



Argos Therapeutics

Second-generation dendritic cell therapy

Encouraging Phase II survival data at ASCO for Argos's lead product AGS-003 in mRCC have failed to move the stock from levels close to its 52-week low and below its IPO price in February 2014. While investors clearly remain cautious of dendritic cell transfer therapies, data expected mid-2014 (Phase IIb for AGS-004 in HIV) and at end 2015 (interim Phase III for AGS-003 in mRCC) could provide upside from the current EV of \$71m.

AGS-003 in mRCC encouraging; fast-track Phase III

Recent Phase II data at ASCO in mRCC with AGS-003 were encouraging, albeit small scale (n = 21). Overall survival (OS) was 30.2 months for AGS-003 + Pfizer's Sutent vs OS in comparator trials of 15.6 months for AGS-003 alone or 14.7 months for first-line treatment with Sutent/other tyrosine kinase inhibitors (International mRCC Database Consortium data). Argos is currently enrolling the 450-patient Phase III ADAPT trial in mRCC and plans to initiate several Phase IIa trials in other solid tumours during 2014.

AGS-004 Phase II data in HIV imminent

Argos's AGS-004 immunotherapy for HIV is in a 53-patient Phase IIb trial, which is fully funded by a \$39.3m NIH contract and reports in mid-2014. If positive, it will allow Argos to initiate two further Phase IIa trials in H214 looking at HIV eradication in adults and long-term viral control in paediatric patients (data due in 2016).

Platform technology with broad applicability

Argos's Arcelis technology consists of injecting a patient's own dendritic cells with RNA from their tumour (or virus) back into them to stimulate an immune response to the disease. Dendritic cells are key to antigen presentation and the goal is to overcome disease-induced immunosuppression and generate immune memory without the toxicity of many oral therapies. Progress with AGS-003 and AGS-004 indicates the platform's potential in oncology and infectious diseases.

Low EV reflects market caution

Argos's EV is only \$71m, including cash of \$83m after the IPO in February 2014. The market appears to be affording little value to the pipeline, perhaps reflecting caution following the unfulfilled promise of Dendreon's Provenge in prostate cancer. Valuation inflection points are likely to be around data publication for AGS-003 (interim Phase III in mRCC end-2015, final data 2016) and AGS-004 in mid-2014.

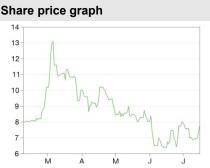
Consensus estimates							
Year end	Revenue (\$m)	PBT (\$m)	EPS (\$)	DPS (\$)	P/E (x)	Yield (%)	
12/12	7.0	(10.5)	(54.6)	0.0	N/A	N/A	
12/13	4.4	(23.9)	(147.4)	0.0	N/A	N/A	
12/14e	4.2	(36.0)	(3.1)	0.0	N/A	N/A	
12/15e	3.2	(41.5)	(3.1)	0.0	N/A	N/A	

Source: Bloomberg

Pharma & biotech

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Business description

Argos Therapeutics, a North Carolina-based biopharmaceutical company, develops 'personalized immunotherapies' using its Arcelis technology based on autologous dendritic cell (DC) transfer. Its product candidates include AGS-003 in Phase III for the treatment of metastatic renal cell carcinoma (mRCC), and AGS-004 in Phase IIb for HIV.

Bull

- mRCC and HIV are significant markets, with current therapies often poorly tolerated.
- Sufficient cash (\$83m) to fund AGS-003 mRCC trials to filing; AGS-004 HIV trials funded by NIH.
- Arcelis technology should offer improvements over previous approaches including only requiring a single isolation of cells from the patient and the ability to load DCs with multiple disease antigens.

Bear

- Use of dendritic cells as immunotherapy is relatively uncharted.
- Dendreon's first-generation DC product Provenge for prostate cancer had disappointing sales.
- Competition from oral products and other immunotherapies for mRCC such as Immatic's cancer vaccine, IMA-901, in Phase III.

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