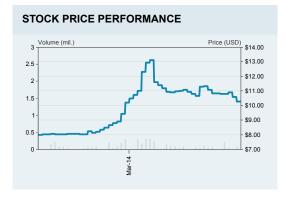


# **Argos Therapeutics, Inc.** (ARGS)

Argos on Track in 2014

MARKET DATA	
Price	\$10.26
52-Week Range:	\$7.97 - \$13.74
Shares Out. (M):	19.0
Market Cap (\$M):	\$194.9
Average Daily Vol. (000):	61.0
Cash (M):	\$47
LT Debt (M):	\$9
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	\$1.3	\$1.2	
	2Q	\$1.5	\$1.0	
	3Q	\$1.0	\$0.8	
	4Q	\$0.7	\$0.3	
	FY	\$4.4	\$3.3	\$0.2
EPS	1Q	(\$34.19)	(\$0.50)	
	2Q	(\$29.91)	(\$0.55)	
	3Q	(\$30.06)	(\$0.57)	
	4Q	(\$36.19)	(\$0.62)	
	FY	(\$147.37)	(\$2.25)	(\$1.63)
	P/E	NM	NM	NM
Previou	s FY	(\$17.36)	(\$2.19)	(\$1.50)
Source: Company reports and JMP Securities LLC				



MARKET OUTPERFORM | Price: \$10.26 | Target Price: \$17.00

## **INVESTMENT HIGHLIGHTS**

Argos reported FY13 with all systems go for two clinical programs; we reiterate our Market Outperform rating and \$17 price target. Argos reported earnings yesterday and provided updates on two programs stemming from its proprietary targeted immunotherapy Arcelis platform. AGS-003, in Phase III development for renal cell carcinoma (RCC), is on track to complete enrollment this year with a patient population in line with our expectations. The Phase IIb study for AGS-004 in HIV patients has completed enrollment and should read out this summer with data that, in our view, should provide proof of mechanism for the platform. Argos has about \$91M in cash proforma after its recent IPO which we believe can see it through pivotal data for AGS-003. In our view, AGS-004 data and readout from various Phase 2 single arm studies for AGS-003 will build value for Argos ahead of Phase III data. Our \$17 price target is based on a risk-adjusted sum-of-the-parts NPV analysis assigning about ~\$14 to AGS-003 in metastatic RCC (mRCC) and ~\$3 in early stage RCC. At this time we see AGS-004 as upside, pending clarity on a regulatory path forward.

**Enrollment on track for AGS-003**. Argos has enrolled about one-third of its pivotal study for mRCC with about 120 sites open. Screening failures are in the range of 40-50% due to patients with non-clear cell mRCC, co-morbidities or poor (over four risk factors) prognosis. About three-quarters of patients are intermediate risk (one or two risk factors), which our analysis suggests should lead to survival in the control arm of about 15-20 months. Management believes enrollment should complete this year with event driven interim analyses (at 25%, 50%, and 75% of events) expected in 2015. As a reminder, each interim analysis will assess if AGS-003 can provide at least a four-month improvement in overall survival; therefore, we see each analysis as incrementally derisking with upside if the study is stopped early for efficacy.

AGS-004 data provides platform proof of mechanism. This summer, we anticipate data from a Phase IIb placebo controlled study of AGS-004 in chronic HIV patients. We see these data as an important value driver for Argos as additional proof of mechanism for the Arcelis platform, as AGS-004 and AGS-003 are derived from the same process. The data expected this summer are from a 53-patient trial looking at viral load reduction in HIV patients after discontinuing anti-retroviral therapy (ART) for 12 weeks. We believe that if patients with very few CD4+ T cells can launch an attack against the HIV virus due to AGS-004, it is supportive of the effect of AGS-003 where patients with tumor immunosuppression can launch an attack against a tumor. Minimally, we would expect successful ART interruption for 12 weeks to correlate with the number of new memory cells targeting the virus. As a reminder, this program is funded by the NIH with no cost to investors.

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**FY13 earnings in line**. Argos reported FY13 loss per share of \$147.37, different from our estimate due to shares outstanding. We anticipate R&D spend to increase this year as Argos initiates trials in early stage RCC, non-clear cell mRCC, and other solid tumors. In our view, these single arm studies can derisk the AGS-003 pivotal study with data confirming proof of mechanism of the Arcelis platform.



## **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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The research analyst(s) who prepared this report does/do hereby certify that the views presented in this report are in accordance with my/our personal views on the securities and issuers discussed in this report. As mandated by SEC Regulation AC no part of my/our compensation was, is or will be directly or indirectly related to the specific views or recommendations expressed herein. This certification is made under the obligations set forth in SEC Regulation AC. Any other person or entity may not use it for any other purpose. This certification is made based on my/our analysis on the date of this report's publication. I/We assume no obligation to update this certification to reflect any facts, circumstances or events that may subsequently come to my/our attention. Signed Heather Behanna and Michael G. King

#### JMP Securities Disclosures:

JMP Securities was manager or co-manager of a public offering, and received compensation for doing so, for Argos Therapeutics, Inc. in the past 12 months.

### **JMP Securities Investment Opinion Definitions:**

Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

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

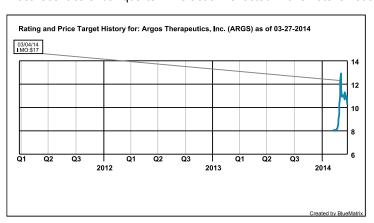
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of March 27, 2014)

		# 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 MARKET PERFORM	Buy Hold	248 137	57.01% 31.49%	Buy Hold	248 137	57.01% 31.49%	99 15	39.92% 10.95%
MARKET UNDERPERFORM COVERAGE IN TRANSITION	Sell	7 43	1.61% 9.89%	Sell	7 43	1.61% 9.89%	0	0% 0%
TOTAL:		435	100%		435	100%	114	26.21%

#### **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.



March 28, 2014

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



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