SPECTRUM PHARMACEUTICALS INC Form SC TO-I March 23, 2009

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549 **SCHEDULE TO** Tender Offer Statement Pursuant to Section 14(d)(1) or 13(e)(1) of the Securities Exchange Act of 1934 SPECTRUM PHARMACEUTICALS, INC. (Name of Subject Company (Issuer) and Filing Person (Offeror)) **OPTIONS TO PURCHASE COMMON STOCK, PAR VALUE \$0.001 PER SHARE** (Title of Class of Securities) 847 63A 108 (CUSIP Number of Class of Securities) (Underlying Common Stock) Raiesh C. Shrotriva. M.D. **Chairman, Chief Executive Officer and President 157 Technology Drive** Irvine, California 92618 (949) 788-6700 (Name, Address and Telephone Numbers of Person Authorized to Receive Notices and Communications on Behalf of Filing Persons) Copy to: Shivbir S. Grewal Michael A. Hedge **Stradling Yocca Carlson & Rauth** 660 Newport Center Drive, Suite 1600 Newport Beach, California 92660 (949) 725-4000

Calculation of Filing Fee

Transaction Valuation * \$1,756,962.00

Amount of Filing Fee * \$98.04

- * Calculated solely for purposes of determining the filing fee. This amount assumes that options to purchase 2,954,072 shares of Common Stock, \$0.001 par value, of Spectrum Pharmaceuticals, Inc. will be purchased pursuant to this offer for an aggregate of \$1,756,962.00 in cash. The actual transaction value will be based on the number of options tendered, if any, which may result in a lesser aggregate amount. The amount of the filing fee, calculated in accordance with Rule 0-11(b) of the Securities Exchange Act of 1934, as amended, equals \$55.80 per million dollars of the value of the transaction. The transaction valuation set forth above was calculated for the sole purpose of determining the filing fee and should not be used for any other purpose.
- o Check the box if any part of the fee is offset as provided by Rule 0-11(a)(2) and identify the filing with which the offsetting fee was previously paid. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

Amount Previously Paid: N/A Form or Registration Number: N/A Filing Party: N/A Date Filed: N/A

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- o Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.
- Check the appropriate boxes below to designate any transactions to which the statement relates:
- o third-party tender offer subject to Rule 14d-1.
- b issuer tender offer subject to Rule 13e-4.
- o going private transaction subject to Rule 13e-3.

o amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer: o

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Item 1. Summary Term Sheet.

The information set forth under Section I (Summary of Terms) in the Offer to Purchase For Cash Employee Stock Options Under the Third Amended and Restated 1997 Stock Incentive Plan and the 2003 Amended and Restated Incentive Award Plan (the Offer to Purchase), attached hereto as Exhibit (a)(1), is incorporated herein by reference. **Item 2. Subject Company Information.**

(a) The name of the subject company is Spectrum Pharmaceuticals, Inc., a Delaware corporation (the Company or Spectrum). The address of the Company s principal executive office is 157 Technology Drive, Irvine, California 92618 and its telephone number is (949) 788-6700.

(b) The information set forth under Section I (Summary of Terms) and Section III.1 (General; Eligibility; Offer Expiration Time) in the Offer to Purchase is incorporated herein by reference.

(c) The information set forth in the Offer to Purchase under Section III.10 (Price Range of Common Stock Underlying Eligible Options) in the Offer to Purchase is incorporated herein by reference.

Item 3. Identity and Background of Filing Persons.

(a) The Company is both the filing person and the subject company. The information set forth under Item 2(a) above and the information set forth in Section III.11 (Interests of Executive Officers; Transactions and Arrangements Concerning Eligible Options) in the Offer to Purchase is incorporated herein by reference.

Item 4. Terms of the Transaction.

(a) The information set forth under Item 2(b) above and in the Offer to Purchase under Section I (Summary of Terms), Section II (Risks of Participating in the Offer), Section III.1 (General; Eligibility; Offer Expiration Time), Section III.2 (Cash Payment for Eligible Options and Share Purchase), Section III.3 (Purpose), Section III.4 (Procedures for Tendering Eligible Options), Section III.5 (Withdrawal Rights), Section III.6 (Acceptance of and Payment for Eligible Options), Section III.7 (Extension of Offer; Termination; Amendment; Subsequent Offering Period), Section III.8 (Material U.S. Federal Income Tax Consequences), Section III.9 (Conditions to Completion of the Offer), Section III.12 (Status of Eligible Options Acquired by Us in the Offer; Accounting Consequences of the Offer; Status & Shares Purchased in the Share Purchase), Section III.13 (Legal Matters; Regulatory Approvals), and Section III.15 (Source and Amount of Consideration) is incorporated herein by reference.

(b) The information set forth in the Offer to Purchase under Section I (Summary of Terms) and Section III.11 (Interests of Executive Officers; Transactions and Arrangements Concerning Eligible Options) is incorporated herein by reference.

Item 5. Past Contacts, Transactions, Negotiations and Agreements.

(e) The information set forth in the Offer to Purchase under Section III.11 (Interests of Executive Officers; Transactions and Arrangements Concerning Eligible Options) and Section III.17 (Corporate Plans, Proposals and Negotiations) is incorporated herein by reference.

Item 6. Purposes of the Transaction and Plans or Proposals.

(a) The information set forth in the Offer to Purchase under Section I (Summary of Terms), Section III.3 (Purpose) is incorporated herein by reference.

(b) The information set forth in the Offer to Purchase under Section I (Summary of Terms), Section III.3 (Purpose) and Section III.12 (Status of Eligible Options Acquired by Us in the Offer; Accounting Consequences of the Offer; Status of Shares Purchased in the Share Purchase) is incorporated herein by reference.

(c) The information set forth in the Offer to Purchase under Section III.17 (Corporate Plans, Proposals and Negotiations) is incorporated herein by reference.

Item 7. Source and Amount of Funds or Other Consideration.

(a) The information set forth in the Offer to Purchase under Section III.15 (Source and Amount of Consideration) is incorporated herein by reference.

(b) Not applicable.

(c) Not applicable.

(d) Not applicable.

Item 8. Interest in Securities of the Subject Company.

(a) The information set forth in the Offer to Purchase under Section III.11 (Interests of Executive Officers; Transactions and Arrangements Concerning Eligible Options) is incorporated herein by reference.

(b) The information set forth in the Offer to Purchase under Section III.11 (Interests of Executive Officers; Transactions and Arrangements Concerning Eligible Options) is incorporated herein by reference.

Item 9. Persons/Assets Retained, Employed, Compensated or Used.

(a) Not applicable.

Item 10. Financial Statements.

(a) Not applicable.

(b) Not applicable.

Item 11. Additional Information.

(a) The information set forth in the Offer to Purchase under Section III.11 (Interests of Executive Officers; Transactions and Arrangements Concerning Eligible Options) and Section III.13 (Legal Matters; Regulatory Approvals) is incorporated herein by reference.

(b) Not applicable. **Item 12. Exhibits.**

(a)(1) Offer to Purchase For Cash Employee Stock Options Under the Third Amended and Restated 1997 Stock Incentive Plan and the 2003 Amended and Restated Incentive Award Plan, dated March 23, 2009.

(a)(2) Form of Introductory Letter.

(a)(3) Letter of Transmittal

(a)(4) Form of e-mail to Eligible Employees announcing Offer to Purchase.

(a)(5) Form of Election Withdrawal Notice.

(a)(6) Form of Reminder Notice of Expiration of Offer.

(a)(7) Form of Stock Purchase Agreement.

(a)(8) The Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2007, filed with the Securities and Exchange Commission on March 14, 2008 (File No. 000-28782) (incorporated herein by reference).

(a)(9) The Company s Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2008, filed with the Securities and Exchange Commission on May 12, 2008 (File No 000-28782); June 30, 2008, filed with the Securities and Exchange Commission on August 11, 2008 (File No 000-28782); and September 30, 2008, filed with the Securities and Exchange Commission on November 7, 2008 (File No 000-28782)(all incorporated herein by reference).

(a)(10) The Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2008 (File No. 000-28782) (incorporated herein by reference).

(a)(11) The Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 30, 2008 (File No. 000-28782) (incorporated herein by reference).

(a)(12) The Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2008 (File No. 000-28782) (incorporated herein by reference).

(a)(13) The Company s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 11, 2008 (File No. 000-28782) (incorporated herein by reference).

(a)(14) The Company s Definitive Proxy Statement for the Company s 2008 Annual Meeting of Shareholders, filed with the Securities and Exchange Commission on April 29, 2008 (File No. 000-28782) (incorporated herein by reference).

(a)(15) A description of the Company s Common Stock contained in the Registration Statement filed with the Securities and Exchange Commission on Form 8-A (File No. 000-28782), as filed on December 26, 2000, under Section 12(g) of the Exchange Act, together with any amendments or reports filed for the purposes of updating such description (incorporated herein by reference).

(a)(16) The Company s Prospectus Supplement No. 1 to the Registration Statement filed with the Securities and Exchange Commission on Form S-3A (File No. 333-150260), as filed on May 2, 2008, together with any amendments or reports filed for the purposes of updating such description (incorporated herein by reference).

(b) Not applicable.

(d)(1) Third Amended and Restated 1997 Stock Incentive Plan, and form of option agreement (incorporated herein by reference from the Registration Statement on Form S-8 (File No. 333-106427) originally filed with the Securities and Exchange Commission on June 24, 2003).

(d)(2) 2003 Amended and Restated Incentive Award Plan and form of option agreement (incorporated herein by reference from the Registration Statement on Form S-8 (File No. 333-119833) originally filed with the Securities and Exchange Commission on October 19, 2004).

(d)(3) Executive Employment Agreement between Spectrum and Rajesh C. Shrotriya, M.D., entered into June 20, 2008 and dated effective as of January 2, 2008 (incorporated herein by reference from the Company s Current Report on Form 8-K originally filed with the Securities and Exchange Commission on June 26, 2008).

(g) Not Applicable.

(h) Not Applicable.

Item 13. Information Required by Schedule 13E-3.

Not Applicable.

SIGNATURES

After due inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct. Dated: March 23, 2009

SPECTRUM PHARMACEUTICALS, INC.

By: /s/ Shyam Kumaria Shyam Kumaria Vice President, Finance and Secretary

EXHIBIT INDEX

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(g) Not Applicable.

(h) Not Applicable.

6;Brien - William Blair & Company - Analyst

Thanks. Can you hear me okay?

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Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Sure. Yes.

Matt O Brien - William Blair & Company - Analyst

Okay. My apologies.

I was just hoping to start off on the FTC side of things. I know Upper Extremities, you don t have to worry much about any issues there. Can you talk a little bit about the diligence you did between your two different foot and ankle portfolios and any risks that we may see to the need to potentially get rid of some products there, specifically on the ankle replacement side of things?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

This will have to go through the normal regulatory hurdles with the FTC. We view the business as the Lower Extremity, the total end-stage arthritis business, which is fusions, ankles everything that goes on down there. So I think that we re in pretty good shape.

We ll go through the required regulatory filings, and I think that we ll just see how it goes. I don t think there is anything alarming that we re looking at right now. So we feel good about where we are in not having these kinds of issues, but we ll see.

Matt O Brien - William Blair & Company - Analyst

Okay. So you re not expecting any kind of need to divest or sell off any assets on the foot and ankle?

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

Matt, we don t expect anything that would derail closing. And, as Bob said, our combined share of the end-stage ankle arthritis market is very small. And there are large competitors there, and there is more all the time. And we don t see that as a big issue. We ll go through the process and see how it works out.

Matt O Brien - William Blair & Company - Analyst

Okay. And then as a followup. I appreciate that you have Chippewa Extremities Company now for the most part. But there are some pretty different call points between foot and ankle specialists and upper extremity specialists and the general orthopods and so on.

Can you just give us a sense because I don t see as much synergistic selling opportunity for the combined entity. Can you just tell me exactly where I am wrong, i.e., there are 30% of our sales with the specialists in foot and ankle with Wright. We re not there with Tornier products or vice versa something along those lines.

Dave Mowry - Tornier - President & CEO

Matt, I m going to jump in on that because as you well know, Tornier already has an upper and a lower sales organization. And we have actually found that having a presence in both upper and lower allows us some access into hospitals and gives us a stronger presence.

I think with Wright s backing, that will further enhance that presence. So as people need to be brought to value committees and have access to contracts, we think the larger footprint will serve us well in that regard. But fundamentally, we don t see synergies in the sales organization from a cost perspective. We see a synergy in being able to bring Biologics and support some of those ancillary products with the knowledge that already comes over with Wright.

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Lance Berry - Wright Medical Group, Inc. - SVP & CFO

Matt, we ve talked in the past before about Wright having a comprehensive Biologics portfolio that really is probably somewhat under distributed. I think that might be an opportunity here.

Matt O Brien - William Blair & Company - Analyst

Got it. Thank you.

Operator

Our next question is from Matt Miksic with Piper Jaffray.

Matt Miksic - Piper Jaffray & Company - Analyst

Hello. Good evening. Thanks for taking our questions.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Hello, Matt.

Matt Miksic - Piper Jaffray & Company - Analyst

One follow up on some of the potential synergy opportunities. I think you mentioned somewhere in the prepared comments growth overseas. And I want to say that that was an opportunity that was before Tornier in sort of bringing more of its foot and ankle products, as they were approved and registered overseas, into those geographies.

So first question is, does this change the pace of that at all? Can you sketch out what that opportunity looks like for you in Europe and elsewhere? And then I have a couple quick follow-ups.

Dave Mowry - Tornier - President & CEO

Matt, at a very high level, I would tell you that what s really interesting is that if you look geographically and overlay the strengths of the two businesses, they re extremely complementary. It s not just about product portfolio. In this case, it s probably more broadly about geographic representation and strength.

Whereas we have a direct sales force in some geographies, I think Wright has a stronger presence than others. It s the ability to leverage that presence and those relationships to bring through and pull through a greater portion of the combined portfolio. So we see that as being, obviously, of benefit.

I think the second thing that s maybe a little bit of an underscore and not totally appreciated is the fact that although the combination of the portfolio is in some cases overlapping, it s also very complementary in other spots. And I think the ability for us to leverage those strong relationships, to pull through some of that complementary product, is going to be I think a great opportunity for us.

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Matt Miksic - Piper Jaffray & Company - Analyst

That s helpful.

And then on the tax side, you mentioned tax will be a benefit at some point not initially, down the road. I guess if you could help us understand how and when that would become a benefit to hold the domicile in the Netherlands and benefit from overseas tax.

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

Matt, I think we view it as probably pretty far out. Right now, neither company is a US taxpayer; and we both have meaningful NOLs. So from a cash basis, it s probably pretty far out as far as cash tax savings. Also, we have full valuation allowance at the moment; so that s not really an effective tax rate benefit.

So we just acknowledged there is a potential long-term benefit there. It really was not a factor in the transaction, and wanted to make sure that everyone understood that they shouldn t be modeling any near-term benefit because they weren t there.

The one thing that could be a benefit near term is just the ability to more freely move cash around the world. That can be helpful and be helpful in getting cash to the right places to drive growth where you need to. But really wouldn t plan on, in the reasonable future, cash tax benefits because of our profile.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Matt, I d also like to say that this combination here was not driven by tax or domicile. The reason that we wound up where we wound up, quite frankly, is that s the only way we could get this transaction done. As we say, this is an all-stock deal.

Had it been an all-cash deal, we might have been a different domicile, including maybe US. But there was really no way to do this, given the intricacies of Dutch law, and have an all-stock deal and not be in the Netherlands. So this is what we had to do really to get the deal done.

Matt Miksic - Piper Jaffray & Company - Analyst

Got it.

And then finally, Bob, the comments you mentioned on the sort of factors impacting the current business in Wright Medical things that you were going to get after and hope to address here in the near term, FX some operation issues that weren t where you wanted them to be. Can you sort of maybe provide a little more color as to ?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

I ll do it briefly, and then we re going to talk more about it on our regular call next week.

To be honest with you, I think we came in \$4 million to \$5 million in the quarter below where we thought we were going to come in. And that was a surprise, particularly at the end of the quarter. Two main issues affected that.

One was some execution issues in the US core foot and ankle business not the total foot and ankle business, but the core foot and ankle business. And we made some changes in that organization. We ve done a bunch of things.

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We had a very weak July and a very weak August. We made the changes that we talked about previously. And we had a very, very strong September; and so far in October, it s off to a very, very strong start. So I think that we are on a great trajectory to end the quarterly year well.

The other piece of the quarter had do with international business, particularly in China, where we did not have great visibility to the underlying distribution inventory that they were holding. As you know, in China you have a distributor; then you have sub distributors; and sometimes under sub distributors, other sub distributors.

So we thought that we were going to be filling orders on some products, particularly biologics, and made a lot of those. And when the orders came in, they were for different products that we didn t have. So I think that that is a one-time kind of an issue.

I think that what we saw in Q3 was really kind of a blip. The underlying fundamentals are still very, very strong growth in both regions, international and domestic. We were short where we thought we d be, and that s on me. I realize that. We probably should have executed things better, and we should have understood the supply-demand issue better; and we ve corrected that.

Matt Miksic - Piper Jaffray & Company - Analyst

Okay. That s helpful. Thanks.

Operator

Next we have Jeff Johnson with Baird.

Jeff Johnson - Robert W. Baird & Company, Inc. - Analyst

Good evening. Most of my questions have been answered at this point.

But, Bob, maybe one question on Augment just on the labeling side. I want to make sure I understand your comments there that probably talking maybe a six-month process or so to get through some of those issues and any final issues. You think somewhere kind of mid 2015 is where we can be thinking about launch date on Augment?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Yes, I think that s a very conservative view, quite frankly. I think that the labeling is not going to be very contentious between the FDA. I think that we ve negotiated lots of elements of that. In their approval letter, the only condition that was put in was the manufacturing inspections. So I think that the labeling is going to be pretty good and where we want it to be.

And just the way that this system works, it takes some time. I wish that we could be in the market in January, but I don t think we will. So sometime probably in the first half is safe. You have my word that we will do everything in the world to expedite this.

The market is waiting for it. There is a lot of pent-up demand. We had a whole group, 20 or 30 investigators, involved that want this product tomorrow.

So I think we will have an opportunity though in the meantime to get our organization trained. It will be sold through the same foot and ankle sales force, so we don t have to add any people. We have some biologics experts that will supplement that effort.

But I think that once we get this approval, we re off and running and run real fast. This is just a terrific outcome. I keep on thinking about where we were a year ago and where we are today. It s hard to believe that we ve come so far.

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Jeff Johnson - Robert W. Baird & Company, Inc. - Analyst

Understood. I think you ve mentioned before but just to confirm that once labeling is done and launch date is set, you don t really have any supply constraints. There shouldn't be anything from a manufacturing standpoint in the .

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

As a matter of fact, I think it was last quarter or it might have been the second quarter, is that we took a risk and bought a complete supply of PDGF because the manufacturer was going out of business. And so we have supply of PDGF that should take us through the next five years or so. So we have all that.

We have our little convoluted supply chain that we re going to straighten out a little bit. All in all, we re ready to go.

Jeff Johnson - Robert W. Baird & Company, Inc. - Analyst

Okay, and last two quick ones. As both companies have some ankle products in the pipeline, some revisions and some primaries, any early thoughts on kind of what shakes out from an ankle pipeline standpoint?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

No, we regoing do whatever customers want us do. One of the things you learn is there are a lot of surgeon preferences that go into these different products.

I ve been a competitor in the Lower Extremity of Tornier for some time now. I have never ever said anything bad about their products. I fully respect their products. They re very good. They have a good following, and we re going to continue that.

Jeff Johnson - Robert W. Baird & Company, Inc. - Analyst

All right. Last one, just one follow up from earlier in the call. I thought an interesting comment on your international distribution then post deal. Can you give us any numbers kind of what percentage of Wright versus Tornier standalone sales force right now is direct internationally, and what that number might go to then on a combined basis? Does it go up, I presume?

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

I don t know if we have done that.

Jeff Johnson - Robert W. Baird & Company, Inc. - Analyst

Qualitatively, I guess the question is, are you much more direct post deal than you are pre deal? Should we think about that, or how should we think about that?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

I don t think that changes much. We are mostly direct in Europe and through distributors in South America and Asia.

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Jeff Johnson - Robert W. Baird & Company, Inc. - Analyst

Okay, the Tornier side I am a little less familiar with.

David, are you more distributor international? I m sorry.

Dave Mowry - Tornier - President & CEO

It s very similar; although I think we have direct in Canada, Australia, and Japan which may add some opportunities.

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

I think it s more, Jeff, you look at the footprint. We re strongly direct in certain areas where Tornier may be direct but doesn t have a strong presence and vice versa. I don t know that the math is going to change overnight.

But when you look at both of us wanting to do strong growth going forward, we re going to be able to leverage the infrastructure of the combined business a lot better than we would just standalone.

Jeff Johnson - Robert W. Baird & Company, Inc. - Analyst

Okay. That s good clarification. Thanks.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Thank you.

Operator

Next is Matt Taylor with Barclays.

Matt Taylor - Barclays Capital - Analyst

Hello. Thanks for taking the question.

So just wanted to ask one follow up on FTC issues. You talked about having a really low percentage of the ankle market. But you do have a high percentage of the total ankle market. Do you think that the FTC will look at that differently? And can you talk about what your total ankle market shares are just roughly?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

I don t think they ll look at it differently. We think it s one market. There are a lot of competitors into it, and it s very dynamic; and so I don t think so.

In terms of total ankle, I think that I m not exactly sure because again it s what s going on in total ankle more, Matt, rather than market share differentiation, is market growth. Is that we always felt that the Lower Extremity, particularly the total ankle market, is a very immature market. And it s just getting up to the point where it s taking off. So it s still about less than 10% of the total procedures done are total ankles, where 90% are fusions.

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Dave Mowry - Tornier - President & CEO

I would just echo Bob s comments that we think that the ankle arthritis market is still a significantly large fusion market. And you have more and more of the large strategics that are starting and looking to get into this space. So, I think the way the FTC looks at it I am sure will be the way that they look at it. But we look at that market as one entity with a lot of players that are in it.

Matt Taylor - Barclays Capital - Analyst

Just to clarify on your earlier growth comments, you are talking about mid-teens growth for the combined entity, being able do that with some disruption and with the positive of Augment. Is that correct?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Yes.

Matt Taylor - Barclays Capital - Analyst

Okay. Great. I appreciate that. Thank you.

Operator

Next is Richard Newitter with Leerink.

Richard Newitter - Leerink Partners - Analyst

Hello. Thanks for taking the questions. Congrats on the deal.

And, Bob, congrats on the Augment approval.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Thanks, Rich.

Richard Newitter - Leerink Partners - Analyst

Just two quick follow-ups.

It s been asked a few times, but maybe kind of a different way. You both carry total ankle portfolios. If I m hearing you correctly, you are saying that there is enough demand for both products; and there are enough nuance differences between the two that you feel like keeping both full-product portfolios on board is the correct strategy going forward?

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Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Yes. As I said, there is a lot of surgeon preference that goes on. The physicians get used to products, and they are very sticky. I have noticed in orthopedics, as opposed to really some of the businesses I have been in, medical devices is these products are very, very sticky. Doctors get involved with a product, and they stick with it.

So we will try to maximize both portfolios. And if things change where doctors prefer one or the other or a new product comes out, that may change. But in the immediate future, I think we intend to fully maximize both portfolios.

Richard Newitter - Leerink Partners - Analyst

And then going back to another question that was asked on the call about being able to leverage the various call points given that you have dedicated sales forces dealing with different specialists and different orthopedic sub specialties in shoulder, foot, and ankle.

Is there another way to think about it? That you are seeing a shift to the decision making at the institutional level going towards hospital administrator, and in some way they re looking to work with fewer vendors and this will position you in that context? Is there something kind of beyond the just cross-selling or typical-cross selling?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

There are two things. First of all, I don t see any leverage between the two different sales forces, Upper and Lower. I think those are separate because, just as you said, there are different call points.

I do think that with our size that we are going to have and having the portfolio of Upper, Lower, and Biologics, is that we may be more effective in contract negotiations than we ever could be separately. And the bigger competitors use this to their advantage. And I think both companies have been successful in still selling into these big institutions.

But I do think that this will give us an advantage that we didn t have, a potential advantage anyway, in terms of contracting.

Richard Newitter - Leerink Partners - Analyst

Great. And then just one last one.

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Bob, your Q4 guidance it looks like is stepping down a touch as well. You said that you ve identified issues with 3Q; 4Q is off to a solid start. Is that just there is some bleeding into the fourth quarter, or can you just describe that?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

It s primarily the trajectory. We are off a lower trajectory than we had anticipated. I think that s the most of it.

Richard Newitter - Leerink Partners - Analyst

Okay. Thanks.

Operator

Next is Glenn Novarro with RBC.

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Glenn Novarro - RBC Capital Markets - Analyst

Hello. Good afternoon.

Bob, just to start with you. Just one more question on your fourth-quarter guidance. I think Dave, when he gave his guidance for 4Q, I think I heard him say he is assuming some disruption created by the announcement of this deal. Do you assume any disruption in your business in the fourth quarter by this announcement?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Yes, but it s hard to quantify. I can t give you how much. There will be some, what I would call, distraction around this. There have been different sales reps or even distributors that have gone from Wright to Tornier and vice versa.

And I m not sure how they re feeling about this, although they should feel fine. But they might feel a little bit threatened, given that they might have recently changed companies. So I think that just history leads me to believe to plan for some distraction that may have some financial impact.

And we have included and I can t say what the exact number is because no one knows but certainly we said this is going to have some effect. We just don t know how much, and it s in our guidance.

Glenn Novarro - RBC Capital Markets - Analyst

Just one follow up for both Bob, for you and for David as we re looking at our models for each company separately. Obviously, Augment now goes into the right model; but Infinity was going to be a big driver. Can you give us an update on how that launch is?

And then for Dave, as I m looking into our model back end of next year and into 2016, we had Simplicity being a nice lift in the growth rate. So maybe if each of you could talk about how these products are going to affect the longer-term outlook? Thank you.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

I will talk about Infinity, and Dave can talk about his product.

Infinity is off to a great start. Even in Q3, we had excess of 20% growth in Infinity. The momentum is strong. Usually you get the benefit like a quarter after you launch it.

We just launched it in Q3, and so that was a terrific start. We ve trained I forget how many. But the leading indicator of success in these products is how many people you get trained.

So we ve trained just about all our sales force now and a great deal of surgeons. So we re looking in Q4 to that actually to ramp up even further; and as we get into next year, to continue going. So that s a strong product. It has a great trajectory, and we think it s going to keep on going.

Dave, you want to comment?

Dave Mowry - Tornier - President & CEO

Thanks, Bob.

Hello, Glenn. Thanks for the question.

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Simplicity, for those of you who follow Tornier, is the less invasive shoulder platform that we had done an FDA IDE trial on. It s a 510-K approval product with IDE support. We are wrapping up the enrollment following up on the patients. The two-year follow up concludes here in November, and we ll be submitting to the FDA our 510-K with clinical results.

Our anticipated completion and approval is about mid year of 2015. And we are preparing right now for the ramp with set builds, as well as training programs et cetera, for the launch of that product. A significant portion of that unfortunately will cannibalize some of our existing total shoulder market.

However, we also believe that Simplicity will recruit in a significant portion of folks that are looking to add younger patients that have the opportunity to have earlier intervention. So we re really excited about Simplicity. And a lot of energy and focus is going into the preparation for it.

Glenn Novarro - RBC Capital Markets - Analyst

Okay. Thanks and congratulations.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Thanks.

Operator

Next is Raj Denhoy with Jefferies.

Raj Denhoy - Jefferies & Company - Analyst

Hello. Good evening.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Hello, Raj.

Raj Denhoy - Jefferies & Company - Analyst

A lot has already been asked, but I just wanted to follow up on revenue growth. From what we heard from other questions, it sounds like a lot of the acceleration, if not most of the acceleration in mid teens, is Augment-based. And so I m curious if there s anything you ve learned through the last year, plus with the FDA, that has changed at all your expectations for that product?

Certainly you re still putting out the same revenue target. But if it all changed how you think about that product at this point?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

No. I think first of all, I would say that in the short term, I think we will be successful when final labeling is approved to have a broad enough label to do just about everything we thought we would be able to do. So it s meeting our expectations.

Longer term, I think that we should all think and this is new, but we have been thinking about this a lot is this is really a platform technology. And what we plan to do is to star other clinical trials.

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We have an IDE approved for the injectable product for elbows that we will ramp up. We put that on hold while we were in the state of limbo. And also we feel that we should start a clinical trial for Upper in the shoulder see what use it can be there.

So we think that we re just at the beginning stages of Augment. It s a very unique product now with this pending PMA approval. I think it s really going to serve us well, and the combined Company is going to have a tremendous result from this.

Raj Denhoy - Jefferies & Company - Analyst

To that point, I mean so much has changed in the last year. I only ask this because, again, unless I m mistaken, so much of the acceleration comes from that product. But a year ago, the FDA didn t really want anything do with it. And now it sounds like you re expecting approval in six months and potentially expanding indications and everything. And so maybe you could just describe what s changed so dramatically at the agency.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

First of all, I think that the core business of both companies is driving most of the growth and particularly from Wright, total ankle accelerating into very strong in the foreseeable future. That s driving most of the growth.

And on the Tornier side, they re very strong and a lot of momentum in their shoulder business. And that s going to continue for the foreseeable future. So I think both of those things are driving most of the growth.

What happened in the agency with Augment, I think, is you might recall the whole history how we got the non-approval letter a year ago. We were going to go through dispute resolution panel. The agency contacted us and said perhaps an amendment might work.

We worked through that. We had a team of people that were outstanding, both internal and external, to drive that; get them the data that they needed to approve the product. And in some cases, it was a little bit different data that was included in the original PMA. So the FDA had new things to look at, to consider; and all that went well.

It was very hard as we went through the process for me to handicap. And I kept on saying this I don t know how this is all going to come out. But what I did notice was a very positive interaction between the agency and the Company.

And that meant that calls were returned promptly, negotiations were done well. It wasn t any of the gamesmanship that sometimes you get. That made me feel good. I can t say it was a surprise that we got approved. But I wouldn t have been surprised if it went the other way either, given the history with Augment. A great result.

Raj Denhoy - Jefferies & Company - Analyst

That shelpful. Congratulations.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Thanks.

Operator

Next is Mike Matson with Needham.

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Mike Matson - Needham & Company - Analyst

Hello. Thanks for taking my question. I guess I just want go back to the cost synergies, that \$40 million to \$45 million. My math indicates it s about 78% of your combined operating expenses.

I know that s consistent with some of the deals we have seen in the space among the larger companies. But your operating expenses on both sides are considerably higher as a percentage of sales. So I guess I would have thought you would be able to get some more significant cost synergies just from the leverage effect of having more revenue over fixed cost and so forth. Can you comment on that?

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

Sure, Mike. This is Lance.

I guess we ve looked at it a slightly different way. First thing I think to think about is we have talked about on the call is these businesses are really very complementary not redundant, not lots of overlap. So that does reduce some the target areas for cost synergies, but is really helpful for revenue which is the most important thing.

The other thing is when you look at the Tornier large joint business, that s really almost a part of the business that s not even applicable to view from a synergy opportunity standpoint. So if you look at the \$40 million to \$45 million, that s about 15% to 16% of Tornier s extremity products revenue. We think that s a very healthy synergy number for these two businesses, given their complementary nature as opposed to something that was highly overlapping. And we think something that we can put a good plan around to go achieve, while still driving high-growth revenue in both businesses.

Mike Matson - Needham & Company - Analyst

Okay. Thanks.

And then just on the total ankle. I know there has already been some commentary, but the 25% number seems pretty low to me, I guess. Because from what I remember, and I might be wrong, but I think your growth rate was considerably higher than that in the year. And now this is the first quarter after Infinity was launched.

I understand it is just getting out there, but I guess I would have hoped that it was at least able sustain the kind of growth we are seeing. So if I m wrong, let me know. Maybe the growth is lower than I thought in the first half.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

No. It was 50% better than Q3 last year, right?

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

No. We grew 50% in Q3 last year.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

That s right. So the comp was pretty and I think the comp was pretty tough. And I also think, Mike, that as I said, you get the benefit the quarter after the launch; you don t get it in the quarter.

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And in the quarter that you launch the product, you re still doing a lot of training. But I know that I sat through last week a whole bunch of what we call quarterly business reviews with district managers. And they have very strong cases reserved for the rest of Q4.

Mike Matson - Needham & Company - Analyst

All right. Thanks a lot.

Operator

Next is Jason Wittes with Brean.

Jason Wittes - Brean Capital, LLC - Analyst

Hello, thanks for fitting me in. Just a couple follow ups here. and congratulations as well on the deal and the Augment approval.

First off, just to push you a little bit on your comments at the very beginning about this quarter s performance and the changes you made. You mentioned something refocusing on the core. Could you just kind of explain what you mean by that?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

We have met, or even maybe exceeded, our expectations on total ankle. But on our core foot and ankle products the plates and screws and all that kind of stuff that s what fell short. And it seems like we needed to improve our execution in that area. We made some organizational structural changes in Q3 that we think addresses that.

Jason Wittes - Brean Capital, LLC - Analyst

Does that mean a shift a little bit more towards the plates and screws away from total ankle, or your just ?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

That s where we fell short. was in the core foot and ankle. Currently, that s a larger business than total ankle.

Jason Wittes - Brean Capital, LLC - Analyst

Right. So I guess I m asking, does that mean you felt maybe you expended too many resources on total ankle and maybe you need to pull back a little bit and refocus?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

No. I see what you re saying. That s why the refocus. No, it s not that. It s that the commercial organization and again, I am in charge of this organization. I take responsibility.

We did not execute particularly in the first parts of Q3 in booking the number of cases that we needed to book to show the growth that we needed to show. And we fell short.

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Jason Wittes - Brean Capital, LLC - Analyst

I understand. And then just a couple of questions on Augment. One, in terms of the label I know there is discussion to be had. But it sounds like it s basically going to be for all fusions, and there is really no black box warning or anything like that to be worried about. Is that ?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

There is no black box warning. It s for hind foot fusions.

Dave Mowry - Tornier - President & CEO

Ankle and hind foot.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Ankle and hind foot fusions, yes.

Jason Wittes - Brean Capital, LLC - Analyst

Okay. And then you mentioned cost effectiveness in the slides. Does that could you kind of just give a little more detail on that? I assume there is some kind of price involved where you feel it s cost-effective verses harvesting. What can you say about the cost effectiveness and about ASP that you re looking to get in the market place?

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

Yes, Jason. We have done some work on this (inaudible) even pre Wright acquisition had done work on this to try and compare really, auto graft is not a no-cost procedure. There are things that go along with that, and particularly if you start bringing in the cost of complications from the second site.

And so when you do that, you can kind of prove on overall economic basis that these things are similar. Whereas Augment offers, obviously, large patient benefits. And that s where the cost effectiveness comes in.

And we ve talked about pricing. We think we can price it at a premium to a lot of the other things that are in the market today but still at a discount to infuse, which is you know pretty highly priced and is still used on foot and ankle for certain particular specific situations.

Jason Wittes - Brean Capital, LLC - Analyst

Okay. Did you ever put out a rough ASP for that?

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

No.

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Jason Wittes - Brean Capital, LLC - Analyst

Okay. Great. Thanks and congratulations again.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Thanks.

Operator

Next is Mark Landy with Summer Street Research.

Mark Landy - Summer Street Research Partners - Analyst

Good evening. Congratulations to everybody and thanks for squeezing me in.

Lance, a quick one for you. If I m not mistaken, you wrote down the Biomedics acquisition. At some point will you have to write it up again, or how will that be handled?

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

That s a broad statement, so I d be careful with generalities. But in general, once you write things down, you don t write them back up. So the intangibles and things like that, those are written off for Augment. And we actually wrote off quite a bit of inventory also. So that will be helpful once the product is approved, as far as profitability is concerned.

Mark Landy - Summer Street Research Partners - Analyst

Yes, that s where I was going; so you kind of get to pass on that.

And then, obviously, cash distribution to the CVR holders when you get approval so around six months or kind of the early part of next year? Is that correct?

Lance Berry - Wright Medical Group, Inc. - SVP & CFO

Yes, Bob said first half is what we ought to be looking at first half 2015.

Mark Landy - Summer Street Research Partners - Analyst

Sure.

Bob, I think that you had kind of stopped everything. You mentioned some of the restarting of the clinical trials. There was work that was already done with protocols in place. There was work completed on the injectable on tendinosis.

Are you still going to look at those protocols, review them, make sure they meet Wright medical standards? Or do you just start those up again? How do you progress with those?

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Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Right now, as I said, this is new. We put a hold to everything, obviously, while this thing was in flux with FDA. And I think we ll take a look at everything. Our main focus though, I have to tell you, is to get the current product that is approved, and will be approved, on the market as quickly as we can. And then we ll start looking at this as to how we can expand this. I do know that we do have an IDE that was active that we stopped enrolling patients on after we got the not approval letter last September. That could probably be the first candidate to get started.

Mark Landy - Summer Street Research Partners - Analyst

And then just, Bob, I guess Dave was asked on his viewpoint of large joints. I don t know if you had an opportunity to respond. It s 9% of the combined business. Obviously, you got rid of the last business you had there. How do you view the large joints?

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

This is I agree with Dave. This is very different than the business that we sold off. This is a business that is primarily in Europe and is contained. It does produce cash flow and EBITDA.

So I don t have a psychological aversion to large joints, if that s what you re getting at. But I do think that, as Dave said, this is something that will be constantly under review like everything else in terms of what s a strategic fit long term and judgments will be made. But there is nothing immediately that we re going go out and do that s any different than what s currently happening.

Mark Landy - Summer Street Research Partners - Analyst

Okay. Thanks and congratulations to all again.

Dave Mowry - Tornier - President & CEO

Thanks, Mark.

Operator

We have no further questions. So I ll pass it over to you, Bob, for any closing comments.

Bob Palmisano - Wright Medical Group, Inc. - President & CEO

Thank you, Operator.

We want to reiterate our excitement for this transaction, which represents an exciting transformation and next chapter for both companies. We believe there is a bright future ahead for the new combined Wright. Dave and I wish to thank the collective teams at Tornier and Wright for working so closely together to get us to where we are today.

Obviously, a lot of work lies ahead of us. But we are extremely excited about the opportunity to bring our two companies together to create the premier high-growth extremities Biologics company. And so on behalf of the management teams at Tornier and Wright, I want to thank you for joining us today. We appreciate your interest and continued support.

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Operator

Great. Thanks for your time and your participation. Have a great rest of the day.

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Note on Non-GAAP Financial Measures

Wright Medical Group, Inc. (Wright) and Tornier N.V. (Tornier) use non-GAAP financial measures, including EBITDA, as adjusted. Their respective management teams believe that the presentation of these measures provides useful information to investors and that these measures may assist investors in evaluating their respective company s operations, period over period. EBITDA is calculated by adding back to net income charges for interest, income taxes and depreciation and amortization expenses. While it is not possible to reconcile the adjusted EBITDA forecast in this communication to the nearest metric under U.S. generally accepted accounting principles (GAAP) of the combined business without unreasonable effort, the adjusted EBITDA forecast excludes non-cash stock based compensation expense and non-operating income and expense, as well as the expected impact of such items as transaction and transition costs, impacts from the sale of Wright s OrthoRecon business and costs associated with distributor conversions and non-competes, all of which may be highly variable, difficult to predict and of a size that could have substantial impact on the combined company s reported results of operations for a period. Investors should consider these non-GAAP measures only as a supplement to, not as a substitute for or as superior to, measures of financial performance prepared in accordance with GAAP.

Important Additional Information and Where to Find It

In connection with the proposed merger, Tornier plans to file with the U.S. Securities and Exchange Commission (SEC) a registration statement on Form S-4 that will include a joint proxy statement of Wright and Tornier that also constitutes a prospectus of Tornier. Wright and Tornier will make the joint proxy statement/prospectus available to their respective shareholders. **Investors are urged to read the joint proxy statement/prospectus when it becomes available, because it will contain important information.** The registration statement, definitive joint proxy statement/prospectus and other documents filed by Tornier and Wright with the SEC will be available free of charge at the SEC s website (www.sec.gov) and from Tornier and Wright. Requests for copies of the joint proxy statement/prospectus and other documents filed by Wright with the SEC may be made by contacting Julie Tracy, Senior Vice President and Chief Communications Officer by phone at (901) 290-5817 or by email at julie.tracy@wmt.com, and request for copies of the joint proxy statement/prospectus and other documents filed by Tornier by phone at (952) 426-7646 or by email at <u>shawn.mccormick@tornier.com</u>.

Wright, Tornier, their respective directors, executive officers and employees may be deemed to be participants in the solicitation of proxies from Wright s and Tornier s shareholders in connection with the proposed transaction. Information about the directors and executive officers of Wright and their ownership of Wright stock is set forth in Wright s annual report on Form 10-K for the fiscal year ended December 31, 2013, which was filed with the SEC on February 27, 2014 and its proxy statement for its 2014 annual meeting of stockholders, which was filed with the SEC on March 31, 2014. Information regarding Tornier s directors and executive officers is contained in Tornier s annual report on Form 10-K for the fiscal year ended December 29, 2013, which was filed with the SEC on February 21, 2014, and its proxy statement for its 2014 annual general meeting of shareholders, which was filed with the SEC on May 16, 2014. These documents can be obtained free of charge from the sources indicated above. Certain directors, executive officers and employees of Wright and Tornier may have direct or indirect interest in the transaction due to securities holdings, vesting of equity awards and rights to severance payments. Additional information regarding the participants in the solicitation of Wright and Tornier shareholders will be included in the joint proxy statement/prospectus.

Cautionary Note Regarding Forward-Looking Statements

This communication includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as anticipate, expect, plan, could, may, will, believe, estimate, for project, and other words of similar meaning. Forward-looking statements in this communication include but are not limited to, statements about the benefits of the transaction; potential synergies and cost savings and the timing thereof; future financial and operating results; the expected timing of the completion of the transaction; the combined company s plans, objectives, expectations and intentions with respect to future operations, products and services, the approvable status and anticipated final PMA approval of Wright s Augment Bone Graft product, and the positive effects such final approval is anticipated to have on the combined business. Each forward-looking statement contained in this communication is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, uncertainties as to the timing of the transaction; uncertainties as to whether Tornier shareholders and Wright shareholders will approve the transaction; the risk that competing offers will be made; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the transaction, or the terms of such approval; the effects of disruption from the transaction making it more difficult to maintain relationships with employees, customers, vendors and other business partners; the risk that shareholder litigation in connection with the transaction may result in significant costs of defense, indemnification and liability; other business effects, including the effects of industry, economic or political conditions outside of Wright s or Tornier s control; the failure to realize synergies and cost-savings from the transaction or delay in realization thereof; the businesses of Wright and Tornier may not be combined successfully, or such combination may take longer, be more difficult, time-consuming or costly to accomplish than expected; operating costs and business disruption following completion of the transaction, including adverse effects on employee retention and on Wright s and Tornier s respective business relationships with third parties; transaction costs; actual or contingent liabilities; the adequacy of the combined company s capital resources; failure or delay in ultimately obtaining FDA approval of Wright s Augment Bone Graft for commercial sale in the United States, and the risks identified under the heading Risk Factors in Wright s Annual Report on Form 10-K, filed with the SEC on February 27, 2014, and Tornier s Annual Report on Form 10-K, file with the SEC on February 21, 2014, as well as both companies subsequent Quarterly Reports on Form 10-Q and other information filed by each company with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this presentation. You are encouraged to read Wright s and Tornier s filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this communication speak only as of the date of this document, and we undertake no obligation to update or revise any of these statements. Our businesses are subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.