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Capital Formation Series, Part 4

Opportunity vs. Vulnerability In New Fundraising Initiatives

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Editor

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

It seems increasingly likely that at least some of Congress's capital formation bills will soon become law, and that those laws will bode well for private biotechs by creating new fundraising pathways.

There's H.R. 1070, which would provide an alternative to the initial public offering (IPO), letting private companies raise up to $50 million publicly through the Regulation A exemption. There's also H.R. 2930, which would let start-ups raise up to $2 million through crowd-funding, essentially opening the private markets to non-accredited investors. (See *BioWorld Insight*, Nov. 21, 2011, and Nov. 28, 2011.)

Both bills passed the House with overwhelming bipartisan support last month, and several other capital formation bills are in the works, leading Columbia University Law School's John Coffee to comment recently that "a bill permitting the dumping of toxic waste . . . would have a fair chance of passage – if it were captioned the 'Job Creation Act of 2011.'"

"It's good to see both parties trying to free up capital," said William Hicks, a partner with law firm Mintz Levin. But in the investment world, new opportunities go hand-in-hand with new vulnerabilities. The key to making Congress's capital formation initiatives a success will be finding the level of deregulation that opens the door to fundraising – but not to fraud.

Rules of Engagement

The responsibility for managing the new fundraising pathways will likely be shared by many parties: lawmakers, federal regulators, state regulators, stock exchanges and individual investors.

Lawmakers have written some investor protections into their bills. H.R. 1070 and its companion Senate bill S. 1544 require Regulation A fundraisers to comply with state "Blue Sky" regulations, even though such state laws are preempted in the IPO process. H.R. 2930 does not subject crowd-funded firms to Blue Sky laws, but it does ban people convicted of

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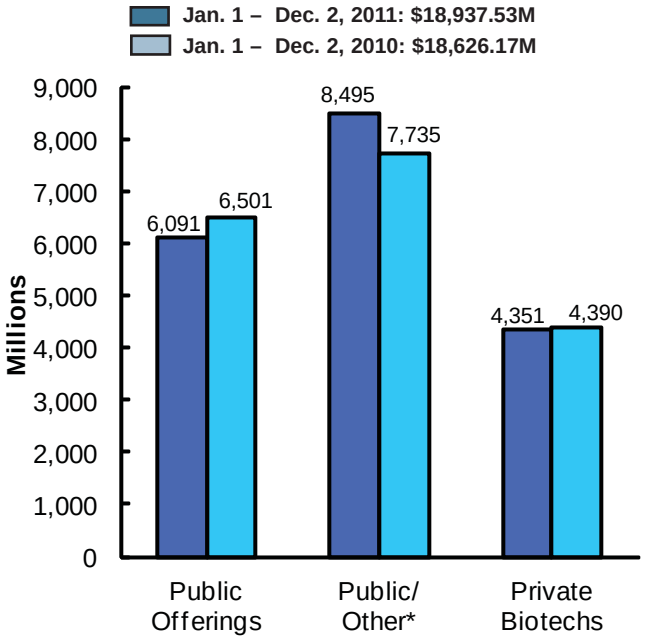
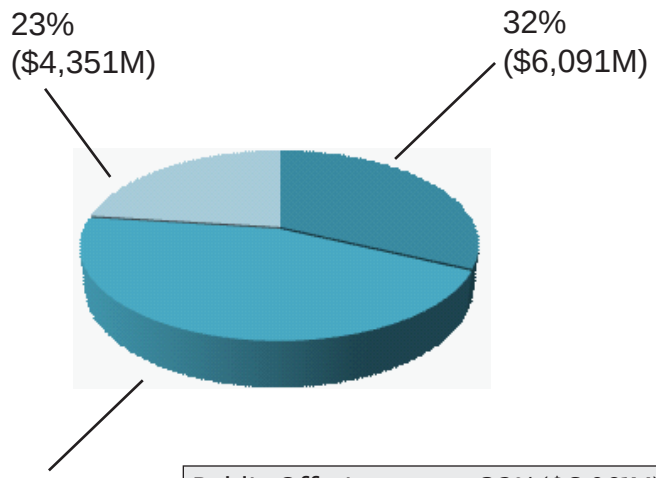
Money Raised By Biotech In 2011 Vs. 2010



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

This Week in BioWorld Insight

Money Raised By Biotech: Jan. 1 - Dec. 2, 2011



Public Offerings	32% ($6,091M)
Public/Other	45% ($8,495M)
Private Biotechs	23% ($4,351M)

Fundraising

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securities law violations from participating in crowd-funding.

Last week, the Senate banking committee held a hearing in which the various capital formation bills were discussed, and while there was much emphasis on the importance of freeing up capital to create jobs, many of the experts giving testimony also emphasized the need to protect investors from fraud.

At the federal level, the SEC will be tasked with much of the regulatory responsibility for the new laws, should they pass. But crowd-funding in particular might be difficult for federal regulators to police, according to Bob Webster, director of communications at the North American Securities Administrators Association (NASAA).

"States are uniquely positioned to regulate crowd-funding offerings," Webster explained. "These deals are smaller in nature compared to the types of transactions the SEC primarily regulates. A regulator in Washington isn't going to spend much, if any, time investigating the loss of a $10,000 investment in a coffee shop in Smalltown, East Dakota."

Hence Webster said the NASAA was concerned that crowd-funding bill H.R. 2930 preempted state Blue Sky regulations.

"Not a single state wants to do anything that might unnecessarily limit the ability of small businesses to raise capital and create jobs," Webster said. "We support capital formation, but we want to ensure it is done in manner that promotes investor protection. We want the ability to try to weed out any bad apples."

Not everyone agrees the states are best suited for the job of weeding out bad apples, however, and there's a risk they may weed out good apples. Mitchell Littman, senior managing partner with law firm Littman Krooks, explained that while federal regulators only check to make sure the appropriate boxes are ticked on a deal, state regulators will "actually look at the merits of a deal" and make a call on what's a good investment. He pointed to the infamous tale of how Massachusetts regulators deemed Apple's IPO too risky and forbade their state's residents from participating.

That was back when IPOs were subject to Blue Sky laws. They are not anymore, and some say the fact that Regulation A financings still are is a problem. Yet Canaccord Genuity Inc. investment banker David Schechner said he has "yet to see a financing not get done due to Blue Sky."

Beyond federal and state regulations, Mintz Levin's Hicks predicted over-the-counter markets will "play a big role" in monitoring companies that start publicly trading their shares after a Regulation A financing, or potentially if crowd-funded companies eventually trade over-the-counter.

The OTC Markets Group has already split its companies into three tiers based on level of disclosure, with the highest tier being reserved for companies that meet strict financial standards. In the lower tiers, symbols placed by a company's stock provide further warnings to investors: A yield sign indicates financial reporting problems, while a skull-and-crossbones signifies fraud investigations or questionable stock promotion practices.

But at the end of the day, "what we really are is an information provider," said OTC's general counsel Dan Zinn. The exchange doesn't have the regulatory authority to enforce laws.

Wisdom of Crowds

Whose role it is to protect investors, and how much protection they need, is to some extent "more philosophy than legal," Littman said.

Zinn agreed that it's ultimately the "investor's responsibility to do due diligence" – and that point is emphasized throughout OTC's website. "Does it sound too good to be true? Then it probably is," the website's investor information page warns.

On the crowd-funding front, the very nature of the investment vehicle might help protect buyers. RocketHub.com founder Brian Meece explained that while his firm validates the identity of each person submitting a project for crowd-funding, it is up to that person to deliver the promised rewards to investors.

"It's really built on trust and social capital," he said, adding that anyone being branded in real time with a bad reputation would be blacklisted by the hyperconnected crowd-funding community.

Stephen Muniz, partner with PureTech Ventures, suggested that once crowd-funding involves equity, perhaps crowd-funding websites should be sanctioned by the SEC.

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Week in Review

Financings
ArGen-X BV raised $37.1 million in a Series B round.
Celsion Corp. is raising $15 million in a private placement of stock and warrants.
Inhibitex Inc. raised $20 million through an at-the-market offering.
NuCana BioMed Ltd. raised $10.5 million in a Series A round for anticancer nucleoside analogues.
Oxigene Inc. established a $20 million standby equity purchase agreement.
Pozen Inc. sold royalties on migraine drug Treximet (sumatriptan/naproxen sodium) for $75 million.
Resverlogix Corp. is raising up to $17.5 million in a private placement of stock.
Rib-X Pharmaceuticals Inc. filed to raise up to $80 million in an initial public offering.
Synergy Pharmaceuticals Inc. is raising $15 million in a public offering of stock and warrants.

Deals
Affitech A/S received a buy-out offer from Trans Nova Investments Ltd. worth about $19 million.
Infinity Pharmaceuticals Inc.'s partner **Mundipharma International Corp. Ltd.** agreed to commit $50 million to various projects in 2013.
MacroGenics Inc. signed a $450 million deal with **Les Laboratories Servier** for a Phase I antibody.
PTC Therapeutics Inc. licensed its spinal muscular atrophy program to **Roche AG** for $490 million.
Purdue Pharmaceutical Products LP optioned **Transcept Pharmaceuticals Inc.**'s Intermezzo.

. . . And More
Celgene Corp. terminated its Phase III trial of Revlimid (lenolidomide) in prostate cancer for futility.
Gilead Sciences Inc. terminated the use of tenofovir gel in a Phase III HIV trial, for futility.
Idera Pharmaceuticals Inc.'s IMO-2055 was dumped by partner **Merck KGaA.**
Transcept Pharmaceutical Inc. gained FDA approval of insomnia drug Intermezzo (zolpidem tartrate).

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Such sites could be responsible not only for keeping investors informed about the risks of their investment, but for helping crowd-funded companies keep track of their shareholders.

"It's hard to keep track of 50 shareholders . . . much less 50,000," Muniz said. Crowd-funding websites might be able to fill a niche by providing record-keeping assistance.

Regardless of how it plays out, controlling fraud in crowd-funding and other new financing pathways will be critical – particularly for biotechs, which already offer as much, if not more, risk than many investors can handle.

But if it all comes together, and if companies are able to access new investors in a way that protects against fraud, it "would be a sea change," Hicks said. He noted that from a global perspective, many investors are less concerned about fraud in the U.S. financial system than they are that the system has lost its appetite for risk. Hicks predicted that "these legislative changes could be the first step in the process of finally getting back to having a securities regulation system that is copied by the rest of the world, not one that is viewed as regressive." ■

Sequencing

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generically with endocrine tests, cardiac tests and so forth?" If such workups will be done only after a trial has been identified, they add to the time between trials – and time is something late-stage cancer patients don't necessarily have. "That's where we have to reconsider how we do these trials."

Chinnaiyan was circumspect about how likely, and how quickly, such restructuring is to proceed. From his own discussions with NIH and NCI researchers, as well as, to a lesser degree, people at the FDA, "they know of this being an issue, but it's unclear how they are going to address it," he said.

LoRusso noted, though, that it may be getting ahead of the game to think about late-stage trials. In her opinion, the reason that mutation targeting is used in early stage trials is due to a practical issue: that's where the targeted drugs are.

"Most of the targeted agents right now are still in clinical development," she said – specifically, in Phase I and II trials.

And just as it is early days for many targeted agents, the same is true for whole-genome sequencing in a clinical setting.

Whole-genome sequencing is "still an investigational tool," she said. "We're a ways away from such a late-stage trial because we're still a ways away from defining how best to use molecular profiling . . . I don't think we're ready yet for Phase III. But we will be." ■