LAIDLAW & COMPANY
Est. 1842
London
New York
San Francisco
Boston

EQUITY RESEARCH
Company Report

November 15, 2018

AIT Therapeutics (AITB - $3.80)

Healthcare/Biotechnology

F2Q19: Partnering Deal Could Be Around the Corner with Multiple Clinical Advancements Starting in 2019

Ticker:	**AITB**
Rating:	**Buy**
Price Target:	**$16.00**

Yesterday after market close, AITB reported F2Q19 financial results with a net loss of ($4.5MM) vs. Laidlaw ($1.4MM) and the Street ($1.6MM) estimates. Net loss/share was ($0.53) vs. ($0.16) and ($0.19) for Laidlaw and the Street. AITB ended the quarter with cash of $4.9MM, plus availability of a $20MM equity line.

- **AIT-PH in PPHM regulatory path changed to PMA from 510(k) has no material impact.** AITB reiterated that the AIT-PH regulatory filing is on-track even the path has been changed to PMA from 510(k), and plans to submit in 2Q19. The FDA approval decision is expected by YE19, similar to what it might be via the 510(k) pathway. The main reason for the change is that the FDA considered AIT-PH as a Class III device. Potential product launch is expected in early 2020. AITB is collaborating with Sparton Corp. for the production of a ventilator-comparable AIT-PH system delivering lower concentrations of NO.
- **Partner could be around the corner, which would be a major positive catalyst for the shares.** During the call, AITB guided that they anticipate a partner might be signed before YE18. Given the short time left till year-end, we believe the probability could be very high. If this materializes and with favorable terms, we believe it would be a major positive catalyst for AITB shares, given monetizing AIT-PH is a critical value driver that could facilitate AITB to advance other clinical developments. We believe AIT-PH could be a disruptive technology based on potential cost saving and operational benefits to hospitals. It is estimated that ~25% of the NO market is in neonatal intensive care units (NICU), while 50-60% in cardiac surgery, and the remaining in treating respiratory distress syndrome.
- **AIT-BRO development updates.** AITB reiterated that the NO-BRO in bronchiolitis pivotal trial is scheduled to start in 4Q19 and complete by 2Q20, with study design similar to that of the prior Phase II study. Although the actual patient size has not been determined, management anticipates it could be substantially larger than the Phase II study, possibly 200+, in order to potentially achieve a statistically significant readout. Possible endpoints could include shortening of hospital stay. Should the study outcome be positive, and approval received, NO-BRO could potentially reach the market for the 2021 winter season.
- **Action.** With a differentiated and promising NO-based treatment modality development in place, we believe AITB shares remain undervalued at current levels. We maintain our Buy rating and $16 price target, which is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses.

Trading Data:

Last Price (11/14/2018)	$3.80
52–Week High (11/24/2017)	$10.00
52–Week Low (3/21/2018)	$2.05
Market Cap. (MM)	$32
Shares Out. (MM)	6.1

Earnings Estimates: (per share)

(**March**)	1Q	2Q	3Q	4Q	FY	P/E
FY-19E	-0.36A	-0.53A	-0.24	-0.23	-1.34	N.A.
FY-18A	-0.46	-1.18	-0.28	0.14	-1.67	N.A.
FY-17A	-0.44	-0.20	-0.45	-1.12	-2.84	N.A.
FY-16A	N.A.	-0.44	N.A.	N.A.	-1.64	N.A.

Source: Laidlaw & Company estimates- 2018 results are calendar year.

Yale Jen, Ph.D.
Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

- **AIT-NTM development update.** AITB recently completed a positive meeting with the FDA regarding the AIT-NTM development and plans to conduct a pilot study possibly starting in 1H19 to explore: 1) real-world home use experience, 2) the possibility of delivering NO higher than 160 ppm, 3) potentially including MAC patients, and 4) potentially to explore the better antibiotic combination regimen. The study will include a one-week hospital treatment, followed by a 12-week at-home use with 2x/ day dosing. The projected patient size of 15. The knowledge gained from this study would be used for designing a pivotal study, which might start in 2020 depending on the funding.

Table 1: Estimated and reported F2Q19 results

F2Q19 Estimates and Reported Results			
($,000)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$0**	**$0**	**$0**
Total op. profit (loss)	**($1,564)**	**($2,413)**	**($1,800)**
R&D	($850)	($648)	
SG&A	($714)	($1,765)	
EPS	**($0.16)**	**($0.53)**	**($0.19)**
Net income (loss)	($1,394)	($4,460)	($1,600)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
AIT-BRO	Bronchiolitis (mainly RSV infection) in infant	Potentially start Phase III trial	**4Q19**	***
		Potentially report Phase III trial data	**YE20**	****
		Potential approval	**2021/2022**	****
AIT-NTM	NTM infection (Mycobacterium abscessus or MABSC)	Potentially start pilot Phase II trial	**1H19**	***
AIT-PH	Pulmonary hypertension (hospital use)	Potential PMA regulatory filing	**2Q19**	****
		Potential approval	**YE-19**	****
		Potential partnership	**2018/2019**	****

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company and company presentation

Yale Jen, Ph.D.
yjen@laidlawltd.com

Major Risks

Clinical study failure could have a major impact on AITB share value. AITB's NO platform has demonstrated promising efficacy and a satisfactory safety profile from prior Phase II studies in three different indications, like bronchiolitis, cystic fibrosis and nontuberculous mycobacteria (NTM) infection by *Mycobacterium abscessus* complex (MABSC). However, there is no assurance that the upcoming Phase II or Phase III clinical studies can demonstrate similar efficacy and safety profiles satisfactory enough for advancing into next step or gaining clinical approval. Given that the clinical successes are the biggest near-term hurdle to be overcome before AITB's NO platform can be advanced into commercialization, clinical study failure could significantly impair the value of the company's asset and shareholder value.

NO-based products may not reach anticipated sales. Although AITB's NO platform has illustrated initial promising efficacy and safety profiles and even with possible approvals of products being developed, the sales potential could fall short of our forecasts. It is difficult to project more accurately the sales potential of the AITB's NO-based products as the culmination of sales would be shaped by each indication that it may be approved for. For bronchiolitis in infants, although there is currently no approved drug for the treatment of RSV infection, many developments on therapeutics and vaccines are underway and some or multiple successes of those endeavors could potentially change the market dynamic significantly. For other indications AITB is exploring, including NTM infection, the increasingly more challenging reimbursement environment could potentially limit AITB to price the products at a premium even if the competition landscape might be more favorable. As such, and since the anticipated sales would largely depend on which indications the NO product is approved for, the commercial outlook could be uncertain and such scenario could significantly impair the company's asset and shareholder value.

Yet-to-be-approved NO device could remain uncertain. Although several clinical study results are positive and promising, the device used for delivering NO is not approved in the U.S. AITB needs to identify and test a device that will receive FDA acceptance for conducting future clinical studies in the U.S. There are risks that the company might not find or take longer time to find such device. In addition, the performance of such device might not replicate the positive outcome demonstrated from prior studies. In any of such scenario, the development of AITB's clinical programs could be delayed or installed. However, we view such negative outcomes might have lower probability.

Additional financings could dilute shareholder value. The company ended the quarter with ~$4.9MM total cash. As such, AITB would most likely need more financial resources going forward if they want to expand and further develop their pipeline unless the company can successfully explore non-dilutive financial sources. Should the future operational expenses significantly increase, especially in the areas of R&D and SG&A, products not receive FDA approval, or product revenue not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Limited trading liquidity limits shareholder options. Given the company just went public very recently and the daily trading volume and name recognition of AITB shares are relatively modest, some investors may hesitate to own the shares as relatively illiquid trading volume could impose constraints if they want to increase or reduce their positions in a volatile stock market.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Figure 1: Income Statement

AIT Therapeutics – Income Statement

($'000)	2015	2016	2017	2018	1Q19	2Q19	3Q19E	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
		Mar-16	Mar-17	Mar-18	Jun-18	Sep-18	Dec-18	Mar-19	Mar-19	Mar-20	Mar-21	Mar-22	Mar-23	Mar-24	Mar-25	Mar-26
Revenue																
NOxBR in Bronchiolitis revenues											22,613	69,381	118,385	169,663	215,010	245,445
NOxNTM in M. abscessus NTM revenues											0	16,724	52,451	85,299	121,025	159,821
Total product revenues	0	0	0	0	0	0	0	0	0	0	22,613	86,105	170,837	254,963	336,035	405,266
Royalty revenues	0	0	0	0	0	0	0	0	0	5,739	11,441	20,269	31,292	40,866	50,523	56,339
Total revenue	0	0	0	0	0	0	0	0	0	5,739	34,054	106,374	202,128	295,829	386,557	461,605
COGS											2,261	8,611	17,084	25,496	33,603	40,527
Total gross profit	0	0	0	0	0	0	0	0	0	5,739	31,792	97,764	185,045	270,332	352,954	421,079
Research and development	(1,167)	(1,620)	(1,868)	(4,636)	(1,063)	(648)	(1,166)	(1,190)	(4,067)	(6,711)	(6,979)	(8,166)	(8,737)	(9,087)	(8,814)	(7,933)
General and administrative	(989)	(589)	(3,081)	(5,311)	(693)	(1,765)	(759)	(769)	(3,986)	(4,344)	(4,692)	(5,020)	(5,272)	(5,535)	(5,812)	(6,102)
Marketing and sales											(28,000)	(30,800)	(32,340)	(33,957)	(35,315)	(36,728)
Total operating expenses	(2,156)	(2,209)	(4,949)	(9,947)	(1,756)	(2,413)	(1,925)	(1,959)	(8,053)	(11,055)	(39,671)	(43,986)	(46,349)	(48,579)	(49,941)	(50,763)
Operating Incomes (losses)	(2,156)	(2,209)	(4,949)	(9,947)	(1,756)	(2,413)	(1,925)	(1,959)	(8,053)	(5,316)	(7,879)	53,778	138,696	221,754	303,013	370,316
Other Income/(Expense)																
Financial expense	411	994	3,738	772	1,245	2,050	160	100	3,555	3,911	4,302	4,732	5,205	5,725	6,298	6,928
Revaluation of warrants to purchase Conve	2,055	152														
Total other income (expense), net	2,466	1,146	3,738	772	1,245	2,050	160	100	3,555	3,911	4,302	4,732	5,205	5,725	6,298	6,928
Pretax income	(4,622)	(3,355)	(8,687)	(10,719)	(3,001)	(4,463)	(2,085)	(2,059)	(11,608)	(1,405)	(3,577)	58,509	143,901	227,479	309,311	377,243
Tax on income	0	127	11	8	5	0	0	0	5	0	0	(21,648)	(53,243)	(84,167)	(114,445)	(139,580)
Net Income (Loss)	**(4,622)**	**(3,482)**	**(8,700)**	**(10,711)**	**(2,996)**	**(4,460)**	**(2,085)**	**(2,059)**	**(11,603)**	**(1,405)**	**(3,577)**	**36,861**	**90,658**	**143,312**	**194,866**	**237,663**
Basic and diluted net loss per share		($1.64)	($2.84)	($1.67)	($0.36)	($0.53)	($0.24)	($0.23)	($1.34)	($0.12)	($0.23)	$2.28	$5.45	$8.36	$11.04	$13.10
Shares outstanding: basic and undiluted		2,123	3,061	6,396	8,400	8,440	8,740	8,990	8,643	11,643	15,643	16,143	16,643	17,143	17,643	18,143
Margin Analysis (% of Sales/Revenue)																
Costs of goods		NA	NA	NA	NA	NA	NA	NA	NA	10%	10%	10%	10%	10%	10%	10%
R&D		NA	NA	NA	NA	NA	NA	NA	NA	-117%	-20%	-8%	-4%	-3%	-2%	-2%
G&A		NA	NA	NA	NA	NA	NA	NA	NA	-76%	-14%	-5%	-3%	-2%	-2%	-1%
M&S		NA	NA	NA	NA	NA	NA	NA	NA	0%	-82%	10%	5%	5%	4%	4%
Operating Income (loss)		NA	NA	NA	NA	NA	NA	NA	NA	-93%	-23%	51%	69%	75%	78%	80%
Pretax		NA	NA	NA	NA	NA	NA	NA	NA	-24%	-11%	55%	71%	77%	80%	82%
Tax Rate		37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Net Income		NA	NA	NA	NA	NA	NA	NA	NA	-24%	-11%	35%	45%	48%	50%	51%
Financial Indicator Growth Analysis (YoY%)																
Total Revenue		NA	NA	NA	NA	NA	NA	NA	NA	NA	493%	212%	90%	46%	31%	19%
Gross Profit		NA	NA	NA	NA	NA	NA	NA	NA	NA	454%	208%	89%	46%	31%	19%
Cost of Goods		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	281%	98%	49%	32%	21%
R&D		39%	15%	148%	80%	-46%	-4%	-27%	-12%	65%	4%	17%	7%	4%	-3%	-10%
SG&A		-40%	423%	72%	-72%	48%	-35%	-4%	-25%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)		2%	124%	101%	-43%	17%	-19%	-20%	-19%	37%	259%	11%	5%	5%	3%	2%
Pretax Income		-27%	159%	23%	4%	-38%	20%	-296%	8%	-88%	155%	-1736%	146%	58%	36%	22%
Net Income		-25%	150%	23%	4%	-38%	20%	-297%	8%	-88%	155%	-1130%	146%	58%	36%	22%
EPS		NA	73%	-41%	-23%	-55%	-16%	-258%	-20%	-91%	89%	-1099%	139%	53%	32%	19%

Yale Jen, Ph.D. 212-953-4978

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Yale Jen, Ph.D.
yjen@laidlawltd.com

DISCLOSURES:

ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

EQUITY DISCLOSURES

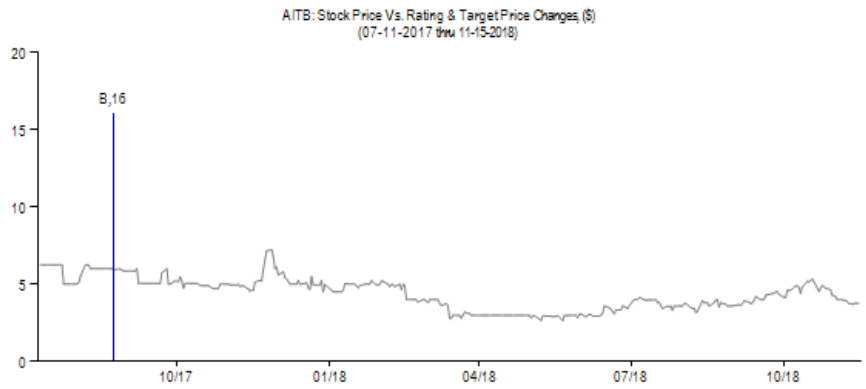
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

Additional information available upon request.

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
08/24/2017	Buy (B)	5.95

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/24/2017	16.00	5.95

Source: Laidlaw & Company **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	59.65%	22.81%	3.51%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	7.02%	1.75%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Sparton Corp. (SPA – Not Rated)

ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate

in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices. market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at www.Laidlawltd.com, or contact your investment representative or Laidlaw & Co (UK), Ltd at 521 Fifth Ave, 12th Floor, New York, NY 10175 USA.

NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com