ALKERMES INC
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SCHEDULE 14A
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INFORMATION REQUIRED IN PROXY STATEMENT
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)

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This filing relates to a planned merger (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 June 7, 2011 at the Goldman Sachs Global Healthcare Conference by James Frates, Senior Vice President, Chief Financial Officer and Treasurer of Alkermes, Inc.

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, Inc. 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 about the benefits of the business combination transaction involving EDT and Alkermes, including future financial and operating results, the combined company s plans, objectives, expectations (financial or otherwise) and intentions and other statements that are not historical facts.

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, Inc. s 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 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; and 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. Additional information and other factors are contained in Alkermes, Inc. s filings with the Securities and Exchange Commission, including Alkermes, Inc. s 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, Inc. disclaims any obligation to update and revise statements contained in these materials based on new information or otherwise.

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 registration or qualification under the securities laws of any such jurisdiction.

In connection with the proposed merger, Alkermes plc will file with the SEC a registration statement on Form S-4 that will include a preliminary prospectus regarding the proposed merger and Alkermes, Inc. will file with the SEC a proxy statement in respect of the proposed merger. After the registration statement has been declared effective by the SEC, a definitive proxy statement/prospectus will be mailed to Alkermes, Inc. s stockholders in connection with the proposed merger. INVESTORS ARE URGED TO CAREFULLY READ 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 and Elan with the SEC regarding the proposed merger as well as other filings containing information about Alkermes, Elan and the merger, free of charge, through the web site maintained by the SEC at www.sec.gov, by directing a request to Alkermes, Inc. s Investor Relations department at Alkermes, Inc., 852 Winter Street, Waltham, Massachusetts 02451, Attn: Investor Relations or to Alkermes, Inc. s 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, Inc. s 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, Inc. shareholder. Alkermes, Inc. 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 will be set forth in the registration statement and the proxy statement/prospectus when it is filed with the SEC. You can find information about Alkermes, Inc. s directors and executive officers in its definitive proxy statements filed with the SEC on July 29, 2010. You can obtain free copies of these documents as described above.

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Final Transcript

Conference Call Transcript
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CORPORATE PARTICIPANTS
Jim Frates
Alkermes, Inc. CFO
CONFERENCE CALL PARTICIPANTS
Terence Flynn
Goldman Sachs Analyst

PRESENTATION

Terence Flynn ***Goldman Sachs Analyst***
Great. Thanks for joining us, everyone. I m Terence Flynn, one of the biotech analysts at Goldman Sachs. And this afternoon we re very pleased to welcome Alkermes, and joining us today from the Company is Jim Frates, CFO.
And maybe first, just to start off, Jim, big picture. This has been a transformative year for the Company. Maybe if you could just kind of walk us through the proposed merger with EDT, Elan Drug Technologies, which you announced early last month. And number one, why EDT? And number two, why now? And then, go through some of the drivers of the deal.

Jim Frates ***Alkermes, Inc. CFO***
Sure. Sure. Thanks, Terence, and I appreciate being here. It s been a number of years [that] we ve done the Goldman conference, and it s always nice to come to Southern California to see the good weather and stay inside and talk about our Company.
I think you re right; it is a transformative deal for us. And any time you can take a step back and have such an accretive deal, taking us from a few years back, after VIVITROL launched the way it did with alcohol dependence and we got the product back from Cephalon, it really made sense for us to really invest in our pipeline, and we ve got three compounds that are now in Phase II.
And as we ve been waiting for VIVITROL and BYDUREON to really grow, the combination with EDT and their breadth of revenues, it takes us from minus $30 million in EBITDA to plus $75 million. And what s not to love about that? And as you lay out revenues and EBITDA and margins over the next five or six years, it really is accretive, substantially so, in every year.
Because just buying revenues for revenues sake is not something that we re interested in, and that has never really worked out over time in biotech or pharma. But with the growth phase of the products that they have, and watching AMPYRA launch in 2010 was quite exciting.
And with INVEGA SUSTENNA, which is potentially competitive with RISPERDAL CONSTA, that s been growing the market, too. And their approval in Europe and the potential launch around the world because, as I m sure most people know, in the long-acting antipsychotic space, two-thirds of the market is actually outside the United States compared to inside the United States.
So with the launch of INVEGA in the EU coming this year, with AMPYRA entering into its second year, with the generic hits that they re taking with Tricor and Skelaxin, which are now essentially done, we think they re actually at a nadir point in terms of and can start growing again. And when you combine that with our growth that can come from VIVITROL and BYDUREON and then our pipeline, we just thought so that s kind of why now and why EDT.
The growth of the products gives us a breadth that we think is quite substantial and important. Because typically in biotech, one of the hard things that we ve had to do, actually, is find good [comps] because either they re not the same size and so they re at entirely different scale.
It s a little bit of a stretch to say that Warner Chilcott is a comp when they re at such a different scale, or other companies that have single-drug risk, but where the drugs are launching really well. But there s no getting away from the fact that that s a single-drug risk and if something goes wrong it s going to go really wrong with the valuation of that company. So, having a base of five products.
The other thing that you worry about with growth in this side of the business and profitability is patent cliffs. And the earliest patent that comes off on this class of the big five that we have is INVEGA SUSTENNA in 2019. With the AMPYRA extension, you can argue that that can go into 2026. They re going to have 10 years of exclusivity in Europe. RISPERDAL CONSTA goes through 2020, 2021. VIVITROL just had a patent that issued that goes to 2029 and BYDUREON is 2026.
So, we re talking about products that are well in the future and ought to have a lot of growth head of them. We think that that s attracted us to the deal.

Terence Flynn ***Goldman Sachs Analyst***

Great. In terms of the guidance you ve given on double-digit growth in 2013, can you just walk us through the assumptions for the various products that you mentioned? The key drivers in terms of what you re assuming for BYDUREON, what you re assuming for AMPYRA? And remember, this deal was announced pre the European decision .

Jim Frates ***Alkermes, Inc.*** ***CFO***
Yes.

Terence Flynn ***Goldman Sachs*** ***Analyst***
on AMPYRA, so maybe how that impacts this guidance you ve given as well.

Jim Frates ***Alkermes, Inc.*** ***CFO***
Yes.

Terence Flynn ***Goldman Sachs*** ***Analyst***
And just what are the key assumptions you ve made when you re projecting that 2013 double-digit (inaudible).

Jim Frates ***Alkermes, Inc.*** ***CFO***
Sure. And obviously, we modeled it a lot of different ways as we looked at the growth. I guess the easiest thing for us to do, though, is to go really with the street models because each of these products is well followed. And that s where we really started, which was, Okay, what are the essentially consensus estimates on each of these products?
And if you build it up from there, you can then do lots of scenarios around well, what if AMPYRA doesn t get approved ever in Europe and what if BYDUREON is delayed or never gets approved, which we don t think will happen. What if VIVITROL never really grows to become a profitable contributor?
And the other benefit, though, as I consider it is the regulatory risk in those five, because we ve learned a lot over the last couple of months. As you mentioned, AMPYRA, we had a very, I think, earlier news than we had anticipated that there was a we had thought there would be a positive outcome in Europe but we didn t model it because when we started the negotiations it was in January when they had the negative approval. So it was actually very easy to take it out of the model and say, Look, that s so uncertain; we re not going to give you credit for that. So that was a positive surprise for us.
And the same is true with BYDUREON. We get the positive European news on the expected approval in Europe now in the next few weeks. And we have to see what happens in the United States, but we re optimistic about that as well.
So, as we look forward, the growth is really where we get to double-digit growth is really getting the VIVITROL launch going and a full year under our belt with opioid dependence. We think that we ll be able to see some growth with that. With AMPYRA, starting to consolidate those areas where it works in the patients and finding the right patient group and restarting that growth, or continuing that growth, from where they stand today.
And with the launch of BYDUREON and INVEGA ex-US, and hopefully BYDUREON in the US in the early part of next year if all goes according to play. That s what s going to accelerate the growth. And this year will be a little bit of growth from where we were last year, but those new products coming on and being in kind of the second year of their launch phase is obviously important.

Terence Flynn ***Goldman Sachs*** ***Analyst***
Great. And maybe just talk about the you re going to be financing some of this merger with debt. Maybe just talk about what the expected interest rate on that debt, and then timing of paying off that debt and how you expect to manage that going forward.

Jim Frates ***Alkermes, Inc. CFO***
Sure. Yes. So, actually, that s another facet of the deal that we love because we re actually able to buy a business with roughly $100 million in EBITDA, adjusted EBITDA, with the cash flows of that business.
So, in the long run, what we will have paid for the business is 25% of our equity 31.9 million shares which we hold very dear, believe me, but that share and the interest that we will have paid on the $450 million of debt for six or seven years, and earlier if we can pay it off early. So that s actually a very, very good purchase price. It s like a little, mini leverage buyout, and I think it puts us in a great position to have a nice return on the equity over time.
So, the debt we actually announced yesterday we re launching the debt now. We ll be having our bank meeting on Thursday. We re looking at two levels of bank debt because it gives us the flexibility to pay it off early.
And we think that as the business improves and EBITDA improves and we start to show that margin improvement, that layering on a more permanent level of bonds and more permanent level of debt capital will make more sense a year from now when the transaction is a little bit big, BYDUREON is approved, and things are more clear as opposed to being the first-time issuer.
So, the flexibility of repayment is why we re looking at that. And the rates, we re looking at, I think, very competitive rates. I think the rating agencies haven t yet issued their reports; we ll see those later this week most likely. But I think we ll be right in the mix of other companies like an Endo, like a Warner Chilcott, like an Axcan. We seem to look similar to them on a pro forma basis.
And if we can get that leverage down by using our excess cash flow to pay off some of that debt, we ll, I think, look even stronger as we go. And then, we can potentially refinance it as we improve our credit rating as we go.
I think people can see as we ve talked to investors and we ve talked to the rating agencies, I think people can very clearly see the power of the combined businesses. We just haven t combined them yet and executed on it, which is obviously a risk, but one we are very comfortable in taking because we think the products are there to provide the growth.

Terence Flynn ***Goldman Sachs Analyst***
Great. Before we move on to the next topic, any questions from the audience on EDT? Okay.
So, just moving on next to VIVITROL. I know we ve touched on this a little bit here, but maybe just bring us back and VIVITROL alcohol launch and what you ve learned from that that maybe you ve applied to the ongoing launch for opioid dependence indications, and we ll start there.

Jim Frates ***Alkermes, Inc. CFO***
Yes, and people ask a lot about that. What s going to make VIVITROL different in alcohol dependence? It is so clearly a different market in so many ways.
So, for instance, one, just really how the patients and the people suffering from this addiction react. In many ways, people who have an opiate addiction know that they can t control the opiates in their lucid moments. And it s harder for people, I think, who are struggling with alcohol addiction to recognize that they have a problem that they can t control.
Second, it s abuse of opiates is illegal, whether it s heroin or prescription opiates. And obviously, alcohol is not illegal. People can drink, and as long as they re not the proximal harm that they cause, if they re not drinking and driving or operating heavy machinery, is much less than, obviously, illicit opiate use.
Third, the tolerance that people exhibit with opiates. It happens so fast and people have to take more and more and more. It seems inevitable that they either run into serious health problems and they end up either wrapped up in the criminal justice system or in the ER. And again, in alcohol, the tolerance is much less, much more slowly. And while it causes major problems I m not discounting that it s very, very different from opioids.
And then finally, as I ve said in the past, to have a market, one needs somebody selling things and somebody buying things that s what a market is. And there s just not a market for the treatment for pharmaceutical treatment of alcohol dependence. And building that market, I think, is much more complicated and we certainly haven t had the resources to really try and build that.

I think it will build over time because I firmly believe, and I think the physicians who are at the forefront of this firmly believe, that medically-assisted treatment, or MAT, is the way to treat alcohol dependence. But the broader community of physicians and counselors is not there yet.

In opiate dependence, it s very different. There is a market, and I think it could be I don t think it s too strong to say that treating an opiate addict without medication would be in many ways viewed as malpractice. So, it s very different in that sense, too.

And I think, finally, the clinical data that we ve had I could go on about the differences, but the clinical data that we ve seen in opioid dependence, and ultimately the label that that data and our panel discussed when we were there in the fall for the prevention of relapse, is very, very important because it really is it s very clear, I think, for people to understand.

You take an opiate antagonist and it treats the abuse of an opiate agonist. It s very clear. And a monthly injection so that that product is on-board over time can have a big impact in a patient s life. And where you talk about in alcohol dependence, Okay, wait a minute, how is my ingestion of ethanol going to be affected by my taking an opiate antagonist? And even though it affects in [the reward] disorder, that s still very complex, so it s much more proximal in opioid dependence.

So, people are being treated right now. There are good medications out there in Suboxone and Methadone, but they re not for everyone. And they really are in essence replacement therapy that probably isn t appropriate forever.

And so for different patients who want to be on an antagonist, who want to be clean from opiates, either because of their job or just their nature or their makeup or their age or how long they ve been abusing opiates, we think that there s a real alternative that VIVITROL provides to the marketplace.

We re getting great feedback, and I think what we re now trying to do is decide where to put our financial resources to help educate the market in the most appropriate way so they can use that product efficiently. And we re looking at people in the field; we re looking at clinical studies; and we re looking at supporting various pilot programs by insurers and providers and states and people in the criminal justice to, again, get real world data.

Because ultimately, if this is going to be a big product, we re going to have to get more data in hand and we re going to have to get more experience in the real world in all these different patient populations and start to help the physicians answer the questions that they ask us about, What s the right sort of patient? And how long should I treat? And how do I detox someone? Because they need to be detoxed off of agonists, obviously. And all of those are questions that we re trying to help answer with the thought leaders and the National Institute of Drug Abuse and others.

So, it s not going to be an overnight market, but we feel like the product has been is a very good product in the sense that it solves some unmet medical needs. And we re going to continue to try and generate that data and work with the users to understand how they can best use it and most appropriately use it.

Terence Flynn ***Goldman Sachs Analyst***

How about in economics to the practice and the physician, how does that differ for opioid dependence versus alcohol? And what have you seen so far in the early days of the launch?

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

Yes. And I think that clearly there are physicians who have it requires a little bit of a change in thinking. I like to liken it in our business to stock trading, right? If people trade stocks, they re very interested it s very easy to say, Okay, great. I want to buy 5,000 shares of IBM. I call up my broker; I get 5,000 shares of IBM. I go online.

If you had to if you ve ever sat on a trading desk and had a new person be the trader to buy that 5,000 shares, it would take you a fair amount of time. You have to stamp it in and you have to then talk to the market leaders and you have to follow this protocol.

And the protocol that you have to use to acquire a specialty injectible product, a reasonably priced product, and interacting with the specialty pharmacies getting it delivered to your office, scheduling the patient, preparing the injection and then getting paid for it is just different from picking up taking out a prescription pad and writing 30 tablets of Suboxone. Thank you very much. And then you can go deal with someone else s back office at CVS Caremark or Walgreens or whatever.

So, it s a process of educating the physicians. Now, there are plenty of physicians who have adjusted their practice to have the right people reimbursement specialists. It makes sense to have one person follow all the VIVITROL prescriptions in the office as opposed to having 10 different people do it. You get some economies of scale and things

like that. And yet, the physicians have to figure that out themselves in many ways. We can t teach them how to do that. So, it does require a little bit of work, but I don t think the economics are prohibitive as long as the physician sees the value of the investment of his or her time. And I think in alcohol dependence, we simply didn t have enough physicians who were convinced that the extra work was worth it for them. They can t get reimbursement in certain ways and there are some insurance companies that do better than others, but we have generally pretty good reimbursement.

And we re continuing to work on that. Taking away prior authorizations, taking away first fail policies on oral Naltraxone, which in many ways, in our view, don t make a lot of sense given the need and the clear issues with oral Naltraxone. These people are addicts. And if they have the problem, on the days they re going to go out and abuse their alcohol or their opiate, they are most likely not going to take their oral tablet.

And we ve seen that I ve certainly heard story after story of people a physician being in a treatment program for opiate abuse having to take oral Naltraxone observed every day. And she came in and she took her oral Naltraxone, and low and behold, it turns out she d taken Tylenol tablets and etched the because they re about the same size as Naltraxone and etched the designs of Naltraxone tablets in each of the Tylenol tablets very precisely so that the person observing her taking them thought she was taking Naltraxone when she s, in fact, taking Tylenol.
So, there s no as anybody who has lived with an addict or been exposed to them, there s no end to their ingenuity to fulfill their drug-seeking behavior, which is really sad. But that s why a monthly antagonist is so important.

Terence Flynn ***Goldman Sachs Analyst***
If you look at the VIVITROL franchise, how close are you guys to cash flow break-even now? And how do you think about that return versus investing incremental dollars, you said, to kind of spend either on the sales side or maybe the .

Jim Frates ***Alkermes, Inc. CFO***
Yes.

Terence Flynn ***Goldman Sachs Analyst***
physician education side? And how are you guys thinking about that as you head into 2012?

Jim Frates ***Alkermes, Inc. CFO***
Well, I think that s a great question. And so when we took the product over from Cephalon, we said, All right, let s work to get to break-even. And I think last year we in essence, as we got to alcohol and we sold roughly $29 million, $28.9 million, we feel like we would have been break-even if we weren t investing in we would have been break-even if we weren t investing in the opiate launch. But we think some investment is required.
We used to say that roughly $30 million was break-even for us before we started to invest in opiates, and we said that we started putting in about $15 million into the launch. So those numbers are still good. We guided, just on a stand-alone basis with Alkermes earlier in May, to $40 million to $50 million in sales for VIVITROL.
Now, that s pretty much a straight line from where we are now. And that was purposeful in many ways because it gets us to that break-even range and it also didn t make any assumptions about accelerating growth, which are, frankly, too early for . I could make some assumptions, but I think we re at the point with VIVITROL where we d rather make our assumptions based on data as opposed to expectations and plans.
So that being said, I think that we will invest where it makes sense, but I think we re going to do it in a way that we can continue to see that positive return, because getting it to break-even is important and I think we can do it in opiate dependence.
And then the other thing is that the lesson that we ve learned is this is a new and complicated market. And to say that I m going to go out and do a $10 million program in XYZ, whether it s adding ten more sales people or adding 10 more MSLs or doing $10 million in pilot programs with states and criminal justice or advertising, all those things are good, positive return, but what we re trying to do now is do little pilots in each of those and see where we have the returns. And then we can say, Aha, this kind of doctor is the sort of doctor that gets VIVITROL. And when we have that circled up, we can then invest in finding those other doctors or we can then invest in doing that other advertising to that right target group or we can invest in that right pilot program.
So right now, we re just getting going with the materials that have been cleared through DDMAC. We got those in late last year; they re through their six-month review. And, really, in June is where we re going to see the hopefully see the benefits of that and a little bit of the targeted research that we re doing now that it s been out in the field, and we ll be able to adjust and spend, I think, appropriately.
But certainly I think we ve said this before if we can get VIVITROL to double, where I don t think it s just going to double once. It is at that stage and it has such a market there was 900,000 people seeking treatment for opiate addictions in the United States and a few thousand are using VIVITROL. So, I think we have an opportunity to (inaudible).

Terence Flynn ***Goldman Sachs Analyst***
What were (inaudible question multiple speakers)?

Jim Frates ***Alkermes, Inc. CFO***
Well, they re still growing and they re over $1 billion now. Now again, it s an agonist, so it s a very different approach. But we certainly don t view ourselves as ultimately directly competitive. There s a logical step from abuse of opiates to Suboxone to VIVITROL. There s a logical step from abuse of opiates to VIVITROL if someone wants to get off opiates faster. And there s also more people who should be treated who aren t getting exposed to medication.
A number that just staggers me every time I think about it, last year there were 260 million prescriptions for opiates in the United States. There s only 310 million people, but there were 260 million prescriptions for opiates. And the abuse of prescription opiates is a massive problem for our prisons and for our healthcare system and for our teens and 20-somethings.
And it s a major part of the drug problem because it leads directly to heroin because of the expense of getting prescription opiates illicitly. And we don t have the answer for it yet. So hopefully, VIVITROL can provide part of the answer, at least get people in treatment and provide another alterative.

Terence Flynn ***Goldman Sachs Analyst***
And as you look at the market, what s kind of historical pricing power here? And do you see that being able to continue going forward?

Jim Frates ***Alkermes, Inc. CFO***
In my mind and the way we think about it at Alkermes is price relates entirely to value. It s very hard to compare I think it s inappropriate to compare a long-acting monthly injection of Naltraxone to an oral generic tablet; they re two entirely different medicines. And the benefits that one gets from VIVITROL and this is how pharmaceutical pricing is often thought of, but in most cases, it s really hard to see the real value. How am I changing someone s life as opposed to just delaying a hospital stay or maybe adding days or weeks to someone s outcomes.
I think when we look at VIVITROL and the cost of the prevention of relapse, it s measures in lives, it s measured in economic outcomes very well, and it can be measured in serious costs like lower costs in prison.
We re doing one pilot program in Massachusetts, and we thought, Okay, how are we going to get over the hurdle of having the prison having to pay for the VIVITROL before these folks go out on parole? And they said, Oh, gosh, if we can just keep one of them from coming back for an extra month, that pays for all the VIVITROL we re ever need. So, we get it.
And unfortunately, it s just now in the states, as I m sure people have noticed, state budgets aren t people running state budgets aren t looking for new things to spend money on. But when you do the calculus of what VIVITROL can do for a state budget in certain scenarios, people get it and they get it very quickly.
And so now what we re trying to do is put some of those systems together and, again, get data in-hand. Let s do a pilot program; that we re all about generating data. And to my knowledge, there hasn t been a single pilot program that we ve done where we haven t been very pleased with the results. So the more that s just going to start to gain some momentum.
From an investment perspective and price perspective, I think that we bring value to the table and we re happy to .
Actually, we just published some data on health economics outcomes from the [IC Group], which is from one of the historical data on what it actually costs in the treatment systems for people on VIVITROL, and those data were very positive and got a good reception publicly.
In alcohol we had to knock on people s doors, and in opiate dependence a lot of the insurers are actually coming to knock on our doors and say, Hey, tell us about this data. Because we know that there s an I could keep going. I ll let you get another question in soon, but there is, it s called a 3-by-3 that s how I refer to it.

But if you these health systems are now starting to pick up people who ve been on three different prescription opiates from three different physicians in the course of three months. And they say, Aha, that s someone who doesn t have a pain problem, and that s someone who s abusing opiates. They re doctor shopping. They re on three different opiates. They re just getting them wherever they can.
And the databases are can absolutely provide that kind of information for all these insurers. And so they say, Aha, this is someone we need to target. What do we do with them? Hey, maybe we should consider obviously, we can consider Suboxone, but we should also consider VIVITROL for reaching out and being proactive with that.
So, we re getting the abuse is costing the system a lot of money, and we think VIVITROL can be a potential solution.

Terence Flynn ***Goldman Sachs Analyst***
That s great. Any questions in the audience on VIVITROL before we move to the pipeline? Okay.
So, just turning now to first, just wondering if there s any other products out there in late stage development that EDT would be eligible to receive a royalty on, that maybe you guys haven t factored into your guidance that we should be on the lookout for over the next, say, 12 to 18 months?

Jim Frates ***Alkermes, Inc. CFO***
I think that we haven t put a lot of stock on the two late stage R&D programs that we have. We essentially said, Look, we re going to pay for your business. That s how we approached the valuation work.
So, I d say the two late stage products that they have there s a product with Zogenix called ZX002, which is a long-acting form of Oxycodone, I believe, without acetaminophen in it, which is in Phase III now. And that s an interesting product because for folks who are on long-term opiate use for cancer pain or chronic pain, the combined acetaminophen can cause liver issues over time. So, that s an interesting market.
And then they have Meloxicam IV, which has finished two Phase II studies, and this is one that EDT controls. And that is a long-acting NSAID, an IV NSAID that could be opiate-sparing. And the target is to develop a drug that s as effective as morphine in terms of a five-minute or less onset of action, or roughly that period of fast onset of action, and a 24-hour coverage. And so that fits in quite nicely. As we learn more about the EDT business, both of those products fit quite nicely into our kind of approach to pain. And particularly, the opiate-sparing aspects of pain can be important.
There s a number of products that they have they ve got deals with major pharmaceutical companies like J&J and Roche and Santa Fe for things in the pipeline where they re, for instance mostly it s around the NanoCrystal technology. It s very hard to anticipate if those Phase I and Phase II programs are going to move forward, and the royalty rates are in the 3% to 5% range. But that s been a very productive business for EDT over time, and that s going to generate more revenue.
We didn t put a lot of value around that, but I think the so the key ones are going to be the Zogenix compound and the Meloxicam IV .

Terence Flynn ***Goldman Sachs Analyst***
Great.

Jim Frates ***Alkermes, Inc. CFO***
that we ll probably sees the news on from EDT.

Terence Flynn ***Goldman Sachs Analyst***
In terms of Alkermes pipeline, I know you ve said 9070. So you ll have some data, I think, coming out by the end of this month.

Jim Frates ***Alkermes, Inc.*** ***CFO***
Yes.

Terence Flynn ***Goldman Sachs*** ***Analyst***
As you think about that asset, how are you thinking about taking that forward on your versus partnering?

Jim Frates ***Alkermes, Inc.*** ***CFO***
Sure.

Terence Flynn ***Goldman Sachs*** ***Analyst***
And what kind of data are you guys looking for to make a go/no-go decision?

Jim Frates ***Alkermes, Inc.*** ***CFO***
First, the data set, in our minds this is going to be a very important study because we feel very comfortable I m thinking of the folks back through all the years of Alkermes has really been doing long-acting delivery since the early 90s. And so the real question is that jump from animal models to humans, and what does the PK profile look like? Okay, we understand it in animals. And now as we jump to humans, what s the difference?
And so that s the information that we ll have with this study. So, we ve study it in roughly 30 people. They are patients, so they have schizophrenia. It s unethical to study these powerful drugs in health volunteers. So, we ve done a single-dose study, single-dose PK.
And this is what, again, I love so much about our pipeline is that we don t have to ask the question about whether Abilify treats schizophrenia we know that. So, as long as we can get to an appropriate blood level of Abilify with acceptable injection site reactions, [so many no] injection site reactions, with acceptable dose-to-dose variability obviously, it can t be greater in you and less in me and the right PK profile, all other things being equal, we feel like we have a drug because we re very good .
Whatever that PK profile is, whether it lasts four weeks or six weeks or eight weeks, we feel very comfortable modeling what repeat dosing is going to look like and how you get to steady state. And the release profile should be such that and again, we have to find this out but as we looked in animals, it should be such that it provides a nice, steady release over time, which is the key.
So, that consistency of the data and the ultimate PK profile is really what we re on the lookout for. And then we feel quite comfortable, really, moving onto pivotal-like studies where we ll be doing efficacy studies with repeat dosing. We may need to do some dose ranging just to see how it behaves, but we ll see how consistent that data is.
And the development pathway for a drug to treat acute schizophrenia is fairly straightforward. And it s one that we know a lot about, having watched J&J do it with CONSTA, having watched Lilly do it with a long-acting Olanzapine and others attempt to do it. So, we feel quite comfortable being able to run that.
It s not a massive program because the signal to noise is quite strong, because it s such a terrible disease, and sadly but .
And so we ll try and go fairly quickly to get into efficacy studies, and then it will just be about accumulating we ll have to do run two well controlled Phase III studies. One will probably be done in Europe and one will be probably be done in the United States.
You have to have an active control because, again, it s unethical to have but that will probably be an oral medication. And you ll do non-inferiority studies, for the most part, (inaudible). But we ll be more clear with the development pathway once we know whether this study is good, but we re quite excited about that one.

And then finally, I would say that everybody said, Well, of course, you re going to have to partner it because all the big guys play in schizophrenia. But when you look at the number of physicians who are actually prescribing a long-acting now, whether it s SUSTENNA or CONSTA, it s a fairly manageable group and it s not very difficult.
Now, in VIVITROL you say, Who are my high prescribers going to be? Very hard to know. And we have people who use a lot of Suboxone that are high subscribers and those who don t who are high subscribers. In long-acting schizophrenia, a long-acting form of Abilify, you call the doctors who use a lot of Abilify and you call the doctors who use a lot of other long-acting preps. And that s a pretty manageable group.
So, probably of all the compared to 37 for opiate-induced constipation, which is going to be again, 260 opiate prescriptions, it s not a small company s job to do that and 33, which is a really interesting drug for reward disorders, possibly depression, possibly binge eating, again, maybe not the most targeted of sales forces.
So, 9070 is probably the most the one where we have the clearest commercial targets. Now, that being said, there s also some logical people who are players in this field. So, we re going to continue on with our development and we ll see where how our other products launch, how much room we have on the P&L, and what potential partners might bring to the table.

Terence Flynn ***Goldman Sachs Analyst***
Great. Well, thank you very much.

Jim Frates ***Alkermes, Inc. CFO***
Thanks, Terence. Thank you very much.

Terence Flynn ***Goldman Sachs Analyst***
Yes.

Jim Frates ***Alkermes, Inc. CFO***
And I hope you have a productive conference.

Terence Flynn ***Goldman Sachs Analyst***
Thank you.

Jim Frates ***Alkermes, Inc. CFO***
It s been good so far. Thanks for your attention.

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