reporting in a manner that meets the reporting requirements in the Territories. Each Party shall notify the other Party within twenty-four (24) hours of such Party becoming aware of any Adverse Event (as defined below) that is attributed to or potentially attributable to the use of a Product. Each Party shall also provide the other Party, on an annual basis and more frequently as reasonably requested by the other Party, a summary report of Adverse Events (as defined below), as well as those Adverse Events that are not attributable to the use of the Products. Notice of an Adverse Event must contain the information required in accordance with 21 C.F.R. § 803.52. In the event either Party fails to include any of the information required pursuant to 21 C.F.R. § 803.52 in the notice set forth in the previous sentence, it must inform the other Party in a follow up notice within twenty-four (24) hours of becoming aware of such information. Each Party agrees to cooperate with the other in submitting any adverse event report as required by the FDA and will undertake to conduct a reasonable investigation of an Adverse Event in order to enable each Party to fulfill the reporting requirements of this Section 6.2(b). In addition, each Party shall notify the other Party within twenty-four (24) hours of such Party's learning of any reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health or an event for which FDA has made a written request. As used herein, unless defined differently by the FDA, "Adverse Event" means any a death or serious illness or injury caused or contributed by the Product which is (1) life-threatening; (2) results in irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage; or (3) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure; or a malfunction of a Product that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

6.3 No Harmful Actions. If either Party believes that the other Party, as the case may be, is taking or intends to take any action with respect to the Product that could reasonably be expected to have a material adverse impact upon the regulatory status of the Product in the Retained Territories or the Territories, then such Party shall have the right to bring the matter to the attention of the JSC. Without limiting the foregoing, subject to the terms and conditions of this Agreement, unless the Parties otherwise agree: (a) Circassia shall not communicate with any Regulatory Authority having jurisdiction in the Retained Territories, unless so ordered by such Regulatory Authority, in which case Circassia shall provide immediately to AIT Therapeutics notice of such order; and (b) Circassia shall not submit any Regulatory Filings or seek Regulatory Approvals for the Products in the Retained Territories.

6.4 Notification of Threatened Action. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including, without limitation, a Regulatory Authority, which may affect the safety or efficacy claims of a Product or the continued marketing of a Product. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

6.5 Remedial Actions. The Parties shall exchange their internal standard operating procedures (“SOPs”) for conducting product recalls reasonably in advance of the First Commercial Sale of Product in the Territories, and shall discuss and resolve any conflicts between such SOPs and issues relating thereto promptly after such exchange. If either Party becomes aware of information relating to any released Product that indicates that a unit or batch of Product may not conform to the specifications hereof, or that potential adulteration, misbranding, and/or other issues have arisen that relate to the safety or efficacy of such released Product, it shall promptly so notify the other Party. To the extent Circassia requires such information to comply with applicable Laws or to determine whether to conduct a recall, AIT Therapeutics shall promptly disclose to Circassia any Information related to such nonconformance, adulteration, misbranding or other related issue. Circassia shall have the right, at its expense (except as provided herein), to control any Product recall, field correction, or withdrawal of any released Product in the applicable jurisdiction in the Territories. AIT Therapeutics shall have the right, at its expense, to control any Product recall, field correction, or withdrawal of any released Product in the Retained Territories. AIT Therapeutics shall be responsible for all costs incurred for any recall, field correction, or withdrawal of any released Product for the Territories to the extent such event of recall, field correction, or withdrawal is due to the material breach by AIT Therapeutics of this Agreement or the Supply Agreement. Circassia shall be responsible for all other costs incurred for any recall, field correction, or withdrawal of any released Product for the Territories. The procedures and consequences of such recalls shall be defined in the Supply Agreement. The Party having the right to control such recall pursuant to this Section 6.5 may, at its sole discretion, take appropriate courses of action, which shall be consistent with the internal SOPs of such Party; provided, however, that such controlling Party shall promptly notify the other Party of any recall action being considered and where practicable, consider the views of the non-controlling Party prior to taking any recall action. Each Party shall maintain complete and accurate records of any recall according to its then current SOPs in the Territories for such periods as may be required by applicable Laws, but in no event for less than three (3) years.

## **7. Export Controls, Modern Slavery and Corruption**

7.1 Export Controls. The Parties acknowledge that export and/or use of any Product may be subject to compliance with laws, rules and regulations of bodies having jurisdiction over such operations. If the export or use of any Products is so controlled, it is the responsibility of the applicable Party to obtain any such approval required by any Laws.

7.2 Anti-Slavery. Each Party shall hold itself and its Affiliates to the highest performance, ethical and compliance standards, including basic human rights, not engaging in any activity, practice or conduct which would constitute an offence under anti-slavery legislation in the United Kingdom or the U.S. encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. In performing its duties under this Agreement, Circassia acknowledges the value and importance of performance and ethical behavior in its performance under this Agreement.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

7.3 Undue Pecuniary Advantage. Each Party warrants that on the Effective Date, it, its directors, officers or employees have not offered, promised, given, authorized, solicited or accepted any undue pecuniary or other advantage of any kind (or implied that they will or might do any such thing at any time in the future) in any way connected with this Agreement and that it has taken reasonable measures to prevent Third Party contractors, agents or other third parties, subject to its control or determining influence, from doing so.

7.4 Anti-Corruption. Each Party agrees that, at all times in connection with and throughout the term of this Agreement, it will comply with and that they will take reasonable measures to ensure that its Affiliates, Third Party contractors or agents will comply with all applicable anti-corruption legislation including the Bribery Act 2010 and the Foreign Corrupt Practices Act 1977. Each Party shall not do, or omit to do, any act that would cause the other Party to be in breach of any anti-corruption legislation including the Bribery Act 2010 or the Foreign Corrupt Practices Act 1977.

## **8. Commercialization.**

### 8.1 [\*]

8.2 Commercialization Plan. Circassia will prepare and submit to the JSC a commercialization plan no later than four (4) months prior to the anticipated date of Regulatory Approval for the first Product in the Territories (the "Commercialization Plan"). Such Commercialization Plan shall incorporate the following Commercialization diligence requirements: Circassia will update such Commercialization Plan on at least an annual basis and will provide quarterly reports to AIT Therapeutics describing Circassia's progress against such Commercialization Plan. Circassia shall use Commercially Reasonable Efforts to maximize sales of the Products in the Territories in accordance with the Commercialization Plan and as approved by the JSC.

8.3 Circassia shall perform all required Commercialization activities at its sole expense, including, but not limited to, hiring qualified sales, marketing and commercial teams; performing user trials required for market adoption; and monitoring competitors in the Territories and pro-actively preparing defense mechanism against competitors' spoiling tactics. Without limiting the generality of the foregoing, Circassia shall:

- (a) fund all Launch and commercial activities;
- (b) fund all user trials required for market adoption;
- (c) hire and fund dedicated field-based teams comprising Key Accounts personnel, Sales Representatives, Medical Science Liaison personnel and Clinical Science Liaison personnel;
- (d) hire and fund office-based Marketing, Customer Experience, Technical Support, Training, Operations Support and Logistics personnel; and
- (e) regularly review the Product's sales performance to rapidly increase field-based and office-based teams as appropriate to make it a success.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

8.4 Circassia shall use Commercially Reasonable Efforts to Launch the Product in the U.S. as soon as commercially reasonable, but not later than ninety (90) calendar days following PMA approval by the FDA, provided the following:

- (a) AIT Therapeutics is able to supply reasonable commercial Launch quantities of the Product in accordance with the Supply Agreement;
- (b) AIT Therapeutics has filed a supplemental PMA for the approval of the additional ventilator systems described herein and agreed to by the Parties; and
- (c) Circassia is not prohibited by injunction or Law from such Launch.

8.5 Trademark. Subject to the remaining terms of this Section, the Parties shall cooperate in good faith with respect to the branding of Products and placement of the Parties' respective trademarks on the Products and the Filters to be Commercialized in the Territories. The Parties shall mutually select the principal trademark for the Product and the Filters (collectively, the "Product Marks") to be used in the countries of the Territories. Each Party shall own all rights in its Product Marks and register and maintain the Product Marks in the countries and regions it determines reasonably necessary. Circassia shall be responsible for clearing such marks with the FDA and the USPTO, and the corresponding Regulatory Authorities in China, at its expense.

8.6 Failure to Achieve Commercialization Events. If, despite Circassia's consistent use of Commercially Reasonable Efforts, Circassia is unable to achieve any particular due diligence event set forth in the Commercialization Plan within sixty (60) days following the date specified in the Commercialization Plan for the achievement or completion of such event, then AIT Therapeutics shall refer the matter first to the JSC, and the Parties shall and discuss in good faith whether the applicable event or events can reasonably be achieved or completed with appropriate revisions to the Commercialization Plan as agreed to by the Parties. For the avoidance of doubt, Circassia shall not have the deciding vote in relation to a revision of the Commercialization Plan pursuant to this Section. Circassia's failure to achieve one or more diligence events in the Commercialization Plan despite its exercise of Commercially Reasonable Efforts shall not constitute a material breach of this Agreement unless Circassia is unable to achieve such diligence event within sixty (60) days following the date specified in the revised Commercialization Plan.

8.7 [\*]

## **9. Reports; Records.**

9.1 Sales Report. During the term of this Agreement after First Commercial Sale of the first Product and/or Filters, Circassia shall furnish or cause to be furnished to AIT Therapeutics within thirty (30) days after the end of each calendar quarter (each a "Reporting Period") a written report or reports (the "Sales Report") covering the applicable Reporting Period and containing the following information:

- (a) The Gross Sales, Net Sales and Gross Profit from the sale of Products and/or Filters (and all associated calculations) in the Territories during the Reporting Period;

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(b) the royalties, payable in U.S. Dollars, which shall have accrued hereunder in respect to such Gross Profit;

(c) withholding taxes, if any, required by Law to be deducted in respect of such royalties; and

(d) the exchange rates used in determining the amount of U.S. Dollars.

9.2 Exchange Rates; Reports With respect to sales of Product invoiced in U.S. Dollars, the Gross Sales, Net Sales, Gross Profit and royalty payable shall be expressed in such currency as it is. With respect to sales of Product invoiced in Chinese Yuan, the Gross Sales, Net Sales, Gross Profit and royalty payable shall be expressed in the domestic currency of China together with the U.S. Dollars equivalent of the royalty payable, calculated using the average monthly exchange rates published by HSBC for each month within each Reporting Period. In each quarterly Sales Report, the final computations of Gross Profit and royalty payable shall be expressed in U.S. Dollars. Circassia and its Affiliates shall keep legible, verifiable and accurate records in sufficient detail to enable the royalties payable hereunder to be determined and substantiated.

9.3 Withholding Tax. Circassia shall deduct any withholding taxes and other statutory duties from all payments set forth herein and pay them to the proper tax authorities if required by applicable Law. Circassia shall maintain official receipts related to any withholding taxes and forward copies of such receipts to AIT Therapeutics. The Parties will exercise their Commercially Reasonable Efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future double taxation agreement between China and the United States of America. If, according to Laws applied to the Parties, this reduction requires a certificate of tax exemption, and in order to achieve such reduction, each Party shall cooperate with the other Party with applicable legal procedure and shall provide the other Party with the claim for a certificate of tax exemption in respect of royalties paid on the official form containing a certification of residence of the competent tax authority and other appropriate documents.

9.4 Audit Rights. AIT Therapeutics shall have the right to have an independent public accounting firm of its own selection but reasonably acceptable to Circassia, and at AIT Therapeutics' own expense (except if the result of such audit reveals an underpayment exceeding five percent (5%) of the amounts actually due to AIT Therapeutics for the audit period in question, in which case such audit shall be at Circassia's expense), examine the relevant books and records of account of Circassia and any of its Affiliates during reasonable business hours upon reasonable prior written notice to Circassia and not more often than once each calendar year, for not more than two (2) previous years, to determine whether appropriate payment have been made to AIT Therapeutics hereunder. AIT Therapeutics may exercise such right until the end of one (1) year after the termination or expiration of any payment obligation by Circassia under this Agreement. Circassia shall promptly pay to AIT Therapeutics the full amount of any undisputed underpayment. If the amount of the underpayment is greater than five percent (5%) on an annualized basis, Circassia shall pay interest on that amount that is in excess of five percent (5%) at the rate of LIBOR plus five percent (5%) per year, or the maximum rate permitted by applicable Law, whichever is less, in either case compounding annually from the date payment was due. Any overpayment by Circassia shall be credited against future Circassia royalty payment obligations hereunder. Such public accounting firm shall treat as confidential, and shall not disclose to AIT Therapeutics, any information other than information which could otherwise be given to AIT Therapeutics pursuant to any provision of this Agreement, all of which shall be treated as Confidential Information of Circassia hereunder.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

9.5 Payment. All payments to AIT Therapeutics shall be in US Dollars.

**10. Representations, Warranties and Covenants; Disclaimer.**

10.1 AIT Therapeutics Representations, Warranties and Covenants. AIT Therapeutics covenants, and represents and warrants to Circassia as of the Effective Date, that:

- (a) AIT Therapeutics is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated.
- (b) AIT Therapeutics owns and/or has licenses to use the AIT Therapeutics Technology and the AIT Therapeutics Regulatory Documentation and has the right to enter into this Agreement and to grant, and is not required to obtain the consent of any Third Party to grant, the licenses to Circassia as herein described.
- (c) Exhibit 1.7 contains a complete and correct list of all AIT Therapeutics Patents Controlled by AIT Therapeutics and its Affiliates as of the Effective Date that are necessary for the Development and Commercialization of the Products in the Field in the Territories.
- (d) AIT Therapeutics has complied in all material respects with all Laws in connection with the prosecution of the AIT Therapeutics Patents, including, with respect to any issued Patents and pending patent applications, any disclosure requirements to the United States Patent and Trademark Office or any other Governmental Authority and has timely paid all filing and renewal fees with respect thereto.
- (e) AIT Therapeutics has obtained, or caused its Affiliates, as applicable, to obtain, assignments from the inventors of all inventorship rights to the AIT Therapeutics Patents, and all such assignments are valid and enforceable, and the inventorship of the AIT Therapeutics Patents is properly identified on each Patent or patent application.
- (f) To AIT Therapeutics' knowledge, no Third Party is infringing any AIT Therapeutics Patent in the Field.
- (g) To AIT Therapeutics' knowledge, the Development, Manufacture or Commercialization of the Products and Filters in the Field in the Territories does not infringe any issued Patent or misappropriate the trade secrets of any Third Party.
- (h) AIT Therapeutics has not received notice of any claims, and there were no judgements or settlements against or owed by AIT Therapeutics or, to AIT Therapeutics' knowledge, any pending or threatened claims or litigation, in each case, claiming that a Patent owned by such Third Party would be infringed by the Development, Manufacture or Commercialization of the Products in the Field in the Territories.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(i) AIT Therapeutics and its Affiliates have taken Commercially Reasonable Efforts consistent with industry practices to protect the secrecy, confidentiality and value of all AIT Therapeutics Trade Secrets that constitutes trade secrets under Laws (including requiring all employees, consultants and independent contractors to execute binding and enforceable agreements requiring all such employees, consultants and independent contractors to maintain the confidentiality of such AIT Therapeutics Trade Secrets) and, to AIT Therapeutics' knowledge, such AIT Therapeutics Trade Secrets have not been used, disclosed to or discovered by any Third Party except pursuant to such confidentiality agreements and there has not been a breach by any party to such confidentiality agreements.

(j) The AIT Therapeutics Patents are, to AIT Therapeutics' knowledge, valid and enforceable, and no Third Party has made any claim against AIT Therapeutics asserting the invalidity, unenforceability or non-infringement of any AIT Therapeutics Patents (including, by way of example, through the institution or written threat of institution of interference, nullity, opposition, *inter partes* or post-grant review or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority).

(k) The AIT Therapeutics Technology is not subject to any funding agreement with any Governmental Authority or any other Third Party, and are not subject to the requirements of the Bayh-Dole Act or any similar provision of any Law.

(l) Neither AIT Therapeutics nor any of its Affiliates (i) are subject to any obligation to or with any Third Party that cause AIT Therapeutics or its Affiliates not to Control (or otherwise have rights to) any Patent or trade secret that would, but for such obligation, be included in the AIT Therapeutics Technology if such Patent or trade secret were Controlled by AIT Therapeutics or an Affiliate.

(m) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to AIT Therapeutics' knowledge, threatened, with any judicial or arbitral body against AIT Therapeutics or any of its Affiliates in connection with the AIT Therapeutics Patents or the Products or Filters.

(n) The Development and Manufacture of the Product have been conducted in all respects in accordance with Laws.

(o) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of AIT Therapeutics enforceable against AIT Therapeutics in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other Laws affecting creditors' rights generally from time to time if effect, and to general principles of equity.

(p) The execution, delivery and performance of this Agreement does not and will not conflict with any other agreement, contract, instrument or understanding, oral or written, to which AIT Therapeutics is a party, or by which it is bound, nor will it violate any Law applicable to AIT Therapeutics.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(q) All necessary consents, approvals and authorizations of all Regulatory Authorities and Governmental Authorities and other Third Party required to be obtained by AIT Therapeutics in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(r) No default has occurred or is continuing under the NitricGen License Agreement, and no event has occurred or condition exists under the NitricGen License Agreement which would, with the giving of notice, the expiration of any cure period or otherwise, constitute a default under the NitricGen License Agreement.

(s) AIT Therapeutics shall supply reasonable commercial Launch quantities of the Product in accordance with the Supply Agreement.

(t) AIT Therapeutics has not granted as of the Effective Date, and will not grant during the term of this Agreement, any licenses to any Affiliate or Third Party under the AIT Therapeutics Patents or AIT Therapeutics Regulatory Documentation which would conflict with the License granted to Circassia hereunder.

10.2 Circassia Representations and Warranties. Circassia covenants, and represents and warrants to AIT Therapeutics as of the Effective Date, that:

(a) Circassia is a corporation duly organized, validly existing and in good standing under the laws of jurisdiction in which it is incorporated and it has full right and authority to enter into this Agreement and to accept the rights and the License granted as herein described.

(b) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of Circassia enforceable against Circassia in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other Laws affecting creditors' rights generally from time to time if effect, and to general principles of equity.

(c) The execution, delivery and performance of this Agreement does not and will not conflict with any other agreement, contract, instrument or understanding, oral or written, to which Circassia is a party, or by which it is bound, nor will it violate any Law applicable to Circassia.

(d) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other persons or entities required to be obtained by Circassia in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(e) Circassia has not as of the Effective Date knowingly performed any acts that are inconsistent with the terms and purposes of this Agreement.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(f) Circassia has undertaken the investigation and has evaluated documents and information as practically it has deemed necessary to enable it to make an informed and intelligent decision with respect to the execution, delivery and performance of this Agreement. Circassia agrees to enter into this Agreement in the terms and conditions herein on the Effective Date based upon its own inspection, examination and determination with respect thereto as to all matters, and without reliance upon any express or implied representations or warranties of any nature made by or on behalf of or imputed to AIT Therapeutics or its Affiliates, except as expressly set forth in this Agreement. Without limiting the generality of the foregoing, and except as expressly set forth in this Agreement, Circassia acknowledges that AIT Therapeutics is making no representation or warranty with respect to any AIT Therapeutics Patent or AIT Therapeutics Regulatory Documentation licensed to Circassia hereunder.

**10.3 Limitation of Warranty.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO ANY OF THE MATERIALS, INFORMATION, SERVICES OR LICENSES PROVIDED PURSUANT TO THIS AGREEMENT.

**10.4 Performance by Affiliates.** The Parties recognize that each Party may perform some or all of its obligations under this Agreement through Affiliates and Third Party contractors; provided, however, that each Party shall remain responsible and liable for the performance by its Affiliates and Third Party contractors and shall cause its Affiliates and Third Party contractors to comply with the provisions of this Agreement in connection with such performance.

## **11. Intellectual Property.**

**11.1 Ownership of Inventions; Assignment.** AIT Therapeutics shall own all AIT Therapeutics Patents and Improvements and all intellectual property rights therein, including any rights to applications and or other protections for any of the foregoing. Circassia agrees to assign and hereby assigns and transfers to AIT Therapeutics all of Circassia's right, title and interest in and to any Improvements (whether invented solely by or on behalf of Circassia, or jointly by Circassia and AIT Therapeutics), and agrees to take, and to cause its employees, agents, and consultants to take, all further acts reasonably required to evidence such assignment and transfer to AIT Therapeutics, at AIT Therapeutics' reasonable expense. Circassia hereby appoints AIT Therapeutics as its attorney-in-fact to sign such documents as AIT Therapeutics deems necessary for AIT Therapeutics to obtain ownership and to apply for, secure, and maintain patent or other proprietary protection of such Improvements if AIT Therapeutics is unable, after reasonable inquiry, to obtain Circassia's (or its employee's or agent's) signature on such a document. Circassia hereby waives, on behalf of itself, its parent, subsidiaries, Affiliates and partners as well as all of its employees and independent contractors, any rights of first refusal it, he, or she may have with respect to any contemplated technology transfer, in whole or in part, of the Improvements or any related patent, patent application, related thereto as well as any right accorded to it, him, or her, by statute or otherwise, to use any Improvements or any Patent or copyright related thereto. Each Party shall own all right, title, and interest in and to any inventions that do not constitute Improvements but which are made solely by such Party's employees, agents, and independent contractors in the course of conducting its activities under this Agreement during the Term, together with all intellectual property rights therein, including any rights to applications or other protections for any of the foregoing. The Parties shall jointly own all inventions that do not constitute Improvements but which are made jointly by the employees, agents, independent contractors or sublicensees of both Parties, in accordance with joint ownership interests of co-inventors under U.S. patent laws. Subject to the provisions of Section 2.4 (Exclusivity), each Party shall have full rights to license, assign and exploit such joint inventions (and any patents arising therefrom) anywhere in the world, without any requirement of gaining the consent of, or accounting to, the other Party.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

11.2 Disclosure of Inventions. Each of the Parties shall, and shall cause its Third Party contractors and Affiliates to, promptly disclose to the other Party any inventions, invention disclosures, or other similar documents, submitted to it by its employees, agents, consultants or independent contractors describing inventions that may be Improvements, and all Information relating to such inventions to the extent necessary for the good faith determination as to whether such invention constitutes an Improvement and, if appropriate, for the preparation, filing and maintenance of any Patent application or Patent with respect to such invention.

11.3 License to Improvement Patents. All Patents claiming or covering any Improvements shall be referred to herein as "Improvement Patents" and all such Improvements (whether or not patented) and Improvement Patents shall automatically become part of the License without any further consideration and without any requirement of any formal amendment, further writing or other action; provided, however, upon the written request of either Party, the Parties shall update Exhibit 1.7 to confirm the inclusion of such Improvements and Improvement Patents in the License.

#### 11.4 Prosecution of Patents.

(a) Except as otherwise provided in this Section 11.4(a), AIT Therapeutics shall have the first right, but not the obligation, to prepare, file, prosecute and maintain the AIT Therapeutics Patents and Improvement Patents at AIT Therapeutics' own costs and expenses using counsel of its choosing. In the event AIT Therapeutics files any applications for any Improvement Patent respecting or claiming any Improvement, such filings shall include, but not be limited to, corresponding applications for Improvement Patents in the Territories; provided, however, that the costs associated with preparing, filing, prosecuting and maintaining any applications for any Improvement Patents in China, or any Improvement Patents issuing in China, shall be borne by Circassia, subject to the remaining terms and conditions of this Section 11.4(a). If AIT Therapeutics determines in its sole discretion to abandon all claims in any AIT Therapeutics Patent or any Improvement Patents in the Territories, then AIT Therapeutics shall provide Circassia with written notice of such determination within a period of time reasonably necessary to allow Circassia to determine its interest in such AIT Therapeutics Patent(s) or Improvement Patent(s), as the case may be. In the event Circassia provides written notice expressing its interest in continuing prosecution of such AIT Therapeutics Patent(s) or Improvement Patent(s), then upon Circassia's written request AIT Therapeutics shall promptly assign and transfer to Circassia all right, title and interest in and to such AIT Therapeutics Patent(s) or Improvement Patent(s), as the case may be, and AIT Therapeutics shall execute and deliver to Circassia such assignments or other instruments of transfer as Circassia may reasonably request to evidence such assignment and transfer as a matter of record. Notwithstanding the foregoing, in the event such transfer or assignment negatively impacts the enforceability or validity of any other patent or claim within the AIT Therapeutics Patents or Improvement Patents, AIT Therapeutics shall not be required to assign such patent. AIT Therapeutics hereby appoints Circassia as its attorney-in-fact to sign such documents as Circassia deems necessary for Circassia to obtain ownership and to apply for, secure, and maintain patent or other proprietary protection of such AIT Therapeutics Patent(s) or Improvement Patent(s) if Circassia is unable, after reasonable inquiry, to obtain AIT Therapeutics' (or its employee's or agent's) signature on such a document. Thereafter, Circassia (i) shall have the right to prosecute and maintain such AIT Therapeutics Patent(s) or Improvement Patent(s) in the Territories, and (ii) shall bear all of the costs of preparation, filing, prosecution and maintenance of such assigned and transferred AIT Therapeutics Patents and Improvement Patents, and Circassia may prosecute such Patents at its sole discretion; provided, however, in the event that Circassia decides to abandon or not maintain any such AIT Therapeutics Patent(s) or Improvement Patent(s), then Circassia shall promptly provide AIT Therapeutics with written notice of such decision. The Parties shall determine which Party will file, prosecute and maintain any Patent claiming or covering any jointly owned invention ("Joint Patent"). In the case of any Improvement Patent or Joint Patent, the Party filing such patent application (the "Filing Party") shall deliver to the other Party (the "Non-Filing Party") drafts of all such patent applications respecting such Improvement Patent or Joint Patent, as the case may be, in confidence before each such patent application is filed, and shall give the Non-Filing Party a reasonable period (not to exceed ninety (90) days) in which to review and comment thereon. Likewise, the Filing Party shall deliver to the Non-Filing Party, or shall cause the Filing Party's patent counsel to deliver to the Non-Filing Party, copies of all office actions and other correspondence from the USPTO and all other patent offices in the Territories respecting any such Improvement Patent or Joint Patent, as the case may be, and all proposed responses thereto for the Non-Filing Party's review, and shall provide the Non-Filing Party a reasonable opportunity to comment thereon. The Filing Party shall use Commercially Reasonable Efforts to accommodate the suggestions of the Non-Filing Party on any such patent application, amendment or office action response. For the avoidance of doubt, the Filing Party shall have the final decision with respect to any patent application, amendment or office action response.

(b) Patent Term Extensions in the Territories. The JSC will discuss and recommend for which, if any, of the Patents within the AIT Therapeutics Patents or Improvement Patents in the Territories the Parties should seek patent term extensions in the Territories. Provided AIT Therapeutics still owns all right, title and interest in and to the affected AIT Therapeutics Patent or Improvement Patent, as the case may be, AIT Therapeutics shall have the final decision-making authority with respect to applying for any such patent term extension respecting the applicable AIT Therapeutics Patent or Improvement Patent, as the case may be, and will act with reasonable promptness in light of the development stage of the Product to apply for any such patent term extension, where it so elects; provided, however, that if only one such Patent can obtain a patent term extension, then the Parties will consult in good faith to determine which such Patent should be the subject of efforts to obtain a patent term extension, and provided AIT Therapeutics still owns all right, title and interest in and to the affected AIT Therapeutics Patent or Improvement Patent, as the case may be, AIT Therapeutics' decision on such matter will control in the case of a disagreement. The Party that does not apply for an extension hereunder will cooperate fully with the other Party in making such filings or actions, for example and without limitation, by making available all required regulatory data and information and executing any required authorizations to apply for such patent term extension. All expenses incurred in connection with activities of each Party pursuant to this Section 11.4 shall be entirely borne by such Party.

#### 11.5 Infringement of AIT Therapeutics Patents or Improvement Patents by Third Parties.

(a) Each Party shall promptly notify the other Party in writing of any existing or threatened infringement in the Territories of the AIT Therapeutics Patents, Improvement Patents or Joint Patents of which it becomes aware, and shall provide all evidence in such Party's possession demonstrating such infringement.

(b) If a Third Party infringes, or is suspected of infringing, any AIT Therapeutics Patent, Improvement Patent or Joint Patent in the Territories by making, using, importing, offering for sale or selling the Product or a competitive product in the Field (each, a "Product Infringement"), each Party shall share with the other Party all Information available to it regarding such alleged infringement or misappropriation.

(c) AIT Therapeutics shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement in the Territories using counsel of its choosing, at which time AIT Therapeutics shall be designated the "Lead Party" and Circassia shall be designated the "Supporting Party." If, within forty-five (45) days of receiving written notice of a Product Infringement hereunder, AIT Therapeutics has not exercised its right to bring an action against a Third Party engaged in Product Infringement in the Territories, then Circassia shall be entitled to do so and to be designated as the "Lead Party" and AIT Therapeutics shall be the "Supporting Party" in such Product Infringement claim.

(d) The Supporting Party shall provide to the Lead Party reasonable assistance in such investigation, claim, litigation or enforcement, at the Lead Party's request, including joining any such action as a party plaintiff. The Lead Party shall keep the Supporting Partner regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the Supporting Party's comments on any such efforts. The Supporting Party shall be entitled to separate representation in such matter by counsel of its own choice.

(e) The Lead Party shall not settle any claim, suit or action that it brought against a Third Party under this Section 11.5 involving AIT Therapeutics Patents, Improvement Patents or Joint Patents without the prior written consent of the Supporting Party, which consent shall not be unreasonably withheld or delayed; provided that the Supporting Party shall be deemed reasonable in withholding its consent in the event the Supporting Party reasonably determines that such settlement would restrict in any material respect the scope of the AIT Therapeutics Patents or Improvement Patents or its rights or interests therein (in the case where AIT Therapeutics is the Supporting Party) or the scope of its rights under the License (in the case where Circassia is the Supporting Party). In the event that consent is withheld by the Supporting Party, the Supporting Party shall be solely responsible for any subsequent and reasonable Litigation Expenses incurred by the Lead Party.

(f) Any recovery from any Product Infringement claim or litigation or any settlement of the Product Infringement claim (including both recovery of damages and recovery of costs incurred in pursuing the claim) shall be shared by the Parties as follows:

- (i) Reimburse each Party for its pro rata share of Total Litigation Expenses (i.e., fifty percent (50%) to each Party, in accordance with Section 11.9 below), then
- (ii) Any remaining balance of recovery will be shared equally between the Parties,

#### 11.6 Defense of Claims for Infringement of Third Party Rights in the Territories

(a) If any Product or Filter becomes the subject of a Third Party's claim or assertion of infringement of a Patent or other intellectual property right granted by a jurisdiction within the Territories or a claim or assertion of misappropriation of the trade secrets of such Third Party, then the Party first having notice of the claim or assertion shall promptly notify the other Party.

(b) Circassia shall have the first right, but not the obligation, to defend any threatened or asserted claim of infringement of a Third Party's Patent by any jurisdiction in the Territories or misappropriation of the trade secrets of such Third Party based on the Development, Manufacture, Commercialization, sale or use of Products or Filters in the Field in a jurisdiction within the Territories. If Circassia undertakes the defense of such threatened or asserted Third-Party claim of infringement or misappropriation, then Circassia shall be designated the "Lead Party" for purposes of such defense, and such defense shall be at Circassia's expense using counsel of its choosing.

(c) If Circassia decides to not defend or does not commence actions to defend such claim no later than thirty (30) days after it receives notice thereof (or within thirty (30) days after it should have given notice thereof to AIT Therapeutics as required by Section 11.6(a)), then to the extent allowed by applicable Laws, AIT Therapeutics shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice. If AIT Therapeutics undertakes the defense of such claim, then AIT Therapeutics shall be designated the "Lead Party" for purposes of such defense, and such defense shall be at AIT Therapeutics' expense.

(d) For purposes of this Section 11.6, the Party that is not the "Lead Party" shall be the "Supporting Party" in the defense of the applicable Third-Party infringement or misappropriation claim. The Supporting Party shall reasonably cooperate with the Lead Partner conducting the defense of the Third-Party claim or assertion, including, if required to conduct such defense, furnishing a power of attorney.

(e) The Supporting Party shall have the right to participate or otherwise be involved in any such action controlled by the Lead Party, in each case at the Supporting Party's cost and expense. If the Supporting Party elects to so participate or be involved, then the Lead Party shall provide the Supporting Party and its counsel with an opportunity to consult with the Lead Party and its counsel regarding the defense of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the Lead Party shall take into account reasonable requests of the Supporting Party regarding such enforcement or defense.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(f) Neither Party shall enter into any settlement of any claim described in this Section 11.6 which settlement, if consummated, would (i) affect the other Party's rights or interests under this Agreement, (ii) affect the scope of any AIT Therapeutics Patent and/or Improvement Patent in any material respect, (iii) affect the scope of the License in any country of the Territories, or (iv) materially affect the Product, whether or not in the Field/Territories without such other Party's written consent, such consent not to be unreasonably withheld or delayed. Each Party shall have the right to decline to defend or to tender defense of any such claim to the other Party upon reasonable notice, including if the other Party fails to agree to a settlement that such Party proposes. If, for purposes of effecting any proposed settlement of any Third-Party claim, action or suit, a Party desires to take a license under any applicable Third Party intellectual property rights for the purpose of based on the Development, Manufacture, Commercialization, sale or use of Products or Filters in the Field in a jurisdiction within the Territories, then such Party shall submit the terms of such license to the JSC for review and approval. Any such license agreement will require the applicable Third Party to grant world wide licenses to Circassia and AIT Therapeutics and will contain a release of any liabilities accrued prior to the effective date of such license agreement, and will be subject to the mutual agreement of the Parties. Any royalties payable by Circassia to such Third Party under such license agreement in respect of the use or Commercialization of Products shall be credited as set forth in Section 3.6 hereof.

11.7 Patent Marking. AIT Therapeutics (or its Affiliate) shall mark each Product and Filter marketed and sold by Circassia (or its Affiliate) hereunder with appropriate patent numbers or indicia.

11.8 Patent Oppositions and Invalidation Proceedings.

(a) If Circassia or any of its Affiliates, employees, officers, directors, contractors, and attorneys initiates, requests, assists or financially supports any Third Party with any interference inter partes review, post grant review, reexamination, nullity action, or opposition proceeding or other action (a "Patent Challenge") with respect to, or making, filing or maintaining any claim to challenge the validity, infringement or enforceability of, any AIT Therapeutics Patent and any claim is found to be patentable, valid, enforceable and/or infringed, as applicable, then AIT Therapeutics may, at its sole discretion, (i) invoice Circassia for all expenses incurred in such Patent Challenge, including reasonable attorneys' fees, experts' fees, and other costs and Circassia shall pay all undisputed amounts within thirty (30) days after receipt of such invoice and/or (ii) terminate its license to such Patent.

(b) For purposes of this Subsection 11.8(b), "Invalidation Proceeding" will mean any declaratory judgment action or claim, *inter partes* review proceeding or other similar action or proceeding initiated by a Third Party seeking a ruling or judgment that any AIT Therapeutics Patent is invalid or unenforceable, and where the proceedings are not connected to proceedings regarding alleged Third-Party infringement (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 11.5, in which case the provisions of Section 11.5 shall govern). AIT Therapeutics will have the first right, but not the obligation, to defend any Invalidation Proceeding, at its expense. If AIT Therapeutics fails or elects not to defend any Invalidation Proceeding, then Circassia will have the right, but not the obligation, to defend the Invalidation Proceeding, at its expense.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(c) If either Party desires to bring a Patent Challenge of a Patent owned or controlled by a Third Party that relates to the Product, or the use, sale, offer for sale or importation of the Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 11.6, in which case the provisions of Section 11.6 shall govern), then such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Circassia and AIT Therapeutics shall each have the right, but not the obligation, to bring at its own expense and in its sole control any such action in the Territories. The Parties shall cooperate fully with the other Party bringing such action. Any awards or amounts received by the Parties shall be retained by the Parties.

11.9 Sharing of Total Litigation Expenses. The Parties shall share equally the Total Litigation Expenses hereunder. The Parties shall act in good faith in the management of litigation and Total Litigation Expenses and any disputes pertaining to same will be referred to the JSC with neither Party having a controlling vote.

11.10 Common Interest Agreement. In connection with the patent prosecution, enforcement or defense of any infringement or misappropriation claim, the Parties shall agree on and enter into an "identity of interest agreement" (or similarly styled agreement), pursuant to which the Parties agree to their shared, mutual interest in the outcome of such intellectual property right, claim or dispute, and thereafter, the Parties shall promptly meet to consider the appropriate course of action.

11.11 Compendial Listing and Register of Exclusive License. Upon request of Circassia, AIT Therapeutics shall cooperate with Circassia to (a) file appropriate information with the applicable Regulatory Authority listing any AIT Therapeutics Patents and/or Improvement Patent in the patent listing source in the Territories if any, and (b) register or record the License granted hereunder to the applicable Regulatory Authority, a patent and trademark office or other relevant governmental agency or offices in the Territories, if any.

## **12. Confidentiality/Publications.**

12.1 Confidentiality. Subject to any other provisions of this Agreement, each Party (the "Receiving Party"), for itself and its Affiliates and their (direct and indirect) licensees, agrees that it shall, during the term of this Agreement and for a period of five (5) years thereafter or ten (10) years from the Effective Date, whichever is longer, (i) hold in confidence using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value (but in no event less than reasonable care) the Confidential Information received before or after the Effective Date from the other Party (the "Disclosing Party"), (ii) not disclose such Confidential Information to any Third Party, except for those disclosures expressly permitted in this Section 12 below, and (iii) not use such Confidential Information for any purpose other than the purposes expressly permitted by this Agreement, without first obtaining the prior written consent of the Disclosing Party. Notwithstanding the foregoing, neither Party shall have any obligation of confidentiality with respect to Information to the extent:

(a) such Information is a part of the public domain, or is known to the Receiving Party or any of its Affiliates without any obligation to keep it confidential, prior to its disclosure by the Disclosing Party to the Receiving Party hereunder; or

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

(b) such Information becomes a part of the public domain after its disclosure by the Disclosing Party to the Receiving Party hereunder without any breach by the Receiving Party of this Agreement; or

(c) such Information which the Receiving Party can demonstrate that it has been independently developed either prior to its disclosure by the Disclosing Party to the Receiving Party hereunder or without the use of Confidential Information of the Disclosing Party; or

(d) such Information is disclosed to the Receiving Party by a Third Party who has the right to make such disclosure; or

(e) such Information is required to be disclosed by Law.

12.2 Authorized Disclosure. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is for a permitted purpose and is reasonably necessary in the following instances:

(a) filing or prosecuting Patents; however, in no event shall the Receiving Party be allowed to disclose a trade secret of the Disclosing Party in a Patent;

(b) as part of or in support of Regulatory Filings (provided that such Party has the right to use the Confidential Information for such purpose under Section 2.1);

(c) in prosecuting or defending litigation;

(d) in order to comply with applicable non-patent Laws (including the rules and regulations of the Securities and Exchange Commission (the "SEC") or any other national securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance; and

(e) disclosure, solely on a "need to know basis", to Affiliates, potential and existing collaborators, permitted acquirers or assignees under Section 21, subcontractors, investment bankers, investors and lenders, and each of the Parties' respective directors, employees, contractors and agents, each of whom prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Section 12 (other than potential and existing investors and lenders of such Party, with respect to which such Party shall use Commercially Reasonable Efforts to be so bound); provided, however, that the Receiving Party shall remain responsible for any failure by any permitted Third Party recipient who receives Confidential Information pursuant to this Section 12.2(e) to treat such Confidential Information as required under this Section 12.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

If and whenever any Confidential Information is disclosed in accordance with this Section 12.2, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible and other than with respect to Section 12.2(e), the Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make such disclosure pursuant to this Section 12.2 sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate in keeping with the terms of this Agreement to protect the confidentiality of the subject Confidential Information.

12.3 Irreparable Injury. The Parties acknowledge that either Party's breach of this Section 12 may cause the other Party irreparable injury for which it may not have an adequate remedy. In the event of a breach, the non-breaching Party shall be entitled to seek injunctive relief (without the necessity of posting bond) in addition to any other remedies it may have under Laws or in equity.

12.4 Terms of this Agreement. The Parties shall treat the terms of this Agreement as Confidential Information of both Parties.

12.5 Relationship to Confidentiality Agreement. This Agreement supersedes the Mutual CDA, provided that all Confidential Information (as defined in the Mutual CDA) previously disclosed or received by the Parties thereunder shall be deemed Confidential Information hereunder and shall be subject to the terms and conditions of this Agreement from and after the Effective Date.

12.6 Publications. If either Party wishes to publish any information, data or results regarding NO Generator or Products in written, oral or other form in any scientific journals or scientific conferences, a manuscript of the proposed publication shall first be sent to the other Party at least thirty (30) days in advance of submission of such publication for review. Unless the reviewing Party informs the other in writing during this thirty (30) day period that the proposed publication must be delayed in order to protect a patentable invention or changed to avoid disclosure of Confidential Information of the reviewing Party, the other Party shall be free to publish such proposed publication without restriction. In the event that a delay of the proposed publication is required, the other Party shall withhold such submission for publication for one additional period, up to sixty (60) days, or such other period as the Parties may mutually agree.

### **13. Term and Termination.**

13.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to Section 13.3, shall continue until the last of the AIT Therapeutics Patents or Improvement Patents to expire (the joint s). Commencing on the first day following the Initial Term, and on each day thereafter, the term of this Agreement shall automatically be extended for one additional day so that a constant three (3) year term will always be in effect unless this Agreement is terminated pursuant to Section 13.3, provided that Circassia may at any time following the Initial Term give notice to AIT Therapeutics that the Agreement shall terminate, such termination to take effect upon the expiry of a period of two (2) years from the date that the notice is received (or such shorter period of notice as AIT Therapeutics may agree, but in no event shall the notice period be less than one (1) year).

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

13.2 Bankruptcy Events. The License granted hereunder shall be treated as a license respecting intellectual property under § 365(n) of the United States Bankruptcy Code, as amended, and AIT Therapeutics acknowledges that in the event of any Bankruptcy Event of AIT Therapeutics, Circassia shall retain and may fully exercise all of its rights under this Agreement to the extent permitted by the United States Bankruptcy Code, as amended.

### 13.3 Termination

(a) Termination by Circassia. Circassia shall have the right to terminate the License with respect to the Commercialization of Products in China upon (90) days written notice to AIT Therapeutics. Upon such written notice, the definition of the "Territories" shall be deemed automatically to delete China

(b) Termination by Either Party. Notwithstanding the stipulation in Section 13.1, either Party may terminate this Agreement (subject to the provisions of the last paragraph of this Section 13.3(b)) upon the occurrence of any of the following itemized events: (i) such Party notifies the other Party of the fact of material default or breach of any material provision in this Agreement by the notified Party, and the notified Party fails to take corrective measures to mitigate or cure such default or breach within sixty (60) days from the date of notification, or, if such default or breach cannot be reasonably cured within sixty (60) days of notification, the notified Party failed to use Commercially Reasonable Efforts to begin to mitigate or cure such default or breach within sixty (60) days of notification; or (ii) the other Party files in any court or agency pursuant to any statute or regulation pertaining to bankruptcy, solvency, or payment of debts, of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if such other Party shall be a party to its dissolution or liquidation, or if such other Party shall make an assignment for the benefit of creditors.

For the sake of clarity, the Licenses granted by AIT Therapeutics in Section 2.1 shall be deemed severable on a country-by-country basis within the Territories. AIT Therapeutics' right of termination pursuant to Section 13.3(b)(i) based on a material breach of Circassia's obligations in one country in the Territories shall not affect Circassia's rights or obligations under the License in the other country of the Territories.

### 14. Effects of Termination or Expiration.

14.1 Survival. Expiration or termination of this Agreement for any reason shall be without prejudice to:

- (a) the obligations of confidentiality provided for in Section 12 shall survive;
- (b) the Parties' right to receive all payments accrued under this Agreement;

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

- (c) AIT Therapeutics' right of inspecting books and account of Circassia and its Affiliates pursuant to Section 9;
- (d) the rights and ownership in any Patents and Regulatory Documentation the respective Party has obtained prior to expiration or termination of this Agreement;
- (e) in the case of a breach of Circassia's obligations with respect to China, Circassia's rights provided for in Section 2.1 shall survive with respect to the United States; and
- (f) any other rights or remedies which either Party may then or thereafter have hereunder or at law or in equity or otherwise.

In addition to the foregoing, the following provisions shall survive expiration or termination of this Agreement for any reason and shall continue in full force and effect: Sections 1, 14.1, 17.3, 20. Unless otherwise provided in this Section 14 and elsewhere herein, the License shall terminate upon termination of this Agreement.

**14.2 Transition Assistance.** Upon any expiration or termination of this Agreement or the License in any country in the Territories, Circassia shall (a) continue to perform its Commercialization obligations under this Agreement to the extent reasonably requested by AIT Therapeutics for a period at least one hundred eighty (180) days (the "Transition Assistance Period") and (b) provide such assistance as reasonably required by AIT Therapeutics including assistance to third parties designated by AIT Therapeutics to transfer the Commercialization services to another vendor or to AIT Therapeutics itself as set forth herein (the "Transition Assistance Services"). During the Transition Assistance Period, Circassia shall be reasonably compensated for its efforts in the transition of AIT Therapeutics on a fee for service basis using the rates agreed upon by the parties, unless such transition is a result of a breach of this Agreement by Circassia or the termination of this Agreement by Circassia without cause, in which case Transition Assistance Services shall be provided at no additional cost and Circassia shall reimburse AIT Therapeutics for its actual costs in transitioning to a successor vendor.

**14.3 Adverse Termination Consequences for Circassia.** Upon termination of this Agreement or the License in any country in the Territories for any reason other than the expiration of its term, (a) Circassia, and its Affiliates shall cease use of the AIT Therapeutics Patents in the country or countries affected by such termination or partial termination, as the case may be (except for purposes of exercising their sell-off rights under Section 14.4) and the AIT Therapeutics Regulatory Documentation, and (b) in the case of a termination of this Agreement in its entirety, Circassia shall destroy or return (with confirmation letter to AIT Therapeutics upon request) to AIT Therapeutics any and all AIT Therapeutics Regulatory Documentation in the possession of Circassia, and its Affiliates, without delay, with the exception that each of Circassia and its Affiliates may keep one copy for its legal files.

**14.4 Inventory Sell-Off.** Upon termination of this Agreement or the License in any country in the Territories for any reason other than the expiration of its term, Circassia shall notify AIT Therapeutics of the amount of the Products and Filters that Circassia and its Affiliates then have on hand (the "Inventory") in the country or countries to which such termination pertains, and, if they so wish, Circassia and its Affiliates shall thereupon be permitted to sell such Inventory in such country or countries at the then-prevailing prices and subject to the then royalty obligations set forth hereunder.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

**15. Announcement.**

No public announcement concerning the existence of or terms of this Agreement shall be made, either directly or indirectly, by any Party to this Agreement, except as may be required by Law or as may be required for recording purposes or as permitted by Section 12.2, without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure. Other than with respect to Section 12.2(e), the Party desiring to make any such public announcement shall inform the other Party of the proposed announcement in reasonably sufficient time prior to public release, and shall provide the other Party with a written copy thereof, in order to allow such other Party to review, comment upon and approve such announcement, which such approval shall not be unreasonably withheld or delayed. It is the intention of the Parties to issue a press release upon signing this Agreement.

**16. Governing Law.**

The formation, validity and performance of this Agreement shall be governed by and interpreted in accordance with the internal substantive laws of the State of Delaware, without giving effect to any choice of law rules in the State of Delaware or elsewhere. The Parties agree that the United Nations Convention on Contracts for the International Sale of Goods does not apply to this Agreement.

**17. Dispute Resolution.**

17.1 Organization Resolution. The Parties will use reasonable efforts to settle their differences amicably between themselves. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the performance or alleged non-performance of a Party of its obligations under this Agreement (“Dispute”), a Party may notify the other Party in writing of such Dispute. If the Parties are unable to resolve the Dispute within sixty (60) days of receipt of the written notice by the other Party, such Dispute shall be referred to a senior executive of Circassia and AIT Therapeutics, who will use their good faith efforts to resolve the Dispute within thirty (30) days after it was referred to them. If the senior executives are unable to resolve the Dispute, the Parties shall refer the Dispute to arbitration as provided for in Section 17.2.

17.2 Jurisdiction by Agreement. Any Dispute that is not resolved as provided in Section 17.1, whether before or after termination of this Agreement, shall be submitted exclusively for resolution to arbitration administered by the American Arbitration Association (“AAA”) and be finally settled in accordance with the Rules of Arbitration of AAA. The arbitration shall be subject to the governing law set forth in Section 16, shall be held in New York, New York, in front of a panel of three (3) arbitrators, shall be conducted in the English language, shall be final and binding determination of the Dispute and not subject to judicial review, and shall not include any award of damages expressly prohibited by Section 17.3, and judgment upon any award rendered by the arbitrators may be entered in any court having jurisdiction over the liable Party. This Section 17 shall not restrict the Parties’ rights to seek equitable remedies, including specific performance or preliminary injunctive relief before a court of competent jurisdiction.

## **18. Notices.**

All notices and reports required under, and other communications with respect to this Agreement shall be in writing, in the English language, and given or sent to the Party to be notified at the respective addresses set forth below either: (a) personally and thereby deemed to be given on that day; (b) by electronic transmission (e.g., email) and thereby deemed to be given on the day following such transmission; (c) by internationally recognized overnight courier service (e.g., Federal Express) and thereby deemed to be given on the third (3rd) business day following dispatch; or (d) by registered letter and thereby deemed to be given on the tenth (10th) day following the day of posting. Notwithstanding the foregoing, notices pursuant to Section 13 (Term and Termination) and Section 20 (Indemnification and Insurance) shall not be effective if delivered by email.

For AIT Therapeutics:

AIT Therapeutics, Inc.  
825 East Gate Blvd.  
Garden City, New York 11530  
Attention: Adam Newman, General Counsel  
Email: adam@ait-pharm.com

With a required copy to:

Moses & Singer LLP  
The Chrysler Building  
405 Lexington Avenue  
New York, NY 10174  
Attn: Jill Anderson, Esq.  
Email: janderson@mosessinger.com

For Circassia:

Circassia Limited  
Northbrook House, Robert Robinson Avenue, Science Park  
Oxford OX4 4GA, United Kingdom  
Attention: General Counsel  
Email: david.williams@circassia.com

Either Party may notify the other Party of a different address to receive the other Party's notices in accordance with the manner described in this Section 18.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

## **19. Force Majeure.**

19.1 Generally. Neither Party shall be liable for any failure to perform as required by this Agreement if such failure is due to circumstances reasonably beyond the control of such Party, including requisition or interference by any government, state or local authorities, war, riots, civil disturbances, terrorism, strikes or other labour disputes, accidents, failure to secure required governmental approval, civil disorders or acts of aggression, acts of God, energy or other conservation shortages, plague or other such occurrences (“Force Majeure”).

19.2 Suspension. If and when any Party is hindered in its performance of its obligations under this Agreement by reason of Force Majeure, the performance shall be suspended during, but not longer than, the continuance of such circumstances.

19.3 Notice of Force Majeure Event. Either Party hereto whose performance of obligations has been hindered by reason of Force Majeure shall, to the extent possible, inform the other Party immediately, and shall use Commercially Reasonable Efforts to overcome the effect of the Force Majeure.

## **20. Indemnification and Insurance.**

20.1 AIT Therapeutics’ General Indemnity. AIT Therapeutics shall defend, indemnify and hold harmless Circassia and its Affiliates, and their officers, directors, employees, agents, distributors and suppliers, and their respective successors, assigns, heirs and representatives (collectively, “Circassia Indemnitees”) from and against all liabilities, damages, losses, suits, proceedings, actions, claims, judgments and costs and expenses (including legal fees, expert witness fees and expenses) resulting from any Third Party claim made or suit brought (collectively, “Losses”) to the extent arising from or related to:

(a) AIT Therapeutics’ material breach of any term of this Agreement (including any express representation or warranty made herein);

(b) the negligence, recklessness or willful misconduct or fraud on the part of AIT Therapeutics or any of its Affiliates, or any of their respective officers, directors, employees, agents, distributors and suppliers, or any of their respective successors, assigns, heirs or representatives with respect to the Products or Filters supplied by AIT Therapeutics or in the performance of AIT Therapeutics’ obligations or exercise of AIT Therapeutics’ rights under this Agreement;

(c) any actual or alleged violation of Law (other than any patent or other intellectual property Laws) in the performance of AIT Therapeutics’ obligations or exercise of AIT Therapeutics’ rights under this Agreement; and

(d) any product liability claim related to the Products or Filters Manufactured, used or sold in the performance of this Agreement by any of AIT Therapeutics or its Affiliates or any of their respective successors, assigns, heirs or representatives, including, without limitation: (i) non-conformance of the Products or Filters to either Laws or the applicable specifications as described in the Supply Agreement and (ii) non-conformance of the Products or Filters according to FDA Quality System Regulation, 21 C.F.R. § 820, and quality systems Law in China, provided that Circassia shall have communicated such requirements to AIT Therapeutics prior to the date such Products or Filters, as applicable, were Manufactured.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

Notwithstanding the foregoing provisions of Section 20.1, AIT Therapeutics shall not be required to indemnify any Circassia Indemnitee under this Section 20.1 to the extent that any such claims or suits arose out of or resulted from the negligence, recklessness or willful misconduct or fraud of any Circassia Indemnitee.

**20.2 Circassia Indemnity.** Circassia shall defend, indemnify and hold harmless AIT Therapeutics or any of its Affiliates, or any of their respective officers, directors, employees, agents, distributors and suppliers, or any of their respective successors, assigns, heirs or representatives (collectively, "AIT Therapeutics Indemnitees") from and against all Losses to the extent the same is arising from:

- (a) Circassia's material breach of any term of this Agreement (including any express representation or warranty made herein);
- (b) the negligence, recklessness or willful misconduct or fraud on the part of any Circassia Indemnitee with respect to the Product or in the performance of Circassia's obligations or exercise of Circassia's rights under this Agreement;
- (c) any actual or alleged violation of Law (other than any patent or other intellectual property Laws) in the performance of Circassia's obligations or exercise of Circassia's rights under this Agreement;
- (d) any product liability claim related to a Product or Filter sold by Circassia or its Affiliates or any of their respective successors, assigns, heirs or representatives during the term of this Agreement or after termination or expiration of this Agreement, unless and to the extent such claim arose out of or resulted from (i) non-conformance of Products or Filters supplied by AIT Therapeutics to specifications, but only to the extent Circassia notifies AIT Therapeutics of such non-conformance in accordance with the Supply Agreement or (ii) non-conformance of Products or Filters supplied by AIT Therapeutics or any of its Affiliates according to FDA Quality System Regulation, 21 C.F.R. § 820, ISO 13485 and applicable quality systems regulations in China; or
- (e) use of any data from any studies conducted by or on behalf of AIT Therapeutics except as permitted herein, without the consent of AIT Therapeutics.

Notwithstanding the foregoing provisions of this Section 20.2, Circassia shall not be required to indemnify any AIT Therapeutics Indemnitee to the extent that any such claims or suits arose out of or resulted from the negligence, recklessness or willful misconduct or fraud of any AIT Therapeutics Indemnitee.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

20.3 Indemnification Procedures. A Party which intends to claim indemnification under Section 20.1 or 20.2 (the “Indemnitee”) will promptly notify the other Party (the “Indemnitor”) in writing of any claim, suit, proceeding or action in respect of which the Indemnitee or any of the other AIT Therapeutics Indemnitees or Circassia Indemnitees, as applicable, intend to claim such indemnification within a reasonable period of time after the assertion of such claim; provided, however, that the failure to provide written notice of such claim within a reasonable period of time will not relieve the Indemnitor of any of its obligations hereunder, except to the extent that the Indemnitor is prejudiced by such failure to provide prompt notice. The Indemnitor will have the right to assume the complete control of the defense, compromise or settlement of any such claim (provided that no settlement of any claim will include any admission of wrongdoing on the part of an Indemnitee or the other AIT Therapeutics Indemnitees or Circassia Indemnitees, as applicable, or materially and adversely affect the rights of the Indemnitee or the other AIT Therapeutics Indemnitees or Circassia Indemnitees, as applicable, in each case without the prior written consent of such Indemnitee, which such consent will not be unreasonably withheld or delayed). The Indemnitor may, at its own expense, employ legal counsel to defend the claim at issue. The Indemnitee may, in its sole discretion and at its own expense, employ legal counsel to represent it and the other AIT Therapeutics Indemnitees or Circassia Indemnitees, as applicable (in addition to the legal counsel employed by the Indemnitor) in any such matter, and in such event legal counsel selected by the Indemnitee will be required to confer and cooperate with such counsel of the Indemnitor in such defense, compromise or settlement for the purpose of informing and sharing information with the Indemnitor. The Indemnitee will, at its own expense, make available to Indemnitor those AIT Therapeutics Indemnitees or Circassia Indemnitees, as applicable, whose assistance, testimony or presence is necessary, useful or appropriate to assist the Indemnitor in evaluating, defending or settling any such claim; provided, however, that any such access will be conducted in such a manner as not to interfere unreasonably with the operations of the businesses of Indemnitee or the other AIT Therapeutics Indemnitees or Circassia Indemnitees, as applicable; and will otherwise fully cooperate with the Indemnitor and its legal counsel in the investigation and defense of such claim.

20.4 Insurance. During the Term, and for a period of three (3) years after the expiration or earlier termination of this Agreement, both Parties shall, at their own expense, maintain commercial general liability insurance, including product liability insurance, in the minimum amount of [\*] per occurrence, and [\*] in the annual aggregate. Any independent insurance carriers must be rated A-, VII or better by A.M. Best Company or the equivalent standard. Each Party shall from time to time provide copies of certificates of such insurance to the other Party upon request.

#### **21. Non-assignability.**

This Agreement is personal to the Parties hereto and shall not be assignable to any Third Party by either Party without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed; provided, however, that any Party may assign this Agreement in full to an Affiliate of such Party without prior written consent, and provided, further, that any Party may assign this Agreement without prior written consent to any entity with which such Party may merge or consolidate (or engage in some other form of corporate combination), or to which it may transfer all or substantially all of its assets to which this Agreement relates. All successors and permitted assignees of a Party shall be subject to, and will be bound by, all the terms and conditions of this Agreement. Any attempted assignment made contrary to the provisions hereof will be void. This Agreement shall inure to the benefit of and be binding on the Parties’ successors, permitted assigns and legal representatives.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

**22. Language.**

22.1 English Language. This text of this Agreement in the English language shall be the original text, and any text in another language, even if such a text is made by translation of the text in English language or prepared by any of the Parties hereto for the purpose of its own convenience, shall have no meaning for any purpose between the Parties hereto.

22.2 Construction. Any information to be provided under this Agreement shall be provided in the English language. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof. The use of the singular shall be deemed to include the plural, and vice versa.

**23. Entire Agreement**

This Agreement (together with the Exhibits attached hereto, which are incorporated herein by reference) shall constitute the entire agreement between the Parties hereto concerning the subject matter hereof and shall supersede any other agreements, whether oral or written, express or implied, with respect to the subject matter hereof, including, without limitation, the Mutual CDA (subject to the provisions of Section 12.5) and the Letter of Intent.

**24. Severability.**

In the event any portion of this Agreement shall be held illegal, void or ineffective, the remaining portions hereof shall remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any applicable Law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such Law. The Parties shall make a good faith effort to replace any invalid or unenforceable term or provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**25. Independent Contractors; No Partnership.**

The Parties hereto are independent contractors. In making and performing this Agreement, the Parties are acting, and intend to be treated, as independent entities performing a contract, and nothing contained in this Agreement is to be construed or implied or deemed to create an agency, partnership, joint venture or an employee/employer relationship between Circassia and AIT Therapeutics. This Agreement is not, and will not be deemed to be, a partnership agreement or joint venture agreement, expressly or by implication. Employees of each Party remain employees of said Party and will be considered at no time agents of or owing a fiduciary duty to the other Party. Neither Party will have any implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any other contract, agreement or undertaking with any Third Party.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

**26. Amendment and Waiver.**

The Parties hereto may amend, modify or alter any of the provisions of this Agreement, but such amendment, modification or alteration will be valid and binding on either Party only if memorialized by a written instrument that explicitly refers to this Agreement and is duly executed by both Parties hereto. A waiver of any condition, or compliance with any term, provision, right or obligation hereunder shall be effective only if in writing and signed by the Party waiving such condition or compliance. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any nonaction of any provision hereof shall not be deemed to be a waiver of any other rights or remedies of such provision or any other provision on such occasion or any succeeding occasion.

**27. Counterparts.**

This Agreement may be executed by the Parties in one or more identical counterparts, all of which together will constitute this Agreement. If this Agreement is executed in counterparts, no signatory hereto will be bound until both Parties have duly executed a counterpart of this Agreement. Facsimile execution and delivery of this Agreement by the Parties shall be legal, valid and binding execution and delivery of this Agreement for all purposes.

**28. Further Assurances.**

The Parties shall execute and deliver such other instruments and documents, and take such other actions, as either Party reasonably requests to evidence or effect the transactions contemplated by this Agreement.

**[BALANCE OF PAGE INTENTIONALLY BLANK. SIGNATURE PAGE FOLLOWS.]**

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate counterparts by their duly authorized representatives, each fully executed copy hereof to be deemed as original, as of the Effective Date.

AIT Therapeutics, Inc.

By: /s/ Steven Lisi

Name: Steven Lisi

Title: Chief Executive Officer

Circassia Limited

By: /s/ Steven Harris

Name: Steven Harris

Title: Chief Executive Officer

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

**EXHIBIT 1.7**

**AIT THERAPEUTICS PATENTS**

<b>Appl. No.</b>	<b>Patent No.</b>	<b>Filing Date</b>	<b>Issue Date</b>
61/542,400	NA	10-03-2011	NA
PCT/US2012/058564	NA	10-03-2012	NA
14/347,479	9,573,110	03-26-2014	02-21-2017
15/372,552	9,896,337	12-08-2016	02-20-2018
15/887,246	NA	02-02-2018	NA

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

**EXHIBIT 1.70**

[\*]

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

**EXHIBIT 3.2**

**Illustrative Example of Royalty Computation**

[8]

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

**EXHIBIT 5.1**  
**DEVELOPMENT PLAN**

[8]

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

**EXHIBIT 8.7**

[\*]

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

**EXHIBIT 15**

**ANNOUNCEMENTS**

**AIT Nearing Definitive Agreement to License Commercial Rights of Its Novel Ventilator Compatible Nitric Oxide Generator and Delivery System for Use in the Hospital Setting in the United States and a Second Country**

*AIT to receive up to \$32.5 million in up-front and regulatory milestones*

*Additionally, AIT to receive a 15%-20% royalty on annual gross profit*

*Partner to receive rights to all indications at nitric oxide concentrations  $\leq$  80 ppm in the hospital setting*

*PMA submission on track for the second quarter of 2019*

**Garden City, NY, and Rehovot, Israel, December 28, 2018** – AIT Therapeutics, Inc. (OTCQB: 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 that, having previously signed a Letter of Intent (LOI), a definitive agreement to license the commercial rights for its novel cylinder free ventilator compatible nitric oxide (NO) generator and phasic-flow delivery system (GeNOvent\*) for use in the hospital setting at NO concentrations  $\leq$  80 ppm to a commercial partner is close to being finalized. The partner will be named upon the signing of a definitive agreement and Board approvals from both companies, which is expected to occur within the next 45 days.

“We are thrilled to announce this agreement at this time. This partnership is a result of the incredible work by the team at AIT, and I am very proud of their efforts. We look forward to working with the highly skilled team of our partner to bring this revolutionary product to market,” remarked Steve Lisi, Chairman and Chief Executive Officer of AIT. “Our partner knows the specialist hospital market well, given its established commercial team.”

**Key Deal Terms**

- AIT grants an exclusive license for the commercialization of the GeNOvent for the treatment of persistent pulmonary hypertension of the newborn (PPHN) and future related indications at concentrations of  $\leq$ 80 ppm in the hospital setting in the United States and another country
- AIT will receive payments up to \$32.5 million in up front and regulatory milestones, of which \$31.5 million is associated with the US market
- AIT will receive royalties based upon gross profit, which is defined as net sales less only payments to AIT for the cost of the GeNOvent and the related filters. Annual royalties range between 15% and 20% after cumulative gross profit first reaches \$50 million (on which a royalty of 5% is payable) and break down as follows:
  - A 15% royalty on the first \$100 million in annual gross profit
  - A 20% royalty on all annual gross profit above \$100 million

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

- The partner shall pay AIT cost plus for generator systems as well as filters
- AIT will be responsible for development, manufacturing, regulatory submissions and system repairs
- The partner will be responsible for all commercial sales and marketing functions including:
  - Hiring and managing dedicated field-based teams, including sales representatives, medical and clinical liaisons, etc.
  - Managing all operations in support of a commercial launch, including marketing, customer support, technical support, distribution, logistics etc.

#### **Impact on AIT**

- AIT's cash is expected to fund operations into the second quarter of 2020, exclusive of regulatory milestones
- The Company will request the trading of its common stock be moved to the NASDAQ exchange
- Allows AIT the ability to increase its infrastructure to support a pivotal bronchiolitis study and a pilot nontuberculous mycobacteria (NTM) study in the U.S., both anticipated to commence prior to year-end 2019
- Enhances the Company's ability to find commercial partners in other key global markets

"We, along with our partner, anticipate entering the U.S. market in the first half of 2020, provided a timely FDA approval before year-end 2019 in PPHN," added Mr. Lisi. "Given the elimination of nitric oxide cylinders and the associated benefits, along with the expertise of our partner, we anticipate our system achieving significant market share in this >\$500m market over the first few years after launch."

#### **Key Benefits Over Cylinder Based Systems**

- AIT's GeNOvent eliminates the need for high-pressure NO cylinders in the hospital setting, which can bring many tangible benefits, including:
  - Reduced company or hospital liability associated with transportation and maintenance of high-pressure cylinders, which are classified as dangerous goods
  - Decreased system set-up time and level of complexity
  - A reduction in potential risk to the patient by removing exposure to inadvertent nitrogen dioxide (NO<sub>2</sub>) boluses by eliminating the need for NO<sub>2</sub> purge procedures prior to starting or re-starting NO therapy
  - Significantly decreased burden on hospital staff by eliminating cumbersome intra-hospital delivery and removal of NO cylinders
  - Improved cart maneuverability due to the greatly reduced cart weight and size
  - Greatly improved inventory management with small NO<sub>2</sub> filters compared to cylinders
  - Drastically improved storage requirements of NO<sub>2</sub> filters compared to cylinders
  - No significant capital investment for hospitals who currently do not offer nitric oxide who would like to offer this inhaled therapy.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

## **About NO**

Nitric oxide (NO) is a crucially important molecule proven to play a critical role in a broad array of biological functions. Inhaled nitric oxide is currently approved for treating term and near-term neonates with Persistent Pulmonary Hypertension of the Newborn (PPHN) in the United States of America and most major markets. In Europe, Japan and Australia, inhaled NO is approved to treat PPHN as well as pulmonary hypertension during the peri-operative cardiac surgery period in neonates, children, and adults. 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 their multi-drug resistant strains.

## **About PPHN**

Persistent pulmonary hypertension of the newborn (PPHN) is a life-threatening condition 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 pulmonary vasodilator and is approved in dozens of countries to improve oxygenation and reduce the need for extracorporeal membrane oxygenation (ECMO) 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 GeNOvent**

GeNOvent is a cylinder free, phasic flow nitric oxide delivery system and has been designated as a medical device by the US Food and Drug Administration (FDA). The device can generate NO on demand for delivery to the lungs at concentrations ranging from 1 part per million (ppm) to 80 ppm. A disposable smart filter is used to remove nitrogen dioxide (NO<sub>2</sub>), a toxic gas. The elimination of the need for large, high-pressure cylinders for NO is a significant advantage in the hospital setting by greatly reducing inventory and storage requirements, and improving overall safety with the elimination of NO<sub>2</sub> purging steps, among other benefits.

## **About AIT**

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 Therapeutics is currently advancing its revolutionary NO Generator and Delivery System in clinical trials for the treatment of bronchiolitis and nontuberculous mycobacteria (NTM). For more information, visit [www.AIT-Pharm.com](http://www.AIT-Pharm.com).

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

Oppenheimer & Co. Inc. is serving as exclusive financial advisor to AIT on the transaction

\*GeNOvent is not an approved name for the product and may not be the final name submitted for approval

### **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 “achieves”, “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.

### **CONTACT**

Steven Lisi, Chief Executive Officer  
AIT Therapeutics, Inc.  
[Steve@AIT-Pharm.com](mailto:Steve@AIT-Pharm.com)

Bob Yedid  
LifeSci Advisors, LLC  
[Bob@LifeSciAdvisors.com](mailto:Bob@LifeSciAdvisors.com)  
(646) 597-6989

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

Circassia to Acquire US and Chinese Commercialisation Rights to Novel Nitric Oxide Product AirNOvent from AIT Therapeutics Inc.

*This announcement contains inside information for the purposes of Article 7 of Regulation 596/2014*

[Click here to download the full press release](#)

**Oxford, UK – 24 January 2019:** Circassia Pharmaceuticals plc (“Circassia” or “the Company”; LSE: CIR), a specialty pharmaceutical company focused on respiratory disease, today announces it has entered into a definitive agreement to acquire the exclusive commercialisation rights from AIT Therapeutics Inc. (“AIT”) to its ventilator compatible nitric oxide product, AirNOvent\*, in the United States and China. The rights cover all potential indications in the hospital setting for the administration of inhaled nitric oxide at up to 80 parts per million, which includes hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn (PPHN). AIT anticipates applying to the US Food and Drug Administration (FDA) for Premarket Approval (PMA) for AirNOvent in Q2 2019 for use in the treatment of PPHN, and the Company anticipates launching the product in the first half of 2020, once approved. Subsequently, AIT plans to seek a label extension for the product’s use in a related indication.

Under the terms of the agreement, Circassia will pay AIT initial consideration of \$7.35 million. Further deferred contingent consideration will be payable upon certain milestones, including \$3.15 million on successful completion of a pre-submission FDA meeting, \$12.6 million on the sooner of the product’s US launch in PPHN or 90 days post FDA approval, \$8.4 million on the US approval of the related indication and \$1.05 million on the product’s launch in China. In addition, the Company will pay tiered royalty payments based on gross profits from future sales of the product. Circassia intends to satisfy the initial consideration, and currently anticipates satisfying the contingent consideration, through the issuance of new Ordinary Shares in the Company to AIT.

**Steve Harris, Circassia’s CEO, said:** *“Acquiring the US and Chinese commercialisation rights to the innovative product AirNOvent represents an important milestone in Circassia’s strategic transformation into a commercially-focused respiratory pharmaceutical business. With our commercial platform established in the United States and our rapid expansion in China nearing completion, we look forward to leveraging our infrastructure to commercialise this novel product, once approved. In the coming months we anticipate significant progress across our business, as we take full commercial control of Tudorza® in the United States, the FDA completes its review of Duaklir®’s NDA and AIT submits AirNOvent for approval. As a result, we look forward to 2019 with great optimism.”*

#### **About AirNOvent**

AirNOvent is a portable system that utilises an electric voltage to produce precise quantities of nitric oxide (NO) from the nitrogen and oxygen in air. It uses disposable smart filters to remove unwanted NO<sub>2</sub> produced during the process.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

Inhaled nitric oxide is a pulmonary vasodilator, which is approved in the United States for use as part of a regimen in the treatment of hypoxic respiratory failure associated with persistent pulmonary hypertension of the newborn. Approvals in a number of other territories, including Europe, also include the use of inhaled nitric oxide as part of the treatment of pulmonary hypertension associated with cardiac surgery. In the United States, only one inhaled nitric oxide product is currently available, INOMAX®. It is used in neonatal intensive care units (NICUs) and its delivery system administers nitric oxide from pressurised cylinders in conjunction with ventilator systems. The product generated estimated US revenues of over \$400 million in 2017.

AIT's AirNOvent offers a number of potential benefits over the existing competition. It is cylinder-free and is smaller, significantly lighter and more convenient than the INOMAX system. It is designed for compatibility with current ventilators, and unlike the INOMAX system does not require special storage and handling. As a result, it has the potential for use by NICUs, as well as smaller clinics without the facilities required to manage nitric oxide cylinders.

AirNOvent is protected by US patents. Development of the core nitric oxide generator is complete, the delivery system is in the finalisation stage of development and the product will be produced by specialist third-party manufacturers. Under the companies' agreement, AIT will remain responsible for the product's development, US regulatory filings and manufacture, with Circassia managing the regulatory process in China. The FDA has confirmed a PMA regulatory route for AirNOvent and AIT anticipates submitting an application for an initial indication in hypoxic respiratory failure associated with PPHN in Q2 2019. The FDA typically completes its review of a PMA within 180 days of accepting the filing, and consequently the Company anticipates launching the product in the first half of 2020, once approved.

#### **Commercialisation plans**

Circassia plans to leverage its existing commercial platform in the United States to launch and promote AirNOvent, once approved. The Company plans to add a modest number of personnel to its field force, including additional key accounts and medical affairs experts, to target top hospitals with NICUs, many of which are already called on by the Company's existing device sales team, as well as units that do not currently use inhaled nitric oxide. The field force will be supported by the Company's commercial operations, marketing, training, technical support and customer experience teams, which are already in place. With over 55% of babies born in the US with hypoxic respiratory failure treated with INOMAX, Circassia plans to target unmet clinical need, including facilities that currently do not use inhaled nitric oxide such as those without the appropriate handling facilities. Following installation of the system, the Company plans to generate ongoing revenues from the supply of disposable smart filters.

#### **About persistent pulmonary hypertension of the newborn**

Persistent pulmonary hypertension of the newborn (PPHN) is defined as the failure of normal circulatory transition after birth. It is characterised by marked pulmonary hypertension that causes hypoxemia secondary to right-to-left extrapulmonary shunting of deoxygenated blood. PPHN is reported to occur in 0.4 – 6.8 per 1,000 live births (approximately 1,500 – 26,200 newborns) in the United States, and despite modern treatment the mortality rate remains approximately 10% in those with moderate to severe forms of the condition. Management of the condition can be complex involving a number of treatments, which in addition to supplemental oxygen can include the administration of inhaled nitric oxide.

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

### **Key transaction terms**

Under the terms of the companies' agreement, AIT grants Circassia an exclusive license for the commercialisation of AIT's nitric oxide generator and delivery system for use at concentrations of  $\leq 80$  ppm in the hospital setting in the United States and China. AIT will receive contingent payments based upon the achievement of certain milestones, which Circassia currently anticipates satisfying through the issuance of new Ordinary Shares in the Company, at a discount of 5% to a volume weighted average share price.

- \$7.35 million payable immediately
- \$3.15 million payable upon successful completion of a pre-submission meeting with FDA
- \$12.6 million payable upon the sooner of the product's US launch in PPHN or 90 days post FDA approval
- \$8.4 million payable upon label expansion in a related indication in the US
- \$1.05 million payable on launch in China.

In addition, AIT will receive royalties from Circassia based upon gross profits on future sales of the product:

- 5% on the first \$50 million in cumulative gross profit in the US
- 5% on the first \$20 million in cumulative gross profit in China;

and thereafter:

- 15% on annual gross profit of up to and including \$100 million (US and China combined)
- 20% on annual gross profit in excess of \$100 million (US and China combined).

### **About Circassia**

Circassia is a world-class specialty pharmaceutical business focused on respiratory disease. Circassia sells its novel, market-leading NIOX® asthma management products directly to specialists in the United States, United Kingdom and Germany, and in a wide range of other countries through its network of partners. In 2017, the Company established a commercial collaboration with AstraZeneca in the United States in which it promotes the chronic obstructive pulmonary disease (COPD) treatment Tudorza®. The Company also has the commercial rights to NDA-stage COPD product Duaklir®, and following the exercise of its option anticipates taking full commercial control of Tudorza® in the US in 2019. For more information please visit [www.circassia.com](http://www.circassia.com).

### **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](http://www.ait-pharm.com).

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---

## Application for listing and total voting rights

Application has been made to the Financial Conduct Authority for admission of 12,300,971 new Ordinary Shares, in respect of the upfront consideration payable to AIT, to the premium listing segment of the Official List and to the London Stock Exchange for admission to trading on the London Stock Exchange's main market for listed securities (together, "Admission"). Admission of the new Ordinary Shares is expected to occur at 8.00 a.m. on 25 January. The new Ordinary Shares will, when issued, be credited as fully paid and will be issued subject to the Company's articles of association and will rank pari passu in all respects with the existing issued Ordinary Shares in the capital of the Company, including the right to receive all dividends and other distributions declared, made or paid on or in respect of such shares by reference to a record date falling after their issue.

Following the issue of the new Ordinary Shares, the Company's issued share capital will comprise 369,587,405 ordinary shares of 0.08p each. The total number of voting rights in the Company following the issue of the new Ordinary Shares will be 369,587,405. This figure may be used by shareholders as the denominator for the calculations by which they will determine if they are required to notify their interest in, or a change to their interest in, the share capital of the Company under the Disclosure Guidance and Transparency Rules of the Financial Conduct Authority.

\*AirNOvent is not an approved name for the product and may not be the final name submitted for approval

*This announcement contains inside information for the purposes of Article 7 of Regulation 596/2014. The person who arranged for the release of this announcement on behalf of Circassia was Julien Cotta, Chief Financial Officer.*

## Contacts

### Circassia

Steve Harris, Chief Executive Officer  
Tel: +44 (0) 1865 405 560  
Julien Cotta, Chief Financial Officer  
Rob Budge, Corporate Communications

### Peel Hunt

James Steel / Dr Christopher Golden  
Tel: +44 (0) 20 7418 8900

### Numis Securities

James Black / Freddie Barnfield  
Tel: +44 (0) 20 7260 1000

### FTI Consulting

Simon Conway / George Kendrick  
Tel: +44 (0) 20 3727 1000

**Forward-looking statements** *This press release contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of Circassia. The use of terms such as "may", "will", "should", "expect", "anticipate", "project", "estimate", "intend", "continue", "target" or "believe" and similar expressions (or the negatives thereof) are generally intended to identify forward-looking statements. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors that could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Nothing contained in this press release should be construed as a profit forecast or profit estimate. Investors or other recipients are cautioned not to place undue reliance on any forward-looking statements contained herein. Circassia undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.*

AIT Therapeutics / Circassia License, Development and Commercialization Agreement

---



CERTIFICATION

I, Steven Lisi, certify that:

1. I have reviewed this Report on Form 10-Q of AIT Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15(d)-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its condensed consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of any transitional report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 14, 2019

/s/ Steven Lisi

---

Steven Lisi  
President and Chief Executive Officer  
(Principal Executive Officer)

---



CERTIFICATION

I, Douglas Beck, CPA certify that:

1. I have reviewed this Report on Form 10-Q of AIT Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13(a)-15(f) and 15(d)-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant including its condensed consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 14, 2019

/s/ Douglas Beck, CPA

Douglas Beck Chief Financial Officer  
(Principal Financial and Accounting Officer)

---



**CERTIFICATION**

In connection with the accompanying Quarterly Report on Form 10-Q of AIT Therapeutics, Inc. for the period ended December 31, 2018 (the Report"), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of AIT Therapeutics, Inc.

*/s/ Steven Lisi*

---

Steven Lisi  
President and Chief Executive Officer  
(Principal Executive Officer)

February 14, 2019

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes—Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of AIT Therapeutics, Inc. or the certifying officers.

---



**CERTIFICATION**

In connection with the accompanying Quarterly Report on Form 10-Q of AIT Therapeutics, Inc. for the period ended December 31, 2018 (the Report), the undersigned hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge and belief, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of AIT Therapeutics, Inc.

*/s/ Douglas Beck*

---

Douglas Beck Chief Financial Officer  
(Principal Financial and Accounting Officer)

February 14, 2019

The certification set forth above is being furnished as an Exhibit solely pursuant to Section 906 of the Sarbanes—Oxley Act of 2002 and is not being filed as part of the Report or as a separate disclosure document of AIT Therapeutics, Inc. or the certifying officers.

---

