FOREST LABORATORIES INC
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Proxy Statement Pursuant to Section 14(a) of the

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20- Jun- 2012

Forest Laboratories, Inc. (FRX)

Investors Meeting

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Howard Solomon

Chairman, President & Chief Executive Officer, Forest Laboratories, Inc.

Marco Taglietti

Senior Vice President, Research & Development, Forest Laboratories, Inc.

Gavin Corcoran

Executive Vice President Research & Development, Early and Clinical Development, Forest Laboratories, Inc.

Harry Sacks

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, please welcome Executive Vice President, Finance and Administration and

Chief Financial Officer, Forest Laboratories, Frank Perier.

Francis I. Perier

Chief Financial Officer & VP-Administration, Forest Laboratories, Inc.

Good morning, everyone, and I wish to welcome you all to our 2012 Investors Conference. It s really great we re kind of oversubscribed and it s great to have our investors, our prospective investors and the members of the analyst committee who are so important to communicating the Forest story to the larger investment audience.

You know no meeting investor meeting will certainly be complete without the requisite disclaimers. So I just need to focus on the Safe Harbor statement for a second and just advise everyone that today s presentation will include, in addition to historical information, certain forward-looking information as defined by the Act. And I d refer everyone to the full disclosure that s included above and is also on our website www.frx.com and that actual results may be somewhat different.

With that said, it s hard to believe that it s been two and a half years since the last investor conference that we had. And I think I can speak on behalf of all my colleagues at no risk of overstatement that a lot has happened in the ensuing two and a half years.

Back then, we had just recently launched two products, and we had six products that were in as said, we have five products six products that were in commercial development. At that time, we spoke to the Late Eight and we were really a development story.

As we look today, we have five newly launched and commercialized products in the market. We ve got two products that are on the verge. We believe we re on the verge of approval with the FDA. And we have two products that we plan to file their NDAs with the FDA by the end of this year.

Collectively the next nine, today we re a commercialization story and we re focused on commercializing that product portfolio in six important therapeutic categories. So that will become a major focus of today s presentation for us.

I think we all know that nothing has ever built without a clear plan and strategy, nothing of true lasting value has ever built without a clear strategy and dynamic plan. Forest Laboratories has been under the leadership of Howard Solomon for a long time. And he has been one of the principal visionaries and you ll hear from him in just a minute.

But you ll also hear from excuse me many of the key leaders in our organization, who guide the organization through the labyrinths of plans that enable the organization to execute the strategy and create the vision. As I ve said, there s been one clear visionary who had led this organization for a long time and that is Mr. Howard Solomon, our Chairman of the Board, Chief Executive Officer and President. And it s my great pleasure to introduce Howard Solomon today to deliver the opening remarks for the for today s meeting. Mr. Howard Solomon?

Howard Solomon

Chairman, President & Chief Executive Officer, Forest Laboratories, Inc.

Thank you, Frank. Good morning, everybody, and welcome to the meeting. So we constantly communicate with our investors. We think it s appropriate to have these larger meetings, so that you can really meet the key executives of the company and they d like to mingle around with you. So you get a lot of information today, and I think you ll find it very informative.

Executives will describe what s happening in their particular areas of responsibility. And taken together what they describe really is what Forest is doing. You ll get an excellent picture of what s going on in Forest. And then, we ll answer any questions that you have.

But first I d like to describe what is our basic company strategy, that is very clear how we go about achieving our success. As you probably know, we don t usually create novel molecules. Not that we couldn t. Not that we might not be as successful or maybe more successful than some of the big pharma companies. And not that we couldn t afford it if we thought it was the right strategy for us. We don t do it because at the present time, we think it s too risky, costs too much and takes too long. And most importantly, we don t have to do it in order to have a continuing flow of product opportunities.

What we ve done for years and expect to continue to do is to acquire product opportunities usually after Phase I at the earliest, rather at the Phase II and Phase IIb, at Phase III sometimes and to acquire them either by license or company acquisition. That s the simple statement of what we re doing.

There have been and still are many opportunities available from many different sources. And we in fact review hundreds every year when we identify opportunities we like, we then conduct what we refer to as our ferocious due diligence [indiscernible] (5:49) avoid making a mistake.

And then we perform all the necessary clinical and scientific studies with the products that have survived our due diligence. And finally, we prepare the NDAs and obtain FDA approvals and then of course we market the products. And I believe that operating results confirm that we do all these activities extremely well.

As Frank has said, we have attained approvals for five products in the past several years. We expect to have two more this year and probably two more next year. You may hear that over and over again because we re very proud of this. And working on products to succeed those nine products, and for years now, we ll talk about the next nine, the next 12 or the next six whatever it turned out to be.

This year the first without Lexapro, we ll have our most modest earnings in many years. I don t expect that you ll ever see that again. What I expect you ll see in the future is the blooming of all of our new products we ve been developing and working on for so many years.

The earliest of our new nine products is Bystolic. This fiscal year commencing April 1, 2012 will be its fourth year on the market. It has actually been on the market for three years. Net sales in the quarter ended March 31st of this year of $97 million, an increase of 33% over the previous year.

And you can estimate what are sales likely to be this year and next year and the years beyond. It was the 16th beta blocker when we introduced it in a highly genericized market. That was originally developed by J&J. And we plan to file for its combination with valsartan and ARB an angiotensin II receptor blocker. The first such combination in one dosage form and we expect that will increase the value of our franchise in the anti-hypertensive market.

And Bystolic sales and this is important for, Bystolic sales are not unique. Some but as many of our other products over the next couple of years will have similar or better successes. Some products grow more rapidly, some may grow more slowly, but the ultimate effect will be steady and significant growth year-after-year, a dip when Namenda goes off patent in 2015, but steady and significant earnings growth nevertheless until we reach and surpass where we were last year. Then we will go on from there.

It surprises me sometimes as some of the investors look at us as if we had no history. But the same company needing substantially the same people who created three cliffs, Celexa, Lexapro and Namenda each with sales in excess of $1 billion. And we are proud of our cliffs.

Because you can t have a cliff unless you have a mountain. I believe in following the best plan for increasing earnings and increasing the company s value. And if you tell then any time that our strategy was not working, or figure a better way to achieve those objectives because it changes the company or changes the world outside then we re certainly going to adjust our strategy because we have in fact several times over the past years.

So the executives you shall meet today cover the whole range of how Forest functions. And it s virtually the same team that created Celexa, Lexapro and Namenda, and now Bystolic and all the rest of our products.

Dr. Marco Taglietti is our newest Senior Executive. He is President and Chief Medical Officer of the Forest Research Institute. He s been with us for five years having succeeded Larry Olanoff who still looks over from the seat on the board, then his one week and a month presence at Forest.

In addition, we have three other executives from FRI Dr. Gavin Corcoran, Executive Vice President of Research and Development. Dr. Harry Sacks, Executive Director, Clinical Development Respiratory, Dr. Paul Grint, President of Cerexa, our antibiotics subsidiary.

And then David Solomon, Senior Vice President, Corporate Planning and Strategic Planning Corporate Development and Strategic Planning. With among his responsibilities he leads the business development group. And then we have Elaine Hochberg, Executive Vice President, Sales and Marketing and Chief Commercial Officer at Forest. And then Bill Meury, Senior Vice President, Global Commercial and U.S. Market that will have these big titles.

And following their presentations, Frank Perier will welcome your questions.

And thank you very much. The next person I m going to introduce is Marco Taglietti. As I said he was Head of FRI. You ve heard about the filings we ve made with the FDA. The approvals we ve gotten recently and Marco is the giant among us, the leader who has been able to achieve that success. And even though he has this utterly seductive Italian charm, he really runs a very, very stiff organization. He s on a combination of [indiscernible] (11:42) and Mussolini. Marco, it s up to you.

Marco Taglietti

Senior Vice President, Research & Development, Forest Laboratories, Inc.

Well, good morning, [ph] buongiorno (12:03). So I promise I will not make my presentation in Italian. So thank you very much Howard for the introduction, your kind words.

So let me try to give you a sense in the next few minutes of what we are in the organization. Creating sustainable growth beyond 2012 has been the motto and the mission of my R&D organization in the last few years. Because we knew and we were very well aware that where was this what we call Lexapro cliff coming. And so we got way before it, by building systematically, methodically, relentlessly a broad pipeline and very important in R&D organization that would deliver pipeline.

Now it s hard to believe that more than two and a half years that by since we had a similar meeting like this one showing by the way how true is the statement that time flies when you are having fun and believe me we had lot of fun in the last two and a half years.

So two and a half years ago, as Frank was mentioning, we were in the same venue, I think actually it was the same identical room and we were talking about the big Late Eight strategy. It was consistent in bringing this eight products new product in to the market to replace the Lexapro sales. And these products were nebivolol, milnacipran, ceftaroline, roflumilast, aclidinium, linaclotide, levomilnacipran and cariprazine. So eight new products to bring to the market.

Now, to be honest to you guys, probably many of you didn t think or were very skeptic that we could make it. But we could bring eight product to the market, why don t you? And to tell you the truth was justified this [indiscernible] (14:14) because as you may know the average success rate of a pipeline in late stage is about 50%, 60%.

So I think I mean probably many of you when you saw that we had eight products that we wanted to bring to the market probably you thought that probably you know four, five maybe six would have been already a success.

But here we are today two year and a half later and here we are. We have four products now on the market. We have two products under review and let me say we expect them to be approved this summer, linaclotide and aclidinium. And we finished successful Phase III program in for other two and we will file the NDAs before the end of the year.

All Late Eight products are on the market or on their way to the market. That is eight out of eight. I think of it well, what is the expression in baseball. I think it s batting a thousand, right? Well I think let s say I m not too much of a baseball and more as you can imagine Italian football, really football type of guy, but Bill Meury that you will hear very shortly who is truly an expert in baseball, it will mean batting 300 already make you walk to go in hall of fame. So I think batting a thousand is quite a remarkable achievement. And to tell you, we are very proud in Forest and in my R&D organization of these achievements.

And now even better in the last year, we have turned or transformed our Late Eight strategy into the next nine strategies by adding Viibryd to our pipeline. So we have been continuing to evolve and now we are looking we are looking to continue to expand it.

I have been asked actually recently more than once what has been really the key of our success. How we ve been able to achieve this remarkable results at Forest. If there is some kind of special recipe, let me just say it, it is not rocket science. There is no magic secret. Our recipe is very, very simple. We have sound strategies and flawless execution.

Sound strategies and flawless execution for each one of the three stages of R&D, which are product selection, product development and marketing support. That s it, no special again, no special secret, no special recipe, actually very, very simple recipe as I always say it s like Italian food good Italian food, very simple recipes with a little bread, touch of tomatoes, a little bit of olive oil, but let me just say, and take my word for it, making good Italian food with following this simple recipe is not easy. You need to really to master the recipes. The same is for development product development. If you want to be successful, you need very simple approach, strong strategies, smooth execution and we at Forest we have mastered, mastered this formula.

So let me go now each one of these three stages and tell you what are our booked strategies and how we execute it. So just to give you a sense of how we operate. For product selection, the strategy is very simple. We select our product based both on solid, well tested, bit science. And on the potential, market relevance of the product. So this is really a strategy that we do and try to let our product and how we secure this once we have a potential product we go through a very, very, thoughtful, deep portfolio with detailed, meticulous due diligence to make sure that we have the right product.

I think Howard defined our due diligence as ferocious, let me just say that s the right word. I think about many of our potential partners it s actually quite a tough experience, when they go through our due diligence because really we do a deep dive into the data, we want to understand the data we want to understand the product. At the end of our due diligence, we want to know the product as well as the licensor or even better than the licensor. And this is why we have been able so many times to get good product and you will hear more from David Solomon how business development, marketing, and R&D work together to get new products in our pipeline.

And after when we start product development what we do is to make sure we have well defined strategy on how we want to position the product. So we spend significant amount of time at the beginning defining the target for our profile, defining how the product will be on the market and after we tailor our development activities around the target for the profile, making sure that our development really will bring the type of product that we were looking for. And Elaine Hochberg later on will tell you more how we blend the commercial and R&D strategies to make sure that we have successful brand.

And finally, once the product is approved and out on the market. Well there is still a lot of work to do. It s not the end of the R&D work. It s quite contrary actually. I think there is this myth that R&D work and R&D activities really start to decrease and go away once the product is approved. It s not true. Actually, there is a tremendous amount of work that needs to be done after the product is on the market.

First of all, well we will have to do all our Phase IV commitment that we agreed with the Agency and with FDA, so that can be quite a substantial amount of work. Now what we tried to do is to take this first approval commitment and to make them useful, to make sure that they may result in additional claims and labeling potential. So we try to not only to satisfy the agency, but also to make them having a positive impact on the product.

Second, we conduct a lot of product profiling. Phase IV studies, because we want to investigate we want to investigate how to use the product on the market, and we look at new lifecycle opportunity, new indication, new claims. And actually you will hear more from Bill Meury about our profiling and lifecycle strategies.

So now let me go next to give you some hard facts and figures about my R&D organization. We have over 1,500 people working in R&D. This is represent about 20% of the total workforce of Forest. So showing the commitment of organization to R&D, out of this 1,500 about 250 have a high degree. So a highly educated workforce.

Our operating budget is about $850 million for the this fiscal year, which is what we really need to support the development of the 18 products that we would discuss today. Our 18 products are divided, four in Phase II, early development Phase I, Phase II, eight in Phase III and six in Phase IV.

Now we have more products in Phase III than for example what you may see in other companies, where they have more products in Phase II and after some of these will go in Phase III. We have more products in Phase III because given our business model you will expect actually that we have more phase products in Phase III because that is our sweet spot, products at the end of Phase II, Phase III or IV we are open to any kind of opportunity.

Let me also point out here pediatric trials. Very important, very, very critical. It is not only because we need to do pediatric trial to meet our regulatory obligation, to assess our products in children. We are doing also pediatric trials because they can give us additional exclusivity potential. So very important part of our business.

Out of these 18 products, we are managing 11 partnerships. And we do co-development with them. And we work together frequently on a global basis. I think one thing I want to point out is the some of these partners actually we re doing more than just one product, showing that we have a lot of return business. And I think David will stress this point also in his presentation.

Continuing, we ve additional facts and figures about our performance in fiscal year 2012. In 2012, we enrolled

22,000 patients in 2,100 sites in 21 different countries. Our organization has been a global organization for now quite a few years, and very successful in enrolling across the globe.

The last five years, we filed seven NDAs/sNDAs in nine different indications. We have six different FDA divisions. So very broad experience, I think there are just a couple of divisions, FDA divisions we have not yet interacted with, but we might soon.

We obtained six approvals, soon to be eight. We ve expected approvals of aclidinium and linaclotide. And actually, let me spend a minute, a couple of words about this point, because I think it s very important. We have been interacting with the agency with many different division of the agencies. And we have shown a remarkable ability to interact with FDA, regardless of the type of agency in a very constructive way.

I think here what has been very, very helpful, so that we have been able to develop a scientific partnership with FDA. We understand their mission. We understand their needs. I think we are able to convey also what is our mission. What is our needs, and so we can have a good discussion, and this is the key of a successful approvals that we had as you may know, with this actually quite a few of our filings have been approval of first cycle, have been approved the first cycle which has not, which is not that common.

So we have a track record now as a very effective R&D machine. And we have a track record of being very able, once we have developed a product to get it through FDA. And this reputation has been truly an asset for us when we look for new products, because it is really to make sure, but when a licensor give us a product, they really feel that they are giving the product to someone who is going to take care of it. As I say it is like for these companies like to give away their baby in foster care and they know we will be excellent foster parents.

Let me also give you a sense of other activities that we are doing. They are called support activities. But they are very critical both for development and for commercialization. We in 2012, we did 48 studies in toxicology, 40 studies in pharmacology, 43 studies in clinical pharmacology, 49 studies in health economics. This is actually quite a significant amount of work that has been done just in fiscal year 2012 to support our program.

And last, but not least, on the on this list. In 2012, we had over 700 publications regarding our product: Manuscript, journal manuscript, posters, abstracts, presentations because all of these increase the awareness of our products in the medical community. So very, very critical.

Now let me now move to the our pipeline. So we our 18 products are divided in six different therapeutic areas. Cardiovascular metabolic, CNS, Pain, GI, Respiratory and Anti-Infectives. Today, you can see here six therapeutic areas.

Next meeting, I can almost guarantee you, you will see probably more therapeutic areas or different therapeutic areas, because we are not afraid to move into a new therapeutic area, because we have expertise to do it. And we have shown that we can get into new areas, new therapeutic areas with ease and very efficiently.

In a minute, I will talk about cardiovascular. But I will have the other areas. Actually that will be described and presented by some of my collaborators. Because I wanted to make sure and I want to make you to give you the opportunity to meet and to know and to see in action the key members of my team, so we will have Dr. Gavin Corcoran, who will present CNS, Pain, and GI pipeline, Dr Harry Sacks will present the Respiratory area, and Dr. Paul Grint will present our Anti-Infectives pipeline.

So let me now move to the cardiovascular metabolic pipeline. When I will talk about it, you will probably notice that there are some themes, common themes that ran across all the therapeutic areas. First, is our focus in maximizing the value of each product by an aggressive product profiling strategies using you know Phase IV studies, lifecycle opportunity, new indication, new claims. So very, very aggressive, Phase IV profiling.

Second, what you will see is our vision of creating a therapeutic franchise by building strategic synergies across different products. What we plan or what we want to do in other word is to create sets of complementary interconnected products, so we can really get the most out of these products by having a synergistic approach both during the development and during the commercialization. And by having this set of product, we can really meet the multiple needs of patients within a therapeutic area, because within the therapeutic areas you have different needs for different patients, and you will see this is a common theme across all the therapeutic area.

Third, our continuous effort to expand the pipeline within and outside of the therapeutic areas.

So let start with our cardiovascular pipeline, because it s a good, good example of these three themes. For example, look at Bystolic. We have two major buckets. I call them buckets. Buckets of R&D activities, the Phase IV support and the Lifecycle. The first one is profiling include profiling Phase IV, so we can better define the role of Bystolic in the treatment of anti-hypertension.

Just to give an idea, since the approval of Bystolic, we completed 11 Phase IV studies. We are on more 3,700 patients in more than 600 sites clinical sites in the United States. All these work actually resulted in hundreds of publication of medical methods about the use of Bystolic. And actually Bill Meury will talk more about the impact of all these activities on the commercialization of Bystolic.

The second bucket on your right is a lifecycle. Now look how can we really exploit and fully take advantage of the profile of the drug. So for Bystolic, we are developing a new fixed dose combination as part of the lifecycle. We have taken Bysotlic that and well I may be biased, but I think our data support that Bystolic, which is the best beta-blocker. And we combine it with valsartan probably the best ARB. And we are providing so a very powerful combination treatment for hypertension. We are currently in Phase III for this program and we expect to file in fiscal year 2014.

But in cardiovascular, we also continue to expand our pipeline. With new products that can meet despite that can meet unmet needs. Azimilide is a product we licensed last year and this is a class III antiarrhythmic for patients with implantable defibrillator devices.

Now this is truly an unmet need because there is really no good treatment or treatment approved for this type of patient. But there is also another twist in the product that I would like to highlight. The fact that this is a hospital product. And so this is a product and this is some of the synergy that I was talking about. This is a product that actually will expand our growing portfolio of hospital products, so again bringing different solution to the patients and to the medical community.

We also licensed a couple of years ago from TransTech TTP399. This is a novel, new mechanism anti-diabetic drug that works by activating selectively the glucokinase in the liver. Now what I want to stress for about this track is again that just few years ago we were not at all in the diabetic area, now we have been very, very active in the last few years.

So again we are not afraid to move to a new area especially when we see a good opportunity because we don t want to be constrained to work just in a few therapeutic areas.

Let me now finish my introduction to R&D showing you our future. First of all, in the last three or four years, the R&D organization has been able to deliver in full our commitment. You re going to see here between fiscal year 2010 up to fiscal year 2013. We filed several NDAs as I mentioned before, most cases approved first cycle. And we have now on the market five new products.

Now I m not showing this to get some accolades, for what our past performance is. The reason I m showing you this is because I know you guys, you are data-driven, you want hard facts. I want this to be hard data that will give you the confidence that we will able to deliver that our we will be able to deliver the our products.

Of course just between us, I do believe that my R&D teams, that serves for commission for the exceptional performance over the last few years. But that you can see here all the new indication, all the new NDAs that we will deliver in the next year. Because we have done it in the past and we will do it in the future.

This is our plan. Look at these all these NDAs like stars popping up in the sky. We expect in the next four to five years to submit at least two NDAs a year let me state it again, at least two NDAs a year for the next four to five fiscal years. This is our commitment from the R&D organization here at Forest. We have achieved this in the past. We can achieve this in the future. And this will be achieved just with the current pipeline, with us camping the new opportunities that we will add to our pipeline in the near future like we did recently with nebivolol.

So I say it s a bright future that we have in front of us, and I think it s of course it s a lot of work from my R&D organization. But as you can see it s a you can see the trends here, it s a realistic plan. We can do it.

So, summary. I want to just make sure I summarize the key messages of my presentation. I make sure that when you go back and you prepare a report here, you will get really the key message with just not remember that this guy talking with a funny accent. I want you to see how we are planning to do it.

First of all, Forest R&D has a track record in product selection, product development, and lifecycle management. That s important because we have a track record and this means that we re ready to develop for the future. We have an effective global R&D organization led by experienced management team, as you will have an opportunity to appreciate in the next few presentations.

Our mission to R&D, very simple, support the present, while building the future. How do we support the present? We support the present with extensive lifecycle management, Phase IV programs, so we get the best out of our marketed products, because marketed product is our present. So support the present. How we build the future? By developing our product effectively and efficiently and by expanding our pipeline within and outside our current therapeutic areas.

So I believe that in the last few years, we have been true to our motto and mission of sustainable growth beyond 2012. This motto I believe has now become a reality.

So thank you for your attention. And what I would like now to do is to introduce our Executive Vice President, in charge of early development and clinical development, who will present the CNS, Pain and GI pipeline, Dr. Gavin Corcoran. Thank you very much.

Gavin Corcoran

Executive Vice President Research & Development, Early and Clinical Development, Forest Laboratories, Inc.

Good morning. Thank you very much for the introduction Marco. Today, I m going to cover three of the therapeutic areas that Marco just mentioned CNS, Pain and GI. In all three, we are developing a pipeline of significant medicines that we believe will enable physicians to make the best choices for their patients.

In the CNS area, we will look at the ongoing development plans for Viibryd as well as our drugs in development levomilnacipran and cariprazine. In pain, we will cover Savella and GRT-6005, the new drug that we have in development. And in GI, I will provide an overview of linaclotide that s currently under review with the FDA.

So let s get started with the CNS portfolio. Psychiatric disorders can be thought of as a spectrum ranging from those predominantly characterized by psychosis such as schizophrenia and mania to those characterized by mood disorders such as anxiety and depression with a great deal of overlap between the syndromes. As a practicing physician, which is less long ago than the lack of hair may suggest, I saw firsthand how psychiatric diseases significantly compromised quality of life. I d like to try to share that perspective with you today.

The best depiction that I ve ever seen of the delusions associated with schizophrenia can be found in the recent movie, A Beautiful Mind starring Russell Crowe. You saw that movie, you were given a view into the world of schizophrenia. The delusions that he had were depicted as real as the rest of his life. It wasn t until the middle of the movie that you start to uncover the differences between reality and delusion.

Now, imagine how frightening daily life is for the patients who really cannot tell the difference at all. For them, there s no clarifying moment in their lives, like there was in the movie. In the movie at some point you realize that in fact the things that you thought were real are not real. However, for patients, they live with that confusion and really cannot tell the difference between reality and delusion. However, they know that there should be a difference.

Similarly for patients with major depression, the feelings of extreme sadness and lack of motivation never go away, regardless of what s happening around them.

It may seem that these patients are well served with all the excellent medicines on the market to treat these diseases. However, a clear unmet medical need remain. For major depressive disorder or MDD, despite the large number of therapeutic options, only 60% to 70% of patients respond to treatments. And up to half of the patients treated with first line monotherapy do not achieve full remission of depressive symptoms.

Similarly in schizophrenia and bipolar disorder, on average patients have to change therapy at least once a year, and may have to take four to five drugs to adequately control their ongoing symptoms.

So we need to keep to look keep looking for new medicine. Like the diseases, the treatments for these conditions involve a spectrum. It s aimed at different targets in the brain known to be associated with the predominant symptoms of each of these diseases; from dopamine for schizophrenia, to serotonin and norepinephrine for depression.

So a wide range of treatment options is needed. Just as there are predominant clinical features of the syndromes at each part of the spectrum, the treatments for those are aimed at receptors in the brain from dopamine to serotonin to norepinephrine.

Forest has on the market or in development a product suitable to treat patients on most parts of the spectrum of the diseases noted here. Viibryd which is an SSRI with the addition of 5-HT1a activity, levomilnacipran which is an SNRI with more affinity for the norepinephrine pathway, and Cariprazine, which is a dopamine partial receptor agonist with the specific preference for the D3 receptor.

Each of these provide a mechanistic nuance for the treatment of these diseases. And together, our portfolio of products provides an important therapy for a wide spectrum of psychiatric disease.

So let s consider each one of these in a little more detail. Starting with the mood disorder part of the spectrum, we have Viibryd or vilazodone. As you know, this is an SSRI indicated for MDD which was launched onto the market last year.

In addition to the symptom relief provided by the SSRI, while not fully understood, the 5-HT1a partial agonisms may contribute to Viibryd s acceptable adverse event profile. Similarly to what Dr. Taglietti described for Bystolic, we have an ongoing development program beyond the studies needed to approve the approval of Viibryd to fully elucidate the utility of this drug.

This includes some studies that were agreed to with the FDA and some additional development programs that we started. So we have the low dose study to further investigate the possibility that some patients may benefit from a dose less than 40 milligram and perhaps even have a more favorable adverse event profile.

Relapse prevention study to examine the long term effect of Viibryd to prevent the relapse of depression once the symptoms are controlled. And the pediatric program to investigate the possible value of the drug for pediatric patients with depression.

In addition, we ve recently started the program to investigate the use of Viibryd for the treatment of another important mood disorder, generalized anxiety disorder or GAD in adults.

Staying with the mood disorders, some patients have more severe depression symptoms that require different kind of therapies such as an SNRI. Levomilnacipran is our new SNRI for the treatment of MDD and is partnered with Pierre Fabre. It is related to Milnacipran that is highly regarded as a treatment for depression outside of the United States. Levomilnacipran is the more active isomer of Milnacipran, has a greater affinity for the norepinephrine transporter which results in relief of symptoms of depression and has the potential for affecting patient functioning such as lack of energy, motivation and fatigue, which are common hallmarks of severe depression.

The registration data comes from three pivotal studies that examined 40 milligrams to 120 milligrams per day for eight weeks in adult patients with MDD. The primary efficacy measure was the change from baseline at week eight for the total MADRS score, which is a score that measures common symptoms of depression. The key additional measure amongst the ones that we did was the effect on the SDS or Sheehan Disability Scale which is a score that measures the effect on function. Statistical significance was demonstrated for the MADRS at week one and continued throughout the treatment period. The dose effect increasing from 40 milligrams to 120 milligrams was noted in the MD-01 study which was the study that included all three doses. The data from the other pivotal studies shows a consistent effect on MADRS at all doses.

For the SDS relative to placebo patients receiving the 80 milligram and a 120 milligram dose had a significant improvement at week eight. In addition for those who are receiving the 120 milligram dose, they had a significant improvement in all three disabilities I mentioned to the scale. This is remarkable, this effect on function measured by the SDS has not been demonstrated in depression and so it gives a great deal of potential for this drug.

From an adverse event standpoint, levomilnacipran has a relatively low incidence of nausea, dizziness, insomnia and diarrhea which are the common side effects for the SNRI class of drugs. Given the higher affinity for the norepinephrine transporter there was an expected slight increase in heart rate and blood pressure but the effect was not dose related and rarely led to discontinuation from the studies. In addition to the registration work, we have ongoing studies to continue to further explore the effects on patient function. We are confident that the effects on function will be as promising as the other effects for this product.

Moving further along the spectrum to the conditions characterized by psychosis and our drug Cariprazine. This is the first antipsychotic that s been developed at Forest and is being co-developed with our partner Gedeon Richter. Cariprazine is a D3-preferring D2/D3 partial agonist. Now I know that sounds like quite a mouthful, so let me explain. What that means is that Cariprazine binds to two specific kind of dopamine receptors D2 and D3 but has a greater affinity for D3. The difference between the receptors is where they re located in the brain and the resultant clinical effect.

There are other antipsychotics that bind to D2 with no others that bind to D3. The other important thing is that it s a partial agonist. What does that mean, that means it doesn t completely mimic the effect of dopamine when it binds to the receptor, which allows for greater flexibility with doses. The mechanism of action makes the drug suitable for treating a range of conditions including schizophrenia, mania in bipolar and other forms of severe depression.

Our initial development program has been focused on schizophrenia and acute mania, which will be the two indications for the first NDA that will be filed later this year. The ongoing program is focused on depression both adjunctive therapy for MDD and acute bipolar depression.

The program to develop data on schizophrenia and acute mania included three studies in both indications. All of which were positive. That s three studies in schizophrenia, three studies in mania and all of them were positive, which is truly a remarkable accomplishment for CNS drugs since as you know many Phase III studies fail for a variety of reasons. The important thing is that it speaks to the consistency of the effect that we ve seen for Cariprazine. The Phase III study for schizophrenia used to change in the PANSS score, the positive and negative schizophrenia score from baseline as the primary outcome measure, both the fixed and flex dose studies are shown here.

As you can see statistically significant improvement was noted at week one and appears to still be continuing at week six. And the comparative study with aripiprazole, the effects of the highest dose of Cariprazine are similar to Abilify but the ongoing improvement at week six does not hold true for the comparison. Similarly, in the studies for acute mania, the pivotal trials examined the effect on acute mania using a range of doses from 3 milligrams to 12 milligrams in adult patients for three-week duration. The primary endpoint of these studies was an improvement in the Young Mania Rating Scale at week three. All studies demonstrated a highly significant separation from placebo to all doses.

The most common adverse events were similar to other antipsychotics insomnia, headache and constipation. In addition, the data from the development program reflected Cariprazine has a low potential for clinically relevant weight gain, somnolence and extrapyramidal syndrome, which is essentially muscle stiffness and a true movement disorder. It led to very few changes in the metabolic parameters such as liver enzymes, blood glucose and lipids, prolactin and CPK, which are all very positive things for this drug.

Let s talk about akathisia. As you know, akathisia is really more restlessness rather than a true movement disorder. It is a manageable side effect that occurs with every antipsychotic. In our studies we noted the rate up to 14% in the schizophrenia studies and 20% in the mania study, most cases were considered mild to moderate by the investigators and led to discontinuation in less than 2% of the patients.

Discontinuation from a study is a key indicator of how bothersome an adverse effect is to the patients from the study. These data therefore seem to suggest that it would be bothersome only to a very small proportion of patients. Overall, the data suggests that Cariprazine will be an important addition to the armamentarium of treatment for psychotic disorders and will provide significant clinical benefit to patients.

In the pain area, currently we have Savella for the treatment of fibromyalgia on the market. It was approved utilizing a novel endpoint and demonstrating one of the points that Marco made about our scientific and regulatory creativity in order to get our products approved in support of our history of successful development of drugs in the pain areas.

Moving forward, we have in development GRT-6005 that we re partnering with Grünenthal, a world leader in discovery of successful drugs in pain. GRT-6005 is an opioid with effects on mu and OLR-1. Pre-clinical data suggests that the synergy between these two receptors may result in a more potent drug. The program to develop the drug to the treatment of chronic pain is currently in Phase II and the product has been investigated in patients with osteoarthritis, low back pain, and neuropathic pain.

Related to our focus on pain is linaclotide in our GI therapeutic area since one part of the mechanism is aimed at the release of abdominal pain. This drug is being developed for chronic constipation and irritable bowel syndrome with constipation. Both of these are very common conditions in United States with few therapeutic options. Some estimates are that 2% to 27% of the U.S. population experiences chronic constipation and 25% to 50% of all referrals to gastroenterologists are for irritable bowel syndrome. These conditions are more common in women than in men and they do increase with age. These socially debilitating conditions are characterized not only by bowel symptoms or disruption in the normal frequency of bowel movement, but very importantly also significant abdominal symptoms or abdominal pain such as discomfort, bloating, fullness and cramping.

Phased and effective long-term therapy is needed, one that s effective for both the bowel symptoms and the abdominal symptoms. Currently this can t be found in any of the other prescription or OTC medicines on the market. Linaclotide works by binding to the GCC receptor in the gut. This results in an increase in [ph] cyclic GOP (55:14) production that stimulates two important effects. It results in an increase fluid secretion into the gut lumen, which addresses the reduced bowel frequency symptom as well as an effect on the afferent nerves. Afferent nerves are those nerves that are responsible for giving us the sensation feeling the sensation of pain. So mechanistically, both kinds of symptoms associated with these conditions will be addressed by this drug, this is somewhat novel in this space.

The evidence for this can be found in our Phase III program that consists of two large studies in each disease state with a long-term follow-up study. The end points were focused on an effect on both bowel and abdominal symptoms. The data in over 3,000 patients showed a significant improvement in all primary and secondary endpoint. The most important disease being shown graphically on the screen and I ll show you some later on as well.

Here relief was noted to be started to be starting within a week of therapy and continuing throughout the treatment. To confirm that the effects were due to the drug, we conducted a randomized withdrawal study. Shown here that demonstrates that upon withdrawal of the drug the symptoms returned proving that the effects could be attributed only to the drug.

On the next slide, you ll see the effect on abdominal symptoms which is also very important starting at week one and continuing over the course of treatment where these in this particular trial for patients with IBS-C. Since linaclotide is absorbed to a negligible amount, the most common adverse effect was noted was diarrhea. It is usually characterized as mild to moderate and led to discontinuation in the low proportion of patients. These results demonstrate that linaclotide will be an important event in the therapy of chronic constipation and IBS-C and provide significant relief for patients suffering from these socially debilitating diseases. We expect linaclotide to be approved and launched later this year and we re excited for the potential relief that it can bring to patients.

So, in summary, in all three therapeutic areas, CNS, pain and GI we have a pipeline of significant medicines. Our approach to having more than one complementary medication in each therapeutic area has resulted in us being able to give physicians a number of therapeutic options for their patients. To help with that effort, we have scientific programs not only focused on getting the products approved in all the geographies that we have rights to but also to continue to generate new data about our products that will help physicians prescribe them appropriately. We continue to be committed to develop medicines to change the lives of patients with significant disease.

Thank you very much. And now fresh from a spat with the FDA and a winner at the PADAC recently, I d like to introduce our Executive Director of Clinical Respiratory Development, Dr. Harry Sacks, who clearly showed his prowess in knowing the respiratory field at the recent PADAC and he is going to share his thoughts with us. Harry.

Harry Sacks

Executive Director, Clinical Development, Respiratory, Forest Laboratories, Inc.

Well, good morning, and thank you for spending a few minutes with me to talk about our very exciting respiratory pipeline.

Our goal is to help people with respiratory conditions breathe easier and live better lives. It s really very simple. As you will see, we are passionate about helping patients with chronic obstructive pulmonary disease or COPD. Today, I m going to walk you through our COPD pipeline, moving from treatment of patients with milder disease all the way through those with severe progressive disease.

You re going to see what we are working on at Forest, treat the full spectrum of this disease. But we aren t stopping at COPD since respiratory medicine includes a broad range of diseases. Asthma for example affects roughly 5% of our U.S. population. When asthma attacks occur or when asthma attacks strike, patients can have a rapid decline from normal lung function to having severe narrowing of the airways. We are planning studies to investigate our existing medicines for the treatment of asthma.

Concurrently, we are seeking out new molecules as Dr. Taglietti described to add to our respiratory portfolio. As an example of our commitment beyond COPD, we have developed Colobreathe, an inhaled antibiotic, which is now marketed in Europe for the treatment of cystic fibrosis. We intend to be the leader in a development of drug for the treatment of respiratory diseases. We are committed developing medicines to treat the full spectrum

of COPD for patients earlier in the disease course to the most severely affected patients. This disease affects as many as 24 million patients in the U.S. Many of whom do not even know that they have the diagnosis because they haven t been tested. Some of you may know Danica Patrick, what does this talk have to do with Danica Patrick. Well, Danica Patrick works with the COPD Foundation and created the drive for COPD, which was a NASCAR race and NASCAR partner in this to have an innovative grass-roots effort to let people know about COPD and how important it is and what a major cause of morbidity and mortality it is in the United States.

It is the third leading cause of death in the United States, that s shocking. It is most commonly caused as you know by a history of prolonged smoking or exposure to lung irritants. It is a progressive disease and there is no cure. However, new treatments can help control symptoms and reduce flare-ups. COPD is also a complex disease with multiple concurrent medical conditions. Different stages require different treatments. Breathlessness is the hallmark of the disease and worsens with declining lung function as it progresses.

Now, imagine for a moment trying to walk up a flight of steps or even for one with severe disease, even walking from the sofa to the bathroom for instance, while trying to breathe through this little straw. Very difficult, have to work hard to breathe through this straw. Well, this is exactly what happens, this is exactly the way COPD patients described their disease. They have to breathe through a straw. Bronchodilators such as aclidinium bromide help to open the airways and relieve the symptoms of COPD, which include breathlessness, coughing, wheezing and mucous production. As the disease worsens multiple bronchodilators maybe needed. And Forest is developing a combination product, specifically for these patients. Now exacerbations or flare-ups are common even with current treatment especially as the disease progresses.

Now let me take my straw again, re-bend it and imagine breathing through this straw that is now 90% occluded. I m a little dizzy. As you can see that s not easy to do and that patients describe this as a horrific feeling, and horrific it is. Moreover frequent exacerbations lead to destruction of lung tissue and is most common in patients who have severe to very severe lung disease. And these are precisely the patients who can least afford to further lose lung functions. So, Daliresp is a once daily oral tablet indicated specifically to reduce exacerbations in patients with severe to very severe COPD. Aclidinium is a novel bronchodilator administered once daily in an easy-to-use inhalation device. Forest has partnered with a premier innovator in respiratory medicine Almirall, based in Barcelona, Spain to develop aclidinium and the aclidinium/formoterol combination product.

In our clinical studies, aclidinium provided reliable and sustained around the clock improvement in lung function as measured by the gold standard, which is improvement in forced expiratory volume or FEV1 in the first second. Aclidinium reaches maximal effect with the first dose of medicine and patients can feel that relief. In clinical studies, improvement in lung functions were also accompanied importantly by patient reported improvements in quality of life as well as reduction in symptoms of breathlessness, the primary complaint with COPD. Rapid metabolism of aclidinium results in low absorption into the blood and therefore has a low potential for interactions with other drugs. In the clinical program there were very few side effects reported and no serious safety signals were identified.

Finally, aclidinium is delivered in an easy-to-operate, patient-friendly device. Now this device looks pretty simple. However, it really is a high-tech, very high-tech delivery system in a simple design. And in fact it was strongly preferred by patients when compared to the device of the market leader. We sought out the best design delivery mechanism we could find. We know that ease of use and reliable delivery are critical to obtaining maximum benefits from the drug. So here s how the device works. Three easy steps, one, the patient removes the dust cap, two, the patient depresses the button, the actuator, and three, the patient inhales. Now I m fortunate because I can take a full breath. I m very fortunate that I can take a full breath. However, the device is also engineered that even patients with severe disease will be able to inhale enough to get a full dose of aclidinium which is a very important feature of any inhalation device. This device does that very, very well.

Now, I think it was Steve Jobs that said, design is not just what something looks and feels like, it s how something works. We chose the design that administers aclidinium in an outstanding device and delivers the full efficacy of the molecules. Only aclidinium provides reliable 24-hour efficacy, excellent tolerability and delivers the drug in this unique patient-friendly device. All of these attributes will make aclidinium an excellent first-line choice once it is approved by the FDA. Gavin was very kind in his comments about our advisory committee. And just to refresh your memory in February, we had a very successful FDA advisory committee meeting that resulted in a 12 to 2 vote recommending approval of aclidinium. It s a very strong vote. We are hoping for an FDA approval for aclidinium over this summer.

Let s take one step back and ask the question why do we even need a new treatment product, a new product to treat COPD. Well, at present the only long-acting antimuscarinic agent or LAMA that is available on the market is the tiotropium and tiotropium is a very good medicine. However, it does not meet the needs of every patient. Individual patients respond differently to each treatment both from an efficacy perspective as well as from side effects perspective. It s important for clinicians to have treatment options within the same class just as they do in almost every other class. In fact, it would be unimaginable today to have only one beta blocker to treat hypertension. Yet that is exactly the case with tiotropium. Right now, it is the only choice in the LAMA class.

Aclidinium will provide another first-line treatment option. Aclidinium stands up quite well to the competition with comparable efficacy and a very acceptable side effect profile and a great device. So I m going to show you an early Phase II study that we did using a crossover design to evaluate lung function using FEV1 over 24 hours, which was also compared to where we compared aclidinium to both placebo and tiotropium. Tiotropium is shown in the purplish line in the middle.

As you can see aclidinium and tiotropium provided very similar release for first 12 hours of the study. However, following the evening dose there is a boost in lung function with aclidinium that persists through the night. Now patients with COPD very commonly complain about worsening of symptoms early in the morning. Our preliminary data suggested aclidinium provides relief of those symptoms perhaps due to the extra boost in lung function that we see through the night. The very positive 24 hour profile that we saw in this study compares favorably with tiotropium and will provide another first-line treatment option to patients.

As Dr. Taglietti discussed, Forest is committed to both providing doctors and their patients with comprehensive information on the use of our product and product differentiation beyond the initial studies required for FDA approval. Several studies are planned to better inform physicians about the real world use of aclidinium.

One study directly compares aclidinium to a leading marketed product to confirm the relative efficacy. Now, based on the data that I showed you from the earlier studies, we are quite confident that aclidinium will compare very favorably to the market leader. Another study will determine if aclidinium can reduce the exacerbation rate at which patient s experience I m sorry can reduce the exacerbation rate for COPD patients treated with aclidinium and reduction of exacerbations is an important goal of COPD treatment.

Our preliminary data from the Phase III program suggest that aclidinium does reduce the rate of COPD exacerbations. Yet another study will evaluate whether aclidinium can improve patient s ability to participate in activities requiring exertions such as walking, climbing steps, showering and other conditions. Now bear in mind that they are trying to do these things while breathing through this straw.

Our previous exercise study, which was conducted with half the dose of aclidinium was highly positive and we are optimistic that the results from this study will confirm the benefits that we ve seen for the drug. We are currently in discussions with the FDA in preparing for a landmark post-marketing study to confirm the long-term safety of aclidinium as well as importantly to determine the effects of aclidinium on exacerbations.

Now, as COPD worsens, a single bronchodilator may not be enough to control the patient s symptoms. Clinical practice guidelines recommend adding another bronchodilator from a different class of drug. The problem is that now these fragile patients have to remember to properly use two different inhalers likely with different designs increasing the likelihood of errors in administration and missed doses. The medicine is not going to work if it doesn t get in.

Our fixed dose combination now well into Phase III, combines aclidinium with the well studied medicine formoterol, a beta 2 agonist in the same type of patient-friendly device used for the aclidinium product. The result is that for patients who need more symptom relief, the aclidinium and formoterol fixed dose combination will provide an important alternative than taking two separate inhalers.

Moreover, this combination will be an important alternative to starting patients on Advair or Symbicort. These are good drugs. However, they both contain steroids which generally according to practice guideline should be reserved for patients with more advanced disease who are experiencing COPD exacerbations. Our Phase II results supported advancing this very important treatment option, which has a potential to be the first LAMA/LABA combination on the market.

In Phase II, our fixed dose combination was superior to Placebo and provided greater benefit than either aclidinium or formoterol alone. Armed with this data, we have proceeded with a robust Phase III clinical program in which nearly 4,000 patients are currently enrolled. Needless to say, we are extremely excited about this medicine and we hope to file an NDA early in the calendar year 2014. Formoterol is a well known entity to the FDA both as a combination product and as a single-entity. Obviously, we hope to have aclidinium approved very shortly so that at the time we file this NDA we will have a highly-competitive device that contains two separately approved drugs.

Finally, we have worked diligently to prospectively address the dose response issues that have vexed several of our competitors. And we plan to be able to supply that information in the NDA submission for the combination product. We will also be conducting in our in the Forest fashion further studies that compare aclidinium and formoterol to other products, determine where aclidinium and formoterol can provide our patients with the greatest benefits. With further progression of lung damage patients are more likely to have flare-ups of the disease also known as exacerbations. Limiting the frequency of these events is a key component of proper COPD management because these events as I mentioned further damage the lung. Exacerbations are associated with accelerated deterioration of lung functions, recurrent hospitalization and unfortunately can be fatal.

Now pulmonologists or lung specialists are keenly aware of the importance of reducing COPD flare-ups. Primary care physicians on the other hand who treat many patients with COPD require further awareness on the importance of reducing exacerbation. So first we need to increase awareness and diagnosis and secondly we need to of COPD, and secondly we need to educate on the importance of controlling exacerbation. So Daliresp has been proven to reduce exacerbations in patients with severe lung disease and a history of exacerbations. When approved in February of 2011, Daliresp was the first and will likely be the only drug approved in this class for COPD. It is an orally easy-to-use orally administered, easy-to-use once daily phosphodiesterase-4 inhibitor or PDE4 inhibitor.

Now we don t know exactly the mechanism by which PDE4 reduces exacerbation. However, what we know is that PDE4 inhibition leads to an increase in cyclic AMP in the lung cells, which may affect multiple factors leading to COPD flare-ups. Daliresp is novel, it represents the first new drug class in a quarter of a century for the treatment

of COPD and there has been much enthusiasm among respiratory specialists because these specialists have extremely limited treatment options. Daliresp is not a bronchodilator, it is used in addition to bronchodilators to help reduce the frequency of exacerbations for patients with severe to very severe disease.

We are currently conducting a real world study that will inform practitioners of the benefits of Daliresp when added to existing standard of care treatment. As you know treatment patterns change over time and this 2,300 patient study will provide the most up-to-date information on the benefits of Daliresp on top of prevailing treatment.

Now this data will help to provide the best treatment for the most severe patients. As you can see, we have addressed the full spectrum of COPD activity with our pipeline of products and we are committed to developing treatments for other respiratory diseases. All of this puts us on the right trajectory to be the leader in drug development in this therapeutic area. With two approved products Daliresp and Colobreathe, one product awaiting FDA approval we hope very shortly and one product in late-stage development and much, much more in the planning phase, our respiratory pipeline meets or exceeds that of any of our competitors.

Thank you for your attention and now I have the pleasure of calling my colleague, the President of Cerexa, Dr. Paul Grint to the podium.

Paul C. Grint

President, Cerexa, Inc.

Thank you very much, Harry. So ladies and gentlemen, good morning. I m delighted to be here today to discuss our anti-effective portfolio. [Indiscernable] I m fortunate to work with what I consider a very exciting portfolio and also a talented development and commercial team both at Cerexa and Forest.

The impact and importance of antibiotics on human healthcare over the past five decades is well recognized. However, things are changing. We are entering the era where the crucial benefit of these drugs is seriously threatened due to antibiotic resistance. As more focus is placed on the cost of healthcare in the U.S., I actually personally find it very disturbing the data from a recent study conducted at Cook County Hospital in Chicago, when extrapolated nationally, would indicate that in fact antibiotic resistance infections accounts for approximately 8 million days of hospital stays at a cost of about $20 billion annually. Just think about that and the impact on healthcare costs.

Recent regulatory climate and economic climate is not being conducive for companies to invest research developments and commercialization of antibiotics. However, the good news is the situation is changing. Articles and stories of antibiotics resistance are now seen daily in the media. Individuals, societies, governments are becoming advocates of creating ways to support new antibiotic drug developments.

Currently, the GAIN legislation generates antibiotic incentives now is included in the PDUFA renewal, which we hope will be signed off and completed by the 4th of July. The Infectious Diseases Society of America or IDSA has been a strong advocate under the banner of Bad Bugs Need Drugs Bad Bugs Need Drugs. And they ve called for 10 new drugs by 2020. Interesting slide, this is actually a slide for a presentation made by the IDSA to the Senate working group last year and the IDSA has characterized Ceftaroline or Teflaro as the first of the new 10.

So over the course of my presentation my goal is to outline our portfolio and demonstrate how I believe we could possibly add an additional two drugs to three drugs to this list possibly for a total of four drugs, significant achievement for one company.

So this slide has details, the spectrum of activity of our portfolio. The bacteria causing significant infections are really at the extremes. On your left, the multi-resistant gram-positive organisms -MRSA there, and on your right the problematic resistant gram-negative infections, these are the bacteria that are becoming harder and harder to treat.

In 2008, these problematic bacteria or pathogens which actually currently cause majority of U.S. hospital infections were grouped under an acronym heading of ESKAPE, for example the S stands for staph, the P for pseudomonas and they are called this as effectively they escape most of the current approved drugs.

The Teflaro is a new generation cephalosporin with predominantly gram-positive activity covering the left hand side and importantly has activity against MRSA. So when you combine this with avibactam, a novel beta- lactamase inhibitor, the spectrum is extended to cover certain gram-negative pathogens. Ceftazidime widely used cephalosporin has activity mainly against gram-negative to the left side including Enterobacteriaceae and Pseudomonas. This activity is enhanced when you combine with avibactam.

We recently announced a new addition to our portfolio BC-3781, this is a drug developed by a company called Nabriva. This is a novel mechanism, novel mechanism antibiotics with both intravenous and oral forms. Predominantly as you can see it has gram-positive activity.

Let me tell you a bit more about Teflaro and what we are doing. Following the U.S. approval and launch of Teflaro we ve been designing and launching further clinical studies including those obviously that were agreed with the FDA as our post-approval commitment. We don t stop there. Additionally we re going to be conducting studies to investigate the broader utility of Teflaro in additional gram-positive infections.

Now partnering with infectious disease physicians who are very excited about the drug, we ve embarked on a very significant program in children. Initially we re studying Teflaro pharmacokinetics. We need to know and understand how to identify appropriate dosing recommendations in young children down to and including newborn babies. We started a comparative clinical program as indicated here studying skin infections, pneumonia, including children at risk of MRSA pneumonia. This program is one of the largest comparative pediatric programs undertaken and our protocols right now would indicate that we ll recruit at least 500 children to actually investigate these indications. But again we don t stop there. We continue to assess if additional infections benefit and in fact how those studies in children will be designed.

Aware Assessing worldwide antimicrobial resistance, Aware is a global, in vitro surveillance program which we conducted with our partner AstraZeneca. We initiated this program in 2008 and we continued to expand number of hospital, clinical, microbiology partners participating. As you can see 70 centers last year, our intention is to increase this to 200 centers this year. This program not only meets regulatory requirements to track potential antibiotic resistance development which we have to do as part of post-approval commitment, but also very importantly provides key information at both the national and local level and those institutions who participated in the Aware program have this information provided back to them.

This information here shows there is no trend of susceptible reduced susceptibility to Teflaro in the key pathogens over the four years that we ve had the surveillance program running. We will continue to run this program for a number of years out.

So let me spend a moment talking about beta-lactam antibiotics. So the beta-lactams are a broad class of drugs that contain a beta-lactam ring in their molecular structure. They work by inhibiting cell wall biosynthesis of the bacteria. Beta-lactam group includes the things you would have heard of commonly, penicillin derivatives, the cephalosporin including Teflaro and ceftazidime, monobactams and the carbapenems. So these antibiotics have been critical drugs used in the treatment of infections and in fact up till 2003 when measured by sales they accounted for more than half of the commercially available antibiotics. That s the beta-lactam.

Now, key resistance mechanism employed by bacteria is the production of an enzyme, beta-lactamase enzyme, which breaks down the beta-lactam ring in the antibiotic and renders it inactive. This resistance mechanism is increasing worldwide. Beta lactamase, it also includes a group you might have heard of, the extended spectrum beta lactamases or ESBLs, which inactivate drugs such as [indiscernible] (01:29:30), ceftriaxone, and ceftazidime, commonly used antibiotics. Additionally, Klebsiella pneumoniae carbapenemase or KPC, currently the most common carbapenemase, first identified less than 10 years ago, so in 1996, this is now spread worldwide.

So we are very excited to introduce to you avibactam. Avibactam is a novel, non beta-lactam, beta lactamase inhibitor, quite a mouthful, itself as a molecule does not possess intrinsic antibacterial activity, however, very importantly, it does inhibit a broad range of clinically important beta-lactamases. Interestingly not associated with resistance induction unlike some of the older beta-lactamase inhibitors. Avibactam is a drug that s administered intravenously and the pharmacokinetic profile is actually compatible for combination with both ceftazidime and ceftaroline and I ll show you in a moment where we are in those development programs. I described this as a non beta-lactam beta-lactamase inhibitor, because avibactam structure does not contain the beta-lactam ring. Why is that important? This is important because this molecule therefore offers the potential to be used in patients who are classified as penicillin allergic, and that is not an insignificant number of patients.

So currently, we re conducting two programs, two combination programs with avibactam. First of these, the ceftazidime/avibactam combination together with AstraZeneca, we ve initiated the pivotal Phase III studies to treat serious gram-negative infections. So this program encompasses few types of infections shown here on the slide, complicated intra-abdominal infections and complicated urinary tract infections. We re evaluating two comparative protocol for each of those diseases and therefore the four studies that result from these will actually form the core of the NDA filing for the ceftazidime/avibactam combination, which we plan to file in fiscal 2015 as Marco Taglietti has outlined previously as part of our submission plan.

The Phase II program for the ceftaroline/avibactam combination is just completing now. Phase III planning has commenced. We re designing studies that will examine the expanded spectrum of ceftaroline conferred by adding avibactam to ceftaroline. We intend to start the Phase III program for this combination next calendar year.

Now on June the 1, not very long ago, just under three weeks ago, we announced an option deal with Nabriva, a biotech company based in Vienna, Austria. BC-3781 belongs to novel class of antibiotics, the pleuromutilins. So we re very excited to actually to be able to work on novel class of antibiotics. And this is the first systemically administrated drug in this class. So we are excited to partner with Nabriva as this molecule actually has activity against a wide range of gram-positive organisms and certain gram-negative pathogens.

Importantly, no cross resistance has been demonstrated to existing resistance mechanisms. And studies conducted so far show in fact that this drug itself has a low propensity for reducing resistance. Phase II programs with an intravenous formulation has been completed, and we re moving forward to develop both intravenous and oral formulations with this drug, and we re expecting to start the Phase III program next year.

Now, BC-3781 complements our existing antibiotic franchise, as the intravenous and oral dosage forms will provide the opportunity to treat patients both in the hospital and when they re discharged with the same antibiotic, in the similar fashion to how linezolid or Zyvox is actually currently used.

So, bad bugs need drugs. And I believe that our significant antibiotic portfolio offers the potential to treat a broad range of pathogens. As an esteemed colleague of mine at Cerexa says, bad bugs don t mutate. We

anticipate the regulatory climate will be supportive of the urgent medical need for new antibiotics due to widespread and growing resistance. And I personally believe that our portfolio, as I previously indicated, offers us the opportunity to add two to three more drugs to the IDSA 10/20 list.

And I ll just end by saying, if I look out at the audience, we have a young healthy audience here and you may be sitting thinking well, this is all very academic, now how important is this? So let me just put it in perspective for you. Just over three weeks ago, I got a call and have to had an interest this is a true story. The interesting discussion with an emergency room physician that my 21-year-old healthy daughter is in the emergency room, having just been diagnosed with community-acquired pneumonia. Though it certainly brought it home for me, but this is an everyday reality we face.

So thank you very much for your attention. Frank, I ll turn back to you.

Francis I. Perier

Chief Financial Officer & VP-Administration, Forest Laboratories, Inc.

Paul, I want to thank you for that very thorough review of the anti-infective portfolio, and if you think about it, we were a company that just a few years ago had no real experience in hospital-based infection and anti-infectives, and today we have a portfolio that basically covers the waterfront of hospital-based infections with one serious product on the market today and many more in development. I also want to thank the other speakers who kind of walked us through this morning the variety of products that we have under development in our very important research pipeline, Dr. Gavin Corcoran, Dr. Harry Sacks and Dr. Marco Taglietti, I would like to give you all a hand for that excellent review of our products.

At this point in time, we re going take a 15-minute break. We ll be back in 15 minutes and take up with the second piece of the presentation in which we will talk more about the commercial side and the business development side of the business. Thank you very much.

[Break] (1:35:59 1:36:03)

Operator: Ladies and gentlemen, please welcome back Frank Perier.

Francis I. Perier

Chief Financial Officer & VP-Administration, Forest Laboratories, Inc.

Okay everyone, if you could please kindly take your seats, we really want to try and stay as close to on schedule as we can.

Fortunately having three kids, I m getting good at herding cats. If you could all please get back to your seats.

We completed basically kind of the scientific overview of the company s portfolio of products. The next phase of the program will look more towards the business development, international strategy side as well as the commercial and sales side, how are we going to commercialize all these products. But to get it started in the second-half of the presentation, I really it will be great pleasure to introduce my very good friend and colleague, David Solomon, who is our Senior Vice President of Business Development, Strategic Planning and responsible for the international operations. And I have to acknowledge for benefit of everyone here today that as you look at the next nine and everything that s in our development portfolio, over David s career here at Forest, his fingerprints are all over every one of those products.

So with that as a backdrop, I d like to welcome David Solomon to the stage, please.

David F. Solomon

SVP-Corporate Development & Strategic Planning, Forest Laboratories, Inc.

Thank you, Frank, and good morning to everyone. I was thinking watching Harry that sometimes getting a transaction done is like breathing through a straw, so the bent straw, that s right. So Forest s objective is to build long-term growth in both our top line and our bottom line. And to achieve this growth, we plan to continue to pursue our fundamental business strategy. This starts with a licensing or acquisition of new product opportunities. All of the next nine are products that were originated by other companies and that we have brought in over the past eight years. We have not invested in basic discovery work and we continue to believe that is the right approach.

Why spend the huge resources required to fund the discovery engine when we can fill our pipeline by licensing or acquiring products that are lower risk and closer to market? And rest assured that we continue to see a plentiful array of compelling product opportunities available for us to partner or to purchase.

Following the license or acquisition, most of our products require further development. And so we need to manage rigorous scientific development programs, typically undertaking large scale clinical work. As my R&D colleagues have highlighted, we ve had success in one program after another across a broad range of therapeutic areas and across various divisions of the FDA. In fact, to repeat Marco s statistics, within the past five years, we have achieved six product approvals from six distinct divisions of the FDA.

Forest of course is well known for our success in commercializing our products. We ve seen multiple blockbusters with Celexa, Lexapro, Benicar, and Namenda, and we have the marketing capability and sales force muscle to achieve this success with our new products as well. After my remarks, Elaine and Bill will talk more about our plans to commercialize the next nine.

Lastly, we recognized the importance of vigorously protecting our intellectual property. We successfully defended our Lexapro patent from generic challenge and we did the same for our Namenda patent. We know the generic companies will challenge every product as soon as they can, and so we must erect the strongest possible patent wall and then defend it effectively. Preserving our branded exclusivity for as long as possible must continue to be a fundamental part of our business strategy.

Though we remain committed to our current strategy, we continue to look for ways to enhance and build upon that strategy as well to enable us to drive further growth in the future. First, we have invested extensively in lifecycle programs. It is our practice to develop a strategic lifecycle plan for each product long before that product is approved. We will consider novel indications, new formulations, successor or next generation compounds and fixed dose combination products as well. We re always particularly interested in lifecycle programs that address an untapped medical need and which allow for new intellectual property.

A few recent examples of our lifecycle approach are combining Bystolic with valsartan to create a unique beta-blocker ARB fixed-dose combination, combine aclidinium with formoterol with a possibility to be the first dual mechanism bronchodilator on the market, enhancing the activity of Teflaro against resistant pathogen by adding avibactam to it, and improving the dosing schedule for Namenda with the XR product, which we will be launching in calendar 2013.

While Forest will continue to take full advantage of our knowledge and expertise and reputation in our established therapeutic areas, an important way for us to extend our business is to also consider new therapeutic areas. We ve always approached our licensing in a highly-opportunistic way, and a good example of this is the acquisition of Cerexa.

Before that acquisition in 2008, we were not developing anti-infectives, but we saw in ceftaroline a novel product addressing a significant unmet need with a growing concern about resistant pathogens. Another example is the linaclotide transaction, which took us into the GI space where we did not previously have a commercial presence. What we saw was a compelling product addressing a significant unmet need in a very large market, and so we made the decision to move into this area. And today, we continue to look at new areas including oncology for example and we will be willing to move into new areas and also out of areas as opportunities arise.

We are also willing to look at products that are earlier in developments than those we have typically considered in the past. While we continue to believe that we should not invest in the discovery engine, that such an investment is not cost effective, we are willing to look at compounds prior to proof of concept provided that the mechanism is compelling, the market opportunity is substantial and we have sufficient animal data or clinical support from other programs to believe the investment is worthwhile.

Two recent examples of this approach are the GK1 program with TransTech, which if it s successful could represent a very significant opportunity in the enormous diabetes category and GRT 6005 with Grünenthal, which could provide an important new option in the treatment of chronic severe pain.

In both cases, we acquired these compounds with limited human clinical data and we will perform very robust Phase II programs to ensure that the compounds perform as hoped prior to investing in Phase III. We re interested in larger molecules or those that may be more difficult to manufacture including biologics, peptides like linaclotide and antibiotics like Teflaro, avibactam and our new Nabriva BC-3781. The benefit of these products of course is that there are certain diseases that cannot be addressed successfully with conventional oral small molecules. And additionally, biologics have the benefit of extended regulatory exclusivity and the fact that there are limited number of manufacturers who can make these kinds of molecules means that there should be fewer generics, and that we should expect to retain some part of our sales even post patent expiration. A similar extended life is available for inhaled product like aclidinium, as generic competitors cannot easily demonstrate equivalence and face significant hurdle to duplicate our unique proprietary device.

We also continue to look at adjacent business opportunities, which take advantage of what Forest does so well. We are highly skilled at developing products, performing clinical studies and working with regulatory agencies. Additionally, we are capable of engaging with doctors about our product and highlighting their unique features. Such capabilities allow us to consider various kinds of related business opportunities, and in the past few years, we have looked at orphan drug products, biologics, diagnostics, therapeutic vaccines, nutraceuticals, hospital critical care products and others. While we have not and will not jump recklessly into such areas, we are prepared to move decisively when we find a compelling opportunity.

Lastly, we are very interested in expanding our business into international markets, and I will talk more about this in a few minutes, but first I would like to share how we approach our business development activity. As I mentioned before, a large part of our approach is opportunistic. However, most of our opportunistic activity is actually engineered. We have a team of highly talented business development professionals who scour the world, attending partnering meetings, building contacts with other companies, studying the medical literature, attending medical meetings.

Additionally, there are opportunities that are coming to us on an unsolicited basis, and we see many opportunities from Wall Street, we meet with investment banks on a regular basis to hear their ideas and we arrange periodic discussions with all the venture capital firms, many of whom have very interesting companies within their portfolios. We also hear regularly from companies who are looking for partners, because they need someone to complete development and to commercialize their products.

Then on the targeted side, we have indentified certain companies we believe are doing interesting novel research work and we have established and built relationships with those companies so that we can be sure to be at the top of their partnering list. We have an interest in continuing to build within the therapeutic franchises we ve established, but we specifically target additional products that will complete the current product lines. We have also identified certain mechanisms that we believe will address significant unmet needs and we have investigated the programs in those areas and pursued them for Forest.

This next slide shows you the scope of activity for our business development group. In a typical year, we review

350 to 450 opportunities. These are all opportunities that we have discussed with the innovator companies and performed at least a preliminary review to assess our level of interest. Of these, about a third, a 100 to 150 are brought in-house for a more serious review. Our internal review will typically include a full technical assessment, looking at the existing clinical data, reviewing the regulatory path, determining what clinical or nonclinical hurdles exist prior to approval.

We also do a full commercial review, studying the market to understand the unmet need and how the opportunity compares to other available products. This typically involves extensive market research both with doctors and payers as pricing and managed care coverage can be critical to understanding potential value. The third leg of the stool is intellectual property and we study the patent estate carefully to make sure we understand what kind of exclusivity we should expect.

We assume that generics will always be as aggressive as possible in challenging our patents, and we want to enter a transaction understanding the risk profile in this area as well. Of all the products we review, about 15 to 25 are taken through a full due diligence process. Now, when Forest does due diligence, we take it extremely seriously.

I have often been told that the diligence we performed was more thorough and insightful than the diligence of the large pharma companies we were competing against and we have surely avoided some very costly mistakes due to the strength of our diligence program.

Out of all of these opportunities, we make just a handful of transactions each year, and given our size if we select the right deals, this is all we need to drive our continued growth. Now, Forest has continued to have tremendous success with our partnership oriented business model. During the last eight years, we have completed 25 product partnerships and acquisitions, which is a great track record for a company our size and which has accounted for the next nine as well as all the other products in our pipeline, and we ve had only a handful of terminations along the way. People often ask me how Forest has been so successful with partnering, and we have seen that Forest continues to be a partner of choice for many companies.

Even in the face of aggressive competition often from the large pharma companies, we are able to close almost all the transactions we pursue seriously. It is in fact very rare that we lose an opportunity that we seriously want. And here is why, first, Forest has earned an excellent reputation as a partner and for treating our partners fairly and with respect. We all know that many issues arise during the course of a long collaboration, many of which were not addressed by the underlying contractual documents and the test of a partner is whether we handle those issues properly, which we always try to do.

Additionally, we consider our size to be in advantage. We are large enough to compete with the largest pharma companies as we have in major therapeutic categories like depression and hypertension and respiratory, but we are also small enough that we maintain a focus on the products we partner. We have 20 to 30 products in development, not the hundreds and hundreds that the large phamas do, which ensures our partners that their products will get the attention they deserve.

Next, our history of success developing and launching our in-licensed product means a great deal to our partners. A company looking for a partner to trust with its crown jewel wants to be sure that they are working with a company who will maximize its value and we have done that over and over again. In fact, Forest has one of the highest success rates in the industry for converting licenses and acquisitions into marketed products.

The engagement of our senior management with our partners is very important, and it further differentiates Forest from our competitors. The senior team you re hearing from today are all actively involved in managing our collaborations and that matters to our partners, because they know they can call us directly and have us involved when they need to.

Our quick decision making and flexible approach to deal making are also critical in some situations. We are not wedded to any particular partnership model or structure, and we are willing to work hard to accommodate our partner s objectives. A good example is the Ironwood partnership for linaclotide. Believe me, there were many large companies interested in linaclotide, but Ironwood had a very strong idea about the kind of company they wanted to become, and they were looking for an unusual partnership model with equal investment and equal decision making across the collaboration, and Forest stepped up and agreed that we would support them in the desire to become a fully integrated company, which is why they chose Forest.

Even in the case of pure acquisitions where the partnership aspect of collaboration may be less important, our quick decision making and creative deal making have enabled us to triumph in highly competitive situations. With both Cerexa and Clinical Data acquisitions, there were other bidders interested in those companies, but we were decisive and beat the other companies to the finish line.

On the Friday before President s Day weekend last year, R. J. Kirk who was the lead investor in Clinical Data told us that he would make the deal with Forest at the price we had offered which was in fact below that day s market price provided we could sign and announce by Tuesday morning and we did. Also as many of the acquisition deals done today include contingent value rights as all of our recent acquisitions have, the sellers do care very much about the ability of the buyer to achieve the objectives and Forest is highly regarded here.

Lastly, Forest does not have a not-invented-here bias, because none of the compounds we are developing were invented here. I believe the hallmark of our success is that we have had numerous repeat partnerships. There is no better indicator than the that the first collaboration has gone well than when the partner agrees to give us additional program. Lundbeck, Merz, Pierre Fabre, Almirall, Gedeon Richter to name a few of our major partners have all partnered with us on second and even third programs.

We are often asked if there is any concern about our ability to continue with the partner-oriented strategy, and the answer is that we continue to see a tremendous volume of novel and interesting product opportunities. We see interesting products from all over, from biotech companies, companies in Europe, in Asia, in Eastern Europe, even from large pharmas who are looking to divest. There are still enormous unmet needs in the treatment of disease and science continues to progress in fascinating and remarkable ways so that we expect to see more than enough opportunities to maintain growth for Forest.

Now, I d like to spend a few minutes on our expansion beyond the United States. There is no question that the U.S. is and will continue to be for the foreseeable future the largest and most lucrative pharmaceutical market in the world. However, we believe we can gain additional growth by expanding strategically into the rest of the world. Historically, we ve been able to support the investment required to acquire and develop our products with the sales of those products within the United States, but the cost of both acquiring these products and developing these products has increased.

As mentioned before, the licensing and acquisition markets have grown more competitive and the FDA and EMA are looking for larger programs with more patients and larger safety databases. Also from an intellectual property perspective, there is value in diversification. Therefore, for Forest, there is real strategic value in expanding our footprint beyond the United States and we ve been doing that slowly, expanding in the last several years from operations in three countries to 10 countries and we intend to continue to expand in a careful and judicious manner where opportunities exist.

We now have a fully established subsidiary in Canada, we ve expanded within Europe and we ve have been looking closely at the high value emerging markets with a particular interest in Brazil and Latin America.

Now taking a closer look at Canada, we re fortunate to have the rights to most of the next nine products in Canada and we will use this product line to support our business there. This past year, we formally established our Canadian subsidiary and the NDS for Bystolic was filed with the launch projected for early calendar 2013. We are also moving ahead to file NDSs for Viibryd and linaclotide in Canada later this year and we expect to file NDSs levomilnacipran and cariprazine next year. With all these products available to us over the next year several years, we will be building a full primary care field force in Canada to launch and promote these products.

Our business in Europe can be divided in to two parts. The first part is our OTC business, which currently provide about $80 million a year in sales driven mostly by a diaper rash cream called Sudacrem, and an infant colic product called Infacol. We sell these products directly in the U.K. and Ireland and export them over 35 countries around the world. This is a highly profitable legacy business for Forest and it continues to grow each year.

Our other business which is where we re looking to grow in Europe is our pharma business, which is currently providing about $50 million in sales. This business is driven mostly by Colistin, which is a nebulized antibiotic used by cystic fibrosis patients to prevent respiratory infections that they are prone to. We have sold this product in the U.K. and Ireland for many years, and then about 18 months ago, we had an opportunity to expand. Grünenthal was then commercializing the same Colistin product in several Central European countries and we were able to acquire that business from Grunenthal.

We then used that business to support the establishment of Forest affiliates in Germany, Austria, Netherlands, Belgium and Switzerland, all of which are now selling our Colistin product. We have also just obtained EMA approval earlier this year for our next generation product, Colobreathe. Colobreathe contains the same antibiotic as Colistin within a dry powder inhaler device. This is a much more convenient device than a nebulizer as a nebulizer typically requires as much as 20 minutes to inhale the medications while our Colobreathe DPI can be used with just a quick puff.

Colobreathe was internally developed at Forest, and so we hold relevant patents and have global rights and we will be using this product to support the establishment of additional affiliates in the other major European markets as well as Scandinavia and high value markets in Eastern Europe. We will be launching Colobreathe this year in five countries and we plan a further roll out across Europe next year.

Now given the reimbursement environment in Europe, we do not anticipate building a primary care presence there in the near-term. Our plan is to focus instead on additional specialty oriented products which can achieve favorable branded level pricing and reimbursement.

I d like to emphasize that Forest will expand internationally with the same kind of strategic emphasis that we ve brought to growing our business so successfully here in the United States. We will build the required infrastructure only as we have the portfolio of product rights to support that infrastructure. We are not interested in being bigger for the sake of being bigger, and we will expand only when we can do so in a way that we are confident will generate long-term, sustainable, profitable growth.

Also, we recognized each market is unique in a number of important ways, including medical practice, pricing and reimbursement, responsiveness to various promotional approaches and customer attitude towards branded medicine. We will therefore build our international affiliates with a sensitivity to the kind of business approach and operational structure that will be most successful and effective within each region. However, wherever we look to build our business around the world, the key to growth will always be obtaining novel innovative products that address important medical needs.

Therefore, a key focus in our business development strategy today is to execute transactions where we can license or acquire global or even regional rights to products so that we can continue to build our pipeline to exploit in these markets.

We have established a European-based business development group, and we will continue to expand our business development capabilities on a global basis. And with the continued growth of our international footprint, Forest now stands as a credible global partner which, in fact, makes it easier for us to obtain this kind of global deals. For example, we already today have international rights for several products including ceftaroline and the ceftaroline/avibactam combination, both of which AstraZeneca will be commercializing for us in other markets, as well as vilazodone, azimilide and TransTech s GKl program.

Finally, while the sales in the rest of the world today represent a small part of our total revenue, we do believe that within the next several years, these international markets will represent a meaningful contributor to our U.S. business, helping to drive both top line and bottom line growth for Forest.

As I commented earlier, Forest s strategy is designed to build long-term growth in years ahead. To achieve this, we ll continue to focus on licensing and acquiring interesting products. We will, of course, work to build on our therapeutic franchises, which my R&D colleagues described in some detail, CNS, cardiovascular, respiratory, pain, GI, and anti-infectives while we will also look at new therapeutic areas, new classes of compounds and other novel business opportunities.

And as I described, we will continue to build our presence internationally. Forest s fundamental business model is still effective and it still works. Without spending a dime on discovery, we have built one of the best pipelines in the industry. I cannot think of another company with a series of product launches to rival our next nine, and I assure you that there are many more opportunities out there, fascinating scientific innovations that we see every day, which will enable us to build the next next nine. That s why so many other companies have tried to imitate our approach, but none do it as well as we do, which is why we continue to be a partner of choice and why we continue to close almost all the deals we want. In sum, Forest has right strategy for today and for the future. Thank you very much.

And now I would like to welcome Forest Lab s Executive Vice President of Sales and Marketing our Chief Commercial Officer, Elaine Hochberg.

Elaine Hochberg

Chief Commercial Officer & Executive VP, Forest Laboratories, Inc.

Thank you, Dave. Good morning, everyone. It is my pleasure to speak with you today. 15 years ago this month, I joined Forest Labs, and since that time Forest truly has transformed itself from a $300 million company to a multi-billion dollar company it is today. 14 product launches, almost one a year representing 17 indications, they have been the building blocks of the rich commercial history that you have and continue to observe.

Now, our products, they span several categories and more than a few such as Celexa, Lexapro, Namenda, Benicar and even the first of the next nine, Bystolic, they ve become significant products in their own right. Now much of this was achieved in what I affectionately describe as the Forest way. And what is that? Its right size, right size to fit the opportunity. We don t invest a penny in SG&A unless we are assured of a good return. As an example, in my area, the sales grew 15 times in that 15 years, head count in the marketing and the sales organization grew a mere five times off of a very small base.

We spend a great deal of time, a great deal of effort understanding what it will take to support a product. We invest judiciously in order to have impact. We strive to be efficient in our competitive effort because we really have seen and I m sure you have too the aftermath of overblown efforts. So, attention to right sizing, right sizing our commercial efforts is what we believe is our strength. That is an important skill and is especially an important skill for a pharmaceutical company of our size.

Before I go into depth about Forest s commercial perspective, I d like to describe my commercial structure. I work with a really talented group who is in part responsible for the success that we have and continue to have in the market place. All six of my functional direct reports are long tenured, very experienced in their respective areas. Two of the six areas are commercial or marketing functions and four are related to sales.

William Meury who will speak in a few minutes heads our commercial and U.S. marketing functions. His area as you can see right here on the chart includes product management and our global efforts, whether it would be from market research to assessment that assists our business development efforts and ultimately the development of global commercialization platform. The second commercial functional areas support our alternative media efforts. Working with the Internet and with digital media is becoming more of a standard in absolutely every industry, and this is the group that helps us stay current of those changes. It s also the group that handles all of our production and promotional approval processes.

Our sales effort, they are divided into four groups; office based sales, institutional sales, managed care sales and trade sales. Office space sales is our biggest sales function, comprises four primary care field forces, two specialty field forces and a contract sales organization. Our field force training department and our sales and administration group, that lovely little group that helps us to assess how we need to right size our field efforts that sits in this overall group as well and its serve the needs of all of our field force.

Our institutional field force covers both hospitals and long-term care accounts, and it works closely with the office based organization to manage our recently hired CSO Forest Pharmacare (2:11:09). Our third sales area covers managed care and commercial, Medicare Part D, long term care, nursing homes and other government accounts, and it also oversees our contracting and reimbursement calculations as well as government affairs activities. And finally, we have a trade sales team that ably calls on U.S. wholesalers and retail chain accounts that stock our products.

Okay, Forest has a reputation for a disciplined and a highly successful sales effort. Many of our partners have sought us out specifically for this very capability. For quite a number of years and through various combinations of products, we have often been recognized as a leading company in sales force. Our 3,500 plus sales personnel reach approximately a quarter of a million, 250,000 physicians across a variety of specialties, almost 3,000 hospitals and clinics and more than 500 long-term care establishments.

In terms of productivity and the quality of the sales calls that we make, we do very well, even given our relatively small size compared to many in the industry. We act by doing more with what we have. We pride ourselves on these statistics, and we believe the success of our portfolio and our reputation in the marketplace are largely built due to the caliber of the effort that these statistics signify. Now it s often posited that success with an access to primary care practitioners in the USA today is harder and harder to achieve. Though I will grant that primary care is different, it is different today than it was 20 10 15, even 5 years ago, I would also say that it is very much alive as long as you know how to access it and that is something that we strive to do.

In fact, we have for each of the last four years been able to reach more than 80% of our target audience and this is no simple feat. We manage it, we manage it carefully. Also note that along with brand reach, we see our audience quite frequently, at least two and half times a month and up to almost 2.8 times a month in 2011. Now, this is important to emphasize. You really need to understand that we were able to increase both reach and frequency to our target audience to record levels in 2011, and this is a direct outgrowth of our constant focus on honing the capability and highlights truly the relevance that our growing portfolio has to our target audience.

Over the last five years, this level of activity has positioned Forest even more highly within primary care whereas so many companies decreased their effort. What s the essence of this? Its essence is that without over sizing even with a product line that has doubled and hopes to triple, we are in a very competitive position going forward and that should help our expanding pipeline.

As far as the description of our sales force efforts, I d like to describe our commercial philosophy. Our philosophy is pretty straightforward. It could be summed up in just six simple points. First, as I ve already mentioned, we firmly believe that opportunity still lies within primary care. So we are watch this primarily primary care centric. Primary care is the gatekeeper function in U.S. healthcare. It is where the volume lies and where the volume will remain as government and healthcare initiatives move live to primary care first in pursuit of appropriate and affordable care.

However, along with primary care comes a host of specialties with each therapeutic category that we re in. For example, we cover, in addition to primary care physicians, psychiatrists, pulmonologists, neurologists, cardiologists, pain specialists and others. In some ways primary care centric keeps us the most flexible and enables us to add specialty products and specialists fairly readily due to our geographics and our therapeutic diversity. As a consequence of being primary care centric, we are as you well know therapeutically agnostic broad based primary health care.

It s got many needs. So we need oh- we actually see the value and staying opportunistic to service. But a pharma company could only serve these needs if it assiduously generates differentiated products. Interestingly, our experience instructs differentiation; it can still be fast even in primary care as long as you accept that it comes in different sizes.

We hunt for that differentiation in our business development effort. We strive to elucidate that differentiation in our intelligent R&D development and rich Phase IV programs. And ultimately we work very, very hard to communicate that differentiation along with the safety and the other product elements that physicians need to know in order to correctly prescribe our products to the right patients.

We remain focused primarily on physicians and health care practitioners, because we believe the right and actually the best way to communicate the intricacies of our products. Doctors need to hear our message many times before they act and they need a longer time still to experience our product in the wide array of patients they treat before those very physicians develop their own position about our drugs.

One reason why we consistently try to sensibly price our products and launch even with their compelling product profile is to facilitate the broadest try by physicians by payers and patients and to deepen the experience with our products early on.

Finally, though we ve mostly concentrated on office-based physicians in the past, we re beginning to diversify to other locations in the U.S. Similar to expanding our business development efforts in other geographies ex-U.S., we are right here in the U.S. going beyond office-based settings. Hospitals are a very good example. Physically, hospitals are a different geography for us and one that we hope to build upon really going forward.

So that s it. That s Forest s commercial point of view. Fairly simple, but I d also venture to say that though it d be simple, it s shored up by the data. For the most part that sizeable products one must go as I ve just said where the business is. In terms of prescriptions, that s still essentially centered around primary care professionals, even with generic prescriptions in the mix, high value primary care physicians generate the lion s share, the lion s share of prescription activity across a host of therapeutic category. Moreover, primary care physicians treat the largest segment of patients who are either new to treatment or new to a specific brand in the therapeutic category. So primary care still is where a lot of the action is in healthcare today.

And this leads to the next point. To serve the market readily, a pharma company s product portfolio simply needs to be appropriately diversified. Forest s product portfolio I contend today and over the next several years will be well suited to serve these needs. So our philosophy is backed by data. And both are backed by the success we ve had with sorry. And both are backed by the success we have had with products that fall squarely within the framework.

Bystolic though not the only example, it s a case in point. A late entrant beta-blocker into highly generic category Bystolic four plus years since launch is still growing into its ultimate self. We measured all primary care physician launches between 2006 and the present. And within this group, only these products have continued to grow in real terms several years post-launch.

Now as you may know a multiyear growth cycle, it doesn t just happen. It takes effort. More importantly, it takes patience. If Rome was not built in a day neither is a meaningful product. A good molecule elucidated by good science and continually supported through good field effort can grow and grow profitably. And with the right lifecycle management, it can grow further still.

And as I said, doctors need to use the product on many patients. It takes time to really understand it and appropriate use it to the max. In our experience, here again exemplified by Bystolic data, it takes two years truly launch a brand. By year two, we see that the responsiveness to our sales efforts really begins to come through and it will continue as it s done for Bystolic beyond that [indiscernible] (02:22:52). Also the acceptance by payers, it too continues to grow over time. Our sensible pricing plans at launch often yield good unrestricted access in the early years. Then doctor and patient demand helped that access grow even further into the future.

So guided by our philosophy, guided by everything I ve just told you so far, guided by our experience, what lies ahead? Well, we ve been telling you for a quite while and as we have today a rich pipeline, a pipeline that s replete with offerings in therapeutic areas that will be meaningful to our target physician universe and to payers and the patients. Already in our fiscal year 2013, we hope to launch aclidinium, second product in COPD marketplace, Linaclotide for chronic constipation and IBSC.

In fiscal year 2014, we hope to launch an extended release version of Namenda; levomilnacipran, an SNRI for depression, and cariprazine for schizophrenia and mania. For fiscal year 2015 and beyond, we have a long list of products in an array of therapeutic areas that s just waiting the links. Mind you, this reflects only our current portfolio and not products in our business development efforts have yet to uncover or obtain.

Now I m sure when you see this list, even as it is today, you re all wondering can we exploit its value. Here too I would point to some data, and this time from a third-party source you probably know ZS Associates. ZS is known to track doctors attitudes and behavior. In a recent piece of research they measured what helped physicians in their adoption of new products. They particularly measured what things doctors said were important, and then they correlated that with how doctors behaved.

In general, a company and its new products it would hope to manifest the attributes that are up there in the top right box. That top right box is exactly where our characteristics as a company are most evident. From good products that are differentiated to meet unmet needs in the marketplace to sales representative support and sampling to assist doctors and patients trial, to sensible pricing, which help secure coverage and manage out-of-pocket cost, these still are the things that continue to drive adoption and they are what we focus on and what we try to do extremely well to right size those efforts and to be at the same time both efficient and effective.

This explains also why we probably have been loath to lavishly spend on certain techniques such as television advertising, where the cost versus the benefit of the effort can sometimes be marginal. Now this research does not mean that the picture is static and that s nothing has changed in terms of doctors needs.

In fact, in another set of research, and the survey this time done by Publicis Touchpoint Solutions, doctors articulated that they do see a benefit in dealing with representatives. They still do, as long as those interactions revolve around serious discussions of therapeutic options. Recent research has assessed that doctors who engage representatives, they are more aware of all information; good, bad or indifferent about a drug.

Their colleagues who do not engage representative are up to four times slower in knowing any of this information. So serious discussions about multiple therapeutic options are what physicians want and in fact need, particularly the magic place, particularly in primary care, where there are so many therapeutic areas and products about which any single physician needs to be knowledgeable. And this is where we and our current portfolio come in.

The largest therapeutic areas and activity are the areas in which we for the most part have multiple offerings. We can engage richly in this disease space and offer more than one treatment option. In cardiovascular and respiratory we have three offerings in each, in CNS and anti-infectives, we will have four in each.

Multiple products in the same therapeutic area like Daliresp and aclidinium, they will help maximize each other perhaps across different therapeutic categories at a minimum, at a minimum will help generate time with physicians because something will be of relevance to those doctors. The value of our portfolio going to be in the mix, in the mix and our ability to exploit its synergies both from an R&D perspective as well as marketing perspective.

And structurally, it s important; structurally this will be very feasible. Looking it on with 100,000 primary care active primary care physicians with our current portfolio 55% today are targets for three of our therapeutic franchise, 80% of the same physicians overlap for at least two of our current therapeutic areas.

Looking forward to Linaclotide, 87% of the Linaclotide primary care prescribing universe overlaps with the categories we already serve. This is the power of primarily primary care centric focus and of the therapeutically agnostic approach. We can serve our target audience with a relevant but varied product offering and we can do so by our right sized effective and efficient sales efforts.

Now as I mentioned earlier, our business development efforts, they re taking us further afield. And here too in the U.S., as I mentioned, we hope to cultivate the geographies hospitals, long-term care. They are institutions that are at the forefront of healthcare no different than primary care physicians, so they are in our sights. Interestingly, they have a different adoption cycle in office space settings. We need to understand this, become familiar with this, and the differences of this setting versus our experience elsewhere. Nonetheless, some things are similar, and in institutions no different than in physicians practices in the community, the more value we can bring them in therapeutic areas that are of importance to them, the more relevant and ultimately the more successful we will be as well.

Forest has enjoyed a rich commercial heritage. We ve launched major products in several therapeutic areas. We ve mostly met with success by following a very straightforward philosophy and one that I would probably add one final point to and that is that we ve learned from the heritage and that we efficiently adapted to the needs of the markets and to our customers, doctors and their patients to realize the potential of the rich portfolio yet to come ultimately to create value for our shareholders.

Now, it s been my pleasure, truly my pleasure to speak to you this morning. And I d like to turn the presentation over to the wonderful, Mr. William Meury, who is our Senior Vice President of Global Commercial and U.S. Marketing, and I m sure you ll learn much from Bill s clear explanation of our product lines progress, and success today. So thank you very much.

William J. Meury

Senior Vice President-Marketing, Forest Pharmaceuticals, Inc.

Elaine thanks so much. Good morning, everyone. Before we get started, I wanted to clarify something that Marco said about baseball earlier in the meeting. I did tell him if he hit 300, you d go to the baseball hall of fame, but I said as long as he didn t use performance enhancing drugs and then lie to Congress about it.

So far we ve talked about our business strategy, the R&D program, and our commercial capabilities, and now we re going to turn to marketing. I m going to talk directly about the performance of our recently launched products and our expectations for our new products. But before I do that, I want to take a few moments to make some general comments about our product lines.

As you heard, we have six different therapeutic areas each with two or three products. Several benefits accrue from that kind of product line depth. The first is our overall selling proposition or value proposition to physicians, whatever you want to call it, is stronger and more efficient when we can promote multiple products for the same conditions.

We can provide physicians with a more complete view of pharmacotherapy than other companies can. For example, Daliresp, aclidinium and aclidinium/formoterol can be described as a single offering in COPD that includes bronchodilation and exacerbation prevention. Physicians can start with aclidinium and then step-up to aclidinium/formoterol and/or Daliresp for more symptom control. The same is true for Viibryd and levomilnacipran. Those two products can be used separately in different populations based on severity or in sequence to address the highly variable response antidepressant therapy.

The second benefit of a deep product line is that the flagship products can pave the way or even accelerate adoption of the follow-on products. Aclidinium will benefit from Daliresp from the access to relationships and the knowledge that we now have. Levomilnacipran will benefit from Viibryd and Bystolic valsartan benefit from Bystolic and ceftazidime/avibactam from Teflaro. The successors benefit from the predecessors and the reverse can also be true. So for example aclidinium becomes a more attractive starting point when the fixed combination is introduced, because physicians know they have now have a more effective step-up option, and we know that from our shared experience with Benicar and Benicar HCT.

And the last benefit here, and Elaine touched on it, is that our promotional investment is more manageable. If we had nine different products in nine different categories, we would need nearly twice as many sales representatives and the same will be true for our marketing expenses. The return on our promotional investment is simply higher promoting two or more products for the same condition to the same audience as opposed to just one. And for physicians, for physicians it s like one stop shopping. Product line depth has clear cut tangible strategic and economic advantages for Forest.

So with that let s turn to our cardiovascular product line. Here we have Bystolic and hope to have a fixed dose combination of Bystolic and valsartan. We launched Bystolic over four years ago as you know. Prior to our launch, physicians had been using the same two or three products fairly consistently for over a decade. And so the test here and it was really a test of the primary care concept was to breakthrough that inertia and to establish utility of Bystolic despite the availability of multiple older generic alternatives. It was a slow but steady growth strategy.

And today, four years later, Bystolic is annualizing at approximately $400 million in sales, has a user base of over a quarter of a million physicians and it s still growing at a double digit rate and there are several reasons for that. The first is we positioned Bystolic as the first line antihypertensive as opposed to a typical beta-blocker that use third or fourth line and we did that because that s where the volume is and that s exactly how physicians are using Bystolic today as you can see from this slide; almost 60% they use as first line, which represents a 4 point change versus prior year.

Second, we have a great deal of clinical data to support our promotional efforts. New data is the lifeblood of any promotional program and some companies do a better job at producing it than others do. And then finally our promotional effort continues to be as large as or larger than that of any other company in the hypertension category. Today we re almost the lone voice in hypertension, which means we can really control that market.

Now the fixed combination of Bystolic and valsartan would join an effective well tolerated beta-blocker with the most effective and mostly widely used ARB. Bystolic valsartan is about expansion and not conversion and we ll pull from these three different patient pools. The market here is worth just over $3 billion in sales. And if approved, the combination product could be as large as Bystolic itself, essentially doubling the size of our cardiovascular franchise.

All right. Let s turn to CNS. Here we have four products, one in neurology and three in psychiatry. Namenda is the largest, Viibryd is the fastest growing and cariprazine and levomilnacipran are the newest. And each product can co-exist with the others. Today, Namenda represents a significant revenue stream for Forest. We ve created and maintained a large and loyal user base and physician and caregiver satisfaction with the drug is quite high. Sales growth for Namenda in the next several years will come from preserving prescription volume and price appreciation.

And then in fiscal year 2014, we ll introduce an approved once-a-day formulation of Namenda. Now, once-a-day dosing in the younger population is perhaps just a nice to have, but in an older Alzheimer s population on multiple medications turned into a real benefit. The new form makes using Namenda in combination with Aricept, which is also a once-a-day therapy much more convenient. And the data supporting the XR formulation is strong in several respects.

First, XR was shown effective when added to not just Aricept, but the other acetylcholinesterase inhibitors too. The improvements observed in cognition and function and behavior with similar to those from our IR trials and

finally the AE profile is consistent with that of Namenda. There are really no tradeoffs here like there have been with other once-a-day formulations that have been introduced into the category. Now we plan on introducing the XR formulation well in advance of IR losing exclusivity and we estimate that we could preserve up to 30% of the Namenda revenue stream for several more years.

All right. Viibryd; early, broad and often, that s what we re seeing in the market right now. Prescriptions were up 20% since the start of the year and sales in the first 12 months are expected to total roughly $70 million. Over 50,000 physicians have tried the product and we continue to add 1,000 new writers each week, which means, by the end of next year, we expect over 100,000 physicians across the United States to be using Viibryd.

Now, the most encouraging signal about this launch so far is that Viibryd is being used early in therapy and at a broad range of patients as opposed to later in therapy and in a narrow population of patients. It s being used first or second line 50% of the time and more often first line and second line. We re not depending on just treatment failures or narrow segment of the market for sales. I d say physicians are using Viibryd more like a novel SSRI than an SNRI, which is exactly what we wanted and their experience with the drug has been positive and entirely consistent with the clinical study results.

The key to sustaining growth and avoiding a premature peak in the future is maintaining a steady stream of new data and a significant promotional effort. Now, the formula here is very similar to that of Bystolic. We started as you heard several different studies to further characterize the effect of Viibryd in depression as well as in anxiety. And if successful, we ll launch on average one new study each year the three years starting in 2013. And that coupled with a heavy detailing effort, which we expect will exceed the levels of the other companies this year, should keep Viibryd on the current trajectory, which in our estimation puts it at a 2% to 3% market share in just a few years, and an indication for GAD or general anxiety disorder could be worth an additional 0.5 point or more.

All right. Let s turn to our second CNS product, levomilnacipran. Is there room for another antidepressant, and can our two antidepressants coexist? The answer to both those questions is yes. It s well-known that an antidepressant that works for one patient may not work or be tolerated in another. And so in our view, physicians are going to be interested in levomilnacipran for several reasons. First is its effect on the MADRS is at the upper end of the range established by the literature. You saw the studies. We had a good 3 to 4 point change on that scale.

Second, in our studies, it showed a statistically significant effect on function as measured by the Sheehan Disability Scale. Only one other antidepressant has such strong data on function and it s for general anxiety disorder. And third, the adverse event rates associated with levomilnacipran are very competitive with those of other SNRIs.

In terms of the second question, can they co-exist, Viibryd, as you know, is an SSRI and 5-HT1A partial agonist. Essentially, it s an SSRI with something different pharmacologically. Levomilnacipran is an SNRI. Both drugs work differently and will be used in different populations and ultimately will be used for different reasons, which is why they can co-exist, just as duloxetine and venlafaxine have co-existed alongside a range of SSRIs for many years. Ultimately, levomilnacipran will be used somewhat later in therapy than Viibryd and perhaps in more severe population and by mostly psychiatrists and some primary care physicians.

Now cariprazine, cariprazine works differently than the nine other D2/5-HT antagonists on the market. It s more like Abilify than it is the other products with greater emphasis on the D3 pharmacology. Clinically, the magnitude effect on the positive and negative symptom subscale is as good as and in certain cases better than what s been reported in the literature for the D2 antagonists in older studies and the rates of EPS and weight gain and somnolence are in a very acceptable and competitive range as Gavin talked about.