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Appili Therapeutics Inc. (T.APL-TSX)

T.APL: FDA Accepts NDA for ATI-1501; PDUFA Date for September 23, 2023…

Based on our probability adjusted DCF model that takes into account potential future revenues of ATI-1701, ATI-1801, and ATI-1501 APLI.T is valued at CAD$0.20/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 (02/21/23)	CAD$0.05
Valuation	**CAD$0.20**

OUTLOOK

On February 14, 2023, Appili Therapeutics Inc. (APLI.T) announced financial results for the third quarter of fiscal year 2023 that ended December 31, 2022 and provided a business update. The FDA recently accepted the new drug application (NDA) for ATI-1501 and assigned a PDUFA date of September 23, 2023. Appili is currently in the process of finalizing definitive contracts with the Department of Defense (DoD) and preparing to initiate IND-enabling toxicology studies for ATI-1701. Lastly, the company is engaging with regulatory authorities on development plans for ATI-1801 and has plans to select a Contract Drug Manufacturing Organization to produce the topical cream formulation. We anticipate an update on the program later this year.

SUMMARY DATA

52-Week High	**$0.17**
52-Week Low	**$0.04**
One-Year Return (%)	**-58.33**
Beta	**1.01**
Average Daily Volume (sh)	**135,490**
Shares Outstanding (mil)	**121**
Market Capitalization ($mil)	**$5**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**20**
Insider Ownership (%)	**21**
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-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of CAD$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	0.0 A	0.0 A	1.4 A	0.0 A	1.4 A
2023	0.0 A	0.0 A	0.0 A	0.0 E	0.0 E
2024					0.0 E
2025					0.0 E

Earnings per Share
(in CAD$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	-$0.12 A	-$0.18 A	-$0.05 A	-$0.05 A	-$0.38 A
2023	-$0.03 A	-$0.01 A	-$0.02 A	-$0.02 E	-$0.08 E
2024					-$0.07 E
2025					-$0.06 E

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WHAT'S NEW

Business Update

FDA Accepts NDA for ATI-1501; PDUFA Date Set for Sep. 23, 2023

On February 8, 2023, Appili Therapeutics Inc. (APLI.TO) announced that the U.S. Food and Drug Administration (FDA) accepted the new drug application (NDA) for ATI-1501 and established a PDUFA action date of September 23, 2023.

ATI-1501 is a taste-masked liquid oral suspension formulation of the antibiotic metronidazole. This was the company's initial R&D program initiated in the first quarter of 2015. Metronidazole is an antibiotic used to treat various protozoan and anaerobic bacterial infections, including giardiasis, trichomoniasis, and amebiasis (Freeman *et al*., 1997). It is a widely used antibiotic, with more than 10 million oral prescriptions written each year (IQVIA™ 2017).

In December 2019, Appili announced a commercial agreement with Saptalis Pharmaceuticals for ATI-1501, in which Appili will be eligible to receive multiple milestones and royalty payments based on the sale of ATI-1501 in the U.S. Saptalis will be responsible for overseeing the regulatory review, manufacturing, and preparation for the anticipated commercialization of ATI-1501 in the U.S. We anticipate Saptalis launching the drug shortly after approval, thus we expect Appili to receive milestone payments in Q3FY24.

The commercial agreement was amended in 2022 to expand the territories that Saptalis will commercialize ATI-1501 to include Europe and Latin America. Saptalis will be responsible for all development and commercialization efforts in those two regions and Appili will be eligible to receive royalties on sales.

Update on ATI-1701

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. Inhalation of *F. tularensis* and development of pneumonic tularemia can lead to breathing difficulties and ultimately be fatal if not treated. Based on its highly infectious nature and ability to cause severe illness, the U.S. government and other governments around the world have made medical countermeasures against *F. tularensis* a high biodefense priority.

Since it is unacceptable 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, typically in two animal models, one of which being a non-human primate, along with safety and clinical biomarkers in a healthy adult population.

Appili previously presented data showing that ATI-1701 protected 100% of rats for 365 days and cynomolgus macaques for 90 days following immunization. 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, and non-vaccinated macaques. The company also previously announced positive one-year challenge results with non-human primates showing a survival rate of 29% (2/7) in the ATI-1701 vaccinated cohort compared to 0% (0/5) in placebo vaccinated controls.

On November 14, 2022, Appili announced that the U.S. Department of Defense (DoD), via the Joint Science and Technology Office of the Defense Threat Reduction Agency (DTRA) in partnership with USAFA, will provide at least US$14 million in funding over two years for the continued development of ATI-1701.

This new funding will replace and expand upon the previous contract to support the advanced development and manufacturing of ATI-1701 that had been awarded to one of Appili's development partners. USAFA will

now serve as the prime contractor, and we anticipate Appili partnering with the USAFA to advance the program, with covered activities including regulatory, nonclinical, and manufacturing to support an IND submission to the FDA. In addition, we anticipate the company providing an update on the timing for starting Phase 1 studies once the contracting discussions are finalized.

Since it is being developed as a medical countermeasure, Appili believes ATI-1701 may be eligible for a priority review voucher (PRV) upon FDA approval. A PRV allows the holder of the voucher to receive an expedited six-month review from the FDA for a new drug application (NDA) or biologics license application (BLA) instead of the usual ten-month review. PRVs are fully transferrable and have consistently sold over the previous couple of years for approximately $100 million each.

Update on ATI-1801

In April 2022, Appili announced the addition of ATI-1801, a late stage clinical program to treat cutaneous leishmaniasis. The product, a topical formulation of paromomycin, was licensed from the U.S. Department of Defense (DOD) via the U.S. Army Medical Material Development Activity (USAMMDA). Appili now holds the full clinical dossier for ATI-1801, which includes the results of a successful randomized, double blind, placebo controlled Phase 3 trial that evaluated the safety and efficacy of ATI-1801 for the treatment of cutaneous leishmaniasis in Tunisia. The results of the study showed that ATI-1801 applied topically once daily for 20 days resulted in a statistically significant improvement in the rate of clinical cure for the index lesion compared to placebo (82% vs. 58%; $P<0.001$).

Appili plans to meet with the FDA in 2023 to discuss the Phase 3 data and determine what will be necessary for a registration package to support a new drug application submission. The company will be pursuing non-dilutive funding and partnership opportunities with non-government organizations (NGOs) and government agencies to assist in completing any remaining development work. In addition, since cutaneous leishmaniasis is a tropical disease, ATI-1801 will likely be eligible for a PRV upon approval by the FDA. ATI-1801 has also received orphan drug designation (ODD) from the FDA for the treatment of certain forms of cutaneous leishmaniasis.

Cutaneous leishmaniasis is a debilitating skin disease caused by approximately 30 different species of the single-celled parasite Leishmania. The disease is spread by the bite of the Phlebotominae sandfly and is endemic in 88 countries throughout Africa, Asia, Europe, and North and South America. While only 50-100 cases are diagnosed each year in the U.S., approximately 1.5 to 2 million new cases are diagnosed each year around the world (AAFP.org). Current treatment options include pentavalent antimony, but this has a high incidence of side effects including fatigue, gastrointestinal issues, liver enzyme elevations, leukopenia, and anemia. Thus, there is an urgent need for additional treatment options.

Financial Update

On February 14, 2023, Appili announced financial results for the third quarter of fiscal year 2023, which ended December 31, 2022. Net loss for the third quarter of fiscal year 2023 was CAD$2.6 million, or CAD$0.02 per share, compared to a net loss CAD$3.2 million, or CAD$0.05 per share, for the quarter ending December 31, 2021. The decrease was primarily due to an CAD$2.4 million decrease in R&D expenditures.

R&D expenses for the third quarter of fiscal year 2023 were CAD$0.9 million, compared to CAD$3.3 million for the third quarter of fiscal year 2022. The decrease was primarily due to a decrease in the favipiravir clinical trials. G&A expenses for the third quarter of fiscal year 2023 were CAD$1.4 million, compared to CAD$1.2 million for the third quarter of fiscal year 2022. The increase was primarily due to increased salaries and benefits partially offset by decreased stock-based compensation.

As of December 31, 2022, Appili had approximately CAD$1.4 million in cash and cash equivalents, and was selected to receive a US$14 million DTRA grant to fund the development costs for the ATI-1701 program, subject to finalizing definitive documentation governing the terms of the grant. We estimate Appili has sufficient capital to fund operations into 2024. As of February 13, 2023, Appili had approximately 121.3 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 180.7 million.

Conclusion

We're glad to see that the FDA has accepted the NDA for ATI-1501 and we look forward to updates from the company as we move towards the PDUFA date of September 23, 2023. In addition, we anticipate updates later this year on finalization of the contract for the development of ATI-1701 as well as the regulatory path forward for ATI-1801 after the company is able to meet with the FDA. We have modified the timelines for development of ATI-1701 and ATI-1801 in regards to when they could receive a PRV, which has decreased our valuation to CAD$0.20.

PROJECTED FINANCIALS

Appili Therapeutics Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY2022 A	Q1FY23 A	Q2FY23 A	Q3FY23 A	Q4FY22 E	FY2023 E	FY2024 E	FY2025 E
ATI-1701	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ATI-1801	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ATI-1501	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$1.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$1.4**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$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	$20.7	$1.0	$0.2	$0.9	$1.5	$3.7	$7.0	$8.0
General & Administrative	$4.6	$1.1	$0.9	$1.4	$1.2	$4.6	$5.0	$5.2
Business Development	$0.7	($0.0)	$0.1	$0.1	$0.2	$0.3	$1.0	$1.0
Other (Income) Expense	$0.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($25.1)	($2.1)	($1.2)	($2.4)	($2.9)	($8.6)	($13.0)	($14.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.0	($0.3)	($0.5)	($0.2)	$0.0	($0.9)	$0.0	$0.0
Pre-Tax Income	($25.1)	($2.3)	($1.7)	($2.6)	($2.9)	($9.5)	($13.0)	($14.2)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($25.1)**	**($2.3)**	**($1.7)**	**($2.6)**	**($2.9)**	**($9.5)**	**($13.0)**	**($14.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.38)**	**($0.03)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.08)**	**($0.07)**	**($0.06)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	66.7	91.0	121.3	121.3	122.0	113.9	175.0	225.0

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

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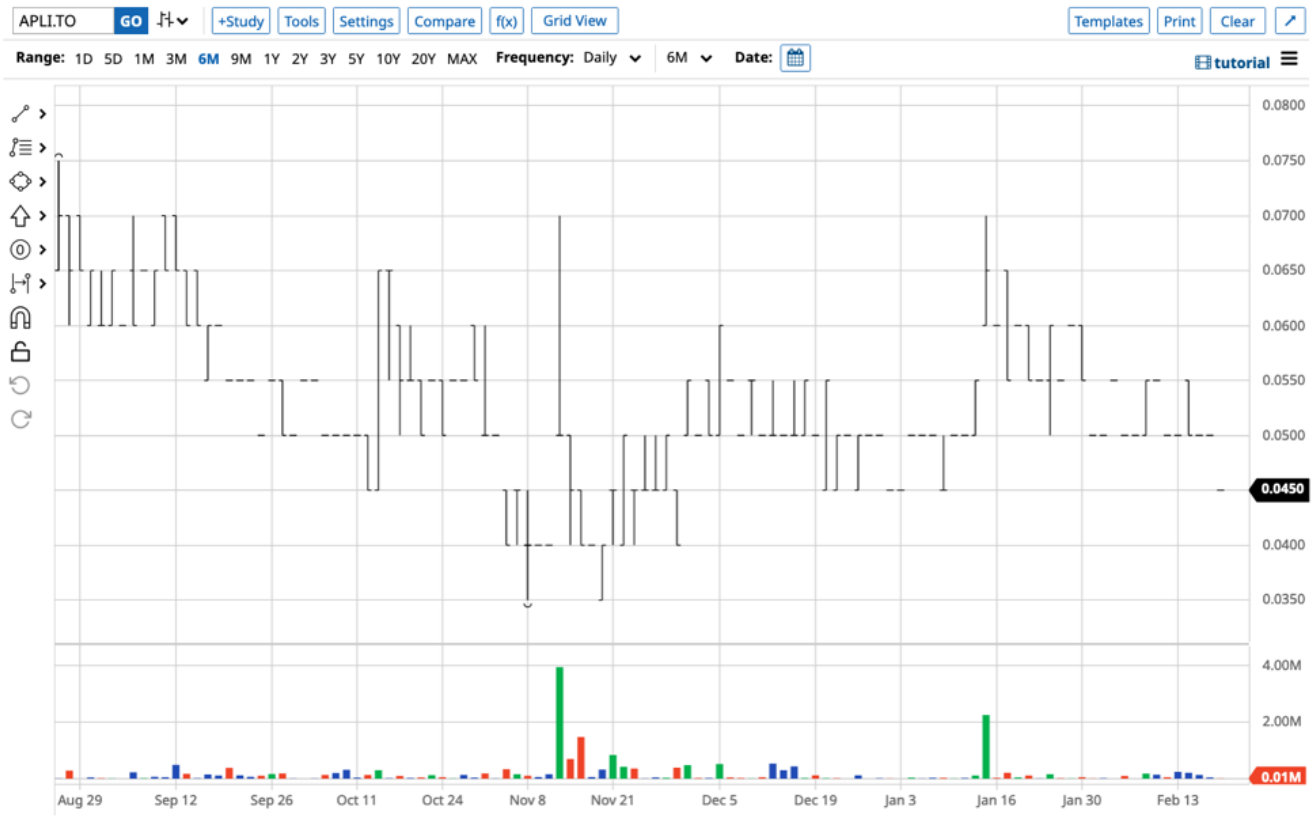

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