

ALKERMES INC
Form DEFA14A
August 02, 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

Filed by a Party other than the Registrant

Check the appropriate box:

- Preliminary Proxy Statement
- Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
- Definitive Proxy Statement
- Definitive Additional Materials
- Soliciting Material Pursuant to § Rule 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):

No fee required.

- 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

Edgar Filing: ALKERMES INC - Form DEFA14A

- o Fee paid previously with preliminary materials:

NOT APPLICABLE

- 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 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 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 a transcript of the Alkermes first quarter fiscal year 2012 earnings conference call held on August 1, 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 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, including but not limited to the continued revenue growth of the combined company's five commercial products; the timing, funding and feasibility of development activities for its products, including ALKS 37, ALKS 5461, and ALKS 9070; and the therapeutic value of the company's products. The statements in this document reflect the expectations and beliefs of the Company's management only as of the date of this document and subsequent events and developments may cause these expectations and beliefs to change. The Company undertakes no obligation to update or revise these statements, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date after the date of this document.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the 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 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; the possibility that clinical trial results for the company's products will not be predictive of real-world results or of results in subsequent clinical trials; decisions by foreign regulatory authorities or the FDA regarding the company's products; the risk that the company's products may prove difficult to manufacture, be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse that could cause the FDA or other health authorities to require post-approval studies or require removal of the company's products from the market; and those risks described in Part 1, Item 1A, Risk Factors of the company's Annual Report on Form 10-K, as amended, for the fiscal year ended March 31, 2011. The information contained herein is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating any forward-looking information contained herein. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this document or other filings with the SEC.

Important Additional Information and Where to Find It

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

In connection with the proposed merger, on June 23, 2011, Antler Science Two Limited, to be re-registered and renamed Alkermes plc, filed with the SEC a registration statement on Form S-4 (commission file number 333-

175078) that includes a preliminary proxy statement of Alkermes and that also constitutes a preliminary prospectus of Antler Science Two Limited regarding the proposed merger. After the registration statement has been declared effective by the SEC, a definitive proxy statement/prospectus will be mailed to Alkermes shareholders in connection with the proposed merger. **INVESTORS ARE URGED TO READ CAREFULLY THE PROXY STATEMENT/PROSPECTUS (INCLUDING ALL AMENDMENTS AND SUPPLEMENTS THERETO) AND OTHER DOCUMENTS RELATING TO THE MERGER FILED WITH THE SEC WHEN THEY BECOME AVAILABLE, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT ALKERMES, EDT AND THE PROPOSED MERGER.** You may obtain a copy of the registration statement and the proxy statement/prospectus (when available) and other related documents filed by Alkermes, Elan or EDT with the SEC regarding the proposed merger as well as other filings containing information about Alkermes, Elan, EDT and the merger, free of charge, through the web site maintained by the SEC at www.sec.gov, by directing a request to Alkermes Investor Relations department at Alkermes, Inc., 852 Winter Street, Waltham, Massachusetts 02451, Attn: Investor Relations or to Alkermes Investor Relations department at (781) 609-6000 or by email to financial@alkermes.com. Copies of the proxy statement/prospectus and the filings with the SEC that will be incorporated by reference in the proxy statement/prospectus can also be obtained, when available,

without charge, from Alkermes website at www.alkermes.com under the heading Investor Relations and then under the heading SEC Filings .

Participants in Solicitation

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

Conference Call Transcript

ALKS Q1 2012 Alkermes Inc Earnings Conference Call

Event Date/Time: Aug 01, 2011 / 08:30PM GMT

THOMSON REUTERS STREETEVENTS | www.streetevents.com | [Contact Us](#)

© 2011 Thomson Reuters. All rights reserved. Republication or redistribution of Thomson Reuters content, including

by

framing or similar means, is prohibited without the prior written consent of Thomson Reuters. Thomson Reuters and

the

Thomson Reuters logo are registered trademarks of Thomson Reuters and its affiliated companies.

**Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call
CORPORATE PARTICIPANTS**

Rebecca Peterson

Alkermes Inc. VP Corp. Communications

Jim Frates

Alkermes Inc. SVP, CFO, Treasurer

Richard Pops

Alkermes Inc. Chairman, President, CEO

CONFERENCE CALL PARTICIPANTS

Anant Padmanabhan

Cowen & Co. Analyst

Bill Tanner

Lazard Capital Markets Analyst

Tom Russo

Robert W. Baird & Co. Inc. Analyst

Karen Jay

JPMorgan Analyst

Steve Byrne

BofA Merrill Lynch Analyst

Ami Fadia

UBS Analyst

PRESENTATION

Operator

Welcome to the Alkermes first-quarter fiscal 2012 financial results conference call. My name is Monica. I will be your operator for today's call.

At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session. Please note that this conference is being recorded.

I will now turn the call over to Rebecca Peterson. Ms. Peterson, you may begin.

Rebecca Peterson *Alkermes Inc. VP Corp. Communications*

Good afternoon and welcome to the Alkermes conference call to discuss our financial results for the first quarter of fiscal 2012, which ended on June 30, 2011. With me today are Richard Pops, our CEO, and Jim Frates, our CFO. Before we begin, let me remind you that, during the call today, we will make forward-looking statements relating to, among other things, our expectations concerning the commercialization of RISPERDAL, CONSTA, and VIVITROL; the financial and operational impact 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 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 risk and uncertainty. 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 contemplated by these forward-looking statements. We undertake no obligation to update or revise the information provided on the call today as a result of new information or future results or developments.

Final Transcript

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

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 transaction. A copy of these materials can 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, Jim Frates will discuss our first-quarter financial results and Richard Pops will provide an update on the Company and the proposed merger with EDT. After their remarks, we will open up the call for Q&A. Now I'd like to turn over the call to Jim.

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

Thanks Rebecca. Good afternoon everyone.

As we work to close the merger with EDT, we're also able to report today another quarter of solid operational and financial performance. We recorded total revenues of \$61.9 million, driven by record manufacturing and royalty revenues from RISPERDAL CONSTA of approximately \$49 million. Worldwide end sales of CONSTA in the quarter were \$404 million.

Additionally, we are very excited to be adding the royalty stream from INVEGA SUSTENNA following the completion of the merger with EDT. With both of these products contributing revenues to our business, Alkermes will have a significant stake in the high-growth, long-acting atypical antipsychotic space.

As J&J stated on their recent earnings call, RISPERDAL CONSTA achieved second-quarter sales growth of 4.5% on an operational basis. Sales in the US of our long acting injectables, including INVEGA SUSTENNA, increased to a strong double-digit growth versus a year ago due to an increase in combined market share.

As I've outlined in the past, RISPERDAL CONSTA manufacturing revenues are based on J&J manufacturing orders and are lumpy in nature. For the second quarter of fiscal 2012, we expect RISPERDAL CONSTA manufacturing revenues to be in the range of \$30 million to \$35 million, and consistent with our initial guidance, we expect full-year manufacturing revenues from RISPERDAL CONSTA to remain in the range of \$120 million to \$125 million.

As we announced at our analyst day two weeks ago, net sales of VIVITROL for the first quarter of fiscal 2012 were \$9.7 million, an increase of 14% quarter-over-quarter, bolstered by continued progress in the opioid dependence indication launch. This represents the eighth consecutive quarter of growth in net sales for VIVITROL.

During the first quarter, Alkermes also recorded a milestone payment of \$3 million related to the approval of VIVITROL in Russia for opioid dependence, which was recorded as R&D revenue. In addition, the launch of BYDUREON in the UK in July triggered a \$7 million milestone payment to Alkermes that will be recorded as R&D revenue in the second quarter of fiscal 2012 as we will also start earning an 8% royalty on net sales of BYDUREON. Turning to expenses, total operating expenses for the first quarter were \$75.8 million. Notably, operating expenses included \$9.5 million of expenses related to the merger with EDT. These transaction expenses were not reflected in the guidance we provided on our May call as we had just announced the merger a few days before. But for these charges, we are right on track with our expense expectations.

Total deal expenses are expected to be up to \$35 million, including the \$9.5 million already incurred in Q1 and breakdown as follows. We expect \$20 million to \$25 million in aggregate transaction related expenses which we will book as SG&A expense as incurred. In addition, we expect approximately \$10 million of financing costs related to the debt issuance which we completed in July and which will be amortized through interest expense over the life of the debt. Excluding the \$9.5 million of deal related charges and the \$5.7 million of share-based compensation expense, we reported a pro forma net income of approximately \$1.9 million this quarter for a pro forma basic and diluted earnings per share of \$0.02.

On a GAAP basis, we reported a net loss of \$13.2 million, or a basic and diluted loss per share of \$0.14. For a full reconciliation of our pro forma net income to GAAP results, as well as further details from our first quarter, you can review the press release issued earlier this afternoon.

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

As we've discussed, when we combine with EDT, on a pro forma basis for the full fiscal year 2012, we expect single-digit revenue growth to \$460 million to \$480 million and adjusted EBITDA margins of 15% to 20% or \$70 million to \$90 million. For fiscal 2013 and beyond, we expect double-digit revenue growth and expanding adjusted EBITDA margins of 30% to 35%. We believe adjusted EBITDA is an appropriate way to evaluate our financial performance going forward. I refer you to our webcast of the analyst day on our website for a more comprehensive modeling discussion on Alkermes PLC.

It's important to note that a key attribute of the Alkermes-EDT merger is the breadth of our commercial product portfolio. Our revenue growth will be driven by five major commercial products, all with significant growth potential. Each of these products, RISPERDAL CONSTA, INVEGA SUSTENNA, AMPYRA, VIVITROL and BYDUREON, offer meaningful therapeutic benefits and real potential. We believe there are many ways to generate this forecasted growth.

We remain in a strong financial position as we progress towards the closing of the merger with EDT. As of June 30, 2011, we have approximately \$285 million in cash and investments. In the short term, we anticipate using this cash to cover transaction and financing costs and approximately \$50 million to finance the transaction.

With that, I'm very much looking forward to our next quarter when we will be discussing the results of the combined Alkermes PLC.

Now I'll turn the call over to Rich.

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

Thank you Jim. Good afternoon everybody. So in the interest of time, I'm going to quickly highlight a few of the most recent developments and provide a quick update on the merger with EDT. Then we'll move right to the Q&A portion of the call.

As Jim mentioned, for a more comprehensive review of the merger, the pipeline, and our perspective on modeling Alkermes PLC, I recommend you listen to the replay of our analyst day webcast which you can find on our website. Let me spend a few minutes on the merger with EDT. This will obviously be a major inflection point for the Company. This will be the last quarter that we are reporting earnings as Alkermes Inc with the merger with EDT expected to close in September. Alkermes PLC will have unique characteristics and will be a completely different company than either of the predecessor companies.

As Jim noted, Alkermes PLC will have five high-growth commercial products with long patent lives, which you've already heard a lot about, RISPERDAL CONSTA, INVEGA SUSTENNA, AMPYRA, VIVITROL, and BYDUREON. We're extremely excited about this portfolio of commercial products. They are significant products in their classes and to the extent that they're partnered, they represent critical revenue drivers for our partners.

In addition, Alkermes PLC will have a robust portfolio of development candidates and the expertise, the operational capacity, and the resources to quickly and efficiently advance them. These pipeline candidates, like ALKS 9070, ALKS 37, ALKS 5461, meloxicam IV, are targeted to address large markets and significant unmet medical needs with a focus in this CNS area. Having such a broad portfolio allows us the flexibility to be pragmatic about our development candidates. If a product in development isn't meeting our target profile, we'll stop working on it, like we recently did for ALKS 33 in binge eating.

On the other hand, we'll also have the flexibility to pursue promising indications and retain rights for our highest value products. It's a great position for us to be in.

In addition to growing the topline in the near and medium term, we're also focused on expanding margins. The margins we'll expand for a pretty simple reason, because we expect our revenues are going to grow at a faster rate than our expenses and we'll be managing the business to that end. We expect to drive the aggressive development of our late-stage pipeline projects while at the same time meeting the financial targets we've laid out.

So it's pretty simple when you add it all up. Following the merger, Alkermes PLC will emerge as a highly differentiated company, one that has a commercial portfolio of products early in their commercial lives, a valuable and rapidly advancing pipeline focused on the CNS, and a corporate structure and management philosophy oriented to deliver strong financial results.

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

So, we look forward to keeping you updated over the coming weeks regarding our progress to close the transaction. We expect the S-4s to go effective later this week and we're on track for the shareholder mailing to take place in August and then the vote in September. At this point, we expect to close in mid-September.

Turning to other developments, this has been an exciting few months for BYDUREON, our once weekly product for the treatment of type II diabetes. We believe that the regulatory ups and downs are now largely behind us, and we're now moving into the commercial phase for this game-changing therapeutic. In June, BYDUREON was approved in the EU, and a few weeks later the product was launched and commercially available in the UK. Our partners will continue launching BYDUREON on a country-by-country basis in the EU.

In the US, in July, we announced the completion of the clean thorough QT study. The results showed that exenatide at and above therapeutic levels did not prolong the corrected QT interval. Just last week, we announced Amylin responded to the FDA with the data requested for BYDUREON, including the results of the thorough QT study. We expect to hear within the next two weeks what the FDA review timeline will be and the new PDUFA date for the application, and we expect a six-month PDUFA clock.

So we are finally off to the races with this exciting commercial product. It's extremely gratifying to everyone in these companies who have been working on for so long and care so deeply about its success.

BYDUREON is on patent for a long time. It has striking commercial benefits and it's just getting going.

On the VIVITROL front, we are making progress in the launch of the opioid dependence indication. As Jim noted, this quarter, we had our eighth consecutive quarter of growth and the early trends are encouraging. We are continuing to roll out our VIVITROL physician education programs. Our reps are now in the field with new marketing materials, and we continue to focus on the use of VIVITROL in the criminal justice system.

I'll turn now to some of the upcoming milestones you can expect in the development of our proprietary products. For ALKS 37, our orally active peripherally restricted opiate antagonist for the treatment of opiate-induced constipation, we recently initiated a definitive Phase II dose ranging study and expect topline results in mid-calendar 2012. We then plan to move forward with the two parallel Phase III studies.

For ALKS 5461, which is ALKS 33 in combination with buprenorphine, we expect results of the recently initiated Phase Ib study in treatment-resistant depression by the end of calendar 2011.

For ALKS 9070, we announced positive results of the Phase Ib study in patients with schizophrenia. ALKS 9070 is designed to provide patients with once-monthly dosing of medication that, once in the body, converts into aripiprazole, a molecule commercially available under the name ABILIFY. Based on the positive results of this study, we are moving forward to advance ALKS 9070 into pivotal clinical development by the end of the calendar year.

So to sum it up, we're pleased with where we are right now and where we're going. We're firing on all cylinders with our development programs progressing into late-stage clinical trials, growing revenues, and the transformation that we expect to consummate in a few weeks with the merger with EDT. It's an exciting time at Alkermes and we think there's much more to come.

So with that, we'll wrap it up and I'll turn the conference back to Rebecca to field the questions.

Rebecca Peterson *Alkermes Inc. VP Corp. Communications*

All right Monica, we'll now open up the lines for Q&A.

QUESTION AND ANSWER

Operator

(Operator Instructions). Steve Byrne, Bank of America.

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

Steve Byrne *BofA Merrill Lynch Analyst*

Good afternoon. Jim, can you help me out a little bit with your CONSTA forecast? The \$38 million in manufacturing royalty was about \$8 million higher than one would expect from the sales. Thus, is that an inventory build by Janssen? If so, why would your fiscal second-quarter number be roughly flat sequentially, excluding that inventory build? Is there some logic behind that that you can help me with?

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

Thanks for the question. You know, I don't think there's anything going on here other than the order patterns that J&J has. If you look back historically, we've had quarters as low as \$19 million and this happens to be one of our highest quarters ever from a manufacturing revenue perspective. So if you really want to get a sense of it, you can go back six or seven quarters and look at the manufacturing revenue. It does go up and down. Again, it's just the ordering patterns and when the batches went out the door. So the full-year guidance remains the same, \$120 million to \$125 million. Sometimes you just can't multiply the quarter by four to get the full year. That's why we wanted to point that out.

Steve Byrne *BofA Merrill Lynch Analyst*

But are you expecting a decline in CONSTA towards the later quarters of the fiscal year in order to come up with that \$120 million to \$125 million full-year guidance?

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

Yes, that's certainly what we expect at this stage. And obviously if that changes, we'll let you know.

Steve Byrne *BofA Merrill Lynch Analyst*

Okay. And then on VIVITROL, can you comment on what fraction of your manufacturing capacity you're currently operating at for VIVITROL?

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

Sure. We have a line that's up and running. We're not near full capacity there. I think we can increase and I think we've said in the past that each VIVITROL line can generate around \$200 million to \$250 million of end sales. We actually have another line that was built under our partnership with Cephalon that's not brought into service yet, but on the one line, we're roughly about 25% of capacity, I would say, for VIVITROL.

Steve Byrne *BofA Merrill Lynch Analyst*

Okay, thank you.

Operator

Karen Jay, JPMorgan.

Karen Jay *JPMorgan Analyst*

Good afternoon. It's Karen Jay for Cory Kasimov. Thanks for taking my questions. I have two. The first is on VIVITROL. You've spoken in the past a couple sources of growth, the second phase of launch and the criminal justice system. Just so we can understand better what is short-term versus sort of long-term projects, could you give us a sense of realistic inflection points over the next few quarters for VIVITROL?

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

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

I'll take this one. It's Rich. I think the past eight quarters are indicative of this kind of building groundswell of utilization of VIVITROL, primarily in the target audience that we're calling on with the sales force. So I would think of the criminal justice system as incubating in a separate environment, and it is very difficult to predict when it will reach an inflection point. We just think it's going to be bigger in the future than it is now, and the leadtime is often long. Some of the leadtime we are well along on because we've been working certain [states] for over a year, and others are newer initiative. So I think the way to think about it is just it will continue to build and when we reach the inflection point, we'll know it because we'll start seeing major systems turning on using VIVITROL in a way they haven't used it before.

Karen Jay JPMorgan Analyst

Okay, thank you. Then secondly, on 9070, any updates or changes to your strategy on a potential partner there, timing-wise, or?

Richard Pops Alkermes Inc. Chairman, President, CEO

I think it's entirely consistent with what I said earlier in that we have a very valuable asset here, it appears. There's interest in this molecule already, even with the positive PK data from patients that we disclosed at the analyst day and showed the curves on. We have a global strategy for 9070, and we don't have global commercial capability right now. So we'll be actively talking to pharmaceutical companies as potential partners for 9070.

Karen Jay JPMorgan Analyst

Thank you for taking my questions.

Operator

Anant Padmanabhan, Cowen & Co.

Anant Padmanabhan Cowen & Co. Analyst

Thanks for taking my questions. I have three questions. First, on AMPYRA, could you talk about your expectation of the rollout of AMPYRA in the EU? It seems like it will be launched in Germany in September. How will this roll-out affect your royalty stream and manufacturing fees?

Second, on I think your VIVITROL comments a few seconds ago, could you discuss if not quantitatively then qualitatively, could you tease out the new patient starts for alcohol dependence and opioid dependence.

Finally, on 9070, in terms of intellectual property and I believe you discussed this a little bit at the analyst day how should we think about the patents for this product, particularly given that the ABILIFY patent goes to 2015?

Richard Pops Alkermes Inc. Chairman, President, CEO

I'll take those in turn. Rebecca may have more color on the [AMPYRA] roll-out in the EU because we don't have a lot of granularity into that (inaudible) the best folks or Biogen are the right folks to ask them about it. That said, Rebecca, do you have (multiple speakers)?

Rebecca Peterson Alkermes Inc. VP Corp. Communications

As heard on the call this morning, they're planning to start with a German roll-out and go from there. I think Biogen is very optimistic about the prospects for that product in Europe, and it certainly will be a major source of revenue for the combined company going forward. I think Biogen is a partner with a lot of expertise in this area, and we're very enthusiastic to work with them and Acorda.

Richard Pops Alkermes Inc. Chairman, President, CEO

Final Transcript

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

On VIVITROL, I would just remind you that, in terms of the launch, essentially all of the commercial activity or the personal promotion and marketing thrust is on the opioid indication right now. Because the base of alcohol prescribers is a fairly concentrated small group of doctors, that flywheel continues to roll in the high prescribers, but I think the growth and the emphasis is clearly on new prescribers now that we have the new marketing materials.

Inpatient we talked about inpatient detoxification centers, high decile [seboximin] prescribers in our current high-prescribing VIVITROL alcohol writers who also see opioid dependent patients.

On 9070, I think that we've said before the first important point is 9070 is its own new chemical entity. It's separately patented with a patent life that extends out towards 2030. It's to answer the IP question requires a discussion on a territory-by-territory basis. That said, even into 2015, it's probably congruent about the time this product will be approaching the market in the US, so we don't expect any impediments to bringing this product to market.

Anant Padmanabhan *Cowen & Co. Analyst*

Okay, thank you.

Operator

(Operator Instructions). Ami Fadia, UBS.

Ami Fadia *UBS Analyst*

Good evening. A couple of follow-ups from the questions I've asked before. On 9070, have you had the chance to meet with the FDA and discuss the trial design for the Phase III? Just a clarification on the patent there so you cannot launch it in the US until the patent expires in 2015, and then you have to wait for the respective patents outside the US to expire. Is that correct?

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

I wouldn't phrase it that way but I'm not going to give a whole lot more specificity. It's a pretty competitive situation we're moving into now with a Phase III asset, but I wouldn't phrase it the way you phrase it, Ami.

Ami Fadia *UBS Analyst*

Okay. Then just on the FDA meetings part of the question have you been?

Rebecca Peterson *Alkermes Inc. VP Corp. Communications*

That meeting has been scheduled, Ami, but we have not had it yet. It will occur in the near term.

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

We'll go to the FDA in the next several weeks.

Ami Fadia *UBS Analyst*

Just another question on AMPYRA. Do you know the price outside the US?

Rebecca Peterson *Alkermes Inc. VP Corp. Communications*

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

I don't think that Biogen and Acorda have announced that yet. But stay tuned, we'll get it you.

Ami Fadia *UBS Analyst*

Thanks.

Operator

Tom Russo, Robert W. Baird & Co.

Tom Russo *Robert W. Baird & Co. Inc. Analyst*

Thanks for taking the questions. With regard to guidance, Jim, I think you reiterated for CONSTA, but in the May update, you still provided kind of a normal outline for Alkermes as a standalone company. I was just wondering if you're maintaining all of that, or is anything changing and specifically with regard to VIVITROL and BYDUREON royalties?

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

Yes, we haven't updated other guidance specifically. The call in May was only three months ago, roughly. So some of the milestone payments, obviously the milestone for BYDUREON and now we have the milestone for Russia, so we are running a little bit ahead on RISPERDAL CONSTA sales. So there's basically the normal movement, I would say. But we're not so we're not making any specific updates to that guidance. When we have our call in November, and more specifically know the timing of the close, we'll be able to give you some more specific guidance on the combined Alkermes PLC, because whether it closes on September 16 or September 30 or plus or minus days there will depend on what the ultimate Alkermes PLC fiscal year '12 looks like. So that's (multiple speakers)

Tom Russo *Robert W. Baird & Co. Inc. Analyst*

Okay, so from your standpoint, there is no update to guidance for VIVITROL specifically right now?

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

No, not specifically. Again, \$9.7 million puts us in the middle of the range of \$40 million to \$50 million.

Tom Russo *Robert W. Baird & Co. Inc. Analyst*

And then apologies if I should know this, but I just wanted to check in. Do you still have an authorization for share repurchase? If so, what's left and what's the strategy there?

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

Yes, we do have an authorization. You're good to remember it. It's roughly a little over \$100 million is left in our authorization. I think our strategy has been actually we've brought in over \$100 million of shares at an average price in the low \$12s. So we are pretty happy with that. As we go forward though, I think that our commitment will likely be to repay the debt and to move that down into a more reasonable longer-term level. And yet, we still have that authorization out forward.

Tom Russo *Robert W. Baird & Co. Inc. Analyst*

Thanks, Jim.

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

Rebecca Peterson *Alkermes Inc. VP Corp. Communications*

Just to follow up on your earlier question, the EU pricing for [Fempira] is about 70% of the US price, which is around \$12,000 WACC annually.

Operator

Bill Tanner, Lazard Capital Markets.

Bill Tanner *Lazard Capital Markets Analyst*

Thanks for taking the question. Jim, on that last point on the timing of when things close, so just in terms of any movement around the original guidance, that would be more related to just the timing, or is there you may not be able to answer, may not wish to answer but it seems like

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

No, yes, sorry if I went too fast. I don't think our Alkermes Inc. guidance is changing. What we will update you on when we close, because then when the companies ultimately combine, obviously we'll know for sure what the purchase price is, what the transaction costs are, etc., and we'll be able to give you some more guidance on those in our November call.

Bill Tanner *Lazard Capital Markets Analyst*

No doubt. That's kind of what I was thinking. But I guess it's not unconventional for there to be a little bit of change subsequent to the closing. Things move around a little bit and it's not unconventional I guess for companies to hold a little bit in reserve. Perhaps things look a little bit better than initially portrayed. But it sounds like the way you're thinking about things, the biggest deviation for the PLC is going to be more related to the timing of the closing, not something that, gosh, look what we found; here is an incremental synergy or incrementally lower tax rate or anything like that.

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

Well, again, I think if we had updates to the guidance today, we'd provide them today. We'll wait until the close to provide more specifics. But again, it's just important to note when we've been talking about pro forma, that's as if the companies were together for the full year. They won't be together for the full year. They'll be together from some date in September going forward. So that's basically what you need to pay attention to, I think, at the highest level when it comes to our guidance.

Bill Tanner *Lazard Capital Markets Analyst*

All right, thanks very much.

Rebecca Peterson *Alkermes Inc. VP Corp. Communications*

I think we have time for one more question.

Operator

(Operator Instructions). We have no further questions in queue this time. This concludes today's conference.

Rebecca Peterson *Alkermes Inc. VP Corp. Communications*

Aug 01, 2011 / 08:30PM GMT, ALKS Q1 2012 Alkermes Inc Earnings Conference Call

Everyone, thanks for dialing in. If you have any additional questions following the call, please don't hesitate to call either Jim Frates or myself. Have a good evening.

Operator

Thank you ladies and gentlemen. This concludes the conference. Thank you for participating. You may now disconnect.

DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

© 2011 Thomson Reuters. All Rights Reserved.