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04 Aug 2016 | **Analysis**

Q&A With Nadim Yared: AdvaMed's Next Chair On Capital Formation And Global Challenges

by David Filmore

Nadim Yared is set to become the first small-company CEO ever to chair AdvaMed's board of directors in March. The CVRx executive spoke to *Medtech Insight* about what that means, the challenge of raising funds in medtech, and AdvaMed's role in the current political environment in the US and abroad.

Nadim Yared at a Food & Drug Law Institute meeting earlier this year.

Source: Ferdous Al-Faruque

Nadim Yared has been fighting the *good fight* of a medtech startup for the past 10 years as CEO of cardiovascular neurostimulation firm *CVRx Inc.*More recently, he has taken on a more prominent role in policy advocacy for industry, first as chairman of AdvaMed Accel, the division of the industry trade group that is focused on emerging-growth companies. And now he has been elected as the next chairman of AdvaMed's board of directors.

When Yared takes on the board chairman role next March, it will be the first time an executive of a small company has filled a post traditionally reserved for the Medtronics, J&Js and BDs of the world. His appointment is no accident, Yared affirms. It is meant as a signal by AdvaMed of the organization's commitment to small-cap company issues and concerns, a message the trade group has been trying to drive home for years.

Yared says as board chair he will continue the priorities already set by AdvaMed, pointing out that all companies, no matter their size, face the same regulatory and reimbursement challenges. But there is no question that he has thought deeply about the capital-formation challenges particular to startups and that he has a lot to offer on that issue.

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"Ten years ago, with those same leadership skills, it may have been still difficult to become the chairman of AdvaMed as compared to today."

Yared spoke to *Medtech Insight* about what's on his mind as he prepares for the high-profile role. A portion of the interview, lightly edited for clarity, is below.

Q ***Medtech Insight*: Congratulations, Nadim.**

A Nadim Yared: Thank you. I am humbled by the responsibility that I would have. It's a big thing, from all of the stuff that we might be faced with, from the Brexit to a new president and possibly a new Congress in the United States. A lot of things going on. Exciting days ahead of us, right?

Q **It is definitely a dynamic period to say the least. I would be curious to get some thoughts on how some of those larger issues will impact the medtech space. But, first of all, I wanted to get your take on how we should interpret that you will be the next chairman of AdvaMed. Before now, it's really been the larger companies that have been more prominent on the board, certainly as chair. What does it mean from your standpoint that you, as a small company CEO, are taking on this responsibility? What's the significance of that?**

A For AdvaMed, it's an important signal. There may have been some perception in the past that AdvaMed caters only to mid- and large-cap companies. That is incorrect. 70 percent to 75 percent of our members are companies smaller in size. Smaller companies have often the absolute same priorities as large companies. We're talking about fluid timelines, burdensomeness of some clinical trials, reimbursement of new therapies, innovations, etc. – those are the same, whether they're obstacles or opportunities, that face larger companies.

However, smaller companies do have some unique constraints, as well, particularly ones related to capital formation. I don't think Medtronic needs to raise money to

develop the next product line, right? Most profitable companies don't face that; but most startups are still in a mode of heavy investment and they need access to capital. That is one of the unique elements.

From AdvaMed's perspective, we've been catering to the needs of smaller companies for a while now. About four years ago, we created a special board of directors—we call it *Accel* —that serves the needs of smaller companies, and I think as an industry trade association, we wanted to send a stronger signal here that everybody counts, that every vote counts, every single company counts. There are no smaller issues.

The current chairman of AdvaMed, Vincent Forlenza, the chairman and CEO of BD, is coming from the diagnostic world and that is new to AdvaMed, as well. Now, between the traditional mid-cap and large cap medtech companies, diagnostic companies and now smaller companies – we are showing that any one of those companies can take the leadership here and guide the trade association.

"Companies right now require more capital from inception to exit than ever before, and the amount of capital available is less than half what it used to be before."

Q **I'm sure your personal attributes were a factor here, but it sounds like you are saying that simply the fact that you are a small-company CEO played a significant role in your election as chairman. That it was a very conscious effort by the board to go in that direction. Is that accurate?**

A I'm not saying it was planned this way, but clearly it played out this way. I demonstrated the leadership skills and the influence that my peers wanted to see, but 10 years ago, with those same leadership skills, it may have been still difficult to become the chairman of AdvaMed as compared to today. It's about being there at the right time, the right moment; having all of the players understand the strategic

imperative of giving voice to smaller companies and sending a strong signal to Capitol Hill and to the industry at-large that AdvaMed serves the needs of everybody. I wish I can tell you that it is all about me. It is not. Part of it is about me, but the rest, the big part, is about the industry and the trade association, and where everybody wants it to go.

Q **What about the other trade groups out there, in particular, the Medical Device Manufacturers Association, which defines itself by a focus on smaller companies?**

A From a size perspective, AdvaMed has the broader representation, no matter which way you cut it, whether by how many employees are in all the companies who are members of AdvaMed, or from a revenue perspective, or even from a number of entities represented – it has the lion's share.
With regards to MDMA, I think there is a role that they can play. Over the past five years, MDMA and AdvaMed had played together very well. You cannot see the light between these two organizations. Many companies are members of both at the same time.

But what we're trying to avoid is having any perception that AdvaMed is for large companies. AdvaMed is for everybody. It's not a competition. It's not about who becomes the largest, just ensuring that, as an industry, we have strong advocates for us on the Hill and worldwide, as well.

Q **Do you plan to take AdvaMed into any new directions as chair?**

A I would continue in the path that Vince Forlenza and, before him, Dave Dvorak, the CEO of Zimmer, and many other CEOs before them have traced. There is no need to change the trajectory. Clearly, the innovation ecosystem is one of our priorities and that will be my priority – to ensure that we are doing whatever possible to create an environment where innovation can continue to blossom in the medtech space, whether it's capital formation, whether it's access to clinical trials in the United States or outside the US, or whether it's access to reimbursement and payments once

those novel therapies are developed.

"In the device space, Wall Street does not reward at-risk behaviors, so we need to educate the market. We need to educate the investors to give more leeway for those large consolidators since there are very few of them right now."

Q **How would you characterize the innovation ecosystem right now? It seems like there's a lot of positive movement, at least in the US policy environment for medtech. For instance, industry, by and large, appears more satisfied with FDA, and you have the recent two-year device tax suspension. Are you feeling pretty good right now? Any particular pain points?**

A We have made so much progress over the past two to three years on all of these fronts. When I say we, it's not only AdvaMed or the industry. That's including the House, Senate and the government agencies. There are still some pockets that need some attention. You mentioned it. FDA has made tremendous progress over the past two to three years. You've seen some guidance issued like the Expedited Access Pathway, focusing on ensuring that novel lifesaving therapies can be made accessible to US patients earlier rather than later. You've seen the FDA, as well, putting a lot of emphasis on bringing first-in-man clinical studies to the United States.
We've seen also CMS deploying some efforts. It's still at the beginning. I think there's still more progress to be made on the coverage and payments of novel, innovative technologies. On the capital formation side, the market is still challenging. It is a buyer's market right now, so investors can dictate valuation of medtech companies. It's a great time to invest in the medtech space from a venture perspective.

But the fact is, companies right now require more capital from inception to exit than ever before and the amount of capital available is less than half what it used to be

before. You add those two together and you'll see why we're facing here still a dramatic shortage of creation of medtech startups. If you look at the number of series A funding in the medtech space, it is still about 25 percent of what it used to be five years ago.

Another concerning statistic: last year, we had more exits in the medtech space than company formations. Usually you need a ratio of about 2.2-2.4 between exits to company creation to sustain a market. Here, we had more exits than company formation. We still have some challenges here that we need to work on. Like you said, we're better today than where we were two years ago. The suspension of the device tax is helping tremendously. We need to make sure that it becomes permanent. There are some other areas of weakness that we need to work on; reimbursement and coverage by CMS and capital formation for the medtech startups.

Q **Regarding capital formation, what do you feel like needs to happen there to solve some of those challenges? What could be done about it, about things like the exit-company formation ratio?**

A A lot of things. One is we need to ensure that the regulatory pathway is the shortest possible. It is still much longer today than it used to be, so right now the discussion about the next wave of user-fee program with FDA is focusing on that. But there's some progress to be made. Clearly the 21st Century Cures proposal by the House would help, creating those breakthrough innovations. The Expedited Access Pathway by FDA is helping. But we need more examples like that to shorten the pathway. We need to have more parallel pathways between FDA and CMS for reimbursement. We need to figure out ways for CMS to be able to commit to reimbursing a product earlier because that is what's holding venture funds, or pension funds, and so forth from investing in the medtech space – the fear that those products, even if they are successful, they may not be reimbursed down the line. We need to figure out a way with CMS to work on a preapproval, or pre-coverage of technologies. There's still a long road ahead of us here.

Finally, we need to create an environment within Wall Street and outside of it, to

reward publicly traded companies that are taking innovation risks, whether it's organic innovation risks, trying something new and failing, or inorganic – like giving larger medtech companies some breathing room to do more acquisitions earlier.

Let me give you an example and expand on this for a second. If you look at the past decade, from 2004 to 2014, it used to take a small company $32 million on average to go from inception to exits. This is an average, meaning you've got some companies, most of those will be 510(k) pathways and smaller product lines, but still, it's $32 million on average. In 2014, that became a $72 million average cost from inception to exit. For the same amount of money available in the market, we can have less than half of the companies created. That's number one, but we also have less money, so the issue is even more compounded.

Q **What has driven up the costs?**

A Why is it $72 million? The FDA regulatory process is taking longer, reimbursement is taking longer. Those are elements of it. There is another one as well. We have seen a wave of risk aversion from a few of the traditional medtech consolidators on the one hand and we've seen a consolidation of the consolidators. What I call a consolidator is a company of medium-to-large size that is able to acquire smaller companies. In the past, a company could have two shots at goal, one with Covidien and the other with Medtronic, now they have only one shot at goal.
Compounded with that is that some of those large medtech companies would prefer to acquire de-risked assets, i.e., a smaller company that has proven not only that the technology works, but that it's approved with the regulatory agencies and thus, being reimbursed, but also retire the adoption risk by demonstrating that the product can be sold. Some of the $72 million on average has been used to develop salesforces; to start selling the product to demonstrate attractiveness, then to be acquired by consolidator, and then those salesforces will be either merged or dissolved. That's money that should have been used to develop new innovations.

Q **What can be done about these issues?**

A We need to keep working with FDA. Give them more tools and ammunition. And, CMS [the US Centers for Medicare and Medicaid Services], can we get them to cover more innovative products? Can we get them to commit to covering earlier in the cycle? Can we get them to do more parallel pathways with FDA.

And with consolidators, can we give them the air cover they need to be able to do those at-risk portfolio acquisitions? When you say, “Well, you know what? Valves are strategic for me, so I’m going to go and buy three or four technologies. One of them will be successful. That’ll be plenty enough. I don’t need to have 100 percent batting rate here in my inorganic investment.” On the pharma side, they do this a lot. Wall Street rewards them for it. In the device space, Wall Street does not reward the at-risk behaviors, so we need to educate the market. We need to educate the investors to give more leeway for those large consolidators since there are very few of them right now.

On Brexit: "We need to be there to guide them and give them the information they need about the implications of the changes they want, whether it’s positive or negative."

Q **What’s involved with educating the market? How does that happen in a way that would actually result in change? Are public policy changes also needed?**

A On the policy side, taxes, particularly the device tax, has hurt us a lot. When people look at the device excise tax, they say, "It’s small.” It is not. When a large consolidator is making 10 percent of EBITDA, you remove 2.3 percent, that’s 23 percent of their EBITDA that is gone. Those guys, where do they start cutting is in their organic and inorganic, the longer-term projects. Accounting could be another area to look at as well. How do we do cash accounting versus GAAP accounting? There could be some work there. I don’t know yet. We need to look into that.

A last one would be to invest in more research; to look at the data and be able to

communicate the data. There is nothing that speaks better to Wall Street than data. If we can provide them valid data showing that large- or mid-size medtech companies were successful in doing those at-risk acquisitions. You know, look at Edwards buying the first transcatheter aortic valve company. People looked at it like, "Wow. You're paying $300 million for this?" Now we look at that and say, "Wow, this is the smartest thing Edwards has ever done." This was way before they got FDA approval, way before they even started doing major clinical trials.

We need to be able to demonstrate that this behavior is actually the right behavior for mid-sized and large-sized companies to try to create an environment where they keep doing what they've done in the valve space. They've done a fantastic job, by the way, in the valve space. If you look at the 2015 statistics, most of the acquisitions that have happened were in the mitral valve-replacement space, trying to mimic what happened on the aortic valve a few years before.

Q **For that type of research, illustrating how these risky acquisitions can bear fruit, is that the type of thing that AdvaMed can play a role in?**

A Usually the best groups that can do this type of research are the major consultancy groups and many of them have partnered with AdvaMed, even in the recent past. You've got also the patient advocacy group –the not-for-profit research group – as well. I think it will be somehow my role to ensure that we try to channel some of those efforts in this direction. It's not necessarily what AdvaMed does, but this is where we could use the AdvaMed forum to try to encourage more of this research to be conducted and published.
That said, AdvaMed used to have a research arm called InHealth. We remerged it back inside AdvaMed so we do have the capability to conduct or fund research from within AdvaMed, either through our usual operating budget or through special assessments. That is something as well that one can look at.

There are a lot of things that, frankly, I don't know yet. I'm using the next few months as the chairman-elect to learn as much as I can.

Q **You started the conversation by mentioning the dynamic period of world affairs we find ourselves in, in particular with Brexit and the US presidential election. How are issues like that impacting the industry and how should the industry engage on those issues?**

A Let's take Brexit as an example. This is happening outside the United States, of course. One would say, "Why would AdvaMed be impacted or involved?" For one, AdvaMed is not a US trade association. We're very global in nature. We have some of our members, like Philips or LivaNova, which are based overseas, and even Medtronic now is an Irish-based company. Our members are global. There is a significant percentage of our budget used to serve the needs for international advocacy for AdvaMed, whether it's in Europe, China, Japan, Southeast Asia, Australia, Canada, and so forth.

We have a sister organization called Eucomed. Eucomed and AdvaMed, we work very, very closely together. With regard to Brexit, Eucomed will be the primary contact point following up on what would be the implication if this proceeds. If Brexit proceeds, what will be the implication on the regulatory pathways and reimbursement pathways in the UK? Would they still follow the CE marking? Would they be like Switzerland? Switzerland is not part of EU, but they do abide by the CE marking, so when a product is CE-marked, it has access to the Swiss market. (Also see "*Brexit: What Now For Device Notified Bodies, CE Marks And The Future MDR/IVDR?*" - Medtech Insight, 30 Jun, 2016.)

Or would they use this opportunity and approach FDA and try to harmonize their regulatory pathway in the UK with FDA, or who knows? We have to engage contacts at the highest levels as they navigate through all of this. We need to be there to guide them and give them the information they need about the implications of the changes they want, whether it's positive or negative.

Q **Any thoughts in terms of the political situation in the US and what that could mean for the industry, for companies? Any thinking there or key issues that you're keeping an eye on in terms of the candidates for White House or Congress?**

A Absolutely. The new president will take office in January. The president has the veto power, has lots of influence. But also there are some questions on whether the House or the Senate might shift board. This will have implications, particularly on one topic right now, which is the device tax. We received a suspension for two years. This has to become permanent. If the device tax is reinstated after two years, it will have dramatic negative impacts on our innovation ecosystem.
We have to be out there educating all of the politicians about the implication of that to ensure that the device tax suspension is either prolonged, but better off, if we can make it permanent and totally repeal the device tax.

Q **But in terms of who will have control of the White House and Congress, do you see an obvious impact in terms of likelihood of permanent repeal of the device tax, or is it just a matter of educating whoever takes office and whoever controls the Congress to make sure that happens?**

A I'm ready to play nice with all parties all of the time to ensure that our industry is successful and that we keep building novel products that address those diseases that are in dire need of solutions. Whether one party would be more favorable or less favorable than the other party, I don't have an opinion on that. Whoever is in the White House or controlling the Senate or the House, we'll be ready to work with them like we did in the past.

From the editors of The Gray Sheet