

# FORM 10-K

## **MEDICINES CO /DE – MDCO**

### Filed: March 05, 2004 (period: December 31, 2003)

Annual report which provides a comprehensive overview of the company for the past year

# **Table of Contents**

### <u>PART I</u>

- Item 1. Business
- Item 2. Properties
- Item 3. Legal Proceedings
- Item 4. Submission of Matters to a Vote of Security Holders

### <u>PART II</u>

- Item 5. Market for Registrant's Common Equity and Related Stockholder Matters
- Item 6. Selected Consolidated Financial Data
- Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
- Item 7A. Quantitative and Qualitative Disclosure About Market Risk
- Item 8. Financial Statements and Supplementary Data
- Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure
- Item 9A. Controls and Procedures

### <u>PART III</u>

- Item 10. Directors and Executive Officers of the Registrant
- Item 11. Executive Compensation
- Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matt
- Item 13. Certain Relationships and Related Transactions
- Item 14. Principal Accountant Fees and Services

SIGNATURES

<u>Signature</u>

INDEX TO EXHIBITS

EX-10.15 (Material contracts)

- EX-10.17 (Material contracts)
- EX-10.18 (Material contracts)

EX-21 (Subsidiaries of the registrant)

EX-23 (Consents of experts and counsel)

<u>EX-31.1</u>

<u>EX-31.2</u>

<u>EX-31.3</u>

<u>EX-32.1</u>		
<u>EX-32.2</u>		
<u>EX-32.3</u>		

### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### Form 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 2003

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 000-31191

to

### THE MEDICINES COMPANY

(Exact name of registrant as specified in its charter)

Delaware

04–3324394 (I.R.S. Employer Identification No.)

07054

(Zip Code)

8 Campus Drive Parsippany, New Jersey (Address of principal executive offices)

(State or other jurisdiction of incorporation or organization)

Registrant's telephone number, including area code: (973) 656–1616

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

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

Common Stock, \$.001 Par Value (Title of each class)

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  $\square$  No  $\square$ 

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 an accelerated filer (as defined in Exchange Act Rule 12b–2). Yes 🗵 No 🗖

The aggregate market value of voting Common Stock held by non-affiliates of the registrant was approximately \$681,078,238 based on the last reported sale price of the Common Stock on the Nasdaq National Market on June 30, 2003.

Number of shares of the registrant's class of Common Stock outstanding as of February 25, 2004: 47,535,395.

THE MEDICINES COMPANY

#### ANNUAL REPORT ON FORM 10-K For the Fiscal Year Ended December 31, 2003

#### TABLE OF CONTENTS

PART I		1
ITEM 1.	BUSINESS	1
ITEM 2.	PROPERTIES	23
ITEM 3.	LEGAL PROCEEDINGS	23
ITEM 4.	SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS	23
PART II		24
ITEM 5.	MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	24
ITEM 6.	SELECTED CONSOLIDATED FINANCIAL DATA	25
ITEM 7.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	26
ITEM 7A.	OUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK	45
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	45
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL	45
ITEM 9A.	DISCLOSURE CONTROLS AND PROCEDURES	45
PART III		46
ITEM 10.	DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT	46
ITEM 11.	EXECUTIVE COMPENSATION	50
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED	53
	STOCKHOLDER MATTERS	
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	57
ITEM 14.	PRINCIPAL ACCOUNTANT FEES AND SERVICES	58
PART IV		59
ITEM 15.	EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K	59

#### PART I

#### Item 1. Business

#### Overview

We are a pharmaceutical company that specializes in acute care hospital products. We acquire, develop and commercialize pharmaceutical products in late stages of their development. Our first acute care hospital product, Angiomax® (bivalirudin), is a direct thrombin inhibitor used as an anticoagulant in patients undergoing coronary angioplasty. We are currently developing two additional late development stage pharmaceutical products as potential acute care hospital products. The first of these, Clevelox<sup>TM</sup> (clevidipine), is an intravenous drug intended for the short–term control of blood pressure in patients undergoing cardiac surgery. The second potential product, cangrelor, is an anticoagulant that prevents platelet clotting factors from activating, which we believe has potential uses in coronary angioplasty and cardiac surgery. We focus our commercial sales and marketing resources on the U.S. hospital market, and our revenues to date have been generated almost entirely from sales of Angiomax in the United States. Our total net revenues were \$14.2 million in 2001, \$38.3 million in 2002 and \$85.6 million in 2003.

Our core strategy is to develop and commercialize products that we believe will help hospitals alleviate the growing pressure to treat patients more efficiently, including the need to improve the effectiveness and safety of treatment while minimizing cost. Cost of treatment in hospitals is predominantly driven by length of patient stay, while length of stay is often driven by the occurrence of treatment complications. Products that are effective, safe and predictable, or that require shorter periods of treatment or are easier to use than current products, may reduce the length of hospital stay and lower total costs. We believe that products with these attributes positively impact the care of patients and are attractive to hospital management, physicians, pharmacists and other care staff. We believe that the products we are developing will address these needs.

As a result of our experience commercializing Angiomax, we have developed in-depth know-how related to the practice of acute hospital care and gained valuable insights into procurement processes, usage patterns, caregiver preferences and the evaluation of products by our hospital customers. Our current and potential hospital customers are technically proficient in specialized areas of acute patient care and demand a high level of technical service for the products they use. They practice in such areas of the hospital as the cardiac catheterization laboratory, where coronary angioplasties are performed, the emergency department, and the operating room. We believe we can successfully address acute care hospital markets without a large sales force and without an internal manufacturing infrastructure.

The United States Food and Drug Administration, or FDA, approved Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary angioplasty in December 2000, and we began selling the product in the United States in January 2001. We believe that Angiomax has the potential to replace heparin, the anticoagulant that historically has been used in the United Stated in the treatment of arterial thrombosis, a condition involving the formation of blood clots in arteries. We believe that in each of the three years we have sold Angiomax, we have gained market share versus heparin in coronary angioplasty. We are evaluating Angiomax for additional uses in open vascular surgery such as coronary artery bypass graft, or CABG, surgery, in medical conditions that require urgent treatment such as unstable angina, in patients with heparin allergy, in children and in peripheral angioplasty.

For Clevelox, we and a contract manufacturer have completed manufacturing development work to produce a sufficient supply of the product for clinical development and, potentially, commercial supply. We commenced a Phase 3 clinical program for Clevelox in 2003, and we believe that we currently have the capability to have Clevelox manufactured and packaged on a commercial scale appropriate for launch of the drug. For cangrelor, which we acquired in December 2003, we have initiated technology transfer activities that should enable our contract manufacturer to produce a sufficient supply of the product for Phase 3 clinical trials.

In markets outside of the United States, we intend to market Angiomax and, eventually, our other products, through distribution agreements. In order to market our products in the European Union and many other foreign jurisdictions, we or our third–party distributors must obtain separate regulatory approvals. Third–party distributors are currently selling Angiomax in Canada, Israel and New Zealand. In August 2003, we filed a market authorization application for approval to sell Angiomax in the European Union. The application is currently under review.

#### Product Acquisition and Development Strategy

We intend to continue building our acute care franchise of hospital products by selectively acquiring and developing late-stage product candidates or products approved for marketing. We believe that products may be acquired from larger pharmaceutical companies in the process of refining their own product portfolios and from smaller companies seeking specialist development or commercial collaborations.

In evaluating product acquisition candidates, we will continue to seek products that have the potential to alleviate the growing pressures on U.S. hospitals to treat patients more efficiently. We look for an anticipated time from acquisition to commercialization of four years or less and existing clinical data which provides reasonable evidence of safety and efficacy, together with the potential to reduce a patient's hospital stay. In addition, we may acquire approved products that can be marketed in hospitals by our commercial organization. In making our acquisition decisions, our approach is to:

- understand the market opportunity and potential cost savings for initially-targeted uses of the drug based on our knowledge of the acute care hospital markets and input from healthcare practitioners;
- assess the investment and development programs that will be necessary to achieve a marketable product profile in these initial uses;
- attempt to structure the design of our development programs to obtain critical information relating to the clinical and economic performance of the product early in the development process, so that we can make or adjust key development decisions; and
- assess the fit with our acute care franchise to enable commercial overlap and minimize the need for expansion of our commercial organization.

We believe that Angiomax, Clevelox and cangrelor each fit the profile set forth above. For each of these products, we structured the license agreements to include an upfront payment, milestone payments upon marketing and regulatory achievements and royalties on eventual product sales. We acquired Angiomax from Biogen, Inc., a predecessor of Biogen Idec, Inc., a biotechnology company. We acquired both Clevelox and cangrelor from AstraZeneca AB, a large pharmaceutical company.

#### Angiomax

#### Overview

Our first product acquisition was Angiomax, which we exclusively licensed from Biogen in 1997. Since acquiring Angiomax, we have invested in manufacturing, clinical and regulatory development. In December 2000, we received marketing approval from the FDA for Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. We began selling Angiomax in the United States in January 2001. In May 2003, we received FDA approval for an improved process for manufacturing Angiomax, known as the Chemilog process, which has increased the efficiency of manufacturing the Angiomax active product ingredient.

We believe that Angiomax, as a direct thrombin inhibitor, has the potential to become a broadly applied intravenous anticoagulant in the treatment of coronary and other arterial thrombosis. Arterial

thrombosis is associated with life-threatening conditions such as ischemic heart disease, peripheral vascular disease and stroke, all of which result from decreased blood flow and diminished supply of oxygen to vital organs. We believe that Angiomax can replace heparin, a generic product manufactured from by-products of cow lungs or pig intestines, that has been the anticoagulant used historically in angioplasty procedures, in most major cardiac and vascular surgical procedures and in the treatment of acute coronary syndromes, including heart attack.

There are three main areas of the hospital where heparin is used for acute treatment of arterial thrombosis: the cardiac catheterization laboratory, where angioplasties are performed; the emergency department, where patients with acute coronary syndromes, including chest pain and heart attacks, are initially treated; and the operating room, where CABG surgery is performed.

We are concentrating our commercial efforts on replacing heparin in the cardiac catheterization laboratory, where the procedure for which Angiomax is approved are performed. We have conducted several clinical trials in angioplasty to evaluate the use of Angiomax compared to heparin in this setting. In these trials, Angiomax use has resulted in fewer ischemic complications and fewer bleeding events, including a reduction in the need for blood transfusion. In addition, Angiomax demonstrated in these trials that its therapeutic effect is more predictable than heparin, which enables simplified dosing.

We are currently conducting Phase 3 clinical trials of Angiomax in the emergency department and the operating room, as we are pursuing regulatory approval to market Angiomax for acute coronary syndromes and for CABG surgery. We are also evaluating Angiomax in clinical trials for use in patients with heparin allergy, in children and in peripheral angioplasty.

#### Scientific Background

*Clotting.* Normally, blood loss at the site of an injury is limited by the formation of blood clots, in a process called coagulation. A blood clot is a collection of cross–linked strands of the protein fibrin, which is made as a result of coagulation and forms a mesh around activated platelets and red blood cells. Blood clots are formed through precisely regulated interactions among the blood vessel wall, plasma clotting factors (including thrombin and fibrinogen) and platelets. Current literature suggests that the clotting process is a series of overlapping phases in which groups of clotting factors are intertwined with platelets, red blood cells and endothelial cells that line the blood vessels. In general, clotting serves a life–saving function by reducing bleeding; however, unwanted clots in arteries can lead to heart attack, stroke or organ failure.

The trigger for the clotting process in an artery is typically a tearing or spontaneous rupture of plaque (deposits of cholesterol, fat and dead cells that build up under a protective layer of cells, known as endothelial cells, on a blood vessel wall). Rupturing may occur without an apparent cause or may be the result of, for example, the use of catheters and other devices in connection with an angioplasty procedure. When the plaque ruptures, substances released from cells and plaque that are not normally exposed to the bloodstream come into contact with the bloodstream. This contact triggers the clotting process. In parallel inter–dependent processes, a small amount of the clotting factor thrombin is produced and a thin protective layer of platelets is deposited at the rupture site.

Thrombin has long been recognized as a key factor in the clotting process. Thrombin, like several other clotting factors, is technically a type of enzyme called a protease. Thrombin not only converts fibrinogen into the fibrin strands that hold a clot together, but it also helps to amplify its own production by activating other clotting factors. Thrombin also provides signals, like a hormone does, to various cell types such as platelets and endothelial cells to initiate responses in coagulation, inflammation and, possibly, other important physiological processes. Thrombin directly activates platelets, by producing effects through means of surface receptors on the platelets called protease–activated receptors, or PARs, that provide binding sites for the effector molecule. PARs carry a hidden

message that is unmasked by the action of the protease, for example, thrombin. Activation of the PAR then transmits the signal to the platelet, which becomes activated.

In addition to being a powerful platelet activator through its action on platelets, thrombin can also recruit more platelets to the site of injury. Activated platelets not only help close the rupture, but the activated platelet's membrane becomes a docking site for other clotting factors. The clotting factors can assemble and much more efficiently produce very large amounts of thrombin. The thrombin produces fibrin, strands of protein that interweave and enmesh the platelets into a thrombus, or clot. The clotting factors on the platelets within the clot continue to produce large amounts of thrombin after the clot is formed, causing the clot to continue to grow.

As a clot blocks the blood vessel, it may then cut off blood supply to the heart muscle, the brain or other organs. A heart attack, also known as a myocardial infarction, or MI, occurs if a clot blocks blood supply to the heart muscle, and the muscle stops working either in part or completely. This may result in irreversible damage to the heart or death.

During medical procedures such as coronary angioplasty, the blood clotting process must be slowed to avoid unwanted clotting in the coronary artery and the potential growth of clots or the movement of a clot or portions of it downstream in the blood vessels to new sites.

Anticoagulation Therapy. Anticoagulation therapy attempts to modify actions of the components in the blood system that activate clot-forming factors leading to blood clots. Anticoagulation therapy is warranted when the risks of clot formation cannot be avoided, or when medical procedures such as angioplasty give rise to an increased risk of clot formation. Anticoagulation therapy has typically involved the use of drugs to inhibit one or more components of the clotting process, thereby reducing the risk of clot formation. Anticoagulation therapy is usually started immediately after a diagnosis of blood clots, or after risk factors for clotting are identified. Because anticoagulation therapy reduces clotting, it also may cause excessive bleeding.

Current anticoagulation therapy focuses on the principal components of the clotting process: thrombin, platelets and fibrin.

The actions of thrombin in the clotting process may be inhibited by direct thrombin inhibitors, such as Angiomax, which act directly on thrombin. Because thrombin activates platelets, direct thrombin inhibitors also prevent platelet clumping. The actions of thrombin in the clotting process may also be inhibited by indirect thrombin inhibitors, such as heparin, which act to turn off clotting factors and turn on natural anti–clotting factors such as antithrombin, or AT.

The aggregation of platelets in the clotting process may be inhibited by products called platelet inhibitors, which act on different pathways leading to platelet activation, including specific enzyme pathways like the cyclo–oxygenase and the adenosine diphosphate, or ADP, pathways. Two important approved products that prevent platelet activation are aspirin and a class of platelet inhibitors that can be administered orally and are referred to as thienopyridines, such as clopidogrel. The use of platelet inhibitors that block activation is considered important therapy.

Other types of platelet inhibitors attempt to block the clumping, or aggregation, of platelets by blocking surface sites, like the glycoprotein IIb/IIIa, or GP IIb/IIIa, receptor, on the platelets that allow them to attach to fibrin and each other. The GP IIb/IIIa inhibitors, although effective at inhibiting platelet aggregation, do not prevent platelet activation. In fact, many studies have found that use of these agents, especially at low levels, is associated with an increase in markers of platelet activation.

Fibrin may be dissolved after clotting has occurred by products called fibrinolytics.

Drugs are currently used alone or in combination with other anticoagulant therapies to target one or more components of the clotting process. Because of the interdependence of clotting factors and

platelets, drugs that target one may have effects on the other. For example, a drug that targets thrombin may have an antiplatelet effect. However, possibly due to the critical, central role of thrombin, while anti-thrombin drugs have been used alone in angioplasty, the use of antiplatelet drugs without thrombin inhibitors generally has not been successful.

#### Disadvantages of Heparin Therapies

In the hospital environment, most patients undergoing anticoagulation therapy for the prevention and treatment of arterial and venous thrombosis receive unfractionated heparin or low molecular weight heparin. In the United States, over 12 million hospitalized patients annually receive heparin therapy. Heparin is a standard component of acute anticoagulation therapy because of the central role of thrombin in the clotting process and heparin's rapid anticoagulant effect.

Heparin's properties as an anticoagulant were discovered in 1916. It is prepared from the intestines of pigs or lungs of cows. Heparin is a complex mixture of animal-derived proteins with variable anticoagulant potencies. The anticoagulant effects of heparin on any given patient are difficult to predict because heparin binds non-specifically to human cells and circulating substances in the blood. For these and other reasons, heparin, as a non-specific, indirect thrombin inhibitor, presents a variety of clinical challenges including:

- Weak effect in clots. Because it is an indirect thrombin inhibitor, heparin is variably effective on thrombin that is bound to clots. In addition, large amounts of thrombin continue to be produced from within the clot after clot formation.
- Activation of platelets. Studies have shown that heparin enhances the clumping of platelets in unstable angina patients. Heparin activates platelets by binding to the GP IIb/IIIa receptor on the platelet surface, and has been shown to decrease the platelet inhibitory effects of GP IIb/IIIa platelet inhibitors.
- Increased risk of bleeding. Patients who receive heparin have a high incidence of bleeding. This is particularly the case with patients who are elderly, female or have low body weight. Recent clinical trials have shown that bleeding risk may also be increased when heparin is used in combination with intravenous platelet inhibitors.
- Unpredictability. A specified dose of heparin provides an unpredictable level of anticoagulation. As a result of this unpredictability, use of heparin requires close monitoring.
- *Risk of clinical immune reaction.* Heparin may cause the formation of antibodies, which antibodies may be associated with a clinical condition known as heparin–induced thrombocytopenia and thrombosis syndrome, or HIT/HITTS, which is characterized by reduced platelet counts and potentially by widespread, life–threatening blood clots.
  - Diminished effect in high-risk patients. Heparin's effect may be reduced in patients who have suffered a prior heart attack and in patients with unstable angina.
    - Indirect thrombin inhibition. Heparin can only bind to thrombin by first binding to AT which may be absent or present in insufficient amounts in some patients. AT deficiency can be severe and unpredictable in infants and children.

Heparin derivatives, including low molecular weight heparins such as enoxapirin, were developed to attempt to diminish some of these disadvantages. Low molecular weight heparins are administered once or twice daily by subcutaneous injection. Although they tend to be more predictable than heparin in their effect, low molecular weight heparins exhibit similar clinical challenges to those of heparin, including a weak effect on thrombin in a clot that has already formed and a comparable risk of bleeding. The effects of low molecular weight heparins are only partially reversible, making their use in surgery or in patients that may be candidates for surgery impractical. Low molecular weight heparins

also have a longer half-life than unfractionated heparin, meaning it takes the body longer to clear the drug and void its effects. This may adversely affect the ability of hospitals to move patients between acute cardiology departments such as the emergency department and cardiac catheterization laboratory or to discharge patients from the hospital.

#### Angiomax Advantages

Angiomax is a synthetic peptide of 20 amino acids that is a rapid-acting, direct and specific inhibitor of thrombin and is administered by intravenous injection. Angiomax is specific in that it only binds to thrombin and does not bind to or activate any other blood factors or cells.

Angiomax was engineered based on the biochemical structure of hirudin, a natural 65-amino acid protein anticoagulant. However, the binding of Angiomax to thrombin is "naturally" reversible because thrombin slowly breaks down the Angiomax molecule, releasing it from binding, while hirudin remains intact and tightly bound to thrombin. This natural reversibility is associated with a reduced risk of bleeding.

Angiomax has numerous pharmacological and clinical advantages over heparin including:

- *Effective in clot-bound thrombin*. Angiomax, as a direct thrombin inhibitor, is equally effective on thrombin in the clot as well as thrombin circulating in the blood.
- Inhibition of platelets. Angiomax directly inhibits thrombin which also inhibits platelet activation through inhibition of platelet activating receptors, such as the PAR receptors, on the surface of platelets.
- *Reduced bleeding risk.* As a reversible thrombin inhibitor, Angiomax has consistently shown clinically meaningful reductions in bleeding compared to heparin in percutaneous coronary intervention trials.
  - Predictability. As a synthetic peptide, a specified dose of Angiomax results in a predictable level of anticoagulation.
- *Effective in high-risk patients.* Angiomax has been shown to be effective in patients having suffered prior heart attacks and patients with acute coronary syndromes.
  - *Reduced incidence of thrombocytopenia.* Angiomax has been shown to result in a significant reduction in thrombocytopenia, or lower platelet counts, an immunogenic disorder associated with heparin.

#### Coronary Angioplasty

Coronary angioplasty has transformed the management of symptomatic arterial disease in the last 10 years. The procedure is used to restore normal blood flow in arteries that supply blood to the heart. In the year 2002, more than one million coronary angioplasty procedures with or without stenting were performed in the United States. The coronary angioplasty procedure itself increases the risk of coronary clotting, potentially leading to heart attacks also known as a myocardial infarction or MI, CABG surgery, or death.

Accordingly, anticoagulation therapy is routinely administered to patients undergoing angioplasty to prevent clotting. Heparin has historically been used as an anticoagulant in virtually all patients undergoing angioplasty. In addition, platelet inhibitors such as aspirin, ADP inhibitors or GP IIb/IIIa inhibitors are often administered to augment heparin.

#### Clinical Trials in Coronary Angioplasty

We invest significantly in the development of clinical data on the mode of action and clinical effects of Angiomax in procedures including coronary angioplasty and stenting.

In almost all of our investigations to date, we have compared Angiomax to heparin, which until relatively recently was the only injectable anticoagulant for use in coronary angioplasty, or combinations of drugs including heparin. Angiomax has been tested against heparin in eight comparative trials and found to reduce significantly the risk of arterial thrombosis and of bleeding. Most of these data formed the basis for FDA approval in late 2000 and of our marketing programs in 2001 and 2002. Our marketing programs in 2003 were based largely on the results of our REPLACE–2 clinical trial, results for which were initially reported in November 2002.

We conducted the REPLACE-2 clinical trial in 2001 and 2002 to evaluate Angiomax as the foundation anticoagulant for angioplasty within the context of modern therapeutic products and technologies, including coronary stents. The trial, which involved 6,002 patients in 233 clinical sites, was designed to evaluate whether the use of Angiomax with provisional use of GP IIb/IIIa inhibitors provides clinical outcomes relating to rates of ischemic and bleeding events that are superior to heparin alone and the same as, or non-inferior to, the current standard of low-dose weight-adjusted heparin plus GP IIb/IIIa inhibitors. These outcomes were designed to be assessed using formal statistical tests for superiority and non-inferiority.

REPLACE-2 employed two randomized arms:

heparin with a GP IIb/IIIa inhibitor, which was either Integrilin or ReoPro; and

Angiomax with the provisional use of a GP IIb/IIIa inhibitor, which was either Integrilin or ReoPro, if deemed necessary by the physician during the procedure.

The trial also evaluated the Angiomax regimen against heparin alone using an historical control arm. The heparin historical control arm of the study was calculated using an average of the event rates from the EPISTENT and ESPRIT trials, which were previous angioplasty trials of other companies in which heparin alone was compared to heparin plus a GP IIb/IIIa inhibitor.

The primary objective of REPLACE-2 was to demonstrate superiority versus heparin and non-inferiority to heparin plus a GP IIb/IIIa inhibitor for the quadruple composite endpoint of death, MI, urgent revascularization or major bleeding. The secondary objectives of REPLACE-2 included superiority versus heparin and non-inferiority to heparin plus a GP IIb/IIIa inhibitor for a triple composite endpoint of death, MI or urgent revascularization.

Based on 30-day, six-month and 12-month patient follow-up results, Angiomax met all primary and secondary objectives for the study:

The primary quadruple composite endpoint of death, MI, urgent revascularization or major bleeding was met at 30 days:

Angiomax was superior to heparin alone.

Angiomax was non-inferior to heparin plus a GP IIb/IIIa inhibitor.

The secondary triple composite endpoint of death, MI or urgent revascularization was met at 30 days and six-months:

Angiomax was superior to heparin alone.

Angiomax was non-inferior to heparin plus a GP IIb/IIIa inhibitor.

The final long-term endpoint of death was met at 12-months:

- Mortality benefit seen at 30 days was maintained.
- A numeric mortality advantage in the Angiomax arm widened from the six-month and 12-month long-term findings, although this numeric advantage was not statistically significant.

Additional findings from the study included:

- The Angiomax treatment group demonstrated a significant decrease in bleeding complications and thrombocytopenia as compared to heparin plus a GP IIb/IIIa inhibitor.
- 7.2% of the patients in the Angiomax treatment group received a GP IIb/IIIa inhibitor on a provisional basis.
- 97% of patients achieved desired anticoagulation targets with the initial dose of Angiomax versus 88% with heparin plus a GP IIb/IIIa inhibitor, resulting in 12% of the patients with heparin plus a GP IIb/IIIa inhibitor having to receive multiple doses of heparin.
- The average patient duration of infusion was 44 minutes with Angiomax versus 12 to 18 hours for patients treated with heparin plus a GP IIb/IIIa inhibitor.
  - A protocol-defined health economic analysis of the 30-day follow-up data, presented at a symposium as part of the 2003 American College of Cardiology conference, demonstrated that the costs associated with treating patients in the Angiomax arm were statistically significantly lower than the costs associated with treating patients in the heparin plus GP IIb/IIIa arm. This reduction in costs included:
    - savings of \$185 per patient due to fewer bleeding, MI and thrombocytopenia complications in patients in the Angiomax arm of the trial
      - savings of \$402 per patient due to lower cost of drugs in the Angiomax arm, which had 7.2% combination use of GP IIb/IIIa inhibitors.

The 30-day findings were published in the Journal of the American Medical Association, or JAMA, in February of 2003. We have submitted the 30-day, six-month and 12-month data for FDA review as part of a supplement to update the product labeling to include the REPLACE-2 data. In addition, we used the REPLACE-2 results as the basis for regulatory updates and submissions in international markets, including Europe and Canada.

#### Angiomax Commercial Operations in Coronary Angioplasty.

We are selling Angiomax in the United States with a hospital sales force of 93 sales representatives and managers as of February 17, 2004. Our sales force has been configured to target, as potential hospital customers, those hospitals with cardiac catheterization laboratories in the United States that perform 500 or more coronary angioplasties per year. These hospitals conduct a significant number of the coronary angioplasties in the United States. In addition, we have medical information and medical affairs support personnel, some of whom have scientific qualifications as physicians, nurses or pharmacists. Our development, medical, marketing and sales professionals are qualified and trained to deal with complex scientific, pharmacy and economic questions on a day–to–day basis.

We are focusing our Angiomax marketing efforts on interventional cardiologists and other key clinical decision-makers at these cardiac catheterization laboratories. We use educational programs, preceptorships in leading medical centers, publications, and other targeted techniques in efforts to educate physicians and other healthcare providers regarding the advantages of Angiomax use. We believe our ability to deliver relevant, advanced and reliable educational programs to our customers and our concentrated customer base provides us with significant market presence even in the highly competitive sub-segments of the hospital market such as cardiology. We work collaboratively with a number of prominent hospitals and teaching institutions around the United States that share our mission to educate our customers in the appropriate use of our products as part of modern practice and that provide independent guidance to their colleagues.

We sell Angiomax primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States, including AmerisourceBergen Drug Corporation, McKesson Corporation and Cardinal Health, Inc., each of which accounted for more than 10% of our revenues for the year ended December 31, 2003. These wholesalers and distributors then sell to hospitals. If Angiomax is approved for use in other indications, we intend to market Angiomax for these indications in the United States by supplementing our commercial organization, or by collaborating with other health care companies.

We market, sell and distribute Angiomax outside of the United States through third-party distributors. In August 2003, we filed a market authorization application for approval to sell Angiomax in the European Union. The application is currently under review. If the application is approved, Nycomed Danmark A/S has exclusive rights for the distribution and promotion of Angiomax in approximately 35 countries, including 12 countries in the European Union. In addition, we expect approvals to market Angiomax in certain South American countries in 2004 or 2005. We have agreements with other third-party distributors, including Grupo Ferrer Internacional, S.A. in certain Latin American countries, for future sales of Angiomax pending regulatory marketing approvals.

#### Angiomax Potential Applications

We believe that Angiomax is the leading replacement for heparin in angioplasty and can become the leading replacement for heparin in the treatment of arterial thrombosis. In particular, we are evaluating Angiomax in the operating room for use in open vascular surgery such as CABG surgery and in the emergency department in medical conditions that require urgent treatment such as unstable angina. We are also studying Angiomax in patients with heparin allergy, in children and in peripheral angioplasty.

Before we can obtain regulatory approvals to market Angiomax for any of these indications, we are required to complete extensive clinical trials to demonstrate safety and efficacy. There are numerous factors that could delay our clinical trials or prevent us from completing our trials successfully. See "Factors That May Affect Future Results—Risks Related to Our Business." If we are able to obtain regulatory approval in these additional indications, we believe that Angiomax could be marketed to customers across a spectrum of hospital–based acute cardiovascular care—in the emergency department, cardiac catheterization laboratory and the operating room.

We are currently focused on Phase 3 clinical trials of Angiomax in the operating room and in the emergency department.

Use of Angiomax in the operating room for CABG surgery. Heparin is used widely as an anticoagulant in major surgical procedures. Many surgery patients, however, develop antibodies to heparin as a result of their exposure to heparin. Heparin antibody positivity is the major marker for the development of HIT/HITTS. Even absent the clinical condition of HIT/HITTS, the presence of heparin antibodies alone has been associated with an increased risk of death or major complications and in length of stay in hospital after CABG surgery. In addition, the effects of heparin are routinely reversed with protamine, the use of which has been associated with an allergic reaction and a subsequent increase in the risk of death or major complications.

Clinical publications have cited several different rates of CABG surgery patients who are heparin antibody positive, ranging from 25% to 50%. Clinical data indicate that heparin antibody positive

patients have a significant increase in major complications of CABG surgery, resulting in increased hospital stay or death. Based on hospital reimbursement data, in the United States in 2002 there were approximately 345,000 CABG surgery procedures performed.

Surgeons conduct CABG surgery either on-pump or off-pump. On-pump CABG surgery is conducted with the use of a cardiac pulmonary bypass machine, a device that pumps the patient's blood while the heart is stopped and the surgery is conducted. For off-pump CABG surgery, physicians slow the heartbeat, stabilize the heart by keeping certain areas immobile with various devices, and therefore do not use a bypass machine.

We have completed a 100 patient Phase 2/3 trial of Angiomax comparing Angiomax to heparin in patients undergoing off-pump CABG surgery. Trial results demonstrated that patients in the trial who received Angiomax experienced more rapid and consistent anticoagulation, a similar level of bleeding and significant improvement in graft patency. We expect the principal investigator to publish the trial data in a medical journal in early 2004.

We have also completed Phase 2/3 dose-finding studies of Angiomax in on-pump CABG surgery. We believe that the optimal dosing regimen for Angiomax in CABG surgery will be employed in the Phase 3 program based on these results.

We are conducting four studies as part of our Phase 3 clinical development program in CABG surgery:

CHOOSE includes on-pump and off-pump studies to evaluate the use of Angiomax in patients identified to be at risk for HIT/HITTS, having tested positive for the heparin antibody or having a history of HIT/HITTS;

EVOLUTION includes on-pump and off-pump studies to evaluate if the use of Angiomax in the general CABG surgery patient population can yield similar results to the heparin plus protamine treatment regimen.

As of February 17, 2004, we have completed enrollment in the EVOLUTION off-pump study, and have enrolled patients in the CHOOSE off-pump study. We plan to commence enrollment of patients in the on-pump studies in 2004. Assuming positive results in the Phase 3 CHOOSE and EVOLUTION studies, we intend to submit the study data to the FDA in an application for approval to market Angiomax in patients at risk for HIT/HITTS, including patients who are heparin antibody positive, undergoing CABG surgery.

Use of Angiomax in the emergency department for urgent medical treatment. Ischemic heart disease patients are subject to chest pain that results from a range of conditions, from unstable angina to acute myocardial infarction, or AMI. The severe onset of these cardiac conditions is collectively referred to as acute coronary syndromes, or ACS. Some ACS patients enter the hospital by way of the emergency department and are triaged to be medically managed with pharmacotherapy and observation, scheduled for an angioplasty procedure, and/or scheduled for CABG surgery.

Unstable angina is a condition in which patients experience the new onset of severe chest pain, increasingly frequent chest pain or chest pain that occurs while they are resting. Unstable angina is caused most often by a rupture of plaque on an arterial wall that results in clot formation and ultimately decreases coronary blood flow but does not cause complete blockage of the artery. Unstable angina is often medically managed in the emergency department with anticoagulation therapy that may include aspirin, indirect thrombin inhibitors such as heparin or a low molecular weight heparin such as enoxaparin and GP IIb/IIIa inhibitors. Many unstable angina patients also undergo coronary angioplasty or CABG surgery depending on the severity of the disease.

AMI is a leading cause of death in ischemic heart disease patients. AMI occurs when coronary arteries, which supply blood to the heart, become completely blocked by a clot. AMI patients are

routinely treated with heparin, with and without fibrinolytics, in combination with GP IIb/IIIa inhibitors. AMI patients are increasingly undergoing angioplasty as a primary treatment to unblock clogged arteries.

Based on hospital reimbursement data, in the United States in 2001 there were approximately 1,680,000 patients hospitalized for ACS, including 758,000 unstable angina patients and 959,000 patients with heart attacks of varying severity.

Angiomax has been the subject of five Phase 2 trials in patients with unstable angina or who had experienced a less serious form of MI known as non Q-wave MI. These trials enrolled a total of 630 patients, of whom 553 received various doses of Angiomax. These studies have demonstrated that Angiomax is an anticoagulant that can be administered safely in patients with unstable angina.

We are currently conducting a Phase 3 trial, ACUITY, to study Angiomax in the ACS population. We plan to enroll a total of 13,800 patients worldwide in three main treatment regimens:

Angiomax monotherapy starting in the emergency department and continued through the cardiac catheterization laboratory, permitting use of GP IIb/IIIa inhibitors for treatment of breakthrough ischemic events prior to percutaneous coronary intervention, or PCI, or for bail–out during PCI;

Angiomax with GP IIb/IIIa inhibitors started either in the emergency department and then continued through the cardiac catheterization laboratory, or Angiomax monotherapy started in the emergency department and GP IIb/IIIa inhibitors started in the cardiac catheterization laboratory only; or

Enoxaparin, a low molecular weight heparin, with GP IIb/IIIa inhibitors started either in the emergency department and then continued through the cardiac catheterization laboratory or enoxaparin monotherapy started in the emergency department and GP IIb/IIIa inhibitors started in the cardiac catheterization laboratory only.

We believe that the Angiomax plus a GP IIb/IIIa inhibitor combination may demonstrate outcomes at least equivalent to enoxaparin plus a GP IIb/IIIa inhibitor. We also believe that the Angiomax alone arm may demonstrate that it is as effective as enoxaparin with a GP IIb/IIIa inhibitor, while at the same time being less likely to cause bleeding. Investigators began enrolling patients in the ACUITY trial in August 2003. We expect recruitment to last until July 2005.

If the results of the ACUITY study confirm our expectations, we intend to submit the study data to the FDA in an application to obtain approval to market Angiomax in patients with ACS, who are starting treatment in the emergency department.

#### Use of Angiomax in Other Indications

We have conducted a number of additional clinical trials evaluating Angiomax for other indications.

*HIT/HITTS.* Approximately one to three percent of patients who receive heparin experience HIT/HITTS. The underlying mechanism for the condition appears to be an immunological response to a complex formed by heparin and another factor, resulting in thrombocytopenia, and in some cases in arterial or venous clotting, which may result in death or the need for limb amputation. In order to treat a HIT/HITTS patient, an alternative anticoagulant is necessary because further administration of heparin is not possible.

Prior to 1997, Angiomax was administered to a total of 39 HIT/HITTS patients treated for a variety of indications, including patients requiring anticoagulation for angioplasty, invasive coronary procedures or treatment of thrombosis. For those patients undergoing angioplasty and other

procedures, Angiomax provided adequate anticoagulation, was well-tolerated and rarely resulted in bleeding complications. In the December 2000 approval letter for Angiomax, the FDA required us to complete our trial designed to evaluate the use of Angiomax for treatment of HIT/HITTS patients undergoing angioplasty. That trial, called ATBAT, was completed in 2003 and the results of the ATBAT trial were part of the supplemental new drug application package submitted to FDA with the REPLACE-2 data in July 2003.

We are also conducting the Phase 3 CHOOSE trials studying the use of Angiomax as an anticoagulant in patients at risk for HIT/HITTS undergoing CABG surgery, with and without the use of a bypass pump.

*Neonates and Infants (AT deficiency).* Heparin can only bind to thrombin by first binding to AT, which may be absent or present in insufficient amounts in some patients. AT deficiency is often severe or unpredictable in infants and children, making the treatment and prevention of thrombosis especially difficult. We are conducting a Phase 2 trial program in neonates and infants up to six months old requiring intravenous anticoagulation due to active thrombosis.

Angiomax Phase 4 trials. In addition to the clinical trials conducted to pursue additional uses of Angiomax, we conduct Phase 4 post–marketing clinical trials. Phase 4 trials are intended to provide information about the use of Angiomax in procedures performed in the cardiac catheterization laboratory in specific patient populations or employing new technologies. These trials include the use of Angiomax:

- when a new device technology known as drug-eluting stents are employed;
- when using new technologies or techniques, such as ablation techniques that blast clots using high pressure water or beta-brachytherapy, which uses radiation to reduce the size of clots;
- when conducting peripheral percutaneous intervention, which is similar to coronary angioplasty, but conducted in arteries outside of the heart such as the carotid artery in the neck;
  - in patients with severe dysfunction of the kidneys, which has been shown to impede cardiovascular treatment; and
  - in patients who started treatment in the emergency department with enoxaparin, who are switched to Angiomax in the cardiac catheterization laboratory.

We believe that these Phase 4, post-market studies provide an important service to our customers. They help us to provide contemporary clinical data about the use of Angiomax and also answer specific questions about the use of Angiomax posed by the marketplace.

#### Regulatory Status

In December 2000, we received approval from the FDA for the use of Angiomax in combination with aspirin in patients with unstable angina undergoing coronary angioplasty. In connection with this approval, the FDA required us to complete our ATBAT trial evaluating the use of Angiomax for the treatment of HIT/HITTS patients undergoing angioplasty. We completed the ATBAT trial and submitted results as part of the submission to the FDA in 2003, which we believe fulfills this post–approval requirement.

In July 2003, we submitted for FDA review an update to the Angiomax product labeling to include the most contemporary data of Angiomax in coronary angioplasty. We submitted data from studies in more than 7,000 patients undergoing coronary angioplasty in the REPLACE-1 and REPLACE-2 trials and the ATBAT study. Also in July 2003, we submitted a Marketing Authorization Application, or MAA, to the European Agency for the Evaluation of Medicinal Products, or EMEA, for authority to market Angiomax in the EU for use in patients undergoing coronary angioplasty. This filing was

conducted with our European distributors, Nycomed and Grupo Ferrer. We believe that this submission addressed the concerns expressed by the Committee of Proprietary Medicinal Products, or CPMP, of EMEA with regard to an MAA submitted in February 1998 that we subsequently withdrew.

Angiomax was approved in New Zealand in September 1999 for use in the treatment of patients undergoing coronary angioplasty. Angiomax was approved in Canada in October 2002 and Israel in June 2002 for use in unstable angina patients undergoing coronary angioplasty. We and our partners have filed applications for marketing authorization in several Latin American countries.

#### Clevelox

#### Overview

In March 2003, we acquired from AstraZeneca exclusive license rights to Clevelox for all countries other than Japan. We acquired this license after conducting development work pursuant to the study and exclusive option agreement with AstraZeneca entered into in March 2002. Since acquiring the product, we have:

- conducted manufacturing development activities to scale the bulk product manufacturing process for clinical study and potential commercial use;
- commenced a Phase 2 clinical trial comparing Clevelox with nitroglycerin, a drug that is typically used to control high blood pressure in patients undergoing cardiac surgery; and
  - commenced a Phase 3 clinical trial program in cardiac surgery after meeting with FDA to define program parameters.

#### Background

Blood pressure control is important in patients undergoing surgery or other interventional procedures in a hospital. These patients are treated by a team of physicians and nurses, which include the surgeon and anesthesiologist. Usually, the anesthesiologist is responsible for controlling blood pressure and, in doing so, these physicians often employ multiple medications, which may increase the duration of the patient's stay in the intensive care unit. These medications include sodium nitroprusside, nicardipine and nitroglycerine. Each of these agents has been shown to increase a cardiac side effect known as reflex tachycardia, which is characterized by a quickening of the patient's heart rate that may cause severe adverse surgical outcomes.

Clevelox belongs to a well-known class of drugs called calcium channel blockers, which are used to control high blood pressure. Clevelox acts by selectively relaxing the smooth muscle cells that line small arteries, resulting in widening of the artery opening and reducing blood pressure within the artery. Unlike some other blood pressure reducing agents, including some other calcium channel blockers, Clevelox does not appear, based on animal studies, to have effects on the coronary arteries or the veins, and has not been associated with reflex tachycardia in anesthetized patients. Moreover, Clevelox has been shown in clinical trials to improve the pumping performance of the heart.

Prior to licensing Clevelox to us, AstraZeneca conducted Phase 2 clinical trials of Clevelox. These clinical trials demonstrated that Clevelox acts to reduce blood pressure rapidly after intravenous infusion. Clevelox is metabolized rapidly by enzymes in the blood, which results in the drug being cleared from the blood stream in a short period of time. Therefore, the effects of Clevelox are short–lived, and clinical trials have demonstrated reductions in blood pressure that are dose–dependent and that cease rapidly after stopping Clevelox infusions.

We believe that attributes of Clevelox demonstrated in clinical trials to date, namely rapid, titratable onset of effect on blood pressure, simple preparation and administration, arterial selectivity and rapid metabolism and elimination, could potentially benefit patients with high blood pressure



undergoing surgical procedures and patients with severely elevated blood pressure that requires rapid reduction.

We are initially focusing our development efforts on the potential use of Clevelox in surgery, particularly cardiac surgery. Cardiac surgery is comprised of CABG surgery conducted on-pump or off-pump, as well as heart valve replacement surgery.

#### Development Investments

After meeting with the FDA in 2003, we defined Phase 3 trials in two programs to investigate the potential of Clevelox to control blood pressure in patients undergoing surgery.

The ESCAPE program consists of two clinical trials to evaluate the efficacy of Clevelox in controlling blood pressure before and after cardiac surgery compared to a placebo control. The protocols provide for approximately 200 patients to be enrolled in these trials. In December 2003, we commenced patient enrollment in this program.

The ECLIPSE program consists of three clinical trials to evaluate the safety of Clevelox in comparison to sodium nitroprusside, nicardipine, and nitroglycerine during and following cardiac surgery. The protocols provide for a total of approximately 1,500 patients in these trials.

We are also conducting a blinded Phase 2 study in approximately 100 patients undergoing cardiac surgery comparing Clevelox with nitroglycerin to evaluate if Clevelox can be feasibly administered in this patient population. Two data safety reviews have been conducted and cleared the study to continue. We expect to complete this Phase 2 study in 2004.

We believe that Clevelox can be efficiently sold by our U.S. sales force to hospital customers, including Angiomax customers, when and if Clevelox is approved for sale by the FDA. We also believe that manufacturing development work conducted in 2003 in conjunction with a manufacturing infrastructure partner has scaled the manufacturing to a level ready for customer demand on an initial commercial scale.

#### Cangrelor

Overview

We acquired cangrelor in December 2003 from AstraZeneca. Under terms of the agreement with AstraZeneca, we acquired exclusive license rights to develop, market and sell cangrelor worldwide excluding Japan, China, Korea, Taiwan and Thailand.

Cangrelor is short-acting injectable platelet inhibitor agent that prevents the aggregation of platelets in the clotting process. We believe that cangrelor may fit into our hospital acute care product portfolio because of potential uses in the cardiac catheterization laboratory and the operating room.

Cangrelor acts directly on the P2Y12 platelet receptor, a clinically validated target to treat or prevent arterial thrombosis by acting on a specific, well studied, enzyme pathway known as ADP. There is currently no short-acting, intravenous, P2Y12 antagonist approved for acute patient care.

In the cardiac catheterization laboratory, the use of platelet inhibitors that block activation is considered important therapy because of several studies of oral platelet inhibitors that have demonstrated better patient outcomes when these agents are administered before coronary angioplasty.

The leading oral platelet activation inhibitor is clopidogrel. Clopidogrel is commonly administered at a high dose by giving patients several oral tablets before the angioplasty procedure. This practice is known as pre-loading. Although clopidogrel pre-loading has been shown to improve ischemic outcomes

in coronary angioplasty, there are several convenience and safety issues with the use of this agent in acute care practice:

- As a pro-drug, clopidogrel requires liver metabolism to form the active agent; therefore, the pre-loading doses require more than six hours to metabolize.
- There is not a clear relationship between increased dosage and intended effect that is consistent across different patient groups.
- The inhibition of platelet function is irreversible, meaning the agent remains active for the life of the platelet, which is typically five days; this may impede patient management and treatment flexibility, especially if a patient needs cardiac surgery, which is usually delayed for days to wait for the clopidogrel to be cleared from the bloodstream.
- Oral agents are difficult to administer in the acute care setting because they need to be swallowed by patients that may be under light anesthesia; this is especially true when there is a need to swallow multiple tablets in a restricted period of time.

Based on input from our hospital customers in the cardiac catheterization laboratory, we believe that the combination of the ischemic outcomes benefits of platelet activation inhibition and the acute care limitations of current oral therapy has created a need for an injectable platelet antagonist that acts quickly and is cleared from the bloodstream rapidly. We believe that cangrelor has demonstrated these attributes in preclinical studies and clinical studies conducted in approximately 500 patients to date. Cangrelor has demonstrated the following characteristics in these studies:

- An immediate inhibitory effect on platelets;
- Inhibition of both platelet activation and aggregation that is proportional to the dose administered;
- Inhibitory effects that are sustainable through a period of infusion;
- Rapid clearance—half life of less than ten minutes: and
  - Platelet function recovery in less than hour.

With these attributes, we believe that cangrelor could also have utility as an anticoagulant administered for surgery patients. Surgeons have never had an approved agent at their disposal to control thrombosis during surgery by inhibiting platelets. The antiplatelet agents currently approved for use in coronary angioplasty, GP IIb/IIIa inhibitors, oral thienopyridines and aspirin, have not demonstrated feasibility in surgery due to bleeding concerns or the necessity of long infusions. We believe that cangrelor has potential for use in surgery due to its rapid effect in inhibiting platelets and the rapid recovery of platelet function following administration.

#### Development

We plan to develop cangrelor for potential use as an antiplatelet agent in the acute care settings of the cardiac catheterization laboratory, the operating room, and/or the emergency department. Several features of the development program may be similar to those followed for Angiomax.

In 2003, we began the process of transferring product technology and data from AstraZeneca. We believe that technology transfer and manufacturing development will take approximately one year to 18 months. Following these activities, we intend to conduct clinical development of cangrelor. We may also study the combination of Angiomax and cangrelor, which we believe are compatible anticoagulants.

#### Manufacturing

We do not build or operate manufacturing facilities but instead contract for manufacturing development and/or commercial supply. We have in-house expertise in manufacturing development, but do not have facilities to manufacture commercial supply products. We believe we can focus successfully on the specialty hospital markets without incurring the substantial fixed overhead costs associated with building or acquiring manufacturing infrastructure.

#### Angiomax

In December 1999, we entered into a commercial development and supply agreement with UCB Bioproducts S.A. for the development and supply of Angiomax bulk drug substance. Together with UCB Bioproducts, we developed a second generation chemical synthesis process to improve the economics of manufacturing Angiomax bulk drug substance. This process, which was approved by the FDA in May 2003, is known as the Chemilog process.

We have agreed that we will purchase a substantial portion of our Angiomax bulk drug substance exclusively from UCB Bioproducts at agreed upon prices for a period ending in September 2010, seven years from the first commercial sale of Angiomax produced under the Chemilog process. Following the expiration of the agreement, which automatically renews for consecutive three year periods unless either party provides notice of non–renewal within one year prior to the expiration of the initial term or any renewal term, or if we terminate the agreement prior to its expiration, UCB Bioproducts has agreed to transfer the development technology to us. We may only terminate the agreement prior to its expiration in the event of a material breach by UCB Bioproducts. If we engage a third party to manufacture Angiomax for us using this technology during the first ten years following the date of the first commercial sale of Angiomax produced under the Chemilog process, we will be obligated to pay UCB Bioproducts a royalty based on the amount paid by us to the third–party manufacturer.

We have developed reproducible analytical methods and processes for the fill-finish of Angiomax drug product by Ben Venue Laboratories, Inc. Ben Venue Laboratories has carried out all of our Angiomax fill-finish activities.

#### Clevelox

Prior to our acquisition of the Clevelox product, Astra Production Chemicals manufactured all clevidipine bulk drug which, after testing and release by Astra Hassle, has been used in clinical trials. Both Astra Production Chemicals and Astra Hassle are divisions of AstraZeneca. The manufacturing process for bulk drug has been transferred to PharmEco, a Johnson Matthey Company, for scale up and manufacture for Phase 3 clinical trials and commercial supplies. We have also entered into an agreement with Fresenius Kabi L.P. pursuant to which, using its formulation technology, Fresenius has agreed to manufacture all finished drug product for all Phase 3 clinical trials and commercial supplies and to carry out release testing and clinical packaging.

#### Competition

The development and commercialization of new drugs is competitive, and we face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Our competitors may develop or license products or other novel technologies that are more effective, safer or less costly than any that have been or are being developed by us, or may obtain FDA approval for their products more rapidly than we may obtain approval for ours.

The acquisition or licensing of pharmaceutical products is a competitive area, and a number of more established companies, which have acknowledged strategies to license or acquire products, may have competitive advantages as may emerging companies taking similar or different approaches to

product acquisition. These established companies may have a competitive advantage over us due to their size, cash flows and institutional experience.

Many of our competitors will have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

#### Angiomax

Due to the incidence and severity of cardiovascular diseases, the market for anticoagulant therapies is large and competition is intense. We are evaluating Angiomax for additional uses in open vascular surgery such as CABG surgery, in medical conditions that require urgent treatment such as ACS, in patients with heparin allergy, in children and in peripheral angioplasty. There are a number of anticoagulant therapies currently on the market, awaiting regulatory approval or in development for these uses.

In general, anticoagulant drugs may currently be classified into four groups according to their interaction with clotting mechanisms.

*Direct thrombin inhibitors.* Direct thrombin inhibitors act directly on thrombin, inhibiting the action of thrombin in the clotting process. Because thrombin activates platelets, direct thrombin inhibitors also prevent platelet aggregation. Direct thrombin inhibitors include Angiomax, Refludan from Berlex Laboratories and Argatroban from GlaxoSmithKline, Encysive Pharmaceuticals Inc, and Mitsubishi Chemical Corp. Both Refludan and Argatroban are approved for use in the treatment of patients with HIT/HITTS. Argatroban is also approved for use in patients with HIT/HITTS.

*Indirect thrombin inhibitors.* Heparin and low molecular weight heparins act by first binding to AT–III. Heparin is manufactured and distributed by a number of companies as a generic product. Low molecular weight heparin products include Lovenox from Aventis Pharmaceuticals, Inc. and Fragmin from Pfizer Inc. Very short molecules of heparin, called pentasaccharide sequences, include Arixtra from Sanofi–Synthelabo Inc. Heparin is widely used in patients with ischemic heart disease. Low molecular weight heparins have been approved for use in the treatment of patients with unstable angina and are being developed for use in angioplasty and vascular surgery. Arixtra has been approved for use in the treatment and prevention of deep vein thrombosis and is being developed for arterial thrombosis.

*Platelet inhibitors.* Platelet inhibitors, such as GP IIb/IIIa inhibitors, block the aggregation of platelets by blocking surface sites on the platelets that allow the platelets to attach to fibrin and to each other. GP IIb/IIIa inhibitors include ReoPro from Eli Lilly and Company and Johnson & Johnson/Centocor, Inc., Integrilin from Millennium Pharmaceuticals, Inc. and Schering–Plough Corporation, and Aggrastat from Merck & Co., Inc. and Guilford Pharmaceuticals Inc. ReoPro is approved and marketed for angioplasty in a broad range of patients. Integrilin is approved and marketed for angioplasty and for the management of acute coronary syndromes. Aggrastat is approved for the management of ACS.

*Fibrinolytics.* Fibrinolytics, or thrombolytics, dissolve fibrin in clots that have already formed. Fibrinolytics include Streptase from Aventis, Retevase from Johnson & Johnson/Centocor, TNKase from Genentech, Inc., and Abbokinase from Abbott Laboratories. These products are approved for use in the treatment of AMI, stroke and/or peripheral vascular arterial blockages.

Although platelet inhibitors and fibrinolytic drugs may be complementary to Angiomax, Angiomax may compete with platelet inhibitors and fibrinolytic drugs for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. Because this amount is not based on the actual expenses the hospital incurs, hospitals may be forced to use either Angiomax or a platelet inhibitor or fibrinolytic drugs but not necessarily several of the drugs together.

In each case, we will compete with other anticoagulant drugs on the basis of efficacy, safety, ease of administration and economic value.

We face potential competition from products that currently are in clinical development. One such potential competitor is an oral direct thrombin inhibitor, Exanta, for which AstraZeneca has submitted a new drug application, or NDA, to the FDA for the prevention of stroke in patients with atrial fibrillation and associated complications. We believe that use of Exanta in these indications will not have an effect upon our planned positioning for Angiomax.

Clevelox

Clevelox will compete with a variety of parenteral antihypertensive agents including nigroglycerine, a generic product, Nipride from Hoffmann-La Roche Inc., Cardene from Hoffmann-La Roche Inc., Brevibloc from Baxter Healthcare Corporation, and Corlopam from Abbott Laboratories.

#### **Research and Development**

Company-sponsored research and development expenses totaled \$35.9 million in 2003, \$38.0 million in 2002 and \$32.8 million in 2001. The funding for Angiomax has represented and will continue to represent a significant portion of our research and development spending. We rely on contract research organizations, including International Health Care, to provide expertise, flexibility and resources in managing clinical trials.

#### Patents, Proprietary Rights and Licenses

Our success will depend in part on our ability to protect the products we acquire or license by obtaining and maintaining patent protection both in the United States and in other countries. We rely upon trade secrets, know-how, continuing technological innovations, contractual restrictions and licensing opportunities to develop and maintain our competitive position. We plan to prosecute and defend any patents or patent applications we acquire or license, as well as any proprietary technology.

In all, as of February 25, 2004, we exclusively licensed 16 issued United States patents and a broadly filed portfolio of corresponding foreign patents and patent applications. We have not yet filed any independent patent applications. The U.S. patents licensed by us are currently set to expire at various dates ranging from March 2010, in the case of the principal patent relating to Angiomax, to November 2019.

We have exclusively licensed from Biogen patents and applications for patents covering Angiomax and Angiomax analogs and other novel anticoagulants as compositions of matter, and processes for using Angiomax and Angiomax analogs and other novel anticoagulants. We are responsible for prosecuting and maintaining patents and patent applications relating to Angiomax. We have exclusively licensed from AstraZeneca, patents and patent applications covering formulations and uses of Clevelox and patents and patent applications covering the formulations and uses of cangrelor. Under both licenses, AstraZeneca is responsible for prosecuting and maintaining these patents and patent applications relating to Clevelox and cangrelor, and we are required to reimburse AstraZeneca for expenses it incurs in connection with the prosecution and maintenance of the patents or patent applications. We have exclusively licensed patents and applications relating to CTV–05, a strain of

bacteria with potential applications in the areas of gynelogical and reproductive health, from GyneLogix, Inc. In December 2002, we sublicensed our rights to develop CTV-05 to Osel, Inc. on an exclusive basis. Osel has assumed our obligation to prosecute and maintain the related patents and patent applications.

The patent positions of pharmaceutical and biotechnology firms like us can be uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of the applications we acquire or license will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications filed prior to November 29, 2000 and patent applications filed within the last 18 months are maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

The development of anticoagulants is intensely competitive. A number of pharmaceutical companies, biotechnology companies, universities and research institutions have filed patent applications or received patents in this field. Some of these applications could be competitive with applications we have acquired or licensed, or could conflict in certain respects with claims made under such applications. Such conflict could result in a significant reduction of the coverage of the patents we have acquired or licensed, if issued, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if patents are issued to other companies that contain competitive or conflicting claims and such claims are ultimately determined to be valid, no assurance can be given that we would be able to obtain licenses to these patents at a reasonable cost, or develop or obtain alternative technology.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology, or that we can meaningfully protect our trade secrets. We have a number of trademarks that we consider important to our business. These trademarks are protected by registration in the United States and other countries in which our products are marketed.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for the our trade secrets in the event of unauthorized use or disclosure of such information.

#### License Agreements

#### Biogen

In March 1997, we entered into an agreement with Biogen, Inc., a predecessor of Biogen Idec, Inc., for the license of the anticoagulant pharmaceutical bivalirudin, which we have developed as Angiomax. Under the terms of the agreement, we acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know-how related to Angiomax. In exchange for the license, we paid \$2.0 million on the closing date and are obligated to pay up to an additional \$8.0 million upon the first commercial sales of Angiomax for the treatment of AMI in the United States and Europe. In addition, we are obligated to pay royalties on sales of Angiomax and on any sublicense royalties on a country-by-country basis earned until the later of (1) 12 years after the date of the first commercial sales of the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent rights in such country. Under the terms of the agreement, the royalty rate due to Biogen on sales increases with growth in annual sales of Angiomax. The agreement also stipulates that we use commercially reasonable efforts to meet certain milestones related to the development and commercialization of Angiomax, including expending at least \$20 million to pay royalties ceases. Either party may terminate the agreement for material breach is not cured within 90 days after written notice. In addition, we may terminate the agreement for any reason upon 90 days prior written notice. Through February 25, 2004, we have paid a total of approximately \$9.6 million in royalties relating to Angiomax under our agreement with Biogen.

#### AstraZeneca

In March 2003, we acquired from AstraZeneca exclusive worldwide license rights to Clevelox for all countries other than Japan. We acquired this license after having studied Clevelox under the study and exclusive option agreement with AstraZeneca that we entered into in March 2002. In exchange for the license, we paid \$1.0 million in 2003 upon entering into the license and may have to pay up to an additional \$5.0 million upon reaching certain regulatory milestones. In addition, we will be obligated to pay royalties on a country–by–country basis on future annual sales of Clevelox, and on any sublicense royalties earned, until the later of (1) the duration of the licensed patent rights which are necessary to manufacture, use or sell Clevelox in a country or (2) ten years from our first commercial sale of Clevelox in such country. The licenses and rights under the agreement remain in force until we cease selling Clevelox in any country or the agreement is otherwise terminated. We may terminate the agreement upon 30 days written notice, unless AstraZeneca, within 20 days of having received our notice, requests that we enter into good faith discussions to redress its concerns. If we cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, we may then terminate the agreement upon 90 days written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice, if the breach is not cured within such 60 days.

In December 2003, we acquired from AstraZeneca exclusive license rights to cangrelor for all countries other than Japan, China, Korea, Taiwan and Thailand. In exchange for the license, we accrued in December 2003 and paid in January 2004 an upfront payment upon entering into the license and may have to make additional payments upon reaching certain regulatory milestones. In addition, we will be obligated to pay royalties on a country–by–country basis on future annual sales of cangrelor, and on any sublicense royalties earned, until the later of (1) the duration of the licensed patent rights which are necessary to manufacture, use or sell cangrelor in a country or (2) ten years from our first commercial sale of cangrelor in such country. The licenses and rights under the agreement remain in force until we cease selling cangrelor in any country or the agreement is otherwise terminated. We may

terminate the agreement upon 30 days written notice, unless AstraZeneca, within 20 days of having received our notice, requests that we enter into good faith discussions to redress its concerns. If we cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, we may then terminate the agreement upon 90 days written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice, if the breach is not cured within such 60 days.

#### **Government Regulation**

Government authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of our products. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, and, in the case of biologics, also under the Public Health Service Act, and implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as a refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

The steps required before a drug may be marketed in the United States include:

- pre-clinical laboratory tests, animal studies and formulation studies;
- submission to the FDA of an investigational new drug exemption, or IND, for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA, or biologics license application, or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMP; and
  - FDA review and approval of the NDA or BLA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND does not necessarily result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the investigational new drug exemption.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent Institutional Review Board before it can begin. Phase 1 usually involves the initial introduction of the investigational drug into

people to evaluate its safety, dosage tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase 2 usually involves trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- evaluate preliminarily the efficacy of the drug for specific indications.

Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. We cannot guarantee that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. Before approving an application, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the application and the manufacturing facilities are acceptable, the FDA will issue an approval letter. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval. The testing and approval process requires substantial time, effort and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all. As a condition of approval of an application, the FDA may require postmarket testing and surveillance to monitor the drug's safety or efficacy.

In addition, holders of an approved NDA or BLA are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We use and will continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and we cannot be sure that future FDA inspections will not identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product may result in restrictions on a product, manufacturer, or holder of an approved NDA or BLA, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

We are also subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products which we sell outside the United States. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. Whether or not we obtain FDA approval, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for these approvals may differ substantially from that required for FDA approval.



Clinical trials in one country may not be accepted by other countries, and approval in one country may not result in approval in any other country. For clinical trials conducted outside the United States, the clinical stages generally are comparable to the phases of clinical development established by the FDA.

#### Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. We have assembled a management team with significant experience in drug development and commercialization.

As of February 25, 2004, we employed 190 persons. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

#### **Available Information**

Our Internet address is http://www.themedicinescompany.com. The contents of our website are not part of this Annual Report on Form 10–K, and our Internet address is included in this document as an inactive textual reference only. We make our Annual Reports on Form 10–K, Quarterly Reports on Form 10–Q, Current Reports on Form 8–K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the Securities and Exchange Commission, or the SEC.

#### **Item 2. Properties**

We currently occupy approximately 20,220 square feet of office space in Parsippany, New Jersey under a lease expiring in January 2013. We have entered into an agreement to lease approximately 12,400 square feet of additional office space in the same building in Parsippany, New Jersey that we plan to occupy in June 2004, with a term expiring in January 2013. In addition, we lease approximately 5,700 square feet of office space in Waltham, Massachusetts under a lease expiring in December 2008. We believe our current arrangements will be sufficient to meet our needs for the foreseeable future and that any required additional space will be available on commercially reasonable terms to meet space requirements if they arise. We also have offices in Milton Park, Abingdon, United Kingdom and Parnell, Auckland, New Zealand.

#### Item 3. Legal Proceedings

In November 2003, the Company received a notice from the Equal Employment Opportunity Commission, or EEOC, that a current employee of the Company had filed a Charge of Discrimination with the EEOC alleging that the Company has engaged in sexual discrimination and sexual harassment in violation of Title VII of the Civil Rights Act of 1964 and the New Jersey Law Against Discrimination. The Company has agreed to participate in non–binding mediation with the complainant to attempt to resolve the matter. If the matter is not resolved through mediation and a lawsuit is subsequently filed, the Company intends to vigorously defend against the allegations.

#### Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of our security holders through solicitation of proxies or otherwise, during the fourth quarter of the year ended December 31, 2003.

#### PART II

#### Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

#### **Market Information and Holders**

Our common stock trades on the Nasdaq National Market under the symbol "MDCO". The following table reflects the range of the high and low bid information per share of our common stock, as reported on the Nasdaq National Market for the periods indicated. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	High		Low	
Year Ended December 31, 2002	 	_		
First Quarter	\$ 14.81	\$	9.86	
Second Quarter	\$ 14.33	\$	7.40	
Third Quarter	\$ 12.50	\$	7.22	
Fourth Quarter	\$ 17.50	\$	9.45	
Year Ended December 31, 2003				
First Quarter	\$ 20.00	\$	15.20	
Second Quarter	\$ 25.91	\$	16.83	
Third Quarter	\$ 31.41	\$	19.25	
Fourth Quarter	\$ 29.98	\$	22.80	

Mellon Investor Services, LLC is the transfer agent and registrar for our common stock. As of the close of business on February 25, 2004, we had 199 holders of record of our common stock.

#### Dividends

We have never declared or paid cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation of our business and do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors.

#### **Recent Sales of Unregistered Securities**

None

#### Item 6. Selected Consolidated Financial Data

In the table below, we provide you with our selected consolidated financial data. We have prepared this information using our audited consolidated financial statements for the years ended December 31, 2003, 2002, 2001, 2000 and 1999. The pro forma net loss per share data reflect the conversion of our convertible notes, and accrued interest, and the conversion of our outstanding redeemable convertible preferred stock, and accrued dividends, into common stock upon the closing of our initial public offering in August 2000. The net loss per share data and pro forma net loss per share data do not include the effect of any options or warrants outstanding. For further discussion of earnings per share, please see note 8 to our consolidated financial statements.

		2003		2002		2001		2000		1999
				(in thousan	ds, except	share and per shar	e data)			
tatements of Operations Data										
Net revenue	\$	85,591	\$	38,301	\$	14,248	\$	—	\$	-
Operating expenses										
Cost of revenue		22,749		10,284		2,110		_		
Research and development		35,905		37,951		32,768		39,572		30,345
Selling, general and administrative		45,082		36,808		36,567		15,034		5,008
Total operating expenses		103,736	_	85,043		71,445		54,606		35,353
Loss from operations		(18,145)		(46,742)		(57,197)		(54,606)		(35,353
Other income (expense), net		1,403		911		2,313		(16,686)		64
Income taxes		(128)						_		
Net loss after taxes		(16,870)		(45,831)		(54,884)		(71,292)		(34,713
Dividends and accretion to redemption value of redeemable convertible preferred stock		_		_		_		(30,343)		(5,89)
Net loss attributable to common stockholders	\$	(16,870)	\$	(45,831)	\$	(54,884)	\$	(101,635)	\$	(40,60
Net loss attributable to common stockholders per common share, basic and diluted	\$	(.37)	\$	(1.23)	\$	(1.67)	\$	(8.43)	\$	(80.0
Shares used in computing net loss attributable to common stockholders per										
common share, basic and diluted Unaudited pro forma net loss attributable		45,624,289		37,209,931		32,925,968		12,059,275		507,063
to common stockholders per common share, basic and diluted	\$	(.37)	\$	(1.23)	\$	(1.67)	\$	(2.10)	\$	(1.9
Shares used in computing unaudited pro forma net loss attributable to common stockholders per common share, basic and diluted		45,624,289		37,209,931		32,925,968		24,719,075		17,799,876
		As of December 3				\$1,				
			2003	200	2	2001		2000		1999
						(in thousands)	1			
alance Sheet Data										
Cash and cash equivalents, available for sale secur accrued interest receivable	ities and	\$	136,85	5 \$	43,638	\$ 54,	016	\$ 80,718	8 \$	7,238
Working capital (deficit)		\$	139,72		54,172		744	68,023		(4,103)
Total assets			166,662		74,714		674	84,363		7,991
Convertible notes				_	·	,			_	5,776
Redeemable convertible preferred stock			_	_	_		_	_	_	85,277
Accumulated deficit			(314,14		297,275)	(251,		(196,560		(94,925)
Total stockholders' (deficit) equity			140,165		53,934		121	69,239	<i>.</i>	(94,558)
			2	5						

#### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Consolidated Financial Data" and our financial statements and accompanying notes included elsewhere in this annual report. In addition to the historical information, the discussion in this annual report contains certain forward–looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated by the forward–looking statements due to the factors set forth under "Factors That May Affect Future Results" below and elsewhere in this annual report.

#### Overview

We are a pharmaceutical company that specializes in acute hospital care with growing revenue from sales of our first product, Angiomax® (bivalirudin). Angiomax is a direct thrombin inhibitor that was approved by the FDA in December 2000 for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary angioplasty. We began selling the product in the United States in January 2001. Our total net revenue was \$14.2 million in 2001, \$38.3 million in 2002, and \$85.6 million in 2003, generated almost entirely from sales of Angiomax in the United States.

Since the announcement of the results of our REPLACE-2 clinical trial, additional hospitals have granted Angiomax formulary approval and hospital demand for the product has increased, which are critical elements of our ability to increase revenues. We expect that these trends will continue, although near-term growth in our sales of Angiomax depends on a variety of factors, including physician acceptance of the REPLACE-2 trial results. In the fourth quarter of 2003, based on data from a third-party industry source, the number of hospitals purchasing Angiomax increased by approximately 15% as compared to the third quarter of 2003 and the number of hospitals purchasing four or more boxes of Angiomax increased by approximately 20% as compared to the third quarter of 2003. We focus on increased use of Angiomax by existing hospital customers, as well as penetration to new hospitals, to evaluate our operating performance.

Since our inception we have generated significant losses, although we achieved profitability for the first time for the three months ended December 31, 2003. Most of our expenditures to date have been for research and development activities and selling, general and administrative expenses. Research and development expenses represent costs incurred for product acquisition, clinical trials, activities relating to regulatory filings and manufacturing development efforts. We outsource our clinical trials and manufacturing development activities to independent organizations to maximize efficiency and minimize our internal overhead. We expense our research and development costs as they are incurred. Selling, general and administrative expenses consist primarily of salaries and related expenses, general corporate activities and costs associated with promotion and marketing activities.

We expect to continue to spend significant amounts on the development of our products in the future. In 2004, we plan to continue to invest in clinical studies to expand the use of Angiomax and to develop Clevelox. In addition, we plan to invest in the manufacturing development of cangrelor. We also plan to continue our sales and marketing programs to educate and inform physicians, nurses, pharmacists and other medical decision–makers about the benefits of Angiomax. In light of these activities, as well as our plan to continue to evaluate possible acquisitions of development–stage or approved products that would fit within our growth strategy, we will likely need to generate greater revenues to maintain profitability.

We have not generated any U.S. taxable income to date. Any taxes paid or accrued have been state taxes based on net worth and some income taxes in international jurisdictions. At December 31, 2003, net operating losses available to offset future taxable income for federal income tax purposes were approximately \$235.2 million. If not utilized, federal net operating loss carryforwards will expire at various dates beginning in 2011 and ending in 2023. We have not recognized the potential tax benefit

of our net operating losses in our balance sheets or statements of operations. The future utilization of our net operating loss carryforwards may be limited based upon changes in ownership pursuant to regulations promulgated under the Internal Revenue Code of 1986, as amended.

#### **Application of Critical Accounting Policies**

The discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect our reported assets and liabilities, revenues and expenses, and other financial information. Actual results may differ significantly from these estimates under different assumptions and conditions. In addition, our reported financial condition and results of operations could vary due to a change in the application of a particular accounting standard.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" where:

the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

the impact of the estimates and assumptions on financial condition or operating performance is material.

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements. Not all of these significant accounting policies, however, fit the definition of "critical accounting estimates." We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates relating to revenue recognition and inventory described below fit the definition.

#### **Revenue** Recognition

*Product Sales.* We sell our products primarily to wholesalers and distributors, who, in turn, sell to hospitals. We do not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay us, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligation to bring about the sale of the product, the amount of returns can be reasonably estimated and collectibility is reasonably assured.

We record allowances for product returns, rebates and discounts at the time of sale, and report revenue net of such allowances. We must make significant judgments and estimates in determining these allowances. In particular, determining the allowances is difficult because we must estimate whether trends in past buying patterns will predict future product sales. We have adjusted the allowances in the past based on our actual sales experience, and we will likely be required to make adjustments to these allowances in the future. In determining the allowances, our considerations include the following:

Our customers have the right to return any unopened product during the 18 month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the allowance for product returns, we must estimate the likelihood that product sold to wholesalers might remain in their inventory to within six months of expiration and determine if it will be returned. We base our estimates on information from wholesalers, historic patterns of returns, industry data and on the expiration dates of product currently being shipped.



Certain hospitals purchasing our products from wholesalers have the right to receive a discounted price and a volume-based rebate if they have a direct contract with us or participate in a group purchasing organization that has a contract with us. As a result, we must estimate the likelihood that product sold to wholesalers might be ultimately sold to a participating hospital. We base our estimates on information from wholesalers and hospitals, industry data, historic patterns of discounts and customer rebate thresholds.

*Collaborations.* Revenue from collaborative agreements with partners may include milestone payments. We record these payments as deferred revenue until contractual performance obligations have been satisfied, and we then recognize these payments ratably over the term of these agreements. When the period of deferral cannot be specifically identified from the contract, we must estimate the period based upon other critical factors contained within the contract. We review these estimates at least annually, which could result in a change in the deferral period.

#### Inventories

We record inventory upon the transfer of title from our vendors. Inventory is stated at the lower of cost or market value, with cost determined using a weighted average of acquisition costs. Prior to FDA approval of Angiomax and of its original manufacturing process in December 2000, we expensed all costs associated with the manufacture of Angiomax bulk drug product and finished product to which title had transferred to us as research and development. We recorded as inventory any Angiomax bulk drug product manufactured according to its original manufacturing process to which we took title after FDA approval. Along with our contract manufacturing partner, UCB Bioproducts S.A., we have developed a second–generation chemical synthesis process, the Chemilog process, for the manufacture of Angiomax bulk drug substance. The Chemilog process involves enhancements to early manufacturing steps to improve the efficiency of synthesizing bivalirudin, the active ingredient of Angiomax. On May 23, 2003, we received FDA approval for this process. Accordingly, all Angiomax bulk drug product manufacture after FDA approval of the Chemilog process has been and will be recorded as inventory. We review our inventory for slow moving or obsolete amounts based on expected revenues. If actual revenues are less than expected, we may be required to make allowances for excess amounts of inventory in the future.

#### **Results of Operations**

#### Years Ended December 31, 2003 and 2002

*Net Revenue.* Net revenue increased 123% to \$85.6 million for the year ended December 31, 2003 as compared to \$38.3 million for the year ended December 31, 2002. Virtually all the revenue in both periods was from U.S. sales of Angiomax. We believe that growth in 2003 was due primarily to increased use of Angiomax by existing hospital customers and adoption of Angiomax by new hospital customers as well as increased prices.

In each of 2003 and 2002, we recognized \$0.1 million of a \$1.5 million non-refundable distributor fee received from Nycomed Danmark A/S, a European pharmaceutical company, pursuant to a collaboration agreement we entered into in 2002. This payment was recorded as deferred revenue in 2002 and is being recognized ratably over the term of our agreement with Nycomed, which we estimated to be twelve years at that time.

*Cost of Revenue.* Cost of revenue in 2003 was \$22.7 million, or 27% of net revenue, compared to \$10.3 million, or 27% of net revenue in 2002. Cost of revenue in 2003 consisted of expenses in connection with the manufacture of the Angiomax sold, which represented 62% of the 2003 cost of revenue, royalty expenses under our agreement with Biogen which represented 25% of the 2003 cost of revenue and the logistics costs of selling Angiomax, such as distribution, storage, and handling, which

represented 13% of the 2003 cost of revenue. Cost of revenue in 2002 consisted of expenses in connection with the manufacture of the Angiomax sold, which represented 58% of the 2002 cost of revenue, royalty expenses under our agreement with Biogen which represented 28% of the 2002 cost of revenue and the logistics costs of selling Angiomax, such as distribution, storage, and handling, which represented 14% of the 2002 cost of revenue.

Prior to obtaining FDA approval for Angiomax and its original manufacturing process, all costs of manufacturing Angiomax were expensed as research and development costs and therefore not reflected in cost of revenue. In late 2000, after obtaining FDA approval for Angiomax and its original manufacturing process, we began recording the costs of manufacturing Angiomax as inventory, which is reflected in cost of revenue when sold, rather than as research and development expense.

During 2002 and in early 2003, we took delivery of drug material manufactured using the Chemilog process. Because this material was manufactured prior to FDA approval of the Chemilog process, we expensed all costs of manufacturing as research and development. This process was approved by the FDA on May 23, 2003, and we are recording all costs of manufacturing Angiomax incurred after May 23, 2003 as inventory.

Although we sold some Angiomax in 2003 that had been manufactured using the Chemilog process, most of the Angiomax that we sold in 2003 was manufactured using the original manufacturing process following the date of FDA approval of Angiomax. We recorded the cost of manufacturing such material as cost of revenue during 2003. In 2002, we sold a greater proportion of Angiomax whose costs had been previously expensed than Angiomax for which the cost of manufacturing needed to be recorded in 2002. As a result, our cost of manufacturing as a percentage of cost of revenue was higher in 2003 compared to 2002.

Late in the third quarter of 2003, we began selling Angiomax produced by the Chemilog process whose cost of manufacturing was previously expensed. As a result, our cost of manufacturing as a percentage of product revenue decreased substantially in the fourth quarter of 2003. We expect that we will begin selling Angiomax produced using the Chemilog process after FDA approval as soon as the second quarter of 2004. At such time, we will experience an increase in our cost of manufacturing as a percentage of net revenue.

#### Research and Development Expenses.

The funding for Angiomax has represented and will continue to represent a significant portion of our research and development spending. Over 76% of our research and development expenses in 2003 and 93% of our research and development expenses in 2002 related to Angiomax. For 2003 and 2002, research and development expenses relating to Angiomax included the costs of clinical trials, manufacturing development costs for the bulk drug product and infrastructure, including the cost associated with preparation of U.S. and worldwide marketing applications. For 2003, research and development expenses relating to Clevelox, which represented 17% of our total research and development expenses, consisted of a \$1.0 million license fee to AstraZeneca and manufacturing development and other start–up costs relating to the Phase 3 clinical trial we commenced in the fourth quarter of 2003 in patients undergoing cardiac surgery. Research and development expenses in 2002 relating to Clevelox, research and development expenses in 2002 relating to cangrelor consisted of an initial payment to AstraZeneca in connection with our license. We had no research and development expenses in 2002 relating to cangrelor.

Research and development expenses decreased 5% to \$35.9 million for 2003, from \$38.0 million for 2002. The decrease in research and development expenses was primarily due to \$17.3 million less of clinical trial costs in 2003 relating to REPLACE-2, which completed enrollment in 2002, and \$4.0 million in lower manufacturing development costs incurred in connection with our receipt of

Angiomax manufactured using the Chemilog process. These lower costs were partly offset by the addition of clinical development costs of \$4.8 million for ACUITY, \$4.0 million in additional costs for clinical trial programs studying Angiomax use in cardiac surgery and \$5.8 million in additional costs relating to Clevelox development.

The following table identifies for each of our clinical trial programs, the indication, development phase and clinical trial spending for the years ended December 31, 2003 and 2002. Spending for past periods is not indicative of spending in future periods.

#### **Major Research and Development Projects**

		Year Ended December 31,					
Program		2003	2002				
		(in tho	usands)				
Angiomax							
Clinical trials	\$	17,970	\$	23,493			
Manufacturing development		3,232		7,184			
Infrastructure		6,105		4,468			
Clevelox		6,052		258			
Other	_	2,546		2,548			
	\$	35,905	\$	37,951			

We currently plan to spend approximately \$49 million to \$52 million on research and development in 2004, of which approximately 80% is planned for Angiomax. However, our success in expanding the approved indications for Angiomax, or developing our product candidates, is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, any of our product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the financial contributions of our third-party distributors to the costs of our clinical trials;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates;
- the effect of competing technological and market developments; and
  - the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We partially funded development activities relating to the Chemilog process, including validation and process batch costs of approximately \$1.2 million and \$6.7 million incurred in 2003 and 2002, respectively. We expensed all of these development costs as research and development in the period incurred.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased 22% to \$45.1 million for 2003, from \$36.8 million for 2002. The increase in selling, general and administrative expenses of \$8.3 million was primarily due to an increase in salary and recruiting expenses relating to our sales force, which grew in early 2003 from 86 to 97 persons, and additional marketing and medical education expenses relating to the promotion of Angiomax, and certain non–cash stock compensation recorded in connection with options granted to non–employees.

*Non–cash Stock Compensation.* We amortize the deferred stock compensation that was recorded in 2000 over the respective vesting periods of the individual stock options. We recorded amortization expense for such deferred compensation of approximately \$2.2 million and \$3.3 million for the years ended December 31, 2003 and 2002, respectively. We expect to record additional amortization expense for the deferred compensation associated with these options of approximately \$0.8 million in 2004. The amortization expense is included in our operating expenses in the consolidated statements of operations.

In May 2003 we granted options to a non-employee consultant to purchase 50,000 shares of common stock. In September 2003, we amended the terms of fully vested options to purchase 10,000 shares of common stock that were granted to a non-employee consultant in May 2001. In connection with these actions, we recorded \$1.2 million in related non-cash stock compensation expense during 2003. The unvested options granted in May 2003 will be revalued, utilizing the Black–Scholes option pricing model, and expensed over the remaining five months of their one-year vesting term. In 2002, we accelerated the vesting of stock options held by terminated employees in connection with their termination agreements, which resulted in \$0.5 million in non-cash compensation expense. Non-cash compensation expense is included in our operating expenses in the consolidated statements of operations.

*Other Income and Expense.* Interest income increased over 49% to \$1.4 million for 2003, from \$0.9 million for 2002. The increase in interest income of \$0.5 million was primarily due to higher cash and available for sale securities balances attributable to our public offerings in 2002 and 2003, offset in part by lower available interest rates on securities. For 2002, interest income was attributable to the investment of the remaining proceeds of our sales of shares of common stock in a private placement in May 2001 and in a public offering in 2002.

We had no interest expense in 2003 as there were no borrowings during this period. We had interest expense of \$33,000 during 2002 associated with the draw down of our revolving line of credit at the end of March 2002. We terminated the revolving line of credit in August 2002.

#### Years Ended December 31, 2002 and 2001

*Net Revenue.* Net revenue increased 169% to \$38.3 million in 2002 as compared to \$14.2 million for 2001. Virtually all the revenue was from U.S. sales of Angiomax, which we commercially launched during the first quarter of 2001. The growth in 2002 was due primarily to increased use of Angiomax by existing hospital customers and penetration to new hospitals. Since we announced the results of REPLACE-2 in November 2002, additional hospitals have granted Angiomax formulary approval and hospital demand for the product has increased.

In 2002, we received \$1.5 million from Nycomed as a non-refundable distributor fee. This payment has been recorded as deferred revenue and is being recognized ratably over the term of our agreement with Nycomed, which we estimated to be twelve years at that time.

*Cost of Revenue.* Cost of revenue in 2002 was \$10.3 million, or 27% of net revenue, compared to \$2.1 million, or 15% of net revenue in 2001. Cost of revenue in 2002 consisted of expenses in connection with the manufacture of the Angiomax sold, which represented 58% of the 2002 cost of revenue, royalty expenses under our agreement with Biogen which represented 28% of the 2002 cost of

revenue and the logistics costs of selling Angiomax, such as distribution, storage, and handling, which represented 14% of the 2002 cost of revenue. Prior to obtaining FDA approval for Angiomax and its original manufacturing process, all costs of manufacturing Angiomax were expensed as research and development costs. In late 2000, after obtaining FDA approval for Angiomax and its original manufacturing process, we began recording the costs of manufacturing Angiomax as inventory, which is reflected in cost of revenue when sold, rather than as research and development expense. As a result, our cost of manufacturing as a percentage of net revenue increased substantially in 2002 as we sold a higher percentage of product manufactured after the date of FDA approval of Angiomax.

*Research and Development Expenses.* Research and development expenses increased 16% to \$38.0 million for 2002, from \$32.8 million for 2001. Over 90% of the 2002 expenses related to Angiomax development activities, of which 60% were associated with REPLACE–2. The increase in research and development expenses was primarily due to higher clinical development costs of \$11.6 million relating to our REPLACE–2 trial and \$1.5 million in higher manufacturing development cost incurred in connection with our receipt of Angiomax manufactured using the Chemilog process. These higher costs were partly offset by the absence of clinical development costs of the HERO–2 trial program, our Phase 3 trial of Angiomax in AMI that we completed in 2001 and other development programs savings.

#### **Major Research and Development Projects**

	Year Ended December 31,				
Program	2002		2001		
	(in thousands)				
Angiomax					
Clinical trials	\$ 23,493	\$	18,774		
Manufacturing development	7,184		5,713		
Infrastructure	4,468		4,459		
Clevelox	258				
Other	2,548		3,822		
	\$ 37,951	\$	32,768		

We partially funded development activities relating to the Chemilog process, including validation and process batch costs of \$6.7 million and \$4.8 million incurred in 2002 and 2001, respectively. We expensed all of these development costs as research and development in the period incurred.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased 1% to \$36.8 million for 2002, from \$36.6 million for 2001. The increase in selling, general and administrative expenses of \$241,000 was primarily due to additional sales expense related to the promotion of Angiomax, offset in part by lower marketing expenses.

*Non-cash Stock Compensation.* We amortize the deferred stock compensation that was recorded in 2000 over the respective vesting periods of the individual stock options. We recorded amortization expense for deferred compensation of approximately \$3.3 million and \$4.1 million for the years ended December 31, 2002 and 2001, respectively. In 2002, we accelerated the vesting of stock options held by terminated employees in connection with their termination agreements, which resulted in \$500,000 in non-cash compensation expense. The amortization and non-cash compensation expense is included in our operating expenses in the consolidated statements of operations.

Other Income and Expense. Interest income decreased 70% to \$944,000 for 2002, from \$3.2 million for 2001. The decrease in interest income of \$2.3 million was primarily due to lower cash

and available for sale securities balances and lower available interest rates on securities. For 2002, interest income was attributable to the investment of the remaining proceeds of our sales of shares of common stock in a private placement in May 2001 and in a public offering in 2002. In 2001, interest income was primarily attributable to the investment of the remaining proceeds of our initial public offering in August and September 2000.

We had interest expense of \$33,000 during 2002 associated with the draw down of our revolving line of credit at the end of March 2002. We terminated the revolving line of credit in August 2002. We had no interest expense for 2001. In 2001, we liquidated our \$3.0 million principal investment in Southern California Edison 5  $^{7/8}$ % bonds, recognizing a loss of \$850,000 on the sale.

#### Liquidity and Capital Resources

*Sources of Liquidity.* Since our inception, we have financed our operations through the sale of common and preferred stock, sales of convertible promissory notes and warrants, interest income and revenues from sales of Angiomax. We experienced our first quarterly profit during the three months ended December 31, 2003.

In August and September 2000, we received \$101.4 million in net proceeds from the sale of common stock in our initial public offering. Since our initial public offering, we have received an additional \$41.8 million in net proceeds in May 2001 from the sale of 4.0 million shares of our common stock in a private placement, \$30.9 million in net proceeds in June 2002 from the sale of 4.0 million shares of our common stock in a public offering and \$91.5 million in net proceeds in March 2003 from the sale of 5.6 million shares of our common stock in a public offering. Prior to our initial public offering, we had received net proceeds of \$79.4 million from the private placement of equity securities, primarily redeemable convertible preferred stock, and \$19.4 million from the issuance of convertible notes and warrants.

In 2003, employees purchased stock pursuant to option exercises and our employee stock purchase plan for aggregate net proceeds to us of approximately \$8.0 million.

In March 2002, we entered into a collaboration agreement with Nycomed, under which Nycomed will serve as the exclusive distributor of Angiomax in approximately 35 countries, including 12 countries in the European Union. Under the agreement, Nycomed paid us an initial non-refundable fee of \$1.5 million and agreed to pay up to \$2.5 million in additional milestones based on regulatory approvals in Europe. In addition, Nycomed purchased 79,428 shares of our common stock for a total purchase price of approximately \$1.0 million.

*Cash Flows.* As of December 31, 2003, we had \$43.4 million in cash and cash equivalents, as compared to \$36.8 million as of December 31, 2002. Our major uses of cash during 2003 include net cash used for operating activities of \$5.2 million and net cash used in investing activities of \$87.7 million, which were more than offset by \$99.5 million received from financing activities.

We used net cash of \$5.2 million in operating activities during 2003. This use of cash consisted of a net loss of \$16.9 million, an increase in accounts receivable of \$0.6 million related to higher sales volume and accrued interest receivable of \$0.9 million related to higher investment balance, a decrease in accounts payable of \$1.0 million, a decrease in prepaid expenses of \$0.3 million, and amortization of deferred revenue of \$0.1 million, partly offset by a increase in accrued expenses of \$6.8 million, non-cash stock compensation of \$3.4 million, a decrease in inventory of \$2.7 million, and depreciation of \$0.6 million and amortization of premium on available for sale securities of \$0.9 million. The increase in accrued expenses can be largely attributed to \$2.1 million additional patient related accruals for our clinical trials currently underway, \$1.1 million additional employee compensation accruals and increased royalty accruals and \$1.3 million additional sales related accruals associated with higher sales volumes.



During 2003, we used \$87.7 million in cash in net investing activities, which consisted principally of the purchase of \$142.8 million of available for sale securities and purchase of \$1.2 million of fixed assets, mostly related to our leasehold improvements, offset by \$56.3 million in proceeds from the maturation and sale of available for sale securities.

Cash provided by financing activities of \$99.5 million during 2003 consisted primarily of the proceeds of the public offering of 5.6 million shares of our common stock in March 2003 that resulted in net proceeds of \$91.5 million. In addition, employees purchased stock pursuant to option exercises and our employee stock purchase plan for aggregate net proceeds to us of approximately \$8.0 million.

*Funding Requirements.* We expect to devote substantial resources to our research and development efforts and to our sales, marketing and manufacturing programs associated with the commercialization of our products. Our funding requirements will depend on numerous factors including:

- the extent to which Angiomax is commercially successful;
- the progress, level and timing of our research and development activities related to our clinical trials with respect to Angiomax, Clevelox and cangrelor;
- the cost and outcomes of regulatory reviews;
- the continuation or termination of third party manufacturing or sales and marketing arrangements;
- the cost and effectiveness of our sales and marketing programs;
  - the status of competitive products;
  - our ability to defend and enforce our intellectual property rights; and
    - the establishment of additional strategic or licensing arrangements with other companies or acquisitions.

We believe, based on our operating plan as of the date of this annual report, which includes anticipated revenues from Angiomax and interest income, that our current cash, cash equivalents and available for sale securities would be sufficient to fund our operations into 2005 and beyond, without requiring us to obtain external financing. We expect, however, to periodically assess our financing alternatives and access the capital markets opportunistically. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated revenues from Angiomax or otherwise, or if we acquire additional product candidates, we may need to sell additional equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities or such a we cannot be certain that additional public or private financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

#### **Contractual Obligations**

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include inventory related commitments to manufacture our products, research and development service agreements, operating leases and other selling and general administrative related obligations.

Future estimated contractual obligations are:

Contractual Obligations	_	2004		2005	 2006		2007		2008		Later Years	 Total
Inventory related commitments	\$	21,318,000	\$	28,574,000	\$ _	\$	_	\$	_	\$	_	\$ 49,892,000
Research and development		9,752,000		3,686,000	602,000		_		_		_	14,040,000
Operating Leases		938,000		1,071,000	1,136,000		1,154,000		1,151,000		4,134,000	9,584,000
Selling, general and administrative		698,000		_	_		_		_		_	698,000
	_		_			_		_		_		
Total contractual obligations	\$	32,706,000	\$	33,331,000	\$ 1,738,000	\$	1,154,000	\$	1,151,000	\$	4,134,000	\$ 74,214,000

Included above are inventory related non-cancellable commitments to make payments to UCB Bioproducts of a total of \$18.7 million during 2004 for Angiomax bulk drug substance to be produced using the Chemilog process and \$2.6 million in related filling, finishing and packaging commitments through August 2004. We also have \$13.8 million of estimated contractual obligations for research and development activities of which \$1.0 million is non-cancellable. The amounts included in selling, general and administrative obligations are primarily related to non-cancellable consulting arrangements.

In addition to the contractual obligations above, we have agreed to make payments upon the achievement of sales and regulatory milestones, and agreed to pay royalties, to Biogen Idec, Inc. and to AstraZeneca AB under our product license agreements for Angiomax, Clevelox and cangrelor. Under the Angiomax license, we have agreed to pay up to an additional \$8.0 million upon the first commercial sales of Angiomax for the treatment of acute myocardial infarction in the United States and Europe. Under the Clevelox license, we have agreed to pay up to an additional \$5.0 million upon reaching certain regulatory milestones. Under the cangrelor license, we have made an upfront payment and will provide milestone payments upon regulatory approval in major markets.

#### **Factors That May Affect Future Results**

This Annual Report on Form 10–K includes forward–looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management, other than statements of historical facts, are forward–looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward–looking statements, although not all forward–looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed or implied in our forward–looking statements. There are a number of important factors that could cause actual results, levels of activity, performance or events to differ materially from those expressed or implied in the forward–looking statements we make. These important factors include our "critical accounting estimates" and the risk factors set forth below. Although we may elect to update forward–looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change, and readers should not rely on those forward–looking statements as representing our views as of any date subsequent to the date of this annual report.

#### **Risks Related to Our Business**

#### We have a history of net losses and may not achieve or maintain profitability

We have incurred net losses on an annual basis since our inception, including a net loss of approximately \$16.9 million for the year ended December 31, 2003. As of December 31, 2003, we had an accumulated deficit of approximately \$314.1 million. We expect to make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, regulatory approvals and commercialization. Although we achieved profitability for the three months ended December 31, 2003, in light of our planned expenditures, we will likely need to generate

significantly greater revenues to maintain profitability. We remain unsure as to when we will become profitable on an annual basis, if at all, or whether we will remain profitable for any substantial period of time. If we fail to achieve profitability on an annual basis within the time frame expected by investors or securities analysts, the market price of our common stock may decline.

#### Our business is very dependent on the commercial success of Angiomax

Angiomax is our only commercial product and, we expect, will account for almost all of our revenues for the foreseeable future. The commercial success of Angiomax will depend upon its continued acceptance by regulators, physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to heparin and other products used in current practice, or currently being developed. If Angiomax is not commercially successful, we will have to find additional sources of funding or curtail or cease operations.

#### Near-term growth in our sales of Angiomax is highly dependent on physician acceptance of the REPLACE-2 trial

In the fall of 2002, we completed a 6,002 patient post–marketing Phase 3b/4 clinical trial of Angiomax in coronary angioplasty called REPLACE–2. In November 2002, the principal investigators of the clinical trial announced that, based on 30–day patient follow–up results, Angiomax met all of the primary and secondary objectives of the trial. In March 2003, we released the results of the detailed cost analysis study to examine per–patient total hospital resource consumption at U.S. clinical trial sites. In September 2003, the principal investigators of the clinical trial further announced that, based on six–month patient follow–up results, Angiomax again met all of the primary and secondary objectives of the trial. In November 2003, the principal investigators presented one–year follow–up mortality data from the trial, which confirmed the 30–day and six–month mortality results.

We believe that the near-term commercial success of Angiomax will depend upon the extent to which physicians, patients and other key decision-makers accept the results of the REPLACE-2 trial. Since the original results were announced, additional hospitals have granted Angiomax formulary approval and hospital demand for the product has increased. We cannot be certain, however, that these trends will continue. Some commentators have challenged various aspects of the trial design of REPLACE-2, the conduct of the study and the analysis and interpretation of the results from the study, including how we define bleeding and the clinical relevance of types of ischemic events. If physicians, patients and other key decision-makers do not accept the trial results, adoption of Angiomax may suffer, and our business will be materially adversely affected.

# We cannot expand the indications for which we are marketing Angiomax unless we receive FDA approval for each additional indication. Failure to expand these indications will limit the size of the commercial market for Angiomax

In December 2000, we received approval from the FDA for the use of Angiomax as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary angioplasty. One of our key objectives is to expand the indications for which Angiomax is approved for marketing by the FDA. In order to market Angiomax for these expanded indications, we will need to complete our clinical trials that are currently underway, conduct additional clinical trials, obtain positive results from those trials and obtain FDA approval for such proposed indications. If we are unsuccessful in expanding the approved indications for the use of Angiomax, the size of the commercial market for Angiomax will be limited.

#### Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing Angiomax abroad

We intend to market Angiomax through distribution partners in international markets, including Europe. In order to market Angiomax in the European Union and many other foreign jurisdictions, we or our distribution partners must obtain separate regulatory approvals. Obtaining foreign approvals may require additional trials and expense. In February 1998, we submitted a Marketing Authorization Application, or MAA, to the European Agency for Evaluation of Medicinal Products, or the EMEA, for use of Angiomax in unstable angina patients undergoing coronary angioplasty. Following extended interaction with European regulatory authorities, the Committee of Proprietary Medicinal Products of the EMEA voted in October 1999 not to recommend Angiomax for approval in coronary angioplasty, and we withdrew our application to the EMEA. In August 2003, we resubmitted an MAA with the results of the REPLACE-2 trial, and we are in discussions with regulatory authorities regarding the resubmitted MAA. We may not be able to obtain approval or may be delayed in obtaining approval from any or all of the jurisdictions in which we seek approval to market Angiomax.

# The development and commercialization of our products may be terminated or delayed, and the costs of development and commercialization may increase, if third parties on which we rely to manufacture and support the development and commercialization of our products do not fulfill their obligations

Our development and commercialization strategy entails entering into arrangements with corporate and academic collaborators, contract research organizations, distributors, third-party manufacturers, licensors, licensees and others to conduct development work, manage our clinical trials, manufacture our products and market and sell our products outside of the United States. We do not have the expertise or the resources to conduct such activities on our own and, as a result, are particularly dependent on third parties in most areas.

We may not be able to maintain our existing arrangements with respect to the commercialization of Angiomax or establish and maintain arrangements to develop and commercialize Clevelox, cangrelor or any additional product candidates or products we may acquire on terms that are acceptable to us. Any current or future arrangements for development and commercialization may not be successful. If we are not able to establish or maintain agreements relating to Angiomax, Clevelox, cangrelor or any additional products we may acquire on terms that we deem favorable, our results of operations would be materially adversely affected.

Third parties may not perform their obligations as expected. The amount and timing of resources that third parties devote to developing, manufacturing and commercializing our products are not within our control. Furthermore, our interests may differ from those of third parties that manufacture or commercialize our products. Disagreements that may arise with these third parties could delay or lead to the termination of the development or commercialization of our product candidates, or result in litigation or arbitration, which would be time consuming and expensive.

If any third party that manufactures or supports the development or commercialization of our products breaches or terminates its agreement with us, or fails to conduct its activities in a timely manner, such breach, termination or failure could:

- delay or otherwise adversely impact the development or commercialization of Angiomax, Clevelox, cangrelor or any additional products that we may acquire or develop;
  - require us to undertake unforeseen additional responsibilities or devote unforeseen additional resources to the development or commercialization of our products; or
    - result in the termination of the development or commercialization of our products.



#### Failure to achieve our revenue targets or raise additional funds in the future may affect the development, manufacture and sale of our products

We will need to generate significantly greater revenues to achieve and then maintain profitability on an annual basis. The product development, including clinical trials, manufacturing development and regulatory approvals, of Angiomax for additional indications, Clevelox and cangrelor, and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future funding requirements depend upon many factors, including our ability to achieve our revenue targets, and may be significantly greater than we expect.

As of the date of this annual report, we believe, based on our current operating plan, which includes anticipated revenues from Angiomax and interest income, that our current cash, cash equivalents and available for sale securities will be sufficient to fund our operations into 2005 and beyond, without requiring us to obtain external financing. If our existing resources are insufficient to satisfy our liquidity requirements due to slower than anticipated sales of Angiomax or otherwise, or if we acquire additional product candidates, we may need to sell additional equity or debt securities or seek additional financing through other arrangements. Any sale of additional equity or debt securities may result in additional dilution to our stockholders, and we cannot be certain that additional public or private financing will be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to delay, reduce the scope of, or eliminate one or more of our planned research, development and commercialization activities, which could harm our financial condition and operating results. In addition, in order to obtain additional financing, we may be required to relinquish rights to products, product candidates or technologies that we would not otherwise relinquish.

# We depend on single suppliers for the production of Angiomax and Clevelox bulk drug substance and different single suppliers to carry out all fill-finish activities

We do not manufacture any of our products and do not plan to develop any capacity to manufacture them. As of the date of this annual report, we obtain all of our Angiomax bulk drug substance from one manufacturer, UCB Bioproducts, and rely on another manufacturer, Ben Venue Laboratories, to carry out all fill–finish activities for Angiomax, which includes final formulation and transfer of the drug into vials where it is then freeze–dried and sealed. The terms of our agreement with UCB Bioproducts require us to purchase a substantial portion of our Angiomax bulk drug product from UCB Bioproducts, which could hinder our ability to obtain an additional supplier for Angiomax.

As of the date of this annual report, we obtain all of our Clevelox bulk drug substance for use in clinical trials from one manufacturer, Pharm–Eco, a Johnson Matthey Company. We will rely on a different single supplier, Fresnius Kabi Clayton, L.P., and its proprietary formulation technology, for the manufacture of all finished Clevelox product, as well as release testing and clinical packaging.

The FDA requires that all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's current good manufacturing practices, or cGMP, regulations and guidelines. There are a limited number of manufacturers that operate under cGMP regulations capable of manufacturing Angiomax. As of the date of this annual report, we do not have alternative sources for production of Angiomax bulk drug substance or to carry out fill–finish activities. In the event that either UCB Bioproducts or Ben Venue is unable to carry out its respective manufacturing obligations, we may be unable to obtain alternative manufacturing or obtain such manufacturing on commercially reasonable terms or on a timely basis. If we were required to transfer manufacturing processes to other third party manufacturers, we would be required to satisfy various regulatory requirements, which could cause us to experience significant delays in receiving an adequate supply of Angiomax. Any delays in the manufacturing process may adversely impact our ability to meet commercial demands for Angiomax on a timely basis and supply product for clinical trials of Angiomax.

# We do not own the technology underlying the Chemilog process and may be unable to utilize the Chemilog process if UCB Bioproducts breaches our agreement

Our agreement with UCB Bioproducts for the supply of Angiomax bulk drug substance provides that UCB Bioproducts owns all of the proprietary technology that was used to develop the Chemilog process. Although the agreement requires that UCB Bioproducts transfer this technology to a secondary supplier of Angiomax bulk drug substance or to us or an alternate supplier at the expiration of the agreement, if UCB Bioproducts fails or is unable to transfer successfully this technology, we would be unable to employ the Chemilog process to manufacture our Angiomax bulk drug substance, which could cause us to experience delays in the manufacturing process and increase our manufacturing costs in the future.

#### Clinical trials of product candidates are expensive and time-consuming, and the results of these trials are uncertain

Before we can obtain regulatory approvals to market any product for a particular indication, we will be required to complete pre-clinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of such product for such indication. As of the date of this annual report, we are evaluating Angiomax in clinical trials for additional uses in open vascular surgery such as CABG surgery, in medical conditions that require urgent treatment such as unstable angina, in patients with heparin allergy, in children and in peripheral angioplasty. As of the date of this annual report, we have commenced a Phase 3 trial program in patients undergoing cardiac surgery to investigate the potential of Clevelox to simplify and improve the treatment of these patients. There are numerous factors that could delay our clinical trials or prevent us from completing our trials successfully. We, or the FDA, may suspend a clinical trial at any time on various grounds, including a finding that patients are being exposed to unacceptable health risks.

The rate of completion of clinical trials depends in part upon the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. In particular, the patient population targeted by some of our clinical trials may be small. Delays in future planned patient enrollment may result in increased costs and program delays.

In addition, clinical trials, if completed, may not show a product candidate to be safe or effective for the intended use. Results obtained in pre-clinical studies or early clinical trials are not always indicative of results that will be obtained in later clinical trials. Moreover, data obtained from pre-clinical studies and clinical trials may be subject to varying interpretations. As a result, the FDA or other applicable regulatory authorities may not approve a product in a timely fashion, or at all. Even if regulatory approval to market a product is granted, the regulatory approval may impose limitations on the indicated use for which the product may be marketed.

#### Our failure to acquire and develop additional product candidates or approved products will impair our ability to grow

We have a single product approved for marketing. In order to generate additional revenues, we intend to acquire and develop additional product candidates or approved products. The success of this growth strategy depends upon our ability to identify, select and acquire pharmaceutical products that meet the criteria we have established. Because we neither have, nor intend to establish, internal scientific research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license product candidates to us. We will be required to integrate any acquired products into our existing operations. Managing the development of a new product entails

numerous financial and operational risks, including difficulties in attracting qualified employees to develop the product.

Any product candidate we acquire will require additional research and development efforts prior to commercial sale, including extensive pre-clinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe, non-toxic and effective or approved by regulatory authorities.

In addition, we cannot assure you that any approved products that we develop or acquire will be:

- manufactured or produced economically;
- successfully commercialized; or
  - widely accepted in the marketplace.

We have previously acquired rights to products and, after having conducted development activities, determined not to devote further resources to those products. We cannot assure you that any additional products that we acquire will be successfully developed.

In addition, proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

# A breach of any of the agreements under which we license commercialization rights to products or technology from others could cause us to lose license rights that are important to our business or subject us to claims by our licensors

We license rights to products and technology that are important to our business, and we expect to enter into additional licenses in the future. For instance, we have exclusively licensed patents and patent applications relating to Angiomax from Biogen and relating to Clevelox and cangrelor from AstraZeneca. Under these agreements, we are subject to commercialization and development, sublicensing, royalty, patent prosecution and maintenance, insurance and other obligations. Any failure by us to comply with any of these obligations or any other breach by us of these license agreements could give the licensor the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim, particularly relating to our agreement with Biogen, could have a material adverse effect on our business. Even if we contest any such termination or claim and are ultimately successful, our stock price could suffer. In addition, upon any termination of a license agreement, we may be required to license to the licensor any related intellectual property that we developed.

#### We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on our ability to attract and retain qualified personnel for the acquisition, development and commercialization activities we conduct or sponsor. If we lose one or more of the members of our senior management, including our executive chairman, Dr. Clive A. Meanwell, or our chief executive officer, David M. Stack, or other key employees or consultants, our ability to implement successfully our business strategy could be seriously harmed. Our ability to replace these key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to acquire, develop and

commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate such additional personnel.

#### Because the market for thrombin inhibitors is competitive, our product may not obtain widespread use

We have positioned Angiomax as a replacement for heparin, which is a widely used, inexpensive, generic drug used in patients with arterial thrombosis. Because heparin is inexpensive and has been widely used for many years, physicians and medical decision-makers may be hesitant to adopt Angiomax. In addition, due to the high incidence and severity of cardiovascular diseases, competition in the market for thrombin inhibitors is intense and growing. There are a number of direct and indirect thrombin inhibitors currently on the market, awaiting regulatory approval and in development, including orally administered agents. The thrombin inhibitors on the market include products for use in the treatment of patients with a clinical condition known as HIT/HITTS, patients with unstable angina and patients with deep vein thrombosis.

# Angiomax may compete with all groups of anticoagulant drugs, including platelet inhibitors and fibrinolytic drugs, which may limit the use of Angiomax

In general, anticoagulant drugs may be classified into four groups: drugs that directly target and inhibit thrombin, drugs that indirectly target and inhibit thrombin, drugs that target and inhibit platelets and drugs that break down fibrin. Because each group of anticoagulants acts on different components of the clotting process, we believe that there will be continued clinical work to determine the best combination of drugs for clinical use. We expect Angiomax to be used with aspirin alone or in conjunction with platelet inhibitors or fibrinolytic drugs. Although platelet inhibitors and fibrinolytic drugs may be complementary to Angiomax, we recognize that Angiomax may compete with these and other anticoagulant drugs to the extent Angiomax and any of these anticoagulant drugs are approved for the same indication.

In addition, platelet inhibitors and fibrinolytic drugs may compete with Angiomax for the use of hospital financial resources. For example, many U.S. hospitals receive a fixed reimbursement amount per procedure for the angioplasties and other treatment therapies they perform. Because this amount is not based on the actual expenses the hospital incurs, hospitals may be forced to use either Angiomax or platelet inhibitors or fibrinolytic drugs but not necessarily several of the drugs together.

# We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do

Our industry is highly competitive. Our success will depend on our ability to acquire and develop products and apply technology, and our ability to establish and maintain markets for our products. Potential competitors in the United States and other countries include major pharmaceutical and chemical companies, specialized pharmaceutical companies and biotechnology firms, universities and other research institutions. Many of our competitors have substantially greater research and development capabilities and experience, and greater manufacturing, marketing and financial resources, than we do. Accordingly, our competitors may develop or license products or other novel technologies that are more effective, safer or less costly than existing products or technologies or products or technologies that are being developed by us or may obtain FDA approval for products more rapidly than we are able. Technological development by others may render our products or product candidates noncompetitive. We may not be successful in establishing or maintaining technological competitiveness.

#### Fluctuations in our operating results could affect the price of our common stock

Our operating results may vary from period to period based on factors including the amount and timing of sales of Angiomax, the availability and timely delivery of a sufficient supply of Angiomax, the



timing and expenses of clinical trials, announcements regarding clinical trial results and product introductions by us or our competitors, the availability and timing of third-party reimbursement and the timing of regulatory approvals. If our operating results do not match the expectations of securities analysts and investors as a result of these and other factors, the trading price of our common stock will likely decrease.

# We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could damage our ability to attain or maintain profitability

We may acquire additional businesses and products that complement or augment our existing business. Integrating any newly acquired business or product could be expensive and time–consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses or products, which may result in dilution for stockholders and the incurrence of indebtedness.

# Our revenues are substantially dependent on a limited number of wholesalers to which we sell Angiomax, and such revenues may fluctuate from quarter to quarter based on the buying patterns of these wholesalers

We sell Angiomax primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. During the year ended December 30, 2003, revenues from the sale of Angiomax to three wholesalers totaled approximately 95% of our net revenues. Our reliance on this small number of wholesalers could cause our revenues to fluctuate from quarter to quarter based on the buying patterns of these wholesalers. In addition, if any of these wholesalers fails to pay us on a timely basis or at all, our financial position and results of operations could be materially adversely affected.

#### **Risks Related to Our Industry**

# If we do not obtain FDA approvals for our products or comply with government regulations, we may not be able to market our products and may be subject to stringent penalties

Except for Angiomax, which has been approved for sale in the United States for use as an anticoagulant in patients undergoing coronary angioplasty, and which has been approved for sale in five other countries for indications similar to that approved by the FDA, we do not have a product approved for sale in the United States or any foreign market. We must obtain approval from the FDA in order to sell our product candidates in the United States and from foreign regulatory authorities in order to sell our product candidates in other countries. We must successfully complete our clinical trials and demonstrate manufacturing capability before we can file with the FDA for approval to sell our products. The FDA could require additional studies as part of the regulatory review process. Delays in obtaining or failure to obtain regulatory approvals may:

- delay or prevent the successful commercialization of any of our product candidates;
  - diminish our competitive advantage; and
    - defer or decrease our receipt of revenues or royalties.

The regulatory review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical data, clinical data and supporting information must be submitted to the FDA for each additional indication to obtain such approvals, and we cannot be certain when we will receive these regulatory approvals, if ever.

In addition to initial regulatory approval, our product and product candidates are subject to extensive and rigorous ongoing domestic and foreign government regulation of, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of our products and product candidates. Any approvals, once obtained, may be withdrawn if compliance with regulatory requirements is not maintained or safety problems are identified. Failure to comply with these requirements may also subject us to stringent penalties.

#### We may not be able to obtain or maintain patent protection for our products, and we may infringe the patent rights of others

The patent positions of pharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual issues. Our success depends significantly on our ability to:

- obtain and maintain U.S. and foreign patents;
- protect trade secrets;
- operate without infringing the proprietary rights of others; and
  - prevent others from infringing our proprietary rights.

We may not have any additional patents issued from any patent applications that we own or license. If additional patents are granted, the claims allowed may not be sufficiently broad to protect our technology. In addition, issued patents that we own or license may be challenged, invalidated or circumvented. Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications.

We exclusively license U.S. patents and patent applications and corresponding foreign patents and patent applications relating to Angiomax, Clevelox, cangrelor and CTV–05. As of the date of this annual report, we exclusively license six issued U.S. patents relating to Angiomax, three issued U.S. patents relating to Clevelox, four issued U.S. patents relating to cangrelor and three issued U.S. patents relating to CTV–05. The principal U.S. patent that covers Angiomax expires in 2010. The U.S. Patent and Trademark Office has rejected our application for an extension of the term of the patent beyond 2010 because the application was not filed on time. We are exploring an alternative to extend the term of the patent, but we can provide no assurance that we will be successful. We have not yet filed any independent patent applications.

We may not hold proprietary rights to some patents related to our product candidates. In some cases, others may own or control these patents. As a result, we may be required to obtain licenses under third-party patents to market some of our product candidates. If licenses are not available to us on acceptable terms, we will not be able to market these products.

We may become a party to patent litigation or other proceedings regarding intellectual property rights. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. If any patent litigation or other intellectual property proceeding in which we are involved is resolved unfavorably to us, we may be enjoined from manufacturing or selling our products without a license from the other party, and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms, or at all.

#### If we are not able to keep our trade secrets confidential, our technology and information may be used by others to compete against us

We rely significantly upon unpatented proprietary technology, information, processes and know-how. We seek to protect this information by confidentiality agreements with our employees, consultants and other third-party contractors, as well as through other security measures. We may not have adequate remedies for any breach by a party to these confidentiality agreements. In addition, our competitors may learn or independently develop our trade secrets.

# We could be exposed to significant liability claims if we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims

Our business exposes us to potential product liability risks, which are inherent in the testing, manufacturing, marketing and sale of human healthcare products. Product liability claims might be made by patients in clinical trials, consumers, health care providers or pharmaceutical companies or others that sell our products. These claims may be made even with respect to those products that are manufactured in licensed and regulated facilities or otherwise possess regulatory approval for commercial sale.

These claims could expose us to significant liabilities that could prevent or interfere with the development or commercialization of our products. Product liability claims could require us to spend significant time and money in litigation or pay significant damages. As of the date of this annual report, we are covered, with respect to our commercial sales and our clinical trials, by primary product liability insurance in the amount of \$20.0 million per occurrence and \$20.0 million annually in the aggregate on a claims–made basis. This coverage may not be adequate to cover any product liability claims.

As we commercialize our products, we may wish to increase our product liability insurance. Product liability coverage is expensive. In the future, we may not be able to maintain or obtain such product liability insurance on reasonable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims.

#### Our ability to generate future revenue from products will depend on reimbursement and drug pricing

Acceptable levels of reimbursement of drug treatments by government authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract collaborative partners to invest in the development of, product candidates. We cannot be sure that reimbursement in the United States or elsewhere will be available for any products we may develop or, if already available, will not be decreased in the future. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products, and may not be able to obtain a satisfactory financial return on our products.

Third-party payers increasingly are challenging prices charged for medical products and services. Also, the trend toward managed health care in the United States and the changes in health insurance programs, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for pharmaceutical products, including any products that may be offered by us. Cost-cutting measures that health care providers are instituting, and the effect of any health care reform, could materially adversely affect our ability to sell any products that are successfully developed by us and approved by regulators. Moreover, we are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business.

#### Item 7A. Quantitative and Qualitative Disclosure About Market Risk

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents and available for sale securities. We place our investments in high–quality financial instruments, primarily money market funds, corporate debt and U.S. government agency securities with maturities or auction dates of less than one year, which we believe are subject to limited interest rate and credit risk. We currently do not hedge interest rate exposure. At December 31, 2003, we held \$135.9 million in cash, cash equivalents and available for sale securities which had an average interest rate of approximately 1.5%. Of this amount, approximately 59% of the cash, cash equivalents and available for sale securities were due on demand or within one year and had an average interest rate of approximately of 1.2%. The remaining 41% were due within two years and had an average interest rate of approximately 1.8%.

Most of our transactions are conducted in U.S. dollars. We do have certain agreements with parties located outside the United States. Transactions under certain of these agreements are conducted in U.S. dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under certain other of these agreements are conducted in the local foreign currency. If the applicable exchange rate undergoes a change of 10.0%, we do not believe that it would have a material impact on our results of operations or cash flows.

#### Item 8. Financial Statements and Supplementary Data

All financial statements and schedules required to be filed hereunder are filed as Appendix A hereto and are listed under Item 15(a).

#### Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure

None

#### Item 9A. Controls and Procedures

Our management, with the participation of our chief executive officers and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31,2003. Based on this evaluation, our chief executive officers and chief financial officer concluded that, as of December 31, 2003, our disclosure controls and procedures were (1) designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our chief executive officers and chief financial officer by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal year ended December 31, 2003 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

#### PART III

#### Item 10. Directors and Executive Officers of the Registrant

Our executive officers, directors and key employees and their respective ages are as follows:

Name	Age	Position
Clive A. Meanwell, M.D., Ph.D.*	45	Executive Chairman and Chairman of the Board of Directors
David M. Stack*	52	Chief Executive Officer, President and Director
Steven H. Koehler, M.B.A.*	53	Vice President and Chief Financial Officer
Gary Dickinson	52	Vice President
John D. Richards, D.Phil.*	47	Vice President
Fred M. Ryan, M.B.A	52	Vice President
Paul M. Antinori, J.D.	50	General Counsel
Leonard Bell, M.D.	45	Director
William W. Crouse, M.B.A. (3)	61	Director
Robert J. Hugin (1)	49	Director
T. Scott Johnson, M.D. (1)	56	Director
Armin M. Kessler (1)(2)(3)	65	Director
Robert G. Savage, M.B.A. (2)(3)	50	Director
James E. Thomas, M.Sc. (2)	43	Director

\*

Executive Officer

(1) (2)

Member of the Audit Committee

Member of the Compensation Committee

(3)

Member of the Nominations Committee

Set forth below is certain information regarding the business experience during the past five years for each of the above-named persons.

*Clive A. Meanwell, M.D., Ph.D.* has been a director since the inception of our company in July 1996 and has served as our Executive Chairman since September 2001. From 1996 to September 2001, Dr. Meanwell served as our Chief Executive Officer and President. From 1995 to 1996, Dr. Meanwell was a Partner and Managing Director at MPM Capital L.P., a venture capital firm. From 1986 to 1995, Dr. Meanwell held various positions at Hoffmann–La Roche, Inc., a pharmaceutical company, including Senior Vice President from 1992 to 1995, Vice President from 1991 to 1992 and Director of Product Development from 1986 to 1991. Dr. Meanwell currently serves as a director of Endo Pharmaceuticals Inc. Dr. Meanwell received an M.D. and a Ph.D. from the University of Birmingham, United Kingdom.

*David M. Stack* has been our President and Chief Executive Officer and a director since September 2001. From April 1, 2000 to September 2001, Mr. Stack served as a Senior Vice President. From January 2000 to September 2001, Mr. Stack also served as President and General Partner of Stack Pharmaceuticals, Inc., a commercialization, marketing and strategy consulting firm serving healthcare companies, and, from January 2000 to December 2001, as a Senior Advisor to the Chief Executive Officer of Innovex Inc., a contract pharmaceutical organization. Mr. Stack served as President and General Manager of Innovex Inc. from May 1995 to December 1999. Mr. Stack currently serves as a director of BioImaging Technologies, Inc. Mr. Stack received a B.S. in biology from Siena College and a B.S. in pharmacy from Albany College of Pharmacy.

Steven H. Koehler, M.B.A. has been our Vice President and Chief Financial Officer since April 2002. From March 2002 to April 2002, Mr. Koehler served as our Vice President, Finance and Business Administration. From July 2001 to March 2002, Mr. Koehler was Vice President, Finance and Chief Financial Officer of Vion Pharmaceuticals, Inc., a biotechnology company which develops cancer

treatments. From April 1999 to July 2001, Mr. Koehler served as Vice President, Finance and Administration and as a member of the executive board of Knoll Pharmaceuticals, Inc., a wholly owned subsidiary of BASF Corporation, the U.S. subsidiary of a transnational chemical and life sciences company. From June 1997 to April 1999, Mr. Koehler was Vice President, Finance and Controlling for Knoll AG in Ludwigshafen, Germany, the former global pharmaceutical subsidiary of BASF AG. From November 1995 to June 1997, he served as Vice President, Value Based Management for Knoll AG. Mr. Koehler was Vice President, Finance and Treasurer for Boots Pharmaceuticals, Inc. from 1993 until its acquisition by Knoll in 1995. Mr. Koehler is a Certified Public Accountant. Mr. Koehler received a B.A. degree from Duke University and an M.B.A. degree from the Kellogg Graduate School of Management, Northwestern University.

Gary Dickinson has been a Vice President since April 2001 with a focus on human resources activities. From March 2000 to April 2001, Mr. Dickinson was the Vice President of Human Resources of Elementis Specialties, Inc., a specialty chemicals manufacturing firm. From January 1997 to April 2001, Mr. Dickinson was the Senior Director of Human Resources of Bristol–Myers Squibb Company, a pharmaceuticals firm. Mr. Dickinson holds a B.A. from the University of Sheffield, United Kingdom.

John D. Richards, D.Phil. joined us in October 1997 and has been a Vice President since 1999, with a focus on product manufacturing and quality. From 1993 until he joined us in October 1997, Dr. Richards was Director of Process Development and Manufacturing at Immulogic Pharmaceutical Corporation, a pharmaceutical company. From 1989 to 1993, Dr. Richards was a Technical Manager at Zeneca PLC, a pharmaceutical company, where he developed and implemented processes for the manufacture of peptides as pharmaceutical active intermediates. In 1986, Dr. Richards helped establish Cambridge Research Biochemicals, a manufacture of peptide–based products for pharmaceutical and academic customers. Dr. Richards received an M.A. and a D.Phil. in organic chemistry from the University of Oxford, United Kingdom, and has carried out post–doctoral research work at the Medical Research Councils Laboratory of Molecular Biology in Cambridge, United Kingdom.

*Fred M. Ryan, M.B.A.* has been a Vice President since April 2000, with a focus on corporate strategic development, new product acquisitions and Angiomax commercial development. From April 2000 to September 2001, Mr. Ryan also served as a Partner and the Vice President of Business Development of Stack Pharmaceuticals, Inc. From July 1991 to April 2000, he held senior management positions with Novartis Pharmaceuticals Corporation, a pharmaceutical company, in the United States in the areas of Finance, Strategic Planning, Business Development and Marketing, serving from 1998 to April 2000 as Executive Director Mature Products responsible for managing sales and marketing activities for a portfolio of products having annual sales in excess of \$500 million. He received a B.S. and a B.A. degrees from Bryant College and his M.B.A. from Fairleigh Dickinson University.

Paul M. Antinori, J.D. has been our General Counsel since May 2002. From March 1998 to April 2002, Mr. Antinori was General Counsel and a consultant to Physician Computer Network, Inc., a healthcare information technology company. Prior to March 1998, Mr. Antinori was a partner at Gibbons, Del Deo, Dolan, Griffinger & Vecchione in Newark, NJ. Mr. Antinori received his J.D. from the University of Virginia School of Law and his B.A. from Boston College.

Leonard Bell, M.D. has been a director since May 2000. From January 1992 to March 2002, Dr. Bell served as the President and Chief Executive Officer, Secretary and Treasurer of Alexion Pharmaceuticals, Inc., a pharmaceutical company. Since March 2002, Dr. Bell has served as the Chief Executive Officer, Secretary and Treasurer of Alexion Pharmaceuticals, Inc. Since 1993, Dr. Bell has served as an Adjunct Assistant Professor of Medicine and Pathology at the Yale University School of Medicine. From 1991 to 1992, Dr. Bell was an Assistant Professor of Medicine and Pathology and co–Director of the Program in Vascular Biology at the Yale University School of Medicine. From 1990 to 1992, Dr. Bell was an attending physician at the Yale–New Haven Hospital and an Assistant

Professor in the Department of Internal Medicine at the Yale University School of Medicine. Dr. Bell was the recipient of the Physician Scientist Award from the National Institutes of Health and Grant–in–Aid from the American Heart Association. Dr. Bell is the recipient of various honors and awards from academic and professional organizations and his work has resulted in more than 45 scientific publications, invited presentations and patent applications. Dr. Bell is an invited Member of the State of Connecticut Governor's Council on Economic Competitiveness and Technology and a director of Connecticut United for Research Excellence, Inc. He also served as a director of the Biotechnology Research and Development Corporation from 1993 to 1997. Dr. Bell currently also serves as a director of Alexion Pharmaceuticals, Inc. Dr. Bell received an A.B. from Brown University and an M.D. from the Yale University School of Medicine.

*William W. Crouse, M.B.A.* has been a director since April 2003. Since January 1994, Mr. Crouse has been a Managing Director of HealthCare Ventures, a venture capital firm with a focus on biotechnology firms. From 1987 to 1993, Mr. Crouse served as Worldwide President of Ortho Diagnostic Systems, a subsidiary of Johnson & Johnson that manufactures diagnostic tests for hospitals, and a Vice President of Johnson & Johnson International. Before joining Johnson & Johnson, Mr. Crouse was a Division Director of DuPont Pharmaceuticals Company, a pharmaceutical firm, where he was responsible for international operations and worldwide commercial development activities. Before joining Dupont, he served as President of Revlon Health Care Group's companies in Latin America, Canada, and Asia/Pacific. Mr. Crouse currently also serves as a director of ImClone Systems, Inc. Mr. Crouse received a B.S. in finance and economics from Lehigh University and an M.B.A. from Pace University.

*Robert J. Hugin* has been a director since April 2003. Since June 1999, Mr. Hugin has been the Senior Vice President and Chief Financial Officer of Celgene Corporation, a biopharmaceutical company focused on cancer and immunological diseases. From 1985 to 1999, Mr. Hugin held positions with J.P. Morgan & Co. Inc., an investment banking firm, serving most recently as a Managing Director. Mr. Hugin also currently serves as a director of Celgene Corporation. Mr. Hugin received an A.B. from Princeton University and an M.B.A. from the University of Virginia.

T. Scott Johnson, M.D. has been a director since September 1996. In July 1999, Dr. Johnson founded JSB Partners, L.P., an investment bank focusing on mergers and acquisitions, private financings and corporate alliances within the health care sector. From September 1991 to July 1999, Dr. Johnson served as a founder and managing director of MPM Capital, L.P., a venture capital firm. Dr. Johnson received both a B.S. and an M.D. from the University of Alabama.

Armin M. Kessler has been a director since October 1998. Mr. Kessler joined us after a 35-year career in the pharmaceutical industry, which included senior management positions at Sandoz Pharma Ltd., Basel, Switzerland, United States and Japan (now Novartis Pharma AG) and, most recently, at Hoffmann–La Roche, Basel where he was Chief Operating Officer and Head of the Pharmaceutical Division until 1995. Mr. Kessler currently also serves as a director of Spectrum Pharmaceuticals, Inc. and Gen–Probe Incorporated. Mr. Kessler received degrees in physics and chemistry from the University of Pretoria, a degree in chemical engineering from the University of Cape Town, a law degree from Seton Hall and an honorary doctorate in business administration from the University of Pretoria.

*Robert G. Savage, M.B.A.* has been a director since April 2003. From March 2002 to April 2003, Mr. Savage was Group Vice President and President for the General Therapeutics and Inflammation Business, of Pharmacia Corporation, a research–based pharmaceutical firm acquired by Pfizer Inc. in April 2003. From September 1996 to January 2002, Mr. Savage held several senior positions with Johnson & Johnson, including Worldwide Chairman for the Pharmaceuticals Group during 2001, Company Group Chairman responsible for the North America pharmaceuticals business from 2000 to 2001, President, Ortho–McNeil Pharmaceuticals from 1998 to 2000 and Vice President Sales &

Marketing from 1996 to 1998. From 1985 to 1996, Mr. Savage held several positions at Hoffmann–La Roche, Inc., a healthcare firm. Mr. Savage also serves as a director for Noven Pharmaceuticals, a leader in the development of advanced drug delivery technologies, and NovaDel Pharma Inc., a specialty pharmaceutical company developing drug delivery systems. Mr. Savage received a B.S. in biology from Upsala College and an M.B.A. from Rutgers University.

*James E. Thomas, M.Sc.* has been a director since September 1996. Since March 2001, Mr. Thomas has served as Managing Partner of Thomas, McNerney & Partners, LLC, a health care private equity investment fund. From 1989 to June 2000, Mr. Thomas served in various capacities, including from 1994 to 2000, as a Partner and Managing Director, at E.M. Warburg, Pincus & Co., LLC, a private equity investment firm. From 1984 to 1989, Mr. Thomas was a Vice President of Goldman Sachs International, an investment banking firm, in London. Mr. Thomas currently also serves as a director of Wright Medical Group. Mr. Thomas received a B.Sc. in finance and economics from The Wharton School of the University of Pennsylvania and an M.Sc. in economics from the London School of Economics.

#### Audit Committee

*Members of the Audit Committee.* Our board of directors has a separately-designated standing audit committee established by our full board for the purposes of overseeing our accounting and financial reporting processes and audits of our financial statements. The members of the audit committee are Robert Hugin, who serves as Chairman, Armin Kessler and T. Scott Johnson.

*Financial Expert on Audit Committee.* Our board of directors has determined that we currently have two audit committee financial experts, Robert J. Hugin and Armin M. Kessler. In deciding whether members of our audit committee qualify as financial experts within the meaning of the SEC regulations and the NASDAQ listing standards, our board considered the nature and scope of experiences and responsibilities members of our audit committee have previously had with reporting companies. Messrs. Hugin and Kessler, like all of the other members of our audit committee, are independent directors.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, executive officers and holders of more than ten percent of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities. Based solely on our review of copies of reports filed by the reporting persons furnished to us, or written representations from reporting persons, we believe that during 2003, the reporting persons complied with all Section 16(a) filing requirements, other than one late filing by Peter Teuber, a former Vice President.

#### Code of Ethics

We have adopted a code of business conduct and ethics applicable to all of our employees, including our principal executive officers, our principal financial officer and our controller. The code of business conduct and ethics is available on our website (www.themedicinescompany.com).

1.	
	From our main web page, first click on "The Medicines Investment."
2.	
	Next, click on "Corporate Governance."
3.	
	Finally, click on "Code of Business Conduct and Ethics."

We intend to satisfy the disclosure requirement under Item 10 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics by posting such information on our website, at the address and location specified above.

#### Item 11. Executive Compensation

The following table presents summary information for the years ended December 31, 2003, 2002 and 2001, for:

our executive chairman and our chief executive officer; and

our two other executive officers who were serving at the end of the fiscal year.

These four individuals are referred to collectively as our named executive officers.

#### **Summary Compensation Table**

					Long–Term Compensation Awards	
Name And Position	Year	 Annual Comj Salary	pensatio	on(1) Bonus	Securities Underlying Options(#)	All Other Compensation(\$)(2)
Clive A. Meanwell (3)	2003	\$ 325,000	\$	250,000	125,000	\$ 1,065
Executive Chairman	2002	\$ 300,000	\$	180,000	123,000	\$ 990
	2001	\$ 300,000	\$	50,000	15,000	\$ 770
David M. Stack (4)	2003	\$ 300,000	\$	150,000	65,000	\$ 1,486
President and Chief Executive Officer	2002	\$ 265,000	\$	115,000	204,000	\$ 1,325
	2001	\$ 197,917	\$	40,000	215,000	\$ 516
Steven H. Koehler (5)	2003	\$ 222,500	\$	100,000	50,000	\$ 1,083
Vice President and Chief Financial Officer	2002	\$ 172,689	\$	65,000	250,000	\$ 874
John D. Richards	2003	\$ 170,000	\$	105,000	50,000	\$ 532
Vice President	2002	\$ 150,000	\$	48,000	25,000	\$ 450
	2001	\$ 150,000	\$	30,000	15,000	\$ 450

(1)

Perquisites for the named executive officers did not exceed the lesser of \$50,000 or 10% of total salary and bonus for the respective fiscal years and accordingly have been omitted in accordance with SEC rules.

#### (2)

The dollar amount in the "Other Annual Compensation" column represents life insurance premium payments made by us on behalf of the named executive officer.

#### (3)

Dr. Meanwell served as our President and Chief Executive Officer from 1996 to September 2001. In September 2001, he became our Executive Chairman.

#### (4)

Mr. Stack became our President and Chief Executive Officer in September 2001. Mr. Stack served as our Senior Vice President from April 2000 to September 2001.

#### (5)

Mr. Koehler became our Vice President in March 2002 and our Chief Financial Officer in April 2002.

#### **Option Grants in 2003**

The following table summarizes information regarding options granted to each of the named executive officers during the year ended December 31, 2003. Options granted in 2003 become exercisable in 48 equal monthly installments, commencing one month after the vesting commencement date, which is typically the grant date.

Amounts in the following table represent hypothetical gains that could be achieved for the respective options if exercised at the end of the option term. The 5% and 10% assumed annual rates of



compounded stock price appreciation are mandated by the rules of the SEC and do not represent an estimate or projection of our future common stock prices. These amounts represent assumed rates of appreciation in the value of our common stock from the fair market value on the date of grant. Actual gains, if any, on stock option exercises are dependent on the future performance of our common stock and overall stock market conditions. The amounts reflected in the following table may not be achieved.

#### **Option Grants in Last Fiscal Year**

		Individual Grants (1)						
	Number Of Securities Underlying	Percent of Options Granted to	Exercise			Potential Realiz Assumed Ann Stock Price Apj Option	ual Ra oreciat	tes of ion for
Name	Options Granted	Employees in 2003	Price Per Share	Expiration Date		5%		10%
Clive A. Meanwell	125,000	6.4% \$	28.01	12/23/13	\$	2,201,917	\$	5,580,091
David M. Stack	65,000	3.3% \$			\$	1,144,997	\$	2,901,647
Steven H. Koehler	50,000	2.6% \$	28.01	12/23/13	\$	880,767	\$	2,232,036
John D. Richards	50,000	2.6% \$	27.81	12/19/13	\$	874,478	\$	2,216,099

(1)

The percentage of total options granted to employees in 2003 is calculated based on options granted to employees under our 1998 stock incentive plan and 2001 non-officer, non-director employee stock incentive plan.

#### Option Exercises in 2003 and Option Values at December 31, 2003

The following table sets forth information regarding any options exercised by the named executive officers during the fiscal year ended December 31, 2003 and exercisable and unexercisable stock options held as of December 31, 2003 by each of the named executive officers.

Amounts shown under the column "Value Realized" represent the difference between the option exercise price and the closing sale price of our common stock on the date of exercise. Amounts shown under the column "Value of Unexercised In-the-Money Options at December 31, 2003" have been calculated based on the closing sale price of our common stock on the Nasdaq National Market on December 31, 2003 of \$29.46 per share, without taking into account any taxes that may be payable in connection with the transaction, multiplied by the number of shares underlying the option, less the exercise price payable for these shares.

#### Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

	Shares Acquired			Underlying Opti	f Securities Unexercised ons at r 31, 2003		Value of Unexercised in-the-Money Options at December 31, 2003			
Name	on Exercise		Value Realized	Exercisable	Unexercisable		Exercisable		Unexercisable	
Clive A. Meanwell				457,320	271,341	\$	10,410,057	\$	2,462,739	
David M. Stack	84,000	\$	1,561,340	294,114	319,386	\$	4,420,865	\$	3,840,782	
Steven H. Koehler	_			100,000	200,000	\$	1,630,500	\$	2,468,000	
John D. Richards	15,000	\$	221,761	35,358	81,208	\$	556,095	\$	536,851	

#### **Director Compensation**

Each of our non-employee directors who attends, either in person or by phone, at least 75% of the meetings of the board of directors held during the year receives annual compensation of \$12,500. In addition, each member of our audit, compensation or nominations committee who attends, either in



person or by phone, at least 75% of the meetings of the committee on which he served held during the year receives an additional \$12,500. Directors are reimbursed for expenses in connection with their attendance at board meetings.

In addition, non-employee directors may receive stock options and other equity awards under our 1998 stock incentive plan and our 2000 outside director stock option plan, or 2000 Plan. In April 2003 upon their initial election to our board of directors, we granted each of Messrs. Crouse, Hugin and Savage a non-statutory stock option under our 2000 Plan to purchase 20,000 shares of common stock at an exercise price of \$17.19 per share. In May 2003, we granted each of Drs. Bell and Johnson, and Messrs. Crouse, Hugin, Kessler, Savage and Thomas an option under our 2000 Plan to purchase 12,500 shares of common stock at an exercise price of \$23.00 per share. We also granted to Fazle Husain, a director until his resignation in October 2003, an option under our 1998 plan to purchase 12,500 shares of common stock at an exercise price of \$23.00 per share. We also granted to Fazle Husain, a director until his resignation in 0ctober 2003, an option under our 1998 plan to purchase 12,500 shares of common stock at an exercise price of \$23.00 per share. We also granted to Fazle Husain, a director until his resignation in 0ctober 2003, an option under our 1998 plan to purchase 12,500 shares of common stock at an exercise price of \$23.00 per share. All of the options vest in 48 equal monthly installments commencing one month after the date of grant.

#### 2000 Outside Director Stock Option Plan

Our 2000 Plan was adopted by our board of directors on May 15, 2000. Under the plan, our non-employee directors are eligible to receive non-statutory options to purchase shares of our common stock. A total of 250,000 shares of our common stock may be issued upon the exercise of options granted under the 2000 Plan. As of December 31, 2003, options to purchase 195,000 shares of our common stock were outstanding under the 2000 Plan.

Under the terms of the 2000 Plan, each non-employee director will be granted an option to purchase 20,000 shares of our common stock on the date of his or her initial election to the board of directors. In addition, since the 2003 annual meeting of stockholders, each non-employee director receives an option to purchase 12,500 shares of our common stock on the date of each annual meeting of our stockholders, other than a director who was initially elected to the board of directors at any such annual meeting.

All options granted under the 2000 Plan vest in 48 equal monthly installments commencing one month after the date of grant and have an exercise price per share equal to the closing sale price of our common stock on the Nasdaq National Market on the date of grant. An optionee may exercise his or her option only while he or she is a director and for one year after he or she ceases to be a director. Unexercised options expire ten years after the date of grant. Options granted under the 2000 Plan are not transferable or assignable other than by will or the laws of descent and distribution and expire upon an acquisition event, which is defined to mean (1) any merger or consolidation which results in our stockholders prior to the transaction holding less than a majority of the voting power of the combined or acquiring entity immediately after the transaction, (2) any sale of all or substantially all of our assets or (3) our complete liquidation.

#### **Employment Agreements**

Dr. Meanwell serves as our Executive Chairman pursuant to the terms of an employment agreement dated September 5, 1996. This agreement renews automatically on a yearly basis unless either party provides written notice of non-renewal at least 90 days prior to the expiration of the then-current term. Pursuant to the terms of the agreement, Dr. Meanwell's annual compensation is determined by our board of directors. If Dr. Meanwell terminates his employment for good reason, as defined in the agreement, or if we terminate his employment other than for cause, Dr. Meanwell will be entitled to three months salary and the same health, disability and other benefits as were provided during his employment for a period ending upon the earlier of (1) three months after the date of his termination, or (2) the date upon which Dr. Meanwell commences full-time employment with a new employer. Dr. Meanwell has agreed not to compete with us during the term of his employment and for

a period of one year after his termination, unless such termination is at our election or at the election of Dr. Meanwell for good reason.

Mr. Stack serves as our Chief Executive Officer and President pursuant to the terms of an employment agreement dated November 1, 2001. This agreement renews automatically on a yearly basis unless either party provides written notice of non-renewal at least 90 days prior to the expiration of the then–current term. Pursuant to the terms of the agreement, Mr. Stack's annual compensation is determined by our board of directors. If Mr. Stack terminates his employment for good reason, as defined in the agreement, or if we terminate his employment other than for cause, Mr. Stack will be entitled to three months salary and the same health, disability and other benefits as were provided during this employment for a period ending upon the earlier of (1) three months after the date of his termination, or (2) the date upon which Mr. Stack commences full–time employment with a new employer. Mr. Stack has agreed not to compete with us during the term of his employment and for a period of one year after his termination, unless such termination is at our election or at the election of Mr. Stack for good reason.

Dr. Richards serves as one of our Vice Presidents pursuant to the terms of an employment agreement dated October 16, 1997. This agreement renews automatically on a yearly basis unless either party provides written notice of non-renewal. Pursuant to the terms of the agreement, Dr. Richards' annual compensation is determined by our board of directors. If Dr. Richards terminates his employment for good reason, as defined in the agreement, or if we terminate his employment other than for cause, Dr. Richards will be entitled to three months salary and the same health, disability and other benefits as were provided during his employment for a period of three months after the date of his termination. Dr. Richards has agreed not to compete with us during the term of his employment and for a period of one year after his termination.

#### **Compensation Committee Interlocks and Insider Participation**

The compensation committee consists of Messrs. Kessler, Savage and Thomas, none of whom ever has been an officer or employee of our company. Messrs. Kessler and Thomas served on the compensation committee throughout 2003 while Mr. Savage began serving on the compensation committee in April 2003. Nicholas J. Lowcock, a former director, served on the compensation committee from January 1, 2003 until April 2003. Mr. Lowcock has never been an officer or employee of our company.

None of our executive officers has served as a director or member of the compensation committee, or other committee serving an equivalent function, of any other entity, one of whose executive officers served as one of our directors or as a member of our compensation committee.

#### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table presents information we know regarding the beneficial ownership of our common stock as of January 31, 2004 for each person, entity or group of affiliated persons whom we know to beneficially own more than 5% of our common stock. The table also sets forth such information for our directors and named executive officers, individually, and our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. Except as indicated by footnote, to our knowledge, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. Common stock purchase warrants and options to purchase shares of common stock that are exercisable within 60 days of January 31, 2004 are deemed to be beneficially owned by the person holding such options for the purpose of computing ownership of such person, but are not treated as outstanding for the purpose of

computing the ownership of any other person. Applicable percentage of beneficial ownership is based on 47,514,460 shares of common stock outstanding as of January 31, 2004.

Unless otherwise indicated in the footnotes, the address of each of the individuals named below is: c/o The Medicines Company, 8 Campus Drive, Parsippany, New Jersey 07054.

Beneficial Owner:	Number of Shares Beneficially Owned	Percentage Beneficially Owned
Wellington Management Company, LLP (1)	5,943,400	12.5%
Biotech Growth N.V. (2)	4,700,000	9.8%
Sectoral Asset Management (3)	3,247,055	6.8%
T. Rowe Price Associates, Inc. (4)	2,370,910	5.0%
Clive A. Meanwell (5)	658,662	1.4%
David M. Stack (6)	326,246	*
Steven H. Koehler (7)	120,750	*
John D. Richards (8)	50,192	*
Leonard Bell (9)	25,347	*
William W. Crouse (10)	7,187	*
Robert J. Hugin (11)	7,187	*
T. Scott Johnson (12)	60,638	*
Armin M. Kessler (13)	97,665	*
Robert G. Savage (14)	7,187	*
James E. Thomas (15)	77,547	*
All directors and executive officers as a group (11 persons)	1,438,608	3.0%

<sup>\*</sup> 

Represents beneficial ownership of less than 1%.

(1)

Includes shares owned by various investors for which Wellington Management Company, LLP serves as investment advisor with shared power to direct investments and/or to vote the shares. The shares were acquired by Wellington Trust Company, NA, a wholly owned subsidiary of Wellington Management Company, LLP. The address of Wellington Trust Company, NA and Wellington Management Company, LLP is 75 State Street, Boston, Massachusetts 02109. This information is based on a Schedule 13G/A filed by Wellington Management Company, LLP with the SEC on February 12, 2004.

(2)

Consists of warrants to purchase 675,925 shares and 4,024,075 shares owned directly by Biotech Growth N.V. with respect to which BB Biotech AG and Biotech Growth N.V. share voting and dispositive power. Biotech Growth N.V. is a wholly owned subsidiary of BB Biotech AG. The address of Biotech Growth N.V. is Calle 53, Urbanizacion Obarrio, Torre Swiss Bank, Piso 16, Panama City, Zona 1, Republic of Panama. This information is based on a Schedule 13G/A filed by BB Biotech AG on behalf of Biotech Growth N.V. with the SEC on February 17, 2004.

(3)

Consists of shares for which Sectoral Asset Management, Inc. has or shares dispositive power and/or voting power in its capacity as an investment adviser. Jérôme G. Pfund and Michael L. Sjöström are the sole shareholders of Sectoral Asset Management, Inc. Jérôme G. Pfund, Michael L. Sjöström and Sectoral Asset Management, Inc. disclaim beneficial ownership of such shares. The address of Sectoral Asset Management is 2120–1000 Sherbrooke St., West Montreal PQ H3A 3G4 Canada. This information is based on a Schedule 13G with the SEC on February 13, 2004.

(4)	Includes shares owned by various individual and institutional investors for which T. Rowe Price Associates, Inc. serves as investment advisor with power to direct investments and/or sole power to vote the shares. For purposes of the reporting requirements of the Securities Exchange Act of 1934, T. Rowe Price Associates, Inc. is deemed to be a beneficial owner of such shares; however, T. Rowe Price Associates, Inc. expressly disclaims that it is, in fact, the beneficial owner of such shares. The address of T. Rowe Price Associates, Inc. is 100 E. Pratt Street, Baltimore, Maryland 21202. This information is based on a Schedule 13G/A filed by T. Rowe Price Associates, Inc. with the SEC on February 6, 2004.
(5)	Includes warrants to purchase 59,143 shares and options to purchase 496,933 shares. Excludes 450,000 shares subject to pre-paid variable forward sales contracts, pursuant to which Dr. Meanwell pledged 450,000 shares to secure future obligation to deliver a maximum of 350,000 shares in February 2006 and 100,000 shares in August 2006.
(6)	Includes options to purchase 321,846 shares.
(7)	Includes options to purchase 118,750 shares.
(8)	Includes options to purchase 43,092 shares.
(9)	Consists of options to purchase 25,347 shares.
(10)	Consists of options to purchase 7,187 shares.
(11)	Consists of options to purchase 7,187 shares.
(12)	Includes 5,000 shares held by Dr. Johnson as trustee, warrants to purchase 13,744 shares held by Dr. Johnson and options to purchase 11,355 shares held by Dr. Johnson.
(13)	Includes 3,000 shares held by Mr. Kessler's wife, warrants to purchase 33,796 shares held by Mr. Kessler and options to purchase 25,955 shares held by Mr. Kessler.
(14)	Consists of options to purchase 7,187 shares.
(15)	Includes options to purchase 25,347 shares.

(4)

The following table provides information as of December 31, 2003 about the securities authorized for issuance under our equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options	Weighted–average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))			
	(a)	 (b)	(c)			
Equity compensation plans approved by security holders	4,404,674(1)(2)	\$ 16.21(2)	455,931(3)			
Equity compensation plans not approved by security holders	911,319(4)	\$ 14.86	4,115(5)			
Total	5,315,993	\$ 15.98(1)(2)(4)	460,046(3)(5)			

### **Equity Compensation Plan Information**

(1)

Includes shares of common stock issuable under our 1998 stock incentive plan and 2000 outside director stock option plan.

(2)

Excludes shares issuable at the end of the then-current offering period under our 2000 employee stock purchase plan.

#### (3)

Includes shares available for issuance as of December 31, 2003 under our 1998 stock incentive plan, 2000 outside director stock option plan and 2000 employee stock purchase plan (which includes shares which were subsequently issued on February 22, 2004 at the close of the then–current offering period). All of the shares available under the 1998 stock incentive plan, and none of the shares available under the 2000 outside director stock option plan or the 2000 employee stock purchase plan, may be issued in the form of restricted stock or other equity–based awards.

(4) (5)

Consists of shares of common stock issuable under our 2001 non-officer, non-director employee stock incentive plan.

Consists of shares available for issuance as of December 31, 2003 under our 2001 non-officer, non-director employee stock incentive plan.

#### 2001 Non-Officer, Non-Director Employee Stock Incentive Plan

In May 2001, our board of directors approved the 2001 plan pursuant to which non-statutory stock options for up to 1,250,000 shares of common stock were authorized to be issued to our employees, consultants and advisors and those of our subsidiaries. The 2001 plan has not been approved by our stockholders.

Our board is authorized to administer the 2001 plan, to adopt, amend and repeal the administrative rules, guidelines and practices relating to the 2001 plan and to interpret the provisions of the 2001 plan. Our board may amend, suspend or terminate the 2001 plan at any time. In accordance with the provisions of the 2001 plan, our board of directors may delegate any or all of its powers under the 2001 plan to one or more committees or subcommittees of the board.

Our board selects the recipients of awards under the 2001 plan and determines:

the number of shares of common stock covered by such awards;

- the dates upon which such awards become exercisable;
- the exercise price of options; and
  - the duration of the options.

If any award granted under the 2001 plan expires or is terminated, surrendered, canceled or forfeited, the unused shares of common stock covered by such option or other award will again be available for grant under the 2001 plan.

Our board is required to make appropriate adjustments in connection with the 2001 plan to reflect any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar event to the extent that the board determines, in good faith, that such as adjustment is necessary and appropriate. Upon the occurrence of an acquisition event, as defined in the 2001 plan, the 2001 plan requires our board to take one or more of the following actions with respect to any then outstanding options and other awards:

- provide that each outstanding option or award will be assumed, or an equivalent option or award will be substituted by, the successor entity or an affiliate of the successor entity;
- provide that all outstanding options become exercisable in full for a specified period of time before such acquisition event takes place, even if such options would not have been exercisable otherwise; and
  - if the acquisition event involves a cash payment to holders of common stock in exchange for their shares of common stock, provide for the termination of all outstanding options and provide for a cash payment to each option holder equal to the amount by which (1) the cash payment per share of common stock paid the holders of common stock multiplied by the number of shares of common stock subject to such outstanding option (whether or not exercisable), exceeds (2) the total exercise price of such options.

Upon the occurrence of a change in control, as defined in the 2001 plan, that is not an acquisition event, each option shall become immediately exercisable in full if, on or prior to the first anniversary of the date of the change in control event, a termination event, as defined in the 2001 plan, occurs, provided that the parties involved in the change of control have not explicitly agreed to the contrary.

#### Item 13. Certain Relationships and Related Transactions

None

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#### Item 14. Principal Accountant Fees and Services

#### **Independent Auditor's Fees**

The following table summarizes the fees of Ernst & Young LLP, our independent auditor, billed to us for each of the last two fiscal years for audit services and billed to us in each of the last two fiscal years for other services:

Fee Category	 2003	2002		
Audit Fees (1)	\$ 359,876	\$	373,296	
Audit-Related Fees (2)	18,000		_	
Tax Fees (3)	60,457		28,988	
All Other Fees	—			
		_		
Total Fees	\$ 438,333	\$	402,284	

<sup>(1)</sup> 

Audit fees consist of fees for the audit of our financial statements, the review of the interim financial statements included in our quarterly reports on Form 10–Q, and other professional services provided in connection with statutory and regulatory filings or engagements.

#### (2)

Audit-related fees consist of fees for assurance and related services that are reasonably related to the performance of the audit and the review of our financial statements and which are not reported under "Audit Fees." These services relate to Sarbanes–Oxley compliance.

#### (3)

Tax fees consist of fees for tax compliance, tax advice and tax planning services. Tax compliance services, which relate to preparation of original and amended tax returns, accounted for all of the total tax fees paid for 2003 and 2002.

#### **Pre-Approval Policy and Procedures**

The audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent auditor. This policy generally provides that we will not engage our independent auditor to render audit or non-audit services unless the service is specifically approved in advance by the audit committee or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, the audit committee may pre-approve specified types of services that are expected to be provided to us by our independent auditor during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

#### PART IV

#### Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a)

Documents filed as part of this Report:

(1) Financial Statements. The Consolidated Financial Statements are included as Appendix A hereto and are filed as part of this Report. The Consolidated Financial Statements include:

	Page
1. Report of Independent Auditors	F-2
2. Consolidated Balance Sheets	F-3
3. Consolidated Statements of Operations	F-4
4. Consolidated Statements of Stockholders' Equity (Deficit)	F-5
5. Consolidated Statements of Cash Flows	F-6
6. Notes to Consolidated Financial Statements	F-7

(2) Financial Statement Schedule. The financial statement schedule following the Notes to Consolidated Financial Statements is filed as part of this Report.

(3) Exhibits. The exhibits set forth on the Exhibit Index following the signature page to this Report are filed as part of this Report. This list of exhibits identifies each management contract or compensatory plan or arrangement required to be filed as an exhibit to this Report.

*(b)* 

Reports on Form 8-K:

On October 21, 2003, we filed a current report on Form 8-K, dated October 21, 2003, with the SEC furnishing our announcement of financial results for the quarter and nine-month period ended September 30, 2003.

### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 5, 2004.

THE MEDICINES COMPANY

By:

/s/ CLIVE A. MEANWELL

Clive A. Meanwell *Executive Chairman* 

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 5, 2004:

Signature	Title(s)					
/s/ CLIVE A. MEANWELL	Executive Chairman and Chairman of the Board of Directory (Driveine)					
Clive A. Meanwell	Executive Chairman and Chairman of the Board of Directors (Principal Executive Officer)					
/s/ DAVID M. STACK	Chief Executive Officer and President and Director (Principal Executive					
David M. Stack	Officer)					
/s/ STEVEN H. KOEHLER	Vice President, Chief Financial Officer, Treasurer and Secretary (Principal					
Steven H. Koehler	Financial and Accounting Officer)					
/s/ LEONARD BELL	Director					
Leonard Bell						
/s/ WILLIAM W. CROUSE	Director					
William W. Crouse						
/s/ ROBERT J. HUGIN	Director					
Robert J. Hugin						
/s/ T. SCOTT JOHNSON	Director					
T. Scott Johnson						
/s/ ARMIN M. KESSLER	Director					
Armin M. Kessler						
/s/ ROBERT G. SAVAGE	Director					
Robert G. Savage						
/s/ JAMES E. THOMAS	Director					
James E. Thomas	60					

APPENDIX A

### INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS OF THE MEDICINES COMPANY

	Page
Report of Independent Auditors	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Stockholders' Equity (Deficit)	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

#### REPORT OF INDEPENDENT AUDITORS

Board of Directors and Stockholders The Medicines Company

We have audited the accompanying consolidated balance sheets of The Medicines Company as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows, for each of the three years in the period ending December 31, 2003. Our audits also included the financial statement schedule listed in Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of The Medicines Company at December 31, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey February 10, 2004

## THE MEDICINES COMPANY

## CONSOLIDATED BALANCE SHEETS

		December 31,				
		2003		2002		
ASSETS						
Current assets:						
Cash and cash equivalents	\$	43,401,610	\$	36,777,007		
Available for sale securities		92,462,883		6,731,728		
Accrued interest receivable		990,824		129,414		
Accounts receivable, net of allowance of approximately \$2.23 million and \$0.64 million at December 31, 2003 and 2002		15,660,148		15,078,488		
Inventories		11,459,771		14,178,660		
Prepaid expenses and other current assets		976,258		660,720		
Total current assets		164,951,494		73,556,017		
Fixed assets, net		1,510,706		924,497		
Other assets		200,265	_	233,854		
Total assets	\$	166,662,465	\$	74,714,368		
LIABILITIES AND STOCKHOLDERS	5' EQUITY					
Current liabilities:						
Accounts payable	\$	7,274,943	\$	8,291,995		
Accrued expenses		17,951,845		11,092,134		
Total current liabilities		25,226,788		19,384,129		
Commitments and contingencies		_		_		
Deferred revenue		1,270,833		1,395,833		
tockholders' equity: Preferred stock, \$1.00 par value per share, 5,000,000 shares authorized; no shares						
issued and outstanding		_		_		
Common stock, \$.001 par value per share, 75,000,000 shares authorized at						
December 31, 2003 and 2002, respectively; 47,443,902 and 39,894,285 issued						
and outstanding at December 31, 2003 and 2002, respectively		47,444		39,894		
Additional paid–in capital		454,804,001		354,239,193		
Deferred compensation		(744,107)		(3,125,494)		
Accumulated deficit		(314,144,531)		(297,274,830)		
Accumulated other comprehensive income		202,037		55,643		
Total stockholders' equity		140,164,844		53,934,406		

See accompanying notes.

### THE MEDICINES COMPANY

### CONSOLIDATED STATEMENTS OF OPERATIONS

	 Year Ended December 31,							
	2003		2002		2001			
Net revenue	\$ 85,590,503	\$	38,301,286	\$	14,247,724			
Operating expenses:								
Cost of revenue	22,748,868		10,284,033		2,110,425			
Research and development	35,904,844		37,951,458		32,767,394			
Selling, general and administrative	45,082,170		36,807,679		36,566,761			
Total operating expenses	103,735,882		85,043,170		71,444,580			
Loss from operations	(18,145,379)		(46,741,884)		(57,196,856)			
Other income/(expense):								
Interest income	1,403,849		943,583		3,163,208			
Interest expense	—		(32,847)		—			
Loss on sale of investment			—		(850,000)			
Pre-tax net loss	(16,741,530)		(45,831,148)		(54,883,648)			
Income taxes	(128,171)				_			
Net loss after taxes	\$ (16,869,701)	\$	(45,831,148)	\$	(54,883,648)			
Basic and diluted net loss per common share	\$ (.37)	\$	(1.23)	\$	(1.67)			
Shares used in computing net loss per common share:								
Basic and diluted	45,624,289		37,209,931		32,925,968			

See accompanying notes.

### THE MEDICINES COMPANY CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) For The Years Ended December 31, 2001, 2002 and 2003

	Common Stock					Accumulated				
	Shares	An	nount	Additional Paid–in Capital	Deferred Stock Compensation	Accumulated Deficit	Compreh Inco (Los	ensive me	Tot Stockho Equity/(l	olders'
Balance at December 31, 2000	30,320,455		30,320	279,126,337	(13,355,694)	(196,560,034)		(1,946)	69,	,238,983
Repurchase of common stock	(11,239)		(11)	—						(11)
Employee stock purchases	297,366		298	743,147						743,445
Issuance of common stock through private placement	4,000,000		4,000	41,798,975					41,	,802,975
Adjustments to deferred compensation for terminations				(626,755)	626,755					_
Amortization of deferred stock compensation					4,135,166				4,	,135,166
Net loss						(54,883,648)			(54,	,883,648)
Currency translation adjustment								47,446		47,446
Unrealized gain on available for sale securities								36,608		36,608
Comprehensive loss									(54,	,799,594)
Balance at December 31, 2001	34,606,582	\$	34,607	\$ 321,041,704	\$ (8,593,773)	\$ (251,443,682)	\$	82,108		,120,964
Employee stock purchases	738,081		738	2,993,498						,994,236
Issuance of common stock-Nycomed purchase	79,428		79	999,921					1,	,000,000
Issuance of common stock-through public sale	4,000,000		4,000	30,906,000					30,	,910,000
Issuance of common stock-Warrant purchases	470,194		470	(547)						(77)
Adjustments to deferred compensation for terminations				(2,191,644)	2,191,644					-
Non-cash stock compensation-terminations				490,261						490,261
Amortization of deferred stock compensation					3,276,635				3,	,276,635
Net loss						(45,831,148)			(45,	,831,148)
Currency translation adjustment								(42,240)		(42,240)
Unrealized gain on available for sale securities								15,775		15,775
Comprehensive loss									(45,	,857,613)
Balance at December 31, 2002 Employee stock purchases	39,894,285 897,783	\$	39,894 898	\$ 354,239,193 8,021,854	\$ (3,125,494)	\$ (297,274,830)	\$	55,643		,934,406 ,022,752
Issuance of common stock—through public sale	5,597,280		5,597	91,506,354						,022,732
•	1,054,554		1,055						91,	(108)
Issuance of common stock—Warrant purchases	1,054,554		1,055	(1,163)	151,491					(108)
Adjustments to deferred compensation for terminations				(151,491)	151,491				1	
Non-cash stock compensation—Consultants				1,189,254	2,229,896					,189,254
Amortization of deferred stock compensation					2,229,896	(16.969.701)				,229,896
Net loss						(16,869,701)		(10, (14)	(10,	,869,701)
Currency translation adjustment								(18,614)		(18,614)
Unrealized gain on available for sale securities								165,008		165,008
Comprehensive loss							_		(16,	,723,307)
Balance at December 31, 2003	47,443,902	\$	47,444	\$ 454,804,001	\$ (744,107)	\$ (314,144,531)	\$	202,037	\$ 140,	,164,844

See accompanying notes.

### THE MEDICINES COMPANY

### CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,						
		2003	2002			2001	
Cash flows from operating activities:							
Net loss	\$	(16,869,701)	\$	(45,831,148)	\$	(54,883,648)	
Adjustments to reconcile net loss to net cash used in operating activities:							
Depreciation		572,103		555,026		470,930	
Amortization of premium on available for sale securities		905,195		66,517		—	
Non-cash stock compensation expense		3,419,150		3,766,895		4,135,166	
Loss on sales and disposal of fixed assets		56,474		1,079		2,113	
Changes in operating assets and liabilities:							
Accrued interest receivable		(861,410)		(122,657)		1,386,171	
Accounts receivable		(581,660)		(9,545,107)		(6,119,325)	
Inventory		2,718,889		2,405,669		(14,620,838)	
Prepaid expenses and other current assets		(314,877)		(108,340)		(85,806)	
Other assets		33,589		(80,778)		96,927	
Accounts payable		(1,020,676)		(516,068)		2,819,943	
Accrued expenses		6,825,628		2,887,070		(377,245)	
Deferred revenue		(125,000)		1,395,833		—	
Net cash used in operating activities		(5,242,296)		(45,126,009)		(67,175,612)	
Cash flows from investing activities:							
Purchase of available for sale securities		(142,847,331)		(6,782,470)		(7,430,886)	
Maturities and sales of available for sale securities		56,375,989		125,000		49,863,097	
Purchase of fixed assets		(1,204,828)		(247,218)		(735,571)	
Net cash (used in)/provided by investing activities Cash flows from financing activities:		(87,676,170)		(6,904,688)		41,696,640	
Proceeds from revolving line of credit borrowings		_		10,000,000			
Repayments of revolving line of credit borrowings		_		(10,000,000)			
Proceeds from issuances of common stock, net		99,534,595		34,904,155		42,546,409	
Net cash provided by financing activities		99,534,595		34,904,155		42,546,409	
Effect of exchange rate changes on cash		8,474		19,173		14,583	
Increase/(decrease) in cash and cash equivalents		6,624,603		(17,107,369)		17,082,020	
Cash and cash equivalents at beginning of period		36,777,007		53,884,376		36,802,356	
Cash and cash equivalents at end of period	\$	43,401,610	\$	36,777,007	\$	53,884,376	
Supplemental disclosure of cash flow information:							
Interest paid	\$		\$	32,847	\$	_	
Taxes paid	\$	49,021	\$	35,069	\$	6,303	

See accompanying notes.

#### THE MEDICINES COMPANY

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS December 31, 2003

#### 1. Nature of Business

The Medicines Company (the "Company") was incorporated in Delaware on July 31, 1996. The Company is a pharmaceutical company engaged in the acquisition, development and commercialization of late–stage development drugs or drugs approved for marketing, and specializes in acute care hospital products. The U.S. Food and Drug Administration approved Angiomax® (bivalirudin) for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary angioplasty in December 2000, and the Company commenced sales of Angiomax in the first quarter of 2001. The Company reported total net revenue of \$85.6 million in 2003, \$38.3 million in 2002, and \$14.2 million in 2001, generated almost entirely from sales of Angiomax in the United States. The Company has invested in, and plans to continue investing in Angiomax development programs to enable the Company to garner additional regulatory approvals. Additionally, the Company plans to continue development investments in Clevelox<sup>TM</sup> (clevidipine) and cangrelor to yield regulatory approval that will enable their use in hospitals.

#### 2. Significant Accounting Policies

#### **Basis of Presentation**

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. The Company has no unconsolidated subsidiaries.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Reclassification

Certain reclassifications have been made to prior years' information to conform to the 2003 presentation.

#### **Risks and Uncertainties**

The Company is subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainties related to regulatory approvals, dependence on key products, dependence on key customers and suppliers, and protection of proprietary rights.

#### **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to concentration of credit risk include cash, cash equivalents, available for sale securities and accounts receivable. The Company believes it minimizes its exposure to potential concentrations of credit risk by placing investments in high–quality financial instruments with high quality institutions. At December 31, 2003, approximately \$21.0 million of the cash and cash equivalents balance was invested in a single fund, the Evergreen Institutional Money Market Fund, a no–load money market fund, with the Capital Advisors Group.

The Company's products are sold primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States, including AmerisourceBergen Drug Corporation, McKesson Corporation and Cardinal Health, Inc., which accounted for 30%, 31% and 34%, respectively, of our revenue for the year ended December 31, 2003. Revenue from each of these customers accounted for similar percentages of total revenue in 2002 and 2001. During 2003, 2002 and 2001, the Company's revenues from these three customers totaled approximately 95%, 94% and 94%, respectively, of net revenues. At December 31, 2003 and 2002, these same customers represented approximately \$16.9 million, or 96%, respectively, of gross accounts receivable. The Company performs ongoing credit evaluations of its customers and generally does not require collateral. The Company maintains reserves for potential credit losses and, during 2003, such losses were within the expectations of management.

## Cash, Cash Equivalents and Available for Sale Securities

The Company considers all highly liquid investments purchased with an original maturity at date of purchase of three months or less to be cash equivalents. Cash equivalents at December 31, 2003 consisted of investments of \$21.0 million in money market funds and \$12.8 million of corporate bonds with original maturities of less than three months. Cash equivalents at December 31, 2002 consisted of investments in money market funds. These investments are carried at cost, which approximates fair value.

The Company considers securities with original maturities of greater than three months to be available for sale securities. Securities under this classification are recorded at fair market value and unrealized gains and losses are recorded as a separate component of stockholders' equity. The cost of debt securities in this category is adjusted for amortization of premium and accretion of discount to maturity. The estimated fair value of the available for sale securities is determined based on quoted market prices or rates for similar instruments.

At December 31, 2003, the Company held available for sale securities with fair value totaling \$92.5 million. These available for sale securities included various certificates of deposit, corporate debt securities and United States government agency notes, \$55.5 million of which had original maturities of more than one year and up to two years and \$37.0 million of which had original maturities of more than three months and up to one year. At December 31, 2002, the Company held available for sale securities with fair value totaling \$6.7 million, all with original maturities greater than three months and up to one year. Available for sale securities consisted of investments in corporate bonds, United States government agency notes and certificates of deposit are summarized as follows:

2003	Cost		Unrealized Gain		Fair Value	
Certificates of deposit	\$	1,099,944	\$	56	\$	1,100,000
Corporate debt securities		10,937,557		8,589		10,946,146
U.S. government agency notes		80,244,599		172,138		80,416,737
Total	\$	92,282,100	\$	180,783	\$	92,462,883
2002		Cost	1	Unrealized Gain		Fair Value
Certificates of deposit	\$	1,499,944	\$	_	\$	1,499,944
Corporate debt securities		2,606,044		7,042		2,613,086
U.S. government agency notes		2,609,965		8,733		2,618,698
Total	\$	6,715,953	\$	15,775	\$	6,731,728
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During 2001, the Company sold its \$3.0 million investment in Southern California Edison 5 <sup>7/8</sup>% bonds, which were originally due on January 15, 2001, realizing a loss of \$850,000 on the sale. There were also maturities of available for sale securities during the year ended December 31, 2001, which are disclosed in the accompanying consolidated statements of cash flows.

#### **Revenue Recognition**

The Company sells its products primarily to wholesalers and distributors who, in turn sell to hospitals. The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay the Company and the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about sale of the product, the amount of returns can be reasonably estimated and collectibility is reasonably assured.

The Company records allowances for product returns, rebates and discounts at the time of sale, and reports revenue net of such allowances. The Company must make significant judgments and estimates in determining the allowances. For instance:

The Company's wholesaler customers have the right to return any unopened product during the 18 month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the allowance for product returns, the Company must estimate the likelihood that product sold to wholesalers might remain in their inventory to within six months of expiration and determine if it will be returned. The Company bases its estimates on information from wholesalers, historic patterns of returns, industry data and on the expiration dates of product currently being shipped.

Certain hospitals purchasing the Company's products from wholesalers have the right to receive a discounted price and a volume-based rebate if they have a direct contract with the Company or participate in a group purchasing organization that has a contract with the Company. As a result, the Company must estimate the likelihood that product sold to wholesalers might be ultimately sold to a participating hospital. The Company bases its estimates on information from wholesalers and hospitals, industry data, historic patterns of discounts and customer rebate thresholds.

If actual results differ from the Company's estimates, the Company will be required to make adjustments to these allowances in the future.

Revenue from collaborative agreements may include milestone payments. These payments are recorded as deferred revenue until contractual performance obligations have been satisfied, and they are recognized ratably over the term of these agreements. When the period of deferral cannot be specifically identified from the contract, the Company must estimate the period based upon other critical factors contained within the contract. The Company reviews these estimates at least annually, which could result in a change in the deferral period.

#### Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs were approximately \$1,422,000, \$837,000 and \$1,258,000, for the years ended December 31, 2003, 2002 and 2001, respectively.

#### Inventories

Inventory is recorded upon the transfer of title from the Company's vendors. Inventory is stated at the lower of cost or market value. Angiomax bulk drug product is classified as raw materials and its



costs are determined using a weighted average of acquisition costs. Work-in-progress costs of filling, finishing and packaging are recorded against specific product batches, or lots. Prior to FDA approval of Angiomax and of its original manufacturing process in December 2000, the Company expensed all of these costs as research and development. The Company recorded as inventory any Angiomax bulk drug product manufactured according to its original manufacturing process to which the Company took title after FDA approval.

Together with its contract-manufacturing partner, UCB Bioproducts S.A., the Company has developed a second-generation chemical synthesis process, the Chemilog process, for the manufacture of Angiomax bulk drug substance. In May 2003, the Company received FDA approval of this process. Accordingly, all Angiomax bulk drug product manufactured using the Chemilog process to which title had transferred to the Company prior to approval was expensed as research and development, and all bulk drug product manufactured after FDA approval has been and will be recorded as inventory upon transfer of title from the Company's vendors.

The major classes of inventory were as follows:

Inventories	2003		2002
Raw materials	\$ 6,237,677		4,126,870
Work-in-progress	4,371,565		8,370,949
Finished Goods	850,529		1,680,841
Total	\$ 11,459,771	\$	14,178,660

# Fixed Assets

Fixed assets are stated at cost. Depreciation is provided using the straight-line method based on estimated useful lives or, in the case of leasehold improvements, over the lesser of the useful lives or the lease terms.

## **Research and Development**

Expenditures for research and development costs are expensed as incurred.

## Stock-Based Compensation

Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock–Based Compensation" encourages, but does not require, companies to record compensation cost for stock–based employee compensation plans at fair value. The Company has elected to account for stock–based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25").

The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation:

	Years Ended December 31,					
		2003		2002		2001
Net loss—As reported	\$	(16,869,701)	\$	(45,831,148)	\$	(54,883,648)
Deduct: Total stock-based compensation expense determined under						
fair value based method for all stock option awards and discounts						
under the Employee Stock Purchase Plan		(10,408,223)		(5,753,913)		(15,058,318)
Add: Amortization of deferred stock compensation		2,229,896		3,276,635		4,135,166
Net loss—Pro forma	\$	(25,048,028)	\$	(48,308,426)	\$	(65,806,800)
Net loss per common share—As reported	\$	(0.37)	\$	(1.23)	\$	(1.67)
Net loss per common share—Pro forma	\$	(0.55)	\$	(1.30)	\$	(2.00)

The fair value of each option grant was estimated on the date of grant using the Black–Scholes option–pricing model with the following weighted average assumptions:

	Years E	nded December 31,				
	2003	2002	2001			
Expected dividend yield	0%	0%	0%			
Expected stock price volatility	86%	90%	96%			
Risk-free interest rate	1.85%	3.0%	4.0%			
Expected option term	2.84	2.79	3.34			
	years	years	years			

## Translation of Foreign Currencies

The functional currencies of the Company's foreign branches and subsidiaries are the local currencies: British pound sterling, Swiss franc and New Zealand dollar. The Company translates its foreign operations using a current exchange rate. In accordance with Statement of Financial Accounting Standards No. 52, assets and liabilities are translated using the current exchange rate as of the balance sheet date. Stockholders' equity is translated using historical rates at the balance sheet date. Expenses and items of income are translated using a weighted average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of stockholders' equity. Foreign exchange transaction gains and losses are included in the results of operations and are not material to the Company's consolidated financial statements.

#### Income Taxes

Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards, and are measured using the enacted tax rates and laws in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with ultimate realization.

## Comprehensive Income (Loss)

The Company reports comprehensive income (loss) and its components in accordance with the provisions of SFAS No. 130, "Reporting Comprehensive Income." Comprehensive income (loss) includes all changes in equity for cumulative translations adjustments resulting from the consolidation of foreign branches and subsidiaries' financial statements and unrealized gains and losses on available for sale securities.

## Net Loss per Share

Basic net loss per share is computed using the weighted average number of shares of common stock outstanding during the period reduced, where applicable, for outstanding, yet unvested, shares. Diluted net loss per share includes the effect of stock options, and warrants outstanding during the period, if dilutive. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share are the same.

#### Segments

The Company manages its business and operations as one segment and is focused on the acquisition, development and commercialization of late–stage development drugs and drugs approved for marketing. The Company has license rights to Angiomax<sup>®</sup>, Clevelox<sup>TM</sup> and cangrelor. Revenues reported to date are derived primarily from the sales of the Company's Angiomax<sup>®</sup> product.

## 3. The Company's Plans and Financing

The Company has incurred substantial losses since inception, although the Company achieved profitability for the first time for the three months ended December 31, 2003. To date, the Company has primarily funded its operations through the issuance of debt and equity. The Company expects to continue to expend substantial amounts for continued product research, development and commercialization activities for the foreseeable future, and the Company plans to fund these expenditures by increasing revenue or through debt or equity financing, if possible, and to secure collaborative partnering arrangements that will provide available cash funding for operations. Should revenue growth or additional debt or equity financing or collaborative partnering arrangements be unavailable to the Company, it will restrict certain of its planned activities and operations, as necessary, to sustain operations and conserve cash resources.

## 4. Fixed Assets

Fixed assets consist of the following:

			Decem	ber 31,	
	Estimated Life (Years)	2003		_	2002
Furniture, fixtures and equipment	3	\$	384,977	\$	785,190
Computer hardware and software	3		1,570,186		1,443,076
Leasehold improvements	5-10		850,178		269,448
			2,805,341		2,497,714
Less: Accumulated depreciation			(1,294,635)		(1,573,217)
		-		-	
		\$	1,510,706	\$	924,497

Depreciation expense was approximately \$572,000, \$555,000 and \$471,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

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## 5. Accrued Expenses

Accrued expenses consist of the following at December 31:

		2003		2002
	¢	2.051.621	¢	2 012 727
Compensation related	\$	3,951,621	\$	2,812,737
Research and development services		6,553,273		3,118,093
Product returns, rebates and discounts		2,929,892		2,320,834
Sales and marketing		910,823		651,375
Royalties and commissions		2,985,463		1,676,718
Legal, accounting and other		620,773		512,377
	\$	17,951,845	\$	11,092,134

## 6. Common Stock Purchase Warrants

In October 1999, the Company issued \$6,000,000 of 8% convertible notes (October Notes) and 1,013,877 Common Stock purchase warrants (October Warrants) to existing investors, raising proceeds of \$6,000,000. The October Notes were ultimately converted into shares of Common Stock of the Company. Each October Warrant provides the holder with the right to purchase one share of Common Stock at a price of \$5.92 per share at any time prior to October 19, 2004. At December 31, 2003 there were 120,946 October Warrants outstanding.

In March 2000, the Company issued \$13,348,779 of 8% Convertible Notes (March Notes) and 2,255,687 Common Stock Purchase Warrants (March Warrants) to current stockholders, raising proceeds of \$13,348,779. The March Notes were ultimately converted into shares of Common Stock of the Company. Each March Warrant provides the holder with the right to purchase one share of Common Stock of the Company at a price of \$5.92 per share at any time prior to March 2005. At December 31, 2003 there were 674,486 March Warrants outstanding.

## 7. Stockholders' Equity

## Preferred Stock

The Company has 5,000,000 shares of preferred stock (Preferred Stock) authorized, none of which has been issued.

## Common Stock

Common stockholders are entitled to one vote per share and dividends when declared by the Company's board of directors (Board of Directors), subject to the preferential rights of any outstanding shares of Preferred Stock.

In May 2001, the Company received \$41.8 million from a private placement of 4,000,000 shares of Common Stock sold to both new and existing shareholders at a price of \$11.00 per share. The shares sold in the private placement were subsequently registered for resale.

In March 2002, the Company received \$1.0 million in proceeds from the sale of shares of Common Stock to Nycomed at the then fair market price of \$12.59 per share at the time of purchase. In June 2002, the Company received \$30.9 million in proceeds from the sale of 4.0 million shares of Common Stock in a public offering at a price of \$8.20 per share.

In March 2003, the Company received \$91.5 million in proceeds from the sale of 5.6 million shares of its common stock in a public offering at the then fair market price of \$17.50 per share at the time of purchase.

Employees of the Company purchased stock pursuant to option exercises and our employee stock purchase plan for aggregate net proceeds to the Company of approximately \$8.0 million, \$3.0 million and \$0.7 million, respectively, for the years ended December 31, 2003, 2002 and 2001, respectively.

During 1996, 1997 and 1998, certain employees of the Company purchased 335,800, 627,070 and 32,850 shares of Common Stock, respectively, for \$0.001 per share. These shares are subject to restriction and vesting agreements that limit transferability and allow the Company to repurchase unvested shares at the original purchase price. The shares vest ratably over a four-year period that generally begins on each employee's hire date. During 2001 and 2002, the Company repurchased 11,239 and 177 shares, respectively, of unvested Common Stock for \$0.001 per share. There were no shares of unvested Common Stock at December 31, 2003.

#### Stock Plans

In April 1998, the Company adopted the 1998 Stock Incentive Plan (the "1998 Plan"), which provides for the grant of stock options, restricted stock and other stock-based awards to employees, directors and consultants. The Board of Directors determines the term of each option, the option price, the number of shares for which each option is granted and the rate at which each option is exercisable. During 1999, the Board of Directors amended all outstanding grants to allow holders the opportunity to exercise options prior to vesting. Exercised options that are unvested are subject to repurchase by the Company at the original exercise price. Options granted under the 1998 Plan generally vest in increments over four years and have a ten year term.

In January 2000, the Board of Directors approved an amendment to the 1998 Plan to increase the number of shares available under the 1998 Plan to 1,448,259. In May 2000, the Board of Directors approved an amendment to the 1998 Plan to increase the number of shares available under the 1998 Plan to 4,368,259. In February 2002, the Board of Directors also adopted, subject to stockholder approval which was received in May 2002, an increase in the number of shares of common stock under the 1998 Plan to 6,118,259 shares.

The Board of Directors also approved the 2000 Employee Stock Purchase Plan (the "2000 ESPP") which provides for the issuance of up to 255,500 shares of Common Stock to participating employees and the 2000 Directors Stock Option Plan which provides for the issuance of up to 250,000 shares of Common Stock to the Company's outside directors. Both the 2000 ESPP and the 2000 Directors Stock Option Plan have received stockholder approval.

In May 2001, the Board of Directors approved the 2001 Non–Officer, Non–Director Employee Stock Incentive Plan (the "2001 Plan"), which provides for the grant of nonstatutory stock options to employees, consultants and advisors, of the Company and its subsidiaries. The 2001 Plan provides for the issuance of up to 1,250,000 shares of stock. The Board of Directors administers the 2001 Plan, although it may delegate its authority to one or more committees and, in limited circumstances, to one or more of the executive officers.

Prior to the Company's IPO, the Board of Directors determined the fair value of the Common Stock in its good faith judgment at each option grant date for grants under the 1998 Plan considering a number of factors including the financial and operating performance of the company, recent transactions in the Common Stock and Preferred Stock, if any, the values of similarly situated companies and the lack of marketability of Common Stock. Following the IPO, the fair value is determined based on the traded value of Common Stock.

During the period January 1, 2000 to September 30, 2000, the Company issued 2,273,624 options at exercise prices below the estimated fair value of the Common Stock as of the date of grant of such options based on the price of the Common Stock in connection with the IPO. The total deferred compensation associated with these options is approximately \$17.3 million. Included in the results of

operations for the years ended December 31, 2003, 2002 and 2001 is compensation expense of approximately and \$2.2 million, \$3.3 million and \$4.1 million, respectively, associated with such options. Total deferred compensation is reduced when the associated options are cancelled prior to exercise. During 2003, 2002 and 2001, cancellation of options that had not been exercised resulted in a reduction in total deferred compensation of approximately \$0.2 million, \$2.2 million and \$0.6 million, respectively.

In May 2003 we granted options to a non-employee consultant to purchase 50,000 shares of common stock. In September 2003, we amended the terms of fully vested options to purchase 10,000 shares of common stock that were granted to a non-employee consultant in May 2001. In connection with these actions, we recorded \$1.2 million in related non-cash stock compensation expense during 2003. The unvested options granted in May 2003 will be revalued, utilizing the Black–Scholes option pricing model, and expensed over the remaining five months of their one-year vesting term. In 2002, we accelerated the vesting of stock options held by terminated employees in connection with their termination agreements, which resulted in \$0.5 million in non-cash compensation expense. Non-cash compensation expense is included in our operating expenses in the consolidated statements of operations.

The Company has elected to follow APB 25 in accounting for its stock options granted to employees because the alternative fair value accounting provided for under SFAS 123, requires the use of option valuation models that were not developed for use in valuing employee stock options. Because the exercise price of the Company's stock options generally equals the market price of the underlying stock on the date of grant, no compensation is recognized under APB 25.

A summary of stock option activity under all the Company's stock option plans are as follows:

		Weighted Average Exercise Price Per
	Number of Shares	Share
Outstanding, December 31, 2000	3,215,154	\$ 9.43
Granted	2,090,000	11.25
Exercised	(216,118)	2.45
Canceled	(329,086)	14.94
Outstanding, December 31, 2001	4,759,950	\$ 10.16
Granted	1,945,700	12.71
Exercised	(708,723)	3.88
Canceled	(1,158,270)	12.39
Outstanding, December 31, 2002	4,838,657	\$ 11.57
Granted	1,945,800	23.45
Exercised	(855,001)	8.84
Canceled	(613,463)	14.88
Outstanding, December 31, 2003	5,315,993	\$ 15.98
Available for future grant at December 31, 2003	293,039	
	270,007	

The weighted average per share fair value of options granted during 2003, 2002 and 2001 was \$12.51, \$6.95 and \$7.17, respectively. There were no options granted during 2003, 2002 and 2001 with an exercise price below the fair market value of the underlying shares on the date of grant. The weighted average fair value and exercise price of options granted during 2000 that were granted with exercise prices below fair market value were \$9.35 and \$4.68, respectively. The weighted average fair value and exercise price of options granted with exercise prices equal to fair value were \$12.51 and \$23.61, respectively, during 2003, \$6.95 and \$12.71, respectively, during 2002, and \$7.17 and \$11.25, respectively, during 2001.

The following table summarizes information about stock options from all the Company's stock option plans outstanding at December 31, 2003:

		Options Outstanding		0 (	<b>T</b> 7 4 1	
Range of Exercise Prices Per Share	Number Outstanding at 12/31/03	Weighted Average Remaining Contractual Life (Years)	ighted Average xercise Price Per Share	Number Outstanding at 12/31/03	Ex	Weighted Average ercise Price Per Share
\$0.69 - \$5.90	795,133	6.41	\$ 4.15	666,059	\$	3.95
\$5.92 - \$10.77	854,637	8.03	9.11	347,917		8.97
\$10.97 - \$13.80	551,352	7.88	12.40	260,305		12.30
\$15.00 - \$15.50	695,948	8.86	15.49	172,615		15.48
\$15.70 - \$19.00	706,115	8.69	17.61	176,113		17.76
\$19.42 - \$25.48	669,133	8.68	23.35	169,138		23.46
\$25.61 - \$27.96	682,175	9.36	27.25	91,940		25.97
\$28.01 - \$31.15	361,500	9.84	28.37	8,604		29.08
	5,315,993	8.35	\$ 15.98	1,892,691	\$	11.28

## Common Stock Reserved for Future Issuance

At December 31, 2003, there were 6,571,546 shares of Common Stock reserved for future issuance under the 2000 ESPP, for conversion of the October Warrants and March Warrants and for grants made under the 1998 Plan, the 2001 Plan and the 2000 Directors Stock Option Plan.

# 8. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share for the respective periods.

	 Year Ended December 31,				
	2003		2002		2001
Basic and diluted					
Net loss	\$ (16,869,701)	\$	(45,831,148)	\$	(54,883,648)
Weighted average common shares outstanding	45,628,258		37,223,342		32,987,766
Less: unvested restricted common shares outstanding	(3,969)		(13,411)		(61,798)
Weighted average common shares used to compute net loss per share	45,624,289		37,209,931		32,925,968
Basic and diluted net loss per share	\$ (0.37)	\$	(1.23)	\$	(1.67)

Options to purchase 5,315,993, 4,838,657 and 4,759,950 shares of Common Stock have not been included in the computation of diluted net loss per share for the years ended December 31, 2003, 2002 and 2001, respectively, as their effects would have been antidilutive. Warrants to purchase 795,432, 2,373,975 and 3,156,073 shares of Common Stock were also excluded from the computation of diluted net loss per share for the years ended December 31, 2003, 2002 and 2001, respectively, as their effects would have been antidilutive.

# 9. Income Taxes

The provision for income taxes in 2003 consists of state taxes paid based on net worth and income taxes in international jurisdictions.

The difference between tax expense and the amount computed by applying the statutory federal income tax rate (34%) to income before income taxes is as follows:

		Year Ended December 31,				
		2003		2002		
Statutory rate applied to pre-tax (loss)	(\$	5,692,000)	(\$	15,583,000)		
Add (deduct):						
State income taxes, net of federal benefit		(709,000)		—		
Foreign		(40,000)		—		
Compensation Expense		648,000		_		
Tax Credits		(1,497,000)		(1,985,000)		
Other		220,000		227,000		
Increase to valuation allowance (net)		7,198,000		17,341,000		
Income taxes	\$	128,000		_		

The significant components of the Company's deferred tax assets are as follows:

		December 31,				
		2003		2002		
Deferred tax assets:						
Net operating loss carryforwards	\$	92,357,000	\$	86,128,000		
Research and development credit		8,449,000		7,556,000		
Intangible assets		807,000		886,000		
Other		3,323,000		1,543,000		
			-			
		104,936,000		96,113,000		
Valuation allowance		(104,936,000)		(96,113,000)		
	¢		¢			
Net deferred tax assets	\$		\$			

The Company has increased its valuation allowance by \$8,823,000 in 2003 to provide a full valuation allowance for deferred tax assets since the realization of these future benefits is not considered more likely than not. Of this amount, \$1,625,000 relates primarily to the current year exercise of non-qualified stock options. The amount of the deferred tax asset considered realizable is subject to change based on estimates of future taxable income during the carryforward period. If the Company achieves profitability, these deferred tax assets would be available to offset future income taxes. The future utilization of net operating losses and credits may be subject to limitation based upon changes in ownership under the rules of the Internal Revenue Code. The Company has not yet determined the effect of these rules on the utilization of its net operating loss and credit carryforwards. The Company assesses the need for the valuation allowance at each balance sheet date based on all available evidence.

At December 31, 2003, the Company had federal net operating loss carryforwards available to reduce taxable income, and federal research and development tax credit carryforwards available to reduce future tax liabilities, which expire approximately as follows:

	Year of Expiration	F Op Ca	Federal Research and Development Tax Credit Carryforwards				
2011		\$	929,000	\$	22,000		
2012			15,260,000		527,000		
2018			27,876,000		425,000		
2019			33,803,000		1,002,000		
2020			45,270,000		1,176,000		
2021			51,100,000		477,000		
2022			41,403,000		1,876,000		
2023			19,525,000		2,268,000		
		\$	235,166,000	\$	7,773,000		
			. ,		. ,		

At December 31, 2003 a total of \$2.8 million of the deferred tax asset valuation allowance related to net operating loss carryforwards associated with the exercise of non-qualified stock options. Such benefits, when realized, will be credited to additional paid-in capital.

For state tax purposes, net operating loss carryforwards of approximately \$206,666,000 expire in the years 2004 through 2011. State research and development tax credit carryforwards are approximately \$676,000.

### **10. License Agreements**

## Angiomax<sup>®</sup> (bivalirudin)

In March 1997, the Company entered into an agreement with Biogen, Inc., a predecessor of Biogen Idec, Inc., for the license of the anticoagulant pharmaceutical bivalirudin, which the Company has developed as Angiomax. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the technology, patents, trademarks, inventories and know-how related to Angiomax. In exchange for the license, the Company paid \$2.0 million on the closing date and is obligated to pay up to an additional \$8.0 million upon the first commercial sales of Angiomax for the treatment of acute myocardial infarction in the United States and Europe. In addition, the Company will pay royalties on future sales of Angiomax and on any sublicense royalties on a country–by–country basis earned until the later of (1) 12 years after the date of the first commercial sale of the product in a country or (2) the date on which the product or its manufacture, use or sale is no longer covered by a valid claim of the licensed patent rights in such country. Under the terms of the agreement, the royalty rate due to Biogen on sales increases with growth in annual sales of Angiomax. The agreement also stipulates that the Company use commercially reasonable efforts to meet certain milestones related to the development and commercialization of Angiomax, including expending at least \$20 million for certain development and commercialization activities, which the Company must in 1998. The license and rights under the agreement remain in force until the Company's obligation to pay royalties cases. Either party may terminate the agreement for material breach by the other party, if the material breach is not cured within 90 days after written notice. In addition, the Company may terminate the agreement for any reason upon 90 days prior written notice. The Company recognized royalty expense under the agreement of \$5.7 million in 2003, \$2.8 million in 2002, and \$1.1 million in 2001 for Angiomax sales.

## Clevelox<sup>TM</sup> (clevidipine)

In March 2003, the Company acquired from AstraZeneca AB exclusive license rights to Clevelox for all countries other than Japan, pursuant to a study and exclusive option agreement with AstraZeneca that the Company entered into in March 2002. The Company plans to develop Clevelox as a short acting blood pressure control agent for use in hospital setting. In exchange for the license, the Company paid \$1.0 million in 2003 upon entering into the license and may have to pay up to an additional \$5.0 million upon reaching certain regulatory milestones. In addition, the Company will be obligated to pay royalties on a country–by–country basis on future annual sales of Clevelox, and on any sublicense royalties earned, until the later of (1) the duration of the licensed patent rights which are necessary to manufacture, use or sell Clevelox in a country or (2) ten years from our first commercial sale of Clevelox in such country. The licenses and rights under the agreement remain in force until the Company ceases selling Clevelox in any country or the agreement is otherwise terminated. The Company enter into good faith discussions to redress its concerns. If the Company cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, the Company may then terminate the agreement upon 90 days written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice, if the breach is not cured within such 60 days.

## Cangrelor

In December 2003, the Company entered into a license agreement with AstraZeneca AB relating to the development and commercialization of a late-stage development compound known as cangrelor. Cangrelor, a non-thienopyridine which is given by injection, acts directly on the P2Y12 platelet receptor, a clinically validated target to treat or prevent arterial thrombosis. Prior to December 2003, AstraZeneca conducted Phase 2 clinical trials studying cangrelor in approximately 500 patients. These studies demonstrate that cangrelor inhibits platelet activation and aggregation within seconds of starting drug administration and that platelet function recovers within less than 60 minutes after stopping infusion. The Company plans to develop cangrelor for potential use as an antiplatelet agent in patients undergoing percutaneous coronary interventions such as angioplasty and stenting.

Under terms of the license agreement, the Company has acquired rights to develop, market and sell cangrelor in all countries other than Japan, China, Korea, Taiwan and Thailand. In exchange for the license, the Company accrued in December 2003 and paid in January 2004 an upfront payment and will provide milestone payments upon regulatory approval in major markets. In addition, the Company will also pay royalties on a country–by–country basis on future annual sales of cangrelor, and on any sublicense royalties earned until the later of (1) the duration of the licensed patent rights which are necessary to manufacture, use or sell cangrelor in a country or (2) ten years from our first commercial sale of cangrelor in such country. The licenses and rights under the agreement remain in force until the Company caeses selling cangrelor in any country or the agreement is otherwise terminated. The Company may terminate the agreement upon 30 days written notice, unless AstraZeneca, within 20 days of having received the Company's notice, requests that the Company enter into good faith discussions to redress its concerns. If the Company cannot reach a mutually agreeable solution with AstraZeneca within three months of the commencement of such discussions, the Company may then terminate the agreement upon 90 days written notice. Either party may terminate the agreement for material breach upon 60 days prior written notice, if the breach is not cured within such 60 days.

## 11. Strategic Alliances and Related Parties

#### **UCB Bioproducts**

In December 1999, the Company entered into a commercial supply agreement with UCB Bioproducts S.A. ("UCB") for the development and supply of the Angiomax bulk drug substance. Under the terms of the commercial supply agreement, UCB completed development of a modified production process known as the Chemilog process and filed an amendment in 2001 to its drug master file for regulatory approval of the Chemilog process by the FDA. In addition, UCB manufactured two validation batches of Angiomax bulk drug substance using the Chemilog process in 2001, with a third validation batch completed in January 2002. In addition, the Company has agreed to purchase a substantial portion of its Angiomax bulk drug product from UCB at agreed upon prices for a period of seven years from the date of the first commercial sale of Angiomax produced using the Chemilog process. Following the expiration of the agreement, or if the Company terminates the agreement prior to its expiration, UCB will transfer the development technology to the Company. If the Company engages a third party to manufacture Angiomax using this technology, the Company will be obligated to pay UCB a royalty based on the amount paid by the Company to the third–party manufacturer.

During 2003, 2002 and 2001 the Company recorded \$11.1 million, \$9.7 million and \$19.4 million, respectively, in costs related to UCB's production of Angiomax bulk drug substance and Angiomax related development activities, of which \$1.1 million, \$6.8 million and \$4.8 million were expensed as research and development in 2003, 2002 and 2001, respectively, as FDA approval of the Angiomax manufacturing processes had not been received. In addition, \$1.5 million was also expensed in 2001 related to cancellation of a contract commitment with UCB.

#### International Health Care

Through December 31, 2003, the Company has entered into approximately six work orders with International Health Care (IHC) to provide clinical research services and has paid IHC a total of \$4.1 million. During 2003 and 2002, expenses incurred for such services were approximately \$5.0 million and \$0.3 million respectively, of which approximately \$1.2 million was recorded in accounts payable and accrued expenses at December 31, 2003.

### PharmaBio

In August 1996, the Company entered into a strategic alliance with one of its stockholders, PharmaBio Development Inc. ("PharmaBio"), a wholly owned subsidiary of Quintiles Transnational Corporation ("Quintiles"). Under the terms of the strategic alliance agreement, PharmaBio and any of its affiliates who work on the Company's projects will, at no cost to the Company, review and evaluate, jointly with the Company, development programs designed by the Company related to potential or actual product acquisitions. The purpose of this collaboration is to optimize the duration, cost, specifications and quality aspects of such programs. PharmaBio and its affiliates have also agreed to perform other services with respect to the Company's products, including clinical and non–clinical development services, project management, project implementation, pharmacoeconomic services, regulatory affairs and post marketing surveillance services and statistical programming, data processing and data management services pursuant to work orders with PharmaBio and has paid PharmaBio a total of \$15.3 million. During 2003, 2002, and 2001, expenses incurred for such services were approximately \$0.8 million, \$1.1 million, and \$2.3 million respectively, of which approximately \$48,000 was recorded in accounts payable and accrued expenses at December 31, 2003.

#### Innovex

In January 1997, the Company entered into a consulting agreement with Innovex, Inc. ("Innovex"), a subsidiary of Quintiles, which was subsequently superceded by a consulting agreement executed with Innovex in December 1998. Pursuant to the terms of the agreement, Innovex provided the Company with consulting services with respect to pharmaceutical marketing and sales. Since December 1997, the Company has also entered into various clinical services agreements with Innovex pursuant to which Innovex has provided project management, clinical monitoring, site management, medical monitoring, regulatory affairs, data management and quality assurance services with respect to clinical trials of Angiomax. None of the clinical services agreements is currently outstanding. Through December 31, 2001, the Company paid Innovex \$1.8 million under these agreements. The Company did not make any payments to Innovex in 2003 or 2002 under these agreements.

In December 2000, the Company signed a master services agreement and a work order with Innovex under which Innovex agreed to provide contract sales, marketing and commercialization services relating to Angiomax. Under the master services agreement and the Angiomax work order, Innovex was to provide a sales force of up to 52 representatives, a sales territory management system and operational support for the launch of Angiomax. The Company provided the marketing plan and marketing materials for the sales force and other sales and marketing support and direction for the sales force. For Innovex services, the Company agreed to pay a daily fee for each day worked by the members of the Innovex sales force. The Company was also responsible for reimbursing Innovex for expenses incurred in providing its services and for the incentive compensation paid to the sales force. The Company had the right to terminate the work order and the master services agreement at my time upon 90 days prior written notice and could hire members of the sales force, potentially incurring additional fees to Innovex. In June 2001, the Company notified Innovex of its decision to terminate the agreement with Innovex, and in October, the Company hired most of the Innovex sales representatives. Through December 31, 2003, the Company has paid Innovex \$7.0 million under the master services agreement and work order.

During 2001, total expenses incurred for services provided by Innovex was approximately \$5.6 million, of which approximately \$275,000 was recorded in accounts payable and accrued expenses at December 31, 2001. There were no expenses recorded in 2003 and 2002, and there were no amounts recorded in accounts payable and accrued expenses at December 31, 2003 and 2002.

#### Stack Pharmaceuticals

In 2000, the Company entered into an agreement with Stack Pharmaceuticals Inc. (SPI), an entity controlled by David M. Stack, then one of the Company's senior vice presidents. Pursuant to the terms of this agreement, SPI performed infrastructure services for the Company, which included providing office facilities, equipment and supplies, and such consulting, advisory and related services for the Company as was agreed upon from time to time. For the infrastructure services, the Company agreed to pay SPI a service fee of \$20,100 per month. From January 2000 through March 2000, SPI provided the Company with consulting agreement that expired on March 31, 2000. In November 2001, the Company terminated its agreement with SPI when David M. Stack became President and Chief Executive Officer of the Company. As part of the termination agreement, the Company assumed SPI's facility lease in Parsippany, New Jersey and acquired all its furniture and equipment for approximately \$70,000. Through December 31, 2001, the Company had paid SPI \$711,000 under these agreements. The Company did not make any payments to SPI in 2003 or 2002.

## 12. Commitments and Contingencies

The Company's long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include inventory related commitments to manufacture the Company's products, research and development service agreements, operating leases and other selling and general administrative related obligations.

Future estimated contractual obligations are:

Contractual Obligations		2004		2005		2006		2007	 2008	L	ater Years		Total
Inventory related commitments	\$	21,318,000	\$	28,574,000	\$	_	\$	_	\$ 	\$	_	\$	49,892,000
Research and development		9,752,000		3,686,000		602,000		_	_		_		14,040,000
Operating Leases		938,000		1,071,000		1,136,000		1,154,000	1,151,000		4,134,000		9,584,000
Selling, general and administrative		698,000		-		_		_	_		_		698,000
	-		_		_					_			
Total contractual obligations	\$	32,706,000	\$	33,331,000	\$	1,738,000	\$	1,154,000	\$ 1,151,000	\$	4,134,000	\$	72,214,000
							-			-		_	

Included above are inventory related non-cancellable commitments to make payments to UCB Bioproducts of a total of \$18.7 million during 2004 for Angiomax bulk drug substance to be produced using the Chemilog process and \$2.6 million in related filling, finishing and packaging commitments through August 2004. The Company also has \$13.8 million of estimated contractual obligations for research and development activities of which \$1.0 million is non-cancellable. The amounts included in selling, general and administrative obligations are primarily related to non-cancellable consulting arrangements.

In addition to the contractual obligations above, the Company has certain milestone payments to Biogen Idec, Inc. and to AstraZeneca AB related to the Company's product licenses for Angiomax, Clevelox and cangrelor. Under the Angiomax license, the Company may have to pay up to an additional \$8.0 million upon reaching certain Angiomax sales milestones, which are the first commercial sales of Angiomax for the treatment of acute myocardial infarction in the United States and Europe. Under the Clevelox license, the Company may have to pay up to an additional \$5.0 million upon reaching certain regulatory milestones. Under the cangrelor license, the Company made an upfront payment and will provide milestone payments upon regulatory approval in major markets.

## Litigation

The Company is involved in ordinary and routine matters and litigation incidental to its business. In the opinion of management, there are no matters outstanding that would have a material adverse effect on the consolidated financial position or results of operations of the Company.

## 13. Employee Benefit Plan

The Company has an employee savings and retirement plan which is qualified under Section 401(k) of the Internal Revenue Code. The Company's employees may elect to reduce their current compensation up to the statutorily prescribed limit and have the amount of such reduction contributed to the 401(k) plan. The Company may make matching or additional contributions to the 401(k) plan in amounts to be determined annually by the Board of Directors. The Company has not made any matching or additional contributions to date.

# 14. Selected Quarterly Financial Data (Unaudited)

The following table presents selected quarterly financial data for the years ended December 31, 2003 and 2002.

	Three Months Ended															
	Mar. 31, June 30, 2003 2003		· · ·			Dec. 31, 2003		Mar. 31, 2002		June 30, 2002		Sept. 30, 2002		Dec. 31, 2002		
						(i	n tho	usands, excep	ot pe	r share data)						
Net revenue	\$	16,705	\$	18,750	\$	21,248	\$	28,888	\$	7,715	\$	7,156	\$	9,133	\$	14,297
Cost of sales		6,263		6,970		6,603		2,914		1,085		1,647		2,227		5,324
Total operating expenses		23,292		25,749		27,820		26,874		19,726		20,439		20,561		24,317
Net (loss)/income		(6,416)		(6,587)		(6,162)		2,296		(11,641)		(13,141)		(11,212)		(9,837)
Basic net (loss) /income per common share	\$	(0.16)	\$	(0.14)	\$	(0.13)	\$	0.05	\$	(0.34)	\$	(0.37)	\$	(0.29)	\$	(0.25)
Diluted net income per common share		_		_		_		0.05		_		_		_		_
Market Price																
High	\$	20.00	\$	25.91	\$	31.41	\$	29.98	\$	14.81	\$	14.33	\$	12.50	\$	17.50
Low	\$	15.20	\$	16.83	\$	19.25	\$	22.80	\$	9.86	\$	7.40	\$	7.22	\$	9.45

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# Schedule II Valuation and Qualifying Accounts Year(s) ended December 31, 2003, 2002 and 2001

	Balance at Beginning of Period		it) Charged to Costs and Expenses(1)	Other Charges (Deductions)(2)			Balance at End of Period
2003							
Allowances for chargebacks, cash discounts and doubtful accounts	\$ 636,000	\$	5,746,000	\$	4,156,000	\$	2,226,000
2002							
Allowances for chargebacks, cash discounts and doubtful accounts	\$ 258,000	\$	1,428,000	\$	1,050,000	\$	636,000
2001							
Allowances for chargebacks, cash discounts and doubtful accounts	\$ _	\$	468,000	\$	210,000	\$	258,000

(1)

amounts presented herein were charged to and reduced revenues

## (2)

represents actual cash discounts, chargeback credits and other deductions

# INDEX TO EXHIBITS

#### Description

3.1(1)	Third Amended and Restated Certificate of Incorporation of the registrant
3.2(2)	Amended and Restated By-laws of the registrant, as amended
4.1(1)	Form of Common Stock Purchase Warrant dated October 19, 1999
4.2(1)	Form of Common Stock Purchase Warrant dated March 2, 2000
10.1(1)*	1998 Stock Incentive Plan, as amended
10.2(2)*	2000 Employee Stock Purchase Plan, as amended
10.3(3)*	2000 Outside Director Stock Option Plan, as amended
10.4(4)	2001 Non-Officer, Non-Director Employee Stock Incentive Plan
10.5(5)	Amended and Restated Registration Rights Agreement, dated as of August 12, 1998, as amended, by and among the registrant and the other parties thereto
10.6(1)†	Chemilog Development and Supply Agreement, dated as of December 20, 1999, by and between the registrant and UCB Bioproducts S.A.
10.7(1)†	License Agreement, dated as of June 6, 1990, by and between Biogen, Inc. and Health Research, Inc., as assigned to the registrant
10.8(1)†	License Agreement dated March 21, 1997, by and between the registrant and Biogen, Inc.
10.9(6)†	Sales, Marketing and Distribution Agreement dated March 25, 2002 by and between Nycomed Danmark A/S and the registrant
10.10(7)	Termination Agreement, dated November 1, 2001, by and between the registrant and Stack Pharmaceuticals, Inc. relating to the Services Agreement dated April 1, 2000, as amended
10.11(1)*	Employment agreement dated September 5, 1996 by and between the registrant and Clive Meanwell
10.12(8)*	Employment Agreement dated October 16, 1997 by and between the registrant and John D. Richards
10.13(7)*	Amended and Restated Employment Agreement, dated November 1, 2001, by and between the registrant and David M. Stack
10.14(7)	Assignment and Assumption of Lease, dated October 18, 2001, by and between the Registrant and Stack Pharmaceuticals, Inc.
10.15	Lease for 8 Campus Drive dated September 30, 2002 by and between Sylvan/Campus Realty L.L.C. and the registrant, as amended
10.16(9)	Lease for 200 Fifth Avenue, Waltham, MA dated June 19, 2003 by and between Prospect Hill Acquisition Trust and the registrant
10.17††	License Agreement effective as of March 28, 2003 by and between AstraZeneca AB and the registrant
10.18††	License Agreement dated as of December 18, 2003 by and between AstraZeneca AB and the registrant

- 21 Subsidiaries of the registrant
- 23 Consent of Ernst & Young LLP, Independent Auditors
- 31.1 Executive Chairman—Certification pursuant to Rule 13a–14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes–Oxley Act of 2002
- 31.2 Chief Executive Officer—Certification pursuant to Rule 13a–14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes–Oxley Act of 2002
- 31.3 Chief Financial Officer—Certification pursuant to Rule 13a–14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes–Oxley Act of 2002
- 32.1 Executive Chairman—Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002
- 32.2 Chief Executive Officer—Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes–Oxley Act of 2002
- 32.3 Chief Financial Officer—Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section

*	Management contract or compensatory plan or arrangement filed as an exhibit to this form pursuant to Items 15(a) and 15(c) of Form 10-K
Ť	Confidential treatment was granted for certain portions of this Exhibit pursuant to Rule 406 promulgated under the Securities Act of 1933, as amended, or Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended
††	Confidential treatment has been requested for certain portions of this Exhibit pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended
(1)	Incorporated by reference to the exhibits to the registration statement on Form S-1 (registration no. 333-37404)
(2)	Incorporated by reference to the exhibits to the registrant's annual report on Form 10-K for the year ended December 31, 2001
(3)	Incorporated by reference to the exhibits to the registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2003
(4)	Incorporated by reference to the exhibits to the registration statement on Form S-8 (registration no. 333-74612)
(5)	Incorporated by reference to the exhibits to the registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2002
(6)	Incorporated by reference to the exhibits to the registrant's quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2002
(7)	Incorporated by reference to the exhibits to the registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2001
(8)	Incorporated by reference to the exhibits to the registration statement on Form S-1 (registration no. 333-53280)
(9)	Incorporated by reference to the exhibits to the registrant's quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2003

Exhibit 10.15

LEASE

FROM:

SYLVAN/ CAMPUS REALTY L.L.C.

LESSOR

TO:

THE MEDICINES COMPANY

LESSEE

BUILDING:

8 CAMPUS DRIVE PARSIPPANY, NEW JERSEY

1.	DESCRIPTION:
2.	TERM:
3.	BASIC RENT:
4.	USE AND OCCUPANCY:
5.	CARE AND REPAIR OF PREMISES/ENVIRONMENTAL:
6.	ALTERATIONS, ADDITIONS OR IMPROVEMENTS:
7.	ACTIVITIES INCREASING FIRE INSURANCE RATES:
8.	ASSIGNMENT AND SUBLEASE:
9.	COMPLIANCE WITH RULES AND REGULATIONS:
10.	DAMAGES TO BUILDING:
11.	EMINENT DOMAIN:
12.	INSOLVENCY OF LESSEE:
13.	LESSOR'S REMEDIES ON DEFAULT:11
14.	DEFICIENCY:
15.	SUBORDINATION OF LEASE:
16.	SECURITY DEPOSIT:
17.	RIGHT TO CURE LESSEE'S BREACH:
18.	MECHANIC'S LIENS:
19.	RIGHT TO INSPECT AND REPAIR:
20.	SERVICES TO BE PROVIDED BY LESSOR/LESSOR'S EXCULPATION:14
21.	INTERRUPTION OF SERVICES OR USE:14
22.	BUILDING STANDARD OFFICE ELECTRICAL SERVICE:14
23.	ADDITIONAL RENT:
24.	LESSEE'S ESTOPPEL:
25.	HOLDOVER TENANCY:
26.	RIGHT TO SHOW PREMISES:
27.	LESSOR'S WORK - LESSEE'S DRAWINGS:19
28.	WAIVER OF TRIAL BY JURY:
29.	LATE CHARGE:
30.	LESSEE'S INSURANCE:

i

31. 32.	NO OTHER REPRESENTATIONS:
	8
33.	INDEMNITY:
34.	ARTICLE HEADINGS:
35.	APPLICABILITY TO HEIRS AND ASSIGNS:
36.	OUTSIDE PARKING SPACES:
37.	LESSOR'S LIABILITY FOR LOSS OF PROPERTY:
38.	PARTIAL INVALIDITY:
39.	LESSEE'S BROKER:
40.	PERSONAL LIABILITY:
41.	NO OPTION:
42.	DEFINITIONS: 23
43	LEASE COMMENCEMENT: 24
44.	NOTICES: 24
45.	ACCORD AND SATISFACTION: 24
46.	EFFECT OF WAIVERS:
47.	LEASE CONDITION: 25
48.	MORTGAGEE'S NOTICE AND OPPORTUNITY TO CURE:
40.	LESSOR'S RESERVED RIGHT:
49. 50.	
	CORPORATE AUTHORITY:
51.	AFTER-HOURS USE:
52.	LESSEE'S EXPANSION/RELOCATION:
53.	BUILDING PERMIT:
54.	OPTION TO RENEW:
55.	RIGHT OF FIRST OFFER:

LEASE, is made the 30th day of September, 2002 between SYLVAN/ CAMPUS REALTY L.L.C. (herein referred to as "Lessor") whose address is c/o Mack-Cali Realty Corporation, 11 Commerce Drive, Cranford, New Jersey 07016 and THE MEDICINES COMPANY (herein referred to as "Lessee") whose address is 5 Sylvan Way, Parsippany, New Jersey, 07054.

#### PREAMBLE

#### BASIC LEASE PROVISIONS AND DEFINITIONS

In addition to other terms elsewhere defined in this Lease, the following terms whenever used in this Lease shall have only the meanings set forth in this section, unless such meanings are expressly modified, limited or expanded elsewhere herein.

- ADDITIONAL RENT shall mean all sums in addition to Fixed Basic Rent payable by Lessee to Lessor pursuant to the provisions of the Lease.
- 2. BASE PERIOD COSTS shall mean the following:
  - A. Base Operating Costs: Those Operating Costs incurred during Calendar Year 2003.
  - B. Base Real Estate Taxes: Those Real Estate Taxes incurred during Calendar Year 2003.
  - C. Base Utility and Energy Costs: Those Utility and Energy Costs incurred during Calendar Year 2003
- 3. BUILDING shall mean 8 Campus Drive, Parsippany, New Jersey.
- 4. BUILDING HOLIDAYS shall be those shown on Exhibit F.
- 5. BUILDING HOURS shall be Monday through Friday, 8:00 a.m. to 6:00 p.m., but excluding those holidays as set forth on Exhibit F attached hereto and made a part hereof, except that Common Facilities, lighting in the Building and Office Building Area shall be maintained for such additional hours as, in Lessor's sole judgement, is necessary or desirable to insure proper operating of the Building and Office Building Area.
- 6. COMMENCEMENT DATE is the date of this Lease. RENT COMMENCEMENT DATE is the date which is the earlier of (i) the date upon which Lessee, or anyone claiming under or through Lessee, commences using the Premises for the conduct of business, or (ii) the date which is ninety (90) days after the date of this Lease.
- 7. DEMISED PREMISES OR PREMISES shall be deemed to be 16,779 gross rentable square feet on the second (2nd) floor as shown on Exhibit A hereto, which includes an allocable share of the Common Facilities as defined in Article 42(b).
- EXHIBITS shall be the following, attached to this Lease and incorporated herein and made a part hereof.

Exhibit A	Location of Premises
Exhibit A-1	Office Building Area
Exhibit B	Rules and Regulations
Exhibit C	Lessor's Work
Exhibit C-1	Air Conditioning & Heating Design Standards
Exhibit D	Cleaning Services
Exhibit E	Building Holidays
Exhibit F	Tenant Estoppel Certificate
Exhibit G	Commencement Date Agreement
Exhibit H	Form of Letter of Credit
Exhibit I	Exclusions from Operating Costs
EVILDIC I	Exclusions fiom operating costs

 EXPIRATION DATE shall be the last day of the month in which the day before the ten (10) year anniversary of the Rent Commencement Date occurs. 10. FIXED BASIC RENT shall mean: FIVE MILLION SEVENTY-FIVE THOUSAND SIX HUNDRED FORTY-SEVEN AND 50/100 DOLLARS (\$5,075,647.50) for the Term commencing on the Rent Commencement Date payable as follows:

Year	Yearly Rate	Monthly Installments
1	\$ 469,812.00	\$ 39,151.00
2	\$ 478,201.50	\$ 39,850.13
3	\$ 486,591.00	\$ 40,549.25
4	\$ 494,980.50	\$ 41,248.38
5	\$ 503,370.00	\$ 41,947.50
6	\$ 511,759.50	\$ 42,646.63
7	\$ 520,149.00	\$ 43,345.75
8	\$ 528,538.50	\$ 44,044.88
9	\$ 536,928.00	\$ 44,744.00
10	\$ 545,317.50	\$ 45,443.13

- 11. LESSEE'S BROKER shall mean Trammell Crow Company.
- 12. LESSEE'S PERCENTAGE shall be 7.80% subject to adjustment as provided in the Lease.
- OFFICE BUILDING AREA is as set forth on Exhibit A-1. 13.
- 14. PARKING SPACES shall mean a total of sixty-three (63) unassigned surface parking spaces.
- 15. PERMITTED USE shall be general office use and for no other purpose.
- 16. SECURITY DEPOSIT shall be EIGHTY-FOUR THOUSAND FIVE HUNDRED NINETY-FIVE  $% \left( {{\left( {{{\left( {{{}}}}} \right)}}} \right.$ AND 00/100 DOLLARS (\$84,595.00)
- 17. TERM shall mean ten (10) years from the Rent Commencement Date, plus the number of days, if any, to have the Lease expire on the last day of a calendar month, unless extended pursuant to any option contained herein.

-- End of Preamble --

2

For and in consideration of the covenants herein contained, and upon the terms and conditions herein set forth, Lessor and Lessee agree as follows:

1. DESCRIPTION:

Lessor hereby leases to Lessee, and Lessee hereby hires from Lessor, the Premises as defined in the Preamble which includes an allocable share of the Common Facilities, as shown on the plan or plans, initialed by the parties hereto, marked Exhibit A attached hereto and made part of this Lease in the Building as defined in the Preamble, (hereinafter called the "Building") which is situated on that certain parcel of land (hereinafter called "Office Building Area") as described on Exhibit A-1 attached hereto and made part of this Lease, together, with the right to use in common with other lessees of the Building, their invitees, customers and employees, those public areas of the Common Facilities as hereinafter defined.

2. TERM:

The Premises are leased for a term to commence on the Commencement Date, and to end at 12:00 midnight on the Expiration Date, all as defined in the Preamble.

3. BASIC RENT:

The Lessee shall pay to the Lessor during the Term, the Fixed Basic Rent as defined in the Preamble (hereinafter called "Fixed Basic Rent") payable in such coin or currency of the United States of America as at the time of payment shall be legal tender for the payment of public and private debts. The Fixed Basic Rent shall accrue at the Yearly Rate as defined in the Preamble and shall be payable, in advance, on the first day of each calendar month during the Term commencing on the Rent Commencement Date at the Monthly Installments as defined in the Preamble, except that a proportionately lesser sum may be paid for the first and last months of the Term of this Lease if the Term commences on a day other than the first day of the month, in accordance with the provisions of this Lease herein set forth. Lessor acknowledges receipt from Lessee of the first monthly installment by check, subject to collection, for Fixed Basic Rent for the first month of the Lease Term. Lessee shall pay Fixed Basic Rent, and any Additional Rent as hereinafter provided, to Lessor at Lessor's above stated address, or at such other place as Lessor may designate in writing, without demand and without counterclaim, deduction or set off.

4. USE AND OCCUPANCY:

Lessee shall use and occupy the Premises for the Permitted Use as defined in the Preamble.

Lessee hereby acknowledges "no smoking" is permitted in the Common Facilities. Lessee shall use its best efforts to enforce Lessor's policy prohibiting its employees, agents or invitees from smoking within the Common Facilities including the areas outside of the Building's main entrance.

- 5. CARE AND REPAIR OF PREMISES/ENVIRONMENTAL:
  - (a) Lessee shall commit no act of waste and shall take good care of the Premises and the fixtures and appurtenances therein, and shall, in the use and occupancy of the Premises, conform to all laws, orders and regulations of the federal, state and municipal governments or any of their departments affecting the Premises and with any and all environmental requirements resulting from the Lessee's particular use of the Premises, this covenant to survive the expiration or sooner termination of the Lease. Notwithstanding anything to the contrary contained in this Lease, Lessee shall not be required to make any repairs, alterations or modifications to the Premises as a result of any laws, orders and regulations of the federal, state and municipal governments or any of their departments affecting the Premises unless the need for

such repairs, alterations or modifications arises from the particular manner in which Lessee uses the Premises, and repairs, alterations or modifications to the Premises as a result of any laws, orders and regulations of the federal, state and municipal governments or any of their departments affecting the Premises which are required of all owners and tenants generally, and do not arise from the particular manner in which an owner or tenant uses its premises, shall be undertaken by and at the sole cost and expense of Lessor and same may be included in Operating Costs pursuant to Article 23 of this Lease. Lessor shall, subject to the same being included in Operating Costs (except as expressly excluded in the immediately preceding sentence.), make all necessary repairs to the Premises, Common Facilities and to the assigned parking areas, if any, except where the repair has been made necessary by misuse or neglect by Lessee or Lessee's agents, servants, visitors or licensees, in which event Lessor shall nevertheless make the repair but Lessee shall pay to Lessor, as Additional Rent, immediately upon demand, the costs therefor. All improvements made by Lessee to the Premises, which are so attached to the Premises, shall become the property of Lessor upon installation. Not later than the last day of the Term, Lessee shall, at Lessee's expense, remove all Lessee's personal property and those improvements made by Lessee which have not become the property of Lessor, including trade fixtures, cabinetwork, movable paneling, partitions and the like; repair all injury done by or in connection with the installation or removal of said property and improvements; and surrender the Premises in as good condition as they were at the beginning of the Term, reasonable wear and damage by fire, the elements, casualty or other cause not due to the misuse or neglect by Lessee, Lessee's agents, servants, visitors or licensees excepted and excluding maintenance and repairs required to be undertaken by Lessor. All other property of Lessee remaining on the Premises after the last day of the Term of this Lease shall be conclusively deemed abandoned and may be removed by Lessor, and Lessee shall reimburse Lessor for the cost of such removal. Lessor may have any such property stored at Lessee's risk and expense.

#### ENVIRONMENTAL

- (b) COMPLIANCE WITH ENVIRONMENTAL LAWS. Lessee shall, at Lessee's own expense, promptly comply with each and every federal, state, county and municipal environmental law, ordinance, rule, regulation, order, directive and requirement, now or hereafter existing ("Environmental Laws"), applicable to the Premises, Lessee, Lessee's operations at the Premises, or all of them, except if there is any violation of Environmental Laws with regard to the Premises existing at the date of this Lease, Lessor shall comply therewith at its sole cost and expense, which cost and expense shall not be included in Operating Costs..
- (c) ISRA COMPLIANCE. Lessee shall, at Lessee's own expense, comply with the Industrial Site Recovery Act, N.J.S.A. 13:1K-6 ET SEQ., the regulations promulgated thereunder and any amending and successor legislation and regulations ("ISRA"), if and to the extent the need for such compliance is triggered by Lessee having become an Industrial Establishment (as defined in ISRA) with respect to its use of the Premises.
- (d) INFORMATION TO LESSOR. At no expense to Lessor, Lessee shall promptly provide all information and sign all documents requested by Lessor with respect to compliance with Environmental Laws.
- (e) LESSOR AUDIT. Lessee shall permit Lessor and its representatives access to the Premises, from time to time, to conduct an environmental assessment, investigation and sampling, all at Lessor's own expense. If such assessment, investigation and sampling reveal a violation of this provision, the cost shall be borne by Lessee.
- (f) LESSEE REMEDIATION. Should any assessment, investigation or sampling reveal the existence of any spill, discharge or placement of Contaminants in, on, under, or about, or migrating from or onto the Premises, the Building or the Office Building Area, as a result of the action or omission of Lessee or a "Lessee Representative", then, in addition to being in default under this Lease and Lessor having all rights available to Lessor under this Lease and by law by reason of such default, Lessee shall, at Lessee's own expense, in accordance with Environmental Laws, undertake all action required by Lessor and any governmental authority, including, without

limitation, promptly obtaining and delivering to Lessor an unconditional No Further Action Letter. For purposes of this Article, the term "Lessee's Representative" shall mean any shareholder, officer, director, member, partner, employee, agent, licensee, assignee, sublessee or invitee of Lessee, or any third party for whom Lessee is legally responsible. In no event shall any of Lessee's remedial action involve engineering or institutional controls, a groundwater classification exception area or well restriction area, and Lessee's remedial action shall meet the most stringent published or unpublished remediation standards for soil, surface water, groundwater and drinking water. Promptly upon completion of all required investigatory and remedial activities, Lessee shall, at Lessee's own expense, to Lessor's satisfaction, restore the affected areas of the Premises, the Building or the Office Building Area, as the case may be, from any damage or condition caused by the investigatory or remedial work.

- (g) ENVIRONMENTAL QUESTIONNAIRE. Upon Lessor's request, contemporaneously with the signing and delivery of this Lease, and thereafter upon renewal of the lease, if at all, Lessee shall complete, execute and deliver to Lessor an environmental questionnaire in form and substance satisfactory to Lessor.
- (h) ENVIRONMENTAL DOCUMENTS AND CONDITIONS. For purposes of this Article, the term "Environmental Documents" shall mean all environmental documentation concerning the Building or the Office Building Area, of which the Premises is a part, or its environs, in the possession or under the control of Lessee, including, without limitation, plans, reports, correspondence and submissions. During the term of this Lease and subsequently, promptly upon receipt by Lessee or Lessee's Representatives, Lessee shall deliver to Lessor all Environmental Documents concerning or generated by or on behalf of Lessee, whether currently or hereafter existing. In addition, Lessee shall promptly notify Lessor of any environmental condition of which Lessee has knowledge, which may exist in, on, under, or about, or may be migrating from or onto the Building or the Office Building Area.
- (i) LESSOR'S RIGHT TO PERFORM LESSEE'S OBLIGATIONS. Notwithstanding anything to the contrary set forth in this Lease, in the event, pursuant to this Lease, Lessee is required to undertake any sampling, assessment, investigation or remediation with respect to the Premises, the Building or the Office Building Area, as the case may be, then, at Lessor's discretion, Lessor shall have the right, if Lessee has failed to do so with reasonable promptness upon notice to Lessee, from time to time, to perform such activities at Lesse's expense, and all sums incurred by Lessor shall be paid by Lessee, as Additional Rent, upon demand.
- (j) INDEMNITY. Lessee shall indemnify, defend and hold harmless Lessor, Lessor's officers, directors, shareholders, employees and personal or legal representatives from and against any and all claims, liabilities, losses, damages, penalties and costs, foreseen or unforeseen, including, without limitation, counsel, engineering and other professional or expert fees, which an indemnified party may incur resulting directly or indirectly, wholly or partly from Lessee's actions or omissions with regard to Lessee's obligations under this Article.

Lessor shall indemnify, defend and hold harmless Lessee, Lesse's officers, directors, shareholders, employees and personal or legal representatives from and against any and all claims, liabilities, losses, damages, penalties and costs, foreseen or unforeseen, including, without limitation, counsel, engineering and other professional or expert fees, which an indemnified party may incur resulting directly or indirectly, wholly or partly from Lessor's actions or omissions with regard to Lessor's obligations under this Article. Any cost or expense incurred by Lessor pursuant to this indemnity shall be excluded from Operating Costs.

- (k) SURVIVAL. This Article shall survive the expiration or earlier termination of this lease. Lessee's failure to abide by the terms of this Article shall be restrainable or enforceable, as the case may be, by injunction.
- (1) INTERPRETATION. The obligations imposed upon Lessee under subparagraphs (a) through (j) above are in addition to and are not intended to limit, but to expand upon, the obligations imposed upon Lessee under this Article 5. As used in this Article, the term "Contaminants" shall include, without limitation, any regulated substance, toxic

substance, hazardous substance, hazardous waste, pollution, pollutant, contaminant, petroleum, asbestos or polychlorinated biphenyls, as defined or referred to in any Environmental Laws. Where a law or regulation defines any of these terms more broadly then another, the broader definition shall apply.

6. ALTERATIONS, ADDITIONS OR IMPROVEMENTS:

Lessee shall not, without first obtaining the written consent of Lessor, make any structural or Building Systems alterations, additions or improvements in, to or about the Premises. Building Systems shall mean any structural, life safety, plumbing, electrical, heating, ventilation or air conditioning system or its components. Lessee shall not, without first obtaining the written consent of Lessor (which shall not be unreasonably withheld or delayed) make any non-Building Systems alterations, additions or improvements in, to or about the Premises. Lessee may, upon notification to Lessor, perform minor cosmetic improvements, such as painting and wallpapering, without prior consent of Lessor.

7. ACTIVITIES INCREASING FIRE INSURANCE RATES:

Lessee shall not do or suffer anything to be done on the Premises which will increase the rate of fire insurance on the Building.

8. ASSIGNMENT AND SUBLEASE:

Provided Lessee is not in default of any provisions of this Lease, Lessee may assign or sublease the within Lease to any party subject to the following:

- In the event Lessee desires to assign this Lease or sublease all or part of the Premises to any other party, the terms and conditions of such assignment or sublease shall be communicated to the Lessor in writing no less than thirty (30) days prior to the effective date of any such sublease or assignment, and, prior to such effective date, the Lessor shall have the option, exercisable in writing to the Lessee, to: (i) recapture in the case of subletting, that portion of the Premises to be sublet or all of the Premises in the case of an assignment ("Recapture Space") so that such prospective sublessee or assignee shall then become the lessee of Lessor hereunder, or (ii) recapture the Recapture Space for Lessor's own use. In the event that Lessor exercise its option to Recapture Space, the within Lessee shall be fully released from any and all obligations hereunder with respect to the Recapture Space and the Fixed Basic Rent and Lessee's Percentage shall be adjusted appropriately. Lessor shall advise Lessee in writing of Lessor's election with respect to the Recapture Space within twenty (20) days after Lessor's receipt of Lessee's notice of its intent to sublet or assign. Notwithstanding the foregoing, Lessor shall have no right to exercise its rights pursuant to clauses (i) or (ii) above if the space that Lessee proposes to sublet is less than eighty percent (80%) of the Premises and the term of such subletting, including renewal options, if any, is to expire at any time prior to the commencement of the last year of the Term.
- b. In the event that the Lessor elects not to recapture the Lease or relet the Premises as hereinabove provided or in the event the proposed sublease falls within the provisions of the last sentence of sub section a. above, the Lessee may assign this Lease or sublet the whole or any portion of the Premises, subject to the Lessor's prior written consent, which consent shall not be unreasonably withheld and shall be deemed to have been given if Lessor does not advise Lessee otherwise in writing not less than twenty (20) days after Lessor's receipt of Lessee's notice of its intent to sublease or assign, on the basis of the following terms and conditions:
  - i. The Lessee shall provide to the Lessor the name and address of the assignee or sublessee.
  - ii. The assignee or sublessee shall assume, by written instrument, all of the obligations of this Lease, and a copy of such assumption agreement shall be furnished to the Lessor within ten (10) days of its execution. Any sublease

shall expressly acknowledge that said sublessee's rights against Lessor shall be no greater than those of Lessee. Lessee further agrees that notwithstanding any such subletting, no other and further subletting of the Premises by Lessee or any person claiming through or under Lessee shall or will be made except upon compliance with and subject to the provisions of this Article 8.

- Each sublease shall provide that it is subject and iii. subordinate to this Lease and to the matters to which this Lease is or shall be subordinate, and that in the event of default by Lessee under this Lease, Lessor may, at its option, take over all of the right, title and interest of Lessee, as sublessor, under such sublease, and such sublessee shall, at Lessor's option, attorn to Lessor pursuant to the then executory provisions of such sublease, except that Lessor shall not (i) be liable for any previous act or omission of Lessee under such sublease or, (ii) be subject to any offset not expressly provided in such sublease which theretofore accrued to such sublease to which Lessor has not specifically consented in writing or by any previous prepayment of more than one month's rent.
- iv. The Lessee and each assignee shall be and remain liable for the observance of all the covenants and provisions of this Lease, including, but not limited to, the payment of Fixed Basic Rent and Additional Rent reserved herein, through the entire Term of this Lease, as the same may be renewed, extended or otherwise modified.
- v. The Lessee and any assignee shall promptly pay to Lessor fifty percent (50%) of any consideration received for any assignment and/or fifty percent (50%) of the rent, as and when received, in excess of the Rent required to be paid by Lessee for the area sublet computed on the basis of an average square foot rent for the gross square footage Lessee has leased after deducting therefrom Lessee's actual and reasonable expenses in connection with such sublease or assignment.
- vi. In any event, the acceptance by the Lessor of any rent from the assignee or from any of the subtenants or the failure of the Lessor to insist upon a strict performance of any of the terms, conditions and covenants herein shall not release the Lessee herein, nor any assignee assuming this Lease, from any and all of the obligations herein during and for the entire Term of this Lease.
- vii. In Lessor's reasonable judgment, the proposed assignee or subtenant is engaged in a business or activity, and the Premises, or the relevant part thereof, will be used in a manner, which (a) is in keeping with the then standard of the Building and (b) is limited to the use of the Premises as general offices.
- viii. The proposed assignee or subtenant is not then an occupant of any part of the Building or any other building then owned by Lessor or its affiliates within the Mack-Cali Business Campus and Lessor has space available for leasing reasonably equivalent to the Premises, in the case of an assignment, or the space proposed to be sublet, in the case of a subletting. For the purposes hereof, the "Mack-Cali Business Campus" shall mean, Two Hilton Court, One Sylvan Way, Two Dryden Way, 4 Campus Drive, 4 Gatehall Drive, 5 Sylvan Way, 6 Campus Drive, 600 Parsippany Road, 7 Campus Drive, 7 Sylvan Way, and 9 Campus Drive.
- ix. The proposed assignee or subtenant is not an entity or a person with whom Lessor is or has been, within the preceding sixty (60) day period, engaged in active negotiations to lease space in the Building or any other building owned by Lessor or its affiliates within the Mack-Cali Business Campus and Lessor has space available for leasing reasonably equivalent to the Premises, in the case of an assignment, or the space proposed to be sublet in case of a subletting.
- x. There shall not be more than three (3) subtenants in the Premises.

- xi. Lessee shall not publicly advertise the subtenancy for less than the then current market rent per rentable square foot for the Premises as though the Premises were vacant; provided that nothing contained herein shall prohibit subleases for less than the then current market rent.
- xii. Lessee shall not have (a) publicly advertised the availability of the Premises without prior notice to and approval by Lessor (which approval shall not be unreasonably withheld or delayed), nor shall any advertisement state the name (as distinguished from the address) of the Building or (b) listed the Premises for subletting or assignment other than with a broker, agent or representative who waives any entitlement to a commission or other fee from Lessor in the event of a recapturing of the Premises;
- xiii. The proposed occupancy shall not, in Lessor's reasonable opinion, exceed the parking allocation presently provided for in this Lease;
- xiv. The proposed assignee or subtenant shall only use the Premises for general offices and shall not be engaged in any of the following:
  - (a) educational, including but not limited to, instructional facilities and correspondence schools;
  - (b) employment agencies;
  - (c) model agencies;
  - (d) photographic studios or laboratories;
  - (e) spas, health, physical fitness or exercise salons;
  - (f) small loan offices;
  - (g) real estate brokerage or real estate sales offices open to the general public or construction offices;
  - (h) medical or dental facilities, including professional offices, treatment facilities, dispensaries or laboratories;
  - (i) federal, state or local government offices;
  - (j) so-called boiler room operations;
  - (k) retail stock brokerage offices; and
  - religious organizations making facilities available to congregations for uses other than business purposes; and
  - (m) executive office suite use.
- xv. The proposed assignee or subtenant shall not be entitled, directly or indirectly, to diplomatic or sovereign immunity and shall be subject to the service of process in, and the jurisdiction of, the state courts of New Jersey.
- xvi. Lessor shall require a FIVE HUNDRED AND 00/100 DOLLAR (\$500.00) payment to cover its handling charges for each request for consent to any sublet or assignment prior to its consideration of the same. Unless it is judicially determined that Lessor has acted in bad faith, Lessee acknowledges that its sole remedy with respect to any assertion that Lessor's failure to consent to any sublet or assignment is unreasonable shall be the remedy of specific performance and Lessee shall have no other claim or cause of action against Lessor as a result of Lessor's actions in refusing to consent thereto.
- If Lessee is a corporation other than a corporation whose stock с. is listed and traded on a nationally recognized stock exchange, the provisions of Sub-section a. shall apply to a transfer (however accomplished, whether in a single transaction or in a series of related or unrelated transactions) of stock (or any other mechanism such as, by way of example, the issuance of additional stock, a stock voting agreement or change in class(es) of stock) which results in a change of control of Lessee as if such transfer of stock (or other mechanism) which results in a change of control of Lessee were an assignment of this Lease, and if Lessee is a partnership or joint venture, said provisions shall apply with respect to a transfer (by one or more transfers) of an interest in the distributions of profits and losses of such partnership or joint venture (or other mechanism, such as, by way of example, the creation of additional general partnership or limited partnership interests) which results in a change of control of such a partnership or joint venture, as if such transfer of an interest in the distributions of profits and losses of such partnership or joint venture which results in

a change of control of such partnership or joint venture were an assignment of this Lease; provided, however: (A) said provisions of Sub-section a. of this Article 7 shall not apply to transactions with a corporation into or with which Lessee is merged or consolidated or to which all or substantially all of Lessee's assets are transferred or to any corporation which controls or is controlled by Lessee or is under common control with Lessee (any of such transactions, a "Capital Transaction"), (B) Lessor's consent shall not be required with respect to a Capital Transaction in which (i) the successor to Lessee has the financial ability, in Lessor's reasonable discretion, to meet Lessee's obligations under the Lease, and (ii) proof satisfactory to Lessor of such financial ability to meet Lessee's obligations shall have been delivered to Lessor at least 10 days prior to the effective date of any such transaction.

d.

In the event that any or all of Lessee's interest in the Premises and/or this Lease is transferred by operation of law to any trustee, receiver, or other representative or agent of Lessee, or to Lessee as a debtor in possession, and subsequently any or all of Lessee's interest in the Premises and/or this Lease is offered or to be offered by Lessee or any trustee, receiver, or other representative or agent of Lessee as to its estate or property (such person, firm or entity being hereinafter referred to as the "Grantor"), for assignment, conveyance, lease, or other disposition to a person, firm or entity other than Lessor (each such transaction being hereinafter referred to as a "Disposition"), it is agreed that Lessor has and shall have a right of first refusal to purchase, take, or otherwise acquire, the same upon the same terms and conditions as the Grantor thereof shall accept upon such Disposition to such other person, firm, or entity; and as to each such Disposition the Grantor shall give written notice to Lessor in reasonable detail of all of the terms and conditions of such Disposition within twenty (20) days next following its determination to accept the same but prior to accepting the same, and Grantor shall not make the Disposition until and unless Lessor has failed or refused to accept such right of first refusal as to the Disposition, as set forth herein.

Lessor shall have sixty (60) days next following its receipt of the written notice as to such Disposition in which to exercise the option to acquire Lessee's interest by such Disposition, and the exercise of the option by Lessor shall be effected by notice to that effect sent to the Grantor; but nothing herein shall require Lessor to accept a particular Disposition or any Disposition, nor does the rejection of any one such offer of first refusal constitute a waiver or release of the obligation of the Grantor to submit other offers hereunder to Lessor. In the event Lessor accept such offer of first refusal, the transaction shall be consummated pursuant to the terms and conditions of the Disposition described in the notice to Lessor. In the event Lessor rejects such offer of first refusal, Grantor may consummate the Disposition with such other person, firm, or entity; but any decrease in price of more than two percent (2%) of the price sought from Lessor or any change in the terms of payment for such Disposition shall constitute a new transaction requiring a further option of first refusal to be given to Lessor hereunder.

- Without limiting any of the provisions of Articles 12 and 13, if e. pursuant to the Federal Bankruptcy Code (herein referred to as the "Code"), or any similar law hereafter enacted having the same general purpose, Lessee is permitted to assign this Lease notwithstanding the restrictions contained in this Lease, adequate assurance of future performance by an assignee expressly permitted under such Code shall be deemed to mean the deposit of cash security in an amount equal to the sum of one year's Fixed Basic Rent plus an amount equal to the Additional Rent for the calendar year preceding the year in which such assignment is intended to become effective, which deposit shall be held by Lessor for the balance of the Term, without interest, as security for the full performance of all of Lessee's obligations under this Lease, to be held and applied in the manner specified for security in Article 16.
- f. Except as specifically set forth above, no portion of the Premises or of Lessee's interest in this Lease may be acquired by any other person or entity, whether by assignment, mortgage, sublease, transfer, operation of law or act of the Lessee, nor shall Lessee pledge its interest in this Lease or in any security deposit required hereunder.

### 9. COMPLIANCE WITH RULES AND REGULATIONS:

Lessee shall observe and comply with the rules and regulations hereinafter set forth in Exhibit B attached hereto and made a part hereof and with such further reasonable rules and regulations as Lessor may prescribe, on written notice to the Lessee, for the safety, care and cleanliness of the Building and the comfort, quiet and convenience of other occupants of the Building. Lessee shall not place a load upon any floor of the Premises exceeding the floor load per square foot area which it was designed to carry and which is allowed by law. Lessor reserves the right to prescribe the weight and position of all safes, business machines and mechanical equipment. Such installations shall be placed and maintained by Lessee, at Lessee's expense, in settings sufficient, in Lessor's judgement, to absorb and prevent vibration, noise and annovance.

## 10. DAMAGES TO BUILDING:

If the Building is damaged by fire or any other cause to such extent the cost of restoration, as reasonably estimated by Lessor, will equal or exceed twenty-five percent (25%) of the replacement value of the Building (exclusive of foundations) just prior to the occurrence of the damage, then Lessor may, no later than the sixtieth (60th) day following the date of damage, give Lessee a notice of election to terminate this Lease, or if the cost of restoration will equal or exceed fifty percent (50%) of such replacement value and if the Premises shall not be reasonably usable for the purpose for which they are leased hereunder, or if restoration of the damage will require more than one hundred eighty (180) days to complete or if such damage is not fully repaired and reasonable access to the Premises restored within one hundred eighty (180) days from the date of damage, then, in any such event, Lessee may, no later than the sixtieth (60th) day following the date of damage or following the end of said one hundred eighty (180) day period, give Lessor a notice of election to terminate this Lease. In either said event of election, this Lease shall be deemed to terminate on the thirtieth (30th) day after the giving of said notice, and Lessee shall surrender possession of the Premises within a reasonable time thereafter, and the Fixed Basic Rent, and any Additional Rent, shall be apportioned as of the date of said casualty and any Fixed Basic Rent or Additional Rent paid for any period beyond said date shall be repaid to Lessee. If the cost of restoration or condition of the Premises shall not entitle Lessor or Lessee to terminate this Lease, or if, despite the cost or such condition, neither Lessor nor Lessee elects to terminate this Lease within the periods provided above, Lessor shall restore the Building and the Premises with reasonable promptness, subject to Force Majeure, and Lessee shall have no right to terminate this Lease, except as set forth above. Lessor need not restore fixtures and improvements owned by Lessee.

In any case in which use of the Premises is affected by any damage to the Building, there shall be either an abatement or an equitable reduction in Fixed Basic Rent, depending on the period for which and the extent to which the Premises are not reasonably usable for the purpose for which they are leased hereunder. The words "restoration" and "restore" as used in this Article 10 shall include repairs. If the damage results from the fault of the Lessee, Lessee's agents, servants, visitors or licensees, Lessee shall not be entitled to any abatement or reduction in Fixed Basic Rent, except to the extent of any rent insurance received by Lessor.

#### 11. EMINENT DOMAIN:

If Lessee's use of the Premises is materially affected due to the taking by eminent domain of (a) the Premises or any part thereof or any estate therein; or (b) any other part of the Building; then, in either event, this Lease shall terminate on the date when title vests pursuant to such taking. The Fixed Basic Rent, and any Additional Rent, shall be apportioned as of said termination date and any Fixed Basic Rent or Additional Rent paid for any period beyond said date, shall be repaid to Lessee. Lessee shall not be entitled to any part of the award for such taking or any payment in lieu thereof, but Lessee may file a separate claim for any taking of fixtures and improvements owned by Lessee which have not become the Lessor's property, and for moving expenses, provided the same shall, in no way, affect or diminish Lessor's award. In the event of a partial taking which does not effect a termination of this Lease but does deprive Lessee of the use of a portion of the Premises, there shall either be an abatement or an equitable reduction of the Fixed Basic Rent, and an equitable

adjustment reducing the Base Period Costs as hereinafter defined depending on the period for which and the extent to which the Premises so taken are not reasonably usable for the purpose for which they are leased hereunder.

#### 12. INSOLVENCY OF LESSEE:

Either (a) the appointment of a receiver to take possession of all or substantially all of the assets of Lessee, or, (b) a general assignment by Lessee for the benefit of creditors, or, (c) any action taken or suffered by Lessee under any insolvency or bankruptcy act, shall constitute a default of this Lease by Lessee, and Lessor may terminate this Lease forthwith and upon notice of such termination Lessee's right to possession of the Premises shall cease, and Lessee shall then quit and surrender the Premises to Lessor but Lessee shall remain liable as hereinafter provided in Article 14 hereof.

### 13. LESSOR'S REMEDIES ON DEFAULT:

If Lessee defaults in the payment of Fixed Basic Rent, or any Additional Rent, or defaults in the performance of any of the other covenants and conditions hereof or permits the Premises to become deserted, abandoned or vacated, Lessor may give Lessee notice of such default, and if Lessee does not cure any Fixed Basic Rent or Additional Rent default within ten (10) days or other default within thirty (30) days after giving of such notice (or if such other default is of such nature that it cannot be completely cured within such period, if Lessee does not commence such curing within such thirty (30) day period and thereafter proceed with reasonable diligence and in good faith to cure such default), then Lessor may terminate this Lease on not less than ten (10) days notice to Lessee, and on the date specified in said notice, Lessee's right to possession of the Premises shall cease but Lessee shall remain liable as hereinafter provided. If this Lease shall have been so terminated by Lessor pursuant to Articles 12 or 13 hereof, Lessor may at any time thereafter resume possession of the Premises by any lawful means and remove Lessee or other occupants and their effects. The unsuccessful party shall pay tothe prevailing party, on demand, such expenses as he prevailing party may incur, including, without limitation, court costs and reasonable attorney's fees and disbursements, in any proceeding relating to this Lease. Notwithstanding the foregoing, Lessee's vacating of the Premises shall not be deemed a default under this Lease, provided that at the time of such vacating of the Premises, Lessee shall deliver to Lessor a certification of the Chief Executive Officer or Chief Financial Officer of Lessee certifying that Lessee has the ability to meet its financial obligations under this Lease.

## 14. DEFICIENCY:

In any case where Lessor has recovered possession of the Premises by reason of Lessee's default, Lessor may, at Lessor's option, occupy the Premises or cause the Premises to be redecorated, altered, divided, consolidated with other adjoining premises or otherwise changed or prepared for reletting, and may relet the Premises or any part thereof, as agent of Lessee or otherwise, for a term or terms to expire prior to, at the same time as or subsequent to, the original Expiration Date of this Lease, at Lessor's option and receive the rent therefor. Rent so received shall be applied first to the payment of such reasonable expenses as Lessor may have incurred in connection with the recovery of possession, redecorating, altering, dividing, consolidating with other adjoining premises, or otherwise changing or preparing for reletting, and the reletting, including brokerage and reasonable attorney's fees, and then to the payment of damages in amounts equal to the Fixed Basic Rent and Additional Rent hereunder and to the costs and expenses of performance of the other covenants of Lessee as herein provided. Lessee agrees, in any such case, whether or not Lessor has relet, to pay to Lessor damages equal to the Fixed Basic Rent and Additional Rent from the date of such default to the date of expiration of the term demised and other sums herein agreed to be paid by Lessee, less the net proceeds of the reletting, if any, received by Lessor during the remainder of the unexpired term hereof, as ascertained from time to time, and the same shall be payable by Lessee on the several rent days above specified. Lessee shall not be entitled to any surplus accruing as a result of any such reletting. In reletting the Premises as aforesaid, Lessor may grant commercially reasonable rent concessions, and Lessee shall not be credited therewith. No such reletting shall constitute a surrender and acceptance or be deemed evidence thereof. If Lessor elects, pursuant hereto, actually to occupy and use the Premises or

any part thereof during any part of the balance of the Term as originally fixed or since extended, there shall be allowed against Lessee's obligation for rent or damages as herein defined, during the period of Lessor's occupancy, the reasonable value of such occupancy, not to exceed, in any event, the Fixed Basic Rent and Additional Rent herein reserved and such occupancy shall not be construed as a release of Lessee's liability hereunder.

Alternatively, in any case where Lessor has recovered possession of the Premises by reason of Lessee's default, Lessor may at Lessor's option, and at any time thereafter, and without notice or other action by Lessor, and without prejudice to any other rights or remedies it might have hereunder or at law or equity, become entitled to recover from Lessee, as Damages for such breach, in addition to such other sums herein agreed to be paid by Lessee, to the date of re-entry, expiration and/or dispossess, an amount equal to the difference between the Fixed Basic Rent and Additional Rent reserved in this Lease from the date of such default to the date of Expiration of the original Term demised and the then fair and reasonable rental value of the Premises for the same period. Said Damages shall become due and payable to Lessor immediately upon such breach of this Lease and without regard to whether this Lease be terminated or not, and if this Lease be terminated, without regard to the manner in which it is terminated. In the computation of such Damages, the difference between an installment of Fixed Basic Rent and Additional Rent thereafter becoming due and the fair and reasonable rental value of the Premises for the period for which such installment was payable shall be discounted to the date of such default at the rate of not more than six percent (6%) per annum.

Lessee hereby waives all right of redemption to which Lessee or any person under Lessee might be entitled by any law now or hereafter in force.

Lessor's remedies hereunder are in addition to any remedy allowed by law.

### 15. SUBORDINATION OF LEASE:

This Lease shall, at Lessor's option, or at the option of any holder of any underlying lease or holder of any mortgages or trust deed, be subject and subordinate to any such underlying leases and to any such mortgages or trust deed which may now or hereafter affect the real property of which the Premises form a part, and also to all renewals, modifications, consolidations and replacements of said underlying leases and said mortgages or trust deed provided, that Lessor shall use commercially reasonable efforts to obtain a non-disturbance agreement from the holder of any such underlying lease, mortgage or trust deed. Any reasonable expenses charged by the mortgagee in connection with the obtaining of the aforesaid agreement shall be paid by Lessee. Although no instrument or act on the part of Lessee shall be necessary to effectuate such subordination, Lessee will, nevertheless, execute and deliver such further instruments confirming such subordination of this Lease as may be desired by the holders of said mortgages or trust deed or by any of the lessor's under such underlying leases. Lessee hereby appoints Lessor attorney-in-fact, irrevocably, to execute and deliver any such instrument for Lessee. If any underlying lease to which this Lease is subject terminates, Lessee shall, on timely request, attorn to the owner of the reversion.

Lessor represents that there currently is no mortgage encumbering the  $\ensuremath{\mathsf{Premises}}$  .

## 16. SECURITY DEPOSIT:

Lessee shall deposit with Lessor on the signing of this Lease, the Security Deposit as defined in the Preamble for the full and faithful performance of Lessee's obligations under this Lease, including without limitation, the surrender of possession of the Premises to Lessor as herein provided. If Lessor applies any part of said Security Deposit to cure any default of Lessee, Lessee shall, on demand, deposit with Lessor the amount so applied so that Lessor shall have the full Security Deposit on hand at all times during the Term of this Lease. In the event of a bona fide sale of the Building, subject to this Lease, Lessor shall have the right to transfer the Security Deposit to the vendee, and Lessor shall be considered released by Lessee from all liability for the return of the Security Deposit; and Lessee agrees to look solely to the new lessor for the return of the Security Deposit, and it is agreed that this shall apply to every transfer or assignment made of the Security Deposit to the new lessor. Provided this Lease is not in default, the Security Deposit (less any portions thereof used, applied or retained by Lessor in accordance with the provisions of this Article 16), shall be returned to Lessee after

the expiration or sooner termination of this Lease and after delivery of the entire Premises to Lessor in accordance with the provisions of this Lease. Lessee covenants that it will not assign or encumber or attempt to assign or encumber the Security Deposit and Lessor shall not be bound by any such assignment, encumbrance or attempt thereof.

In the event of the insolvency of Lessee, or in the event a petition is filed by or against Lessee under any chapter of the bankruptcy laws of the State of New Jersey or the United States of America, then in such event, Lessor may require the Lessee to deposit additional security in an amount which in Lessor's sole judgement would be sufficient to adequately assure Lessee's performance of all of its obligations under this Lease including all payments subsequently accruing. Failure of Lessee to deposit the security required by this Article 16 within ten (10) days after Lessor's written demand shall constitute a material breach of this Lease by Lessee.

Lessee may deliver to Lessor after the date hereof, in lieu of the cash deposit set forth in this Article, an irrevocable negotiable letter of credit in amount set forth in Paragraph 16 of the Preamble and substantially in the form annexed hereto as Exhibit H. Said letter of credit shall be for a term of not less than one (1) year and shall be renewed by Lessee (without notice from Lessor) no later than forty-five (45) days prior to its expiration, and the expiration of each replacement thereof, until Lessor shall be required to return the security to Lessee pursuant to the terms of this Lease but in no event earlier than ninety (90) days after the Expiration Date, and each such renewal letter of credit shall be delivered to Lessor no later than forty-five (45) days prior to the expiration of the letter of credit then held by Lessor. If any portion of the security deposit shall be utilized by Lessor in the manner permitted by this Lease, Lessee shall, within five (5) days after request by Lessor, replenish the security account by depositing with Lessor, in cash or by letter of credit, an amount equal to that utilized by Lessor. Failure of Lessee to comply strictly with the provisions of this Article shall constitute a material breach of this Lease and Lessor shall be entitled to present the letter of credit held by for payment (without notice to Lessee). If the cash security is converted into a letter of credit, the provisions with respect to letters of credit shall apply (with the necessary changes in Points of detail) to such letter of credit deposit. In the event of a bank failure or insolvency affecting the letter of credit, Lessee shall replace same within twenty (20) days after being requested to do so by Lessor

## 17. RIGHT TO CURE LESSEE'S BREACH:

If Lessee breaches any covenant or condition of this Lease, Lessor may, on reasonable notice to Lessee (except that no notice need be given in case of emergency), cure such breach at the expense of Lessee and the reasonable amount of all expenses, including attorney's fees, incurred by Lessor in so doing (whether paid by Lessor or not) shall be deemed Additional Rent payable on demand.

18. MECHANIC'S LIENS:

Lessee shall, within fifteen (15) days after notice from Lessor, discharge or satisfy by bonding or otherwise any mechanic liens for materials or labor claimed to have been furnished to the Premises on Lessee's behalf.

## 19. RIGHT TO INSPECT AND REPAIR:

Lessor may enter the Premises but shall not be obligated to do so (except as required by any specific provision of this Lease) at any reasonable time on reasonable notice to Lessee (except that no notice need be given in case of emergency), in such a manner and at such times as to minimize interference with Lessee's business, for the purpose of inspection or the making of such repairs, replacement or additions in, to, on and about the Premises or the Building, as Lessor deems necessary or desirable. Lessee shall have no claims or cause of action against Lessor by reason thereof. In no event shall Lessee have any claim against Lessor for interruption of Lessee's business, however occurring, including but not limited to that arising from the negligence of Lessor, its agents, servants or invitees, or from defects, errors or omissions in the construction or design of the Premises and/or the Building, including the structural and non-structural portions thereof. 20. SERVICES TO BE PROVIDED BY LESSOR/LESSOR'S EXCULPATION:

Subject to intervening laws, ordinances, regulations and executive orders, Lessor agrees to furnish, except on holidays, as set forth on Exhibit E attached hereto and made a part hereof:

- a. The cleaning services, as set forth on Exhibit D attached hereto and made a part hereof, and subject to the conditions therein stated. Except as set forth on Exhibit D, Lessee shall pay the cost of all other cleaning services required by Lessee.
- b. Heating, ventilating and air conditioning (herein "HVAC") as appropriate for the season, and as set forth on Exhibit C-1, attached hereto and made a part hereof, together with Common Facilities lighting and electric energy all during Building Hours, as defined in the Preamble.
- c. Cold and hot water for drinking and lavatory purposes.
- d. Elevator service during Building Hours (if the Building contains an elevator or elevators for the use of the occupants thereof).
- e. Restroom supplies and exterior window cleaning when reasonably required.
- f. Notwithstanding the requirements of Exhibit C-1 (as to HVAC) or D or any other provision of this Lease, Lessor shall not be liable for failure to furnish any of the aforesaid services when such failure is due to Force Majeure, as hereinafter defined. Lessor shall not be liable, under any circumstances, including, but not limited to, that arising from the negligence of Lessor, its agents, servants or invitees, or from defects, errors or omissions in the construction or design of the Premises and/or the Building, including the structural and non-structural portions thereof, for loss of or injury to Lessee or to property, however occurring, through or in connection with or incidental to the furnishings of, or failure to furnish, any of the aforesaid services or for any interruption to Lessee's business, however occurring.
- 21. INTERRUPTION OF SERVICES OR USE:

Interruption or curtailment of any service maintained in the Building or at the Office Building Area, if caused by Force Majeure, as hereinafter defined, shall not entitle Lessee to any claim against Lessor or to any abatement in rent, and shall not constitute a constructive or partial eviction, unless Lessor fails to take measures as may be reasonable under the circumstances to restore the service without undue delay. If the Premises are rendered untenantable in whole or in part, for a period of five (5) consecutive business days, by the making of repairs, replacements or additions, other than those made with Lessee's consent or caused by misuse or neglect by Lessee, or Lessee's agents, servants, visitors or licensees, there shall be a proportionate abatement of Rent from and after said fifth (5th) consecutive business day and continuing for the period of such untenantability. In no event, shall Lessee be entitled to claim a constructive eviction from the Premises unless Lessee shall first have notified Lessor in writing of the condition or conditions giving rise thereto, and if the complaints be justified, unless Lessor shall have failed, within a reasonable time after receipt of such notice, to remedy, or commence and proceed with due diligence to remedy such condition or conditions, all subject to Force Majeure as hereinafter defined.

22. BUILDING STANDARD OFFICE ELECTRICAL SERVICE:

The cost of electric current which is supplied by the Lessor for use by the Lessee in the Premises, other than for heating or air conditioning purposes, shall be reimbursed to the Lessor at terms, classification and rates normally charged by the public utilities corporation serving that part of the municipality where the subject Premises are located.

a. From and after the Commencement Date, Lessee agrees to pay as Additional Rent an estimated electrical charge of \$.10 per square foot per month, payable on the first day of each and every month, until such time as an electrical survey can be performed pursuant to Article 22(b) below.

b.

- Lessee agrees that an independent electrical engineering consultant shall make a survey of electric power demand of the electric lighting fixtures and the electric equipment of Lessee used in the Premises to determine the average monthly electric consumption thereof, and the costs of said survey shall be borne by Lessee but not in excess of \$350.00. The findings of said consultant as to the average monthly electric consumption of Lessee shall, unless objected to by Lessee within forty-five (45) days, be conclusive and binding on Lessor and Lessee. After Lessor's consultant has submitted its report, Lessee shall pay to Lessor, within ten (10) days after demand therefor by Lessor, the amount (based on the monthly consumption found by such consultant) as owing from the Lease Term's Commencement Date, and the then expired months, to include the then current month and thereafter adjusted for the estimated electrical charges already paid pursuant to Article 22(a), on the first day of every month, in advance, the amount set forth as the monthly consumption in said report. Said amounts shall be treated as Additional Rent due hereunder. Proportionate sums shall be payable for periods of less than a full month if the Term commences or ends on any other than the first or last day of the month. If Lessee objects to said findings, Lessee shall nevertheless pay and continue to pay the amount determined by Lessor's consultant until the issue is finally resolved, but Lessee may, at its expense, seek the services of an independent electrical consultant who shall make a survey as provided above. If Lessor's and Lessee's consultant cannot agree as to Lessee's consumption within thirty (30) days of Lessee's consultant's findings either Lessor or Lessee may request the American Arbitration Association in Somerset, New Jersey to appoint an electrical engineering consultant whose decision shall be final and binding on Lessor and Lessee, and whose cost shall be shared equally. Upon the issue being finally resolved, any overpayment made by Lessee shall be promptly refunded.
- c. In the event that there shall be an increase or decrease in the rate schedule (including surcharges or demand adjustments), of the public utility for the supply of Building Standard Office Electrical Service, or the imposition of any tax with respect to such service or increase in any such tax following the Lease Term's commencement, the Additional Rent payable hereunder shall be adjusted equitably to reflect the increase or decrease in rate or imposition or increase in the aforesaid tax. All computations shall be made on the basis of Lessee's surveyed usage as if a meter exclusively measuring such usage to the Premises was in place.
- d. Lessee covenants that it shall notify Lessor immediately upon the introduction of any office equipment or lighting different from that on the Premises as of Lessor's electrical survey or in addition to the aforesaid equipment or lighting on the Premises as of said survey. The introduction of any new or different equipment or lighting shall be cause for, at Lessor's election, a resurveying of the Premises at Lessee's expense. Lessor reserves the right to inspect the Premises to insure compliance with this provision.
- e. Lessor shall not be liable in any way to Lessee for any loss, damage or expense which Lessee may sustain or incur as a result of any failure, defect or change in the quantity or character of electrical energy available for redistribution to the Premises pursuant to this Article 22 nor for any interruption in the supply, and Lessee agrees that such supply may be interrupted for inspection, repairs and replacement and in emergencies. In any event, the full measure of Lessor's liability for any interruption in the supply due to Lessor's acts or omissions shall be an abatement of Fixed Basic Rent and Additional Rent, unless Lessor fails to take such measures as may be reasonable under the circumstances to restore such service without undue delay. In no event shall Lessor be liable for any business interruption suffered by Lessee.
- f. Lessor, at Lessee's expense, shall furnish and install all replacement lighting tubes, lamps, ballasts and bulbs required in the Premises. Lessee, however, shall have the right to furnish and/or install any or all of the items mentioned in this Article 22(f).
- g. Lessee's use of electrical service as contemplated herein shall be during Building Hours, and any use in excess of said Building Hours shall result in an adjustment as set forth in Article 22(a) hereof to reflect such additional consumption.

## 23. ADDITIONAL RENT:

It is expressly agreed that Lessee will pay in addition to the Fixed Basic Rent provided in Article 3 hereof, an Additional Rent to cover Lesse's Percentage as defined in the Preamble, of the increased cost to Lessor, for each of the categories enumerated herein, over the "Base Period Costs", as defined in the Preamble for said categories.

- OPERATING COST ESCALATION -- If the Operating Costs incurred for the Building in which the Premises are located and Office Building Area for any Lease Year or Partial Lease Year during the Lease Term shall be greater than the Base Operating Costs (adjusted proportionately for periods less than a Lease Year), then Lessee shall pay to Lessor, as Additional Rent, Lessee's Percentage of all such excess Operating Costs. Operating Costs shall include, by way of illustration and not of limitation: personal property taxes; management fees; labor, including all wages and salaries; social security taxes, and other taxes which may be levied against Lessor upon such wages and salaries; supplies; repairs and maintenance; maintenance and service contracts; painting; wall and window washing; laundry and towel service; tools and equipment (which are not required to be capitalized for federal income tax purposes); fire and other insurance; trash removal; lawn care; snow removal and all other items properly constituting direct operating costs according to standard accounting practices (hereinafter collectively referred to as the "Operating Costs"), but not including any of the exclusions from Operating Costs set forth on Exhibit I attached hereto
- b. FUEL, UTILITIES AND ELECTRIC COST ESCALATION (hereinafter referred to as "Utility and Energy Costs") - If the Utility and Energy Costs, including any fuel surcharges or adjustments with respect thereto, incurred for water, sewer, gas, electric, other utilities and heating, ventilating and air conditioning for the Building, to include all leased and leasable areas (not separately billed or metered within the Building), and Common Facilities electric, lighting, water, sewer and other utilities for the Building and Office Building Area, for any Lease Year or Partial Lease Year, during the Term, shall be greater than the Base Utility and Energy Costs (adjusted proportionately for periods less than a Lease Year), then Lessee shall pay to Lessor as Additional Rent, Lessee's Percentage of all such excess Utility and Energy Costs. As used in this Article 23, the Base Utility and Energy Costs shall be as defined in the Preamble.
- c. TAX ESCALATION -- If the Real Estate Taxes for the Building and Office Building Area at which the Premises are located for any Lease Year or Partial Lease Year, during the Lease Term, shall be greater than the Base Real Estate Taxes (adjusted proportionately for periods less than a Lease Year), then provided that such increase in Real Estate Taxes is not the result of expansion or addition to the Building and the Office Building Area at which the Premises are located, Lessee shall pay to Lessor as Additional Rent, Lessee's Percentage as hereinafter defined, of all such excess Real Estate Taxes. Lessor represents to Lessee that the Building and Office Building Area at which the Premises are located are assessed for Real Estate Tax purposes as of the date of this Lease as fully completed.

As used in this Article 23(c), the words and terms which follow mean and include the following:

- i. "Base Real Estate Taxes" shall be as defined in the Preamble.
- "Real Estate Taxes" shall mean the property taxes and ii. assessments imposed upon the Building and Office Building Area, or upon the rent, as such, payable to the Lessor, including, but not limited to, real estate, city, county, village, school and transit taxes, or taxes, assessments, or charges levied, imposed or assessed against the Building and Office Building Area by any other taxing authority, whether general or specific, ordinary or extraordinary, foreseen or unforeseen. If due to a future change in the method of taxation, any franchise, income or profit tax shall be levied against Lessor in substitution for, or in lieu of, or in addition to, any tax which would otherwise constitute a Real Estate Tax, such franchise, income or profit tax shall be

deemed to be a Real Estate Tax for the purposes hereof; conversely, any additional real estate tax hereafter imposed in substitution for, or in lieu of, any franchise, income or profit tax (which is not in substitution for, or in lieu of, or in addition to, a Real Estate Tax as hereinbefore provided) shall not be deemed a Real Estate Tax for the purposes hereof.

- d. LEASE YEAR -- As used in this Article 23, Lease Year shall mean a calendar year. Any portion of the Term which is less than a Lease Year as hereinbefore defined, that is, from the Commencement Date through the following December 31, and from the last January 1, falling within the Term to the end of the Term, shall be deemed a "Partial Lease Year". Any reference in this Lease to a Lease Year shall, unless the context clearly indicates otherwise, be deemed to be a reference to a Partial Lease Year if the period in question involves a Partial Lease Year.
- e. PAYMENT -- At any time, and from time to time, after the establishment of the Base Period Costs for each of the categories referred to above, Lessor shall advise Lessee in writing of Lessee's Percentage share with respect to each of the categories as reasonably estimated for the next twelve (12) month period (or proportionate part thereof if the last period prior to the Lease's expiration is less than twelve (12) months) as then known to the Lessor, and thereafter, the Lessee shall pay as Additional Rent, Lessee's Percentage share of these costs for the then current period affected by such advice (as the same may be periodically revised by Lessor as additional costs are incurred) in equal monthly installments, such new rates being applied to any months, for which the Fixed Basic Rent shall have already been paid which are affected by the Operating Cost Escalation and/or Utility and Energy Cost Escalation and/or Tax Escalation Costs above referred to, as well as the unexpired months of the current period, the adjustment for the then expired months to be made at the payment of the next succeeding monthly rental, all subject to final adjustment at the expiration of each Lease Year as defined in Article 23(e) hereof (or Partial Lease Year if the last period prior to the Lease's termination is less than twelve (12) months).

In the event the last period prior to the Lease's termination is less than twelve (12) months, the Base Period Costs during said period shall be proportionately reduced to correspond to the duration of said final period.

f.

- BOOKS AND REPORTS -- For the protection of Lessee, Lessor shall maintain books of account which, together with the back-up materials thereto, shall be open to Lessee and its representatives at all reasonable times so that Lessee can determine that such Operating, Utility and Energy and Real Estate Tax Costs have, in fact, been paid or incurred. Lessee's representatives shall not (i) perform such inspection and/or audit on a contingency basis, or (ii) perform such an inspection and/or audit for any other tenant in the Building. At Lessor's request, Lessee shall execute a confidentiality agreement reasonably acceptable to Lessor prior to any examination of Lessor's books and records. In the event Lessee disputes any one or more of said charges, Lessee shall attempt to resolve such dispute with Lessor, provided that if such dispute shall not be satisfactorily settled between Lessor and Lessee, the dispute shall be referred by either party to an independent certified public accountant to be mutually agreed upon, and if such an accountant cannot be agreed upon, The American Arbitration Association may be asked by either party to select an arbitrator, whose decision on the dispute will be final and binding upon both parties, who shall jointly share any cost of such arbitration. If the arbitrator determines that Lessor has overstated the disputed sum by more than five percent (5%), then Lessor shall pay the entire cost of the arbitration. Pending resolution of said dispute the Lessee shall pay to Lessor the sum so billed by Lessor subject to its ultimate resolution as aforesaid. The parties agree to make any adjustment to such Operating, Utility and Energy and Real Estate Tax Costs payments determined to be necessary as a result of such review by Lessee and/or arbitration.
- g. RIGHT OF REVIEW -- Once Lessor shall have finally determined said Operating, Utility and Energy or Real Estate Tax Costs at the expiration of a Lease Year, then as to the item so established, Lessee shall only be entitled to dispute said charge as finally established for a period of six (6) months after such charge is finally established, and

Lessee specifically waives any right to dispute any such charge at the expiration of said six (6) month period.

h.

OCCUPANCY ADJUSTMENT -- If, with respect to Operating Cost Escalation, as established in Article 23(a) hereof, and Utility and Energy Cost Escalation, as established in Article 23(b) hereof, the Building is less than ninety-five percent (95%) occupied during the establishment of the respective Base Periods, then the Base Costs incurred with respect to said Operating Cost or Utility and Energy Cost shall be adjusted during any such period within the Base Period so as to reflect ninety-five percent (95%) occupancy. Similarly, if during any Lease Year or Partial Lease Year, subsequent to the Base Period the Building is less than ninety-five percent (95%) occupied, then the actual costs incurred for Operating Cost and Utility and Energy Cost shall be increased during any such period to reflect ninety-five percent (95%) occupancy so that at all times after the Base Period the Operating Cost or Utility and Energy Cost shall be actual costs, but in the event less than ninety-five percent (95%) of the Building is occupied during all or part of the Lease Year involved, the Operating Cost or Utility and Energy Cost shall not be less than that which would have been incurred had ninety-five percent (95%) of the Building been occupied. The aforesaid adjustment shall only be made with respect to those items that are in fact affected by variations in occupancy levels.

## 24. LESSEE'S ESTOPPEL :

Lessee shall, from time to time, on not less than ten (10) days prior written request by Lessor, execute, acknowledge and deliver to Lessor a written statement, substantially in the form of Exhibit F attached hereto, certifying that the Lease is unmodified and in full force and effect, or that the Lease is in full force and effect as modified and listing the instruments of modification; the dates to which the rents and charges have been paid; and, to the best of Lessee's knowledge, whether or not Lessor is in default hereunder, and if so, specifying the nature of the default. It is intended that any such statement delivered by Lessee pursuant to this Article 24 may be relied on by a prospective purchaser of Lessor's interest or mortgagee of Lessor's interest or assignee of any mortgage of Lessor's interest.

Lessor shall, from time to time, on not less than ten (10) days prior written request by Lessee, execute, acknowledge and deliver to Lessee a written statement reasonably acceptable to Lessee, certifying that the Lease is unmodified and in full force and effect, or that the Lease is in full force and effect as modified and listing the instruments of modifications; the dates to which the rents and charges have been paid; and whether or not Lessee is in default hereunder, and if so, specifying the nature of the default. It is intended that any such statement delivered by Lessor pursuant to this Article24 may be relied on by the person to whom Lessee requests that such statement be addressed.

#### 25. HOLDOVER TENANCY:

If Lessee holds possession of the Premises after the Expiration Date of this Lease, Lessee shall (i) become a tenant from month to month under the provisions herein provided, but at one hundred fifty percent (150%) of the monthly Fixed Basic Rent for the last month of the Term, plus the Additional Rent, for the first two (2) months of Lessee's holding over and two hundred percent (200%) of the monthly Fixed Basic Rent for the last month of the Term, plus the Additional Rent, thereafter, which shall continue as provided in the Lease which sum shall be payable in advance on the first day of each month, and without the requirement for demand or notice by Lessor to Lessee demanding delivery of possession of said Premises, and such tenancy shall continue until terminated by Lessor, or until Lessee shall have given to Lessor, at least thirty (30) days prior to the intended date of termination, a written notice of intent to terminate such tenancy, which termination date must be as of the end of a calendar month; and (ii) indemnify Lessor against loss or liability resulting from the delay by Lessee in so surrendering the Premises including, without limitation, any claims made by any succeeding occupant founded on such delay. Lessee's obligations under this Section shall survive the expiration or sooner termination of the Lease. The time limitations described in this Article 25 shall not be subject to extension for Force Majeure.

## 26. RIGHT TO SHOW PREMISES:

Lessor may show the Premises to prospective purchasers and mortgagees; and during the twelve (12) months prior to termination of this Lease, to prospective tenants, during Building Hours on reasonable notice to Lessee.

#### 27. LESSOR'S WORK - LESSEE'S DRAWINGS:

Lessee shall accept the Premises "as is". Such term shall mean in the same condition and repair in which the prior tenant vacated such space, and Lessee shall be responsible for any demolition and removal of any improvements existing in the Premises in connection with the prior tenant's occupancy, and all other work as may be necessary to convert the Premises to Lessee's requirements. Lessor shall not be responsible for performing any work with respect to such space. Any work, changes or improvements made to such space shall be performed at Lessee's expense in accordance with the terms of Exhibit C of this Lease.

#### 28. WAIVER OF TRIAL BY JURY:

To the extent such waiver is permitted by law, the parties waive trial by jury in any action or proceeding brought in connection with this Lease or the Premises.

## 29. LATE CHARGE:

Anything in this Lease to the contrary notwithstanding, at Lessor's option, Lessee shall pay a "Late Charge" of five percent (5%) of any installment of Fixed Basic Rent or Additional Rent paid more than five (5) business days after the due date thereof, to cover the extra expense involved in handling delinquent payments, said Late Charge to be considered Additional Rent. The amount of the Late Charge to be paid by Lessee shall be reassessed and added to Lesse's obligations for each successive monthly period until paid.

Notwithstanding anything in this Section to the contrary, Lessor shall waive a Late Charge one time during each Lease Year provided, however, the installment of Fixed Basic Rent or Additional Rent so due is paid by the fifteenth (15th) day of the month.

## 30. LESSEE'S INSURANCE:

- a. Lessee covenants to provide at Lessee's cost and expense on or before the earlier of (i) the Commencement Date, or (ii) Lessee's taking actual possession for the purpose of completing any improvement work, and to keep in full force and effect during the entire Term and so long thereafter as Lessee, or anyone claiming by, through or under Lessee, shall occupy the Premises, insurance coverage as follows:
  - Commercial General Liability insurance with contractual i . liability endorsements with respect to the Premises and the business of Lessee in which Lessee shall be adequately covered under limits of liability of not less than FIVE MILLION AND 00/100 DOLLARS (\$5,000,000.00) combined single limit per occurrence for bodily or personal injury (including death) and property damage. Such insurance may be carried (x) under a blanket policy covering the Premises and other locations of Lessee, if any, provided that each such policy shall in all respects comply with this Article and shall specify that the portion of the total coverage of such policy that is allocated to the Premises is in the amounts required pursuant to this Article 30 and (y) under a primary liability policy of not less than ONE MILLION AND 00/100 DOLLARS (\$1,000,000.00) and the balance under an umbrella policy. Notwithstanding anything to the contrary contained in this Lease, the carrying of insurance by Lessee in compliance with this Article 30 shall not modify, reduce, limit or impair Lessee's obligations and liability under Article 33 hereof.

ii. Fire and Extended Coverage, Vandalism, Malicious Mischief, Sprinkler Leakage and Special Extended Coverage Insurance in an amount adequate to cover the cost of replacement of all personal property, decoration, trade fixtures, furnishings, equipment in the Premises and all contents therein. Lessor shall not be liable for any damage to such property of Lessee by fire or other peril includable in the coverage afforded by the standard form of fire insurance policy with extended coverage endorsement attached (whether or not such coverage is in effect), no matter how caused, it being understood that the Lessee will look solely to its insurer for reimbursement.

- iii. Worker's Compensation Insurance in the minimum statutory amount covering all persons employed by Lessee.
- Said limits shall be subject to periodic review and iv. Lessor reserves the right to increase said coverage limits if, in the reasonable opinion of Lessor, said coverage becomes inadequate and is less than that commonly maintained by tenants in similar buildings in the area by tenants making similar uses. On or before the Commencement Date, and thereafter at Lessor's request, Lessee shall provide Lessor evidence of the insurance coverage required herein in the form of a duplicate original insurance policy, an insurance binder (countersigned by the insurer), or Evidence of Insurance (in form ACORD 27 with respect to property insurance and ACORD 25-S with respect to liability insurance) for each of the insurance policies Lessee is required to carry in compliance with its obligations under this Lease.
- b. All of the aforesaid insurance shall (i) name Lessor as an additional insured on a primary basis; (ii) be written by one or more responsible insurance companies licensed in the State of New Jersey satisfactory to Lessor and in form satisfactory to Lessor; (iii) contain endorsements substantially as follows: "It is understood and agreed that the insurer will give to Lessor, or any successor lessor, c/o Mack-Cali Realty Corporation, 11 Commerce Drive, Cranford, New Jersey, thirty (30) days prior written notice of any material change in or cancellation of this policy."; (iv) shall be written on an "occurrence" basis and not on a "claims made" basis.
- c. Lessee shall be solely responsible for payment of premium and Lessor (or its designee) shall not be required to pay any premium for such insurance. Lessee shall deliver to Lessor at least fifteen (15) days prior to the expiration of such policy, either a duplicate original or a certificate it being the intention of the parties hereto that the insurance required under the terms hereof shall be continuous during the entire Term of this Lease and any other period of time during which pursuant to the Term hereof, said insurance is required. Any insurance carried by Lessee shall be in excess of and will not contribute with the insurance carried by Lessor for injuries or damage arising out of the Premises.
- d. Lessee agrees, at its own cost and expense, to comply with all rules and regulations of the National Fire Protection Association (NFPA) National Fire Code. If, at any time or from time to time, as a result of or in connection with any failure by Lessee to comply with the foregoing sentence or any act or omission or commission by Lessee, its employees, agents, contractors or licensees, or a result of or in connection with the use to which the Premises are put (notwithstanding that such use may be for the purposes hereinbefore permitted or that such use may have been consented to by Lessor), the fire insurance rate(s) applicable to the Premises shall be higher than that which would be applicable for a business office legally permitted therein, Lessee agrees that it will pay to Lessor as Additional Rent, such portion of the premiums for all Lessor's fire insurance policies in force with respect to the building and the contents of any occupant thereof as shall be attributable to such higher rate(s).
- e. Lessor makes no representation that the limits of liability specified to be carried by Lessee or Lessor under the terms of this Lease are adequate to protect Lessee against Lessee's undertaking under this Article 30, and in the event Lessee believes that any such insurance coverage called for under this Lease is insufficient, Lessee shall provide, at is own expense, such additional insurance as Lessee deems adequate.

- Lessor and Lessee shall procure a clause in, or endorsement on, each of their policies for fire or extended coverage insurance covering the Premises or personal property, fixtures or equipment located therein, pursuant to which the insurance company waives subrogation or consents to a waiver of right of recovery against the other party. Lessor and Lessee agree not to make claims against, or seek to recover from, the other party for loss or damage to its property or property of others covered by such insurance (or which would be covered by insurance required to be maintained hereunder). To the extent either party shall be a self-insurer, such party waives the right of recovery, if any, against the other party, its agents and employees, for loss, damages or destruction of such self-insured party's property. In the event of any conflict between the provisions of this Section 30 f. and any other provision of this Lease, the provisions of this Section 30f. shall control.
- g. Should Lessee fail to maintain the insurance coverage as set forth in this Article 30, then Lessee shall be in default hereunder and shall be deemed to have breached its covenants as set forth herein.

## 31. NO OTHER REPRESENTATIONS:

No representations or promises shall be binding on the parties hereto except those representations and promises contained herein or in some future writing signed by the party making such representation(s) or promise(s).

#### 32. QUIET ENJOYMENT:

f.

Lessor covenants that if, and so long as, Lessee pays Fixed Basic Rent, and any Additional Rent as herein provided, and performs Lessee's covenants hereof, neither Lessor nor anyone claiming by, through or under Lessor shall do anything to affect Lessee's right to peaceably and quietly have, hold and enjoy the Premises for the Term herein mentioned, subject to the provisions of this Lease.

#### 33. INDEMNITY:

Lessee shall defend, indemnify and save harmless Lessor and its agents against and from; (a) any and all claims (i) arising from (x) the conduct or management by Lessee, its subtenants, licensees, its or their employees, agents, contractors or invitees on the Premises or of any business therein, or (y) any work or thing whatsoever done, or any condition created (other than by Lessor for Lessor's or Lessee's account) in or about the Premises during the Term of this Lease, or during the period of time, if any, prior to the Commencement Date that Lessee may have been given access to the Premises, (z) any default by Lessee under the terms, covenants and conditions of this Lease or (ii) arising from any negligent or otherwise wrongful act or omission of Lessee or any of its subtenants or licensees or its or their employees, agents, contractors or invitees, and (b) all costs, expenses and liabilities including attorneys fees and disbursements incurred in or in connection with each such claim, action or proceeding brought thereon. In case any action or proceeding be brought against Lessor by reason of any such claim, Lessee, upon notice from Lessor, shall resist and defend such action or proceeding.

Lessor shall indemnify and save harmless Lessee and Lessee's shareholders, officers, directors, employees, agents and contractors (collectively, the "Lessee INDEMNITEES") from and against (a) any and all claims of whatever nature against Lessee and/or the Lessee Indemnitees (i) arising from (x) the conduct or management by Lessor, its employees, agents, contractors or invitees on the Office Building Area or the Building, or (y) any work or thing whatsoever done, or any condition created by Lessor for Lessor's or Lessee's account in or about the Office Building Area or the Building during the Term of this Lease, (z) any default by Lessor in the performance of Lessor's obligations under this Lease, or (ii) arising from any negligent or otherwise wrongful act or omission of Lessor or any of its employees, agents or contractors, and (b) all costs, expenses and liabilities including attorneys' fees and disbursements incurred in or in connection with each such claim, action or proceeding brought thereon. In case any action or proceeding be brought against Lessee by reason of any

such claim, Lessor, upon notice from Lessee, shall resist and defend such action or proceeding.

## 34. ARTICLE HEADINGS:

The article headings in this Lease and position of its provisions are intended for convenience only and shall not be taken into consideration in any construction or interpretation of this Lease or any of its provisions.

35. APPLICABILITY TO HEIRS AND ASSIGNS:

The provisions of this Lease shall apply to, bind and inure to the benefit of Lessor and Lessee, and their respective heirs, successors, legal representatives and assigns. It is understood that the term "Lessor" as used in this Lease means only the owner, a mortgagee in possession or a term lessee of the Building, so that in the event of any sale of the Building or of any lease thereof, or if a mortgagee shall take possession of the Premises, the Lessor herein shall be and hereby is entirely freed and relieved of all covenants and obligations of Lessor hereunder accruing thereafter, and it shall be deemed without further agreement that the purchaser, the term lessee of the Building, or the mortgagee in possession has assumed and agreed to carry out any and all covenants and obligations of Lessor hereunder.

#### 36. OUTSIDE PARKING SPACES:

Lessee's occupancy of the Premises shall include the use of the number of outside parking spaces as set forth in the Preamble. Lessor shall not be responsible for any damage or theft of any vehicle in the parking area and shall not be required to keep parking spaces clear of unauthorized vehicles or to otherwise supervise the use of the parking area. Lessee shall, upon request, promptly furnish to Lessor the license numbers of the cars operated by Lessee and its subtenants, licensees, invitees, concessionaires, officers and employees. If any vehicle of the Lessee, or of any subtenant, licensee, concessionaire, or of their respective officers, agents or employees, is parked in any part of the Common Facilities other than the employee parking area(s) designated therefor by Lessor, Lessee shall pay to Lessor such reasonable penalty as may be fixed by Lessor from time to time. All amounts due under the provisions of this Article 36 shall be deemed to be Additional Rent.

#### 37. LESSOR'S LIABILITY FOR LOSS OF PROPERTY:

Lessor shall not be liable for any loss of property from any cause whatsoever, including but not limited to theft or burglary from the Premises, and any such loss arising from the negligence of Lessor, its agents, servants or invitees, or from defects, errors or omissions in the construction or design of the Premises and/or the Building, including the structural and non-structural portions thereof, and Lessee covenants and agrees to make no claim for any such loss at any time.

#### 38. PARTIAL INVALIDITY:

If any of the provisions of this Lease, or the application thereof to any person or circumstances, shall to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such provision or provisions to persons or circumstances other than those as to whom or which it is held invalid or unenforceable, shall not be affected thereby, and every provision of this Lease shall be valid and enforceable to the fullest extent permitted by law.

# 39. LESSEE'S BROKER:

Lessee represents and warrants to Lessor that its broker, as defined in the Preamble is the sole broker with whom Lessee has negotiated in bringing about this Lease and Lessee agrees to indemnify and hold Lessor and its mortgagee(s) harmless from any and all claims of other

22

brokers claiming to have dealt with Lessee and expenses in connection therewith arising out of or in connection with the negotiation of or the entering into this Lease by Lessor and Lessee. In no event shall Lessor's mortgagee(s) have any obligation to any broker involved in this transaction. In the event that no broker was involved as aforesaid, then Lessee represents and warrants to the Lessor that no broker brought about this transaction, and Lessee agrees to indemnify and hold Lessor harmless from any and all claims of any broker claiming to have dealt with Lessee arising out of or in connection with the negotiations of, or entering into of, this Lease by Lessee and Lessor.

## 40. PERSONAL LIABILITY:

Notwithstanding anything to the contrary provided in this Lease, it is specifically understood and agreed, such agreement being a primary consideration for the execution of this Lease by Lessor, that there shall be absolutely no personal liability on the part of Lessor, its constituent members (to include but not be limited to, officers, directors, partners and trustees) their respective successors, assigns or any mortgagee in possession (for the purposes of this Article, collectively referred to as "Lessor"), with respect to any of the terms, covenants and conditions of this Lease, and that Lessee shall look solely to the equity of Lessor in the Building (including, without limitation, rental income and proceeds of sale, insurance and condemnation) for the satisfaction of each and every remedy of Lessee in the event of any breach by Lessor of any of the terms, covenants and conditions of this Lease to be performed by Lessor, such exculpation of liability to be absolute and without any exceptions whatsoever.

#### 41. NO OPTION:

The submission of this Lease Agreement for examination does not constitute a reservation of, or option for, the Premises, and this Lease Agreement becomes effective as a Lease Agreement only upon execution and delivery thereof by Lessor and Lessee.

## 42. DEFINITIONS:

- a. AFFILIATE -- Affiliate shall mean any corporation related to Lessee as a parent, subsidiary or brother-sister corporation so that such corporation and such party and other corporations constitute a controlled group as determined under Section 1563 of the Internal Revenue Code of 1986, as amended and as elaborated by the Treasury Regulations promulgated thereunder or any business entity in which Lessee has more than a fifty percent (50%) interest.
- b. COMMON FACILITIES -- Common Facilities shall mean the non-assigned parking areas; lobby; elevator(s); fire stairs; public hallways; public lavatories; all other general Building facilities that service all Building tenants; air conditioning rooms; fan rooms; janitors' closets; electrical closets; telephone closets; elevator shafts and machine rooms; flues; stacks; pipe shafts and vertical ducts with their enclosing walls. Lessor may at any time close temporarily any Common Facilities to make repairs or changes therein or to effect construction, repairs or changes within the Building, or to discourage non-tenant parking, and may do such other acts in and to the Common Facilities as in its judgement may be desirable to improve the convenience thereof, but shall always in connection therewith, endeavor to minimize any inconvenience to Lessee.
- c. FORCE MAJEURE -- Force Majeure shall mean and include those situations beyond Lessor's reasonable control, including by way of example and not by way of limitation, acts of God; accidents; repairs; strikes; shortages of labor, supplies or materials; inclement weather; or, where applicable, the passage of time while waiting for an adjustment or insurance proceeds. Any time limits required to be met by either party hereunder, whether specifically made subject to Force Majeure or not, except those related to the payment of Fixed Basic Rent or Additional Rent, shall, unless specifically stated to the contrary elsewhere in this Lease, be automatically extended by the number of days by which any performance called for is delayed due to Force Majeure.

LESSEE'S PERCENTAGE -- The parties agree that Lessee's Percentage, as defined in the Preamble, reflects and will be continually adjusted to reflect the ratio of the gross square feet of the area rented to Lessee (including an allocable share of all Common Facilities) [the numerator] as compared with the total number of gross square feet of the entire Building (or additional buildings that may be constructed within the Office Building Area) [the denominator] measured outside wall to outside wall, but excluding therefrom any storage areas. Lessor shall have the right to make changes or revisions in the Common Facilities of the Building so as to provide additional leasing area. Lessor shall also have the right to construct additional buildings in the Office Building Area for such purposes as Lessor may deem appropriate, and subdivide the lands for that purpose if necessary, and upon so doing, the Office Building Area shall become the subdivided lot on which the Building in which the Premises is located. However, if any service provided for in Article 23(a) or any utility provided for in Article 23(b) is separately billed or separately metered within the Building, then the square footage so billed or metered shall be subtracted from the denominator and the Lessee's proportionate share for such service and/or utility shall be separately computed, and the Base Costs for such item shall not include any charges attributable to said square footage. Lessee understands that as a result of changes in the layout of the Common Facilities from time to time occurring due to, by way of example and not by way of limitation, the rearrangement of corridors, the aggregate of all Building tenant proportionate shares may be equal to, less than or greater than one hundred percent (100%).

## 43. LEASE COMMENCEMENT:

The Rent Commencement Date of this Lease, as defined in the Preamble to this Lease, shall occur regardless of Lessee's failure to complete tenant improvement work pursuant to Exhibit C attached hereto. Lessor and Lessee shall ratify and confirm the Rent Commencement Date and Expiration Date by completing and signing Exhibit G attached hereto and made a part hereof.

#### 44. NOTICES:

d.

Any notice by either party to the other shall be in writing and shall be deemed to have been duly given only if (i) delivered personally or (ii) sent by registered mail or certified mail return receipt requested in a postage paid envelope addressed or (iii) sent by nationally recognized overnight delivery service, if to Lessee, at the Building (except that any notice to Lessee prior to the Rent Commencement Date shall be addressed to Lessee at 5 Sylvan Way, Parsippany, NJ 07054); if to Lessor, at Lessor's address as set forth above; or, to either at such other address as Lessee or Lessor, respectively, may designate in writing. Notice shall be deemed to have been duly given, if delivered personally, on delivery thereof, if mailed, upon the tenth (10th) day after the mailing thereof or if sent by overnight delivery service, the next business day.

### 45. ACCORD AND SATISFACTION:

No payment by Lessee or receipt by Lessor of a lesser amount than the rent and additional charges payable hereunder shall be deemed to be other than a payment on account of the earliest stipulated Fixed Basic Rent and Additional Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment for Fixed Basic Rent or Additional Rent be deemed an accord and satisfaction, and Lessor may accept such check or payment without prejudice to Lessor's right to recover the balance of such Fixed Basic Rent and Additional Rent or pursue any other remedy provided herein or by law.

### 46. EFFECT OF WAIVERS:

No failure by Lessor to insist upon the strict performance of any covenant, agreement, term or condition of this Lease, or to exercise any right or remedy consequent upon a breach thereof, and no acceptance of full or partial rent during the continuance of any such breach, shall constitute a waiver of any such breach or of such covenant, agreement, term or condition. No consent, or waiver, express or implied, by Lessor to or of any breach of any covenant, condition or duty of Lessee shall be construed as a consent or waiver to or of any other breach of the same or any other covenant, condition or duty, unless in writing signed by Lessor.

47. LEASE CONDITION: INTENTIONALLY OMITTED

#### 48. MORTGAGEE'S NOTICE AND OPPORTUNITY TO CURE:

Lessee agrees to give any mortgagees and/or trust deed holders, by registered mail, a copy of any notice of default served upon Lessor, provided that, prior to such notice, Lessee has been notified in writing (by way of notice of assignment of rents and leases or otherwise) of the address of such mortgagees and/or trust deed holders. Lessee further agrees that, if Lessor shall have failed to cure such default within the time provided for in this Lease, then the mortgagees and/or trust deed holders shall have an additional thirty (30) days within which to cure such default, or if such default cannot be cured within that time, then such additional time as may be necessary, if within such thirty (30) days, any mortgagee and/or trust deed holder has commenced and is diligently pursuing the remedies necessary to cure such default (including but not limited to commencement of foreclosure proceedings if necessary to effect such cure), in which event this Lease shall not be terminated while such remedies are being so diligently pursued.

#### 49. LESSOR'S RESERVED RIGHT:

Lessor and Lessee acknowledge that the Premises are in a Building which is not open to the general public. Access to the Building is restricted to Lessor, Lessee, their agents, employees and contractors and to their invited visitors. In the event of a labor dispute including a strike, picketing, informational or associational activities directed at Lessee or any other tenant, Lessor reserves the right unilaterally to alter Lessee's ingress and egress to the Building or make any change in operating conditions to restrict pedestrian, vehicular or delivery ingress and egress to a particular location.

#### 50. CORPORATE AUTHORITY:

If Lessee is a corporation, Lessee represents and warrants that this Lease has been duly authorized and approved by the corporation's Board of Directors. The undersigned officers and representatives of the corporation represent and warrant that they are officers of the corporation with authority to execute this Lease on behalf of the corporation, and within fifteen (15) days of execution hereof, Lessee will provide Lessor with a corporate resolution confirming the aforesaid.

#### 51. AFTER-HOURS USE:

Lessee shall be entitled to make use of said Standard Electric Service and HVAC beyond the Building Hours, at Lessee's sole cost and expense, provided Lessee shall notify the Lessor by 3:00 p.m. on the day that Lessee shall require said overtime use if said overtime use is required on any weekday, and by 3:00 p.m. on Friday for Saturday and/or Sunday overtime use. It is understood and agreed that Lessee shall pay the sum of SEVENTY-FIVE AND 00/100 DOLLARS (\$75.00) per hour per zone for air-conditioning service and SIXTY AND 00/100 DOLLARS (\$60.00) per hour per zone for heating services, plus such additional percentage increase of the aforesaid hourly sum computed by measuring the percentage increase between the rate in effect (including fuel surcharges or adjustments) during the month for which such overtime use is requested and the Base Rate. The Base Rate for purposes hereof shall be the average of the rates in effect (including surcharges and/or adjustments) during Calendar Year 2003.

25

In no event shall the Lessee pay less than the sum of SEVENTY-FIVE AND 00/100 DOLLARS (\$75.00) per hour per zone for such overtime air-conditioning service or less than SIXTY AND 00/100 DOLLARS (\$60.00) per hour per zone for such overtime heating service.

#### 52. LESSEE'S EXPANSION/RELOCATION: INTENTIONALLY OMITTED

53. BUILDING PERMIT:

Intentionally Omitted.

- 54. OPTION TO RENEW
  - (a) If the term of this Lease shall then be in full force and effect and Lessee is not in default hereunder beyond applicable notice and grace periods, Lessee shall have the option to extend the term of this Lease for a period of five (5) years (the "Renewal Term") commencing on the day immediately following the Expiration Date, provided however that Lessee shall give Lessor notice of its election to extend the term no earlier than eighteen (18) months prior to the Expiration Date nor later than nine (9) months prior to the Expiration Date of the initial term. TIME BEING OF THE ESSENCE in connection with the exercise of Lessee's option pursuant to this Article.
  - Such extension of the term of this Lease shall be upon the same (b) covenants and conditions, as herein set forth except: (i) for the Fixed Basic Rent (which shall be determined in the manner set forth below), (ii) the Base Period Costs shall be re-set to be those incurred in the first year of the Renewal Term, and (iii) that Lessee shall have no further right to extend the term of this Lease after the exercise of the single option described in paragraph (a) of this Section. If Lessee shall duly give notice of its election to extend the term of this Lease, the Renewal Term shall be added to and become a part of the Term of this Lease (but shall not be considered a part of the initial Term), and any reference in this Lease to the "Term of this Lease", the "Term hereof", or any similar expression shall be deemed to include such Renewal Term, and, in addition, the term "Expiration Date" shall thereafter mean the last day of such Renewal Term. Lessor shall have no obligation to perform any alteration or preparatory or other work in and to the Premises and Lessee shall continue possession thereof in its "as is" condition
  - (c) If Lessee exercises its option for the Renewal Term, the Fixed Basic Rent during the Renewal Term shall be the fair market rent for the Premises, as hereinafter defined.
  - (d) Lessor and Lessee shall use their best efforts, within thirty (30) days after Lessor receives Lessee's notice of its election to extend the Term of this Lease for the Renewal Term ("Negotiation Period"), to agree upon the Fixed Basic Rent to be paid by Lessee during the Renewal Term. If Lessor and Lessee shall agree upon the Fixed Basic Rent for the Renewal Term, the parties shall promptly execute an amendment to this Lease stating the Fixed Basic Rent for the Renewal Term.
  - (e) If the parties are unable to agree on the Fixed Basic Rent for the Renewal Term during the Negotiation Period, then within fifteen (15) days after notice from the other party, given after expiration of the Negotiation Period, each party, at its cost and upon notice to the other party, shall appoint a person to act as an appraiser hereunder, to determine the fair market rent for the Premises for the Renewal Term. Each such person shall be a real estate broker or appraiser with at least ten years' active commercial real estate appraisal or brokerage experience (involving the leasing of office space as agent for both landlords and lessees) in the County of Morris. If a party does not appoint a person to act as an appraiser within said fifteen (15) day period, the person appointed by the other party shall be the sole appraiser and shall determine the aforesaid fair market rent. Each notice containing the name of a person to act as appraiser shall contain also the person's address. Before proceeding to establish the fair market rent, the appraisers shall subscribe and swear to an oath fairly and impartially to determine such rent.

If the two appraisers are appointed by the parties as stated in the immediately preceding paragraph, they shall meet promptly and attempt to determine the fair market rent. If they are unable to agree within forty-five (45) days after the appointment of the second appraiser, they shall attempt to select a third person meeting the qualifications stated in the immediately preceding paragraph within fifteen (15) days after the last day the two appraisers are given to determine the fair market rent. If they are unable to agree on the third person to act as appraiser within said fifteen (15) day period, the third person shall be appointed by the American Arbitration Association (the "Association"), upon the application of Lessor or Lessee to the office of the Association nearest the Building. The person appointed to act as appraiser by the Association shall be required to meet the qualifications stated in the immediately preceding paragraph. Each of the parties shall bear fifty percent (50%) of the cost of appointing the third person and of paying the third person's fees. The third person, however selected, shall be required to take an oath similar to that described above.

The three appraisers shall meet and determine the fair market rent. A decision in which two of the three appraisers concur shall be binding and conclusive upon the parties. In deciding the dispute, the appraisers shall act in accordance with the rules then in force of the Association, subject however, to such limitations as may be placed on them by the provisions of this Lease.

Notwithstanding the foregoing, in no event shall the Fixed Basic Rent during the Renewal Term be less than the Fixed Basic Rent during the last year of the initial Term of this Lease.

- (f) After the fair market rent for the Renewal Term has been determined by the appraiser or appraisers and the appraiser or appraisers shall have notified the parties, at the request of either party, both parties shall execute and deliver to each other an amendment of this Lease stating the Fixed Basic Rent for the Renewal Term.
- (q) If the Fixed Basic Rent for the Renewal Term has not been agreed to or established prior to the commencement of the Renewal Term, then Lessee shall pay to Lessor an annual rent ("Temporary Rent") which Temporary Rent shall be equal to the Fixed Basic Rent payable by Lessee for the last year of the initial Term. Thereafter, if the parties shall agree upon a Fixed Basic Rent, or the Fixed Basic Rent shall be established upon the determination of the fair market rent by the appraiser or appraisers, at a rate at variance with the Temporary Rent (i) if such Fixed Basic Rent is greater than the Temporary Rent, Lessee shall promptly pay to Lessor the difference between the Fixed Basic Rent determined by agreement or the appraisal process and the Temporary Rent, or (ii) if such Fixed Basic Rent is less than the Temporary Rent, Lessor shall credit to Lessee's subsequent monthly installments of Fixed Basic Rent the difference between the Temporary Rent and the Fixed Basic Rent determined by agreement or the appraisal process.
- (h) In describing the fair market rent during the Renewal Term, the appraiser or appraisers shall be required to take into account the rentals at which leases are then being concluded (as of the last day of the initial Term) (for five (5) year leases without renewal options with the lessor and lessee each acting prudently, with knowledge and for self-interest, and assuming that neither is under undue duress) for as-is comparable space in the Building and in comparable office buildings in the County of Morris, without a Lessor contribution for tenant fit-up but with new base years.

#### 55. RIGHT OF FIRST OFFER

a. i. Subject to the provisions of this Article, Lessee shall have the option to lease from Lessor space on the east wing of the second (2nd) floor as shown on the attached floor plan, ("Additional Space") at the expiration of the existing space lease(s) for such Additional Space, or to the extent any portion of the Additional Space is presently vacant, at the expiration of the initial lease for such vacant space. If the Term of this Lease shall be in full force and effect on the expiration or termination date of the existing space lease(s) or initial space lease, as the case may be, for the Additional Space, subject to Lessor's right to

renew such lease(s), and the date upon which Lessee shall exercise the option hereinafter referred to, Lessee shall have the option to lease all, but not less than all of the Additional Space on an as-is basis, provided Lessee gives Lessor written notice of such election within fifteen (15) business days after Lessee shall receive Lessor's notice that such Additional Space is available for leasing to Lessee. If Lessee fails or refuses to exercise this option within the time period set forth above (TIME BEING OF THE ESSENCE), then and in such event Lessee shall have no further rights under this Section with respect to such Additional Space. If Lessee shall elect to lease said Additional Space: (v) said Additional Space shall be deemed incorporated within and part of the Premises on the date that Lessor shall notify Lessee that such Additional Space is ready for occupancy by Lessee and shall expire on the Expiration Date of this Lease, (x) the Fixed Basic Rent payable under this Lease shall be increased by an amount such that during the balance of the term of this Lease the Fixed Basic Rent for said Additional Space shall be the then fair market rent for the Additional Space, as determined in the manner set forth in clause (ii) below, (y) Lessee's Percentage Share shall be proportionately increased, and (z) all other terms and provisions set forth in this Lease shall apply, except that Lessor not be required to perform any work with respect to said Additional Space.

The parties shall promptly execute an amendment of this Lease confirming Lessee's election to lease said Additional Space and the incorporation of said Additional Space into the Premises.

ii. Lessor and Lessee shall use their best efforts, within thirty (30) days after Lessor receives Lessee's notice of its election to lease said Additional Space, ("Negotiation Period") to agree upon the Fixed Basic Rent to be paid by Lessee for said Additional Space. If Lessor and Lessee shall agree upon the Fixed Basic Rent, the parties shall promptly execute an amendment to this Lease stating the Fixed Basic Rent for the Additional Space.

> If the parties are unable to agree on the Fixed Basic Rent for said Additional Space during the Negotiation Period, then within fifteen (15) days notice from the other party, given after expiration of the Negotiation Period, each party, at its cost and upon notice to the other party, shall appoint a person to act as an appraiser hereunder, to determine the fair market rent for the Additional Space. Each such person shall be a real estate broker or appraiser with at least ten (10) years' active commercial real estate appraisal or brokerage experience (involving the leasing of similar space as agent for both landlords and tenants) in Morris County. If a party does not appoint a person to act as an appraiser within said fifteen (15) day period, the person appointed by the other party shall be the sole appraiser and shall determine the aforesaid fair market rent. Each notice containing the name of a person to act as appraiser shall contain the person's address. Before proceeding to establish the fair market rent, the appraisers shall subscribe and swear to an oath fairly and impartially to determine such rent.

> If the two appraisers are appointed by the parties as stated in the immediately preceding paragraph, they shall meet promptly and attempt to determine the fair market rent. If they are unable to agree within forty-five (45) days after the appointment of the second appraiser, they shall attempt to select a third person meeting the qualifications stated in the immediately preceding paragraph within fifteen (15) days after the last day the two appraisers are given to determine the fair market rent. If they are unable to agree on the third person to act as appraiser within said fifteen (15) day period, the third person shall be appointed by the American Arbitration Association, upon the application of Lessor or Lessee to the office of the Association nearest the Building. The person appointed to act as appraiser by the Association shall be required to meet the qualifications stated in the immediately preceding paragraph. Each of the parties shall bear fifty percent (50%) of the cost of appointing the third person and of paying the third person's fees. The third person, however selected, shall be required to take an oath similar to that described above.

The three appraisers shall meet and determine the fair market rent. A decision  $% \left( {{{\left[ {{{A_{\rm{s}}}} \right]}_{\rm{s}}}_{\rm{s}}} \right)$ 

in which two of the three appraisers concur shall be binding and conclusive upon the parties. In deciding the dispute, the appraisers shall act in accordance with the rules then in force of the American Arbitration Association, subject however, to such limitations as may be placed on them by the provisions of this Lease.

After the Fixed Basic Rent for the Additional Space has been determined by the appraiser or appraisers and the appraiser or appraisers shall have notified the parties, at the request of either party, both parties shall execute and deliver to each other an amendment of this Lease stating the Fixed Basic Rent for the Additional Space.

If the Fixed Basic Rent for said Additional Space has not been agreed to or established prior to the incorporation of said Additional Space in the Premises, then Lessee shall pay to Lessor an annual rent ("Temporary Rent") which Temporary Rent on a per square foot basis shall be equal to the Fixed Basic Rent, on a per square foot basis, then being paid by Lessee for the Premises.

Thereafter, if the parties shall agree upon a Fixed Basic Rent, or the Fixed Basic Rent shall be established upon the determination of the fair market rent by the appraiser or appraisers, at a rate at variance with the Temporary Rent (i) if such Fixed Basic Rent is greater than the Temporary Rent, Lessee shall promptly pay to Lessor the difference between the Fixed Basic Rent determined by agreement or the appraisal process and the Temporary Rent, or (ii) if such Fixed Basic Rent is less than the Temporary Rent, Lessor shall credit to Lessee's subsequent monthly installments of Fixed Basic Rent the difference between the Temporary Rent and the Fixed Basic Rent determined by agreement or the appraisal process.

In determining the fair market rent for said Additional Space, the appraiser or appraisers shall be required to take into account the rentals at which leases are then being concluded for comparable space in the Building and in comparable buildings in the County of Morris, New Jersey, without a Lessor contribution for tenant fit-up. In no event shall the Fixed Basic Rent for the Additional Space, on a per square foot basis, be less than the Fixed Basic Rent for the Premises, on a per square foot basis.

The option granted to Lessee under this Article 55 may b. be exercised only by Lessee, its permitted successors and assigns, and not by any subtenant or any successor to the interest of Lessee by reason of any action under the Bankruptcy Code, or by any public officer, custodian, receiver, United States Trustee, trustee or liquidator of Lessee or substantially all of Lessee's property. Lessee shall have no right to exercise any of such options subsequent to the date Lessor shall have the right to give the notice of termination referred to in Article 13. Notwithstanding the foregoing, Lessee shall have no right to exercise the option granted to Lessee hereunder if, at the time it gives notice of such election (i) Lessee shall not be in occupancy of substantially all of the Premises or (ii) the Premises or any part thereof shall be the subject of a sublease. If Lessee shall have elected to exercise its option hereunder, such election shall bee deemed withdrawn if, at any time after the giving of notice of such election and prior to the occupancy of the Additional Space, Lessee shall sublease all or any part of the Premises.

### 56. ROOF RIGHTS.

Without limiting any other provision of this Lease, Lessee shall have the non-exclusive right to install one satellite dish ( the "Dish") and a supplemental air conditioning unit for the Premises (the "Air Conditioner" and, together with the Dish, the "Facilities") on the roof of the Building (including necessary connection to the Demised Premises) for use by Lessee, provided any such installations shall be subject to Lessor's prior consent, which consent shall not be unreasonably withheld, conditioned or delayed. Any such Facilities shall be installed in accordance with all applicable laws and building codes. Lessee shall remove such Facilities at the expiration or earlier termination of the Lease; provided Lessee shall repair any damage to the roof caused by such removal. Prior to making any installations on the roof of the Building, Lessee shall use a roofing contractor for all work to be performed by Lessee on the roof of the Building approved by Lessor, which approval shall not be unreasonably withheld.

Lessee shall furnish detailed plans and specifications for the Facilities (or any modifications thereof) to Lessor for its approval. The parties agree that Lessee's use of the rooftop of the Building is a non-exclusive use and Lessor may permit the use of any other portion of the roof to any other person for any use including installation of other satellite dishes, antennas and support equipment. Lessee shall use its reasonable efforts to insure that its use of the rooftop does not impair such other person's data transmission and reception via its respective antennas and support equipment. If Lessee's construction, installation, maintenance, repair, operation or use of the Dish shall interfere with the rights of Lessor (including, without limitation, Lessor's right to reasonably use the remainder of the roof) or other lessees in the Building, Lessee shall cooperate with Lessor or such other lessees in eliminating such interference; provided, however, the cost of remedying such interference shall be borne by the party which is suffering such interference, unless such party was not suffering such interference prior to the use of the Dish causing such interference by Lessee, in which case the cost of remedying such interference shall be borne by Lessee. Lessee shall secure and keep in full force and effect, from and after the time Lessee begins construction and installation of the Facilities, such supplementary insurance with respect to the Facilities as Lessor may reasonably require, provided that the same shall not be in excess of that which would customarily be required from time to time by Lessors of buildings of similar class and character in Morris County, New Jersey with respect to similar installations.

In connection with the installation, maintenance and operation of the Facilities , Lessee, at Lessee's sole cost and expense, shall comply with all legal requirements and shall procure, maintain and pay for all permits required therefor, and Lessor makes no warranties whatsoever as to the permissibility of the Facilities under applicable legal requirements or the suitability of the roof of the Building for the installation thereof. If Lessor's structural engineer deems it advisable that there be structural reinforcement of the roof in connection with the installation of the Facilities, Lessor shall perform same at Lessee's cost and expense and Lessee shall not perform any such installation prior to the completion of any such structural reinforcement. The installation of the Facilities shall be subject to the provisions of Articles 5 and 6 applicable to alterations and installations. For the purpose of installing, servicing or repairing the Facilities, Lessee shall have access to the rooftop of the Building, upon reasonable notice to Lessor, and Lessor shall have the right to require, as a condition to such access, that Lessee (or its employee, contractor or other representative) at all times be accompanied by a representative of Lessor. Lessee shall pay for all electrical service required for Lessee's use of the Facilities, in accordance with the provision set forth in Article 22 hereof.

Lessee, at its sole cost and expense, shall promptly repair any and all damage to the rooftop or to any other part of the Building caused by the installation, maintenance and repair, operation or removal of the Facilities. Lessee shall be responsible for all costs and expense for repairs of the roof which result from Lessee's use of the roof for the construction, installation, maintenance, repair, operation and use of the Facilities. All installations made by Lessee on the rooftop or in any other part of the Building pursuant to the provisions of this Article 56 shall be at the sole risk of Lessee, and neither Lessor, nor any agent or employee of Lessor, shall be responsible or liable for any injury or damage to, or arising out of, the Facilities. Lessee's indemnity under Article 33 shall apply with respect to the installation, maintenance, operations, presence or removal of the Facilities by Lessee.

Upon the expiration of the Term, the Facilities shall be removed by Lessee at its sole cost and expense, and Lessee shall repair any damage to the rooftop or any other portions of the Building to substantially their condition immediately prior to Lessee's installation of the Facilities (ordinary wear and tear excepted).

Notwithstanding anything to the contrary contained in this Article 56, Lessor shall have the right, at Lessor's expense, on not less than thirty (30) days' prior notice, to relocate the Facilities to another location on the roof of the Building, such expense to include, without limitation, the removal of the existing Facilities, the purchasing of labor, materials and equipment necessary for the relocation thereof and the reinstallation of the Facilities at such other location as reasonably designated by Lessor on the roof of the Building, provided that Lessor does not, except if work is reasonably required to be performed on the roof or in the

Building, either materially interfere with or adversely affect the receipt of and/or transmittal of microwaves or other similar signals, and Lessee shall cooperate in all reasonable respects with Lessor in any such relocations; provided, however, that if such relocation is done pursuant to any legal requirement, the cost thereof shall be borne by Lessee (unless such legal requirement relates to, or results from, other actions taken, or permitted to be taken, by Lessor, in which event Lessor shall bear all of the costs and expenses of such relocation).

The rights granted in this Article 56 are given in connection with, and as part of the rights created under this Lease and are not separately transferable or assignable.

If the installation of the Facilities or act or omission relating thereto should revoke, negate or in any manner impair or limit any roof warranty or guaranty obtained by Lessor, then Lessee shall reimburse Lessor for any loss or damage sustained or costs or expenses incurred by Lessor as a result of such impairment or limitation.

### 57. LESSOR'S INSURANCE:

During the Term, Lessor shall maintain the following insurance, insuring Lessor and any mortgagee, as their respective interests may appear: (x) insurance against damage to the Building and Office Building Area by all risks of direct physical loss in an amount equivalent to the full replacement cost thereof; (y) comprehensive general liability insurance against claims for bodily injury and property damage occurring in or about the Common Facilities in amounts customarily carried by owners of similar buildings in the Morris County, New Jersey area; and (z) insurance against such other hazards as, from time to time, are then commonly insured against for buildings similarly situated in amounts normally carried with respect thereto. All insurance maintained pursuant to this Article 57 may be effected by blanket insurance policies.

#### 58. OTHER AGREEMENTS:

Lessor shall deliver to Lessee, upon the execution of this Lease, the written agreement of Mack-Cali Morris Realty L.L.C. ("MCMR"), in form and substance reasonably satisfactory to Lessee, providing for: (i) effective as of the Rent Commencement Date of this Lease, the termination of that certain Lease, dated August 15, 2000, by and between MCMR and The Medicines Company ("TMC"), and that certain Lease, dated February 28, 2000, between MCMR and Stack Pharmaceuticals, Inc., assigned to TMC by Assignment and Assumption of Lease dated October 18, 2001, relating to premises located at 5 Sylvan Way, Parsippany, New Jersey, in each case as if such termination were occurring upon the respective expiration dates of such leases, and (ii) the extension of the term of that certain Storage Space License, dated October 12, 2001, between MCMR and TMC until the earlier of (x) the Expiration Date of this Lease, or (y) such date as storage space, similar in size and quality to the space which is the subject of such license, shall be available in the Building for use by Lessee. If storage space in the Building shall become available for leasing, Lessor shall use commercially reasonable efforts to notify Lessee and Lessee shall have fifteen (15) business days to accept Lessor's offer upon the terms and conditions set forth in Lessor's offer. A failure of Lessor to notify Lessee of the availability of such storage space shall not constitute default under this Lease.

31

EACH PARTY AGREES that it will not raise or assert as a defense to any obligation under this Lease or make any claim that this Lease is invalid or unenforceable due to any failure of this document to comply with ministerial requirements including, but not limited to, requirements for corporate seals, attestations, witnesses, notarizations, or other similar requirements, and each party hereby waives the right to assert any such defense or make any claim of invalidity or unenforceability due to any of the foregoing.

IN WITNESS WHEREOF, the parties hereto have hereunto set their hands and seals the day and year first above written.

# LESSOR:

## LESSEE:

SYLVAN/ CAMPUS REALTY L.L.C

THE MEDICINES COMPANY

- By: Grove Street Associates of Jersey City Limited Partnership, member
- By: Mack-Cali Sub IV, Inc., its general partner
- By: /s/ Steven H. Koehler Name: Steven H. Koehler

Title: Chief Financial Officer

32

EXHIBIT A

# LOCATION OF PREMISES

#### Exhibit A - Page 1

#### EXHIBIT A-1

## OFFICE BUILDING AREA

All that certain lot, piece or parcel of land, with the buildings and improvements thereon erected, situate, lying and being in the Township of Parsippany-Troy Hills, County of Morris, State of New Jersey:

BEGINNING at an iron pipe at a corner common to Lot 3.10 and Lot 3.11 Block 202 on the easterly right-of-way line of Hilton Court as shown on a map entitled "Final Plat of Prudential Business Campus, Block 202, Lots 3.02 thru 3.12 Tax Map Sheet Nos. 62 & 63, 66 & 67, 69 & 70, situated in Parsippany-Troy Hills Township, Morris County, New Jersey, Sheet 1 of 2" prepared by Henderson and Bodwell, Russell S. Bodwell, P.E. & L.S., N.J. License No. 8456. Said map being filed in the Morris County Clerk's Office on April 29, 1980 as Map #3908; thence

- Along the easterly right-of-way line of Hilton Court on the arc of a curve to the left having a radius of 525.00 feet, an arc length of 118.00 feet and a central angle of 12? 52' 40" to a point of tangency; thence
- Continuing along same, N 08? 47' 00" E 490.89 feet to a point of curvature; thence
- 3. Along the arc of a curve to the right having a radius of 90.00 feet, an arc length of 141.37 feet and a central angle of 90? 00' 00" to a concrete monument at a point of tangency on the southerly right-of-way line of Campus Drive; thence
- 4. Along same, S 81 (degree) 12' 00" E 455.00 feet to a concrete monument at a point of curvature; thence
- 5. Along the arc of a curve to the right having a radius of 40.00 feet, an arc length of 62.83 feet and a central angle of 90 (degree) 00' 00", to a concrete monument at a point of tangency; thence along the westerly right-of-way line of Dryden Way on the following three courses:
- 6. S 08 (degree) 47' 00" W 704.33 feet to a concrete monument; thence
- 7. N 81 (degree) 13' 00" W 2.00 feet to a concrete monument; thence
- 8. S 08 (degree) 47' 00" W 89.88 feet to an iron pipe; thence
- 9. Along a line common to Lot 3.10 and Lot 3.11, Block 202, N 68 (degree) 20' 20" W 611.59 feet to the point of BEGINNING.

All that certain tract, or parcel of land and premises, hereinafter particularly described, situate, lying and being in the Township of Parsippany-Troy Hills, in the County of Morris, and the State of New Jersey:

BEGINNING at the point of intersection of the projection of the westerly sideline of Parsippany Road and the northerly sideline of Eastman's Road, running thence South 85 (degree) 19' 57" West 96.53 feet to the true point Of the beginning and running thence;

- (1) Along the northerly sideline of said Eastman's Road, 60 feet wide, South 85 (degree) 19' 57" West 393.30 feet; thence
- (2) North 53 (degree) 22' 15" West 238.00 feet; thence
- (3) North 50 (degree) 43' 10" West 216.33 feet; thence
- (4) North 39 (degree) 16'50" East 134.14 feet along southeasterly sideline of Interstate Route 287 (formerly U.S. Route 202) as shown on a plat entitled "New Jersey State Highway Department General Property Parcel Map Route U.S. 202 Freeway Section 1" sheets 1 through 4 dated December, 1953 and filed in the Morris County Clerk's Office on February 18, 1955 as Map No. 1560-F; thence

Exhibit A - Page 1

- (5) At right angles to said Interstate Route 287 South 50 (degree) 43' 10" East 5.00 feet; thence
- (6) At right angles to the previous course and along the southerly sideline of said Interstate 287 as shown on a plat entitled "New Jersey State Highway Department General Property Parcel Map Route U.S. 202 Freeway Section 1" sheets 1 through 4 dated December, 1953 and filed in the Morris County Clerk's Office on February 18, 1955 as Map No. 1560-F, North 39 (degree) 16' 50" East 355.00 feet; thence
- (7) Leaving the southeasterly sideline of said Interstate Route 287, North 85 (degree) 16' 50" East 135.00 feet; thence
- (8) South 67 (degree) 43' 10" East 145.00 feet; thence
- (9) South 50 (degree) 43' 10" East 105.00 feet; thence
- (10) South 30 (degree) 43' 10" East 75.00 feet; thence
- (11) South 18 (degree) 24' 25" East 361.30 feet along the westerly sideline of Parsippany Road; thence
- (12) Along the westerly sideline of Parsippany Road, South 17 (degree) 35' 00" East 44.13 feet; thence
- (13) South 51 (degree) 30' 00" West 100.73 feet; to the point of BEGINNING.

The forgoing premises are shown on a survey make by Couvrette Associates Inc. Consulting Engineers, Rockaway, New Jersey, dated September 21, 1978, last revised to April 1, 1992 showing Lot 1, Block 738, Tax Maps Township of Parsippany-Troy Hills, Morris County, New Jersey.

The foregoing survey reference shall not be deemed or construed to limit or diminish the estate more particularly described above and encumbered hereby.

Exhibit A - Page 2

# EXHIBIT B

### RULES AND REGULATIONS

- 1. OBSTRUCTION OF PASSAGEWAYS: The sidewalks, entrance, passages, courts, elevators, vestibules, stairways, corridors and public parts of the Building shall not be obstructed or encumbered by Lessee or used by Lessee for any purpose other than ingress and egress. If the Premises are situated on the ground floor with direct access to the street, then Lessor shall, at Lessor's expense, keep the sidewalks and curbs directly in front of the Premises clean and free from ice, snow and refuse.
- 2. WINDOWS: Windows in the Premises shall not be covered or obstructed by Lessee. No bottles, parcels or other articles shall be placed on the windowsills, in the halls, or in any other part of the Building other than the Premises. No article shall be thrown out of the doors or windows of the Premises.
- 3. PROJECTIONS FROM BUILDING: No awnings, air-conditioning units, or other fixtures shall be attached to the outside walls or the window sills of the Building or otherwise affixed so as to project from the Building, without prior written consent of Lessor.
- 4. SIGNS: No sign or lettering shall be affixed by Lessee to any part of the outside of the Premises, or any part of the inside of the Premises so as to be clearly visible from the outside of the Premises, without the prior written consent of Lessor, which consent shall not be unreasonably withheld or delayed. However, Lessee shall have the right to place its name on any door leading into the Premises the size, color and style thereof to be subject to the Lessor's approval. Lessee shall not have the right to have additional names placed on the Building directory without Lessor's prior written consent.
- 5. FLOOR COVERING: Lessee shall not lay linoleum or other similar floor covering so that the same shall come in direct contact with the floor of the Premises. If linoleum or other similar floor covering is desired to be used, an interlining of builder's deadening felt shall first be fixed to the floor by a paste or other material that may easily be removed with water, the use of cement or other similar adhesive material being expressly prohibited.
- 6. INTERFERENCE WITH OCCUPANTS OF BUILDING: Lessee shall not make, or permit to be made, any unseemly or disturbing noises or odors and shall not interfere with other tenants or those having business with them. Lessee will keep all mechanical apparatus in the Premises free of vibration and noise which may be transmitted beyond the limits of the Premises.
- 7. LOCK KEYS: No additional locks or bolts of any kind shall be placed on any of the doors or windows by Lessee. Lessee shall, on the termination of Lessee's tenancy, deliver to Lessor all keys to any space within the Building either furnished to or otherwise procured by Lessee, and in the event of the loss of any keys furnished, Lessee shall pay to Lessor the cost thereof. Lessee, before closing and leaving the Premises, shall ensure that all windows are closed and entrance doors locked. Nothing in this Paragraph 7 shall be deemed to prohibit Lessee from installing a burglar alarm within the Premises, provided: (1) Lessee obtains Lessor's consent which will not be unreasonably withheld or delayed; (2) Lessee supplies Lessor with copies of the plans and specifications of the system; (3) such installation shall not damage the Building; and (4) all costs of installation shall be borne solely by Lessee.
- 8. CONTRACTORS: No contract of any kind with any supplier of towels, water, toilet articles, waxing, rug shampooing, venetian blind washing, furniture polishing, lamp servicing, cleaning of electrical fixtures, removal of waste paper, rubbish, garbage, or other like service shall be entered into by Lessee, nor shall any machine of any kind be installed in the Building or the Office Building Area (other than ordinary office equipment) without the prior written consent of the Lessor. Lessee shall not employ any persons other than Lessor's janitors for the purpose of cleaning the Premises without prior written consent of Lessor. Lessor shall not be responsible to Lessee for any loss of property from the Premises however occurring, or for any damage to the effects of Lessee by such janitors or any of its employees, or by any other person or any other cause.

Exhibit B - Page 1

- 9 PROHIBITED ON PREMISES: Lessee shall not conduct, or permit any other person to conduct, any auction upon the Premises, manufacture or store goods, wares or merchandise upon the Premises without the prior written approval of Lessor, except the storage of usual supplies and inventory to be used by Lessee in the conduct of his business, permit the Premises to be used for gambling, make any unusual noises in the Building, permit to be played musical instrument on the Premises, permit any radio to be played, or television, recorded or wired music in such loud manner as to disturb or annoy other tenants, or permit any unusual odors to be produced on the Premises. Lessee shall not permit any portion of the Premises to be occupied as an office for a public stenographer or typewriter, or for the storage, manufacture, or sale of intoxicating beverages, narcotics, tobacco in any form or as a barber or manicure shop. Canvassing, soliciting and peddling in the Building and the Office Building Area are prohibited and Lessee shall cooperate to prevent the same. No bicycles, vehicles or animals of any kind shall be brought into or kept in or about the Premises.
- 10. PLUMBING, ELECTRIC AND TELEPHONE WORK: Plumbing facilities shall not be used for any purpose other than those for which they were constructed; and no sweepings, rubbish, ashes, newspaper or other substances of any kind shall be thrown into them. Waste and excessive or unusual amounts of electricity or water is prohibited. When electric wiring of any kind is introduced, it must be connected as directed by Lessor, and no stringing or cutting of wires will be allowed, except by prior written consent of Lessor, and shall be done by contractors approved by Lessor. The number and locations of telephones, telegraph instruments, electrical appliances, call boxes, etc. shall be subject to Lessor's approval.
- 11. MOVEMENT OF FURNITURE, FREIGHT OR BULKY MATTER: The carrying in or out of freight, furniture or bulky matter of any description must take place during such hours as Lessor may from time to time reasonably determine and only after advance notice to the superintendent of the Building. The persons employed by Lessee for such work must be reasonably acceptable to the Lessor. Lessee may, subject to these provisions, move freight, furniture, bulky matter, and other material into or out of the Premises on Saturdays between the hours of 9:00 a.m. and 1:00 p.m., provided Lessee pays additional costs, if any, incurred by Lessor for elevator operators or security guards, and for any other expenses occasioned by such activity of Lessee. If, at least three (3) days prior to such activity, Lessor requests that Lessee deposit with Lessor, as security of Lessee's obligations to pay such additional costs, a sum of which Lessor reasonably estimates to be the amount of such additional cost, the Lessee shall deposit such sum with Lessor as security of such cost. There shall not be used in the Building or Premises, either by Lessee or by others in the delivery or receipt of merchandise, any hand trucks except those equipped with rubber tires and side guards, and no hand trucks will be allowed in the elevators without the consent of the superintendent of the Building.
- 12. SAFES AND OTHER HEAVY EQUIPMENT: Lessor reserves the right to prescribe the weight and position of all safes and other heavy equipment so as to distribute properly the weight thereof and to prevent any unsafe condition from arising.
- 13. ADVERTISING: Lessor shall have the right to prohibit any advertising by Lessee which in Lessor's reasonable opinion tends to impair the reputation of the Building or its desirability as a building for offices, and upon written notice from Lessor, Lessee shall refrain from or discontinue such advertising.
- 14. NON-OBSERVANCE OR VIOLATION OF RULES BY OTHER TENANTS: Lessor shall not be responsible to Lessee for non-observance or violation of any of these rules and regulations by any other tenant.
- 15. AFTER HOURS USE: Lessor reserves the right to exclude from the Building between the hours of 6:00 p.m. and 8:00 a.m. and at all hours on Saturdays, Sundays and Building Holidays, all persons who do not present a pass to the Building signed by the Lessee. Each Lessee shall be responsible for all persons for whom such a pass is issued and shall be liable to the Lessor for the acts of such persons.
- 16. PARKING: Lessee and its employees shall park their cars only in those portions of the parking area designated by Lessor.

Exhibit B - Page 2

- 17. Lessor hereby reserves to itself any and all rights not granted to Lessee hereunder, including, but not limited to, the following rights which are reserved to Lessor for its purposes in operating the Building:
  - a) the exclusive right to the use of the name of the Building for all purposes, except that Lessee may use the name as its business address and for no other purposes; and
  - b) the right to change the name or address of the Building, without incurring any liability to Lessee for doing so; and
  - c) the right to install and maintain a sign on the exterior of the Building; and
  - d) the exclusive right to use or dispose of the use of the roof of the Building; and
  - e) the right to limit the space on the directory of the Building to be allotted to Lessee; and
  - f) the right to grant to anyone the right to conduct any particular business or undertaking in the Building.
- 18. The Lessee shall be responsible for initiating, maintaining and supervising all health and safety precautions and/or programs required by Law in connection with the Lessee's use and occupancy of the Premises.
- 19. The Lessee shall not store, introduce or otherwise permit any material known to be hazardous within the Premises, other than normal office cleaners and substances used in ordinary office machines. Any material within the Premises which is determined to be hazardous shall be removed and properly disposed of by the Lessee at the Lessee's sole expense.

-- END --

Exhibit B - Page 3

## LESSEE'S WORK AND ALTERATIONS

 Lessee may make the alterations required for Lessee's use of the Premises (hereinafter the "Work") after the Commencement Date subject to the following:

a.	Lessee, at its sole cost and expense, shall prepare and submit to Lessor, for Lessor's and governmental approval, the following descriptive information, detailed architectural and engineering drawings and specifications (hereinafter the "Plans") for the Work. The Plans shall be as complete and finished as required to completely describe the Work and shall include, but not be limited to, the following:										
	i.	Demolition Plans depicting all existing conditions to be removed, abandoned or cut patched.									
	ii.	Architectural floor plans depicting partition locations and types; door location, size, and hardware types.									
	iii.	Structural plans, if required, depicting new structural components and their connections to existing elements.									
	iv.	Electrical plans depicting all new and existing electrical wiring, devices, fixtures and equipment.									
	v.	Mechanical plans depicting all new plumbing, piping, heating, ventilating, air conditioning equipment, and duct work and its connections to existing elements.									
	vi.	Life Safety System plans depicting all new or altered alarm system fixtures, devices, detectors and wiring within the Premises and their connection to existing systems.									
	vii.	Coordinated reflected ceiling plan showing ceiling systems and materials and all of the above items and their proximity to one another.									
	viii.	Finish plans showing locations and types of all interior finishes with a schedule of all proposed materials and manufacturers.									
	The Plans shall provide for all systems and construction components complying with the requirements of all governmental authorities and insurance bodies having jurisdiction over the Building.										
b.	approva however they ar of the Buildin within Approva portion of the obtain expense with th require governm complie cost an simulta	The Plans for the Work are subject to Lessor's prior written approval which shall not be unreasonably withheld, provided, however, that Lessor may in any event disapprove the Plans if they are incomplete, inadequate or inconsistent with the terms of the Lease or with the quality and architecture of the Building. Lessor agrees to approve or disapprove the Plans within three (3) business days of receipt of same (the "Lessor Approval Period"). If Lessor disapproves the Plans or any bortion thereof, Lessor shall promptly notify Lessee thereof and of the revisions which Lessor reasonably requires in order to obtain Lessor's approval Lessee shall, at its sole cost and expense, submit the Plans, in such form as may be necessary, with the appropriate governmental agencies for obtaining required permits and certificates. Any changes required by any governmental agency affecting the Work or the Plans shall be complied with by Lessee in completing said Work at Lessee's so ison and expense. Lessee shall submit completed Plans to Lesso simultaneously with Lessee's submission of said plans to the local building department.									

- Lessor shall permit Lessee to solicit competitive pricing and select its own general and/or individual subcontractors to perform the Work at its sole cost
  - All general contractors shall be subject to Lessor's prior written approval, which shall not be unreasonably withheld. Lessor hereby approves Interior Resource Group as

Exhibit C - Page 1

Lessee's general contractor for the Work.

- b. Lessee shall instruct all approved general contractors to exclusively use Lessor's Base Building Sub-Contractors for heating, ventilation, air conditioning, electrical, fire suppression and life safety systems (hereinafter "Building Systems"). Other subcontractors may be used only when specifically approved in writing by Lessor, which approval shall not be unreasonably withheld or delayed.
- c. The Base Building Sub-Contractors and their respective trades are set forth in Paragraph 6 below.
- d. Lessee notifies Lessor in writing of Lessee's selection of general and subcontractors.
- e. All costs associated with the biding process soliciting competitive pricing will be at the sole cost and expense of the Lessee.
- f. Lessee's workmen and mechanics shall work in harmony and not interfere with the labor employed by Lessor, Lessor's mechanics or contractors or by any other occupant of the Building or their mechanic or contractors, if any. If at any time Lessee and/or its contractors cause disharmony or interference with the operation of the Building, Lessor shall give forty-eight (48) hours written notice to Lessee and within twenty-four (24) hours Lessee shall resolve any dispute so that the tenor of the construction process and the operation of the Building is returned to that which existed prior to Lessor's notice. Such entry by Lessee's contractors shall be deemed controlled by all of the terms, covenants, provisions and conditions of the Lease.
- g. Prior to the commencement of the Work, Lessee shall provide Lessor with evidence of Lessee's contractors and sub-contractors carrying such worker's compensation, general liability, personal and property insurance required by law and in amounts no less than the amounts set forth in Paragraph 7 herein. Lessor shall not be liable in any way for any injury, loss or damage which may occur to any portion of the Work, Lessee's decorations, or installments so made, the same being solely at Lessee's risk.
- h. In the event Lessor approves the use of subcontractors other than Lessor's Base Building sub-contractors, all proposed Building System work, including the preparation of the plans and specifications identified herein, shall be approved by Lessor's engineers (the "Engineering Review"), and any cost thereof shall be Lessee's responsibility.
- i. Lessor shall afford Lessee and its contractors the opportunity to use the Building facilities at reasonable cost in order to enable Lessee and its contractors to perform the Work, provided however, that Lessee and its contractors shall remain responsible for the scheduling and transportation of materials and equipment used in the performance of such work. Lessee shall give Lessor adequate prior notice with regard to the scheduling and transportation of materials in and out of the Building. Lessor shall furnish, at Lessor's expense, water, electricity, heat and ventilation during the performance of the Work during regular construction trade hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, exclusive of trade holidays. Scavenger service shall be provided by Lessor at Lessee's expense.
- j. All plans, changes to the plans and work installed by Lessee and its sub-contractors shall require inspections to be made by Lessor's Base Building Sub-Contractors at Lessee's or Lessee's contractors expense (the "Inspection Fees"). The Base Building Sub-Contractors shall supply Lessor with certification that work so preformed has been completed in accordance with the Plans which have been previously approved by Lessor. If a Base Building Sub-Contractor is selected and actually installs the work, the Inspection Fees described in this paragraph with respect to such work shall not be required.
- k. Lessee shall be responsible for all cleaning and removal of debris necessitated by the performance of the Work. If Lessee fails to provide such cleaning and removal, the same may be performed by Lessor on Lessee's behalf and Lessee will pay Lessor an amount equal to the contractor's charge therefore, plus twenty percent (20%) thereof.

- Neither the outside appearance nor the strength of the Building or of any of its structural parts shall be affected by the Work.
- m. The proper functioning of any of the Building Systems shall not be adversely affected or the usage of such systems by Lessee shall not be materially increased above the projected usage of such systems indicated by the current plans and specifications of the Building.
- n. Lessee and its general and sub-contractors shall be bound by and observe all of the conditions and covenants contained in the Lease and this Exhibit A.
- o. Lessor shall designate a "Project Manager" as its representative in the Building who shall be responsible for coordination and supervision of the Work as it pertains to the daily operation of the Building. The Project Manager and his subordinates shall be granted access to the Premises at all times during the construction period.
- p. Lessee agrees to pay Lessor three percent (3%) of the contract awarded to Lessee's general contractor and/or any subcontractors to reimburse Lessor for coordination, supervision, and utility costs.
- 3. Intentionally Omitted
- 4. Any part of the Work within the Premises shall become the property of the Lessor upon installation. Furthermore, with respect to any material and installation which is part of the Work, Lessee shall not be entitled to remove, pledge or sell same unless otherwise agreed to in writing by Lessor and Lessee. No refund, credit, or removal of said items shall be permitted at the termination of the Lease. Items installed that are not integrated in any such way with other common building materials do not fall under this provision (Example: shelving, furniture, trade fixtures).
- 5. Lessor shall provide a cash contribution of THREE HUNDRED SIXTY-NINE THOUSAND ONE HUNDRED THIRTY-EIGHT AND 00/100 DOLLARS (\$369,138.00) ("Lessor's Construction Allowance") for payment of the costs associated with the completion of The Work. Lessor's Construction Allowance shall be payable within fifteen (15) business days of Lessor's receipt of the following:
  - a. Copy of the Certificate of Occupancy (temporary and permanent) issued by the local construction official;
  - b. AIA Document G704, Certificate of substantial completion issued and signed by Lessee's Architect;
  - c. Release of Lien statements from the general and all sub-contractors associated with the Work; and
  - d. Lessee shall provide Lessor a set of reproducible drawings of the Plans and a "CAD" file (in .DWG or .DXF format) of the "As-Built" Plans.
- 6. The Base Building Sub-Contractors are:

FIRE SPRINKLER CONTRACTOR "To be provided by Lessor upon request from Lessee."

ELECTRICAL CONTRACTOR "To be provided by Lessor upon request from Lessee."

PLUMBING CONTRACTOR "To be provided by Lessor upon request from Lessee."

HVAC CONTRACTOR "To be provided by Lessor upon request from Lessee."

7. Lessee's Contractor's Insurance:

Exhibit C - Page 3

a.

The Lessee shall require any and all contractors of the Lessee performing work on or about the Premises to obtain and/or maintain specific insurance coverage for events which could occur while operations are being performed and which could occur after the completion of the work. The insurance coverage of the contractor shall be at least equal to the coverage required by Article 30 of the Lease and the contractor shall name Lessor and, if requested, Mortgagee as additional insureds on all policies of liability insurance.

- b. The contractor shall purchase and maintain such insurance as will protect itself and Lessor and Lessee from claims set forth below which may arise out of or result from its operations under the contract and after contract completion with Lessee, whether such operations are performed by the contractor or by any subcontractor or by anyone directly or indirectly employed by any of them or by anyone for whose acts any of them may be liable. The insurance coverage shall include but not be limited to protection for:
  - i. Claims under Workers or Workmens Compensation, Disability Benefits, and other Employee Benefit Acts;
  - Claims for damages because of bodily injury, occupational sickness, disease or death of its employees;
  - iii. Claims for damages because of bodily injury, sickness, disease, or death of any person other than its employees;
  - iv. Claims for damages insured by the usual personal injury liability coverages which are sustained by (i) any person as a result of an offense directly or indirectly related to the employment of such person by the contractor, or (ii) by any other person;
  - Claims for damages, other than to the work itself, because of injury to or destruction of tangible property, including loss of use resulting therefrom;
  - vi. Claims for damages because of bodily injury or death of any person and/or property damage arising out of the ownership, maintenance, or use of any motor vehicle; and
  - vii. Claims which include the foregoing, but not limited thereto, which may occur while operations are being performed and claims which may occur after operations are completed.
- c. Lessee shall secure evidence of Lessee's contractor's insurance coverage adequate to protect Lessor and Lessee.
  - d. The contract between the Lessee and its contractor shall require that the Lessee's contractor hold the Lessor harmless in a form and manner equal to the indemnity agreement in Article 33, "Indemnity" of the Lease agreement.
  - e. Lessee shall cause to be executed a waiver of all rights their contractors have or may have against Lessor and any Mortgagee involved in the Premises in any way, for damages caused by fire or other perils so insured.
  - f. If request by Lessor, Lessee shall obtain and furnish surety in a form satisfactory to Lessor, covering the faithful performance of the work and the payment of all obligations arising thereunder.
- 8. All sums payable by Lessee to Lessor in connection with this Exhibit C and any other work to be performed by Lessor within the Premises and billable to Lessee shall be deemed Additional Rent.

-END-

Exhibit C - Page 4

## EXHIBIT C - 1

#### AIR CONDITIONING & HEATING DESIGN STANDARDS

The following are design standards for the building air-conditioning system for cooling and heating in the air in the subject building:

- During the normal heating season to maintain an average indoor dry bulb temperature of not less than 70 degrees F (21 degrees C) or more than 76 degrees (24.4 degrees C) when the outdoor dry bulb temperature is lower than 65 degrees F (18 degrees C) but not lower than 0 degrees F (-13 degrees C).
- To maintain comfort cooling for an average indoor dry bulb temperature of not more than 78 degrees F when the outside dry bulb temperature is 95 degrees F (24 degrees C).
- 3. During the intermediate seasons, when the outside dry bulb temperature is below 55 degrees (13 degrees C), cooling will be provided by outside air usage in conjunction with operating of return air, outside air and exhaust air dampers.
- 4. To furnish not less than .10 cubic foot of fresh air per minute per square foot of rentable area, and between .20 and 1.0 cubic feet of total air per minute, per square foot of rentable occupied space.
- 5. Lessor will not be responsible for the failure of the air-conditioning system if such failure results from (i) the occupancy of the Premises with more than an average of one (1) person for each one hundred (100) usable square feet of floor area (ii) the installation or operation by Lessee of machines and appliances, the installed electrical load of which when combined with the load of all lighting fixtures exceeds five (5) watts per square foot of floor area and in any manner exceeding the aforementioned occupancy and electrical load criteria, or (iii) rearrangement of partitioning after the initial preparation of the Premises. If interference with normal operation of the air-conditioning system in the Premises results, necessitating changes in the air conditioning system servicing the Premises, such changes shall be made by Lessor upon written notice to Lessee at Lessee's sole cost and expense. Lessee agrees to lower and close window coverings when necessary because of the sun's position whenever the air conditioning system is in operation, and Lessee agrees at all times to cooperate fully with Lessor and to abide by all the Rules and Regulations attached hereto as well as reasonable rules and regulations which Lessor may hereafter prescribe involving the air-conditioning system.

-- END --

Exhibit C-1 - Page 1

#### CLEANING SERVICES (Five Nights Per Week)

LESSEE'S PREMISES

- 1. Vacuum clean all carpeted areas.
- Sweep and dust mop all non-carpeted areas. Wet mop whenever necessary. 2.
- 3 All office furniture such as desks, chairs, files, filing cabinets, etc. shall be dusted with a clean treated dust cloth whenever necessary and only if such surfaces are clear of Lessee's personal property including but not limited to plants.
- 4 Empty and wash ashtrays.
- Empty wastepaper baskets and remove waste to the designated areas. 5.
- 6 All vertical surfaces within arms reach shall be spot cleaned to remove finger marks and smudges. Baseboard and window sills are to be spot cleaned whenever necessary.
- 7. All cleaning of cafeterias, vending areas, kitchen facilities are excluded. Lessee may make necessary arrangements for same directly with Lessor's cleaning maintenance company.
- 8 Cleaning hours shall be Monday through Friday between 5:30 p.m. and 11:00 p.m.
- 9. No cleaning service is provided on Saturday, Sunday and Building Holidays.
- 10 Cartons or refuse in excess which can not be placed in wastebaskets will not be removed. Lessee is responsible to place such unusual refuse in trash dumpster.
- 11. Cleaning maintenance company will not remove nor clean tea, office cups or similar containers. If such liquids are spilled in waste baskets, the waste baskets will be emptied but not otherwise cleaned. Lessor will not be responsible for any stained carpet caused from liquids leaking or spilling from Lessee's wastepaper receptacles.
- Upon completion of cleaning, all lights will be turned off and doors 12 locked leaving the Premises in an orderly condition.
- Glass entrance doors will be cleaned nightly. Interior glass doors or 13. glass partitions are excluded. Lessee may make arrangements for same with Lessor's cleaning maintenance company.

#### COMMON AREAS

- Vacuum all carpeting in entrance lobbies, outdoor mats and all 1. corridors.
- 2 Wash glass doors in entrance lobby with a clean damp cloth and dry towel.
- 3. Clean cigarette urns. Sweep and/or wet mop all resilient tile flooring. Hard surface floors such as quarry tile, etc., shall be cleaned nightly.
- Wash, clean and disinfect water fountains. 4.
- 5. Clean all elevators and stairwells.
- 6 Lavatories -- Men and Women.
  - a. Floors in all lavatories shall be wet mopped each evening with a germicidal detergent to ensure a clean and germ free surface.
  - b. Wash and polish all mirrors, shelves, bright work including any piping and toilet seats.
  - Wash and disinfect wash basins and sinks using a germicidal с. detergent.
  - d. Wash and disinfect toilet bowls and urinals.
  - e. Keep lavatory partitions, tiled walls, dispensers and receptacles in a clean condition using a germicidal detergent when necessary. f. Empty and sanitize sanitary disposal receptacles.

  - g. Fill toilet tissue holders, towel dispensers and soap dispensers. Refills to be supplied by Lessor.
- 7. Clean all air ventilation grill work in ceilings.

EXHIBIT E

BUILDING HOLIDAYS

BUILDING CLOSED

- \* NEW YEAR'S DAY \*
- \* MEMORIAL DAY \*
- \* INDEPENDENCE DAY \*
  - \* LABOR DAY \*
- \* THANKSGIVING DAY \*
  - \* CHRISTMAS DAY \*

-- END --

Exhibit E - Page 1

## EXHIBIT F

#### TENANT ESTOPPEL CERTIFICATE

TO: MORTGAGEE and/or its affiliates and/or whom else it may concern:

- 1. The undersigned is the Lessee (Tenant) under that certain Lease dated
   \_\_\_\_\_\_by and between \_\_\_\_\_\_ as Lessor (Landlord) and
   \_\_\_\_\_\_as Lessee, covering those certain premises commonly known and
   designated as \_\_\_\_r.s.f. on the \_\_\_\_() floor of \_\_\_\_\_\_,NJ.
- 2. The Lease has not been modified, changed, altered or amended in any respect (except as indicated following this sentence) and is the only Lease or agreement between the undersigned and the Lessor affecting said premises. If none, state "none".
- 3. The undersigned has made no agreements with Lessor or its agents or employees concerning free rent, partial rent, rebate of rental payments or any other type of rental concession (except as indicated following this sentence). If none, state "none".
- 4. The undersigned has accepted and now occupies the premises, and is and has been open for business since\_\_\_\_\_, 200\_. The Lease term began\_\_\_\_\_, 2002, and the rent for said premises has been paid to and including\_\_\_\_\_\_, 2002 in conformity with this Lease agreement. No rent has been prepaid for more than two (2) months. The fixed minimum rent being paid as above is \$ \_\_\_\_\_\_ per month. If Lessee is not in full possession, whether Lessee has assigned the Lease, sublet all or any portion of the Premises, Lessee agrees to provide a copy of such assignment, sublease, or transfer upon request.
- 5. The Lease is not in default and is in full force and effect. As of the date hereof, the undersigned is entitled to no credit, no free rent and no offset or deduction in rent.
- 6. All alterations, improvements, additions, build-outs, or construction required to be performed under the Lease have been completed in accordance with the terms of the Workletter attached to Lease as Exhibit C.
- 7. The Lease does not contain and the undersigned doesn't have any outstanding options or rights of first refusal to purchase the premises or any part thereof or the real property of which the premises are a part.
- No actions, whether voluntary or otherwise, are pending against the undersigned under the bankruptcy laws of the United States or any State thereof.
- 9. There are currently no valid defenses, counterclaims, off-sets, credits, deductions in rent, or claims against the enforcement of any of the agreements, terms, or conditions of the Lease.
- 10. The undersigned acknowledges that all the interest of Lessor in and to the above-mentioned Lease is being duly assigned to MORTGAGEE or one of its affiliates hereunder and that pursuant to the terms thereof (i) all rental payments under said Lease shall continue to be paid to Lessor in accordance with the terms of the Lease unless and until you are otherwise notified in writing by MORTGAGEE, or its successor or assigns and (ii) no modification, revision, or cancellation of the Lease or amendments thereto shall be effective unless a written consent thereto of such mortgagee is first obtained.
- 11. The undersigned is authorized to execute this Tenant Estoppel Certificate on behalf of the Lessee.

Dated this \_\_\_\_\_ day of \_\_\_\_\_, 2002

LESSEE:

-----

Name: Title:

Exhibit F - Page 1

### EXHIBIT G

#### RENT COMMENCEMENT DATE AGREEMENT

# 1.0 PARTIES

THIS AGREEMENT made the \_\_\_\_\_day of \_\_\_\_\_, 2002 is by and between \_\_\_\_\_\_ (hereinafter "Lessor") whose address is c/o Mack-Cali Realty Corporation, 11 Commerce Drive, Cranford, New Jersey 07016 and \_\_\_\_\_\_ (hereinafter "Lessee") whose address is

### 2.0 STATEMENT OF FACTS

2.1 Lessor and Lessee entered into a Lease dated \_\_\_\_\_\_, 2002 (hereinafter "Lease") setting forth the terms of occupancy by Lessee of approximately \_\_\_\_\_\_ rentable square feet on the \_\_\_\_\_\_ (\_\_\_) floor (hereinafter "Premises") at \_\_\_\_\_\_ (hereinafter "Building"); and

- 2.2 The Term of the Lease is ten (10) years with the Rent Commencement Date being defined in the Preamble to the Lease as being subject to certain alternatives; and
- 2.3 It has been determined that \_\_\_\_\_, 2002 is the Rent Commencement Date of the Lease.

### 3.0 STATEMENT OF TERMS

NOW, THEREFORE, in consideration of the Premises and the covenants hereinafter set forth, it is agreed:

- 3.1 The Rent Commencement Date of the Lease is \_\_\_\_\_\_, and the Expiration Date thereof is \_\_\_\_\_\_\_, and the Lease Preamble Articles 6 shall be deemed modified accordingly.
- 3.2 This Agreement is executed by the parties hereto for the purpose of providing a record of the Rent Commencement Date and Expiration Dates of the Lease.

EXCEPT as modified herein, the Lease covering the Premises shall remain in full force and effect as if the same were set forth in full herein and Lessor and Lessee hereby ratify and confirm all the terms and conditions thereof.

THIS AGREEMENT shall be binding upon and inure to the benefit of the parties hereto and their respective legal representatives, successors and permitted assigns.

EACH PARTY AGREES that it will not raise or assert as a defense to any obligation under the Lease or this Agreement or make any claim that the Lease or this Agreement is invalid or unenforceable due to any failure of this document to comply with ministerial requirements including, but not limited to, requirements for corporate seals, attestations, witnesses, notarizations, or other similar requirements, and each party hereby waives the right to assert any such defense or make any claim of invalidity or unenforceability due to any of the foregoing.

IN WITNESS THEREOF, Lessor and Lessee have hereunto set their hands and seals the date and year first above written and acknowledge one to the other they possess the requisite authority to enter into this transaction and to sign this Agreement.

LESSOR

Bv:

#### LESSEE

By:

Michael K. Nevins Vice President - Leasing Name: Title:

Exhibit G - Page 1

# EXHIBIT H

#### LETTER OF CREDIT

#### [DATE]

TO: [Name of Beneficiary] [Address]

Re: Irrevocable Letter of Credit

Gentlemen:

By order of our client,									, we	here	eby e	establ	ish
our irrev	rocable	Letter	of C	redit	No.	 in	your	favor	for	a si	um oi	sums	not
to exceed	l\$			(			U.S	S. Doli	lars	) in	the	aggre	gate
effective	immedi	iatelv.											

This Letter of Credit shall be payable in immediately available funds in U.S. Dollars. Funds under this credit are payable to you upon your presentation to us a sight draft drawn on us in the form annexed hereto. All drafts must be marked: "Drawn under Letter of Credit No. \_\_\_\_\_ of [Name of Issuing Bank].

This Letter of Credit shall expire twelve (12) months from the date hereof; but is automatically extendable, so that this Letter of Credit shall be deemed automatically extended, from time to time, without amendment, for one year from the expiration date hereof and from each and every future expiration date, unless at least sixty (60) days prior to any expiration date we shall notify you by registered mail that we elect not to consider this Letter of Credit renewed for any such additional period. The final expiration date hereof shall be no EARLIER than [fill in suitable date after expiration of lease].

This Letter of Credit is transferable and may be transferred one or more times. However, no transfer shall be effective unless advice of such transfer is received by us in our standard form.

We hereby agree to honor each draft drawn under and in compliance with this Letter of Credit, if duly presented at our offices at \_\_\_\_\_\_ or at any other of our offices.

This Letter of Credit is subject to the International Standby Practices 1998, International Chamber of Commerce Publication No. 590.

[Name of Bank]

By:

[Annex Bank's Form of Sight Draft]

Exhibit H- Page 1

#### EXCLUSIONS FROM OPERATING COSTS

Any ground lease rental;

(2) Costs of items considered capital repairs, replacements, improvements and equipment under generally accepted accounting principles consistently applied or otherwise, except as set forth below ("Capital Items");

(3) Rentals for items (except when needed in connection with normal repairs and maintenance of permanent systems) which if purchased, rather than rented, would constitute a Capital Item which is specifically excluded in (2) above (excluding, however, equipment not affixed to the Building which is used in providing janitorial or similar services);

(4) Costs incurred by Lessor for the repair of damage to the Building to the extent that Lessor is or should be reimbursed by insurance proceeds, regardless of whether such repairs are covered by insurance;

(5) Costs, including permit, license and inspection costs, incurred with respect to the installation of tenant or other occupants' improvements in the Building or incurred in renovating or otherwise improving, decorating, painting or redecorating vacant space for tenants or other occupants of the Building;

(6) Depreciation, amortization, and interest payments, except as provided herein and except on materials, tools, supplies, and vendor-type equipment purchased by Lessor to enable Lessor to supply services Lessor might otherwise contract for with a third party when such depreciation, amortization and interest payments would otherwise have been included in the charge for such third party's services, all as determined in accordance with generally accepted accounting principles, consistently applied, and when depreciation or amortization is permitted or required, the item shall be amortized over its reasonably anticipated useful life;

(7) Marketing costs, including without limitation, leasing commissions, attorneys' fees in connection with the negotiation and preparation of letters, deal memos, letters of intent, leases, subleases and/or assignments, space planning costs, and other costs and expenses incurred in connection with lease, sublease and/or assignment negotiations and transactions with Lessee or present or prospective tenants or other occupants of the Building;

(8) Expenses for services or other benefits that are not offered to Lessee or for which Lessee is charged for directly but that are provided to another tenant or occupant of the Building;

(9) Costs incurred by Lessor because of the violation by Lessor or any tenant of the terms and conditions of any lease of space in the Building;

(10) Overhead and profit increment paid to Lessor or to subsidiaries or affiliates of Lessor for goods and/or services in or to the Building to the extent the same exceeds the costs of such goods and/or services rendered by unaffiliated third panics on a competitive basis;

(11) Interest, principal, points and fees on debts or amortization on any mortgage or mortgages or any other debt instrument encumbering the Building or the Land;

(12) Lessor's general corporate overhead and general and administrative expenses;

(13) Any compensation paid to clerks, attendants or other persons in commercial concessions operated by Lessor or in the parking garage of the Building or wherever Lessee is granted its parking privileges and/or all fees paid to any parking facility operator;

(14)  $\,$  Rentals and other related expenses incurred in leasing HVAC systems, elevators or

other equipment ordinarily considered to be Capital Items, except for (a) expenses in connection with making repairs on or keeping such Building systems in operation while repairs are being made and (b) costs of equipment not affixed to the Building which is used in providing janitorial or similar services;

(15) Advertising and promotional expenditures, and costs of signs in or on the Building identifying the owner of the Building;

(15A) The cost of any electrical power used by any tenant in the Building in excess of the Building-standard amount, or electric power costs for which any tenant directly contracts with the local public service company or for which any tenant is separately metered or submetered and pays Lessor directly;

(16) Services and utilities provided, taxes attributable to, and costs incurred in connection with the operation of the retail and restaurant operations in the Building, except to the extent the square footage of such operations are included in the rentable square feet of the Building and do not exceed the services, utility and tax costs that would have been incurred had the retail and/or restaurant space been used for general office purposes;

(17) Costs incurred in connection with upgrading the Building to comply with life, fire and safety codes, ordinances, statutes or other laws in effect before the Commencement Date, including, without limitation, the ADA, including penalties or damages incurred because of that non-compliance;

(18) Tax penalties incurred as a result of Lessor's failure to make payments and/or to file any tax or informational returns when due;

(19) Costs for which Lessor has been compensated by a management fee, and any management fees in excess of those management fees which are normally and customarily charged by landlords of comparable buildings;

(19A) Costs arising from the negligence or fault of other tenants or Lessor or its agents, or any vendors, contractors, or providers of materials or services selected, hired or engaged by Lessor or its agents including, without limitation, the selection of Building materials;

(20) Notwithstanding any contrary provision of the Lease, including, without limitation, any provision relating to capital expenditures, any and all costs arising from the presence of hazardous materials or substances (as defined by applicable laws in effect on the date this Lease is executed) in or about the Premises, the Building or the Office Building Area including, without limitation, hazardous substances in the ground water or soil, not placed in the Premises, the Building or the Land by Lessee;

(21) Costs arising from Lessor's charitable or political contributions;

(22) Costs arising from defects in the base, shell, or core of the Building or improvements installed by Lessor or repair thereof;

(23) Costs for the acquisition of (as contrasted with the maintenance of) sculpture, paintings, or other objects of art;

(24) Costs (including in connection therewith all attorneys' fees and costs of settlement judgments and payments in lieu thereof) arising from claims, disputes or potential disputes in connection with potential or actual claims litigation or arbitrations pertaining to Lessor and/or the Building and/or the Office Building Area;

(25) Costs associated with the operation of the business of the partnership or entity which constitutes Lessor as the same are distinguished from the costs of operation of the Building, including partnership accounting and legal matters, costs of defending any lawsuits with or claims by any mortgagee (except as the actions of Lessee may be in issue), costs of selling, syndicating, financing, mortgaging or hypothecating any of Lessor's interest in the Building, costs of any disputes between Lessor and its employees (if any) not engaged in Building operation, disputes of Lessor with

Building management, or outside fees paid in connection with disputes with other tenants;

(26) Costs of any "tap fees" or any sewer or water connection fees for the benefit of any particular tenant in the Building;

(27) Costs incurred in connection with any environmental clean-up, response action, or remediation on, in, under or about the Premises or the Building or the Office Building Area, including but not limited to, costs and expenses associated with the defense, administration, settlement, monitoring or management thereof;

(28) Any expenses incurred by Lessor for use of any portions of the Building to accommodate events including, but not limited to shows, promotions, kiosks, displays, filming, photography, private events or parties, ceremonies, and advertising beyond the normal expenses otherwise attributable to providing Building services, such as lighting and HVAC to such public portions of the Building in normal Building operations during standard Building hours of operation;

(29) Any entertainment, dining, or travel expenses for any purpose;

(30) Any flowers, gifts, balloons, etc. provided to any entity whatsoever, to include, but not limited to, Lessee, other tenants, employees, vendors, contractors, prospective tenants, and agents;

(31) Any "validated" parking for any entity;

(32)  $\;$  Any "finders' fees," brokerage commissions, job placement costs, or job advertising cost;

(33) Any "above-standard" cleaning, including, but not limited to construction cleanup or special cleanings associated with parties/events and specific tenant requirements in excess of service provided to Lessee, including related trash collection, removal, hauling and dumping;

(34) The cost of any magazine, newspaper, trade or other subscriptions;

(35) The cost of any training or incentive programs, other than for tenant life safety information services;

(36) The cost of any "tenant relations" parties, events or promotion not consented to by an authorized representative of Lessee in writing;

(37) "In-house" legal and/or accounting fees; and

(38) Reserves for bad debts or for future improvements, repairs, additions, etc.; and

It is understood that Operating Costs shall be reduced by all cash discounts, trade discounts, quantity discounts, rebates, or other amounts received by Lessor or Lessor's managing agent in the purchase of any goods, utilities, or services in connection with the operation of the Building. Lessor shall make payments for goods, utilities, or services in a timely manner to obtain the maximum possible discount. If Capital Items which are customarily purchased by landlords of comparable buildings are leased by Lessor, rather than purchased, the decision by Lessor to lease the item in question shall not serve to increase Lessee's Percentage of Operating Costs beyond that which would have applied had the item in question been purchased.

If any facilities, services, or utilities used for the Building are provided from another building owned or operated by Lessor or vice versa, the costs incurred by Lessor for those facilities, services, or utilities shall be allocated to Operating Costs by Lessor on a reasonably equitable basis.

If any repair, replacement or improvement within the definition of Operating Costs is capitalized under generally accepted accounting principles, then (A) the cost of any such repair, replacement or improvement shall only be included in Operating Costs if such repair, replacement or improvement (i) is necessary to comply with any governmental or quasi-governmental law, statute,

ordinance, rule, order, requirements or regulation, which is enacted or promulgated after the date hereof, (ii) is reasonably intended to reduce Operating Costs or (iii) constitutes a replacement which in Lessor's reasonable judgment is economically prudent to make in lieu of repairs, (B) the cost thereof shall be amortized on a straight line basis over the useful life of such repair, the amount so amortized attributable to such repair, replacement or improvement and (C) there shall be included in Operating Costs in each Lease Year for such portion of the amortization period which occurs during the Term, provided, however, that all amounts thereof included in Operating Costs in any Lease Year subsequent to the year paid shall have added thereto interest from the date Lessor incurred such cost. For amortization purposes, applicable interest shall be two (2) percentage points in excess of the prime rate charged by Chase Manhattan Bank, or its successor, at the time of expenditure.

#### PARTIES

1.1 THIS AGREEMENT made the 30th day of June, 2003 is between SYLVAN/CAMPUS REALTY L.L.C. ("Lessor") whose address is c/o Mack-Cali Realty Corporation, 11 Commerce Drive, Cranford, New Jersey 07016 and THE MEDICINES COMPANY ("Lessee"), whose address is 8 Campus Drive, Parsippany, New Jersey.

## 2. STATEMENT OF FACTS

- 2.1 Lessor and Lessee previously entered into a Lease dated September 30, 2002 (the "Lease") covering approximately 16,779 gross rentable square feet on the second (2nd) floor ("Premises") in the building located at 8 Campus Drive, Parsippany, New Jersey ("Building"); and
- 2.2 The Term of the Lease is for ten (10) years from the Rent Commencement Date with the Rent Commencement Date of the initial Term being defined in the Preamble to the Lease as the earlier of (i) the date upon which Lessee, or anyone claiming under or through Lessee, commences using the Premises for the conduct of business, or (ii) the date which is ninety (90) days after the date of this Lease.
- 2.3 It has been determined in accordance with Paragraph 6 of the Preamble to the Lease that January 6, 2003 was the Rent Commencement Date of the Term of the Lease.
- 2.4 The Term of the Lease expires at 11:59 p.m. on January 31, 2013 ("Expiration Date"); and
- 2.5 Lessee desires to expand the Premises by leasing approximately 3,450 gross rentable square feet on the second (2nd) floor of the Building ("Expansion Premises"), as shown on Exhibit A attached hereto and made a part hereof; and
- 2.6 The parties desire to amend certain terms of the Lease as set forth below.

### AGREEMENT

NOW, THEREFORE, in consideration of the terms, covenants and conditions hereinafter set forth, Lessor and Lessee agree as follows:

- 3.1 The above recitals are incorporated herein by reference.
- 3.2 All capitalized and non-capitalized terms used in this Agreement which are not separately defined herein but are defined in the Lease shall have the meaning given to any such term in the Lease.
- 3.3 The Term applicable to the Expansion Premises shall commence on the Effective Date (as defined below) and shall terminate at 11:59 p.m. on January 31, 2013.
- 3.4 The effective date applicable to the Expansion Premises shall be the earlier of (i) the day Lessor substantially completes the improvements to be made to the Expansion Premises in accordance with Exhibit B attached hereto and made part hereof and obtains a (temporary or final) certificate of occupancy for the Expansion Premises (if required by local law) or (ii) the date Lessee or anyone claiming under or through Lessee shall occupy the Expansion Premises (the "Effective Date").
- 3.5 Lessor, at its sole cost and expense, shall perform the improvement work to the Expansion Premises in accordance with Exhibit B attached hereto and made part hereof.
- 3.6 From and after the Effective Date, the following shall be effective:
  - a. Lessor shall lease to Lessee and Lessee shall hire from Lessor the Expansion Premises as shown on Exhibit A attached hereto and made part hereof.
  - b. The Premises shall be defined as approximately 20,229 gross rentable square feet on the second (2) floor of the Building and Paragraph 7 of the Preamble

to the Lease and Exhibit A shall be deemed amended accordingly.

c.

In addition to the Fixed Basic Rent payable applicable to the Premises, Lessee shall pay Lessor Fixed Basic Rent applicable to the Expansion Premises which shall accrue as follows and Paragraph 10 of the Preamble to the Lease shall be deemed supplemented accordingly:

- commencing on the Effective Date through and including the day prior to the second (2nd) month anniversary of the Effective Date, the Fixed Basic Rent applicable to the Expansion Premises shall be ZERO AND 00/100 DOLLARS (\$0.00).
- (ii) commencing on the second (2nd) month anniversary of the Effective Date through and including January 31, 2005, the Fixed Basic Rent applicable to the Expansion Premises shall be NINETY-ONE THOUSAND FOUR HUNDRED TWENTY-FIVE AND 00/100 DOLLARS (\$91,425.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of SEVEN THOUSAND SIX HUNDRED EIGHTEEN AND 75/100 (\$7,618.75); and
- (iii) commencing on February 1, 2005 through and including January 31, 2006, the Fixed Basic Rent applicable to the Expansion Premises shall be NINETY-THREE THOUSAND ONE HUNDRED FIFTY AND 00/100 DOLLARS (\$93,150.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of SEVEN THOUSAND SEVEN HUNDRED SIXTY-TWO AND 50/100 DOLLARS (\$7,762.50); and
- (iv) commencing on February 1, 2006 through and including January 31, 2007, the Fixed Basic Rent applicable to the Expansion Premises shall be NINETY-FOUR THOUSAND EIGHT HUNDRED SEVENTY-FIVE AND 00/100 DOLLARS (\$94,875.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of SEVEN THOUSAND NINE HUNDRED SIX AND 25/100 DOLLARS (\$7,906.25); and
- (v) commencing on February 1, 2007 through and including January 31, 2008, the Fixed Basic Rent applicable to the Expansion Premises shall be NINETY-EIGHT THOUSAND THREE HUNDRED TWENTY-FIVE AND 00/100 DOLLARS (\$98,325.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of EIGHT THOUSAND ONE HUNDRED NINETY-THREE AND 75/100 DOLLARS (\$8,193.75); and
- (vi) commencing on February 1, 2008 through and including January 31, 2009, the Fixed Basic Rent applicable to the Expansion Premises shall be ONE HUNDRED THOUSAND FIFTY AND 00/100 DOLLARS (\$100,050.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of EIGHT THOUSAND THREE HUNDRED THIRTY-SEVEN AND 50/100 DOLLARS (\$8,337.50); and
- (vii) commencing on February 1, 2009 through and including January 31, 2010, the Fixed Basic Rent applicable to the Expansion Premises shall be ONE HUNDRED ONE THOUSAND SEVEN HUNDRED SEVENTY-FIVE AND 00/100 DOLLARS (\$101,775.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of EIGHT THOUSAND FOUR HUNDRED EIGHTY-ONE AND 25/100 DOLLARS (\$8,481.25); and
- (viii) commencing on February 1, 2010 through and including January 31, 2011, the Fixed Basic Rent applicable to the Expansion Premises shall be ONE HUNDRED THREE THOUSAND FIVE HUNDRED AND 00/100 DOLLARS (\$103,500.00) per annum, payable in advance on the first day of each and every calendar month in equal

monthly installments of EIGHT THOUSAND SIX
HUNDRED TWENTY-FIVE AND 00/100 DOLLARS
(\$8,625.00); and

- (ix) commencing on February 1, 2011 through and including January 31, 2012, the Fixed Basic Rent applicable to the Expansion Premises shall be ONE HUNDRED FIVE THOUSAND TWO HUNDRED TWENTY-FIVE AND 00/100 DOLLARS (\$105,225.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of EIGHT THOUSAND SEVEN HUNDRED SIXTY-EIGHT AND 75/100 DOLLARS (\$8,768.75); and
- (x) commencing on February 1, 2012 through and including January 31, 2013, the Fixed Basic Rent applicable to the Expansion Premises shall be ONE HUNDRED SIX THOUSAND NINE HUNDRED FIFTY AND 00/100 DOLLARS (\$106,950.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of EIGHT THOUSAND NINE HUNDRED TWELVE AND 50/100 DOLLARS (\$8,912.50).
- d. Parking Spaces shall be defined as seventy-six unassigned spaces and Paragraph 14 of the Preamble to the Lease shall be deemed amended accordingly.
- e. Lessee shall pay Lessor the cost of electricity consumed within the Expansion Premises in accordance with Article 22 BUILDING STANDARD OFFICE ELECTRICAL SERVICE of the Lease.
- f. Lessee shall pay Lessor, as Additional Rent, Lessee's Percentage applicable to the Expansion Premises of the increased cost to Lessor for each of the categories set forth in Article 23 ADDITIONAL RENT over the Base Operating Costs, Base Real Estate Taxes and Base Utility and Energy Costs incurred during Calendar Year 2004.
- g. Lessee's Percentage applicable to the Expansion Premises shall be 1.6%.
- 3.7 This Agreement shall not extend or otherwise amend the Term or Fixed Basic Rent applicable to the Premises as defined herein.
- 3.8 No later than thirty (30) days after the determination of the Effective Date, the parties shall agree to memorialize the Effective Date in writing.
- 3.9 Lessee represents and warrants to Lessor that no broker, other than Trammel Crow Company, brought about this transaction, and Lessee agrees to indemnify and hold Lessor harmless from any and all claims of any other broker claiming to have been engaged by Lessee in connection with negotiations of, or entering into of, this Agreement.
- 3.10 Lessee hereby represents to Lessor that (i) except for any default which may exist as a result of the filing of certain liens against the Building, there exists no default under the Lease either by Lessor or Lessee; (ii) Lessee is entitled to no credit, free rent or other offset or abatement of the rents due under the Lease; and (iii) there exists no offset, defense or counterclaim to Lessee's obligation under the Lease.
- 3.11 Except as expressly amended herein, the Lease, as amended, shall remain in full force and effect as if the same had been set forth in full herein, and Lessor and Lessee hereby ratify and confirm all of the terms and conditions thereof.
- 3.12 This agreement shall be binding upon and inure to the benefit of the parties hereto and their respective legal representatives, successors and permitted assigns.
- 3.13 Each party agrees that it will not raise or assert as a defense to any obligation under the Lease or this Agreement or make any claim that the Lease or this Agreement is invalid or unenforceable due to any failure of this document to comply with ministerial requirements including, but not limited to, requirements for corporate seals, attestations, witnesses, notarizations, or other similar requirements, and each party hereby waives the right to assert any such defense or make any claim of

invalidity or unenforceability due to any of the foregoing.

IN WITNESS WHEREOF, Lessor and Lessee have hereunto set their hands and seals the date and year first above written, and acknowledge one to the other that they possess the requisite authority to enter into this transaction and to sign this Agreement.

4

# LESSOR:

# LESSEE:

# SYLVAN/CAMPUS REALTY L.L.C.

By: Grove Street Associates of Jersey City Limited Partnership, member

- By: Mack-Cali Sub IV, Inc., its general partner

THE MEDICINES COMPANY

By: /s/ Clive A. Meanwell

Name: Clive A. Meanwell Title: Chairman

# EXHIBIT A

# LOCATION OF EXPANSION PREMISES

[Schematic diagram of original premises and expansion premises]

# 5

# EXHIBIT B

#### NOTES

RE: Workletter Agreement for office space on the second (2nd) floor at 8 Campus Drive, Parsippany, New Jersey

June 30, 2003

LESSEE:

#### THE MEDICINES COMPANY

You ("Lessee") and we ("Lessor") are executing simultaneously with this Workletter Agreement a written lease amendment ("Amendment"), covering the space referred to above, as more particularly described in the Amendment ("Expansion Premises").

To induce Lessee to enter into the Amendment (which is hereby incorporated by reference) and in consideration of the covenants hereinafter contained, Lessor and Lessee mutually agree as follows:

- Lessor shall have its architect prepare the following architectural and mechanical drawings and specifications based upon the sketch layout supplied to Lessor by Lessee, attached hereto and made a part hereof, upon full execution of this Lease.
  - a. Architectural drawings and specifications for Lessee's partition layout, reflected ceiling, placement of electrical outlets and other installations for the work to be done by Lessor.
  - b. Mechanical plans and specifications where necessary for installation of air conditioning systems, ductwork and heating.

All such plans and specifications are expressly subject to Lessor's written approval, which Lessor covenants it will not unreasonably withhold.

- 2. Lessor agrees to cause the partition plan, electrical plan and the reflected ceiling plan to be delivered to Lessee on or before the fifteenth (15th) day after Lessee's approved sketch layout. Lessee agrees to approve said plans by initialing and returning same to Lessor within three (3) days of receipt of each plan. Upon approval of the plans initialed by Lessee, Lessor shall file said plans with the appropriate governmental agencies.
- 3. Lessor agrees, at its expense and without charge to Lessee (unless otherwise provided), to do the work in the Expansion Premises as shown on the plans dated May 16, 2003, as amended June 24, 2003, created by First Floor, attached hereto and described on the "Description of Materials" schedule attached hereto and in conformance with the Premises originally leased by Lessee under the Lease, which shall hereinafter be referred to as "The Work" "Building Standard" shall mean the type and grade of material, equipment and/or device designated by Lessor as standard for the Building. All items are Building Standard unless otherwise noted. The provisions of Article 6 of the Lease shall apply to any alterations made to the Expansion Premises after the initial work to be performed herein.
- 4. Intentionally omitted.
- All low partitioning, workstation modules, bank screen partitions and prefabricated partition systems shall be furnished and installed by Lessee.
- 6. The installation or wiring of telephone and computer (data) outlets is not part of The Work. Lessee shall bear the responsibility to provide its own telephone and data systems at Lessee's sole cost and expense. Upon expiration or sooner termination of the Lease, Lessee shall remove all telephone and data equipment and wiring from the Expansion Premises and the Building risers upon vacation of same.

7. Changes in The Work, if necessary or requested by the Lessee, shall be accomplished after submission of Lessee's final approved sketch layout, and without invalidating any part of the Lease or Workletter Agreement, by written agreement between Lessor and Lessee hereinafter referred to as a Change Order. Each Change Order shall be prepared by Lessor and signed by both Lessee and Lessor stating their agreement upon all of the following:

- a. The scope of the change in The Work; and
- b. The cost of the change; and
- c. Manner in which the cost will be paid or credited; and
- d. The estimated extent of any adjustment to the Effective Date (if any) as a result of the change in The Work.
  - Each and every Change Order shall be signed by Lessor's and Lessee's respective construction representatives. In no event shall any Change Order(s) be permitted without such authorizations. A 10% supervision plus 10% overhead charge will be added to the cost of any Change Order and to the cost of any other work to be performed by Lessor in the Expansion Premises after Lessor's completion of The Work. If Lessee shall fail to approve any such Change Order within one (1) week, the same shall be deemed disapproved in all respects by Lessee and Lessor shall not be authorized to proceed thereon. Any increase in the cost of The Work or the change in The Work stated in a Change Order which results from Lessee's failure to timely approve and return said Change Order shall be paid by the Lessee. Lessee agrees to pay to Lessor the cost of any Change Order promptly upon receipt of an invoice for same. Similarly, any cost savings resulting from such Change Order(s) shall be credited to the Lessee
- 8. If Lessee elects to use the architect suggested by Lessor, this architect becomes the Lessee's agent solely with respect to the plans, specifications and The Work. If any change is made after completion of schematic drawings and prior to completion of final construction documents which result in a Change Order and additional costs, such costs shall be the responsibility of the Lessee.
- 9. Prior to Lessee's occupancy of the Expansion Premises, Lessee shall identify and list any portion of The Work which does not conform to this Workletter Agreement ("Punch List"). The Lessor shall review with the Lessee all of the items so listed and correct or complete any portion of The Work which fails to conform to the requirements of this Workletter Agreement.
- 10. The terms contained in the Amendment (which include all exhibits attached thereto) constitute Lessor's agreement with Lessee with respect to the work to be performed by Lessor on Lessee's behalf. If the architectural drawings are in conflict with the terms of the Amendment, then the Lease shall be deemed the controlling document.
- 11. All materials and installations constructed for the Lessee within the Expansion Premises shall become the property of the Lessor upon installation. No refund, credit or removal of said items is to be permitted at the termination of the Lease. Items installed that are not integrated in any such way with other common building materials do not fall under this provision (e.g. shelving, furniture, etc.).
- 12. It is agreed that notwithstanding the date provided in the Lease for the Effective Date, the term applicable to the Expansion Premises shall not commence until Lessor has "substantially completed" all work to be performed by Lessor as hereinbefore set forth in Paragraph 3 above and as set forth in the Amendment; provided, however, that if Lessor shall be delayed in substantially completing said work as a result of:
  - a. Lessee's failure to approve the plans and specifications in accordance with Paragraph 2 hereof; or
  - Lessee's failure to furnish interior finish specifications, i.e., paint colors, carpet

selection, etc., to Lessor by the fifth (5th) working day after Lessor has approved the plans and specifications submitted by Lessee referred to in Paragraph 2 hereof; or

- c. Lessee's request for materials, finishes or installations other than Lessor's Building Standard; or
- d. Lessee's changes in The Work; or
- e. The performance of a person, firm, partnership or corporation employed by Lessee and the completion of the said work by said person, firm, partnership or corporation;

then the Effective Date of the term of said Lease shall be accelerated by the number of days of such delay and Lessee's obligation to pay Fixed Basic Rent and Additional Rent shall commence as of such earlier date. As to matters described in clauses (a) - (e) above, Lessor shall advise Lessee of any delay that Lessor knows is reasonably likely to occur as a result of the matter described, within a reasonable time after Lessor becomes aware of such likelihood.

- 13. Lessor shall permit Lessee and its agents to enter the Expansion Premises prior to the Commencement Date in order that Lessee may perform through its own non-union contractors (or union contractor if required by Lessor) such other work and decorations as Lessee may desire at the same time Lessor's contractors are working in the Expansion Premises. The foregoing license to enter prior to the Commencement Date, however, is conditioned upon:
  - Lessee's workmen and mechanics working in harmony and not interfering with the labor employed by Lessor, Lessor's mechanics or contractors or by any other Lessee or its mechanics or contractors; and
  - b. Lessee providing Lessor with evidence of Lessee's contractors and subcontractors carrying such worker's compensation, general liability, personal and property insurance as required by law and in amounts no less than the amounts set forth in Article 30 of the Lease. If at any time such entry shall cause disharmony or interference therewith, this license may be withdrawn by Lessor upon forty-eight (48) hours written notice to Lessee. Such entry shall be deemed controlled by all of the terms, covenants, provisions and conditions of said Lease, except as to the covenant to pay Fixed Basic Rent and Additional Rent. Lessor shall not be liable in any way for any injury, loss or damage which may occur to any of Lessee's decorations or installations so made prior to the Effective Date, the same being solely at Lessee's risk.
- 14. No part of the Expansion Premises shall be deemed unavailable for occupancy by the Lessee, or shall any work which the Lessor is obligated to perform in such part of the Expansion Premises be deemed incomplete for the purpose of any adjustment of Fixed Basic Rent payable hereunder, solely due to the non-completion of details of construction, decoration or mechanical adjustments which are minor in character and the non-completion of which does not materially interfere with the Lessee's use of such part of the Expansion Premises.
- 15. Lessee is responsible for all costs related to the repairs and maintenance of any additional or supplemental HVAC systems, appliances and equipment installed to meet Lessee's specific requirements. Lessee shall purchase a service contract for this equipment so that the equipment is covered by such service contract each year of the term of the Lease and shall forward a copy of such contract to Lessor.
- 16. If construction is to occur in a space occupied by Lessee's employees, Lessee shall be liable for all costs associated with a delay if Lessee shall fail to comply with a submitted construction schedule to relocate personnel, furniture, or equipment. These costs shall include, but not be limited to the following:
  - a. cost of construction workers time wasted; and
  - b. cost of any overtime work necessary to meet schedule deadlines; and

- c. any other costs associated with delays in final completion.
- 17. This workletter is based on the quantities and specifications listed herein. Any change to these specifications shall require the recalculation of the construction costs. Such recalculation shall not negate any other section of this Lease.
- 18. All sums payable by Lessee to Lessor in connection with this Exhibit B and any other work to be performed by Lessor within the Expansion Premises and billable to Lessee shall be deemed Additional Rent.
- 19. With respect to the construction work being conducted in or about the Expansion Premises, each party agrees to be bound by the approval and actions of their respective construction representatives. Unless changed by written notification, the parties hereby designate the following individuals as their respective construction representatives:

FOR LESSOR:

FOR LESSEE:

c/o Mack-Cali Realty Corporation

Dave Mitchell The Medicines Company 8 Campus Drive, Parsippany, NJ (973) 647-6069

#### PARTIES

1.1 THIS AGREEMENT made the 31st day of December, 2003 is between SYLVAN/CAMPUS REALTY L.L.C. ("Lessor") whose address is c/o Mack-Cali Realty Corporation, 11 Commerce Drive, Cranford, New Jersey 07016 and THE MEDICINES COMPANY ("Lessee"), whose address is 8 Campus Drive, Parsippany, New Jersey 07054.

# 2. STATEMENT OF FACTS

- 2.1 Lessor and Lessee previously entered into a Lease dated September 30, 2002, as amended by First Amendment to Lease dated June 30, 2003 (together, the "Lease") covering approximately 20,229 gross rentable square feet on the second (2nd) floor in the building located at 8 Campus Drive, Parsippany, New Jersey ("Building"); and
- 2.2 Lessee desires to expand the office space subject to the Lease by leasing approximately 12,437 gross rentable square feet on the first (1st) floor of the Building ("Expansion Premises"), as shown on Exhibit A attached hereto and made a part hereof; and
- 2.3 The parties desire to amend certain terms of the Lease as set forth below.

### 3. AGREEMENT

NOW, THEREFORE, in consideration of the terms, covenants and conditions hereinafter set forth, Lessor and Lessee agree as follows:

- 3.1 The above recitals are incorporated herein by reference.
- 3.2 All capitalized and non-capitalized terms used in this Agreement which are not separately defined herein but are defined in the Lease shall have the meaning given to any such term in the Lease.
- 3.3 The Term applicable to the Expansion Premises shall commence on the Effective Date (as defined below) and shall terminate at 11:59 p.m. on January 31, 2013.
- 3.4 The effective date applicable to the Expansion Premises shall be the earlier of (i) the day Lessor substantially completes the improvements to be made to the Expansion Premises in accordance with Exhibit B attached hereto and made part hereof and obtains a (temporary or final) certificate of occupancy for the Expansion Premises (if required by local law) or (ii) the date Lessee or anyone claiming under or through Lessee shall occupy the Expansion Premises (the "Effective Date").
- 3.5 Lessor, at its sole cost and expense, shall perform the improvement work to the Expansion Premises in accordance with Exhibit B attached hereto and made part hereof.
- 3.6 From and after the Effective Date, the following shall be effective:
  - a. Lessor shall lease to Lessee and Lessee shall hire from Lessor the Expansion Premises as shown on Exhibit A attached hereto and made part hereof.
  - b. The Premises shall be defined as approximately 32,666 gross rentable square feet consisting of 20,229 gross rentable square feet on the second (2nd) floor and 12,437 gross rentable square feet on the first (1st) floor of the Building and Paragraph 7 of the Preamble to the Lease and Exhibit A shall be deemed amended accordingly.
  - c. Lessee shall pay Lessor Fixed Basic Rent applicable to the Expansion Premises which shall accrue as follows and Paragraph 10 of the Preamble to the Lease shall be deemed supplemented accordingly.
    - (i) commencing on the Effective Date through and including January 31, 2006, the Fixed Basic Rent applicable to the Expansion Premises shall be THREE HUNDRED FORTY-TWO THOUSAND SEVENTEEN AND 52/100 DOLLARS (\$342,017.52) per annum, payable in advance on the first day of each and every calendar month

in equal monthly installments of TWENTY-EIGHT THOUSAND FIVE HUNDRED ONE AND 46/100 DOLLARS (28,501.46); and

- (ii) commencing on February 1, 2006 through and including January 31, 2007, the Fixed Basic Rent applicable to the Expansion Premises shall be THREE HUNDRED FORTY-EIGHT THOUSAND TWO HUNDRED THIRTY-SIX AND 00/100 DOLLARS (\$348,236.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of TWENTY-NINE THOUSAND NINETEEN AND 67/100 DOLLARS (\$29,019.67); and
- (iii) commencing on February 1, 2007 through and including January 31, 2008, the Fixed Basic Rent applicable to the Expansion Premises shall be THREE HUNDRED FIFTY-FOUR THOUSAND FOUR HUNDRED FIFTY-FOUR AND 50/100 DOLLARS (\$354,454.50) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of TWENTY-NINE THOUSAND FIVE HUNDRED THIRTY-SEVEN AND 88/100 DOLLARS (\$29,537.88); and
- (iv) commencing on February 1, 2008 through and including January 31, 2009, the Fixed Basic Rent applicable to the Expansion Premises shall be THREE HUNDRED SIXTY THOUSAND SIX HUNDRED SEVENTY-THREE AND 00/100 DOLLARS (\$360,673.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of THIRTY THOUSAND FIFTY-SIX AND 08/100 DOLLARS (\$30,056.08); and
- (v) commencing on February 1, 2009 through and including January 31, 2010, the Fixed Basic Rent applicable to the Expansion Premises shall be THREE HUNDRED SIXTY-SIX THOUSAND EIGHT HUNDRED NINETY-ONE AND 50/100 DOLLARS (\$366,891.50) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of THIRTY THOUSAND FIVE HUNDRED SEVENTY-FOUR AND 29/100 DOLLARS (\$30,574.29); and
- (vi) commencing on February 1, 2010 through and including January 31, 2011, the Fixed Basic Rent applicable to the Expansion Premises shall be THREE HUNDRED SEVENTY-THREE THOUSAND ONE HUNDRED TEN AND 00/100 DOLLARS (\$373,110.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of THIRTY-ONE THOUSAND NINETY-TWO AND 50/100 DOLLARS (\$31,092.50); and
- (vii) commencing on February 1, 2011 through and including January 31, 2012, the Fixed Basic Rent applicable to the Expansion Premises shall be THREE HUNDRED SEVENTY-NINE THOUSAND THREE HUNDRED TWENTY-EIGHT AND 50/100 DOLLARS (\$379,328.50) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of THIRTY-ONE THOUSAND SIX HUNDRED TEN AND 71/100 DOLLARS (\$31,610.71); and
- (viii) commencing on February 1, 2012 through and including January 31, 2013, the Fixed Basic Rent applicable to the Expansion Premises shall be THREE HUNDRED EIGHTY-FIVE THOUSAND FIVE HUNDRED FORTY-SEVEN AND 00/100 DOLLARS (\$385,547.00) per annum, payable in advance on the first day of each and every calendar month in equal monthly installments of THIRTY-TWO THOUSAND ONE HUNDRED TWENTY-EIGHT AND 92/100 DOLLARS (\$32,128.92).

Notwithstanding the foregoing, Tenant shall be entitled to a credit against Fixed Basic Rent in the amount of \$14,095.27 per month for the period commencing on the Effective Date through and including the first twelve (12) months.

- d. Parking Spaces shall be increased by forty-seven (47) unassigned spaces, and Paragraph 14 of the Preamble to the Lease shall be deemed amended accordingly.
- e. Lessee shall pay Lessor the cost of electricity consumed within the Expansion Premises in accordance with Article 22 BUILDING STANDARD OFFICE ELECTRICAL SERVICE of the Lease.
- f. Lessee shall pay Lessor, as Additional Rent, Lessee's Percentage applicable to the Expansion Premises of the increased cost to Lessor for each of the categories set forth in Article 23 ADDITIONAL RENT.
- g. Lessee's Percentage applicable to the Expansion Premises shall be 5.78%.
- h. Base Period Costs with respect to the Expansion Premises (as defined herein) only shall be as follows and Paragraph 2 of the Preamble to the Lease shall be supplemented accordingly:

(A) Base Operating Costs: Those costs incurred for the Building and Office Building Area during the Calendar Year 2004.

(B) Base Real Estate Taxes: Those Real Estate Taxes incurred for the Building and Office Building Area during Calendar Year 2004.

(C) Base Utility and Energy Costs: Those costs incurred for the Building and Office Building Area during Calendar Year 2004.

- 3.7 Article 54 of the Lease shall be applicable to the Expansion Premises.
- 3.8 This Agreement shall not extend or otherwise amend the Term or Fixed Basic Rent applicable to the Premises as defined herein.
- 3.9 No later than thirty (30) days after the determination of the Effective Date, the parties shall agree to memorialize the Effective Date in writing.
- 3.10 Lessee represents and warrants to Lessor that no broker, other than Trammel Crow Company, brought about this transaction, and Lessee agrees to indemnify and hold Lessor harmless from any and all claims of any other broker claiming to have been engaged by Lessee in connection with negotiations of, or entering into of, this Agreement.
- 3.11 Lessee hereby represents to Lessor that (i) except for any default which may exist as a result of the filing of certain liens against the Building, there exists no default under the Lease either by Lessor or Lessee; (ii) Lessee is entitled to no credit, free rent or other offset or abatement of the rents due under the Lease; and (iii) there exists no offset, defense or counterclaim to Lessee's obligation under the Lease.
- 3.12 Except as expressly amended herein, the Lease, as amended, shall remain in full force and effect as if the same had been set forth in full herein, and Lessor and Lessee hereby ratify and confirm all of the terms and conditions thereof.
- 3.13 This agreement shall be binding upon and inure to the benefit of the parties hereto and their respective legal representatives, successors and permitted assigns.
- 3.14 Each party agrees that it will not raise or assert as a defense to any obligation under the Lease or this Agreement or make any claim that the Lease or this Agreement is invalid or unenforceable due to any failure of this document to comply with ministerial requirements including, but not limited to, requirements for corporate seals, attestations, witnesses, notarizations, or other similar requirements, and each party hereby waives the right to assert any such defense or make any claim of invalidity or unenforceability due to any of the foregoing.

IN WITNESS WHEREOF, Lessor and Lessee have hereunto set their hands and seals the date and year first above written, and acknowledge one to the other that they possess the requisite

authority to enter into this transaction and to sign this Agreement.

LESSEE:

THE MEDICINES COMPANY

SYLVAN/CAMPUS REALTY L.L.C.

LESSOR:

By: Mack-Cali Realty, L.P., member

- By: Mack-Cali Realty Corporation, its general partner
- Michael K. Neving By: s/ Michael K. Nevins By: s/ Steven H. Koehler Michael K. Nevins Vice President - Leasing

\_\_\_\_\_ \_\_\_\_\_ Name: Steve H. Koehler Title: CFO

# EXHIBIT A

# LOCATION OF PREMISES

#### [Schematic diagram of expansion premises]

# 5

### EXHIBIT B

RE: Workletter Agreement for office space on the first (1st) floor at 8 Campus Drive, Parsippany, New Jersey.

December 31, 2003

### LESSEE:

### THE MEDICINES COMPANY

You ("Lessee") and we ("Lessor") are executing simultaneously with this Workletter Agreement a written lease amendment ("Amendment"), covering the space referred to above, as more particularly described in the Amendment ("Expansion Premises").

To induce Lessee to enter into the Amendment (which is hereby incorporated by reference) and in consideration of the covenants hereinafter contained, Lessor and Lessee mutually agree as follows:

- Lessor shall have its architect prepare the following architectural and mechanical drawings and specifications based upon the sketch layout supplied to Lessor by Lessee, attached hereto and made a part hereof, upon full execution of this Amendment.
  - a. Architectural drawings and specifications for Lessee's partition layout, reflected ceiling, placement of electrical outlets and other installations for the work to be done by Lessor.
  - b. Mechanical plans and specifications where necessary for installation of air conditioning systems, ductwork and heating.

All such plans and specifications are expressly subject to Lessor's written approval, which Lessor covenants it will not unreasonably withhold.

- 2. Lessor agrees to cause the partition plan, electrical plan and the reflected ceiling plan to be delivered to Lessee on or before the fifteenth (15th) day after Lessee's approved sketch layout. Lessee agrees to approve said plans by initialing and returning same to Lessor within five (5) days of receipt of each plan. Upon approval of the plans initialed by Lessee, Lessor shall file said plans with the appropriate governmental agencies.
- 3. Lessor agrees, at its expense and without charge to Lessee (unless otherwise provided), to do the work in the Expansion Premises as shown on the plans attached hereto and described on the "Description of Materials" schedule attached hereto; which shall hereinafter be referred to as "The Work". The Work shall include Lessor's general conditions and overhead amounts indicated on the Description of Materials. "Building Standard" shall mean the type and grade of material, equipment and/or device designated by Lessor as standard for the Building. All items are Building Standard unless otherwise noted. The provisions of Article 6 of the Lease shall apply to any alterations made to the Expansion Premises after the initial work to be performed therein.
- 4. Lessor has estimated the cost of The Work based upon the plans, specifications and Description of Materials attached hereto. If the cost of The Work shall exceed \$310,925.00, the amount in excess of \$310,925.00 shall be deemed Additional Rent and paid by Lessee as follows: (i) fifty percent (50%) upon Lessee's execution and delivery of this Amendment and (ii) fifty percent (50%) upon Lessor's substantial completion of The Work and prior to Lessee's occupancy of the Expansion Premises. If the cost of The Work is less than \$310,925.00, the amount by which the cost of The Work is less than \$310.925.00 shall be credited in payment of the Fixed Basic Rent applicable to the Expansion Premises in the order in which such Fixed Basic Rent shall become due. All subcontracts which exceed \$10,000.00 in cost will be competitively bid by at least three (3) subcontractors. Lessee's construction representative identified in Paragraph 19 of this Exhibit B shall be given notice of and the opportunity to participate in progress meetings with respect to The Work.
- All low partitioning, workstation modules and prefabricated partition systems shall be furnished and installed by Lessee.

- 6. The installation or wiring of telephone and computer (data) outlets is not part of The Work. Lessee shall bear the responsibility to provide its own telephone and data systems at Lessee's sole cost and expense. Upon expiration or sooner termination of the Lease, Lessee shall remove all telephone and data equipment and wiring from the Expansion Premises and the Building risers upon vacation of same.
- 7. Changes in The Work, if necessary or requested by the Lessee, shall be accomplished after submission of Lessee's final approved sketch layout, and without invalidating any part of the Lease or Workletter Agreement, by written agreement between Lessor and Lessee hereinafter referred to as a Change Order. Each Change Order shall be prepared by Lessor and signed by both Lessee and Lessor stating their agreement upon all of the following:
  - a. The scope of the change in The Work; and
  - b. The cost of the change; and
  - c. Manner in which the cost will be paid or credited; and
  - d. The estimated extent of any adjustment to the Effective Date (if any) as a result of the change in The Work.

Each and every Change Order shall be signed by Lessor's and Lessee's respective construction representatives. In no event shall any Change Order(s) be permitted without such authorizations. A 10% supervision plus 10% overhead charge will be added to the cost of any Change Order. If Lessee shall fail to approve any such Change Order within one (1) week, the same shall be deemed disapproved in all respects by Lessee and Lessor shall not be authorized to proceed thereon. Any increase in the cost of The Work or the change in The Work stated in a Change Order which results from Lessee's failure to timely approve and return said Change Order shall be paid by the Lessee. Lessee agrees to pay to Lessor the cost of any Change Order promptly upon receipt of an invoice for same. Similarly, any cost savings resulting from such Change Order(s) shall be credited to the Lessee.

- 8. If any change is made after completion of schematic drawings and prior to completion of final construction documents which result in a Change Order and additional costs, such costs shall be the responsibility of the Lessee.
- 9. Prior to Lessee's occupancy of the Expansion Premises, Lessee shall identify and list any portion of The Work which does not conform to this Workletter Agreement ("Punch List"). The Lessor shall review with the Lessee all of the items so listed and correct or complete any portion of The Work which fails to conform to the requirements of this Workletter Agreement.
- 10. The terms contained in the Amendment (which include all exhibits attached thereto) constitute Lessor's agreement with Lessee with respect to the work to be performed by Lessor on Lessee's behalf. If the architectural drawings are in conflict with the terms of the Amendment, then the Lease shall be deemed the controlling document.
- 11. All materials and installations constructed for the Lessee within the Expansion Premises shall become the property of the Lessor upon installation. No refund, credit or removal of said items is to be permitted at the termination of the Lease. Items installed that are not integrated in any such way with other common building materials do not fall under this provision (e.g. shelving, furniture, etc.).
- 12. It is agreed that notwithstanding the date provided in the Lease for the Effective Date, the term applicable to the Expansion Premises shall not commence until Lessor has "substantially completed" all work to be performed by Lessor as hereinbefore set forth in Paragraph 3 above and as set forth in the Amendment; provided, however, that if Lessor shall be delayed in substantially completing said work as a result of:
  - a. Lessee's failure to approve the plans and specifications in accordance with Paragraph 2 hereof; or

- b. Lessee's failure to furnish interior finish specifications, i.e., paint colors, carpet selection, etc., to Lessor by the fifth (5th) working day after Lessor has approved the plans and specifications submitted by Lessee referred to in Paragraph 2 hereof; or
- c. Lessee's request for materials, finishes or installations other than Lessor's Building Standard; or
- d. Lessee's changes in The Work; or
- e. The performance of a person, firm, partnership or corporation employed by Lessee and the completion of the said work by said person, firm, partnership or corporation;

then the Effective Date of the term of said Lease shall be accelerated by the number of days of such delay and Lessee's obligation to pay Fixed Basic Rent and Additional Rent shall commence as of such earlier date. As to matters described in clauses (a) - (e) above, Lessor shall advise Lessee of any delay that Lessor knows is reasonably likely to occur as a result of the matter described, within a reasonable time after Lessor becomes aware of such likelihood. If Lessee causes any delay in the Effective Date by reason of any act and/or omission of Lessor or its agents, then such delay by Lessee shall not result in an acceleration of the Effective Date as set forth above.

- 13. Lessor shall permit Lessee and its agents to enter the Expansion Premises prior to the Commencement Date in order that Lessee may perform through its own non-union contractors (or union contractor if required by Lessor) such other work and decorations as Lessee may desire at the same time Lessor's contractors are working in the Expansion Premises. The foregoing license to enter prior to the Commencement Date, however, is conditioned upon:
  - a. Lessee's workmen and mechanics working in harmony and not interfering with the labor employed by Lessor, Lessor's mechanics or contractors or by any other Lessee or its mechanics or contractors; and
  - b. Lessee providing Lessor with evidence of Lessee's contractors and subcontractors carrying such worker's compensation, general liability, personal and property insurance as required by law and in amounts no less than the amounts set forth in Article 30 of the Lease. If at any time such entry shall cause disharmony or interference therewith, this license may be withdrawn by Lessor upon forty-eight (48) hours written notice to Lessee. Such entry shall be deemed controlled by all of the terms, covenants, provisions and conditions of said Lease, except as to the covenant to pay Fixed Basic Rent and Additional Rent. Lessor shall not be liable in any way for any injury, loss or damage which may occur to any of Lessee's decorations or installations so made prior to the Effective Date, the same being solely at Lessee's risk.
- 14. No part of the Expansion Premises shall be deemed unavailable for occupancy by the Lessee, nor shall any work which the Lessor is obligated to perform in such part of the Expansion Premises be deemed incomplete for the purpose of any adjustment of Fixed Basic Rent payable hereunder, solely due to the non-completion of details of construction, decoration or mechanical adjustments which are minor in character and the non-completion of which does not materially interfere with the Lessee's use of such part of the Expansion Premises.
- 15. Lessee is responsible for all costs related to the repairs and maintenance of any additional or supplemental HVAC systems, appliances and equipment installed to meet Lessee's specific requirements. Lessee shall purchase a service contract for this equipment so that the equipment is covered by such service contract each year of the term of the Lease and shall forward a copy of such contract to Lessor.
- 16. If construction is to occur in a space occupied by Lessee's employees, Lessee shall be liable for all costs associated with a delay if Lessee shall fail to comply with a submitted construction schedule to relocate personnel, furniture, or equipment. These costs shall include, but not be limited to the following:

a. cost of construction workers time wasted; and

- b. cost of any overtime work necessary to meet schedule deadlines; and
- c. any other costs associated with delays in final completion.
- 17. This workletter is based on the quantities and specifications listed herein. Any change to these specifications shall require the recalculation of the construction costs. Such recalculation shall not negate any other section of this Lease.
- 18. All sums payable by Lessee to Lessor in connection with this Exhibit B and any other work to be performed by Lessor within the Expansion Premises and billable to Lessee shall be deemed Additional Rent.
- 19. With respect to the construction work being conducted in or about the Expansion Premises, each party agrees to be bound by the approval and actions of their respective construction representatives. Unless changed by written notification, the parties hereby designate the following individuals as their respective construction representatives:

FOR LESSOR:

FOR LESSEE:

JIM CORRIGAN c/o Mack-Cali Realty Corporation 6 CAMPUS DRIVE PASIPPANY, NJ Dave Mitchell The Medicines Company 8 Campus Drive, Parsippany, NJ (973) 647-6069

</TEXT>

</DOCUMENT>

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

10 April, 2003

The Medicines Company 8 Campus Drive Parsippany New Jersey 07054 United States

Att: Clive Meanwell Executive Chairman

RE: OPTION AGREEMENT REGARDING CLEVIDIPINE ENTERED INTO BY AND BETWEEN ASTRAZENECA AB ("ASTRAZENECA") AND THE MEDICINES COMPANY, ON 5 MARCH 2002, WITH SUBSEQUENT AMENDMENTS DATED 31 JULY 2002 AND 20 NOVEMBER 2002, (THE "OPTION AGREEMENT")

Dear Mr. Meanwell,

(Each term used herein and defined in the Option Agreement shall have the meaning so defined therein.)

We would hereby like to confirm our mutual decision for the License Agreement to enter into effect. Hence, despite the fact that the Final Report has yet not been received by AstraZeneca, and regardless of whether the Trigger has been met or will be met, License Agreement Notice shall be deemed to have been given by The Medicines Company. As a consequence hereof the License Agreement shall be deemed to have entered into force. 28 March 2003 shall constitute the License Agreement Effective Date.

AstraZeneca would appreciate payment of [\*\*] U.S. Dollars (USD [\*\*]) in accordance with Article 6.1.1 of the License Agreement to be made by wire transfer to the following account of AstraZeneca.

Bank name: [\*\*] Account No.: [\*\*] Swift: [\*\*] If the above correctly reflects our agreement please sign both originals of this Letter Agreement where indicated below and return one signed original to Dr. Anders Waas at the following address: AstraZeneca R&D Molndal, Global Licensing, SE-431 83 Molndal Sweden.

Yours sincerely,

ASTRAZENECA AB (publ)

[illegible]

Name:

Agreed and accepted

Date:

THE MEDICINES COMPANY /s/ Clive Meanwell

\_\_\_\_\_

Name: Clive Meanwell

cc: Steven D. Singer Hale and Dorr 60 State Street Boston, MA 02109 United States TABLE OF CONTENTS

ARTICLE

1.	Definitions	2
2.	Grant of License	11
3.	Development and Commercialisation	14
4.	Supply Matters	23
5.	Exchange of Information	25
б.	Consideration	28
7.	Intellectual Property - Prosecution and Maintenance	35
8.	Claims Regarding Infringement and Invalidity	37
9.	Trademark	42
10.	Indemnity	45
11.	Confidentiality	47
12.	Adverse Events	49
13.	Representation and Warranty	50
14.	Term and Termination	53
15.	Consequences of Termination	55
16.	Force Majeure	58
17.	General Provisions	59
	- Assignment	59
	- Severance	60
	- Notices	60
	- Contact Information	61
	- Agency, Partnership or Joint Venture Excluded	62
	- Entire Agreement	62
	- Agreement to Supersede earlier Agreements	62
	- Amendments	62
		62
	- Publicity and Announcements	
	- Waiver	63
1.0	- No Benefit to Third Parties	63
18.	Governing Law and Arbitration	63

Page \_\_\_\_

- 18. Governing Law and Arbitration
  - i

### LICENSE AGREEMENT

This Agreement is entered into on the License Agreement Effective Date

by and between

ASTRAZENECA AB, a company incorporated under the laws of Sweden with its registered office at S-151 85 Sodertalje, Sweden ("ASTRAZENECA") and

THE MEDICINES COMPANY, a company incorporated under the laws of Delaware with its registered office at One Cambridge Center, Cambridge, Massachusetts 02142, United States ("TMC");

### WITNESSETH

WHEREAS, ASTRAZENECA performs research, development and marketing of pharmaceutical compounds and products inter alia in the cardiovascular therapy area; and

WHEREAS, ASTRAZENECA has developed the intravenous product Clevidipine for indications such as the control of blood pressure; and

WHEREAS, TMC performs development of pharmaceutical compounds and marketing of pharmaceutical products particularly in the cardiovascular therapy area; and

WHEREAS, ASTRAZENECA has expressed an interest to license Clevidipine to TMC and TMC has expressed an interest to license said compound; and

WHEREAS, it is a mutual objective of the Parties to maximise the sales of the Product.

NOW THEREFORE, the Parties hereto agree to the following.

#### 1. DEFINITIONS

When used in this Agreement the following expressions shall have the meanings defined herein. The singular form of the defined expression shall include the plural form thereof and vice versa.

ii

1.1. "Adverse Event" shall mean the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product whether or not considered causally related to such product.

1.2. "ANDA Act" shall have the meaning defined in Article 8.3.1(a).

1.3. "Affiliate" with respect to a Person shall mean any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. For the purposes of this Article 1.3 only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with", shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise, and/or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person.

1.4. "Agreement" shall mean this document including any and all schedules, appendices and other addenda to it as may be changed, added and/or amended from time to time in accordance with the provisions of this Agreement.

1.5. "ASTRAZENECA IP" shall mean the ASTRAZENECA Patent Rights, the ASTRAZENECA Know-How and, subject to what is stated in Article 9.1, the ASTRAZENECA Trademark.

1.6. "ASTRAZENECA Indemnified Party" shall have the meaning defined in Article 10.1.1.

1.7. "ASTRAZENECA Know-How" shall mean any Know-How relating to the Compound and/or the Product, developed, acquired or licensed by ASTRAZENECA prior to the License Agreement Effective Date and in ASTRAZENECA's possession at the License Agreement Effective Date.

1.8. "ASTRAZENECA Patent Rights" shall mean the patents and patent applications as set out in Schedule A and any Patent Rights claiming priority thereto.

1.9. "ASTRAZENECA Trademark" shall mean the trademark Clevelox(TM) which ASTRAZENECA as of the License Agreement Effective Date has registered for the Product in the countries set forth in Schedule B.

1.10. "Combination Product" shall mean any pharmaceutical product in a finished dosage form which comprises the Compound and at least one other active pharmaceutical ingredient.

1.11. "Commercially Reasonable Efforts" shall mean with respect to the efforts to be expended by a Party with respect to any objective, the use of reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that with respect to the research, development or commercialisation of Product, such efforts shall be substantially equivalent to those efforts and resources commonly used by a Party for a product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, Regulatory Authority-approved labelling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the Product, the likelihood of

regulatory approval given the regulatory structure involved, the profitability of the Product taking into account the royalties payable to licensors of patent or other intellectual property rights, alternative products and other relevant commercial factors. Commercially Reasonable Efforts shall be determined on a country-by-country basis for the Product, and it is anticipated that the level of effort will change over time (including, to the extent appropriate, the reduction or cessation of active promotional efforts), reflecting changes in the status of the Product and the market(s) involved

1.12. "Compound" shall mean ASTRAZENECA's proprietary compound named Clevidipine with the chemical structure as shown in Schedule C, attached hereto, including all salts, esters, complexes, chelates, hydrates, isomers, stereoisomers, crystalline and amorphous forms, prodrugs, solvates, metabolites and metabolic precursors (whether active or inactive) thereof.

1.13. "Confidential Information" shall mean (i) in the case of TMC being the receiving Party, ASTRAZENECA IP, and (ii) in the case of ASTRAZENECA being the receiving Party TMC IP, and (iii) in the case of either Party being the receiving Party, data generated by either or both Parties hereunder and trade secrets and/or confidential information relating to technology, including but not limited to compound(s), composition(s), formulation(s) and/or manufacturing information, and/or relating to the business affairs, including but not limited to commercial forecasts, plans, programs, customers, assets, financial projections, costs and customer lists and/or finances of the Disclosing Party, supplied or otherwise made available to the Receiving Party or coming into Receiving Party's possession in relation to the performance of this Agreement.

1.14. "Disclosing Party" shall mean the Party which discloses Confidential Information to the other Party.

1.15. "Documents" shall mean reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM, computer programs and documents thereof, computer information storage means, samples of material, other graphic or written data and any other media on which Know-How can be permanently or temporarily stored.

1.16. "European Union" shall mean the countries that are, whether at the License Agreement Effective Date or at any time thereafter, members of the European Union.

1.17. "European Economic Area" shall mean the European Union plus Norway, Iceland and Liechtenstein.

1.18. "FDA" shall mean the United States Food and Drug Administration or any successor agency thereto.

1.19. "FTE Day" shall mean the equivalent of one person employed by ASTRAZENECA or TMC, as applicable, or their respective Affiliates full time for one day.

1.20. "Filing of an NDA" shall mean the date of acceptance for review by the competent registration body in a given country of an NDA.

1.21. "Force Majeure" shall mean any cause preventing either Party from performing any or all of its obligations which arises from or is attributable to acts, events, omissions or

accidents beyond the reasonable control of the Party so prevented, act of God, war, riot, civil commotion, malicious damage, accident, breakdown of plant or machinery, fire, flood or storm.

1.22. "Fresenius" shall mean Fresenius Kabi Nutrition AB, S-751 74 Uppsala, Sweden.

1.23. "Launch" or "Launched" shall mean the first invoiced commercial sale by TMC, its Affiliates, sub-licensees or distributors, however not including sales made by one such entity to another such entity, of the Product in a country following NDA Approval in such country.

"Know-How" shall mean technical and other information, which is not 1.24 subject to published patent rights and which is not in the public domain, including, but not limited to, information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing, including results of research or development, processes, including manufacturing processes, specifications and techniques, laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries and information contained in submissions to and information from ethical committees and regulatory authorities. Know-How includes Documents containing Know-How, including but not limited to any rights including trade secrets, copyright, database or design rights protecting such Know-How. The fact that an item is known to the public shall not be taken to preclude the possibility that a compilation including the item, and/or a development relating to the item, is not known to the public.

1.25. "License Agreement Effective Date" shall have the meaning defined in the Option Agreement.

1.26. "Major Market" shall mean each of  $[\,^{\star\star}]$  and  $[\,^{\star\star}].$  Further  $[\,^{\star\star}]$  shall constitute one Major Market.

1.27. "NDA" shall mean a fully completed marketing license application comparable to a New Drug Application filed with the FDA, including all supporting documentation and data required for such application to be accepted for review by the competent health regulatory authorities for any country requesting approval for commercialisation of the Product for a particular indication in such country. NDA as herein defined shall for this purpose include applications for pricing or reimbursement approval where appropriate.

1.28. "NDA Approval" shall mean the approval by the competent registration body for a given country of an NDA.

1.29. "Net Sales" shall mean the gross sales of Product by a Party or its Affiliates, and, regarding sales in the United States, its sub-licensees or distributors, to Third Parties after deduction of:

- a) [\*\*] and/or [\*\*];
- b) amounts [\*\*] determined in good faith;
- c) [\*\*] such sales; and

d) [\*\*] the Product.

In the event the Product is sold as part of a Combination Product, the Net Sales from the Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product (as defined in the standard Net Sales definition), during the applicable royalty reporting period, by the fraction, A/A+B, where A is the average sale price of the Product when sold separately in finished form and B is the average sale price of the other product(s) included in the Combination Product when sold separately in finished form, in each case during the applicable royalty reporting period or, if sales of both the Product and the other product(s) did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred, as adjusted, as necessary, for inflation from the date when both the Product and all other product(s) last were sold and the date of determination of Net Sales under this Article 1.29. In the event that such average sale price cannot be determined for both the Product and all other products(s) included in the Combination Product, Net Sales for the purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction of C/C+D where C is the fair market value of the Product and D is the fair market value of all other pharmaceutical product(s) included in the Combination Product. In such event, the selling Party shall in good faith make a determination of the respective fair market values of the Product and all other pharmaceutical products included in the Combination Product, and shall notify the other Party of such determination and provide the other Party with data to support such determination. The other Party shall have the right to review such determination and supporting data, and to notify the selling Party if it disagrees with such determination. If the other Party does not agree with such determination and if the Parties are unable to agree in good faith as to such respective fair market values, then such matter shall be referred to arbitration pursuant to Article 18.1.

Net Sales shall exclude (i) the transfer of a commercially reasonable quantity of free samples of Product to be given out to customers for promotional purposes; (ii) the transfer of Product for use in clinical trials; and (iii) the sales or transfers of Product among a Party and its Affiliates, and, in the United States, its sub-licensees or distributors, unless the receiver is the consumer or user of the Product; however, the resale or transfer of such Product to a Third Party shall be included in Net Sales.

Product sold or otherwise transferred (x) in other than an arms length transaction or for other property (e.g. barter); or (y) where no separate price has been decided for the Product but a price is decided jointly for the Product plus at least one other product, shall be deemed invoiced at its fair market price in the country of sale or transfer.

It is acknowledged that sub-licensees of a Party or its Affiliates and conventional distributors whose function is to purchase and resell Product, will be considered Third Parties when referring to Product sold outside the United States. The Parties agree further that for the purpose of the first

paragraph of this Article 1.29 the Net Sales of the Product outside the United States by TMC or its Affiliates to such sub-licensees and distributors shall be the Net Sales received by TMC or its Affiliates from such sub-licensee or distributor for the Product or [\*\*] percent ([\*\*]%) of the actual gross sales, less deductions under subsections (a) through (d) above, of the Product by such sublicensee or distributor, whichever amount is the higher.

1.30. "Option Agreement" shall mean the Study and Exclusive Option Agreement entered into by and between the Parties on 5 March 2002.

1.31. "Party" or "Parties" shall mean TMC and/or ASTRAZENECA.

1.32. "Patent Rights" shall mean patent applications and patents, utility models, utility certificates, certificates of addition and all foreign counterparts of them in all countries, including any divisional applications and patents, refilings, renewals, continuations, continuations-in-part, patents of addition, extensions (including patent term extensions), reissues, substitutions, confirmations, registrations, revalidations, pipeline and administrative protections and additions, and any equivalents of the foregoing in any and all countries of or to any of them, as well as any supplementary protection certificates and equivalent protection rights in respect of any of them.

1.33. "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.34. "Procedure" shall have the meaning defined in Article 3.5.1.

1.35. "Product" shall mean any pharmaceutical formulation or product for intravenous application containing the Compound as the sole active ingredient in a finished dosage form suitable for administration to patients. Apart from in this Article 1.35, and unless the context clearly requires otherwise in this Agreement, when mentioned in this Agreement Product shall be deemed to include Combination Product.

1.36. "Phase III Clinical Trial" shall mean a large scale, pivotal multicentre, human clinical trial to be conducted in a number of patients estimated to be sufficient to establish safety or efficacy in the particular claim and indication and at a standard suitable to obtain NDA Approval.

1.37. "Receiving Party" shall mean the Party which receives Confidential Information from the other Party.

1.38. "Results" shall have the meaning defined in Article 7.8.

1.39. "Supply Agreement" shall have the meaning described in Article 4.3.1.

1.40. "TMC IP" shall mean TMC Know-How and TMC Patent Rights.

1.41. "TMC Indemnified Party" shall have the meaning defined in Article 10.2.1.

1.42. "TMC Know-How" shall mean any Know-How relating directly to the Compound and/or the Product developed, acquired or licensed by TMC during the term of this Agreement.

1.43. "TMC Patent Rights" shall mean any Patent Rights directly relating to the Compound and/or the Product developed, acquired or licensed by TMC during the term of this Agreement.

1.44. "TMC Trademark" shall have the meaning defined in Article 9.1.

1.45. "Territory" shall mean any country in the world except Japan.

1.46. "Third Party" shall mean any Person not including the Parties or the Parties' respective Affiliates.

#### 2. GRANT OF LICENSE

2.1. LICENSE GRANT. ASTRAZENECA hereby grants to TMC an exclusive license in the Territory under the ASTRAZENECA IP to perform research on, have research performed on, develop, have developed, use, have used, make, have made, import, have imported, market, have marketed, sell and have sold the Compound and the Product for all indications. Notwithstanding the foregoing, TMC's license to the ASTRAZENECA Trademark included in the license now granted shall be subject to what is stated in Article 9.1.

2.2. GRANT TO TMC'S AFFILIATES. TMC's Affiliates shall have the benefit and burden of the licenses and rights set out in Article 2.1 for the same purposes and under the same conditions as set forth herein, provided that TMC shall remain fully responsible for the compliance by such Affiliates with the terms and conditions of this Agreement as if such Affiliates were TMC hereunder.

2.3. RIGHT TO SUBLICENSE. TMC shall have the right to grant sub-licenses to the rights granted under Article 2.1, provided that TMC shall notify ASTRAZENECA of each such sublicense without unreasonable delay following any such grant of sub-license. TMC shall ensure that all of its sub-licensees will comply with all terms and conditions of this Agreement and TMC shall remain fully responsible for the compliance by such sub-licensees with the terms and conditions of this Agreement as if such sub-licensees were TMC hereunder.

2.4. RIGHT TO APPOINT DISTRIBUTORS. TMC shall also have the right to appoint distributors in the Territory for the sale of the Product. TMC shall at all times ensure that its distributors act fully in compliance with the terms and conditions of this Agreement.

2.5. DURATION OF LICENSE GRANT. The licenses set out in Article 2.1 shall continue in accordance with what is stated therein on a country-by-country basis until royalty payment is no longer due in the country concerned in accordance with what is stated in Article 6.4, except for the license to the ASTRAZENECA Trademark which shall be governed by what is stated in Article 6.5. The licenses set out in Article 2.1 shall, subject again to what is stated in Article 6.5 regarding the license to the ASTRAZENECA Trademark, thereafter continue on a non-exclusive basis and become fully paid up and royalty-free in the country concerned.

2.6. FIRST RIGHT OF REFUSAL OF TMC REGARDING JAPAN. Should ASTRAZENECA within its sole discretion at any time determine that ASTRAZENECA will not Launch the Product in Japan and/or that ASTRAZENECA will not license, transfer or otherwise dispose of its interest in the ASTRAZENECA IP regarding Japan, then ASTRAZENECA shall offer to TMC, by providing written notice, the first right to negotiate a license on exclusive rights to commercially exploit the Compound and the Product under the ASTRAZENECA IP in Japan on terms similar to those under this Agreement. Should TMC wish to exercise such right, then TMC shall notify ASTRAZENECA hereof in writing no later than ninety (90) days upon receipt of ASTRAZENECA's notice. In reasonable connection with such notice the Parties

shall enter into good faith negotiations using their reasonable endeavours to reach a mutually acceptable agreement providing for such TMC's commercial exploitation as mentioned in this Article 2.6.

2.7. TMC GRANT OF RIGHTS TO ASTRAZENECA REGARDING JAPAN.

2.7.1. In consideration of the rights granted by ASTRAZENECA hereunder, TMC hereby grants to ASTRAZENECA, at no cost or remuneration, a sub-licensable non-exclusive license under the TMC IP to perform research on, have research performed on, develop, have developed, use, have used, make, have made, import, have imported, market, have marketed, sell and have sold the Compound and the Product for all indications in Japan.

2.7.2. TMC shall for the purpose of the license granted in Article 2.7.1 make available to ASTRAZENECA, upon ASTRAZENECA's request, any Filings of an NDA in the Territory, any NDA Approvals obtained in the Territory and any related documents and any TMC's correspondence with any regulatory authorities in the Territory regarding any such Filing of an NDA, NDA Approval or related issues, and shall allow ASTRAZENECA to make cross-references to any such Filing of an NDA or NDA Approval in the Territory. For any services or assistance performed by TMC pursuant to this Article 2.7.2, ASTRAZENECA shall reimburse TMC for TMC's out-of-pocket costs for such activities plus [\*\*]U.S. Dollars (\$[\*\*]) per FTE Day.

2.7.3. Should TMC have selected the TMC Trademark in the Territory, then the license under Article 2.7.1 shall include an exclusive right and license for ASTRAZENECA to utilize the TMC Trademark in Japan. Should ASTRAZENECA use the TMC Trademark in connection with the sales and marketing of Product in Japan, then ASTRAZENECA shall pay to TMC a running royalty of [\*\*]percent ([\*\*]%) on the annual Net Sales of the Product in Japan.

2.8. SECTION 365(n) OF TITLE 11. All rights and licenses granted under or pursuant to any section of this Agreement, including amendments hereto, are, for all purposes of Section 365(n) of Title 11 of the United States Bankruptcy Code ("Title 11"), licenses of rights to "intellectual property" as defined in Title 11. The Parties shall retain and may fully exercise all of their respective rights under this Agreement pursuant to Title 11. Rejection of this Agreement pursuant to Section 365 of Title 11 constitutes a material breach of this Agreement for material breach upon written notice. Upon bankruptcy of either Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

# 3. DEVELOPMENT AND COMMERCIALIZATION

3.1. TRANSFER OF ASTRAZENECA KNOW-HOW. Without unreasonable delay following the License Agreement Effective Date, ASTRAZENECA shall make available and transfer to TMC the following ASTRAZENECA Know-How.

a) a description of the process used by ASTRAZENECA for the manufacturing of the Compound intended for Phase III

Clinical Trials and a summary report of the development of such process;

 b) a description of the process, available to AstraZeneca at the License Agreement Effective Date, for the manufacture of the [\*\*] to be used for the manufacturing of the Compound;

c) a description of the analytical methods and validation reports for the starting materials and intermediates to be used in the manufacturing of the Compound.

It is acknowledged that at the License Agreement Effective Date some of those analytical methods are not fully developed and validated, and such development and validation will not be continued or completed by ASTRAZENECA. ASTRAZENECA will, however, provide a summary report of the status of these methods at the License Agreement Effective Date;

d) the description of the tentative test-methods used by ASTRAZENECA for validating the bulk Compound manufactured, and a brief summary of the validation done thereon by ASTRAZENECA;

e) to the extent available to ASTRAZENECA at the License Agreement Effective Date, reference and analytical standard compounds to be used as reference material in the conduct of comparative analyses in relation to the manufacturing process with the Compound. It is explicitly understood that no such compound may be used for any other purpose than the purpose now stated;

f) a description of all ASTRAZENECA Know-How relating to clinical trials conducted by ASTRAZENECA using the Product prior to the License Agreement Effective Date.

g) reports, the names of which are set forth in Schedule D, containing ASTRAZENECA Know-How relating to the manufacturing of the Compound.

Any documents contemplated by this Article 3.1 shall be in English when transferred to TMC.

### 3.2. THIRD PARTY MANUFACTURERS.

3.2.1. It is acknowledged that TMC may present the ASTRAZENECA Know-How described under Article 3.1 to Third Party manufacturers for the purposes permitted under Article 11.2.4. TMC shall notify ASTRAZENECA in writing regarding the date of submission of such information to any such Third Party manufacturer(s). ASTRAZENECA shall in this connection assist TMC to address questions raised about such ASTRAZENECA Know-How by no more than three (3) of such Third Party manufacturer(s) selected by TMC, during a period of three (3) months from the date of presentation of such ASTRAZENECA Know-How to the Third Party manufacturer concerned. ASTRAZENECA shall also provide TMC with advice on the technical merits of proposals regarding manufacturing of the

Compound brought forward by such Third Party manufacturer(s). Any assistance provided under this Article 3.2.1 may be given by telephone or e-mail or by other appropriate means as agreed by the Parties.

3.2.2. ASTRAZENECA undertakes to participate in no more than one (1) meeting in person with one Third Party manufacturer, selected by TMC, to outline details of the manufacturing synthesis regarding the Compound, provided that such meeting shall take place at ASTRAZENECA's manufacturing site in Sodertalje, Sweden.

3.2.3. ASTRAZENECA further undertakes, should TMC not have exercised its right under Article 2.9 of the Option Agreement, upon having received written notice from TMC, for a period of three (3) months starting sixty (60) days upon ASTRAZENECA's receipt of such notice, to assist TMC, by telephone, e-mail or other appropriate means as agreed by the Parties, in TMC's discussions with Fresenius in connection with Fresenius' restart of the formulation program regarding the Product. The Parties agree, however, that TMC may not give such notice contemplated above in this Article 3.2.3 later than eight (8) months of the License Agreement Effective Date.

3.2.4. ASTRAZENECA agrees to provide reasonable assistance to the Third Party manufacturer selected by TMC, by telephone, e-mail or other appropriate means as agreed by the Parties, in connection with the start-up of manufacturing operations for the Product for a period of twelve (12) months following commencement of process development by such contract manufacturer or fifteen (15) months of the License Agreement Effective Date, whichever is the earliest to occur.

3.3. DURATION OF AND COMPENSATION FOR ASSISTANCE BY ASTRAZENECA.

3.3.1. The Parties agree that any assistance to be provided by ASTRAZENECA under Articles 3.1, 3.2 and 3.5.1 shall be given to an extent necessary and reasonable and shall be given only within the first four (4) years of the License Agreement Effective Date and shall not in total exceed [\*\*]. It is acknowledged that ASTRAZENECA may at its discretion carry out any such assistance for up to [\*\*] percent ([\*\*]%) of such [\*\*] by using Third Party consultants.

3.3.2. For any services or assistance performed by ASTRAZENECA pursuant to Article 3.3.1, TMC shall reimburse ASTRAZENECA for ASTRAZENECA's out-of-pocket costs for such activities plus [\*\*]U.S. Dollars (\$[\*\*]) [\*\*]. Should ASTRAZENECA use a Third Party consultant(s) for carrying out assistance for a certain FTE Day, or part thereof, then, for the avoidance of doubt, the FTE Day rate now stated shall apply thereon, and the out-of-pocket costs for consultants, if any, as indicated above in this paragraph, shall apply only to costs for consultants which would typically have been incurred should the assistance have been actually carried out by an employee(s) of ASTRAZENECA or its Affiliates.

3.3.3. ASTRAZENECA shall invoice TMC for all assistance during each relevant time period within thirty (30) days of the expiration of each calendar half-year.

3.4. DEVELOPMENT OF PRODUCT.

3.4.1. TMC shall, subject to the obligations stated in this Article 3 and in Article 5, carry out the development work permitted hereunder within its sole discretion and at its own cost and expense.

3.4.2. TMC shall use Commercially Reasonable Efforts to develop Product up until the stage of Filing of an NDA in each country of the Territory.

#### 3.5. REGULATORY FILINGS.

3.5.1. TMC shall be responsible for the preparation, submission and prosecution of all Filings of an NDA in each country in which TMC, its Affiliates, sub-licensees or distributors will sell Product. TMC, its Affiliates, sub-licensees or distributors shall be the owner and party of record for all such filings, applications and approvals. ASTRAZENECA agrees to provide assistance requested by TMC as reasonably necessary for preparation and prosecution of such filings and applications in the European Union (it being contemplated that such filings and applications will be done by using the then most efficient centralised procedure for applying for and obtaining multi-country NDAs in the European Union (the "Procedure")), and in the United States. TMC shall reimburse ASTRAZENECA for any costs and expenses incurred in such assistance. TMC shall be responsible for any costs associated with preparation, submission and prosecution of all such Filing of an NDA and NDA Approvals required.

3.5.2. TMC shall, at its own expense, use Commercially Reasonable Efforts in Filing of an NDA and prosecution thereof and in obtaining NDA Approvals in its own name or in the name of its Affiliate(s) in each Major Market and other country of the Territory.

3.5.3. Regarding any country in the European Union where TMC makes a Filing of an NDA, TMC shall for such purpose use the Procedure, unless TMC can clearly establish that Filing of an NDA regarding one or more separate countries within the European Union would be more advantageous to the Product from a regulatory or commercial perspective.

3.5.4. TMC shall promptly inform ASTRAZENECA in writing of any Filing of an NDA and of any NDA Approval, and shall in immediate connection therewith provide ASTRAZENECA with a written summary of any such Filing of an NDA and NDA Approval, or with a copy thereof, whichever ASTRAZENECA may elect.

3.5.5. Following NDA Approval in a certain Major Market or other country of the Territory TMC shall use its Commercially Reasonable Efforts to Launch the Product in such Major Market or other country

3.6. MARKETING AND SALES OF PRODUCT.

3.6.1. Regarding any country of the Territory where the Product is Launched, TMC shall promptly inform ASTRAZENECA writing of the occurrence of such Launch.

3.6.2. TMC shall, in each Major Market or other country of the Territory where the Product has been Launched, at its own expense, or the expense of its Affiliates, sub-licensees or distributors, use Commercially Reasonable Efforts to market and sell the Product.

3.6.3. For the avoidance of doubt, what is stated regarding the obligations of TMC in this Article 3 or elsewhere in this Agreement shall always be subject to what is stated in Articles 2.2 and 2.3, such that any of TMC's obligations may be performed by one or more of TMC's Affiliates or sublicensees. Further, in accordance with what is stated in Article 2.4, any of TMC's obligations under this Article 3.6 and under Article 3.7 may be performed by one or more of TMC's distributors.

3.7. SPECIFIC TIME LIMITS FOR PERFORMANCE. Notwithstanding what is stated in Articles 3.4.2, 3.5.2, 3.5.5 and 3.6.2, and without limiting the general performance criteria stated therein, the following performance criteria stated in this Article 3.7 shall apply to the situations herein described.

3.7.1. Time Limit for entering into Phase III Clinical Trials. TMC shall no later than [\*\*] have made the first dosing of a patient in a Phase III Clinical Trial regarding the Compound.

3.7.2. Time Limit for Filing of an NDA.

(a) TMC shall no later than  $\left[ \,^{\star\star} \right]$  have made a Filing of an NDA in the United States.

(b) TMC shall no later than [\*\*] or [\*\*] after having made a Filing of an NDA in the United States, whichever is the earlier, have made a Filing of an NDA in at least three (3) additional Major Markets, provided, however, that if such Filing of an NDA has been made in the European Union then such one (1) Major Market shall be sufficient.

(c) TMC shall no later than [\*\*] or [\*\*] after having made the last Filing of an NDA under Article 3.7.2(b), whichever is the earlier, have made a Filing of an NDA in all Major Markets.

3.7.3. TIME LIMIT FOR LAUNCH OF THE PRODUCT

TMC shall no later than [\*\*] following NDA Approval in any Major Market Launch the Product in the country(ies) concerned.

- 3.8. REMEDY FOR FAILURE.
- 3.8.1. NON-COMPLIANCE.

Should TMC at any time not comply with the applicable criteria of performance as set forth in Articles 3.4.2, 3.5.2, 3.5.5, 3.6.2, 3.7.1, 3.7.2 or 3.7.3, then TMC shall promptly so notify ASTRAZENECA in writing.

- (i) In case of non-compliance with the performance criteria set forth in Articles 3.4.2 or 3.7.1 ASTRAZENECA shall have the right, by giving ninety (90) days written notice to TMC, to require the license granted hereunder to terminate regarding the Compound and the Product, subject to Article 3.8.3.
- (ii) In case of non-compliance with the performance criteria set forth in Articles 3.5.2, 3.5.5, 3.6.2, 3.7.2 (a) or 3.7.3, ASTRAZENECA shall have the right, by giving ninety (90) days written notice to TMC, to require the license granted hereunder to terminate regarding the Compound and the Product in the Major Market or other country concerned, subject to Article 3.8.3.
- (iii) In case of non-compliance with the performance criteria set forth in Article or 3.7.2 (b) or (c), ASTRAZENECA shall have the right, by giving ninety (90) days written notice to TMC, to require the license

granted hereunder to terminate regarding the Compound and the Product in any Major Market(s) other than the Major Market(s) regarding which the performance criteria concerned was fulfilled (and, in the case of non-compliance with Article 3.7.2 (c), the Major Market(s) regarding which such criteria had been fulfilled under Article 3.7.2 (b)), subject to Article 3.8.3.

(iv) If ASTRAZENECA makes a request under (i), (ii) or (iii) above, and provided that TMC has not remedied the default concerned within the ninety-days period stated, then, provided that ASTRAZENECA notifies TMC in writing hereof within thirty (30) days upon the expiration of such ninety-days period, the license regarding the Major Market or other country contemplated by such notice for the Compound and the Product shall terminate and what is stated in Article 15.1 shall apply regarding such Major Market or other country subject to Article 3.8.3.

### 3.8.2. NON-COMPLIANCE REGARDING THE EUROPEAN UNION

Should TMC have failed to comply with any such criteria of performance referred to under Article 3.8.1, and should such non-compliance relate to the European Union, then TMC shall anyway be considered to have fulfilled such performance criteria provided always that the countries within the European Union to which such non-compliance relate are less than five (5). Notwithstanding what is stated in Article 1.16, European Union for the purpose of this Article 3.8.2 shall constitute only those countries being members of European Union at the License Agreement Effective Date.

#### 3.8.3. REASONABLE DELAY OR OTHER NON-COMPLIANCE.

a) Should TMC upon receipt of notice from ASTRAZENECA according to Article 3.8.1 (i) through (iii) be able to show that the delay or other non-compliance in the country(ies) concerned is justifiable from a clinical, scientific or regulatory perspective, then the Parties shall meet and consult whether the situation so occurred could be reasonably solved. Should the Parties, despite such consultations, not be able to find a mutually acceptable solution within three (3) months upon having entered into such consultations, then ASTRAZENECA may terminate the license regarding the country(ies) concerned by giving TMC a notice of same in writing, whereupon the license regarding such country(ies) shall immediately terminate and what is stated in Article 15.1 shall apply regarding such country(ies).

b) Should, following the initiation of the consultations pursuant to the first paragraph of this Article 3.8.3, either Party reasonably believe that a solution to the situation arisen may be solved through such consultations, but not within the initial three-month timeframe, then such Party may notify the other Party hereof; and the three-months period provided for in Article 3.8.3 a) shall be extended with a time-period as requested by such Party in such notice but with no more than three (3) months from the date of the notice.

3.9. The remedies stated in Article 3.8 shall be ASTRAZENECA's sole remedy in case of any failure by TMC to comply with what is stated in this Article 3.

## 4. SUPPLY MATTERS

4.1. TRANSFER OF BULK COMPOUND TO TMC. ASTRAZENECA undertakes to supply to TMC [\*\*] approximately ten (10) kilograms of bulk Compound no later than ninety (90) days after the License Agreement Effective Date. The transport of such entire quantity of bulk Compound shall be entirely at TMC's risk and expense. It is explicitly understood that this quantity of Compound was manufactured by ASTRAZENECA at an earlier date, and was not made for the purpose of the supply now stated, and that ASTRAZENECA gives no guarantee whatsoever as to the characteristics of the Compound or the Compound's fitness for any particular purpose.

4.2. ASSIGNMENT OF AGREEMENT WITH FRESENIUS. Unless such Contract has been assigned or terminated in accordance with what is stated in Article 2.8 of the Option Agreement, Astra Hassle AB, subsequently merged into ASTRAZENECA, and Fresenius are at the License Agreement Effective Date parties to a Development and Commercial Supply Contract of 28 December 1995 providing for the supply by Fresenius to ASTRAZENECA of Product. Should Fresenius agree with TMC on the supply of Product to TMC and with ASTRAZENECA to release ASTRAZENECA from any obligation under said Contract, then ASTRAZENECA will, provided always that the release or termination of such Contract or TMC's entering into any such arrangement will not incur any expenses or liability on ASTRAZENECA, agree to assign its rights under the Contract to TMC, or to terminate the Contract with Fresenius, whichever TMC desires and notifies ASTRAZENECA in writing of.

It is explicitly understood and agreed by the Parties that ASTRAZENECA shall have no obligations whatsoever to transfer or supply, other than as explicitly provided under Article 4.1, any quantity of Compound or Product to TMC.

4.3. SUPPLY OF COMPOUND AND PRODUCT BY TMC.

4.3.1. TMC undertakes to supply ASTRAZENECA's Affiliate in Japan, AstraZeneca KK, at TMC's [\*\*], AstraZeneca KK's entire need of Product for clinical trials, sale, promotion and marketing in Japan, pursuant to the Supply Agreement between TMC and AstraZeneca KK, attached hereto, subject to what is stated in Article 4.3.3, as a Schedule E.

4.3.2. TMC further undertakes to supply ASTRAZENECA, subject to Article 15.1 (i), at TMC's [\*\*] and otherwise under terms to be as consistent as possible with those under the Supply Agreement, ASTRAZENECA's entire need of Product for clinical trials, sale, promotion and marketing in any country where the license granted under Article 2 has been terminated pursuant to Article 3.8; provided always that such TMC's obligation shall not become effective unless and until TMC has Launched the Product in at least with one (1) country of the Territory.

4.3.3. The Supply Agreement may not have been entered into on the License Agreement Effective Date due to the Parties' desire to expeditiously enter into the Option Agreement, not delaying such procedure by awaiting the completion of the Supply Agreement. The parties acknowledge the substantial need for ASTRAZENECA to rely on TMC for its supply of the Product for the countries mentioned in Articles 4.3.1 and 4.3.2 and that entering into the Supply Agreement is a substantial prerequisite to ASTRAZENECA for entering into the Option Agreement. Should regardless hereof the Supply Agreement not have been concluded within six (6) months of the License Agreement Effective Date for other reasons than ASTRAZENECA's lack of good faith in conducting such negotiations or unnecessary delays

caused by ASTRAZENECA, then ASTRAZENECA shall have the right to terminate this Agreement forthwith by giving written notice to TMC.

Should ASTRAZENECA have failed, however, to provide to TMC in accordance with what is stated in Article 2.10 of the Option Agreement a first draft of the Supply Agreement, then, notwithstanding what is stated in the first paragraph of this Article 4.3.3, ASTRAZENECA shall not have the right to terminate this License Agreement.

## 5. EXCHANGE OF INFORMATION

5.1. OBLIGATION OF TMC TO SHARE INFORMATION. In addition to the obligations specifically requiring TMC to inform ASTRAZENECA regarding particular events, TMC undertakes to keep ASTRAZENECA informed about the progress of the development work regarding the Compound hereunder. For this purpose:

5.1.1. the Parties will, up until the date when Filing of an NDA has been made in the last Major Market, meet at least once a year to review TMC's progress and efforts in the development work contemplated herein. Such meeting will take place on a location to be agreed by the Parties, or, should the Parties not be able to agree, alternately with each Party at a site to be determined by the Party hosting the meeting. In advance of such meeting, TMC will provide ASTRAZENECA a reasonable written summary of such development work, including, without limitation, summaries of protocol designs of any clinical trials conducted or to be conducted, any changes to same and any Results developed during the period concerned;

5.1.2. TMC shall further in advance of such meeting provide ASTRAZENECA in writing a timetable for the expected Filings of an NDA, expected NDA Approvals and expected Launches during the one-year period, or other shorter applicable period, to come. In connection therewith TMC shall provide to ASTRAZENECA in writing, for the same period of time, a non-binding marketing plan and sales forecast for the Product in any Major Market where the Product by that time has been Launched or is expected to be Launched during the applicable period immediately to come;

5.1.3. TMC shall notify ASTRAZENECA forthwith and provide particulars of any halt or substantial delay in any development program or clinical trial, any obstacles in the Product reaching the market and any substantial changes anticipated in the sales potential of the Product;

5.1.4. TMC shall notify ASTRAZENECA forthwith regarding, and provide copies of, any correspondence with the regulatory authorities in the Territory that could reasonably be of any significance regarding the possibility, time frame or scope of any Filing of an NDA or any NDA Approval by ASTRAZENECA in Japan or which may otherwise relate to such Filing of an NDA or NDA Approval.

5.2. OBLIGATION OF ASTRAZENECA TO SHARE INFORMATION. ASTRAZENECA shall keep TMC informed about the progress of the clinical trials, sale, promotion and marketing of Product in any country in which ASTRAZENECA has rights to sell Product. For this purpose:

5.2.1. ASTRAZENECA shall at least once each year provide TMC in writing a timetable for the expected Filings of an NDA, expected NDA Approvals and expected Launches during the one-year period to come.

5.2.2. ASTRAZENECA shall notify TMC forthwith regarding, and provide copies of, any correspondence with the regulatory authorities in any Major Market that could reasonably be of any significance regarding the possibility, time frame or scope of any Filing of an NDA or any NDA Approval by TMC in any country for which TMC has yet to file an NDA or receive NDA Approval.

#### 6. CONSIDERATION

In consideration of the rights granted hereunder TMC shall pay to ASTRAZENECA the remuneration stated in this Article 6.

#### 6.1. MILESTONE PAYMENTS.

6.1.1. Within thirty (30) days of the License Agreement Effective Date TMC shall pay to ASTRAZENECA the amount of One Million U.S. Dollars (U.S. \$1,000,000).

6.1.2. Within thirty (30) days of the date of TMC's Filing of an NDA in the first Major Market, TMC shall pay to ASTRAZENECA the amount of [\*\*] U.S. Dollars (U.S. \$[\*\*]).

6.1.3. Within thirty (30) days of TMC's receipt of NDA Approval in the first Major Market TMC shall pay to ASTRAZENECA the amount of [\*\*] U.S. Dollars (U.S. [\*\*]).

6.1.4. Within thirty (30) days of the TMC's receipt of NDA Approval in the second Major Market, TMC shall pay to ASTRAZENECA the amount of [\*\*] U.S. Dollars (U.S. [\*\*]).

6.1.5. Within thirty (30) days of the TMC's receipt of NDA Approval in the third Major Market, TMC shall pay to ASTRAZENECA a final milestone payment in the amount of [\*\*] U.S. Dollars (U.S. \$[\*\*]).

### 6.2. ROYALTY RATE.

6.2.1. Following Launch of the Product, on a country-by-country basis for the period set out in Article 6.4 TMC shall pay to ASTRAZENECA, subject to what is stated in Article 6.2.2, a running royalty on the annual Net Sales of the Product as follows:

Annual	Net Sales	Royalty Rate
[**] [**] [**] [**] [**] [**] [**]		[**] [**] [**] [**] [**] [**] [**]
[**]		[ ^ ]

The relevant royalty rate so stated shall apply to the amount of annual Net Sales within the applicable layer only.

For convenience of example only and without limiting the above, the royalty rate of [\*\*]% shall apply to the amount of annual Net Sales under [\*\*] should the annual Net Sales exceed [\*\*] then the royalty rate of [\*\*]% shall apply only to the amount of annual Net Sales exceeding [\*\*] (and up to [\*\*]).

6.2.2. Notwithstanding the royalty rates set forth in Article 6.2.1, on the Net Sales of the Product during the time period starting on the License Agreement Effective Date and ending on December 31, 2007, the running royalty rate shall be reduced to [\*\*] percent ([\*\*]%) of the rate otherwise stated in Article 6.2.1.

6.2.3. For the purpose of Article 6.2.1 the term "annual" shall refer to calendar years, provided, however, that for the purpose of determining what royalty rates to apply during the first or last calendar year of the royalty payment period pursuant to Article 6.4, which parts may not constitute a full calendar year, the following shall apply.

a) The applicable royalty rate under each of items (a) through (i) of Article 6.1.1, subject to what is stated in Article 6.2.2, shall apply to the Net Sales exceeding the amount "A" in the following formula.

where "NM" is the "number of full months" of sales attracting royalty hereunder, regardless of the number of countries in which sales are being made, during the calendar year concerned; and where "TA" is the applicable "threshold amount" under the respective items (a) through (i) of Article 6.2.1.

b) For convenience of example only and without limiting the above standing, the following calculation shows the application of the provision stated.

If Launch occurs in the first country three months before the end of the calendar year, the formula will read, regarding the royalty rate of [\*\*]% under 6.2.1(a): \$[\*\*] x 3/12 = \$[\*\*]. The royalty rate of [\*\*]% under 6.2.1(b) will then become applicable on any Net Sales exceeding \$[\*\*] (and up to \$[\*\*]) and a royalty rate of [\*\*]% will be applicable on any Net Sales up to and including \$[\*\*]. Notwithstanding the foregoing, as this example is with respect to sales in the first country in which Launch occurs, the above stated royalty rates may be reduced by [\*\*] percent ([\*\*]%) pursuant to Article 6.2.2.

6.3. MINIMUM ROYALTY. Notwithstanding what is stated in Article 6.2, during the second through fourth full calendar years following Launch in the first Major Market the aggregate annual royalty amount due by TMC to ASTRAZENECA for sales of the Product shall, regardless of the actual Net Sales amount accrued during such calendar year, not go below the following amounts during the years specified.

6.3.1. Second full calendar year following Launch: [\*\*] U.S. Dollars (\$[\*\*]);

6.3.2. Third full calendar year following Launch: [\*\*] U.S. Dollars (\$[\*\*])

6.3.3. Fourth full calendar year following Launch: [\*\*]U.S. Dollars (\$[\*\*])

6.3.4. Should the Net Sales by TMC for any calendar year not generate the relevant royalty amount indicated under this Article 6.3, then TMC shall pay the difference between the minimum royalty amount stated and the amount actually generated within thirty (30) days after the date when the royalty payment for the last full quarter of the calendar year concerned is due according to Article 6.6.1.

6.4. DURATION OF ROYALTY PAYMENTS. Royalties under Article 6.2 shall be payable on a country by country basis for the longer of :

a) the life of ASTRAZENECA Patent Rights which are necessary to continue to manufacture, use or sell the Product in such country; or

b) a period of [\*\*] years from Launch in that country (provided always that in the case of a country within the European Economic Area such [\*\*] years period shall run from the date of Launch anywhere in the European Economic Area);

6.5. ASTRAZENECA TRADEMARK ROYALTY. Unless the license to the ASTRAZENECA Trademark has been reverted pursuant to Article 9.1, TMC shall, following expiration of the period indicated under Article 6.4 on a country-by-country basis, and for as long as TMC sells the Product in any country in the Territory, in consideration of the exclusive license in the Territory to use the ASTRAZENECA Trademark in connection with the sales and marketing of the Product pay to ASTRAZENECA an annual running royalty on the Net Sales of the Product of [\*\*] percent ([\*\*]%).

## 6.6. REPORTS.

6.6.1. TMC shall deliver to ASTRAZENECA within sixty (60) days after the end of each calendar quarter ending March 31, June 30, September 30 and December 31, a written report showing its computation of the remuneration due to ASTRAZENECA under this Agreement during such calendar quarter including (i) the quantity of the Product sold by or on behalf of TMC during such calendar quarter; and (ii) the total remuneration due in respect thereof and at the same time make the payment of the remuneration due. Any payment to be made hereunder shall be made in U.S. Dollars. Each such report mentioned in this Article 6.6.1 shall include the rates of exchange used for conversion to U.S. Dollars from the currency in which such sales were made.

6.6.2. In the event that ASTRAZENECA, its Affiliates or sublicenses sells Product pursuant to Article 2.7.3, then ASTRAZENECA shall deliver to TMC within sixty (60) days after the end of each calendar quarter ending March 31, June 30, September 30 and December 31, a written report showing its computation of the remuneration due to TMC under this Agreement during such calendar quarter including (i) the quantity of the Product sold by or on behalf of ASTRAZENECA during such calendar quarter; and (ii) the total remuneration due in respect thereof and at the same time make the payment of the remuneration due. Any payment to be made hereunder shall be made in U.S. Dollars. Each such report mentioned in this Article 6.6.2 shall include the rates of exchange used for conversion to U.S. Dollars from the currency in which such sales were made.

## 6.7. TAXES.

6.7.1. The payments to be made hereunder by either Party shall be net payments i.e. without deduction of any bank or transfer charges.

6.7.2. ASTRAZENECA shall pay any and all taxes levied on account of, or measured exclusively by, all payments it receives under this Agreement, including without limitation Swedish Value Added Tax ("mervardesskatt"). Amounts payable from TMC to ASTRAZENECA under this Agreement shall be paid by TMC without deduction for any tax, provided however that TMC may withhold income tax as required by internal laws of any applicable jurisdiction. In the case of such withholding being applicable, ASTRAZENECA may apply for the reduction of rate of withholding tax (including under the U.S./Sweden tax treaty) with the assistance of TMC and provided evidence of acceptance of this claim is submitted to TMC, TMC shall apply this rate accordingly. If applicable laws require that taxes be withheld, TMC will deduct those taxes from the remittable payments, make timely payment of the taxes to the proper taxing authority and send proof of such payment to ASTRAZENECA within sixty (60) days following that payment.

6.7.3. TMC shall pay any and all taxes levied on account of, or measured exclusively by, all payments it receives under this Agreement. Amounts payable from ASTRAZENECA to TMC under this Agreement shall be paid by ASTRAZENECA without deduction for any tax, provided however that ASTRAZENECA may withhold income tax as required by internal laws of any applicable jurisdiction. In the case of such withholding being applicable, TMC may apply for the reduction of rate of withholding tax (including under the U.S./Sweden tax treaty) with the assistance of ASTRAZENECA and provided evidence of acceptance of this claim is submitted to ASTRAZENECA, ASTRAZENECA shall apply this rate accordingly. If applicable laws require that taxes be withheld, ASTRAZENECA will deduct those taxes from the remittable payments, make timely payment of the taxes to the proper taxing authority and send proof of such payment to TMC within sixty (60) days following that payment.

6.8. EXCHANGE RATES. For the purpose hereof, the rate of exchange to be used for conversion hereunder to U.S. Dollars shall be the average rate of exchange for the period to which the payment relates, as published by the Wall Street Journal.

BOOKS AND AUDIT. Each Party shall keep complete and accurate books and 6.9. records with respect to its sale of the Product and remuneration payable hereunder. Each Party shall have the right to have such pertinent books and records of the other Party inspected and examined once each calendar year for the purpose of determining the accuracy of payments made hereunder. Such inspection and examination shall be conducted by an independent, certified, public accountant selected by the Party requesting such examination. Such accountant shall not disclose to such Party any information except for information necessary to verify the accuracy of the records and payments made pursuant to this Agreement. The charges of the independent, certified, public accountant shall be paid by the Party requesting examination except if the payments pursuant to this Agreement have been understated by more than five percent (5%) in which case the Party who has underpaid will bear the cost and pay the shortfall in payment pursuant to this Agreement with interest to the other Party. Should instead the payments have been overstated the Party who has overpaid may deduct any such amount from the royalty payments due hereunder until such amount has been recovered by such Party.

#### 6.10. WIRE TRANSFER INSTRUCTIONS.

6.10.1. Unless otherwise instructed by ASTRAZENECA, all payments by TMC hereunder shall be made from the United States by wire transfer in the requisite amount to the following account of ASTRAZENECA.

Bank Name:	[**]
Account No:	[**]
Swift:	[**]

6.10.2. Unless otherwise instructed by TMC, all payments by ASTRAZENECA hereunder shall be made from Sweden by wire transfer in the requisite amount to the following account of TMC.

Bank Name:	[**]
Account No:	[**]
Bank Code:	[**]

6.10.2.1. INTEREST. If any sum payable pursuant to this Agreement shall not have been paid to a Party by the due date then (without prejudice to any other claim or remedy of such Party) the Party owing such sum shall pay interest thereon to the other Party at an annual rate of LIBOR + three percent (3%) from time to time published in respect of the period starting on the due date of payment and ending on the actual date of payment.

"LIBOR" shall mean the thirty (30) days US dollar BBA London Interbank Offered Rate as published by Reuter.

#### 7. INTELLECTUAL PROPERTY - PROSECUTION AND MAINTENANCE

7.1. Any and all ASTRAZENECA IP vested in ASTRAZENECA shall as between ASTRAZENECA and TMC remain vested in ASTRAZENECA.

7.2. Any and all TMC IP vested in TMC shall as between TMC and ASTRAZENECA remain vested in TMC.

7.3. ASTRAZENECA shall, during the term of this Agreement be responsible for the filing, prosecution and maintenance of the ASTRAZENECA Patent Rights and the ASTRAZENECA Trademark in the Territory. Should registration of the ASTRAZENECA Trademark be necessary or appropriate in any country, then ASTRAZENECA shall be responsible for obtaining such registration.

TMC shall reimburse ASTRAZENECA for any out-of-pocket expenses (including fees to outside counsel and consultants) incurred by ASTRAZENECA in relation to any action taken by ASTRAZENECA pursuant to this Article 7.3.

7.4. TMC shall have the right to give comments and recommendations as to the overall strategy regarding the filing, prosecution and maintenance of the ASTRAZENECA Patent Rights and the ASTRAZENECA Trademark; and before taking any significant step in the filing, prosecution or maintenance of the ASTRAZENECA Patent Rights or the ASTRAZENECA Trademark, ASTRAZENECA shall allow TMC to comment on the action proposed to be taken and ASTRAZENECA shall consider any such comments.

7.5. In the event that ASTRAZENECA should decide to permit any pending patent application or any patent included in the ASTRAZENECA Patent Rights to lapse by any action, inaction or failure to take any action or to pay any fee when due, ASTRAZENECA shall promptly inform TMC of such decision, but no later than fifteen (15) days prior to such action, inaction or failure to pay, provided that such period is available to ASTRAZENECA, so that TMC might, for the avoidance of doubt at TMC's expense, seek such patent protection or prevent any such lapse.

7.6. ASTRAZENECA shall not be liable to TMC in contract, tort, negligence, breach of statutory duty or otherwise for any economic loss or other loss of turnover, profits, savings, business or goodwill or any loss, damage, costs or expenses of any nature whatsoever incurred or suffered by TMC because of ASTRAZENECA's actions pursuant to or as a consequence of this Article 7.

PATENT TERM EXTENSIONS

7.7. Should ASTRAZENECA not be able to lawfully apply for patent term extensions, including, but not limited to, Supplementary Protection Certificates, relating to the ASTRAZENECA Patent Rights in the Territory in its own name, or should ASTRAZENECA otherwise require, TMC shall co-operate with ASTRAZENECA in any issue regarding the gaining of such patent term extension by assisting ASTRAZENECA with any actions or documents needed for such purpose.

Should in any country in the Territory any decision have to be made as to what product, claim or otherwise to apply for such patent term extension regarding, then ASTRAZENECA shall have the right to make such decision at its own discretion.

7.8. RIGHTS TO THE RESULTS. Any patents and other intellectual property rights, information, ideas, knowledge, data or know-how relating solely to the Compound, and/or the Product

developed during the term of this Agreement (hereinafter referred to as "Result(s)") shall as between TMC and ASTRAZENECA be TMC IP and the sole property of TMC. TMC shall have the sole management of, and shall bear the cost of, any Results. ASTRAZENECA shall be given the reasonable opportunity to comment on important aspects of the prosecution of any patent applications, and shall use its reasonable endeavours to assist TMC in the prosecution of any patent applications.

#### 8. CLAIMS REGARDING INFRINGEMENT AND INVALIDITY

8.1. NOTIFICATION OF CLAIM. If a Third Party notifies ASTRAZENECA or TMC, or their respective Affiliates or sub-licensees, that any act by TMC, or its Affiliates or sub-licensees, utilizing the ASTRAZENECA IP allegedly infringes in the Territory any Patent Rights or other intellectual property rights owned by or licensed to the Third Party, ASTRAZENECA or TMC shall promptly notify the other in writing.

8.2. DEFENCE OF CLAIMED INFRINGEMENT.

8.2.1. ASTRAZENECA shall have no obligation to defend or settle any claim by a Third Party that the manufacture, sale or other use of the Product by TMC resulting from the use or exercise of the license granted hereunder under the ASTRAZENECA IP infringes any Patent Rights or other intellectual property rights owned by or licensed to a Third Party, subject to the provisions of Article 10.

8.2.2. If a Third Party makes an infringement claim or files an infringement action against ASTRAZENECA, its Affiliates or sub-licensees, or TMC, its Affiliates or sub-licensees, arising out of TMC's, its Affiliates' or sub-licensees' manufacture, sale or other use of the Product in the Territory, or if a Third Party challenges any of the ASTRAZENECA IP, then TMC shall defend or settle the claim or action at its expense, subject to the provisions of Article 10.

8.2.3. ASTRAZENECA may join such proceedings mentioned under sub-section 8.2.2 voluntarily, subject always to TMC's, its Affiliates' or sub-licensees', right to decide the conduct over such litigation. Any such joining of the proceedings shall be at ASTRAZENECA's cost and expense. ASTRAZENECA shall for such purpose have the right to independently retain legal counsel and consultants, at its sole cost and expense.

8.2.4. It is understood between the Parties that any proposed settlement will be subject to ASTRAZENECA's prior written approval, which approval shall not be unreasonably withheld. Such approval might be withheld primarily on the grounds that ASTRAZENECA reasonably determines that the settlement proposed is overly burdensome, financially or strategically, that ASTRAZENECA determines that TMC's conduct of the defence has a reasonable chance of succeeding or that ASTRAZENECA intends to continue such defence itself.

Should ASTRAZENECA withhold such approval, then ASTRAZENECA shall have the right, but not the obligation (other than in the case that ASTRAZENECA has announced to TMC its intention to continue such defence itself), to continue the defence of the claim or action at its own expense. In such case TMC, its Affiliates or sub-licensees shall, at ASTRAZENECA's request and at ASTRAZENECA's expense for TMC's, its Affiliates' or sub-licensees' costs and expenses, assist in the prosecution of such action, including, but not limited to, consenting to being joined in such action as a voluntary plaintiff.

8.2.5. Should TMC reasonably believe that the Third Party rights contemplated by Article 8.2.1 are valid in a certain country(ies) and that infringement is likely to be occurring in such country(ies), TMC may seek and enter into a licence thereto from such Third Party on appropriate commercial terms, whereby any remuneration and any costs and expenses (including but not limited to reasonable external legal costs) for such license shall be shared equally between TMC and ASTRAZENECA according to the following.

TMC may deduct an amount equivalent to [\*\*] percent ([\*\*]%) of TMC's payments to such Third Party pursuant to such arrangement as indicated in the first paragraph of this Article 8.2.5 from the royalty payments to be made by TMC to ASTRAZENECA on the Net Sales in the country concerned pursuant to Article 6.2 to cover ASTRAZENECA's obligation to carry [\*\*] percent ([\*\*]%) of such payments and costs. This deduction shall be subject to the proviso that the royalty payments due to ASTRAZENECA shall not be reduced in total by more than [\*\*] percent ([\*\*]%) in any calendar year, and any residue not offset may be carried forward by TMC until such time as it has recovered ASTRAZENECA's [\*\*] per cent ([\*\*]%) share of such costs and expenses, or until the royalty payment obligations of TMC hereunder expire, whichever is the earlier.

8.3. THIRD PARTY INFRINGEMENT. If a Third Party shall, in the reasonable opinion of either Party, infringe any ASTRAZENECA Patent Rights or ASTRAZENECA Trademark in the Territory, then the Party having such opinion shall promptly notify the other Party.

8.3.1. Further, each Party shall within five (5) working days or as soon as reasonably possible thereafter advise the other Party of receipt of any notice of:

a) any certification filed under the U.S. "Drug Price Competition and Patent Term Restoration Act of 1984" ("ANDA Act"), claiming that any ASTRAZENECA Patent Rights are invalid or claiming that the ASTRAZENECA Patent Rights will not be infringed by the manufacture, use or sale of a product for which an application under the ANDA Act is filed or;

b) any equivalent or similar certification or notice in any other jurisdiction.

8.3.2. TMC, its Affiliates or sub-licensees shall have the initial sole right to commence an action for infringement in the Territory against the Third Party, in its own name, together with the right to enforce and collect any judgement thereon. ASTRAZENECA may join such proceedings voluntarily, subject always to TMC's, its Affiliates' or sub-licensees' right to decide the conduct over such litigation. Any such joining of the proceedings shall be at ASTRAZENECA's cost and expense. ASTRAZENECA shall for such purpose have the right to independently retain legal counsel and consultants, at its sole cost and expense.

8.3.3. Any monetary recovery (whether by settlement or judgement) in connection with an infringement action commenced by TMC, its Affiliates or sub-licensees shall be applied first to reimburse TMC, its Affiliates or sub-licensees for their out-of-pocket expenses (including reasonable attorneys fees) incurred in prosecuting such action and the expenses of ASTRAZENECA borne by TMC hereunder. Any balance remaining shall be allocated among ASTRAZENECA and TMC in a manner reasonably calculated to correspond to the distribution of profits, in accordance with what would normally be provided for under this Agreement, on the sales of Product to which such recovery pertains.

8.3.4. Should neither TMC, nor its Affiliates or sub-licensees, take appropriate and diligent action with respect to any such infringement or challenge as contemplated in this Article 8.3 within forty-five (45) days, or, in the case of a certification filed under the ANDA Act or similar certification or notice as contemplated under Article 8.3.1, within twenty (20) days, after receiving notice of any infringement or possible infringement or challenge, then ASTRAZENECA shall have the right, but not the obligation, to take such action, at its own expense, in its own name, and the right to enforce and collect any judgement thereon.

a) Should ASTRAZENECA elect to take such action then TMC, its Affiliates or sub-licensees, shall, at ASTRAZENECA's request and at ASTRAZENECA's expense for TMC's, its Affiliates' or sub-licensees', costs and expenses, assist in the prosecution of such action, including, but not limited to, consenting to being joined in such action as a voluntary plaintiff.

b) If the recovery of such action as contemplated in this Article 8.3.4 exceeds ASTRAZENECA'>s out-of-pocket expenses (including reasonable attorneys fees) for prosecuting the action, then such excess recovery shall be shared by the Parties on a [\*\*] basis.

8.3.5. ASTRAZENECA, its Affiliates or sub-licensees shall have the sole right to commence an action for infringement of the ASTRAZENECA IP in Japan or in any other country in which the license granted to TMC hereunder has reverted to ASTRAZENECA pursuant to Article 3.8 against the Third Party, in its own name, together with the right to enforce and collect any judgement thereon. TMC may join such proceedings voluntarily, subject always to ASTRAZENECA's, its Affiliates' or sub-licensees' right to decide the conduct over such litigation. Any such joining of the proceedings shall be at TMC's cost and expense. TMC shall for such purpose have the right to independently retain legal counsel and consultants, at its sole cost and expense. Any monetary recovery (whether by settlement or judgement) in connection with an infringement action commenced by ASTRAZENECA shall be retained by ASTRAZENECA.

#### 9. TRADEMARK

9.1. Should TMC not within twelve (12) months of the License Agreement Effective Date notify ASTRAZENECA that TMC wishes to maintain its exclusive license to the ASTRAZENECA Trademark as granted under Article 2.1, or should TMC within such twelve-months period notify ASTRAZENECA in writing that TMC does not wish to maintain such exclusive license to the ASTRAZENECA Trademark, then upon the expiration of such twelve-months period or the date of such written notice, whichever is the earlier,

- (a) the exclusive license insofar as it relates to the ASTRAZENECA Trademark under Article 2.1 shall immediately cease and the ASTRAZENECA Trademark shall cease to be a part of the ASTRAZENECA IP for all purposes of this Agreement;
- (b) all rights so granted in the ASTRAZENECA Trademark to TMC shall revert to ASTRAZENECA;
- (c) TMC shall immediately return to ASTRAZENECA any ASTRAZENECA Know-How relating to the ASTRAZENECA Trademark and grant to

ASTRAZENECA a non-exclusive, perpetual, remuneration-free and world-wide license to use any Know-How developed by TMC relating to the ASTRAZENECA Trademark for the purpose of commercialising the Product.

Should the rights have been so reverted, then TMC shall select a trademark of its own, not being confusingly similar to the ASTRAZENECA Trademark, to use in connection with the sales, marketing and distribution of the Product and shall be the owner and party of record of such trademark (the "TMC Trademark"). TMC shall have sole responsibility for clearance and registration of said TMC Trademark. TMC shall be responsible for all decisions and costs relating to selection, clearance, registration, defence and maintenance of the TMC Trademark.

## 9.2. UTILISATION OF THE ASTRAZENECA TRADEMARK

9.2.1. Unless the license to the ASTRAZENECA Trademark has been reverted pursuant to Article 9.1, TMC shall, as soon as reasonably possible upon completion of the item concerned, but no later than one (1) year prior to the estimated Launch in each country, notify ASTRAZENECA in a clearly visible manner how TMC intends to utilise the ASTRAZENECA Trademark in connection with the marketing, sales and distribution of the Product in the country concerned, including but not limited to showing the shape, size and colour of the intended logo containing the ASTRAZENECA Trademark, the intended packages of the Product and the intended promotional materials regarding the Product in such country. TMC may not utilise the ASTRAZENECA Trademark in any context without ASTRAZENECA's prior written approval, such approval not to be unreasonably withheld.

9.2.2. Should ASTRAZENECA not approve such TMC's proposal, or part thereof, under Article 9.2.1, then ASTRAZENECA shall submit to TMC a proposal, within sixty (60) days of having received TMC's proposal, on how to utilise the ASTRAZENECA Trademark in this regard.

9.2.3. Should TMC not accept ASTRAZENECA's proposal, or part thereof, provided under Article 9.2.2, then TMC may notify ASTRAZENECA of a new proposal on the utilisation of the ASTRAZENECA Trademark, or such part thereof, in such way as set forth in Article 9.2.1; such proposal to be noticeably different from all previous proposals. Should ASTRAZENECA not approve such proposal, then what is stated in Article 9.2.2. shall apply.

9.2.4. Should ASTRAZENECA not within forty-five (45) days of such notice as stated in Article 9.2.1 have notified TMC that it objects all or in part to such TMC's proposal, or should ASTRAZENECA after having not approved a proposal, or part thereof, fail to present a proposal as stated under Article 9.2.2, then the proposal presented by TMC shall be considered to have been approved by ASTRAZENECA.

9.3. TMC shall use the ASTRAZENECA Trademark in accordance with applicable laws in any country where TMC markets, sells or distributes the Product utilising the ASTRAZENECA Trademark. Unless the rights to the ASTRAZENECA Trademark have been reverted pursuant to Article 9.1, TMC undertakes to use the ASTRAZENECA Trademark at any time when the Product is sold, marketed or distributed in the Territory and not to use any trademark other than the ASTRAZENECA Trademark in connection with the sales, marketing and distribution of the Product. TMC further undertakes not to use any

trademark being confusingly similar to the ASTRAZENECA Trademark in connection with marketing, sales and distribution of any other product.

9.4. Should in any country of the Territory TMC by legal, regulatory or similar reasons be prevented from using the ASTRAZENECA Trademark or should usage of the ASTRAZENECA Trademark in connection with the sales, marketing and distribution of the Product prove to be commercially unreasonable in such country because of such legal, regulatory or similar reasons, then TMC shall immediately notify ASTRAZENECA Trademark for the marketing, sales and distribution of the Product in the country concerned. The Parties shall in such case meet and in good faith endeavour to find a new trademark as similar to the ASTRAZENECA Trademark as possible. Such new trademark selected for the country concerned shall for all purposes of this Agreement be considered an ASTRAZENECA Trademark.

TMC shall carry all costs and expenses for the development and creation of such new trademark, provided always that should such costs be disproportionately high in relation primarily to the estimated value of the Product then TMC may offer ASTRAZENECA to carry all or part of such costs, or, should ASTRAZENECA notify TMC in writing that it declines to do so, notify ASTRAZENECA that it does not wish to maintain the license to the ASTRAZENECA Trademark for the country concerned; whereupon what is stated in Articles 9.1. (a) through (c) shall apply regarding such country.

9.5. TMC undertakes, should ASTRAZENECA so require in writing, to mention on all packages, package inserts and promotional and advertising materials for the Product "Licensed from AstraZeneca AB" or the equivalent wording in the major language(s) of the country in which the Product is sold, or, should legal, regulatory or similar reasons prevent the use of that wording, such other wording as close as possible to the wording herein stated.

- 10. INDEMNITY
- 10.1. INDEMNITY BY TMC.

10.1.1. TMC shall be responsible for and shall indemnify ASTRAZENECA, its Affiliates and its and its Affiliates' directors, officers, other employees, agents and consultants (collectively the "ASTRAZENECA Indemnified Party") against any and all liability, loss, damage, cost and expense (including legal costs) incurred or suffered by the ASTRAZENECA Indemnified Party as a result of any claim brought against an ASTRAZENECA Indemnified Party by a Third Party (i) arising out of the testing, manufacture, sale, use or promotion by TMC, its Affiliates or sub-licensees of any Compound or Product hereunder; (ii) arising out of any theory of product liability (including, but not limited to, actions in the form of tort, warranty or strict liability) based on Compounds or Products developed by TMC hereunder; or (iii) arising out of any other activities to be carried out by TMC, its Affiliates or sub-licensees pursuant to this Agreement to the extent not included in (i) and (ii) above, except where such liability, loss, damage, cost and expense has been incurred or suffered as a result of a material breach of warranty or representation of ASTRAZENECA set out in Article 13 or by gross negligence or misconduct on the part of ASTRAZENECA

10.1.2. An ASTRAZENECA Indemnified Party that intends to claim indemnification under Article 10.1.1 shall notify TMC promptly of any such liability, loss, damage, cost and expense and permit TMC to control the defence and disposition thereof and further agrees to

reasonably cooperate at TMC's expense with TMC in the handling thereof. The ASTRAZENECA Indemnified Party shall not compromise or settle such claim. TMC agrees to keep ASTRAZENECA informed of the progress in the defence and disputation of such claims and to consult with ASTRAZENECA with regard to any settlement thereof which TMC proposes to enter into and will provide ASTRAZENECA with suitable information regarding the same.

10.1.3. TMC will maintain appropriate liability insurance against such product and other liability as contemplated under Article 10.1.1 at levels appropriate for products and activities of the relevant type.

#### 10.2. INDEMNITY BY ASTRAZENECA.

10.2.1. ASTRAZENECA shall be responsible for and shall indemnify TMC, its Affiliates and its and its Affiliates' directors, officers, other employees, agents and consultants (collectively the "TMC Indemnified Party") against any and all liability, loss, damage, cost and expense (including legal costs) incurred or suffered by the TMC Indemnified Party as a result of any claim brought against the TMC Indemnified Party by a Third Party (i) arising out of the testing, manufacture, sale, use or promotion by ASTRAZENECA, its Affiliates or sub-licensees, of any Compound or Product hereunder; (ii) arising out of any theory of product liability (including, but not limited to, actions in the form of tort, warranty or strict liability) based on Compounds or Products sold by ASTRAZENECA hereunder; or (iii) which arises as a result of a breach of a warranty or representation of ASTRAZENECA set out in Article 13, except where such liability, loss, damage, cost and expense has been incurred or suffered as a result of a material breach of TMC's obligations under this Agreement or by gross negligence or misconduct on the part of TMC.

10.2.2. A TMC Indemnified Party that intends to claim indemnification under Article 10.2.1 shall notify ASTRAZENECA promptly of any such liability, loss, damage, cost and expense and permit ASTRAZENECA to control the defence and disposition thereof and further agrees to reasonably cooperate at ASTRAZENECA's expense with ASTRAZENECA in the handling thereof. The TMC Indemnified Party shall not compromise or settle such claim. ASTRAZENECA agrees to keep TMC informed of the progress in the defence and disputation of such claims and to consult with TMC with regard to any settlement thereof which ASTRAZENECA proposes to enter into and will provide TMC with suitable information regarding the same.

10.2.3. ASTRAZENECA will either maintain appropriate liability insurance or be self insured against such liability as contemplated under Article 10.2.1.

## 11. CONFIDENTIALITY

11.1. CONFIDENTIAL INFORMATION. At all times during the term of this Agreement and for a period of five (5) years following termination or expiration hereof, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose and not use, directly or indirectly, for any purpose, any Confidential Information provided to it by the other Party, PROVIDED, THAT, each Party may disclose and use the Confidential Information of the other Party to the extent such disclosure or use is expressly permitted by the terms of this Agreement, including without limitation those purposes set forth in Article 11.2, or is otherwise reasonably necessary for the performance of this Agreement.

11.2. PERMITTED USE AND DISCLOSURE. The Receiving Party may use and/or disclose Confidential Information to the extent that such disclosure is:

11.2.1. made in response to a valid order of a court of competent jurisdiction or other competent authority provided however that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or authority or, if disclosed, be used only for the purpose for which the order was issued; and provided further that if a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

11.2.2. made by the Receiving Party to a regulatory authority as required in connection with any Filing of an NDA; provided, however, that reasonable measures will be taken to assure confidential treatment of such information;

11.2.3. made by the Receiving Party to a patent authority as required in connection with any filing or application for Patent Rights; or

11.2.4. made by the Receiving Party to Third Parties as may be necessary or useful in connection with the development, manufacturing, marketing, use and sale of the Compound or the Product as contemplated by this Agreement, including subcontracting, sublicensing and distribution transactions in connection therewith, provided that any such Third Party has undertaken confidentiality obligation with respect to the Confidential Information disclosed by the Receiving Party to it and the results of any such activities. Regardless hereof, TMC may not disclose to such Third Party which compound(s), other than the Compound, that [\*\*] may be used as a manufacturing starting material, or intermediate, for.

11.3. RELEASE FROM RESTRICTIONS. Notwithstanding the foregoing, Confidential Information shall not include any information that, as determined by competent written proof:

11.3.1. is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the Receiving Party;

11.3.2. can be demonstrated by documentation or other competent proof to have been in the Receiving Party's possession prior to disclosure by the Disclosing Party;

11.3.3. is subsequently received by the Receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to the said information;

 $11.3.4.\,$  is generally made available to Third Parties by the Disclosing Party without restriction on disclosure; or

11.3.5. is independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information.

12. ADVERSE EVENTS

12.1. REPORTING OF ADVERSE EVENTS.

12.1.1. TMC shall be fully responsible for reporting to the relevant regulatory or other competent authorities in the Territory any Adverse Event(s) which are or might be attributed to the use or application of the Compound or the Product. At ASTRAZENECA's request in writing TMC shall inform ASTRAZENECA of any Adverse Event in the country(ies) contemplated, and during the time period contemplated, by such notice.

12.1.2. ASTRAZENECA shall be fully responsible for reporting to the relevant regulatory or other competent authorities in any country outside the Territory or for which the license to TMC hereunder has been terminated any Adverse Event(s) which are or might be attributed to the use or application of the Compound or the Product. At TMC's request in writing ASTRAZENECA shall inform TMC of any Adverse Event in the country(ies) contemplated, and during the time period contemplated, by such notice. For the avoidance of doubt ASTRAZENECA may appoint any Affiliate(s) or sub-licensee(s) carrying out the marketing of the Product in the country concerned to fulfil any such obligation as stated hereunder.

12.1.3. Without limiting what is stated in Article 12.1, the Parties shall at an appropriate point of time during development of the Product jointly establish any such Adverse Event reporting procedures, including, but not limited to, any agreement regarding safety data exchange, as may be required or useful.

#### 13. REPRESENTATION AND WARRANTY

13.1. REPRESENTATIONS AND WARRANTIES OF ASTRAZENECA. ASTRAZENECA represents and warrants to TMC as follows:

30

a) as of the License Agreement Effective Date it is the sole and exclusive owner of the ASTRAZENECA Patent Rights and ASTRAZENECA Trademark; all of which is free and clear of any liens, charges and encumbrances; and

b) as of the License Agreement Effective Date ASTRAZENECA has not previously assigned, transferred, licensed, conveyed or otherwise encumbered its right, title and interest in the ASTRAZENECA Patent Rights or the ASTRAZENECA Trademark; and

c) as of the License Agreement Effective Date and to the best of ASTRAZENECA's knowledge, no Person other than ASTRAZENECA or any of its Affiliates, has or shall have any claim of ownership with respect to ASTRAZENECA Patent Rights or the ASTRAZENECA Trademark; and

d) as of the License Agreement Effective Date and to the best of ASTRAZENECA's knowledge, the manufacture, use and sale of the Compound does not infringe upon any intellectual property rights of any Third Party, although it is expressly acknowledged by TMC that ASTRAZENECA has made no particular searches or investigations to determinate whether such infringement occurs; and

e) as of the License Agreement Effective Date there are no claims, judgements or settlements against or owed by ASTRAZENECA or pending or threatened claims or litigation relating to the ASTRAZENECA Patent Rights or the ASTRAZENECA Trademark; and

f) except as insofar relating to any kind of formulation, or work or development related thereto, of the Product, there are no other Patent Rights or Know-How owned or licensed by ASTRAZENECA required to develop and/or commercialise the Product, and ASTRAZENECA shall not assert against TMC any Patent Rights or other intellectual property owned or licensed by ASTRAZENECA as of the License Agreement Effective Date or at any time thereafter which are or may be infringed by the Compound or the Product; and

g) as of the License Agreement Effective Date ASTRAZENECA has disclosed to TMC any known interference with the ASTRAZENECA Patent Rights or re-examination or reissue proceeding concerning such ASTRAZENECA Patent Rights; and

h) as of the License Agreement Effective Date ASTRAZENECA has no knowledge from which it can reasonably be inferred that the granted ASTRAZENECA Patent Rights or the ASTRAZENECA Trademark are invalid or that the applications for ASTRAZENECA Patent Rights or ASTRAZENECA Trademark will not proceed to grant.

13.2. ACKNOWLEDGEMENT OF TMC. TMC is aware that the ASTRAZENECA Patent Rights or the ASTRAZENECA Know-How may not sufficiently enable TMC to manufacture or conduct any other operational or manufacturing-related activities with respect to the formulation of the Product, and it is explicitly understood by TMC that TMC will have to independently conduct any analysis, evaluation and investigation regarding what intellectual property, techniques, routes, equipment or other help or assistance that will be required for such purpose and it will be entirely at TMC's risk to find such intellectual property, techniques, routes, equipment or other help or assistance in order to conduct such activities.

13.3. REPRESENTATIONS AND WARRANTIES OF THE PARTIES. Each Party represents and warrants to the other Party that it is a duly organized and validly existing corporation under the laws of its jurisdiction of incorporation, and has taken all required corporate action to authorize the execution, delivery and performance of this Agreement; it has the full right, power and authority to enter into this Agreement and perform all of its obligations hereunder; the execution and delivery of this Agreement and the transactions contemplated herein do not violate, conflict with, or constitute a default under its Articles of Association or similar

organization document, its by-laws or the terms or provisions of any material agreement or other instrument to which it is a party or by which it is bound, or any order, award, judgement or decree to which it is a party or by which it is bound; and upon execution and delivery, this Agreement will constitute the legal, valid and binding obligation of it.

13.4. LIMITATIONS. EXCEPT AS OTHERWISE SET FORTH IN THIS AGREEMENT ASTRAZENECA EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR EXPRESS WARRANTIES AND MAKES NO EXPRESS OR IMPLIED WARRANTY, STATUTORY OR OTHERWISE, OF ANY KIND, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE REGARDING THE COMPOUND, ASTRAZENECA'S CONFIDENTIAL INFORMATION, DOCUMENTS, ASTRAZENECA KNOW-HOW, ASTRAZENECA PATENT RIGHTS, OR PRODUCTS.

#### 14. TERM AND TERMINATION

14.1. TERM. This Agreement shall become effective on the License Agreement Effective Date and shall expire when TMC ceases to sell the Product in the last country of the Territory or otherwise terminates this Agreement as set forth in Article 14.2.

14.2. TERMINATION BY TMC. Should TMC determine that it does no longer consider it viable to continue to exercise the rights under this Agreement, then TMC may give written notice to ASTRAZENECA, whereupon this Agreement shall terminate thirty (30) days of such notice, unless ASTRAZENECA, within twenty (20) days of having received such notice, requests TMC in writing to enter into good faith discussions to see whether TMC's concerns could be reasonably overcome. However, upon TMC having given such notice TMC shall not be liable for any payments under Articles 6.1.2 through 6.1.5 or for any payments under Articles 6.3.1 unless corresponding to the royalty amounts actually due, which become due after the expiration of the 30-days period mentioned above in this Article 14.2.

Should the Parties not within three (3) months of the date of commencement of such good faith discussions mentioned above in this Article 14.2 have managed to reach a mutually acceptable solution to TMC's concerns, then TMC may terminate this Agreement by giving ninety (90) days written notice.

14.3. TERMINATION FOR BREACH. In the event that either Party (the "Breaching Party") shall be in significant default in the performance of any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the "Complaining Party") may have, the Complaining Party may terminate this Agreement by sixty (60) days prior written notice (the "Notice Period") to the Breaching Party, specifying the breach and its claim of right to terminate, provided always that the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach complained about during the Notice Period.

14.4. SURVIVAL OF OBLIGATIONS. Termination or expiration of this Agreement shall not relieve either Party from any obligation incurred hereunder prior thereto.

14.5. SURVIVAL OF PROVISIONS UPON TERMINATION AND/OR EXPIRATION. Subject to what is stated in Article 15, the provisions of Articles 1, 7.1, 7.2, 10, 11, 12, 13, 14.5, 15, 17 and 18 shall survive termination or expiration of this Agreement. The provisions of Article 2.5 shall

survive only upon expiration of this Agreement. The provisions of Article 11 shall survive termination or expiration of this Agreement and shall continue to be in force for a period of five (5) years after termination or expiration of this Agreement.

#### 15. CONSEQUENCES OF TERMINATION

#### 15.1. TERMINATION AND HANDBACK OF LICENSE

In addition to any remedy either Party may have in law, tort or in contract, subject to what is stated in Article 3.9, upon termination of the Agreement or the license in a certain country, the following shall apply.

Upon termination of this Agreement by TMC pursuant to Article 14.2 or by ASTRAZENECA pursuant to Article 14.3, or by ASTRAZENECA in a certain country pursuant to Article 3.8, the license granted under Article 2.1 regarding the country(ies) contemplated by the termination concerned shall cease, and TMC shall, regarding the Territory or the country concerned, whichever is applicable:

- (a) at the option of ASTRAZENECA, grant to ASTRAZENECA a non-exclusive, world-wide or for the country concerned, whichever is applicable, sub-licensable licence under the TMC IP to develop, have developed, make, have made, use, have used, import, have imported, market, have marketed, sell and have sold the Compound and the Product for any indications. The term of such non-exclusive licence shall continue on a country by country basis for the longer of the life of the TMC Patent Rights, or for ten (10) years from first commercial sale of any resultant product in such country by ASTRAZENECA, its Affiliates, sub-licensees or nominees, whichever is the longer. TMC shall do all such acts and things as may reasonably be necessary to fulfil this obligation. The licence set out in this Article 15.1 (a) shall be royalty-free and free from any other remuneration.
- (b) return to ASTRAZENECA any ASTRAZENECA Know-How and deliver to ASTRAZENECA a copy of any TMC Know-How;
- (c) deliver to ASTRAZENECA any and all quantities of Product in its possession, power, custody or control subject always to TMC's right to dispose of Product which is the subject of pre-termination date orders pursuant to Article 15.1 (h). For the avoidance of doubt, should this Article 15.1 (c) become applicable because of termination regarding a certain country or countries pursuant to Article 3.8, then the quantities of Product referred to herein shall mean only those quantities clearly designated, by marking, labelling or similar, for the country or countries concerned and which could only be used for the country or countries concerned;
- (d) ensure that its patent attorneys transfer to ASTRAZENECA a copy of the patent files relating to the TMC Patent Rights which TMC has been prosecuting and maintaining and ASTRAZENECA shall be entitled to prosecute and shall maintain such TMC Patent Rights at its own cost and expense on terms similar to those set out in Article 7.3 and to deal with infringers on terms similar to those set out in Article 8.2 and 8.3.



TMC further undertakes to take any action and produce any documents so as to enable ASTRAZENECA to apply for patent term extensions, including, but not limited to, Supplementary Protection Certificates, relating to the TMC Patent Rights in ASTRAZENECA's name.

- (e) Should this Article 15.1 become applicable because of the termination of the license regarding a certain country or countries pursuant to Article 3.8, then TMC shall, notwithstanding the license granted under Article 15.1 (a), on the request by ASTRAZENECA continue to prosecute, maintain and defend the TMC Patent Rights.
- (f) commensurate with legislative and regulatory requirements, transfer to ASTRAZENECA or its nominee all NDA Approvals, and regulatory filings for the Compound or Product (including, without limitation, all information and documentation used in the Filings of an NDA and NDA approvals referred to in Article 3.5.2 and 3.5.4). In the event that in any country such a transfer is not possible, TMC shall use reasonable endeavours to ensure that ASTRAZENECA has the benefit of the relevant NDA Approvals, NDAs and other related regulatory filings and approvals and, to this end, consents to any regulatory authority cross-referencing to the data and information on file with any regulatory authority as may be necessary to facilitate the granting of second NDA Approvals to and permit Filings of an NDA by ASTRAZENECA, and TMC agrees to complete whatever other procedures that are reasonably necessary in relation to the same to enable ASTRAZENECA (either itself or in conjunction with a Third Party) freely to develop and sell the Product in substitution for TMC;
- (g) if applicable, assign the TMC Trademark or grant a royalty-free exclusive licence to ASTRAZENECA to use the TMC Trademark for the marketing, sales and distribution of the Product;
- (h) not after the date of termination itself take any further action to develop, manufacture, have manufactured, use, market, distribute or sell the Compound or Product during the life of the TMC Patent Rights or the ASTRAZENECA Patent Rights, whichever is the longer, except that TMC has the right to dispose of that part of its inventory of Product on hand as of the effective date of termination which is the subject of orders for Product accepted prior to the date of notice of termination for a period of three (3) months after the effective date of termination, and, within thirty (30) days after disposition of such inventory pursuant to the fulfilment of such orders, TMC will forward to ASTRAZENECA a final report and pay all royalties due on the Net Sales of Product during such period; and
- (I) PROVIDE ASTRAZENECA, SHOULD ASTRAZENECA SO REQUIRE, WITH REASONABLE ASSISTANCE IN RELATION TO ASTRAZENECA'S APPOINTMENT OF A THIRD PARTY MANUFACTURER OF PRODUCT.
  - 34

Upon such termination as stated in this Article 15.1, ASTRAZENECA shall have the right to disclose Confidential Information, to Third Parties for the purpose only of, and only to the extent necessary for, enabling such Third Party to evaluate the financial and scientific status of the Compound or Product for the purpose of making a financial offer to ASTRAZENECA on the licensing or acquisition of the rights returned to ASTRAZENECA and the rights licensed to ASTRAZENECA under this Article 15.1, and, if such licensing or acquisition occurs, as necessary to exploit or enforce such rights.

#### 15.2. TERMINATION FOLLOWED BY CONTINUED LICENSE

Upon the termination of this Agreement by TMC pursuant to Article 14.3, ASTRAZENECA's licences granted to TMC under Article 2 shall continue, provided that TMC continues to make payments pursuant to Article 6 as if the Agreement was still in effect.

#### 16. FORCE MAJEURE

16.1. If either Party is prevented or delayed in the performance of any of its obligations under this Agreement by Force Majeure, that Party shall forthwith serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to Force Majeure, and shall subject to service of such notice and to Article 16.3 have no liability in respect of the performance of such of its obligations as are prevented by the Force Majeure event during the continuation of such events, and for such time after they cease as is necessary for that Party, using all reasonable endeavours, to recommence its affected operations in order for it to perform its obligations.

16.2. If either Party is prevented from performance of its obligations, due to Force Majeure, for a continuous period in excess of six (6) months, the other Party may terminate this Agreement forthwith on service of written notice upon the Party so prevented. In the event of termination under this Article 16.2 the provisions of Article 15 shall not apply immediately and the Parties shall meet to discuss the ASTRAZENECA IP and TMC IP and agree on a process for arrangements upon termination.

16.3. The Party claiming to be prevented or delayed in the performance of any of its obligations under this Agreement by reason of Force Majeure shall use its reasonable endeavours to bring the Force Majeure event to a close or to find a solution by which the Agreement may be performed despite the continuation of the Force Majeure event.

- 17. GENERAL PROVISIONS
- 17.1. ASSIGNMENT.

17.1.1. Subject to Articles 17.1.2 and 17.1.3, neither Party shall without the prior written consent of the other Party assign, transfer, charge or deal in any other manner with this Agreement or any of its rights under it.

17.1.2. Each Party shall be entitled to assign its rights under this Agreement to an acquiror of all or substantially all of its capital stock or assets related to the pharmaceutical business described in this Agreement, whether through purchase, merger, consolidation or otherwise.

17.1.3. Each Party shall be entitled to assign its rights under this Agreement to an Affiliate provided that such Party shall require that any such Affiliate to whom it assigns any of its rights under this Agreement shall assign such rights back to the assigning Party immediately prior to it ceasing to be an Affiliate of the assigning Party.

17.2. SEVERANCE.

17.2.1. If any provision of this Agreement shall be found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, such invalidity or unenforceability shall not, provided that the general content of the Agreement remains substantially the same as prior to such invalidity or unenforceability, affect the other provisions of this Agreement which shall remain in full force and effect.

17.2.2. The Parties agree, in the circumstances referred to in Article 17.2.1, to attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision which achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision.

17.3. NOTICES.

17.3.1. All notices and other communications given or made in relation to this Agreement;

17.3.2. shall be in English and in writing;

17.3.3. shall be delivered by hand or sent by first class registered post or facsimile;

17.3.4. shall be delivered or sent to the Party concerned at the relevant address or facsimile number, shown in Article 17.4 subject to such amendments as may be notified from time to time in accordance with this Article by the relevant Party to the other Party by no less than three business days notice; and

17.3.5. shall be deemed to have been duly given or made if addressed in the aforesaid manner;

17.3.6. if delivered by hand, upon delivery;

17.3.7. if posted by first class registered post, four (4) business days after posting;

17.3.8. if sent by facsimile, when a complete and legible copy of the communication has been received at the appropriate address

17.4. CONTACT INFORMATION. Initial details for the purposes of Article 17.3 are:

For ASTRAZENECA

Address: AstraZeneca AB, S-151 85 Sodertalje, Sweden Facsimile: +46-8 553 290 00 For the attention of: President & CEO

For TMC

Address: The Medicines Company, 5 Sylvan Way, Parsippany,

New Jersey 07054, United States Facsimile: +1-973-656-9898 For the attention of: Clive Meanwell, Executive Chairman

with a copy to

Steven D. Singer Hale and Dorr, LLP 60 State Street Boston MA 02109 United States

17.5. AGENCY, PARTNERSHIP OR JOINT VENTURE EXCLUDED.

17.5.1. Nothing in this Agreement shall be construed so as to constitute either Party to be the agent of the other.

17.5.2. Nothing in this Agreement and no action taken by the Parties pursuant to this Agreement shall constitute a partnership or joint venture of any kind between the Parties.

17.6. ENTIRE AGREEMENT. Each of the Parties acknowledges and agrees that in entering into this Agreement, and the documents referred to in it, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any Person (whether party to this Agreement or not) other than as expressly set out in this Agreement as a warranty. Nothing in this Article shall either operate to limit or exclude any liability for fraud.

17.7. AGREEMENT TO SUPERSEDE EARLIER AGREEMENTS. The Confidential Disclosure Agreement entered into by and between the Parties on 9 April 2001 ceases to have effect from the date of this Agreement, except such termination does not affect a Party's accrued rights and obligations at the date of termination.

17.8. AMENDMENTS. No amendment to or variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of each of the Parties.

17.9. PUBLICITY AND ANNOUNCEMENTS.

17.9.1. Subject to Article 17.9.2 no press release, announcement or any other communication to any Third Party concerning the transaction contemplated by this Agreement, the financial terms of this Agreement, the subject matter of this Agreement or any ancillary matters shall be made or permitted or authorized to be made by either Party without the prior written approval of the other, such approval not to be unreasonably withheld or delayed and such approval to be given by an authorized representative of the Party in question.

17.9.2. Either Party may make an announcement concerning the transaction contemplated by this Agreement or any ancillary matter if required by law, existing contractual obligations or any securities exchange or Regulatory Authority or governmental body to which either Party is subject or submits, wherever situated, provided that the Party required to make such announcement notifies the other Party of the details of the announcement prior to making such announcement and in sufficient time for the other Party to consider and comment on the

announcement, and takes advantage of all provisions to keep confidential as many terms of the Agreement as possible.

17.10. WAIVER. Failure or delay by either Party to exercise any right or remedy under this Agreement shall not be deemed to be a waiver of that right or remedy, or prevent it from exercising that or any other right or remedy on that occasion or on any other occasion.

17.11. NO BENEFIT TO THIRD PARTIES. No Third Party shall be deemed a third party beneficiary under this Agreement for any purpose. Without limiting the foregoing, the Contracts (Rights of Third Parties) Act 1999 and any legislation amending or replacing such Act shall not apply in relation to this Agreement or any agreement, arrangement, understanding, liability or obligation arising under or in connection with this Agreement.

18. GOVERNING LAW AND ARBITRATION

18.1. ARBITRATION. The Parties shall use their reasonable efforts to settle amicably any dispute arising out of or in connection with this Agreement. In case the Parties are not able to settle such dispute between themselves, such dispute shall be finally resolved by arbitration in accordance with the Rules of the International Chamber of Commerce. The arbitration proceedings shall be held in London. Any proceedings shall be held in the English language.

18.2. GOVERNING LAW. The validity, construction and interpretation of this Agreement and any determination of the performance which it requires shall be governed by the laws of England.

IN WITNESS WHEREOF this License Agreement has entered into force on the License Agreement Effective Date.

ASTRAZENECA AB

THE MEDICINES COMPANY

(publ)

# Schedule A

# ASTRAZENECA Patent Rights

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# PATENT FAMILY LIST

Family App./Propr Title Inventors	: : :	A1262 Astra AB Short acting dihydropyridines ANDERSSON, Kjell NORDLANDER, Margareta WESTERLUND, Christer
		MEDIENED, CHLIDCCL

Country	SN	F	App No	App Date	Pat No.	Grant Dt.	Exp. Dt	Status
Argentina	1		329878	24.10.1994	253845	13.12.1999	13.12.2014	Granted
Argentina	2		980104360	01.09.1998				Filed
Austria	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Australia	1	P	81196/94	03.11.1994	685532	07.05.1998	03.11.2014	Granted
Belgium	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Brazil	2		PI110048-7	06.05.1997				Filed
Canada	1	P	2174969	03.11.1994				Filed
Switzerland	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
China P.R.	1	P	94194500.6	03.11.1994	94194500.6	20.11.1999	03.11.2014	Granted
Czech Republ	1	P	PV1273/96	03.11.1994	285691	17.08.1999	03.11.2014	Granted
Germany	1	х	95900347.6	03.11.1994	6942515.2	05.07.2000	03.11.2014	Granted
Denmark	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Estonia	1	P	P9600051	03.11.1994	03230	20.10.1999	03.11.2014	Granted
Egypt	1		689/94	02.11.1994	20539	31.07.1999	03.11.2004	Granted
European Pat	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Spain	1	х	95900347.6	03.11.1994	ES2150544	05.07.2000	03.11.2014	Granted
Finland	1	P	961914	03.11.1994				Filed
France	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Great Britain	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Greece	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Hong Kong	1		98114638.2	02.12.1998	1013292	08.12.2000	03.11.2014	Granted
Hungary	1	P	P9601187	03.11.1994	215591	04.12.1998	03.11.2014	Granted
Indonesia	1		P-941873	02.11.1994	ID0004550	06.12.1999	02.11.2014	Granted
Ireland	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Israel	1		111127	03.10.1994	111127	22.02.2001	03.10.2014	Granted
Iceland	1		4218	30.09.1994	1674	31.12.1997	30.09.2014	Granted
Italy	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Korea South	1	P	96/702346	03.11.1994				Filed
Lithuania	1	х	95900347.6					Docketed
Luxembourg	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Latvia	1	Е						Docketed
Monaco	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Mexico	1		948392	28.10.1994	196540	22.05.2000	28.10.2014	Granted
Malaysia	1		PI94002934	04.11.1994	MY111770A	30.12.2000	30.12.2015	Granted
Netherlands	1	х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Norway	1	P	961776	03.11.1994	305656	05.07.1999	03.11.2014	Granted

New Zealand	1	P	275915	03.11.1994	275915	29.09.1997	03.11.2014	Granted
Philippines	1		49112	04.10.1994	1-1994-49112	28.04.2000	28.04.2017	Granted
Poland	1	P	P314128	03.11.1994				Filed
Portugal	1	Х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Russian Fed	1	P	96112152	03.11.1994	2139278	10.10.1999	03.11.2014	Granted
Saudi Arabia	1		94150250	19.10.1994				Filed
Sweden	1		9303657-2	05.11.1993				Inactive
Sweden	1	Х	95900347.6	03.11.1994	0726894	05.07.2000	03.11.2014	Granted
Slovak Repub	1	P	PV0559/96	03.11.1994	281467	10.01.2001	03.11.2014	Granted
Thailand	1		024372	04.11.1994				Filed
Taiwan	1		83108995	29.09.1994	NI-078831	15.10.1996	29.09.2014	Granted
Ukraine	1	P	96041753	03.11.1994				Filed
United States	1	P	356224	03.11.1994	5856346	05.01.1999	05.01.2016	Granted
South Africa	1		94/7570	28.09.1994	94/7570	26.07.1995	28.09.2014	Granted

# PATENT FAMILY LIST

Family
App./Propr
Title
Inventors

A1279
Astra AB
Pharmaceutical emulsion
ANDERSSON, Kjell BYROD, Eva NORDLANDER, Margareta WESTERLUND, Christer HANSSON, Anna-Carin

Country	SN	F	App No	App Date	Pat No.	Grant Dt.	Exp. Dt	Status
Argentina	1		330005	04.111994	255314	01.11.2001	01.11.2016	Granted
Argentina	2		990105741	11.11.1999				Filed
Austria	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Australia	1	P	10371/95	03.11.1994	678650	25.09.1997	03.11.2014	Granted
Belgium	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Brazil	1	P						Inactive
Canada	1	P	2176360	03.11.1994				Filed
Switzerland	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
China P.R.	1	P	94194111.6	03.11.1994	94194111.6	11.08.2001	03.11.2014	Granted
Czech Republ	1	P	PV1338/96	03.11.1994				Filed
Germany	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Denmark	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Estonia	1	P	P9600052	03.11.1994	03223	20.10.1999	03.11.2014	Granted
Egypt	1		710/94	09.11.1994	20764	31.01.2000	09.11.2014	Granted
European Pat	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Spain	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Finland	1	P	961999	03.11.1994				Filed
France	1	Х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Great Britain	1	Х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Greece	1	Х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Hong Kong	1		98114639.1	22.12.1998				Filed
Hungary	1	P	P9601268	03.11.1994				Filed
Indonesia	1		P-941957	11.11.1994	ID0004476	01.11.1999	11.11.2014	Granted
Ireland	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Israel	1		111345	20.10.1994	111345	03.12.2000	20.10.2014	Granted
Iceland	1		4224	21.10.1994				Filed
Italy	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Korea South	1	P	96/702485	03.11.1994				Filed
Liechtenstei	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Lithuania	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Luxembourg	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Latvia	1	Е						Docketed
Monaco	1	х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Mexico	1		948732	10.11.1994				Filed

Malaysia Netherlands Norway	1 1 1	X P	PI94003029 95900965.5 961898	14.11.1994 03.11.1994 03.11.1994	0727997	13.02.2002	03.11.2014	Filed Granted Filed
New Zealand	1	P	276197	03.11.1994	276197	18.09.1997	03.11.2014	Granted
Philippines	1		49235	25.10.1994				Filed
Poland	1	P	P314263	03.11.1994	181462	31.07.2001	03.11.2014	Granted
Portugal	1	Х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Russian Fed	1	P	96112112	03.11.1994	2144358	20.01.2000	03.11.2014	Granted
Saudi Arabia	1		94150314	13.11.1994				Filed
Sweden	1	Х	95900965.5	03.11.1994	0727997	13.02.2002	03.11.2014	Granted
Slovak Repub	1	P	PV0597/96	03.11.1994				Filed
Thailand	1		024457	11.11.1994				Filed
Ukraine	1	P	96051803	03.11.1994	40633	15.08.2001	03.11.2014	Granted
United States	1	P	08/364953	03.11.1994	5739152	14.04.1998	14.04.2015	Granted
South Africa	1		94/8180	18.10.1994	94/8180	26.07.1995	18.10.2014	Granted

# PATENT FAMILY LIST

Family	:	A2004
Appl./Propr	:	AstraZeneca AB
Title	:	NEW MANUFACTURING PROCESS

Country	SN	F	App No	App Date	Pat No.	Grant Dt.	Exp. Dt	Status
Australia	1	P	20105/00	22.11.1999				Filed
Canada	1	P	2349195	22.11.1999				Filed
European Pat	1	х	99963732.5	22.11.1999				Filed
Hong Kong	1		[**]	[**]				Filed
New Zealand	1	P	511503	22.11.1999				Filed
United States	1	P	09/508260	22.11.1999				Filed
South Africa	1	Ρ	2001/3434	22.11.1999				Filed

# Schedule B

# Trademark Registrations

# 1

# Trademark Family Report

TRADEMARK	: CLEVELOX
TM Family Number TM Attorney Project Resp. RPT Project Description Project Number Project Cost Centre Therapeutic Area Owner	: A02243 : MST : MST : Clevidipine : 20298 : 20298 : Cardio vascular :

Country	SN	Appl De	Reg. Dt	Reg No	Expir. Dt	Status
United Arab Emi	1					Inactive
Argentina	1	05.12.1997				Inactive
Austria	1	24.11.1997	06.02.1998	173947	29.02.2008	Registered
Australia	1	26.11.1997	26.11.1997	749529	26.11.2007	Registered
Brazil	1					Inactive
Benelux	1	21.11.1997	21.11.1997	622377	21.11.2007	Registered
Canada	1	16.12.1997				Filed
Switzerland	1	21.11.1997	02.04.1998	450528	21.11.2007	Registered
China P.R.	1	28.11.1997	14.02.1999	1246211	14.02.2009	Registered
Colombia	1	03.12.1997				Filed
Czech Repub	1	03.12.1997	27.05.1999	217843	03.12.2007	Registered
Germany	1	22.11.1997	30.01.1998	39756082	30.11.2007	Registered
Denmark	1	21.11.1997	15.09.1998	199802513	15.09.2008	Registered
Egypt	1	01.12.1997				Filed
Spain	1	26.11.1997	20.05.1998	2128403	26.11.2007	Registered
Finland	1	21.11.1997	13.11.1998	211790	13.11.2008	Registered
France	1	24.11.1997	24.11.1997	97705657	24.11.2007	Registered
Great Britian	1	21.11.1997	21.11.1997	2151563	21.11.2007	Registered
Greece	1	17.11.1997	17.11.1999	135252	17.11.2007	Registered
Hong Kong	1	08.12.1997	08.12.1997	3239/99	08.12.2004	Registered
Hungary	1	27.11.1997	08.02.1999	155530	27.11.2007	Registered
Indonesia	1	12.12.1997	12.12.1997	427623	12.12.2007	Registered
Ireland	1	30.10.1997	21.11.1997	208749	21.11.2007	Registered
Israel	1	24.11.1997	07.02.1999	116095	24.11.2004	Registered
India	1	26.11.1997				Filed
Iceland	1	24.11.1997	28.01.1998	210/1998	28.01.2008	Registered
Italy	1	25.11.1997	18.05.2000	813581	25.11.2007	Registered
Japan	1	09.01.1998	02.04.1999	4257306	02.04.2009	Registered
Japan	2	17.04.2000	07.09.2001	4504229	07.09.2011	Registered
South Korea	1	27.11.1997	27.11.1998	431337	27.11.2008	Registered
Mexico	1	04.12.1997	04.12.1997	568689	04.12.2007	Registered
Malaysia	1	28.11.1997				Filed
Norway	1	21.11.1997	18.06.1998	190954	18.06.2008	Registered
New Zealand	1	25.11.1997	25.11.1997	285223	25.11.2004	Registered

Pakistan	1	25.11.1997				Filed
Poland	1	25.11.1997	06.03.2001	123629	25.11.2007	Registered
Portugal	1	25.11.1997	15.05.1998	327385	15.05.2008	Registered
Romania	1	05.12.1997	05.12.1997	33325	05.12.2007	Registered
Russian Federat	1	03.12.1997	24.02.1999	172676	03.12.2007	Registered
Saudi Arabia	1	12.01.1998	12.01.1998	474/30	22.09.2007	Registered
Sweden	1	21.11.1997	06.08.1999	332270	06.08.2009	Registered
Singapore	1	15.12.1997				Filed
Slovak Republic	1	25.11.1997	14.12.1999	188597	25.11.2007	Registered
Thailand	1	09.12.1997	09.12.1997	80071	09.12.2007	Registered
Turkey	1	26.12.1997	26.12.1997	195964	26.12.2007	Registered
Taiwan	1	04.12.1997	16.10.1998	820735	16.10.2008	Registered
United States	1	21.11.1997				Inactive
United States	2	19.04.2001				Filed
Vietnam	1	05.01.1998	07.05.1999	30808	05.01.2008	Registered
South Africa	1	01.12.1997	01.12.1997	97/18422	01.12.2007	Registered

Schedule C

Compound

1

SCHEDULE C, COMPOUND

CHEMICAL STRUCTURE, CHEMICAL NAME AND MOLECULAR FORMULA

CHEMICAL STRUCTURE

Figure 1. Chemical structure of clevidipine

CHEMICAL NAME

Butyroxymethyl methyl 4-(2',3'-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridinedicarboxylate.

MOLECULAR WEIGHT

456.3 g/mol.

MOLECULAR FORMULA

C SUB(21)H SUB(23)Cl SUB(2)NO SUB(6)

# Schedule D

# Reports

REPORTS TO BE TRANSLATED AND SENT TO TMC

REPORT	PAGES	COMMENT
[**]	7	
[**]	10+6	
[**]	12	
[**]	15	
[**]	21	
[**]	9	
[**]	2	
[**]	2	
[**]	2	
[**]	24	
[**]	15	Written in English
[**]	7	WITCEEN IN ENGLISH
[**]	17	
[**]	15	
[**]	6	
[**]	33	
[**]	6	
[**]	17	Written in
[]	17	English
[**]	5	Written in
[""]	5	English
[**]	22	Clevidipine,
[""]	22	delivered batch
[**]	26	401/97
• •		
[**]	28	
[**]	23	
[**]	10-20	

## Schedule E

# Supply Agreement

- i -

### THE MEDICINES COMPANY

February 13, 2004

Anders Buren AstraZeneca AB S-151 85 Sodertalje Sweden

Facsimile No.: 46 8 553 233 00

Re: License Agreement regarding Clevidipine, effective as of March 28, 2003

Dear Anders:

This is to advise AstraZeneca AB, pursuant to Section 9.1 of the License Agreement, effective as of March 28, 2003 (the "License Agreement"), between AstraZeneca AB and The Medicines Company ("TMC") that TMC wishes to maintain its exclusive license to the ASTRAZENECA Trademark, Clevelox, granted to TMC under Article 2.1 of the License Agreement.

Sincerely,

/s/ Clive A. Meanwell

Clive A. Meanwell, M.D. Executive Chairman

cc: Dr. Margareta Nordlander Dr. Anders Waas

- ii -

## CONFIRMATION

This Confirmation sets forth the Parties' mutual understanding of the interpretation of Article 6.2.1 of the License Agreement effective as of 28 March 2003 (the "License Agreement") entered into by and between AstraZeneca AB, with its registered office at SE-151 85 Sodertalje, Sweden ("ASTRAZENECA"), and The Medicines Company, with its registered office at 8 Campus Drive, Parsippany, New Jersey 07054, United States ("TMC").

Any term with capital initial letter and defined in the License Agreement shall when used in this Confirmation document have the meaning ascribed to it in the License Agreement. The Parties hereby confirm that it is their mutual understanding that the annual Net Sales mentioned in Article 6.2.1 refers to the annual Net Sales in the whole Territory.

The Parties confirm that the Agreement shall remain in full force and effect in accordance with its terms and conditions.

\_\_\_\_\_

IN WITNESS WHEREOF, the Parties have executed this Confirmation document in two (2) original copies.

ASTRAZENECA AB (publ)

THE MEDICINES COMPANY

/s/ Gunner Olsson

/s/ Clive Meanwell

Name: Gunner Olsson Title: VP & Head of CV TA Name: Clive Meanwell Title: Executive Chairman

December 19, 2003

8 Campus Drive Parsippany, New Jersey 07054 Tel: (973) 656-1616 Fax (973) 656-9898

</TEXT> </DOCUMENT> Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

# LICENSE AGREEMENT

Entered into by and between AstraZeneca AB and The Medicines Company as of the 18th day of December, 2003

1.	DEFINITIONS2
2.	GRANT OF LICENSE11
3.	DEVELOPMENT AND COMMERCIALIZATION15
4.	SUPPLY MATTERS
5.	EXCHANGE OF INFORMATION
б.	CONSIDERATION
7.	INTELLECTUAL PROPERTY - PROSECUTION AND MAINTENANCE
8.	CLAIMS REGARDING INFRINGEMENT AND INVALIDITY42
9.	TRADEMARK
10.	INDEMNITY
11.	CONFIDENTIALITY
12.	ADVERSE EVENTS
13.	REPRESENTATIONS, WARRANTIES AND COVENANTS
14.	TERM AND TERMINATION
15.	CONSEQUENCES OF TERMINATION
16.	FORCE MAJEURE
17.	GENERAL PROVISIONS
18.	GOVERNING LAW AND ARBITRATION

# -i-

#### LICENSE AGREEMENT

This Agreement is entered into as of the 18th day of December, 2003 (the "Effective Date")

### by and between

ASTRAZENECA AB, a company incorporated under the laws of Sweden with its registered office at SE-151 85 Sodertalje, Sweden ("ASTRAZENECA") and

THE MEDICINES COMPANY, a company incorporated under the laws of Delaware with its registered office at 8 Campus Drive, Parsippany, New Jersey 07054, United States ("TMC").

#### WITNESSETH

WHEREAS, ASTRAZENECA performs research, development and marketing of pharmaceutical compounds and products inter alia in the cardiovascular therapy area; and

WHEREAS, ASTRAZENECA has developed an intravenous pharmaceutical compound designated AR-C69931MX for the selective inhibition of ADP-induced platelet activation and aggregation; and

WHEREAS, TMC performs development of pharmaceutical compounds and marketing of pharmaceutical products particularly in the cardiovascular therapy area; and

WHEREAS, ASTRAZENECA has expressed an interest to license AR-C69931MX to TMC [\*\*] for intravenous administration [\*\*], and TMC has expressed an interest to license said compound; and

WHEREAS, it is a mutual objective of the Parties to maximise the sales of the Product.

NOW THEREFORE, the Parties hereto agree to the following.

## 1. DEFINITIONS

When used in this Agreement the following expressions shall have the meanings defined herein. The singular form of the defined expression shall include the plural form thereof and vice versa.

- 1.1. "ANDA Act" shall have the meaning defined in Article 8.3.1(a).
- 1.2. "[\*\*]" shall mean ASTRAZENECA's proprietary compound with the chemical structure as shown in Schedule E.
- 1.3. "Adverse Event" shall mean the development of an undesirable medical condition or the deterioration of a pre-existing medical condition following or during exposure to a pharmaceutical product whether or not considered causally related to such product.
- 1.4. "Affiliate" with respect to a Person shall mean any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. For the purposes of this Article 1.4 only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with", shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise, and/or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person.
- 1.5. "Agreement" shall mean this document including any and all schedules, appendices and other addenda to it as may be changed, added and/or amended from time to time in accordance with the provisions of this Agreement.

- 1.6. "ASTRAZENECA IP" shall mean the ASTRAZENECA Patent Rights and the ASTRAZENECA Know-How.
- 1.7. "ASTRAZENECA Indemnified Party" shall have the meaning defined in Article 10.1.1.
- 1.8. "ASTRAZENECA Know-How" shall mean any Know-How relating to the Compound for intravenous administration [\*\*] and/or the Product, developed, acquired or licensed by ASTRAZENECA prior to the Effective Date and in ASTRAZENECA's possession at the Effective Date.
- 1.9. "ASTRAZENECA Patent Rights" shall mean the patents and patent applications as set out in Schedule A, and any Patents Rights derived therefrom.
- 1.10. "Baseline Quarter" shall mean the Quarter preceding the Quarter in which ASTRAZENECA receives NDA Approval of an [\*\*] Product.

The definition "NDA Approval" shall, for the purpose of this Article 1.10 (and Articles 1.43 and 6.2.3) only, be deemed to refer to [\*\*] Product instead of Product.

- 1.11. "Combination Product" shall mean any pharmaceutical product which has only an intravenous route of administration, and [\*\*], in a finished dosage form which comprises the Compound and at least one other active pharmaceutical ingredient.
- 1.12. "Commercially Reasonable Efforts" shall mean with respect to the efforts to be expended by a Party with respect to any objective, the use of reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that with respect to the research, development or commercialisation of Product, such efforts shall be

substantially equivalent to those efforts and resources commonly used by a Party for a product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, regulatory authority-approved labelling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the Product, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the Product taking into account the royalties payable to licensors of patent or other intellectual property rights, alternative products and other relevant commercial factors. Commercially Reasonable Efforts shall be determined on a country-by-country basis for the Product, and it is anticipated that the level of effort will change over time (including, to the extent appropriate, the reduction or cessation of active promotional efforts), reflecting changes in the status of the Product and the market(s) involved.

- 1.13. "Compound" shall mean ASTRAZENECA's proprietary compound named AR-C69931MX with the chemical structure as shown in Schedule C, attached hereto, including all salts, esters, complexes, chelates, hydrates, isomers, stereoisomers, crystalline and amorphous forms and solvates thereof.
- 1.14. "Confidential Information" shall mean (i) in the case of TMC being the Receiving Party, ASTRAZENECA IP, and (ii) in the case of ASTRAZENECA being the Receiving Party TMC IP, and (iii) in the case of either Party being the Receiving Party, data generated by either or both Parties hereunder and trade secrets and/or confidential information relating to technology, including but not limited to compound(s), composition(s), formulation(s) and/or manufacturing information, and/or relating to the business affairs, including but not limited to commercial forecasts, plans, programs, customers, assets, financial projections, costs and customer lists and/or finances of the Disclosing Party, supplied or otherwise made available to the Receiving Party or coming into Receiving Party's possession in relation to the performance of this Agreement.

- 1.15. "Disclosing Party" shall mean the Party which discloses Confidential Information to the other Party.
- 1.16. "Documents" shall mean reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM, computer programs and documents thereof, computer information storage means, samples of material, other graphic or written data and any other media on which Know-How can be permanently or temporarily stored.
- 1.17. "Drug Product" shall mean the Compound in such formulation and associated primary packaging of dosage forms for intravenous administration as has been developed by ASTRAZENECA as of the Effective Date, used for, or intended for use in, human clinical trials, as described in the Product Master File, the table of contents of which is attached as Schedule B (the "PMF").
- 1.18. "Excluded Countries" shall mean [\*\*].
- 1.19. "European Union" shall mean the countries that are, whether at the Effective Date or at any time thereafter, members of the European Union.
- 1.20. "European Economic Area" shall mean the European Union plus Norway, Iceland and Liechtenstein.
- 1.21. "FDA" shall mean the United States Food and Drug Administration or any successor agency thereto.
- 1.22. "FTE Day" shall mean the equivalent of one person employed by ASTRAZENECA or TMC, as applicable, or their respective Affiliates full time for one day.
- 1.23. "Filing of an NDA" shall mean the date of acceptance for review by the competent registration body in a given country of an NDA.

- 1.24. "Force Majeure" shall mean any cause preventing either Party from performing any or all of its obligations which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the Party so prevented, act of God, war, riot, civil commotion, malicious damage, accident, breakdown of plant or machinery, fire, flood or storm.
- 1.25. "[\*\*]" shall mean any of ASTRAZENECA's proprietary compounds
  [\*\*], including all salts, esters, complexes, chelates, hydrates,
  isomers, stereoisomers, crystalline and amorphous forms,
  solvates, metabolites and prodrugs of any such compound.
- 1.26. "[\*\*] Product" shall mean any pharmaceutical formulation or product which has [\*\*] containing [\*\*] as the sole active ingredient in a finished dosage form suitable for administration to patients.
- 1.27. "Know-How" shall mean technical and other information, which is not subject to published patent rights and which is not in the public domain, including, but not limited to, information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, assays, research plans, procedures, designs for experiments and tests and results of experimentation and testing, including results of research or development, processes, including manufacturing processes, specifications and techniques, laboratory records, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports, manufacturing data or summaries and information contained in submissions to and information from ethical committees and regulatory authorities. Know-How includes Documents containing Know-How, including but not limited to any rights including trade secrets, copyright, database or design rights protecting such Know-How. The fact that an item is known to the public shall not be taken to preclude the possibility that a compilation including the item, and/or a development relating to the item, is not known to the public.

- 1.28. "Launch" or "Launched" shall mean the first invoiced commercial sale by TMC, its Affiliates, sub-licensees or distributors, however not including sales made by one such entity to another such entity, of the Product in a country following NDA Approval in such country.
- 1.29. "Major Market" shall mean each of [\*\*].
- 1.30. "NDA" shall mean a fully completed marketing license application comparable to a New Drug Application filed with the FDA, including all supporting documentation and data required for such application to be accepted for review by the competent health regulatory authorities for any country requesting approval for commercialisation of the Product for a particular indication in such country. NDA as herein defined shall for this purpose include applications for pricing or reimbursement approval where appropriate.
- 1.31. "NDA Approval" shall mean the approval by the competent registration body for a given country of an NDA.
- 1.32. "Net Sales" shall mean (i) the gross sales of Product by a Party or its Affiliates, or, regarding sales in the United States, its sub-licensees or distributors, to Third Parties, and (ii) royalties or other revenues, to the extent not included under (i), received by such Party or its Affiliates from its sub-licensees of the rights granted hereunder, or from its distributors, for sales of the Product outside the United States, after deduction of:
  - a) [\*\*] and/or [\*\*];
  - b) amounts [\*\*] determined in good faith;
  - c) [\*\*] such sales; and
  - d) [\*\*] the Product.

In the event the Product is sold as part of a Combination Product, the Net Sales from the Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product (as defined in the standard Net Sales definition), during the applicable royalty reporting period, by the fraction, A/(A+B), where A is the average sales price of the Product when sold separately in finished form and B is the average sale price of the other product(s) included in the Combination Product when sold separately in finished form, in each case during the applicable royalty reporting period or, if sales of both the Product and the other product(s) did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred, as adjusted, as necessary, for inflation from the date when both the Product and all other product(s) last were sold and the date of determination of Net Sales under this Article 1.32. In the event that such average sales price cannot be determined for both the Product and all other products(s) included in the Combination Product, Net Sales for the purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction of C/(C+D) where C is the fair market value of the Product and D is the fair market value of all other pharmaceutical product(s) included in the Combination Product. In such event, the selling Party shall in good faith make a determination of the respective fair market values of the Product and all other pharmaceutical products included in the Combination Product, and shall notify the other Party of such determination and provide the other Party with data to support such determination. The other Party shall have the right to review such determination and supporting data, and to notify the selling Party if it disagrees with such determination. If the other Party does not agree with such determination and if the Parties are unable to agree in good faith as to such respective fair market values, then such matter shall be referred to arbitration pursuant to Article 18.1.

Net Sales shall exclude (i) the transfer of a commercially reasonable quantity of free samples of Product to be given out to customers for promotional purposes; (ii) the transfer of Product for use in clinical trials; and (iii) the sales or transfers of Product among a Party and its Affiliates, and, in the United States, its sub-licensees or distributors, unless the receiver is the consumer or user of the Product; however, the resale or transfer of such Product to a Third Party shall be included in Net Sales.

Product sold or otherwise transferred (x) in other than an arms length transaction or for other property (e.g. barter); or (y) where no separate price has been decided for the Product but a price is decided jointly for the Product plus at least one other product, shall be deemed invoiced at its fair market price in the country of sale or transfer.

It is acknowledged that sub-licensees of a Party or its Affiliates and conventional distributors whose function is to purchase and resell Product, will be considered Third Parties when referring to Product sold outside the United States. The Parties agree further that for the purpose of the first paragraph of this Article 1.32 the Net Sales of the Product outside the United States by TMC or its Affiliates to such sub-licensees and distributors shall be the Net Sales received by TMC or its Affiliates from such sub-licensee or distributor for the Product or [\*\*] percent ([\*\*]%) of the actual gross sales, less deductions under subsections (a) through (d) above, of the Product by such sublicensee or distributor, whichever amount is the higher.

- 1.33. "PMF" shall have the meaning defined in Article 1.17.
- 1.34. "Party" or "Parties" shall mean TMC and/or ASTRAZENECA.
- 1.35. "Patent Rights" shall mean patent applications and patents, utility models, utility certificates, certificates of addition and all foreign counterparts of them in all countries, including any divisional applications and patents, refilings, renewals, continuations, continuations-in-part, patents of addition,

extensions (including patent term extensions and patent term restorations), reissues, substitutions, confirmations, registrations, revalidations, re-examinations, pipeline and administrative protections and additions, and any equivalents of the foregoing in any and all countries of or to any of them, as well as any supplementary protection certificates and equivalent protection rights in respect of any of them.

- 1.36. "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.
- 1.37. "Phase III Clinical Trial" shall mean a large scale, pivotal multicentre, human clinical trial to be conducted in a number of patients estimated to be sufficient to establish safety or efficacy in the particular claim and indication and at a standard suitable to obtain NDA Approval.
- 1.38. "Procedure" shall have the meaning defined in Article 3.5.1.
- 1.39. "Product" shall mean any pharmaceutical formulation or product which has only an intravenous route of administration, and [\*\*], containing the Compound as the sole active ingredient in a finished dosage form suitable for administration to patients. Apart from in this Article 1.39, and unless the context clearly requires otherwise in this Agreement, when used in this Agreement, the term "Product" shall be deemed to include "Combination Product".
- 1.40. "Quarter" shall mean a calendar quarter ending March 31, June 30, September 30 or December 31.
- 1.41. "Receiving Party" shall mean the Party which receives Confidential Information from the other Party.

- 1.42. "Results" shall have the meaning defined in Article 7.8.
- 1.43. "Subsequent Quarter" shall mean the Quarter in which ASTRAZENECA receives NDA Approval of an [\*\*] Product or any subsequent Quarter.

The definition "NDA Approval" shall, for the purpose of this Article 1.43 (and Articles 1.10 and 6.2.3) only, be deemed to refer to [\*\*] Product instead of Product.

- 1.44. "Supply Agreement" shall have the meaning described in Article 4.2.1.
- 1.45. "TMC IP" shall mean TMC Know-How, TMC Patent Rights and the TMC Trademark.
- 1.46. "TMC Indemnified Party" shall have the meaning defined in Article 10.2.1.
- 1.47. "TMC Know-How" shall mean any Know-How relating directly to the Compound and/or the Product developed, acquired or licensed by TMC during the term of this Agreement.
- 1.48. "TMC Patent Rights" shall mean any Patent Rights directly relating to the Compound and/or the Product developed, acquired or licensed by TMC during the term of this Agreement.
- 1.49. "TMC Trademark" shall have the meaning defined in Article 9.1.
- 1.50. "Territory" shall mean every country in the world, except the Excluded Countries.
- 1.51. "Third Party" shall mean any Person not including the Parties or the Parties' respective Affiliates.
- 2. GRANT OF LICENSE
- 2.1. LICENSE GRANT.

- 2.1.1. ASTRAZENECA hereby grants to TMC, subject to what is stated in Article 2.1.2, an exclusive license in the Territory under the ASTRAZENECA IP to perform research on, have research performed on, develop, have developed, use, have used, make, have made, import and have imported the Compound for intravenous administration [\*\*], and to perform research on, have research performed on, develop, have developed, use, have used, make, have made, import, have imported, market, have marketed, sell and have sold the Product for all indications [\*\*].
- 2.1.2. The license granted under Article 2.1.1 shall not apply to the Compound or the Product in relation to any formulation or product which contains both the Compound and one or more [\*\*] as active ingredients, whether or not such formulation or product contains active ingredients in addition to the Compound and the [\*\*], and such rights shall, for the avoidance of doubt, be retained by ASTRAZENECA.
- 2.2. GRANT TO TMC'S AFFILIATES. TMC'S Affiliates shall have the benefit and burden of the licenses and rights set out in Article 2.1 for the same purposes and under the same conditions as set forth herein, provided that TMC shall remain fully responsible for the compliance by such Affiliates with the terms and conditions of this Agreement as if such Affiliates were TMC hereunder.
- 2.3. RIGHT TO SUB-LICENSE. TMC shall have the right to grant sub-licenses to the rights granted under Article 2.1, provided that TMC shall notify ASTRAZENECA of each such sub-license without unreasonable delay following any such grant of a sub-license. TMC shall ensure that all of its sub-licensees will comply with all terms and conditions of this Agreement and TMC shall remain fully responsible for the compliance by such sub-licensees with the terms and conditions of this Agreement as if such sub-licensees were TMC hereunder.

- 2.4. RIGHT TO APPOINT DISTRIBUTORS. TMC shall also have the right to appoint distributors in the Territory for the sale of the Product. TMC shall at all times ensure that its distributors act fully in compliance with the terms and conditions of this Agreement.
- 2.5. DURATION OF LICENSE GRANT. The licenses set out in Article 2.1 shall continue in accordance with what is stated therein on a country-by-country basis until royalty payment is no longer due in the country concerned in accordance with what is stated in Article 6.4. The licenses set out in Article 2.1 shall thereafter continue on a non-exclusive basis and become fully paid up and royalty-free in the country concerned.
- 2.6. FIRST RIGHT OF REFUSAL OF TMC REGARDING THE EXCLUDED COUNTRIES. Should ASTRAZENECA within its sole discretion at any time determine that ASTRAZENECA will not Launch the Product in one or more Excluded Countries and/or that ASTRAZENECA will not license, transfer or otherwise dispose of its interest in the ASTRAZENECA IP regarding one or more Excluded Countries, then ASTRAZENECA shall offer to TMC, by providing written notice, the first right to negotiate a license on exclusive rights to commercially exploit the Compound and the Product under the ASTRAZENECA IP in the Excluded Country(ies) concerned on terms similar to those under this Agreement. Should TMC wish to exercise such right, then TMC shall notify ASTRAZENECA hereof in writing no later than ninety (90) days upon receipt of ASTRAZENECA's notice. In reasonable connection with such notice the Parties shall enter into good faith negotiations using their reasonable endeavours to reach a mutually acceptable agreement providing for such TMC's commercial exploitation as mentioned in this Article 2.6.
- 2.7. TMC GRANT OF RIGHTS TO ASTRAZENECA REGARDING THE EXCLUDED COUNTRIES.

- 2.7.1. In consideration of the rights granted by ASTRAZENECA hereunder, TMC hereby grants to ASTRAZENECA, at no cost or remuneration, a sub-licensable non-exclusive license under the TMC IP to perform research on, have research performed on, develop, have developed, use, have used, make, have made, import, have imported, market, have marketed, sell and have sold the Compound and the Product for all indications in the Excluded Countries.
- 2.7.2. TMC shall for the purpose of the license granted in Article 2.7.1 make available to ASTRAZENECA, upon ASTRAZENECA's request, any Filings of an NDA in the Territory, any NDA Approvals obtained in the Territory and any related documents and any TMC's correspondence with any regulatory authorities in the Territory regarding any such Filing of an NDA, NDA Approval or related issues, and shall allow ASTRAZENECA to make cross-references to any such Filing of an NDA or NDA Approval in the Territory. For any services or assistance performed by TMC pursuant to this Article 2.7.2, ASTRAZENECA shall reimburse TMC for TMC's out-of-pocket costs for such activities plus USD [\*\*] (\$[\*\*]) per FTE Day.
- 2.7.3. The license under Article 2.7.1 shall include an exclusive right and license for ASTRAZENECA to utilize the TMC Trademark in the Excluded Countries. Should ASTRAZENECA use the TMC Trademark in connection with the sales and marketing of Product in an Excluded Country, then ASTRAZENECA shall pay to TMC a running royalty of [\*\*] percent ([\*\*]%) on the annual Net Sales of the Product in such Excluded Country.

In each Excluded Country where ASTRAZENECA utilises, and for as long as ASTRAZENECA utilises, the license granted under this Article 2.7.3, ASTRAZENECA shall reimburse TMC its reasonable costs for maintaining the TMC Trademark in such Excluded Country. Such reimbursement shall be made within thirty (30) days of the expiration of each calendar year during which ASTRAZENECA has utilised such license.

SECTION 365(n) OF TITLE 11. All rights and licenses granted under or pursuant to any section of this Agreement, including amendments hereto, are, for all purposes of Section 365(n) of Title 11 of the United States Bankruptcy Code ("Title 11"), licenses of rights to "intellectual property" as defined in Title 11. The Parties shall retain and may fully exercise all of their respective rights under this Agreement pursuant to Title 11. Rejection of this Agreement pursuant to Section 365 of Title 11 constitutes a material breach of this Agreement and entitles the aggrieved Party to terminate this Agreement for material breach upon written notice. Upon bankruptcy of either Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

3. DEVELOPMENT AND COMMERCIALIZATION

2.8.

- 3.1. TRANSFER OF ASTRAZENECA KNOW-HOW.
- 3.1.1. TRANSFER OF ASTRAZENECA KNOW-HOW. Without unreasonable delay following the Effective Date, ASTRAZENECA shall make available and transfer to TMC the following ASTRAZENECA Know-How.
  - a description of the process used by ASTRAZENECA for the manufacturing of the Compound intended for Phase III Clinical Trials and a summary report of the development of such process;
  - b) a description of the process, available to ASTRAZENECA at the Effective Date, for the manufacture of all intermediates to be used for the manufacturing of the Compound;

c) a description of the analytical methods and validation reports, available to ASTRAZENECA at the Effective Date, for the starting materials and intermediates to be used in the manufacturing of the Compound.

It is acknowledged that at the Effective Date some of those analytical methods are not fully developed and validated, and such development and validation will not be continued or completed by ASTRAZENECA. ASTRAZENECA will, however, provide a summary report of the status of these methods at the Effective Date.

- d) the description of the tentative test-methods used by ASTRAZENECA for validating the bulk Compound manufactured, and a brief summary of the validation done thereon by ASTRAZENECA;
- e) to the extent available to ASTRAZENECA at the Effective Date, reference and analytical standard compounds to be used as reference material in the conduct of comparative analyses in relation to the manufacturing process with the Compound. It is explicitly understood that no such compound may be used for any other purpose than the purpose now stated;
- f) a description of the formula and manufacturing process used by ASTRAZENECA for the manufacturing of the Drug Product intended for Phase III Clinical Trials. Where available, ASTRAZENECA will provide TMC with summary reports of the development of such processes;

As a prerequisite of ASTRAZENECA providing the ASTRAZENECA Know-How contemplated under this sub-section f) TMC shall notify ASTRAZENECA in writing of the vial strengths and batch size that TMC initially intends to manufacture the Drug Product in and

ASTRAZENECA's obligations under this sub-section f) shall apply only in relation to such strengths and size.

g) a description of the analytical methods used by ASTRAZENECA in the testing and stability assessment of the Drug Product;

It is acknowledged that at the Effective Date some of those analytical methods are not fully developed and validated, and such development and validation will not be continued or completed by ASTRAZENECA. ASTRAZENECA will, however, provide a summary report of the status of these methods at the Effective Date.

- h) stability data and shelf-life recommendations for the Drug Product used in previous clinical trials;
- a description of the Drug Product formulations and processes used in previous clinical trials. This information will be contained within existing reports available at the Effective Date.
- j) specifications on the Compound and Drug Product used in clinical trials conducted by ASTRAZENECA prior to the Effective Date.
- k) project-related reports and documentation, which are designated with an asterisk in Schedule D, containing ASTRAZENECA Know-How relating to the manufacturing of the Compound. Additional reports contained in Schedule D will be made available by ASTRAZENECA to TMC upon request by TMC to ASTRAZENECA in writing.
- the PMF and, upon request by TMC to ASTRAZENECA in writing, other relevant reports, if available to ASTRAZENECA, containing ASTRAZENECA Know-How relating to the manufacturing of the Drug Product.

Any documents contemplated by this Article 3.1 shall be in English when transferred to TMC.

- 3.1.2. Any activities to be carried out by ASTRAZENECA under Article 3.1.1 shall be made to an extent necessary and reasonable and ASTRAZENECA shall not be obligated to devote more than the equivalent of [\*\*] FTE Days thereon and under no circumstances to carry out such activities beyond the date [\*\*] months from the Effective Date. It is acknowledged that ASTRAZENECA may at its discretion carry out assistance under Article 3.1.1 for up to [\*\*] percent ([\*\*]%) of such FTE Days by using Third Party consultants.
- 3.2. THIRD PARTY MANUFACTURERS.

3.2.1. It is acknowledged that TMC may present the ASTRAZENECA Know-How described under Article 3.1.1 to Third Party manufacturers for the purposes permitted under Article 11.2.4. TMC shall notify ASTRAZENECA in writing regarding the date of submission of such information to any such Third Party manufacturer(s). ASTRAZENECA shall in this connection assist TMC to address questions raised about such ASTRAZENECA Know-How by no more than three (3) of such Third Party manufacturer(s) of the Compound and no more than three Third Party manufacturers of the Drug Product selected by TMC, during a period of three (3) months from the date of presentation of such ASTRAZENECA Know-How to the Third Party manufacturer concerned. ASTRAZENECA shall also provide TMC with advice on the technical merits of proposals regarding manufacturing of the Compound brought forward by such Third Party manufacturer(s). Any assistance provided under this Article 3.2.1 may be given by telephone or e-mail or by other appropriate means as agreed by the Parties.

- 3.2.2. ASTRAZENECA undertakes to participate in no more than one (1) meeting in person with one Third Party manufacturer, selected by TMC, to outline details of the manufacturing synthesis regarding the Compound, provided that such meeting, at ASTRAZENECA's sole discretion, shall take place either at ASTRAZENECA's Charnwood site at Loughborough, UK, or at the Third Party manufacturer's site.
- 3.2.3. ASTRAZENECA undertakes to participate in no more than one (1) meeting in person with one Third Party manufacturer, selected by TMC, to outline details of the manufacture of the Drug Product. Such meeting shall, at ASTRAZENECA's sole discretion, take place either at ASTRAZENECA's Charnwood site at Loughborough, UK, or at the Third Party manufacturer's site.
- 3.2.4. ASTRAZENECA further undertakes, upon having received written notice from TMC, for a period of three (3) months starting sixty (60) days upon ASTRAZENECA's receipt of such notice, to assist TMC, by telephone, e-mail or other appropriate means as agreed by the Parties, in TMC's discussions with Drug Product contractors in connection with the formulation program regarding the Product. The Parties agree, however, that TMC may not give such notice contemplated above in this Article 3.2.4 later than eight (8) months after the Effective Date.
- 3.2.5. ASTRAZENECA agrees to provide reasonable assistance to the Third Party manufacturer selected by TMC, by telephone, e-mail or other appropriate means as agreed by the Parties, in connection with the start-up of manufacturing operations for the Product for a period of twelve (12) months following commencement of process development by such contract manufacturer or fifteen (15) months after the Effective Date, whichever is the earliest to occur.
- 3.3. DURATION OF AND COMPENSATION FOR ASSISTANCE BY ASTRAZENECA.

- 3.3.1. The Parties agree that any assistance to be provided by ASTRAZENECA under Articles 3.2 and 3.5.1 shall be given to an extent necessary and reasonable and shall be given only within the first [\*\*] years after the Effective Date and shall not in total exceed [\*\*] FTE Days. It is acknowledged that ASTRAZENECA may at its discretion carry out any such assistance for up to [\*\*] percent ([\*\*]%) of such [\*\*] FTE Days by using Third Party consultants.
- 3.3.2. For any services or assistance performed by ASTRAZENECA pursuant to Articles 3.1.2 and 3.3.1, TMC shall reimburse ASTRAZENECA for ASTRAZENECA's out-of-pocket costs for such activities plus USD [\*\*] (\$[\*\*]) per FTE Day. Should ASTRAZENECA use a Third Party consultant(s) for carrying out assistance for a certain FTE Day, or part thereof, then, for the avoidance of doubt, the FTE Day rate now stated shall apply thereon, and the out-of-pocket costs for consultants, if any, as indicated above in this paragraph, shall apply only to costs for consultants which would typically have been incurred should the assistance have been actually carried out by an employee(s) of ASTRAZENECA or its Affiliates.
- 3.3.3. ASTRAZENECA shall invoice TMC for all assistance during each relevant time period within thirty (30) days of the expiration of each calendar half-year.
- 3.4. DEVELOPMENT OF PRODUCT.
- 3.4.1. TMC shall, subject to the obligations stated in this Article 3 and in Article 5, carry out the development work permitted hereunder within its sole discretion and at its own cost and expense.
- 3.4.2. TMC shall use Commercially Reasonable Efforts to develop Product up until the stage of Filing of an NDA in each country of the Territory.
- 3.5. REGULATORY FILINGS.

- 3.5.1. TMC shall be responsible for the preparation, submission and prosecution of all Filings of an NDA in each country in which TMC, its Affiliates, sub-licensees or distributors will sell Product. TMC, its Affiliates, sub-licensees or distributors shall be the owner and party of record for all such filings, applications and approvals. ASTRAZENECA agrees to provide assistance requested by TMC as reasonably necessary for preparation and prosecution of such filings and applications in the European Union (it being contemplated that such filings and applications will be done by using the then most efficient centralised procedure for applying for and obtaining multi-country NDAs in the European Union (the "Procedure")), and in the United States. TMC shall reimburse ASTRAZENECA in accordance with Article 3.3 for any costs and expenses incurred in such assistance. TMC shall be responsible for any costs associated with preparation, submission and prosecution of all such Filing of an NDA and NDA Approvals required.
- 3.5.2. TMC shall, at its own expense, use Commercially Reasonable Efforts in Filing of an NDA and prosecution thereof and in obtaining NDA Approvals in its own name or in the name of its Affiliate(s), sub-licensee(s) or distributors in each country of the Territory.
- 3.5.3. Regarding any country in the European Union where TMC makes a Filing of an NDA, TMC shall for such purpose use the Procedure, unless TMC can clearly establish that Filing of an NDA regarding one or more separate countries within the European Union would be more advantageous to the Product from a regulatory or commercial perspective.
- 3.5.4. TMC shall promptly inform ASTRAZENECA in writing, and by facsimile in accordance with Article 17.4.2, of any Filing of an NDA and of any NDA Approval, and shall in immediate connection therewith provide ASTRAZENECA with a written summary of any such Filing of an NDA and NDA Approval, or with a copy thereof, whichever ASTRAZENECA may elect.

- 3.5.5. Following NDA Approval in a country of the Territory TMC shall use its Commercially Reasonable Efforts to Launch the Product in such country.
- 3.6. MARKETING AND SALES OF PRODUCT.
- 3.6.1. Regarding any country of the Territory where the Product is Launched, TMC shall promptly inform ASTRAZENECA in writing of the occurrence of such Launch.
- 3.6.2. TMC shall, in each country of the Territory where the Product has been Launched, at its own expense, or the expense of its Affiliates, sub-licensees or distributors, use Commercially Reasonable Efforts to market and sell the Product.
- 3.6.3. For the avoidance of doubt, what is stated regarding the obligations of TMC in this Article 3 or elsewhere in this Agreement shall always be subject to what is stated in Articles 2.2 and 2.3, such that any of TMC's obligations may be performed by one or more of TMC's Affiliates or sublicensees. Further, in accordance with what is stated in Article 2.4, any of TMC's obligations under this Article 3.6 and under Article 3.7 may be performed by one or more of TMC's distributors.
- 3.7. SPECIFIC TIME LIMITS FOR PERFORMANCE. Notwithstanding what is stated in Articles 3.4.2, 3.5.2, 3.5.5 and 3.6.2, and without limiting the general performance criteria stated therein, the following performance criteria stated in this Article 3.7 shall apply to the situations herein described.
- 3.7.1. TIME LIMIT FOR ENTERING INTO PHASE III CLINICAL TRIALS.

TMC shall no later than [\*\*] have made the first dosing of a patient in a Phase III Clinical Trial regarding the Compound.

3.7.2. TIME LIMIT FOR FILING OF AN NDA.

- a) TMC shall no later than [\*\*] have made a Filing of an NDA [\*\*].
- b) TMC shall no later than [\*\*] or [\*\*] after having made a Filing of an NDA in the United States, whichever is the earlier, have made a Filing of an NDA [\*\*].
- c) TMC shall no later than [\*\*] or [\*\*] after having made the last Filing of an NDA under Article 3.7.2 (b), whichever is the earlier, have made a Filing of an NDA [\*\*].
- 3.7.3. Notwithstanding what is stated in Article 3.7.2 c), TMC shall not be obligated to make a Filing of an NDA in [\*\*] until the [\*\*] patent application no. [\*\*] is granted insofar it relates to the Compound to the extent licensed to TMC under this Agreement. For the avoidance of doubt, such exemption from those obligations now stated shall not relieve TMC from its obligations under Article 3.7.2 b).
- 3.7.4. TIME LIMIT FOR LAUNCH OF THE PRODUCT

TMC shall no later than [\*\*] following NDA Approval in any Major Market Launch the Product in the Major Market in which such NDA Approval was obtained.

- 3.8. REMEDY FOR FAILURE.
- 3.8.1. NON-COMPLIANCE.

Should TMC at any time not comply with the applicable criteria of performance as set forth in Articles 3.4.2, 3.5.2, 3.5.5, 3.6.2, 3.7.1, 3.7.2 or 3.7.4, then TMC shall promptly so notify ASTRAZENECA in writing.

a) In case of non-compliance with the performance criteria set forth in Article 3.7.1, ASTRAZENECA shall have the right, by giving ninety (90) days written notice to TMC, to require the license granted

hereunder to terminate regarding the Compound and the Product, subject to Article 3.8.2.

- b) In case of non-compliance with the performance criteria set forth in Articles 3.4.2, 3.5.2, 3.5.5, 3.6.2, 3.7.2 (a) or 3.7.4, ASTRAZENECA shall have the right, by giving ninety (90) days written notice to TMC, to require the license granted hereunder to terminate regarding the Compound and the Product in the Major Market or other country concerned, subject to Article 3.8.2.
- c) In case of non-compliance with the performance criteria set forth in Article or 3.7.2 (b) or (c), ASTRAZENECA shall have the right, by giving ninety (90) days written notice to TMC, to require the license granted hereunder to terminate regarding the Compound and the Product in any Major Market(s) other than the Major Market(s) regarding which the performance criteria concerned was fulfilled (and, in the case of non-compliance with Article 3.7.2 (c), the Major Market(s) regarding which such criteria had been fulfilled under Article 3.7.2 (b) or that was exempted under Article 3.7.3), subject to Article 3.8.2.
- d) If ASTRAZENECA makes a request under (a), (b) or (c) above, and provided that TMC has not remedied the default concerned within the ninety-day period stated, then, provided that ASTRAZENECA notifies TMC in writing hereof within thirty (30) days after the expiration of such ninety-day period, the license regarding the Compound and the Product shall terminate for the Major Market or other country contemplated by such notice and what is stated in Article 15.1 shall apply regarding such Major Market or other country, subject to Article 3.8.2.

3.8.2.

REASONABLE DELAY OR OTHER NON-COMPLIANCE.

- a) Should TMC upon receipt of notice from ASTRAZENECA according to Article 3.8.1 (a) through (c) be able to show that the delay or other non-compliance in the country(ies) concerned is justifiable from a clinical, scientific or regulatory perspective, then the Parties shall meet and consult whether the situation so occurred could be reasonably solved. Should the Parties, despite such consultations, not be able to find a mutually acceptable solution within three (3) months after having entered into such consultations, then ASTRAZENECA may terminate the license regarding the country(ies) concerned by giving TMC a notice of same in writing, whereupon the license regarding such country(ies) shall immediately terminate and what is stated in Article 15.1 shall apply regarding such country(ies).
- b) Should, following the initiation of the consultations pursuant to the first paragraph of this Article 3.8.2, either Party reasonably believe that a solution to the situation arisen may be solved through such consultations, but not within the initial three-month timeframe, then such Party may notify the other Party thereof; and the three-month period provided for in Article 3.8.2 a) shall be extended with a time-period as requested by such Party in such notice but with no more than three (3) months from the date of the notice.
- 3.9. The remedies stated in Article 3.8 shall be ASTRAZENECA's sole remedy in case of any failure by TMC to comply with what is stated in this Article 3.
- 4. SUPPLY MATTERS
- 4.1. TRANSFER OF BULK COMPOUND TO TMC. ASTRAZENECA undertakes to supply to TMC [\*\*] approximately [\*\*] kilograms of bulk Compound no later than ninety (90) days after the Effective Date. The transport of such entire quantity of bulk Compound shall be entirely at TMC's risk and expense. It is explicitly understood that this quantity of Compound was

manufactured by ASTRAZENECA at an earlier date, and was not made for the purpose of the supply now stated, and that ASTRAZENECA gives no guarantee whatsoever as to the characteristics of the Compound or the Compound's fitness for any particular purpose. It is explicitly understood and agreed by the Parties that ASTRAZENECA shall have no obligations whatsoever to transfer or supply, other than as explicitly provided under this Article 4.1, any quantity of Compound or Product to TMC.

- 4.2. SUPPLY OF COMPOUND AND PRODUCT BY TMC.
- 4.2.1. TMC undertakes to supply ASTRAZENECA and/or any of its Affiliates, at TMC's [\*\*] ASTRAZENECA's and/or its Affiliates entire need of Product for clinical trials, sale, promotion and marketing in the Excluded Countries, pursuant to the Supply Agreement between TMC and ASTRAZENECA, attached hereto, subject to what is stated in Article 4.2.3, as Schedule F. In addition ASTRAZENECA will reimburse TMC for costs specifically pertaining to the development of a formulation necessary only for the purpose of enabling ASTRAZENECA to obtain NDA Approval in one or more of the Excluded Countries.
- 4.2.2. TMC further undertakes to supply ASTRAZENECA, subject to Article 15.1 (i), at [\*\*] and otherwise under terms to be as consistent as possible with those under the Supply Agreement, ASTRAZENECA's entire need of Product for clinical trials, sale, promotion and marketing in any country where the license granted under Article 2 has been terminated pursuant to Article 3.8; provided always that such TMC's obligation shall not become effective unless and until TMC has Launched the Product in at least one (1) country of the Territory.
- 4.2.3. The Supply Agreement has not been entered into on the Effective Date due to the Parties' desire to expeditiously enter into this Agreement, not delaying such procedure by awaiting the completion of the Supply Agreement. The parties acknowledge the substantial need for

ASTRAZENECA to rely on TMC for its supply of the Product for the countries mentioned in Articles 4.2.1 and 4.2.2 and that entering into the Supply Agreement is a substantial prerequisite for ASTRAZENECA entering into this Agreement. Should regardless hereof the Supply Agreement not have been concluded within six (6) months of the Effective Date for other reasons than ASTRAZENECA's lack of good faith in conducting such negotiations or unnecessary delays caused by ASTRAZENECA, then ASTRAZENECA shall have the right to terminate this Agreement forthwith by giving written notice to TMC.

- 5. EXCHANGE OF INFORMATION
- 5.1. OBLIGATION OF TMC TO SHARE INFORMATION. In addition to the obligations specifically requiring TMC to inform ASTRAZENECA regarding particular events, TMC undertakes to keep ASTRAZENECA informed about the progress of the development work regarding the Compound hereunder. For this purpose:
- 5.1.1. the Parties will, up until the date when Filing of an NDA has been made in the last Major Market, meet at least once a year to review TMC's progress and efforts in the development work contemplated herein. Such meeting will take place on a location to be agreed by the Parties, or, should the Parties not be able to agree, alternately with each Party at a site to be determined by the Party hosting the meeting. In advance of such meeting, TMC will provide ASTRAZENECA a reasonable written summary of such development work, including, without limitation, summaries of protocol designs of any clinical trials conducted or to be conducted, any changes to same and any Results developed during the period concerned;
- 5.1.2. TMC shall further in advance of such meeting provide ASTRAZENECA in writing a timetable for the expected Filings of an NDA, expected NDA Approvals and expected Launches during the one-year period, or other shorter applicable period, to come. In connection therewith TMC shall

provide to ASTRAZENECA in writing, for the same period of time, a non-binding marketing plan and sales forecast for the Product in any Major Market where the Product by that time has been Launched or is expected to be Launched during the applicable period immediately to come;

- 5.1.3. TMC shall notify ASTRAZENECA forthwith and provide particulars of any halt or substantial delay in any development program or clinical trial, any obstacles in the Product reaching the market and any substantial changes anticipated in the sales potential of the Product;
- 5.1.4. TMC shall notify ASTRAZENECA forthwith regarding, and provide copies of, any correspondence with the regulatory authorities in the Territory that could reasonably be of any significance regarding the possibility, time frame or scope of any Filing of an NDA or any NDA Approval.
- 5.2. OBLIGATION OF ASTRAZENECA TO SHARE INFORMATION. ASTRAZENECA shall keep TMC informed about the progress of the clinical trials, sale, promotion and marketing of Product in any country in which ASTRAZENECA has rights to sell Product. For this purpose:
- 5.2.1. ASTRAZENECA shall at least once each year provide TMC in writing a timetable for the expected Filings of an NDA, expected NDA Approvals and expected Launches during the one-year period to come.
- 5.2.2. ASTRAZENECA shall notify TMC forthwith regarding, and provide copies of, any correspondence with the regulatory authorities in any Major Market that could reasonably be of any significance regarding the possibility, time frame or scope of any Filing of an NDA or any NDA Approval by TMC in any country for which TMC has yet to file an NDA or receive NDA Approval.

#### 6. CONSIDERATION

In consideration of the rights granted hereunder TMC shall pay to ASTRAZENECA the remuneration stated in this Article 6.

- 6.1. MILESTONE PAYMENTS.
- 6.1.1. Within thirty (30) days after the Effective Date TMC shall pay to ASTRAZENECA the amount of USD [\*\*] (\$[\*\*]).
- 6.1.2. Within thirty (30) days of TMC's receipt of NDA Approval in the first Major Market TMC shall pay to ASTRAZENECA the amount of USD [\*\*] (\$[\*\*]).
- 6.1.3. Within thirty (30) days of TMC's receipt of NDA Approval in the second Major Market, TMC shall pay to ASTRAZENECA the amount of USD [\*\*] (\$[\*\*]).
- 6.2. ROYALTY RATE.
- 6.2.1. Following Launch of the Product, on a country-by-country basis for the period set out in Article 6.4, TMC shall pay to ASTRAZENECA, subject to what is stated in Articles 6.2.2 and 6.2.3, a running royalty on the annual Net Sales of the Product in the Territory as follows:

	Annual Net Sales in the Territory	Royalty Rate
a)	up to USD [**] (\$ [**])	[**] percent ([**]%)
b)	above USD [**] (\$ [**]) and up to USD [**] (\$[**])	[**] percent ([**]%)

с)	above USD [**] (\$ [**]) and up to USD [**] (\$ [**])	[**] percent ([**]%)
d)	above USD [**] (\$ [**]) and up to USD [**] (\$ [**])	[**] percent ([**]%)
e)	above USD [**] (\$ [**])	[**] percent ([**]%)

The relevant royalty rate so stated shall apply to the amount of annual Net Sales within the applicable layer only.

For convenience of example only and without limiting the above, the royalty rate of [\*\*]% shall apply to the amount of annual Net Sales under [\*\*] and should the annual Net Sales exceed [\*\*] then the royalty rate of [\*\*]% shall apply only to the amount of annual Net Sales exceeding [\*\*] (and up to [\*\*]).

- 6.2.2. Notwithstanding the royalty rates set forth in Article 6.2.1, the running royalty rate on the Net Sales of the Product during the time period starting on the Effective Date and ending on the date which is one (1) year after the date of the Launch of the Product in the first country in which the Product is Launched, shall be reduced to [\*\*] percent ([\*\*]%) of the rate otherwise stated in Article 6.2.1.
- 6.2.3. In the event that in a country in the Territory ASTRAZENECA receives NDA Approval of an [\*\*] Product, and TMC's Net Sales in such country for a certain Subsequent Quarter is less than TMC's Net Sales in such country in the Baseline Quarter for such country, the royalty payable to ASTRAZENECA by TMC under Article 6.2.1 with respect to Net Sales in such country in the Subsequent Quarter concerned shall be reduced by (i), if such reduction in Net Sales is [\*\*] percent ([\*\*]%) or less compared to the

Net Sales in the Baseline Quarter for such country, a percentage equal to such reduction in Net Sales expressed in percent, or (ii), if such reduction in Net Sales exceeds [\*\*] percent ([\*\*]%) compared to the Net Sales in the Baseline Quarter for such country, [\*\*] percent ([\*\*]%). The calculation of the reduction in Net Sales under this Article 6.2.3 shall, in case Net Sales in such country is not denominated in USD, be conducted in local currency. The percentage of each Net Sales reduction contemplated in this Article 6.2.3 shall be determined by the fraction (A-B)/A multiplied by 100 where A is TMC's Net Sales during the Baseline Quarter and B is TMC's Net Sales during the Subsequent Quarter concerned.

The definition "NDA Approval" shall, for the purpose of this Article 6.2.3 (and Articles 1.10 and 1.43) only, be deemed to refer to [\*\*] Product instead of Product.

For convenience of example only and without limiting the above standing, the following calculation shows the application of the provision stated.

 a) If TMC's Net Sales in country A are \$[\*\*] in the Baseline Quarter for such country and \$[\*\*] in a Subsequent Quarter the reduction of the royalty payable to ASTRAZENECA would be determined as follows.

The reduction in Net Sales is [\*\*]% ((\$ [\*\*]) / \$ [\*\*] = [\*\*]%) and hence the royalty payable to ASTRAZENECA with respect to Net Sales in country A in the Subsequent Quarter concerned shall be reduced by [\*\*]%.

b) If TMC's Net Sales in country A are \$[\*\*] in the Baseline Quarter for such country and \$[\*\*] in a Subsequent Quarter the reduction of the royalty payable to ASTRAZENECA would be determined as follows.

The reduction in Net Sales is [\*\*]% ((\$[\*\*]) / \$ [\*\*] = [\*\*]%) and hence the royalty payable to ASTRAZENECA with respect to Net Sales in country A in the Subsequent Quarter concerned shall be reduced by [\*\*]%.

For the purpose of determining what royalty rate to apply with respect to Net Sales in one specific country, the following shall apply.

The applicable royalty rate under each of items (a) through (e) of Article 6.2.1 shall apply to TMC's Net Sales in one specific country exceeding the amount "C" in the following formula.

where "NS" is TMC's Net Sales in the specific country during the calendar year concerned; and where "aNS" is TMC's annual Net Sales in the Territory during such calendar year; and where "TA" is the applicable "threshold amount" under the respective items (a) through (e) of Article 6.2.1.

- 6.2.4. For the purpose of Article 6.2.1 the term "annual" shall refer to calendar years, provided, however, that for the purpose of determining what royalty rates to apply during the first or last calendar year of the royalty payment period pursuant to Article 6.4, which parts may not constitute a full calendar year, the following shall apply.
  - a) The applicable royalty rate under each of items (a) through
     (e) of Article 6.2.1, subject to what is stated in Article
     6.2.2 and 6.2.3, shall apply to the Net Sales exceeding the amount "A" in the following formula.

12

where "NM" is the "number of full months" of sales attracting royalty hereunder, regardless of the number of countries in which sales are being made, during the calendar year concerned; and where "TA" is the applicable "threshold amount" under the respective items (a) through (e) of Article 6.2.1.

b) For convenience of example only and without limiting the above standing, the following calculation shows the application of the provision stated.

If Launch occurs in the first country three months before the end of the calendar year, and Net Sales in such three month period are \$ [\*\*], royalties payable would be determined as follows:

(i) the [\*\*]% royalty rate under 6.2.1(a) would apply to the first \$ [\*\*]of Net Sales (\$[\*\*]); and

(ii) the [\*\*]% royalty rate under 6.2.1(b) would apply to Net Sales above \$ [\*\*] (\$[\*\*]).

The foregoing notwithstanding, as this example is with respect to sales in the year of first Launch, the above stated royalty rates would be reduced by [\*\*] percent ([\*\*]%) pursuant to Article 6.2.2.

MINIMUM ROYALTY. Notwithstanding what is stated in Article 6.2, during the second through fourth full calendar years following Launch in the first Major Market, the aggregate annual royalty amount due by TMC to ASTRAZENECA for sales of the Product shall, regardless of the actual Net Sales amount accrued during such calendar year, not go below the following amounts during the years specified:

6.3.1. Second full calendar year following Launch: USD [\*\*] (\$[\*\*]);

License Agreement - The Medicines Company

6.3.

- 6.3.2. Third full calendar year following Launch: USD [\*\*] (\$[\*\*])
- 6.3.3. Fourth full calendar year following Launch: USD [\*\*] (\$[\*\*])
- 6.3.4. Should the Net Sales by TMC for any calendar year not generate the relevant royalty amount indicated under this Article 6.3, then TMC shall pay the difference between the minimum royalty amount stated and the amount actually generated within thirty (30) days after the date when the royalty payment for the last full quarter of the calendar year concerned is due according to Article 6.5.1.
- 6.4. DURATION OF ROYALTY PAYMENTS.

Royalties under Article 6.2 shall be payable on a country by country basis for the longer of :

- a) the life of ASTRAZENECA Patent Rights which are necessary to continue to manufacture, use or sell the Product in such country; or
- b) a period of [\*\*] years from Launch in that country (provided always that, in the case of a country within the European Economic Area, such [\*\*] year period shall run from the date of Launch anywhere in the European Economic Area).

## 6.5. REPORTS.

6.5.1.

TMC shall deliver to ASTRAZENECA within sixty (60) days after the end of each Quarter, a written report showing its computation of the remuneration due to ASTRAZENECA under this Agreement during such Quarter including (i) the quantity of the Product sold by or on behalf of TMC during such Quarter; and (ii) the total remuneration due in respect thereof; and TMC shall at the same time make the payment of the remuneration due. Any payment to be made hereunder shall be made in U.S. Dollars. Each such report mentioned in this Article 6.5.1 shall include the

rates of exchange used for conversion to U.S. Dollars from the currency in which such sales were made.

6.5.2. In the event that ASTRAZENECA, its Affiliates or sublicensees sells Product pursuant to Article 2.7.3, then ASTRAZENECA shall deliver to TMC within sixty (60) days after the end of each Quarter, a written report showing its computation of the remuneration due to TMC under this Agreement during such Quarter including (i) the quantity of the Product sold by or on behalf of ASTRAZENECA during such Quarter; and (ii) the total remuneration due in respect thereof and at the same time make the payment of the remuneration due. Any payment to be made hereunder shall be made in U.S. Dollars. Each such report mentioned in this Article 6.5.2 shall include the rates of exchange used for conversion to U.S. Dollars from the currency in which such sales were made.

## 6.6. TAXES.

- 6.6.1. The payments to be made hereunder by either Party shall be net payments i.e. without deduction of any bank or transfer charges.
- 6.6.2. ASTRAZENECA shall pay any and all taxes levied on account of, or measured exclusively by, all payments it receives under this Agreement. Amounts payable from TMC to ASTRAZENECA under this Agreement shall be paid by TMC without deduction for any tax, provided however that TMC may withhold income tax as required by internal laws of any applicable jurisdiction. In the case of such withholding being applicable, ASTRAZENECA may apply for the reduction of rate of withholding tax (including under the U.S./Sweden tax treaty) with the assistance of TMC and provided evidence of acceptance of this claim is submitted to TMC, TMC shall apply this rate accordingly. If applicable laws require that taxes be withheld, TMC will deduct those taxes from the remittable payments, make timely payment of the taxes to the proper taxing authority and send proof of such payment to ASTRAZENECA within sixty (60) days following that payment.
- 6.6.3. TMC shall pay any and all taxes levied on account of, or measured exclusively by, all payments it receives under this Agreement. Amounts payable from ASTRAZENECA to TMC under this Agreement shall be paid by ASTRAZENECA without deduction for any tax, provided however that ASTRAZENECA may withhold income tax as required by internal laws of any applicable jurisdiction. In the case of such withholding being applicable, TMC may apply for the reduction of rate of withholding tax (including under the U.S./Sweden tax treaty) with the assistance of ASTRAZENECA and provided evidence of acceptance of this claim is submitted to ASTRAZENECA, ASTRAZENECA shall apply this rate accordingly. If applicable laws require that taxes be withheld, ASTRAZENECA will deduct those taxes from the remittable payments,

make timely payment of the taxes to the proper taxing authority and send proof of such payment to TMC within sixty (60) days following that payment.

- 6.6.4. For the avoidance of doubt, TMC shall be responsible and liable for all import duties and levies payable on bulk Compound imported to the US and to all related import clearance requirements. The value for customs purposes of this material provided free of charge should be the manufacturing cost to ASTRAZENECA.
- 6.6.5. The parties shall cooperate fully to ensure that where legally possible no import duties are paid by TMC in respect of Product supplied to ASTRAZENECA for sale in the Excluded Countries.
- 6.6.6. All payments under this Agreement shall be exclusive of Value Added Tax where applicable.
- 6.7. EXCHANGE RATES. For the purpose hereof, the rate of exchange to be used for conversion hereunder to U.S. Dollars shall be the average rate of exchange for the period to which the payment relates, as published by the Wall Street Journal.
- 6.8. BOOKS AND AUDIT. Each Party shall keep complete and accurate books and records with respect to its sale of the Product and remuneration payable hereunder. Each Party shall have the right to have such pertinent books and records of the other Party inspected and examined once each calendar year for the purpose of determining the accuracy of payments made hereunder. Such inspection and examination shall be conducted by an independent, certified, public accountant shall not disclose to such Party any information except for information necessary to verify the accuracy of the records and payments made pursuant to this Agreement. The charges of the independent, certified, public accountant shall party

requesting examination except if the payments pursuant to this Agreement have been understated by more than five percent (5%) in which case the Party who has underpaid will bear the cost and pay the shortfall in payment pursuant to this Agreement with interest to the other Party. Should instead the payments have been overstated the Party who has overpaid may deduct any such amount from the royalty payments due hereunder until such amount has been recovered by such Party.

- 6.9. WIRE TRANSFER INSTRUCTIONS.
- 6.9.1. Unless otherwise instructed by ASTRAZENECA, all payments by TMC hereunder shall be made from the United States by wire transfer in the requisite amount to the following account of ASTRAZENECA.

Bank Name: AstraZeneca AB Account No: [\*\*] Bank: [\*\*] Swift: [\*\*] Corr bank: [\*\*]

6.9.2. Unless otherwise instructed by TMC, all payments by ASTRAZENECA hereunder shall be made from Sweden by wire transfer in the requisite amount to the following account of TMC.

> Bank Name: Comerica Bank - California Account No: [\*\*] Bank Code: 121137522

6.10. INTEREST. If any sum payable pursuant to this Agreement shall not have been paid to a Party by the due date then (without prejudice to any other claim or remedy of such Party) the Party owing such sum shall pay interest thereon to the other Party at an annual rate of LIBOR + three percent (3%) from

time to time published in respect of the period starting on the due date of payment and ending on the actual date of payment.

"LIBOR" shall mean the thirty (30) days U.S. Dollar BBA London Interbank Offered Rate as published by Reuter.

- 7. INTELLECTUAL PROPERTY PROSECUTION AND MAINTENANCE
- 7.1. Any and all ASTRAZENECA IP vested in ASTRAZENECA and/or its Affiliates shall as between ASTRAZENECA and TMC remain vested in ASTRAZENECA and/or its Affiliates.
- 7.2. Any and all TMC IP vested in TMC shall as between TMC and ASTRAZENECA remain vested in TMC.
- 7.3. ASTRAZENECA or its agent shall, during the term of this Agreement be responsible for the filing, prosecution and maintenance of the ASTRAZENECA Patent Rights (including, without limitation, subject to Article 7.7, patent term extension rights).

TMC shall reimburse ASTRAZENECA or its agent for any out-of-pocket expenses (including fees to outside counsel and consultants) incurred by ASTRAZENECA or its agent in relation to any action taken by ASTRAZENECA or its agent pursuant to this Article 7.3.

7.4. TMC shall have the right to give comments and recommendations as to the overall strategy regarding the filing, prosecution and maintenance of the ASTRAZENECA Patent Rights; and before taking any significant step in the filing or prosecution of the ASTRAZENECA Patent Rights, ASTRAZENECA or its agent shall allow TMC to comment on the action proposed to be taken and ASTRAZENECA or its agent shall consider any such comments. For purposes of this Article 7.4 only, significant step means the filing of a dependent application (including but not limited to divisional

or continuation applications); filing for patent term extension; or any step taken during an appeal, re-examination, re-issue or opposition procedure, provided, however, that no such action now mentioned is a response to an office action. Notwithstanding the foregoing, ASTRAZENECA or its agent may, at its own discretion, ask for TMC's input in relation to such office action.

- 7.5. In the event that ASTRAZENECA should decide to permit any pending patent application or any patent included in the ASTRAZENECA Patent Rights to lapse by any action, inaction or failure to take any action or to pay any fee when due, ASTRAZENECA or its agent shall promptly inform TMC of such decision, but no later than thirty (30) days prior to the date by which such action, inaction or failure to pay will result in lapse of the patent application or the patent, provided that such period is available to ASTRAZENECA, so that TMC might, for the avoidance of doubt at TMC's expense, seek such patent protection or prevent any such lapse.
- 7.6. ASTRAZENECA shall not be liable to TMC in contract, tort, negligence, breach of statutory duty or otherwise for any economic loss or other loss of turnover, profits, savings, business or goodwill or any loss, damage, costs or expenses of any nature whatsoever incurred or suffered by TMC because of ASTRAZENECA's or its agent's actions pursuant to or as a consequence of Articles 7.3 and 7.4.
- 7.7. Should ASTRAZENECA not be able to lawfully apply for patent term extensions, including, but not limited to, Supplementary Protection Certificates, relating to the ASTRAZENECA Patent Rights in the Territory in its own name, or should ASTRAZENECA otherwise require, TMC shall co-operate with ASTRAZENECA or its agent in any issue regarding the gaining of such patent term extension by assisting ASTRAZENECA or its agent with any actions or documents needed for such purpose.

Should in any country in the Territory any decision have to be made as to what product, claim or otherwise to apply for such patent term extension regarding, then ASTRAZENECA or its agent shall have the right to make such decision at its own reasonable discretion and provided that ASTRAZENECA or its agent shall allow TMC to comment on the action proposed to be taken and ASTRAZENECA or its agent shall consider any such comments.

- 7.8. RIGHTS TO THE RESULTS. Any patents and other intellectual property rights, information, ideas, knowledge, data or know-how relating solely to the Compound and/or the Product and that;
  - (i) relate solely to an intravenous route of administration; and
  - (ii) do not have [\*\*]; and
  - (iii)do not relate to any formulation or product which contain(s) both the Compound and one or more [\*\*]as active ingredients, whether or not such formulation or product contain(s) active ingredients in addition to the Compound and the [\*\*]

developed during the term of this Agreement (hereinafter referred to as "Result(s)") shall as between TMC and ASTRAZENECA be TMC IP and the sole property of TMC. TMC shall have the sole management of, and shall bear the cost of, any Results. ASTRAZENECA shall be given the reasonable opportunity to comment on important aspects of the prosecution of any patent applications, and shall use its reasonable endeavours to assist TMC in the prosecution of any patent applications.

Any patents and other intellectual property rights, information, ideas, knowledge, data or know-how falling outside any or all of (i) through (iii) above in this Article 7.8 and relating to the Compound and/or the Product

shall, as between TMC and ASTRAZENECA, be the sole property of ASTRAZENECA.

- 8. CLAIMS REGARDING INFRINGEMENT AND INVALIDITY
- 8.1. NOTIFICATION OF CLAIM. If a Third Party notifies ASTRAZENECA or TMC, or their respective Affiliates or sub-licensees, that any act by TMC, or its Affiliates or sub-licensees, utilizing the ASTRAZENECA IP allegedly infringes in the Territory any Patent Rights or other intellectual property rights owned by or licensed to the Third Party, ASTRAZENECA or TMC shall promptly notify the other in writing.
- 8.2. DEFENCE OF CLAIMED INFRINGEMENT.
- 8.2.1. ASTRAZENECA shall have no obligation to defend or settle any claim by a Third Party that the manufacture, sale or other use of the Product by TMC resulting from the use or exercise of the license granted hereunder under the ASTRAZENECA IP infringes any Patent Rights or other intellectual property rights owned by or licensed to a Third Party, subject to the provisions of Article 10.
- 8.2.2. If a Third Party makes an infringement claim or files an infringement action against ASTRAZENECA, its Affiliates or sub-licensees, or TMC, its Affiliates or sub-licensees, arising out of TMC's, its Affiliates' or sub-licensees' manufacture, sale or other use of the Product in the Territory, or if a Third Party challenges any of the ASTRAZENECA IP, then TMC shall defend or settle the claim or action at its expense, subject to the provisions of Article 10.
- 8.2.3. ASTRAZENECA may join such proceedings mentioned under sub-section 8.2.2 voluntarily, subject always to TMC's, its Affiliates' or sub-licensees' right to decide the conduct over such litigation. Any such joining of the proceedings shall be at ASTRAZENECA's cost and expense.

ASTRAZENECA shall for such purpose have the right to independently retain legal counsel and consultants, at its sole cost and expense.

8.2.4.

It is understood between the Parties that any proposed settlement will be subject to ASTRAZENECA's prior written approval, which approval shall not be unreasonably withheld. Such approval might be withheld primarily on the grounds that ASTRAZENECA reasonably determines that the settlement proposed is overly burdensome, financially or strategically, to ASTRAZENECA or that ASTRAZENECA intends to continue such defence itself.

Should ASTRAZENECA withhold such approval, then ASTRAZENECA shall have the right, but not the obligation other than in the case that ASTRAZENECA has announced to TMC its intention to continue such defence itself, to continue the defence of the claim or action at its own expense. In such case TMC, its Affiliates or sub-licensees shall, at ASTRAZENECA's request and at ASTRAZENECA's expense for TMC's, its Affiliates' or sub-licensees' costs and expenses, assist in the prosecution of such action, including, but not limited to, consenting to being joined in such action as a voluntary defendant.

8.2.5.

Should TMC reasonably believe that the Third Party rights contemplated by Article 8.2.1 are valid in a certain country(ies) and that infringement is likely to be occurring in such country(ies), TMC may seek and enter into a licence thereto from such Third Party on appropriate commercial terms, whereby any remuneration and any costs and expenses (including but not limited to reasonable external legal costs) for such license shall be [\*\*] between TMC and ASTRAZENECA according to the following.

TMC may deduct an amount equivalent to [\*\*] percent ([\*\*]%) of TMC's payments to such Third Party pursuant to such arrangement as indicated in the first paragraph of this Article 8.2.5 from the royalty payments to be made by TMC to ASTRAZENECA on the Net Sales in the country

concerned pursuant to Article 6.2 to cover ASTRAZENECA's obligation to carry [\*\*] percent ([\*\*]%) of such payments and costs. This deduction shall be subject to the proviso that the royalty payments due to ASTRAZENECA shall not be reduced in total by more than [\*\*] percent ([\*\*]%) in any calendar year, and any residue not offset may be carried forward by TMC until such time as it has recovered ASTRAZENECA's [\*\*] per cent ([\*\*]%) share of such costs and expenses, or until the royalty payment obligations of TMC hereunder expire, whichever is the earlier.

- 8.3. THIRD PARTY INFRINGEMENT. If a Third Party shall, in the reasonable opinion of either Party, infringe any ASTRAZENECA Patent Rights in the Territory, then the Party having such opinion shall promptly notify the other Party.
- 8.3.1. Further, each Party shall within five (5) working days or as soon as reasonably possible thereafter advise the other Party of receipt of any notice of:
  - a) any certification filed under the U.S. "Drug Price Competition and Patent Term Restoration Act of 1984" ("ANDA Act"), claiming that any ASTRAZENECA Patent Rights are invalid or claiming that the ASTRAZENECA Patent Rights will not be infringed by the manufacture, use or sale of a product for which an application under the ANDA Act is filed or;
  - b) any equivalent or similar certification or notice in any other jurisdiction.
- 8.3.2. TMC, its Affiliates or sub-licensees shall have the initial sole right to commence an action for infringement in the Territory against the Third Party, in its own name, together with the right to enforce and collect any judgement thereon. ASTRAZENECA may join such proceedings voluntarily, subject always to TMC's, its Affiliates' or sub-licensees' right to decide the conduct of such litigation. Any such joining of the proceedings

shall be at ASTRAZENECA's cost and expense. ASTRAZENECA shall for such purpose have the right to independently retain legal counsel and consultants, at its sole cost and expense.

- 8.3.3. Any monetary recovery (whether by settlement or judgement) in connection with an infringement action commenced by TMC, its Affiliates or sub-licensees shall be applied first to reimburse TMC, its Affiliates or sub-licensees for their out-of-pocket expenses (including reasonable attorneys fees) incurred in prosecuting such action and the expenses of ASTRAZENECA borne by TMC hereunder. Any balance remaining shall be allocated among ASTRAZENECA and TMC in a manner reasonably calculated to correspond to the distribution of profits, in accordance with what would normally be provided for under this Agreement, on the sales of Product to which such recovery pertains.
- 8.3.4. Should neither TMC, nor its Affiliates or sub-licensees, take appropriate and diligent action with respect to any such infringement or challenge as contemplated in this Article 8.3 within forty-five (45) days, or, in the case of a certification filed under the ANDA Act or similar certification or notice as contemplated under Article 8.3.1, within twenty (20) days, after receiving notice of any infringement or possible infringement or challenge, then ASTRAZENECA shall have the right, but not the obligation, to take such action, at its own expense, in its own name, and the right to enforce and collect any judgement thereon.
  - a) Should ASTRAZENECA elect to take such action, then TMC, its Affiliates or sub-licensees, shall, at ASTRAZENECA's request and at ASTRAZENECA's expense for TMC's, its Affiliates' or sub-licensees', costs and expenses, assist in the prosecution of such action, including, but not limited to, consenting to being joined in such action as a voluntary plaintiff.

- b) If the recovery of such action as contemplated in this Article 8.3.4 exceeds ASTRAZENECA's out-of-pocket expenses (including reasonable attorneys fees) for prosecuting the action, then such excess recovery shall be shared by the Parties on a [\*\*].
- 8.3.5. ASTRAZENECA, its Affiliates or sub-licensees shall have the sole right to commence an action for infringement of the ASTRAZENECA IP in the Excluded Countries or in any other country in which the license granted to TMC hereunder has reverted to ASTRAZENECA pursuant to Article 3.8 against the Third Party, in its own name, together with the right to enforce and collect any judgement thereon. TMC may join such proceedings voluntarily, subject always to ASTRAZENECA's, its Affiliates' or sub-licensees' right to decide the conduct of such litigation. Any such joining of the proceedings shall be at TMC's cost and expense. TMC shall for such purpose have the right to independently retain legal counsel and consultants, at its sole cost and expense. Any monetary recovery (whether by settlement or judgement) in connection with an infringement action commenced by ASTRAZENECA under this Article 8.3.5 shall be retained by ASTRAZENECA.

#### 9. TRADEMARK

- 9.1. TMC shall select a trademark to use in connection with the sales, marketing and distribution of the Product and shall be the owner and party of record of such trademark (the "TMC Trademark"). TMC shall have sole responsibility for clearance and registration of said TMC Trademark. TMC shall be responsible for all decisions and costs relating to selection, clearance, registration, defence and maintenance of the TMC Trademark.
- 9.2. TMC undertakes, should ASTRAZENECA so require in writing, to mention on all packages, package inserts and promotional and advertising materials for the Product "Licensed from AstraZeneca AB" or the equivalent wording in the major language(s) of the country in which the Product is sold, or,

should legal, regulatory or similar reasons prevent the use of that wording, such other wording as close as possible to the wording herein stated.

- 10. INDEMNITY
- 10.1. INDEMNITY BY TMC.
- 10.1.1. TMC shall be responsible for and shall indemnify ASTRAZENECA, its Affiliates and its and its Affiliates' directors, officers, other employees, agents and consultants (collectively the "ASTRAZENECA Indemnified Party") against any and all liability, loss, damage, cost and expense (including legal costs) incurred or suffered by the ASTRAZENECA Indemnified Party as a result of any claim brought against an ASTRAZENECA Indemnified Party by a Third Party (i) arising out of the testing, manufacture, sale, use or promotion by TMC, its Affiliates or sub-licensees of any Compound or Product hereunder; (ii) arising out of any theory of product liability (including, but not limited to, actions in the form of tort, warranty or strict liability) based on Compounds or Products developed by TMC hereunder; or (iii) arising out of any other activities to be carried out by TMC, its Affiliates or sub-licensees pursuant to this Agreement to the extent not included in (i) and (ii) above, except where such liability, loss, damage, cost and expense has been incurred or suffered as a result of a material breach of ASTRAZENECA's representations, warranties or obligations under this Agreement or by gross negligence or misconduct on the part of ASTRAZENECA.
- 10.1.2. An ASTRAZENECA Indemnified Party that intends to claim indemnification under Article 10.1.1 shall notify TMC promptly of any such liability, loss, damage, cost or expense and permit TMC to control the defence and disposition thereof and further agrees to reasonably cooperate at TMC's expense with TMC in the handling thereof. The ASTRAZENECA Indemnified Party shall not compromise or settle such claim. TMC agrees to keep ASTRAZENECA informed of the progress in the defence and

disputation of such claims and to consult with ASTRAZENECA with regard to any settlement thereof which TMC proposes to enter into and will provide ASTRAZENECA with suitable information regarding the same.

10.1.3. TMC will maintain appropriate liability insurance against such product and other liability as contemplated under Article 10.1.1 at levels appropriate for products and activities of the relevant type.

#### 10.2. INDEMNITY BY ASTRAZENECA.

- 10.2.1. ASTRAZENECA shall be responsible for and shall indemnify TMC, its Affiliates and its and its Affiliates' directors, officers, other employees, agents and consultants (collectively the "TMC Indemnified Party") against any and all liability, loss, damage, cost and expense (including legal costs) incurred or suffered by the TMC Indemnified Party as a result of any claim brought against the TMC Indemnified Party by a Third Party (i) arising out of the testing, manufacture, sale, use or promotion by ASTRAZENECA, its Affiliates or sub-licensees, of any Compound or Product hereunder; (ii) arising out of any theory of product liability (including, but not limited to, actions in the form of tort, warranty or strict liability) based on Compounds or Products sold by ASTRAZENECA hereunder; or (iii) which arises as a result of a material breach of ASTRAZENECA's representations, warranties or obligations under this Agreement, except where such liability, loss, damage, cost and expense has been incurred or suffered as a result of a material breach of TMC's representations, warranties or obligations under this Agreement or by gross negligence or misconduct on the part of TMC.
- 10.2.2. A TMC Indemnified Party that intends to claim indemnification under Article 10.2.1 shall notify ASTRAZENECA promptly of any such liability, loss, damage, cost and expense and permit ASTRAZENECA to control the defence and disposition thereof and further agrees to reasonably cooperate at ASTRAZENECA's expense with ASTRAZENECA in the handling thereof. The TMC Indemnified Party shall not compromise or settle such

claim. ASTRAZENECA agrees to keep TMC informed of the progress in the defence and disputation of such claims and to consult with TMC with regard to any settlement thereof which ASTRAZENECA proposes to enter into and will provide TMC with suitable information regarding the same.

10.2.3. ASTRAZENECA will either maintain appropriate liability insurance or be self insured against such liability as contemplated under Article 10.2.1.

#### 11. CONFIDENTIALITY

- 11.1. CONFIDENTIAL INFORMATION. At all times during the term of this Agreement and for a period of five (5) years following termination or expiration hereof, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose and not use, directly or indirectly, for any purpose, any Confidential Information provided to it by the other Party, PROVIDED, THAT, each Party may disclose and use the Confidential Information of the other Party to the extent such disclosure or use is expressly permitted by the terms of this Agreement, including without limitation those purposes set forth in Article 11.2, or is otherwise reasonably necessary for the performance of this Agreement.
- 11.2. PERMITTED USE AND DISCLOSURE. The Receiving Party may use and/or disclose Confidential Information to the extent that such disclosure is:
- 11.2.1. made in response to a valid order of a court of competent jurisdiction or other competent authority provided however that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or authority or, if disclosed, be used only for the purpose for which the order was issued; and provided further that if a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to

that information which is legally required to be disclosed in response to such court or governmental order;

- 11.2.2. made by the Receiving Party to a regulatory authority as required in connection with any Filing of an NDA; provided, however, that reasonable measures will be taken to assure confidential treatment of such information;
- 11.2.3. made by the Receiving Party to a patent authority as required in connection with any filing or application for Patent Rights; or
- 11.2.4. made by the Receiving Party to Third Parties as may be necessary or useful in connection with the development, manufacturing, marketing, use and sale of the Compound, Drug Product or the Product as contemplated by this Agreement, including subcontracting, sublicensing and distribution transactions in connection therewith, provided that any such Third Party has undertaken confidentiality and non-use obligations in all material respects equal to those undertaken by the Receiving Party hereunder with respect to the Confidential Information disclosed by the Receiving Party to it and the results of any such activities.
- 11.3. RELEASE FROM RESTRICTIONS. Notwithstanding the foregoing, Confidential Information shall not include any information that, as determined by competent written proof:
- 11.3.1. is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the Receiving Party;
- 11.3.2. can be demonstrated by documentation or other competent proof to have been in the Receiving Party's possession prior to disclosure by the Disclosing Party;

- 11.3.3. is subsequently received by the Receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to the said information;
- 11.3.4. is generally made available to Third Parties by the Disclosing Party without restriction on disclosure; or
- 11.3.5. is independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information.
- 12. ADVERSE EVENTS
- 12.1. REPORTING OF ADVERSE EVENTS.
- 12.1.1. TMC shall be fully responsible for reporting to the relevant regulatory or other competent authorities in the Territory any Adverse Event(s) which are or might be attributed to the use or application of the Compound or the Product. At ASTRAZENECA's request in writing TMC shall inform ASTRAZENECA of any such Adverse Event in the country(ies) contemplated, and during the time period contemplated, by such notice.
- 12.1.2. ASTRAZENECA shall be fully responsible for reporting to the relevant regulatory or other competent authorities in any country outside the Territory or for which the license to TMC hereunder has been terminated any Adverse Event(s) which are or might be attributed to the use or application of the Compound or the Product. At TMC's request in writing ASTRAZENECA shall inform TMC of any Adverse Event in the country(ies) contemplated, and during the time period contemplated, by such notice. For the avoidance of doubt ASTRAZENECA may appoint any Affiliate(s) or sub-licensee(s) carrying out the marketing of the Product in the country concerned to fulfil any such obligation as stated hereunder.

- 12.2. Without limiting what is stated in Article 12.1, the Parties shall at an appropriate point of time during development of the Product jointly establish any such Adverse Event reporting procedures, including, but not limited to, any agreement regarding safety data exchange, as may be required or useful.
- 13. REPRESENTATIONS, WARRANTIES AND COVENANTS
- 13.1. REPRESENTATIONS, WARRANTIES AND COVENANTS OF ASTRAZENECA. ASTRAZENECA represents and warrants to, and covenants with, TMC as follows:
  - as of the Effective Date ASTRAZENECA and/or its Affiliates is the sole and exclusive owner of the ASTRAZENECA Patent Rights; which to the extent covered by the license granted hereunder is free and clear of any liens, charges and encumbrances; and
  - b) as of the Effective Date ASTRAZENECA and/or its Affiliates has not assigned, transferred, licensed, conveyed or otherwise encumbered its right, title and interest in the ASTRAZENECA Patent Rights to the extent covered by the license granted hereunder, to a Third Party; and
  - c) as of the Effective Date ASTRAZENECA has the authority from its Affiliates to grant to TMC the license specified in Article 2.1 of this Agreement; and
  - as of the Effective Date and to the best of ASTRAZENECA's knowledge, no Person other than ASTRAZENECA or any of its Affiliates, has or shall have any claim of ownership with respect to ASTRAZENECA Patent Rights; and
  - e) as of the Effective Date and to the best of ASTRAZENECA's knowledge, the manufacture, use and sale of the Compound does not

infringe upon any intellectual property rights of any Third Party, although it is expressly acknowledged by TMC that ASTRAZENECA has made no particular searches or investigations to determinate whether such infringement occurs; and

- f) as of the Effective Date there are no claims, judgements or settlements against or owed by ASTRAZENECA or pending or threatened claims or litigation relating to the ASTRAZENECA Patent Rights; and
- g) except as insofar relating to any kind of formulation, or work or development related thereto, of the Product, there are no other Patent Rights or Know-How owned or licensed by ASTRAZENECA required to develop and/or commercialise the Product, and ASTRAZENECA shall not assert against TMC any Patent Rights or other intellectual property owned or licensed by ASTRAZENECA as of the Effective Date or at any time thereafter which are or may be infringed by TMC when utilizing its rights under this Agreement; and
- h) as of the Effective Date ASTRAZENECA has disclosed to TMC any known interference with the ASTRAZENECA Patent Rights or re-examination or reissue proceeding concerning such ASTRAZENECA Patent Rights; and
- as of the Effective Date ASTRAZENECA has no knowledge from which it can reasonably be inferred that the granted ASTRAZENECA Patent Rights are invalid or unenforceable or that the applications for ASTRAZENECA Patent Rights will not proceed to grant; and
- j) the agreements in force on the Effective Date between ASTRAZENECA or its Affiliates and Third Parties regarding investigational use of the Compound in laboratory research animals or for testing in vitro will, if possible to ASTRAZENECA, be assigned to TMC by ASTRAZENECA. Regarding those agreements that are not possible for ASTRAZENECA to assign to TMC, ASTRAZENECA

shall keep TMC informed about the results and publications generated by the Third Part(ies) under the agreements concerned. None of the Third Parties to the agreements referred to in this Article 13.1 j) has any license or ownership rights under such agreement(s) in the results of their investigations, or in the Compound, the Product or the ASTRAZENECA IP that will have any material impact on the license granted to TMC under this Agreement.

13.2. ACKNOWLEDGEMENT OF TMC.

TMC is aware;

- a) that the ASTRAZENECA Patent Rights or the ASTRAZENECA Know-How may not sufficiently enable TMC to manufacture or conduct any other operational or manufacturing-related activities with respect to the formulation of the Product, and it is explicitly understood by TMC that TMC will have to independently conduct any analysis, evaluation and investigation regarding what intellectual property, techniques, routes, equipment or other help or assistance that will be required for such purpose and it will be entirely at TMC's risk to find such intellectual property, techniques, routes, equipment or other help or assistance in order to conduct such activities; and
- b) that certain Third Parties have access to the Compound under the agreements referred to in Article 13.1 j) in order to conduct investigations regarding the Compound.
- 13.3. REPRESENTATIONS AND WARRANTIES OF THE PARTIES. Each Party represents and warrants to the other Party that it is a duly organized and validly existing corporation under the laws of its jurisdiction of incorporation, and has taken all required corporate action to authorize the execution, delivery and performance of this Agreement; it has the full right, power and authority to enter into this Agreement and perform all of its obligations hereunder; the execution and delivery of this Agreement and the transactions contemplated

herein do not violate, conflict with, or constitute a default under its Articles of Association or similar organization document, its by-laws or the terms or provisions of any material agreement or other instrument to which it is a party or by which it is bound, or any order, award, judgement or decree to which it is a party or by which it is bound; and upon execution and delivery, this Agreement will constitute the legal, valid and binding obligation of it.

13.4. LIMITATIONS. EXCEPT AS OTHERWISE SET FORTH IN THIS AGREEMENT ASTRAZENECA EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR EXPRESS WARRANTIES AND MAKES NO EXPRESS OR IMPLIED WARRANTY, STATUTORY OR OTHERWISE, OF ANY KIND, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE REGARDING THE COMPOUND, ASTRAZENECA'S CONFIDENTIAL INFORMATION, DOCUMENTS, ASTRAZENECA KNOW-HOW, ASTRAZENECA PATENT RIGHTS OR PRODUCTS.

#### 14. TERM AND TERMINATION

- 14.1. TERM. This Agreement shall become effective on the Effective Date and shall expire when TMC ceases to sell the Product in the last country of the Territory or otherwise terminates this Agreement as set forth in Article 14.2.
- 14.2. TERMINATION BY TMC. Should TMC determine that it does no longer consider it viable to continue to exercise the rights under this Agreement, then TMC may give written notice to ASTRAZENECA, whereupon this Agreement shall terminate thirty (30) days after such notice, unless ASTRAZENECA, within twenty (20) days of having received such notice, requests TMC in writing to enter into good faith discussions to see whether TMC's concerns could be reasonably overcome. However, upon TMC having given such notice TMC shall not be liable for any payments under Articles 6.1.2 and 6.1.3 or for any payments under Article 6.3

corresponding to the royalty amounts actually due, which become due after the expiration of the 30-day period mentioned above in this Article 14.2.

Should the Parties not within three (3) months of the date of commencement of such good faith discussions mentioned above in this Article 14.2 have managed to reach a mutually acceptable solution to TMC's concerns, then TMC may terminate this Agreement by giving ninety (90) days written notice.

- 14.3. TERMINATION FOR BREACH. In the event that either Party (the "Breaching Party") shall be in significant default in the performance of any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the "Complaining Party") may have, the Complaining Party may terminate this Agreement by sixty (60) days prior written notice (the "Notice Period") to the Breaching Party, specifying the breach and its claim of right to terminate, provided always that the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach complained about during the Notice Period.
- 14.4. SURVIVAL OF OBLIGATIONS. Termination or expiration of this Agreement shall not relieve either Party from any obligation incurred hereunder prior thereto.
- 14.5. SURVIVAL OF PROVISIONS UPON TERMINATION AND/OR EXPIRATION. Subject to what is stated in Article 15, the provisions of Articles 1, 7.1, 7.2, 10, 12, 13, 14.5, 15, 17 and 18 shall survive termination or expiration of this Agreement. The provisions of Article 2.5 shall survive only upon expiration of this Agreement. The provisions of Article 11 shall survive termination or expiration of this Agreement and shall continue to be in force for a period of five (5) years after termination or expiration of this Agreement.

#### 15. CONSEQUENCES OF TERMINATION

### 15.1. TERMINATION AND HANDBACK OF LICENSE

In addition to any remedy either Party may have in law, tort or in contract, subject to what is stated in Article 3.9, upon termination of the Agreement or the license in a certain country, the following shall apply.

Upon termination of this Agreement by TMC pursuant to Article 14.2 or by ASTRAZENECA pursuant to Article 14.3, or by ASTRAZENECA in a certain country pursuant to Article 3.8, the license granted under Article 2.1 regarding the country(ies) contemplated by the termination concerned shall cease, and TMC shall, regarding the Territory or the country concerned, whichever is applicable:

- a) at the option of ASTRAZENECA, grant to ASTRAZENECA a non-exclusive, world-wide or for the country concerned, whichever is applicable, sub-licensable licence under the TMC IP to develop, have developed, make, have made, use, have used, import, have imported, market, have marketed, sell and have sold the Compound and the Product for any indications. The term of such non-exclusive licence shall continue on a country by country basis for the longer of the life of the TMC Patent Rights, or for ten (10) years from first commercial sale of any resultant product in such country by ASTRAZENECA, its Affiliates, sub-licensees or nominees, whichever is the longer. TMC shall do all such acts and things as may reasonably be necessary to fulfil this obligation. The licence set out in this Article 15.1 (a) shall be [\*\*].
- b) return to ASTRAZENECA any ASTRAZENECA Know-How and deliver to ASTRAZENECA a copy of any TMC Know-How;
- c) deliver to ASTRAZENECA any and all quantities of Product in its possession, power, custody or control subject always to TMC's right to

dispose of Product which is the subject of pre-termination date orders pursuant to Article 15.1 (h). For the avoidance of doubt, should this Article 15.1 (c) become applicable because of termination regarding a certain country or countries pursuant to Article 3.8, then the quantities of Product referred to herein shall mean only those quantities clearly designated, by marking, labelling or similar, for the country or countries concerned and which could only be used for the country or countries concerned;

- d) ensure that its patent attorneys transfer to ASTRAZENECA a copy of the patent files relating to the TMC Patent Rights which TMC has been prosecuting and maintaining and ASTRAZENECA shall be entitled to prosecute and shall maintain such TMC Patent Rights at its own cost and expense on terms similar to those set out in Article 7.3 and to deal with infringers on terms similar to those set out in Articles 8.2 and 8.3. TMC further undertakes to take any action and produce any documents so as to enable ASTRAZENECA to apply for patent term extensions, including, but not limited to, Supplementary Protection Certificates, relating to the TMC Patent Rights in ASTRAZENECA's name.
- e) Should this Article 15.1 become applicable because of the termination of the license regarding a certain country or countries pursuant to Article 3.8, then TMC shall, notwithstanding the license granted under Article 15.1 (a), on the request by ASTRAZENECA continue to prosecute, maintain and defend the TMC Patent Rights.
- f) commensurate with legislative and regulatory requirements, transfer to ASTRAZENECA or its nominee all NDA Approvals, and regulatory filings for the Compound or Product (including, without limitation, all information and documentation used in the Filings of an NDA and NDA approvals referred to in Article 3.5.2 and 3.5.4) for the Territory or the country concerned, to the extent applicable. In the event that in

any country such a transfer is not possible, TMC shall use reasonable endeavours to ensure that ASTRAZENECA has the benefit of the relevant NDA Approvals, NDA's and other related regulatory filings and approvals and, to this end, consents to any regulatory authority cross-referencing to the data and information on file with any regulatory authority as may be necessary to facilitate the granting of second NDA Approvals to and permit Filings of an NDA by ASTRAZENECA, and TMC agrees to complete whatever other procedures that are reasonably necessary in relation to the same to enable ASTRAZENECA (either itself or in conjunction with a Third Party) freely to develop and sell the Product in substitution for TMC;

- g) if applicable, assign the TMC Trademark or grant a royalty-free exclusive licence to ASTRAZENECA to use the TMC Trademark for the marketing, sales and distribution of the Product;
- h) not after the date of termination itself take any further action for the Territory or the country concerned, to the extent applicable, to develop, manufacture, have manufactured, use, market, distribute or sell the Compound or Product during the life of the TMC Patent Rights or the ASTRAZENECA Patent Rights, whichever is the longer, except that TMC has the right to dispose of that part of its inventory of Product on hand as of the effective date of termination which is the subject of orders for Product accepted prior to the date of notice of termination for a period of three (3) months after the effective date of termination, and, within thirty (30) days after disposition of such inventory pursuant to the fulfilment of such orders, TMC will forward to ASTRAZENECA a final report and pay all royalties due on the Net Sales of Product during such period; and

i) provide ASTRAZENECA, should ASTRAZENECA so require, with reasonable assistance in relation to ASTRAZENECA's appointment of a Third Party manufacturer of Product.

Upon such termination as stated in this Article 15.1, ASTRAZENECA shall have the right to disclose Confidential Information to Third Parties for the purpose of, and to the extent necessary for, enabling such Third Party to evaluate the financial and scientific status of the Compound or Product for the purpose of making a financial offer to ASTRAZENECA on the licensing or acquisition of the rights returned to ASTRAZENECA and the rights licensed to ASTRAZENECA under this Article 15.1, and, if such licensing or acquisition occurs, as necessary to exploit or enforce such rights.

15.2. TERMINATION FOLLOWED BY CONTINUED LICENSE

Upon the termination of this Agreement by TMC pursuant to Article 14.3, ASTRAZENECA's licences granted to TMC under Article 2 shall continue, provided that TMC continues to make payments pursuant to Article 6 as if the Agreement was still in effect.

- 16. FORCE MAJEURE
- 16.1. If either Party is prevented or delayed in the performance of any of its obligations under this Agreement by Force Majeure, that Party shall forthwith serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to Force Majeure, and shall subject to service of such notice and to Article 16.3 have no liability in respect of the performance of such of its obligations as are prevented by the Force Majeure event during the continuation of such events, and for such time after they cease as is necessary for that Party, using all reasonable endeavours, to recommence its affected operations in order for it to perform its obligations.
- 16.2. If either Party is prevented from performance of its obligations, due to Force Majeure, for a continuous period in excess of six (6) months, the other Party

may terminate this Agreement forthwith on service of written notice upon the Party so prevented. In the event of termination under this Article 16.2 the provisions of Article 15 shall not apply immediately and the Parties shall meet to discuss the ASTRAZENECA IP and TMC IP and agree on a process for arrangements upon termination.

- 16.3. The Party claiming to be prevented or delayed in the performance of any of its obligations under this Agreement by reason of Force Majeure shall use its reasonable endeavours to bring the Force Majeure event to a close or to find a solution by which the Agreement may be performed despite the continuation of the Force Majeure event.
- 17. GENERAL PROVISIONS
- 17.1. ASSIGNMENT.
- 17.1.1. Subject to Articles 17.1.2 and 17.1.3, neither Party shall without the prior written consent of the other Party assign, transfer, charge or deal in any other manner with this Agreement or any of its rights under it.
- 17.1.2. Each Party shall be entitled to assign its rights under this Agreement to an acquiror of all or substantially all of its capital stock or assets related to the pharmaceutical business described in this Agreement, whether through purchase, merger, consolidation or otherwise.
- 17.1.3. Each Party shall be entitled to assign its rights under this Agreement to an Affiliate provided that such Party shall require that any such Affiliate to whom it assigns any of its rights under this Agreement shall assign such rights back to the assigning Party immediately prior to it ceasing to be an Affiliate of the assigning Party.

#### 17.2. SEVERANCE.

- 17.2.1. If any provision of this Agreement shall be found by any court or administrative body of competent jurisdiction to be invalid or unenforceable, such invalidity or unenforceability shall not, provided that the general content of the Agreement remains substantially the same as prior to such invalidity or unenforceability, affect the other provisions of this Agreement which shall remain in full force and effect.
- 17.2.2. The Parties agree, in the circumstances referred to in Article 17.2.1, to attempt to substitute for any invalid or unenforceable provision a valid or enforceable provision which achieves to the greatest extent possible the same effect as would have been achieved by the invalid or unenforceable provision.
- 17.3. NOTICES.
- 17.3.1. All notices and other communications given or made in relation to this Agreement;
- 17.3.2. shall be in English and in writing;
- 17.3.3. shall be delivered by hand or sent by first class registered post or facsimile;
- 17.3.4. shall be delivered or sent to the Party concerned at the relevant address or facsimile number, shown in Article 17.4.1 subject to such amendments as may be notified from time to time in accordance with this Article by the relevant Party to the other Party by no less than three business days notice; and
- 17.3.5. shall be deemed to have been duly given or made if addressed in the aforesaid manner;
  - a) if delivered by hand, upon delivery;

- b) if posted by first class registered post, four (4) business days after posting;
- c) if sent by facsimile, when a complete and legible copy of the communication has been received at the appropriate address.

17.4. CONTACT INFORMATION.

- 17.4.1. Initial details for the purposes of Article 17.3 are: For ASTRAZENECA F Address: AstraZeneca AB, SE-151 85 Sodertalje, Sweden Facsimile: +46-8 553 290 00 For the attention of: President & CEO For TMC Address: The Medicines Company, 8 Campus Drive, Parsippany, New Jersey 07054, United States Facsimile: +1-973-656-9898 For the attention of: Clive Meanwell, Executive Chairman
- 17.4.2. Any notice pursuant to Article 3.5.4 shall, in addition to being delivered in accordance with Articles 17.3 and 17.4.1, be delivered to the following address by facsimile.

AstraZeneca AB, Global Intellectual Property, Sweden. Facsimile: +46 8 553 288 20 For the attention of: Francis Tierney

What is stated in Articles 17.3.1, 17.3.2, 17.3.4 and 17.3.5 c) shall apply to such notice as well.

- 17.5. AGENCY, PARTNERSHIP OR JOINT VENTURE EXCLUDED.
- 17.5.1. Nothing in this Agreement shall be construed so as to constitute either Party to be the agent of the other.
- 17.5.2. Nothing in this Agreement and no action taken by the Parties pursuant to this Agreement shall constitute a partnership or joint venture of any kind between the Parties.
- 17.6. ENTIRE AGREEMENT. Each of the Parties acknowledges and agrees that in entering into this Agreement, and the documents referred to in it, it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any Person (whether party to this Agreement or not) other than as expressly set out in this Agreement as a warranty. Nothing in this Article shall either operate to limit or exclude any liability for fraud.
- 17.7. AGREEMENT TO SUPERSEDE EARLIER AGREEMENTS. The Confidential Disclosure Agreement entered into by and between the Parties on 27 February 2003 ceases to have effect from the Effective Date, except such termination does not affect a Party's accrued rights and obligations thereunder at the date of termination.
- 17.8. AMENDMENTS. No amendment to or variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of each of the Parties.
- 17.9. PUBLICITY AND ANNOUNCEMENTS.
- 17.9.1. Subject to Article 17.9.2 no press release, announcement or any other communication to any Third Party concerning the transaction contemplated by this Agreement, the financial terms of this Agreement, the subject matter of this Agreement or any ancillary matters shall be made or permitted or authorized to be made by either Party without the prior written approval of the other, such approval not to be unreasonably withheld or delayed and

such approval to be given by an authorized representative of the Party in question.

- 17.9.2. Either Party may make an announcement concerning the transaction contemplated by this Agreement or any ancillary matter if required by law, existing contractual obligations or any securities exchange or regulatory authority or governmental body to which either Party is subject or submits, wherever situated, provided that the Party required to make such announcement notifies the other Party of the details of the announcement prior to making such announcement and in sufficient time for the other Party to consider and comment on the announcement, and takes advantage of all provisions to keep confidential as many terms of the Agreement as possible.
- 17.10. WAIVER. Failure or delay by either Party to exercise any right or remedy under this Agreement shall not be deemed to be a waiver of that right or remedy, or prevent it from exercising that or any other right or remedy on that occasion or on any other occasion.
- 17.11. NO BENEFIT TO THIRD PARTIES. No Third Party shall be deemed a third party beneficiary under this Agreement for any purpose. Without limiting the foregoing, the Contracts (Rights of Third Parties) Act 1999 and any legislation amending or replacing such Act shall not apply in relation to this Agreement or any agreement, arrangement, understanding, liability or obligation arising under or in connection with this Agreement.

18. GOVERNING LAW AND ARBITRATION

18.1. ARBITRATION. The Parties shall use their reasonable efforts to settle amicably any dispute arising out of or in connection with this Agreement. In case the Parties are not able to settle such dispute between themselves, such dispute shall be finally resolved by arbitration in accordance with the Rules of the

International Chamber of Commerce. The arbitration proceedings shall be held in London. Any proceedings shall be held in the English language.

18.2. GOVERNING LAW. The validity, construction and interpretation of this Agreement and any determination of the performance which it requires shall be governed by the laws of England.

IN WITNESS WHEREOF this Agreement has entered into force on the Effective Date.

ASTRAZENECA AB (PUBL)

THE MEDICINES COMPANY

Signature:/s/Martin Nicklasson	Signature: /s/ Clive A. Meanwell		
Name: Martin Nicklasson	Name: Clive A. Meanwell		
Title: EVP, Global Drug Development	Title: Executive Chairman		

## Schedule A

# ASTRAZENECA Patent Rights

CASE	COUNTRY	APPLICATION NO.		PATENT NO.	EXPIRY DATE
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
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AT	Austria
AU	Australia
BD	Bangladesh
BE	Belgium
BR	Brazil
ВҮ	Belarus
CA	Canada
CH	Switzerland
CO	Colombia
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EG	Egypt
EP	European Patent Office
ES	Spain
FI	Finland
FR	France
GB	United Kingdom
GR	Greece
HU	Hungary
ID	Indonesia

IE	Ireland
IL	Israel
IN	India
IS	Iceland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MC	Monaco
MK	Macedonia
MX	Mexico
MY	Malaysia
NL	Netherlands
NO	Norway
NZ	New Zealand
PH	Philippines
PK	Pakistan
PL	Poland
PT	Portugal
RO	Romania
RU	Russia
SA	Saudi Arabia
SE	Sweden
SG	Singapore
SI	Slovenia
SK	Slovak Republic
TR	Turkey
UA	Ukraine
US	USA
VE	Venezuela

### Schedule B

## [\*\*]

PRODUCT MASTER FILE

Product Monograph

This section represents the current status of the project

CONTENTS:

Clinical Supplies Strategies / Vial Strengths

Health and Safety - Assessment of health risks involved during manufacture

## Composition

- Description and intended use of product
- Presentations and product numbers
- Qualitative formulation
- Quantitative formulation and formulation numbers

#### Manufacture

- Manufacturer(s)
- Manufacturing formula
- Manufacturing process and filling
- Equipment and manufacturing facilities

License Agreement - The Medicines Company

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- Process flow diagram
- Standard process instructions
- In-process controls
- Control of intermediates
- Justification of specification for intermediates
- Test methods for intermediates

### Control Tests on Inactive Ingredients

- Name and address of supplier
- Specifications and test methods for inactive ingredients
- Justification of specification for inactive ingredients
- Test methods for inactive ingredients

### Control Tests on Drug Substance

- Name and address of suppliers and corresponding batch details
- Statement of current route of synthesis
- Drug substance specification
- Product specific parameters

## Control Tests on Product

- Product specification
- Product release specification
- Justification for product specification
- Test methods for product
- Sampling plan

Packaging (Container / Closure / Device)

- Description of packaging material and PCKs
- Manufacturers of packaging materials
- Specifications of packaging materials
- Justification of specifications of packaging materials

- Test methods for packaging materials

## Stability of Drug Substance

- Shelf-life recommendations

## Stability of Product

- Shelf-life recommendation
- Compatibility
- Test methodology used for stability of product
- Stability reports

Special Notes

Product Development Master Record

This section contains archived / superseded information (eg previous versions of specifications) and is therefore the development history.

# CONTENTS:

Health and Safety - Assessment of health risks involved during manufacture

### Composition

- Description and intended use of product
- Presentations and product numbers
- Qualitative formulation
- Quantitative formulation and formulation numbers

### Manufacture

- Manufacturer(s)
- Manufacturing formula
- Standard process instructions

Control Tests on Inactive Ingredients

- Name and address of supplier
- Specifications and test methods for inactive ingredients
- Justification of specification for inactive ingredients
- Test methods for inactive ingredients

Control Tests on Drug Substance

- Drug substance specification

Control Tests on Product

- Product specification
- Product release specification
- Justification for product specification
- Test methods for product
- Sampling plan

Packaging (Container / Closure / Device)

- Description of packaging material and PCKs
- Manufacturers of packaging materials
- Specifications of packaging materials
- Justification of specifications of packaging materials
- Test methods for packaging materials

Stability of Drug Substance

- Shelf-life recommendations

Stability of Product

- Shelf-life recommendation
- Test methodology used for stability of product
- Stability reports

### Special Notes

Summary Reports

- [\*\*]

- [\*\*]

## Placebo Monograph

Composition

- Presentations and product numbers
- Qualitative formulation
- Quantitative formulation and formulation numbers

### Manufacture

- Manufacturer(s)
- Manufacturing formula
- Manufacturing process and filling
- Equipment and manufacturing facilities
- Process flow diagram
- Standard process instructions
- In-process controls
- Control of intermediates
- Justification of specification for intermediates
- Test methods for intermediates

Control Tests on Inactive Ingredients

- Name and address of supplier
- Specifications and test methods for inactive ingredients
- Justification of specification for inactive ingredients

- Test methods for inactive ingredients

#### Control Tests on Drug Substance

- Not applicable
- Name and address of suppliers and corresponding batch details
- Statement of current route of synthesis
- Drug substance specification
- Product specific parameters

## Control Tests on Product

- Product specification
- Product release specification
- Justification for product specification
- Test methods for product
- Sampling plan

## Packaging (Container / Closure / Device)

- Description of packaging material and PCKs
- Manufacturers of packaging materials
- Specifications of packaging materials
- Justification of specifications of packaging materials
- Test methods for packaging materials

## Stability of Drug Substance - Not applicable

- Shelf-life recommendations

## Stability of Product

- Shelf-life recommendation
- Compatibility
- Test methodology used for stability of product
- Stability reports

Placebo Development Master Record

Contains archived / superseded information

PMF Appendices

Essentially this is the "working area" of the PMF containing:

- Stability Protocols for Drug Substance
- Stability Reports (front cover only
- this references report number with all reports filed in archive)
- Stability Protocols for Drug Product and Placebo Product
- Stability Reports (main reports in full, others front cover only
- this references report number with all reports filed in archive)
- Protocols and Development Reports (all Investigational Protocols and Development Reports referenced)
- Compatibility with Infusion Fluids and Giving Sets (all Reports / Studies referenced)
- Product Design Report (all Reports referenced)
- Regulatory Documents (CMC submissions referenced)
- Cleaning Verification (Reports referenced)
- Manufacturing Protocols (for clinical trial supplies manufacture at Sodertalje (Astra Liquid Production Facility)
- Primary and Secondary Reference Standards

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CHEMICAL STRUCTURE [\*\*]

# [Diagram of proprietary compound deleted]

License Agreement - The Medicines Company

## Schedule D

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License Agreement - The Medicines Company

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Schedule E

[Diagram of proprietary compound deleted]

License Agreement - The Medicines Company

### Schedule F

Supply Agreement [To be provided upon completion -- See Section 4.2.3]

License Agreement - The Medicines Company

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## EXHIBIT 21

The following is a list of the subsidiaries of The Medicines Company, all of which are wholly owned:

 NAME OF SUBSIDIARY
 JURISDICTION OF INCORPORATION OR ORGANIZATION

 ----- ----- 

 The Medicines Company Limited
 New Zealand

 The Medicines Company UK Limited
 England and Wales

# Consent of Independent Auditors

We consent to the incorporation by reference in the Registration Statements (Forms S-8 No. 333-44884, 333-74612 and 333-98191) pertaining to the 1998 Stock Incentive Plan, the 2000 Outside Director Stock Option Plan, the 2000 Employee Stock Purchase Plan and the 2001 Non-Officer, Non-Director Employee Stock Incentive Plan of The Medicines Company of our report dated February 10, 2004, with respect to the consolidated financial statements and schedule of The Medicines Company included in the Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

MetroPark, New Jersey March 5, 2004

### CERTIFICATIONS

- I, Clive A. Meanwell, certify that:
- I have reviewed this Annual Report on Form 10-K of The Medicines Company;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC release 34-47986]
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Clive A. Meanwell Clive A. Meanwell Executive Chairman

Dated: March 5, 2004

### CERTIFICATIONS

I, David M. Stack, certify that:

- I have reviewed this Annual Report on Form 10-K of The Medicines Company;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:
  - c) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - d) [Paragraph omitted in accordance with SEC transition instructions contained in SEC release 34-47986]
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ David M. Stack ------David M. Stack President and Chief Executive Officer

Dated: March 5, 2004

### CERTIFICATIONS

I, Steven H. Koehler, certify that:

- I have reviewed this Annual Report on Form 10-K of The Medicines Company;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:
  - e) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - f) [Paragraph omitted in accordance with SEC transition instructions contained in SEC release 34-47986]
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Steven H. Koehler Steven H. Koehler Chief Financial Officer

Dated: March 5, 2004

### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

### AS ADOPTED PURSUANT TO

### SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of The Medicines Company (the "Company") for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Clive A. Meanwell, M.D., Executive Chairman of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

BY: /S/ CLIVE A. MEANWELL

Dated: March 5, 2004

Clive A. Meanwell, M.D. Executive Chairman

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A signed original of this written statement required by Section 906 has been provided to The Medicines Company and will be retained by The Medicines Company and furnished to the SEC or its staff upon request

### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

### AS ADOPTED PURSUANT TO

### SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of The Medicines Company (the "Company") for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David M. Stack, Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

BY: /S/ DAVID M. STACK

Dated: March 5, 2004

David M. Stack Chief Executive Officer

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A signed original of this written statement required by Section 906 has been provided to The Medicines Company and will be retained by The Medicines Company and furnished to the SEC or its staff upon request

### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

### AS ADOPTED PURSUANT TO

### SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of The Medicines Company (the "Company") for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven H. Koehler, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

BY: /S/ STEVEN H. KOEHLER

Dated: March 5, 2004

Steven H. Koehler Chief Financial Officer

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A signed original of this written statement required by Section 906 has been provided to The Medicines Company and will be retained by The Medicines Company and furnished to the SEC or its staff upon request

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