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Appili Therapeutics Inc.

(OTCQX: APLIF)

APLIF: Executes Initial Contract with USAFA for Development of ATI-1701…

Based on our probability adjusted DCF model that takes into account potential future revenues of ATI-1701, ATI-1801, and ATI-1501 APLIF is valued at $0.15/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 (07/17/23)	$0.03
Valuation	**$0.15**

OUTLOOK

On June 23, 2023, Appili Therapeutics Inc. (APLIF) announced financial results for the fourth quarter and full fiscal year 2023 that ended March 31, 2023 and provided a business update. The company 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	**$0.02**
One-Year Return (%)	**-38.93**
Beta	**-0.60**
Average Daily Volume (sh)	**126,733**
Shares Outstanding (mil)	**121**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**1**
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 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $USD)

	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 E	0.0 E	0.0 E	0.0 E	0.0 E
2025					0.0 E
2026					0.0 E

Earnings per Share
(in $USD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2023	-$0.03 A	-$0.01 A	-$0.02 A	-$0.01 A	-$0.06 A
2024	-$0.02 E	-$0.01 E	-$0.01 E	-$0.01 E	-$0.06 E
2025					-$0.04 E
2026					-$0.04 E

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WHAT'S NEW

Business Update

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

In May 2023, Appili Therapeutics Inc. (APLIF) 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 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.

PDUFA Date for ATI-1501 is Sep. 23, 2023

In February 2023, Appili 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. Appili recently received US$250,000 in milestone payments and we expect Appili to receive additional milestone payments in 3Q23 and 4Q23 based on Saptalis' commercialization plans.

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-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 June 23, 2023, Appili announced financial results for fiscal year 2023, which ended March 31, 2023. Revenues for FY2023 were CAD$0.3 million compared to CAD$1.4 million in FY2022. The revenue in 2022 was due to a one-time milestone payment of CAD$1.3 million from FUJIFILM Toyoma Chemical Co. Ltd. for data licensing fee in FY 2022. The revenue in FY2023 was due to milestone payments received from Saptalis in respect to the ATI-1501 program.

R&D expenses for fiscal year 2023 were CAD$3.6 million, compared to CAD$20.7 million for fiscal year 2022. The decrease was primarily due to decreased expenses associated with the favipiravir clinical trials and the ATI-2307 program. G&A expenses for fiscal year 2023 were CAD$4.4 million, compared to CAD$4.6 million for fiscal year 2022. The decrease was primarily due to decreased stock-based compensation partially offset by increased G&A expenses and salaries and benefits.

As of March 31, 2023, Appili had approximately CAD$2.5 million in cash and cash equivalents and receivables and investment tax credits receivable of CAD$0.4 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. With the USAFA grant providing full reimbursement for direct costs and labor associated with the budgeted program activities for the ATI-1701 program, as well as covering a portion of overhead costs, we don't anticipate Appili having funding issues for the foreseeable future.

As of June 22, 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

The signing of the initial contract with the USAFA for funding for the ATI-1701 program is an important development for the company and will allow the initial work to begin as the company is hoping to file an IND for ATI-1701 in 2024. We look forward to updates from Appili as we move towards the PDUFA data for ATI-1501 of September 23, 2023. 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. Our valuation remains at $0.15.

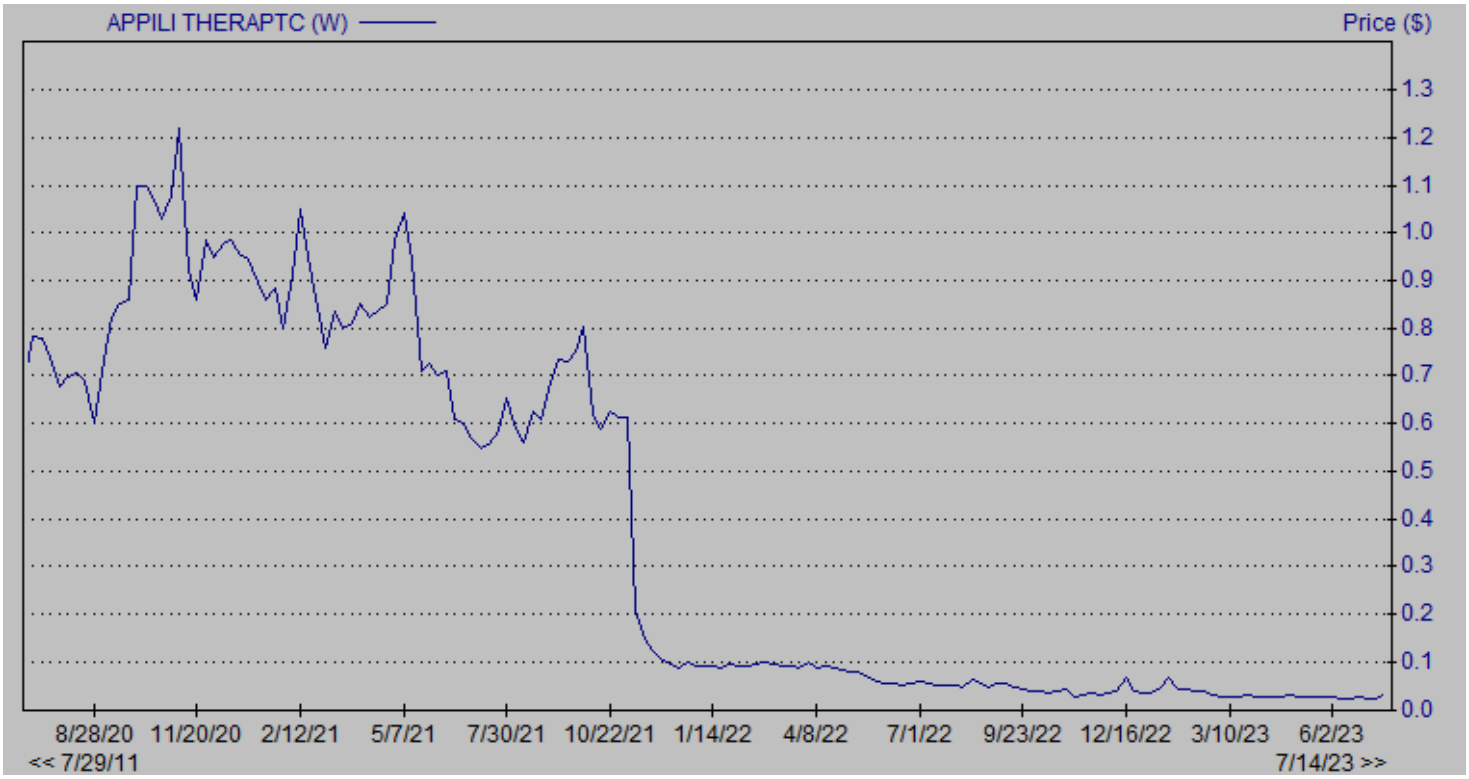
PROJECTED FINANCIALS

Appili Therapeutics Inc. Fiscal Year Ends Mar. 31 / in U.S. dollars	FY2023 A	Q1FY24 E	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	$2.8	$0.8	$0.8	$0.9	$1.0	$3.6	$3.8	$4.0
General & Administrative	$3.4	$0.8	$0.9	$0.9	$0.9	$3.6	$3.6	$3.7
Business Development	$0.1	$0.1	$0.1	$0.1	$0.1	$0.3	$0.4	$0.4
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($6.0)	($1.7)	($1.8)	($1.9)	($2.0)	($7.4)	($7.8)	($8.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($1.0)	($0.2)	($0.2)	($0.3)	($0.3)	($1.1)	($1.1)	($1.1)
Pre-Tax Income	($7.0)	($2.0)	($2.1)	($2.2)	($2.3)	($8.5)	($9.0)	($9.3)
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	**($7.0)**	**($2.0)**	**($2.1)**	**($2.2)**	**($2.3)**	**($8.5)**	**($9.0)**	**($9.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.06)**	**($0.02)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.06)**	**($0.04)**	**($0.04)**
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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