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INSTITUTIONAL RESEARCH

Healthcare and Technology

INDUSTRY NOTE

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Advaxis, Inc.
(Nasdaq/ADXS/$13.44/Not rated)

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Significant Corporate Collaboration Spurs I/O Group

Cancer Immuno-therapy technology (I/O), not based around CAR-T cells, finally got a significant vote of endorsement this week with the announcement that Amgen (NASDAQ/AMGN/$173.59/Not rated) and Advaxis have entered into a global agreement for the development and commercialization of Advaxis' ADXS-NEO technology. ADXS-NEO is a preclinical patient-specific immune activation system designed to respond to and against the unique mutations, or neoepitopes, contained in and identified from each individual patient's tumor. These neoepitopes are produced in the microenvironment of a patient's tumor and can play a key role in the "deactivation" of the patient's immune response to early neoplasm development. Neoepitopes are also implicated in a tumor's changing profile at it progress towards treatment resistance. This collaboration brings together Amgen's development expertise in immuno-oncology with Advaxis' next generation proprietary MINE™ (My Immunotherapy Neo-Epitopes) personalized medicine program, which is uniquely positioned to develop a customized approach to cancer treatment.

In our view, this collaboration marks a watershed validation event for I/O based cancer treatments. Further, AMGN's commitment to this approach at a preclinical stage of development will likely have coat-tails for other companies in the space as it supports the premise that effective cancer treatment will be based upon combining and changing approaches over the patient's course of treatment. Lastly, we believe that this collaboration, and perhaps others to come, hints at a potential risk with checkpoint inhibitors as, in and among themselves, they may prove disappointing as direct treatments, just as has been seen in some CAR-T trials.

Following the typical format for these types of collaborations, Amgen receives exclusive worldwide rights to develop and commercialize ADXS-NEO for which Amgen will make an upfront payment to Advaxis of $40 million and purchase $25 million of Advaxis common stock. Amgen will take over full responsible for funding clinical and subsequent commercial activities. Advaxis will lead the clinical development of ADXS-NEO

through proof-of-concept and retain manufacturing control. In return, Advaxis will receive development, regulatory and sales milestone payments of up to $475 million and royalty payments anticipated in the range of high single digit to mid-double digit royalty payments based on worldwide sales.

From a science perspective, the ADXS-NEO technology is novel in that is it based upon a strategy that employs massive parallel DNA sequencing of the patient's own live cells. This is in contrast to the evolving "predictive algorithm" approach being developed by many molecular diagnostic and other cancer therapeutics companies. For ADXS-NEO, DNA from each patient's primary tumor and/or metastases as well as normal cells, is sequenced and compared to identify mutations in genes coding for potential neo-antigens in the cancer. Advaxis then engineers and manufactures patient-specific *Lm*-LLO (listeriolysin O) vectors capable of immunizing them against neoepitopes exclusive to their cancer. Clinical trials for ADXS-NEO are expected to begin in 2017.

This major industry news follows on the heels of a stand-out response to the recent quarterly results reported by Celgene (NASDAQ/CELG/$116.00/Not rated) in July. The Celgene news appears to have sparked a renewed focus on biotech stocks lately. Leadership by Celgene may be fostering a major technical breaking-out from group-wide lackluster performance since early Spring. Such leadership could provide the underpinnings necessary for a sustainable rally as we move into the fall. *SG*

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