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Biotech entrepreneurs swoon over proposed fundraising changes

In the pharmaceutical industry, where a single drug can cost more than a billion dollars to develop, $50 million may sound like small change. But to many biopharma startups, that amount of cash can be the difference between getting off the ground or crashing and burning.

In the US, a law known as Regulation A allows small, private companies, including biopharmas, to sell up to $5 million in public shares without having to file lengthy, expensive paperwork and divulge financial details to the country's Securities and Exchange Commission (SEC). But a bipartisan piece of legislation working its way through Congress, known as the Small Company Capital Formation Act, proposes to modify Regulation A such that these companies could sell up to $50 million in public shares with the same exemption.

"The original purpose [of Regulation A] was to provide smaller companies with a simpler mechanism for accessing capital, by streamlining bookkeeping requirements," says Jeff Hatfield, president and chief executive of Philadelphia-based Vitae Pharma, which makes novel drugs for conditions such as chronic kidney disease. "Today, the real need is to increase the eligibility threshold [for the exemption] while maintaining all those benefits."

Updating the $5 million cap, which was set in 1992, is becoming more crucial in the current unpredictable global economy, according to industry expert William Sahlman at the Harvard Business School in Boston. Dollar inflation, along with a need for greater innovation and more jobs today, are other factors that necessitate a higher cap in the struggling biopharma industry.

Private companies that want to sell their stocks to the public usually have to 'go public', meaning that they must officially register with the SEC. However, businesses that qualify for Regulation A benefits can sell $5 million worth of shares publicly without registering, thus avoiding the dangers of being fully exposed to the government's peering gaze. The financial statements these companies need to file are far less complicated and do not need to be audited, cutting down additional costs. This exemption is a way for small, private companies with limited funding to test the waters and gauge public interest in their product without full-blown SEC scrutiny.

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Cashing in: Small pharma hopes to take advantage of looser SEC regulations.

In November, the bill to update Regulation A cleared the House in a 421-1 vote, prompting excitement among entrepreneurs. As *Nature Medicine* went to press, lawmakers were pushing for it to be passed in the Senate by the start of 2012. If it is given a green light in Congress and signed into law, it will help biotech innovators raise much-needed capital in these bleak financial times. "Over 40% of venture capital firms have decreased investments in biotech because the return on investment is seen as being far lower than [returns from] social media start-ups, like Groupon," says Donald deBethizy, president and chief executive of Targacept, a now-public biopharma start-up based in North Carolina.

In the cash lane

For life sciences entrepreneurs looking for new ways to fund clinical trials, an increase in the regulatory cap could be a great option for kick-starting drug development. "In general, it takes 10 to 12 years and millions of dollars for a small company with a drug to go from discovery and development onto approval" by the US Food and Drug Administration, Hatfield says.

The possibility of the tenfold cap increase is very attractive to Robert Bargatze, who heads a small vaccine development company called LigoCyte Pharmaceuticals in Montana. "Five million dollars only represents two to three months of operating time for a very small company like ours to conduct clinical trials," he says. "But $50 million could fund a lot more than a whole year of R&D activity."

The general consensus is that $50 million could get a small company through phase 2 trials in a few hundred patients, beyond which costs can skyrocket up to a billion dollars.

At that point, notes Sahlman, an expert in biotech finance, the bill has practical utility for small companies. "If they need a big partner like a pharmaceutical company, they've produced enough information for the pharma company to bet on," he says.

Sahlman warns, however, that the change will not solve all the problems of financing entrepreneurial biopharma ventures. "This bill is part of a complex puzzle," he says. "It is one of multiple steps that need to be taken in order to get the level of innovation that this country needs."

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