PREDIX PHARMACEUTICALS HOLDINGS INC
Form 425
June 13, 2006

Filed by EPIX Pharmaceuticals, Inc.
Pursuant to Rule 425 under the Securities Act of 1933, as amended
Subject Company: Predix Pharmaceuticals Holdings, Inc.
Commission File Number: 333-133513

The following communications contain 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 approximate value of the merger transaction and net debt to be assumed at the closing; the approximate percent of the combined company that EPIX stockholders will own upon closing of the merger; the expectation that Chris Gabrieli will remain Chairman of the Board of Directors of the combined company; the expectation that EPIX will appeal the FDA s approvable letters of January and November 2005 relating to Vasovist ; the expectation that PRX-00023 will enter Phase II for depression in 2007; the expectation that PRX-03140 will enter Phase IIa for Alzheimer s disease later this year; the expectation that PRX-08066 will enter Phase IIa for pulmonary hypertension (associated with COPD) later this year; the expectation that PRX-07034 will be developed for obesity and cognitive impairment; the anticipated timing and structure of partnering strategies; the expectation that the full results of EP-2104R s Phase IIa trial will be available in the second half of 2006; the expectation that the results from PRX-00023 s first Phase III trial in GAD will be available in the second half of 2006; the expectation to finalize a partnership with a pharmaceutical/biotech partner(s) to license select drug candidate(s) in the second half of 2006 or first quarter of 2007; the expectation to advance at least one candidate into the clinic annually; the goal of completing the first of at least two pivotal Phase III trials for PRX-00023 for the treatment of anxiety; the expected receipt of $200,000 $800,000 in Vasovist royalty revenue in 2006 and its anticipated growth for the rest of the decade; the expectation that there will be no additional registration trial(s) pending the appeal to the FDA relating to Vasovist ; the anticipated focus of EP-2104R on the evaluation of patients at risk of stroke; the expected notification by Schering AG of its decision to exercise its option of EP-2104R in the second half of 2006; the belief that Predix will be achieving significant clinical and corporate milestones ahead; the belief in PRX-00023 s potential to meet unmet needs including an improved tolerability and side effect profile, to drive long-term compliance and to capture market share and its potential profile including efficacy compared to SSRIs, once-daily dosing, no sexual dysfunction, no effect on sleep or appetite, no withdrawal symptoms and no expected black box warning; the belief that the aging of baby boomers will have a large impact on the Alzheimer s disease market size in the U.S. as the population of people aged 65 and over is expected to increase as well as the prevalence of Alzheimer s disease in that population; the expectation that PRX-08066 will provide symptomatic relief through selective vasodilation and slow disease progression by blocking signaling pathways; the belief that PRX-00023 for the treatment of GAD has the potential to meet the significant unmet medical need for a once-daily treatment to relieve anxiety without the troublesome side effects associated with many of the other drugs used to treat this disorder and that its indicated well tolerability will be an important differentiator for PRX-00023 in this therapeutic area; and the efficacy of PRX-00023 s design to have minimal affinity for the GPCRs believed to be associated with the side effects of 5-HT1A agonists that are in the azapirone chemical class, and to have a more convenient dosing profile than azapirones. 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, should, believes, estimates, projects, potential, expects, plans, anticipates, intends designed, goal, or the 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 these communications. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of these communications. All forward-looking statements are qualified in their entirety by this cautionary statement.

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THE FOLLOWING IS THE TEXT OF SLIDES FROM A SLIDESHOW PRESENTATION PRESENTED BY EPIX TO
INVESTORS AND OTHERS ON JUNE 13, 2006

THE FOLLOWING IS THE PRESS RELEASE ISSUED BY PREDIX ON JUNE 13, 2006
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NEWS RELEASE

FOR IMMEDIATE RELEASE
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PHASE II CLINICAL DATA FOR PREDIX S LEAD DRUG CANDIDATE SHOW POSITIVE RESULTS IN GENERALIZED ANXIETY DISORDER

Results Presented at 46th Annual New Clinical Drug Evaluation Unit Meeting Show Efficacy in Anxiety Patients with Minimal Side Effects

LEXINGTON, Mass., June 13, 2006 Predix Pharmaceuticals, which recently announced a definitive agreement to merge with EPIX Pharmaceuticals (Nasdaq:EPIX), announced today that a Phase II clinical trial of its lead drug candidate, PRX-00023, showed significantly reduced symptoms and was well-tolerated in the 21 patients with generalized anxiety disorder (GAD) participating in the four-week, open-label study. The results are being presented at the 46th Annual New Clinical Drug Evaluation Unit (NCDEU) meeting in Boca Raton, Fla.

Lead investigator Sanjay J. Mathew, M.D., Assistant Professor of Psychiatry at the Mount Sinai School of Medicine, commented, The Phase II data suggest that PRX-00023 has the potential to meet the significant unmet medical need for a once-daily treatment to relieve anxiety without the troublesome side effects associated with many of the other drugs used to treat this disorder. A Phase III clinical trial is ongoing with PRX-00023, and the results from that study will provide further clinical insight into the efficacy and tolerability of this drug candidate in generalized anxiety.

The Phase II data, which were reported by the Company last year, showed that the GAD patients enrolled in the study had significantly reduced GAD symptoms from day 1, including the Hamilton Anxiety Rating Scale (HAM-A). Six of the 19 patients (32%) with week 4 evaluations achieved remission criteria based on the HAM-A, and 52% had a 50% or greater reduction in the HAM-A total scale. Patients had a diagnosis of GAD, HAM-A screening scores of 20 or greater when they entered the study, and had stopped taking other medicines for the treatment of anxiety.

Investigators noted a particularly low drop-out rate for this study in comparison to other studies in generalized anxiety, which may indicate that PRX-00023 is well tolerated, stated Michael G. Kauffman, president and CEO of Predix. GAD is a chronic illness, and if we continue to see excellent tolerability in our Phase III studies, then we believe this will be an important differentiator for PRX-00023 in this therapeutic area.

During the trial, patients initially received placebo for one week, and then were given PRX-00023, a novel non-azapirone 5-HT1A selective agonist. PRX-00023 was administered once daily at 40 mg per day for days 1 through 4, 80 mg for days 5 through 14, and 120 mg for days 15 through 28, and then drug was stopped. There were no serious adverse events reported, no discontinuations due to adverse events, no withdrawal symptoms following the 28 days of dosing, and no reports of ataxia, dizziness, insomnia or sexual dysfunction. Additionally, no significant clinical laboratory, vital sign, or ECG effects were observed.

PRX-00023 is currently being studied in patients with GAD in a Phase III clinical trial.. The Phase III trial is an eight-week, double-blind, placebo-controlled, multi-center study. The trial includes 25 sites in the United States and has enrolled approximately 310 patients with moderate-to-severe GAD randomized equally into one of two arms: a placebo arm or a PRX-00023 treatment arm, in which patients receive a dose of 40 mg once daily for three days followed by 80 mg once daily for the remainder of the study. The primary objectives in this trial are to evaluate the efficacy of PRX-00023 in GAD as measured by the change from baseline in the HAM-A scale, and to assess the safety and tolerability of PRX-00023 during treatment of patients with GAD. The HAM-A scale is the FDA-accepted standard for the evaluation of anti-anxiety activity, and it is used in all pivotal trials of drug candidates for the treatment of GAD. This trial will be the first of at least two pivotal trials with PRX-00023 for the treatment of GAD.

About PRX-00023

PRX-00023 is Predix s lead drug candidate and represents a novel, highly selective, non-azapirone class of 5-HT1A agonists discovered using the company s proprietary G-Protein Coupled Receptors (GPCR) modeling, screening and lead optimization technology. Buspirone is currently the only 5-HT1A agonist approved in the United States for the treatment of anxiety, but is taken three times a day, requires approximately three to four weeks of dose adjustment to reach therapeutic levels, and may cause lightheadedness, nausea, headache and restlessness. Several other 5-HT1A agonists have shown efficacy in Phase II and III clinical trials in depression. However, most of these drugs belong to a chemical class of drugs called azapirones, and their development has been hindered by poor tolerability at therapeutic doses, need for dosing up to three times daily, and by the requirement of gradual dose escalation to effective doses because of side effects such as nausea, dizziness, and restlessness which are thought to be caused by azapirones binding to non-5-HT1A GPCRs.

In contrast, PRX-00023 is designed to have minimal affinity for the GPCRs believed to be associated with the side effects of 5-HT1A agonists that are in the azapirone chemical class, and to have a more convenient dosing profile than azapirones. PRX-00023 has a half-life of 12 hours, allowing it to be administered once daily.

The *Journal of Medicinal Chemistry*, the official peer-reviewed journal of the American Chemical Society, recently published a paper highlighting PRX-00023 s novel discovery process as illustrative of a new paradigm in drug discovery utilizing in silico methods together with medicinal chemistry that resulted in a substantially reduced discovery timeline for this drug candidate.

About Predix Pharmaceuticals Holdings, Inc.

Predix, based in Lexington, MA, is a pharmaceutical company focused on the discovery and development of novel, highly selective, small-molecule drugs that target G-Protein Coupled Receptors (GPCRs) and ion channels. Using its proprietary drug discovery technology and approach, Predix has advanced four internally-discovered drug candidates into clinical trials and has five additional programs in preclinical development and discovery. Predix is expected to complete the first of at least two pivotal Phase III clinical trials for generalized anxiety disorder for its lead drug candidate, PRX-00023, in the second half of 2006. In addition to PRX-00023, Predix has three other clinical-stage drug candidates: PRX-03140 for the treatment of Alzheimer s disease, which is expected to enter Phase IIa later this year; PRX-08066 for the treatment of pulmonary hypertension (PH) and PH associated with chronic obstructive pulmonary disease, which recently completed a Phase Ib trial and is expected to enter Phase IIa in mid-2006; and, PRX-07034, which recently entered a Phase I trial and is expected to be developed for the treatment of obesity and also cognitive impairment associated with Alzheimer s disease or schizophrenia. Additional information about Predix can be found on the company s website at www.predixpharm.com.

Additional Information About the Merger And Where To Find It

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. 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 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 proxy statement/prospectus that has been filed with the Securities and Exchange Commission and is available free of charge as indicated above.

Safe Harbor Statement

Certain statements in this news release concerning Predix s business are considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, those relating to the timing and results of future clinical development of PRX-00023, the potential efficacy of PRX-00023 and the expected safety and tolerability of PRX-00023 as compared to other drugs treating anxiety. Any or all of the forward-looking statements in this press release can be affected by inaccurate assumptions Predix might make or by known or unknown risks and uncertainties, including, but not limited to: the early stage of product development; uncertainties as to the future success of ongoing and planned clinical trials; and the unproven safety and efficacy of products under development. Consequently, no forward-looking statement can be guaranteed, and actual results may vary materially. Predix undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise, except as required by applicable law.

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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.