RADICAL FIRM
FLIES SOLO IN $770-MILLION MARKET

BY GREG MILLER
SENIOR TECHNOLOGY ANALYST
Regenerative medicine is a fascinating field that’s only going to grow in the years ahead as the global population continues to rise.

Indeed, the Alliance for Regenerative Medicine says these regenerative treatments could save $250 billion per year in direct costs associated with tackling chronic diseases.

So our timing couldn’t be better for getting in on my next recommendation.

The promising biotech company I just discovered uses bioengineering technology to design regenerated organs for human transplant. Its specific area of expertise is the trachea, and its the company’s technology grows entirely new tracheas from scratch for direct transplant into the throat.
It does this using the patient’s own cells, which eliminates the chance of the body rejecting the organ. It also solves the problem of not being able to find a suitable donor.

In recent months, the company has had to raise substantial additional capital... at a price that was highly dilutive to existing shareholders. The move culminated in the stock sinking from around $8.50 per share in August 2014 to a 52-week low of $1.85 on February 11.

It was then that the firm raised additional equity, at $1.75 per share.

That’s what makes our timing perfect now. With that equity issuance now complete, the stock has shot past $4 per share.

I think that’s just the beginning for this stock, which is why I’m making it an official VentureCap Strategist recommendation. Here’s my full analysis...

A $770-MILLION-MARKET OPPORTUNITY

It’s important to remember that this firm, Harvard Apparatus Regenerative Technology (HART), is a development-stage company. That means there’s not a lot to say about its financial results – for all intents and purposes, there are none yet!

But we can talk about the market opportunity here.

Every year in the United States and Europe, there are approximately 7,700 people who could benefit from an artificial trachea. In numerical terms, it’s a $770-million market. Keep in mind, this only comprises the very sickest patients – i.e., those in danger of dying without a new trachea.

That’s where the company’s lead product, HART-TRACHEA, comes in.

Simply put, this is an artificial trachea, which is constructed with the company’s exclusive polymer scaffold and the patient’s own bone-marrow stem cells. So far, the product has been demonstrated on several patients.
with very encouraging results.

And that’s just the beginning of the possibilities for HART...

**TARGET: $15**

The company hopes to leverage what it’s learning about tracheas to create an artificial replacement for the esophagus, the bronchus, and even heart valves. And it’s this potential that analysts are looking at when they come up with their target prices.

Of the Wall Street analysts covering HART, one calls for $19 per share; the other predicts $24.

My target is a little more conservative – $15 per share within 18 months. That’s on the longer-term end of my investment horizon, but I think you’ll agree that it’s not a particularly long time to wait if my target is hit.

The aggressive Wall Street forecasts may end up being correct. But let’s get to $15 first and then we’ll re-evaluate.

As for HART’s trachea process itself, there are four main stages...

The company makes a copy of a patient’s trachea with its proprietary lattice technology – each trachea is different and customized for that patient.
Stem cells from the patient’s own body are harvested from the patient’s own bone marrow and fed into HART’s proprietary bioreactor to coat the lattice with the cells. Because the lattice is customized to fit the patient and the eventual trachea will be lined with the patient’s own cells, rejection is a non-issue.

The cells in the bioreactor are programmed to act like regular trachea cells.

The completed trachea is transplanted into the patient.

The question is: How is the science working in the real world?

**WHY HART WANTS TO BE AN ORPHAN**

So far, HART has completed transplants in patients who’ve received their country’s approval for “compassionate use” treatments. Basically, these patients were believed to be in imminent danger of dying, and doctors determined that no existing treatment would prevent those deaths.

The next step for HART is to receive “orphan” designation for its process. This means the company has exclusive rights to develop this treatment for seven to 10 years. It’s received such designation in the United States and expects to receive it in Europe shortly.

After that... clinical trials. HART has designed a trial for 30 patients at six leading medical centers, which will begin after some bureaucracy with the FDA.

If everything falls into place, the company can finally get approval for the treatment and begin generating real revenue.

There’s another major catalyst here – the most important factor when it comes to investing in the most lucrative small-cap stocks. **Demand Alpha...**
IT’S ALL ABOUT THE ALPHA

In my recent video, I talked about Demand Alpha – the sudden demand for a stock from large institutions.

I mentioned the factors that these institutions look for before investing in a stock – including liquidity and a good model of future dilution.

Well, with HART’s recent equity issuance, Demand Alpha has begun. In spades!

Even before the equity issuance, HART was popular with institutional accounts. But in the recent round, issuance went almost entirely to institutions.

In fact, at least one large institution, known for its savvy emerging healthcare investing, drove the structure of this issuance. It did so with a “preferred” stock model so it could increase its ownership of HART while complying with its internal rules!

I believe that – adjusted for the company’s deal – 70% to 80% of HART shares are already in institutional hands – hands that won’t be selling this stock anytime soon. I also believe that many accounts don’t own any shares, and it will become the must-own small-cap healthcare stock of 2015.

Demand without sufficient supply is what drives up prices – and that’s what we’re looking for here.

However, as a small-cap development-stage biotech firm, there are certain risks...

**Effectiveness:** For one, the treatment could prove to be less effective than hoped. So far, though, the results have been very encouraging. We’ll obviously monitor the company’s progress closely as clinical trials get underway.

**More Capital?** Even after the recent round of equity, HART will still need
capital, probably sometime in 2016. However, because of the Demand Alpha characteristics I describe above, I believe that capital will be raised at a much higher price than now... and thus be much less dilutive to shareholders.

Alternatively, HART may be able to raise money by pairing with a partner, who can help the company scale up when appropriate. In that case, dilution will be much less.

Either way, it’s something we’ll be watching closely – and we’ll place a stop loss on the stock to protect ourselves if it looks like the price will decline in anticipation of future equity issuance.

Rivals? What Rivals?

One big bonus with HART is that it currently faces no competition. What’s more, with regulatory exclusivity and patents on the scaffold and bioreactor, there isn’t likely to be any competition coming, either.

That being said, different treatments to solve the same problems are always a possibility, so we’ll be keeping an eye on further developments. However, much like HART’s product, any competing therapy faces years of trials and bureaucracy, so we’ll have plenty of time to see it coming.

Finally, management is vastly experienced, which is unusual for a startup company. Aside
from being top-notch scientists, the team built a successful predecessor of HART called **Harvard Biosciences** (HBIO). When several members of a management team migrate to a spinoff, rather than staying with the successful company they’ve already built, that’s a sign of confidence in the new firm.

**Action to Take:** *Buy Harvard Apparatus Regenerative Technology* (HART) under $5. My price target is $15 within 18 months. Because HART is a development-stage company, this is a riskier stock than usual. Thus, our prognosis and target price are subject to revision as time passes. I'll set a stop loss for the stock shortly, which will rise as the share price does.

**UPDATE AS OF AUGUST 13, 2015:** Please note: We’ve currently moved this position to a “Hold,” pending the company’s quarterly earnings announcement and any updates on its future business outlook and financial guidance. Do not enter a new position at this time, while we evaluate the latest news.

To living and investing in the future,

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Greg Miller
Senior Technology Analyst, VentureCap Strategist