

I don't follow the Japanese stock market, nor do I follow Japanese companies. The nuances of following a company, especially in Japan, require an analyst to be, essentially, in country and exclusively focused. On the other hand, when a company I do follow, like Gilead Sciences, announces its intention to build Gilead Japan and not go through a Japanese marketing partner, that tells me Gilead is very serious about penetrating the HCV market—and that the company is intent on realizing and enhancing a return on its \$11B acquisition of Pharmasset. It will do this by making sure its oral, pan-genotypic nucleoside sofosbuvir (formerly GS-7977), which it got in the Pharmasset deal, not only does well in Japan but also that it doesn't split the profits with a Japanese national.

TLSR: I know you follow Melbourne, Australia-based [Mesoblast Ltd. \(MSB:ASE; MBLTY:OTCPK\)](#), a Pacific Rim company. Tell me about it.

JK: Australia is definitely emerging as a biotechnology powerhouse. I am interested in covering Australian companies, but I am very aware of the differences between Australia and the U.S. in terms of biotech and stem cell business development. It was no accident that Dr. Silviu Itescu founded Mesoblast in Australia. It was Dr. Itescu's goal to avoid some of the problems that micro-cap biotechnology stocks have seen in the U.S., where if companies go public early, and are initially plagued with failures, it hurts valuations. [Geron Corp.'s \(GERN:NASDAQ\)](#) departure from the stem cell space is a great example; it made 10 years of investments only to see its programs fail. It is interesting that Geron's programs have been acquired by BioTime Acquisition Corp., a subsidiary of [BioTime Inc. \(BTX:NYSE\)](#), and Dr. Tom Okarma, the former Geron CEO, is now at BioTime.

"Australia is definitely emerging as a biotechnology powerhouse."

On the other hand, in the world of pharmaceuticals and biotechnology, it's almost a misnomer to think of a company as Australian, Japanese or American. Investors have to think of companies as global. That's very much in evidence with Mesoblast, in that it's moving forward with a global, 1,700-patient congestive

heart failure (CHF) trial that will be paid for and run by [Teva Pharmaceutical Industries Ltd. \(TEVA:NASDAQ\)](#). When you think about the implications of running that kind of trial, you can understand how Mesoblast is not merely an Australian company. It's a global company.

TLSR: What were some of the issues that Dr. Itescu wanted to avoid by founding the company in Australia?

JK: Dr. Itescu looked at the market capitalizations of the U.S. cell therapy companies. He was very keenly aware of what his benchmarks would be if he founded Mesoblast in the States.

For example, how do you differentiate what Mesoblast is doing versus what [Athersys Inc. \(ATHX:NASDAQ\)](#) is doing? As someone who has studied those two companies in great detail, I could walk you through that differentiation process, but the reality is that both programs are allogeneic, meaning they use other people's cells, and they both represent the pills-in-a-bottle or cells-in-a-bottle pharma model. They both have the potential to treat local disease, like heart disease or bone defects, as well as systemic disease. In addition to heart disease, Mesoblast is pursuing degenerative disc disease (DDD) and spinal fusion, both local indications, and systemically, type 2 diabetes and rheumatoid arthritis, all with its mesenchymal precursor cells (MPCs). Athersys is pursuing ischemic stroke in the framework of a systemic disease, graft versus host disease, which is systemic, and acute heart disease. Athersys is partnered with [Pfizer Inc. \(PFE:NYSE\)](#) in an ulcerative colitis program, and Mesoblast is partnered with Teva. In many ways, Athersys and Mesoblast look similar.

What's different is that Mesoblast was incorporated in Australia, and the initial funds were raised there. What drove the valuation in Mesoblast was the partnership it was able to make with Cephalon Inc. (which was acquired by Teva in October 2011). Being an Australian company made the capital-raising process easier because a dynamic exists in Australia that does not exist in the U.S.: Retail shareholders are able to invest directly in the company. They can literally mail checks to the company. I've seen other Australian companies do this as well. [Prima BioMed Ltd. \(PRR:ASX\)](#) has successfully raised capital in the home market in Australia.

Why do companies then leave Australia? Ultimately, I think they outgrow the country, and must look for the larger acquisition of capital that exists in the U.S. marketplace—although Mesoblast recently raised \$175 million (\$175M) overseas, which seems to contradict this logic.

TLSR: You have Mesoblast rated Buy, and your target price is \$11. The company is currently trading at \$6.50. What is your investment thesis here?

JK: I am often asked the question: If Mesoblast is currently trading at a \$2B market cap with \$178M in cash, or an enterprise value (EV) of about \$1.8B, versus Athersys, which is trading at a market cap closer to \$88M, or an EV closer to \$50M, how can you have a Buy rating on Mesoblast?

The answer is that I don't look at Athersys to make a valuation decision about Mesoblast. This is a very important point. While Athersys may trade at \$50M EV, I would argue that Athersys is too low, rather than Mesoblast being too high. As an analyst I've been trained to determine whether there's enough on the balance sheet to get to the next inflection point. I have concluded that yes, \$178M at the current burn rate will allow Mesoblast to operate for at least three years.

Three years from now the company is going to have a dramatically different outlook in terms of its data sets. In January, the company announced data around its spinal fusion program. It ran two phase 2 clinical trials, and looked at low-dose and high-dose applications of its MPCs versus autologous bone graft. Investigators were able to show the rate of fusion success was equivalent—not better and not worse—to the autograft, where bone is harvested from the patient's hip.

If surgeons can avoid harvesting bone from a patient's hip, that's significant because the process can leave a patient with lagging pain. It is also an opportunity for infection at the donor site. Many side effects in autograft procedures occur as a result of the bone harvest itself. Every orthopedic surgeon we've spoken with has said that if bone harvest can be avoided, fusion becomes a home-run product. We are waiting for one more trial to report—the third trial, which evaluates DDD. We should see the phase 2 results by April. That trial hopes to restore vertebral height in patients and, in doing so, help patients avoid becoming spinal fusion candidates. We believe the animal (ovine) models that Mesoblast based this trial on are predictive in humans. In fact, this is one of the company's core strengths—its ability to create preclinical data sets that derisk the clinical programs in humans.

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About 30M people in the U.S. who suffer from back pain seek medical help—usually in the form of steroid injections—before they become candidates for a fusion. What we're talking about is a therapy using cells rather than the temporary aid of steroid injections. The neurologist, instead of steroids, would inject cells in much the same process.

To get back to your question: How do you value something like that? The treatment has huge potential. The phase 2 fusion data look good, and I believe Mesoblast will replicate those results in a larger trial. When I add it all up, I see the potential of Mesoblast's technology to change the paradigm of how we treat failing hearts, as well as its potential in orthopedics and the fact that Mesoblast doesn't have to repeat phase 1 trials because it has already proven its cells are safe. Multiple indications exist for these cells, and what's unique about cell therapy is that once the phase 1 work is complete, it doesn't need to be repeated. All the company needs do is demonstrate safety and efficacy in an animal model that is predictive in humans, and then try the therapy in a phase 2 clinical trial in humans.

Maybe the most exciting indication is one that no one is talking about at Mesoblast—the ability for these cells to be a multifactorial solution to a multifactorial problem—rheumatoid arthritis (RA). That market is worth between \$10–25B globally. The potential for Mesoblast to become a significant player in RA is very great.

What else differentiates Mesoblast from Athersys, [Pluristem Therapeutics Inc. \(PSTI:NASDAQ\)](#) or [Cytora Therapeutics Inc. \(CYTX:NASDAQ\)](#)? Maybe the single largest differentiator is the amount of money Mesoblast has—\$178M on its balance sheet as of Dec. 31, while Teva is paying for its global CHF trial. Mesoblast is in a position to run well-designed clinical trials and not be held back by a lack of capital.

Those factors combine to make me very bullish on the potential of this company. It has so many irons in the fire. It's well financed and is clearly in a strong position to change the paradigm.

TLSR: You can't patent cells, which are products of nature. The cells possess the physiological mechanisms within them, and their paracrine effects are natural. I'm wondering why Athersys, Pluristem or anyone else can't come along and use Mesoblast's technology. How does a company protect its development?

JK: I want to correct you. You can patent these cells. Companies cannot patent part of the human body, but they can patent other specifics of the cells. Mesoblast has multiple patents, from composition of matter to methods of manufacturing and methods of use. The investigators have picked a target cell, a mesenchymal precursor cell. It's unique. A monoclonal antibody is used to pick out the specific cell type, which originates in the bone marrow as an early precursor to a mesenchymal cell. Mesoblast uses a highly proprietary manufacturing process and tightly controls the expansion of the cells into what ultimately becomes the final product. These steps are patentable and, in fact, we have seen multiple patents issued to companies with existing commercial stem cell products, such as [Osiris Therapeutics Inc.'s \(OSIR:NASDAQ\)](#) Prochymal (remestemcel-L). The reality is that the Athersys cell, the Pluristem cell and the Mesoblast cell are all different.

TLSR: So patent protection begins with the selection of the cell, the separation of cells using the antibody and the expansion and manufacturing process. There are multiple factors that can be protected as intellectual property (IP), correct?

JK: I would call them hurdles. Competitive hurdles, as well as IP hurdles, prevent competitors from coming in. Each company has IP around its cell types, cell characteristics, methods of use and manufacturing processes—so much so that, in fact, I don't think the concern is that someone will knock off anyone's product.

TLSR: You've mentioned Athersys several times in the context of Mesoblast. I get the impression that you like the company. Your thoughts?

JK: I like Athersys. I see it as a mini-Mesoblast—in many ways equivalent to Mesoblast—but it doesn't have the market cap. Athersys, with its MultiStem (multipotent adult progenitor cell) product, has one of the best manufacturing processes in allogeneic cell therapy that I've ever seen. If the results from its phase 2 ulcerative colitis/Crohn's disease trial, which is being run by Pfizer, are good, this stock could take off. If the results from its European phase 2 stroke trial are good, again, this stock could take off.

I also respect the management team, the fundamental science and quality of science that is practiced at Athersys. Gil Van Bokkelen was previously the head of the Alliance for Regenerative Medicine. He is a very down-to-earth, practical CEO, with high ethics and standards. Not every CEO in this space meets this standard.

TLSR: Would you mention another company?

JK: I also cover [Dendreon Corp. \(DNDN:NASDAQ\)](#) and [ImmunoCellular Therapeutics Ltd. \(IMUC:OTCBB\)](#), therapeutic vaccine companies.

I view Dendreon's Provenge (sipuleucel-T) as a breakthrough cell therapy for the treatment of prostate cancer, but it's a first-generation product, meaning it's not perfect. Another company I follow, [Medivation Inc. \(MDVN:NASDAQ\)](#), has an oral, small molecule, chemotherapy agent, Xtandi (enzalutamide), which is close to Provenge in terms of efficacy. In fact, Xtandi may turn out to be more efficacious, cheaper, easier to manufacture and more convenient for the patient. Provenge is very inconvenient for the patient, because each time a "batch" is made, the patient must go through a cumbersome [apheresis](#) process. Provenge is very expensive to manufacture and the margins are low by comparison to traditional biotechnology drugs.

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ImmunoCellular Therapeutics was founded by Dr. John Yu, a practicing neurologist at the department of neurosurgery at Cedars-Sinai Medical Center. Dr. Yu had a vision that dendritic cells (antigen-presenting cells that make up part of the immune system) could offer hope for patients with glioblastoma multiforme (GBM), an aggressive brain tumor that is essentially a death

sentence. One of the differences between the approaches that ImmunoCellular and Dendreon have taken is that Provenge targets one antigen expressed in prostate cancer, the prostate-specific antigen (PSA). Cancer cells are smart. If you are killing a cancer based on one antigen, the cancer will often down-regulate the expression of that antigen as a survival mechanism.

But it's less likely that cancer cells can simultaneously down-regulate the expression of six antigens. ImmunoCellular's cancer vaccine, ICT-107, targets six. The probability that the cancer cell can down-regulate two or even three antigens is lower than for one. It makes scientific and pragmatic sense.

TLSR: Jason, you commented that Dendreon's margins were very low with Provenge, and that investors are now concerned about margins associated with autologous cell therapies. What about the cost of manufacturing the cells used in ICT-107?

JK: Remember that Dendreon's Provenge was a first-generation cell therapy. ImmunoCellular's ICT-107 is a second-generation dendritic cell. Actually, I consider it a third-generation cell because it's so innovative. It is more robust and, in fact, can be cryopreserved (frozen). Prostate cancer patients receiving Provenge must have each dose made fresh. Patients treated with ICT-107 would sit down once for the apheresis procedure, and from that multiple doses—as many as 30, let's say—could be made, cryopreserved and used to treat the patient. The cost of goods sold (COGS) of ICT-107 is in line with more biotechlike products, and the vaccine becomes a high-margin product.

TLSR: You've made the case for ImmunoCellular targeting multiple antigens and the potential for significantly improved efficacy with its platform, as well as for much improved margins. But what are the data saying? Please speak to the valuation as well.

JK: I'm very hopeful that we are going to see not just good efficacy, but *dramatic efficacy*. A phase 2 clinical trial has been completed. It is event-driven with a mortality endpoint. We will see how many patients who got the vaccine are still alive versus patients who got the control. If there is a dramatic difference, as was seen in the open-label phase 1 clinical trial, then this drug would be rapidly adopted in the orphan population of GBM. Beyond that, it suggests the ImmunoCellular platform is very viable.

It's very rare for me to take what is essentially a \$2.50 stock and put an \$18 target on it. But even if the vaccine doesn't work, ImmunoCellular's stock does not go to zero, because the vaccine is a second-generation product. If ICT-107 does work, the reward is dramatic.

ImmunoCellular has a second vaccine, ICT-121, targeting recurrent GBM, which is resistant to most types of therapies and for which no standard treatment is available. This dendritic cell-based vaccine stimulates an immune response to CD-133, a novel cell-membrane protein that has been identified as a marker of a subset of neural stem cells and glioblastoma stemlike cells. The company has begun a physician-sponsored, FDA-approved, phase I trial at Cedars-Sinai, enrolling 12–15 patients.

Beyond these two vaccines is another, ICT-140, a multivalent, dendritic cell-based vaccine for the treatment of ovarian cancer. Ovarian cancer is the fifth most common cancer among American women and usually has a poor prognosis. The five-year survival rate is approximately 47%. ICT-140 is designed to target multiple antigens, including EphA2 and mesothelin. The company licensed the IP surrounding EphA2 (a tyrosine kinase receptor highly expressed in ovarian cancer and other advanced metastatic cancers) from the University of Pittsburgh. Additionally, ImmunoCellular has licensed the IP surrounding mesothelin (an antigen highly expressed in pancreatic cancer, ovarian cancer and mesothelioma) from Johns Hopkins University.

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TLSR: Just for curiosity, is anyone working on an off-the-shelf therapeutic vaccine, an allogeneic model?

JK: The dendritic cells in the ImmunoCellular paradigm always come from the patient. But [Bavarian Nordic \(BAVA:OMX\)](#) is working on a new and novel allogeneic vaccine, Prostavac. It is the subject of several ongoing clinical trials in men with metastatic castrate-resistant prostate cancer and is intended for use in patients whose disease has recurred after surgery or radiotherapy, an unmet medical need. Prostavac and its related PSA-containing poxviral vaccines have been investigated in more than 500 patients already. According to the company, Prostavac significantly improved overall survival (OS) to 8.5

months on average. It is currently being evaluated in a large phase 3 study; data is not expected until 2015.

One key opinion leader we spoke with said: "If Prostavac demonstrates an OS benefit equal to or superior to Provenge, combined with its ease of manufacturing and distribution, and substantially lower COGS, it could become a category killer."

In the out-years, there will likely be multiple new cancer vaccines. While none are a threat to Provenge today, the development of these new products bears watching.

TLSR: Can you give me another name?

JK: Let's talk about Cytori Therapeutics. Most people don't understand fat—adipose tissue. In and around fat cells is what's called a stromal vascular fraction, and in this cell bed are stem cells. In fact, it turns out that adipose tissue is about 10,000 times more plentiful a source of stem cells than bone marrow. Cytori has a machine, called the Celution system, for which it is pursuing an Investigational Device Exemption/premarket approval (PMA) around the indication of chronic myocardial ischemia (CMI). It is in a phase 2 pilot study. The only reason I add the word pilot is because I want to highlight the device pathway for approval. When you go down the device pathway, safety is generally not an issue. Companies just have to show efficacy. This trial, ATHENA, is enrolling very rapidly.

The Celution device is a highly engineered smart centrifuge. The patient's own adipose tissue—about the volume of a full soda can—is taken, typically from the abdomen using liposuction. The tissue is loaded into the machine, where a collagenase digests the fat. An hour later the machine generates a dose of stem cells—what the company calls its adipose-derived stem and regenerative cells (ADRCs). It is important to note that this is a point-of-care, very inexpensive way to do cellular processing. It has the potential to change the balance for CMI, a chronic indication.

Let me differentiate the indications. If you have an acute myocardial infarction—a heart attack—you don't want to have liposuction and wait an hour before your treatment can begin. In fact, you don't want to wait a minute. You want to be rushed into the cath lab, and as the interventional cardiologist is placing the stent to unblock the coronary occlusion, you'd like him or her to have the stem cells to inject. Though it seems unbelievable, many heart attack patients won't return to the hospital once released, so a cardiologist's best chance to treat the heart is right there, in the cath lab, during the crisis. I worry when companies claim it is best to wait until the heart becomes hypoxic, and then deliver cells. I believe, for acute injury, you want allogeneic models like those being developed by Mesoblast, Pluristem and Athersys.

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On the other hand, the autologous model, like Cytori's or IntelliCell BioSciences Inc.'s (SVFC:OTCPK) adipose sonification process (cells are separated using sonic energy), could be very attractive for cardiac patients with CMI. If we think of the lowest of the low-hanging fruit, we think of anybody undergoing a tummy tuck. What is happening to that fat now? It's

being thrown away. Imagine if that was reintroduced into your body for rejuvenation. Now the person getting liposuction is a candidate for stem cell therapy. Many physicians are actually doing this today under minimally manipulated and homologous guidelines. The area is in dispute and represents a gray area in terms of FDA regulations.

I can see a day when stem cells from these procedures are cryopreserved. Down the road, should you break your arm or your ankle, those cells could be used to help you heal rapidly. I think Cytori's device has enormous potential. I respect the fact that it is targeting CMI with a peak oxygen consumption endpoint along a PMA (device) pathway.

Once the company completes the current phase 2 study successfully, all it will need to do is one modestly sized phase 3 trial. Proving safety is less of an issue with the device pathway, so the pivotal trial's focus is a p-value (statistically valid result) on a relevant endpoint.

TLSR: Do you have one or two ideas to close with?

JK: I'd like to talk about IntelliCell BioSciences—and I know this will be controversial, only because its CEO, Dr. Steven Victor, is also the founder of ReGen Medical. ReGen Medical is a state-of-the-art hospital in midtown Manhattan that provides stromal vascular fraction cellular therapy, which contains stem cells, to patients today. The hospital is a beautiful, brand-new facility that treats high-end patients.

The therapy is provided to patients through physicians (orthopedists, urologists, plastic surgeons, etc.) that have practicing rights at ReGen Medical. The clinicians are allowed to put a patient's own cells back into his or her own body, provided the cells are not manipulated, processed or expanded. This is in accordance with the FDA's "minimal manipulation and homologous use" rule.

The IntelliCell process, branded IntelliSonics, is similar to the Cytori process in that they both use lipoaspirate. But the IntelliCell process produces a different cellular population because, with its sonification (ultrasound) process, the blood components are not washed out. The stromal vascular fraction of IntelliCell contains the hematopoietic cells. The final product is quality-controlled, checked for any contamination and cell viability is measured.

IntelliCell BioSciences has completed the preclinical protocols in anticipation of beginning a clinical trial for osteoarthritis of the knee under an FDA investigational new drug application in mid-2013. The company provides product today to ReGen Medical, and in doing so is building fantastic database of patient experience that will be used to focus on clinical applications.

I'd also like to mention [Aastrom Biosciences Inc. \(ASTM:NASDAQ\)](#). This company is working to complete a phase 3 pivotal trial of its stem cell therapy in critical limb ischemia (CLI). Based on the phase 2 data set and the size and powering of the pivotal trial, we believe Aastrom has a good probability of success.

The trial's goal is to demonstrate an improvement in the amputation-free survival rate of the treated patients. Aastrom uses a bone marrow aspirate and expands the cells, optimizing the heterogeneous population mix. Key to Aastrom's success will be validating the thesis that the cell product has been optimized and therefore is advantageous.

Aastrom is positioned to have the first approved therapy for CLI in the marketplace. We believe "first mover advantage" is vitally important for the company, as it is likely to face future competition from others, such as Pluristem, in CLI. Investors should appreciate that Aastrom's core expertise is in cell manufacturing. As such, the company's COGS are low for an autologous-processed product. By comparison, the processing COGS associated with the [Baxter International Inc. \(BAX:NYSE\)](#), [NeoStem Inc. \(NBS:NYSAA\)](#) and [Cytomedix Inc. \(CMXI:OTCBB\)](#) approaches are very high. The fact that the NeoStem product requires more than 20 bone marrow needle punctures and multiple pulls on each needle concerns us, as does the Baxter approach of administering granulocyte colony-stimulating factor (GcSF) to CMI patients and then subjecting them to apheresis. Investors today are fearful of all the autologous models, as the Dendreon experience is still fresh in their minds.

We believe that companies like ImmunoCellular, Cytori, IntelliCell and Aastrom represent new paradigms in autologous therapy, whereas other approaches are closer to the labor-intensive and less-patient-friendly Dendreon model. We believe low COGS, availability and on-site processing may be critical success factors, dependent on the indication (acute or chronic), whether the therapy meets an unmet medical need and whether there is intense competition in the space.

The good news is that cell therapy has virtually arrived. It's no longer a question of if, but when. There are multiple late stage trials ongoing now. Strengths, weakness, opportunities and threats, also known as SWOTs, will be deciding factors in the future.

Will a product be first in the marketplace in a selected indication? Is the product virtually off the shelf? Is the cost of goods high or low? Investors need to ask these questions as companies position themselves for the market-share battles of the future.

TLSR: It's been a pleasure speaking with you. Best wishes.

JK: My pleasure. Thank you.

Jason Kolbert has worked extensively in the healthcare sector as product manager for a leading pharmaceutical company, as a fund manager and as an equity analyst. Prior to joining Maxim Group, he spent seven years at Susquehanna International Group LLP, where he managed a healthcare fund and later founded SIG's sellside biotechnology team. Previously, Kolbert served as the healthcare strategist for Salomon Smith Barney. He is frequently quoted in Barron's and is regularly featured on CNBC. Prior to beginning his Wall Street career, Kolbert served as a product manager for Schering-Plough in Osaka, Japan. He received a bachelor's degree in chemistry from State University of New York at New Paltz, and a master's degree in business administration from the University of New Haven.

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