

Edgar Filing: BIOMIMETIC THERAPEUTICS, INC. - Form 425

BIOMIMETIC THERAPEUTICS, INC.

Form 425

January 08, 2013

Filed by Wright Medical Group, Inc.

Commission File No. 000-32883

Pursuant to Rule 425 of the Securities Act of 1933

and deemed filed pursuant to Rule 14a-12

of the Securities Exchange of 1934

Subject Company: BioMimetic Therapeutics, Inc.

Commission File No.: 000-51934

This filing relates to the proposed acquisition by Wright Medical Group, Inc., a Delaware corporation (Wright), of BioMimetic Therapeutics, Inc., a Delaware corporation (BioMimetic), pursuant to the terms of an Agreement and Plan of Merger, dated as of November 19, 2012, by and among Wright, BioMimetic and Wright s direct wholly owned merger subsidiaries, Achilles Merger Subsidiary, Inc., a Delaware corporation and Achilles Acquisition Subsidiary, LLC, a Delaware limited liability company.

Company Name: Wright Medical Group
Company Ticker: WMGI US
Date: 2013-01-07
Event Description: J.P. Morgan Global Healthcare Conference

Market Cap: 843.43
Current PX: 21.2594
YTD Change(\$): +.2694
YTD Change(%): +1.283

Bloomberg Estimates - EPS
Current Quarter: -0.020
Current Year: 0.209
Bloomberg Estimates - Sales
Current Quarter: 120.857
Current Year: 480.533

J.P. Morgan Global Healthcare Conference

Company Participants

Robert J. Palmisano

Other Participants

Kim W. Gailun

MANAGEMENT DISCUSSION SECTION

Kim W. Gailun

Good afternoon and welcome. I'm Kim Gailun with the JPMorgan med-tech team, and presenting next, we're happy to have Wright Medical.

And so I'd like to introduce the President and CEO, Bob Palmisano. After the presentation, we're going to head down the hall for a breakout session in the Yorkshire room.

Robert J. Palmisano

Thank you, Kim, and thanks for the invitation and thank you all for coming, and my pleasure to tell you a little bit about what's going on at Wright Medical.

A lot of forward looking statements, I won't go through this. You can read these, if you will, on our website or seek out our Head of Corporate Communications, Julie Tracy, who is up here in front and will be happy to answer any questions about this. It would take about half this presentation if I went through that.

So I want to talk a little bit about our overall strategy where we are versus where we thought we'd be, the different platforms that we have in our company. We announced a transaction in November, I'll talk a little about where we are in that and then as we see this business unfolding over the next year or two.

So we're a global company. Currently, about 60 percentage of our company is in the U.S., about 40% outside the U.S. Our 2012 estimated sales, which is the guidance, the midpoint of the guidance that we gave at the end of Q3, is approximately \$480 million. Our market cap is about \$840 million as of couple of days ago. And we currently do business in about 60 countries and we have about 115 different product lines.

We have two large markets. In the Extremities business. Particularly we're aligned more to the lower extremity, and we'll talk of that, but that more we're the recognized leader in Foot & Ankle business. That is primarily a U.S. business although it is growing outside the U.S. and the focus of this business is growth.

Our Ortho-Recon business, this is a very large market, but we're a very small player in this market or, as I said in the slide, a mid-sized player. About 60% of our Ortho-Recon business is outside the U.S., so it's primarily international business. And our focus, as we go forward here, is on efficiency and cash generation.

So we're focused on the higher growth market segments in orthopedics. If you look at really the highest growth opportunity seem to be in the Foot & Ankle business, which is growing at about 10%, and in the Biologics end of the business, which is growing about 7%. This combines for the business that we look at as Extremities and Biologics with a growth profile in the 8% to 10% area. The Ortho-Recon business, we're a small player in a land of giants. This is a market - this is looking at a growth rate of zero to 3%.

Company Name: Wright Medical Group	Market Cap: 843.43	Bloomberg Estimates - EPS
Company Ticker: WMGI US	Current PX: 21.2594	Current Quarter: -0.020
Date: 2013-01-07	YTD Change(\$): +.2694	Current Year: 0.209
Event Description: J.P. Morgan Global Healthcare	YTD Change(%): +1.283	Bloomberg Estimates - Sales
Conference		Current Quarter: 120.857
		Current Year: 480.533

So wherever we've been in 2011/2012, we were a company that was in looking at market growth, low market growth, low margins, and we're operating essentially in very cash-intensive businesses. So, in 2012, we began executing a transformational plan with the clear focus of accelerating growth and improving our overall performance.

Our priorities that we laid out last year when we were here was to accelerate our Foot & Ankle growth, have a steady stream of new products, a continued investment in medical education and improved sales force productivity. What we didn't talk about at that point that happened throughout the year was re-orientating our sales force from being an indirect, distributor-led sales force to being a direct organization, and we'll talk about that later in the presentation.

We also said that we needed to improve our overall efficiency of Ortho-Recon business. We needed to be focused in the money that was spent in R&D. So we pared down the number of projects that we went after to being ones that are smaller in number or broader in scope, and to focusing our sales and marketing activities accordingly, and improving our inventory and instrument productivity.

Lastly is we wanted to be a cash producer. We wanted really to demonstrate our ability to produce cash on an ongoing basis, and we set some aggressive targets that we think we have actually surpassed.

And so we have we're executing on all three of these strategies. These are both short-term and long-term, and I think that we're right in the middle of these things right now.

So just a few numbers and results that indicate that our execution is on track, and our strategy is on track. At the end of Q3 of this year, we had converted 80% of our indirect sales force in our Foot & Ankle business to a direct sales organization. And that is very, very important as we go forward. We did not think that we would be able to get the growth opportunity that is out there in Foot & Ankle if we did not have more control over our distribution channel. So this was a big bet, and I think it's working out extremely well, and we couldn't be happier.

Secondly is that we needed to intensify and focus on medical education is that we are asking physicians to make a change. They're used to doing a procedure in one way with one kind of result, and we're saying if you did it in a different way, you're

Edgar Filing: BIOMIMETIC THERAPEUTICS, INC. - Form 425

likely to have a better result. So this change needs a lot of education behind it.

In 2011, we trained about 600 physicians in Foot & Ankle. Last year, through the first three quarters of the year, we trained over 1,300 physicians. And this played a dramatic effect, as you can see, as our growth rate increased to 14% in Q3.

So this really combined, the sales force the changes we made and the increase in medical education we were able really increase our growth rate. A year ago, at the end of Q4 of last year, our growth rate was 7%. So we're up to 14%. And we have said that we thought this would continue to accelerate. So this is a good story.

Regarding cash, in 2011, we produced about \$14 million in cash. And we had targeted, at the end of the year at the beginning of the year for 2012 to produce \$25 million to \$30 million in cash. And we were going to do this through a lot of means. A lot of dealing with inventory and other kinds of issues that we were going to focus on this. And where we were at the end of Q3 is that we were already at \$44 million, and had given guidance to be between \$44 million to be between \$45 million and \$50 million by the end of the year.

So again, this all indicates to me and to a lot of folks that this execution is working and we're on track.

The platforms that we have very fundamentally sound in terms of the products that we have. I'll talk first about Extremities, where we have a comprehensive portfolio and strong R&D.

The market that we are participating in Foot & Ankle is about a little over a \$1 billion market. There are about 7,500 physicians between MDs and surgical podiatrists that we have the opportunity to deal with. It is a centralized call point. There are complex treatment issues and less mature products. It's a business that is open to innovation and new product development all the time.

Company Name: Wright Medical Group	Market Cap: 843.43	Bloomberg Estimates - EPS
Company Ticker: WMGI US	Current PX: 21.2594	Current Quarter: -0.020
Date: 2013-01-07	YTD Change(\$): +.2694	Current Year: 0.209
Event Description: J.P. Morgan Global Healthcare Conference	YTD Change(%): +1.283	Bloomberg Estimates - Sales
		Current Quarter: 120.857
		Current Year: 480.533

The strong drivers of the business are in trauma, diabetes, as well as osteoarthritis and obesity. These are higher-margin products than we have in the other part of our business, and it's an underpenetrated market. If we look at both total ankle replacements as well as the hammertoe market, just two pieces of it, these are only about 10% penetrated today and have the opportunity really to accelerate as the technology and the training evolves.

So I talked a little bit about our direct sales force makes a big difference. Secondly is we have the most comprehensive product portfolio of anybody. We are really recognized as the market leader in this very high growth area of orthopedics. And we continue to invest in R&D. In 2012, we introduced six major new products. Four or five of them are really, really significant. And we anticipate this kind of a product pipeline as we go forward into this year and the next couple of years.

So what we're saying is we want to maximize this opportunity. This is an opportunity that if we don't grab quickly is that others may be tempted, and I think a lot of people are. However, I think that we are not going to stand still. So we are maximizing the opportunity.

We're introducing new products. This is a kind of a list that we had. We also have new products planned for 2013. And very, very importantly and we'll talk more about this a little bit later in this presentation is that we've announced a transaction to really transform our biologics platform by purchasing a company, BioMimetic, with their Augment Bone Graft products. And I think this is going to be a terrific addition to Wright Medical.

We will continue to invest and accelerate our medical education, and we are targeting a 50% increase in sales force productivity with our direct sales force. When we put this together and we looked at where we were on productivity, we were doing about \$600,000 of revenue per rep. And we set a goal of getting that up to \$1 million of revenue per rep. So at the end of Q3, that's the benchmark. And when we report our final year-end numbers, I guess it's sometime in February, is that we'll then give you a look at where we are with the first quarter done with the new sales force.

So we think this as the big opportunity is increasing sales force productivity. We're doing that by management having direct management over this organization training activities, incentive programs, all kinds of change management things that are necessary to get this productivity rate up.

Edgar Filing: BIOMIMETIC THERAPEUTICS, INC. - Form 425

And lastly is that international market development. It's a small business but growing very rapidly, our Foot & Ankle business, all over the world. So this is another big opportunity, I think, that we have.

The second part of the business I'll talk about is the Ortho-Recon business, specifically hips and knees. This is a very large market, about \$13 billion. It's very large, entrenched competitors. And we are a relatively small player in this market.

And we decided, when we looked at the opportunities ahead of us, is to focus on efficiency and cash generation in this business. And we have gone through a period of time, as we were under our deferred prosecution agreement, as a result of some compliance activities, that made it necessary that we part company with some customers. And this had caused deterioration in some cases of sales revenues.

But we think that this is mostly behind us. The DPA was withdrawn—the deferred prosecution agreement was withdrawn in September. We are still under a CIA, but that is a lot less intrusive. However, our compliance programs are first-rate, world-class as we speak, and we intend to keep it that way.

And so we are focusing this business very strongly on not so much growth but getting back to a position where we're growing at markets, but secondly, being a very strong cash generator. And we've seen the results of that. We have great products. We have a great knee system, it's called the EVOLUTION knee. And we have a very innovative hip portfolio with what's called SUPERPATH technique that preserves tissues and has a faster recovery. We have both modular and fixed hip systems and a very comprehensive cup system.

So we are eliminating a number of projects, as I mentioned, from an R&D point of view. A year and a half ago or so, when I first joined Wright, we had about 40 some odd R&D projects going on in our Ortho-Recon business. That's down to three or four. But these are major kinds of efforts, as opposed to small little one-off products.

Company Name: Wright Medical Group	Market Cap: 843.43	Bloomberg Estimates - EPS
Company Ticker: WMGI US	Current PX: 21.2594	Current Quarter: -0.020
Date: 2013-01-07	YTD Change(\$): +.2694	Current Year: 0.209
Event Description: J.P. Morgan Global Healthcare	YTD Change(%): +1.283	Bloomberg Estimates - Sales
Conference		Current Quarter: 120.857
		Current Year: 480.533

Our sales and marketing efforts are much more focused, and we have a very improved inventory and instrument management program for our inventory. And we've streamlined our international distributor network to get us fewer distributors but more-focused distributors.

We have big opportunities, we think, to grow our international business. Our Ortho-Recon business is primarily an international business. And so we are defending our core business and looking for further development in certain key markets.

And we're additionally looking on a geographical basis a big opportunity to drive additional revenues through the exciting Foot & Ankle business that we've talked about. We are also in Japan, which is our largest single country that we have and a very profitable business that we have in Japan, as we are looking to improve our Ortho-Recon execution. All companies that did business in Japan every two years go through a pricing regimen. Prices were decreased significantly by the government in 2012, and as soon as we anniversary that, I think that we'll be back on a great trend.

Secondly is we've launched some significant new products in Japan in the fourth quarter that will build as we get into 2013.

In the rest of the world is we're shifting a lot of inventory and instrument sets to support growth, and we have very active market development activities underway in China, [ph] India (15:17), Brazil and Argentina. And we are, again, developing and maximizing opportunities in the Foot & Ankle business.

Now I just want to talk a little bit about the pending transaction that we have with BioMimetics.

If you look at right, we are the recognized leader in foot and ankle. We've talked about that. The data supports that. We have financial strength and scale is that as those of you follow the company we did a re-capitalization couple of months ago that gave us all the resources that we need to be able to do the types of M&A activity that the company may need. And we have, as we talked about very importantly, a dedicated sales team, and we have expertise in physician training.

Edgar Filing: BIOMIMETIC THERAPEUTICS, INC. - Form 425

BioMimetic is a fantastic company led by a great staff that have developed a significant product in regenerative medicine. It's clinically differentiated technology. Platform that's based on PDGF. And the whole company is resplendent in terms of its talent and expertise.

This adds a breakthrough platform for us, and a pipeline of other products to come, in a business that currently is about \$300 million in terms of its size. It provides additional pipeline products in bone repair and soft tissue applications, and significantly accelerates our transformation to be a company that is about 60% Extremities and Biologics and about 40% Ortho-Recon.

And we have a very high expectation of our Foot & Ankle business, but there was no way we felt we could get to that percentage, that business shift, without making a major transaction. And this will help us get to our goal of having a high-teens type of operating margin company. And so we'll see how this all plays out, but we're very optimistic that this transaction will really be very, very significant and additive to Wright Medical.

The structure, as announced, \$190 million upfront, of which about \$140 million is in Wright stock, which we think is an advantage to the buyers. I think our stock is going to be valuable, and more valuable particularly as this product gets approved. We have additional milestone contingent payments on FDA approval, which is another \$190 million, as well as some revenue milestones that relate to sales execution downstream.

We expect this acquisition to close in the first quarter of this year, and we expect the product to be approved before the end of the year. And we're very optimistic that this all will happen.

In terms of its impact on our earnings, that's still being sorted out. In terms of GAAP EPS, we'll assess the impact on future GAAP earnings upon closing of the transaction. Adjusted EBITDA is dilutive until second year post-FDA approval of Augment Bone Graft and accretive thereafter.

Company Name: Wright Medical Group	Market Cap: 843.43	Bloomberg Estimates - EPS
Company Ticker: WMGI US	Current PX: 21.2594	Current Quarter: -0.020
Date: 2013-01-07	YTD Change(\$): +.2694	Current Year: 0.209
Event Description: J.P. Morgan Global Healthcare	YTD Change(%): +1.283	Bloomberg Estimates - Sales
Conference		Current Quarter: 120.857
		Current Year: 480.533

So not an inexpensive deal at all. Not a deal without risk. But we think that although it was an expensive deal, it was not too expensive. And although there is some risk, we feel very confident that the risk is something that we were certainly willing to take.

So the future where we're going is in terms of where we were in the past, in terms of the three priorities that I outlined of growing our Foot & Ankle business dramatically, of stabilizing Ortho-Recon business and producing cash, as we are out from under the deferred prosecution agreement. We are in businesses that have market growth going forward that is different than market growth in the past. We had products that we were essentially in the low margins, very cash intensive and a mix of business that was 40% Extremities and 60% Ortho-Recon.

Where we are going is again successfully exiting the DPA, being a market leader in foot and ankle, the highest growth market we think in orthopedics today, having a stable Ortho-Recon business, having a higher margin business as will reflect when BioMimetics is approved as well as the more of our revenue that comes from, the more of our product mix that comes from the Foot & Ankle business, strong cash flow, more geographical mix helps to get somewhere close to 50:50 in the future and a mix of business where 60% of our business would come from Extremities and Biologics as 40% from Ortho-Recon where it's a direct reversal as to where we have been.

Just some numbers, the revenue that we're anticipating for this year is about \$480 million is what we had anticipated. As we looked at the customer losses that were affected by the deferred prosecution agreement and the contractual issues that we had around that, our EPS had the same issue as well as the investment that we are willing to make in our direct sales force and growing our Foot & Ankle business.

Cash, again, a very bright spot for the company as we manage that as we focused on that as where we had \$14 million in cash last year is that we have given a guidance towards somewhere between \$45 million and \$50 million for this year. So that's quite good.

The Foot & Ankle business quarterly growth. Last year, as I said at the end of Q4, we were at 7%. That has increased every quarter that we have and we were at 14% at the end of Q3. And we had said at that time that we think this will continue to accelerate. So it's a real growth opportunity in terms of cash and inventory management.

Edgar Filing: BIOMIMETIC THERAPEUTICS, INC. - Form 425

We made the commitment that we thought that we would be able to save about generate about \$100 million in cash from inventory savings over a four-year period. We're actually ahead of our schedule there and tend to keep on working on this. We did in 2012, I said we're a little bit ahead, so we might have gotten a little bit of 2013 into 2012 but we still think that cash generation is something that we are going to be focused on and be able to produce these kinds of cash flows as we go forward. So we're focused on this, so we've made great progress in our cash generation, and it's a terrific story.

So we're in a position now where I think momentum is building. We're looking for productivity gains in U.S. Foot & Ankle. As we get these products, our direct sales force for the full year, we look at keep on accelerating our growth pattern in there. We think that by the end of this year we can stabilize our Ortho-Recon business as we anniversary the customer losses that took place in 2011 and 2012. We believe we will close the BMTI transaction. We also believe that this will be approved in 2012. We will continue to have sustained cash flow and continued progress on our inventory initiatives. And as our product mix changes and other things that we pay attention to, we think our gross margins also have a chance of improving this year.

So our strategy is to focus on areas where we can win and put our money and our resources against those, that's primarily in extremities, lower extremities and biologics; building on two solid businesses that we have that both will contribute to the overall cash generation of the company and certainly in the future a very clear and focused goal of improving our performance; and accelerating our growth and our profitability with very, very strong cash generation.

So that's where we are today. It's been a great year, we think, for Wright Medical. We've done a lot of very big transformational things in this year that set us up to have a good solid high-performing, highly profitable company in the future.

Thank you all and we'll see you at the breakout session. Thank you.

Company Name: Wright Medical Group	Market Cap: 843.43	Bloomberg Estimates - EPS
Company Ticker: WMGI US	Current PX: 21.2594	Current Quarter: -0.020
Date: 2013-01-07	YTD Change(\$): +.2694	Current Year: 0.209
Event Description: J.P. Morgan Global Healthcare	YTD Change(%): +1.283	Bloomberg Estimates - Sales
Conference		Current Quarter: 120.857
		Current Year: 480.533

This transcript may not be 100 percent accurate and may contain misspellings and other inaccuracies. This transcript is provided as is, without express or implied warranties of any kind. Bloomberg retains all rights to this transcript and provides it solely for your personal, non-commercial use. Bloomberg, its suppliers and third-party agents shall have no liability for errors in this transcript or for lost profits, losses, or direct, indirect, incidental, consequential, special or punitive damages in connection with the furnishing, performance or use of such transcript. Neither the information nor any opinion expressed in this transcript constitutes a solicitation of the purchase or sale of securities or commodities. Any opinion expressed in the transcript does not necessarily reflect the views of Bloomberg LP.

© COPYRIGHT 2013, BLOOMBERG LP. All rights reserved. Any reproduction, redistribution or retransmission is expressly prohibited.

Additional Information about the Transaction and Where to Find It

This communication is being made in respect of the proposed merger transaction involving Wright and BioMimetic. In connection with the proposed transaction, Wright has filed with the SEC a registration statement on Form S-4, which includes a proxy statement/prospectus and other relevant materials in connection with the proposed transaction, and each of Wright and BioMimetic intend to file with the SEC other documents regarding the proposed transaction. The proxy statement/prospectus and this filing are not offers to sell Wright securities and are not soliciting an offer to buy Wright securities in any state where the offer and sale is not permitted. The final proxy statement/prospectus will be mailed to the stockholders of BioMimetic. INVESTORS AND SECURITY HOLDERS OF BIOMIMETIC ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND THE OTHER RELEVANT MATERIAL CAREFULLY IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT WRIGHT AND BIOMIMETIC AND THE PROPOSED TRANSACTION.

The proxy statement/prospectus and other relevant materials (when they become available), and any and all documents filed with the SEC, may be obtained free of charge at the SEC's web site at www.sec.gov. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by Wright by directing a written request to Wright Medical Group, Inc., 5677 Airline Road, Arlington, TN 38002, Attention: Investor Relations, and by BioMimetic by directing a written request to BioMimetic Therapeutics, Inc., 389 Nichol Mill Lane, Franklin, TN 37067, Attention: Investor Relations. In addition, investors and security holders may obtain free copies of the documents filed with the SEC by Wright by going to Wright's investor information web site at <http://phx.corporate-ir.net/phoenix.zhtml?c=129751&p=irol-irhome> and by BioMimetic by going to BioMimetic's investor information web site at <http://investor.biomimetics.com/phoenix.zhtml?c=196896&p=irol-sec>.

Participants in Solicitations

BioMimetic and its respective executive officers and directors and other persons, including Wright and its respective executive officers and directors, may be deemed to be participants in the solicitation of proxies from its stockholders in connection with the proposed transaction. Information about the executive officers and directors of BioMimetic and their ownership of BioMimetic common stock is set forth in its annual report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 13, 2012 and the proxy statement for BioMimetic's 2012 annual meeting of stockholders, filed with the SEC on April 27, 2012. Information about the executive officers and directors of Wright is set forth in its annual report on Form 10-K for the year ended December 31, 2011, filed with the SEC on February 24, 2012 and the proxy statement for Wright's 2012 annual meeting of stockholders, filed with the SEC on March 27, 2012. Certain directors and executive officers of BioMimetic and other persons may have direct or indirect interests in the merger due to securities holdings, pre-existing or future indemnification arrangements and rights to severance payments if their employment is terminated prior to or following the transaction. If and to the extent that any of the BioMimetic participants will receive any additional benefits in connection with the transaction, the details of those benefits will be described in the proxy statement/prospectus relating to the transaction. Investors and security holders may obtain additional information regarding the direct and indirect interests of BioMimetic and its executive officers and directors in the transaction by reading the proxy statement/prospectus regarding the transaction when it becomes available.

Forward-Looking Statements

This filing may contain forward-looking statements as defined under U.S. federal securities laws. These statements reflect management's current knowledge, assumptions, beliefs, estimates, and expectations and express management's current view of future performance, results, and trends. Forward looking statements may be identified by their use of terms such as anticipate, believe, could, estimate, expect, intend, may, plan, predict, project, will, and other similar terms. Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements. In addition to those described below, forward looking statements contained in this filing may include, without limitation, statements concerning the possibility of FDA approval of Augment Bone Graft, statements regarding market acceptance of, and expected annual market demand for Augment Bone Graft, statements regarding the expected impact of the transaction with BioMimetic on Wright's adjusted EBITDA and other financial results, and statements about the timing and expected benefits of the transaction. The reader should not place undue reliance on forward-looking statements. Such statements are made as of the date of

this filing, and Wright undertakes no obligation to update such statements after this date. In addition to those described above, risks and uncertainties that could cause Wright's actual results to materially differ from those described in forward-looking statements are discussed in Wright's filings with the Securities and Exchange Commission (including those described in Item 1A of Wright's Annual Report on Form 10-K for the year ended December 31, 2011 and Wright's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, in each case under the heading "Risk Factors" and elsewhere in such filings). By way of example and without implied limitation, such risks and uncertainties include: the failure of BioMimetic stockholders to adopt the merger agreement or the failure of either Wright or BioMimetic to meet any of the other conditions to the closing of the transaction; the failure to realize the anticipated benefits from the transaction or delay in realization thereof; future actions of the United States Attorney's office, the FDA, the Department of Health and Human Services or other U.S. or foreign government authorities that could delay, limit or suspend Wright's development, manufacturing, commercialization and sale of products, or result in seizures, injunctions, monetary sanctions or criminal or civil liabilities; any actual or alleged breach of the Corporate Integrity Agreement to which Wright is subject through September 2015 which could expose Wright to significant liability including exclusion from Medicare, Medicaid and other federal healthcare programs, potential criminal prosecution, and civil and criminal fines or penalties; adverse outcomes in existing product liability litigation; new product liability claims; inadequate insurance coverage; the possibility of private securities litigation or shareholder derivative suits; demand for and market acceptance of Wright's new and existing products; potentially burdensome tax measures; lack of suitable business development opportunities; product quality or patient safety issues; challenges to Wright's intellectual property rights; geographic and product mix impact on Wright's sales; Wright's inability to retain key sales representatives, independent distributors and other personnel or to attract new talent; inventory reductions or fluctuations in buying patterns by wholesalers or distributors; inability to realize the anticipated benefits of restructuring initiatives; negative impact of the commercial and credit environment on Wright, Wright's customers and Wright's suppliers; and the potentially negative effect of Wright's ongoing compliance enhancements on Wright's relationships with customers, and on Wright's ability to deliver timely and effective medical education, clinical studies, and new products.