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November 30, 2020
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Appili Therapeutics Inc. (T.APL-TSX)

T.APL: Joins Consortium to Develop Favipiravir as COVID-19 Treatment…

Based on our probability adjusted DCF model that takes into account potential future revenues of ATI-2307, ATI-1701, ATI-1501, and favipiravir APLI.T is valued at CAD$3.25/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 (11/30/20)	CAD$1.25
Valuation	**CAD$3.25**

OUTLOOK

On October 30, 2020, Appili Therapeutics Inc. (APLI.T) announced it had entered into a collaboration, development, and supply agreement with Dr. Reddy's Laboratories Ltd. and Global Response Aid that works in harmony with a prior agreement that includes the aforementioned companies and FUJIFILM Toyama Chemical Co. to coordinate and accelerate the worldwide development, commercialization, and distribution of favipiravir as a potential treatment for COVID-19. Appili will design and implement multiple pivotal Phase 3 trials for the potential regulatory submission for the use of favipiravir in treating COVID-19 in the U.S. and Canada. In addition, Appili has initiated a Phase 2 trial to test favipiravir as a prophylactic to prevent COVID-19 infections in long-term care facilities.

SUMMARY DATA

52-Week High	**$1.89**
52-Week Low	**$0.50**
One-Year Return (%)	**N/A**
Beta	**1.55**
Average Daily Volume (sh)	**175,228**
Shares Outstanding (mil)	**62**
Market Capitalization ($mil)	**$78**
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)
2020	0.0 A	0.0 A	0.2 A	0.0 A	0.2 A
2021	0.0 A	0.0 A	0.9 E	0.0 E	0.9 E
2022					0.0 E
2023					0.0 E

Earnings per Share
(in CAD$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	-$0.06 A	-$0.03 A	-$0.04 A	-$0.04 A	-$0.16 A
2021	-$0.05 A	-$0.04 A	-$0.04 E	-$0.05 E	-$0.18 E
2022					-$0.20 E
2023					-$0.21 E

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WHAT'S NEW

Business Update

Joins Consortium to Develop Favipiravir as COVID-19 Therapy

On October 30, 2020, Appili Therapeutics, Inc. (T.APLI) announced that it has entered into a collaboration, development, and supply agreement with Dr. Reddy's Laboratories Ltd. (DRL) and Global Response Aid (GRA) that will work in harmony with a prior global licensing transaction (excluding Japan, Russia, and China) between DRL, GRA, and FUJIFILM Toyama Chemical Co. (FFTC) for the worldwide development, commercialization, and distribution of favipiravir for the potential treatment and prevention of COVID-19. A few highlights of the agreement include:

- Appili will assume key responsibilities for the design and implementation of the consortium's global clinical programs that includes multiple Phase 3 trials (see below) and regulatory submissions (if supported by the data) for favipiravir's use in treating COVID-19 in the U.S. and Canada.

- DRL and GRA will still be responsible for the manufacturing, commercialization, and distribution of favipiravir. FFTC originally developed favipiravir for use in pandemic influenza and is contributing its knowledge base (e.g., clinical data and intellectual property) to support the consortium's activities.

- Appili will receive a profit share on all U.S. and Canadian sales for a specified term and is also eligible to receive royalties on sales in Europe and Latin America for a specified term.

Multiple Trials Underway Evaluating Favipiravir Against COVID-19

On November 24, 2020, Appili announced the initiation of the Phase 3 PEPCO (Post Exposure Prophylaxis for COVID-19) study to evaluate favipiravir for the prevention of COVID-19 among vulnerable individuals who have had recent direct exposure to someone with confirmed COVID-19 infection. Appili has also initiated another Phase 3 trial (PRESECO) for the treatment of COVID-19 patients with mild to moderate symptoms and a Phase 2 trial (CONTROL) to test whether favipiravir can prevent outbreaks of COVID-19 in long-term care facilities.

PEPCO: This is a randomized, double blind, placebo controlled, multinational Phase 3 trial that will enroll approximately 1,156 participants at 47 centers. The purpose of the study is to determine if favipiravir can prevent the development of COVID-19 in asymptomatic individuals who had direct exposure (within the past 72 hours) to someone with COVID-19. Enrollment will include any individual over the age of 60 along with those 18 years and older with at least one significant underlying health condition.

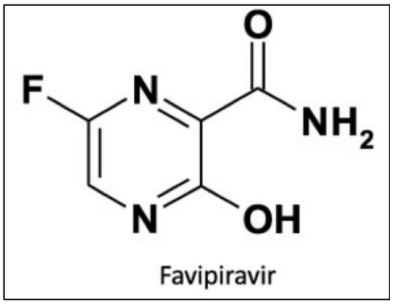
PRESECO: This is a randomized, double blind, placebo controlled Phase 3 trial that plans to enroll 826 participants who were recently diagnosed with COVID-19 and have mild to moderate symptoms. The purpose of the trial is to determine if favipiravir can shorten the time to clinical recovery, prevent progression to severe disease, and decrease the period of infectiousness.

CONTROL: This is a Phase 2 cluster-randomized, placebo controlled trial evaluating the effectiveness of favirpiravir to prevent COVID-19 outbreaks in long-term care facilities. They anticipate approximately 760 participants enrolling across 16 long term care facilities, with eight facilities administering favipiravir to its residents and the other eight administering placebo. Facilities are eligible to be enrolled in the trial after two or more residents test positive for SARS-CoV-2 by PCR testing. Following enrollment of the facility, all residents (elderly patients with co-morbidities) and front-line healthcare workers will be administered either favipiravir or placebo with the primary outcome of the trial being outbreak control, defined as no new cases of COVID-19 in residents for 24 consecutive days up to Day 40 after the start of prophylactic treatment.

These trials are a part of Appili's strategy to determine those who may benefit most from the use of favipiravir in treating or preventing COVID-19. Topline data from these trials could be available in mid-2021. Even with effective COVID-19 vaccines, we believe there will be a high need for effective antiviral therapy as (just like with influenza) not everyone will be vaccinated. Despite the yearly influenza vaccine being available, Tamiflu® generated >$1 billion in sales before going off patent, and we believe similar success for effective antivirals for COVID-19 are possible.

Favipiravir

Favipiravir is a broad-spectrum antiviral compound that selectively inhibits the RNA-dependent RNA polymerase (RdRP) of influenza and many other RNA viruses (Shiraki *et al*., 2020). It was discovered by Toyoma Chemical Co., Ltd. through the screening of a large chemical library looking for compounds with anti-influenza activity. Favipiravir shows activity against influenza strains A, B, and C, which includes seasonal strains as well as pandemic strains (Fruruta *et al*., 2002).



Source: Shiraki *et al*., 2020

The drug interferes with viral replication through binding of RdRP and acting as a chain terminator at the site of incorporation (Jin *et al*., 2013). However, in comparison to other anti-viral compounds, it does not appear to generate resistant strains. For example, influenza virus strains that are resistant to oseltamivir (Tamiflu®) have emerged, however a favipiravir-resistant virus never appeared in Phase 3 clinical trials (Takashita *et al*., 2016). This is encouraging, as the use of favipiravir will likely not lead to a reduction in efficacy should the drug be utilized during the current coronavirus pandemic.

Favipiravir is currently approved for the treatment of pandemic influenza in Japan under the brand name Avigan®. However, it is contraindicated for use in pregnant women since it showed teratogenic and embryotoxic effects in animals. Other potential side effects include nausea, vomiting, diarrhea, and hepatic injury.

Favipiravir and COVID-19

India and Russia have both approved favipiravir-based antiviral medications for the emergency treatment of COVID-19. There are a number of research groups around the world studying favipiravir for the treatment of COVID-19 as evidenced by the 40 clinical trials either completed, ongoing or intending to start listed on clinicaltrials.gov.

In September 2020, FFTC announced that the primary endpoint was met in a Phase 3 clinical trial of favipiravir that was conducted in Japan in COVID-19 patients. It was a randomized, single blind, placebo controlled trial in 156 COVID-19 patients with non-severe pneumonia. The primary endpoint was time to negative conversion of detectable SARS-CoV-2 viral RNA by PCR. The results showed that the median value for the primary endpoint was 11.9 days for patients treated with favipiravir and 14.7 days for the placebo group (P=0.0136). These data are very encouraging and show the potential for favipiravir to have a positive effect on COVID-19 patients.

Additional Funding for ATI-1701 Program

In October 2020, Appili announced it entered into an agreement with Ology Biosciences, a biologics contract development and manufacturing organization, in which Ology will manufacture ATI-1701 following award of a

U.S. Department of Defense contract of US$6.3 million. The contract will cover the production of vaccine supply for the development of the ATI-1701 program.

ATI-1701 is a vaccine for the prevention of tularemia caused by *Francisella tularensis*, a pathogen that is a Tier 1 biological threat agent according to the CDC (Dennis *et al*., 2001). Its potential as a bioterror agent is based on the fact that only a very small number of *F. tularensis* cells (10-50) can cause disease and the organism can be aerosolized to infect a large area. It is an intracellular bacterium that primarily infects macrophages (Clemens *et al*., 2007). Symptoms typically occur three to five days following exposure and include sudden chills, fever, headaches, diarrhea, muscle aches, and progressive weakness (CDC). Streptomycin is the standard of care for tularemia, although gentamicin is an acceptable alternative, and treatment typically lasts for 10 days. Tetracyclines may also be used in place of aminoglycosides, but treatment with those agents is done for 14 days. Ciproflaxin and other fluoroquinolones are not FDA-approved to treat tularemia, but they have shown good efficacy *in vitro* and i*n vivo*.

Since it is no longer acceptable to test the efficacy of a tularemia vaccine in a human population, ATI-1701 is being developed via the FDA Animal Rule. Products developed via this pathway are required to show efficacy in two animal models, one of which being a non-human primate, along with safety in a healthy adult population. The company previously presented data showing ATI-1701 protected rats for 365 days and cynomolgus macaques for 90 days following immunization, while challenges of aerosolized F. tularesnsis resulted in 100% fatality in non-vaccinated rats and macaques. We anticipate the vaccine entering clinical trials in healthy volunteers in the first half of 2022.

Financial Update

On November 13, 2020, Appili announced financial results for the second quarter of fiscal year 2021, which ended September 30, 2020. Net loss for the second quarter of fiscal year 2021 was CAD$2.5 million, or CAD$0.04 per share, compared to a net loss of CAD$1.1 million, or CAD$0.03 per share, for the second quarter of fiscal year 2020. The increase was primarily due to increased R&D and G&A expenses.

R&D expenses for the second quarter of fiscal year 2021 were CAD$1.1 million, compared to CAD$0.6 million for the second quarter of fiscal year 2020. The increase was primarily due to increased spending for the favipiravir clinical trials and the ATI-2307 program. G&A expenses for the second quarter of fiscal year 2021 were CAD$1.4 million compared to CAD$0.7 million for the second quarter of fiscal year 2020. The increase was primarily due to increased salaries and benefits and stock-based compensation.

As of September 30, 2020, Appili had approximately CAD$22.9 million in cash, cash equivalents, and short-term investments. In June 2020, the company completed a public offering of approximately 12.9 million units at a price of CAD$1.20 per unit for gross proceeds of approximately CAD$15.5 million. Each unit consisted of one share of common stock and one-half of one common share purchase warrant. Each warrant has an exercise price of CAD$1.50 and expires on June 10, 2023. Concurrently on June 10, 2020, the company closed a non-brokered private placement of 1.2 million units for gross proceeds of CAD$1.44 million.

As of November 12, 2020, Appili has approximately 63.4 million shares outstanding, 15.0 million warrants, and 4.5 million options for a fully diluted share count of approximately 81.8 million.

Conclusion

We look forward to updates regarding the favipiravir program and believe it could have an important impact on the coronavirus epidemic. As mentioned previously, even with effective COVID-19 vaccines there will be a need for antiviral therapeutics to treat or prevent progression to severe disease since we don't anticipate everyone being vaccinated. With no changes to the model our valuation remains at CAD$3.25.

PROJECTED FINANCIALS

Appili Therapeutics Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY2020 A	Q1FY21 A	Q2FY21 A	Q3FY21 E	Q4FY21 E	FY2021 E	FY2022 E	FY2023 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	$0.2	$0.0	$0.0	$0.9	$0.0	$0.9	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.2**	**$0.0**	**$0.0**	**$0.9**	**$0.0**	**$0.9**	**$0.0**	**$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	$2.1	$1.6	$1.1	$2.0	$2.0	$6.7	$8.0	$9.0
General & Administrative	$3.3	$1.0	$1.4	$1.0	$1.0	$4.4	$3.3	$3.3
Business Development	$0.9	$0.1	$0.2	$0.3	$0.3	$0.9	$1.0	$1.0
Other (Income) Expense	$0.0	$0.0	($0.2)	$0.0	$0.0	($0.2)	$0.0	$0.0
Operating Income	($6.1)	($2.7)	($2.5)	($2.4)	($3.3)	($11.0)	($12.3)	($13.3)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.7	$0.1	$0.0	$0.1	$0.1	$0.3	$0.0	$0.0
Pre-Tax Income	($5.4)	($2.6)	($2.5)	($2.4)	($3.3)	($10.7)	($12.3)	($13.3)
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	**($5.4)**	**($2.6)**	**($2.5)**	**($2.4)**	**($3.3)**	**($10.7)**	**($12.3)**	**($13.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.16)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.05)**	**($0.18)**	**($0.20)**	**($0.21)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	34.3	50.2	61.6	62.0	62.0	59.0	62.0	62.0

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

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