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Appili Therapeutics Inc. (T.APL-TSX)

T.APL: FDA Approves LIKMEZ™ (ATI-1501)…

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 (10/05/23)	CAD$0.05
Valuation	**CAD$0.20**

OUTLOOK

On September 25, 2023, Appili Therapeutics Inc. (APLI.T) announced that the FDA approved LIKMEZ (ATI-1501), Appili's liquid oral reformulation of the antibiotic metronidazole. We anticipate Appili receiving milestone payments and royalties from its commercialization partner, Saptalis Pharmaceuticals, LLC, based on the FDA approval and Saptalis' commercialization plans. The company also recently executed the initial contract with the U.S. Air Force Academy (USAFA) for the previously announced approximately US$14 million funding for the ATI-1701 program. The initial funding (US$7.3 million) will be used to initiate early-stage development and regulatory activities. Appili will be engaging USAFA for additional tranches of funding to continue development of ATI-1701 through the IND filing.

SUMMARY DATA

52-Week High	**$0.08**
52-Week Low	**$0.03**
One-Year Return (%)	**0.00**
Beta	**1.11**
Average Daily Volume (sh)	**191,440**
Shares Outstanding (mil)	**121**
Market Capitalization ($mil)	**$6**
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)
2023	0.0 A	0.0 A	0.0 A	0.3 A	0.3 A
2024	0.0 A	0.0 E	0.0 E	0.0 E	0.0 E
2025					0.0 E
2026					0.0 E

Earnings per Share
(in CAD$)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2023	-$0.03 A	-$0.01 A	-$0.02 A	-$0.02 A	-$0.08 A
2024	-$0.01 A	-$0.02 E	-$0.02 E	-$0.02 E	-$0.07 E
2025					-$0.06 E
2026					-$0.05 E

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WHAT'S NEW

Business Update

LIKMEZ™ (ATI-1501) Approved by the FDA

On September 25, 2023, Appili Therapeutics Inc. (APLI.TO) announced that the U.S. Food and Drug Administration (FDA) approved metronidazole oral suspension 500 mg/5 mL (ATI-1501) along with the brand name LIKMEZ™.

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. Appili recently received US$250,000 in milestone payments and we expect Appili to receive additional milestone payments in calendar 4Q23 based on Saptalis' commercialization plans.

The commercial agreement was amended in 2022 to expand the territories that Saptalis will commercialize LIKMEZ 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.

Secures Contract for ATI-1701 Funding from U.S. Air Force Academy

In May 2023, Appili announced the execution of the initial contract with the U.S. Air Force Academy (USAFA) for the previously announced funding of the ATI-1701 program, which will provide at least US$14 million. This initial funding of US$7.3 million will be utilized to begin the early-stage development and regulatory activities for ATI-1701. Appili will be engaging the USAFA for additional tranches of funding to continue the development of ATI-1701 through the IND filing.

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 significant 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.

ATI-1701 is being developed as a medical countermeasure, thus Appili believes it 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 is working on a technology transfer of ATI-1801 to the company's contract manufacturing organization. The company 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 could 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 August 11, 2023, Appili announced financial results for the first quarter of fiscal year 2024, which ended June 30, 2023. R&D expenses for the first quarter of fiscal year 2024 were CAD$1.2 million, compared to CAD$1.0 million for the first quarter of fiscal year 2023. The increase was primarily due to an increase in spending on the ATI-1701 program and increased salaries and benefits. G&A expenses for the first quarter of fiscal year 2024 were CAD$0.9 million, compared to CAD$1.1 million for the first quarter of fiscal year 2023. The decrease was primarily due to decreased salaries and benefits and stock-based compensation.

As of June 30, 2023, Appili had approximately CAD$0.5 million in cash and cash equivalents along with amounts receivable and investment tax credits receivable of CAD$1.3 million. In addition, there is an anticipated approximately CAD$14 million in funding available for the development of ATI-1701. In June 2023, Appili entered into a definitive agreement for a CAD$300,000 bridge loan from Bloom Burton & Co. Inc. This loan is only for short-term funding of company operations in the event reimbursements from the USAFA take longer than anticipated.

As of August 11, 2023, Appili had approximately 121.3 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 187.4 million.

Conclusion

We're very glad to see that the FDA has approved LIKMEZ (ATI-1501). Based on the approval, we anticipate Appili receiving two milestone payments in the fourth quarter of calendar 2023 from Saptalis. Lastly, we are looking forward to updates on the regulatory path forward for ATI-1801 after the company is able to meet with the FDA later this year. With no changes to our model, our valuation remains at CAD$0.20.

PROJECTED FINANCIALS

Appili Therapeutics Inc. Fiscal Year Ends Mar. 31 / in Canadian dollars	FY2023 A	Q1FY24 A	Q2FY24 E	Q3FY24 E	Q4FY24 E	FY2024 E	FY2025 E	FY2026 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	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.3**	**$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	$3.6	$1.2	$1.1	$1.2	$1.3	$4.8	$5.0	$5.3
General & Administrative	$4.4	$0.9	$1.2	$1.2	$1.2	$4.5	$4.8	$4.9
Business Development	$0.2	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.5
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($7.9)	($2.2)	($2.4)	($2.5)	($2.6)	($9.7)	($10.3)	($10.7)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($1.3)	$0.7	($0.3)	($0.4)	($0.4)	($0.4)	($1.5)	($1.5)
Pre-Tax Income	($9.2)	($1.5)	($2.7)	($2.9)	($3.0)	($10.1)	($11.8)	($12.2)
Income Taxes	$0.0	$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	**($9.2)**	**($1.5)**	**($2.7)**	**($2.9)**	**($3.0)**	**($10.1)**	**($11.8)**	**($12.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.08)**	**($0.01)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.07)**	**($0.06)**	**($0.05)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	113.7	121.3	140.0	160.0	160.0	145.3	200.0	225.0

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

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