



THE **MEDICINES** COMPANY



ANNUAL REPORT 2001





## THE **MEDICINES** COMPANY

Our strategy is to build a biopharmaceutical business focused on acute hospital care where we can deliver differentiated products with economic advantages to hospital decision makers. We seek to acquire products in late stages of clinical development and invest in further product development and commercialization. We aim to minimize our fixed costs by partnering with highly proficient contract organizations and seek to maximize value creation through strategic brand management led by our experienced in-house project teams.

## COMPANY PROFILE

### TABLE OF CONTENTS

Milestones	1
Letter to Stockholders	2
ANGIOMAX in Interventional Cardiology	4
Clinical Development and Applications	6

## M I L E S T O N E S

### FIRST QUARTER

We launched ANGIOMAX® (bivalirudin) in the United States as the first thrombin inhibitor approved for use as an anticoagulant during angioplasty. We believe the product can be a valuable replacement for heparin—especially among the many coronary angioplasty patients who have ongoing thrombosis, high risk of bleeding, renal impairment or risk of thrombocytopenia.

### SECOND QUARTER

We received approval from the FDA to store ANGIOMAX at controlled room temperature, providing greater convenience for practitioners.

We completed the REPLACE-1 study in coronary angioplasty. Results showed that patients who had received ANGIOMAX had fewer ischemic and bleeding complications of coronary angioplasty than patients who had received heparin.

We completed a \$44 million equity placement in a PIPE transaction.

### THIRD QUARTER

We completed the 17,000 patient HERO-2 trial of ANGIOMAX in combination with streptokinase in heart attack patients. While not achieving the primary mortality endpoint, results showed that ANGIOMAX significantly reduced second heart attacks compared to heparin.

As of October 1, our expanded sales force of 86 representatives became employees of the Company, establishing MDCO as an operating company with a commercial infrastructure in marketing and sales.

### FOURTH QUARTER

We commenced enrollment in our large-scale REPLACE-2 trial, studying ANGIOMAX in the modern setting. This trial is designed to expand ANGIOMAX uses in coronary angioplasty.

ANGIOMAX sales accelerated quarter on quarter. We reported revenues of \$14.2 million in our first year of selling ANGIOMAX in the United States.

### CONTINUING INITIATIVES

To date, we have signed agreements with international distributors to market ANGIOMAX in 59 countries, including the European Union, Australia, Israel, Argentina, Brazil, and Mexico.





David Stack, *Chief Executive Officer,  
President & Director*

Clive Meanwell, M.D., Ph.D.,  
*Executive Chairman & Director*

Dear Fellow Stockholders:

During 2001 we continued to execute our plan to build a valuable biopharmaceutical operating business. We have established ANGIOMAX as an important new therapy to cost-effectively improve treatment of patients undergoing angioplasty in the cardiac catheterization laboratory. We have built a commercial presence in the marketplace that complements our strengths in the development of late stage pharmaceutical products. Since January 2001, we have grown into a 160-person enterprise with ex-U.S. distribution arrangements in 59 countries.

In January 2001, we launched ANGIOMAX as the first and only thrombin inhibitor approved by the FDA for use during coronary angioplasty. The product is uniquely positioned as a replacement for heparin that reduces both the thrombotic and bleeding risks associated with coronary interventions. We have created relationships through clinical studies, educational initiatives and by helping clinicians and pharmacists cost-effectively improve patient care.

Since product launch, we have introduced ANGIOMAX to interventional cardiology teams in over 500 hospitals—to doctors, nurses, pharmacists and administrators. The product is currently stocked in over 400 hospitals and is on formulary in over 300 hospitals, and we estimate that ANGIOMAX is being used in over 10,000 patients each month. Through this very successful launch, we believe we are on our way to establishing a major hospital brand in acute coronary care in the United States.

Our progress and future rest on the dedicated efforts of our employees, and on the interest and support of our customers. We would like to take this opportunity to thank them all. Our progress has been driven by our key initiatives:

- We continued to invest aggressively in ANGIOMAX development. The REPLACE program of trials involved more than 100 centers in the United States during 2001. We also established the ANGIOMAX Foundation Program, a phase IV initiative examining the particular benefits of the product among patients and clinicians facing the limitations of heparin during coronary angioplasty.
- We reported the results of two major ANGIOMAX trials. Results from REPLACE part one in coronary angioplasty showed that ANGIOMAX reduced complications of angioplasty compared to the current “gold standard” of care. This trial paved the way for REPLACE part two, a randomized, double-blind study of six thousand patients which is ongoing. Results from the HERO-2 trial, which studied ANGIOMAX vs. heparin in over 17,000 acute myocardial infarction patients worldwide, showed that ANGIOMAX had an overall clinical benefit compared to heparin when used with a fibrinolytic. The incidence of death, reinfarction or non-fatal disabling stroke in the HERO-2 trial was reduced in the ANGIOMAX arm, without significant increases in bleeding. ANGIOMAX patients in the HERO-2 trial showed a reduced incidence of second heart attack compared to heparin patients.
- Our health economics analyses demonstrate that ANGIOMAX reduces expensive ischemic and bleeding events, lowers a hospital’s cost of treating an angioplasty patient by reducing patient time in the catheterization lab, and decreases hospital resource consumption while improving patient care.
- We continue to develop ANGIOMAX beyond the cardiac catheterization lab for use in patients undergoing surgery, for the emergency management of acute coronary syndromes, as anticoagulant therapy in neonates and in patients who are allergic to heparin.

We also made progress with associated commercial initiatives during 2001. We completed our testing of a new manufacturing method designed to reduce the cost of producing ANGIOMAX. The FDA has issued an approvable letter for this process, and we expect bulk product manufactured using this process to be available in 2003.

We added depth and breadth to our management team in product development, marketing and sales, and human resources. We decided to share the leadership of the company because we know what it takes to drive a business dedicated to excellent products in a complex and competitive industry.

With 2002 already underway, we are excited by the continued promise we see. With a keen eye on our blueprint for growth, we look forward to serving our customers, stockholders and employees in 2002 and beyond.

Sincerely,



CLIVE MEANWELL  
*Executive Chairman*



DAVE STACK  
*President & CEO*

Physicians value ANGIOMAX because of the clinical, practical and economic advantages it has demonstrated over heparin.

#### ANGIOMAX: fundamentally superior technology to heparin

Heparin was discovered 86 years ago. It is a natural extract from the intestines of pigs and lungs of cows and is associated with antigenic or allergic reactions that can be life-threatening. Heparin is non-specific (binding somewhat indiscriminately to cells and other substances in blood) and acts only by accelerating the normal anticoagulant actions of antithrombin already present in human blood. The anticoagulant effect of heparin is highly variable, and the effect is dependent on patient factors and on the dose given. Heparin has also been shown to increase platelet aggregation in blood from patients with acute coronary syndromes—a highly undesirable effect.

In contrast, ANGIOMAX is a synthetic peptide that is a specific thrombin inhibitor and its action is independent of antithrombin. As a direct thrombin inhibitor, ANGIOMAX inhibits all functions of thrombin, including the formation of fibrin strands that create the scaffolding for a blood clot *and* thrombin-mediated platelet activation and aggregation. Unlike other thrombin inhibitors, ANGIOMAX is spontaneously reversible at the molecular level and has a short period of effect.

#### ANGIOMAX: technology translates into significant advantages

Interventional cardiologists who have used ANGIOMAX have cited its superior clinical safety, improved effectiveness and utility in special patient groups compared to heparin. Perhaps first among these features is improved safety. During 2001, our clinical trial programs in angioplasty continued to demonstrate reduced risk of bleeding and short duration of action of ANGIOMAX compared to heparin. These results contribute in part to physicians' observations that ANGIOMAX patients recover from procedures quickly, that vascular access devices can be removed early and that patient length of hospital stay is decreased. Each of these features provide substantial economic benefits to the treating institution since prolonged length of stay is the most important driver of excess costs associated with angioplasty.



*"ANGIOMAX provides for us an added margin of safety for patients at high risk for bleeding complications undergoing coronary angioplasty. We have been impressed with the good clinical results that we have obtained in these high-risk patients and the ease with which ANGIOMAX has been incorporated into our routine."*

Jeffrey J. Popma, M.D.  
Director, Interventional Cardiology  
Brigham & Women's Hospital, Boston, Massachusetts

*"The combination of improved efficacy and reduced bleeding seen with [ANGIOMAX] in [the Bivalirudin Angioplasty] study suggests that the risk/benefit ratio for [ANGIOMAX] may be unique among anticoagulants. No other anticoagulant evaluated as an alternative to heparin has shown this pattern of improved risk/benefit ratio."*

John Bittl, M.D.  
*The American Heart Journal*



Physicians also cite the improved effectiveness of ANGIOMAX over heparin in patients undergoing angioplasty shortly after a heart attack, or those with unstable coronary syndromes that have proven resistant to heparin. Finally, physicians cite the impressive performance of ANGIOMAX in special patient populations such as the elderly and those with impaired kidney or liver function.

We have learned a great deal from the daily interactions with interventionalists after product launch, and some of the ideas that have come out of this collaborative process are being put to use in the refinement of ANGIOMAX use in angioplasty. We established the ANGIOMAX Foundation Program (AFP) in 2001 as a national, phase IV clinical trials program and the AFP has now initiated more than 50 clinical protocols. The program is providing important information to physicians, nurses, technicians, pharmacists and administrators in the appropriate use of ANGIOMAX in leading-edge practices. These developments are also disseminated by ANGIOMAX Centers of Excellence—institutions that provide preceptorships and other accredited educational programs—to facilitate a greater understanding of ANGIOMAX in the practicing community.

A major clinical trial, REPLACE part two, was initiated in 2001. Our aim is to enroll six thousand patients to compare ANGIOMAX and provisional use of a GP 2b/3a inhibitor to heparin with a GP 2b/3a inhibitor used in all patients. This double-blind, randomized trial is designed to provide impetus for considering ANGIOMAX use in all patients as a standard practice in angioplasty. We expect to have information from this important trial available by the end of the year.



*"[ANGIOMAX] is the first anticoagulant approved by the U.S. Food and Drug Administration for use in patients undergoing percutaneous coronary intervention, where it has been shown to be superior to heparin. Although there is clearly a need for more data regarding [ANGIOMAX] use in patients with other indications, the evidence is mounting that this agent provides an unprecedented net clinical benefit by uncoupling efficacy and bleeding. [ANGIOMAX] may well become the foundation anticoagulant for use in patients with acute coronary syndromes."*

Professor Harvey White, D.Sc.  
*The American Heart Journal*

Replacing heparin with ANGIOMAX in angioplasty is only the beginning. Heparin is currently used in over 1.8 million procedures per year in the cardiac catheterization lab in the United States alone. In addition, more than 5 million patients are treated with heparin in a hospital acute care setting outside the cardiac catheterization lab, for a total hospital acute care market potential of more than 7 million patients every year in the U.S.

#### *The Operating Room*

Heparin is an essential—but therapeutically limited—component of cardiac and vascular surgery. ANGIOMAX may be an alternative to heparin in off-pump coronary bypass graft (CABG) surgery including patients with heparin allergy, on-pump CABG, and vascular surgery. The most pressing need in this arena cited by surgeons and anesthesiologists is for a product that does not cause immune reactions associated with heparin such as thrombocytopenia. ANGIOMAX may be able to help solve this problem.

#### *The Emergency Room, Critical Care Unit, Intensive Care Unit*

During 2001 we were encouraged by results from the HERO-2 trial in heart attack patients that demonstrated that ANGIOMAX reduced the incidence of second heart attacks compared to heparin. Now that many of these patients are sent to the cardiac catheterization laboratory to unblock coronary arteries, we believe that ANGIOMAX has the potential to play an important role in primary angioplasty and acute coronary syndromes.

We also believe ANGIOMAX has much to offer as an improved anti-thrombin and anti-platelet agent in such areas as neonatology, pediatrics, heparin allergy, and as an anticoagulant for use in peripheral angioplasty. Further investigations are underway or starting shortly.



## 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, 1997, 1998, 1999, 2000 and 2001. The pro forma net loss per share data reflects the conversion of our convertible notes and accrued interest, and the conversion of

our outstanding convertible preferred stock, and accrued dividends, into common stock upon the closing of our initial public offering in August 2000. The pro forma net loss per share data does not include the effect of any options or warrants outstanding. For further discussion of earnings per share, please see note 8 to the consolidated financial statements.

	Year Ended December 31,				
	1997	1998	1999	2000	2001
<i>In thousands, except share and per share data</i>					
<b>Statements of Operations Data</b>					
Net revenue	\$ —	\$ —	\$ —	\$ —	\$ 14,248
Operating expenses					
Cost of revenue	—	—	—	—	2,110
Research and development	16,044	24,005	30,345	39,572	32,768
Selling, general and administrative	2,421	6,248	5,008	15,034	36,567
Total operating expenses	18,465	30,253	35,353	54,606	71,445
Loss from operations	(18,465)	(30,253)	(35,353)	(54,606)	(57,197)
Other income (expense), net	659	1,302	640	(16,686)	2,313
Net loss	(17,806)	(28,951)	(34,713)	(71,292)	(54,884)
Dividends and accretion to redemption value of redeemable convertible preferred stock	(2,018)	(3,959)	(5,893)	(30,343)	—
Net loss attributable to common stockholders	\$ (19,824)	\$ (32,910)	\$ (40,606)	\$ (101,635)	\$ (54,884)
Net loss attributable to common stockholders per common share, basic and diluted	\$ (4.06)	\$ (6.03)	\$ (80.08)	\$ (8.43)	\$ (1.67)
Shares used in computing net loss attributable to common stockholders per common shares, basic and diluted	4,887,230	5,454,653	507,065	12,059,275	32,925,968
Unaudited pro forma net loss attributable to common stockholders per common share, basic and diluted			\$ (1.94)	\$ (2.10)	\$ (1.67)
Shares used in computing unaudited pro forma net loss attributable to common stockholders per common shares, basic and diluted			17,799,876	24,719,075	32,925,968
<b>As of December 31,</b>					
	1997	1998	1999	2000	2001
<i>In thousands</i>					
<b>Balance Sheet Data</b>					
Cash, cash equivalents, available for sale securities and accrued interest receivable	\$ 25,416	\$ 29,086	\$ 7,238	\$ 80,718	\$ 54,016
Working capital (deficit)	18,779	24,570	(4,103)	68,023	59,744
Total assets	25,595	29,831	7,991	84,363	77,901
Convertible notes	—	—	5,776	—	—
Redeemable convertible preferred stock	40,306	79,384	85,277	—	—
Accumulated deficit	(21,409)	(54,319)	(94,925)	(196,560)	(251,444)
Total stockholders' (deficit) equity	(21,387)	(54,266)	(94,558)	69,239	61,121



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

We operate as a pharmaceutical company selling and developing products for the treatment of hospital patients. We acquire, develop and commercialize biopharmaceutical products that are in late stages of development or have been approved for marketing. We began selling Angiomax, our lead product, in U.S. hospitals in January 2001 as an anticoagulant replacement for heparin, selling \$14.2 million of Angiomax in 2001. In December 2000, we received marketing approval from the U.S. Food and Drug Administration for Angiomax for use as an anticoagulant in combination with aspirin in patients with unstable angina undergoing coronary balloon angioplasty. Coronary balloon angioplasty is a procedure used to restore normal blood flow in an obstructed artery in the heart. In August and September 2000, we consummated our initial public offering resulting in \$101.4 million in net proceeds. In May 2001, we completed a private placement of 4.0 million shares of common stock resulting in net proceeds of \$41.8 million.

We began selling Angiomax in the United States in January 2001. Until October 1, 2001, we marketed Angiomax in the United States using a sales force contracted from Innovex, Inc., which we managed. On October 1, 2001, we hired as our full-time employees certain members of the Innovex sales force. In addition, during September 2001 we hired additional employees, which resulted in an increase of the sales force of approximately 30%.

Since our inception, we have incurred significant losses. 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 generally 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 product sales and marketing activities. Interest expense consists of costs associated with convertible notes that were issued in 2000 and 1999 to fund our business activities. These convertible notes were converted into equity in 2000.

We expect to continue to incur operating losses for the foreseeable future as a result of research and development activities attributable to new and existing products and costs associated with the sales and marketing of our products. We will need to generate significant revenues to achieve and maintain profitability.

During the year ended December 31, 2000, we recorded deferred stock compensation on the grant of stock options of approximately \$17.3 million, representing the difference between the exercise price of such options and the fair market value of our common stock at the date of grant of such options. The exercise prices of these options were below the estimated fair market value of our common stock as of the date of grant based on the estimated price of our common stock in our initial public offering. No deferred compensation was recorded during 2001 because all grants of stock options during this period were issued at the fair market value on the date of grant.

We amortize deferred stock compensation over the respective vesting periods of the individual stock options. We recorded amortization expense for deferred compensation of approximately \$3.7 million and \$4.1 million for the years ended December 31, 2000 and 2001, respectively. We expect to record amortization expense for the deferred compensation as follows: approximately \$3.7 million in 2002, approximately \$3.6 million in 2003 and approximately \$1.3 million in 2004.

We have not generated taxable income to date. At December 31, 2001, net operating losses available to offset future taxable income for federal income tax purposes were approximately \$173 million. If not utilized, federal net operating loss carryforwards will expire at various dates beginning in 2011 and ending 2021. We have not recognized the potential tax benefit of our net operating losses in our statements of operations. The future utilization of our net operating loss carryforwards may be limited pursuant to regulations promulgated under the Internal Revenue Code of 1986, as amended.

### 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 the 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 December 2001, the SEC requested that all registrants discuss their "critical accounting policies" in the discussion and analysis of their financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of the company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

Our significant accounting policies are more fully described in Note 2 to our financial statements. Not all of these significant accounting policies, however, require management to make difficult, complex or subjective judgments or estimates. We believe that our accounting policies relating to revenue recognition and inventory described below fit the definition of "critical accounting policies."

#### **Revenue Recognition**

Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and determinable, delivery has occurred, and collectibility is reasonably assured. Revenue is recorded net of allowances, including estimated allowances for returns, rebates and other discounts. In accordance with Statement of Financial Accounting Standards No. 48 "Revenue Recognition When Right of Return Exists," revenue is recognized when the price to the buyer is fixed, the buyer is obligated to pay us and the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from us, we have no obligations to bring about the sale of the product and the amount of returns can be reasonably estimated. Our returns during 2001 were not material.

#### **Inventories**

Inventory is recorded upon transfer of title from our vendors. Inventory is stated at the lower of cost or market with cost determined using a weighted average of costs. All costs associated with the manufacture of Angiomax bulk drug product and finished product to which the title transferred to us prior to FDA approval of Angiomax was expensed as research and development. In December 2000, we received FDA approval for Angiomax and any Angiomax bulk drug product to which we took title after FDA approval is recorded as inventory. We review the inventory for slow moving or obsolete amounts based on expected revenues. If actual revenues are less than expected, allowances for excess amounts may be required in the future.

#### **Results of Operations**

##### **Years Ended December 31, 2001 and 2000**

*Net Revenue.* We had net revenue of \$14.2 million in 2001 from sales of Angiomax. We had no net revenue in 2000.

*Cost of Revenue.* Cost of revenue during 2001 was \$2.1 million, or 15% of product revenue. The cost of revenue consisted of expenses in connection with the manufacture of the Angiomax sold, the logistical costs of selling Angiomax and royalty expenses under our agreements with Biogen. The cost of manufacturing as a percentage of product revenue was approximately 2% during 2001 because we sold Angiomax that was manufactured prior to the date of FDA approval of Angiomax in December 2000. The cost associated with the

manufacture of Angiomax incurred by us prior to date of FDA approval was expensed as research and development. In 2002, we expect to sell Angiomax manufactured after the date of FDA approval, as a result of which we expect our cost of manufacturing as a percentage of product revenue will increase substantially by the end of 2002.

*Research and Development Expenses.* Research and development expenses decreased 17% from \$39.6 million in 2000 to \$32.8 million in 2001. The decrease in research and development expenses of \$6.8 million was primarily due to lower manufacturing development costs related to UCB Bioproduct's manufacture of Angiomax bulk drug product in 2000, which was expensed prior to FDA approval, and to lower clinical development costs associated with the completion in 2001 of the HERO-2 trial program, our Phase 3 clinical trial in AMI. Partly offsetting this decrease in research and development costs were higher costs related to our trials in angioplasty called REPLACE-1 and REPLACE-2 and higher development costs related to our modified production process known as the Chemilog process.

We have a number of clinical trial programs currently underway, or about to commence, for expanding the applications of Angiomax in the treatment of ischemic heart disease and for use as a procedural anticoagulant. The funding for Angiomax, our main product, has represented and will continue to represent a significant portion of research and development spending. For 2001 and 2000, research and development expenses related to Angiomax included the costs of clinical trials, development manufacturing costs for the bulk drug product and the cost associated with preparation of U.S. and worldwide marketing applications. In late 2000, after obtaining FDA approval for Angiomax, we began recording as inventory bulk drug supply purchased, reducing the amount classified as research and development expense. We are currently working on a second generation manufacturing process for Angiomax, called Chemilog, for which we have received an approvable letter from the FDA, and will continue to incur research and development expenses until we receive FDA approval of this process. The amount of future research and development expenses associated with Angiomax are not reasonably certain as these costs are dependent upon the regulatory process and the timing for obtaining marketing approval for other applications of the product in the United States and other countries. However, they are expected to be substantial.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased 143% to \$36.6 million in 2001 from \$15.0 million in 2000. The increase in selling, general and administrative expenses of \$21.5 million was primarily due to an increase in marketing and selling

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS (continued)

expenses and corporate infrastructure costs arising from an increase in activity relating to the commercial launch of Angiomax in 2001, including the addition of sales personnel.

*Other Income and Expense.* Interest income increased 19% to \$3.2 million in 2001 from \$2.7 million in 2000. The increase in interest income of \$459,000 was primarily due to interest income arising from the investment of the proceeds of our initial public offering in August and September 2000 and from the investment of the proceeds from our sale of 4.0 million shares of our common stock in a private placement in May 2001.

We had no interest expense in 2001. Interest expense of \$19.4 million in 2000 was related to interest charges and amortization of the discount on our convertible notes issued in October 1999 and March 2000.

During the second quarter of 2001, we liquidated our \$3.0 million principal investment in Southern California Edison 5 $\frac{7}{8}$ % bonds, recognizing a loss of \$850,000 on the sale.

**Years Ended December 31, 2000 and 1999**

*Net Revenue/Cost of Revenue.* We had no net revenue or cost of revenue in 2000 or 1999.

*Research and Development Expenses.* Research and development expenses increased 30% from \$30.3 million in 1999 to \$39.6 million in 2000. The increase of \$9.3 million was primarily due to the increased enrollment rate of our Phase 3 clinical trial in AMI, called HERO-2, during 2000, initiation in 2000 of a Phase 3b trial in angioplasty called REPLACE-1 and the recognition of \$12.2 million of research and development costs in connection with the completion of UCB Bioproduct's manufacture of Angiomax bulk drug substance prior to FDA approval. The increase in costs was partly offset by reduced development expenses reflecting our termination of the semi-log manufacturing development program with Lonza AG in the fourth quarter of 1999 and a reduction in development activity for IS-159 in 2000.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased 200% from \$5.0 million in 1999 to \$15.0 million in 2000. The increase of \$10.0 million was primarily due to an increase in marketing and selling expenses and corporate infrastructure costs arising from an increase in activity in preparation for the commercial launch of Angiomax.

*Interest Income and Interest Expense.* Interest income increased 223% from \$838,000 in 1999 to \$2.7 million in 2000. The increase of \$1.9 million was primarily due to interest income arising from investment of the proceeds of our initial public offering.

Interest expense was \$19.4 million in 2000 and was related to interest charges and the amortization of the discount on our convertible notes issued in October 1999 and March 2000. The notes were converted into shares of series IV convertible preferred stock in May 2000, accelerating the remaining unamortized discount.

**Liquidity and Capital Resources**

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.

In August and September 2000, we received \$101.4 million in net proceeds from the sale of common stock in our initial public offering and 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. Prior to the 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.

As of December 31, 2001, we had \$54.0 million in cash, cash equivalents and available for sale securities, as compared to \$79.3 million as of December 31, 2000. The decrease in cash, cash equivalents and available for sale securities of \$25.3 million was primarily attributable to cash used in operating activities and for purchases of fixed assets, partly offset by funds received from maturities and sales of available for sale securities and financing activities and sales of Angiomax.

We used net cash of \$67.2 million in operating activities during 2001. This consisted of a net loss of \$54.9 million, combined with increases in accounts receivable of \$5.3 million and inventory of \$14.6 million, and partly offset by a decrease in accrued expenses of \$1.1 million, in accrued interest receivable of \$1.4 million and an increase in accounts payable of \$2.8 million, and from non-cash amortization of deferred compensation of \$4.1 million and depreciation of \$471,000. The increase in inventory of \$14.6 million was primarily attributable to the scheduled receipt of bulk Angiomax from our supplier, UCB Bioproducts.

During 2001, we generated approximately \$41.7 million of cash from net investing activities, which consisted principally of the maturity or sale of available for sale securities, partly offset by the purchase of fixed assets of \$736,000, which is primarily computer related equipment. During 2001, we received \$42.5 million from financing activities primarily related to proceeds from the sale of shares of our common stock in a private placement and from employees purchasing stock under our stock plans.

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:

- whether Angiomax is commercially successful;
- the progress, level and timing of our research and development activities;
- 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 current operating plan, plus 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 for approximately 18 months. 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. The 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.

In March 2002, we entered into a loan and security agreement with Comerica Bank—California. Under the agreement, we may borrow up to \$10,000,000. Amounts outstanding under the agreement are collateralized by all of the Company's personal property. The agreement has a term of one year and provides for interest on amounts outstanding at a rate of one percent above the prime rate. In order to draw on the facility, and while borrowings are outstanding, we must satisfy certain covenants, including covenants related to cash,

working capital and revenues. As of March 29, 2002, we had drawn down the full \$10.0 million under the agreement.

### **Contractual Obligations**

Our long-term contractual commitments consist of operating leases for our facilities in Cambridge, Massachusetts and Parsippany, New Jersey, which expire in August 2003 and September 2005, respectively. Future annual minimum payments under these operating leases are \$669,000, \$502,000, \$282,000 and \$177,000 in 2002, 2003, 2004 and 2005, respectively. In addition to amounts accrued or payable as of December 31, 2001, we expect to make payments to UCB Bioproducts of a total of \$7.5 million during 2002 and 2003 for Angiomax bulk drug substance produced using the Chemilog process.

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

This Annual Report 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 disclosed in our forward-looking statements. There are a number of important factors that cause actual results or events to differ materially from those disclosed in the forward-looking statements we make. These important factors include our "critical accounting policies" 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 filing this Annual Report.

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

WE HAVE A HISTORY OF NET LOSSES, AND WE EXPECT TO CONTINUE TO INCUR NET LOSSES AND MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY

We have incurred net losses since our inception, including net losses of approximately \$54.9 million for the year ended December 31, 2001. As of December 31, 2001, we had an accumulated deficit of approximately \$251.4 million. We expect to

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS *(continued)*

make substantial expenditures to further develop and commercialize our products, including costs and expenses associated with clinical trials, regulatory approval and commercialization of products. As a result, we are unsure when we will become profitable, if at all, and if we do become profitable, we may not remain profitable for any substantial period of time. If we fail to achieve profitability 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

Other than Angiomax, our products are in clinical phases of development and, even if approved by the FDA, are a number of years away from entering the market. As a result, Angiomax will account for almost all of our revenues for the foreseeable future. The commercial success of Angiomax will depend upon its acceptance by physicians, patients and other key decision-makers as a safe, therapeutic and cost-effective alternative to heparin and other products used in current practice. If Angiomax is not commercially successful, we will have to find additional sources of revenues or curtail or cease operations.

## FAILURE TO RAISE ADDITIONAL FUNDS IN THE FUTURE MAY AFFECT THE DEVELOPMENT, MANUFACTURE AND SALE OF OUR PRODUCTS

Our operations to date have generated substantial and increasing needs for cash. Our negative cash flow from operations is expected to continue into the foreseeable future. The clinical development and regulatory approval of Angiomax for additional indications, the development and regulatory approval of our other product candidates and the acquisition and development of additional product candidates by us will require a commitment of substantial funds. Our future capital requirements are dependent upon many factors and may be significantly greater than we expect.

We believe, based on our current operating plan, plus anticipated sales of Angiomax and interest income, that our current cash, cash equivalents and available for sale securities will be sufficient to fund our operations for approximately 18 months. 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. The 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 CANNOT EXPAND THE INDICATIONS FOR 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 balloon angioplasty. One of our key objectives is to expand the indications for which the FDA will approve Angiomax. In order to do this, we will need to conduct additional clinical trials and obtain FDA approval for each proposed indication. 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 our products in international markets, including Europe. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. In February 1998, we submitted a Marketing Authorization Application (MAA) to the European Agency for the Evaluation of Medicinal Products, or the EMEA, for use of Angiomax in unstable angina patients undergoing 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 angioplasty. The United Kingdom and Ireland dissented from this decision. We have withdrawn our application to the EMEA and plan to resubmit an MAA with the results of the REPLACE-2 program if positive. We may not be able to obtain approval from any or all of the jurisdictions in which we seek approval to market Angiomax. Obtaining foreign approvals may require additional trials and additional expense.

## THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS MAY BE TERMINATED OR DELAYED, AND THE COSTS OF DEVELOPMENT AND COMMERCIALIZATION MAY

INCREASE, IF THIRD PARTIES WHO WE RELY ON 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. Although we manage these services, 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 clevidipine or any additional product candidates or products on terms that are acceptable to us. Any current or future arrangements for the development and commercialization of our products may not be successful. If we are not able to establish or maintain agreements relating to Angiomax, clevidipine or any additional products on terms which we deem favorable, our financial condition 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 may not be 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, clevidipine, our other product candidates or any additional product candidates 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.

WE ARE CURRENTLY DEPENDENT ON A SINGLE SUPPLIER FOR THE PRODUCTION OF ANGIOMAX BULK DRUG SUBSTANCE AND A DIFFERENT SINGLE SUPPLIER TO CARRY OUT ALL FILL-FINISH ACTIVITIES FOR ANGIOMAX

We have no experience in manufacturing, and we lack the facilities and personnel to manufacture products in accordance with FDA regulations. Currently, we obtain all of our Angiomax bulk drug substance from one manufacturer, UCB Bioproducts S.A., and rely on another manufacturer, Ben Venue Laboratories, Inc., 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 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 Practice, or cGMP, regulations and guidelines. There are a limited number of manufacturers that operate under cGMP regulations capable of manufacturing Angiomax. We do not currently have alternative sources for production of Angiomax bulk drug substance or to carry out fill-finish activities. In the event that either of our current manufacturers is unable to carry out its respective manufacturing obligations to our satisfaction, 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.

IF WE DO NOT SUCCEED IN DEVELOPING A SECOND-GENERATION PROCESS FOR THE PRODUCTION OF BULK ANGIOMAX DRUG SUBSTANCE, OUR GROSS MARGINS MAY BE BELOW INDUSTRY AVERAGES

We are currently developing with UCB Bioproducts a second-generation process for the production of bulk Angiomax drug substance. This process involves changes to the early manufacturing steps of our current process in order to improve our gross margins on the future sales of Angiomax. If we cannot develop the process successfully or regulatory approval of the process is not obtained or is delayed, then our ability to improve our gross margins on future sales of Angiomax may be limited.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS *(continued)*

CLINICAL TRIALS OF OUR PRODUCT CANDIDATES ARE EXPENSIVE AND TIME-CONSUMING, AND THE RESULTS OF THESE TRIALS ARE UNCERTAIN

Before we can obtain regulatory approvals for the commercial sale of any product that we wish to develop, we will be required to complete pre-clinical studies and extensive clinical trials in humans to demonstrate the safety and efficacy of such product. We are currently conducting clinical trials of Angiomax for use in the treatment of ischemic heart disease and for additional potential hospital applications as a procedural anticoagulant. 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 any potential product to be safe or effective. 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 drug may be marketed.

OUR FAILURE TO ACQUIRE AND DEVELOP ADDITIONAL PRODUCT CANDIDATES OR APPROVED PRODUCTS WILL IMPAIR OUR ABILITY TO GROW

As part of our growth strategy, we intend to acquire and develop additional pharmaceutical product candidates or approved products. The success of this strategy depends upon our ability to identify, select and acquire pharmaceutical products in late-stage development or that have been approved 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.

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 of our 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.

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.

IF WE BREACH ANY OF THE AGREEMENTS UNDER WHICH WE LICENSE COMMERCIALIZATION RIGHTS TO PRODUCTS OR TECHNOLOGY FROM OTHERS, WE COULD LOSE LICENSE RIGHTS THAT ARE IMPORTANT TO OUR BUSINESS

We license commercialization 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 acquired our first four products through exclusive licensing arrangements. Under these licenses we are subject to commercialization and development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. In addition, upon the termination of the license we may be required to license to the licensor the intellectual property that we developed.

OUR ABILITY TO MANAGE OUR BUSINESS EFFECTIVELY COULD BE HAMPERED IF WE ARE UNABLE TO ATTRACT AND RETAIN KEY PERSONNEL AND CONSULTANTS

The biopharmaceutical 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 the biotechnology industry with the breadth of skills and experience required to 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.

WE FACE SUBSTANTIAL COMPETITION, WHICH MAY RESULT IN OTHERS DISCOVERING, DEVELOPING OR COMMERCIALIZING COMPETING PRODUCTS BEFORE OR MORE SUCCESSFULLY THAN WE DO

The biopharmaceutical 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 a market for our products. Potential competitors in the United States and other countries include major pharmaceutical and chemical companies, specialized 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.

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 widely used and inexpensive, for use in patients with ischemic heart disease. Because heparin is inexpensive and has been widely used for many years, medical decision-makers may be hesitant to adopt our alternative treatment. In addition, due to the high incidence and severity of cardiovascular diseases, the market for thrombin inhibitors is large and competition is intense and growing. There are a number of thrombin inhibitors currently on the market, awaiting regulatory approval and in development, including orally administered agents.

THE LIMITED RESOURCES OF THIRD-PARTY PAYORS MAY LIMIT THE USE OF OUR PRODUCTS

In general, anticoagulant drugs may be classified in three groups: drugs that directly or 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 other therapies. Although we are not positioning Angiomax as a direct competitor to platelet inhibitors or fibrinolytic drugs, platelet inhibitors and fibrinolytic drugs may compete with Angiomax for the use of hospital financial resources. 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, U.S. hospitals may have to choose among Angiomax, platelet inhibitors and fibrinolytic drugs.

FLUCTUATIONS IN OUR OPERATING RESULTS COULD AFFECT THE PRICE OF OUR COMMON STOCK

Our operating results may vary from period to period based on the amount and timing of sales of Angiomax to customers in the United States, 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 our competitors, the availability and timing of third-party reimbursement and the timing of approval for our product candidates. 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 businesses 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, which may result in dilution for stockholders and the incurrence of indebtedness.



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS *(continued)*

WE HAVE SIGNIFICANT CREDIT EXPOSURE BECAUSE WE SELL ANGIOMAX TO A LIMITED NUMBER OF WHOLESALERS

Our products are sold primarily to a limited number of national medical and pharmaceutical distributors and wholesalers with distribution centers located throughout the United States. We generally do not require collateral from these distributors and wholesalers. During 2001, our revenues from four of our customers totaled approximately 93% of our net revenues. As a result, failure to pay us by any of these wholesalers could impair our financial position and results of operations.

### **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 and New Zealand, 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 us to repeat clinical trials 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 products and product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation. 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 and biotechnology companies like us are generally uncertain and involve complex legal, scientific and factual issues. Our success depends significantly on our ability to:

- obtain 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 patents issued from any patent applications that we own or license. If 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 are maintained in secrecy until patents issue, others may have filed or maintained patent applications for technology used by us or covered by our pending patent applications without our being aware of these applications. In all, we exclusively license 10 issued U.S. patents and a broadly filed portfolio of corresponding foreign patents and patent applications. 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. We are currently covered, with respect to our commercial sales in the United States and New Zealand 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 the cost of developing and manufacturing of drugs and treatments related to those drugs by government authorities, private health insurers and other organizations will have an effect on the successful commercialization of, and attracting collaborative partners to invest in the development of, our 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 payors 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 in the future. 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.

#### **Quantitative and Qualitative Disclosure About Market Risk**

Our exposure to market risk is confined to our cash, cash equivalents and available for sale securities. We place our investments in high-quality financial instruments, primarily money market funds and corporate debt securities with maturities or auction dates of less than one year, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. At December 31, 2001, we held \$54.0 million in cash, cash equivalents, and available for sale securities, all due within one year, which had an average interest rate of approximately 2.0%.

Most of our transactions are conducted in U.S. dollars. We do have certain development and commercialization agreements with vendors 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%, we do not believe that it would have a material impact on our results of operation or cash flows.



## CONSOLIDATED BALANCE SHEETS

	December 31,	
	2000	2001
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 36,802,356	\$ 53,884,376
Available for sale securities	42,522,729	125,000
Accrued interest receivable	1,392,928	6,757
	80,718,013	54,016,133
Accounts receivable, net of allowances of \$823,000 in 2001	—	5,346,684
Inventories	1,963,491	16,610,928
Prepaid expenses and other current assets	465,650	550,564
Total current assets	83,147,154	76,524,309
Fixed assets, net	965,832	1,223,528
Other assets	250,144	153,076
Total assets	\$ 84,363,130	\$ 77,900,913
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,987,213	\$ 8,805,476
Accrued expenses	9,136,934	7,974,473
Total current liabilities	15,124,147	16,779,949
Commitments and contingencies	—	—
Stockholders' equity:		
Common stock, \$.001 par value, 75,000,000 shares authorized at December 31, 2000 and December 31, 2001, respectively; 30,320,455 and 34,606,582 issued and outstanding at December 30, 2000 and December 31, 2001, respectively	30,320	34,607
Additional paid-in capital	279,126,337	321,041,704
Deferred compensation	(13,355,694)	(8,593,773)
Accumulated deficit	(196,560,034)	(251,443,682)
Accumulated other comprehensive income (loss)	(1,946)	82,108
Total stockholders' equity	69,238,983	61,120,964
Total liabilities and stockholders' equity	\$ 84,363,130	\$ 77,900,913

See accompanying notes.



## CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	1999	2000	2001
Net revenue	\$ —	\$ —	\$ 14,247,724
Operating expenses:			
Cost of revenue	—	—	2,110,425
Research and development	30,344,892	39,572,297	32,767,394
Selling, general and administrative	5,008,387	15,033,585	36,566,761
Total operating expenses	35,353,279	54,605,882	71,444,580
Loss from operations	(35,353,279)	(54,605,882)	(57,196,856)
Other income (expense):			
Interest income	837,839	2,704,126	3,163,208
Interest expense	(197,455)	(19,390,414)	—
Loss on sale of investment	—	—	(850,000)
Net loss	(34,712,895)	(71,292,170)	(54,883,648)
Dividends and accretion to redemption value of redeemable preferred stock	(5,893,016)	(30,342,988)	—
Net loss attributable to common stockholders	\$(40,605,911)	\$(101,635,158)	\$(54,883,648)
Basic and diluted net loss attributable to common stockholders per common share	\$ (80.08)	\$ (8.43)	\$ (1.67)
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share	\$ (1.94)	\$ (2.10)	\$ (1.67)
Shares used in computing net loss attributable to common stockholders per common share:			
Basic and diluted	507,065	12,059,275	32,925,968
Unaudited pro forma basic and diluted	17,799,876	24,719,075	32,925,968

See accompanying notes.



THE MEDICINES COMPANY

CONSOLIDATED STATEMENTS OF REDEEMABLE PREFERRED STOCK  
AND STOCKHOLDERS' EQUITY (DEFICIT)

For the Years Ended December 31, 1999, 2000 and 2001

	Redeemable Convertible		Common Stock	
	Preferred Stock			
	Shares	Amount	Shares	Amount
Balance at December 31, 1998	21,493,621	\$ 79,384,470	889,778	\$ 890
Repurchase of common stock			(56,378)	(56)
Dividends on preferred stock	1,468,729	5,351,178		
Accretion of preferred stock to redemption value		541,765		
Issuance of warrants associated with convertible notes				
Net loss				
Currency translation adjustment				
Unrealized loss on marketable securities				
Comprehensive loss				
Balance at December 31, 1999	22,962,350	85,277,413	833,400	834
Repurchase of common stock			(22,205)	(22)
Employee stock purchases			227,525	226
Issuance of redeemable preferred stock	5,946,366	25,688,284		
Accretion and dividend on preferred stock	1,751,241	4,898,537		
Beneficial conversion of redeemable convertible preferred stock				
Issuance of warrants associated with convertible notes				
Issuance of common stock through initial public offering			6,900,000	6,900
Conversion of preferred stock to common stock	(30,659,957)	(115,864,234)	22,381,735	22,382
Deferred compensation expense associated with stock options				
Adjustments to deferred compensation for terminations				
Amortization of deferred stock compensation				
Net loss				
Currency translation adjustment				
Unrealized loss on marketable securities				
Comprehensive loss				
Balance at December 31, 2000	—	—	30,320,455	30,320
Repurchase of common stock			(11,239)	(11)
Employee stock purchases			297,366	298
Issuance of common stock through private placement			4,000,000	4,000
Adjustments to deferred compensation for terminations				
Amortization of deferred stock compensation				
Net loss				
Currency translation adjustment				
Reclassification adjustment for realized loss on available for sale securities				
Comprehensive loss				
<b>Balance at December 31, 2001</b>	<b>—</b>	<b>\$ —</b>	<b>34,606,582</b>	<b>\$34,607</b>

See accompanying notes.

For the Years Ended December 31, 1999, 2000 and 2001

Additional Paid-In Capital	Deferred Stock Compensation	Accumulated Deficit	Comprehensive Income (Loss)	Total Stockholders' Equity/Deficit
\$ 13,810 (21)		\$ (54,319,117)	\$ 38,658	\$ (54,265,759) (77)
		(5,351,251)		(5,351,251)
		(541,765)		(541,765)
325,355				325,355
		(34,712,895)		(34,712,895)
			(3,847)	(3,847)
			(7,416)	(7,416)
				<u>(34,724,158)</u>
339,144	—	(94,925,028)	27,395	(94,557,655) (22)
286,068				286,294
		(4,898,537)		— (4,898,537)
25,444,299		(25,444,299)		—
18,789,805				18,789,805
101,343,162				101,350,062
115,841,732				115,864,114
17,279,612	\$(17,279,612)			—
(197,485)	197,485 3,726,433			— 3,726,433
		(71,292,170)		(71,292,170)
			5,141	5,141
			(34,482)	(34,482)
				<u>(71,321,511)</u>
279,126,337	(13,355,694)	(196,560,034)	(1,946)	69,238,983
—				(11)
743,147				743,445
41,798,975				41,802,975
(626,755)	626,755 4,135,166			— 4,135,166
		(54,883,648)		(54,883,648)
			47,446	47,446
			36,608	36,608
				<u>(54,799,594)</u>
<b>\$321,041,704</b>	<b>\$ (8,593,773)</b>	<b>\$(251,443,682)</b>	<b>\$ 82,108</b>	<b>\$ 61,120,964</b>



## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	1999	2000	2001
<b>Cash flows from operating activities:</b>			
Net loss	\$ (34,712,895)	\$ (71,292,170)	\$ (54,883,648)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	207,663	277,307	470,930
Amortization of discount on convertible notes	101,674	19,013,486	—
Amortization of deferred stock compensation	—	3,726,433	4,135,166
Loss on sales and disposal of fixed assets	—	14,631	2,113
Changes in operating assets and liabilities:			
Accrued interest receivable	690,290	(1,337,703)	1,386,171
Accounts receivable	—	—	(5,346,684)
Inventory	—	(1,963,491)	(14,620,838)
Prepaid expenses and other current assets	39,141	(312,027)	(85,806)
Other assets	(3,349)	(82,391)	96,927
Accounts payable	5,528,544	(1,823,602)	2,819,943
Accrued expenses	1,258,366	5,708,535	(1,149,886)
<b>Net cash used in operating activities</b>	<b>(26,890,566)</b>	<b>(48,070,992)</b>	<b>(67,175,612)</b>
<b>Cash flows from investing activities:</b>			
Purchases of available for sale securities	—	(51,098,901)	(7,430,886)
Maturities and sales of available for sale securities	18,796,493	9,083,090	49,863,097
Purchase of fixed assets	(258,788)	(834,160)	(735,571)
<b>Net cash provided by (used in) investing activities</b>	<b>18,537,705</b>	<b>(42,849,971)</b>	<b>41,696,640</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible notes and warrants	6,000,000	13,348,779	—
Proceeds from issuances of preferred stock, net	—	6,095,338	—
Proceeds from issuances of common stock, net	—	101,636,356	42,546,420
Repurchases of common stock	(77)	(22)	(11)
Dividends paid in cash	(73)	(118)	—
<b>Net cash provided by financing activities</b>	<b>5,999,850</b>	<b>121,080,333</b>	<b>42,546,409</b>
Effect of exchange rate changes on cash	(1,245)	(280)	14,583
<b>Increase (decrease) in cash and cash equivalents</b>	<b>(2,354,256)</b>	<b>30,159,090</b>	<b>17,082,020</b>
Cash and cash equivalents at beginning of period	8,997,522	6,643,266	36,802,356
<b>Cash and cash equivalents at end of period</b>	<b>\$ 6,643,266</b>	<b>\$ 36,802,356</b>	<b>\$ 53,884,376</b>
<b>Non-cash transactions:</b>			
Dividends on preferred stock	\$ 5,351,178	\$ 31,894,474	\$ —
<b>Supplemental disclosure of cash flow information:</b>			
Interest paid	\$ —	\$ 255,781	\$ —

See accompanying notes.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2001

**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. The U.S. Food and Drug Administration approved Angiomax® (bivalirudin) for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty in December 2000 and the Company commenced sales of Angiomax in the first quarter of 2001. The Company was considered to be a development-stage enterprise, as defined in Statement of Financial Accounting Standards No. 7, "Accounting and Reporting by Development Stage Enterprises" through December 31, 2000. With the commencement of sales in 2001, the Company is no longer considered to be a development-stage enterprise.

**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.

**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 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, 2001, approximately \$52,352,000 of the cash and cash equivalents balance was invested in a single fund, the Merrill Lynch Premier Institutional Fund, a no-load money market fund.

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. 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 2001, such losses were within the expectations of management. During 2001, the Company's revenues to four of its customers totaled approximately 93% of net revenues. At December 31, 2001, these same customers represented approximately \$5.9 million, or 97%, of gross accounts receivable.

**Cash, Cash Equivalents and Available for Sale Securities**

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents at December 31, 2001 consist 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 estimated fair value of the available-for-sale securities is determined based on quoted market prices or rates for similar instruments. At December 31, 2000, available-for-sale securities consisted of investments in corporate bonds and certificates of deposit with maturities of less than one year and are summarized as follows:

	Cost	Unrealized Loss	Fair Value
December 31, 2000	\$42,559,337	\$(36,608)	\$42,522,729
<b>December 31, 2001</b>	<b>\$ 125,000</b>	<b>\$ —</b>	<b>\$ 125,000</b>

At December 31, 2000 and 2001, the Company held a certificate of deposit for \$125,000 with a one-year term that was pledged as a security deposit on its facility lease in Parsippany, New Jersey.

During the second quarter of 2001, the Company sold its \$3.0 million investment in Southern California Edison 5<sup>7</sup>/<sub>8</sub>% 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 years ended December 31, 2000 and 2001, which are disclosed in the accompanying consolidated statements of cash flows.

**Revenue Recognition**

The Company recognizes revenue from product sales in accordance with generally accepted accounting principles in the United States including the guidance in Staff Accounting

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 2001

Bulletin 101. Revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured.

The Company's products are sold with limited rights of return. In accordance with Statement of Financial Accounting Standards No. 48 (SFAS 48) "Revenue Recognition When Right of Return Exists," revenue is recognized when the price to the buyer is fixed, 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 obligations to bring about sale of the product and the amount of returns can be reasonably estimated. Returns during 2001 were not material.

The Company does not offer price protection to its customers. The Company offers its customers rebates based on the volume of a customers' purchases. The Company provides for such estimated rebates at the time of sale and such amounts are reported net of revenues.

### Advertising Costs

The Company expenses advertising costs as incurred. Advertising costs were approximately \$484,000, \$807,000 and \$1,258,000 for the years ended December 31, 1999, 2000 and 2001, respectively.

### Inventories

The Company records inventory upon the transfer of title from its vendor. Inventory is stated at the lower of cost or market with cost determined using a weighted average of costs. All costs associated with the manufacture of Angiomax bulk drug product and finished product to which title transferred to the Company prior to FDA approval of Angiomax were expensed as research and development. In December 2000, the Company received FDA approval for Angiomax and any Angiomax bulk drug product to which the Company took title after FDA approval is recorded as inventory. At December 31, 2001 the inventory consists of substantially all raw materials and work-in-process.

### 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.

### 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).

### 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 exchanged using the current exchange rate as of the balance sheet date. Expenses and items of income are exchanged 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 carry-forwards, and are measured using the enacted tax rates and laws that will be 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.

### Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board (FASB) issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The Company adopted SFAS No. 133 effective January 1, 2001 and it did not have a material impact on the Company's financial condition or results of operations.

In September 2000, the Emerging Issues Task Force (EITF) of the Financial Accounting Standards Board reached a consensus on Issue 00-19, "Determination of Whether Share Settlement is Within the Control of the Issuer for Purposes of Applying Issue No. 96-13, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock." The consensus provides guidance regarding when a contract indexed to a company's own stock must be classified in stockholders' equity versus classified as an asset or liability. Any new contracts entered into after the date of consensus must comply with the consensus, and any contracts outstanding as of the September 2000 consensus date must

comply with the consensus by June 2001. The Company adopted this consensus in the quarter ended June 30, 2001, and it did not have a material impact on the Company's financial condition or results of operations.

In June 2001, the FASB issued SFAS No. 141, "Business Combinations," and SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 141 supersedes APB No. 16, Business Combinations, and SFAS No. 38, "Accounting for Preacquisition Contingencies of Purchased Enterprises," and requires that all business combinations be accounted for by a single method—the purchase method. SFAS No. 141 also provides guidance on the recognition of intangible assets identified in a business combination and requires enhanced financial statement disclosures. SFAS No. 142 adopts a more aggregate view of goodwill and bases the accounting for goodwill on the units of the combined entity into which an acquired entity is integrated. In addition, SFAS No. 142 concludes that goodwill and intangible assets that have indefinite useful lives will not be amortized but rather will be tested at least annually for impairment. Intangible assets that have finite lives will continue to be amortized over their useful lives. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001. The adoption of SFAS No. 142 is required for fiscal years beginning after December 15, 2001, except for the nonamortization and amortization provision, which are required for goodwill and intangible assets acquired after June 30, 2001. The Company believes that the adoption of SFAS No. 141 and SFAS No. 142 will not have a material impact on the Company's financial position or results of operations.

In August 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations." The standard requires entities to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred. When the liability is initially recorded, the entity capitalizes a cost by increasing the carrying amount of the related long-lived asset. Over time, the liability is accreted to its present value each period, and the capitalized cost is depreciated over the useful life of the related asset. Upon settlement of the liability, an entity either settles the obligation for its recorded amount or incurs a gain or loss upon settlement. The standard is effective for fiscal years beginning after June 15, 2002, with earlier application encouraged. The Company believes that the adoption of SFAS No. 143 will not have a material impact on the Company's financial position or results of operations.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-lived Assets." SFAS No. 144 supersedes SFAS No. 121, "Accounting for the Impairment of Long-lived Assets and for Long-lived Assets to be Disposed of," and certain provisions of Accounting Principles Board (APB) Opinion No. 30, "Reporting the Results of Operations—Reporting the Effects of Disposal of a Segment of a Business, Extraordinary, Unusual and Infrequent

Occurring Events and Transactions." SFAS No. 144 requires that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The standard is effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. The Company believes that the adoption of SFAS No. 144 will not have a material impact on the Company's financial position or results of operations.

#### **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, warrants and redeemable convertible preferred stock and convertible notes 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.

#### **Unaudited Pro Forma Net Loss Per Share**

Unaudited pro forma net loss per share is computed using the weighted average number of common shares outstanding, including the pro forma effects of automatic conversion of all outstanding redeemable convertible preferred stock and accrued dividends and convertible notes and accrued interest through the balance sheet date into shares of the Company's common stock effective upon the closing of the Company's initial public offering, as if such conversion had occurred at the date of original issuance.

#### **Segments**

The Company is focused on the acquisition, development and commercialization of late-stage development drugs and drugs approved for marketing. The Company has license rights to three potential products, Angiomax, CTV-05 and IS-159. The Company manages its business and operations as one segment. The only revenues reported to date are from the sales of the Company's Angiomax product.

### **3. Management's Plans and Financing**

The Company has incurred substantial losses since inception. 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 management 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.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 2001

Should revenue growth or additional debt or equity financing or collaborative partnering arrangements be unavailable to the Company, management will restrict certain of the Company's planned activities and operations, as necessary, to sustain operations and conserve cash resources.

**4. Fixed Assets**

Fixed assets consist of the following:

	Estimated Life (Years)	December 31,	
		2000	2001
Furniture, fixtures and equipment	3	\$ 547,748	\$ 675,482
Computer hardware and software	3	728,333	1,314,358
Leasehold improvements	5	243,060	250,585
		1,519,141	2,240,425
Less: Accumulated depreciation		(553,309)	(1,016,897)
		\$ 965,832	\$ 1,223,528

Depreciation expense was approximately \$208,000, \$277,000 and \$471,000 for the years ended December 31, 1999, 2000 and 2001, respectively.

**5. Accrued Expenses**

Accrued expenses consist of the following at December 31:

	2000	2001
Development services	\$5,998,117	\$3,394,720
Sales & marketing	1,106,119	2,202,632
Other	2,032,698	2,377,121
	\$9,136,934	\$7,974,473

**6. Convertible Notes**

In October 1999, the Company issued \$6,000,000 of 8% Convertible Notes (the October Notes) and 1,013,877 Common Stock Purchase Warrants (the October Warrants) to existing investors, raising proceeds of \$6,000,000. The October Notes were convertible into shares of stock of the Company upon a subsequent sale of stock of the Company provided that such sale resulted in aggregate gross proceeds of at least \$6,000,000. Each October 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 October 19, 2004. The Company recorded \$325,355 as the fair value of the October Warrants using the Black-Scholes method and the estimated fair value of the Company's Common Stock on the date of the issuance of the October warrants, and \$5,674,645 as the value of the October Notes on the issuance date. The discount on the October Notes was amortized to interest expense over the expected term of the October Notes to June 2000. Since the October Notes were issued in October 1999, the carrying amount at December 31, 1999 approximated their fair value at December 31, 1999. Upon completion of the

Company's sale of Series IV Preferred Stock in May 2000, the principal and accrued interest on the October Notes was converted into 1,393,909 shares of Series IV Preferred Stock.

In March 2000, the Company issued \$13,348,779 of 8% Convertible Notes (the March Notes) and 2,255,687 Common Stock Purchase Warrants (the March Warrants) to current stockholders, raising proceeds of \$13,348,779. The March Notes were convertible into shares of stock of the Company upon a subsequent private sale of stock of the Company provided that such sale resulted in aggregate gross proceeds of at least \$6,000,000. 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. The Company recorded approximately \$18,800,000 as the value of the March Warrants using the Black-Scholes method and the estimated fair value of the Company's Common Stock on the date of the issuance of the March warrants. The discount on the March Notes was amortized over the expected term of the Notes to June 2000. For the year ended December 31, 2000, amortization of the discount was approximately \$18,800,000 and is included with the interest expense in the accompanying financial statements. Upon completion of the Company's sale of Series IV Preferred Stock in May 2000, the principal and accrued interest on the Notes was converted into 3,141,457 shares of Series IV Preferred stock.

**7. Redeemable Preferred Stock and Stockholders' Equity**

On June 29, 2000, the Company's Board of Directors approved a reverse split of .73 shares for every one share of Common Stock then outstanding. The reverse stock split became effective on August 4, 2000. The accompanying financial statements and footnotes including all share and per share amounts reflect the reverse stock split.

**Series I, Series II, Series III and Series IV Redeemable Convertible Preferred Stock**

During 1999 and 2000, the Company had designated four series of redeemable convertible preferred stock. A brief summary of the Series I, Series II, Series III and Series IV Redeemable Convertible Preferred Stock follows. At December 31, 2000 and 2001, there was no Redeemable Preferred Stock outstanding.

In August 1998, the Company executed an agreement (the "Exchange Agreement") under which 8,892,912 shares of Common Stock and 41,992 shares of Series A Redeemable Preferred Stock were exchanged for 2,506,000 shares of Series I Redeemable Convertible Preferred Stock and 10,565,714 shares of Series II Redeemable Convertible Preferred Stock. Holders of Series A Redeemable Preferred Stock were entitled to receive preferential cumulative annual dividends payable in additional shares of Series A Redeemable Preferred Stock at the rate of 7% per annum of the stated value. Prior to the Exchange Agreement, dividends earned from January 1, 1998

through the date of the Exchange Agreement were paid to the holders of Series A Redeemable Preferred Stock. During 1997, certain preferred shareholders waived their right to a portion of earned dividends and the Company paid agreed-upon amounts through December 31, 1997. To the extent that all or any part of the Stock would have resulted in the issuance of a fractional share of the Series A Preferred stock, the amount of such fraction, multiplied by the stated value, was paid in cash.

On May 17, 2000, the Company issued 1,411,000 shares of Series IV Redeemable Convertible Preferred Stock for net proceeds of \$6,095,520. In addition, on May 17, 2000, the October and March Notes and accrued interest were converted into 4,535,366 shares of Series IV Redeemable Convertible Preferred Stock. The Series IV Preferred Stock carried terms and conditions similar to the Series I, II, III Preferred Stock. The Series IV Preferred Stock was convertible into Common Stock at a 1-for-0.73 conversion rate and automatically converted upon the closing of the Company's initial public offering (IPO). The Series IV Redeemable Convertible Preferred Stock issued on May 17, 2000 contained a beneficial conversion feature based on the estimated fair market value of common stock into which it is convertible. In accordance with EITF 98-5, the total amount of such beneficial conversion is approximately \$25,450,000. The beneficial conversion is analogous to a dividend and was recognized during 2000 when issued. Simultaneously with the closing of the Company's IPO, 30,659,957 shares of the Series I, II, III and IV Redeemable Convertible Preferred Stock then outstanding (including accrued dividends for the period August 1, 2000 to August 11, 2000) were converted into 22,381,735 shares of Common Stock.

#### **Common Stock**

Common Stockholders are entitled to one vote per share and dividends when declared by the Board of Directors, subject to the preferential rights of preferred stockholders.

In its IPO on August 11, 2000, the Company sold 6,000,000 shares of its common stock at a price of \$16.00 per share. In addition, on September 8, 2000, the underwriters of the IPO exercised their over-allotment option and purchased an additional 900,000 shares of Common Stock at a price of \$16.00 per share. The Company received proceeds of approximately \$101.4 million, net of underwriting discounts and commissions, and expenses. Simultaneously with the closing of the IPO, 30,659,957 shares of Redeemable Convertible Preferred Stock then outstanding (including accrued dividends for the period August 1, 2000 to August 11, 2000) were converted into 22,381,735 shares of Common 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.

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 1999, 2000 and 2001, the Company repurchased 56,378, 22,205 and 11,239 shares, respectively, of unvested Common Stock for \$0.001 per share. There were 1,672 shares of Common Stock unvested at December 31, 2001.

#### **Stock Plans**

In April 1998, the Company adopted the 1998 Stock Incentive Plan (the "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 plan generally vest in increments over four years.

In January 2000, the Board of Directors approved an amendment to the Plan to increase the number of shares available under the Plan to 1,448,259. In May 2000, the Board of Directors approved an amendment to the Plan to increase the number of shares available under the Plan to 4,368,259. In addition, the Board of Directors also approved the 2000 Employee Stock Purchase Plan 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 Employee Stock Purchase Plan 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 Company's Common Stock in its good faith judgment at each option grant date for grants under the Plan considering a number of factors including the financial and operating performance of the company, recent transactions in the Company's Common and Preferred Stock,



NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 2001

if any, the values of similarly situated companies and the lack of marketability of the Company's Common Stock. Following the Company's IPO, the fair value is determined based on the traded value of the Company's 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 Company's Common Stock as of the date of grant of such options based on the price of the Company's Common Stock in connection with the Company's 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, 2000 and 2001 is compensation expense of approximately \$3.7 million and \$4.1 million, respectively, associated with such options.

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. Had compensation costs for the Plan been determined based on the fair value at the grant dates as calculated in accordance with SFAS 123, the Company's net loss for the year ended December 31, 1999, 2000 and 2001 would have been increased to the pro forma amounts indicated below.

	Years Ended December 31,		
	1999	2000	2001
Net loss attributable to common stockholders—			
As reported	\$40,605,911	\$101,635,158	\$54,883,648
Net loss attributable to common stockholders—			
Pro forma	\$40,771,828	\$106,150,604	\$65,806,800
Net loss per share attributable to common stockholders—			
As reported	\$ (80.08)	\$ (8.43)	\$ (1.67)
Net loss per share attributable to common stockholders—			
Pro forma	\$ (80.41)	\$ (8.80)	\$ (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 Ended December 31,		
	1999	2000	2001
Expected dividend yield	0%	0%	0%
Expected stock price volatility	70%	70%	96%
Risk-free interest rate	5.45%	6.32%	4.0%
Expected option term	3.30 years	3.35 years	3.34 years

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

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding, December 31, 1998	705,271	\$ 1.12
Granted	239,075	1.23
Canceled	(175,380)	1.05
Outstanding, December 31, 1999	768,966	\$ 1.16
Granted	3,080,424	9.80
Exercised	(227,523)	1.26
Canceled	(406,713)	1.22
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
<b>Outstanding, December 31, 2001</b>	<b>4,759,950</b>	<b>\$10.16</b>
Available for future grant at December 31, 2001	662,631	

The weighted average per share fair value of options granted during 1999, 2000 and 2001 was \$0.62, \$10.34 and \$7.17, respectively. There were no options granted during 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 \$13.19 and \$24.96, respectively, during 2000 and \$7.17 and \$11.25, respectively during 2001.

The following table summarizes information about stock options from all the Company's plans outstanding at December 31, 2001:

Range of Exercise Prices Per Share	Options Outstanding		Options Vested	
	Number Outstanding at 12/31/01	Weighted Average Remaining Contractual Life (Years)	Number Outstanding at 12/31/01	Weighted Average Exercise Price Per Share
\$ 0.69-\$ 4.79	1,528,931	8.10	748,270	\$ 3.01
\$ 5.90-\$ 9.50	1,067,120	9.17	221,979	5.91
\$10.11-\$14.88	1,220,775	9.46	90,188	12.78
\$15.00-\$18.10	278,200	9.18	30,833	17.45
\$21.50-\$30.63	664,924	8.92	182,929	25.06
	4,759,950	8.87	1,274,199	\$ 7.72

### Common Stock Reserved for Future Issuance

At December 31, 2001, there were 9,047,113 shares of common stock reserved for future issuance under the Employee Stock Purchase Plan, for conversion of the Common Stock Warrants and for grants made under the 1998 Stock Incentive Plan, the 2001 Non-Officer, Non-Director Employee Stock Incentive Plan and the 2000 Director Stock Option Plan.

### 8. Net Loss and Unaudited Pro Forma Net Loss Per Share

The following table sets forth the computation of basic and diluted, and unaudited pro forma basic and diluted net loss per share for the respective periods. The unaudited pro forma basic and diluted net loss per share for 1999 and 2000 gives effect to the conversion of the redeemable convertible preferred stock and the convertible notes and accrued interest as if converted at the date of original issuance.

	Year Ended December 31,		
	1999	2000	2001
Basic and Diluted			
Net loss	\$(34,712,895)	\$ (71,292,170)	<b>\$(54,883,648)</b>
Dividends and accretion on redeemable convertible preferred stock	(5,893,016)	(30,342,988)	—
Net loss attributable to common stockholders	\$(40,605,911)	\$(101,635,158)	<b>\$(54,883,648)</b>
Weighted average common shares outstanding	850,238	12,225,537	<b>32,987,766</b>
Less: unvested restricted common shares outstanding	(343,173)	(166,262)	<b>(61,798)</b>
Weighted average common shares used to compute net loss per share	507,065	12,059,275	<b>32,925,968</b>
Basic and diluted net loss per share	\$ (80.08)	\$ (8.43)	<b>\$ (1.67)</b>
	Year Ended December 31,		
	1999	2000	2001
Unaudited Pro Forma Basic and Diluted			
Net loss	\$(34,712,895)	\$(71,292,170)	<b>\$(54,883,648)</b>
Interest expense on convertible notes	197,455	19,390,414	—
Net loss used to compute pro forma net loss per share	\$(34,515,440)	\$(51,901,756)	<b>\$(54,883,648)</b>
Weighted average common shares used to compute net loss per share	507,065	12,059,275	<b>32,925,968</b>
Weighted average number of common shares assuming the conversion of all redeemable convertible preferred stock and convertible notes and accrued interest at the date of original issuance	17,292,811	12,659,800	—
Weighted average common shares used to compute pro forma net loss per share	17,799,876	24,719,075	<b>32,925,968</b>
Unaudited pro forma basic and diluted pro forma net loss per share	\$ (1.94)	\$ (2.10)	<b>\$ (1.67)</b>

Options to purchase 768,966, 3,215,154 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, 1999, 2000 and 2001, respectively, as their effects would have been antidilutive. Warrants to purchase 1,013,877, 3,269,564 and 3,156,073 shares of common stock were excluded from the computation of diluted net loss per share for the years ended December 31, 1999, 2000 and 2001, respectively, as their effect would be antidilutive.

### 9. Income Taxes

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

	December 31,	
	2000	2001
Deferred tax assets:		
Net operating loss carryforwards	\$ 48,494,000	<b>\$ 68,689,000</b>
Research and development credit	3,576,000	<b>5,062,000</b>
Intangible assets	1,233,000	<b>998,000</b>
Other	86,000	<b>491,000</b>
	53,389,000	<b>75,240,000</b>
Valuation allowance	(53,389,000)	<b>(75,240,000)</b>
Net deferred tax assets	\$ —	<b>\$ —</b>

The Company has increased its valuation allowance by \$21,851,000 in 2001 to provide a full valuation allowance for deferred tax assets since the realization of these future benefits is not considered more likely than not. The amount of the deferred tax asset considered realizable is subject to change based on estimates of future taxable income during the carry-forward 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 will assess the need for the valuation allowance at each balance sheet date based on all available evidence.

At December 31, 2001, 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	Federal Net Operating Loss Carryforwards	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	33,800,000	1,000,000
2020	45,335,000	1,176,000
2021	49,700,000	1,000,000
	<b>\$172,900,000</b>	<b>\$4,150,000</b>

For state tax purposes, net operating loss carryforwards of approximately \$165,000,000 expire in the years 2002



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 2001

through 2005. State research and development tax credit carryforwards are approximately \$900,000.

## 10. License Agreements

### Angiomax

In March 1997, the Company entered into an agreement with Biogen, Inc. for the license of the anticoagulant pharmaceutical bivalirudin (now known 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 million on the closing date and is obligated to pay up to an additional \$8 million upon reaching certain Angiomax sales milestones, including the first commercial sale of Angiomax for the treatment of AMI in the United States and Europe. In addition, the Company will pay royalties on future sales of Angiomax and on any sublicense royalties 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 right in such country. 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 met in 1998. The license and rights under the agreement remain in force until the Company's obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and the Company may terminate the agreement for any reason upon 90 days prior written notice. During 2001, the Company recognized royalty expense under the agreement of \$1.1 million for Angiomax sales.

### CTV-05

In August 1999, the Company entered into an agreement with Gynelogix, Inc. for the license of the biotherapeutic agent CTV-05, a strain of human lactobacillus currently under clinical investigation for applications in the areas of urogenital and reproductive health. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the patents and know-how related to CTV-05. In exchange for the license, the Company has paid \$400,000 and is obligated to pay an additional \$100,000 upon reaching certain development and regulatory milestones. The Company and Gynelogix have mutually agreed to extend the development activities of CTV-05 at a reduced level of effort through January 2003. In addition, the Company is obligated to pay royalties on future sales of CTV-05 and on any sublicense royalties earned until the date on which the product is no longer covered by a valid claim of the licensed patent rights in a country. The agreement also stipulates that the Company must use commercially reasonable efforts in pursuing the development, commercialization and

marketing of CTV-05 to maintain the license. The license and rights under the agreement remain in force until the Company's obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and may terminate the agreement for any reason upon 60 days prior written notice.

### IS-159

In July 1998, the Company entered into an agreement with Immunotech S.A. for the license of the pharmaceutical IS-159 for the treatment of acute migraine headache. Under the terms of the agreement, the Company acquired exclusive worldwide rights to the patents and know-how related to IS-159. In exchange for the license, the Company paid \$1 million on the closing date and is obligated to pay up to an additional \$4.5 million upon reaching certain development and regulatory milestones. In addition, the Company will pay royalties on future sales of IS-159 and on any sublicense royalties earned until the date on which the product is no longer covered by a valid claim of the licensed patent rights in a country. The agreement also stipulates that the Company must use commercially reasonable efforts in pursuing the development, commercialization and marketing of IS-159 and meet certain development and regulatory milestones to maintain the license. The licenses and rights under the agreement remain in force until the Company's obligation to pay royalties ceases. Either party may terminate the agreement for material breach, and the Company may terminate the agreement for any reason upon 60 days prior written notice.

## 11. Strategic Alliances

### UCB

In December 1999, the Company entered into a commercial supply agreement with UCB-Bioproducts S.A. (UCB) to develop and supply 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. During 2000 and 2001, expenses incurred for such services were approximately \$560,000 and \$4.8 million, respectively, of which approximately \$789,000 was recorded in accounts payable and accrued expenses at December 31, 2000. There were no outstanding balances recorded in accounts payable and accrued expenses at December 31, 2001. In addition, the Company has agreed to purchase Angiomax bulk drug product exclusively 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 1999, the Company placed an order with UCB Bioproducts for the manufacture of Angiomax bulk drug product. During 2000, UCB manufactured \$14.2 million of this material, of which \$12.2 million was expended during the period. All costs associated with the manufacture of Angiomax bulk drug product and finished products to which title was transferred to the Company prior to the date of FDA approval of Angiomax were expensed as research and development. The Company recorded any Angiomax bulk drug product to which title transferred after the date of FDA approval of Angiomax as inventory. In November 2000, the Company placed additional orders with UCB Bioproducts for the manufacture of Angiomax bulk drug product. Under the terms of these orders, the Company took title to material for a total of \$14.5 million in 2001 and for \$2.9 million in January 2002.

The Company has ordered commercial supplies of Angiomax bulk drug substance produced by the Chemilog process for a total of \$5.3 million to be delivered in 2002 and 2003.

#### **Lonza**

In September 1997, the Company entered into an agreement with Lonza AG (Lonza) for the development of a new commercial manufacturing process for an advanced intermediate compound used in the manufacturing of Angiomax (Angiomax intermediate). In November 1998, the Company entered into an additional agreement with Lonza for the engineering, procurement and installation of equipment for the initial manufacturing of the Angiomax intermediate using the new process. The agreement also contemplated the purchase of the Angiomax intermediate from Lonza at specified prices for an anticipated two-year period following initial production and stipulated the basic principles of a long-term commercial supply contract. In January 2000, the Company notified Lonza of its intention to terminate the agreement. As a result of the termination, the Company retained certain ownership rights to intellectual property and was responsible for reimbursement of all costs incurred under the terms of the agreement through the date of notice. There were no outstanding obligations to Lonza at December 31, 2000 and 2001.

#### **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 our products, including clinical and non-clinical development services, project management, project implementation, pharmacoeconomic services, regulatory affairs and post marketing surveillance services and statistical, statistical programming, data processing and data management services pursuant to work orders agreed to by the Company and PharmaBio from time to time. Through December 31, 2001, the Company has entered into approximately 45 work orders with PharmaBio and has paid PharmaBio a total of \$13.4 million. During 1999, 2000 and 2001, expenses incurred for such services were approximately \$3.7 million, \$2.3 million and \$2.3 million, respectively, of which approximately \$813,000 and \$229,000 was recorded in accounts payable and accrued expenses at December 31, 2000 and 2001, respectively. In addition, at December 31, 2001, the Company had open work orders with PharmaBio for such services that reflect estimated aggregate future payments of approximately \$581,000.

#### **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 provides 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 has paid Innovex \$1.8 million 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



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

December 31, 2001

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 any 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, 2001, the Company has paid Innovex \$6.8 million under the master services agreement and work order.

During 1999, 2000 and 2001, total expenses incurred for services provided by Innovex were approximately \$616,000, \$1.7 million and \$5.6 million, respectively, of which approximately \$280,000, \$440,000 and \$275,000 were recorded in accounts payable and accrued expenses at December 31, 1999, 2000 and 2001, respectively.

**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 services under a 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. There was no outstanding obligation to SPI at December 31, 2001.

**12. Commitments and Contingencies**

The Company leases its facilities in Cambridge, Massachusetts and Parsippany, New Jersey and certain office furniture and equipment at those facilities under operating leases. The leases for the Cambridge and Parsippany facilities expire in August 2003 and September 2005, respectively. As part of the termination agreement with SPI, the Company assumed the facilities lease in Parsippany. Future annual minimum payments under all non-cancelable operating leases are \$669,000, \$502,000, \$282,000 and \$177,000 in 2002, 2003, 2004 and 2005, respectively. Rent expense was approximately \$442,000, \$504,000 and \$634,000 in 1999, 2000 and 2001, respectively.

The Company is involved in ordinary and routine matters and litigation incidental to its business. There are no such matters pending that the Company expects to be material in relation to its financial condition or results of operations.

**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, 2000 and 2001.

	Three Months Ended							
	Mar. 31, 2000	June 30, 2000	Sept. 30, 2000	Dec. 31, 2000	Mar. 31, 2001	June 30, 2001	Sept. 30, 2001	Dec. 31, 2001
In thousands, except per share data								
Net revenue	\$ —	\$ —	\$ —	\$ —	\$ 1,861	\$ 2,048	\$ 3,526	\$ 6,813
Total operating expenses	11,840	8,706	10,297	23,763	21,987	18,196	15,623	15,639
Net loss	(19,243)	(20,408)	(9,459)	(22,182)	(19,056)	(16,003)	(11,309)	(8,516)
Net loss attributable to common stockholders	(20,773)	(47,596)	(11,083)	(22,182)	(19,056)	(16,003)	(11,309)	(8,516)
Basic and diluted net loss attributable to common stockholders per common share	\$ (32.91)	\$ (68.65)	\$ (0.67)	\$ (0.74)	\$ (0.63)	\$ (0.49)	\$ (0.33)	\$ (0.25)
Pro forma basic and diluted net loss attributable to common stockholders per common share	(0.55)	(0.38)	(0.34)	(0.74)	(0.63)	(0.49)	(0.33)	(0.25)

The increasing level of revenues in each subsequent quarter of 2001 of the Company's first commercial product, Angiomax, began with the launch of the product in the first quarter of 2001. The higher gross margins from those revenues were attributed to the expensing in 2000 of all bulk drug substance received prior to FDA approval as research and development costs. Higher selling, general and administrative expenses associated with the commercial launch of Angiomax starting in the fourth quarter of 2000 continued throughout 2001, but were partly offset by lower development costs in 2001 associated with completion of the HERO-2 trial in AMI and with lower manufacturing development costs in 2001. Net losses and net losses attributed to common stockholders in each subsequent quarter of 2001 were favorably impacted by the increases in sales, lower development costs, and to lower interest expense related to the amortization of the discount of convertible notes that were converted in the first half of 2000. In the second quarter of 2000, the higher net loss attributed to common stockholders related to the recording of a dividend from the beneficial conversion associated with the issuance of convertible preferred stock in prior periods.

#### **15. Subsequent Events**

On March 6, 2002, the Company entered into an agreement with AstraZeneca PLC for the licensing, development and commercialization of clevidipine, an intravenous, short-acting calcium channel blocker. Clevidipine will be developed in Phase 3 by the Company for the short-term control of high blood pressure in the hospital setting. AstraZeneca has completed clinical pharmacology, dose-finding and efficacy studies that demonstrate that clevidipine has a short duration of action, a short plasma half life, and a selective effect on blood pressure. The agreement covers all worldwide territories except Japan. The Company will perform further clinical development and has the right to commercialize the product in all other territories worldwide including the United States.

On March 25, 2002, the Company entered into a collaboration with Nycomed Danmark A/S, a European pharmaceutical company, to be the exclusive distributor of Angiomax (bivalirudin) in 35 countries. The agreement includes European and other countries. Nycomed will exclusively market and distribute Angiomax within the territory. Nycomed will pay an initial fee of \$1.5 million with up to \$2.5 million in additional milestones based on regulatory approval in Europe. In addition, Nycomed purchased 79,428 shares of the Company's common stock for a total purchase price of approximately \$1.0 million. The Company and Nycomed will work together to achieve regulatory approval in the countries covered by the agreement and share costs of clinical trials used to extend indications in Europe beyond coronary angioplasty.

On March 26, 2002, the Company signed a Loan and Security agreement with Comerica Bank—California providing for borrowings of up to \$10 million. Amounts outstanding under the agreement are collateralized by all of the Company's personal property. In order to draw on the facility, and while borrowings are outstanding, the Company must satisfy certain covenants, including covenants related to cash, working capital and revenues. The borrowings will be used to support working capital needs. As of March 29, 2002, the Company had drawn down the full \$10.0 million under the agreement.



THE MEDICINES COMPANY

## 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, 2000 and 2001, and the related consolidated statements of operations, redeemable preferred stock and stockholders' equity (deficit), and cash flows, for each of the three years in the period ending December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements 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, 2000 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 2 to the financial statements, in 2001 the Company changed its method of accounting for derivatives in accordance with Statement of Financial Accounting Standards No. 133.

Boston, Massachusetts

February 8, 2002, except for Note 15, as to which the dates are March 6, March 25, March 26 and March 29, 2002

# C O R P O R A T E I N F O R M A T I O N

## Officers and Directors

Clive A. Meanwell, M.D., Ph.D.  
*Executive Chairman and Director*

David M. Stack  
*Chief Executive Officer, President and Director*

Steven H. Koehler  
*Vice President and Chief Financial Officer*

John M. Nystrom, Ph.D.  
*Vice President and Chief Technical Officer*

Gary Dickinson  
*Vice President*

David C. Mitchell  
*Vice President*

John D. Richards, D.Phil.  
*Vice President*

Fred M. Ryan, M.B.A.  
*Vice President*

Peter Teuber, Ph.D.  
*Vice President*

John W. Villiger, Ph.D.  
*Vice President*

Leonard Bell, M.D.  
*Chief Executive Officer*  
*Alexion Pharmaceuticals, Inc.*

Stewart J. Hen, M.B.A., M.S.  
*Vice President*  
*Warburg Pincus LLC*

M. Fazle Husain, M.B.A.  
*Executive Director*  
*Morgan Stanley & Co. Incorporated*

T. Scott Johnson, M.D.  
*Partner and Co-Founder*  
*JSB Partners L.P.*

Armin M. Kessler, Dh.c.  
*Former Chief Operating Officer and*  
*Head of the Pharmaceutical Division*  
*Hoffmann-LaRoche, Inc.*

Nicholas J. Lowcock, M.B.A.  
*Managing Director*  
*Warburg Pincus LLC*

James E. Thomas, M.Sc.  
*Managing Partner*  
*Thomas, McNerney & Partners, LLC*

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(800) 288-9541

## Independent Auditors

Ernst & Young LLP  
200 Clarendon Street  
Boston, MA 02116  
(617) 266-2000

## Corporate Counsel

Hale and Dorr LLP  
60 State Street  
Boston, MA 02109

## Annual Meeting

The Annual Meeting of Stockholders will take place on May 30, 2002 at the offices of Hale and Dorr LLP.

A formal notice of the meeting, along with a proxy statement and a form of proxy, is being mailed to each stockholder with this annual report.

## Investor Relations

Call (617) 225-9099 or email  
investor.relations@themedco.com



## Form 10-K

The Medicines Company welcomes inquiries from its stockholders and other interested investors. To obtain a free copy of the Company's 2001 Annual Report on Form 10-K filed with the Securities and Exchange Commission, please send your request to:

Investor Relations  
The Medicines Company  
One Cambridge Center  
Cambridge, MA 02142  
(617) 225-9099

## Stock Information

The total number of registered holders of The Medicines Company's common stock as of April 15, 2002 was 241. The Company believes the number of beneficial stockholders is in excess of 4,500.

The following table sets forth, for the periods indicated, the high and low intraday sales prices per share, as quoted by Nasdaq, of the Company's common stock.

2000	HIGH	LOW
Fourth Quarter	\$34.75	\$17.13
2001		
First Quarter	\$20.48	\$ 8.75
Second Quarter	\$22.05	\$ 9.10
Third Quarter	\$22.20	\$ 4.52
Fourth Quarter	\$12.15	\$ 4.81
2002		
First Quarter	\$14.81	\$ 9.86

The Medicines Company has never declared or paid cash dividends on the Company's common stock. The Company anticipates that it will retain all future earnings, if any, for use in the expansion and operation of its business and does not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of the Company's Board of Directors. In addition, covenants in our loan and security agreement impose restrictions on the Company's ability to pay dividends.

We own or have rights to various trademarks and trade names used in our business, including The Medicines Company name and logo and Angiomax®.

*\*When used in this report, the words "believes," "anticipates," "plans," "expects," "intends," "may" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause the Company's actual results to differ materially from those indicated by the forward-looking statements contained in this report. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of April 29, 2002. The Company undertakes no obligation to republish revised forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Readers are also urged to review carefully and consider the various disclosures made by the Company that attempt to advise interested parties of the factors that affect the Company's business, including the disclosures made under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors Which May Affect Future Results" in this report, as well as the Company's periodic reports on Forms 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission from time to time.*



THE **MEDICINES** COMPANY

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