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PAGE 1 OF 7

Roche Snags Anadys for \$230M Amid Changing HCV Landscape

By Jennifer Boggs
Managing Editor

Anadys Pharmaceuticals Inc., which had been seeking a partner for its hepatitis C virus (HCV) candidate setrobuvir (ANA598), found an acquirer instead, with Roche AG plunking down about \$230 million in cash in a deal that analysts say could signal a wave of consolidation in the HCV space as drugmakers race to develop the first all-oral, interferon-free treatment regimen.

Roche already has a good start. The Swiss big pharma has been testing combinations of RG7128, an HCV cytosine nucleoside polymerase inhibitor partnered with Princeton, N.J.-based Pharmasset Inc., and danoprevir (RG7227), a protease inhibitor it gained from Brisbane, Calif.-based InterMune Inc. last year. Anadys' setrobuvir has the potential to be a third component in a multidrug regimen.

The trick with combining direct-acting antivirals (DAA)

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Third Rock Start-up Sage Debuts with \$35M Series A

By Catherine Shaffer
BioWorld Today Contributing Writer

Third Rock Ventures LLC launched a new company, Sage Therapeutics, with a \$35 million Series A financing to develop new therapies for schizophrenia, depression, pain and traumatic brain injury based on modulation of GABA and glutamate neurotransmitters.

Central nervous system (CNS) disorders are an area of great unmet need, but those indications also are regarded as highly challenging for drug development.

"This isn't easy, but I don't know an area in drug discovery that is easy," Third Rock Ventures founding partner and Sage interim CEO Kevin Starr told *BioWorld Today*.

The Boston-based company said imbalances in the brain from over- or underactivity of GABA and glutamate neurotransmitters are believed to cause many CNS

See Sage, Page 4

J&J Launches Incubator with No Strings-Attached Biz Model

By Trista Morrison
Staff Writer

SAN DIEGO – Johnson & Johnson is expected to announce Tuesday the launch of Janssen Labs at San Diego, a 30,000-square-foot incubator designed to serve as the future home for 18 to 20 biotech start-ups.

Incubators run by universities and economic development groups have long provided the facilities, expertise and even funding to help biotechs bridge the valley of death. But incubators run by drug companies have garnered mixed results.

Pfizer Inc. and Biogen Idec Inc. launched the industry's first corporate incubators back in 2007. Both provided facilities as well as funding, and both took a strategic angle, aiming to eventually acquire or negotiate some sort of option deal on the technologies passing through their doors. (See *BioWorld Today*, March 19, 2007.)

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Financings Roundup

ChemoCentryx Looks to IPO To Groom Drug Candidates

By Mari Serebrov
Washington Editor

With a stable full of promising contenders, ChemoCentryx Inc. hopes to raise \$69 million in an initial public offering (IPO) to keep its drug candidates on the clinical development track.

The Mountain View, Calif.-based biotech is proposing the yet-to-be priced IPO to help it groom four candidates already in trials and move at least one preclinical candidate into Phase I. Along with \$12 million in stock purchases from two principal investors and \$79.9 million in cash as of June 30, the IPO is expected to fund clinical development for at least another year, according to a preliminary prospectus filed with the SEC Friday.

Glaxo Group Ltd. and Techne Corp., the investors, have agreed to purchase \$7 million and \$5 million in shares,

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Clinic Roundup

- **AB Science SA**, of Paris, began recruitment in a Phase III trial of masitinib in the treatment of patients with relapsing multiple myeloma who have received one previous therapy. The double-blind, controlled study will enroll about 300 subjects at 75 centers around the world. The trial subjects will be evenly randomized into a masitinib/bortezomib/dexamethasone arm and a placebo/bortezomib/dexamethasone arm. Masitinib is an orally administered tyrosine kinase inhibitor that targets mast cells, important for immunity, as well as a limited number of kinases that play key roles in various cancers.

- **Dendreon Corp.**, of Seattle, began enrolling patients in a Phase II trial of DN24-02, for HER2-positive cancer. The trial will include 180 patients, and evaluate the safety and efficacy of its immunotherapy, DN24-02, as adjuvant therapy for HER2-positive invasive urothelial carcinoma compared to the standard of care.

- **Infinity Pharmaceuticals Inc.**, of Cambridge, Mass., completed enrollment in a Phase II trial of IPI-926 for pancreatic cancer. The trial has enrolled 122 patients and will compare IPI-926 in combination with gemcitabine to placebo and gemcitabine with a primary endpoint of overall survival. In a previous Phase Ib trial, once-daily oral IPI-926 and gemcitabine generated a response rate of 31 percent, compared to a historic overall response rate of less than 10 percent for gemcitabine.

- **Lpath Inc.**, of San Diego, began dosing in a Phase II trial of iSONEP for wet age-related macular degeneration. The double-blind trial will enroll 160 subjects with incomplete responses to a VEGF inhibitor to receive a VEGF inhibitor alone, VEGF inhibitor plus low-dose iSONEP, VEGF inhibitor plus high-dose iSONEP, and iSONEP alone. Its primary endpoints will be visual acuity, change in retinal thickness and change in lesion size.

- **The Medicines Co.**, of Parsippany, N.J., reported that its investigational antifibrinolytic agent, MDCO-2010,

Stock Movers

10/17/11

Company	Stock Change
Nasdaq Biotechnology	-\$22.62 -2.24%
Anadys Pharmaceuticals Inc.	+\$2.61 +250.96%
Inhibitex Inc.	+\$0.43 +13.44%
OxiGene Inc.	+\$0.14 +10.61%
Synta Pharmaceuticals Corp.	-\$0.31 -9.04%

(Biotechs showing significant stock changes Monday)

demonstrated safety, reduced blood loss and lowered transfusion requirements compared to placebo in a Phase IIa trial. MDCO-2010 is being developed as a therapy to limit blood loss in surgery. The double-blind, placebo-controlled trial enrolled 32 subjects undergoing open heart surgery who received MDCO-2010 or placebo immediately after a heparin bolus. Five dose cohorts were tested, and blood loss was measured by the amount of blood drained by a chest tube after 12 hours.

Other News To Note

- **Acura Pharmaceuticals Inc.**, of Palatine, Ill., said partner New York-based **Pfizer Inc.** has started executing U.S. commercialization of Oxecta (oxycodone HCl) to treat pain, following the drug's approval in June. Oxecta incorporates Acura's Aversion abuse-deterrent opioid drug delivery technology, and Acura will receive tiered royalties ranging from 5 percent to 25 percent on net sales.

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Anadys

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is that each agent needs to work via a different mechanism of action, said Steve Worland, president and CEO of San Diego-based Anadys. Given Roche's existing HCV pipeline, "our drug fit that bill very well."

Anadys' setrobuvir is a non-nucleoside polymerase inhibitor. Last week, the firm reported positive interim efficacy and safety data from an ongoing Phase IIb study testing setrobuvir in combination with standard of care – pegylated interferon and ribavirin – in patients with genotype 1 HCV. Seventy-eight percent of treatment-naïve patients and, perhaps most notably, 76 percent of treatment-experienced patients (i.e. relapsers or partial responders) had undetectable virus at week 12.

"It was very satisfying to see that," Worland said.

Those numbers compared to 56 percent of treatment-naïve patients and 44 percent of treatment-experienced patients getting placebo plus standard of care.

The biotech also had been working with an undisclosed company to test setrobuvir in combination with another investigational antiviral. Worland was not able to disclose whether that mystery firm had been Roche, but Anadys' drug does have the advantage of being at the same stage of development as RG7128 and danoprevir, both of which also are in Phase IIb.

That means Roche could be poised to launch Phase III trials in pretty short order, positioning it as the first firm potentially to offer an all-oral regimen – not to mention offsetting any loss of revenue from its Pegasys (pegylated interferon) product if interferon, as expected, starts to lose favor in HCV treatment.

Terms of the deal call for Roche to pay \$3.70 per share for Anadys, a whopping 256 percent premium over Friday's closing price of \$1.04, though the deal looks a bit less impressive when weighed against Anadys' previous investments. Founded in 2000 by biotech veterans Stelios Papadopoulos and Kleantis Xanthopoulos, the biotech had pulled in more than \$60 million in venture funding prior to going public via a \$44 million initial public offering priced at \$7 per share in 2004.

Since going public, Anadys' offerings have raised more than \$120 million. As of June 30, the company had about \$25.8 million on its balance sheet.

Shares of Anadys (NASDAQ:ANDS), trading nearly 125 times their normal volume, gained \$2.61, or 251 percent, to close Monday at \$3.65.

Yet not everyone was happy with the deal. Monday afternoon, Levi & Korsinsky said it was investigating Anadys' board for possible breaches of fiduciary duty and other violations in regard to the Roche acquisition. The New York-based law firm alleged that the board had failed to shop around for the best deal.

Anadys had been pursuing a partner for setrobuvir for the past couple of years – last year even hiring Lazard

Freres & Co. LLC to help review strategic alternatives – though some industry experts questioned whether Anadys' drug would stack up against other DAAs in the increasingly crowded HCV space. (See *BioWorld Today*, Oct. 18, 2010.)

Roche's new ownership could give the drug its best chance at success as part of a combo regimen. In fact, Piper Jaffray analyst Edward Tenthoff expects further consolidation in HCV as the sector moves toward all-oral regimens.

"We see several larger HCV players who need additional drugs," he wrote in a research note, mentioning Achillion Pharmaceuticals Inc. and Pharmasset as possible buyout targets with HCV pipelines.

Achillion, of New Haven, Conn., is working on ACH-1625, a once-daily protease inhibitor, and ACH-2684, a second-generation NS5A inhibitor, while Pharmasset, in addition to its Roche-partnered candidate, retains full ownership of earlier HCV compounds, including PSI-7977, a nucleoside analogue polymerase inhibitor that garnered headlines when abstracts for the upcoming American Association for the Study of Liver Diseases went public earlier this month. (See *BioWorld Today*, Oct. 5, 2011.)

The overall HCV space got a huge boost earlier this year when the FDA approved the first two protease inhibitors Incivek (telaprevir), from Vertex Pharmaceuticals Inc., and Victrelis (boceprevir), from Merck & Co. Inc.), drugs that, when combined with interferon and ribavirin, offered a major advancement in treatment, nearly doubling cure rates and shortening treatment duration.

But Anadys' Worland said that's just the start.

"There's a second transformation coming that's probably going to be even more dramatic," he told *BioWorld Today*, referring to the multi-DAA, interferon-free regimens coming down the pipeline. "I honestly believe that what's coming will make that initial launch [of the protease inhibitors] pale in comparison," he added.

Besides Roche, other firms are working on all-oral regimens. Johnson & Johnson subsidiary Tibotec BVBA and Boehringer Ingelheim GmbH are in late-stage trials testing protease inhibitor combos without interferon. Cambridge, Mass.-based Vertex inked a deal in June for rights to preclinical nucleotide analogues from Alios BioPharma Inc. that could work well with Incivek and its investigational NS5B polymerase inhibitor VX-222. (See *BioWorld Today*, June 14, 2011.)

There's also Pharmasset, which has a deal with Bristol-Myers Squibb Co. to test PSI-7977 in combination with BMS' NS5A inhibitor BMS-790052. And Gilead Sciences Inc. is in trials with a four-drug regimen – non-nucleotide polymerase inhibitor GS 9190, protease inhibitor GS 9451, NS5A inhibitor GS 5885 and ribavirin – as well as three-drug combos omitting either GS 9190 or ribavirin. (See *BioWorld Today*, Sept. 7, 2011.)

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Sage

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disorders. Its positive and negative allosteric modulator (PANAM) chemistry platform is designed to identify receptor modulators that can bring balance to disrupted neuronal activity.

The company is focusing on nonbenzodiazepine and nonglycine modulators.

"Nature has provided certain allosteric binding sites that . . . finely tune upward or downward glutamate and its receptors or GABA and its receptors," said Steven Paul, a Sage co-founder, adding that mimicking the transmitter is "too crude" an approach to be effective.

"A lot of drugs that companies go after directly agonize or antagonize. In these particular receptors, agonism and antagonism disrupt normal brain rhythm in those circuits," Starr said. "What we found and hope will prove out in the clinic is that allosteric modulation restores those rhythms to normal function and normal signals so the brain can interpret it the right way."

The company already has supporting data in animals and in humans showing proof of concept.

The \$35 million financing will fund two sets of programs at Sage. Formulation-based programs will advance work already done on prototypical molecules. Starr said those molecules could enter the clinic within two years.

A second program will focus on lead optimization, and is expected to reach the investigational new drug application stage in two to three years.

Currently marketed therapies for CNS disorders fail a majority of patients, according to Sage. It said that two-thirds of patients with depression fail to respond to medications. Schizophrenia medications also have low response rates, plus some serious side effects.

Additionally, drugs for schizophrenia only address psychotic symptoms, but do not treat the highly disabling negative and cognitive symptoms of the disease.

Sage estimated the market for brain injury includes 1.7 million people per year due to accidents, sports and combat. There are no drugs approved to protect the injured brain.

Addex Pharmaceuticals Inc. is developing a number of positive allosteric modulators (PAM) and negative allosteric modulators (NAM) in the CNS area, generating some high-dollar deals, but some of its programs have experienced setbacks.

In July, Merck and Co. Inc. handed back rights to ADX63365 and other PAMs targeted at the mGluR5 receptor for schizophrenia that it had acquired in 2008 for \$22 million up front. If successful, that deal could have been worth up to \$702 million for Addex. (See *BioWorld Today*, Jan. 4, 2008.)

In September, Merck dropped the other shoe, exiting from a license agreement with Addex for a modulator of the mGluR4 receptor, for which it paid \$170 million up front in 2007. (See *BioWorld Today*, Dec. 4, 2007.)

Addex continues to work on those programs internally. Paul said Sage is expecting challenges, but the firm contended its programs are strong and its leadership experienced. "We like where we are with respect to our chemical scaffolds. We believe they have already built in safety," he noted.

"We've thought this out very very carefully," Starr said. "We thought this through in terms of getting to the finish line. We felt we brought the team on board and various partners on board that can help get there."

Third Rock is not the only organization that is looking for an opportunity in CNS and schizophrenia, in particular. Takeda Pharmaceutical Co. signed two deals with biotech companies this year for schizophrenia drugs.

In April, it signed a deal worth up to \$106.3 million with Heptares Therapeutics Ltd. to characterize the structure and deliver early leads against a G-protein coupled receptor involved in schizophrenia. (See *BioWorld Today*, April 12, 2011.)

And in March, it signed a deal worth up to \$750 million with Intra-Cellular Therapies Inc. for worldwide development and commercialization of Intra-Cellular's preclinical selective phosphodiesterase type 1 (PDE1) inhibitors for cognitive impairment associated with schizophrenia. (See *BioWorld Today*, March 4, 2011.) ■

Anadys

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While retrovir clearly was the focus of Roche's acquisition, the big pharma also is picking up rights to Anadys' ANA773, a small-molecule inducer of endogenous interferons that acts via the Toll-like receptor 7 pathway. It's based on the idea of activating innate immunity – discoveries that recently landed scientists Bruce Beutler and Jules Hoffmann the Nobel – and is just as exciting for its potential in HCV as retrovir, Worland said.

"But [ANA773 is] a very complex program," he added, "so it's great to have it in Roche's hands." ■

Other News To Note

- **Affitech A/S**, of Copenhagen, Denmark, inked an exclusive worldwide license with **GE Healthcare Life Sciences**, of Chalfont St. Giles, UK, for marketing and sales of products containing recombinant Protein L. Affitech will receive a royalty on net product sales.

- According to **biOasis Technologies Inc.**, of Vancouver, British Columbia, its Herceptin (trastuzumab, Roche AG) conjugate BT2III was superior at killing a HER2+ breast cancer cell line compared to trastuzumab alone. The conjugate contains trastuzumab and the biOasis Transcend vector. The presence of the drug was also confirmed in animal brain cells. The work was carried out by the BC Cancer Research Centre.

Incubator

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Pfizer's incubator housed a handful of start-ups including Wintherix LLC, RGo Bioscience LLC and Fabrus LLC, while Biogen's incubator invested in Neostasis Inc., Provasculon Inc. and Escoublac Inc. But neither facility seems to be bustling these days: Pfizer confirmed its incubator building in La Jolla, Calif., is currently for sale, and the contact number for Biogen's incubator is no longer in service.

Diego Miralles, site head for Johnson & Johnson Pharmaceutical Research and Development LLC's West Coast research center, is well aware of the challenges corporate incubators have faced. J&J did extensive research on incubators prior to launching its own initiative, he said, and they identified several factors they feel will allow them to succeed.

First, "having professional management is key," Miralles told *BioWorld Today*. Throwing 20 companies into a shared space would be chaos without someone to oversee maintenance, equipment training, safety and other such functions, so J&J hired Prescience International, the external firm that runs the San Jose BioCenter, among other incubators.

Second, Janssen Labs has "absolutely no strings attached," Miralles said. There are no options or first rights or any type of strategic pipeline building arrangements in the lease contracts. There is no relationship with J&J's research group or with its corporate venture arm. Miralles acknowledged that the incubator companies might have a better shot at forming those relationships if they so desired, thanks to proximity, but the incubator is "totally separate from our internal efforts."

That makes J&J's incubator quite different from corporate incubators of the past.

Mark Benedyk, who ran Pfizer's incubator from 2008 until January of this year, noted that "different companies approach incubators in different ways." He commended Miralles for J&J's approach.

It took a lot of internal discussion for everyone at J&J to agree on the strategy, and Miralles emphasized that it is an experiment. But he believes giving the incubator companies their independence is critical because, as he said, "entrepreneurs don't like to be owned."

In fact, Miralles wouldn't even confirm whether J&J will give priority incubator space to start-ups working in areas of strategic interest to the big pharma. He said the details have yet to be determined, but J&J is looking first for compelling science, second for focus on an unmet need, third for a credible management team and fourth for the ability of the start-up to meet the financial obligations of the lease.

And that appears to answer one aspect of the question: What does J&J get out of the deal? Start-ups have to pay rent to stay in the incubator.

Like all big pharma, J&J has had its fair share of layoffs over the past few years, but rather than contribute to the glut of wet lab space on the San Diego market, the firm appears to have found a better use for it. Miralles declined to specify whether the incubator represents a significant investment for J&J or whether the company plans to at least break even on the subleases.

The more important benefit, from Miralles' view, is the opportunity to support the biotech industry. "We feel the biotech sector is undergoing significant challenges," he said. "A healthy biotech sector is critical to our future. We believe the tide will rise for all ships, and we will all benefit."

Companies in the J&J incubator will get access to their own space, as well as common areas that house equipment for nuclear magnetic resonance, mass spectrometry, flow cytometry and other analyses. In exchange for short, renewable leases, they will get "cost-efficient, flexible, turnkey wet labs," Miralles said.

Janssen Labs at San Diego will begin accepting applications on Tuesday and is slated to be operational in the first quarter of 2012. ■

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Financings Roundup

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respectively, in a separate private placement at a price per share equal to the IPO price. In addition, Techne will convert a \$10 million convertible note, issued last month, into shares, based on the IPO price, and it will receive 10-year warrants to purchase 300,000 shares at an exercise price of 200 percent of the IPO price.

ChemoCentryx, with its focus on the chemokine system, has five candidates in trials and plans to advance another one into clinical development next year. Four of the candidates are subject to a 2006 collaboration agreement with Glaxo Group, an affiliate of GlaxoSmithKline plc (GSK). (See *BioWorld Today*, Aug. 25, 2006.)

Under that agreement, which is worth up to \$1.5 billion, ChemoCentryx has received about \$220 million from GSK in up-front and milestone payments, equity investments, research funding and an option exercise fee, according to the SEC filing.

GSK has exercised its option on an exclusive license to further develop and commercialize Crohn's disease treatment Traficet-EN, which is in two Phase III pivotal trials. It is expected to decide, by year-end, whether to exercise its option on CCX354, an arthritis treatment that has completed a Phase II proof-of-concept trial.

The London-based biopharma has similar options on CCXI68 and CCX832 if the proof-of-concept trials are successful. CCXI68 is in a Phase II proof-of-concept trial for the treatment of anti-neutrophil cytoplasmic antibody (ANCA), or ANCA-associated vasculitis. CCX832, a skin-inflammation drug, recently completed Phase I.

ChemoCentryx's lead independent candidate, CCXI40, recently completed a Phase II trial in Type II diabetes and is in two Phase II trials for diabetic nephropathy. Another independent candidate, CCX662, is expected to enter a Phase I trial for glioblastoma multiforme in the second half of 2012.

This is not the first time ChemoCentryx has proposed an IPO. Four years ago, the biotech filed to raise up to \$57.5 million in an IPO. Like this time, it didn't disclose the targeted number of shares or share price, and it planned to trade on Nasdaq under the symbol "CCXI." (See *BioWorld Today*, Nov. 13, 2007.)

The first proposal was intended to fund development of Traficet-EN after it yielded positive Phase II data for Crohn's disease. GSK exercised its worldwide rights on the compound in 2010 and is conducting the Phase III trials through its Center of Excellence for External Drug Discovery.

Since it opened its doors in 1997, the biotech has raised \$164 million from venture capital, corporate and private equity sources. It also has received \$23 million in government grants – two from the National Institutes of Health and two from the Defense Advanced Research Projects Agency.

In Friday's SEC filing, ChemCentryx reported losses

of \$14.2 million for the first six months of 2011 and an accumulated deficit of \$103.9 million. It had more than 57 million preferred shares outstanding; it proposes converting 48.7 million to common stock. Shares in the company's equity investment plans were valued at \$2.24 midyear, and warrants on 319,000 shares had an exercise price of \$2.60 per share.

In other financings news:

- **Hookipa Biotech GmbH**, of Vienna, Austria, said it raised €7 million (US\$9.6 million) in a Series A round led by Sofinnova Partners, with Forbion Capital Partners joining as co-investor. The biotech start-up is developing next-generation vaccines based on its Vaxwave technology platform, which is designed to create genetic vaccines for prophylactic and therapeutic use against viral diseases. Series A funding will help the firm advance its lead program, HB101, through preclinical and Phase I testing, and further industrialize and validate the Vaxwave technology.

- **Marina Biotech Inc.**, of Bothell, Wash., said it entered a purchase agreement with Lincoln Park Capital Fund LLC, which has committed to invest up to \$15 million of equity capital. The company will control timing and amount of any future investment during the 30-month term of the agreement. Proceeds will be used to advance both the firm's FAP clinical program and broad nucleic acid-based drug discovery platform, as well as to support other general corporate purposes.

- **Sernova Corp.**, of London, Ontario, said it proposes to extend the term of its common share purchase warrants issued Oct. 30, 2009, to 4 p.m. Pacific time April 30, 2012. Sernova develops devices and drug/device combination products. ■

Other News To Note

- **Capstone Therapeutics**, of Tempe, Ariz., is cutting 14 of its 18 full-time employees to preserve cash during ongoing discussions with potential partners for dermal scarring drug AZX100. The company has been struggling since Phase IIa trials fell short of statistical significance last year. (See *BioWorld Today*, Dec. 15, 2010.)

- **The Infectious Disease Research Institute**, of Seattle, has joined the Advanced Immunization Technologies (ADITEC) program, a collaboration focused on accelerating the development of the next generation of vaccines. The five-year, \$54.5 million European research initiative was launched Oct. 1 with funding from the European Union and collaborating organizations.

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U.S. Patent Disclosures

• **Innocoll Inc.**, of Ashburn, Va., received a notice of allowance for a patent covering products comprising any amino amide or amino ester anesthetic in a collagen matrix intended for the provision of local analgesia or anesthesia.

• **Kylin Therapeutics Inc.**, of West Lafayette, Ind., received a notice of allowance for a patent broadly covering therapeutic RNA technology, as well as expanded areas on Kylin's nanoparticle technology platform, pRNA. It covers multivalent RNA structures.

• **Lpath Inc.**, of San Diego, received U.S. Patent Nos. 8,025,877, and 8,026,342, which claim methods and composition of matter for its anti-sphingosine-1-phosphate antibody, sonepcizumab, the active component in the firm's lead compounds ISONEP and ASONEP.

• **Marina Biotech Inc.**, of Bothell, Wash., received a notice of allowance for a patent covering a library of more than 1x10¹⁵ peptides. The patent is part of the company's Trp Cage Library portfolio.

• **Ohr Pharmaceuticals Inc.**, of New York, received U.S. Patent No. 7,981,876, titled "Polymorphic and Amorphous Salt Forms of Squalamine Dilactate," which relates to composition-of-matter claims for the lactate salt form of squalamine and its delivery using any pharmaceutically

acceptable carrier.

• **Prolor Biotech Inc.**, of Nes-Ziona, Israel, received a notice of allowance for a patent covering its long-acting CTP-enhanced human growth hormone.

Other News To Note

• **NeoStem Inc.**, of New York, closed its previously announced acquisition of privately held stem cell firm **Amorcyte Inc.**, of Hackensack, N.J. (See *BioWorld Today*, July 18, 2011.)

• **Vivus Inc.**, of Mountain View, Calif., said it resubmitted its new drug application for obesity drug Qnexa (phentermine/topiramate). The move follows an agreement in September with the FDA to resubmit the application with a label restriction that would exclude women of childbearing age. The agency rejected the drug last year and later raised issues regarding a possible link between topiramate and birth defects. Vivus agreed in May to conduct a retrospective observational study dubbed FORTRESS (Fetal Outcome Retrospective TopiRamate ExpoSure Study) to assess the risk of major congenital malformations and oral cleft in offspring of women exposed to topiramate. Assuming results of that study show no significant risk, Vivus could seek an expanded label for the drug. (See *BioWorld Today*, Nov. 1, 2010, May 4, 2011, and Sept. 16, 2011.)

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