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SMALL SIZE, BIG PRIZE

An esteemed panel of marketers from small biotech companies discusses the unique challenges and opportunities of bringing novel products to market. **James Chase** moderates the session

James Chase (MM&M): Each of your companies is built on a foundation of scientific discovery. What are the challenges of making the transition to more of a commercial mindset?

Stefanie Nacar (Infinity Pharmaceuticals): When you're at a smaller company I think there is always the challenge to change the culture and get people comfortable with commercialization. Sometimes, to the scientists, it's like they're selling their drug out when they see the commercial people come in. I think the hesitancy comes from a lack of awareness or education about why these certain functions are important. It's not just about trying to show activity in your compound, but how it could be clinically relevant once your drug is approved. You need to educate and share the story about why it matters.

Unfortunately, I think a lot of the smaller companies probably learn that the hard way, where they resist and resist, and then all of a sudden they come up with a challenging environment where it's either competitive and the data's not getting as much of a foothold as they would think. Or we all think that the results are fantastic yet it's not being covered in the media. Or it's not getting the right placement at scientific congresses. And a lot of it has to do with building that foundation and that awareness and building that story to frame the data.

As a commercial person at a smaller organization that hasn't been through



it before, I think you have to have a certain personality where you have to be comfortable knocking on people's doors and saying, "This is where I could provide value. Let me be a part of this meeting. This is how this could be helpful, and this is why."

Lori Horvat (Ariad Pharmaceuticals): I think what's interesting is a situation where scientists recognize the need to involve commercial but they don't recognize when is the right time. I remember last year our head of biology put together a meeting. He said, "We have this exciting preclinical asset that we've invested all these resources in and just want to make sure that you're bought in." And after the course of the discussion, at the end of the day we killed it, because from a commercial perspective it really wasn't worth the investment and the resources.

He was crushed. I mean, the fact that he pulled us into a meeting to get our buy-in was good, but it was a little bit too late. That conversation probably should have occurred earlier. So I do think part of the battle is recognition of the value of commercial, but then the other part of the battle is involving us at the right time.

Paul Merrigan (Aegerion Pharmaceuticals): My situation's unique in that we were a commercial organization almost from the beginning. Our CEO is a sales and marketing guy, and came over and bought an asset that was in a Phase-III [trial]. So we have no research, but we have development. So instead of hearing that the product will sell itself, it was always the mentality that we all have to be in this together.

And so when you're building small, functions didn't exist yet. So everyone was always at the table all along the way to learn about what's coming down the line in commercialization and why we had to do certain things and the certain functions that you had mentioned.

Stefanie (Infinity): Do you think having a CEO from a sales and marketing perspective precipitated your shift in culture, or how that was embraced, or how that steered your strategy, or the support that you had?

Paul (Aegerion): There's quite an advantage to having a scientist start a company and run it. But there's tremendous advantage of having a commercialization person do the same. At the beginning, some of the things we learned were when you hire people there is specialization within specialization. For instance, if you're a regulatory group whose primary goal and success and achievement has been getting approval but has no experience in the post-marketing world, and has to learn promotional review, then that causes a learning issue internally.

James (MM&M): Carolyn, you've worked with a number of smaller companies, both science-led and commercially minded. What are your observations?



Carolyn Morgan (LehmanMillet): Both have their pros and their cons. When we work with companies who have been started more from a scientific standpoint we find ourselves having to work a lot harder to help the organization see the benefits of commercial. They're very analytically driven, so they want to

see results before they're willing to put in the investment. So we spend a lot of our time helping the commercial folks inside these organizations justify why you have to establish yourself as a brand.

On the flip side, commercially-charged organizations can act almost too risky. We had one that was going to go down with just a brochure and then release the rest of their materials at risk. We admire that and it's kind of cool... but we don't want to be the agency that got the letter.

James (MM&M): Presumably, smaller companies are forced to build functions and develop processes on-the-fly. Has that been your experience, and can you share any examples?







Lori (Ariad): We made a strategic decision to build an infrastructure in Europe. There were individuals that were hired to build—from scratch—an entire European launch plan in six months, which was pretty miraculous. And here we are, on the fly, a year and a half into it, and we've never really taken the time, gone off site, and defined what is the role of global marketing versus the role of EU sales and marketing, versus what's the role of each individual country marketer? And that's just marketing. I could say the same for medical affairs, global health economics. I mean, I could go down the laundry list. We still haven't defined some of the processes that I think ultimately will be important for us to be successful in the long run. That's a challenge.

"You have to be comfortable with knocking on doors, and saying 'Let me be a part of this meeting'"

- Stefanie Nacar, Infinity Pharmaceuticals

Stefanie (Infinity): I think that it's a challenge, too. And a lot of times letting the different functions fall and thinking about what experience do I have, what experience do my colleague and I have, and it doesn't matter what function or what title you're in; it's about how can we best move this forward? You're forced to be comfortable with that in a smaller organization versus a larger organization, where from my experience, you are in your expertise, and your function, and your silo, and everyone has their responsibility and their area. So there is a lot of building processes on the fly.

Lori (Ariad): I came from Bristol-Myers Squibb, from big pharma, and now I actually appreciate some of the processes and structures that big pharma has in place. I love being in a biotech and it's great that, you know, everybody rolls up their sleeves and gets it done. It's a fun environment to work in, but I feel like it has to be the right balance. So I think there is some beauty and some lessons learned for those who have been in a big company to kind of bring a little bit of that rigor, processes and structures.

Paul (Aegerion): Flying the plane and building it too is kind of exciting and scary, and it's all at the same time. You have comfort, in that, okay, it's still flying. But you're uncomfortable that "I don't

know if I have wheels to land," or "am I going up?", or whatever. So I think that when we started it was like, boy, we need some processes. So wait, do we even have an SOP process to create an SOP? I mean, we're starting from scratch. And everything really needs a process ultimately at some point in time, or you don't get consistency, you don't have compliance, you can't expand, you can't transfer knowledge.

And, combined with every other commercial piece that you do, whatever playbook you put together, every marketing plan... there isn't a guide that says this is the right way to do it. So from the beginning, every system, whether it's sales, operations, distribution, each function has to create its own process on the fly. And it is hard sometimes to be able to come in and say, "Well, we're lucky we have phones, okay?" as opposed to "Do the phones work?" You're at that level in a startup company. But we get to shape it ourselves, and that's the fun part about it.

James (MM&M): So, the scenarios that you have just described... would you say they've been detrimental to your progress so far?

Lori (Ariad): Not at all. I think it's really when you're in launch mode. Once again, we're all focused on one prize, and so in the short term, get it done, launch, drive sales. But we're going to have to start to refine and make adjustments. And I think it's more in the longer term where I think we are going to need processes to be successful. So I don't think it was a detriment in the last year and a half, but moving forward we've got to lengthen that runway, we've got to be efficient, we've got to make the right choices globally.

Paul (Aegerion): My experience and training of a large global company was you would have a global strategic plan and you would roll it out. And it would give guidance on what were your critical success factors, your objectives, what each country should be considering for being launch-ready, etc.

And so when I joined Aegerion, that's what I started doing, because that's what I knew. And then I realized, well, who am I sending it to? Myself? No, I mean, that was like the joke. And then time started running out. Every year is different from the year before, from lessons learned.

Carolyn (LehmanMillet): I think that when you're thinking about a global organization, we have these conversations often with our







clients... do you start in the US and then move outward, or do you start from a global structure? And it's a little bit of a crapshoot because it really does come down to investment of resources and really how you can allocate. And if you're not going to be going truly global at first, then to really invest that in that kind of scaling is a challenge for a lot of companies.

But I'm always a big believer in making sure that we're at least thinking that way and making sure that we've got a little bit of that long-term vision in play, or else we're going to end up with a plan that isn't really executable if it's only born from one location. It's rare that we find ourselves not working on a global scale in one capacity or another.

Lori (Ariad): We're talking right now about three small Cambridge-based biotechs who want to go it alone and global... we all want the big prize of being global entities. And that's a very different philosophical approach from 10 years ago where all small biotechs were partnering with big pharma to commercialize outside the US. It is fascinating.

Stefanie (Infinity): I think innately it's a certain type of person, it's the underdog... small companies want to be able to do it and show that there is tremendous value in doing it. But when you look at what now needs to be done to get these compounds to patients, it's such a disheartening story. You see smaller companies that have a very good compound but because of the nature of the business they're just not able to get that compound, that treatment to patients.

Where is the balance between the patients and between getting a product, finding value for your investors as a public company. And how do you think about letting go of some of that control for the greater good to get the drug to patients faster?

James (MM&M): Does the collaboration that's required to get the product to patients always have to involve concessions to a big pharma company?

Stefanie (Infinity): There's a lot of things that come into play, and I think every company's philosophy might be different. I mean, you could partner with a very large pharmaceutical company, and they just want to niche your drug to a certain indication because they might have other pipeline products going on that might end up competing. There are always other things in play. You just need to

find the right partner that could collaborate well across the different functions and see the vision in a similar way.

Paul (Aegerion): It could be the opposite, too. I mean, particularly in a highly specialized area, a well-defined rare disease, if you provide this to a non-patient-centric, large pharmaceutical company, they won't know what to do with it, and it won't get to as many patients. And so this is a trade-off. It goes on both ends.

"Flying the plane, and building it too, is kind of exciting and scary —and it's all at the same time"

- Paul Merrigan, Aegerion Pharmaceuticals

James (MM&M): We've talked a lot about the issues, the challenges, the roadblocks of being small, but there is another side to it, that you guys are nimble and cutting-edge. Do you see opportunities in being small?

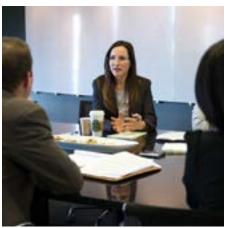
Lori (Ariad): Yes, it's a huge advantage; we can react quicker. I mean, the amount of information we have at our fingertips and our ability to turn our strategy on a dime and our messaging is clearly a competitive advantage. Because in a large company there's just a lot more bureaucracy, processes take a lot longer.

If you want to bring something through a medical legal review process you might need a one-month lead time, whereas I can bring everybody together and get them in a room tomorrow, if it's urgent.

Stefanie (Infinity): I completely agree. I think that my experience selling for a large pharmaceutical company and then also launching, you're almost slotting your compound into the sales force that you have and figuring out what physicians you're going to call on, and you have your approach. But we really have the opportunity to say, "What do our customers need? How do they want to learn about this? How do they want to engage?" We could be creative.

You can think of it more as a customer engagement, not that you're pushing information out to get a prescription written. It's, how do patients need to feel about the drug in order to accept the treatment? How do physicians need to accept the information







to feel comfortable and confident that this patient type is the right patient? You're looking at it from a completely different perspective.

Paul (Aegerion): You get in there for one quarter and you say, okay, what did we get right and what did we get wrong, and you end up getting more things wrong. But the things you got wrong, you can pivot from. You can incrementally grow within a quarter. If you go back and ask, "Did we follow the plan?" you would think we didn't do very well. But if you looked at it and said, "You didn't really follow your plan because you changed it as you learned, and because of that you've got to be successful," and you were, then that was the right thing to do. In the end we have to change the world. We have to change the thinking and the perceptions of the product or the disease.

"In big pharma, if you want an MLR review, you might need one month; I can bring them together tomorrow"

- Lori Horvat, Ariad Pharmaceuticals

Lori (Ariad): It's interesting because we all are one-product companies as well, right? So our people are 100% dedicated every single day to the one product. You're not competing with a sales representative that has three products in their bag.

And it's a lot easier to control the message when you have a lot fewer people. In an ideal world, all marketers would love to believe that everybody's on message, but that's just not the case. We know that ultimately people are going to adjust conversations to whichever direction that physician takes them, which is appropriate. But our ability to really keep people focused and driving toward one strategy and one goal gives us an advantage, because we're competing against Pfizer, Novartis and Bristol-Myers Squibb... all of these sales representatives have multiple products in their bag.

James (MM&M): Are you experiencing the same rep access issues as the rest of the industry?

Paul (Aegerion): Yes and no. I would say that it depends on what specialty. It is challenging. But when you get engaged in a rare disease, that's highly specialized, when it's mostly not about this product,

it's about a patient in need and maybe this product can help them, it's engaging. And once you do that, you can get hours with people. But getting that foot in the door and being differentiated as a company—how you came to be, what you are all about—is a challenge. A lot of what you do at first is selling your company name.

We have the advantage of being tied to an academic specialist, so there are things you learn that people will respond to, because the academic people want the other academic people to win, too, and that this is a partnership approach of doing this. So we figured out what are the buzzwords to get us in the door and differentiate us from other companies. But it's a big challenge.

Stefanie (Infinity): Which brings up a really interesting conundrum; smaller companies have to be very selective about where they're going to invest. So where and how do you now get that information and that message to these customers in that way? What types of mediums are you going to use? How do you shift your focus and your tactics differently because of that? And then also within the budgetary constraints of making everything that you do as impactful as possible, rather than large pharma, large budget, just going through your playbook of activities.

Paul (Aegerion): We try to take a different approach. If you can't get the physician, get the nurse, get anybody you can and say, "I'm here to help find if there are patients falling through the cracks. Do you have patients that look like this, that come like this? Anybody you know who's like 30 years of age and under who's had a heart attack? Do you know why they had a heart attack? Is it a genetic condition?"

And they might say, "Well yeah, I remember this guy Jim." So now I want to talk to your physician about Jim, because there could be something available for Jim now. So you got to come at it a different way. Because if we come in, I've got this product, so they don't know the disease, they don't know the product name, and they don't see reps, you're done, right at the beginning. So you got to be creative. And peer-to-peer is probably where you end up going to get other people to kind of get the word out for you.

For more discussion from the group on topics such as: non-manpower promotion, digital communication and social media, balancing the needs of different stakeholders and responsibility towards patients, see an extended version of this article at mmm-online.com.