

Appili Therapeutics Inc.

(V.API-TSXV)

V.API: Positive Interim Data Presented for ATI-1701 Biodefense Program...

Based on our probability adjusted DCF model that takes into account potential future revenues of ATI-2307, ATI-1701, and ATI-1501, APLI is valued at CAD\$3.00/share. This model is highly dependent upon continued clinical success of the company's pipeline and will be adjusted accordingly based on future clinical results.

Current Price (03/17/20) CAD\$0.50
Valuation CAD\$3.00

OUTLOOK

In January 2020, Appili Therapeutics Inc. (V.APLI) announced positive interim data for ATI-1701, the company's biodefense program to combat *Francisella tularensis*, which is categorized by the NIH as a Category A pathogen (an organism that poses the highest risk to national security and public health). The data presented by Appili showed complete protection 365 and 90 days after vaccination from a lethal exposure to *F. tularensis* in both rats and cynomolgus macaques, respectively. We anticipate data on the efficacy of ATI-1701 up to 365 days in cynomolgus macaques being reported later this year.

SUMMARY DATA

52-Week High \$1.09
52-Week Low \$0.32
One-Year Return (%) 25.78
Beta N/A
Average Daily Volume (sh) 15,050

Shares Outstanding (mil) 46
Market Capitalization (\$mil) \$23
Short Interest Ratio (days) N/A
Institutional Ownership (%) 54
Insider Ownership (%) 42

Annual Cash Dividend \$0.00
Dividend Yield (%) 0.00

5-Yr. Historical Growth Rates
Sales (%) N/A
Earnings Per Share (%) N/A
Dividend (%) N/A

P/E using TTM EPS N/A
P/E using 2019 Estimate N/A
P/E using 2020 Estimate N/A

Risk Level High
Type of Stock Small-Growth
Industry Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(in millions of CAD\$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2018	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2019	0.0 A	0.0 A	0.2 A	0.0 E	0.1 E
2020					0.9 E
2021					0.0 E

Earnings per Share

(in CAD\$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2018	-\$0.01 A	-\$0.04 A	-\$0.04 A	-\$0.05 A	-\$0.14 A
2019	-\$0.06 A	-\$0.03 A	-\$0.04 A	-\$0.04 E	-\$0.16 E
2020					-\$0.22 E
2021					-\$0.24 E

WHAT'S NEW

Business Update

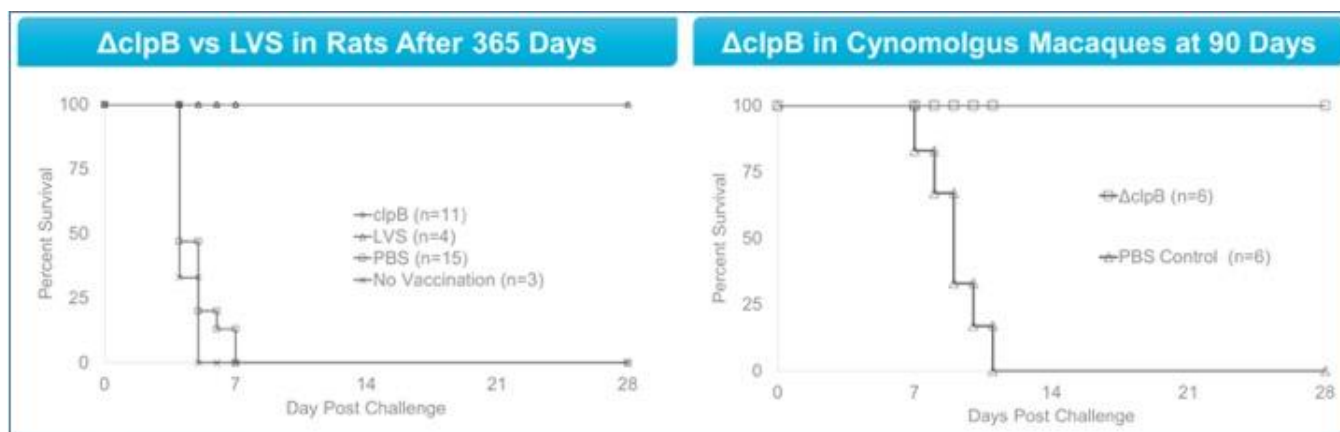
Appili Therapeutics Inc. (APLI.V) is a biopharmaceutical company devoted to acquiring and developing novel treatments for infectious diseases. The company was founded in 2015, and since that time has focused on building a diverse pipeline of anti-infective programs, which includes the following four lead programs: ATI-2307 for the treatment of fungal infections; ATI-1701 for the prevention of *Francisella tularensis* infection; ATI-1503 for the development of novel Gram-negative targeting antibiotics; and ATI-1501 is a taste-masked liquid oral suspension formulation of metronidazole.



Source: Appili Therapeutics Inc.

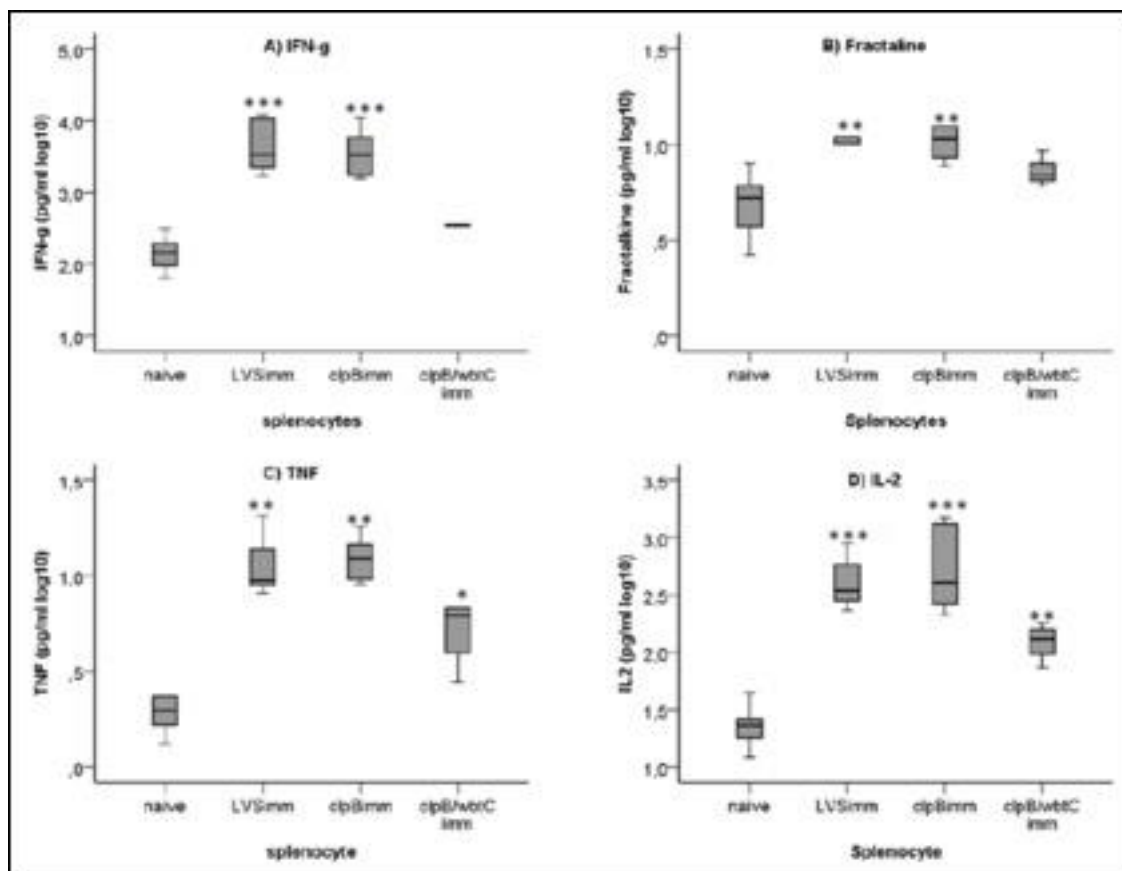
Positive Interim Data Presented for ATI-1701

On January 28, 2020, Appili [announced](#) positive interim data was presented for ATI-1701 at the 2020 ASM Biothreats conference hosted by the American Society for Microbiology. The company had previously presented similar results at the Chemical and Biological Defense Science & Technology Conference in Nov. 2019. The results presented in November 2019 showed that ATI-1701 (denoted $\Delta clpB$) protected rats for 365 days and cynomolgus macaques for 90 days following immunization, as shown in the following figures. This was tested by challenging vaccinated animals with aerosolized *F. tularensis*, which resulted in 100% fatality in non-vaccinated rats, rats immunized with the legacy *F. tularensis* vaccine (LVS), and non-vaccinated macaques.



Source: Gelhaus *et al.*, 2019

In addition to showing that ATI-1701 offered a survival advantage to immunized animals, the following figure shows that immunized animals had strong immune responses as exhibited by significantly higher production of interferon-gamma (IFN-g), fractalkine (CX3CL1), tumor necrosis factor (TNF), and interleukin-2 (IL-2) compared to naïve animals.



Source: Gelhaus et al., 2019

The conclusions from the study are that ATI-1701 can be manufactured in a stable form and it protects both rats and macaques for at least 365 and 90 days, respectively. We anticipate the company releasing data on the 365-day protection assays for macaques later this year.

Changes to Board of Directors

On January 27, 2020, Appili [announced](#) the appointment of Juergen Froehlich, MD to its Board of Directors. Dr. Froehlich has 30 years of experience in medical and regulatory affairs at a number of companies including Boehringer Ingelheim, Genetech, Quintiles, Vertex, and Aradigm Corporation. As Chief Medical Officer and Head of Regulatory Affairs at Aradigm Corporation, Dr. Ingelheim initiated, oversaw, and completed a Phase 3 clinical program for a liposomal formulation of ciprofloxacin for inhalation in patients with non-cystic fibrosis bronchiectasis and chronic *Pseudomonas aeruginosa* lung infections.

Appili also announced the appointment of Mr. Ian Mortimer as Chair of the Board. Mr. Mortimer has been an Appili Board Member since 2017. He is currently the President and CFO of Xenon Pharmaceuticals.

Financial Update

On February 28, 2020, Appili announced financial results for the third quarter of fiscal year 2020 that ended Dec. 31, 2019. The company reported revenues of CAD\$0.2 million for the three months ending Dec. 31, 2019 from the out-licensing of ATI-1501 to Saptalis Pharmaceuticals LLC while no revenue was recorded for the comparable time frame in 2018. R&D expenses in the third quarter of fiscal year 2020 were CAD\$0.5 million compared to CAD\$0.8 million in the third quarter of fiscal year 2019. The decrease was primarily due to

decreased spending for ATI-1501, ATI-1503, ATI-1701, salaries and benefits, and stock-based compensation. G&A expenses in the third quarter of fiscal year 2020 were CAD\$0.8 million compared to CAD\$0.5 million in the third quarter of fiscal year 2019. The increase was primarily due to an increase in salary and benefits partially offset by decreased stock-based compensation. Business development expenses increased slightly to CAD\$0.22 million for the three months ending Dec. 31, 2019 from CAD\$0.15 million for the three months ending Dec. 31, 2018 due to increased legal costs associated with the acquisition of ATI-2307. Government assistance decreased from CAD\$0.3 million in the third quarter of fiscal year 2019 to CAD\$0.25 million in the third quarter of fiscal year 2020 due to different government grants and loans the company had in 2019 compared to 2020.

As of Dec. 31, 2019, Appili had approximately CAD\$2.44 million in cash and cash equivalents. In February 2020, the company [raised](#) net proceeds of approximately CAD\$9.2 million through the sale of 12,812,500 units at a price of CAD\$0.80 per unit. Each unit consisted of one share of common stock and one-half of one share purchase warrant, with each warrant having an exercise price of CAD\$1.10. We estimate the company has sufficient capital to fund operations for at least the next 12 months. As of Feb. 27, 2020, Appili had approximately 46.4 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 52.5 million.

Conclusion

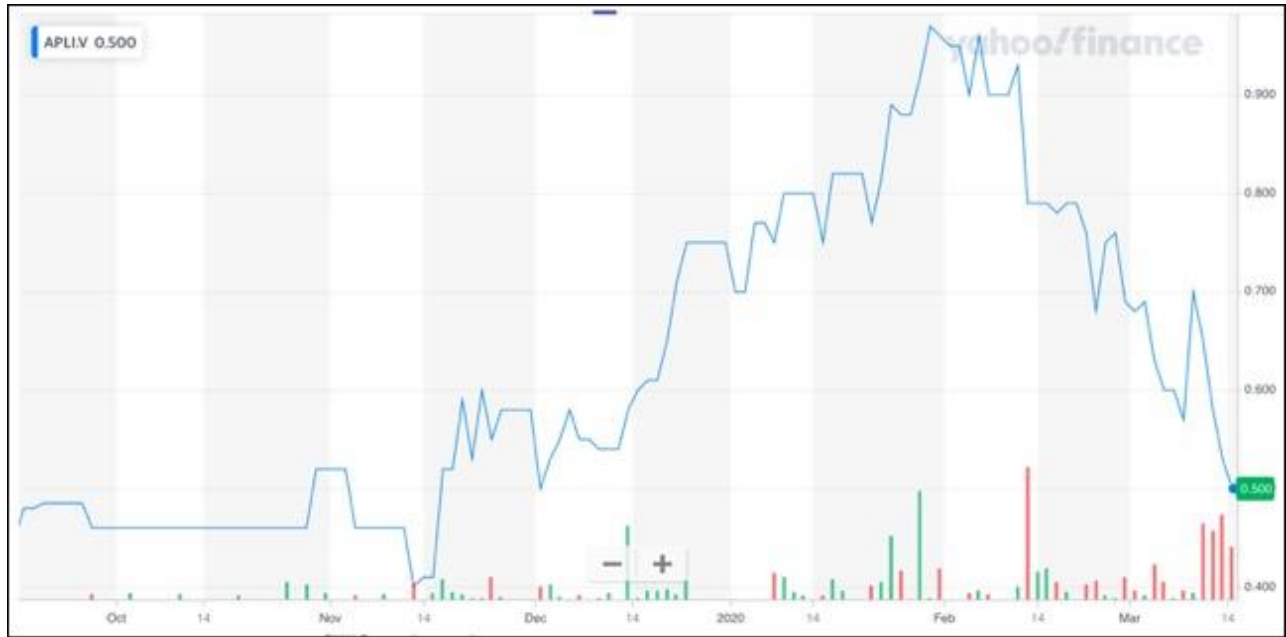
We look forward to the 365-day efficacy data for ATI-1701 in macaques that should be announced in the first half of 2020. The market opportunity for ATI-1701 includes its use in the U.S. Strategic National Stockpile (past contracts for the SNS have ranged from approximately \$500 million to \$1.6 billion), for immunizing members of the military, and the priority review voucher (PRV) that will be issued upon its approval (the most recent of which have sold for approximately \$100 million). Our current valuation for Appili is CAD\$3.00.

PROJECTED FINANCIALS

Appili Therapeutics Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY2019 A	Q1FY20 A	Q2FY20 A	Q3FY20 A	Q4FY20 E	FY2020 E	FY2021 E	FY2022 E
ATI-2307	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
ATI-1701	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
ATI-1503	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
ATI-1501	\$0.0	\$0.0	\$0.0	\$0.2	\$0.0	\$0.2	\$0.9	\$0.0
Other Income	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Total Revenues	\$0.0	\$0.0	\$0.0	\$0.2	\$0.0	\$0.2	\$0.9	\$0.0
Cost of Sales	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	\$3.3	\$0.6	\$0.6	\$0.5	\$0.6	\$2.3	\$7.7	\$10.0
General & Administrative	\$2.4	\$0.9	\$0.7	\$0.8	\$0.8	\$3.2	\$3.2	\$3.3
Business Development	\$0.9	\$0.5	\$0.1	\$0.2	\$0.2	\$1.1	\$1.0	\$1.0
Other (Income) Expense	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	(\$6.5)	(\$1.9)	(\$1.4)	(\$1.4)	(\$1.6)	(\$6.3)	(\$11.0)	(\$14.3)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$2.2	\$0.1	\$0.2	\$0.2	\$0.1	\$0.7	\$0.0	\$0.0
Pre-Tax Income	(\$4.3)	(\$1.8)	(\$1.1)	(\$1.2)	(\$1.5)	(\$5.6)	(\$11.0)	(\$14.3)
Income Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0	\$0
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$4.3)	(\$1.8)	(\$1.1)	(\$1.2)	(\$1.5)	(\$5.6)	(\$11.0)	(\$14.3)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	(\$0.14)	(\$0.06)	(\$0.03)	(\$0.04)	(\$0.04)	(\$0.16)	(\$0.22)	(\$0.24)
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	30.3	30.3	33.6	33.6	42.0	34.9	50.0	60.0

Source: Zacks Investment Research, Inc. David Bautz, PhD

HISTORICAL STOCK PRICE



Source: Yahoo Finance

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