

# **Argos Therapeutics, Inc.** (ARGS)

Immunological Data from Patients on AGS-004 Sets the Stage

Price       \$12.3         52-Week Range:       \$7.97 - \$11.5         Shares Out. (M):       19.	
Shares Out. (M):	0
,	3
	0
Market Cap (\$M): \$233.	7
Average Daily Vol. (000): 176.	0
Cash (M): \$8	5
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2013E	2014E	2015E	
Revenue (\$M)	1Q	\$0.8A	\$1.2		
	2Q	\$1.0A	\$1.0		
	3Q	\$1.5A	\$0.8		
	4Q	\$1.7	\$0.3		
	FY	\$5.0	\$3.3	\$0.2	
EPS	1Q	(\$4.83)A	(\$0.50)		
	2Q	(\$4.78)A	(\$0.51)		
	3Q	(\$4.19)A	(\$0.57)		
	4Q	(\$3.82)	(\$0.61)		
	FY	(\$17.36)	(\$2.19)	(\$1.50)	
	P/E	NM	NM	NM	
Source: Company reports and JMP Securities LLC					



MARKET OUTPERFORM | Price: \$12.30 | Target Price: \$17.00

## **INVESTMENT HIGHLIGHTS**

Immunological data from patients on AGS-004 sets the stage; reiterate Market Outperform rating and \$17 price target on Argos Therapeutics. New analyses investigating the immune responses before and after AGS-004 therapy were presented at the Conference for Retroviruses and Opportunistic Infections. As a reminder, AGS-004 is a dendritic cell therapy using patient derived HIV mutated antigens that is engineered to ignite immune responses in the face of baseline immunosuppresion. Our key takeaways from these data are that 1) therapy induced memory stem cells correlate with better outcomes, 2) patients with worse outcomes had cells that expressed PD-1, and 3) AGS-004 can affect latent reservoirs of virus, a key step in virus eradication. In our view, these data are supportive of the Arcelis platform and suggest potential for synergistic combinations with PD-1/PDL-1 inhibitors in HIV and oncology. We look forward to data confirming these observations when the placebo controlled study of AGS-004 reads out in 2Q14. Our \$17 price target is based on an NPV sum-of the-parts analysis including future revenue for AGS-003 in mRCC (~\$14) and early stage RCC (~\$3). We do not include AGS-004 in our valuation as the path forward is not defined; however, we believe these data support potential for disease eradication.

**New immunological data from chronic HIV patients**. Argos presented immunological data from a subset of patients in its Phase 2a study of AGS-004 in patients chronically infected with HIV (Figure 1). In about 70% of patients, CD28+CD45RA+CD27+ cells were induced after AGS-004 treatment. These cells have been recently characterized as memory stem cells (Tscm cells) - cells that survive much longer than normal memory cells.

Tscm cell increases correlate to time to viral rebound. To understand the role of Tscm cells, patients were grouped by time to rebound into "late" and "early" rebounders. The four patients in the "late" group were those patients with the greatest increase in Tscm cells from baseline (Figure 2). In our view, these data are supportive of a clear mechanism of action, suggesting that outcomes are directly related to AGS therapy.

**Anti-PD-1/PDL-1 synergies possible**. Patient cells were also looked at for PD-1 expression, and although the correlation is not perfect, it appears that increases in PD-1 expression led to shorter time of treatment interruption (Figure 3). In our view, this suggests that AGS products can be synergistic with PD-1 inhibitors in HIV as well as oncology.

**Acute study sets stage for future studies**. Argos presented data from a small study (n=6) in acute patients who had been infected with HIV for 45 days or less before beginning ART after the fourth AGS-004 dose. These patients were monitored after three doses of AGS-004 and if they demonstrated an increase of memory cells (> 2 fold increase of CD28+CD45RA-CD8+ cells over baseline), they were able to stop ART.

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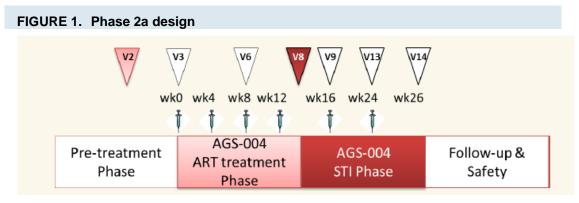
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Takeaways from this study are:

- All patients showed an increase in proliferating, functional memory cells, supporting the mechanism of action of AGS-004.
- One patient of the six had a positive antigenic response to all four antigens and he has been off ART for 268 days, suggesting that breadth of response may be a key factor in controlling the virus long term.
- This patient, as well as two others, demonstrated decreases in the reservoir of 25%, 47% and 63%, demonstrating that AGS-004 can decrease reservoir levels while patients are on ART, suggesting that virus eradication is possible.

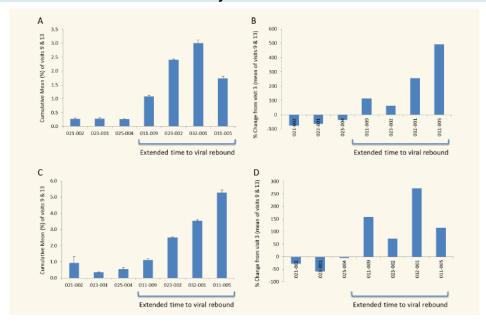
Next steps? In our view, these data help elucidate the mechanism of action of AGS-004; we look to further confirmation when the blinded Phase 2 study reads out this summer. The decrease in reservoir levels suggests that the combination of latency reversion therapy (HDAC inhibitor) with AGS-004 holds some promise for disease eradication; Argos will test this hypothesis this year. The company will also run a pediatric study, driven by the observations for the acute study as both populations have baseline healthy immune systems. This study will likely be an adaptive design that will look for breadth of immune response against all antigens as well as increase in memory cells before taking patients off ART, potentially allowing for disease control long term. As a reminder, we do not include AGS-004 in our valuation at this time and look to data in the coming year to provide clarity on a path forward.



Source: CROI 2014



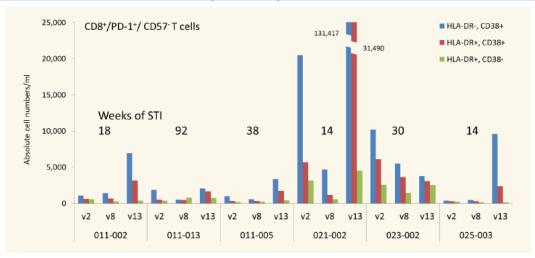
FIGURE 2. Correlation of memory cells to late rebounders



Top: CD4 cells; Bottom CD8 cells

Source: CROI 2014





Source: CROI 2014



## **Company Description**

North Carolina-based Argos Therapeutics is a biopharmaceutical company focused on personalized immunotherapy for cancer and infectious disease. Its products are based in Argos's proprietary Arcelis platform with lead candidate AGS-003 in Phase III development for metastatic renal cell carcinoma in combination with Sutent as first line therapy. Argos is also developing AGS-004 for HIV eradication.

## **Investment Risks**

Clinical. Drug development is inherently risky and Argos's studies may not succeed. Argos is conducting a Phase III study based on a single arm Phase II trial, which carries various risks. It is possible that the study may not be powered properly to demonstrate a benefit of AGS-003. There is also risk that the combination of AGS-003 and Sutent will not outperform Sutent alone due to changes in patient population between Phase II and Phase III. Phase II data may be driven by factors outside of the mechanism of action of AGS-003 and may not translate into Phase III success. Manufacturing of AGS-003 may hinder enrollment rates, pushing out timelines to data. The company is also developing AGS-004 for HIV, an area where there has yet to be a successful vaccine. It is possible AGS-004 will not succeed in allowing patients to discontinue anti-retroviral therapy.

**Regulatory.** AGS-003 pivotal study ADAPT is being conducted under a SPA with FDA; however, this does not guarantee approval. It is not known if the EMA will want more data, either clinical or on manufacturing before allowing Argos to file for EMA approval. For AGS-004, the regulatory path forward and potential commercial market is unclear. The timing of validation of automated manufacturing could lead to a delay in filing the BLA for AGS-003.

**Commercial**. Argos is developing personalized immunotherapies for cancer and infectious disease. The development of these products requires patient sample, either blood or tumor from surgery or biopsy, and patient cells obtained through leukapheresis. This may represent a paradigm shift in treatment and physicians may not be comfortable working these therapies into practice, creating commercial risk. Argos is finalizing automation of its manufacturing process; timing delays add risk to regulatory filing submissions. Unanticipated problems with automation may hinder Argos's ability to produce its therapies.

**Competitive.** Oncology drug development is competitive, with various companies bringing technologies forward that could make Argos's products obsolete. There are other targeted immunotherapies in development that, if successful, could be applied in RCC, adding direct competition to AGS-003.

**Balance sheet.** Following its IPO, Argos has cash to reach pivotal data; however, the company may seek additional equity financing, leading to dilution risk for shareholders. The company may seek debt financing for AGS-003 manufacturing facilities.



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Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

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JMP Securities Research Ratings and Investment Banking Services: (as of March 4, 2014)

							# Co's Receiving IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	245	56.32%	Buy	245	56.32%	95	38.78%
MARKET PERFORM MARKET UNDERPERFORM	Hold Sell	139 8	31.95% 1.84%	Hold Sell	139 8	31.95% 1.84%	18 0	12.95% 0%
COVERAGE IN TRANSITION	2011	43	9.89%		43	9.89%	0	0%
TOTAL:		435	100%		435	100%	113	25.98%

#### Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar guarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



#### **Argos Therapeutics, Inc. (ARGS)**



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