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PAGE 1 OF 7

Biotechs Going Commercial

Is the FIPCO Dead? Slow Starters May Burn Bright

By **Trista Morrison**
BioWorld Insight Editor

Editor's Note: This special reprint from BioWorld Insight is the second in a two-part series on newly commercial biotechs. To read Part I, which discussed why initial sales miss analyst expectations, email trista.morrison@bioworld.com.

Despite the fact that recent biotech product launches have fallen short of analyst expectations across the board, there's reason to believe these drugs might yet achieve their peak sales potential and foster a new wave of fully integrated pharmaceutical companies.

"There's value inherent in having an approved biologic for an unmet need," J.P. Morgan analyst Cory Kasimov wrote in a recent research note. He lowered his 2011 estimates for Savient Pharmaceuticals Inc.'s Krystexxa (pegloticase)

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An Easier Fix?

Are Splicing Mutations Behind Many Hereditary Diseases?

By **Anette Breindl**
Science Editor

Splicing made headlines earlier this week when researchers from the National Institutes of Health reported that telomere-induced changes to the splicing machinery appear to be a major mechanism of cellular aging. (See *BioWorld Today*, Jun 14, 2011.)

Now, a separate study has concluded that splicing may have a larger role in hereditary diseases than is currently recognized as well.

"We are proposing that 22 percent of human mutations in the Human Gene Mutation Database have some kind of splicing defect," William Fairbrother told *BioWorld Today*. Fairbrother is an assistant professor at Brown University and the senior author of the paper describing the findings, which appeared in the Jun 13, 2011, online edition of the

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New Co News

MingSight to Offer 'Bright' Solution for Diabetic Eye Disease

By **Marie Powers**
BioWorld Today Contributing Writer

Using technology acquired from Pfizer Inc., San Diego-based biotech MingSight Pharmaceuticals Inc. has its eye on an oral therapy for retinal diseases.

MS-553, the lead compound licensed under the exclusive worldwide agreement, has demonstrated efficacy in preclinical models of diabetic retinopathy (DR). A second compound also has demonstrated supportive properties in both in vitro and in vivo studies.

Eventually, the company hopes to develop therapies to treat not only DR but also diabetic macular edema (DME), uveitis and dry eye.

Michael Niesman, MingSight's chief scientific officer, left

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Coming at BIO 2011

Starting Up Biotechs in the New Normal World

Private biotechs raised just \$1.76 billion through May 2011 – putting this year on pace to come in below the \$4.48 billion raised last year and even the \$4.13 billion raised in 2008. But Seed and Series A funding – at 27.5 percent – accounted for more of the pie than usual . . . if you count a couple of hefty non-VC rounds.

Want to know more? Don't miss BioWorld's panel at BIO 2011:

**Starting Up Biotechs in the New Normal World
10 a.m. Wednesday, June 29, 2011, Room 149AB**

Speakers include Art Pappas of Pappas Ventures, Susan Molineaux of Calithera Biosciences Inc., Walter Ogier of Acetylon Pharmaceuticals Inc. and Ted Tenthoff of Piper Jaffray & Co.

The panel will be moderated by BioWorld Managing Editor Lynn Yoffee. For more information, visit BioWorld's

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INSIDE:

- OTHER NEWS TO NOTE: ABBOTT, ACTINOBAC BIOMED, AMARANTUS2
- CLINIC ROUNDUP: CORMEDIX, D-PHARM, IMMUNOGEN, NEURALSTEM7



Other News To Note

• **Abbott**, of Abbott Park, Ill., said the FDA approved an infant-specific dose of Creon (pancrelipase) delayed-release capsules to treat exocrine pancreatic insufficiency due to cystic fibrosis.

• **Actinobac Biomed Inc.**, of New Brunswick, N.J., reported in vivo data showing that the company's psoriasis candidate Leukothera was effective in treating the disease in a humanized mouse xenograft transplantation model. Studies showed that Leukothera, which is designed to work by targeting leukocyte function antigen-1 on diseased white blood cells, was as effective or more effective than once-marketed Raptiva (efalizumab, Genentech Inc./Roche AG), even when using significantly lower drug dosage levels. Data were published in the *Journal of Investigative Dermatology*.

• **Amarantus BioSciences Inc.**, of Sunnyvale, Calif., said it completed its capital restructuring initiatives, which included a 25-for-1 forward stock split. The firm, which is working on drugs for diseases related to protein misfolding and apoptosis, has about 67 million shares issued and outstanding.

• **Agenus Inc.**, of Lexington, Mass., announced that its wholly owned subsidiary Antigenics signed a license agreement with **Integrated BioTherapeutics Inc.**, of Gaithersburg, Md., for the use of Antigenics' QS-21 Stimulon adjuvant in the development of a vaccine against Ebola and Marburg viruses. Agenus said it is entitled to receive a license fee and potential milestone payments and worldwide royalties on net sales. Integrated BioTherapeutics was awarded a multi-year contract in September 2008 by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, for development of a vaccine to protect against Ebola and Marburg viruses.

Coming Thursday in *BioWorld Perspectives:*

'BioWorld Bytes,' Cranky Commentary by Cynthia Robbins-Roth

Read about bad drug names, the best science story from the past month and potential proof that bankers really are aliens – all in "BioWorld Bytes," a run-down of the weirdest and most newsworthy stories about biotech.

You can find "BioWorld Bytes" every month in *BioWorld Perspectives*.

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Stock Movers

06/14/11

Company	Stock Change
Nasdaq Biotechnology	+\$9.02 +0.84%
Chelsea Therapeutics	+\$0.37 +8.17%
Lorus Therapeutics Inc.	-\$0.11 -15.28%
Pacira Pharmaceuticals Inc.	-\$1.62 -12.25%
Pharmacyclics Inc.	+\$0.84 +10.46%
SIGA Technologies Inc.	-\$1.24 -10.25%

(Biotechs showing significant stock changes Tuesday)

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FIPCO

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after the gout drug's slow launch and disappointing first quarter sales, yet he maintained that Krystexxa's long-term value proposition – which analysts peg at between \$300 million and \$600 million worldwide – “has not dramatically changed.”

Ditto for Dendreon Corp.'s prostate cancer vaccine Provenge (sipuleucel-T). Sales of \$48 million in 2010 were one-third less than the \$72 million Cowen and Co. analyst Eric Schmidt was predicting a year ago. Yet Schmidt said there “appears to be plenty of demand” to satisfy Dendreon's 2011 sales guidance of \$350 million to \$400 million, and he expects Provenge to quickly become a blockbuster.

The story is similar for many recently launched biotech drugs: Auxilium Pharmaceuticals Inc.'s Xiaflex (collagenase clostridium histolyticum) for Dupuytren's contracture, Acorda Therapeutics Inc.'s multiple sclerosis drug Ampyra (dalfampridine), Dyax Corp.'s Kalbitor (ecallantide) for acute hereditary angioedema, AMAG Pharmaceuticals Inc.'s iron replacement therapy Feraheme (ferumoxytol), Allos Therapeutics Inc.'s peripheral T-cell lymphoma drug Folutyn (pralatrexate) and Avanir Pharmaceuticals Inc.'s Nuedexta (dextromethorphan hydrobromide and quinidine sulfate) for pseudobulbar affect.

Initial sales for each of those drugs failed to meet analyst expectations for a variety of reasons. Yet Schmidt said it's possible the “good drugs will still achieve their peak potential,” although “the shape of the curve has changed.” (See Part I of this article in *BioWorld Insight*, May 23, 2011.)

Looking at the Bottom Line

As the latest class of commercial biotechs overcome launch difficulties and improve their sales performance, several should start turning profits.

Dyax has said it will break even on cash flow in 2013 and turn the corner to profitability in 2014. Wedbush PacGrow LifeSciences analyst Greg Wade models Avanir becoming profitable in 2013. Jefferies analyst Thomas Wei predicts Auxilium will turn a profit in 2012.

Does that mean the much-touted fully integrated pharmaceutical company (FIPCO) business model isn't dead after all?

Back in 2005, you couldn't make it through a biotech investor presentation without hearing about “multiple shots on goal.” Companies were built with broad pipelines and positioned for IPOs, all with the hope that they'd grow independently and eventually launch a handful of products, becoming the next Amgen or Genentech.

But after the 2008 financial crisis, “tightly focused” became the catchphrase of the day. Biotechs emphasized whatever single product would give them the best chance of being acquired. More than a few experts proclaimed that the FIPCO business model was dead. (See *BioWorld*

Insight, June 15, 2009.)

The newest commercial biotechs seem to have the potential to become earnings stories, even with just one product.

Michael Schick, vice president of sales and marketing at Allos, said that his company absolutely could become profitable based on Folutyn alone – particularly if the drug becomes the backbone of treatment regimens for both solid and liquid tumors as Allos intends.

“It's silly to say the FIPCO model is dead,” Schmidt told *BioWorld Insight*, pointing to Alexion Pharmaceuticals Inc. as a biotech that launched a product and became profitable within the last five years. “Companies that have great drugs will realize their commercial potential and become great stocks. Nobody in biotech investing is giving up on that.”

Yet Piper Jaffray & Co. analyst Ted Tenthoff isn't so sure how many FIPCOs biotech will see in the future. He noted that the biggest success stories – including Genentech Inc., Genzyme Corp., MedImmune Inc. and others – have been acquired by big pharma. Even companies that are on track to become FIPCOs – like Plexxikon Inc. and Calistoga Pharmaceuticals Inc. – are increasingly being bought out. Future potential FIPCOs like Vertex Pharmaceuticals Inc. and Regeneron Pharmaceuticals Inc. have been named as possible acquisition targets as well, although Tenthoff said he hopes they remain independent and grow much larger.

Will the latest commercial biotechs remain independent? That's “the best way for shareholders,” Dyax President and CEO Gustav Christensen told *BioWorld Insight*. But he added that if someone “bids so much that the shareholders vote you out, then it's out of your control.”

Does FIPCO Have a Future?

While a handful of biotechs have launched products and become FIPCOs over the past few years, and a handful more are poised to follow in their footsteps, venture investor Stephen Bloch noted that all of these companies have been around a long time and have been able to access a lot of capital in the public markets.

Vertex, for example, recently said during a conference call that it took \$4 billion and 20 years to get to last month's FDA approval of hepatitis C drug Incivek (telaprevir). (See *BioWorld Today*, May 24, 2011.)

Bloch, a general partner with Canaan Partners, said building a company with a “grand vision” – like Vertex or Millennium – takes an “enormous amount of capital.” Even building a company with just one or two products takes a lot of resources, he said. Those resources are not available through an initial public offering and subsequent public financings like they were for biotechs in the past, and venture capitalists are not going to put up that kind of money.

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Splicing

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Proceedings of the National Academy of Sciences.

Adding those 22 percent to the diseases where alternate splicing has already been identified as the cause, nearly one in three hereditary diseases may have malfunctioning splicing at their root.

Splicing, which cuts out and pastes together the coding parts, or exons, of a gene after transcription and pastes them together into the final messenger RNA that will be used to make the protein, is commonplace: "It happens about 10 times, on average, in a human gene," Fairbrother said. And sometimes, alternative splicing is part of the genome's way of making slightly different versions of the same protein. But at other times, alternative splicing can wreak havoc on a protein's function. (See *BioWorld Today*, July 20, 2009.)

Splicing may be basic, but that doesn't mean that figuring it out was simple. "For a long time, it was not clear how the cell knew" which parts to cut, Fairbrother said. The RNA sequence contains "a little bit of information," on where to splice the unprocessed RNA transcript, he said, but not nearly enough. In an average intron of perhaps 100,000 base pairs length, "could have hundreds of sites that look like perfectly good splice sites, but are never chosen."

The discovery of enhancers and silencers – helper sequences located within the exons themselves – solved part of the mystery of how the spliceosome recognizes its work sites. They are "very dependent on position," Fairbrother said – "they had to be at a certain place" relative to the splice site itself. Some splicing proteins can either increase or decrease splicing, depending on whether the RNA sequence they bind to is in the exon or the intron of an RNA sequence.

In their new paper, Fairbrother and his team took an alternate approach to identifying splicing signals. They began from the idea that "we know where all the splice sites are," and went from there to analyze all the hexamers, or six-nucleotide sequences, surrounding them.

In a nutshell, the approach amounts to counting how often a given six-letter sequence appears around the known splice sites, and comparing it to how often that sequence would be expected. Fairbrother and his team soon found certain sequences "will either tend to be avoided around splice sites, or be more frequent."

After identifying potential splice signaling sequences, Fairbrother and his team tested those sequences further, to see how different their distribution was from what would be expected. They found that sequences with a larger difference between the expected and observed distributions were more likely to affect splicing.

The authors next went back to the bench and tested mutations associated with diseases including albinism and colorectal cancer that their program had predicted would affect splicing. They found that four out of the six mutations they tested did indeed affect splicing.

If splicing is in fact behind a large number of hereditary diseases, that could be good news in terms of treating such diseases – both because it might enable targeting of a few splicing signals, rather than a plethora of mutated proteins, and because the targeting itself could be easier than alternative approaches such as gene therapy.

"A processing defect," Fairbrother said, "may be able to be detected and fixed much more easily and safely than a protein coding defect."

Companies such as Isis Pharmaceuticals Inc. and AVI Biopharma Inc. are in the clinic with RNA-based therapeutics that attempt to influence splicing. ■

FIPCO

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It's a rare biotech indeed that can get a product all the way to approval without tapping the public markets or tying itself to a big pharma partner. Gloucester Pharmaceuticals Inc. did it in 2009 with cutaneous T-cell lymphoma drug Istodax (romidepsin) – and was promptly acquired by Celgene Corp. (See *BioWorld Insight*, Nov. 16, 2009.)

Between the scarcity of capital and the abundance of big pharma business development activity, Bloch doesn't expect to see any next-generation Amgens or Biogens emerging any time soon. But that's not necessarily a bad omen for the future of the biotech industry.

Bloch – like many VCs – believes small companies and big companies have different strengths. "I'd like to think small companies can succeed at innovation and have a ready and willing group of partners willing to pay for it," he told *BioWorld Insight*. Biotech can be big pharma's pipeline, he added, and "there is not anything wrong with that." ■

Other News To Note

- **Cell Therapeutics Inc.**, of Seattle, said a recent meeting with the FDA's Division of Oncology Drug Products produced a pathway for resubmitting the company's new drug application for pixantrone for relapsed or refractory aggressive non-Hodgkin's lymphoma, including the potential for accelerated approval based on the PIX301 study results. The company said it anticipates filing additional information later this year, and could obtain FDA approval in the first half of 2012.

- **Evolva Holding SA**, of Reinach, Switzerland, announced that **Roche AG**, of Basel, Switzerland, will make a milestone payment of an undisclosed amount related to the achievement of diverse, purified active compounds that derive from Evolva's synthetic biology platform. Evolva said the collaboration with Roche, which began in January 2010, uses Evolva's technology platform to create compounds with activity on targets in oncology and infectious disease.

MingSight

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academic ophthalmology research in 1998 to join the Lajolla, Calif.-based biotech start-up Agouron Pharmaceuticals Inc., which was acquired by Warner-Lambert Co. in 1999 before that firm was subsequently swallowed up by Pfizer. (See *BioWorld Today*, Nov. 5, 1999.)

Niesman headed Pfizer's ophthalmology research until 2009, when the program was among a slew of indications axed by the company as it reshuffled its priorities. (See *BioWorld Today*, Oct. 1, 2008.)

Niesman and colleagues pursued several opportunities to spin out the ophthalmology assets while they were still inside Pfizer, but their efforts were hampered by the global financial crisis. Serendipitously, a venture capitalist introduced Niesman to Kai Zhang, a physician with experience in the pharmaceutical industry who had moved to San Diego and was interested in starting a company. The two began to talk, and by the end of 2009, they had formed MingSight – a name that incorporates the Chinese word for “bright.”

MS-553 is the product of the Pfizer's most advanced ophthalmology program, according to Niesman. Targeting DR, the compound involves components to treat both the leakage produced by high glucose levels in the blood as well as the inflammatory cascade that occurs when the condition becomes chronic, leading to diabetic macular edema (DME). In a diabetic mouse model, MS-553 reduced retinal leakage by 100 percent after just three days of treatment. A precedent compound obliterated 95 percent of the retinal leakage induced by vascular endothelial growth factor (VEGF) – one of the key drivers of diabetic eye disease.

Importantly, those results were produced after diabetes was well established, working “in an intervention mode, not a prevention mode,” Niesman told *BioWorld Today*.

In addition, MS-553 has anti-inflammatory properties, down-regulating the expression of Intercellular Adhesion Molecule-1, or ICAM-1, and reducing retina leukostasis by 80 percent to 90 percent. MS-553 also has demonstrated normalized retinal flow in diabetic animals and humans.

Oral administration – the compound would be taken once daily – provides for better ocular efficacy and lower systemic toxicity than invasive treatments such as Lucentis (ranibizumab, Roche AG and Novartis AG) and off-label Avastin (bevacizumab, Roche), Niesman said. Although clinical trials of those drugs have suggested promising prospects for treating DR and DME, “the best results require an injection about once a month, and for a young diabetic patient with diabetic macular edema, that's a daunting proposition,” he observed.

Even in pill form, MS-553 crosses the blood-retina barrier to achieve high concentrations in the retina.

“Our hypothesis is that we can achieve that kind of

efficacy with an oral treatment, with better compliance and no side effects from the intraocular injection,” Niesman said.

As part of the licensing agreement, signed in October 2010, MingSight agreed to pay Pfizer an undisclosed up-front fee and a convertible note as well as development and sales-related milestones and royalties on future sales. The company also established a joint venture with an undisclosed pharmaceutical manufacturer in China, which is providing financial support to move the compound through chemical manufacturing and control and toxicity studies and gear up for production there.

MingSight retains the rights to MS-553 outside China and, long term, hopes to attract a global development partner.

Though officials declined to specify how much the company has raised to date, the amount is sufficient to advance the compound to commercialization in China, according to Zhang, the company's CEO and only other full-time employee. MingSight expects the funding to cover its budget through Phase II U.S. studies of MS-553, as well.

The compound was nearly ready to enter safety studies when Pfizer halted the ophthalmology program, “so we're picking it up from there,” Niesman said. “We're about 14 months away from first in humans.”

Competitors continue to emerge in the diabetic eye disease space. In addition to Lucentis and Avastin, last month Molecular Partners AG, of Schlieren, Switzerland, secured a potential \$420 million deal with Irvine, Calif.-based Allergan Inc. for its lead molecule, the VEGF antagonist MPO12, in ophthalmic indications. (See *BioWorld Today*, May 5, 2011.)

At the Association for Research in Vision and Ophthalmology meeting in Fort Lauderdale, Fla., Molecular Partners reported positive data from two Phase I/IIa trials in patients with wet age-related macular degeneration or DME.

But the fact that MS-553 had a track record at Pfizer – and is administered orally – differentiates MingSight in the market, Niesman said.

“This was licensed out from a big pharma, so it has a very strong background,” he explained. “The compound itself was formulated in a structure-based drug design program, so it's quite potent and selective. Plus, when we give this compound orally, we get good exposure levels in the eye without having to give a large dose. We'll have a combination of safety and efficacy without having to resort to invasive administration.” ■

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Wondering What You Missed in *BioWorld Insight*?

Cancer Treatment: From Targeted to Genomics

George Sledge, outgoing president of the American Society of Clinical Oncology, has a rather catchy way of summarizing where cancer treatment needs to be going. In a nutshell, oncologists and drug developers are now smarter than “stupid cancers,” and they need to become smarter than “smart cancers.” But how?

Reputation Rx: Genentech Leads, Others Play Catch Up

Despite its acquisition by Roche AG, Genentech Inc. still has the best image amongst oncologists and hematologists, according to a study by Market Strategies International. *BioWorld Insight* explored what it takes to be beloved by cancer docs – including how both sales and research efforts factor into the equation – and what oncology companies need to do to compete with Genentech.

As Cancer Trial Costs Mount, Sponsors Look Broad, Virtual

Data presented at the annual meeting of the American Society of Clinical Oncology confirmed that more clinical trials focus on cancer than any other disease, sparking debate about how to control the costs of those trials and – ultimately – of the many new cancer drugs coming onto the market. Among the approaches being explored: broader Phase II trials, smaller sample sizes and virtual trials.

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Other News To Note

- **IntelGenx Corp.**, of Saint Laurent, Quebec, executed a binding term-sheet with **RedHill Biopharma Ltd.**, of Tel Aviv, Israel, to co-develop and license an antipsychotic oral thin film product based on its VersaFilm drug delivery technology. The termsheet sets out criteria for a future agreement, under which RedHill would obtain exclusive worldwide rights to market and sell IntelGenx’s product in exchange for up-front, milestone and external development fees totaling up to \$2.3 million. Upon commercialization, IntelGenx would receive up to 50 percent of all proceeds. The company also reported that the FDA accepted the company’s resubmission of its new drug application for antidepressant CPI-300, in response to a February 2010 complete response letter, as a complete, Class 2 response and set Nov. 13 as the target PDUFA date.

- **Pacira Pharmaceuticals Inc.**, of Parsippany, N.J., reported that the FDA extended the PDUFA date for its review of the new drug application for Exparel (bupivacaine extended-release liposome injection), for postoperative analgesia by infiltration, by three months to Oct. 28. The company said it submitted additional information requested by the FDA, which determined that the information constituted a major amendment.

- **Teva Pharmaceutical Industries Ltd.**, of Jerusalem, and **Cephalon Inc.**, of Frazer, Pa., announced that each company has received a request for additional information from the U.S. Federal Trade Commission in connection with Teva’s pending acquisition of Cephalon. The companies said they have been and intend to continue cooperating with the FTC to obtain clearance. (See *BioWorld Today*, May 3, 2011.)

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Clinic Roundup

• **CorMedix Inc.**, of Bridgewater, N.J., completed patient enrollment in its Phase II CI-AKI (Contrast Induced Acute Kidney Injury) study of CRMD001. The trial is designed to test safety and efficacy of the drug on biomarkers of acute kidney injury and kidney function. CorMedix expects to report final results before year-end. CRMD001 is a formulation of oral iron chelator deferiprone.

• **D-Pharm Ltd.**, of Rehovot, Israel, said the protocol for its ongoing Phase III study of neuroprotective candidate DP-b99, published in the *International Journal of Stroke*, calls for the evaluation of safety and therapeutic effects of intravenous 1 mg/kg/day DP-b99, initiated within nine hours of stroke onset in patients with moderately severe hemispheric acute ischemic stroke, as the primary objective. The primary efficacy outcome is the mRS score at day 90. The study, dubbed MASCI (Membrane Activated Chelator Stroke Intervention), will enroll 770 patients and is being conducted under a special protocol assessment with the FDA.

• **ImmunoGen Inc.**, of Waltham, Mass., said Bayer HealthCare Pharmaceuticals, a unit of Berlin-based **Bayer AG**, filed an investigational new drug application for TAP (Targeted Antibody Payload) candidate BAY 94-9393, triggering a \$2 million milestone payment to ImmunoGen. That compound emerged from the companies' collaboration involving ImmunoGen's TAP technology to develop cancer drugs targeting mesothelin. Under the terms, ImmunoGen could receive milestones of up to \$170.5 million for each program, plus royalties on sales.

• **Neuralstem Inc.**, of Rockville, Md., said the safety monitoring board unanimously approved advancing the ongoing Phase I trial of the company's spinal cord stem cells in amyotrophic lateral sclerosis patients to transplantation in the cervical region. The next three patients, all of whom are ambulatory, will each receive five injections, unilaterally, in the cervical spinal cord. The FDA also must approve the trial's advancement to the next level of transplantations. Neuralstem said it anticipates presenting data from the first 12 patients who received injections in the lumbar region of the spine only to the FDA in the near future.

• **Neurelis Inc.**, of San Diego, said results of a randomized, crossover pilot study in healthy volunteers showed a similar bioavailability of NRL-1, its intranasal diazepam, compared to intravenous administration. NRL-1 also was well tolerated, with only mild adverse events reported.

• **Orexo AB**, of Uppsala, Sweden, reported data from the first OX27 pharmacokinetic trial showing that three different doses, administered to healthy subjects, indicated that the active pharmaceutical ingredient in the sublingual tablet was rapidly absorbed and subsequently eliminated,

rendering the product suitable for treating breakthrough cancer pain. Orexo plans to initiate and complete the next clinical study in healthy volunteers in the fourth quarter of this year.

• **QRxPharma Ltd.**, of Sydney, Australia, completed Study 022, an exploratory Phase III study comparing the tolerability and safety profile of MoxDuo IR to equi-analgesic doses of either morphine or oxycodone alone, with data showing that MoxDuo effectively reduced pain with less respiratory depression.

• **Sangart Inc.**, of San Diego, started a Phase IIb study of MP4OX, an oxygen therapeutic agent, plus standard of care in severely injured trauma patients with lactic acidosis due to hemorrhagic shock. About 360 patients will be enrolled, and the primary objective is to measure the proportion of patients discharged alive from the hospital, as well as a number of secondary endpoints, including lactic acidosis resolution.

• **Tengion Inc.**, of East Norriton, Pa., said it is working to collect additional clinical data while modifying the surgical approach for future implants for the Phase I trial with its Neo-Urinary Conduit candidate in patients with bladder cancer who have had cystectomies. The firm expects to submit those data and changes to the FDA in the third quarter, prior to enrolling additional patients in the trial.

• **TwI Biotechnology Inc.**, of Taipei, Taiwan, said the company enrolled more than 50 percent of the total 240 patients for its Phase IIb trial of AC-201 in Type II diabetes. The study is designed primarily to evaluate the HbA1c-lowering effects, while the cardiovascular safety profile will be monitored according to FDA guidance. AC-201 is an oral small molecule aimed at modulating the transcriptional cytokine synthesis of IL-1 beta and IL-1RA.

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