

Argos Therapeutics, Inc. (ARGS)

Reports 3Q14 Earnings

MARKET DATA

Price	\$9.45
52-Week Range:	\$5.61 - \$13.74
Shares Out. (M):	19.0
Market Cap (\$M):	\$179.6
Average Daily Vol. (000):	187.0
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)
Previous FY	(\$2.61)	(\$1.75)	NC

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



MARKET OUTPERFORM | Price: \$9.45 | Target Price: \$17.00

INVESTMENT HIGHLIGHTS

Argos Therapeutics reported 3Q14 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. We remind investors that as an early discovery and clinical stage company, ARGS share performance is primarily derived through the progression of its pipeline assets against developmental milestones, and not necessarily through financial results. ARGS reported a 3Q14 net loss of \$15.1MM or earnings of (\$0.77) per share, greater than JMP estimates of \$11.6MM or (\$0.59) primarily due to higher than expected R&D expense (\$13MM versus JMP's estimate of \$10MM). ARGS provided guidance that anticipates contract revenues and the recent venture loan, in conjunction with \$69.5MM in cash and cash equivalents, will provide a sufficient runway to continue operations to mid-2016.

Phase II successes helping to drive enrollment in the Phase III trial of AGS-003 in synchronous, metastatic, clear cell RCC. Enrollment in the Phase III trial continues on track with 60% enrollment of 260 patients (190 patients reported at the 2Q14 update) out of an expected total of 450. Screen failures have been higher than expected, with nearly 50% of patients not advancing into the trial based on their tumor histology. Inclusion criteria include patients who are suitable candidates for surgery and standard targeted therapy (initiating with, but not limited to, sunitinib), KPS \geq 70%, life expectancy of at least six months, with 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 during 1Q15 with results in 2016. Interim safety and futility analyses at 25%, 50% and 75% of events are expected throughout 2015. Phase II trials in early stage RCC, non-clear metastatic RCC and other tumors are planned in early 2015.

Clinical read-outs expected to predict the impact of AGS-004 on HIV viral immunity; Management also 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 were presented in a poster by Dr. Irina Tcherepanova at the International AIDS Society (IAS) Towards a Cure Symposium in July. The vaccine exerted direct immune control resulting in selective pressure on viral diversity, and initial patient viral diversity strongly correlated with viral load control. We believe 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. The company plans to initiate Stage 2 of the HIV eradication trials through the introduction of a latency reversing drug, by early 2015, in addition to investigator initiated trials for the elimination of antiretroviral therapy in pediatric patients.

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FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO JMP FACTS AND DISCLOSURES SECTION.

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. The company detailed that it has enough evidence to understand the mechanism of activity to begin scaling up manufacturing. We eagerly await publication of ARGS pre-clinical results.

Financial prospects secure with venture loan. In September, the company closed a \$25MM venture loan with Horizon Technology Finance Corporation. The proceeds of this non-dilutive funding will support continued clinical development and the construction of a 1,000,000 sq. ft. bio-manufacturing facility. This facility, which began construction in October 2014, will support the manufacturing of Arcelis platform therapies including AGS003.

FIGURE 1. Estimates and Changes to Our Model

ARGS	F3Q14		F4Q14 est		FY14 est		FY15 est	
	JMP est	Actual	JMP old	JMP New	JMP old	JMP New	JMP old	JMP New
Total revenue	0.8	0.4	0.3	0.3	24.2	1.5	0.2	0.2
R&D	10.0	13.0	10.5	10.5	76.8	42.5	40.0	40.0
SG&A	2.0	2.3	2.0	2.0	14.1	8.1	7.9	8.2
Total operating expense	12.0	15.3	12.5	12.5	90.8	50.7	47.7	48.2
Net income (loss)	(11.6)	(15.1)	(12.6)	(12.6)	(66.5)	(50.7)	(41.7)	(42.0)
Shares outstanding (diluted)	19.7	19.7	19.8	19.7	29.6	17.3	23.9	23.8
GAAP EPS (diluted)	(\$0.59)	(\$0.77)	(\$0.64)	(\$0.64)	(\$2.25)	(\$2.92)	(\$1.75)	(\$1.76)

Source: JMP Securities LLC and Company Reports

FIGURE 2. Income Statement

Argos Income Statement

	FY012A	FY013A	Mar-14A	Jun-14A	Sep-14A	Dec-14E	FY014E	FY015E	FY016E	FY017E	FY018E	FY019E	FY20E	FY21E	FY22E	FY23E	FY24E
Revenues:																	
Total product revenue	0	0	0	0	0	0	0	0	0	8,538	28,610	111,577	208,348	310,413	451,212	588,010	633,557
Total revenue	7,039	4,422	799	473	399	300	1,497	200	0	8,538	28,610	111,577	208,348	310,413	451,212	588,010	633,557
Operating expenses:																	
COGS	0	-	-	0	0	-	-	-	-	6,233	13,733	31,242	37,503	55,874	81,218	105,842	114,040
R&D	17,617	23,991	8472	10569	12998	10500	42,540	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000	40,000
G&A	6,136	4,662	1933	1866	2320	2000	8,119	8,201	12,000	18,000	25,000	31,250	39,063	48,828	61,035	76,294	95,367
Total operating expenses	23,752	28,653	10406	12,435	15,318	12,500	50,659	48,201	52,000	64,238	78,735	102,492	116,566	144,703	182,254	222,136	249,408
Loss from operations	(16,713)	(24,232)	(9,607)	(11,962)	(14,920)	(12,200)	(49,162)	(48,001)	(52,000)	(55,700)	(50,125)	9,085	91,783	165,710	268,958	365,874	384,149
Other income (expense):																	
Interest income	6242	13	5	9	14	9	29	6334	83	92	56	38	63	3	5	9	14
Interest expense	0	13	(399)		(180)	(399)	(1596)	(270)	(270)	(270)	(270)	0	0	0	0	0	0
Other, net	0	(9953)	(863)	0	(16)												
Total other income (expense)	6242	310	(1257)	(22)	(181)	(390)	(1567)	6064	(187)	(178)	(214)	38	63	3	5	9	14
Pretax income	(10,471)	(23,922)	(10,864)	(11,984)	(15,101)	(12,590)	(50,729)	(41,936)	(52,187)	(55,878)	(50,339)	9,122	91,846	165,713	268,964	365,883	384,163
Income Taxes	(352)	-	0.06	124			-	-	-	-	-	456	9,185	24,857	67,241	109,765	134,457
Net loss	(10,824)	(23,922)	(10,864)	(11,984)	(15,101)	(12,590)	(50,729)	(41,999)	(52,187)	(55,878)	(50,339)	8,666	82,661	140,856	201,723	256,118	249,706
EPS																	
Basic	(9.10)	(147.37)	(1.05)	(0.61)	(0.77)	(0.64)	(2.92)	(1.76)	(1.72)	(1.81)	(1.61)	0.27	2.56	4.29	6.05	7.57	7.27
Weighted Shares Outstanding																	
Basic	1,190	230	10,377	19,655	19,656	19,706	17,348	23,848	30,348	30,848	31,348	31,848	32,348	32,848	33,348	33,848	34,348

Source: JMP Securities LLC and 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.

JMP FACTS AND DISCLOSURES

Analyst Certification:

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JMP Securities currently makes a market in the security of Argos Therapeutics, Inc.

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.

JMP Securities expects to receive OR intends to seek compensation for investment banking services from Argos Therapeutics, Inc. in the next 3 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.

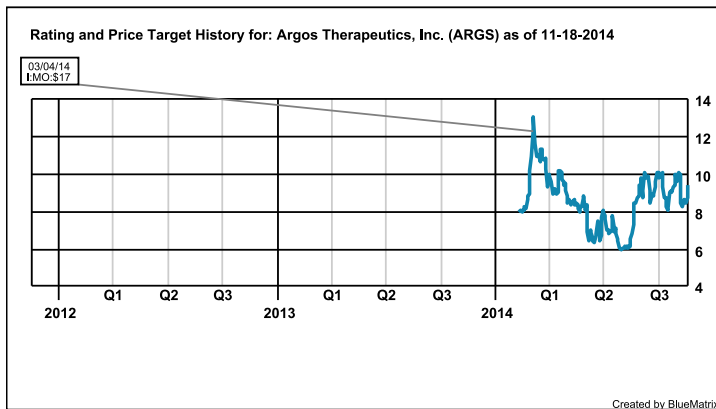
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of November 19, 2014)

JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months				
				Regulatory Equivalent	# Co's Under Coverage	% of Total	% of Co's With This Rating	
MARKET OUTPERFORM	Buy	286	60.98%	Buy	286	60.98%	105	36.71%
MARKET PERFORM	Hold	143	30.49%	Hold	143	30.49%	16	11.19%
MARKET UNDERPERFORM	Sell	2	0.43%	Sell	2	0.43%	0	0%
COVERAGE IN TRANSITION		35	7.46%		35	7.46%	0	0%
TOTAL:		469	100%		469	100%	123	26.23%

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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