Argos Therapeutics (ARGS) — Overweight

KOL Diligence Puts AGS-003 In Spotlight For mRCC

CONCLUSION

Argos hosted a post-ASCO call to review developments in kidney cancer, including the company's Arcelis platform. As a result of takeaways from this call and our ASCO diligence, we have enhanced conviction on the design, targeted enroll, and potential for the ongoing ADAPT Phase III to read positively and for AGS-003 to play a prominent role in emerging cancer immunotherapy. The call included the co-PI for the company's pivotal ADAPT study in metastatic renal cell carcinoma (mRCC), and it focused to a large extent on the data for checkpoint inhibitor nivolumab that was presented.

- **In broad strokes,** the investigator believes there is a good promise for this class of agents in kidney cancer and other cancers that have not historically been seen as strongly immunogenic, but also pointed to several issues to be wary of, such as safety in combination with TKIs and possibly an inability to identify responders based on biomarkers. That said, he was enthusiastic about the strong enrollment for ADAPT and expects the study to hit its peri-year end '14 targets. We reiterate our Overweight rating and $18 price target on Argos in light of increasing evidence of the potential for an effective immunotherapy-driven paradigm in RCC and anticipated clinical progress with AGS-003.

- **Beyond the "standard" checkpoint inhibitors,** there's Arcelis. While checkpoint inhibitors have been in the spotlight, and vaccines less so due to prior failures, Dr. Figlin appears optimistic about the future of vaccine-type immunotherapeutics for kidney cancer. Regarding the AGS-003 updates from ASCO, he noted that the patient population in Argos' studies is different than the checkpoint-inhibitor studies described below; those studies have generally had healthier/better-prognosis patients. This makes the '003 Phase II PFS and OS data, ~2x better survival vs. historical Sutent data, more impressive, in our view. Dr. Figlin pointed out a historical challenge is that kidney cancer is immunosupressive. Argos believes Arcelis can overcome this, and has shown that memory T-cell induction correlates with responses and survival. We look forward to the ADAPT interims in 2015 and final data 1H16 as we believe the study has been optimally designed and may bring an effective and safe alternative to the TKIs to market.

RISKS TO ACHIEVEMENT OF PRICE TARGET

Failure of AGS-003 in mRCC Phase III or other studies.

COMPANY DESCRIPTION

Argos Therapeutics develops dendritic cell vaccines for oncology and infectious diseases.

PRICE: US$6.98
Note: Price as of the close June 9, 2014.

TARGET: US$18.00
DCF of AGS-003 in metastatic renal cell carcinoma in the U.S. + a technology/pipeline value of ~$5/share

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Changes	Previous	Current
Rating	—	Overweight
Price Tgt	—	US$18.00
FY14E Rev (mil)	—	US$6.8
FY15E Rev (mil)	—	US$0.0
FY14E EPS	—	US$(3.36)
FY15E EPS	—	US$(4.00)

52-Week High / Low	US$13.74 / US$6.21
Shares Out (mil)	19.9
Market Cap. (mil)	US$138.9
Avg Daily Vol (000)	51
Book Value/Share	US$6.93
Net Cash Per Share	US$8.04
Debt to Total Capital	0%
Div (ann)	NA
Fiscal Year End	Dec

Price Performance - 1 Year

Source: Bloomberg

YEAR	REVENUE (US$ m)						EARNINGS PER SHARE (US$)					
	Mar	Jun	Sep	Dec	FY	FY RM	Mar	Jun	Sep	Dec	FY	FY P/E
2013A	—	—	—	0.7	4.4	31.6x	—	—	—	(36.19)	(147.37)	NM
2014E	0.8A	2.0	2.0	2.0	6.8	20.4x	(1.05)A	(0.77)	(0.77)	(0.77)	(3.36)	NM
2015E	—	—	—	—	0.0	NA	—	—	—	—	(4.00)	NM

Dr. Figlin reviewed 3 abstracts for anti-PD-1 antibody nivolumab (BMS) in kidney cancer. Abstract 5009 described a monotherapy nivolumab Phase II study. Key points, in our view, were that the response rate of ~20-22% probably didn't meet most clinicians' expectations (benchmarked by melanoma data) and that there was no dose response between 0.3, 2, and 10mg/kg. Dr. Figlin believes that the ~50 patients per dose-arm is too small to see all but very large dose-dependancies. He believes the safety was very good and response levels promising, supportive of the Phase III vs. everolimus in 2nd-line RCC.

The next abstract, 5010, looked at nivolumab plus TKI (Sutent or Votrient). The study is more complex, with a dose escalation in 2nd-line and expansion in 1st-line patients, and had prior-treatment imbalances between the TKI arms. In any case, the key takeaways were that it didn't seem possible to differentiate responses by PD-L1 expression in the tumor and the high levels of kidney and liver tox increase uncertainty around the ability to combine checkpoint inhibitors with these TKIs. The latter point we think may provide a compelling competitive advantage to vaccine technologies like Arcelis, which has no overlapping toxicity with current agents nor do we expect any with the checkpoint inhibitors.

Finally, on the checkpoint inhibitor front, Dr. Figlin discussed a Phase I of nivolumab plus ipilimumab in mRCC (all comers), abstract 4504. He was interested in the study as it could point to a first effective combination w/o TKIs. Here too, there wasn't an observed difference in response between drug arms nor was a difference based on PD-L1 expression apparent. However, safety and efficacy appears promising. A Phase III in 1st-line mRCC of the combination vs. Sutent will start this year. In general, Dr. Figlin sounded optimistic that immunotherapy holds promise in kidney cancer and he felt that combination studies of vaccine + checkpoint-modulator are likely warranted.

Argos ($ in thousands, except per share amounts)	2011	2012	2013	1Q14	2Q14E	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E
Income Statement																
Revenue																
License and milestone fees, grants	7,643	7,039	4,422	799	2,000	2,000	2,000	6,799	-	-	-	-	-			
% total revenue		*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*na*	*na*	*na*	*na*	*na*	*na*	*0%*	*0%*
Revenues under collaborative agreements	-	-	-	-	-	-	-	-	-	-	-	-	-			
% total revenue		*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*na*	*na*	*na*	*na*	*na*	*na*	*0%*	*0%*
Product sales and royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	-	33,503	109,677
% total revenue		*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*na*	*na*	*na*	*na*	*na*	*na*	*100%*	*100%*
Total Revenues	**7,643**	**7,039**	**4,422**	**799**	**2,000**	**2,000**	**2,000**	**6,799**	**-**	**-**	**-**	**-**	**-**	**-**	**33,503**	**109,677**
Costs & Expenses:																
Cost of product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3,350	10,968
R&D	12,668	17,617	23,991	8,472	6,000	6,000	6,000	26,472	6,090	6,181	6,274	6,368	24,914	27,405	28,775	30,214
SG&A	3,704	6,136	4,662	1,933	4,000	4,000	4,000	13,933	4,060	4,121	4,183	4,245	16,609	17,440	21,799	25,069
Total Operating Expenses	**16,372**	**23,752**	**28,653**	**10,406**	**10,000**	**10,000**	**10,000**	**40,406**	**10,150**	**10,302**	**10,457**	**10,614**	**41,523**	**44,844**	**53,925**	**66,251**
Operating Income (loss)	**(8,729)**	**(16,713)**	**(24,232)**	**(9,607)**	**(8,000)**	**(8,000)**	**(8,000)**	**(33,607)**	**(10,150)**	**(10,302)**	**(10,457)**	**(10,614)**	**(41,523)**	**(44,844)**	**(20,422)**	**43,426**
Investment income	1	5	3	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest expense	(6,656)	(292)	(1)	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expense	(4,756)	6,530	308	(394)	-	-	-	(394)	-	-	-	-	-	-	-	-
Income (loss) before income taxes	**(20,141)**	**(10,471)**	**(23,922)**	**(10,001)**	**(8,000)**	**(8,000)**	**(8,000)**	**(34,001)**	**(10,150)**	**(10,302)**	**(10,457)**	**(10,614)**	**(41,523)**	**(44,844)**	**(20,422)**	**43,426**
Income tax (benefit) provision	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax rate	-	-			*35.0%*	*35.0%*	*35.0%*	*26.3%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*
Net operating loss		0	31,054	34,387	37,054	39,721	42,387	42,387	45,771	49,205	52,690	56,228	56,228	71,176	77,984	63,508
Net operating loss offset			-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	**(20,141)**	**(10,471)**	**(23,922)**	**(10,001)**	**(8,000)**	**(8,000)**	**(8,000)**	**(34,001)**	**(10,150)**	**(10,302)**	**(10,457)**	**(10,614)**	**(41,523)**	**(44,844)**	**(20,422)**	**43,426**
Net loss from non-controlling interest	(63)	-	-													
Net income (loss) available to common stockholders	**(20,078)**	**(10,471)**	**(23,922)**	**(10,001)**	**(8,000)**	**(8,000)**	**(8,000)**	**(34,001)**	**(10,150)**	**(10,302)**	**(10,457)**	**(10,614)**	**(41,523)**	**(44,844)**	**(20,422)**	**43,426**
Add back: accretion of redeemable convertible preferred stock	(927)	(352)	4,773					-								
Less: net income attributable to participating securities	-	-	(14,726)	(863)				(863)								
Net income (loss) to common shareholders	**(21,004)**	**(10,824)**	**(33,875)**	**(10,864)**	**(8,000)**	**(8,000)**	**(8,000)**	**(34,864)**	**(10,150)**	**(10,302)**	**(10,457)**	**(10,614)**	**(41,523)**	**(44,844)**	**(20,422)**	**43,426**
Basic Earnings Per Share	(32.88)	(9.10)	($147.37)	($1.05)	($0.77)	($0.77)	($0.77)	($3.36)	($0.98)	($0.99)	($1.01)	($1.02)	($4.00)	($2.74)	($1.25)	$2.65
Diluted Earnings Per Share	**(32.88)**	**(9.10)**	**($147.37)**	**($1.05)**	**($0.77)**	**($0.77)**	**($0.77)**	**($3.36)**	**($0.98)**	**($0.99)**	**($1.01)**	**($1.02)**	**($4.00)**	**($2.74)**	**($1.25)**	**$2.65**
Basic Shares Outstanding	639	1,190	230	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	10,377	16,377	16,377	16,377
Diluted Shares Outstanding	**639**	**1,190**	**230**	**10,377**	**10,377**	**10,377**	**10,377**	**10,377**	**10,377**	**10,377**	**10,377**	**10,377**	**10,377**	**16,377**	**16,377**	**16,377**

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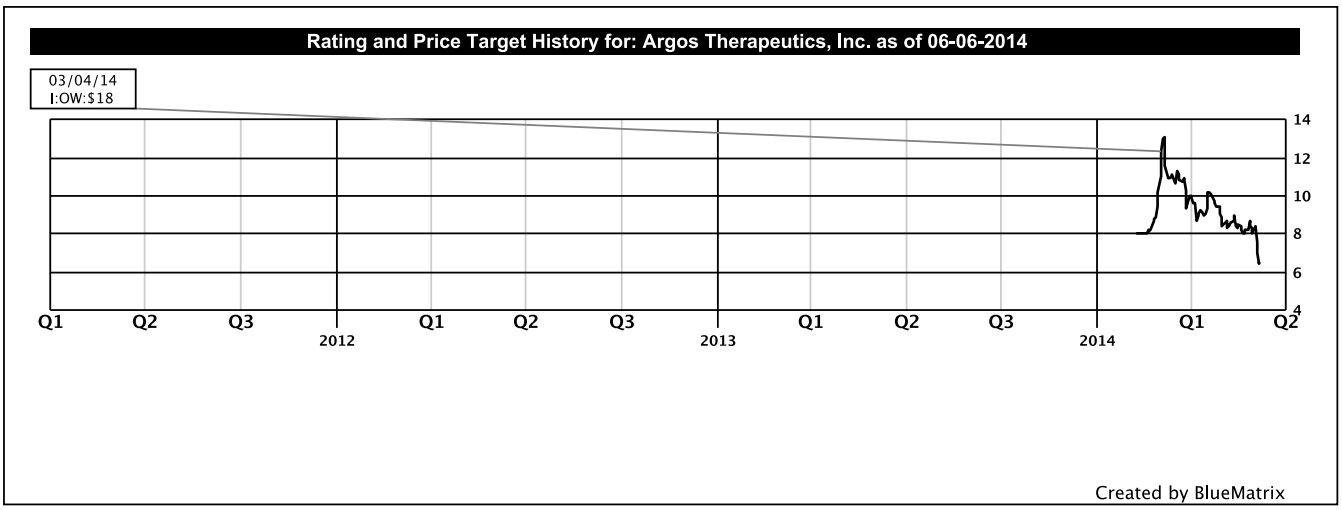

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N: Neutral
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Piper Jaffray

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BUY [OW]	354	61.78	90	25.42
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