PREDIX PHARMACEUTICALS HOLDINGS INC
Form 425
April 05, 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: 000-51551

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 Company s management. 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 Pharmaceuticals, Inc. (EPIX) or Predix Pharmaceuticals Holdings, Inc. (Predix), 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 belief that PRX-03140 has the potential for a dual mechanism of action to both improve cognition and memory by increasing acetylcholine production in the brain, and to potentially slow the progression of Alzheimer s disease; the belief that PRX-03140 has the potential to be combined with treatments currently on the market for Alzheimer s disease; the belief that PRX-03140 may increase the neuroprotectants soluble amyloid precursor protein (sAPP) and brain-derived neurotrophic factor (BDNF) in regions of the brain known to be important for memory; the expectation that Predix will initiate Phase IIa combination studies with PRX-03140 and acetylcholinesterase inhibitors by mid-2006; the expectation of the increase in the incidence of Alzheimer s disease with an aging population and the projection that by the year 2050, the range of individuals with Alzheimer s disease could be from 11 million to 16 million; the belief that, in parallel with effective therapeutics in other neurodegenerative diseases (e.g. Parkinson s disease), replacement of the prominent neurotransmitter lost in Alzheimer s disease should provide significant clinical benefit; the belief that the search for agents which increase the production and/or release of ACh only in the brain, which can be used alone or in combination with AChE inhibitors, may yield a drug with significant clinical benefit and the belief in early data suggesting that PRX-03140 may meet this need; the belief that, because PRX-03140 has shown minimal peripheral side effects to date, dosing should not be limited by tolerability; the expectation that Predix will 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; the expectation that PRX-08066, for the treatment of pulmonary arterial hypertension will begin Phase IIa trials by mid-2006; and the belief that the recognition by R&D Directions further validates Predix s approach to drug discovery through its proprietary technology. 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 SEC.

EPIX and Predix undertake no obligation and do 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 PRESS RELEASE ISSUED BY PREDIX ON APRIL 5, 2006.

FOR IMMEDIATE RELEASE

Contact:
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(949) 608-0841

PREDIX S DRUG CANDIDATE FOR ALZHEIMER S DISEASE NAMED TO R&D DIRECTIONS 100 GREAT INVESTIGATIONAL DRUGS

PRX-03140 Noted As Unique, Highly Selective Serotonin 4 Receptor Agonist; Proprietary Drug Discovery Technology Produces Novel Drug Candidates

LEXINGTON, Mass., April 05, 2006 Predix Pharmaceuticals announced today that PRX-03140, its highly selective, proprietary serotonin 4 (5-HT4) receptor agonist, was highlighted in *R&D Directions* newest annual listing of 100 Great Investigational Drugs. This designation marks the company s first to the publication s industry listing of potential breakthrough medical treatments. All selected drug candidates were unique compounds, showing strong potential in a major or blossoming therapeutic area, and actively being studied in Phase I, Phase II or Phase III of clinical drug development.

We are honored to receive industry recognition for our drug candidate PRX-03140, as we believe it has the potential for a dual mechanism of action to both improve cognition and memory by increasing acetylcholine production in the brain, and to potentially slow the progression of Alzheimer s disease. PRX-03140 has a desirable tolerability profile and the potential to be combined with treatments currently on the market for this condition, said Michael G. Kauffman, M.D., Ph.D., president and CEO of Predix. This recognition further validates Predix s approach to drug discovery through our proprietary technology, which has enabled us to advance three internally discovered drug candidates into clinical trials in three years.

On April 3, 2006, Predix announced a definitive agreement to merge with EPIX Pharmaceuticals (Nasdaq: EPIX) to create a specialty pharmaceutical company with capabilities in both therapeutics and imaging.

About PRX-03140

PRX-03140 is Predix s second of three drug candidates currently in clinical development discovered utilizing computer-based G-Protein Coupled Receptors (GPCR) models and optimized with integrated computational-medicinal chemistry. PRX-03140 is highly selective for the 5-HT4 receptor found in the brain. Preclinical studies have shown that it improves cognitive function, increases levels of acetylcholine (ACh), demonstrates synergy with acetylcholinesterase inhibitors, and may increase the neuroprotectants soluble amyloid precursor protein (sAPP) and brain-derived neurotrophic factor (BDNF) in regions of the brain known to be important for memory.

PRX-03140 was well tolerated in a Phase Ib clinical trial in Alzheimer s disease patients and also in two additional Phase I clinical trials in healthy adult and elderly volunteers. In the two-week Phase Ib clinical trial, treatment with PRX-03140 resulted in changes in brain wave activity in Alzheimer s patients that are consistent with those seen in clinical trials with currently approved drugs to treat this condition. Predix anticipates initiating Phase IIa combination studies with PRX-03140 and acetylcholinesterase inhibitors by mid-2006.

About Alzheimer s Disease

An estimated 4.5 million Americans have Alzheimer s disease (AD), with epidemiological data suggesting a growing increase in disease incidence with an aging population. Currently, nearly one in 10 people over age 65 and as many as five in 10 people over age 85 have AD. According to recent studies, by the year 2050, the range of individuals with AD could be from 11 million to 16 million.

Acetylcholinesterase (AChE) inhibitors, the major class of drugs approved for the treatment of Alzheimer s disease, are active in patients provided that endogenous production of ACh is sufficient to maintain local levels. As Alzheimer s disease progresses, ACh production declines, and brain levels of this critical neurotransmitter decline. Because of their side effects, primarily nausea, diarrhea, and vomiting, doses of AChE cannot be increased as Alzheimer s disease progresses. In parallel with effective therapeutics in other neurodegenerative diseases (e.g., Parkinson s disease), replacement of the prominent neurotransmitter lost in Alzheimer s disease should provide significant clinical benefit. However, neither ACh nor its components can be given in sufficient quantities to increase brain ACh levels with tolerable side effects. The search for agents which increase the production and/or release of Ach only in the brain, which can be used alone or in combination with AChE inhibitors, may therefore yield a drug with significant clinical benefit. Early data suggest that PRX-03140 may meet this need. Moreover, PRX-03140 has shown minimal peripheral side effects to date and therefore dosing should not be limited by tolerability.

About Predix Pharmaceuticals Holdings, Inc.

Predix Pharmaceuticals Holdings, Inc., 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 three internally discovered drug candidates into clinical trials and has six 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. Predix has two other clinical-stage drug candidates: PRX-03140 for the treatment of Alzheimer s disease, which is expected to enter Phase II trials later this year and PRX-08066 for the treatment of pulmonary arterial hypertension, currently completing Phase I clinical trials with Phase IIa trials planned for mid-2006. 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 intends to file 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. Investors and security holders are advised to read the joint proxy statement/prospectus (including any amendments or supplements thereto) regarding the proposed merger when it becomes available 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 will be included in the registration statement containing the proxy statement/prospectus that will be 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 proxy statement for its 2005 Annual Meeting of Stockholders, which was filed with the Securities and Exchange Commission on April 29, 2005. You can obtain free copies of these documents using the contact information above.

This press release contains forward-looking statements that are based on current expectations of Predix Pharmaceuticals Holdings, Inc., including, but not limited to, statements about: the expected timing, progress and success of our current and anticipated clinical trials and preclinical research programs; the anticipated efficacy of our drug candidates; the expected benefits of our drug candidates over other therapies; and statistical information concerning the markets in which we expect our drug candidates to compete, if approved. These statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in these forward-looking statements. Such risks include, among others: the risk that we *will be unable to consummate the merger with EPIX Pharmaceuticals, Inc.; the failure to successfully integrate* our *business* with *EPIX, 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 we may be unable to successfully secure regulatory approval of and market our drug candidates, risks associated with our new and uncertain technology, and 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, continues, forecast, designed, goal, or the negative of those words or other comparable words to be uncertain and forward-looking. We undertake no obligation and do not intend to update these forward-looking statements to reflect events or circumstances occurring after this press release. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement.*

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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 will be included in the registration statement containing the proxy statement/prospectus that will be 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 proxy statement for its 2005 Annual Meeting of Stockholders, which was filed with the Securities and Exchange Commission on April 29, 2005. You can obtain free copies of these documents using the contact information above.