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MiMedx Group, Inc. (MDXG)

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MANAGEMENT DISCUSSION SECTION

Mike Matson
Analyst, Needham & Co. LLC

All right. So, good afternoon, everyone. I'm Mike Matson, Medical Device Analyst here at Needham & Company. I'm pleased to introduce MiMedx today. From the company we have Pete Petit Chairman and CEO; Chris Cashman Chief Commercialization Officer; and Mark Landy, Senior Vice President of Strategic Initiative (sic) [Initiatives] (00:31).

QUESTION AND ANSWER SECTION

Mike Matson
Analyst, Needham & Co. LLC

Q

So it's going to be a fireside chat format, I've got a list of the questions I've put together. I guess I just want to start out kind of with the base business. So, Pete, could you just start out by giving us a quick overview of MiMedx and kind of what makes your company unique?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Thank you. Thanks. Number one is the fact that MiMedx, some months ago, was named the fifth fastest-growing public company in America by Fortune magazine, that's a good place to start. Revenue growth is still robust. Regenerative medicine product line serves the advanced wound care sector of healthcare as well as numerous surgical procedures. That particular technology is based on the placenta and components of placenta – amniotic membrane, the umbilical cord and the placenta itself. We have about 46 patents on that technology and just won our first patent lawsuit recently.

As I mentioned, the revenue growth still remains robust. We have just announced a few weeks ago that we're going to exceed the first quarter revenue estimate we gave last December; we'll exceed $92 million. We also reiterated our revenue forecast for the year of $383 million to $387 million. So, in effect, I think that part of the business is going well and we continue to focus on those fundamentals and should continue to see good growth. I think everyone is well-aware of the fact that our audit committee has announced the fact there's going to be – and are conducting as we speak, a in-depth investigation on all of the allegations that has been made by short-sellers and others about the company. We expect that to be concluded and at the conclusion of that, we'll issue our 2017 numbers and probably, by that time, our first quarter numbers.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. So you've been seeing some really strong growth in both the Wound and the SSO – Surgical, Sports Medicine and Orthopedics, so I'm getting back at them right there.

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Yeah.

Mike Matson
Analyst, Needham & Co. LLC

Q

All right. So can you talk about the key factors that's been driving the growth in each of the businesses?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Well, I think we continue to become more of a maturing business with great experience and adopters in the marketplace. So our sales organization to level set there. We now are right on plan. We went over [ph] $400 million (03:02) in that organization. At the turn of the year, we'll probably finish the quarter somewhere around [ph] $415 million to $420 million (03:07). We expect to continue to hire [ph] per plan (03:12), probably I'd be around [ph] $465 million to $470 million (03:14), if not more by the end of the year.

What are the drivers ultimately? It's the planning and the processes that we put in place with these individuals and with management. They're more and more adopting the informatics that we're giving them. They're becoming more and more focused on the day-to-day processes and the education with the customers. When you look at that organization, we're able now to work three to four times the size of any of the competitions, so who we're able to go into secondary and tertiary markets and day-in and day-out service and support and educate in those spaces. So our competition can't do that.

We've had a number of clinical trials that are either completed and published, probably [indiscernible] (04:05) published. On the Wound Care side, it's been very robust. We continue to see expansion of that market. We talked about, all the time, the 1.4 million diabetic foot ulcers and venous leg ulcers that are chronic every year and less than 10% of those patients ever get a skin substitute. So it's hard to believe. So we're very focused, from an education standpoint, doing peer-to-peer symposiums. From a clinical standpoint, as I start to speak to, we announced the VLU trial, the multi-center, [indiscernible] (04:42) multi-center trial which was recently published, that's going to be a driver for commercial payers and positive health policy; and we have the DFU study that hopefully will be coming out soon as well.

On the SSO side, we continue to see greater adoption, more clinical work, greater experience with our – the surgeon base and as they see the results more and more that it gets more ingrained. And we're very much focused on working with them on the intended uses of an enhanced healing and inflammation modulation that acts as a barrier. And it's those types of things where the doctors apply it to specific surgical-type procedures where maybe the patients are more compromised. They're more complex types of surgical processes and where the material really has a huge cost benefit value proposition. So, we're – to be quite honest, we're hitting on all cylinders right now.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. And the sales force numbers that you mentioned, can you just talk about, is that split between I think you have maybe some pain reps now and you have the Wound reps and maybe do you have SSO specific reps as well or...?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

We do. We have a good – the majority of our representatives are still in the Wound Care area.

They moved from wound care clinic to office in the operating room. But we have, as we embarked on about two years ago, we do have specialist organizations where we supplement. So, on the SSO side, we have surgical – our operating room specialists that are doing orthopedics, foot and ankle, and general abdominal-type procedures. And then we have just in the last year begun to add specialists in musculoskeletal pain. Of course, at this time, most of that market is a cash pay market, but we're starting to build that up in anticipation as more clinical trials come out our Phase 2B data that we just recently released on the top line that's bringing more and more interest and again helping to bring more doctors to the fold to trial it and evaluate it.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. And then from a product standpoint, can you talk about the products that are driving growth, I guess, in SSO as well as in Wound, and I think there's a new product story as well, right?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Yeah. We launched inside of the – about a year-and-a-half now a number of new products but I do want to say that it's still our core business is still growing strong as well. It's really not – we're hitting again on all of these different channels and all of these different products are contributing. So EpiFix is still at the core of our growth; and AmnioFix is still at the core of our growth. We added a couple of different line extensions; one was utilizing umbilical cord we branded as EpiCord and AmnioCord. They have both wound care applications as well as surgical applications and that product has been accepted well and they're going through various clinical trials right now, which we'll be reporting on. We also have introduced a placental tissue product called AmioFill which is really for complex and complicated types of wounds and dehisced wounds and that also has been accepted well in the marketplace.

Mike Matson
Analyst, Needham & Co. LLC

Q

And I know you gave some of the numbers on the sales force, but can you maybe just talk about which businesses that the reps that you're adding in which areas they're going into, both product-wise and geographic-wise?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Sure. Well we're still hiring across the board throughout the U.S. We have informatics that really informs us. I've talked about before where we look at our GPO/IDN contracts, we look at our reimbursement and policies and we overlay all of this. We look at populations and so that informs where we're putting these individuals. There isn't

any one area that we're focused on. It's still a broad expansion, but it is important that we are also going into secondary and tertiary markets as I spoke to earlier. Predominantly, they're still – the majority is still in the Wound Care area. We're adding more and more specialists both in surgical as well as on the pain side. So it's still about two-thirds Wound and then it balances in the other areas.

Mike Matson
Analyst, Needham & Co. LLC

Q

And can you – just on the secondary and tertiary markets, can you just explain how the [ph] tradeoff there to (08:59) mean? I'm wondering if it might be a smaller opportunity but...

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Sure.

Mike Matson
Analyst, Needham & Co. LLC

Q

I guess there's probably not a lot of competition either for that business?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Well, when you think of our territory alignments, when we started out and really started to have great progress, our territories had – they could have 40 accounts or 50 accounts. And now we've been able to refine them to a point where you might have 8 to 10 accounts. But really three to five are the anchor accounts, and they're able to focus and do business in those accounts and go deeper and support the providers.

We're in Atlanta. So an example of the secondary market would be Macon. You know Macon is about an hour and 45 minutes south of Atlanta. Most companies don't put a direct individual. They just reside in Macon and focuses on Macon and that's enough. Usually that's not enough, business-wise and opportunity-wise but in the markets that we're in, we're able to put not just one but maybe even expand it two or three that just focus on Macon every day instead of trying to reach it from Atlanta or surrounding other areas, so that's an example where we're being more and more successful.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. And then can you talk about the international business? I know it's in the early stages but which initial markets you're targeting...

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Sure.

Mike Matson
Analyst, Needham & Co. LLC

Q

...and what's the process? I know it's slower because every market, in particular in Europe is a little unique with reimbursement and their regulatory rule?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Right. Every country is different. The regulatory processes, whether they look at the products as a pharmaceutical or if it is a regenerative or tissue or is it a medical device. And so we do go through a lot of that interaction and open communications without really determining where it's slotted correctly. We've been very active both in the EU as well as in Asian countries. We are registered now in the UK, Switzerland. We're focused in areas like Austria coming on; Italy will come on very soon. And then in Asia, Australia is an area that we've been going down the path of regulatory processes and then some of the other Asian markets like Japan.

But needless to say, once you get registration and you're allowed in the country, that's not really where the works stops. Very often, clinics are required sometimes if they don't necessarily accept just the U.S.-based studies; they want it in their own demographic and so we also have to work through that, the health policy side of this very often as to what's going to be required. We are, from our perspective, making significant investments and it's going to pay off for us in the years to come. May not be next – in the next few months but we are, from our perspective again, from a competitive standpoint, way ahead of where others are and it's very important to our five-year strategy.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. All right. And then, I know you've run a couple of trials in the Wound area – some randomized controlled trials. So, like one of those was in the diabetic foot ulcers or DFUs, so I don't think we've seen the results from that yet, so I just – Pete, maybe if you could give us an update on where things stand with that?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Well, generally-speaking, we've been pretty quick once we have a trial finished to get publication. This time, we thought because of DFU, because of diabetes et cetera, we might try a little different pathway, so it's a little slower than our others have gone, but we're getting close. That's all I can say. And there was a change in editors in the middle of those things, that's why we're a little bit slow this time.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Does that mean we could see it may be a higher profile journal than where the Wound area maybe?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

We're trying.

Mike Matson
Analyst, Needham & Co. LLC

Q

And then in the venous leg ulcer, VLU, you had your trial data; it looked really good. You've been working to try to expand insurance coverage there, so is there any update in terms of the [indiscernible] (12:50)...

A

Shortly. Yeah, we've gotten some changes. We're just waiting for an official announcement before we press release those, so...

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. All right. So, I wanted to shift gears to the pipeline questions. So there's been a lot of attention on the four IND trials that you have going on; two of them are now in Phase 3. You just started enrolling in the AmnioFix Injectable for Achilles tendonitis IND trial, can you give us an update on the overview – give us a start – can you give us an overview of the trials; the number of patients and sites and what you're expecting with regard to endpoints and when you expect the trials to be done? Sorry, that was a mouthful. Just tells us about the trial.

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Well, let's start today with, I hope you all saw the press release today that we've enrolled our first patients in our Phase 2B Study for osteoarthritis, pain related to osteoarthritis of the knee; [ph] MiMedx (13:51) for our RMAT designated AmnioFix Injectable, so that's a big milestone for us that sets kind of the clock on when we expect to complete enrollment there and also for when we expect to see data. So, now that was the big news today. January, when you have a look at the studies where we're at, we're in Phase 3 with our Achilles tendonitis program as well as with our plantar fasciitis program. The way we constructed the clinical trial protocols is they build one off the other.

So, if you look to our Phase 2B Study on plantar fasciitis, we read out not too long ago, a week ago, oon our final data there. It looked spectacular. So it was a 76% reduction in the control group versus a 45% reduction – sorry, in the active group versus a 45% reduction in the control group; highly significant, 0.0001, so very, very significant; and also most importantly very clinically meaningful. So, we were reporting on a 145 patients. The plantar fasciitis study is going to enroll 164. The Achilles tendonitis study is going to enroll 158. The endpoints are the same. So, it's a VAS score. It's a reduction in VAS from baseline, the mean score at three months with a six-month endpoint on the safety.

Now, remember, the Phase 2B started out with a two-year requirement for blood draw; that was reduced to a year while we're going through the study and ultimately we've landed up in the Phase 3 for plantar fasciitis with a six-month safety endpoint. So, the question that we get and is often thrown out there online is the safety aspect of the product. The FDA would not be reducing our adverse event time rate if they do not feel that they were asked to be comfortable with the safety of the study.

So, when you have a look at how that program is laid out and that the Phase 2B which sets up the Phase 3 for both Achilles tendonitis and plantar fasciitis. And as we said before, the goal is to get a general tendonitis claim. We will not stop the filing of the BLA if one trial kind of runs behind the other. So, we have enrolled – enrollment is going well. Both studies are around 15 centers. We are getting into the spring months, so a lot of people have been dormant through the winter, so this is when you start seeing musculoskeletal issues, plantar fasciitis coming up, Achilles tendonitis, strain, et cetera so we're starting to get into the period where we start to see enrollment picking up, so things are going really well there.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. And the data that was just released for the plantar fasciitis, the Phase 2B, so that was the final data and I think because I've heard some kinds of questions – there's been some confusion around the earlier data that was put out but that was really, was that just...

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.
A

The guide that we've put – so obviously as you have your discussions with the agents and you go through the program, you set up your next program, we read out the interim data on a 102 patients. We made a commitment to follow up, enroll and then follow up all the patients per protocol, 145. The data that we read out is the final data, which was remarkably similar to the data that we read out in August of last year.

Mike Matson
Analyst, Needham & Co. LLC
Q

Right.

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.
A

So if you look at the [indiscernible] (17:14) introduction, the baseline VAS was 71 in both groups. It was a 54-point reduction in the treatment arm versus a 32-point reduction in the control arm, which gave you then a 54% versus a – sorry, a 76% versus a 32% reduction, highly statistically significant.

Mike Matson
Analyst, Needham & Co. LLC
Q

Okay.

A

We announced those results in August of last year and that was the interim, so the FDA allowed us to go to Phase 3 based on that interim because it was so strong...

Mike Matson
Analyst, Needham & Co. LLC
Q

Okay

A

...we just had to follow it through, okay? And then we're just going to finish up the safety, it goes through 12 months. So it's not fully complete there but what we've announced is the top line efficacy and...

Mike Matson
Analyst, Needham & Co. LLC
Q

Okay. And then can you talk about the plantar fasciitis, or I guess, tendonitis market opportunity more broadly maybe?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Sure. It's a little bit more difficult to really put barriers or boundaries or brackets around those markets. The literature seems to be all over the show. I think I'll give you some general kind of pointers that you can think about. So around 9% of the population suffers from some form of plantar fasciitis, about a million of those seek treatment and of those 60% are probably indicated for an injection.

So when we look at that market we look, at say, at 60% of the 100 that present for treatment as being the target market for AmnioFix Injectable in both plantar fasciitis.

The Achilles – sorry, the tendonitis is a little bit more difficult because as it's all over the show, right? So we're not looking at a single indication. The best way that we look at it it's kind of how we build it up is, there are 12 million injections that are done that were done in 2013, so there's been some growth or some sort of pain into or around the joint. 25% to 30% of those are due to some form of tendon-related issue.

So if you haven't looked at the opportunity that [indiscernible] we have said (19:08) and this includes plantar fasciitis, it's a roughly kind of at 3 million to 3.5 million kind of injection market – annual market. So depending on pricing, you can get out to kind of a $1 billion or $1 billion plus in terms of market opportunity for tendonitis alone, so it's a good market. The big market obviously is the knee osteoarthritis market in the program that we have there.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. So I wanted to shift to some of the FDA questions. So can you talk about the final guidance that the FDA put out last year, what do you think that really means for your sheet products, that's one; and then your injectable products, two?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Well the final guidance came out pretty much where we expected it to be. We were kind of a subject of this focus back in August of 2013 when we got that untitled letter. So we worked very closely with the FDA over these years and I think we're pretty astute in terms of knowing where this was coming. And the fact it's not going to affect us, frankly at all. With the sheet product we may have to change some labeling on there, but that's not going to affect reimbursement or whatever that have been manufactured out there with that same labeling for years.

Relative to the micronized product, that's created a great opportunity for us because we started down that pathway with the FDA in 2013 to go down this BLA pathway. So we're years ahead of anybody else, years. So it was painful to start with but in working with the agency and then working with us, I think we came to some compromises and those showed up in this document. So we're frankly very happy that the guidance came out as it did.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. And then so part of the guidance was that the FDA was going to allow for kind of enforcement discretion?

A

Right.

Mike Matson
Analyst, Needham & Co. LLC

Q

...on the new guidance?

A

Correct.

Mike Matson
Analyst, Needham & Co. LLC

Q

.. to kind of give companies time to adapt, which I think makes sense. And you've mentioned you might have to change some of the marketing claims around the sheet products. So have you talked with FDA? I mean what's your sense of – will that enforcement discretion apply to this and like what's the timeframe in which you think you have to change the way you talk about this product?

A

Well, first of all, [indiscernible] (21:29) by three years of enforcement discretion. They're very focused on safety. And, again, we're the manufacturers. We manufactured a million of this allograft and shipped them; almost flawless safety record and you can tell from the studies the way the clinical staff is treating us, they're allowing us to move forward aggressively. So, this company does not have safety issues with our product. The FDA shouldn't have any safety issues with us. So, we're going to continue right down this pathway and we think we're perfectly aligned with them.

A

Yeah.

A

Yeah. And just to add to that, I mean on the sheet side, it came out, as Pete said, exactly where we thought it was going to. But we'll evaluate, it's HCT/P 361. Done, that's it. I mean there's no questions about it. When we look at labeling to the point, we might make some changes over the next three years but that's just how you kind of promote it a little bit. It's not going to change where it's positioned. It's on the micronization of the tissue which, again, is the same, just smaller particles.

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Yeah.

A

But if that process where if you have an IND running, you get that enforcement discretion while it's still on the market as you see coming ...

A

We could consider taking our seat down that same BLA pathway, which will give us indication for use. There are significant barriers to entry if we were to do that.

A

Yeah.

A

But there's other considerations. So, we're busy. We're just trying to make those kind of ...

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

I think the one thing that's overlooked very much from where we are relative to the guidelines and where our competitors are, is our manufacturing capabilities, right. Because we are already in Phase 3, we are CGMP compliant. Now, we also have USP. So, when you really have a look at the product that is coming out of the MiMedx facility, it is to a BLA specification and a drug specification; very specifically related to potency, [ph] prudency (23:09), consistency. These are very important things that, with time, are going to become more and more important. So, when we sit with the agency, I mean we look at the competitors, you really have to look at the opportunity to market and also the ability to manufacture at specific levels and it may just come to pass as the manufacturing side is going to become a lot more important than the kind of, let's say, the labeling side.

A

Right. So as we move forward, you'll see line extensions in the near-term off the HCT/P, but as you look at us mid- and longer-term, it's more of BLAs. As you look at our other programs too, you've got respiratory, cardiovascular and other areas we haven't talked about yet.

Q

Okay. And I think you also recently announced that also related to the guidelines or guidance that AmnioFix Injectable for osteoarthritis indication was granted a regenerative medicine, advanced therapy designation. So can you describe what that is?

A

Sure.

Mike Matson
Analyst, Needham & Co. LLC

Q

... and what that really means to, and how much it tolerates the...

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

I think the two points that you really have to understand which, one, is the interaction that you have with the FDA. So if you do a BLA, you get three meetings with them; a pre-IND meeting and end of Phase 2 pre-Phase 3 meeting, and then a pre-filing meeting. So you get three opportunities to discuss and those are essentially one-way guide. You tell the FDA stuff and not a whole lot comes back.

What you get with RMAT is a very, very active dialogue with the agency at a high-level. So every step of the way, you have an understanding of where you need to go which is very different. The other opportunity is to accelerate your programs. So when you think about RMAT, think about Fast Track and Breakthrough as it is for drugs. Then what they've also done is they've linked in unmet needs with the 21st Century Cures Act, which then allows you for the opportunity to get an approval with data that's generated in the real world, also using surrogate endpoints of biomarkers. So, from an AmnioFix perspective, I think it's a little too early to tell what the clinical trial benefit is on our pain. We've got a head-on meeting with the FDA, but where you would see a benefit as we're looking at it is as we look forward down the line when we look at our disease attenuation and disease modification claims that really is going to help us so we'll have a better handle off when we meet with the agency.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Understand. And I think, we're almost out of time, but there was one question I wanted to touch on because it's gotten – also got some attention recently. So it's – you've apparently gotten a few 483s in the past from some of the inspections...

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Right.

Mike Matson
Analyst, Needham & Co. LLC

Q

... and can you talk about where – just talk about these and where things stand and addressing them, Pete?

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

Well, 483s, I hate to say it this way but rather routine; that's when the agency comes in and we've had inspectors in the past where we got no 483s and we've had some where we get one or two's. It's not a failure. It's something that the agency wants you to focus on and clear up. So during this inspection last year in January, was our first inspection on the Good Manufacturing Practices (sic) [Practice] (26:08), which is a major issue, so we expected 483s. By the end of the year and earlier this year, we cleared all those up and we're – as Mark indicated, we're manufacturing now on a GMP, which is substantially different than the old GTP tissue practices.

A

At that time, we were just still implementing the GMP processes and procedures, and we had an endpoint and we were in the middle of that, so it was normal to have a 483.

A

That 483 because we wanted to finish with our processes.

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

At best, we had no requirements to manufacture to the standard...

Mike Matson
Analyst, Needham & Co. LLC

Q

Right.

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

..the product that was going into the market was not – had no requirement to be BLA product.

A

Right.

Parker H. Petit
Chairman & Chief Executive Officer, MiMedx Group, Inc.

A

This is all part of the progression as we say towards being where we are. So I will just flip this around. Good luck to our competitors. They have to go down these processes. This is not an easy process.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay.

A

Frankly, it's much ado about nothing, I would say it that way.

Mike Matson
Analyst, Needham & Co. LLC

Q

All right. I think we're going to have to wrap up there. We're little over time. So...

Unverified Participant

Thanks, Mike.

Parker H. Petit

Chairman & Chief Executive Officer, MiMedx Group, Inc.

Thanks, Mike. I appreciate it.