Argos Therapeutics, Inc. (ARGS)

Reports 2Q14 Results and Highlights Clinical Development

MARKET OUTPERFORM | Price: $6.11 | Target Price: $17.00

MARKET DATA

Price	$6.11
52-Week Range:	$5.61 - $13.74
Shares Out. (M):	19.0
Market Cap ($M):	$116.1
Average Daily Vol. (000):	10.0
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	$0.4A	--
	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)	($0.61)A	--
	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

Argos Therapeutics (ARGS) reported 2Q14 earnings results, and provided details on the clinical development of AGS003 in renal cancer and AGS004 in HIV, as well as a newly disclosed novel autoimmune target; we reiterate our Market Outperform rating and $17 price target, based on a SOTP NPV analysis. ARGS reported a 2Q14 net loss of $12 million or earnings of ($0.61) per share, somewhat greater than JMP estimates of $11.2 million or ($0.57), primarily due to higher than expected operating costs ($12.43 million versus JMP estimate of $10.7 million). The company finished the quarter with $71.8 million in cash and cash equivalents, which should provide sufficient runway to continue operations to mid-2016. Management guided that it will most likely seek out non-dilutive sources of funding to cover major expenditures in manufacturing. Current R&D expenses for this quarter are $10.6 million, and S&G expenses are $1.9 million.

Phase II successes drive on-track enrollment in the Phase III trial of AGS-003. Encouraging results from the long-term survival data of 11 intermediate metastatic renal cell carcinoma patients treated with AGS-003 and sunitinib had a median overall survival of 57.1 months compared to expectations of sunitinib alone of 20.5 months. Twenty-three percent of patients had survival of greater than five years. Enrollment in the Phase III trial to treat patients with synchronous, metastatic, clear cell RCC is currently at 190 patients out of an expected 450. Exclusion rates have been high, with nearly 50% of tumor samples not advancing into the trial. Inclusion criteria include patients who are good candidates for surgery and standard targeted therapy (initiating with, but not limited to, sunitinib), KPS ≥ 70%, life expectancy of at least six months, no serious comorbidities, and adequate end organ function. Primary outcomes will include overall survival from the start of the trial until 42 months or 290 deaths have accrued. The company expects enrollment to reach 450 patients in 1Q15, with results anticipated in 2016. Phase II trials in early stage RCC, non-clear metastatic RCC, and other tumors are planned in 4Q14.

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Clinical read-outs expected to predict AGS-004 impact on viral immunity. Management highlighted the progress made in AGS-004 development, and the additional sub-analysis of its Phase IIb trial in 53 patients with chronic HIV infection. Data was presented in a poster by Dr. Irina Tcherepanova at the International AIDS Society (IAS) Towards a Cure Symposium. The vaccine exerted direct immune control, resulting in selective pressure on viral diversity, and initial patient viral diversity strongly correlated with viral load control. In upcoming weeks, management expects to release data and analysis from this trial, which will include viral load levels, immune and inflammation responses, and blood cell dynamics. Continued clinical development of AGS-004 included the initiation of the first stage of a Phase II trial in May 2014 in the eradication of HIV in combination with the latency reversing drug vorinostat, and the initiation of a Phase II clinical trial for the elimination of antiretroviral therapy in pediatric patients in 2H14. We believe the results from the Phase IIb trial, if positive, will be a strong validation of the Arcelis platform, not only in HIV treatment, but also as a modulator of immunity, and further bolster our opinion of its utility in oncologic indications.

Novel autoimmune target disclosed - recombinant CD83. CD83 is a cell surface ectoenzyme catalyzing the conversion of NAD into calcium mobilizing metabolites NAADP and cADPR. It has been implicated in the regulation of dendritic and T-cell responses, and knockout mice have accelerated development of lupus-like symptoms. On the call, ARGS conveyed that it had discovered potent long-lasting immunomodulation that does not cause generalized immune suppression. The therapeutic potential of recombinant CD38 is intriguing in autoimmune and inflammatory disease, as well as transplant rejection. We eagerly await publication of preclinical results.

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.

JMP FACTS AND DISCLOSURES

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

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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.
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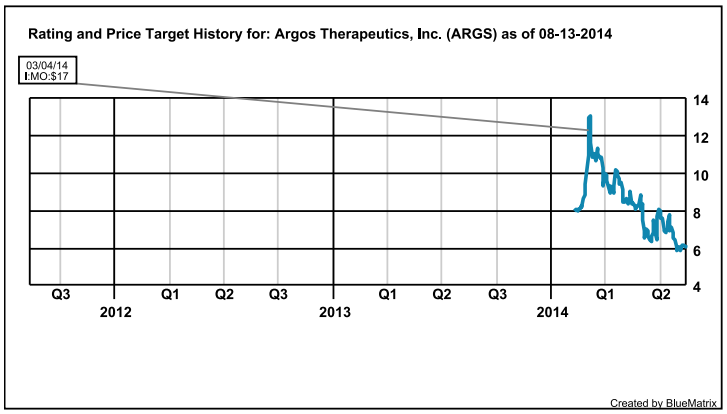
JMP Securities Research Ratings and Investment Banking Services: (as of August 14, 2014)

JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	267	*60.00%*	Buy	267	*60.00%*	97	*36.33%*
MARKET PERFORM	Hold	138	*31.01%*	Hold	138	*31.01%*	18	*13.04%*
MARKET UNDERPERFORM	Sell	4	*0.90%*	Sell	4	*0.90%*	0	*0%*
COVERAGE IN TRANSITION		36	*8.09%*		36	*8.09%*	0	*0%*
TOTAL:		445	*100%*		445	*100%*	115	*25.84%*

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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