SCHERING PLOUGH CORP
Form 8-K
October 21, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): October 21, 2008
SCHERING PLOUGH CORPORATION
(Exact Name of Registrant as Specified in its Charter)

New Jersey	1-6571	22-1918501
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

2000 Galloping Hill Road
Kenilworth, NJ 07033
(Address of Principal Executive Office)
Registrant s telephone number, including area code: (908) 298-4000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Schering-Plough today issued a press release titled Schering-Plough Reports Financial Results for Third Quarter of 2008 and provided additional supplemental financial data. The press release is furnished as Exhibit 99.1 to this 8-K. The supplemental financial data is furnished as Exhibit 99.2 to this 8-K.

ITEM 8.01 OTHER EVENTS

Risk Factors

Below are updated risk factors relating to Schering-Plough and its business. Schering-Plough s future operating results and cash flows may differ materially from the actual results due to risks and uncertainties related to Schering-Plough s business, including those discussed below. In addition, these factors represent risks and uncertainties that could cause actual results to differ materially from those implied by forward-looking statements contained in this 8-K, including each exhibit, the comments of Schering-Plough officers during the earnings teleconference/webcast on October 21, 2008, beginning at 8 a.m. (EDT), and other written reports and oral statements made from time to time by Schering-Plough.

Key Schering-Plough products generate a significant amount of Schering-Plough s profits and cash flows, and any events that adversely affect the markets for its leading products could have a material and negative impact on results of operations and cash flows.

Schering-Plough s ability to generate profits and operating cash flow depends largely upon the continued profitability of Schering-Plough s cholesterol franchise, consisting of VYTORIN and ZETIA, and other key products such as REMICADE, NASONEX, TEMODAR, PEGINTRON, CLARINEX, FOLLISTIM, AVELOX, CLARITIN and NUVARING. As a result of Schering-Plough s dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or OTC availability of Schering-Plough s product or a competitive product, the discovery of previously unknown side effects, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason.

There is a high risk that funds invested in research will not generate financial returns because the development of novel drugs requires significant expenditures with a low probability of success.

There is a high rate of failure inherent in the research to develop new drugs to treat diseases. As a result, there is a high risk that funds invested by Schering-Plough in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

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Schering-Plough s success is dependent on the successful development and marketing of new products, which are subject to substantial risks.

Products that appear promising in development may fail to reach market for numerous reasons, including the following:

findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;

failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, and increasing uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;

lack of economic feasibility due to manufacturing costs or other factors; and

preclusion from commercialization by the proprietary rights of others.

Intellectual property protection for innovation is an important contributor to Schering-Plough s profitability. Generic forms of Schering-Plough s products may be introduced to the market as a result of the expiration of patents covering Schering-Plough s products, a successful challenge to Schering-Plough s patents, or the at-risk launch of a generic version of a Schering-Plough product, which may have a material and negative effect on results of operations.

Intellectual property protection is critical to Schering-Plough s ability to successfully commercialize its products. U.S. patents relating to Schering-Plough s significant products are of material importance to Schering-Plough. Upon the expiration or the successful challenge of Schering-Plough s patents covering a product, competitors may introduce lower-priced generic or similar branded versions of that product, which may include Schering-Plough s well-established products.

A generic manufacturer may file an Abbreviated New Drug Application seeking approval after the expiration of the applicable data exclusivity and alleging that one or more of the patents listed in the innovator s New Drug Application are invalid, not infringed or unenforceable. This allegation is commonly known as a Paragraph IV certification. The innovator then has the ability to file suit against the generic manufacturer to enforce its patents. Generic manufacturers have used Paragraph IV certifications extensively to challenge patents on a wide array of innovative pharmaceuticals, and it is anticipated that this trend will continue. In recent years, some generic manufacturers have launched generic versions of products before the ultimate resolution of patent litigation (commonly known as at-risk product launches). Generic entry may result in the loss of a significant portion of sales or downward pressures on the prices at which Schering-Plough offers formerly patented products. Please refer to Legal Proceedings in Schering-Plough s 2007 10-K/A and subsequent 10-Qs for descriptions of pending intellectual property litigation.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies, which could diminish or eliminate sales and profits from those regions and negatively affect Schering-Plough s results of operations. Further, recent court decisions relating to other companies U.S. patents, potential U.S. legislation relating to patent reform, as well as regulatory initiatives may result in further erosion of intellectual property protection.

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Patent disputes can be costly to prosecute and defend and adverse judgments could result in damage awards, increased royalties and other similar payments and decreased sales.

Patent positions can be highly uncertain and patent disputes in the pharmaceutical industry are not unusual. An adverse result in a patent dispute involving Schering-Plough s patents, or the patents of its collaborators, may lead to a determination by a court that the patent is not infringed, is invalid, and/or is unenforceable. Such an adverse determination could lead to Schering-Plough s loss of market exclusivity. An adverse result in a patent dispute alleging that Schering-Plough has infringed patents held by a third party may lead to a determination by a court that the patent is infringed, valid, and enforceable. Such an adverse determination may preclude the commercialization of Schering-Plough s products and/or may lead to significant financial damages for past and ongoing infringement. Due to the uncertainty surrounding patent litigation, parties may settle patent disputes by obtaining a license under mutually agreeable terms in order to decrease risk of an interruption in manufacturing and/or marketing of its products.

The potential for litigation regarding Schering-Plough s intellectual property rights always exists and litigation may be initiated by third parties attempting to abridge Schering-Plough s rights. Even if Schering-Plough is ultimately successful in a particular dispute, Schering-Plough may incur substantial costs in defending its patents and other intellectual property rights. See Patent Challenges Under the Hatch-Waxman Act in Part II, Item 1, Legal Proceedings in Schering-Plough s second quarter 10-Q for a list of current Paragraph IV certifications for Schering-Plough products.

Multi-jurisdictional regulations, including those establishing Schering-Plough s ability to price products, may negatively affect Schering-Plough s sales and profit margins.

Schering-Plough faces increasing pricing pressure globally from managed care organizations, institutions and government agencies and programs that could negatively affect Schering-Plough s sales and profit margins. For example, in the U.S., the Medicare Prescription Drug Improvement and Modernization Act of 2003 contains a prescription drug benefit for individuals who are eligible for Medicare. The prescription drug benefit became effective on January 1, 2006 and has resulted in increased use of generics and increased purchasing power of those negotiating on behalf of Medicare recipients, which in turn has resulted in increased price pressure on Schering-Plough s products.

In addition to legislation concerning price controls, other trends could adversely affect Schering-Plough s sales and profit margins. These trends include legislative or regulatory action relating to pharmaceutical pricing and reimbursement, health care reform initiatives, drug importation legislation and involuntary approval of medicines for OTC use. These trends also include non-governmental initiatives and practices such as consolidation among customers, managed care practices and health care costs containment. Increasingly, market approval, reimbursement of products, prescribers practices and policies of third-party payors may be influenced by health technology assessments by the National Institute for Health and Clinical Excellence in the UK and other such organizations.

In the U.S., as a result of the government s efforts to reduce health care expenditures and other payors efforts to reduce health care costs, Schering-Plough faces increased pricing pressure as payors continue to seek price discounts with respect to Schering-Plough s products.

In other countries, many governmental agencies strictly control, directly or indirectly, the prices at which pharmaceutical products are sold. In these markets, cost control methods including restrictions on physician prescription levels and patient reimbursements; emphasis on greater use of generic drugs; and across-the-board price cuts may decrease revenues internationally.

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Through the acquisition of OBS, Schering-Plough acquired marketed products and pipeline projects in new therapeutic areas, including women s health and fertility, anesthesia, and neuroscience, each of which carry unique risks and uncertainties which could have a negative impact on future results of operations.

With its acquisition of OBS, Schering-Plough acquired products in additional therapeutic areas. Each therapeutic area presents a different risk profile, including different benefits and safety issues that must be balanced by Schering-Plough and regulators as various research and development and marketing decisions are made; unique product liability risks; different patient and prescriber priorities; and different societal pressures. While adding new therapeutic areas may strengthen Schering-Plough s business by increasing sales and profits; making the combined company more relevant to patients and prescribers; and diversifying enterprise risk across more areas, such positives may not outweigh the additional risk in a particular therapeutic area or could result in unanticipated costs that could have a significant adverse impact or results of operations and cash flows.

Market forces continue to evolve and can impact Schering-Plough s ability to sell products or the price Schering-Plough can charge for products.

A number of intermediaries are involved between drug manufacturers, such as Schering-Plough, and patients who use the drugs. These intermediaries impact the patient s ability, and their prescribers ability, to choose and pay for a particular drug, which may adversely affect sales of a particular Schering-Plough drug. These intermediaries include health care providers, such as hospitals and clinics; payors and their representatives, such as employers, insurers, managed care organizations and governments; and others in the supply chain, such as pharmacists and wholesalers. Examples include: payors that require a patient to first fail on one or more generic, or less expensive branded drugs, before reimbursing for a more effective, branded product that is more expensive; hospitals that stock and administer only a generic product to in-patients; managed care organizations that may penalize doctors who prescribe outside approved formularies which may not include branded products when a generic is available; and pharmacists who receive larger revenues when they dispense a generic drug over a branded drug. Further, the intermediaries are not required to routinely provide transparent data to patients comparing the effectiveness of generic and branded products or to disclose their own economic benefits that are tied to steering patients toward, or requiring patients to use, generic products rather than branded products.

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Government investigations involving Schering-Plough could lead to the commencement of civil and/or criminal proceedings involving the imposition of substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs, which could give rise to other investigations or litigation by government entities or private parties.

Schering-Plough cannot predict whether future or pending investigations to which it may become subject would lead to a judgment or settlement involving a significant monetary award or restrictions on its operations.

The pricing, sales and marketing programs and arrangements and related business practices of Schering-Plough and other participants in the health care industry are under increasing scrutiny from federal and state regulatory, investigative, prosecutorial and administrative entities. These entities include the Department of Justice and its U.S. Attorneys Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. Many of the health care laws under which certain of these governmental entities operate, including the federal and state anti-kickback statutes and statutory and common law false claims laws, have been construed broadly by the courts and permit the government entities to exercise significant discretion. In the event that any of those governmental entities believes that wrongdoing has occurred, one or more of them could institute civil or criminal proceedings which, if resolved unfavorably, could subject Schering-Plough to substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs. In addition, an adverse outcome to a government investigation could prompt other government entities to commence investigations of Schering-Plough or cause those entities or private parties to bring civil claims against it. Schering-Plough also cannot predict whether any investigations will affect its marketing practices or sales. Any such result could have a material adverse impact on Schering-Plough s results of operations, cash flows, financial condition, or its business.

A number of governmental entities in the U.S. have made inquiries or initiated investigations into the timing and disclosures relating to the ENHANCE clinical trial, as well as the timing of certain stock sales by an executive vice president. These include several letters from Congress, investigations by state Attorneys General offices, and requests for information from U.S. Attorneys Offices and the Department of Justice.

Regardless of the merits or outcomes of any investigation, government investigations are costly, divert management s attention from Schering-Plough s business and may result in substantial damage to Schering-Plough s reputation.

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There are other legal matters in which adverse outcomes could negatively affect Schering-Plough s results of operations, cash flows, financial condition, or business.

Unfavorable outcomes in other pending litigation matters, or in future litigation, including litigation concerning product pricing, securities law violations, product liability claims, ERISA matters, patent and intellectual property disputes, and antitrust matters could preclude the commercialization of products, negatively affect the profitability of existing products and subject Schering-Plough to substantial fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs. Any such result could materially and adversely affect Schering-Plough s results of operations, cash flows, financial condition, or business.

Further, aggressive plaintiffs counsel often file litigation on a wide variety of allegations whenever there is media attention or negative discussion about the efficacy or safety of a product and whenever the stock price is volatile; even when the allegations are groundless Schering-Plough may need to expend considerable funds and other resources to respond to such litigation.

Please refer to Legal Proceedings in Item 3 in Schering-Plough s 2007 10-K/A and Part II, Item 1, Legal Proceedings, in Schering-Plough s second quarter 10-Q for descriptions of significant pending litigation.

Issues concerning the Merck/Schering-Plough Cholesterol Joint Venture s clinical trials could have a material adverse effect on the joint venture s sales of VYTORIN and ZETIA, which in turn could have a material adverse impact on Schering-Plough s financial condition.

See Recent Cholesterol Clinical Trials, in Part II of Schering-Plough s second quarter 10-Q and ENHANCE Matter in Part II, Item 1, Legal Proceedings of Schering-Plough s second quarter 10-Q for background information about the Merck/Schering-Plough cholesterol joint venture s clinical trials and related matters.

There was significant negative media surrounding the release of the ENHANCE results. As the Merck/Schering-Plough cholesterol joint venture s ENHANCE and SEAS clinical trial results are further reviewed, VYTORIN and ZETIA may receive additional media attention, which could lead to reduced sales, or affect enrollment in clinical trials. In the nine months ended September 30, 2008, sales of VYTORIN and ZETIA in the U.S. decreased by 20 percent compared to the nine months ended September 30, 2007. If sales of these products continue to trend down further in the U.S., Schering-Plough s results of operations, cash flow, financial position, business and prospects could also be materially adversely affected. In addition, current or future investigations, analysis of the ENHANCE and SEAS data by various agencies, litigation concerning the sale and promotion of these products, or the securities and other class action litigation relating to such matters could, if resolved unfavorably to Schering-Plough or the joint venture, have a material adverse effect on Schering-Plough s results of operations, cash flow and financial position.

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Schering-Plough and third parties acting on its behalf are subject to governmental regulations, and the failure to comply with, as well as the costs of compliance with, these regulations may adversely affect Schering-Plough s results of operations, cash flow and financial position.

Manufacturing and research practices of Schering-Plough and third parties acting on its behalf must meet stringent regulatory standards and are subject to regular inspections. The cost of regulatory compliance, including that associated with compliance failures, can materially affect Schering-Plough s results of operations, cash flow and financial position. Failure to comply with regulations, which include pharmacovigilance reporting requirements and standards relating to clinical, laboratory and manufacturing practices, can result in suspension or termination of clinical studies, delays or failure in obtaining the approval of drugs, seizure or recalls of drugs, suspension or revocation of the authority necessary for the production and sale of drugs, withdrawal of approval, fines and other civil or criminal sanctions.

Schering-Plough also is subject to other regulations, including environmental, health and safety, and labor regulations.

Developments following regulatory approval may adversely affect sales of Schering-Plough s products.

Even after a product reaches market, certain developments following regulatory approval, including results in post-marketing Phase IV trials, may decrease demand for Schering-Plough s products, including the following:

the re-review of products that are already marketed;

new scientific information and evolution of scientific theories;

the recall or loss of marketing approval of products that are already marketed;

changing government standards or public expectations regarding safety, efficacy or labeling changes; and

greater scrutiny in advertising and promotion.

In the past several years, clinical trials and post-marketing surveillance of certain marketed drugs of competitors within the industry have raised safety concerns that have led to recalls, withdrawals or adverse labeling of marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials have led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following the wake of product withdrawals of other companies and other significant safety issues, health authorities such as the FDA, the European Medicines Agency and the Pharmaceuticals and Medicines Device Agency have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the U.S., on advertising and promotion and in particular, direct-to-consumer advertising.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of Schering-Plough s products, it could significantly reduce demand for the product or require Schering-Plough to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, Schering-Plough is at risk for product liability claims for its products.

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New products and technological advances developed by Schering-Plough s competitors may negatively affect sales.

Schering-Plough operates in a highly competitive industry. Schering-Plough competes with a large number of multinational pharmaceutical companies, biotechnology companies and generic pharmaceutical companies. Many of Schering-Plough s competitors have been conducting research and development in areas served both by Schering-Plough s current products and by those products Schering-Plough is in the process of developing. Competitive developments that may impact Schering-Plough include technological advances by, patents granted to, and new products developed by competitors or new and existing generic, prescription and/or OTC products that compete with products of Schering-Plough or the Merck/Schering-Plough cholesterol joint venture. In addition, it is possible that doctors, patients and providers may favor those products offered by competitors due to safety, efficacy, pricing or reimbursement characteristics, and as a result Schering-Plough will be unable to maintain its sales for such products.

Competition from third parties may make it difficult for Schering-Plough to acquire or license new products or product candidates (regardless of stage of development) or to enter into such transactions on terms that permit Schering-Plough to generate a positive financial impact.

Schering-Plough depends on acquisition and in-licensing arrangements as a source for new products. Opportunities for obtaining or licensing new products are limited, however, and securing rights to them typically requires substantial amounts of funding or substantial resource commitments. Schering-Plough competes for these opportunities against many other companies and third parties that have greater financial resources and greater ability to make other resource commitments. Schering-Plough may not be able to acquire or license new products, which could adversely impact Schering-Plough and its prospects. Schering-Plough may also have difficulty acquiring or licensing new products on acceptable terms. To secure rights to new products, Schering-Plough may have to make substantial financial or other resource commitments that could limit its ability to produce a positive financial impact from such transactions.

Schering-Plough relies on third-party relationships for its key products, and the conduct and changing circumstances of such third parties may adversely impact the business.

Schering-Plough has several relationships with third parties on which Schering-Plough depends for many of its key products. Very often these third parties compete with Schering-Plough or have interests that are not aligned with the interests of Schering-Plough. Notwithstanding any contracts Schering-Plough has with these third parties, Schering-Plough may not be able to control or influence the conduct of these parties, or the circumstances that affect them, either of which could adversely impact Schering-Plough.

The relationships are long-standing and, as the third party s work and Schering-Plough s work evolves, priorities and alignments also change. At times new issues develop that were not anticipated at the time contracts were negotiated. These new issues, and related uncertainties in the contracts, also can adversely impact Schering-Plough.

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Schering-Plough s global operations expose Schering-Plough to additional risks, and any adverse event could have a material negative impact on results of operations.

A majority of Schering-Plough s operations are outside the U.S. With the acquisition of OBS in late 2007, Schering-Plough s global operations in Human Prescription Pharmaceuticals and Animal Health increased. Acquisitions, such as the recently completed purchase of OBS, further expanded the size, scale and scope of Schering-Plough s global operations. Risks inherent in conducting a global business include:

changes in medical reimbursement policies and programs and pricing restrictions in key markets;

multiple regulatory requirements that could restrict Schering-Plough s ability to manufacture and sell its products in key markets;

trade protection measures and import or export licensing requirements;

diminished protection of intellectual property in some countries; and

possible nationalization and expropriation.

In addition, there may be changes to Schering-Plough s business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease.

The integration of the businesses of Schering-Plough and OBS to create a combined company is a complex process and may be subject to unforeseen developments, which could have an adverse impact on the results of future operations.

As the two companies are combined, the workforces of Schering-Plough and OBS will continue to face uncertainties until the completion of the integration phase. Cultural integration particularly in trans-Atlantic transactions are complex and can take several years. Although substantial efforts are being made to complete the integration phase of the OBS acquisition as quickly as possible, it is difficult to predict how long the integration phase will last.

The workforces of both companies are learning to use new processes as work is integrated and streamlined. Further, for those employees of the new combined company who have not in the past worked for a U.S.-based global company, the applicable regulatory requirements are different in a number of respects. While substantial efforts are being made to facilitate smooth execution of integration including thorough training and transparent and motivational employee communications there may be an increased risk of slower execution of various work processes, repeated execution to achieve quality standards and reputational harm in the event of a compliance failure with new and complex regulatory requirements, even if such a failure were inadvertent. Any such events could have an adverse impact on the results of future operations.

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The acquisition of OBS expanded Schering-Plough s animal health business worldwide, which increases the risk that negative events in the animal health industry could have a negative impact on future results of operations.

Through the acquisition of OBS animal health businesses, Schering-Plough s global animal health business is now a more significant business segment. The combined company s future sales of key animal health products could be adversely impacted by a number of risk factors including certain that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as Bovine Spongiform Encephalopathy (BSE) or mad cow disease, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely impact Schering-Plough s results of operations. Also, the outbreak of any highly contagious diseases near Schering-Plough s main production sites could require Schering-Plough to immediately halt production of vaccines at such sites or force Schering-Plough to incur substantial expenses in procuring raw materials or vaccines elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. As the animal health segment of Schering-Plough s business becomes more significant, the impact of any such events on future results of operations would also become more significant.

The acquisition of OBS increased Schering-Plough s biologics human and animal health product offerings, including animal health vaccines. Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful development, testing, manufacturing and commercialization of biologics, particularly human and animal health vaccines, is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics, including:

There may be limited access to and supply of normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions such as the U.S. and European states within the EU, could result in restricted access to, or transport or use of, such materials. If Schering-Plough loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, Schering-Plough may not be able to conduct research activities as planned and may incur additional development costs.

The development, manufacturing and marketing of biologics are subject to regulation by the FDA, the European Medicines Agency and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the U.S., a Biologics License Application, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates and FDA approval for the release of each manufactured lot.

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, Schering-Plough may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.

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Biologics are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

The use of biologically derived ingredients can lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

There currently is no process in the U.S. for the submission or approval of generic biologics based upon abbreviated data packages or a showing of sameness to another approved biologic, but there is public dialogue at the FDA and in Congress regarding the scientific and statutory basis upon which such products, known as biosimilars or follow-on biologics, could be approved and marketed in the U.S. Schering-Plough cannot be certain when Congress will create a statutory pathway for the approval of biosimilars, and Schering-Plough cannot predict what impact, if any, the approval of biosimilars would have on the sales of Schering-Plough products in the U.S. In Europe, however, the EMEA has issued guidelines for approving biological products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of Schering-Plough s products were approved in Europe, it could have a negative effect on sales of the product.

Schering-Plough is exposed to market risk from fluctuations in currency exchange rates and interest rates.

Schering-Plough operates in multiple jurisdictions and, as such, virtually all sales are denominated in currencies of the local jurisdiction. Additionally, Schering-Plough has entered and will enter into acquisition, licensing, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since Schering-Plough cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates and interest rates could negatively affect Schering-Plough s results of operations and/or cash flows.

In order to mitigate against the adverse impact of these market fluctuations, Schering-Plough will from time to time enter into hedging agreements. While hedging agreements, such as currency options and interest rate swaps, limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks are costly and not always successful.

The current stock market and credit market conditions are extremely volatile and unpredictable. It is difficult to predict whether these conditions will continue or worsen, and if so, whether the conditions would impact Schering-Plough and whether such impact could be material.

Schering-Plough has exposure to many different industries and counterparties, including commercial banks, investment banks and customers (which include wholesalers, managed care organizations and governments) that may be unstable or may become unstable in the current economic environment. Any such instability may impact these parties ability to fulfill contractual obligations to Schering-Plough or they might limit or place burdensome conditions upon future transactions with Schering-Plough. Customers may also reduce spending during times of economic uncertainty. Also, it is possible that suppliers may be negatively impacted. In such events, there could be a resulting material and adverse impact on operations and results of operations.

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Although Schering-Plough currently has no plan to access the equity or debt markets to meet capital or liquidity needs, constriction and volatility in these markets may restrict future flexibility to do so if unforeseen capital or liquidity needs were to arise.

Further, the conditions have resulted in severe downward pressure on the stock and credit markets, which could reduce the return available on invested corporate cash, reduce the return on investments under the pension plans and thereby potentially increase funding obligations, all of which if severe and sustained could have material and adverse impacts on Schering-Plough s results of operations and cash flows.

Insurance coverage for product liability may be limited, cost prohibitive or unavailable.

Schering-Plough maintains insurance coverage with such deductibles and self-insurance to reflect market conditions (including cost and availability) existing at the time it is written, and the relationship of insurance coverage to self-insurance varies accordingly. For certain products, third-party insurance is increasingly cost prohibitive, available on more limited terms than past coverage, or unavailable.

Schering-Plough is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations.

Schering-Plough is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining Schering-Plough s tax liabilities, and Schering-Plough s tax returns are periodically examined by various tax authorities. Schering-Plough believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

In addition, Schering-Plough may be impacted by changes in tax laws including tax rate changes, changes to the laws related to the remittance of foreign earnings, new tax laws and revised tax law interpretations in domestic and foreign jurisdictions.

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Item 9.01 Financial Statements and Exhibits.
(d) Exhibits

99.1	Press release dated October 21, 2008 titled Schering-Plough Reports Financial Results for Third Quarter of 2008
99.2	Supplemental Financial Data

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Schering-Plough Corporation

By: /s/ Steven H. Koehler
Steven H. Koehler
Vice President and Controller

Date: October 21, 2008

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Exhibit Index

Exhibit Number	Description
99.1	Press release dated October 21, 2008 titled Schering-Plough Reports Financial Results for Third Quarter of 2008
99.2	Supplemental Financial Data