



Troubled Times Tool Kit



Weathering the Current Economic Storm: A Tool Kit for Life Science Companies

BioNJ CFO Forum – December 11, 2008

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BioNJ's CFO Forum, part of the association's virtual "Tool Kit for Troubled Times," brought together industry executives, strategists, and entrepreneurs for an extraordinary morning of discussion and analysis about how best to weather the current economic crisis.

Panelists addressed a wide range of issues, from understanding the funding environment to adopting new business models. Realizing that the bioscience model (lean operations and heavy up-front investment) may be particularly susceptible in this economic downturn, a "survivor roundtable" featured invaluable financial, legal, and communications advice.

Most of all, the forum set the tone for the industry with a reminder that focused, innovative companies have survived economic downturns before – and they will again.

I – Assessing the State – Understanding the Funding Environment

BioNJ President Debbie Hart welcomed more than 75 attendees with an acknowledgement that the current climate might be grim, but bioscience companies have been through tough times before. She announced the launch of BioNJ's "Troubled Times Tool Kit," and introduced the forum as one of a series of initiatives designed to offer practical advice to companies.

In "Assessing the Stage – Understanding the Funding Environment," **Paul Schmitt, Managing Director of Novitas Capital, and Todd Brady, MD, PhD, a Principal at Domain Associates**, offered their views on what their venture capital (VC) companies are looking for, and how things have changed in this economy.

"Looking at the environment today, we feel good that there are very heavy VC resources," said Schmitt. "Everyone's doing triage, but lots of funds have raised a lot of money and it has to be put to work."

The emphasis today is on a company's ability to produce cash. "No one is into company building. They're looking for products to be sold quickly," he said. He noted that one CEO search has dropped the "visionary" requirement from its job description, saying that management teams don't want to spend money on infrastructure, preferring companies that have project management and outsourcing capabilities.

Brady noted that he had recently met with a KleinerPerkins partner and had three "must-do's" for biotech companies:

- Conserve cash
- Hit your milestones
- Don't expect any cash in 2009.

He said that even though this is always good advice for companies, remembering these basics is imperative now.

Brady agreed that VCs that have raised funds will have to deploy this capital, and there may be a flurry of activity in the second half of 2009. "The good news is that it's a very good time to be a private company with lots of money," he said, "and it's a reasonably good time to be a public company. It's a bad time to be raising money, at least for the next 12 months."

Brady warned against the danger of a "fire sale" mentality. "The perception from buyers is that everything right now is really cheap, and no one expects to pay for anything."

He noted that there is a massive initiative in every VC firms to arrange portfolios to raise non-diluted capital, and agreed with Schmitt that there are many mechanisms to tap into, including government grants from NIH, NCI, and SBIR.

"The days of building out companies are really over now," he agreed. "This is not the time to come to a private financier to build a massive operation – that's not going to happen."

Brady said he is generally an optimist, but noted that bioscience is usually the last to feel a recovery. "We will see a small shakeout on companies like we did in the nuclear winter."

He gave this personal example: "In 1999, I left VC to form a genomics company. We had seed funding and the industry was hot. Then genomics crashed, and we spent 18 months without salary trying to raise money. We finally got \$1 million from Novartis, which triggered \$10 million from Johnson & Johnson, but it was very hard. It all worked out, and eventually there was light at the end of the tunnel."

Why is there a lack of IPOs and M&As?

Schmitt – Big pharma has stacks of distressed deals looking for funding. Next year could be a good year for pharma deals. They will need product, and they're especially concerned with efficacy and safety.

Brady – The best way to raise money is to act like you don't need it. Now is the time to develop relationships, but don't ask for money. Preparing for M&A is a 12-month process. Now is the time to focus on that, rather than raising money.

Is it advisable to go to pharma and ask what they want in advance, rather than waiting until you've hit milestones?

Schmitt – This is absolutely the best way to go. Optimize your value with a sense of how to position your drug in the market place so we know what to invest in. Remember that there's a two-year window to make a pharma deal, and the people you're dealing with are more likely to leave due to retirement or layoffs.

How do you improve ability to get grants?

Schmitt – If your CEO or founder has been a proven academic grant getter, that's helpful because academics have the skills. If you want a DOD grant, political help is useful. Obviously, the science has to be good.

II – Partnerships and Collaborations

As Debbie Hart noted, “in this environment partnerships and collaborations become more important.” **Brian Lenz, CPA-CFO Arno Therapeutics**, moderated the conversation among the representatives of three distinct company types: small bio, large bio, and big pharma.

Shiv Krishnan, PhD, Senior Director, Partnering & Innovation, sanofi-aventis, presented a snapshot of the partnership structure at his company.

“Like everyone, sanofi is going through tough times,” he said, “but we are weathering the storm. A new CEO takes the helm in January, and he will revamp the company by revisiting organization and strategy. These changes will include R&D strategy and organization.”

He noted that there will be tremendous emphasis on partnering, innovation, and building relationships with companies that can fill the pipeline. “This will be a change from the past four years, when sanofi was very selective about creating partnerships.”

Sanofi continues to maintain a great interest in breakthrough innovation. “We are willing to take a risk for first-to-market,” he said.

Going forward, there will be a new emphasis on regionalization. “There will be much more distribution of decision-making into regional areas,” he said. “This presents an

opportunity as decision-making devolves for better understanding of innovation and market needs.”

Krishnan warned that China will pose a strong challenge to American research in the future. “Many drugs produced in China now are me-too products, but many Chinese scientists were trained in America and are doing cutting edge research in China. There has been a massive injection of government funds – \$1 billion just in drug discovery.”

John Maki, President & CEO, Vicus Therapeutics, described the process of shifting to a new business model to adapt to the new business environment.

“Vicus has three drugs in clinical development,” he said. “It requires \$40-50 million per drug to bring to NDA, and in this environment, that’s tricky. Capital markets and partnering interests are frozen, especially for atypical assets, such as biotech’s early-stage assets. It’s not a particularly attractive time to raise money.”

Vicus has turned to a model that was successful in 2003, when Aspreva partnered with Roche. “Just as Aspreva did, Vicus is re-purposing drugs, bring products to a new indication and adding the repurposed drug to improve efficacy.”

Maki noted that in a cancer regimen, many patients drop off or become intolerant after only one or two cycles. “Adding one or two additional cycles to a drug can mean a better treatment and a significant increase in sales,” he said.

“This model works for many reasons,” Maki said. “It addresses serious unmet medical needs, provides a high ROI, and creates no risk for primary indication, since the partnered drug is not tested against placebos or competing drugs.”

Maki added that there are many opportunities that get passed over because no one has figured out how to make them profitable. “You must show the potential to add value,” he concluded.

Christian Schade, Senior VP Finance and Administration and CFO, Medarex, said that Medarex has always worked with partners and will continue to do so. “As a public company, we’re dependent on capital markets,” he said. “We’re looking to the future development of our pipeline, and believe that a potential source for funding will be from big pharma companies in need of new product development opportunities. The blockbuster model of product development is no longer viable, and companies will no longer be looking for home runs, but they will still need solid base hits. Biotech is going to provide many of these products.”

Schade said it’s important to remain focused and concentrate on what your company can and cannot - do. “For one particular program, we did not have the internal band-width to do a large Phase II study, so we structured a deal with MedImmune to meet our needs. We got cash up front and all costs of clinical development were borne by MedImmune through to proof-of-concept clinical trials. At proof-of-concept, we have the opportunity

to then opt-in as a co-promotion partner. This structure directly benefits both Medarex and MedImmune.

Schade made these points:

- Don't underestimate the value of your technology platform – it has value to big pharma – try to negotiate non-exclusive licenses
- Don't overlook dilutive funding – it's not pretty financing, but nonetheless, it's money, and it may keep you in the game
- Remain focused on your business platform
- If you're a public company, stay visible with investors
- Be ready to finance – update documents, due diligence, and keep bankers and other advisors close
- Be ready for the day when the window will open again- and it will!

Brian Lenz asked all three companies what they are doing to “hunker down” and survive:

Krishnan – There are layoffs in North America to conserve cash. We will continue to focus our R&D resources on highly promising areas. We're diversifying into other types of products, such as nutraceuticals and OTC that are faster to market.

Maki – We've stopped spending on Phase II projects because we don't have \$40 million to spend. These projects will wait until we have the money or a partner.

Schade – We currently have a healthy balance sheet, so hopefully we can weather the storm. We've never spent more than we needed to execute our business strategy. We have no idea when the capital markets will open, but we remain focused on executing on product development opportunities as the catalyst for future value creation.

III – Survivor Round Table with Industry Experts

With a cry of “No voting off the island!”, moderator **James Dentzer, CFO, Amicus Therapeutics**, urged attendees to consider not only the current environment, but also what the environment will look like when the financial window opens, and position themselves now to be successful in the future.

Michael D. Becker, President & CEO, MD Becker Partners LLC, an independent management consulting firm with a concentration in the biotechnology, pharmaceutical, and medical device industries, offered this investor relations advice:

- Don't adopt a bunker mentality – be visible
- Your contacts will move around – take advantage of these changes to create opportunities to expand analyst coverage and shareholder base
- Stay in touch with investors but don't over promise

- Build long-term relationships – short-term relationships produce short-term investments
- Don't lose your credibility – you can't get that back when economic conditions get better!
- Stay focused on the business, not the stock price
- Speak with one voice – get all your constituents on the same page

Raymond Thek, Vice-Chair, Technology, Lowenstein Sandler, offered timely advice taken from the jar of Hellmann's mayonnaise in his refrigerator – “Keep cool – don't freeze!” He noted that the climate has changed considerably – there has been no IPO market for the past year, and it's difficult to close M&A on a value-backed company with the value subject to rapid change. VCs are reluctant to invest because they don't know how much they need to reserve. All these factors will continue to make it difficult to close deals through the first half of 2009.

Thek said that the risk of exposure to complaints rises significantly in a distressed economic climate. When offering insider financing, be certain that the board is “papered” and protected against claims of sweetheart deals. Be aware that investors who have lost everything will look for cash, and company officers are always a target.

For companies facing bankruptcy, Thek advised preparing a scenario with a realistic wind-down plan:

- Check insurance coverage - if it's claims made (as opposed to occurrence) directors and officers may be personally liable when the coverage expires
- Be honest with creditors – officers in private companies can be personally liable for claims of fraudulent misrepresentation, and officers of public companies could find themselves “making new friends at the SEC”
- Make payroll tax payments – Set up an escrow account to protect against bank account sweeps and maintain the ability to pay taxes – or “make new friends at the IRS”
- Make sure your reputation doesn't suffer – Remember Nixon's Vietnam strategy – “Declare victory – and get out!”

Allen Wilen, CPA, Partner, Restructuring Services Practice; Amper, Politziner & Mattia, urged attendees to speak with their accountants sooner rather than later. “If your cash flow is good for 18-24 months, you've got time. If I get called when you're left with 4 months, there's only one solution – you have to fold up.”

Wilen said that cash flow projections should be realistic. “Many people are still using projections that are dated. If your ROI is down and inflation is affecting your assets, you need to ask if you've factored that into your projections.”

Most importantly, Wilen reminded attendees that they have both a legal and a moral responsibility to their companies and to themselves. “Do what you have to do with honesty and integrity. This is not the time to do something stupid. Remember that no distressed situation is worth going to jail for or losing your reputation.”

Tom Gordon, Relationship Manager –Life Sciences, Silicon Valley Bank, said that he is seeing a steady increase in companies looking for venture debt. Companies with eligibility for venture debt should have several products in development and be willing to work with other companies. Venture debt can be easier to obtain in this environment than venture capital, but there is a downside: new investors will want guarantees that their capital will not be used to repay existing debt, and this can be a huge stumbling block to future deals.

What’s the greatest exposure to liability?

Wilen – D&O liability, usually because someone misrepresented in a white paper for an investor – there must be a basis for those numbers.

Thek – Fraud claims. Remember that these are always viewed in hindsight. Even if you were dealing with all the information you had at the time, a judge or jury will always look at the facts and ask “How could you not have known this?”

Becker – Communications should always be vetted. Always have two people in media and investor-related discussions – it’s good practice if you’re questioned later, and the second person can also make subsequent adjustments/disclosures if you are venturing into areas where you shouldn’t go.

Is there a way to discuss a difficult financial situation with vendors without creating a problem?

Wilen – It’s difficult. Public companies can’t hide when they’re in the zone of insolvency- anyone can look. If your company is private, you run the risk of overselling when trying to reassure.

Take Advantage of BioNJ’s Resources!

Debbie Hart concluded the session by noting recent developments that will help BioNJ members:

In New Jersey, the **Economic Development Authority** has announced a new grant program that provides rewards for capital investment and new jobs created. Also, the NOL provisions have been extended from 7 years to 20 years.

BIO is urging Congress to enact an economic stimulus program for the bioscience industry, including some provisions, especially NOLs, which are modeled on New Jersey’s program.

BioNJ has launched its “Troubled Times Toolkit,” intended to offer strategies, stories, and tools to help companies weather this economic climate. The virtual program is live at www.BioNj.org and will be updated with new information.

Hart also offered reminders of these additional services:

- Purchasing program through **Fisher Scientific**, which has saved BioNJ members more than \$2 million since its inception
- **Workforce development**, including free training and career services
- **New Jersey Knowledge Initiative**, free access to research databases such as *Nature* through the New Jersey Knowledge Initiative (NJKI), which is available through the New Jersey State Library

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