PRESENTATION

Chris Schott - JPMorgan Chase & Co. - Analyst

Good morning everyone. I'm Chris Schott, the pharmaceutical analyst at JPMorgan. I'm very pleased today to be introducing Pfizer. From Pfizer we have Martin Mackay who is President of Pfizer’s Global Research and Development. And with that, I'm going to turn it over to Martin.

Martin Mackay - Pfizer Inc. - SPresident, Pfizer Global Research & Development

Thank you very much, Chris. Exceptional thanks for the invite. I have rarely known to have to fight through a crowd to actually come to the presentation but thank you.

I'm going to go through a number of -- the progress that we're making at Pfizer and and have made in the last year. But first of all if I could just turn your attention to the forward-looking statements before I delve into the presentation.

Okay, when I took the position as head of R&D at Pfizer at the back end of 2007, we laid out a very clear five-point plan both internally and externally. And just briefly to remind you of those points, I'll go into a little more detail particularly around a couple of the points as I go through the presentation.

But first and foremost was to deliver our extensive Phase II portfolio, move these compounds into Phase III and deliver those late stage compounds. The second was simply to make sure that we were both working in the right disease areas and on the right compounds.

So we have had extensive reviews of our portfolio, again internally and with external experts to make sure that we've got the very best portfolio that we could have. Thirdly to become a top tier company in biotherapeutics. At the same time as assuming this position, we hired Cory Goodman to lead the biotherapeutics and bioinnovation center based here in San Francisco.

And I will say a little more about that later. But suffice it to say, it has been a resounding success so far. Critical hire, built really great people and companies around the federation as he calls them and as I say, I'll say a wee bit more about it.

Fourthly and importantly, and this is known to all of you, productivity in our industry hasn’t been what it should be particularly over the last decade. (inaudible) been working on a number of areas to improve that productivity both in terms of cycle times and development, cost of development and of course I think most importantly, the Holy Grail, which is increasing Phase II survival. And again, we have worked on all areas quite diligently.

And then lastly but not least, to make sure that we are accessing the very best external science that we could. And I will say something about the deals that we have done, some of the collaborations that we have with academia. Even with the magnificent budget we have at Pfizer to [prosecute] a portfolio, it was very clear that we had to make more inroads into topline academic science and we have done that last year and will continue to do it.
Just a couple of slides on achievements. If I was to pick out any point of the five-point plan, it would be number one, we tried very hard to focus the entire organization on delivering this portfolio. It was well-known that we had a lot of compounds in Phase II but the critical thing was to get those into Phase III -- and I will show you some data on that -- and then clearly very importantly to translate those into submissions, approvals and into the marketplace.

We have had a number of global approvals this year, global submissions. I would like to see more NCE derived from our pipeline being on that list. This is still to come although there is a couple of superb compounds in here. But by and large, this is very important bread and butter work to make sure that we maximize the value of the compounds that we have and access the largest number of patients that need those compounds. I'd pay particular credit to the Japanese organization this year who had a simply outstanding year both in terms of approvals and submissions.

If we move a little earlier in the portfolio -- and again from a personal point of view, this is the piece that has pleased me most, the number of Phase III starts that we have had and the progress that we have made with our Phase III compounds. I'm going to speak about those compounds later in the talk but suffice it to say it's a healthy mix of new chemical entities, important product line extension. Some of them come from deals or acquisitions that we have done.

The health of an R&D organization can be measured by its earlier portfolio. And again we have made good progress in 2008. We had ten positive proof-of-concepts against therapeutic areas mostly in the area of invest-to-win, those that we really are pushing hard but also had 19 first-in-patients and 26 first-in-human starts.

And I have mentioned this before that there is barely a week goes by at Pfizer without one of our new compounds either going into volunteers or going into patients. Such is the depth of our portfolio. And in business development, again we've been quite active with our range of early technology platform deals, some larger deals with academic institutions such as you UCSF and UPENN then some later deals like Auxilium and Encysive where we have brought in compounds that we believe can lead to short-term revenues in important areas of medical need.

And really importantly, at the same time we have continued to transform the way that we work at Pfizer. It is very clear that a large organization has some challenges and our launching of the business units towards the end of last year is one of the ways that we handle this within a large company. Six business units -- primary care, specialty, oncology, established products, emerging markets, and animal health, each with a single leader, a single point of accountability with very clear P&L responsibility.

At the same time within research and the BBC, we named a number of Chief Scientific Officers to look at particular disease areas. So we have a head of cardiovascular metabolic. We have a head of pain, a head of oncology. Some of those were internal promotions, others we hired from other companies.

But again, these CSO's as we call them, are empowered to take our compounds right through to the proof-of-concept stage, ready for the business units to take on and do full development; very clear decision-making within the organization. Of course the challenge for any big organization is then how do you benefit from the scale of that organization. We have got great manufacturing, great pharmaceutical sciences, drug safety, development operations, and these are global organizations that support the entire business units.

One of the most important things for me is to be able to go through these changes and not take a hit on productivity. And I can safely say as we went through the transformation to this business unit model, we didn't take any hit on productivity.

We didn't miss any milestone in terms of Phase II starts, Phase III starts. We managed to keep the organization fully focused on the work that we're here to do, yet we also recognized we have to evolve this organization and we did so with the formation of these business units.

The pipeline, as you know, we publish now twice a year. This is the most recent publication in September at 2008. We will publish again probably around the March timeframe of 2009.
The important things to note are the progression of compounds from Phase I into Phase II, Phase II into Phase III. Clearly it is that latter part now which has to be our focus to make sure that we take these compounds from Phase III into registration, approval and onto the marketplace and that is a natural part of the process for this portfolio.

On March 5, I spoke about the commitments that we made both to ourselves and to the outside world, 15 to 20 Phase III starts by the end of '09 which would lead to around 24 to 28 entities in Phase III but most importantly, these 15 to 20 submissions in the 2010-2012 timeframe. As I stand today, I'm very pleased to report we're on track to meet those commitments as we stand today.

In terms of working on the most valuable portfolio and the one that we think we can prosecute to the very best of our ability, we made some decisions and we highlighted some disease areas as what we called invest-to-win and those are Alzheimer’s disease, oncology, schizophrenia, immunology, inflammation, pain and diabetes. And these areas at a time when our budget is staying relatively flat, are in fact growing in the organization.

A number of other disease areas that we also believe are valuable but we've said won't grow in the organization rather more a stay-the-course approach, so we continue to work in infectious disease, asthma and COPD etc. Then we made hard decisions about those areas that we would simply exit and that was both in terms of disease areas and compounds that we are prosecuting.

And one thing I'll speak about a little bit later, in the past when we made decisions like this, those assets would simply sit on the shelf at Pfizer gathering dust. We have now found an outlicensing team under the leadership of David Rosen who has a team of people and we're looking to outlicense these assets whether it be by bundles or individual assets and in fact we have got somewhere up to 100 assets within that group, the majority of them having clinical data.

In terms of the disease area exits, a number of those that we announced, again both internally and externally really to make sure we were focused on those areas of highest value. Briefly on the biotherapeutics and bioinnovation, (inaudible) based here in San Francisco.

As I say, it's hard to believe it's barely been a year since Corey came on board and has developed this group. With acquisitions of companies such as CovX, Rinat, with the transformation of our Research Technology Center in Cambridge, Massachusetts to an (inaudible) center; a number of simply outstanding academic deals and other deals that Corey has done to build his federation.

Again the thing that has pleased me most about this, there is always a challenge when you do something like this in a large organization. How will scientists interact together? And the interaction has been tremendous.

As I look at our portfolio across the therapeutic areas and look at the number of CovX bodies that have been applied to targets across many therapeutic areas or the Rinat technology being applied in several therapeutic areas. Similarly (inaudible) where we place our bets on the best targets, it really has been a magnificent collaboration and a great success today.

Of course there's much more to come. Whilst we've built quite a reasonable portfolio of biotherapeutics with many early stage projects, the 17 in development, clearly our challenges is to translate this work into revenue generation.

We have relatively modest revenues from our biotherapeutics to date and we need to translate those development compounds into major forces. And again I'm going to talk about a couple of them later in the talk with some specifics.

These biotherapeutics are applied to nine of our therapeutic areas. We're working on several mortalities including antibodies, interference RNA, peptides, etc. Most of the portfolio is antibodies.

And then about 18 months ago we decided to move into the field of therapeutic vaccines and we have internal groups established in Sandwich and Kent; La Jolla, California where we're really making a play into therapeutics. We will grow these groups internally
but we will also look at acquisitions as we have done in the past that will enhance our technology platforms, groups like CovX, Rinat, etc.

The most recent play we have made is to form a regenerative medicine unit which is based in both Cambridge, England; and Cambridge, Massachusetts under the leadership of Ruth McKernan, a terrific scientist. And although this is clearly longer-term work, we feel this is exactly the right time to move into this exciting area.

So, in terms of the late stage portfolio now, as I say, the thing that has [heartened] me most over the last year is how we have really started to populate our cadre of Phase III compounds. There is a very good mix of new chemical entities in there, a very good mix of important product line extensions with key assets such as Sutent, Geodon, Lyrica, all with additional indications; new entries into Phase III like Tanezumab, our NGF antibody, our IGF-1R antibody in non-small cell lung carcinoma; and the deal that we recently announced with meditation Medivation with Dimebon, an Alzheimer’s drug that we’re very pleased with.

The (inaudible) are growing accordingly so that we can meet our commitments and similarly the new indications for existing drugs, a very important part of the business. Just a quick look at the figures to really punctuate this.

We only have to go back around two years when we had eight entities in Phase III and at that time we set aggressive goals in populating this area. And in fact, we have about traveled the entities that we have in there and certainly are online to meet our commitments of how many that we will have by the end of 2009.

But again, I can’t reinforce enough, it is now the challenge to translate those into submissions and approvals and that will be a very strong focus of the organization over the next period. I’m just going to mention in the time remaining, some of our late-stage candidates and give some thumbnail sketches.

Most of this data has either been published or discussed at meetings. I’ll go through these relatively quickly. Tanezumab which was the NGF antibody that we acquired as part of the Rinat deal; our JAK-3 inhibitor, CP-690 which we have published on quite a lot last year at top meetings; Dimebon I mentioned from Medivation, the co-development that we’re doing their; CP-751 which is our IGF-1R antibody which is progressing nicely in Phase III. And lastly just a brief update on where we are with Sutent and those Phase III indications that we have.

So Tanezumab has been quite special to watch. Since we acquired the Rinat organization in 2006 and this antibody was in Phase II at the time, (inaudible) the Pfizer team on it under the leadership of Ken Vergburg, and I’m sure some of you know, Ken was responsible for the development or at least partly responsible for the development of both Celebrex and Lyrica; an absolutely seasoned professional that’s taken this humanized antibody through (inaudible) high specificity for the NGF molecule.

Again, I won’t go into many details on the mechanism of action. There are still studies going. But it is known what NGF does. (inaudible) early studies showing that NGF was injected, it caused pain cessation -- sensation and bound to several (inaudible) such as prostaglandins, (inaudible) etc.

So we’ve got a pretty reasonable handle on the mechanism of action of an antibody against this and now that we have actually run extensive Phase II studies and the molecule is now moved into Phase III, we expect to get a lot more data. At the moment we have a five-minute IV infusion. It has been given twice, once every eight weeks and I will show you some of the results that we have on this. But really importantly, it’s now moved into Phase III, recruitment is on track and over the rest of this year and into next year we expect to see a lot more data on this antibody.

At the moment, we’re pushing the osteoarthritis indication but we have a number of other indications coming up at the back including chronic low back pain which is in Phase II. And again, results we’re very interesting.
These data we've published already looking at walking and knee pain, multiple doses of Tanezumab against placebo, as mentioned, the five-minute IV injection. We're also working on subcutaneous formulations which would clearly make a significant difference to this treatment.

But the things that were exceptional here were certainly pain relief and again talking to folks like Ken Verburg who is very used to looking at this data with other end (inaudible) for example, this is outstanding pain relief data. And the toleration for the molecule was also very good, some side effects that were affected and we believe manageable.

But again I'll stress these are Phase II data in hundreds of patients. We will have a lot more information when we get into the Phase III setting. But certainly so far, so good with this exciting new therapy. It really is -- pain is a flagship area for us both in terms of the compounds we have on the marketplace and late-stage development, an array of very novel new mechanisms in this area of high unmet medical need.

Moving quickly to JAK-3, most people know the story here, how we were involved in the area initially in transplant and then we did an early signals of efficacy study in rheumatoid arthritis a while ago which we've recently published using three doses at that time and about 264 patients. We followed that up with another study using multiple doses from one milligram up to 20, 30 milligrams over that time period. A 12-week [readout], we have run it to 24 weeks. We will continue the study and again with a view to looking at the efficacy which has been pretty clear today and also the safety measures that are important to us.

We aim to put this into Phase III around the end of first quarter this year. We are now in active and very positive dialogue with regulatory agencies around the world. Again, we will push this in rheumatoid arthritis into first place. But importantly, the basic mechanism here can be applied we believe to several indications and we have Phase II plans ongoing now in other indications and Phase I starts and moving along with this compounds.

Again I will not dwell on these data. They've been published over the last period. But suffice it to say we're looking at TNF-like efficacy.

The side effects we've seen apart from the very normal ones you see in studies, certainly infection, we're looking at it and we are running intensive safety studies on this. Clearly again when this moves into Phase III and we're able to monitor a much larger population, we will show this compound. As I stand here today, excellent efficacy, good safety profile and I really think we have got a super compound in CP-690.

Moving onto Dimebon, one of the newest entries and our deal with Medivation has been really quite exciting. And what was particularly exciting was to look at the Phase II data that Medivation produced and I'll just show a graph from them. But again, suffice it to say we're pushing ahead in Phase III with Alzheimer's disease.

We are also interested in other diseases of neurodegeneration, indications such as Huntington's. But we're really quite excited about the early data that we have seen on this compound, very pleased to have done the deal with Medivation.

Here's an ADS COG graph that has been published, again showing very good clinical improvement with Dimebon in a Phase II setting. Of course when we look at Phase III, greater numbers of patients from different sources. It will be very interesting to see that we maintain this level of efficacy which really is quite impressive.

Moving quickly along, CP-751 is our IGF-1R antibody that I mentioned which has its lead indication as non-small cell lung carcinoma and a number of other tumor types coming off the back of Phase II. This is a fully human IDG-2 monoclonal antibody.

As you know, it is a very intense competitive area. We believe we are out front with this and have a potential to be first in class with the molecule. Over 1000 patients have now been through clinical trials with this antibody and again it is looking very promising indeed.
I won't go into details here but this was one of the multinational studies that we showed in bulky squamous tumors in the United States and Europe. And again showing significant reductions in tumor mass after the treatment of this antibody.

And lastly in terms of the compound, Sutent continues to progress [at a pace]. Clearly we have registered for renal cell carcinoma, gastrointestinal stromal tumor. The lead indication in Phase III is breast cancer and a little behind with colorectal cancer and lung cancer. And then in 2008 we started Phase III trials in hepatic cellular carcinoma and hormone refractory prostate cancer; again looking to increase the value of this quite terrific compound in terms of the value and to patients. In the interest of time, I won't go through the breast cancer results but they are the furthest ahead in Phase III and we're looking to progress this at the same speed that we did the others.

The last couple of slides, very briefly to say these are the commitments that we made on March 5. We are on track to meet these commitments. Clearly the bottom one is the most important for us now.

As we have begun to populate Phase III level, that makes us happy -- or not happy but happy our -- more compounds will move through from Phase II this year. But clearly this critical transition into submissions and into the marketplace is what will really determine how the R&D organization has performed over this next time period.

I have mentioned some of the areas of interest. Apart from the invest-to-win areas that I spoke about, we're still interested in doing deals with platform technologies that will help us improve our productivity. We're still looking in terms of biotherapeutics, both in terms of platforms and individual entities. We're building our therapeutic vaccines position. We're building our position in regenerative medicine, all keen areas to look for partnering.

And then one of the most significant changes I believe that I've witnessed at my time at Pfizer is their flexibility we are prepared to have now in terms of the types of relationships that we will do from clearly the licensing that we've always done, the co-development, co-promote, alliances, joint ventures. The apixaban would be a great would be a great example of where we're working with Bristol-Myers.

As I mentioned, we're very keen to realize value from these assets that we have. Most of the assets that we have for ourlicensing are in the clinic. They have passed the criteria to take compounds into the clinic and be efficacious and David Rosen is the person that you should speak to in that respect. And then continuing to build on our academic alliances network across the world which we really started to do with [Gusto] in 2007, 2008 and we will continue to do so.

So with that, I would like to thank you for your attention. Thank you.