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Study: Recording Collaboration Revenue Sticky Spot for Biotech

By Jennifer Boggs
Assistant Managing Editor

Recognizing collaboration revenue has never been as easy as it sounds – that impressive \$100 million up-front payment, for instance, actually might be amortized over the life of the partnership. But increased SEC scrutiny on collaboration revenue, combined with the growing complexity of biotech deals, has proved a headache for accounting departments throughout the biotech industry.

Much of that is due to the fact that existing accounting requirements at the SEC and the Financial Accounting Standards Board (FASB) for recording collaboration revenue is unclear.

According to a recent study commissioned by the Biotechnology Industry Organization and conducted by Glass, Lewis & Co. Inc., that lack of clarity hurts the biotech

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Genentech: Avastin Sales up but Earnings Miss the Mark

By Donna Young
Washington Editor

After trading ended Tuesday, Genentech Inc. reported that sales of its cancer drug Avastin (bevacizumab) were stronger than anticipated, at \$704 million, an 18 percent increase over a year ago. The company said the growth was due primarily to increased usage of Avastin in metastatic breast cancer, an indication approved in February. (See *BioWorld Today*, Feb. 25, 2008.)

However, third-quarter earnings fell short of expectations, which the South San Francisco-based firm attributed to the cost of an employee retention program related to the \$89 per share purchase price it rejected from Roche Holding AG.

Refusing to give in to the pleas from analysts during a conference call Tuesday evening, CEO Arthur Levinson provided

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Vertex's Telaprevir Starts Phase III for Treatment-Experienced HCV

By Trista Morrison
Staff Writer

While Vertex Pharmaceuticals Inc. advances a pivotal Phase III trial of protease inhibitor telaprevir in treatment-naïve hepatitis C patients, partner Tibotec BVBA kicked off enrollment in a pivotal Phase III trial of the drug for treatment-experienced HCV.

Tibotec is a unit of New Brunswick, N.J.-based Johnson & Johnson, and Vertex previously inked a potential \$545 million deal licensing certain telaprevir international rights to another J&J company, Janssen Pharmaceutica NV. Cambridge, Mass.-based Vertex retains North American rights. (See *BioWorld Today*, July 5, 2006.)

Vertex said in August that it had received regulatory clearance for Tibotec to proceed with the second Phase III telaprevir trial, dubbed REALIZE (Re-treatment of Patients

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NEW CO NEWS

Q Therapeutics Seeks to Repair Rather than Replace Neurons

By Trista Morrison
Staff Writer

Deborah Eppstein, president and CEO of Q Therapeutics Inc., acknowledges that developing stem cell therapies to replace damaged organs is a daunting task.

That's why her company uses glial progenitor cells to repair rather than replace neurons, an approach she anticipates may be applicable in treating a host of neurodegenerative diseases.

The company's Q-Cells are "technically not stem cells," Eppstein explained. They are lineage-restricted glial progenitor cells that differentiate into oligodendrocytes, which produce the myelin sheaths that insulate neurons,

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Q Therapeutics

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and astrocytes, which make growth factors and support the health of neurons.

The name Q-Cells refers to the cells' ability to follow endogenous cues. "We don't have to direct them," Eppstein said, adding that the cells are harvested from donor tissue; isolated, purified and frozen; and then injected into the brain or spinal cord near the point of injury. From there, the cells migrate to the lesion and start their repair work, which includes remyelination as well as supporting neuronal health.

The Q-Cells were identified by Q Therapeutics' co-founder Mahendra Rao through research conducted at the University of Utah and the National Institutes of Health, where he headed stem cell work for the National Institute of Aging. Rao started the company in 2004 with help from Dennis Farfar, a founder of Myriad Genetics Inc. and other biotechs.

Q Therapeutics raised about \$5 million in a Series A financing in May 2004. Earlier this year, the Salt Lake City-based company got another \$8 million in the first close of its Series B round. Its investors include vSpring Capital, Invitrogen Corp., Epic Ventures, Toucan Capital, University of Utah Research Foundation, Salt Lake Life Science Angels and Q management.

Eppstein said Q Therapeutics hopes to raise between \$7 million and \$12 million in the second tranche of its Series B round, set to close in the first quarter of 2009. That money will allow the company to get its first clinical data, which Eppstein noted will include both safety and initial efficacy findings.

Q Therapeutics plans to conduct a dose-ranging Phase I/IIa trial at Johns Hopkins University to evaluate a single dose of Q-Cells in patients with transverse myelitis, a severe form of multiple sclerosis in which patients are wheelchair-bound. Preclinical studies are under way, and data published in the June 2008 issue of *Cell Stem Cell* showed that Q-Cells remyelinated neurons in mice and improved survival in what otherwise would be a lethal murine model.

No abnormal affects have been observed in preclinical studies to date. The company expects to file its investigational new drug application in 2009 and start the trial shortly after.

Eppstein said the company has talked with several pharmaceutical companies that are "very interested in working with us" if the Q-Cells can create myelin in humans the way they have in mice.

In addition to demyelinating diseases such as multiple sclerosis, Q-Cells may be applicable in cerebral palsy, spinal cord injuries, white matter stroke, amyotrophic lateral sclerosis (ALS), Parkinson's disease and Alzheimer's disease. The company has grants supporting early research in ALS and spinal cord injury, and Eppstein said the team plans to seek additional grants to complement its venture capital investment.

Q Therapeutics also has a collaboration with the Buck

Institute for Age Research to study Q-Cells in Parkinson's disease.

Because many of its intended indications are orphan diseases, Eppstein said Q Therapeutics may be able to conduct truncated clinical programs consisting of Phase I/IIa and Phase IIb/III studies. She doesn't anticipate needing to enroll large numbers of patients but said the company has a Q-Cell source sufficient to address multibillion-dollar markets.

In the interim, Q Therapeutics is developing drug discovery research tools based on its cells. Eppstein projected the tools could be on the market and starting to generate revenue within a year.

Q Therapeutics has 10 full-time employees. ■

OTHER NEWS TO NOTE

- **Lipoxen plc**, of London, said it entered a research agreement with **Cambridge Biostability Ltd.**, of Cambridge, UK, as well as the University of Cambridge, UK, and The Health Protection Agency, to develop a vaccine technology aimed at achieving greater efficacy and eliminating the need for cold-chain distribution. Under the terms, the parties will be working to create vaccine materials that are more stable, have a long shelf life, require fewer doses in order to be effective and overcome the cold-chain storage and distribution problem associated with traditional vaccines. The program will use Lipoxen's liposomal Co-Delivery technology, which combines DNA and protein forms of an antigen in liposomes, and CBL's VitRIS technology, which is designed to generate thermostable formulations. Financial terms were not disclosed.

- **Lorus Therapeutics Inc.**, of Toronto, said it received a \$150,000 milestone payment from Zor Pharmaceuticals LLC, a subsidiary of Zoticon Bioventures Inc., raising the first tranche in financing from the development of Virulizin, an immunotherapeutic agent being tested in cancer. That brought the total payment to Lorus to \$250,000. Lorus also reported that Central America was added to the territories covered in the exclusive licensing agreement with Zor, which means Lorus will receive an additional \$2 million upon achievement of specific development and sales milestones, in addition to royalties. The total potential milestone payment from the deal now exceeds \$12 million.

- **NeoPharm Inc.**, of Lake Bluff, Ill., said it signed a Cooperative Research and Development Agreement with the National Institute of Neurological Diseases and Stroke (NINDS) for research on a therapeutic agent for untreatable brain diseases in humans. Under the terms, NINDS will deliver NeoPharm's drug, Cintredekin Besudotox (IL13-PE38QQR) in conjunction with a surrogate marker via NINDS' methodology of Convection Enhanced Delivery. The company will provide both the drug and technical resources to study its effects in various brain cancers in humans. Financial terms were not disclosed.