

**Battelle Ventures Spins Out Life Science Company from MIT,
Committing \$5 Million in Series A Funding to Hepregen Corp.**

Start-up is developing bioengineered solutions for drug development, including a platform for advanced toxicity screening and drug discovery

PRINCETON, N.J., Feb. 25, 2009 – Battelle Ventures, LP, has spun out Hepregen Corporation from the Massachusetts Institute of Technology (MIT), with a commitment of a \$5-million Series A investment from the fund and its Tennessee affiliate, Innovation Valley Partners.

The company, which is developing bioengineered solutions for drug development, received the first \$3 million from the funds last summer, leaving an additional \$2 million committed and available at management’s request.

“Hepregen is currently focused on advancing and commercializing a microliver platform into the drug-development pipeline for the pharmaceutical and biotechnology sectors,” said Battelle Ventures General Partner Mort Collins.

“As with all our investments, we look for opportunities in which breakthrough technologies fill a key market need – and mitigate marketplace pain,” continued Collins. “In the case of Hepregen, its *in vitro* model mimics the *in vivo* human liver offering a bioengineered solution for predicting the liver’s response to drugs along the path of development. The technology gives every indication of presenting a breakthrough for toxicity screening and a new platform for drug discovery.

“Liver toxicity is the leading cause of preclinical failures of drugs, post-market drug withdrawals, black-box warnings and acute liver failures,” he explained. “With the typical cost of developing a drug and taking it to market being more than a billion dollars, improved predictivity can dramatically increase drug-development success rates and greatly improve economics for pharmaceutical and biotech companies.

“We’re not talking about nurturing the ‘fail faster, fail cheaper’ model for drug research and development that has led to minimal success, but rather about helping the industry to devise a strategy for developing winning drug candidates and minimizing failure,” said Collins, who is chairman of the Hepregen Board of Directors.

“Since up to 80 percent of all drugs are metabolized or detoxified in the liver, the safety of drugs as they travel through the liver is of prime importance to the pharmaceutical industry,” said Hepregen President and CEO Bernadette (Bonnie) Fendrock, who co-founded the Medford, Mass.-based company after 15 years in the biotech industry.

(more)

“Platform technologies that improve clinical predictivity and generate higher content data for faster, more-informed decision making offer significant value for the sector. Hepregen’s platform combines tissue engineering and microfabrication to create optimized, precise and organized microlivers that are highly functional, but streamlined in a multi-well industrial format,” she added.

“Current tests for liver toxicity often use rats or rat liver cells, which don’t always respond to toxins in the same way that human cells do; or they use dying human cells that survive for only a few days in the lab so you can’t discover how a drug would affect the liver over prolonged, or chronic, exposures, in a way that would more closely resemble how the drug would actually be tolerated and processed by a patient,” Fendrock explained.

“Others in the field, both providers of simple cultures of hepatocytes and providers of *in vitro* liver models, have either been restricted by the limitations of functionality or the complexity of their platforms,” she continued.

“But Hepregen,” she said, “is producing a unique, bioengineered microliver platform that is highly functional and stable, more representative of an *in vivo* liver.” She said that:

- Hepregen human microlivers are stable for four to six weeks, compared with a few days, at most, for traditional testing;
- Hepregen’s rat microlivers are stable for 10-12 weeks *in vitro*;
- Hepregen’s microlivers do not require specialized equipment or specially trained personnel. As a two-dimensional system, multi-well plates containing the microlivers can fit in existing robotic-fluid handling systems for medium- to high-throughput screening applications and are also amenable to plate readers and automated microscopy use; and
- Hepregen’s microlivers may also be modified to represent diseased livers (such as with diabetes or infectious disease) and would provide a unique system for drug discovery.

Fendrock said that Hepregen’s co-founders are Drs. Sangeeta Bhatia and Salman Khetani, the two MIT scientists behind the technology, for which Hepregen has an exclusive license agreement with MIT for 10 patents and patent applications, including two core patents and two applications that relate to the Hepregen microliver platform technology.

This intellectual property portfolio, she said, represents more than 15 years of research by Dr. Bhatia, an MIT professor, a Howard Hughes Medical Institute investigator and an internationally recognized pioneer in the application of micro- and nanotechnology in tissue repair and regeneration. Dr. Bhatia is chair of Hepregen’s scientific advisory board and a consultant to the company.

Dr. Khetani, she said, is the co-developer of Hepregen’s platform technology and now Hepregen’s director of research. He was an MIT postdoctoral fellow who worked closely with Dr. Bhatia in the field of liver-tissue engineering and has more than eight years of experience studying and engineering *in vitro* models of rodent and human liver tissues using novel microfabrication technologies.

(more)

“The Series A funds will enable Hepregen to work in partnership with select companies and contract research organizations to assess the robustness of the platform for rational decision making and to prove its relevance to novel applications in drug discovery,” said Fendrock.

“We believe that Hepregen will provide the pharmaceutical industry with a robust, reliable and resource-sparing tool that will enable compound engineering through short iterative improvement loops that requires minimal drug material. Our goal is to provide advanced bioengineered solutions that add value to the overall drug-development cycle.”

Said Collins: “By providing a superior toxicity-testing platform, Hepregen is expected to detect complications in drug development far earlier, saving millions in research and development costs, as well as preventing the downstream catastrophic cost of drug recall, potential liability and, most important, patient harm.”

Collins noted that Hepregen is the eighth company now in the funds’ health-and-life sciences portfolio and is that sector’s third spinout from a university or National Laboratory. Cardiovascular-device company EndoValve was spun out of the University of Pennsylvania and regenerative-medicine company NellOne Therapeutics was spun out of the U.S. Department of Energy’s Oak Ridge National Laboratory.

About Battelle Ventures and Innovation Valley Partners

Battelle Ventures and its affiliate fund, Innovation Valley Partners (IVP), have a combined \$255 million under management to create and accelerate the development of early-stage technology companies with breakthrough solutions to key marketplace problems. The funds enjoy close relationships with the technology transfer offices of the National Laboratories that Battelle Memorial Institute (Battelle) manages or co-manages for the U.S. Department of Energy. They also have established similar associations with a number of university tech transfer and commercialization departments. Battelle is the \$220-million Battelle Ventures fund’s sole limited partner and Eastern Tennessee business leaders back the \$35-million IVP fund; the two funds invest side by side in all deals. For information about the funds’ joint health & life sciences portfolio, go to www.battelleventures.com/health_life_sciences.html. For more information about Hepregen, please visit www.hepregen.com.

Note: Battelle Ventures and Innovation Valley Partners are registered trademarks of BVP Partners, LLC. The names of other entities, organizations, companies, products or services mentioned herein may be the trademarks of their respective owners.