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Appili Therapeutics Inc.

(OTCQX: APLIF)

APLIF: Phase 3 PRESECO Trial Readout in Late March 2021…

Based on our probability adjusted DCF model that takes into account potential future revenues of ATI-2307, ATI-1701, ATI-1501, and favipiravir APLIF is valued at $2.50/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 (01/29/21)	$0.78
Valuation	**$2.50**

OUTLOOK

On January 28, 2021, Appili Therapeutics Inc. (APLIF) provided an update on the Phase 3 PRESECO (PREventing SEvere COvid-19) trial that is evaluating favipiravir for the early treatment of COVID-19 in the outpatient setting. Based upon current enrollment forecasts, the company anticipates an interim data readout by late March 2021. Appili is prioritizing resources to accelerate recruitment and data analysis for the PRESECO trial, but is also continuing the CONTROL and PEPCO trials as label expansion studies for the use of favipiravir in post-exposure prophylaxis indications.

SUMMARY DATA

52-Week High	**$1.22**
52-Week Low	**$0.60**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**16,969**
Shares Outstanding (mil)	**63**
Market Capitalization ($mil)	**$49**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $USD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	0.0 A	0.0 A	0.1 A	0.0 A	0.1 A
2021	0.0 A	0.0 A	0.7 E	0.0 E	0.7 E
2022					0.0 E
2023					0.0 E

Earnings per Share
(in $USD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	-$0.05 A	-$0.03 A	-$0.03 A	-$0.02 A	-$0.11 A
2021	-$0.04 A	-$0.03 A	-$0.03 E	-$0.04 E	-$0.14 E
2022					-$0.15 E
2023					-$0.16 E

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WHAT'S NEW

Business Update

Update on PRESECO Trial

On January 28, 2021, Appili Therapeutics, Inc. (APLIF) provided an update on the company's Phase 3 PRESECO ((PREventing SEvere COvid-19) trial that is evaluating favipiravir for the treatment of COVID-19 in the outpatient setting. The trial is currently recruiting patients in 12 out of 20 sites in the U.S. and is pursuing approvals to expand the trial into sites in Mexico, Brazil, and Columbia.

The PRESECO trial 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.

Appili is prioritizing resources to accelerate recruitment and data analysis for the PRESECO trial and is planning to use the information gathered from the ongoing CONTROL and PEPCO trials (discussed below) as label expansion studies to evaluate if favipiravir is efficacious as a post-exposure prophylaxis treatment. Based on current enrollment rates for PRESECO, the company anticipates interim data from that trial by late March 2021.

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.

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.

In October 2020, Appili announced that it had 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.

In December 2020, the consortium announced that Dr. Reddy's Canada filed an application on behalf of the consortium for REEQONUS™ (favipiravir) tablets for the acute treatment of mild to moderate COVID-19 in adult patients under Health Canada's Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. The consortium was the first in Canada to file an application for oral solid tablets for COVID-19 treatment in Canada such that if successful clinical trial results are obtained favipiravir could be approved for use in an expeditious manner.

Kuwait Trial of Favipiravir Not Successful, but Sub-Group Analysis Encouraging

On January 27, 2021, DRL and GRA announced that the Avigan (favipiravir) study in Kuwait focused on moderate to severe COVID-19 patients in the hospital would be terminated.

The results showed that there was not a statistically significant difference in the primary endpoint (time to sustained hypoxia resolution) for Avigan vs. placebo (7 days vs. 8 days; *P*>=0.05) with the full data set on 353 subjects being available by the end of February 2021. While the primary endpoint was not achieved, a sub-group analysis of 181 patients in the low-risk category showed a 3-day earlier discharge in the Avigan group compared to placebo (8 days vs. 11 days; P=0.0063), which was a secondary endpoint.

While the results of the Kuwait trial are disappointing, the subgroup analysis does support the idea that anti-viral therapy is more likely to be successful as part of an early intervention in COVID-19 patients before the disease progresses to moderate or severe status, which is what the PRESECO trial is testing.

Conclusion

We are looking forward to the data from the PRESECO trial, which we anticipate will be in late March 2021. Multiple successful vaccines have already been approved against COVID-19, however just as influenza is combated with both vaccines and antivirals, so too will doctors need both vaccines and antivirals in their arsenal to battle COVID-19. In addition, news of COVID-19 vaccines having less efficacy against SARS-CoV-2 variants further emphasizes the point that effective antivirals are necessary, particularly those that can be administered at home shortly after a diagnosis is given. As we await the results of the PRESECO trial there are no changes to our model and the valuation remains at CAD$3.25.

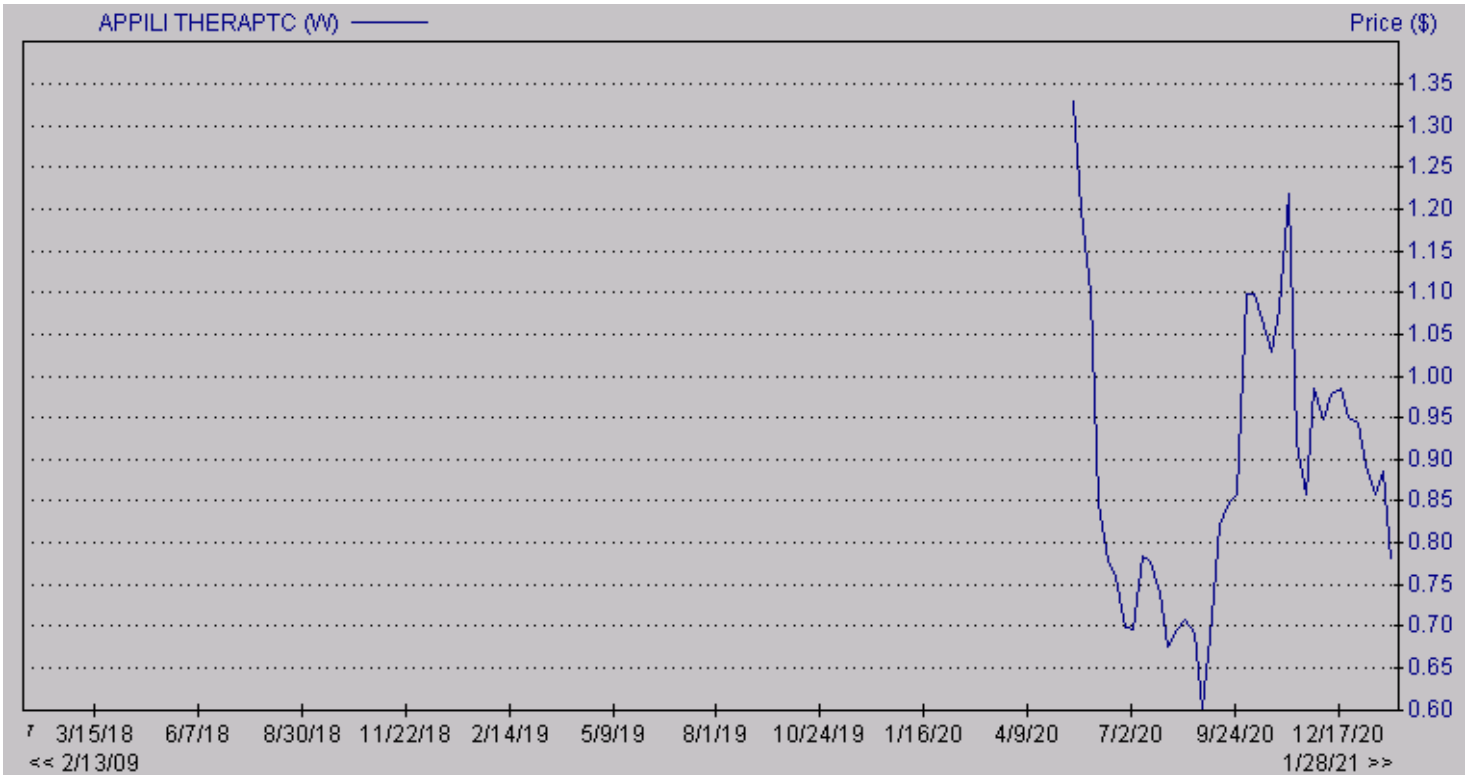
PROJECTED FINANCIALS

Appili Therapeutics Inc. Fiscal Year Ends Mar. 31 / in U.S. 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	$0.1	$0.0	$0.0	$0.7	$0.0	$0.7	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.1**	**$0.0**	**$0.0**	**$0.7**	**$0.0**	**$0.7**	**$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	$1.6	$1.2	$0.8	$1.5	$1.5	$5.1	$6.1	$6.8
General & Administrative	$2.5	$0.8	$1.1	$0.8	$0.8	$3.4	$2.5	$2.5
Business Development	$0.7	$0.1	$0.1	$0.2	$0.2	$0.7	$0.8	$0.8
Other (Income) Expense	$0.0	$0.0	($0.1)	$0.0	$0.0	($0.1)	$0.0	$0.0
Operating Income	($4.6)	($2.1)	($1.9)	($1.8)	($2.5)	($8.3)	($9.3)	($10.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.5	$0.1	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	($4.1)	($2.0)	($1.9)	($1.8)	($2.5)	($8.1)	($9.3)	($10.1)
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	**($4.1)**	**($2.0)**	**($1.9)**	**($1.8)**	**($2.5)**	**($8.1)**	**($9.3)**	**($10.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.12)**	**($0.04)**	**($0.03)**	**($0.03)**	**($0.04)**	**($0.14)**	**($0.15)**	**($0.16)**
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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