Argos Therapeutics, Inc. (ARGS)

Dr. Figlin Weighs in on Future Kidney Cancer Landscape

MARKET OUTPERFORM | Price: $6.98 | Target Price: $17.00

MARKET DATA

Price	$6.98
52-Week Range:	$6.21 - $13.74
Shares Out. (M):	19.0
Market Cap ($M):	$132.6
Average Daily Vol. (000):	22.0
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

Dr. Robert Figlin, a key opinion leader, is excited about the potential for immunotherapy in kidney cancer; reiterate our Market Outperform rating and $17 price target on Argos Therapeutics based on a risk-adjusted, sum-of-the-parts NPV analysis. Dr. Figlin, a thought leader in kidney cancer and lead investigator for Argos's pivotal ADAPT study, provided a 30,000 foot view of the possibilities for immunotherapy in mRCC following the ASCO meeting last week. Our takeaways include: 1) interest is high and enrollment is on track for the ADAPT study; 2) toxicities observed for checkpoint inhibitors are not a factor in early studies but may be harder to manage when used in the community; 3) the sicker population studied by Argos in its pivotal study should lead to approval timelines affording a first-mover advantage; and 4) in Dr. Figlin's view, the future promise of agents such as AGS-003 and checkpoint inhibitors could move hard-to-tolerate TKI therapies to second line. We believe the recent sell-off in Argos shares is unfounded and we recommend purchasing shares ahead of data for AGS-004, a personalized immunotherapy for HIV, due this month. We believe these data will read-through to AGS-003 as first proof-of-mechanism for the Arcelis platform in a blinded study.

ADAPT on track. Argos is currently enrolling ADAPT, the pivotal study for targeted immunotherapy, AGS-003, in mRCC. As of June 1, 450 patients had been screened with 150 randomized and enrolled - one-third of target enrollment, with an additional 100 in the screening process. There has been interest in the study, although roughly half of the patients screened are not enrolled due to histology, co-morbidities, or a life expectancy of less than six months. We anticipate screening will be complete at the end of the year with randomization completed soon after. We are encouraged that 70% of patients enrolled in the study are intermediate risk, in line with our expectations. As a reminder, intermediate-risk patients in the Phase II study survived a median of 57.1 months.

Some combinations should be used with caution. The side effect profile of tyrosine kinase inhibitors (TKIs), first-line therapy for mRCC, makes it difficult to use these agents in combination. This was confirmed with checkpoint (PD-1 inhibitor) + TKI data presented last week at ASCO where renal, liver, and GI toxicities were higher than would have been anticipated for each agent alone. A TKI-free combination of PD-1 inhibitor nivolumab and CTLA4 inhibitor ipilimumab (ipi) demonstrated expected side effects that investigators considered "manageable"; however, Dr. Figlin believes early data represents a best case scenario as centers running these small studies have a lot of experience in managing ipi side effects.

In contrast to the combination therapies, AGS-003 with Sutent does not exacerbate the side effect profile of Sutent, making combination therapy attractive as first line.

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We note that patients on long-term combination therapy with AGS-003 and Sutent have been able to skip cycles of Sutent or dose reduce to mitigate side effects.

ADAPT enrollment suggests on-time results and first-mover advantage. As mentioned above, Argos has seen enrollment of ~70% intermediate-risk patients in its study and 30% poor risk. Analysis of databases of risk-stratified patients on TKI therapy alone suggests that this mix of patients should have a median overall survival of about 15 months, a benchmark for the control arm of ADAPT. In our view, this places ADAPT on track to report data in 1H16 when 200 events have been reported. In contrast, the checkpoint combination data presented at ASCO enrolled patients comprised of mostly favorable and intermediate risk. Our analysis suggests that a control arm for this population would be expected to have at least a 25-month overall survival; therefore we would expect these studies to be of longer duration. Dr. Figlin suggests studies could take 3+ years to read-out. In our view, this suggests AGS-003 should have a significant first-mover advantage; we anticipate a late 2017 launch.

The future is in combination. Dr. Figlin was hopeful for future therapies in mRCC with the potential to replace TKIs as first-line agents. As a reminder, TKIs, such as Sutent, lower tumor immunosuppression, priming the immune system for AGS-003. We believe immunotherapies, such as checkpoint inhibitors, could play a similar role in combination with AGS-003, priming the immune response to allow for generation of tumor specific memory T cells, potentially leading to durable responses to therapy.

Phase 2b data for AGS-004 this month may further validate Arcelis platform. We anticipate data in the coming weeks from an NIH-funded, placebo-controlled, Phase IIb 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. However, AGS-004 uses HIV mRNA in lieu of tumor RNA. 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.

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 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 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' 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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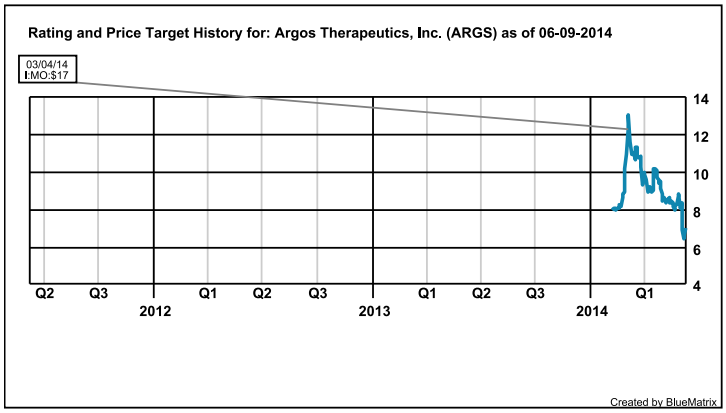
MARKET OUTPERFORM	Buy	257	*58.28%*	Buy	257	*58.28%*	97	*37.74%*
MARKET PERFORM	Hold	137	*31.07%*	Hold	137	*31.07%*	19	*13.87%*
MARKET UNDERPERFORM	Sell	4	*0.91%*	Sell	4	*0.91%*	0	*0%*
COVERAGE IN TRANSITION		43	*9.75%*		43	*9.75%*	0	*0%*
TOTAL:		441	*100%*		441	*100%*	116	*26.30%*

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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