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## Stem Cell Innovations Advancing Drug Discovery With PluriCells

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At a time when the issue of embryonic stem cell research is making headlines again in the wake of a Senate bill calling for federal funding followed by the anticipation of an almost-certain presidential veto, a Houston-based cell biology company quietly is advancing its research with a slightly less controversial stem cell source.

Founded early last year, Stem Cell Innovations Inc. (SCI) was formed by the merger of three companies – Amphioxus Cell Technologies Inc., which focused on in vivo toxicology, along with Plurion Inc., which had intellectual property relating to stem cell lines and Interferon Sciences Inc., a public shell that provided immediate access to public markets.

SCI's CEO James Kelly, formerly of Amphioxus, said the initial goal was to expand the business at Amphioxus, which focused on toxicology testing using liver cell-based assays.

"We were thinking of ways to expand [the business], and we knew that Plurion's IP was just sitting there," he said. That IP involved patented work by cell biologist Brigid Hogan, who discovered pluripotent stem cells derived from primordial germ cells of fetal tissue.

Because those cells come from fetal germ cells, as opposed to viable embryos, they were able to slip through the U.S. ban on federally funded stem cell research.

The technology surrounding those stem cells also circumvents the ongoing patent dispute on embryonic stem cell IP held by the Wisconsin Alumni Research Foundation, which licensed rights to embryonic stem cell players, such as Menlo Park, Calif.-based Geron Corp. (See *BioWorld Today*, April 4, 2007.)

In fact, the U.S. Patent and Trademark Office's recent denial of claims related to three of WARF's stem cell patents was based, in part, on the existing Hogan patents, which "pre-date the WARF patents," Kelly told *BioWorld Today*. That's why "we felt that, by acquiring that IP," from Plurion, "we'd have the freedom to operate in [the stem cell] space."

With the addition of the human stem cell technology, called PluriCells, SCI was "able to get started in stem cell work," Kelly said.

The company continues Amphioxus' work on liver cell lines, but now can "generate different cell types, such as heart, lung, kidney, and plug them into our infrastructure."

In her work on the PluriCell technology, Hogan had developed a number of mouse cell lines and completed some work in humans. SCI picked up where she left off and is focusing entirely on human testing, using the technology to develop cell lines and to develop differentiated cells for use in drug discovery.

There have been some successes with therapies using adult stem cells – Baltimore-based Osiris Therapeutics Inc., for example, recently reported positive six-month data from a 53-patient study of its mesenchymal stem cell product, Provacel, in heart attack patients. But Kelly said working with adult stem cells can be difficult when it comes to generating sufficient cell mass. The benefits of embryonic stem cells include the ability to generate unlimited quantities of cells and the ability to manipulate those cells into any cell type.

There are two primary sources of "truly pluripotent" stem cells: blastocyst embryos and those derived from primordial germ cells, Kelly said. However, unlike stem cells from blastocysts, SCI's PluriCells do not require the use of feeder layers and can be more easily cloned and frozen.

SCI is working on growing pure cultures of different cell types to create a portfolio of human primary cell models that can be used as research tools for drug discovery.

The company is partnering with academic and research institutions to use PluriCells in different therapeutic areas, such as the neurodegenerative space.

In December, SCI entered a two-year collaboration with the ALS Association, a nonprofit organization aimed at finding a cure for amyotrophic lateral sclerosis. In that

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alliance, SCI will develop human motor neuron models based on the PluriCell technology for high-throughput screening.

“Modern drug discovery in [the neurodegenerative space] is difficult because you can’t get a supply of pure motor neurons, so it’s hard to use high-throughput screening processes,” Kelly said. “So we hope to generate those kinds of cell lines.”

Under the collaboration terms, SCI will receive €400,000 (US\$512,000) from the ALS Association and has the option to further develop certain cell therapy applications based on results identified in the program.

The company’s goal is to focus initially on providing drug discovery services, with hopes of becoming “a major supplier of disease models,” Kelly said. In that vein, SCI

also plans to expand its toxicology business. But in the future, perhaps, the firm might consider moving into the cell therapy space.

To date, SCI has brought in about \$6 million in funding. Most of its work is done internally by the company’s 23 employees, most of whom are divided between its Houston headquarters and a lab in the Netherlands that opened about a year ago to meet the demands of the European market. The company also has an office in Scotch Plains, N.J.

SCI is publicly traded on the Over-the-Counter Bulletin Board under the ticker “SCLL.” Its shares closed Friday at 5 cents, up .004 cents. ■