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Reg A Revival

Creating an IPO Alternative for Small Biotechs

By Trista Morrison
Editor

Editor's Note: This is the second in a four-part series exploring new fundraising options for small biotechs.

Of the four Congressional bills aimed at providing small companies with new fundraising options, H.R. 1070 – which would allow private firms to raise up to $50 million publicly and trade their shares without the expense of becoming a reporting company – is likely to have the most immediate impact on biotech.

The bill, introduced by Rep. David Schweikert (R-Ariz.) and known as the Small Company and Capital Formation Act of 2011, passed the House in a 421-to-1 vote earlier this month. It is now in the Senate, where companion bill S. 1544 was introduced by Sen. Jon Tester (D-Mont.). William Hicks, partner with Mintz Levin, said the bills "could have an instant catalytic effect" on mid-stage biotechs that are running out of venture support, but aren't big enough for a traditional initial public offering (IPO).

In essence, H.R. 1070 seeks to revive an underused exemption known as Regulation A. As it stands now, Regulation A allows private companies to raise up to $5 million in an unregistered public offering, targeting anyone from venture funds and high net worth investors to mutual funds and non-accredited retail investors. The required SEC filing is less cumbersome than an S-1, and after the offering, Regulation A filers are held to looser SEC standards on items like audited financial statements and quarterly financial reporting. Although such noncompliance would preclude a NASDAQ listing, the company's shares are unrestricted and can be traded over the counter.

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Targacept Turmoil

Quality Questions Bedevil Developing World Trials

By Catherine Shaffer
***BioWorld Insight* Contributing Writer**

It seemed like a good idea at the time. Run a Phase II clinical trial and reduce your costs by as much as 10-fold. A top academic medical center in India charges only $1,500 to $2,000 per case report, less than one tenth the cost at a second-tier U.S. medical center. And trends show a majority of clinical study sites are now located outside the U.S., many in developing countries, especially Eastern Europe, Russia and India.

But a string of recent Phase III failures has raised troubling questions about the reproducibility of data from clinical trials carried out in developing countries. Investors and analysts who previously raised only token objections about comparability of U.S. and overseas trials are now howling with indignation following yet another Phase III flame out, this time by Targacept Inc.'s promising depression drug. (See *BioWorld Today*, Nov. 9, 2011.)

Targacept's TC-5214 missed its endpoint in the first of four Phase III trials, after a very successful Phase IIb. Targacept carried out the Phase IIb trial at 20 sites in India and three in the U.S. In that trial, patients treated with TC-5214 as an adjunct to citalopram hydrobromide showed an improvement of six points (13.75 points) compared to those that received add-on placebo (7.75 points).

But in the Phase III RENAISSANCE trial of TC-5214 as an adjunct therapy in major depression, the drug failed to separate from placebo at all. The self-flagellating response of The Street's Adam Feuerstein sums up a significant and growing sentiment about Indian and Russian trials, "The lesson from Tuesday's Targacept (TRGT) TC-5214 tragedy:

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"What's exciting is . . . the cost of doing the offering is a lot less than an IPO," Hicks explained. It could be hundreds of thousands of dollars less, once you consider legal, accounting, underwriting and printing fees, he said.

Additionally, Regulation A filers are allowed to test the waters by soliciting investor interest ahead of their deal – something prohibited in traditional registered offerings. As Tim Ryan, managing director and head of business development for OTC Markets explained, Regulation A would "open up the ability to see what kind of interest there is from the investment community; right now, you spend the money [to file] up front before you even see what the interest is."

Despite its many benefits, Regulation A is rarely used. The reason, according to Mitchell Littman, senior managing partner with law firm Littman Krooks, is that while registered offerings, including IPOs, are exempt from state Blue Sky regulations, Regulation A offerings are not. For a total raise of $5 million, the cost of coordinating with each state just isn't worth the trouble.

Enter H.R. 1070, which would boost the Regulation A fundraising limit to $50 million. Although the latest version of the bill did not add a Blue Sky exemption, Hicks noted that such an exemption might come, either now or a few years down the road, and in the interim there are service providers that specialize in helping companies with Blue Sky compliance.

Another Arrow

The details of H.R. 1070 and S. 1544 have yet to be finalized – the Senate version requires annual filing of audited financial statements and calls for a study on the impact of Blue Sky laws. But in general, Littman thinks the bills could "jump start the small IPO world."

Back in the 1990s, boutique banks like Robertson Stephens and Hambrecht & Quist often helped early stage biotechs complete small IPOs. As John Craighead, managing director of investor relations and business development for the Biotechnology Industry Organization, said during a recent conference, about two-thirds of the biotech IPOs in 2000 were preclinical. (See *BioWorld Today*, Oct. 26, 2011.)

Today however, even clinical-stage firms struggle to go public. With the exception of last week's pricing by Clovis Oncology Inc., every biotech IPO this year has taken a haircut on price. Revenue-generating specialty pharma firms have even had it tough – which made this month's $50 million

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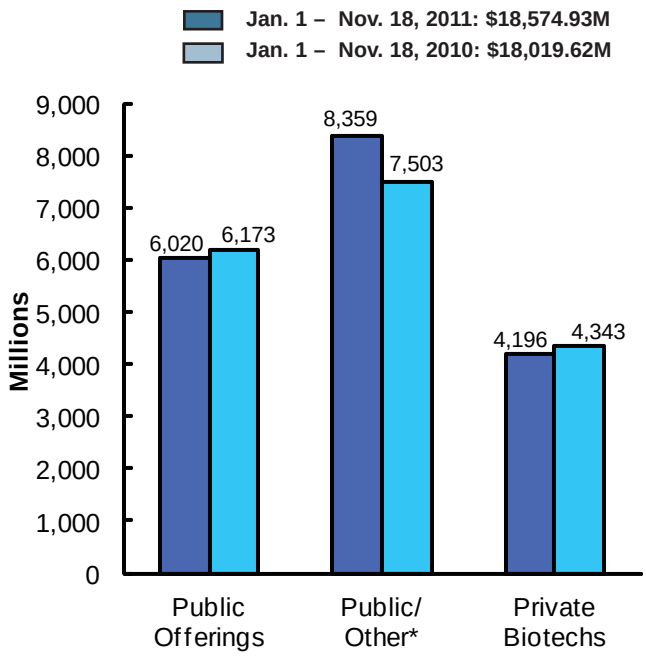
Money Raised By Biotech In 2011 Vs. 2010



* Includes financings of public biotech firms with the exceptions of public offerings and certain investments from corporate partners.

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EDITORIAL
Lynn Yoffee: **(404) 262-5408**
Trista Morrison: **(858) 901-4785**
Donald R. Johnston: **(404) 262-5439**
Internet: http://www.bioworld.com

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IPO filing from preclinical cancer stem cell firm Verastem Inc. all the more shocking. (See *BioWorld Today,* Nov. 4, 2011, and Nov. 17, 2011.)

"The IPOs that get out today have gotten so big . . . there's just a crying need for a $30 million to $50 million IPO alternative," Hicks said.

Canaccord Genuity Inc. investment banker David Schechner said he sees Regulation A as "one more arrow" in the biotech fundraising quiver – along with reverse mergers and Form 10 filings – but, he added, "I don't think it's a game changer."

The reason is that "even when the markets are volatile and challenging, quality companies can still get money" through an IPO, Schechner said, pointing to NewLink Genetics Corp. and Zeltiq Aesthetics Inc. He added that he expects the cost of capital in Regulation A offerings to be high, because such deals are not likely to offer investors significantly reduced risk or increased liquidity over a private round, and it's already a buyer's market.

"Investors in Reg A are not going to give you a discount over what you could get in a private round," Schechner said. "But it's one more opportunity to raise money."

Escaping Obscurity

In many ways, a Regulation A offering would be similar to raising money by reverse merging into an OTC-traded, cash-rich shell – although without the reporting burdens. In both cases, the move could be a stepping stone on the way to gaining momentum and eventually coming into reporting compliance and transferring to Nasdaq.

Yet for every reverse merger success story like Cougar Biotechnology Inc. or OncoGenex Pharmaceuticals Inc., there are many more that fail to gain traction with investors and find their future financing potential hobbled by low stock prices and limited liquidity. (See *BioWorld Insight*, July 25, 2011.)

What investors want, Schechner explained, is a good company with enough liquidity to allow them to get in and out of the stock. Once a company's market cap falls below $75 million to $100 million or its float falls below 50 million to 75 million, "it's not going to trade well," he said. That's what happened with some of the reverse mergers, and many of the small Series A filers will "automatically be in that camp," he said.

The OTC is also not known for liquidity, prompting one venture capitalist to predict that Regulation A offerings would be a financing, but not an exit. Hicks agreed it probably wouldn't provide instant gratification to VCs, but he noted IPOs don't either anymore, and at least Regulation A could give some portfolio companies who've run out of venture funding a chance.

Additionally, Ryan noted that OTC Markets Group's platform has "really transformed" over the last few years and is gaining traction with institutional investors. The system is now electronic rather than paper-based, and OTC Markets Group has split the marketplace into three tiers aimed at helping investors distinguish between highly reputable companies, emerging companies, and high risk companies. More than 10,000 firms trade on OTC, including close to 300 U.S. biotechs. "We've seen an incredible increase in trading volume," Ryan said.

Schechner agreed that OTC "has made a lot of changes and they are doing all the right things to attract investors. It's just a matter of time until it has the appropriate liquidity it deserves, but it doesn't happen overnight."

Even so, he thinks there will be demand for Regulation A offerings. "There's a whole group of people who like small, illiquid stocks," Schechner said, pointing to the fact that companies like Xoma Ltd. and Adventrx Pharmaceuticals Inc. have been able to raise money.

Hicks added that "a lot of the good banks and good investors and good companies" are realizing reverse mergers and Form 10 filings can be successful, and he believes the same will prove true for Regulation A. "If you put together good companies with good investors, I think these techniques could work and should work," he said.

If Regulation A takes off, companies will need H.R. 2167 to prevent them from being forced into SEC reporting once they hit 500 shareholders. Most private firms that fall into this trap under current law bite the bullet and go public, like Google. H.R. 2167, which is still in the House, would raise the reporting threshold to 1,000 shareholders of record and exclude accredited investors and employees who receive shares through a compensation plan. ■