Argos Therapeutics, Inc. (ARGS)

AGS-004 Data Preview

MARKET OUTPERFORM | Price: $6.78 | Target Price: $17.00

MARKET DATA

Price	$6.78
52-Week Range:	$6.21 - $13.74
Shares Out. (M):	19.0
Market Cap ($M):	$128.8
Average Daily Vol. (000):	20.0
Cash (M):	$83
LT Debt (M):	$9

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2013A	2014E	2015E
Revenue ($M)	1Q	$1.3	$0.8A	--
	2Q	$1.5	$0.8	--
	3Q	$1.0	$0.8	--
	4Q	$0.7	$0.3	--
	FY	**$4.4**	**$2.7**	**$0.2**
EPS	1Q	($34.19)	($1.05)A	--
	2Q	($29.91)	($0.57)	--
	3Q	($30.06)	($0.59)	--
	4Q	($36.19)	($0.64)	--
	FY	**($147.37)**	**($2.61)**	**($1.75)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

The first blinded study of an Arcelis product is set to read-out this month; reiterate our Market Outperform rating and $17 price target on Argos Therapeutics. We anticipate data in the coming weeks from AGS-004, a personalized immunotherapy for HIV designed to target a patient's unique antigens and jump-start the immune system independent of CD4 T-cells. The 53 patient trial is the first read-out of a blinded study for Argos's proprietary Arcelis platform and, in our view, a positive correlation of efficacy with therapy driven immune response will read-through to the platform as a whole, including lead asset AGS-003, currently in Phase III development for kidney cancer. We believe the immunological read-out from the study is more relevant than the primary endpoint of the study - change in viral load versus placebo. Therefore, our key expectation for these data is to confirm the previously observed correlation of AGS-004 driven immune response to outcomes, which we believe can increase investor confidence. We also believe these data may identify biomarkers to predict response to therapy, helping to direct future development. Our $17 price target is based on a risk-adjusted, sum-of-the-parts NPV analysis driven by AGS-003.

AGS-004 - personalized immunotherapy for HIV. AGS-004 is based on Argos's Arcelis platform, combining a patient's unique mutated antigens and the ability to activate a patient's immune system in the absence of functioning CD4+ T cells, a target of the HIV virus. AGS-004 is similar to Argos's lead product, AGS-003, for kidney cancer, but it loads dendritic cells with mRNA of HIV antigens isolated from the blood of patients whereas AGS-003 loads antigens from a tumor sample.

Blinded data should provide key proof-of-mechanism for the platform. The Phase IIb study is the first read-out of an Arcelis product in a randomized, controlled setting. In our view, these data should confirm correlation of immunological response to outcomes observed in the Phase IIa trial. We believe the differences in memory cell induction between therapy and placebo should help to understand the true drug effect and increase investor confidence in Argos's technology.

Markers of response may drive program forward. Argos does not anticipate running a Phase III study similar to the Phase IIb trial; our conversations with management suggest strong sentiment against placebo-controlled treatment interruption studies. Therefore, an important factor for the future direction of AGS-004 is the identification of biomarkers of response to treatment that can provide a roadmap as to whether or not a patient can be taken off antiviral therapy. Due to the uncertainty of the steps forward, we do not include AGS-004 in our valuation at this time.

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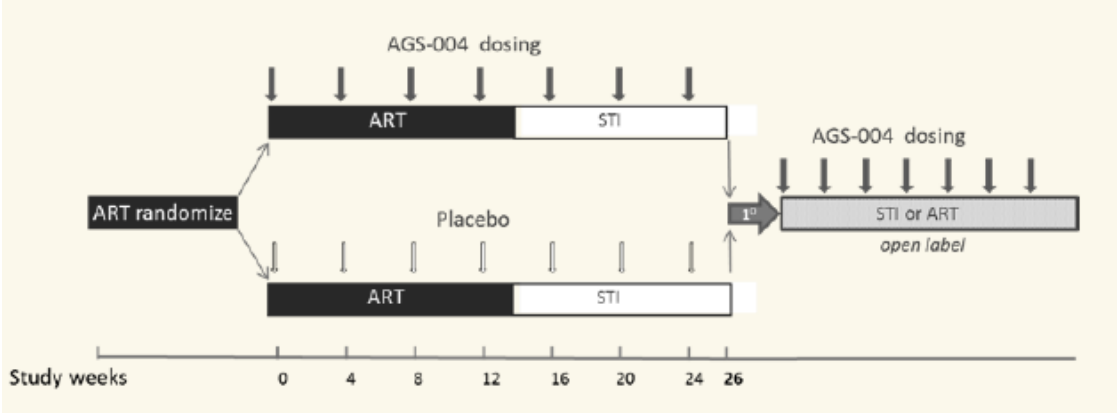
FIRST BLINDED READ-OUT OF THE ARCELIS PLATFORM

Argos is conducting an NIH-funded, placebo-controlled, randomized Phase IIb study of AGS-004 to confirm the AGS-004 Phase IIa results in a blinded setting and collect immunological data to further establish proof of mechanism. Patients are dosed continuously once a month with AGS-004 – four doses on top of background ART and then through 12 weeks after ART treatment interruption (TI). After the 12-week TI, AGS-004 can still be dosed without ART if CD4+ T-cell counts are above 450 cells/mm^3 and viral load is under 10,000 copies, a number considered to be correlative to a low risk of developing AIDS.

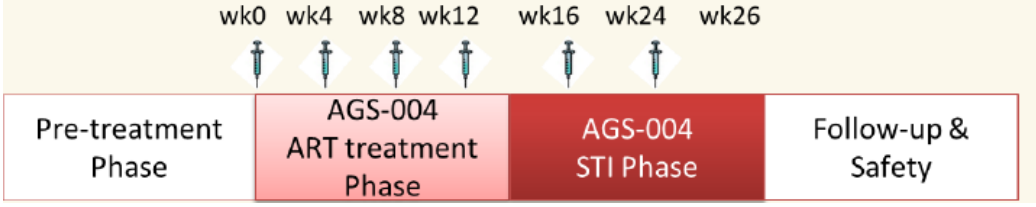
The study is randomized 2:1, with enrollment targeted to 36 patients; however, 53 patients were enrolled to reach 36 that could complete the 12-week treatment interruption period. For safety, patients were put back on ART during the TI period if: 1) they had two tests with viral load above 10,000 copies (tests run two weeks apart), or 2) CD4+ T-cell count decreased by 20% or went below 350 cells/mm^3. The primary endpoint is the difference in viral load between drug-treated and placebo cohorts. However, we believe the more important read-out from the study will be the secondary endpoints, such as correlation of immune response with outcomes as measured by reservoir reduction, time to viral rebound, and extent of viral rebound compared to viral set point (pre-ART). This study design is similar to the single-arm Phase IIa study with the key difference being continuous monthly dosing in the current trial compared to only six doses in the Phase IIa study (Figures 1 and 2).

FIGURE 1. Phase IIb Trial Design



Source: Company reports

FIGURE 2. Phase IIa Trial Design



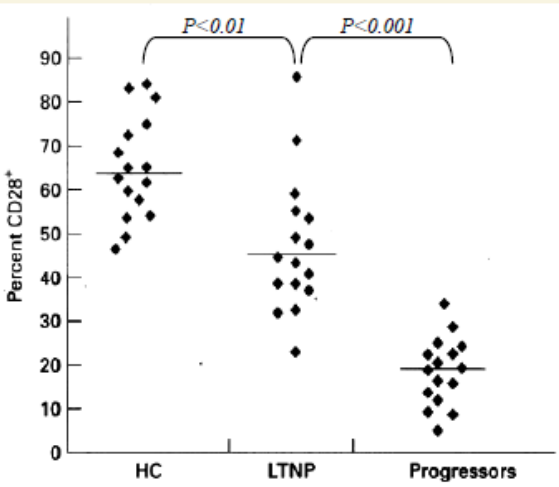
Source: Company reports

Immunological data can support the Arcelis mechanism of action

In our view, the most important read-out from the Phase IIb study will be immunological data. The Arcelis platform is designed to induce antigen specific memory cells; in people infected with HIV, memory cells are associated with patients not progressing in their disease (Figure 3).

In the Phase IIa study, extensive immunological data was not procured for all patients; however, a subset of patient samples were analyzed for the presence of memory T-cells. Consistent with what has been observed for AGS-003 in kidney cancer patients, the greater the change in the number of memory cells from baseline to treatment interruption, the longer time to viral rebound (Figure 4). We look to Phase IIb data to confirm these data in a larger patient population and we believe the comparison to patients on placebo can help fully characterize the effect of therapy. In our view, this is the most important data for the study and if a positive correlation is observed, we believe this can add value to Argos shares.

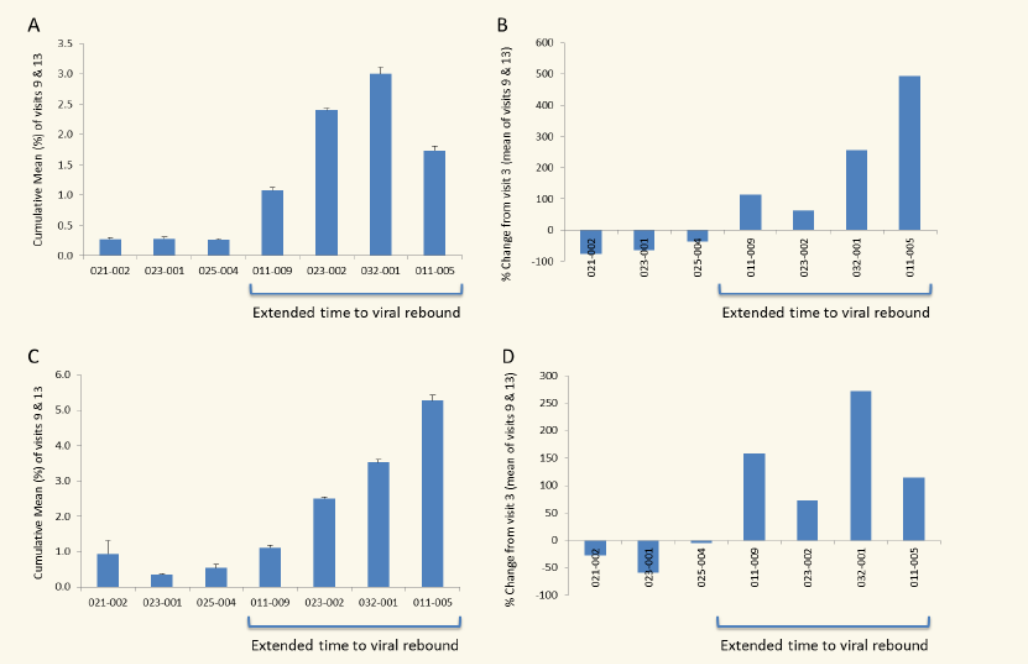
FIGURE 3. Memory Cells are Higher in Non-Progressors



HC = healthy controls; LTNP = long-term non-progressors

Source: Clin Exp Immunol, 1996; 105: 220-224

FIGURE 4. Numbers and Change in Memory Cells Correlates with Time to Rebound



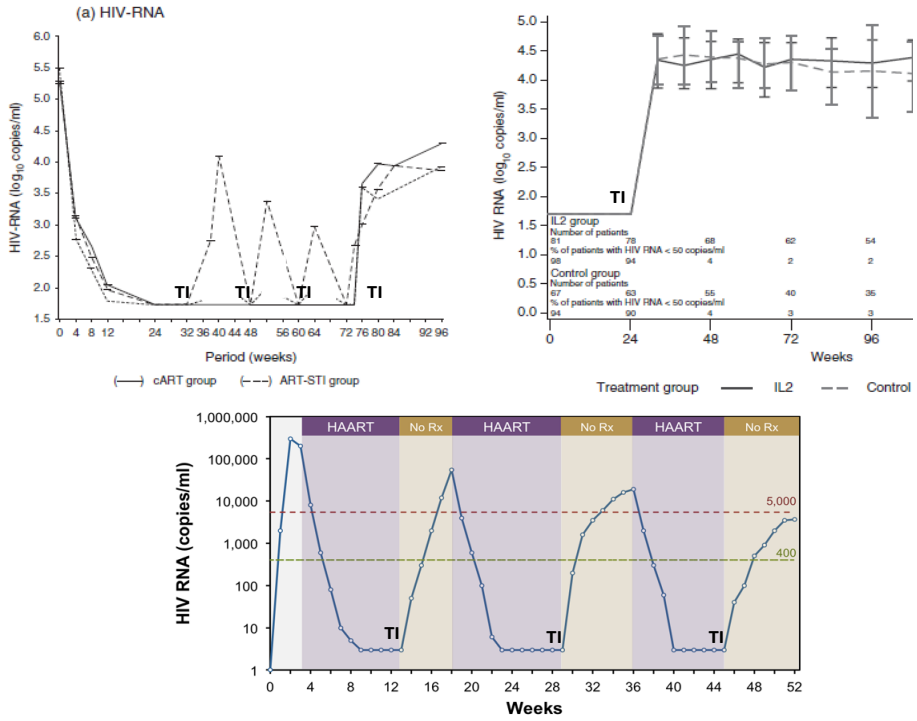
Source: Company reports

Primary endpoint constrained due to study design

The primary endpoint of the study is to compare viral load levels at the end of 12 weeks of treatment interruption between AGS-004 and placebo; success is defined as ≥1.1 log lower viral load in treated patients versus placebo. Only patients who successfully completed the 12 weeks of TI are eligible for the primary endpoint analysis, as a reminder, one of the stopping criteria for treatment interruption is viral load of 4.0 logs (10,000 copies/mL) at two time points, two weeks apart. We remind investors that 17 of the 53 patients in the study, or one-third of patients, were unable to complete treatment interruption. If the large majority of these patients are placebo treated, this will translate as a win for AGS-004 on the primary endpoint.

What are expectations for the placebo group? Our analysis of the literature suggests that most chronic HIV patients will return to their set point (viral load prior to HIV therapy) between 4-8 weeks after ART is interrupted (Figure 5). Most chronic HIV patients have a set point above 10,000 copies; implying that most placebo patients should not be eligible to complete 12 weeks of TI. However, patients with better than expected immune responses may make it to the end of 12 weeks with no therapy, and in our view, the trial design selects for these above-average responders. This may, in turn, narrow the potential delta between the placebo and AGS-004, making it difficult for the study to hit its primary endpoint. Considering these factors, we believe the primary endpoint is driven by the stopping criteria more than the drug effect of AGS-004 and, in our view, the immunological data is more of a true read-out of efficacy than the primary endpoint.

FIGURE 5. Examples of Viral Load Rebound After Treatment Interruption (TI)



TI = treatment interruption

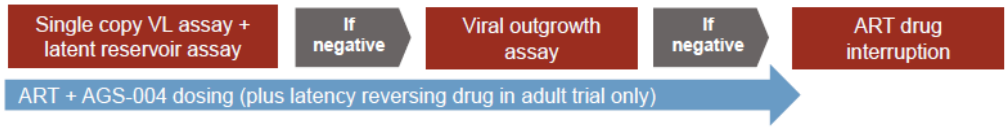
Source: AIDS 2012

Phase IIb data could provide a path forward

Even if the data read-out positive, we do not expect Argos to run a similarly designed Phase III study as there is a push to not put patients at risk in a placebo-controlled study. Advances in technology, such as detecting single copies of virus or the ability to measure latent reservoirs of HIV virus in organs such as the brain or bone marrow (not depleted with ART therapy), have led Argos and collaborators to initiate two studies this year based on adaptive trial design.

A Phase II study currently enrolling adults with chronic HIV aims to look at a latency reversing drug, vorinostat (releasing virus from DNA reservoirs) in combination with AGS-004 (Figure 6). The first phase of the study will investigate kinetics of immune response to AGS-004 in patients on ART, to determine how to best combine AGS-004 with vorinostat and stage two of the study will look at using these drugs in combination (Figure 6).

FIGURE 6. Phase II Design



Source: Company reports

A second study to begin this year will focus on pediatric patients who have been on ART since birth or shortly thereafter and have very few latent reservoirs of virus. The immune system of these patients has never been exposed to the virus; therefore, AGS-004 will be a surrogate immune system that can deplete the small amounts of virus that are present in an attempt to turn these patients into elite controllers. There is likely no infectious plasma archived for these patients to extract RNA; thus, Argos can grow the virus ex vivo from reservoir samples to make product.

Data from the Phase IIb trial can help guide these studies by determining immunological markers to predict response. If this is accomplished, it opens up a pathway to a registration study. At this point, before seeing the data, we do not know if this is feasible; therefore, we exclude AGS-004 from our valuation at this time.

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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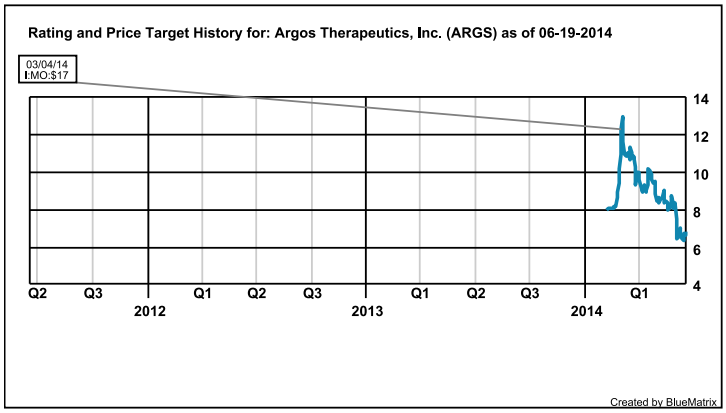
MARKET OUTPERFORM	Buy	265	*59.28%*	Buy	265	*59.28%*	100	*37.74%*
MARKET PERFORM	Hold	138	*30.87%*	Hold	138	*30.87%*	19	*13.77%*
MARKET UNDERPERFORM	Sell	4	*0.89%*	Sell	4	*0.89%*	0	*0%*
COVERAGE IN TRANSITION		40	*8.95%*		40	*8.95%*	0	*0%*
TOTAL:		447	*100%*		447	*100%*	119	*26.62%*

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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