

RBJ



Profile
Suzanne Clarridge's
My Brands Inc.
leverages
brand loyalty.
Page 10

Special Report
The federal stimulus
is no magic bullet for
local construction,
engineering firms.
Page 23



The List
The University of
Rochester is the area's
No. 1 private-sector
employer.
Page 9

WWW.RBJDAILY.COM

MAY 8, 2009

VirtualScopics eyes push into new market

Diagnostics opportunity offers growth potential

By SMRITI JACOB

VirtualScopics Inc. is in the early stages of formulating a strategy to tap a lucrative opportunity: diagnostics. If the medical image analysis company's plans bear fruit, its product could be the first to market.



Jeffrey Markin and
Molly Henderson

Officials at VirtualScopics expect to present their initial assessment of the market in a proposal to the firm's board of directors this month. Shareholders are slated to get details at the company's annual meeting May 28.

It is likely that VirtualScopics' first product will be in the area of oncology, officials said, though the firm is iron-

Continued on page 28

VIRTUALSCOPICS

Continued from page 1

ing out details and researching questions related to reimbursement, go-to-market plans and regulatory approval. A treatment monitoring tool, it would indicate whether a patient is responding to a particular therapy.

Jeffrey Markin, president and CEO of VirtualScopics, hopes the company will begin generating revenue with a product in the market within two years. He would like to have an operational model to prove its viability even sooner, he said.

"I think one of the things that gives us a lot of optimism is that what we're talking about here is stuff we've done in trials (from the technology standpoint), so it's not something that somebody has just sort of come up with an idea," Markin said. "The drug companies have lots of experience; we've done these kinds of analyses in hospitals all over the world, using equipment from all of the major providers."

If VirtualScopics' plan for diagnostics takes off, it could signal growth for the company.

Officials predict that the market for the first product would be more than the \$450 million domestic clinical trial market where the company is a player. In addition, Markin pointed out, each diagnostic application has its own market, so as the firm develops other applications or tests for other areas, it would be additive. Depending on how VirtualScopics' plans shape up, he envisions a separate unit to focus on diagnostics.

By the numbers

Now that VirtualScopics' core business is on solid footing, the company can take a look at diagnostics, Markin said.

For the first time in its history, the company generated cash in its first quarter. VirtualScopics reported Tuesday that first-quarter revenues increased 31 percent to more than \$2.1 million, and gross profit rose 85 percent to \$1.1 million. Its net loss was \$756,113 or 4 cents a share, compared with \$924,513, or 4 cents a share, a year ago. The operating loss for the quarter was reduced by \$591,243, or 62 percent, to \$360,412. At the end of March, VirtualScopics had roughly \$3.1 million in cash and cash equivalents. It hit the break-even point for cash flow in the fourth quarter.

VirtualScopics, which has offices at Linden Oaks, has hired seven staffers in 2009, bringing the total employee count to 62. It expects to add five to 10 more employees this year.

VirtualScopics' technology provides information on the progression of diseases, by extracting complex information from computed tomography and magnetic resonance imaging scans. The company has 33 active customers; it works with big names in the pharmaceutical industry, including Pfizer Inc.

In April, VirtualScopics said its project balance exceeds \$31 million, up more than 120 percent from \$13.7 million a year ago. It calculates that balance as the amount remaining to be recognized from active and awarded contracts.

New opportunity

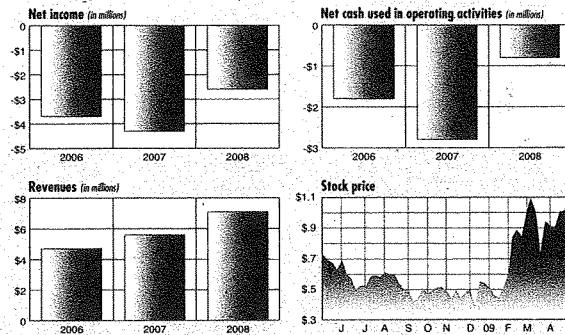
The acceptance of VirtualScopics' technology by pharmaceutical companies has increased significantly, which makes this a good time to explore the diagnostics area, chairman Robert Klimasewski said.

"We always realized that if we were successful in the clinical trial aspect of drug development, that that would inevitably lead to being able to sell our services in the diagnostic marketplace," he said.

The University of Rochester spinoff took its first look at the diagnostics market in

VirtualScopics' upward trend

The medical image analysis firm posted higher revenues and a smaller loss in 2008, while using less net cash. And its stock has risen sharply since early this year.



2002, using a consultant. The market for an oncology application did not exist seven years ago, because anti-angiogenic drugs that usually cut off blood supply to tumors were not yet approved. But the report offered an overview of the marketplace, including regulatory and reimbursement issues, for musculoskeletal applications.

Molly Henderson, chief business and financial officer of VirtualScopics, said for those applications it was estimated that running a trial and proving that a device works as expected would take seven to 10 years and \$10 million to \$15 million.

"The cost/time range the consultant provided was done in general terms on the average time it takes/costs to get diagnostic type products into the market," she said. "Our application today is a bit different, but again, we're still assessing that."

For the company at that time, the clinical trials business was easier to penetrate—it did not require regulatory approvals.

"What we had always envisioned is: OK, once we get our feet wet with this business, we'll cumulate the data, we'll understand the true value proposition out there to the industry, we'll see how the technology works and see how receptive this community is to this type of technology and really where it can go," Henderson said. "We're now there."

Making plans

At this point, officials said, VirtualScopics' customers have vetted its technology. The firm has collected data in the area of oncology, which could save it some time in proving the viability of the device. Markin expects that the company will be able to use the data from its work on clinical trials of drugs that are on the market or are soon to be on the market.

"So that data is all viable, kind of valuable data that we can use as we then prove viability and get forward, to get reimbursement and get approved by the FDA," he said. "So it hasn't been we've lost that time; actually we've reduced that time, and gotten paid for it through pharma."

VirtualScopics' tool for oncology would be able to determine if a treatment is effective for a patient. Depending on the drug involved, it could provide some analyses in 24 to 48 hours. Markin said the product would focus on drug mechanisms. So, for example, if a drug is expected to shut off blood flow to a tumor, the tool could measure that.

VirtualScopics' intellectual property and expertise allow it to offer reproducible results. Those factors make its tool the first to market with a diagnostic application.

"There's no sort of tracks in the sand ahead of us," Markin said.

VirtualScopics is examining the value proposition for the oncology tool, from understanding how oncologists make their

decisions to the regulatory process and reimbursement issues.

"You've got to go in with your eyes open," Henderson said. "I've started researching and looking into this ... (to) get a better understanding (of) the market, what kinds of issues are hidden under the rocks out there, and there's a lot. You really have to be smart and systematic in how you approach this."

VirtualScopics is in talks locally with groups of clinicians and payers such as HMOs, to get feedback.

"We've got more discussions planned, and we just want to make sure if we're going forward that we've got all the sort of mines in the minefields identified," Markin said. "But people are excited. The more we talk to people about it, the more excited people get about it externally."

VirtualScopics still is evaluating its go-to-market strategy but expects the oncology application to target clinicians.

"Now the way we get to the oncologists, that's what we need to work out," Markin said. "It could be that this is a companion diagnostic to the drug, it could be that it gets sold along with some other therapy like radiation therapy or something else, and those are the things that we're trying to work out, or what we need to work out."

A plus, Henderson said, is that the business model for diagnostics is the same as the firm's existing one.

"It's service-based, it's data capture, providing that information back, for a lab model," she said. "That makes it a lot easier to be able to prognosticate what to expect."

Depending on how quick the return on investment turns out to be, VirtualScopics will decide if it needs capital to fund its entry into diagnostics.

"If we go through this plan and realize the market is ripe, we could really start

generating significant revenues in the next 12 to 18 months, I think we'd be more apt to go out with a story to the street," Henderson said. "Until we really have that visibility, I'm not inclined to say (whether the company would seek capital)."

Growth prospects

VirtualScopics' eye on diagnostics has attracted the attention of John Putnam, analyst at NextWave Research Inc.

"As large as one might imagine the clinical trial market to be for (VirtualScopics') services, there looms a much larger market for the company to address—that of personalized medicine," he wrote in a report on the company.

In a separate report on personalized medicine, which Putnam terms the integration of therapeutics and diagnostics, he lists the local company as a notable example.

"By virtue of the fact that (VirtualScopics') technology is so sensitive as to be able to detect a change in solid tumor size or other anatomical function in a matter of a few days, we believe it could also become the standard of care in determining whether a specific drug is effective in treating a patient," he wrote.

First, the company has to make sure there is demand for its product.

"Ultimately, we believe this opportunity for (VirtualScopics) could dwarf that of its current clinical business, but we recognize that it will take some time to develop," NextWave's Putnam said. "In the interim, the company has a very attractive business opportunity upon which to capitalize and be successful."

VirtualScopics has been pursuing new customers for its clinical trials business, and its European unit has seen an uptick in activity. The company also continues to tell its story to institutional investors.

VirtualScopics expects to have \$9 million to \$10 million in revenue this year. Its stock price has gained ground, trading at 52 cents on Jan. 2 and \$1.06 on Tuesday.

VirtualScopics aims to regain compliance with Nasdaq listing rules. The stock exchange in March told the firm it had extended the temporary rule suspension of the \$1 minimum bid price requirement until July 20. As a result, VirtualScopics now has until Nov. 9 to comply. Henderson said the company will conduct a reverse stock split—it is a proxy item for shareholder approval—if it appears that VirtualScopics is not going to regain compliance by September or October. The company must have had a closing bid price of \$1 or more for a minimum of 10 consecutive trading days.

Officials voice optimism about VirtualScopics' future.

"We may be small in revenues and number of employees, but we're solving big problems," Henderson said.

sjacob@rj.net / 585-546-8303