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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2005

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 0-27570

PHARMACEUTICAL PRODUCT DEVELOPMENT, INC.

(Exact name of registrant as specified in its charter)

North Carolina	**56-1640186**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
3151 South Seventeenth Street Wilmington, North Carolina	**28412**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (910) 251-0081

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.05 per share
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $2.33 billion as of June 30, 2005, based on the closing price of the Common Stock on that date on the Nasdaq National Market System. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such person might be deemed to be an affiliate. This determination of affiliate status might not be conclusive for other purposes.

As of February 28, 2006, there were 116,480,752 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The Company's definitive Proxy Statement for its 2006 Annual Meeting of Stockholders (certain parts, as indicated in Part III).

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PART I

Statements in this Report that are not descriptions of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements reflect management's current view with respect to future events and financial performance, but are subject to risks and uncertainties. Actual results could differ materially from those currently anticipated due to a number of factors, including those set forth herein and in our other SEC filings, and including, in particular, the factors discussed in Item 1A, "Risk Factors."

Item 1. Business

Overview

We are a leading global contract research organization providing drug discovery and development services, post-approval expertise and compound partnering programs. Our clients and partners include pharmaceutical, biotechnology, medical device and government organizations. Our corporate mission is to help clients and partners maximize returns on their research and development investments and accelerate the delivery of safe and effective therapeutics to patients.

We have been in the drug development business for more than 20 years. Our development services include preclinical programs and Phase I to Phase IV clinical development services. We have extensive clinical trial experience across a multitude of therapeutic areas and various parts of the world, including regional, national and global studies. In addition, for marketed drugs, biologics and devices, we offer support services such as product launch services, medical information, patient compliance programs, patient and disease registry programs, product safety and pharmacovigilance, Phase IV monitored studies and prescription-to-over-the-counter, or Rx-to-OTC, programs.

With offices in 28 countries and more than 8,000 professionals worldwide, we have provided services to 46 of the top 50 pharmaceutical companies in the world as ranked by 2004 healthcare research and development spending. We also work with leading biotechnology and medical device companies and government organizations that sponsor clinical research. We believe that we are one of the world's largest providers of drug development services to pharmaceutical, biotechnology and medical device companies and government organizations based on 2005 annual net revenues generated from contract research organizations.

Building on our outsourcing relationship with pharmaceutical and biotechnology clients, we established our discovery services business in 1997. This business primarily focuses on preclinical evaluations of anticancer and diabetes therapies and compound development and commercialization collaborations. We have developed a risk-sharing research and development model to help pharmaceutical and biotechnology clients develop compounds. Through collaborative arrangements based on this model, we assist our clients by sharing the risks and potential rewards of the development and commercialization of drugs at various stages of development. In February 2005, we completed the acquisition of a biomarker business. The acquisition expanded our discovery sciences business by adding biomarker discovery and patient sample analysis capability to the services offered by us.

We believe that our integrated drug discovery and development services offer our clients a way to identify and develop drug candidates more quickly and cost-effectively. We use our proprietary informatics technology to support these development services. In addition, with global infrastructure, we are able to accommodate the multinational drug discovery and development needs of our customers. As a result of having core areas of expertise in discovery and development, we provide integrated services across the drug development spectrum.

Industry Overview

Discovering and developing new drugs is an extremely expensive, high risk and time-consuming process. In May 2003, the Tufts Center for the Study of Drug Development released a study that estimates the total fully allocated cost to develop a new prescription drug increased from approximately $231 million in 1987 to

approximately $897 million in 2000. Adjusted for inflation, this 2000 figure rises to $971 million in 2004 dollars. In addition, it generally takes between 10 and 15 years to develop a new prescription drug and obtain approval to market it in the United States.

The drug development services industry provides independent product development services to pharmaceutical, biotechnology and medical device companies, and government organizations. This industry has evolved from providing limited clinical trial services in the 1970s to a full-service industry today characterized by broader relationships with customers and by service offerings that encompass the entire drug development process, including preclinical evaluations, study design, clinical trial management, data collection, biostatistical analysis, regulatory consulting, clinical laboratory and diagnostic services, product registration support and post-approval support.

Over the past 20 years, technological advances, as well as the emergence of the biotechnology industry, have dramatically changed the drug discovery process. New and improved technologies have evolved such as ultra high-throughput screening, new *in vitro* and *in vivo* preclinical profiling techniques, biomarker research, and the revolution in genetic-based drug research commonly referred to as genomics. The objective of these innovations is to find more drug targets and to screen against targets much more quickly with literally millions of chemical compounds. This process is expected to produce many more molecules having the ability to affect biological activity. These molecules then need to be tested quickly and economically to determine their viability as potentially safe and effective drug candidates. Moreover, many industry participants, including pharmaceutical, biotechnology and contract research companies, have broadened their efforts to collaborate technically and financially to optimize their drug pipelines.

The Drug Discovery and Development Process

Drug discovery and development is the process of creating drugs for the treatment of human disease. The drug discovery process aims to generate safe and effective drug candidates, while the drug development process involves the testing of these drug candidates for safety and efficacy in animals and humans and to meet regulatory requirements.

The Drug Discovery Process

Targets. Historically, scientists have used classical cellular and molecular biology techniques to map biological pathways in cells to provide a cellular basis for understanding disease processes. Based on this information, scientists are now using genomics to pinpoint genes responsible for cellular disease functions. Once genes are identified, they are tested in cellular assays or animals to identify which genes seem to have a causal link between cellular function and occurrence of disease. The preferred genes encode proteins that are used as drug targets in chemical screens.

Screening. After identifying a potential drug target, researchers develop tests, or assays, to screen chemicals for their ability to alter the functional activity of the target. Ones that do so are called “hits.” Thousands of chemicals can be quickly screened when these assays are incorporated into high-throughput screening processes. Hits that have good potency and selectivity are called “leads” and are then tested for their potential as drug candidates.

Lead Generation. Scientists now also design compound libraries to provide a starting point to identify leads in the drug discovery process and to better understand the biochemistry and therapeutic relevance of targets. High quality libraries contain compounds of known purity, structure and weight, and also have diverse structural variations. Once a hit is identified in a functional assay, the compound is profiled for drug characteristics such as solubility, metabolism, stability and feasibility for commercial production.

Lead Optimization. The process of “lead optimization” involves refining the chemical structure of a lead to improve its drug characteristics, with the goal of producing a preclinical drug candidate. Lead optimization typically combines empirical and rational drug design. In empirical design procedures, large numbers of related compounds are screened for selected chemical characteristics. In rational drug design, chemicals are optimized based on the three-dimensional structure of the target. A lead that has been optimized to meet particular drug candidate criteria and is ready for toxicity testing is called a preclinical candidate.

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