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What Venture Contraction? Flagship Closes $270M Fund

By Jennifer Boggs
Managing Editor

SAN FRANCISCO – A day after Canaan Partners disclosed a $600 million fund – a third of that dedicated to the life sciences – Flagship Ventures closed a $270 million round, well above its $250 million fundraising goal.

Such exuberant venture fundraising to start the year is almost enough to make one wonder whether reports of venture contraction – Prospect Venture Partners failure to close its latest round, for example – have been greatly exaggerated.

"There has been a flow of confusing news, particularly for early stage companies," acknowledged Noubar Afeyan, Flagships' managing partner and chief executive. "It's been pretty worrisome to innovators and entrepreneurs."

The contraction is real, Afeyan said. But money is not

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Biotech Showcase 2012

Hopes High as Regenerative Med Moves from Lab to Clinic

By Marie Powers
Staff Writer

SAN FRANCISCO – Regenerative medicine is coming of age, and not a day too soon to address an expected 80 percent increase in individuals older than 65 expected by 2030, from 40 million to more than 70 million in the U.S. alone.

The same population shift is expected to occur in Europe and may be even more pronounced in Asia, which has experienced lower growth over the past two decades.

Aging populations will bring with them enormous increases in cardiovascular disease, neurological conditions, inflammatory and immune disorders and renal disease, prompting an explosion in health care interventions and related costs.

"The reality is that we don't have the resources to

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Exercise in a Pill

Signaling Molecule Browns Fat, Slims Down Rodents

By Anette Breindl
Science Editor

The anti-aging compound resveratrol is sometimes described as an attempt at delivering the benefits of caloric restriction in pill form.

Now, scientists may have identified a companion compound that delivers the benefits of exercise in a pill. In the Jan. 12, 2012, edition of *Nature*, scientists have reported that rodents treated with a newly identified signaling hormone, irisin, lost weight and improved their blood sugar control.

If they pan out, the findings would certainly make for easier-to-keep New Year's resolutions. 2012's "Eat less and exercise more" could conceivably be replaced by 2022's "get prescriptions for resveratrol and irisin."

In a nutshell, the authors reported in their paper that

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Social Media: Building a Presence on YouTube

By Mari Serebrov
Washington Editor

Editor's note: This is the second in a series on biopharma best practices in using social media. The next article will look at disease awareness pages.

When it comes to getting social, biopharma has to get over itself, because being social is not about building a brand, promoting a drug or lecturing to the masses.

Rather, social media is all about the patient and his or her experience, said Mike Myers, president of Palio Communications. That's just as true with YouTube, with its controlled messages, as it is with Facebook, which thrives on interaction.

While Facebook and Twitter are great for stimulating the conversation, YouTube is more about providing information. It is a "tremendous opportunity for pharma," Myers told companies participating in a Thompson Media

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INSIDE:

AHC Media

Financings Roundup

Arena Back on Track with A $33M Equity Financing

By Catherine Shaffer
***BioWorld Today* Contributing Writer**

Just one day after resubmission of its new drug application for lorcaserin, Arena Pharmaceuticals Inc. is selling nearly 10 million shares of common stock to raise $33 million, demonstrating that it is moving forward following the October 2010 complete response letter from the FDA.

The registered direct public offering consists of 9,953,250 shares of common stock at $1.65775 per share, and 9,953 shares of preferred stock at $1,657.75 per share. The buyers of the stock are affiliated with Deerfield Management, and the offering is expected to close on Jan. 13; 156,046,069 common shares will be outstanding upon completion of the offering.

The first $5 million of the proceeds will be used to pay off part of the principal in a loan from Deerfield that would otherwise be due in June 2013. The remainder will support the regulatory process for obesity candidate Lorqess (lorcaserin), as well as preclinical and clinical development of other pipeline products.

Concurrently, Deerfield will purchase 8.6 million shares of Arena common stock, in exchange for cancellation of warrants to purchase an aggregate of 13.6 million shares of Arena common stock. That group of warrants include warrants to purchase 11.8 million shares at $5.42 per share, and warrants to purchase 1.8 million shares at $3.45 per share. The new warrants will be exercisable at $1.745 through June 17, 2015.

The FDA said it rejected Arena's application because potential risks of tumors, psychiatric effects and heart problems outweighed any benefits of weight loss with lorcaserin. (See *BioWorld Today*, Sept. 17, 2010.)

Arena's response to the complete response letter includes data and analyses not present in the original NDA, particularly the results of the Phase III BLOOM-DM trial in patients with Type II diabetes. The new data address concerns about tumors from a study of lorcaserin carcinogenicity in rats, as well as cell culture studies on serotonin subtype 2 receptor activity.

The FDA accepted Arena's resubmission, and assigned a June 27 PDUFA date.

Arena, Vivus Inc. and Orexigen Therapeutics Inc. all experienced setbacks in 2010 related to registration of their respective obesity candidates, lorcaserin, Qnexa (phentermine/topiramate), and Contrave (naltrexone HCl/bupropion HCl).

As Arena moves forward with NDA resubmission and financing, Vivus has agreed with the FDA to apply for a more restrictive label in conjunction with a retrospective observational study for topiramate exposure in pregnancy, and Orexigen is hammering out a new clinical trial plan for Contrave. (See *BioWorld Today*, Sept. 22, 2011.)

In other financing news:

• **Chelsea Therapeutics International Ltd.**, of Charlotte, N.C., completed an underwritten public offering of 4,989,275 shares of common stock at $4.75 per share. Underwriters exercised in full their overallotment option. Net proceeds were $22.1 million. ■

Stock Movers

1/11/12

Company	Stock Change	
Nasdaq Biotechnology	+$6.34	+0.55%
AcelRx Pharmaceuticals Inc.	+$0.58	+26.48%
Dendreon Corp.	+$1.52	+11.85%
Human Genome Sciences Inc.	+$1.41	+17.56%
Santarus Inc.	+$0.40	+10.47%
XOMA Corp.	+$0.16	+11.35%

(Biotechs showing significant stock changes Wednesday)

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AHC Media

JPM

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impossible to find.

Flagship's fourth fund includes investments from pension funds, foundations, fund-of-funds, corporations and individuals. "Essentially, all our existing LPs [returned], and we added another half-dozen to the mix," he told *BioWorld Today*.

Canaan general partner Brent Ahrens told *BioWorld Today* earlier this week that convincing limited partners (LP) to back health care investments for the firm's ninth round took some doing, and Canaan faced "a lot of trepidation." But Canaan was able to sway those LPs with an impressive track record. (See *BioWorld Today*, Jan. 10, 2012.)

Flagship can say the same. The Cambridge, Mass.-based venture firm, which has a total of about $600 million under management, has a portfolio of 65 firms. Of those, about 20 have found exits. Recent such successes include the buyout of Yale University spinout CGI Pharmaceuticals Inc. for $120 million by Gilead Sciences Inc. and initial public offerings by BG Medicine Inc. and AVEO Pharmaceuticals Inc. (See *BioWorld Today*, March 15, 2010, June 29, 2010, and Feb. 8, 2011.)

But what sets Flagship apart from a lot of other life sciences venture firms is that it really focuses on early stage companies.

"We look for breakthrough technology, strong IP and the potential for generating multiple products," he said.

The particular therapeutic area is less important. But Flagship steers clear of those firms that are created to in-license and develop only one product. "We don't subscribe to the virtual model," he added.

An example of a Flagship-backed company is Eleven Biotherapeutics Inc., a start-up that boasted a promising protein engineering technology but was still far from the clinic. In 2010, Flagship co-led a $35 million Series A financing for Eleven, along with Third Rock Ventures, another firm known for early stage investments. (See *BioWorld Today*, Feb. 17, 2010.)

Flagship usually leads or co-leads its investments. And, in some cases, even helps found the company.

Afeyan said there's been a lot of interest in Flagship VentureLabs, an entrepreneurial unit of the venture firm aimed at establishing firms around promising emerging technologies. Firms such as AVEO and CGI Pharmaceuticals emerged from that program.

With the latest fund, Flagship anticipates backing roughly 20 firms, Afeyan said, with about half of the investments going into drug development. The remaining half will be split among medtech, diagnostics and sustainability firms.

He added that Flagship typically invests between $10 million and $20 million in each of its portfolio firms, "over the life of the company."

Whether this latest fund will help boost venture dollars for the industry in 2012 is anyone's guess this early in the year.

BioWorld Insight recently reported that private biotechs raised $4.5 billion globally in 2011, holding steady to 2010 figures. Many experts expect similar numbers for 2012.

In addition to investing in early stage firms, Flagship will dedicate a portion of its fund to late-stage value investing opportunities resulting from the current capital-constrained environment. ■

Other News To Note

• **Burrill and Co**., of San Francisco, completed the first close of its Burrill Brazil Fund I for a total of $125 million. It received approvals from Brazilian authorities Jan. 9 to commence operation of the fund. The fund will support life science in Brazil. Its target for the second close is $200 million.

• **Bridge Bioresearch plc**, of London, completed preclinical studies of 2hydroxyoleic acid (2OHOA) for obesity and metabolic disorders. The product showed biological activity without observed toxicity. In animal models, it improved hypertension and Type II diabetes associated with obesity.

• **China Nuokang Bio-Pharmaceutical Inc.**, of Beijing, acquired Chinese rights to manufacture and market Alpha Lipoic Acid Capsules for diabetic neuropathy from **Shandong Qidu Pharmaceutical Co. Ltd.**, of Shandong, China, in exchange for RMB18 million (US$2.9 million).

• **Evotec AG**, of Hamburg, Germany, achieved a milestone in its multiyear, multitarget drug discovery alliance with **Boehringer Ingelheim GmbH**, of Ingelheim, Germany, triggering a €2.5 million (US$3.2 million) milestone payment. The milestone involved the identification and selection of an oncology compound to be advanced into extended profiling prior to preclinical development. The companies entered the collaboration in 2004 and extended it in 2009.

• **Hemispherx Biopharma Inc.**, of Philadelphia, said the FDA granted the company's request for more time to modify its Ampligen new drug application, following a complete response letter received in 2009 for chronic fatigue syndrome (CFS). Hemispherx said new research around a potential companion diagnostic for CFS prompted the decision. (See *BioWorld Today*, Dec. 3, 2009.)

• **OctoPlus NV**, of Leiden, the Netherlands, signed an agreement with a major pharmaceutical company based in the U.S. to explore the feasibility of a controlled-release formulation of a compound for delivery to the joints. Under the agreement, OctoPlus will develop the formulation using its PolyActive technology. If successful, there is potential for a development and manufacturing license agreement.

Other News To Note

• **The Infectious Disease Research Institute** (IDRI), a nonprofit based in Seattle, received more than $500,000 from the Bill & Melinda Gates Foundation to augment a multimillion dollar award made last year as part of the foundation's Tuberculosis (TB) Drug Accelerator program. IDRI will use the additional funds to expand several areas of work in early drug discovery, including increasing its capacity to screen for anti-tubercular compounds, evaluation of hit compounds and novel drug target identification. The institute said the funding will allow it to screen a wider variety of compounds and advance them more rapidly into TB drug candidates.

• **Spherix Inc.**, of Bethesda, Md., said it completed a 28-day rat toxicology study of potential dyslipidemia compound SPX-106 and found "an ample margin of safety" with the dosing planned for its first clinical trial. The company plans to submit an investigational new drug application in the second quarter of 2012. Shares of Spherix (NASDAQ:SPEX) gained 21 cents, or 17.7 percent, to close at $1.40 on Wednesday.

Clinic Roundup

• **Advaxis Inc.**, of Princeton, N.J., said dosing began in a 67-subject Phase II trial evaluating Advaxis' ADXS-HPV construct for advanced cervical cancer. The study is sponsored by the Gynecologic Oncology Group, with the majority of funding from the National Cancer Institute. The trial is in a population similar to a 110-patient study Advaxis is conducting in India. Both studies will assess safety and efficacy in cervical cancer patients who have not responded to conventional cytotoxic treatment and whose cancer has metastasized. Enrollment in India is about 80 percent complete.

Biotech Showcase

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deal with this problem," said Gil Van Bokkelen, CEO of Athersys Inc., of Cleveland, and chairman of the Alliance for Regenerative Medicine.

That is, unless regenerative medicine can ride to the rescue as part of the biopharma solution, Van Bokkelen and a panel of specialty biotechs and pharmas told attendees at Biotech Showcase 2012, held at the same time as the 2012 J.P. Morgan Healthcare Conference in San Francisco.

The Alliance was formed two years ago to improve networking among large and small biopharmas, private and public companies, nonprofits and advocacy groups seeking to advance regenerative medicine therapies in order to "reduce the Mt. Everest of health care" into a manageable beast, Van Bokkelen said.

The clinical opportunities are broad and deep. In the cardiovascular arena, more patients survive heart attacks, but progress to congestive heart failure – a greater long-term clinical and financial burden. Millions of individuals live with vascular diseases such as critical limb ischemia, but endure amputations. Each year, more than 2 million people in the U.S., Europe and Japan, combined, suffer a stroke, and many require long-term care. The list goes on and on, Van Bokkelen said, from neurodegenerative diseases to traumatic brain injury, rheumatoid arthritis to multiple sclerosis – and diabetes, almost a class in itself.

Regenerative medicine firms are seeking "to innovate our way out of these problems," he said. "None of us believe that all of the approaches will be successful and, frankly, they don't need to be. The reality is that if just a few of them are successful, they will have a transformational impact on clinical medicine as we know it."

The range of investigative efforts encompasses not just cell-based approaches but also tissue engineering, medical devices and the interface between small molecules and cell therapy. Although the number of marketed products is small, especially in comparison with conventional biotech compounds, the field now boasts tens of thousands of research citations exploring the biology of regenerative medicine as well as a growing list of programs – more than 20,000 in cell therapy, alone, according to NeoStem Inc. Chairman and CEO Robin Smith – that have advanced to clinical trials.

And the space is attracting the interest of pharmas, as evidenced by last year's blockbuster acquisition of Genzyme Corp. by Sanofi-Aventis SA, of Paris, and the last-minute nab of Advanced BioHealing Inc. (ADH), by Shire plc, of Dublin, Ireland. (See *BioWorld Today*, Feb. 17, 2011, and May 19, 2011.)

"When you're a pharma looking at this field, one of the most fundamental decisions to make is whether to build capabilities, buy capabilities, invest externally, partner, wait or watch and see," said Jay Siegel, chief biotechnology officer and head of pharmaceutical global regulatory affairs for New Brunswick, N.J.-based Johnson & Johnson. "Our strategy is a combination of all of those activities."

Access to public markets and partnerships represent two important keys to propelling regenerative medicine, said Silviu Itescu, CEO of Melbourne, Australian-based Mesoblast Ltd. Regenerative medicine requires "serious financial commitments," Itescu said. "This is not about being able to spend $10 million or $15 million, if we're really serious about putting regenerative medicine on the map."

Mesoblast is one of the few regenerative medicine companies to present around the corner at the J.P. Morgan conference.

In 2010, Mesoblast inked a $350 million strategic alliance with Cephalon Inc. (now part of Teva Pharmaceutical Industries Ltd.) to develop and commercialize its mesenchymal precursor cell (MPC) therapeutics for hematopoietic stem cell transplantation in cancer patients, as well as degenerative conditions of the central nervous and cardiovascular systems, including congestive heart failure. The deal could potentially exceed $1 billion in milestone payments. (See *BioWorld Today*, Dec. 9, 2010.)

The cash influx helped Mesoblast move its stem cell technology forward rapidly, Itescu said. Last May, the company reported that its allogeneic adult stem cell product, Revascor, significantly reduced cardiovascular deaths in a randomized, placebo-controlled Phase II trial. The company plans to begin a large Phase III in congestive heart failure in the near future, according to Itescu.

Aastrom Biosciences Inc., of Ann Arbor, Mich., expects to launch its Phase III REVIVE-CLI study of ixmyelocel-T, its expanded multicellular therapy, this quarter in patients with critical limb ischemia, CEO Tim Mayleben told conference attendees. In November, the company reported Phase II data at the American Heart Association Scientific Sessions in Orlando.

In one indicator of how far regenerative therapies have progressed, "several years ago, you would not have found a cell therapy company presenting real Phase II data – placebo-controlled industry-standard clinical trials – at a major medical meeting," Mayleben said. "For us to be able to present at that venue speaks to the regenerative medicine industry's development over the past few years."

In fact, some regenerative medicine executives insist the discipline is not a subset but the next iteration of biotechnology.

"With regenerative medicine, we're not treating the symptoms of these diseases," Mayleben said. "We're actually changing the course of the disease, and we've seen that in the results of our Phase II clinical trials."

Dean Tozer, senior vice president of corporate development at ADH, agreed, noting that the company often struggled to find "like-minded partners" during its formative years.

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Fat

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irisin is produced by muscle cells during exercise, and stimulates the conversion of white to brown fat cells. Brown fat, which burns energy instead of storing it, was once thought to exist only in hibernating animals and newborn humans. But more recent research has shown that adult humans, too, still have some brown fat – and that increasing the number of those fat cells might have positive effects on weight and metabolism.

In 2009, Bruce Spiegelman and his colleagues published work showing how to convert white to brown fat by engineering certain transcription factors into immature cells that could induce them to become brown fat cells. (See *BioWorld Today*, July 30, 2009.)

At that point, Spiegelman said finding a signaling hormone that could induce the switch from white to brown fat cells "is reasonable to think that it might provide a direct anti-obesity treatment."

In the new paper, Spiegelman – who is again the senior author – and his team showed that irisin fits the bill for such a hormone. In their experiments, Spiegelman and his team started by looking at which genes were influenced by a transcription activator that is known to mediate some of the beneficial effects of exercise: PGC1-alpha. Among the genes they identified was the membrane protein FNDC5. Part of the full-length FNDC5, in turn, is cut and secreted from the membrane as a signaling hormone – which Spiegelman and his team named irisin after the Greek messenger goddess Iris.

Sedentary, obese mice that were treated with irisin for 10 days improved their blood sugar and glucose values, and lost some weight. The work has obvious commercial potential, and that potential is being tapped by Boston-based start-up Ember Therapeutics Inc. The company was co-founded by Spiegelman.

"There are two brown fat cell lineages," Ember president and interim CEO Lou Tartaglia told *BioWorld Today*. One type is "pretty adipose-like" – essentially, a white fat cell running a different gene expression program. The other looks the same, but is descended from a different cell lineage developmentally. Irisin appears to work on the former type of cell, expressing brown fat-like gene expression programs in white fat cells. The hormone did not appear to have major effects on existing brown fat cells, presumably because they are already running the gene expression program that irisin would induce.

Ember, which got its official start last December with a $34 million Series A financing from Third Rock Ventures LLC, has an exclusive license to irisin, though the work now published in *Nature* was funded by academic grants, not through the company.

Ember is developing anti-obesity therapeutics based on irisin, as well as potential diabetes drugs that are also based on work out of Spiegelman's lab. (See *BioWorld Today*, July 22, 2010, and Dec. 15, 2011.)

Tartaglia said that Ember's management hopes to be ready for an investigational new drug application filing some time in 2014, but did not want to narrow down the possible date any more than that – partly because the company plans to run preclinical studies in primates as well as in rodents, and finding the best primate model can take time.

"Brown fat is very different in different mammals," he said, and although "it's good to do initial studies in the rodent to get a sense of what's going on," the best chances for success come from picking a good primate model and making sure an approach has good efficacy there, as well as in rodents. Although in at least one respect, irisin is impressively similar in mice and the primate homo sapiens: while the DNA sequences of the two species are 85 percent identical on the average, for irisin they are 100 percent identical. ■

Clinic Roundup

• **Intercell AG**, of Vienna, and **Statens Serum Institut**, of Copenhagen, reported the start of the first Phase II study in their collaboration to develop tuberculosis (TB) vaccines. The randomized, double-blind trial will evaluate the immunogenicity and safety of two doses of H1IC, a combination of Statens' Ag85B-ESAT-6 and Intercell's IC31, in HIV-positive subjects in South Africa and Tanzania. The study, funded by the European and Developing Countries Clinical Trials Partnership, is being conducted in collaboration with several groups, including the South African TB Vaccine Initiative. First results are expected in 2013, and a second Phase II trial is being planned to assess the safety and immunogenicity of the vaccine candidate in healthy adolescents.

• **Pharmos Corp.**, of Iselin, N.J., said the first U.S. patients have been dosed with its levotofisopam (S-tofisopam) in a Phase IIa proof-of-concept trial in hyperuricemia and gout. In two Phase I studies, completed by Vela Pharmaceuticals, which merged with Pharmos in 2006, levotofisopam was generally well tolerated and was associated with a large, rapid reduction in serum uric acid values. Once the proof-of-concept trial is completed, Pharmos plans to seek a partner to further develop levotofisopam.

• **Vical Inc.**, of San Diego, reported that results from the completed Phase II proof-of-concept trial of its TransVax, a cytomegalovirus DNA vaccine, were published in the online issue of *The Lancet Infectious Diseases*. The occurrence and duration of cytomegalovirus viraemia episodes were significantly reduced when cytomegalovirus-seropositive patients received up to four doses of the vaccine. Vical's partner, **Astellas Pharma Inc.**, of Tokyo, is preparing to move TransVax into a multinational Phase III trial to control cytomegalovirus reactivation in hematopoietic stem cell transplant recipients, plus a Phase II trial in solid organ transplant recipients. (See *BioWorld Today*, July 18, 2011, and Jan. 9, 2012.)

Social Media

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webinar on effective use of social media. (See *BioWorld Today*, Dec. 12, 2011.)

Of all the social media communities, YouTube is the safest for a regulated industry because companies have more control over the message, he added. However, companies shouldn't use it as just another venue for running drug ads. After all, 90 percent of people who can skip television ads do so. Ads on YouTube are likely to meet the same fate.

Like other social media, YouTube is about communicating, not broadcasting. And, as the No. 2 most searched site on the Internet, it's a busy place. Although YouTube doesn't release its numbers, it's been estimated that it has more than 400 million unique viewers, with about 800 million user visits per month and more than 3 billion videos viewed each day, Myers said.

As for demographics, YouTube has broad appeal, attracting viewers age 18 to 54; about 70 percent of YouTube traffic comes from outside the U.S.

Besides allowing biopharma to control the message, YouTube is a strong medium for presenting fair balance as it permits companies to share a lot of content, Myers said. As a result, YouTube is safer and potentially more effective for biopharma than Facebook and Twitter.

YouTube also allows drugmakers to have a dialogue or a monologue "in a way that facilitates people out in the social media space taking the information and sharing it with others," Myers said. This sharing, often through Facebook and Twitter, repurposes YouTube content and circulates it on the Internet quickly.

Despite the advantages, many biopharma companies, although engaged in social media, have shied away from YouTube. In an informal *BioWorld Today* survey last year, only 24 percent of the respondents were on YouTube, while 71 percent were on LinkedIn, 56 percent were on Facebook and 48 percent tweeted. (See *BioWorld Today*, July 5, 2011.)

Biopharma's Growing Presence

But thanks to some big pharma companies that have figured out how to create holistic YouTube channels, biopharma's presence on YouTube is growing, both in content and subscribers. For smaller companies looking to create their own YouTube channels, Myers recommended that they use the successful big pharma channels as a model.

In the absence of FDA guidance for social media, Myers said, "the way that people are learning is by learning from each other and seeing what is working, what is not working, and what is coming under regulatory scrutiny and the ire of the FDA." (See *BioWorld Today*, Jan. 10, 2012.)

One of the strongest and most prolific biopharma channels on YouTube is the Johnson & Johnson (J&J) Health Channel, he said. It includes discussions about different disease states such as HIV and AIDS, and profiles of health care providers and some of the company's staff. J&J dove into the medium early on. "Their viewership and ability to use YouTube as a promotional and education tool has benefited as a result of their commitment to it," Myers said.

Other channels he recommended include:

• **The Novartis Channel**. It provides videos dedicated to various disease states. While Novartis has drugs approved for the diseases, the videos aren't ads for the product. Instead, they discuss the disease, overall treatment, patient lifestyle and patient care. The channel isn't about brand. "It's about patient experience; it's about overall health; it's about improving outcomes," Myers said.

• **AbbottChannel**. Besides discussing disease states, the channel talks about the things Abbott does in the community. Instead of a one-dimensional advertising message, Abbott provides a complete picture of what it's doing. Subsequently, "it doesn't come off as big, bad pharma with one more drug that many people think is overpriced," Myers said. "It comes off as a firm that's very committed to community, committed to patient care, committed to truly beneficial outcomes."

• **AstraZeneca**. Like AbbottChannel, this channel provides a "holistic story about [the] firm, and ultimately the halo effect transfers over the brands themselves," Myers said.

• **Boehringer Ingelheim**. Some of the videos on this channel use a lot of advanced technology and graphics to explain complex concepts, so they can be used as educational tools. Boehringer also has done a great job in syncing all its social media sites, Myers said. For instance, its YouTube channel includes links to its Facebook, Twitter, Flickr, Web and news sites. The company's latest social media foray is gaming, "which is a huge growth area for promotion in general and it's absolutely going to be hitting pharma," he added. ■

Appointments and Advancements

• **Accera Inc.**, of Broomfield, Colo., appointed Holger Kunze CEO and board member. It also named Sven Thormahlen to the board.

• **Adeona Pharmaceuticals Inc.**, of Ann Arbor, Mich., appointed John Monahan senior vice president of R&D.

• **Advanced Cell Technology Inc.**, of Marlborough, Mass., named Gregory D. Perry and Zohar Loshitzer to its board.

• **Affimed Therapeutics AG**, of Heidelberg, Germany, named Eugene Zhukovsky chief scientific officer.

• **Agensys Inc.**, of Santa Monica, Calif., a subsidiary of Astellas Inc., appointed Frank P. Hudson vice president of finance and named Wolfgang Noe vice president of process sciences and manufacturing.

• **Amarantus BioSciences Inc.**, of Sunnyvale, Calif., added Mark J. Benedyk as strategic advisor.

• **Ambit Biosciences Inc.**, of San Diego, appointed Michael A. Martino president, CEO and board member.

• **AM-Pharma BV**, of Bunnik, the Netherlands, appointed Russell Greig chairman.

• **AmpliPhi Biosciences Corp.**, of Seattle, appointed Philip J. Young president and CEO.

• **Anthera Pharmaceuticals Inc.**, of Hayward, Calif., promoted Debra Odink to chief technology officer and senior vice president.

• **ATyr Pharma Inc.**, of San Diego, appointed R. Alan Ezekowitz to its therapeutic advisory board.

• **Auxilium Pharmaceuticals Inc.**, of Malvern, Pa., appointed Adrian Adams president, CEO and board member.

• **AVI BioPharma Inc.**, of Bothell, Wash., appointed Jayant Aphale senior vice president of technical operations.

Biotech Showcase

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"We didn't fit into pharma, we didn't fit into device and we didn't fit into biotech," he said. "We always believed that regen med was going to be an entirely new field. We built a company to accomplish that, and I think that's why we were successful."

Unlike traditional big pharmas and some biotechs, many regenerative medicine companies are developing platforms that can be developed across multiple diseases.

"The ability to cross-reference common manufacturing platforms and safety data and then apply that to accelerate therapies into midstage clinical development and beyond is very powerful from an investor perspective," Van Bokkelen observed. "It means you can develop these therapies more efficiently and cost-effectively."

And regenerative medicine companies are making swift progress in their ability to capture and report compelling clinical data. For example, Aldagen Inc., of Durham, N.C., has an ongoing Phase II trial of ALD-401, a stem cell population derived from a patient's own bone marrow, for the treatment of stroke – an indication that has seen its share of failures with small molecules and other approaches.

"This is an area where cell therapy has a unique opportunity, because stroke is a multifactorial problem," said Ed Field, Aldagen's chief operating officer.

The 100-patient, randomized, double-blind study was the largest of its kind initiated for cell therapy study in stroke when it was approved by the FDA last January, according to Field.

"We need to do studies the right way in cell therapy, and the randomized double-blind method is the standard," he said. The size and design of the study "allow us to look at an endpoint that the FDA will accept for approval of a stroke therapy. We can actually power a Phase III appropriately from the 100-patient Phase II study. We're about 12 months away from having a major Phase II data set in a very large unmet need for cell therapy."

Regenerative medicine companies face the same regulatory hurdles cited by other biotechs, including those attending J.P. Morgan. (See *BioWorld Today*, Jan. 11, 2012.)

Members of the Alliance are seeking to keep the lines of communication open with the agency through frequent conversations "about common concerns," Van Bokkelen said. "Our experience with the FDA has been a very, very positive one. The FDA is anxious to learn from us, just as we are anxious to learn from them, about how we can work together to establish a more transparent regulatory framework." ■

Appointments and Advancements

• **Biocartis**, of Lausanne, Switzerland, appointed Nayan Gregory Parekh CEO.

• **Bionovo Inc.**, of Emeryville, Calif., added David Boyle as senior vice president and chief financial officer.

• **BioSpecifics Technologies Corp.**, of Lynbrook, N.Y., appointed George Gould to its board.

• **BioTime Inc.**, of Alameda, Calif., and its subsidiary, OncoCyte Corp., each appointed Andrew von Eschenbach to their boards.

• **Boston Therapeutics Inc.**, of Manchester, N.H., elected Henry J. Esber to its board.

• **Catalyst Pharmaceutical Partners Inc.**, of Coral Gables, Fla., named Richard P. Rieger vice president of commercial operations. Catalyst also promoted Alicia Grande to vice president, chief financial officer and treasurer.

• **CBio Ltd.**, of Brisbane, Australia, named Ralph Craven chairman and appointed Helen Cameron interim managing director.

• **Cerenis Therapeutics**, of Toulouse, France, appointed John F. Paolini chief medical officer and named Richard C. Pasternak to its board.