

## Face Cream Derived From Human Umbilical Stem Cells Aimed At U.S. Market

An agreement between soon-to-merge South Korean firm Histostem and Tampa, Fla.-based Stem Cell Therapy International is expected to deliver a skin-care product derived from human umbilical cord stem cells to the U.S. market in January.

Called *SteMixx*, the facial cream stimulates and rejuvenates the skin's own stem cells, Stem Cell Therapy CEO David Stark told “The Rose Sheet” Dec. 3.

Its main ingredient is a protein called Human Stem Cell Conditioned Media, created during the culture of umbilical cord stem cells, he said.

“In most instances people think that you could use the stem cell to put on top of your skin, [but] the molecules actually [are] too big of a product to actually get through the epidermis,” Stark explained.

“What we’ve done is kind of cleaved off important communication factors of fibroblastic cells ... so it stimulates the inherent stem cells that you have in your body,” he said.

Stem Cell Therapy joins a handful of enterprising companies bringing skin care to market that contains “specialized peptides or plant stem cells that help protect or stimulate the skin's own stem cells to multiply and divide,” as noted by dermatologist Jeanette Jacknin.

Jacknin recently listed stem cells among the top 10 “cutting-edge” cosmeceutical technologies (“The Rose Sheet” Nov. 23, 2009).

Voss Laboratories markets *Amatokin*, an anti-aging line said to activate one's own stem cells to combat aging (“The Rose Sheet” July 20, 2009).

Emerge Labs has licensed technology from Mibelle Biochemistry for its *Swiss Apple Stem Cell Serum*, which it says boosts the productivity of human skin stem cells (“The Rose Sheet” Sept. 29, 2008).

### Stem Cell Therapy Seeking U.S. Distribution

Stem Cell Therapy is looking to secure U.S. distributors for *SteMixx*. Stark anticipates the product will be available to consumers in January for less than \$200 for a 10-day supply.

The product has been on the market in South Korea for two years and was extensively tested and approved by its FDA. The firm plans to voluntarily register the product with U.S. FDA and seek “validations” from European regulatory authorities.

While it plans to advertise *SteMixx* in the U.S. in conjunction with the product's release, it will hold back on its performance claims for now, according to Stark.

“What we'd like to do is substantiate our claims that have been brought out in Korea by U.S.-run clinical studies,” he said. In the next 12 months, the firm plans an Institutional Review Board FDA-approved clinical study, “and we will be able to substantiate all overt claims at that time.”

Given the claims it makes overseas, Stem Cell Therapy might need to be careful in crafting its U.S. claims to stay within the boundaries of cosmetic applications and not cross into drug marketing territory.

According to its Web site, Histostem sponsored "anti-aging" clinical trials for over 500 patients using stem cell treatments, though it is unclear if the trials featured SteMixx.

Stem Cell Therapy aims to submit protocol for IRB review within the next 30 to 60 days.

### Targeting "Problem Areas"

SteMixx is a fluid cream and is applied by plunger applicators to ensure consumers use an equal amount of product each day.

Stark recommends the product for "problem areas" and has heard from representatives "in the field" that consumers are seeing results in the first two to three days, including lessening of crow's feet, reduction of skin discoloration and tightening of skin around the neck.

"It's a very specific form of treatment, it's not like an overall [face cream]," he said. "We plan to come out down the road with an overall, but right now we really want to make sure it gets to the problem areas."

Stark indicated that face cream, eye cream and body cream may be added to the line next year.

Stem Cell Therapy places itself in the field of regenerative medicine, "devoted to the treatment of patients with stem cell transplantation therapy," according to a recent release. "We have other disease states we would like to focus on," but "the stem cell cream is our chief product and we're very excited about it," said Stark.

Stem Cell Therapy recorded a net loss of \$411,151 in the third quarter, according to financial documents the company filed with the Securities and Exchange Commission Nov. 13, and a net loss of roughly \$4.44 million since its inception in late 2004. It did not record any revenue in the quarter.

Also in its filings the firm says it "has not emerged from the development stage" and its ability to continue "is dependent upon the company's ability to generate additional financing and ultimately increase operations and to achieve a level of profitability."

Recent releases from the company are more optimistic. Stem Cell Therapy announced a \$5 million investment from Socius Life Science Capital Group, LLC in November. It said the funds would be available no later than Dec. 31 and would be used "for various growth initiatives, including the launch of its stem cell based facial cream, the initiation of clinical trials, maintaining and advancement of current GMP facility as well as ongoing working capital and general corporate purposes."

Stem Cell Therapy and Histostem are set to merge by the end of the year. The new company will be headquartered in Northern California and be called AmStem International Corporation.

Seoul-based Histostem holds six patents and has five pending for its stem cell technology. The biotech firm owns and operates an umbilical cord bank it says is the largest in the world.

"To its knowledge Histostem is one of the very few stem cell companies in the world currently earning several million dollars in income from its products and technology," Stem Cell Therapy notes.

– Lauren Nardella ([l.nardella@elsevier.com](mailto:l.nardella@elsevier.com))

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