ALKERMES INC
Form DEFA14A
May 19, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
SCHEDULE 14A
(Rule 14a-101)
INFORMATION REQUIRED IN PROXY STATEMENT
SCHEDULE 14A INFORMATION
Proxy Statement Pursuant to Section 14(a) of the Securities
Exchange Act of 1934 (Amendment No.)

Filed by the Registrant þ
Filed by a Party other than the Registrant o
Check the appropriate box:
o Preliminary Proxy Statement
o **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
o Definitive Proxy Statement
o Definitive Additional Materials
þ Soliciting Material Pursuant to Rule 240.14a-12

ALKERMES, INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):
þ No fee required.

o Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

NOT APPLICABLE

(2) Aggregate number of securities to which transaction applies:

NOT APPLICABLE

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

NOT APPLICABLE

(4) Proposed maximum aggregate value of transaction:

NOT APPLICABLE

(5) Total fee paid:

NOT APPLICABLE

o Fee paid previously with preliminary materials.

o Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

NOT APPLICABLE

(2) Form, Schedule or Registration Statement No.:

NOT APPLICABLE

(3) Filing Party:

NOT APPLICABLE

(4) Date Filed:

NOT APPLICABLE

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 Alkermes, Inc. s fiscal year 2011 earnings conference call, held on May 18, 2011.

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 future financial and operating performance, business plans or prospects; the successful manufacture and commercialization of VIVITROL and RISPERDAL CONSTA, including continued revenue growth from VIVITROL and RISPERDAL CONSTA; statements by Amylin concerning the expected commencement date and duration of the tQT study and timing around the submission of such study results to the FDA; the timing and approval of BYDUREON for the treatment of type 2 diabetes; the likelihood that the merger with EDT is consummated and the timing of such consummation; the financial and operational impact of the Alkermes and EDT merger; the timing, funding and feasibility of clinical trials for our products; and the therapeutic value of the company s products. You are cautioned that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: the company s ability to manufacture RISPERDAL CONSTA and VIVITROL on a commercial scale, economically or in sufficient quantities to supply the market; the company s ability to successfully commercialize VIVITROL in the U.S.; Janssen s ability to successfully commercialize RISPERDAL CONSTA and VIVITROL in Russia; the company s ability to successfully conduct clinical trials in a timely and cost-effective manner; the possibility that the merger with EDT will not be completed because of the failure of one or more conditions, including but not limited to the failure to obtain the required regulatory approval and the failure of Alkermes shareholders to approve the merger; the possibility that the anticipated benefits from the proposed merger with EDT cannot or will not be fully realized; the possibility that costs or difficulties related to integration of the two companies will be greater than expected; whether clinical trial results for the company s products will be predictive of real-world results or of results in subsequent clinical trials; whether advancement of BYDUREON will be delayed due to actions or decisions by Amylin with regard to development and regulatory strategy, timing and funding which are out of the company s control; whether the tQT study will be completed on time or at all; whether the results of the tQT study will demonstrate that exenatide causes an effect on heart rhythm; decisions by foreign regulatory authorities or the FDA regarding the company s products, including the FDA s decision regarding Amylin s New Drug Application submission for BYDUREON; and whether the company s products may have unintended side effects, adverse reactions or incidents of misuse that could cause the 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.

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 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 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 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 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.

Final Transcript

May 18, 2011 / 08:30PM GMT, ALKS Q4 2011 Alkermes Inc Earnings Conference Call

CORPORATE PARTICIPANTS

Rebecca Peterson
Alkermes, Inc. VP of Corporate Communications
Richard Pops
Alkermes, Inc. Chairman, President, CEO
James Frates
Alkermes, Inc. SVP, CFO and Treasurer

CONFERENCE CALL PARTICIPANTS

Stephen Byrne
BofA Merrill Lynch Analyst
Ami Fadia
UBS Analyst
Cory Kasimov
JPMorgan Chase & Co. Analyst
Steve Yoo
Leerink Swann & Company Analyst
Chris Hamblett
Cowen and Company Analyst
Mario Corso
Caris & Company Analyst
Tom Russo
Robert W. Baird & Company, Inc. Analyst

PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by. Welcome to the Alkermes conference call to discuss the Company s fiscal year 2011 financial results. At this time, all participants are in a listen-only mode. There will be a question-and-answer session to follow. Please be advised that this call is being recorded at Alkermes request. At this time, I would like to introduce your host for today s call, Ms. Rebecca Peterson, Vice President of Corporate Communications at Alkermes. Please go ahead.

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

Good afternoon, and welcome to the Alkermes conference call to discuss our financial results for fiscal 2011, which ended on March 31, 2011 and our financial expectations for fiscal 2012. With me this afternoon are Richard Pops, our CEO, and Jim Frates, our CFO.

Before we begin today, let me remind you that we will make forward-looking statements relating to, among other things, our expectations concerning the commercialization of RISPERDAL CONSTA and VIVITROL; the consummation of the merger between Alkermes and Elan Drug Technologies, which we will refer to as EDT; the timing of additional development activities for Bydureon; the approval and commercialization of Bydureon; our future financial expectations and business performance; and our expectations concerning the therapeutic value and the development of our product candidates. Listeners are cautioned that these forward-looking statements are neither promises nor guarantees, and are subject to a high degree of uncertainty and risk. Our press release issued today, and our filings with the SEC, including our Annual Report on Form 10-K, identify certain factors that could cause our actual performance and results to differ materially from those projected or suggested in the forward-looking statements.

Final Transcript

May 18, 2011 / 08:30PM GMT, ALKS Q4 2011 Alkermes Inc Earnings Conference Call

We undertake no obligation to update or revise the information provided on this call as a result of new information, or future results or developments. This call is 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 registration statement and proxy statement, prospectus and other materials filed with the SEC, because they will contain important information about Alkermes, EDT, and the proposed merger transaction. A copy of these materials may be obtained, when available, free of charge from the SEC s website, or through the Alkermes website. Please reference the text of the full legend contained in our earnings press release issued earlier today.

This afternoon, Richard Pops will comment on our fiscal year 2011, and Jim Frates will discuss our fiscal 2011 financial results and provide financial expectations for fiscal 2012. After our remarks, we will open it up for Q&A. Now I d like to turn the call over to Richard.

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

Great, thank you, Rebecca. Hello everybody. So I suppose it would be an understatement to say that we are in the midst of exciting times here at Alkermes. Last week, we were thrilled to announce our agreement to merge with EDT, which will transform the Company both financially and operationally, turning Alkermes into a very significant biopharmaceutical company and positioning us for near- and long-term growth.

As you no doubt know by now, the transaction has a number of attractive features. It will be immediately accretive to us, and will create a global Company that is immediately profitable on a cash earnings basis, with growing pro forma revenues in excess of $450 million and the resources to invest smartly in an innovative pipeline of proprietary drugs. The size and global reach provided by the transaction will make Alkermes PLC one of the most exciting CNS-focused biopharmaceutical companies in the world, with diverse revenues from 25 commercial products. This includes five major products, RISPERDAL CONSTA, INVEGA SUSTENNA, Bydureon, Ampyra and VIVITROL, all at the commercial stage, with long patent lives.

These products create an extraordinary opportunity. In addition to driving the top-line growth, these products will lead to expanding margins over time, as more of the high-margin products contribute increasing percentages of our revenue. Bydureon and SUSTENNA are 100% margin products, with no associated costs. Our share of Ampyra is 18% of the top-line, and we expect VIVITROL s margins to expand with increasing sales. And, as our proprietary products come to market, they will capture an increasing share of the top-line as well.

Let me go to an even higher altitude and give you a larger perspective on this transaction. We are not looking for a simple additive or incremental growth for Alkermes through the combination with EDT. Rather, we think that the financial profile, the corporate structure, and the scale of Alkermes PLC are going to allow us to accelerate our ambitious plans to build a major biopharmaceutical company. We are planning for, and managing toward, a quantum difference for Alkermes.

In the biopharmaceutical industry, we don t see many companies with revenues derived from multiple products, including 5 major medicines in important classes with long patent lives, growing top and bottom lines in a real pipeline, sitting at the valuation tier we currently occupy. We think that if we operate the business intelligently, and our expectations play out in a reasonable way, we have a long way to go to take the valuation of the Company. This vision and proposed transaction are only possible because of the hard work we have been doing here at the Company over the past couple of years, so let me now give you a sense of some of the progress we have made, and what we can expect looking ahead into the new fiscal year.

On the financial side, RISPERDAL CONSTA continued to be the financial engine of the Company, posting its strongest quarter ever on a unit and sales basis during the fourth fiscal quarter. RISPERDAL CONSTA, with its global presence and long history of safety and efficacy, is J&J s third largest pharmaceutical product, and a major blockbuster. CONSTA will continue to be an important revenue stream for Alkermes as a standalone Company and, we believe, for Alkermes PLC as well. Among the most obvious benefits of the proposed merger with EDT will be the inclusion of royalty revenues from INVEGA SUSTENNA, another long-acting antipsychotic medication and one also sold by J&J. The addition of SUSTENNA, a complementary product to CONSTA, will position Alkermes PLC as the clear leader in this space and remove any concerns about the positioning of the two products in markets around the

world.

Turning to VIVITROL, the launch of the new opioid dependence indication is continuing and sales are ramping. With the recent clearance of marketing materials by DDMAC, we are now expanding the commercialization effort and we are now calling on high-decile Suboxone prescribers, inpatient treatment centers with medical models in place, and, of course, continuing with our existing high-volume VIVITROL prescribers. Next month, we are rolling out several key components of our commercialization plan including peer-to-peer education through speaker programs and lunch and learn seminars. Further, we will deploy eight medical science liaisons, MSLs, who will enter the field for the first time to answer medically-oriented questions and be responsive to prescribers requests for medical information.

So we are expanding activities, targeting physicians, and adding new resources that will be available to prescribers. As we continue this step-wise launch in the opioid dependence indication, we will provide what we believe is conservative guidance for VIVITROL sales. As we monitor the impact of these new initiatives, we will adjust the guidance accordingly. I can also report today two new developments for VIVITROL. First, we recently received approval in Russia for the treatment of opioid dependence. It will be sold there by our partner, J&J. Second, a patent extension for VIVITROL was recently granted that extends VIVITROL s US patent coverage into 2029.

Turning to Bydureon, Bydureon continues to make significant progress toward commercialization. Most importantly, the CHMP issued a positive opinion recommending approval of Bydureon in the EU, and a final decision is expected in the June/July timeframe. On the US regulatory front, the tQT study for Bydureon requested by the FDA is well underway, and Amylin plans to resubmit to the FDA in the second half of calendar 2011. So we re looking forward to significant regulatory progress for Bydureon both here in the US and in the EU in the near-term. We expect Bydureon to have an important financial impact on Alkermes, which will manifest itself immediately after the launch, since we will receive a $7 million milestone payment on first commercial sales in both the EU and in the US, and we will begin to receive royalty revenues from the first vial sold.

One other point on Bydureon. In March, we announced positive results from the Phase II study of Bydureon once-monthly, an injectable suspension formulation of exenatide in patients with Type-2 diabetes. After 20 weeks of treatment, patients in the Bydureon once-monthly treatment arm experienced an average reduction in A1C ranging between 1.3% and 1.5%. Based on the encouraging results of this study, our partners are proceeding with regulatory interactions to outline the next steps for this development program.

So I ll turn now some rapid progress that we are making with the rest of our pipeline candidates. Let s start with ALKS 37. For ALKS 37 we announced positive results of the Phase II study in opioid-induced constipation in February. The results of this study were presented just last week at the Digestive Disease Week meeting in Chicago. With this positive data in hand, we met with FDA s division of gastroenterology products to map out next steps for the expanded program. We will initiate the definitive Phase II dose-ranging study this summer, followed by two parallel Phase III efficacy studies starting next year. This is an exciting molecule in an important class and we are moving ahead aggressively.

For 33, we expect significant progress throughout calendar 2011. For the binge eating indication, we expect data from a Phase II study of ALKS 33 in mid-calendar 2011. For ALKS 33 in combination with buprenorphine, we plan to initiate a Phase I/II study in treatment-resistant depression in mid 2011, and in cocaine addiction, we expect to commence a Phase II study, funded by NIDA, in mid-calendar 2011.

For ALKS 9070, which is designed to be a once-monthly, injectable, extended-release version of aripiprazole, or Abilify, we initiated a Phase I/II study in 32 patients and we expect top-line data by the end of June. This dose escalation study is designed to evaluate 9070 s safety, tolerability and pharmacokinetic profile, following a single dose in patients with schizophrenia. Data from this study will allow us to model the steady-state PK profile and, if positive, will trigger an aggressive expanded program. So that s a quick review on our progress. With that, I ll turn it over to Jim.

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Thanks, Rich. Good afternoon, everyone. Fiscal year 2011 was another solid year from a financial perspective. Our disciplined financial management enabled us to end the year with a strong cash position of almost $295 million and no debt, and it is this strong foundation that has positioned us to be able to capitalize on the EDT merger opportunity. In a minute, I will provide financial guidance for Alkermes, Inc on a standalone basis and also reiterate some pro forma top-line guidance for the combined companies.

But first, let me start by discussing our financial results for fiscal year 2011. Alkermes recorded total revenues of $186.6 million, driven by the strength of RISPERDAL CONSTA, which provided over $154 million to Alkermes top line in fiscal 2011. CONSTA grew more than 7% on a unit basis, reaching over $1.5 billion in end-market net sales. RISPERDAL CONSTA remains a key brand in the antipsychotic space, and because of its long patent protection, it will remain an important source of revenue for the Company for years to come. And of course, as Rich mentioned, the addition of INVEGA SUSTENNA royalty revenues from EDT will put us in an even stronger position in the

long-acting antipsychotic space.

Net sales of VIVITROL for fiscal 2011 were $28.9 million; an increase of 43% compared to fiscal 2010, bolstered by the first phase of the opioid dependence indication launch. For the fourth quarter, net sales of VIVITROL increased to $8.5 million, a sequential increase of approximately 10%, and this represented the seventh consecutive quarter of growth in net sales.

Turning to expenses, total operating expenses for the fiscal year were $232.3 million, which included $19.8 million of share-based compensation expense. We also recorded $2.2 million of non-cash charges within interest expense, associated with the early redemption of the non-recourse RISPERDAL CONSTA secured 7% notes. Excluding these non-cash charges, we reported a pro forma net loss of approximately $23.5 million this year. On a GAAP basis, we reported a net loss of $45.5 million, or a basic and diluted loss per share of $0.48, well within the guidance range we provided in February. For a full reconciliation of our pro forma net loss to GAAP results, as well as further details from our fiscal 2011 revenues and expenses, you can review the press release issued earlier this afternoon.

As of March 31, 2011, we had approximately $295 million in cash and investments. This cash balance reflects a net cash outflow from operations of approximately $5.9 million during the fiscal year, significantly better than the $25 million to $35 million we anticipated at the start of the fiscal year. This improvement resulted from increased cash flows from RISPERDAL CONSTA and disciplined management of our working capital. As you remember, back in July 2010, we used $46 million of our cash to redeem in full our non-recourse 7% notes. This early redemption made Alkermes debt-free, which will assist us in securing favorable financing terms for the proposed merger with EDT.

I will now outline our financial expectations for fiscal 2012. Before I go through the line items, I want to provide some context around our expectations. There are obviously a lot of moving parts as we enter this new fiscal year with the proposed merger. The expectations I will share reflect our expectations for Alkermes, Inc. as a standalone Company. We expect total revenues to range from $205 million to $229 million, which we break out as follows. Total manufacturing revenues in the range of $121 million to $127 million, with $120 million to $125 million related to RISPERDAL CONSTA, based on current exchange rates, and $1 million to $2 million related to the production of polymer for Bydureon. For the first quarter of fiscal 2012, we anticipate manufacturing revenues from RISPERDAL CONSTA to be in the range of $33 million to $38 million.

We expect total royalty revenues in the range of $37 million to $45 million, with $37 million to $39 million related to RISPERDAL CONSTA; up to $5 million related to Bydureon sales in the EU; and royalty revenues from sales of VIVITROL in Russia of up to $1 million. As we continue through the launch phase of the opioid indication, we are remaining conservative in our guidance on VIVITROL with expected net product sales in the range of $40 million to $50 million. Lastly, we expect R&D revenues of $7 million, related to the milestone payment due from Amylin upon the first commercial sale of Bydureon in the EU.

Turning to expenses for fiscal 2012, we expect cost of goods to range from $46 million to $57 million, R&D expenses to range from $110 million to $125 million, which reflects the continuing development of ALKS 33, plans to advance ALKS 37 and 9070 into expanded studies, and does not take into account any potential collaborative partnerships. We expect SG&A expenses to range from $85 million to $95 million, share-based compensation expense, included in the operating expenses just discussed, is expected to be in the range of $20 million to $25 million. Net interest income should range from $0 to $3 million and we do not expect to incur any taxes this fiscal year as a standalone company. Our GAAP net loss for fiscal 2012 is expected to be in the range of $36 million to $45 million, or approximately $0.38 to $0.47 per basic and diluted share, and finally, net cash flow from operations and adjusted EBITDA are expected to be in the range of negative $5 million to negative $15 million.

Turning now to our expectations for the combined Alkermes – EDT business. On a trailing 12-month basis as of March 31, 2011, the combined Company would have had pro forma revenues of approximately $450 million, and adjusted EBITDA of approximately $80 million. We plan to provide more comprehensive guidance for the combined companies upon closing of the transaction. But for now, I will reiterate our expectations for Alkermes PLC as we discussed last week. On a pro forma basis, we expect revenues for Alkermes PLC will continue to grow in fiscal 2012 and reach double-digit growth in fiscal year 2013 and beyond. Pro forma adjusted EBITDA margins for Alkermes PLC are expected to be in the range of 15% to 20% in fiscal year 2012, yielding pro forma adjusted EBITDA of between $70 million and $90 million, and we expect adjusted EBITDA margins to expand to the 30% to 35% range in fiscal year 2013 and beyond.

So clearly, this is an exciting transaction for us on many levels, and we look forward to executing on our goals. With that, I will turn the call back over to Rich.

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

That s great, thank you, Jim. We ll finish, let me just make a couple of final remarks. So if you fast-forward to 2015 and look at Alkermes PLC, we think this an important year to focus on from an operational and a financial perspective. So what will we look like then? RISPERDAL CONSTA and INVEGA SUSTENNA are growing the long-acting injectable class overall in markets around the world; VIVITROL will have another four years of growth under its belt, and will be playing an important role in the medicalized treatment of opioid dependence for patients, physicians and in government and criminal justice systems; Ampyra will be approaching peak sales in the US; Bydureon will be well into its global launch as the first and only once-weekly medication for Type-2 diabetes, and the next-generation forms, such as the dual chamber device

and the once-monthly formulation, are expanding the opportunity. Our pipeline candidates, like 37, 9070, 33, as well as others resulting from the merger with EDT, will have clearly identifiable value as they come to market.

So we believe that by 2015, you will see a remarkable Company, one that is backed by a stable base of cash flows and earnings, sustainable growth from a portfolio of commercialized products, the resources to invest in an innovative pipeline of proprietary drugs for future growth, plus a world-class team with proven development capabilities and a strong track record for innovation. So we think we are building an incredibly strong foundation. With that, I ll now turn the call back to Rebecca.

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

Thanks, Rich. So, we will now open it up for Q&A, operator?

QUESTION AND ANSWER

Operator

Thank you. (Operator Instructions). The first question comes from Steve Byrne from Banc of America. Please go ahead.

Stephen Byrne ***BofA Merrill Lynch Analyst***

Yes, thank you. I was wondering if you would consider transferring the IP on VIVITROL to Newco, and remind me what your net operating loss carry forwards now at the end of the fiscal year, and would that be sufficient to offset the gain?

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Yes, hi Steve. Jim Frates here. When we took a step back and looked at potential assets to transfer, obviously, from an IP perspective, as we build the future of this company, we have an NOL of approximately $270 million going forward. And, as we look at the value of the products, actually, we decided and we talked about this in our 8-K in the transaction, that we would transfer Bydureon and the royalties from Bydureon and the intellectual property of Bydureon, so VIVITROL is likely to stay in the US as an asset for the foreseeable future, but we will continue to plan and optimize around taxes as we go forward.

Stephen Byrne ***BofA Merrill Lynch Analyst***

Okay. And, speaking of VIVITROL, can you talk a moment about what personnel you have on board working at the state-level efforts to assist in reimbursements of the state Medicare and the drug court operations at the state-level?

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

Hi, Steve, it s Rich. We have a pretty small group on this now, but it s expanding this year. We have about six people now involved in the government and state criminal justice affairs, and as we mentioned to you, I think last time, we ve targeted six key states where we are breaking ground on this, and with success there, we will expand that footprint.

Stephen Byrne ***BofA Merrill Lynch Analyst***

And then, I have one last financial one for you, Jim. Just looking at EDT s financials, it looks like their gross margins are somewhere in the mid-50% range, is there anything that you think you can to bolster that?

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

I think, Steve, you re right in looking back historically, I think as volumes grow with Ampyra, and as the royalties INVEGA SUSTENNA come in, which is a pure royalty, those are probably the two main things that are going to drive gross margins up in the EDT business over time.

Stephen Byrne ***BofA Merrill Lynch Analyst***

Okay, thank you.

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

Thanks, Steve. Next question?

Operator

Thank you. The next question comes from Ami Fadia from UBS. Please go ahead.

Ami Fadia ***UBS Analyst***

Hi, good evening. I had a couple of questions. First of all, could you give us a little bit more color on VIVITROL and in the progress that you have had in the six states, what can we watch for? And what is kind of the next step in each of these states, and other states that you might be considering working on?

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

Hi, Ami, it s Rich. I don t think I ll go into the forensics on each of the six states, but as a general matter, the first observation I would say is that it s a completely different environment for opioid dependence than we found for alcohol dependence. Recall that we started these state initiatives on a small basis with the approval in alcohol because within states, alcohol dependency is every bit as devastating financially and on lives as opioid dependence, but you can see completely different attitudes toward the treatment within the states as it relates to opioid dependence.

We have talked about successes we ve had in states like Michigan and Missouri, Florida, Ohio, Massachusetts, and I think that the key thing in these state initiatives, it s not a matter of sending a representative in to call in a doctor, it s a systematic approach to dealing with multiple constituencies within the state, because at the end of the day, even if these constituencies believe in the efficacy and the positioning of VIVITROL, it ultimately in the states is about funding, and so we have to burn in the funding sources, and that usually happens first in a small way, through a pilot program in which that particular jurisdiction can develop data that is relevant to them, in determining whether VIVITROL is cost effective and good medicine. So, that usually take some time to get that first pilot program organized, and what we ve learned over the years is that sampling or getting free drug or sponsoring those types of studies ourselves doesn t do any good. The state has to learn how to procure the VIVITROL.

Then, if we get a pilot program going where data is generated, let that data play out over time. The data tends I can t think of a case where we haven t had a positive result in that, that leads to a subsequent appropriation cycle at a higher level, and so on, and so on. That s why we ve always said we just can keep chipping away at these state, we re going to keep on making success, and then we think other states will follow, even if they are not part of our focus of the first few that we go after.

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

Okay. That s helpful. The next question is on RISPERDAL CONSTA. It s probably obvious that is growing outside the US, but what are your internal assumptions around quarterly growth in fiscal year 2012 versus fourth-quarter fiscal 2011?

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Yes, I will take that, Ami. We are actually continuing to see growth, in fact, the growth has been accelerating through fiscal year 2011 in the United States. And, sequentially, we are up in the third quarter, which we were very happy to see. So, I think you can see in our guidance, which

is also informed by the J&J order patterns, we are taking our manufacturing guidance up, compared to the year, and we re taking our royalty guidance up during the year. So, I think we see continued growth and we ve laid it out kind of in the single digits, but we think that RISPERDAL CONSTA is remaining a very, very important part for physicians, and even as INVEGA SUSTENNA has come to the market in the United States, it appears to be growing the market overall, and not really taking share from CONSTA.

Ami Fadia ***UBS Analyst***

Thanks. I one last question on the R&D, you said in your previous call as well, that you do expect to continue to invest more in R&D, do you see that sort of continuing to grow more in terms of dollar value every year or do you see that tapering off at some point?

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

Let me take that again, and Jim can fill in as well. The important distinction to make, and this is on the Alkermes stand-alone basis, as well as on the combined Alkermes PLC with EDT, when we are expanding the R&D line, it is not because we are hiring lots of new scientists and building new buildings to do more drug research. The spend is proportional to the progress we re making in the clinics, so the reason it s going up is because 33 is progressing, 9070 we expect to progress into a significantly expanded program and 37 is expanding into a program that will lead to pivotal studies next year. So that s what s driving the R&D line.

What we haven t accounted for it is the likelihood that we will partner in some way among these assets, because even though we are going to be a substantially larger Company, we don t have a global, commercialization footprint at the time being. Because of the demand for innovative products, we see a lot of interest in partnering, we probably will partner, we re just not going to guide on the R&D line, making that assumption.

Ami Fadia ***UBS Analyst***

Okay. All right. Thank you so much.

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

You re welcome.

Operator

The next question comes from Cory Kasimov from JPMorgan. Please go ahead.

Cory Kasimov ***JPMorgan Chase & Co. Analyst***

Hi, good afternoon guys, thanks for taking the questions. I want to start with VIVITROL as well, and now that you ve begun to broaden you reach with the product, can you comment on some of the feedback you re getting from the field? I guess, what aspects of the products are physicians most receptive to or excited about, and then on the flip side, what are the key obstacles that are out there still to gaining traction?

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

Hi, Cory, the feedback is positive. That s what s so nice and the feedback is positive because this is a completely new therapeutic alternative, the idea of a long-acting antagonist. As you know, this is already an established market in the opioid dependence, but it s all driven by agonists or what we might call partial agonists. So, this is the first antagonist that has a real chance of making inroads. So we re getting very positive feedback from people in that regard. In the doctors offices, as well as in the states and in the criminal justice system.

The biggest negative on VIVITROL continues to be the biggest negative on VIVITROL from the beginning, which is that it is a specially injectable product in a physician base that isn t used to getting reimbursement or access to these types of drugs. So, there s a significant amount of learning that has to go into being able to use VIVITROL for the first time. The second point is, as we expand the calling pattern into areas or

types of physicians that have not used VIVITROL before, to use VIVITROL in opioid-dependent patient requires detoxification and so, certainly these docs who have been using only agonists don t have experience detoxing patients. Some do, and that s obviously the easiest place to go, inpatient detox centers and physicians who are familiar with detoxing patients. But over time, more and more doctors will need to get comfortable with the idea of detoxing patients to the point where they are opioid free before initiating VIVITROL treatment. But, we re quite encouraged by what we are seeing.

Cory Kasimov ***JPMorgan Chase & Co. Analyst***

Okay, and I guess in line with that, in your prepared comments, you mentioned that you re going to start lunch and learn seminars. Do you have KOLs that already on board with this? And how far-reaching to expect these will be?

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

We do. We actually think this is a really important part of the roll out of VIVITROL in the opioid dependence indication. These two components that I mentioned, one is peer-to-peer speaker, where we have a DDMAC-approved slide deck where doctors can talk to other doctors, particularly doctors who have used VIVITROL, and these lunch and learn programs. We already have the KOLs in place for these, and we re excited to see what happens as we go into the field with these. So, that s why we are kind of thinking, as it relates to the experience to date, we ve had nice growth, we see great interest in the product, all without any of these more advanced marketing tools that we are going to use in the second half of the year.

Cory Kasimov ***JPMorgan Chase & Co. Analyst***

Okay, and then the last question I have is on ALKS 37. What additional doses are you looking at in the dose-ranging Phase II? And then given all the recent developments at Alkermes, has rethinking or your strategy changed in terms of what you ll do with this product, long-term and if you re going to keep it or find a partner pre-Phase III?

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

Well, I suppose where we stand on it is that we re more excited about 37 than ever, in terms of how it looks like it s stacking up against other competitive efforts, or call them complementary efforts, because we will be building a new market here, really. We do see interest in partnering this product from pharma, and given the fact that it probably has the potential as a once-a-day oral product, this can be a product that we would collaborate around. Not entirely, we would like to keep some share of the commercial activity in the US because we think we can do a good job with it. But I think that the development program is pretty straightforward, we met with the FDA as we said, and we have a good sense of what we re going to go. In this next study, we re going to explore one notch higher in the dose, because it was so well tolerated through the 100-milligram dose, we are going to go to 150 and we will recapitulate the dose range at the low end from by about 25-milligrams up through 150.

Cory Kasimov ***JPMorgan Chase & Co. Analyst***

Okay. Great, thanks for taking the questions.

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

You re welcome.

Operator

The next question comes from Steve Yoo from Leerink Swann. Please go ahead.

Steve Yoo ***Leerink Swann & Company Analyst***

Thanks for taking my questions. I just want to dig a little bit deeper into R&D guidance, you mentioned that you re looking to do an aggressive development of 9070 too, if the trial results are positive. So, are you envisioning a potentially viable 505B2 pathway where you go to pivotal right away? And is that in your guidance? Or where do you think along those lines?

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

This is Rich, Steve. What we are going to do is we ll get that single-dose PK data, and then we ll model the steady-state concentrations of it, and we ll look and see the various aspects of the data so we fully understand the profile of the molecule in patients. It s an NCE, so there is not a 505B2 pathway, it s an NCE, so that does not mean that we couldn t move very quickly to an efficacy study, because the question would be scientifically, what do we need to learn? But we have a plan that if we can model the steady-state PK well, that we might do one additional study looking at multi-dose PK, or we might go right into a pivotal study. But, we will agree on that with the FDA first.

Steve Yoo ***Leerink Swann & Company Analyst***

Okay, and you said Phase III studies for ALKS 37 for opioid-induced constipation next year. Would they starting early next year? So that s included and party to the guidance, or will that be later next year?

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

I don t think we will give specificity on that yet, but there s probably a bit of it in the guidance assumptions, Jim is nodding his head, and we will run this multi-dose dose-ranging Phase II, and then move as quickly as we can into the Phase III program.

Steve Yoo ***Leerink Swann & Company Analyst***

Okay. And one last question on VIVITROL. You have mentioned in the past that overall, the VIVITROL margins could get to the CONSTA margins level. Can you tell me how quickly it could get there if the sales levels could expect similar margin levels?

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Yes, Steve, it is Jim. I think we re seeing that the expansion is moving nicely. And if things go according to plan in fiscal year 2012, you ll see those margins expand in VIVITROL. At current capacity levels, we ve been taking idle capacity charge and we don t anticipate having an idle capacity charges as we go forward. So, that s one of the reasons why our margins are improving in our guidance that we ve given for next year.

Steve Yoo ***Leerink Swann & Company Analyst***

Okay, thank you very much for taking my questions.

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

You re welcome.

Operator

The next question comes from Chris Hamblett from Cowen and Company. Please go ahead.

Chris Hamblett ***Cowen and Company Analyst***

Final Transcript

May 18, 2011 / 08:30PM GMT, ALKS Q4 2011 Alkermes Inc Earnings Conference Call

Thanks for taking the question, guys. Just following up on the dose-ranging study for ALKS 37, how long of a study will this be, and will the endpoints be similar to what we saw in the DDW presentation?

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

Yes, this is Rebecca. I think the endpoints will be similar, and we will post the clinical study design on ClinicalTrials.gov upon study start, which would be this summer.

Chris Hamblett ***Cowen and Company Analyst***

Okay, thanks, and just to follow up, what is the patent position currently on 9070?

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

9070 is an NCE, we expect we ll have exclusivity into the 20s on this, but we ll obviously continue to refine and mature that patent state.

Chris Hamblett ***Cowen and Company Analyst***

Okay, thank you.

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

Thanks very much.

Operator

The next question comes from Mario Corso from Caris & Company. Please go ahead.

Mario Corso ***Caris & Company Analyst***

Yes, thanks. A couple of quick financial questions for us. In terms of cost of goods, it looked like there was some margin improvement in the fourth quarter. And, I m wondering, it looks like with the guidance, that s continuing. I wonder if you could talk a little bit about what s going on there. On the R&D side, when we think about the budget, and what s budgeted for ALKS 33, is there really a lead indication, quite set there? And my final question, non-financial, on VIVITROL, conceptually speaking, now into the launch to the point you are, what can you say about the view of Suboxone being used as a maintenance therapy versus tapering Suboxone and using something like VIVITROL, and that may not be the paradigm now, but do you get the sense that things could be trending in that direction? Thanks a lot.

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

Maybe I will take them in reverse order. I think the Suboxone question is an important one, because it really relates to the positioning of VIVITROL in the marketplace, and it s just important to understand that we see this hardly at all as a zero-sum game. There are a lot of patients out there, Suboxone has become a very important drug for many patients, but there are many patients for whom long-term maintenance therapy on methadone or Suboxone is not indicated or desired or even legal. So, for example, in the criminal justice system, in many states, they have not embraced the use of agonist therapy.

So, if you think of the Venn diagram the large set of people who are on Suboxone, there s a subset of that group that we think would be logical to taper from Suboxone in their particular circumstances and put onto an antagonist therapy, but there s also an entirely separate circle in the Venn diagram that doesn t overlap with the Suboxone world of patients who have never been considered or sought agonist therapy, or might be in these other systems like the criminal justice system, so that s why we are so encouraged that the addition of a long-lasting antagonist broadens this

market, builds market, increases the use of medication-assisted therapy in the treatment of opioid addiction. And we actually think that we ll have a positive feedback loop into alcohol as well.

On 33, it s a very good question because 33 is a very multivalent molecule, and has a lot of interesting indications. We have proved its tolerability and safety and initial pharmacodynamics in an alcohol study. We re not budgeting in this year s guidance, additional alcohol work. The indications that we have right now are binge eating, treatment-resistant depression and cocaine in combination with buprenorphine. So, we will get important read-outs this year in those indications, and we will be able to make a determination of what the lead indication for 33 is thereafter.

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Let me take the margin question, Mario. It really had to do with volumes. And, since they make both CONSTA and VIVITROL in the same plant in Ohio, the more volumes that we can drive through in a particular quarter, that helps improve our per unit cost. So, I think we continue to see those volumes growing for both products. So, and that s what led to our guidance there are COGS for the next year.

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

Thanks, operator. I think we have time for one more question.

Operator

Thank you. Today s final question comes from Tom Russo from Baird. Please go ahead.

Tom Russo ***Robert W. Baird & Company, Inc. Analyst***

Hi, good afternoon, thanks for taking my question. Just back to VIVITROL, obviously, your guidance, you re characterizing it as conservative, but also showing pretty nice growth year-over-year, and we re seeing what looked like two different curves when you look at the retail scripts, or at least the scripts that show up in the retail databases versus the institutional. On the one hand, we re seeing a big ramp in the retail scripts, and then on institutional, it looks like more of that kind of gradual, sustained growth, and just from your standpoint, as we track this, which is more reflected in your view?

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Yes, hi, Tom. This is Jim. And you re right, the guidance we gave, the range is from 38% to 73% growth for VIVITROL, so we do see growth and we do see the growth accelerating, and we re very confident in the product, but I think as Rich mentioned, we are still in the early stages of our launch efforts in opioid dependence. So, that led to our guidance. With regards to the IMS retail numbers, I think one has to be very careful with IMS, because from our understanding in discussions with them, they ve changed the methodology and the sources of data that they are using, without correcting for that additional data in past periods. So, that can lead to more growth than is really there.

So I think we re going to have to continue to watch IMS, and match it with our actual net sales results before you can really start to make judgments about the direction of sales. And, we will continue to do that, and we ll continue to work with you guys to give you as much information as we can. But, we are seeing that growth, it s just not as dramatic as some of those IMS curves in the last few weeks have shown.

Tom Russo ***Robert W. Baird & Company, Inc. Analyst***

And then, on the follow-up on the COGS question, but over on the EDT side, I guess it is not necessarily a COGS question you mentioned for SUSTENNA, it s entirely a royalty, and I think you said it s a tiered royalty. Can you give us a sense? I mean, is that 7.5% similar to CONSTA on a net royalty basis now, or what is the structure of the tiers for SUSTENNA?

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Yes, and we can t give exact details, but EDT has disclosed in the past, Elan has disclosed in the past that it is actually an increasing royalty, so as sales grow, the royalty grows, and it s tiered in a structure between 5% and 9%, so as you look out, we ve essentially told people to model the net economics to Alkermes to be a push, to be exactly the same.

Tom Russo ***Robert W. Baird & Company, Inc. Analyst***

Great. And then with regard to Ampyra, what is I don t know what the right way is to think about this, but is the COGS to EDT, or what would be the COGS to you on that 18% royalty? Is there a cost against that? How should we model that?

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Yes, there is a cost against that, but it hasn t been disclosed, and I think the best thing to do is go back to look at the EDT quarterly results which are outlined in each of Elan s quarterly press releases. And, those costs are generally will improve as time goes, but you can get a good sense of what they stand with current in the last 12 months, results from EDT.

Tom Russo ***Robert W. Baird & Company, Inc. Analyst***

Okay, last question and then I ll be done. You mentioned at the time of the transaction that there might be $20 million of synergies and today, you re providing guidance from the Alkermes stand-alone basis. Would the synergies perhaps lower any of the R&D or SG&A guidance that you gave today? Or would the synergies primarily reside on the other side?

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

Well, I think the main point of the synergies is, they actually had a $10 million to $15 million charge every year Elan for corporate services that were provided, so that s the major opportunity for synergies, and the other area is going to be within R&D, as we look at the combined companies historically, the two companies have spent around $150 million in R&D. So, as most of our Alkermes R&D is spent, Tom, as you know, on external programs, and not on big labs or a lot of discovery work, as Rich talked about, it will really depend on which programs we invest in, going forward. And so therefore, there ll also be some savings there, rather than just pushing the two R&D budgets together. But, that s going to be a process where we put where we scientifically look at all of our programs, and pick the best ones go forward.

Tom Russo ***Robert W. Baird & Company, Inc. Analyst***

Okay, thanks, Jim.

James Frates ***Alkermes, Inc. SVP, CFO and Treasurer***

You bet. Thank you.

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

All right, everyone thanks for dialing in today, and if you have any additional questions, please don t hesitate to give us a call here at the Company. Have a great evening.

Operator

Thank you for participating in the Alkermes financial results conference call. This concludes the conference for today. You may all disconnect at this time.

Final Transcript

May 18, 2011 / 08:30PM GMT, ALKS Q4 2011 Alkermes Inc Earnings Conference Call