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Appili Therapeutics Inc. (V.API-TSXV)

V.API: Initiating Prophylactic Phase 2 Trial of Favipiravir to Prevent COVID-19…

Based on our probability adjusted DCF model that takes into account potential future revenues of ATI-2307, ATI-1701, ATI-1501, and favipiravir APLI is valued at CAD$3.50/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 (05/22/20)	CAD$1.81
Valuation	**CAD$3.50**

OUTLOOK

On May 21, 2020, Appili Therapeutics Inc. (APLI.V) announced that Health Canada provided clearance for a prophylactic Phase 2 clinical trial of favipiravir, which is an antiviral compound that is approved for the treatment of pandemic influenza in Japan (Avigan®), for the prevention of COVID-19 in long-term care facilities. It will be a cluster randomized, partially blinded, placebo controlled trial that will enroll approximately 760 participants across 16 long-term care facilities. Residents will begin taking prophylactic favipiravir after at least two positive cases of SARS-CoV-2 are reported at a facility. The primary endpoint of the trial will be outbreak control, which is defined as no new cases of COVID-19 in residents for 24 consecutive days up to Day 40 after the start of prophylactic treatments.

SUMMARY DATA

52-Week High	**$1.89**
52-Week Low	**$0.32**
One-Year Return (%)	**110.0**
Beta	**N/A**
Average Daily Volume (sh)	**155,070**
Shares Outstanding (mil)	**46**
Market Capitalization ($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

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WHAT'S NEW

Business Update

Initiating Prophylactic Phase 2 Trial to Prevent COVID-19

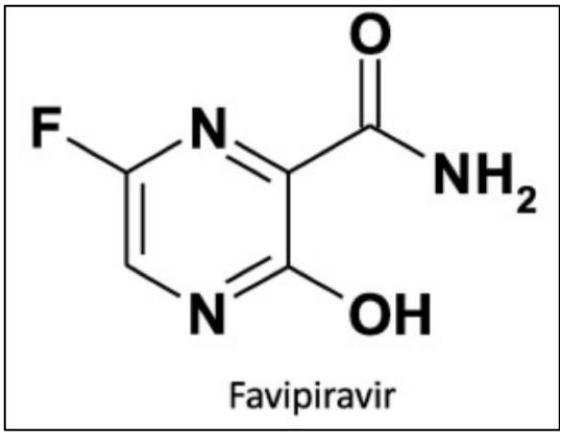
On May 21, 2020, Appili Therapeutics Inc. (APLI.V) announced that Health Canada has provided clearance for a prophylactic Phase 2 clinical trial of favipiravir for the prevention of COVID-19, a respiratory infection caused by the SARS-CoV-2 coronavirus, in long-term care facilities.

The ongoing coronavirus epidemic has hit the elderly the hardest, particularly those that reside in long-term care facilities. In Canada, approximately 80% of all COVID-19 deaths have occurred in long-term care facilities, while in the U.S. a number of states report that >50% of deaths occur in them. Thus, finding a means to prevent the spread of COVID-19 among this population could have a significant effect on mitigating the epidemic.

The cluster randomized, partially blinded, placebo controlled trial will look to enroll approximately 760 participants 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. Following enrollment of the facility, all residents 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. Secondary objectives include safety, rates of infection, disease progression, and fatality rates.

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

There are a number of research groups around the world studying favipiravir for the treatment of COVID-19 as evidenced by the 14 clinical trials either ongoing or intending to start listed on clinicaltrials.gov. Thus far there have been two reports in the media about trials in China and Japan that tested favipiravir in patients with COVID-19, however it should be noted that those studies examined treatment with favipiravir after the patients had already been diagnosed with COVID-19.

Cai *et al*., 2020: This open label, non-randomized trial was performed in Shenzhen, China and compared favipiravir to lopinavir/ritonavir (control arm) for the treatment of COVID-19. Results showed that patients treated with favipiravir had a shorter viral clearance time compared to the control arm (4 days vs. 11 days; $P<0.001$) and showed significant improvement in chest imaging compared to the control arm (91.4% vs. 62.2%; $P=0.004$). In addition, fewer adverse reactions were seen in the favipiravir arm compared to the control arm.

Chen *et al*., 2020: This randomized, open label trial was performed in Wuhan, China and compared favipiravir to umifenovir (control arm) for the treatment of COVID-19. The primary endpoint was clinical recovery at Day 7, which did not significantly differ between the favipiravir (71/116, 61%) and control (62/120, 52%) group (P=0.1396). However, treatment with favipiravir led to shorter duration of fever (difference of 1.7 days; $P<0.0001$) and cough (difference of 1.75 days; $P<0.0001$).

These reports are encouraging and show that favipiravir has antiviral activity against SARS-CoV-2 along with a relatively benign side effect profile.

Conclusion

We look forward to updates regarding the Phase 2 trial of favipiravir and believe it could have an important impact on the coronavirus epidemic as the elderly are clearly the most vulnerable and treatments to prevent the spread of disease in that population are desperately needed. Valuing favipiravir for the prevention of COVID-19 in the elderly is very difficult at this point, however we model for it to be a $100 million opportunity, which would likely take the form of selling the compound to be stockpiled and distributed by the government. This has raised our valuation to CAD$3.50.

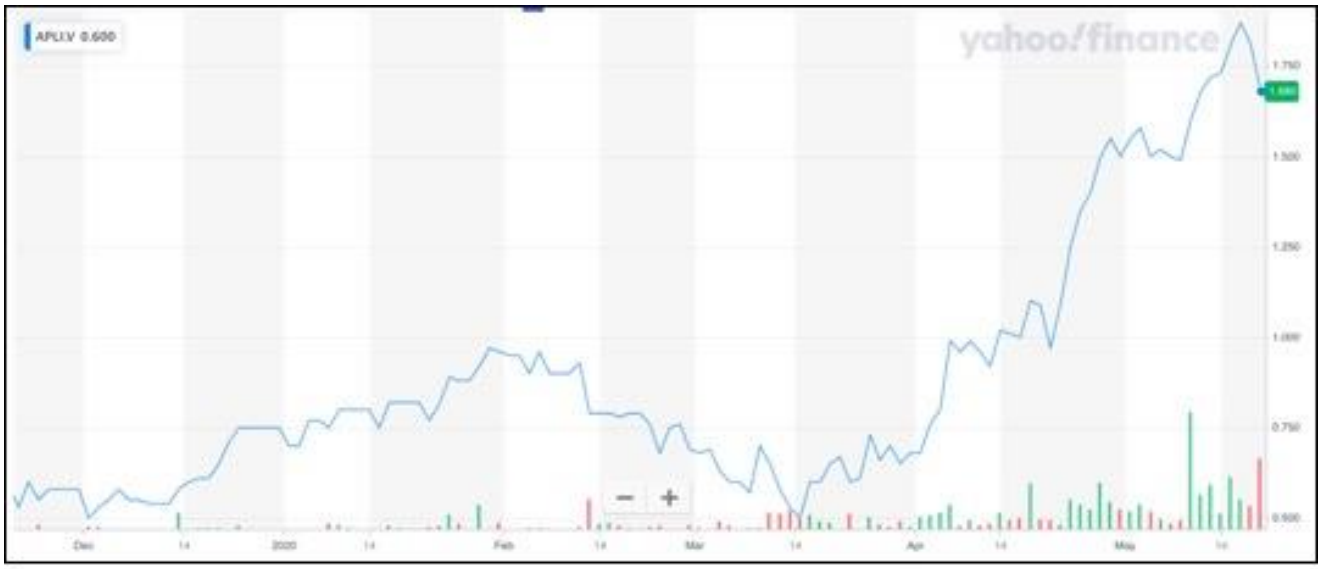
PROJECTED FINANCIALS

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*

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HISTORICAL STOCK PRICE



Source: Yahoo Finance

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