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Radius Follows Up Reverse Merger with 'Reverse' IPO

By Catherine Shaffer
Staff Writer

Radius Health Inc. is the latest to join the ranks of biotech companies with pending initial public offerings (IPOs).

The Cambridge, Mass.-based firm specializes in developing therapeutics for osteoporosis and indications relevant to women's health. Its lead product candidate is a synthetic peptide analogue of human parathyroid hormone-related protein (hPTHrP), designated BA058.

Funds from the potential offering will support the company's goals, including completing a pivotal Phase III study of BA058 injection for osteoporosis in the first half of 2014. It has not yet specified a number of shares or a price range, but the maximum offering price listed was $86.25 million.

Radius' public offering is not a typical IPO. The company started the process of becoming public in early

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Financings Roundup

Synchroneuron Raises $6M for Movement Disorders Candidate

By Marie Powers
Staff Writer

Privately held Synchroneuron Inc. raised $6 million in a Series A financing from Morningside Ventures to advance a candidate targeting tardive dyskinesia (TD) and related movement disorders.

Waltham, Mass.-based Synchroneuron was founded by Barry Fogel, a neurologist and psychiatrist who serves as the company's chief scientific officer, along with the principals of Accellient Partners, a privately held drug development organization also based in Waltham.

Accellient partner and CEO William Kerns, who serves as Synchroneuron's interim CEO, is an entrepreneur whose resume in drug development includes tenure at Eisai Co. Ltd. and SmithKline Beecham (now GlaxoSmithKline plc), where Kerns helped to bring new compounds through

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PharmaFocus

'Back to the Future' as GSK Hopes to Boost Innovation

By Nuala Moran
Staff Writer

Editor's note: BioWorld has always kept a watchful eye on big pharma developments as they relate to the biotech space. Now we're introducing a new feature that will occasionally delve deeper into big pharma issues.

LONDON – By splitting its internal research effort into dozens of small teams, with each focusing on a particular disease or pathway, GlaxoSmithKline plc is on track to solve its productivity woes and push its return on investment in R&D to 14 percent.

"We are now more confident than ever we have the right model," said CEO Andrew Witty, following a three-year review of the 38 Discovery Performance Units (DPUs). GSK formed

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NewCo News

Oligomerix Targets Tau Protein To Tackle Alzheimer's Disease

By Catherine Shaffer
Staff Writer

New York-based biotech start-up Oligomerix Inc. is pressing a multipronged attack against tau protein, an alternate Alzheimer's disease target, using a combination of small-molecule and antibody therapeutics coupled with biomarker strategies.

Formed in 2006, Oligomerix adopted the tau protein theory of Alzheimer's disease origin over the more popular beta amyloid theory.

Specifically, it is focusing on small, cellular oligomers of tau. "A lot of evidence in the literature suggested these were the more neurotoxic entities relative to other types of aggregated species," Jack Pasini, chief commercial

See Oligomerix, Page 6

AHC Media

Other News To Note

• **Acorda Therapeutics Inc.**, of Hawthorne, N.Y., partnered with a subsidiary of **Watson Pharmaceuticals Inc.**, of Parsippany, N.J., to launch an authorized generic version of Zanaflex (tizanidine hydrochloride) capsules for spasticity. Acorda will receive a royalty, but specific terms were not disclosed.

• **Alexion Pharmaceuticals Inc.**, of Cheshire, Conn., completed its acquisition of Montreal-based **Enobia Pharma Corp.**, gaining midstage enzyme therapy candidate asfotase alfa for ultra-orphan disease hypophosphatasia. The deal, disclosed in late December, calls for Alexion to pay $610 million up front, and up to $470 million in sales and regulatory milestones. (See *BioWorld Today*, Jan. 3, 2012.)

• **Almirall SA**, of Barcelona, Spain, made regulatory submissions for Sativex to a number of European countries including Belgium, Finland, Iceland, Ireland, Luxemburg, the Netherlands, Norway, Poland, Portugal and Slovakia. The submission was made to health authorities by **GW Pharmaceuticals plc**, of Salisbury, UK, under a mutual recognition procedure. A response is expected within the first half of 2012, and the approval processes will continue in each country according to local regulations.

• **Amicus Therapeutics Inc.**, of Cranbury, N.J., received a two-year, $186,000 grant from the Muscular Dystrophy Association (MDA) to evaluate the effect of the pharmacological chaperone AT2220 (duvoglustat HCl) on immunogenicity related to the enzyme replacement therapy (ERT) alglucosidase alfa, the only approved treatment for Pompe disease. As part of the MDA grant, Amicus will investigate the ability of AT2220 to mitigate ERT-specific immunogenicity from blood samples obtained in the ongoing open-label Phase II drug-drug interaction study of AT2220 co-administered with ERT in individuals with Pompe disease and from normal donors.

• **Cadence Pharmaceuticals Inc.**, of San Diego, voluntarily recalled a single lot of Ofirmev (acetaminophen injection), lot number V005710, due to the presence of an unidentified, visible particle in one vial of that lot during routine stability testing. Cadence contended that fewer than 1,000 vials remain in the market, and it has not received any reports of adverse patient events associated with particulate matter in the product.

• **EpiCept Corp.**, of Tarrytown, N.Y., filed for fast-track designation of AmiKet (amitriptyline 4 percent, ketamine 2 percent cream) in chemotherapy-induced peripheral neuropathy. The firm is seeking a special protocol assessment from the FDA on a Phase III trial.

• **Genentech Inc.**, of South San Francisco, a unit of the Roche Group, said the FDA accepted its biologics license application and granted priority review for pertuzumab in combination with Herceptin (trastuzumab) and docetaxel chemotherapy in HER2-positive metastatic or locally recurrent, unresectable breast cancer patients who have not received previous treatment or whose disease has relapsed after adjuvant therapy. The FDA confirmed the action date of June 8.

Stock Movers

2/7/12

Company	Stock Change	
Nasdaq Biotechnology	-$9.62	-0.76%
Achillion Pharmaceuticals Inc.	-$1.19	-10.33%
Astex Pharmaceuticals Inc.	-$0.60	-21.51%
DARA Biosciences Inc.	+$0.43	+26.87%
Galena Biopharma Inc.	-$0.25	-19.84%
Immunocellular Therapeutics	+$0.25	+15.15%
NeurogesX Inc.	-$0.27	-23.61%

(Biotechs showing significant stock changes Tuesday)

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Radius

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2011 by merging with MPM Acquisition Corp., an unlisted public reporting shell company. The surviving company was named Radius Health Inc., continuing as a reporting company with the SEC.

The maneuver set Radius up to become a public company upon registration of its private stock for resale with the SEC.

The order of events was reversed from a standard IPO. According to Radius, a traditional IPO would bring significant uncertainty in terms of proceeds as it entered Phase III trials with its lead product. Instead, it raised $91 million in equity and debt financing, followed by a shift to public status about nine months later. (See *BioWorld Today*, May 25, 2011.)

Radius has generated more than $197 million in funding since its founding in 2003.

Its prospects for success on the public markets are uncertain. On one hand, Boston-based Verastem Inc. had a very successful recent offering, and even surged 10 percent above its offering price on its first day of trading. Verastem's IPO raised hopes that the chilly IPO market was warming up. (See *BioWorld Today*, Jan. 30, 2012.)

But shortly after Verastem's debut, Cempra Inc. took a huge cut below its $11 to $13 target range to make its IPO. Cempra sold 8.4 million shares for $6 apiece, raising a total of $50.4 million. And, unfortunately, Cempra's experience is more representative of recent IPOs than Verastem's. (See *BioWorld Today*, Feb. 6, 2012.)

Radius began dosing patients in a Phase III trial of BA058 in April 2011. The trial will enroll 2,400 patients in Europe, Latin America and Asia. Therapy with BA058 injection 80 mcg will last for 18 months, with data anticipated in 2013.

The primary endpoints of the study are safety and efficacy compared to placebo for prevention of vertebral fractions in otherwise healthy postmenopausal women ages 50 to 85 who have severe osteoporosis.

The trial also will compare BA058 to Forteo (terparatide, Eli Lilly and Co.) with regard to secondary efficacy outcomes like bone mineral density of the spine, hip and femoral neck and hypercalcemia.

Forteo had worldwide sales of $830 million in 2010, but Radius believes that BA058 may show greater efficacy, faster benefit and offer a shorter therapy course.

Radius completed its Phase II trial of BA058 in 2009. Data from that trial showed that the drug significantly increased bone mineral density of the lumbar spine and femoral neck after six months.

Improvements were even greater in a subgroup treated for 12 months, and at both time points BA058 outperformed Forteo.

However, Radius's partner, Novartis AG, passed on an option attached to its 2007 partnership deal. That deal was worth up to $500 million, but the Swiss big pharma decided not to exercise an option that would have given it exclusive, worldwide rights to the drug outside of Japan. (See *BioWorld Today*, Sept. 18, 2007.)

Radius also is developing BA058 in the form of a microneedle patch in partnership with 3M Drug Delivery Systems, of St. Paul, Minn., for osteoporosis.

In December 2011, Radius reported that transdermal BA058 microneedle patch showed positive results in a Phase Ib trial, showing rapid release of drug and increase of bone formation marker P1NP in serum after seven days. The drug was tested in a group of 74 healthy postmenopausal women.

In addition to BA058 injection and BA058 microneedle patch, Radius's pipeline includes RAD1901, licensed from Eisai Co. in 2006, for hot flashes associated with menopause.

UBS Investment Bank and Leerink Swann LLC are acting as joint book-running managers and underwriters for the offering. Cowen and Co. LLC and Rodman and Renshaw LLC are named as co-managers.

Upon pricing, Radius' stock will trade under the symbol "RDUS" on NASDAQ. ■

Other News To Note

• **Jennerex Inc.**, of San Francisco, published data in *Molecular Therapy* that validated mechanisms by which its product, JX-594, targets and kills cancer cells. The study showed multiple mechanisms that were dependent on biological traits of the cells. Replication of JX-594 was activated by epidermal growth factor receptor/Ras pathway signaling, cellular thymidine kinase levels and cancer cell resistance to Type I interferons.

• **NeurogesX Inc.**, of San Mateo, Calif., saw its shares plummet 24 percent after the FDA's Center for Drug Evaluation and Research (CDER) released briefing documents for the Anesthetic and Analgesic Drug Products Advisory Committee meeting, scheduled for Feb. 9, to discuss Qutenza for the management of neuropathic pain associated with HIV-PN. The CDER document cited "statistical concerns regarding multiplicity" and said the absence of replicated statistically significant results "have raised the question of whether evidence of substantial efficacy has been demonstrated for this proposed treatment regimen." Although CDER acknowledged the unmet need to control the "often severe and disabling" neuropathic pain in HIV, "it would not be in the best interest of these patients for us to approve a product for which substantial evidence of efficacy has not been demonstrated, or one for which the benefits do not clearly outweigh the risks," according to the briefing document. The stock (NASDAQ:NGSX) lost 27 cents, or 23.6 percent, closing Tuesday at 88 cents, on 10 times its average trading volume.

Financings Roundup

Continued from page 1

investigational new drug-enabling programs, regulatory approvals and early clinical trials.

For now, Accellient will manage Synchroneuron as a virtual drug development company, with Fogel as Synchroneuron's only employee.

In his practice, Fogel said he had seen a number of patients with TD, which results from exposure to dopamine receptor-blocking drugs, including antipsychotics as well as drugs used to prevent nausea and vomiting. TD can develop in weeks to months, according to Fogel, causing often irreversible and disfiguring facial tics as well as involuntary movements of the body and limbs. At worst, the drugs convert psychiatric patients into neurology patients, he said, "because people become more disabled by the movement disorder than they were by the original psychiatric condition."

The FDA has no approved drugs designed to treat TD, so Fogel set about to fill that gap. First, he examined the underlying mechanism, discovering that "this is not about dopamine." Rather, TD is caused by an imbalance between excitatory and inhibitory neurotransmission, "causing oscillating loops in the brain that generate these movements," Fogel explained.

Next, Fogel searched for – and found – existing compounds with the ability to affect both glutamate and GABA transmission. One compound, in particular, was safe but poorly absorbed.

"In order to get a therapeutic effect, you had to give someone nine or 10 pills a day," he said. "That's not something patients can easily tolerate, particularly when they're on other medications."

With seed financing from family and friends, Fogel formed a company and applied for a number of patents with the goal of reformulating the active ingredient, which he declined to name. Although TD is the initial indication, the compound has potential applications in Parkinson's disease, Tourette's syndrome and other movement disorders, he said.

In 2004, Fogel licensed the patents to a venture-funded pharmaceutical company to conduct the reformulation work. After three years on the back burner, the patents reverted to Fogel and he decided his own start-up would give the drug more attention and greater resources. An introduction to Kerns led to the interest by Accellient and the formation of Synchroneuron, whose name references the "synchronicity" in the drug's discovery as well as its synchronized action.

Since the compound has a well-established safety profile, the company expects to complete the reformulation work within several months and begin Phase I trials during the second half of 2012. A Phase IIa proof-of-concept study is expected to begin in the first quarter of 2013.

"If we have a superior formulation developed in the laboratory, getting an [investigational new drug application] and bringing it into the clinic to do some pharmacokinetic studies in human volunteers is very realistic," Fogel said.

The Series A should see Synchroneuron though the Phase IIa program, which is expected to report top-line data by the end of 2013, Kerns said. Long term, the company will consider whether to market an approved drug in-house or seek to license the compound following Phase II, he added.

Several other biotechs are seeking to exploit the relationship between GABA and glutamate. Third Rock start-up Sage Therapeutics, of Boston, raised $35 million last year to develop therapies for schizophrenia, depression, pain and traumatic brain injury based on modulation of GABA and glutamate neurotransmitters. (See *BioWorld Today*, Oct. 18, 2011.)

And Seaside Therapeutics Inc., of Cambridge, Mass., is examining whether its investigational compound, STX209, may have efficacy against the core symptoms of Fragile X syndrome. The company hypothesizes that the pathologies of Fragile X and some autism spectrum disorders also are caused by excessive activation of glutamate receptors and an imbalance of excitatory to inhibitory neurotransmission in the brain. (See *BioWorld Today*, June 3, 2011.)

In other financing news:

• **Spherix Inc.**, of Bethesda, Md., said it closed its $1.15 million public offering of common stock and warrants. The firm issued about 1.1 million shares priced at $1.08 each, plus warrants to purchase an additional 212,963 shares at an exercise price of $1.40 per share. Net proceeds are expected to support continued development of SPX-106T, as well as general development and commercialization efforts.

• **Synta Pharmaceuticals Corp.**, of Lexington, Mass., sold 1.05 million additional shares in a fully exercised overallotment of its public offering, generating additional net proceeds of approximately $4.3 million. Jefferies & Co. Inc. acted as the sole book-running manager for the offering, with Canaccord Genuity Inc. and Roth Capital Partners LLC acting as co-managers. ■

Other News To Note

• **Pieris AG**, of Freising, Germany, received a €1 million (US$1.325 million) grant for development of PRS-110 in cancer. The funding will specifically fund work on a biomarker strategy. Pieris will present preclinical results for PRS-110 at the upcoming American Association for Cancer Research annual meeting.

• **Pluristem Therapeutics Inc.**, of Haifa, Israel, said it plans to expand its R&D efforts in acute radiation exposure. Pluristem's PLX cells previously were shown to mitigate acute radiation syndrome and increase survival in animal models.

GSK

Continued from page 1

those in 2008 as it set about tackling patent expiries and the fact that for the previous decade new approvals had stalled at two product line extensions per year.

The DPUs are expected to deliver 30 new Phase IIb assets over the next three years. "This increase in productivity would mean GSK is moving toward sustainable replenishment of its late-stage pipeline with no increase in cost," Witty said.

R&D expenditure is no longer determined as a percentage of sales, but instead allocated using very strict return on investment criteria. In 2012, R&D spending will be broadly the same as 2007, at around £3.7 billion (US$5.9 billion). However, the introduction of DPUs saw R&D staff numbers fall by 4,500 to 10,500. The amount of lab space fell by 45 percent and fixed costs by 20 percent.

In 2006, London-based GSK had six compounds in Phase III; now it has 15 compounds in Phase III, with 30 ongoing Phase III trials, representing a very significant increase in output from that smaller cost base.

The DPUs were set up around four key principles, including focusing on the best science and going outside the company to find the best projects. As a result, the number of external partnerships at GSK has risen from 10 in 2006 to 50 now.

The reform of the R&D organization "has transformed the capability of the business," Witty said addressing GSK's annual results meeting in London Tuesday.

There are now more than 200,000 patients in active clinical trials compared to 100,000 in 2007 and the formation of DPUs "has brought back to life creativity" and "completely transformed the story of discovery," Witty said.

The DPUs will continue to be subject to regular and disciplined assessments. "We will consistently prune and focus," Witty added. The three-year review was carried out by a board that included senior R&D staff in GSK, alongside venture capital investors in pharma and biotech and payers.

At the heart of how DPUs have increased productivity has been giving scientists greater personal accountability and more scope to achieve their potential. Individual researchers are invited to suggest projects that GSK should follow, and new DPUs have been funded as a result. Putting all experts in the same place also has been helpful. Before the changes, GSK had neuroscience researchers spread across three sites in three time zones, and chemists and biologists were in separate laboratories.

The DPUs have "created greater potential for serendipity" and "the chance for spontaneous insights," Witty said. That may look like "back to the future" for anyone who worked in a drugs lab in the 1970s and 1980s, "but you can take it from me, it's transformed our culture," Witty said.

In parallel with reforming R&D, GSK has expanded into emerging markets and now derives 38 percent of its revenues from outside the traditional pharma markets in Europe and the U.S. The move has had the effect of depressing margins, but the new products that are coming through the pipeline will provide the opportunity to start increasing margins again. That will particularly be the case in the U.S., where Witty said GSK "has burnt off the patent cliff," and in Japan, where reforms to patents rules and pricing have made the country more receptive to innovative products.

Europe, on the other hand has slipped in terms of its willingness to pay for innovation.

"We have to face the reality that's it's about the U.S. and excitingly about Japan in terms of where innovation should be driven," Witty noted. Given a propensity "not to pay for innovation," Europe will not be driving the company's agenda in the same way. GSK has halved its headcount in Europe and will be staging fewer clinical trials there.

Although Europe is a very heterogeneous market, there are two general phenomena – price cuts and extensive delays in getting new products approved and reimbursed – that are discouraging GSK and leading it to focus elsewhere.

"Europe is stuck in a bad place," Witty said. "We will still register drugs in Europe, but we won't [shape] them for Europe." ■

Clinic Roundup

• **Aduro BioTech Inc.**, of Berkeley, Calif., reported Phase I data showing intravenous administration of ANZ-100 and CRS-207 was well tolerated in subjects with advanced treatment-refractory cancers. Data also showed evidence of immune activation, induction of tumor-specific immunity and that 37 percent of end-stage cancer subjects treated with CRS-207 lived 15 months or longer. Those results were published in *Clinical Cancer Research*. ANZ-100 is the first candidate based on Aduro's live-attenuated, double-deleted *Listeria monocytogenes* vaccine platform, while CRS-207 is further engineered to express mesothelin.

Other News To Note

• **Prismic Pharmaceuticals Inc.**, of Scottsdale, Ariz., acquired the assets of UK-based **Scarista Ltd.**, including an exclusive license to London-based **Amarin Corp. plc**'s intellectual property portfolio covering highly purified forms of omega-3 fatty acids for central nervous system disorders. Terms were not disclosed. Prismic said it is now looking to partner those assets with one or more pharmaceutical companies.

Oligomerix

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officer for Oligomerix, told *BioWorld Today*.

The company's core technological competencies include purification and characterization of soluble protein aggregates, and antibody and small-molecule development.

Oligomerix was able to secure Small Business Innovation Research (SBIR) grants to screen inhibitors of tau oligomer formation, and to develop antibodies to specific species of tau oligomer that it purified.

"Looking at these species, we realized that some of them have an intrinsic proteolytic activity," Pasini said. Within the past year, Oligomerix has prioritized the effort to understand that activity. "We've demonstrated that it's not only responsible for tau cleavage, but it can also cut other proteins that may be important to Alzheimer's disease."

Examples of those other proteins include tubulin and some peptide neurotransmitters.

When Oligomerix researchers, working in collaboration with Ottavio Arancio, at Columbia University Medical Center, introduced tau oligomers into mouse brain via cannula, there was impairment of learning and memory in the mice, localized to the oligomeric tau in the hippocampus. Monomeric tau showed no effect.

The company also is targeting tau protease activity, which causes a self-cleavage of tau. The fragments produced by tau protease represent important biomarkers for Alzheimer's disease.

Oligomerix has developed a screening assay for tau protease, and it has found a number of inhibitors that are active against it. "We're just at the point of undergoing small-molecule discovery efforts with that approach," Pasini said.

One difference between Oligomerix and other companies attacking tau is that Oligomerix is focusing more on extracellular tau as a target for therapeutic intervention. The company contended that much of tau's pathology is actually extracellular and concentrations of tau outside the neuron are much lower than inside.

"I think that we have the most unique approach in tau pathology," Pasini said. According to him, most other companies in the field are targeting tau aggregation alone.

Tau protein has inspired a flurry of dealmaking activity within recent months. Bristol-Myers Squibb Co. is funding the Gladstone Institute's efforts to identify Alzheimer's disease targets that affect tau dysfunction, with the goal of finding new disease-modifying therapies for Alzheimer's.

ADx NeuroSciences Inc. signed an agreement with K. U. Leuven in November 2011 to develop and commercialize antibodies that selectively bind phosphorylated Tau aggregates. That same month, Signum Biosciences Inc. signed a deal with GlaxoSmithKline (China) R&D Co. Ltd. to screen for drugs that target phosophoprotein phosphatase 2A (PP2A), with the intention of bridging the link between PP2A methylation and tau hyperphosphorylation.

Many of those deals may represent disillusionment with Alzheimer's strategies based on amyloid beta. A number of anti-amyloid drugs have failed in late stage trials, including Alzhemed (Neurochem Inc.), and Flurizan (Myriad Genetics Inc.).

Oligomerix currently is looking for a partner to work with to accelerate its preclinical programs. Pasini said it has "very good traction" with large pharma, and the firm is talking with multiple companies.

It has used a combination of grants and equity investment – a total of $4.7 million – to fund the company thus far.

Its most recent grant award, disclosed in November 2011, was for $1.6 million from the National Institute on Aging to discover small molecules and antibodies targeting tau protein oligomers. The grant supports screening of compound libraries at the Michigan High Throughput Screening Center.

"We've kept the company small purposely, so as not to grow too quickly," Pasini said.

Oligomerix is putting together a financing round from an equity investor, and is considering writing an application for an extension of its second phase SBIR grant. That extension grant would be worth $3 million over three years. ■

Pharma: Clinic Roundup

Editor's note: BioWorld has always kept a watchful eye on big pharma developments as they relate to the biotech space. Now we're making it easier for readers by separating pharma business and clinical news into these columns of brief news.

• **Eli Lilly and Co.**, of Indianapolis, reported data from a Phase III study showing that both Cialis (tadalafil) and tamsulosin significantly improved scores on the International Prostate Symptom Score, compared to placebo, in men with signs and symptoms suggestive of benign prostatic hyperplasia (BPH). Cialis improved erectile dysfunction (ED) in those men who had both signs and symptoms of BPH and ED. Data were published in *European Urology*.

• **Merck & Co. Inc.**, of Whitehouse Station, N.J., reported top-line results from the TRA-2P (Thrombin Receptor Antagonist in Secondary Prevention of atherothrombotic ischemic events) study of vorapaxar, showing the drug, an oral protease activated receptor 1 thrombin receptor angonist, met the primary endpoint in preventing clot formation and reducing cardiovascular events. Data showed the addition of vorapaxar to standard of care significantly reduced the risk of the protocol-specific primary endpoint of the composite of cardiovascular death, heart attack, stroke or urgent coronary revascularization compared to standard of care alone. The firm did report, however, that there was a significant increase in bleeding, including intracranial hemorrhage (ICH), among patients in the vorapaxar group, though there was a lower risk of ICH in patients without a history of stroke.

Other News To Note

• **Rib-X Pharmaceuticals Inc.**, of New Haven, Conn., received a $3 million milestone payment from Paris-based **Sanofi SA** under a collaboration signed in July 2011 relating to the RX-04 antibiotic program. That is the fourth payment thus far, for a total of $22 million. Sanofi has the right to license an unlimited number of product candidates from Rib-X that target a discrete binding site in the ribosome. (See *BioWorld Today*, July 7, 2011.)

• **Salix Pharmaceuticals Ltd.**, of Raleigh, N.C., said the FDA granted priority review to a new drug application for crofelemer 125-mg tablets. The proposed indication is diarrhea in patients with HIV who are on antiretroviral therapy. Salix said crofelemer may inhibit chloride secretion by gut cystic fibrosis transmembrane conductance regulator protein and gut calcium-activated chloride channel.

• **Thrasos Inc.**, of Montreal, said *Nature Medicine* published results of a collaborative research program detailing the role of the bone morphogenic protein (BMP) pathway in the development of kidney disease. The research described the potential for Thrasos' compounds to target receptors in that pathway, potentially leading to the control of fibrosis and induction of kidney regeneration. The preclinical studies detailed in the report demonstrated that the activin-like kinase 3 (Alk3) receptor is elevated early in diseased kidneys following injury and suggested Alk3-mediated signaling can protect kidneys by inhibiting fibrosis. A representative small peptide agonist from Thrasos' portfolio, THR-123, designed to bind selectively to the BMP receptors, was shown to control and reverse fibrosis and to induce kidney regeneration in preclinical models of chronic renal injury. THR-123 was delivered orally in the studies and achieved its effects without inducing bone formation. (See *BioWorld Today*, Sept. 14, 2011.)

• **Tocagen Inc.**, of San Diego, inked a companion diagnostics partnership with Siemens Healthcare Diagnostics, which initially will support clinical trials related to Tocagen's viral gene therapy (Toca 511 and Toca FC) in primary brain cancer. That could be followed by potential commercialization of diagnostic tests for therapy monitoring, subject to FDA approval. Financial terms were not disclosed. Siemens also signed a deal with ViiV Healthcare Co., a joint venture between London-based **GlaxoSmithKline plc** and New York-based **Pfizer Inc.**, for diagnostic tests related to Celsentri/Selzentry (maraviroc), a CCR5 co-receptor antagonist for CCR5-tropic HIV.

• **ViroPharma Inc.**, of Exton, Pa., said the FDA issued a complete response letter regarding manufacturing expansion activities for Cinryze (C1 esterase inhibitor). The FDA made three comments related to cleaning validation. ViroPharma said it plans to complete needed additional activities quickly. The FDA has not yet completed review of ViroPharma's updated responses to the FDA's observations from a September 2011 inspection of the Amsterdam facility.

Clinic Roundup

• **Anacor Pharmaceuticals Inc.**, of Palo Alto, Calif., said it plans to focus on developing AN2728 for atopic dermatitis in 2012 and will defer the start of a planned Phase III trial in psoriasis, which was being designed under a special protocol assessment. The decision was based on the higher unmet need in atopic dermatitis and recent positive data from a Phase IIa atopic dermatitis trial. Anacor also released positive preliminary data from two safety studies of AN2728, showing it is well tolerated when applied to large body surface areas and sensitive skin.

• **Bio-Path Holdings Inc.**, of Houston, said it completed treatment of the second dosage cohort in its Phase I trial of lead candidate BP-100-1.01 (liposomal Grb-2), in development as a systemic treatment for blood cancers such as acute myeloid leukemia, chronic myelogenous leukemia, acute lymphoblastic leukemia and myelodysplastic syndrome. Data from the six-patient cohort showed the drug was well tolerated, with no treatment-related serious adverse events reported, and results continue to suggest some possible anti-leukemia activity.

• **Omeros Corp.**, of Seattle, said recent positive clinical developments allowed it to revise the planned analysis for its ongoing Phase III study of OMS302, a drug that combines an anti-inflammatory agent with one that causes mydriasis and is in development for use during cataract surgery and other lens replacement procedures to maintain intraoperative mydriasis and to reduce postoperative pain. Based on data from earlier studies, Omeros is revising its planned analysis to identify maintenance of mydriasis as the single primary endpoint rather than as a co-primary endpoint with pain reduction. A second Phase III study is expected to start following Omeros' meeting with European regulators.

Earnings Roundup

• **Amylin Pharmaceuticals Inc.**, of San Diego, reported 2011 non-GAAP operating income of $25.7 million, compared to a non-GAAP operating loss of $4.4 million in 2010. Total revenues for the 12 months ending Dec. 31, 2011, were $650.7 million. Net product sales of $621.6 million included $517.7 million for Byetta (exenatide) and $103.9 million for Symlin (pramlintide acetate). In comparison, Amylin reported net product sales of $651.1 million in 2010, including $559.3 million for Byetta and $91.8 million for Symlin. Non-GAAP operating income for the quarter ending Dec. 31 was $17.6 million, compared to non-GAAP operating income of $22.9 million for the same period in 2010. Amylin reported cash, equivalents, short-term investments and restricted cash of $214.6 million as of Dec. 31. The company cited among 2011 operating highlights the FDA approval of Bydureon (exenatide extended-release for injectable suspension) as the first once-weekly medication approved in the U.S. and the European Union for Type II diabetes and the FDA approval of a new use for Byetta as an add-on therapy to insulin glargine, with or without metformin and/or a thiazolidinedione. Shares of Amylin (NASDAQ:AMLN) gained 20 cents to close Tuesday at $16.89. (See *BioWorld Today*, Jan. 30, 2012.)