

Antibe Therapeutics

FQ220 Update. Extending Timelines to Phase II Data Into Q120 Does Not Bear Significantly On Our ATB-346 Thesis

ATE-TSXV: \$0.40
Speculative BUY
\$1.40 Target

Event: ON-based drug developer Antibe Therapeutics provided an update for the firm's FQ220 September-end quarter. Since our investment thesis is still primarily focused on Phase II-stage hydrogen sulfide-releasing naproxen analog drug ATB-346 and its now-revised timelines to data, Antibe's financial data itself bears minimally on our PT and valuation, but herein we will provide an overview of the firm's revenue-positive regenerative medicine division Citagenix along with an update of Antibe's pipeline that additionally includes analogs of ketoprofen (ATB-352, targeting post-surgical pain) and acetylsalicylic acid (ATB-340, targeting stroke prevention).

Bottom line: While timelines to trial data now likely to extend into FQ320/CQ120 as we will summarize below, we do not see this as significant delays on timelines on our existing forecasts nor as a reflection on ATB-346's pharmacologic profile or its potential to demonstrate naproxen-like analgesia without naproxen-like side effects. We expect more aggressive patient enrollment to resume in early FQ420 and for target enrollment to be achieved by mid-quarter, with data read-out near end-of-FQ420. Our model still assumes that pivotal Phase III knee osteoarthritis pain testing can commence by H121, leading to final filing/approval by F2024. Hence, **we continue to maintain our Speculative BUY rating and one-year PT of \$1.40**, with our valuation still based on NPV (40% discount rate) and multiples of our F2025 EBITDA/EPS forecasts.

Revised timelines to trial data yet again due to trial logistics rather than pharmacology of lead drug ATB-346. Before delving into the firm's financial data, we observed that the firm will be shifting projected timelines for the Phase II trial yet again into FQ320 (CQ120), with the delay cited as factors relating to slow patient recruitment due to holiday season in H219. The trial recruitment rate has presently breached the 70% mark, with a total of 40 clinical sites to date. Recall the trial is currently testing lead hydrogen sulfide-releasing naproxen analog ATB-346 in patients with knee osteoarthritis, for which primary endpoint is assessing changes in WOMAC-confirmed pain intensity from baseline and in comparison to placebo at 48 hours and again at two weeks, with the longer time duration clearly more relevant to the drug's clinical benefits as a longer-term analgesic, and of course to its potential in future Phase III pain studies for which FDA and other agencies will undoubtedly require demonstration of longer-term benefit.

Patient inclusion/exclusion criteria were always stringent, but we have long advised conservatism on patient enrollment even if protracted timelines to data ensued: While we agree that seasonal factors could in part hinder patient enrolment (as with the prior case of a slowdown in patient enrolment during slower summer months), we believe that stringent patient enrollment inclusion/exclusion criteria may have modestly attenuated rate of patient randomization. As we commented before, all patient characteristics seem reasonable to us, with exclusion criteria usually focused on patient symptoms that could have in our view impacted patient perceptions of pain, such as for example, a history of GI bleeding and ulceration rate, and thus additionally excluding patients who have tested positive for *H. Pylori* infection and thus with pre-existing peptic ulcers or at minimum, a pre-condition for developing peptic ulcers down the road (see our [initial coverage report](#)).

Projected Return: 254%
Valuation: NPV, 20x EPS, 12.5x EV/EBITDA (F2025 est, 40% disc)

Market Data

Basic Shares O/S (M)	274.2
FD Shares O/S (M)	355.9
Market capitalization (\$M)	108.3
Enterprise Value (\$M)	100.8
Adj pro forma cash (\$M, most rec Q)	9.6
LT debt (\$M, most rec Q)	2.1
52 Week Range	\$0.24-\$0.54
Avg. Weekly Volume (M)	3.83
Fiscal Year End	Mar-31

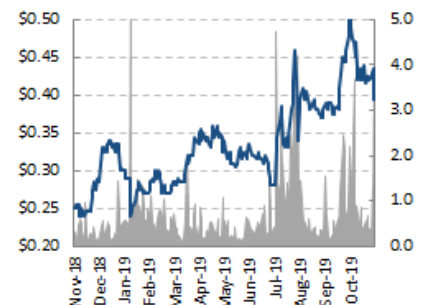
Key Milestone

Phase II data, ATB-346 knee OA trial	CQ120
Commence ATB-346 knee OA pain trial started in Mar/19	CQ418
Phase II, ATB-346, GI ulceration rate data (completed Mar/18)	CQ118
Phase II, open-label knee osteoarthritis data (completed Aug/16)	CQ316

Financial Metrics

In C\$	2018A	2019A	2020E
Total Revenue (\$000)	8,510	9,539	10,016
EBITDA (\$000)	(5,594)	(8,786)	(8,505)
Adj net inc (\$000)	(7,430)	(12,816)	(10,037)
EPS (basic)	(\$0.05)	(\$0.06)	(\$0.04)
EPS (FD)	(\$0.03)	(\$0.05)	(\$0.03)
P/E	NA	NA	NA
EV/EBITDA	NA	NA	NA

Antibe is a clinical stage drug developer, with lead clinical asset - hydrogen sulfide-releasing naproxen analog ATB-346 - focused on knee osteoarthritis as initial pain market. Ketoprofen-based ATB-352 & aspirin-based ATB-340 are in preclinical testing



Source: Consensus Data - FactSet, Forecasts/Estimates - Echelon Wealth Partners

We know through prior diligence that rate of NSAID discontinuations in patients with osteoarthritis is fairly high, and also that NSAID-associated GI pathologies are correspondingly high, and we are sympathetic to Antibe's view that patients who are either refractory to or sensitive to naproxen or other NSAIDs may not be responsive to ATB-346 independent of its unique molecular structure, and this criterion alone may have slowed down the pace of enrollment until now. We endorse any trial design elements that allow Antibe to distinguish GI-sparing effects of ATB-346 with minimal variability in patient's prior pharmacologic history. Obliging, the trial is excluding any patients currently sustained on background drug regimens that could interact with the cytochrome P450 enzymes (mainly CYP 2C9 & 1A2), which undoubtedly excludes multiple knee osteoarthritis subjects for whom the drug may eventually be shown to be effective.

Exhibit 1 – Income Statement & Financial Forecast Data for Antibe

(C\$000, except EPS)	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Product Sales, Citagenix	9,539	10,016	10,517	11,043	11,595	12,174	12,783	13,422	14,093	14,798
Royalty revenue, ATB-346	0	0	0	0	0	70,895	172,879	249,816	303,713	355,780
Total revenue	\$9,539	\$10,016	\$10,517	\$11,043	\$11,595	\$83,070	\$185,662	\$263,238	\$317,806	\$370,578
Revenue growth (%)	12%	5%	5%	5%	5%	616%	124%	42%	21%	17%
EBITDA	(\$8,786)	(\$8,505)	(\$5,445)	(\$4,709)	(\$2,319)	\$66,270	\$165,407	\$240,888	\$294,283	\$346,426
EBITDA growth (%)	57%	(3%)	(36%)	(14%)	(51%)	(2958%)	150%	46%	22%	18%
EBITDA margin (%)	(92%)	(85%)	(52%)	(43%)	(20%)	80%	89%	92%	93%	93%
Non-operating expenses	\$3,928	\$1,557	\$1,557	\$1,557	\$1,557	\$1,557	\$1,557	\$1,557	\$1,557	\$1,557
Net interest expense (income)	\$525	\$427	\$427	\$427	\$427	\$427	\$427	\$427	\$427	\$427
Net income, fully-taxed	(\$12,816)	(\$10,037)	(\$6,977)	(\$6,241)	(\$3,851)	\$45,316	\$114,712	\$167,549	\$204,925	\$241,425
Fully-taxed EPS (basic)	(\$0.06)	(\$0.04)	(\$0.02)	(\$0.02)	(\$0.01)	\$0.16	\$0.40	\$0.59	\$0.72	\$0.85
Fully-taxed EPS (fd)	(\$0.05)	(\$0.03)	(\$0.02)	(\$0.02)	(\$0.01)	\$0.12	\$0.31	\$0.46	\$0.56	\$0.66
P/E (basic)	NA	NA	NA	NA	NA	2.7x	1.1x	0.7x	0.6x	0.5x
EV/EBITDA	NA	NA	NA	NA	NA	1.6x	0.7x	0.4x	0.4x	0.3x
S/O, basic (M)	220.0	274.2	284.2	284.2	284.2	284.2	284.2	284.2	284.2	284.2
S/O, fd (M)	259.8	355.9	365.9	365.9	365.9	365.9	365.9	365.9	365.9	365.9

Source: Historical data - Company filings, forecasts/estimates - Echelon Wealth Partners

Citagenix contributes to incremental improvements in income statement metrics on a y/y basis: On income statement metrics, the firm reported FQ220 revenue/gross margin of \$2.27M/\$0.94M/41.4%, which compares favourably on a y/y basis from FQ219 financial data of \$2.07M/\$0.83M/40.0%, though relatively softer in contrast to q/q data at \$2.76M/\$1.04M/37.5%. Revenue and subsequent gross margin continue to be primarily derived from the firm's regenerative medicine business Citagenix. Although Antibe does not generate revenue through its pharmaceutical division (but generates expenses through this division), we did observe that Citagenix contributed to earnings before tax (EBT) of (\$0.41M), which is fairly stable on a y/y basis from FQ219 at (\$0.43M). Geographic distribution of revenues continue to be North America biased, at 54% of revenues derived from Canada, and 31% of revenues derived from the United States.

At quarter-end, Citagenix's implied equity value (simply derived from backing out \$3.6M in Citagenix liabilities from segment specific asset balance of \$6.77M) was \$3.17M. We remain encouraged to see y/y top-line growth in combination with compression of EBT loss, the combination of which could be attractive to future acquirers of this business, assuming Antibe might in time see regenerative medicine as non-core to its drug development operations once the latter begins to sustain momentum following the conclusion of Phase II activities. As before, we still believe that Antibe will view Citagenix less strategically if/when ATB-346's clinical potential is documented in new Phase II data, and that suitable acquirers of this business (ideally at a value approaching 0.7x-1.0x annual revenue) could be identified once the firm transitions into positive operating income territory. We remain optimistic that sustained revenue growth at recent pace, coupled with stable gross margin and operating expenses, can put Citagenix on pace to turn profitable next year.

R&D activities expected to intensify over coming quarters than soften: R&D cost in the quarter was \$2.37M, tapering down from FQ219 at \$3.28M, although we anticipate that costs will be elevated rather than softening with Phase II activities now intensifying. Operating cash loss was (\$3.63M) in the quarter excluding working capital surplus of \$0.46M. By our count, EBITDA was (\$3.62M), and thus roughly in line with operating cash loss.

A few competitors are still advancing Phase II/III-stage knee osteoarthritis pain therapies, but our model assumes that ATB-346 can capture a substantial proportion of the market niche already established for naproxen itself: That said, we do track a few advanced-stage knee osteoarthritis pain drugs that could conclude pivotal testing and advance into regulatory activities in coming quarters, and these include but are not limited to Centrexion Therapeutics' (Private) intraarticularly-injected capsaicin analog CNTX-4975 (data from the 850-patient Phase III VICTORY-3 trial expected by CQ120), Ampio Pharmaceuticals' (AMPE-NY, NR) low-molecular weight human serum albumin fraction aspartyl-alanyl diketopiperazine-containing drug Ampion (data from a 1,034-patient three-month trial are also expected by H220), Sorrento Therapeutics' (SRNE-Q, NR) functional capsaicin analog resiniferatoxin (a 390-patient three-month trial is poised to commence before end-of-C2019, with data expected in C2022), and Regeneron (REGN-Q, NR)/Teva's (TEVA-Q, NR) anti-nerve growth factor mAb drug fasinumab (data from a substantial 5,331-patient one-year trial that started in C2016 are expected by early C2022), to name four.

Exhibit 2 – Valuation Scenarios for Antibe

NPV, discount rate	20%	30%	40%	50%	60%	70%
Implied value per share	\$3.52	\$2.05	\$1.37	\$0.76	\$0.47	\$0.30
Price/earnings multiple, F2025	10x	15x	20x	25x	30x	35x
Implied share price ¹	\$0.82	\$1.22	\$1.63	\$2.04	\$2.45	\$2.86
EV/EBITDA multiple, F2025	5x	10x	12.5x	15x	17.5x	20x
Implied share price ^{1,2}	\$0.58	\$1.17	\$1.47	\$1.76	\$2.05	\$2.35
One-year Antibe target price (C\$)¹	\$1.49					

¹ Based on F2025 fd fully-taxed EPS of \$0.31; EBITDA of \$165.6M, discounted at 40%, FD S/O of 355.9M, but with notional fd S/O of 365.9M embedded in our model

² EV incorporates proforma cash of \$9.6M (consisting of FQ220 cash of \$8.3M and post quarter exercise of 5.7M warrants for total proceeds of \$1.3M) and total debt of \$2.1M

Source: Forecasts/estimates - Echelon Wealth Partners

In a more recent development, Taiwan Liposome Company (TLC-Q, NR) just recruited the first patient for a Phase III knee osteoarthritis pain trial testing its sustained-release lipid-based dexamethasone formulation TLC599, for which topline data from the 500-patient EXCELLENCE trial could be available by mid-C2021. Other later-stage therapies we are tracking also include Techfields Pharma's (Private) ibuprofenamine hydrochloride spray X0002 (currently in a 600-patient Phase III trial with topline data expected by YE2021), Samumed's Wnt pathway inhibitor injection Lorecivint/SM04690 (currently in a 725-patient Phase III STRIDES-X-ray trial, with topline anticipated by YE2020), Taisho Pharmaceutical's esflurbiprofen plaster (a NSAID delivered via patch formulation; 312-patient Phase III trial comparing the therapy against diclofenac gel, with topline data expected by H220), and lastly, TRB Chemedica's/ ArthroLab's (Private) IL-1 inhibitor diacerein (currently in a 380-patient Phase III trial, with the active comparator being Pfizer's (PFE-NY, NR) COX-2 inhibitor celecoxib, and with topline data anticipated by YE2019; [poster presentation](#) in Jun/19 via the *Annals of the Rheumatic Diseases* (2019; Volume 78, Issue Supplement 2) showing a mean change in WOMAC pain of -11.14 against celecoxib at -11.82, thereby meeting the noninferiority criterion, but with higher incidence of GI side effects in the form of diarrhea in the treatment arm versus celecoxib arm).

Summary & valuation: For now, we are maintaining our Speculative BUY rating and PT of \$1.40 on ATE, with our valuation still based on NPV (40% discount rate) and multiples of our F2025 adjusted EBITDA/EPS forecasts of \$165.4M/\$0.31, with our share-based forecasts assuming notional fd S/O of 365.9M (the firm exited the quarter with 274.2M common shares outstanding, and 355.9M fd shares outstanding). Our EV incorporates proforma cash of \$9.6M (consisting of FQ220 cash of \$8.3M and \$1.3M generated from warrants exercised post quarter) as well as total debt of \$2.1M.

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Company: Antibe Therapeutics | ATE:TSXV

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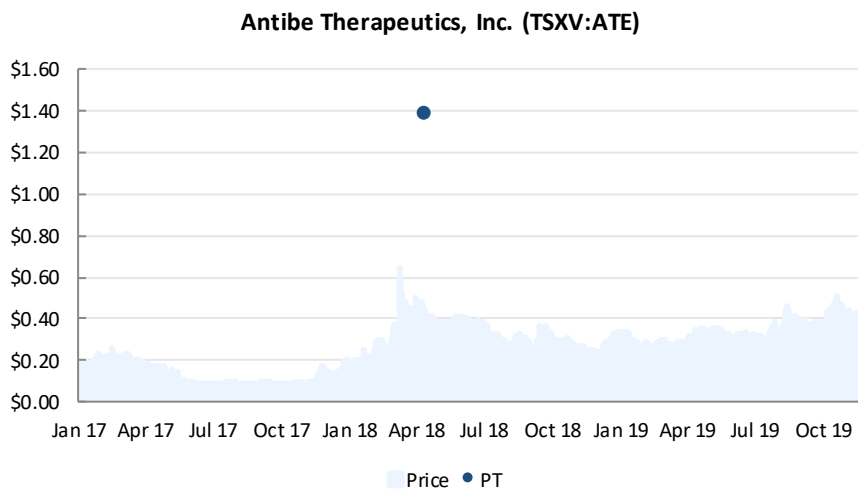
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Date	Target (C\$)	Rating
19 Apr 2018	\$1.40	Spec Buy

Coverage Initiated: Apr 19, 2018
Data sourced from: FactSet

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