PREDIX PHARMACEUTICALS HOLDINGS INC
Form 425
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Subject Company: Predix Pharmaceuticals Holdings, Inc.
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The following communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on current expectations of the management of EPIX Pharmaceuticals, Inc. (EPIX). These statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties, many of which are beyond the control of EPIX, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. Such forward-looking statements include statements regarding: The expected timeframe for the completion of the merger; the potential milestone payment for a clinically significant milestone to Predix shareholders for Predix products in connection with the merger; the expected timing of the commencement of clinical trials, including the expectations that PRX-00023 will enter Phase II for depression in 2007, that PRX-03140 will enter Phase IIa for Alzheimer s disease later this year, and that PRX-08066 will enter Phase IIa for pulmonary hypertension (associated with COPD) later this year; the expected timing for receiving data from existing clinical trials, including full results of EP-2104R s Phase IIa trial in the second half of 2006 and the results from PRX-00023 s first Phase III trial in GAD in the second half of 2006; the expectation that Chris Gabrieli will be the chairman of the board of directors of the combined company; the expected approval of the sale of Vasovist™ in Switzerland and other European countries; the expected timing of appealing the FDA s approvable letters regarding Vasovist™ and the outcome of that appeal; the expected decision of Schering AG regarding its option of EP-2104R and the actions to be taken if Schering AG does not exercise its option; the potential for developing PRX-07034 for cognitive impairment; the expectations regarding receipt of patent protection for the compounds; the expected partnering strategies and timing thereof for the compounds; the expected growth in the market for the treatment of anxiety; and the belief the PRX-00023 may have one of the best, if not the best, effect profile of the current drugs available and approved for anxiety and depression. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: costs related to the merger, failure of EPIX s or Predix s stockholders to approve the merger, EPIX s or Predix s inability to satisfy the conditions of the merger, the risk that EPIX s and Predix s businesses will not be integrated successfully, the combined company s inability to further identify, develop and achieve commercial success for new products and technologies, the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials, the risk that clinical trials may not result in marketable products, the risk that the combined company may be unable to successfully secure regulatory approval of and market its drug candidates, the risks associated with reliance on outside financing to meet capital requirements, risks associated with Predix s new and uncertain technology, the development of competing systems, the combined company s ability to protect its proprietary technologies, patent-infringement claims, risks of new, changing and competitive technologies and regulations in the U.S. and internationally. You are urged to consider statements that include the words may, will, would, could, sho believes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, c negative of those words or other comparable words to be uncertain and forward-looking. These factors and others are more fully discussed in EPIX s periodic reports and other filings with the Securities and Exchange Commission. EPIX undertakes no obligation and does not intend to update these forward-looking statements to reflect events or circumstances occurring after the date of this communication. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this communication. All forward-looking statements are qualified in their entirety by this cautionary statement.

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THE FOLLOWING IS THE TRANSCRIPT OF THE PRESENTATION
PRESENTED BY EPIX TO INVESTORS AND OTHERS ON JUNE 13, 2006

EPIX PHARMACEUTICALS, INC.
AT PACIFIC GROWTH EQUITIES 2006 LIFE SCIENCES GROWTH CONFERENCE
JUNE 13, 2006

CALL PARTICIPANTS

Katherine Xu	*Pacific Growth Equities, Research Analyst and Moderator*
Michael Kauffman	*Predix Pharmaceuticals, President and CEO*

PRESENTATION

Katherine Xu: Good morning. Good morning. My name is Katherine Xu. I m a research analyst here at Pacific Growth Equities. It s my great pleasure today to welcome EPIX Pharmaceuticals to Life Sciences Growth Conference. As we know, EPIX and a private company, Predix, have recently announced a merger agreement and the transaction is going to close sometime in July. So, the new company has a very exciting pipeline of small molecules as well as imaging agents, the need of product candidates as in Phase III in depression. The data is coming out later this year.

We re just really happy to have president and CEO of Predix Pharmaceuticals, Dr. Michael Kauffman, to give us the story on the new company. Michael?

Michael Kauffman: Thank you. Actually, just apologies on Andrew Uprichard s behalf. Andrew is the president and COO of EPIX. He had a family emergency and has had to go back to Ireland and so he regrets he could not be here today. I ll try to answer questions around the EPIX products, if possible, and if I can t I will certainly forward them on and we ll get back to you. We ll make forward-looking statements, obviously, and then just a quick comment. So, the merger is due to close on approximately July 28 next month. Everything is moving ahead along those lines.

Very quickly on this transaction. It s pretty much a 50-50 transaction. There s an additional potential milestone payment for a clinically significant milestone to the Predix shareholders for our products coming into the merger. Chris Gabrieli, who is currently the chairman of EPIX, will be the chairman of the new board and most of us are locked up from 90 to 180 days.

The S-4 is available on the EPIX website as are the two separate presentations. We re not allowed to give you this presentation together, but you can get them as one Predix and one EPIX. The company, as was mentioned, has we think is a pretty exciting pipeline. In fact, I m just going to jump into looking at the pipeline. We are selling Vasovist, actually, sharing and selling Vasovist in Europe now. It s on sale in seven countries. We have full EU approval. Additional approval in Switzerland and a number of other countries looking close to approval.

The U.S. situation we ll go into in a minute, but we appealing the FDA s approvable letters and we should have more news on that in July as well. Our Phase III is actually in anxiety with a secondary endpoint on depression. Those data will be out in the second half of the year. We announced accrual completion there and we ll talk about that product in some detail. That s our PRX-23 for anxiety and depression. Schering has an option right for a compound called 2104 for thrombus imaging and that decision will be made in the second half of the year as well. And we will have an update on that. We will not develop this imaging agent ourselves, but if Schering does not take it, we will partner that. PRX-03140 is entering Phase II in combination with Aricept in the second half of the year. We re all gearing up to do that. PRX-08066 for pulmonary hypertension, either alone or in combination with COPD is just announced positive proof of concept data in a Phase Ib study. We ll show you those data. And that compound will be entering a Phase II in COPD patients. That s a randomized controlled study that s in the next quarter or so.

We just entered a Phase I with PRX-07034 for obesity and that will also be developed, potentially, for cognitive impairment. This is a serotonin type six antagonist. And all of these compounds have come out of the Predix discovery platform or the EPIX discovery platform as in the case of the imaging agent. So, there are all homegrown new chemical entities. We have filed composition of matter. All of the patents have published across the top three compounds and have issued on 08066. We don t expect any problems on the issuance on 23 or 40.

Our plan is to partner the programs where we will need to and it s pretty obvious for a company of our size that we re not going to be filling primary sales forces in anxiety, depression, Alzheimer s or obesity. But for pulmonary hypertension and possibly a specialty sales force in Alzheimer s in the U.S. we will be considering that strongly. The latest stage compounds will be partnered after they hit a significant value inflection point, which, as you all know these days is Phase IIb or Phase III, typically, and that s our goal here. We really have shied away from discovery phase partnerships. This tends to be a bit of a distraction. We have a small partnership with the cystic fibrosis foundation for about $12.5 million to discovery correctors for CFTR as well as the agonists on the P2Y2.

In terms of near-term news flow, we have ongoing presentations. In fact, today, we announced the detailed data from our Phase II study with PRX-23. And we ll go into that a little bit today. The appeal and the filing for Vasovist will be announced within the next month or so. And we will be looking for a decision on FDA on whether to proceed with an appeal to the public hearing or how they want to proceed in the July-August timeframe. Total results to 2104R in the second half and then the Schering option at that time the IIa in both COPD and Alzheimer s in the second half and the results of the Phase III, which is the biggest value driver in GAD generalized anxiety disorder coming out in the second half of the year.

The management team is really geared around drug development. With this kind of pipeline, it s critical to have people that have been through both the IND process as well as getting drugs approved. I was responsible for the initial clinical development and then program leadership at for Velcade and the filing of the Phase II data for the NDA there. Andrew Uprichard, who as I mentioned, couldn t be here today, has about 18 years experience, including three or four NDAs, about 12 INDs and a great background at Parke-Davis.

And Steve Donahue, who is our VP of clinical, currently reporting to me, eventually reporting to Andrew, comes from Merck and Bristol-Myers Squibb in charge of Vytorin and some of their glitazone muraglitazar programs at Bristol-Myers. And I just mentioned that, so I ll skip ahead.

Okay. In terms of priorities and we ll dive into the products. We will be filing the [Veda Vistatile], asking the FDA for full approval. We ll show you why we think we should be granted full approval. The European Union obviously believes we should because we re being sold there in the EU and that approval came about a year ago and was one of the fastest approvals of any imaging agent. The Phase III data coming out will be the first of two. This trial is being conducted under a special protocol assessment with the FDA. We, in addition, will be starting trials in major depression in the next year. The Phase IIs in Alzheimer s and pulmonary hypertension as well as obesity following the Phase I and partnerships within, I would say, the next year for our large products.

Next page Vasovist. First and briefly is a vascular imaging agent. Currently, surprisingly, for MR angiography, there is no drug that is currently approved in the U.S. for MR angiography. Gadolinium, which is used for brain tumor enhancement and looking for other central nervous system disorders is used off label at about three times the dose and the images require about one minute to be taken or else they can t be they can t be taken. So, Vasovist is a drug that stays in the vasculature and allows imaging out to one hour on the label and two to three hours in the clinic. This allows imaging of multiple vascular beds and means that the technician doesn t have to run out of the room and take a picture within a minute. There were actually four different pivotal trials done at FDA s request to get a broad label here, too, in the aortal iliac region, one in the kidney and one in the foot, covering all different types of vascular beds over 1,400 exposures to this agent. T-values were less than 001 and, as I mentioned, this drug received a very rapid I think it was four to five months approval in the European Union for the imaging across all vascular beds and is currently being sold by sharing the following seven countries with additional EU countries and Switzerland coming online shortly.

So, after, really, two approval letters and some ineffective meetings with FDA, the decision was made that EPIX would appeal this approvable letter and state that they had actually met with FDA at the two end of Phase II meetings, had agreement with FDA on the endpoint, reached those endpoints, and with the new leader of the FDA in charge of the imaging division, he had other ideas, which is perfectly fine, but typically one has to go with what was agreed to at the end of Phase II meetings. And that is the foundation for the appeal.

We will be updating on that as soon as we file the appeal and then the FDA has [to do] for 30 days to respond and make a decision. The decisions can range from full approval to no approval to public hearing and the public hearing tends to be with an advisory committee tends to be the outcome of most of these appeals. Interestingly, in the imaging division, the last appeal was actually met by an immediate approval. So, we ll see what happens. 2104R is a fibrin imaging agent. It goes right to clot and this will be optioned in or not by Schering. If it s not taken by Schering, there s $5 million option fee with some milestones and royalties later on. Then we will sell it to someone else. We will not develop this agent ourselves.

Predix is, as mentioned, a private company, that was started, based on technology, coming out of Tel Aviv University and leading to a platform and I know that s a bad word these days but a platform for the discovery of G-protein coupled receptor drugs that are taken by mouth and have good pharmacokinetics. It was really quite an interesting platform. Since the inception of the company as a drug development or discovery development company in the U.S. about three-and-a-half years ago, we have been to move four novel compounds into the clinic, in almost all cases against receptors that are well validated in the clinic. Announced a fairly rapid development plan and to take these through now into a Phase III to two Phase IIs about the start in the Phase I. So, fairly efficient process, a company of about 50 people at this point.

One of the reasons GPCRs are exciting is because 40% of the top-selling drugs target G-protein coupled receptors and ion channels which are similar in the sense that they fit in the membrane. The reason our platform is of interest is because it s been impossible to date, to crystallize G-protein coupled receptors, in a way that s useful for drug discovery. And so, typically, chemists, who are very successful at this, but require, really, a hit or miss approach to moving drugs rapidly through lead optimization, following initial hits. So, with a company of 50 people, we ve been able to use in silico screening and in silico aided lead optimization to move us with our nine medicinal chemists ahead with the compounds that we ve talked about.

Now, the proof of any platform is really in the footing or, I guess, these days in the eating. And so, let s take a look at our top compounds. We ll spend most of the time on the GAD compound and then discuss some of the others. The this market is about a $20 billion in 2005. It s a growing market. And as drugs have gotten safer, the market itself will be grown because patients are more willing to take drugs and there s a lower threshold for physicians to prescribe them.

There are really two major drivers right now. And in fact, the largest driver in the market, particularly for anxiolytics, but also for anti-depressions, is intolerability. There is growing recognition that patients who are on drugs for an average of five to six years sometimes up to 10 years with these diseases, sometimes a lifetime really do not stay on one drug or the other. They typically will cycle. In fact, in anxiety, compliance is even worse that in depression because patients with anxiety are naturally less willing to take on side effects.

And so, there s a big push to come up with drugs that patients will start on and stay on, as opposed to simply start on and take for two months and then come off of. The big issues on the side effects of the serotonin reuptake inhibitors and the mixed reuptake inhibitors are sexual dysfunction and insomnia and appetite changes in perception of taste and smell of food. And the other big problem, particularly with Paxil and Effexor are withdrawal. That is, if a pill is missed, there is a significant withdrawal syndrome with Effexor it can last a week, with Paxil can last two to three or four days. This sounds like an annoying side effect, maybe not a big deal. It s a big deal if you re on a drug for five years. And so, there s a cycling on and off. Having said that, the drugs that are in these markets tend to do multiple billion dollar sales.

PRX-23 goes after a target that has been around a long time and it s one of the reasons we and the FDA felt comfortable moving expeditiously through this program. PRX-23 is the most selective and the longest acting serotonin Type 1a agonist that has gone to clinic to date. [Uscra] was the first and only approved agent in the U.S. Tandospirone, out of Sumitomo, is approved in Japan and China for anxiety as well. Uscra was approved in 1986. When it was approved, no one knew what the target was and it tends to be difficult to make a good drug when you re not sure what it s hitting.

About three years after, the target was identified and people have tried to make, basically, patent busts on buspirone. Now, the problem is that buspirone s backbone is metabolizes very quickly as are all these [aspirones]. And so, it s a three times a day drug with some nasty side effects with lightheadedness, headache and dizziness as well as nausea that require that you start at a low dose and only after three to four weeks do you get to the target dose. Another thing is patients today particularly with anxiety are not willing to do is wait three or four weeks to get to the target dose, never mind taking a drug three times a day.

And what we have is a drug with a 12-hour half life that is extremely well tolerated and biologically is active on day one. So, about six years after buspirone was approved, it was discovered that there is a transient and mild and I stress both of those words transient and mild doubling of the prolactin levels in the brain and it s over in six hours. The prolactin comes from the brain and so one knows if buspirone is hitting the target, one can measure at the highest dose buspirone, you get about a 25 nanogram per mil bump in prolactin. With PRX-23 at its starting dose, which I ll cut to the chase, is 40 milligrams, you get the same bump as you get with buspirone after three weeks.

So, on day one, we are at a biologically active dose. I can t guarantee that 40 milligrams is going to be active on anxiety, but I can say it absolutely induces prolactin. And we get a maximum effect between 60 and 90 milligrams and this is really, statistically, all of these doses show the same effect beyond about 60 milligrams. So, the starting dose is 40 for three days and then we go up to 80. This is standard for almost every SSRI and SNRI. We start at a low dose, Phase I through III or so and if your drug is well tolerated, you go up to the target.

Now, based on this study and we just, as I said, announced the details today. We after consultation and a very good discussion with the neuropharm division, then headed by [Ralph Ducat], decided to embark on a small Phase II followed by a large study that was statistically powered. And I really make a point about that because one of the problems in both anxiety and depression is that small studies will lead you to some comfort which are not terribly relevant to these diseases which have a significant placebo effect. And so, the goal here, if your drug is tolerated, is to get into a statistically powered study as rapidly as possible.

Based on the biomarker data and based on the 20 patients we looked at in Phase II so what we did in Phase III was a one-week placebo run-in, where the patients didn t know they were getting placebo, followed by 40, then 80 and then FDA insisted we go to 120, above the target dose. We looked at, mainly tolerability, which was excellent. We had no dropouts. Typically, one would expect a 10-15% dropout rate, particularly in these patients who have been on other drugs. Now, with 20 patients, you might expect two to three drop out. Nobody did. You could argue that statistically, you might have none. We won t debate that.

I can say that in Phase III, our dropout rate is commensurate with we ve seen in Phase I and II. And the Phase III study is the standard two month long study. So, we were pleased to see that. What was, I think, more impressive to most of the doctors and Sanjay Mathew, our lead investigator is leading this, in the study, is that we had six out of the 20 people had a remission, which is a reduction in the Hamilton anxiety score from above 20 to a score of seven or less, which is considered normal.

The average drop in this study was 11.5 points. Most of that was within the first two weeks of drug. So, we saw a little bit of drop on placebo as one would expect for a placebo effect disease. We saw most of the effect in the first two weeks on drug and then, at the 120 milligram dose, we saw a little bit more as an improvement in the anxiety score. We took these data to FDA along with our three-month animal tox data and had agreement under a special protocol assessment to move into a large pardon me, we moved very quickly right through the slide a large Phase III study. This study is powered at 90% to detect the expected two point or better difference between the drug treatment arm and the placebo arm [that we gate]. This is the standard design. This is practically the only design that FDA recognizes for the approval of anxiolitics. The last drug to be approved for chronic anxiety was Lexapro. They conducted three of these studies, ranging from 240 to 310 patients, all powered at 90%, all studies have statistical significance in those with Lexapro three out of three.

So, this study was designed with the same statistical power. Twenty-five centers in the U.S. only and the primary endpoint, as I mentioned is the Hamilton anxiety score, change at [we gate] versus placebo. The secondary endpoint is the clinical global impression improvement. That s the doctors assessment. We also have validated questionnaires on sexual dysfunction and withdrawal symptoms, following withdrawal drug or cessation of drug because these will be on the label.

[Demadris] is a depression endpoint. The secondary endpoint is exploratory. We will initiate Phase IIb or Phase II in depression next year, depending on how the data look on that secondary endpoint. Enrollment is completed about a month ahead of schedule. We announced last month and we will have data shortly. This compound will be partnered. We obviously are not going to have a sales force in primary care, but we re looking to have efficacy in both anxiety and depression. And we think that this compound could have one of the best, if not the best side effect profile of the current drugs available and approved for anxiety or depression. And we believe this is attributed to both its selectivity and its very long half life, so that the brain is bathed in fairly constant levels of drugs.

Let me just go in the last five minutes, quickly, on our other two compounds in the clinic. Alzheimer s disease tough area, large markets, relatively low hurdle for efficacy because we don t have very effective drugs. The major drugs here, as you all know, are the cholinesterase inhibitors, Aricept doing about $1.6 billion last year, despite modest efficacy.

The mechanism of action of our drug is really a ying and yang, if you will, with Aricept. And we take our lesson from what we do in Parkinson s. In Parkinson s disease, we treat with drugs that increase the production of the missing hormone, which is dopamine and we come up we have drugs that block the body s ability to remove dopamine or block its degradation. And I always use this kitchen sink analogy, where you turn on the faucet, block the drain, and that s how you elevate levels of a neurotransmitter.

Our drug is a serotonin type four agonist. It is highly selective to the brain isoforms of HT4. It does not have any GI side effects that we ve seen to date. The compound turns on new acetylcholine production in the brain in humans. It has a 10-hour half life, so it s once a day. It is well tolerated, up to 250 milligrams per day. And this compound will be featured in an oral presentation in a month in Spain at the International Alzheimer s Conference. It was ranked one of the top 100 compounds, experimental compounds, in the world last year by pharma.

Just quickly, I hate to show animal data, but it really illustrates what we ll be doing in the upcoming Phase II. And this is a memory test in a rat where you show a rat food and you ask it to remember. Rats get it right 20% of the time random. If you give them [Yanzen s] cholinesterase inhibitor, [Razidine], you can double it. You give them our drug, you get the same effect. Although, the trouble is if you give a human this dose of Razidine, they will have nausea, vomiting and diarrhea, as all the cholinesterase inhibitors do.

If you drop the dose to a tolerated dose of Razidine in humans, at least the rat equivalent, you lose the activity. You drop this is an eightfold drop drop our drug 30-fold. Now, put the 30-fold and the eightfold drops together and you restore complete activity. Presumably in humans, this will be without the side effects because we don t have GI side effects with this dose and Razidine has minimal GI side effects with this dose.

It s first important to show you increased acetylcholine in humans. In rats, you stick a probe in their brain and you measure that. In humans, you can t do that, but you can measure on the outside of their brain, a quantitative electro encephalogram. And we announced sometime ago now a statistically significant improvement in a brainwave pattern, which correlates with acetylcholine increase. And this is a well documented surrogate endpoint. So, the next study that will start shortly will be a combination study of our drug plus Aricept.

The last compound I want to talk about is our pulmonary hypertension drug. This is a new target in pulmonary hypertension. It is a pulmonary selective vasodilator. We ve now demonstrated that in both rats, mice and now humans, most recently. This target is the HT2B receptor. HT2B has gotten a little bit infamous because it is the receptor that causes valve disease and pulmonary hypertension due to the anorexigen s reduction of fen-fen. In fact, all drugs that simulate HT2B cause valve disease and pulmonary hypertension. Our drug is a blocker on HT2B and, in a sense, it s validated in humans in a reverse kind of way because we have drugs that simulate and cause disease.

Again, let me skip. The drug has a 16-hour half life in humans. It s once a day. We just completed a proof of concept study, where we took conditioned athletes and exposed them to low oxygen in order to induce pulmonary hypertension. They felt this transiently. You get about a nine millimeter increase in their pulmonary pressure. You have no effect on their systemic blood pressure. And at two [intermittent] twice a day for three days, we got a 40% statistically significant drop in their pulmonary pressure with absolutely no effect on their systemic blood pressure. This correlates with what we see in animals. It may be a little bit better. Typically, we get about a 30% drop in animals. So, we re excited about this. This is a mechanism deliver face drug. It s oral. Because of today we will be initiating a randomized blinded Phase II study for two weeks in COPD patients with significant pulmonary hypertension. We re excited about this area. There are currently no approved drugs for COPD associated PAH.
And in conclusion, we have now a company with $125 million in cash at the end of March last quarter. We have a company with many things in the clinic, a drug on the market in Europe with revenues coming in, a small royalty stream coming in from that, potential for approval in the U.S. for that drug, a Phase III compound to Phase II, with an ongoing Phase I in obesity. Lots of near term and longer term value drivers.
And thank you very much for your attention.

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EPIX has filed a registration statement on Form S-4 with the Securities and Exchange Commission containing a joint proxy statement/prospectus in connection with the proposed merger with Predix Pharmaceuticals. Investors and security holders are advised to read the joint proxy statement/prospectus (including any amendments or supplements thereto) regarding the proposed merger because it contains important information about EPIX, Predix and the proposed transaction and other related matters. The joint proxy statement/prospectus will be sent to stockholders of EPIX and Predix seeking their approval of the proposed transaction. Investors and security holders may obtain a free copy of the joint proxy statement/prospectus and any amendments or supplements thereto (when they are available) and other documents filed by EPIX at the Securities and Exchange Commission s web site at www.sec.gov. The joint proxy statement/prospectus and such other documents may also be obtained for free by directing such request to EPIX Pharmaceuticals, Inc. 161 First Street, Cambridge, Massachusetts, Attn: Investor Relations, tel: (617) 250-6000; e-mail: ahedison@epixpharma.com or Predix Pharmaceuticals Holdings, Inc., 4 Maguire Road, Lexington, Massachusetts 02421, Attn: Investor Relations, tel: (781) 372-3260; e-mail: investors@predixpharm.com.

EPIX and Predix and their respective directors, executive officers and other members of management and employees may be deemed to be participants in the solicitation of proxies with respect to the adoption of the merger agreement and the transactions associated with the merger. A description of any interests that EPIX and Predix directors and executive officers have in the merger is included in the registration statement containing the joint proxy statement/prospectus filed with the Securities and Exchange Commission and available free of charge as indicated above. Information regarding EPIX s executive officers and directors is also available in EPIX s Form 10-K, as amended, for the year ended December 31, 2005, which was filed with the Securities and Exchange Commission on March 1, 2006 and amended on April 28, 2006. You can obtain free copies of these documents using the contact information above.