Argos Therapeutics, Inc. (ARGS)

Primary Endpoint of Phase IIb AGS-004 in HIV Not Met, Minimal Read-Through to AGS-003

MARKET DATA

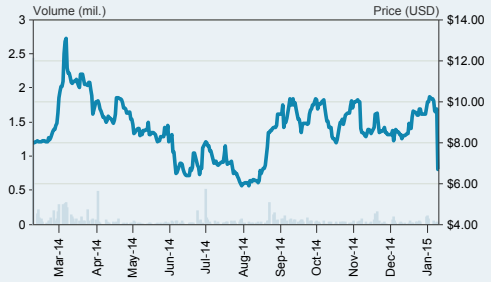
Price	$6.51
52-Week Range:	$5.61 - $13.74
Shares Out. (M):	19.0
Market Cap ($M):	$123.7
Average Daily Vol. (000):	21.0
Cash (M):	$83
LT Debt (M):	$9

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014E	2015E	2016E
Revenue ($M)	1Q	$0.8A	--	--
	2Q	$0.5A	--	--
	3Q	$0.4A	--	--
	4Q	$0.3	--	--
	FY	**$1.5**	**$0.2**	**$0.0**
EPS	1Q	($1.05)A	--	--
	2Q	($0.61)A	--	--
	3Q	($0.77)A	--	--
	4Q	($0.64)	--	--
	FY	**($2.92)**	**($1.76)**	**($1.72)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



MARKET OUTPERFORM | Price: $6.51 | Target Price: $17.00

INVESTMENT HIGHLIGHTS

Although Argos Therapeutics' AGS-004 did not meet its primary endpoint in HIV-1 patients, we reiterate our Market Outperform rating and $17 price target, based on a SOTP (of AGS-003 in mRCC and early stage RCC) NPV analysis on our perspective of a minimal read-through to AGS-003. On Friday, Argos announced that treatment of chronically infected HIV patients with its personalized dendritic cell vaccine, AGS-004, failed to achieve the primary endpoint of a 1.1 log decline in median viral load (VL) after 12 weeks of treatment interruption of antiretroviral therapy (ATI) in the active cohort versus the placebo. We believe this setback to AGS-004 represents minimal impact to the overall ARGS opportunity, as the main driver of value extends from the development of ARG-003 in renal cell carcinoma.

Failure to show efficacy. Of the 54 patients that enrolled in the Phase IIb study, 36 patients completed the trial. Refer to Figure 3 for a description of the study design. After four months, ART was interrupted in order to measure viral load at 12 weeks. Despite being unable to demonstrate efficacy in HIV-1 patients in this setting, nearly 70% of patients that received AGS-004 (versus 0% of placebo patients) showed a positive antiviral memory T cell response at week 8, which investigators attribute to AGS-004 treatment (Figure 1). This immune response in the treatment arm increased at week 18 (85%) and week 26 (91%). Surprisingly, at weeks 18 and 26, the placebo arm also showed a detectable immune response (27% and 50%, respectively), which investigators believe coincided with a viral rebound during the ATI. More importantly, investigators highlighted their observations regarding the latent reservoir (cells that contain chromosomally integrated HIV DNA), wherein a statistically significant effect was revealed when comparing immune responders to non-responders in the AGS-004 treatment group (Figure 2). In our view, the effects seen in this sub-group after as few as two doses, where CD4+ T cell copy number are significantly reduced in the immune responders, still shows some promise for this therapy. If induced memory T cell responses directly impact the latent reservoir as the data suggests, it is possible that a combination of AGS-004 and concurrent ATI may increase the effect on the latent HIV reservoir. Taken together, management views the results to the T-cell responses as relevant to the ongoing adult HIV study, as well as the planned pediatric HIV study. In addition, the company is moving forward in conjunction with its investigators to examine the combination of AGS-004, ATI, and the HDAC inhibitior, vorinostat (Zolinza), in the expectation that this combination may have the desired effect on the latent viral reservoir. Overall, we remain cautiously optimistic of the potential of AGS-004 in HIV-1, but see no read-through to the oncology side of the company's Arcelis platform.

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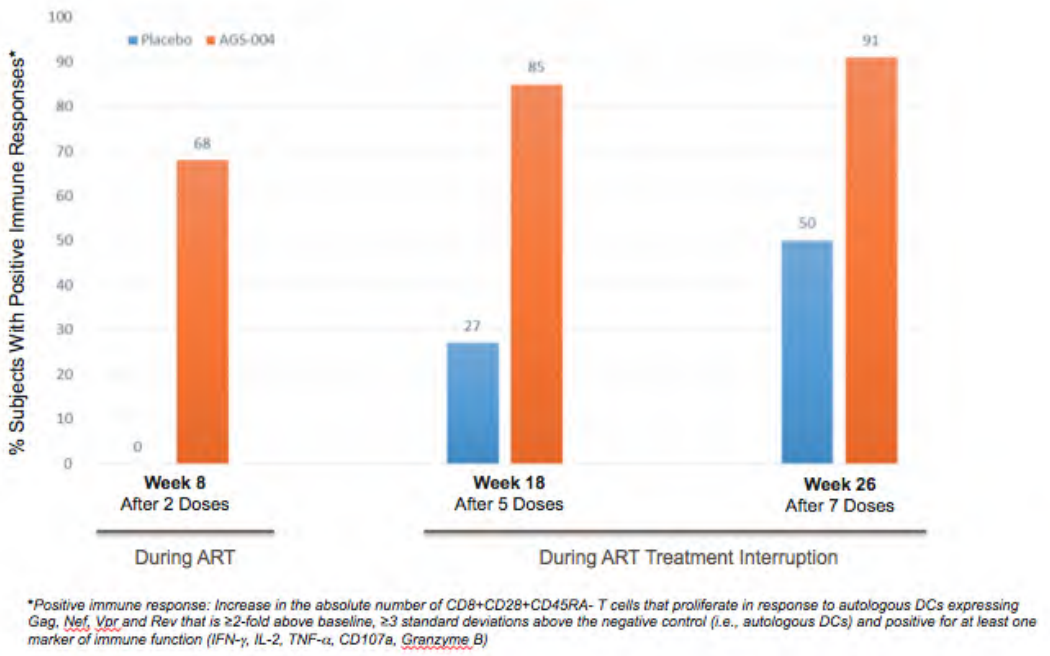
AGS-003 remains the key value driver. Recall that the ongoing ADAPT Phase III trial is a randomized, multi-center, open-label clinical trial, designed to evaluate AGS-003 in combination with standard targeted therapy (AGS-003 with sunitinib, or another TKI if sunitinib is not tolerated) in newly diagnosed, unfavorable metastatic renal cell carcinoma (MRCC) patients versus a control arm of standard alone. Enrollment of the Phase III ADAPT trial of AGS-003 continues on track to complete accrual in 1Q15, and interim/safety/futility analyses are expected throughout 2015 and 1H16 (first interim look in 2Q15, second interim look in 2H15, third interim look in 1H16, and final data expected in mid-2016). On the call, management disclosed that the trial currently has 300 patients enrolled, with a randomization goal of 450 patients. We remain encouraged by the steady pace of the program and look forward to the first interim data release expected in 2Q15.

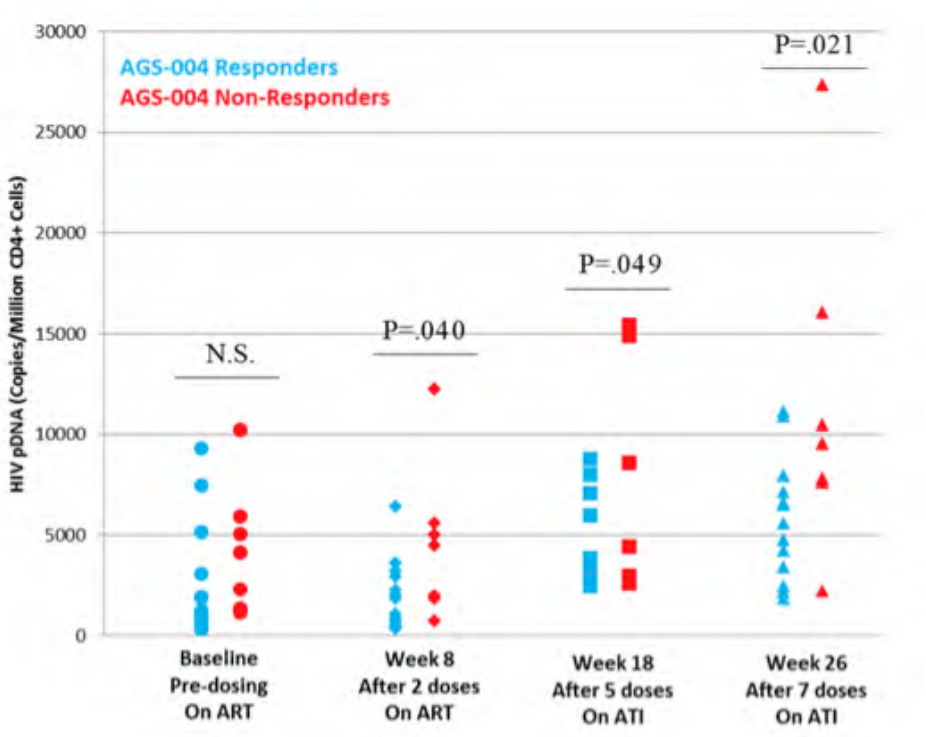
FIGURE 1. Percentage of Patients With Positive Immune Responses Above Baseline



*Positive immune response: Increase in the absolute number of CD8+CD28+CD45RA- T cells that proliferate in response to autologous DCs expressing Gag, Nef, Vpr and Rev that is ≥2-fold above baseline, ≥3 standard deviations above the negative control (i.e., autologous DCs) and positive for at least one marker of immune function (IFN-γ, IL-2, TNF-α, CD107a, Granzyme B)

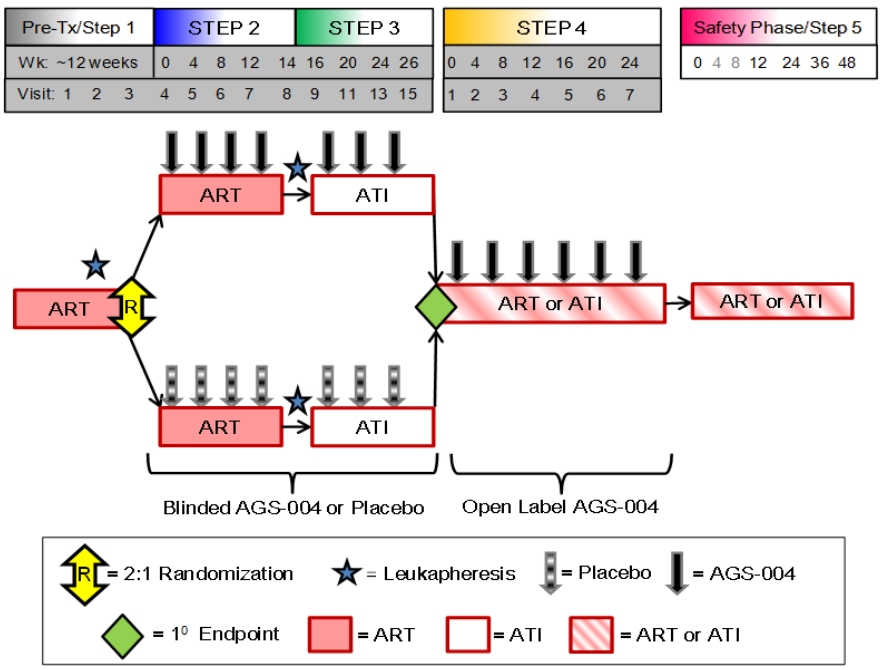
Source: Company Reports

FIGURE 2. CD4+T Cells With Integrated HIV DAN in AGS-004-Treated Subjects



Source: Company Reports

FIGURE 3. AGS-004 Phase IIb Study



Source: Company Reports

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 that carries various risks. It is possible 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 that AGS-004 will not succeed in allowing patients to discontinue anti-retroviral therapy.

Regulatory. The 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 require additional 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' 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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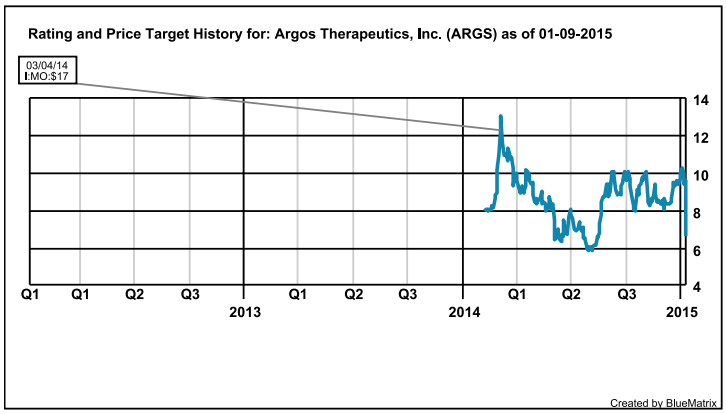
MARKET OUTPERFORM	Buy	294	*65.19%*	Buy	294	*65.19%*	103	*35.03%*
MARKET PERFORM	Hold	151	*33.48%*	Hold	151	*33.48%*	17	*11.26%*
MARKET UNDERPERFORM	Sell	3	*0.67%*	Sell	3	*0.67%*	0	*0%*
COVERAGE IN TRANSITION		1	*0.22%*		1	*0.22%*	0	*0%*
TOTAL:		451	*100%*		451	*100%*	122	*27.05%*

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 quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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