ALKERMES INC
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SCHEDULE 14A
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SCHEDULE 14A INFORMATION
PROXY STATEMENT PURSUANT TO SECTION 14(a) OF THE SECURITIES EXCHANGE ACT OF 1934 (Amendment No.)

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o Definitive Proxy Statement
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ALKERMES, INC.
(Name of Registrant as Specified In Its Charter)
(Name of Person(s) Filing Proxy Statement if Other Than the Registrant)

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This filing relates to a planned merger between Alkermes, Inc. and the global drug delivery technologies business of Elan (known as EDT) (such combination, the Business Combination) pursuant to a Business Combination Agreement and Plan of Merger (the Business Combination Agreement) by and among Elan Corporation, plc (Elan), a public limited company incorporated in Ireland, Antler Science Two Limited, a private limited company incorporated in Ireland, Elan Science Four Limited, a private limited company incorporated in Ireland, EDT Pharma Holdings Limited, a private limited company incorporated in Ireland, EDT US Holdco, Inc., a Delaware corporation, Antler Acquisition Corp., a Pennsylvania corporation and direct wholly owned subsidiary of U.S. Holdco, and Alkermes, Inc., a Pennsylvania corporation. The businesses will be combined under New Alkermes, a new holding company incorporated in Ireland that will be re-registered as a public limited company, and renamed Alkermes plc, at or prior to the completion of the Business Combination. The Business Combination Agreement is on file with the Securities and Exchange Commission as an exhibit to the Current Report on Form 8-K filed by Alkermes, Inc. on May 9, 2011.

The following is the transcript of an investor presentation made on July 18, 2011 as part of the Alkermes, Inc. Analyst and Investor Day.

Forward Looking Statements

Information set forth herein contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, which involve a number of risks and uncertainties. Alkermes cautions readers that any forward-looking information is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking information. Such forward-looking statements include, but are not limited to, statements concerning the likelihood that the merger with EDT is consummated and the timing of such consummation; future financial and operating performance, business plans or prospects of Alkermes plc; the timing, funding and feasibility of product development activities; and the therapeutic value of the Company s products. The statements in this document reflect the expectations and beliefs of the Company s management only as of the date of this document and subsequent events and developments may cause these expectations and beliefs to change. The Company undertakes no obligation to update or revise these statements, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company s views as of any date after the date of this document.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the ability to obtain regulatory approvals of the transaction on the proposed terms and schedule; the failure of Alkermes stockholders to approve the transaction; the outcome of pending or potential litigation or governmental investigations; the risk that the businesses will not be integrated successfully or such integration may be more difficult, time-consuming or costly than expected; uncertainty of the expected financial and operational performance of Alkermes plc following completion of the proposed transaction; Alkermes plc s ability to achieve the cost savings and synergies contemplated by the proposed transaction within the expected time frame; disruption from the proposed transaction making it more difficult to conduct business as usual or maintain relationships with customers, employees or suppliers; the calculations of, and factors that may impact the calculations of, the acquisition price in connection with the proposed merger and the allocation of such acquisition price to the net assets acquired in accordance with applicable accounting rules and methodologies; the ability to develop sucessfully our products in a timely and cost-effective manner, including the risk that clinical trial results for the company s products will not be predictive of real-world results or of results in subsequent clinical trials; decisions by regulatory authorities regarding the company s products; and the risk that the company s products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse that could cause the U.S. Food and Drug Administration (FDA) or other health authorities to require post-approval studies or require removal of the company s products from the market. Additional information and other factors are contained in Alkermes filings with the Securities and Exchange Commission, including Alkermes Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and other SEC filings, which are available at the SEC s web site http://www.sec.gov. Alkermes disclaims any obligation to update and revise statements contained in these materials based on new information or otherwise. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this document or other filings with the SEC.

Important Additional Information and Where to Find It

This communication does not constitute an offer to sell, or the solicitation of an offer to sell, or the solicitation of an offer to subscribe for or buy, any securities nor shall there be any sale, issuance or transfer of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to or qualification under the securities laws of any such jurisdiction.

In connection with the proposed merger, on June 22, 2011, Antler Science Two Limited, to be re-registered and renamed Alkermes plc, filed with the SEC a registration statement on Form S-4 (commission file number 333-175078) that includes a

preliminary proxy statement of Alkermes and that also constitutes a preliminary prospectus of Antler Science Two Limited regarding the proposed merger. After the registration statement has been declared effective by the SEC, a definitive proxy statement/prospectus will be mailed to Alkermes shareholders in connection with the proposed merger. INVESTORS ARE URGED TO READ CAREFULLY THE PROXY STATEMENT/PROSPECTUS (INCLUDING ALL AMENDMENTS AND SUPPLEMENTS THERETO) AND OTHER DOCUMENTS RELATING TO THE MERGER FILED WITH THE SEC WHEN THEY BECOME AVAILABLE, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT ALKERMES, EDT AND THE PROPOSED MERGER. You may obtain a copy of the registration statement and the proxy statement/prospectus (when available) and other related documents filed by Alkermes, Elan or EDT with the SEC regarding the proposed merger as well as other filings containing information about Alkermes, Elan, EDT and the merger, free of charge, through the web site maintained by the SEC at www.sec.gov, by directing a request to Alkermes Investor Relations department at Alkermes, Inc., 852 Winter Street, Waltham, Massachusetts 02451, Attn: Investor Relations or to Alkermes Investor Relations department at (781) 609-6000 or by email to financial@alkermes.com. Copies of the proxy statement/prospectus and the filings with the SEC that will be incorporated by reference in the proxy statement/prospectus can also be obtained, when available, without charge, from Alkermes website at www.alkermes.com under the heading Investor Relations and then under the heading SEC Filings .

Participants in Solicitation

This communication is not a solicitation of a proxy from any Alkermes shareholder. Alkermes and its directors, executive officers and certain other members of management and employees may, however, be deemed to be participants in the solicitation of proxies in respect of the proposed merger. Information regarding the persons who may, under the rules of the SEC, be considered participants in the solicitation of proxies in respect of the proposed merger is set forth in the preliminary proxy statement/prospectus filed with the SEC. You can find information about Alkermes directors and executive officers in its definitive proxy statement filed with the SEC on July 29, 2010. You can obtain free copies of these documents as described above.

Final Transcript

Conference Call Transcript
ALKS Alkermes Inc Analyst and Investor Day
Event Date/Time: Jul 18, 2011 / 07:00PM GMT

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PRESENTATION
Rebecca Peterson ***Alkermes Inc. VP Corporate Communications***
All right, everyone, thank you very much for coming to the Alkermes Analyst and Investor day. As you know, we typically don t have these events in the summer, but there s been so much going on at the Company that we really felt it was an opportune time to gather everyone and update you on our progress.
Before we begin today I will remind you that we will make forward-looking statements under the meanings of the Private Securities Litigation Reform Act of 1985. And I encourage you to read our forward-looking statements in our SEC filings.
Further, and I apologize in advance for doing this, but I need to remind you that the presentations and discussions today are not a solicitation of proxies from any Alkermes shareholder, or an offer to buy or sell securities in connection with our proposed merger with EDT. Investors are urged to carefully read the joint proxy statement/prospectus filed on Form S-4 and other materials filed with the SEC because they contain important information about Alkermes, EDT and their proposed merger transaction.

Once deemed effective by the SEC, a copy of these materials will be sent to all of Alkermes shareholders in connection with the proposed transaction and may also be obtained free of charge from the SEC website or the Alkermes website. Please refer to the text of the full legend on the slide today for more information. It s within all of your binders and also available on the webcast.

Now, on to business. I m pleased today to be joined by my esteemed colleagues. Richard Pops will be giving essentially an overview about the creation of the Alkermes of Alkermes PLC, and also talk a little bit about the merger and how we believe there s a lot of layers of values. Rich excuse me, Elliot will then talk about recent news flow just since we announced the transaction there s been a plethora of progress across the portfolio. And I think when you look at it holistically it s pretty amazing.

Shane Cooke we re delighted to have with us today. He is the head of EDT and will be incoming president of Alkermes PLC, and we re really pleased to have him here. And then Jim Frates, our CFO, will essentially give you the elements needed to model the combined company going forward. And after that we ll invite the guys up and we would happily invite your participation during the Q&A so we can really have a casual conversation about the merger, and any questions that you have we d be happy to answer.

So, without further ado, I will turn the podium over to Richard Pops.

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

Good afternoon, everybody. Can you hear me in the back all right? Good. Well, first of all, thank you to everybody for taking the time to come here. As Rebecca said, it s unusual for us to do something in the middle of July. But, literally, we ve been inundated with requests for information about this exciting new deal. So we re going to try to do three things today, and Rebecca touched on them.

First, we re going to try to just give you a sense from my perspective of what this combined company looks like. I think a lot of people have the facile understanding of what it looks like, but I think as you get into the depths of it, you ll be impressed with the layers of complexity.

Number two, Elliot will just give you an update on all kinds of things happening in the R&D pipeline. We re drinking out of a fire hose here and I think it s in many ways indicative of what we re going to see in Alkermes PLC. One of the amazing things when you put two companies of these sizes together with such a forward-looking business plan, we have so many variables between the five major commercial products and the pipeline and the manufacturing and the partnerships and all, that the news flow is quite remarkable.

And the number three is really pragmatic. That s literally how to model this business because we re seeing all kinds of different approaches to modeling it. And the model has gotten a little more complicated now with the combination into an Irish PLC, with the amortization of the purchase price using purchase price accounting, a lot of non-cash stuff flowing through the GAAP line, with the debt and so on. So it d be nice if everybody has their own structure in hand to be able to model the business.

But what you ll hear from us repeatedly is that we re not interested in telling you how to model the top line. You all are expert at that. But what s fascinating is what emerges from doing that exercise is this idea of this portfolio, and how the portfolio itself is going to grow from where it stands today into what it will become. So, my job is to tell you a little bit about some of these layers of complexity. And we ve talked about this within the Company of these various layers.

The first layer, I think, people have gotten by now. The deal if financially transformative. And what you ll see is the hydraulics of the P&L are such that from where we stand today in 2011 to where we ll be in 2014, 2015, 2016 is that it feels like it s going up. And we ll talk a little bit more about that.

But the reason why it s financially transformative is that we end up with this portfolio. And you hear biotech and biopharma companies talking about portfolio all the time. But what portfolio usually means is a combination of some here and now products, and a bunch of things that may occur sometime in the future.

This portfolio is a commercial portfolio of major drugs early in their lives, with long expected periods of exclusivity that are going to drive the growth of the top line for long periods of time. And so, you can have decidedly different points of view. Within this room there ll be people who have models for Bydureon that peak at $500 million, and we ll have others that have models that peak at $2 billion. And it doesn t really matter because when you put these all together in this portfolio it s difficult to see how the overall top line doesn t grow.

But what s interesting is that the five products didn t originate through some type of licensing and specialty pharma approach. They originate from a really sophisticated capability to make drugs, both on the EDT side and on the Alkermes side. For better or for worse, we ve been doing this for a long time.

We have invested a lot of time, a lot of sweat equity, a lot of years, in learning how to develop innovative products, taking them through clinical trials, building manufacturing plants, gaining regulatory approvals around the world, and watching these things move into the marketplace.

And I think the best predictor of our future success is probably what we ve done in the past. And we re quite excited about the combined capacity of the two companies to innovate. And what s what even more exciting from a management point of view, when we put them together it s a jump ball to come up with the best in class between both of the companies.

So, that is a really important engine. And when you push that engine forward in time, it becomes more obvious, then, how important this corporate structure is going to end up being. We are becoming an Irish PLC through this transaction. And we can talk a little bit about it and what that means. As the top line and the bottom line begin to grow, things like tax rate and operational flexibility become increasingly important.

And finally, and this ll probably be the homework assignment, we can t really see another company that looks like this company when it s done. If we do what we say we re going to do, in any reasonable approximation, what we end up with is one of the most differentiated and unique companies in the whole biopharma space.

So, let s take these in turn. In terms of the financial transformation, this will become self evident as you model the business. But the simple top line, we go from losing money to making money. That s a good thing. And we do so off of a revenue base that pro forma combined at the outset is $450 million. So, this isn t a trivial sized company. This is a meaningful company, a revenue base of $450 million, that we expect to grow. And Jim will take you through detail on that.

It ll grow not just at the top line; it ll grow at the bottom line as well. And we ll be introducing this term to you of adjusted EBITDA, which accounts for some of the non-cash noise in the GAAP earnings, and as well as the expanding margins. And the margins expand for a pretty simple reason, because our revenues are going to grow at a rate faster than our expenses are going to grow. And we can manage the business to that end.

The reason the revenues are going to grow is not based on an expectation that FDA will approve a certain number of drugs in the future. We have five major products now that are commercial stage products that are driving that top line growth. And at the top of the list is this repatriation or the uniting of RISPERDAL CONSTA and INVEGA SUSTENNA.

This removes the principal overhang in the marketplace with respect to RISPERDAL CONSTA s growth, introduces into the revenue mix INVEGA SUSTENNA, which developed by EDT, an exciting product that s going to grow the market for long-acting atypicals. And what s interesting, it gives us essentially a pure play on the growth of the long acting atypical market. Which even with RISPERDAL CONSTA, at a $1.5 billion worldwide, in the US represents less than 5% market share, of efficacious medicine for the treatment of this disease.

So, that becomes, instead of RISPERDAL CONSTA being 85% of Alkermes on a standalone basis revenue, now the combination of these two is a pure play into a growing multibillion dollar market. Ampyra development by EDT, where EDT captures 18% of the top line. So, Alkermes PLC will have 18% of the revenues from Ampyra around the world. This is a singular product in its class, and we think it s a surpassingly efficacious product for the patients that it benefits and it s just in the beginning of its lifecycle.

VIVITROL. You all are very familiar with VIVITROL. Launching in a new indication in the opioid dependence indication, an indication where $1 billion of commerce is being done right now and where we have a completely differentiated product. The first product approved to prevent relapse to opioid dependence in this patient population.

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And finally, last but hardly least, is BYDUREON. And the story about BYDUREON is finally a story where we re leaving the regulatory drama behind and moving now into its commercial phase. Just launched last week in the UK, our first patients are getting commercial BYDUREON now. It s extremely gratifying to everybody in these companies that have been working on it for so long.

But this is a product that s on patent for a long time. It has amazing clinical benefits and it s just getting going. With the completion of the QT study, which Elliot will refer to in a little bit, we re on track to file again with the FDA in Q3. And I think we re going to be off to the races finally for this exciting commercial product.

And these products, as I said, it s a portfolio. Most of them are on patent into the late teens or into the 20s and beyond. They re critical products in their classes. And importantly for us, to the extent they re partnered, which they all are except for VIVITROL, they really represent some of the critical products for our partners. So, INVEGA SUSTENNA and RISPERDAL CONSTA RISPERDAL CONSTA is J&J s third largest pharmaceutical product.

Ampyra is the whole ballgame for Acorda at this moment from a commercial point of view. BYDUREON, critical to Amylin s success. And so, what we essentially are leveraging is the work of all these other companies driving these brands into the marketplace around the world. That s why, as I said, the hydraulics of the P&L are such that if you believe that these products have a life ahead of them, from where they re starting in 2011 to where they re going to end up, we re just at the beginning of the story.

That growth we think will continue to accelerate because of the pipeline that originates from these organizations that have shown the ability to do it. Elliot will take you through this in more detail. But we re excited about the fact that we ve got things like ALKS 9070, ALKS 37, ALKS 5461, Meloxicam IV, and others.

And what you can see with the combined businesses at the scale they are, with an R&D capacity that we have, at both the revenue the spend side and also operational capacity, with a portfolio like this, we have the ability to make tough decisions.

If a product isn t meeting our target product profile, we ll stop working on it. We won t spend money there because other parts of the organization are competing for those dollars, and we re excited to provide the dollars in places where they re going to drive the most shareholder value.

Coupled with that, of course, is our ability to partner with these products to address territories outside the US in a world where big pharmaceutical companies are increasingly seeking out products that have been developed off of proven technical platforms. So, as the top line grows from $450 million to what it will become, and the bottom line begins to grow, of course in the P&L, taxes and other things start becoming incredibly important.

This Irish structure was a major hurdle for us to consider, and in contemplating this transaction with our colleagues at EDT, that decision then to leverage the 40 years of operating experience of EDT in Ireland with a large manufacturing base in Ireland 500 employees in Ireland and become an Irish company gives us amazing operational flexibility going ahead.

Obviously, tax rate is one part of it, but we ve actually got the ability to access expertise wherever it may lie. So for example, if it makes more sense to do R&D and development in the US because that s where the talent lies or the patients lie or the sites are, we can do it in the US.

If it makes more sense to manufacture something in Ireland, we can transfer IP there and do it in Ireland. It s a global company. We have that operational flexibility to source and domicile our work where it makes the most sense. And I think that s going to become more and more important as the Company becomes more and more profitable. And you ll see that as you model it yourselves.

And so, finally, to that point I made earlier, we think we emerge as one of these really unique companies. So you ask yourself how many companies are there that are profitable, rapidly growing, with a late stage pipeline that emanates from proprietary technologies with proven utility, with a CNS focus? There are very, very few.

And we think this area of CNS focus is a really important differentiating one for us because we re talking about areas of CNS that have proven tractable to new drug development, places like pain, schizophrenia, depression and the like, not in completely new areas driven by novel biology or new pathways.

So I ll finish up with this last point, which is this idea of what are the direct comparables? And, again, I don t have an answer to this but I pose it to you really in a provocative way to think about this as we go ahead. This is just a run that we did of companies with market caps in excess of $2 billion. There s two slides $2 billion to $5 billion, and $5 billion and beyond. And the blue lines demarcate tiers of billions, so there s $2 billion, $3 billion and $4 billion on this slide. And there s these are by the time companies get to this level there s a couple observations you would make. Number one, between the two slides there are very few companies. There s just not that big of a population of companies in these two slides. Number two is that a lot of them have valuations that are still very speculative. They re being paid in advance for products that have yet to arrive.

There s very few of these companies that have a portfolio that are diversified, that have growth, that don t have patent at the cliffs, that have the attributes that Alkermes PLC will have. We re really thrilled that on a pro forma combined basis, given where the stocks are now, we ll end up at about $2.5 billion pro forma combined coming out of the transaction.

And our view, as we look at the $2 billion companies and the $3 billion companies and the $4 billion companies and the $5 billion companies, it starts getting very thin. There s a couple $6 billion companies, $7 billion, $8 billion, $10 billion. It goes very, very quickly. The scarcity value of these types of assets is extremely high, and it s part of the reason why we re so committed in the combined company with our colleagues at EDT to execute on the plan that we have in front of us.

We have an operating plan that we re building right now that we re quite confident that we can hit. This business has all kinds of starts and stops as you know, but what gives us enormous amount of comfort is that we have so many variables now, so many things we can tune from a management point of view, that we re quite confident that we re on our way now.

So, that s all with the dare to be great speech. Now, I ll stop there and I ll turn it over to Elliot Ehrich, who actually will get into the meat of it all and tell you some of the updates on the pipeline. Elliot?

Elliot Ehrich ***Alkermes Inc.*** ***Chief Medical Officer***

Well, thank you, Richard, and thank you all for being here today. At my time at Alkermes I don t think I ve been here in a phase where there s been so much activity going on. I think the point I want to make is that it s not frenetic activity. It s highly focused activity at driving our portfolio and our platforms forward.

So I m really going to get into it quite quickly. What I ll do is I ll walk you through some highlights, particularly the events that have occurred since we ve announced the merger and then go into some further detail on our key programs. Shane will also follow me and touch on some of the EDT programs. But I think it should become quite clear the great progress that we ve made in bringing our products forward.

So let s look at the recent highlights, starting with RISPERDAL CONSTA where there s been an important IP development. Our longest-running patent, it s a process patent, and we ve received an extra two years Patent Office extension on that, so that brings that out now in the US to 2023.

With VIVITROL, we are approved now for opioid dependence in Russia. We were also, in the United States, recently granted a patent that extends out. It s a use patent and it extends out to 2029. So, a very long period of coverage there.

BYDUREON was approved in the EU in June. It s been recently launched as Richard mentioned in the UK and sales are already begun there. Importantly, that key data element, the QT study for the US refilling we ve announced a clean QT study and with that data in hand we re prepared to go back and re-file later this quarter. There s also been positive data that s been presented on once monthly, and I ll show that to you a little bit later on once monthly exenatide that was presented at the ADA.

FAMPYRA, so that s the European name for AMPYRA, was recommended for approval by the European committee.

ALKS 5461 we ve initiated a study in patients with depression. ALKS 33 we reported data from our binge eating disorder. We got a clear result, and we made the disciplined decision to discontinue that program. ALKS 37 we re initiating our definitive Phase IIb study for the treatment of opioid-induced constipation, OIC.

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ALKS 9070 we reported positive clinical data and we plan to initiate pivotal studies by the end of the calendar year. And INVEGA SUSTENNA there s been some early data reported by J&J that s been quite favorable and a multi-center, multinational Phase I study is underway. So overall, I think you see we re making enormous progress, forward momentum with our portfolio.

So let s get into some of our specific programs starting with VIVITROL. So this is our proprietary program with our new indication in opioid dependence. And I think most of you know that there s an epidemic of opioid dependence in this country that s reached crisis proportions. It s in the news media broad, really recognized Wall Street Journal, Time Magazine, CNN, New York Times. So, it s really become part of our national dialogue, this crisis.

But it s not just the news media. The medical and research community is beginning to take up the charge and investigate new ways to combat that. And they re looking at VIVITROL as a real solution to this opioid dependence crisis. And if you go on clinicaltrials.gov now and search for VIVITROL, you ll see dozens of studies being done with VIVITROL, many of them being sponsored by the research community or the National Institutes of Health.

And what this means is that we should expect to see new data generated repeatedly over time, which will continue to inform and substantiate the clinical use. So it s very exciting to see the community begin to take up the charge here and look at VIVITROL in a number of interesting ways.

And one area of particular interest is the Clinical Justice System. And we know that more than 65% of prisoners meet criteria for substance use disorder. And in the treatment of opioid dependence, there s a need for a treatment that s not addictive, that it can t be diverted or abused, and VIVITROL meets those needs.

And so, here in particular is a study that was looking at re-arrest rates in the Missouri and Michigan court system. And in this particular study there was a 69% reduction in re-arrest rates associated with VIVITROL use. So, an important result.

Beyond re-arrest rates, there s also a real public health issue in terms of HIV and hepatitis transmission in this population. And some of the other studies that you ll see on clinicaltrials.gov are beginning to address this issue as well. So overall, I think again, over the next few years we can expect to see more and more data and clinical use. And we ll see the criminal justice system as an important arena for increased utilization of VIVITROL moving ahead.

So in addition to the externally-sponsored research that s taking place, Alkermes are also beginning some additional research. And we re announcing for the first time today the initiation of the VICTORY study.

So, this is a registry. It s going to be looking at patients who are being prescribed VIVITROL in clinical use and there a number of important outcome measures in this study we re going to look at, particularly health outcome-related quality of life and health economics.

So when we take a look at all of this research that s taking place, the external and the research that we re sponsoring, I think you ll see that there s these elements that are in place to continue to build the understanding of VIVITROL, and really hopefully begin to provide an important solution to this opioid dependence crisis.

So BYDUREON there s been substantial progress with BYDUREON over the past few weeks. And the key point, again, as Richard indicated, is that BYDUREON has now moved from a development project to a commercial product.

So in June, the EU Commission approved BYDUREON and it s being launched on a country by country basis in Europe. Indicated as well that just last week in the UK. There s other crucial development of tQT study showing clear results, unambiguous results, frankly. And we re on track to re-file this quarter with the FDA.

And then, layered on top of that there s progress in terms of enhancing and optimizing the product presentation, including the once monthly data that was presented at the ADA.

So, let s start with a QT slide. And I hope this is the last time that we find ourselves presenting QT data in this kind of a setting. Just to be absolutely crystal clear about this, Amylin met with the FDA prior to the study and got full agreement in terms of the study design and the analysis plan.

The study looked at both therapeutic and supratherapeutic concentrations of exenatide and the result was no increase in QT interval, and that includes looking at that data using multiple correction methodologies. Furthermore, there was no correlation between exenatide concentration and QTc. So there s a clear path forward for getting this drug approved in the US, and we should be refilling quite shortly.

So again, on top of that, looking back only on the diabetes population, first of all it s huge. It s growing and it s a progressive disease. And you can see there are, for example, 10 million patients using oral agents. There are 5 million patients using injectable agents. This is just in this country alone, and we know that these patients will continue to progress. It s clear that the GLPs have a great opportunity to impact the treatment, and there s going to be a larger role as we move ahead.

Also, within each of these large buckets there are patients that require different types of treatment formats, and it s really the basis of our work with Amylin and Eli Lilly in rolling out these subsequent administration formats. So starting with BYDUREON where we expect US approval in 2012, layering on top of that is the dual chamber pen. And then, there will be ready-to-use suspensions, a weekly ready-to-use suspension so no reconstitution, and then a once monthly.

And let me show you the data from the once monthly. This is data that was presented at ADA. And you can see that with once monthly administration of the ready-to-use suspension you get the same hemoglobin A1c normalization as observed with the once weekly BYDUREON. So, a very impressive result.

And thinking about this and again, in terms of that landscape of millions of patients in these various treatment designations, there are going to be patients who are not able to inject themselves. And the once monthly format for them opens up the possibility of having that injection done either by a visiting nurse or done at their healthcare provider. So, it could fit in very well with a number of patient s needs.

There are other patients, frankly, for whom having the once monthly injection means they don t have to think about the fact that they re diabetic for a month at a time. So again, another type of patient population for whom once monthly might be just the answers.

So our partners plan to meet with the FDA in the second half of the calendar year to discuss Phase III planning for once monthly. But on the topic of once monthly, let s talk about Alkermes once monthly program, and this is our 9070 product. 9070 is our proprietary once monthly treatment for schizophrenia. It leverages LinkeRX technology, and it converts in vivo to aripiprazole, which is the active ingredient in the widely used antipsychotic ABILIFY.

It has a 21st century product presentation, so there s no reconstitution required It s non-refrigerated, and it uses a small gauge needle. It s a novel composition, so we have composition of matter, patents pending that should extend out to 2030 and perhaps beyond.

Now, I want to make it clear that 9070 is distinct from our microsphere products. It s a proprietary chemical composition. It has a lipid tail. It has a self-disassociating linker and then it has the warhead aripiprazole. And as you can see in this schematic, once it s injected the 9070 molecule, it dissolves slowly. The tail gets cleaved off enzymatically. The linker disassociates spontaneously, and aripiprazole is released into the circulation where it can travel up into the brain.

And we recently completed a Phase I study in patients with schizophrenia. This was done in 32 patients. We looked at multiple dose levels, 150, 300 and 400, and we had key study objectives to look at, the duration of action, the predictability of release and injection site tolerability.

And the results we were quite pleased with the data. We got some excellent PK. And I think considering the fact that this is our first study with our new technology it s really in some ways could be considered a home run, frankly. First of all, you can see release of aripiprazole, as being shown in this graph, extending beyond a month. So, that s important. That means that the dosing is entirely consistent with a once monthly dosing format.

The release was dose proportional, and that s important in two ways. One, it s important for a clinician. They can know that as they go up in dose that the dose that patients receive is going to be well-predicted by the dose that s administered. From a development perspective it s important.

Dose proportional means that we can predict both the important PK parameters of Cmax and AUC through a linear function. And we can use that data to then model expected concentrations, and not all complex dosage forms actually achieve dose proportionality.

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And in terms of predictability, you can see on that prior slide as well on the let me see where that little clicker is on the error bar, so those are standard deviations. And you can see those standard deviations are quite small and in fact we have a very favorable degree of inter-patient variability. And frankly, the injections were very well-tolerated as well.

So we were able to take this data. We envision a product and you can see on the next slide, where patients will be taking oral aripiprazole. They ll be getting injections and within two weeks or so they ll discontinue aripiprazole, and be able to continue on the long-acting injectable. There won t be a need for a loading dose.

And on the following slide, you can see our predicted steady state concentrations of ALKS 9070 and this looks a little bit like a cartoon. This is actual predicted data. It s highly it shows a very, very even concentrations, minimal peak to trough variability within the clinical dose range. And this is entirely consistent with this once monthly product format. So, again, we re very pleased with the data and with this in hand we re going to move the program forward.

Now, the development program for treatment of schizophrenia is quite clear, and we ll be meeting with the FDA in the second half of this year to discuss the Phase III program and the Phase III study, which will include a number of validated outcome measures, including the PANSS scores, Positive And Negative Symptom Scores, and the Brief Psychiatric Rating Scale.

ALKS 37. So ALKS 37 is our proprietary treatment for opioid-induced constipation or OIC. And OIC, I think as you know, is a big medical issue. It s caused by activation of the mu opioid receptor in the gut tissue and it occurs in patients who are taking opioids for the treatment of pain, which is a very large number of patients now in this country. In the design of the ALKS 37 molecule, we were very deliberate. So first of all, it s highly selective, ALKS 37, for the mu opioid receptor. And we did this because we wanted to minimize off target interactions and to have the most really the most safe molecule as possible by having receptor selectivity.

And the other key parameter relates to GI targeting. So, ALKS 37 is specifically targeted to interact with the GI tract. This is the tissue of interest, particularly the large colon, which is slowed down in the context of opioid-induced constipation. And following oral administration, ALKS 37 has very low systemic exposure because we weren t interested in causing opioid blockade in other tissues.

And ALKS 37 is also peripherally restricted. That means it doesn t get into the central nervous system. And that reason is that we absolutely did not want to interfere with pain relief of the opioid antagonists being taken by these patients. And here s some preclinical work using radiolabeled ALKS 37 that illustrates these design features. On the left you can see ALKS 37 is specifically concentrated in the large intestine. That middle bar there. And that s the site of action. On the right, you re looking at brain penetration. You can see it doesn t get into the brain.

And then we took ALKS 37 into the clinic, and these are results from our proof of concept study in patients with OIC. And we observed important clinical effects, so increase in spontaneous and complete spontaneous bowel movements at 30 and 100 milligrams.

So, we re excited by the data. We went down, we talked with the FDA, and we re moving rapidly forward with the program. And we have a Phase IIb definitive dose ranging study. We re just announcing that for the first time today. The study will evaluate dose levels of 25 up to 150 milligrams. And when we get this data in hand we ll move directly into confirmatory studies.

So finally, let s talk about ALKS 5461 which is our functional kappa antagonist. This is an early-stage program but it s a really good example of how we leverage the pharmacology of existing molecules.

Now in depression, there are a dearth of new treatments particularly for patients with treatment-resistant depression. And I think you ve all heard about the biogenic amine story. What s that? That s serotonin, that s epinephrine, that s dopamine. And those stories have been very important over the past years, but they ve really played themselves out at this point.

And there s a need for new alternative mechanisms of action. And there exists some substantial literature and this is reviewed in the article, this is included in your background information, to indicate that the kappa opioid system may have a very important role in treating stress and mood disorders including treatment-resistant depression.

The problem has been is that there s not been good kappa antagonists for testing this hypothesis in humans. And a number of large pharma companies have tried to make specific kappa antagonists. It s proven to be quite difficult, particularly given the significant homology that exists between the kappa delta and mu opioid receptors so getting a selective receptor antagonist has been difficult.

However, with ALKS 5461, what we ve done is used existing molecules to develop a functional antagonist. So ALKS 5461 starts with Buprenorphine. And Buprenorphine is a partial mu agonist on the right. And on the left, as you can see, it s a potent mu antagonist. We then add into it ALKS 33.

So ALKS 33 is our proprietary opioid modular. It s a mu antagonist and it s co-formulated in a single sublingual tablet. And as you can see, ALKS 33 essentially cancels out or attenuates those mu agonist effects of Buprenorphine, and it renders that combination a functional kappa antagonist.

ALKS 33 is unique in being able to facilitate this combination because of its high potency, and also because it happens to be very well absorbed sublingually which is how Buprenorphine is given. So, it permits a co-formulation as a single sublingual tablet.

So we ve taken that combination sublingual tablet and we have a study underway. It s a Phase Ib study in patients with depression. We re looking primarily at safety and we expect data coming out shortly in this second half of the calendar year. We ll use that data to develop a more formal proof of concept study in the indication.

In addition to work that we re doing with the combination, the National Institute of Health has funded us with a several million dollar grant to study this combination in cocaine dependence and this program is underway as well.

So overall, when we take a look at the portfolio, there s a lot of elements here. There s a lot of programs in play. And it shows you, I think, just graphically the number and breadth of opportunities that we have as a combined organization. And we ll have the opportunity as we come together to really put that portfolio together and use our approach to come together with a succinct combined Alkermes PLC portfolio.

One thing that s not going to change as we come together as a combined company is our R&D strategy, our underlying principles which are to pursue new and innovative products based on established pharmacology, so leveraging molecules that we know how they work and understand their pharmacology. And we ll also continue to use this expertise in CNS which is becoming more and more of a singular strength of this company.

Layering on top is going to be our disciplined portfolio management in triage so it will continue to be driven by data, and will be facilitated by programs again with known pharmacology that often are a characteristic of being able to get to do a Phase I or Phase II study and very rapidly get a read-out. And then derisk our program on that basis and make an intelligent go/no-go decision prior to getting into later-stage larger development studies.

So, I want to thank you for your attention today. And I d like to hand over to Shane Cook, who will become the President of the combined organization. I d just like to say it s been a real pleasure getting to know Shane as part of this process and I m very much looking forward to working with him directly once our transaction closes. So thank you very much. Shane?

Shane Cooke ***EDT. EVP***

Thanks, Elliot, and good afternoon to everybody. It s great to see such a full room of very many familiar faces to me, and who I ve known in my time in Elan where I was the CFO for the last 10 years and I ve been responsible for the EDT business since 2007, a business that I ve grown to know and cherish. And we ve spent a lot of time within EDT working through the best strategy to grow the business and to capitalize on the many opportunities that we see that exist.

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So what I want to try and do for you in the next 20 or 30 minutes is to give you an overview of the business model that we have been adopting and transitioning really within EDT. The portfolio of assets that we have both in terms of the products that are in the portfolio, the technologies in the pipeline that we have, and as well as some of the things that we re doing on the manufacturing side that I think will be interesting in the future.

I think the interesting thing that you need to keep in your mind when you think about EDT is that it is a portfolio of products that have been built up over the last 40 years and by applying technologies to improve existing molecules that are on the market.

If you take a step back, what we re doing within the EDT business is developing and manufacturing innovative pharmaceutical products that deliver clinically meaningful benefits to patients leveraging the experience that we have for proprietary technologies. And that s a business that was started in Ireland 40 years ago.

A snapshot of that company now, you can see that over the 40 years we ve developed 36 products. And, of those products, 21 of them are still on the market and still generating revenues for EDT. There is a portfolio of products that have been on the market for 10 years, 20 years, and then there are some recently launched products that we think will fuel the future growth.

Within the business model that we have, we do not have any commercial infrastructure and so all of these products are marketed by our partners. We have a pipeline of products, 11 clinical programs, and three of those are what we would call proprietary products. We have not yet partnered them. We [have on] all of the economics. And then the remaining eight are partnered. And our interest is in terms of royalties and all of the development and commercialization will be done by our partners. And so, we re leveraged to the upside there.

On the manufacturing and development side, we have two FDA and EMA registered manufacturing facilities, one in Ireland where we have about 500 highly-skilled people that are manufacturing products for six or seven different major pharma companies and then for a number of smaller companies. And this is a business that we ve been in for many, many years.

We have a similar facility a smaller facility in Gainesville outside of Atlanta. This is a DEA-approved facility, where we manufacture Ritalin and Focalin and other products on behalf of, again, some of the major pharma companies. And, again, this is a very experienced group of people, very high compliance, and a business we think that there is a lot of leverage in given the fixed cost-base that is there.

In terms of revenues, the business generates about $280 million in revenues and about $100 million of EBITDA. And, again, we see that there s a lot of leverage in the business through growing revenues while keeping our costs in tow. And that s something that you ll see later in the presentation that we ve been very successful at doing.

Over the last 10 years, we had on average launched one new product each year. And that s important when you look at the current portfolio of products where we have 20 or 21 products. Ten of those have been launched in the last 10 years, so 10 of them have been on the market for longer than 10 years. So what tends to happen with a lot of these products is that they stay and continue to generate business and revenues for a lot longer than you might think.

So looking at the business model, where EDT has really been focused over the last number of years but has been moving more towards a proprietary model in the last five or six years is to apply proprietary technologies that we have, the NanoCrystal technology, oral-control release technologies, in order to improve existing molecules, generate new products that create meaningful benefit for patients, and then to either partner those products or to license the technologies to our partners to develop products on their behalf.

And then this business turns into generating revenues for us both from a royalty perspective and also from manufacturing. One of the big attractions for EDT in this transaction, in this deal, is it allows us to accelerate that transition from being a technology licensing company with a small ability to do proprietary products to switching that to being largely proprietary products with some small licensing. And that s something that we ve been working to do over the last number of years.

But being owned by Elan, it has proved difficult because all of the funds that come from this business are invested in Elan s biotechnology pipeline and also in supporting the debt. So, this is a very attractive deal not just for Elan and for Alkermes which obviously the market has opined on, but it s also very attractive for EDT and for the people in EDT to

become a part of the business and to accelerate the strategic implementation of the plans that we have had in place.

So looking at the portfolio approach, over the last five years or so the EDT business has generated $500 million in cash flow which as I say has gone to fund Elan s pipeline and support its debt. In the near to medium-term, we expect to see the portfolio within EDT change.

We will see some of the older products declining, but that will be more than compensated for by near-term revenue growth particularly from INVEGA SUSTENNA and AMPYRA which have been launched in the US and are going to be launched in Europe.

AMPYRA has just been approved or just received positive recommendation and is expected to be approved later this month. And XEPLION has just been approved and is now, I think, on the market in five countries in Europe. And, again, we think that those two products particularly will generate very nice growth for the EDT business.

In addition to that, we have a pipeline of products which I ve mentioned and some of which I ll go through with you in a bit more detail later on in the presentation. So, again, that will provide further revenue growth.

Another area that we see that there is potential for revenue growth is on the manufacturing side where we have excess capacity. And so, we can leverage that capacity in the fixed cost base to generate additional revenues.

So when you look at the portfolio, you can see that there are some very nice and strong growth potential coming in the next coming years and that will more than compensate for some of the mature products as they come off patent and face generic competition. And when you combine that with the very strong financial discipline in terms of the costs, you ll see margin expansion coming through into the income statement.

As I mentioned from a cost side, if you look back over the last four or five years, you ll see that the cost structure within EDT has been very stable, and that against a background of increasing costs, particularly in Europe. And what we have been able to do is to try and develop a pipeline of products with limited investment and to focus on providing a very high quality manufacturing product to our customers. And that is something that is obvious from looking back over the last number of years.

One of the areas of opportunity from this merger is that as we change our model away from being more of a licensing technology model to more of a proprietary product model, the resources that we need are different. And so, we see a very large opportunity there to leverage on the infrastructure that Alkermes has in place and the clinical development expertise and that Alkermes has in place.

And so, we re able to reduce some of the resources that we have in the earlier formulation and CMC space. And that we think will drive about $20 million in synergies out of this merger. And if you look at that as a percentage of the SG&A and R&D spend that we have in EDT, it s about 20% or 25% reduction. So, again, this is something that we re quite focused on and will largely come about from site consolidation.

So what I m going to do is touch on the products themselves, so we re going to have a couple of products that I mentioned from near-term growth in terms of INVEGA SUSTENNA and AMPYRA. Then, I ll look at the portfolio maturing products together which will be declining, and just to give you some flavor for what s in that portfolio. And I m going to touch on some of the manufacturing revenues, before I touch on the pipeline in a bit more detail as well.

So AMPYRA and Rich has spoke about AMPYRA already. And AMPYRA is indicated for improving walking in MS patients. And this is a big issue for most MS patients. It becomes an issue fairly shortly after diagnosis. And AMPYRA has shown itself to be effective right across the range of disease, so from early stage through to late stage. It is a key focus for Acorda. It is their main product, and they are marketing the product in the US with Biogen Idec marketing the product outside of the US. And obviously, Biogen Idec has a great strength in the MS market and I think they will do a great job. It was launched in the US in March of 2010 and is currently, after only 15 months or so on the market, is on a run rate of about $200 million which is something that I think Acorda should be extremely proud of.

Despite an initial decline in terms of approval in Europe, Acorda and Biogen together were able to turn that around and have received a positive recommendation for approval and we expect that approval to then come through later this month. And it s also been approved in Australia. Importantly, as Rich mentioned, this product has a long patent life, 2026 and 2025 in Europe. And so, we believe it will have a long life and will generate revenues for us for many years to come.

Again, our share of the economics on this are 18% in terms of royalties. We manufacture the product in our factory in Athlone. And analyst expectations are that this could be a $500 million to $700 million drug. We re working with

Acorda on expanding out the franchise through improving the existing product, and that s something that we re very keen to do.

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The next product, INVEGA SUSTENNA and XEPLION which it s branded under in Europe. And this is a long-acting injectable antipsychotic for schizophrenia. And it s the first depot NanoCrystal product to come to the market, something that we re very excited about. It really complements RISPERDAL CONSTA which is a twice weekly product.

The economics that we receive on this product are very similar on a net basis to the economics that are received on RISPERDAL CONSTA. Interestingly as well, J&J or Johnson & Johnson are working on a three-month depot. It s in Phase I. And we also, because it s a NanoCrystal formulation, we got similar economics on that.

So it s a very attractive business for us to have and a share of the economics from J&J s long-acting injectable products. And it s not just RISPERDAL CONSTA, but it s the one-month and potentially the three-month of INVEGA. So this is a very important franchise. And when you take all of these products together, and the actual depot market is expanding about 14%, 15% per annum, and that s a very attractive business for us to be involved in.

If you look at the mature products, many of you who know me from Elan and EDT, will have heard me say that this portfolio is transitioning from some of the older products to the newer growth products. And that s what s evidenced from this slide, where you will have seen mature products have declined from about $238 million to $186 million since 2011.

But that has been replaced by the launch and the growth in AMPYRA and INVEGA in particular. There are around 20 products that are included in that portfolio. The $187 million is about 40% or so of the pro forma combined revenues of Alkermes PLC. And we think that over the coming years, and I ll bring you through some of those products, that that will decline to probably somewhere around $80 million, which will, at that time, be probably 10% to 15% of the revenues of the combined business over the next in five years time.

These products are all at a different stage in their lifecycle, and some have had Paragraph IV certifications against when the ANDA is filed, and they are products that we will watch very closely.

Looking at the makeup of those products, again, this is the way the industry works. There is a number of products that we ve received Paragraph IV litigation are in Paragraph IV litigation, ANDAs have been filed. Some have been settled, and some have not been settled, and we continue to litigate.

And but again, from our experience, if you look at this portfolio, I think that in five years time, we ll still be generating $80 million plus in revenues from this portfolio. And if you put that in the context of the costs of running our two factories, and that s about $80 million. So again, these will be while declining, will still be a meaningful source of revenues for the future, and a good way to cover some of our fixed cost base.

And talking about our fixed cost base, our two factories have got capacity available to put more products through. And this has been an area that, over the years, we have, on an ad hoc basis, looked to bring additional business in with some success. We have products manufactured for Lilly, and for Pfizer, and Merck, Novartis, and many other of the big pharma companies.

About a year ago, we decided to put a more focused effort on this, and we appointed a vice president of sales to go out and actually market this capacity. And we ve seen some very good results from that and have signed up a number of contracts, one of which has been signed up in the last few weeks with a major pharma on an existing marketed product that should generate $15 million to $20 million per annum in revenues, once we get the product transferred into the facility in Athlone.

So, again, we think that this is a way to generate additional EBITDA and profits from the cost base that we have in place, leveraging the capacity that we have.

So maybe just finishing up on the pipeline. So the pipeline, as I mentioned, is a mixture of products that we haven t partnered yet, and those that we have, and all of these would incorporate our technologies. And I ll go through a couple of these in a bit more detail, but just to maybe highlight a couple.

MEGACE, in Europe. MEGACE is a product that is on the market in the US for cachexia and weight loss and does about $70 million a year. It s marketed by Strativa. We have the rights in Europe, and so we ve filed in Europe for this. We think it could be a $50 million-ish product. We own all of the rights, and an approval could come by the end of next year. It s not a big product, but it s, I think, one that we think could be interesting.

And then, I think, again, you ll see that the three-month INVEGA SUSTENNA, XEPLION, is something that we think could be very attractive, and is something that, I think, J&J said could be filed sometime before 2015.

Maybe a little bit more detail on one of the proprietary products that have, Meloxicam IV. This is indicated for acute pain. This is a it s a NanoCrystal formulation. And what we re targeting here is to get a very fast onset of action, which we ve seen 10 minutes with a peak analgesic effect within 40 minutes. We re looking to get 24-hour coverage. The idea being to potentially have opioid-sparing.

And this could be a very attractive market, as Elliot referred to, with the constipation issue. So, if we can do that from another direction, I think this could be very interesting. There are 70 million surgical procedures in the US, and really the standard of care is opioid. So we think there could be a very interesting place for Meloxicam IV, and, again, it could be hundreds of millions of dollars in the market s potential, given some of the research that we have done.

Another product in the pain area, which is partnered Zohydro. And this is an oral controlled-release hydrocodone. It could be the only single-agent hydrocodone product, and it incorporates the SODAS Elan s SODAS technology. And, again, this would address some of the safety issues concerned with using the existing combination products with hydrocodone.

We licensed the product after a Phase II. So we brought the product through Phase II within EDT and proof of concept, licensed to Zogenix, which is a small, listed company in San Diego, who are focusing on pain. And should the product get approved, we will market this or we would manufacture the product in our facility in Gainesville. And our share of the economics is in the double digit percentage range if you include manufacturing and royalties. And it s patented out to 2019. And Zogenix are expecting the results in the Phase III by the end of this year, with the filing in the first quarter first half of next year. So, again, this is for chronic pain, and I think could be an interesting opportunity for us and again is in the CNS space, which I think is something that I think is neat.

So to conclude, we are, within EDT the managers of EDT are very excited about this merger. I think that when you look everybody that I ve spoken to who looks at this says, why wasn t this thought about before? It s so obvious. And when you put the two businesses together, it makes strategic sense. It makes financial sense. It creates a really interesting, diversified pharma company, biopharma company, with a pipeline and the ability to continuously generate new products within that pipeline.

And we re very excited to get the transaction closed, and to really get going on this. And I think the portfolio approach that we have, both within EDT and in Alkermes, is what will lead to sustainable high margins, and in a business that s growing.

So with that, I will finish up, and I m going to had the presentation over to Jim, and make sure that he has a pointer to start here.

Jim Frates ***Alkermes Inc. CFO***

Thank you, Shane. Good afternoon, everyone. Appreciate your coming out this afternoon. And I think Shane s correct. One of the words I ve heard most about this transaction is how transformative it is. And I think nowhere is it as transformative as on our product and loss statement, our income statement. So what I want to do is take you through a little bit of that, to allow you to go back to your offices and really do a model because we ve been living with this transaction for the last seven months.

We ve run dozens of scenarios, upside and downside cases, through the revenue, through the expense side. And we need to make sure that you can do that as well. So we have a little bit of time left, and I did bring the 426 page S4 and I just thought we d take the next three hours to run through that page by page and I ll give you a little background on that.

No, we ll put that down and I will stay at a higher level, but really want to go through line by line. On the revenue side, you re going to have to think about a number of major products. And most of us focus on the big five, but there s also a new pipeline that you re going to have to

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consider, as Shane and Elliot talked about, and there s also that mature revenue stream from EDT. So you want to make sure, and as we model it, these are the lines we have on our revenue side.

On the expenses, it s obvious you re going to have to think about costs of goods sold, R&D, SG&A. But there s going to be a fourth new line, or new line on the model and that s the amortization of intangibles. So this is the old FAS 144R, the new ASC 805-10, the purchase price accounting essentially for the EDT acquisition. So at a point in time, and it s going to be non-cash, but that s going to affect our P&L for some time. So we ll talk about that as well.

Obviously, we re borrowing $450 million to finance this transaction, so interest expense and interest income because we have over $200 million in cash. So that s going to be an important line on your model. We have the tax line. Rich touched on it a little bit. I ll talk about it a little bit more. And it s not as simple as looking at a blended tax rate. You really do have to model the Company as a US business and an international business. So, give you some guidance on that.

And that s how we get to GAAP earnings, obviously. But we ve been talking about adjusted EBITDA because there s a lot of non-cash items in that P&L, particularly the amortization, the purchase price accounting, our share-based compensation, and, of course, some one-off items associated with the expenses of the transaction.

The other thing that s important to note, we ve been talking about pro forma a lot; pro forma fiscal 12, pro forma fiscal 11. Obviously, historically, the businesses weren t together, but depending on when the deal closes, and we expect it to close in September at this stage, you re going to have a stub period of the old Alkermes for the first part of our fiscal year, and then the combined businesses from the closing date on forward in fiscal year 12.

So our actual GAAP results for fiscal 12 are going to be very different from the pro forma results we ve talked about. So we try and be careful with that and we ll keep track of that, hopefully, as we go.

So the next element down, what s so transformative about this transaction? And one of the things beyond revenue growth, beyond the growth of these products, beyond these product launches, is our ability to expand our margins.

And Shane touched on that a little bit. We can grow revenues faster than we can grow expenses. A lot of that has to do with the product launches that are occurring, has to do with the business structure that we have, our tax rate, and we ll touch on a lot of those.

Now this is not new guidance. This is the guidance you saw back in May when we announced the transaction. We ve reiterated it today. Single digit growth, again, pro forma fiscal year 12 with adjusted EBITDA margins in that 15% to 20% range. It s essentially where they were in fiscal year 11.

And we think with the product launches, our target is to get double digit revenue growth, in 13 and beyond and adjusted EBITDA margins in the 30% to 35% range. Clearly, that s transforming the old Alkermes business, and we re very excited about PLC.

Now, also have put in here fiscal year 2015. So as we go forward, I m going to talk about each of the revenue lines in turn, but I want to focus you, not just on 10 and 11. And for each of the major five products we have a chart that looks like this, slide 74, where on the left-hand side there s some details about the products, new news, how the products have been doing historically.

And then on the right, just a sense of where the estimates are from the Street about each of these major products, out in 2015, all the way to the right. So you ll see the points are actuals. 2010, 2011 again March fiscal year, pro forma in this case because we re combining SUSTENNA and CONSTA in this franchise, and then we re going to move you out and focus you on 15.

Not particularly for guidance purposes, because we don t guide that far, but this again is where the Street analysts are and where I think each of you have to delve in and do the work and obviously make your own decisions about each of the products. But it gives you a guide about what people are thinking. And this is really some of the bases of the base cases that we did because as we did a lot of modeling around the business, obviously this is where we started.

So let s touch on this combined franchise of INVEGA SUSTENNA and RISPERDAL CONSTA. Again, it s one known by many of you. Importantly, from an economic perspective, the royalties that we receive, pure royalty in the case of INVEGA SUSTENNA and XEPLION and a manufacturing royalty of around 10% that nets out to around 7.5. So those are both very similar for Alkermes PLC going forward. And so, we re very excited about being part of both of these franchises moving forward. Shane also touched about the recent news and launches around the world for INVEGA SUSTENNA, so that s very exciting for us. We think this is a growth franchise again.

But I want to just touch on the US results, because this is where people have been so focused for the last couple of years, and these are actual numbers going back three years and just in the US now. And I ll remind you that in August, September of fiscal year 10 was when INVEGA SUSTENNA was launched. But if you look back historically, I think it s very clear to see this is a growth franchise, again, for Alkermes.

And as we launch around the world, that growth rate from relatively low penetration areas, for the overall atypical antipsychotics is something that gets us very excited as the real core of our business. That s why, I think, as Elliot touched on, we re so excited about 9070, our own proprietary long-acting ABILIFY, because we thing this market has a lot of room to grow.

So let s turn to VIVITROL, again, very important information on the left-hand side, 35% unit growth, fiscal year to fiscal year. We just announced this afternoon pre-announced really, the Q1 number, $9.7 million in net sales for VIVITROL in the United States, a number we re excited about. That represents 14% growth compared to the March quarter. And just points you to, also, the long patent life, which is something consistent across these five key products as we grow.

And then to the right, we see again, the approval for opioid indication, very new and important indication. And again, moving out now four years, same convention, 2015, we see the range of analyst estimates. Now, the bottom end of that range is actually a lower growth rate than we just showed in the last quarter, if we just manifest that out over the next few years.

And so, it s a range where we think as we do our modeling I ll show you now a graph of our internal models that s modeling done on 43% to 70% annual growth rates. Okay? If you annualize our last quarter 14%, lo and behold, you get 56%. That happens to be the average of 43% and 70%. So, you can see what we re doing. We re just doing math. And no one would expect linear growth in any new launching product for four years. But the message here really is that we re very excited about this indication for VIVITROL and I think it s worth looking at the opioid indication again. And we can t predict when that inflection point is going to come, but we re certainly working hard. And as Elliot talked about, continuing to invest in the business to hopefully deliver on that inflection point.

Just another look at a slide that some of you have seen before and one of the reasons why we re excited about the upside for VIVITROL. Given its long patent life into 2029, we have the time to launch this product appropriately. But there s 900,000 prescriptions for opioid dependence in the United States. This is a real market. It s over $1 billion in sales and commerce that s going on for the treatment of opioid dependence. I m not sure too many people are satisfied with the outcomes of that treatment broadly from a public health perspective, so there is an opportunity for VIVITROL.

And as you see in the middle of that grid, which is really, just looking at duration of therapy on one axis, and the amount of sales on the other we re targeting roughly 40,000 patients to get us to those potential goals that we model. So as we model this a lot of different ways, and look at whether those models make sense, 40,000 patients in the backdrop of 900,000 patients makes us feel comfortable that there s a market worth investing in here. And certainly, our clinical data has us believing that it s certainly a market that it s worth investing, from a human perspective, in these patients, and giving them additional treatment alternatives.

So let s turn to AMPYRA, another very exciting product, also in the very early stages of its launch phase. And let s just touch on, briefly, what s happened since we announced the transaction. That is we ve have gotten new word on a US patent that s been allowed, that will take the product out to 2026. That s a new piece of news since May 9th. The other new piece of news is, as Shane mentioned, the positive recommendation from the CHMP in Europe.

So this is a very important product for us. I won t go into further detail because Shane talked about it earlier, but that 18% royalty, combined with the royalty of manufacturer revenues for us, is something that we re very excited about. And again, analyst estimates there out in 2015, four years beyond 2011, gives us a lot of confidence that this can be an

important product for us.

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And then finally, in our major keystone products, BYDUREON entering the commercial phase. I m very pleased to be able to report that last week we had the launch in the UK. I m sure you know about that. And we ve earned our $7 million milestone and will earn our 8% royalty now going forward on each vial sold around the world. So for Alkermes now, it s the culmination of a lot of work on BYDUREON.

We re looking forward, obviously, to good news in the United States as well. The QT study results were obviously very important for us but, a new phase. So now you have to model it in our revenue line for BYDUREON. And again, it s for you to decide. And I look around the room and I see lots of differing opinions on some are above that line, some are below that bar, out in 2015. But for us, wherever the bar is, obviously from a portfolio perspective it becomes very, very important for us.

I just want to touch on why we re excited about BYDUREON, again, from a financial perspective. There is a very large market for the treatment of diabetes. And again, I think from a public health perspective, if you take a step back, I m not sure too many people are satisfied with the treatment options that we have for patients at this stage because it s still a progressive disease, and causes a lot of excess suffering and cost for the healthcare system.

Today, you see the GLPs at only 3% of the overall market, so a lot of room to grow, and a lot of excitement about the potential class. We also see that the daily entry into the market, in only its second year, is predicted to be over $1 billion in sales. So we re quite excited to imagine what a weekly form of GLP can do in this market, because we believe that there s a lot of growth to come.

Okay, so the five key products, summarized here are really as we look at INVEGA, SUSTENNA and RISPERDAL CONSTA, counts to almost as one, in our franchise as we model it, are clearly going to show growth out through 2015. And again not meant to be projections, there s various scenarios you could run, and I know each of you will do that.

But as we go out to 2015, you also have to look at new products coming on. And this is the stable of late stage opportunities that we have, both from EDT and from Alkermes, including the manufacturing deals that Shane touched on. So again, 2014, 2015 and beyond, you re going to have to have a line for new products, things that aren t generating revenue today.

Beyond that, in gray, you re going to have to have an estimate for the legacy products. And, as Shane has talked about, I don t believe we have heroic assumptions about what needs to happen and be delivered from the legacy products. But they re going to be an important contributor. And the other key thing is, as you build the different scenarios, I think you ll find and it s very important to go and view scenarios for each of the lines here on our revenue side I think you ll find that you can understand then how we feel very confident that double digit growth is a real potential from 2013 and forward.

So let s just touch on that a little bit more. This is a slide 82 is a shot of our current, again, pro forma fiscal year 11 now, looking in the rearview mirror, about what the mix of revenues are. But as you go forward, you ll learn, revenues are going to grow, and whether you think the CONSTA-SUSTENNA-XEPLION franchise is going to be the lion s share and grow quickly, whether people think that AMPYRA is going to grow, whether you think it can be BYDUREON, or whether you think it s going to be VIVITROL.

And I know as I look around, as I said earlier, there are people who have these kind of representations for each of the products, and there s debate in the room about which ones are going to grow, but what is very clear for us is that together we re going to be able to deliver a very, very attractive top line growth and an opportunity to continue to invest in the pipeline.

So let s now turn to our operating expenses, and touch on each of the cash operating expenses, as you would, going forward. So what we like about this business is it gives us a lot of levers. And it s also very important that you don t simply take each line and relate it to the total overall revenue line because there are different drivers in here. So let s go through and talk about that a little bit.

First of all for COGS. Again, people talk obviously as a place to start people talk about margins. The important thing for our business though is that two of our key revenue drivers, BYDUREON, and INVEGA SUSTENNA are pure royalties. So as they become more mature in the launch phase for SUSTENNA launching around the world, and for

BYDUREON, not really just launched, not yet reported in any of our quarters, that s going to be pure top line revenue, without any expenses associated with them.

So that s a key opportunity for margin expansion, and you simply can t key your COGS line off your revenue line. It s going to have to be one level down of complexity there.

The other thing is that Shane touched on, we actually have a lot of built capacity for AMPYRA and for VIVITROL. So as those sales continue to increase, we re actually going to see margin expansion in those areas. And again, another thing that gets us to the idea of expanding our EBITDA margins so that s COGS.

SG&A, you saw a little bit of and those financials for EDT are actually broken out for historical years, not only in our S4 now, it s filed, but also in the old Elan financial statements, and you see an Alkermes G&A expense. And I think we ve done a very thorough job of modeling that G&A. I think we re controlled, and we re going to grow that at essentially the rate of inflation, if you just look on the G&A side. We don t actually have our offices here with waterfront views. We just rent these for the afternoon, and we go back to Waltham at much lower rents.

On the S side, the sales side is going to be entirely related, really, to the VIVITROL growth, and VIVITROL profits. So as we grow the S line it s going to be because VIVITROL is growing, and not vice versa. And we ll be able to control that, again, and so the way we think about it internally, is really bucketing the S side of things to the VIVITROL growth side.

And then there s going to be potential in out years too, to talk about selling our own products that s one of the key attributes of this deal but that ll be very key, and again, to certain lines of revenue. But I don t think you can just say, Oh, SG&A, industry-wide, average, boom, that s what we re going to apply to the new Alkermes because of the nuanced revenue lines that we have.

And then, finally R&D. This is really our major lever of control, and one where we think we have substantial resources. If you look at the right-hand side, now these are the historical Alkermes and EDT, kind of pro forma and R&D spend, going back historically, and you can see that neither company has been profligate spenders on the R&D side.

I think we invest wisely. We ve had a very good track record of success, both in developing products that ultimately get to approval, but also in paring back on products that aren t making it forward. And so again, in the margin range, if you look at growing revenues, you can look at an R&D budget that s in the $160 million to $180 million range in the out years, that gives us sufficient funds to push our pipeline forward.

We re going to be very focused on developing those products that are moving forward. We re going to be selective in what we move forward. It s been described as a jump ball, putting our best programs together and investing in them, and we think we ll have the opportunity to do that.

Another part of the expense control, as it were, is I think we see the opportunity to really take advantage of pharmaceutical partnerships. One of the things that is unique about this era, is that the pipeline cupboards of many of the large pharma companies, and even many of the medium sized biotech companies, large sized biotech companies, are in need of new and growing products. So we think it s a good time to be a seller of these assets to larger companies. And we think we can manage that portfolio to our benefit.

And I think we re quite proud of our track record at Alkermes, and clearly the track record at EDT can show you that these partnerships can be done and done effectively. And again, they give us an outlet to develop more products than perhaps we could of our own P&L, and do it in a way that can lead to expanding margins.

So now let s talk about the other, the new fourth line as it were, in the Alkermes P&L, and that s the modeling of the amortization of intangible assets. So again, back to merger accounting, if you look on the left-hand side here, we re going to have to take the purchase price, and allocate that across our P&L.

The purchase price, because we re using some shares, is only going to be decided it s going to be the closing price on whatever day we close, September 5th, September 20th, whatever, whenever the shareholder vote is. And as I say that s on track for September, but we ll determine that.

And then we re going to have to allocate that, some to the balance sheet. Net balance sheet assets, this is the property and equipment, the inventory that s coming over, that s going to be roughly $300 million. Down at the bottom we also have goodwill, which is the patents and the brand name and things like that, that s roughly going to be $90 million to $100 million.

And the remaining $600 million or $700 million and this is a good thing because this is all done by external experts, we don t really have a choice in it anymore, in the new accounting rules. So we ve hired Duff and Phelps and our

auditors PWC have reviewed all the financial models, and what s nice is that much of the value that we re paying is related to the hard assets, the physical assets of the plant, the fair value and the fair value of the royalty streams from the approved products that Elan has in its work.

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So we re going to have an anticipated annual amortization charge of $45 million for the full year first full year, pro forma 12 as it were, moving up to probably in the $80 million to $85 million dollar range, again as those sales increase, because they re related to the sales, and then no more is the straight line, okay you have $700 million. It s 10 years so you get $70 million. It s going to grow over time with the sales and then decrease over time with the sales. And we ll give you more specific guidance on that now, but that s something that we wanted to make sure you understood as you start to build your models.

I will remind you, this is all non-cash. It s essentially a way that the accounting profession takes a snapshot of what we paid for the business on September X when we close. But now we re going to be saddled with that for the next 10 or 15 years, running that point in time estimate through the balance sheet through the income statement, excuse me.

So that s one of the reasons why we ve been talking about adjusted EBITDA. It s very important, we think, to get to a cash number, an operating number that you can look at, quarter to quarter, that isn t saddled with one-time decisions that have been made in the past. And other companies that do acquisitions do this as well. So that s why we re going to talk about adjusted EBITDA.

For those of you who want to see our definitions, and broader definitions, there s a lexicon sheet at the end of my presentation in your charts that takes you through the specific definitions there. So that s our operating expense above the line.

Interest income, this is actually, I think, an exciting part of the financial aspect of this transaction for us because we ve been able to purchase this asset using $450 million of debt that we ve circled. It s pending a close of the close of the transaction, but our book has been distributed, and we have the deal terms in place. And I think they re quite favorable in this market environment.

First, we have a bank loan which has no penalties to pre-pay, and has no quarterly maintenance covenants, which we think is important for our flexibility as we run our biotech company here. It s also with a floating rate note, a floating rate interest rate, excuse me of 7.6%, and 1% principal amortization a year, so it s and six and seven-year terms so, again, it gives us the flexibility to get the business together, and we think, with the cash flows that the business can generate.

And as part of the loan we re committed to using 50% of our excess cash flow. So again, an important part of the model make sure you have your interest rate there for the debt, which will be there at close, but also that you have a small calculator that takes any excess cash flow you have, and we ll be paying that debt off as we go.

Again, we re obligated to pay 50% of the free cash flow each year, but we re interested in using more because we ll still have $220 million, roughly, of cash at the end of this transaction. So quite a bit lower net debt number, and again, we wanted to be able to have the flexibility to finance this company appropriately over the long term.

Once the company is together and as I ve been told many times the debt world looks in the rearview mirror I do think that if we can deliver on these growing cash flows, that it makes sense to have a layer of permanent debt on. But we ll be able to look at that with a bit more time once this acquisition financing is in place. So we re very excited about the debt terms for the transaction.

Finally, taxes. Before we get to our adjusted EBITDA, we have to understand the tax rate. And again, a lot of questions have come in about our estimates for future tax rates. And we ve stayed at a relatively high level because it s appropriate to do so this early in the transaction, I believe. But one thing we do have to go one level down we really have to start looking at this, again as a US operating business and as a European operating business, because we ll have different tax rates and expense structures with both.

So the US tax rate will apply to US income. At this stage that s generally driven by, mainly driven by RISPERDAL, CONSTA and VIVITROL. We re also borrowing in the United States, so we ll have our interest costs in the United States, and the expenses of R&D that we have here, that s owned by the US subsidiary. We have some NOLs, roughly $80 million after the BYDUREON transfer that will continue to reside in the US. We might have some state taxes that we have to deal with as well, so again, that s the US side of the business.

On the Irish side, we ll have the profits associated with the EDT revenues and royalties, AMPYRA, INVEGA SUSTENNA, now BYDUREON as well, because we ve transferred, or will transfer at close. But that transfer has been

set in place in an announcement, as you know, and that standard tax rate is 12.5%.

So, we ll give you more guidance as we go, but our high level guidance is do the math on each of the different businesses and you get to a blended rate of roughly 20% and then obviously we ll do our best to give you better guidance as we go and as each of the products gets more experience behind it we ll know more about the revenues and the tax rates there.

So in closing, we re quite pleased with the business and the levers that the business allows us. We ve got a diverse portfolio driving the top line. We re very excited not to have single product risk in delivering on these top lines. And beyond the portfolio of key assets, there s also parts of the business, as Shane talked about, the 19 legacy products, and the new products coming on from the pipeline and later stage products that are going to drive our top line.

We have the ability to invest quite substantially in a pipeline that we think is quite exciting, and we have the ability to invest on our own and also to invest together with partners. And so it s very important to us, too, to have future growth because that s one of the businesses. And we think we have an engine that can generate future growth going forward.

And finally, both of those things, as well as the corporate structure and the launches of the products, drive us to expanding EBITDA margins. And we re quite excited as a management team to be able to deliver on the growth that is provided with this business and be judged by our financial performance over time as we go.

You know, my dad used to quote this Archimedes to me a long time. It was said that years ago, thousands of years ago he said, Give me a lever long enough and a place to stand on and I can move the earth. This business gives us a lot of levers as a management team to control, from the top line, on the bottom line and I think that s why we re excited to come together and to deliver financially for you in the years to come.

So with that I ll close. Appreciate your attention. We have just a little last segment. I promise I won t go through the S4, a little last segment of questions. I m going to invite Elliot, Shane and Richard to come up and if you just give us a moment to set up we ll get going with questions.

QUESTION AND ANSWER

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

Okay. Is everybody miced up?

Unidentified Company Representative

I think so.

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

Okay, good. So I ll emcee this. There are some mikes that are moving around. We re webcasting right now so if you would holler for a mike, Cory wants one, and then the people on the web can hear the question.

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Cory Kasimov ***JPMorgan Analyst***

Is this on? Okay, thanks. Cory Kasimov, JPMorgan, two questions for you, one related to the merger and one on the pipeline. As far as the merger is concerned, is there anything you can say about progress being made with the SEC and whether or not you ve passed HSR yet?

And then the pipeline question is on 9070, and if you could maybe talk a little bit about the business development strategy with that asset and how far you want to go on your own?

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

Well, I ll kick it off. I ll give you the update on the SEC and HSR, and it s good news on both fronts actually. We learned just recently that SEC will not be reviewing the S4 so it s all systems go now for us. We ll go effective after we file the Q, which we expect to do at the beginning of August. So we re on track for the shareholder mailing and then the vote in September as Jim was referring to.

HSR we passed the notification period and we have no HSR issues as well. So that s good news for us. 9070, I hope you all realize that the data that Elliot showed was we ve never shown that before. In fact, there are a lot of pharmaceutical companies who have been anxious to see those PK profiles on 9070.

So what you saw was exactly what we had hoped to see, which was the dose proportionality, the tolerability and the once monthly dosing that we can then model at steady state. Our plan is to be able to commercialize 9070 ourselves in the US, if that makes the most sense. We can really follow in the footsteps of RISPERDAL CONSTA and of VIVITROL, which is another product that s a largely it was a big Medicaid component. State buyers are important. Reimbursement is complicated, especially injectable.

Outside the US where you ll recall over 2/3 of the sales of CONSTA come from, we expect a partner, and we ve already been approached by pharmaceutical companies on the 9070 opportunity. But the important thing is, unlike other partnering stories you hear from younger companies, we re not [rate] limited by the need for a partnership. We are hammering along this now on our own timeline. That s why we re going to start the pivotal program.

In this indication it was pretty clear what one needs to do to gain approval. Other long-acting atypical injectables have been approved, so we re going to go as hard as we can. And we ll partner when it makes the most sense.

Thanks, Cory. Kim, you can go ahead and give him the mike for the second one.

Ami Fadia ***UBS Analyst***

Hi, thank you. This is Ami Fadia from UBS. One question on ALKS 37, how do you plan to develop this product beyond the dose-ranging study and longer term do you intend to partner it or try to market it on your own?

And just to follow up on the 9070, if you had to continue to develop it on your own, how big a Phase III study would you have to do and would it be one or two studies? Thanks.

Richard Pops ***Alkermes Inc.*** ***Chairman, President, CEO***
Great. Elliot can chime in and I ll start. 37 is a product that is an oral compound for the treatment of opioid-induced constipation, as you know. The commercial footprint for 37 is bigger than a 9070 would be because 9070 is going to be focused in the community mental health center where and the limited number of physicians who prescribe long-acting atypical (inaudible).
We can see a commercial partnership around 37 which would provide a GP wraparound to a specialty force that we might not. But we re pretty flexible on how we would approach that. [OUS] we see partnering. We don t see necessarily at this moment building commercial infrastructure in all countries to be able to sell ALKS 37.
9070, our guidance that we ve given you for this year in the R&D spend presupposes success in this clinical trial and that we would be starting the pivotal program sometime in the fiscal year. We ll meet with FDA and outside the US regulatory authorities to completely round out the program. So I can t really give you an answer yet, but our annual guidance accounts for our running the Phase III ourselves and it will next year as well if we haven t partnered by then. He s got the mike and there s a request for a mike up here.
Terence Flynn ***Goldman Sachs*** ***Analyst***
Thanks. Terence Flynn, Goldman, two questions. The first on VIVITROL. I know you gave some details on patient penetration model here. And you assumed a duration of treatment of three to nine months. Can you just tell us what that s based on? Then number two, where is the product currently tracking out there in the market?
And second question on ALKS 37, I think you guys have previously talked about going into a Phase III following the first Phase II trial you did, but I noticed today you re talking about a Phase IIb. Maybe just what additional questions you re looking to answer with these new doses you re exploring that you didn t learn from the first Phase II study that you did? Thanks a lot.
Richard Pops ***Alkermes Inc.*** ***Chairman, President, CEO***
Okay. Why don t I start with the second one first and then maybe you ll get tired of hearing from me and we ll let somebody else say something. The I m sorry. I forgot the question. Honest to God. I just I was thinking about the first one and the second one went. So the 37 one was
Unidentified Company Representative
37 why are we doing a Phase IIb (inaudible multiple speakers).

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Richard Pops ***Alkermes Inc. Chairman, President, CEO***

So Terrence, we had made the point about the IIb several weeks ago when we first met with FDA. So the big change is we actually went down to FDA, showed them the data, laid out the plan, and FDA suggested this definitive IIb study to fully elaborate the doses.

So you ll notice we re testing a higher dose at 150 to get the back end of the curve figured out, and we ve jettisoned the lower doses so it s 25 to 150. And as soon as we re done with that study we ll we plan on launching the two parallel Phase III studies next year.

And on VIVITROL, a lot of what Jim showed you was math. That was simply saying if you take our current persistency in alcohol, which is low, it s only two or three months, we know from the opioid market already that there s an instinct towards longer periods of use of VIVITROL, but we ll see what it turns out to be.

It just made the point with fairly modest number of patients with fairly modest assumptions about duration. We drive those numbers. So it s really just a sensitivity exercise more than anything.

Terence Flynn ***Goldman Sachs Analyst***

(Inaudible microphone inaccessible).

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

The question was are we seeing durations longer than [alcohol]? It s too early to say right now because we ve just really been in the indication for a short period of time. That s our hope and our expectation but we don t have data yet.

David Pearl ***Epoch Investment Partners Analyst***

David Pearl, Epoch Investment Partners, just thinking about the merger, EDT has quite a bit of manufacturing capacity. What s the utilization and how do you look at the synergies as far as moving a product over, personnel, after this merger because there should be a lot of operating leverage with the combination?

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

Yes, Shane, you want to?

Shane Cooke ***EDT. EVP***

Sure. I think you ve got to look at the manufacturing capabilities of the two businesses are different. And because Alkermes has injectables. We have [solid] oral dosages so there s not going to be much synergy from that perspective. I think where we see that there is and this is something that we ve been working on before this transaction, is that with the fixed cost base that we have place and the revenues that we re generating from manufacturing are it s a very profitable business but we could probably do two or three or four times as much volume through the same with the same cost base.

So what we ve been doing is actively going out and working with the industry to collaborate with some of the pharma companies around bringing capacity into both Athlone and in Gainesville. And as I said, we ve successfully signed up three or four contracts now, one of which has been pretty significant for us and then which is in the process of being transferred into Athlone now and will generate somewhere around $15 million or $20 million in revenues per annum in two or three years time, which is pretty significant in the context of the size of that operation.

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

It s remarkable. When you look at EDT and Alkermes, Alkermes manufacturing in Wilmington, Ohio is incredibly specialized, these aseptic manufacturing processes for these polymeric microspheres for injection. As a result, the principal customer for our manufacturing has been J&J and ourselves.

Contrast that at EDT where EDT has a very, very broad and excellent reputation in big pharma. And so when Shane made the decision to dial up the contract business within EDT it was off of a platform of a lot of notoriety, experience and reputation in big pharma, which I think they can continue to leverage.

Steve Byrne ***Bank of America-Merrill Lynch Analyst***

Steve Byrne, BofA, with respect to the states being increasingly squeezed on their budgets, do you think that potentially could help you with overcrowded jails and the costs thereof? Or might it hurt you if states start to trim out their drug court budgets?

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

So the answer to the question is yes. So it s a really interesting dynamic. It s not so much focused, Steve, on the drug court itself, but the basic phenomenon of states being squeezed in terms of their ability to spend.

We ve had state directors tell us, I can t afford to save money. Even if I know that if I purchase VIVITROL based on the data, we ll save money over time, but I don t have line item latitude to be able to purchase the pharmaceutical product. In those cases, we re inserting ourselves from a policy point of view to help that process along.

But one thing that s clear is that as states and the federal government, A, get more cash-strapped, and B, start focusing more and more on long-term outcomes as opposed to just a spot pharmacy cost, not just VIVITROL but BYDUREON, CONSTA, SUSTENNA, 9070, these long-term type of chronic diseases where we re driving pharmacoeconomic outcomes, become really relevant.

So our job in the states, I think, is if you think about it this way. In the targeted states where we re doing the most work, which you re aware of, generate an incontrovertible data about the value of using VIVITROL. And we believe that other states are going to fall like dominoes, because the data becomes pretty self-evident. The paper that Elliot showed in Michigan and Missouri, 97% reduction of recidivism rates or re-arrest rates, that s a criminal justice-type outcome, but also translates into dollars. And we re hearing a lot of feedback from that from the states.

Final Transcript

Jul 18, 2011 / 07:00PM GMT, ALKS Alkermes Inc Analyst and Investor Day

Steve Byrne ***Bank of America-Merrill Lynch Analyst***

And if I may, how do you justify spending on new novel targets like the ALKS 33 or the 5461 when you have this portfolio of technologies to pursue already demonstrated pharmacotherapies? Why invest in the new novel targets rather than double down on the alternative?

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

I m glad you asked the question because it brings the point that for neither ALKS 33 nor some of the other things where even the product that we re showing for treatment-resistant depression, we re not really in the game of novel targets. 33 derives from a deep literature with respect to opioid receptor antagonism. And the advance of 33, of course, was a different metabolic profile and a different potency as well.

So our game, what we re most interested in is not going after novel targets. We ll go after novel molecules because they have NCE protection and we can engineer in novel attributes to those molecules. But we ve been reluctant to go after de novo targets at all.

Now, as the Company gets bigger and the portfolio continues to be bigger, we ll have the ability to at both ends of the spectrum to dabble a little bit more or less in these types of things. But right now we feel like we can make significant improvements in medicines by going after pharmacology that s pretty well-established.

Jim Frates ***Alkermes Inc. CFO***

I d also say, too, that you can get a fast answer. We didn t spend a lot of money on the binge eating study with ALKS 33, but obviously if it had worked I think it would be a very exciting area to invest in. But to get that answer for $3 million or $4 million for the whole program that we can get fast I think is something that, again, distinguishes us from maybe some other pharma companies.

Let s invest in these interesting areas and see if there s a return because if it works that early proof of concept gives you a lot more confidence. We have a lot more confidence now investing in 9070. Had it not worked we could have moved on to another investment, but now that we ve seen the data that we saw in the known area we have a lot of confidence investing more to bring it to market.

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

But to Steve s point, 9070, take that example Jim just raised. If we had failed in this first clinical trial we did double down. We have a back up to 9070 already in [man] because we were so convinced that this is a business opportunity where we can win that we didn t want to leave it behind.

Jeanne Hynes ***Wellington Management Partner***
Jeanne Hynes from Wellington, a couple of questions on 9070, so is this going to be a 505b2 filing or is it going to be an NCE? I know you talked about patents, so is this a new chemical entity? Do you need to wait for the aripiprazole patent to expire?
Maybe a third question is Otsuka has a long-acting aripiprazole, so maybe you can compare and contrast your technology to their technology. And then, finally, are you working with this technology on olanzapine? Thank you.
Richard Pops ***Alkermes Inc. Chairman, President, CEO***
So 9070 is an NCE. It s an bona fide new chemical entity. It will be developed as such, but we will be able to reference existing information on aripiprazole, so it gives us kind of a hybrid registration strategy for the product. It s a global registration strategy. So to answer the IP question is actually an incredibly layered answer.
All the patents aren t the same in all territories and in all jurisdictions at all times. So our point is to develop it as fast as we can. We don t think we re going to be [rate] limited to launching the product in key territories. And the timeline s, even given where we see it mapping out, we don t see a lot of slip between the expiration of the major country patents and when we would be able to bring it to market. So our goal is just to get it moving as fast as we possibly can.
Otsuka has a Phase III complete of a long-acting aripiprazole product. It appears to be an unmodified native aripiprazole. We ve not seen data. We were hoping to see some at APA this year. We didn t see much about it, so it s difficult for us to compare and contrast. The whole logic of our developing 9070 as an NCE was driven by some of the inherent limitations of aripiprazole as an intramuscular depot product, namely that it s pro-inflammatory. When you inject aripiprazole into a muscle of an animal and in a human, you get inflammation.
So the formulation work in front of us or at Otsuka, or anybody who is working with native aripiprazole, would be to attenuate that inflammatory property. 9070 does that through the chemical linker tail that Elliot described. Elliot, do you want to add anything more?
Elliot Ehrich ***Alkermes Inc. Chief Medical Officer***
Yes, I think that s actually one of the biggest differentiation, is that local tolerability. And what we do by modifying the aripiprazole molecule, we literally mask its inflammatory activity in the subcutaneous or the intramuscular tissue following injection, and it s really only after it dissolves and then becomes mature. So that s one really important feature of the molecule.
The other is actually because of the its crystalline form and the way that, in our suspension vehicle, we feel that we re actually able to deliver fairly substantial doses in that. As we sort of move ahead and continue to develop the product, we think that we ll actually be able to have a more expanded dose range that will cover more effectively that dose range that s required for the treatment of schizophrenia.
Richard Pops ***Alkermes Inc. Chairman, President, CEO***
As Elliot points out, there s a wide range of commercial doses of oral aripiprazole that are used clinically, and so we d like to be able to map depot corresponding doses. That s why proportionality and duration meant so much in this study.
Olanzapine, we ve disclosed that we re working on a LinkeRX formulation of olanzapine, but it s not ready for show time yet.

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Mario Corso ***Caris & Co. Analyst***

Mario Corso, of Caris & Company. A couple of pipeline questions, on the 5461, can you talk about your plans there, in terms of looking at potentially keep it or out license? And then, on ALKS 37, would you consider the molecule more closely related to Naltrexone or Naloxone? And kind of related there, what do you think the differentiating advantages there might be to some of the other products in Phase III development? Thank you.

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

Yes, 5461 is too early for us to say what our much like ALKS 33 and binge, our philosophy is let s get the data, and let s see what it tells us. We re quite excited about the clinical program that Elliot s group has designed. We re using kind of an enriched way of looking at efficacy, to try to get to one of those gold stars early in the program, to see whether there is something of interest.

I can tell you in big pharma, treatment-resistant depression or major depressive disorder is big time. That s something that there s a lot of interest in. It s a [tractable] area for drug development. FDA sees a need for new medications, and so on. So, we ll do what we did with 33, we ll move into the clinic, see if we can get a read out, then we ll make a decision about it.

37, I ll let Elliot comment on a little bit, but I think that intellectually it began with Naltrexone as a starting point, but recall that Naltrexone has a black box warning for liver metabolism, liver toxicity, so we wanted to do a few things. We wanted to bypass the liver, hepatic concerns, we wanted to increase the potency, we wanted to make it sublingually bioavailable, and we wanted to probably have some effect on other opiate modulating systems if that was necessary. So Elliot was really the architect behind this, so you can comment on it.

Elliot Ehrich ***Alkermes Inc. Chief Medical Officer***

Yes, for ALKS 37, it, again, gets back to our core strategy of taking molecules that we know work and enhance their properties with directed chemistry. And so we used our proprietary Palladium chemistry platform to modify the molecule. And one of the issues with molecules that you re targeting for the GI tract is that, not only is there metabolism in the liver, but there s a lot of metabolism that literally takes place in the gut tissue.

So we modified the molecule so that to imbue it with it s in the morphinane group of molecules, but we imbued it with a metabolic robustness, so to speak, so that it sort of perpetuates in the GI tract, and works in a more potent and effective fashion. We got pre-clinical data to suggest that it would be more potent and more active than some of the other, existing molecules that people have tried, and that was really the basis for taking that [in]. And so far, our clinical data has borne that out.

Rebecca Peterson ***Alkermes Inc. VP Corporate Communications***

All right, everyone, I think let s take two more questions, and then we ll wrap it up. Ami, I think you were next.

Ami Fadia ***UBS Analyst***
Thanks. Is this on?
Unidentified Company Representative
Yes, it s on.
Ami Fadia ***UBS Analyst***
Okay, two financial questions. Firstly, you said that somewhere in the outer years, you could expect the R&D expense run rate to be about $160 million to $180 million. Do you think that that s a good range, thinking over the next five to seven years, or should we think it grows?
Jim Frates ***Alkermes Inc. CFO***
Sure, I think the reason for that is because as you know, is the further you model out, the more difficult it is to know specifically which programs you re going to be spending on. And so what we did, was we looked at comparable companies of similar sizes, and you ll find that s in that same 20% to 25% margin spent on R&D, which large companies live with, year in, year out. So I think that s where that guidance came from, and that s the math.
As you look at revenues growing for a few years, you do the margin on the R&D, and you get to money in that range. And, suffice it to say, I wanted to give a goalpost, really, for people, because obviously we ll decide in those out years what we have to spend on R&D. Revenues could be a lot higher. We could have done a partnership, maybe we spend less.
So it s really going to be driven, and I think what you re hearing from us, really from the day one of this transaction, was a commitment to delivering on expanding EBITDA markets. And the exercise today was to, hopefully, allow you to see that that s very doable, if we can deliver on the broad revenues.
Ami Fadia ***UBS Analyst***
Thanks, and then secondly on the tax rate, you mentioned a 20% tax rate. Now, beyond a change in the product mix, what other levers do you have to lower the tax rate beyond that 20%?
Jim Frates ***Alkermes Inc. CFO***
Yes, it s a good question about tax rate, and it s ultimately driven by, again, that tale of which part of Alkermes PLC owns the assets that are being sold. And, where is the work done, because obviously if we decide to manufacture VIVITROL for launch in a European country, outside

the United States, where we do that work I think the at highest level of abstraction as I look at it, where you add the value, where you take the risk, where the investment is made, is where your profits match with.

So pull back, most of the again, at a high level, where s the ownership of each of the products, how much product is at excuse me, how much profit is that product generating, in which jurisdiction, and that profit and ownership will guide where we re taxed. So it will depend a lot on, again, as people have very different views. If someone thinks VIVITROL is going to be a huge product, well, right now, that s owned a lot that s owned entirely in the United States, so that will be a US. tax rate.

Someone thinks BYDUREON is going to be huge product, that is a ex-US product. It s owned in Ireland, or it will be owned in Ireland, so that will be an Irish tax rate. So you really have to have the tax rates follow each of the products, and I outlined where the current late stage products are owned, and where we choose to own a 9070 or a 37 will all depend on what s best for our overall financial situation.

Tom Brakel ***Federated Investors Analyst***

Hi, Tom Brakel, Federated. Just as a follow-up to that, companies that are domiciled in areas with low tax rates seem to spend a fair amount of time looking for opportunities for inorganic growth. Is that a discussion for the reception, or do you have some comments about this? And should it be in the CNS focus area?

Richard Pops ***Alkermes Inc. Chairman, President, CEO***

That s a good question, Tom. We ve got so much inherent organic growth that we don t need to go chasing inorganic growth at this time. That said, we ll be a much larger business over time, and as a matter of course, we ll be looking to do things. But it s one of the key points I d like you to leave the meeting from, is this understanding how much of the organic growth is already hard-wired into the P&L, and also in the DNA of the company, with the pipeline that we ve been working on so hard, and also with the technology assets that EDT and Alkermes share from all of the manufacturing assets.

So many of these situations that you ve referred to, they got where they were because of the tax strategy and a rollup strategy. We ve come at it from a different place, which is innovative R&D driving important products. And I actually think that s the highest value place to be going forward.

All right, well, maybe we ll stop there. I just wanted to take this opportunity I want to thank you guys for coming, I want to thank Rebecca Peterson and her whole corporate communications team, most of them are here today. It s a huge project to do this for you, and I really appreciate it. They re a great resource to you, and I know you guys avail yourselves of them all the time. There s a great set of refreshments, some are Irish-themed, that are next door. And anything else, Rebecca, that you needed to tell people?

Rebecca Peterson ***Alkermes Inc. VP Corporate Communications***

Thank you very much.

Richard Pops ***Alkermes Inc.*** ***Chairman, President, CEO***
Thank you all, very much.