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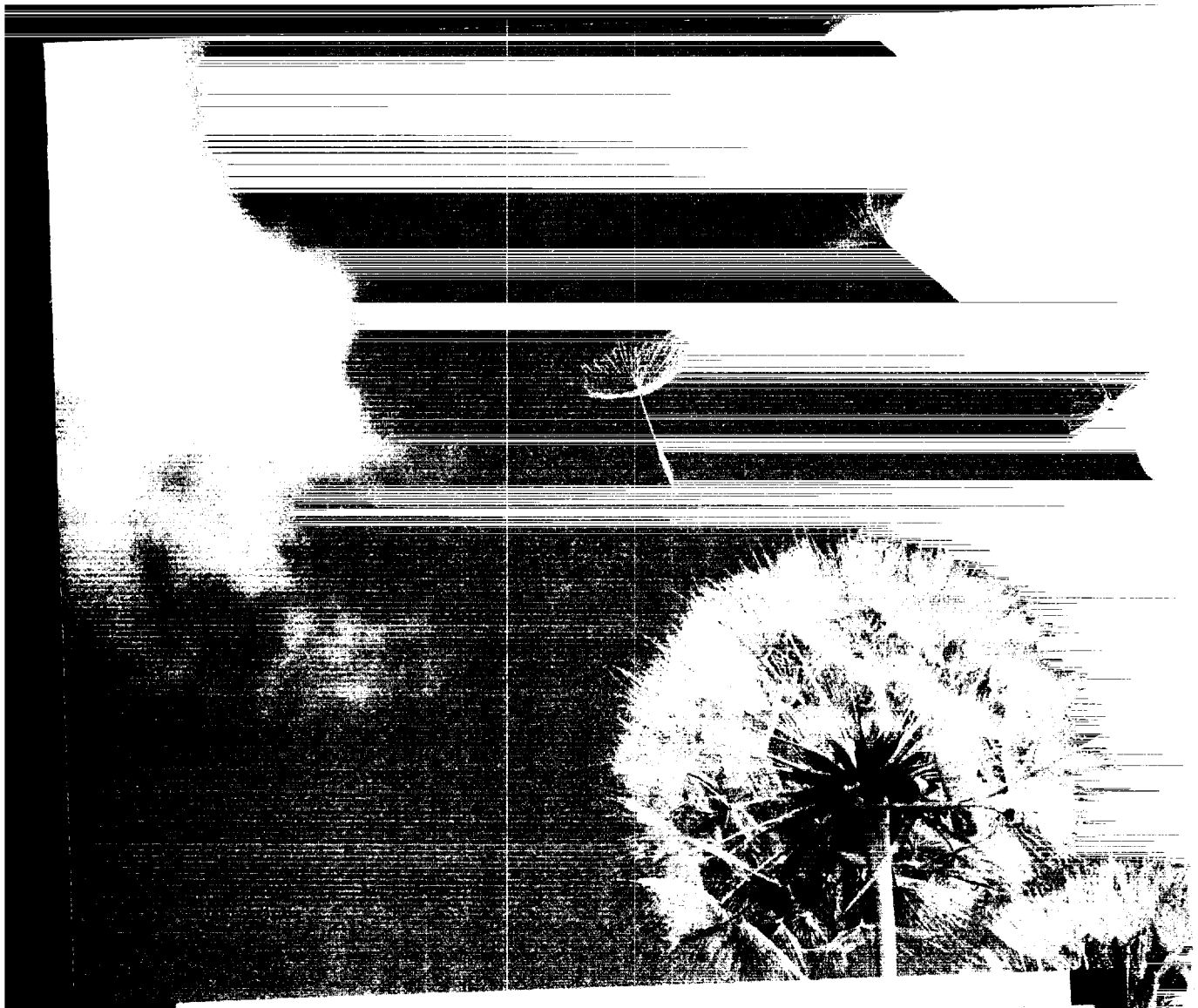
ImClone Systems Incorporated

Annual Report 2004

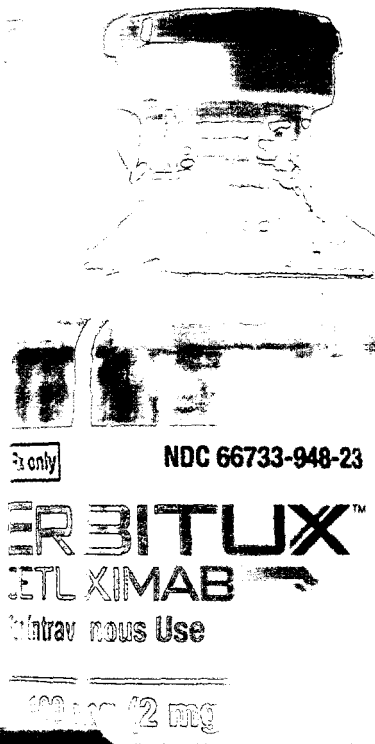


ImClone Systems is dedicated to developing and commercializing novel therapeutic products in the field of oncology. Our efforts have resulted in a broad spectrum of innovative product candidates with potential application in multiple tumor types. As a member of the oncology community, we are committed to providing treatments to meet the unmet needs of cancer patients. To fulfill this commitment, ImClone Systems fosters integration of the principles of teamwork and scientific integrity into all facets of the Company's activities. We believe that these values will benefit patients, physicians, and our employees while creating value for our shareholders.

CHAPTER

DEAR SHAREHOLDER

This past year was a landmark year for ImClone Systems. On February 12, 2004, the U.S. Food and Drug Administration approved our first therapeutic oncology product, Erbitux®. Today, thousands of patients with metastatic colorectal cancer – among the deadliest cancers – are being treated with Erbitux, which is now commercially available in over 30 countries.

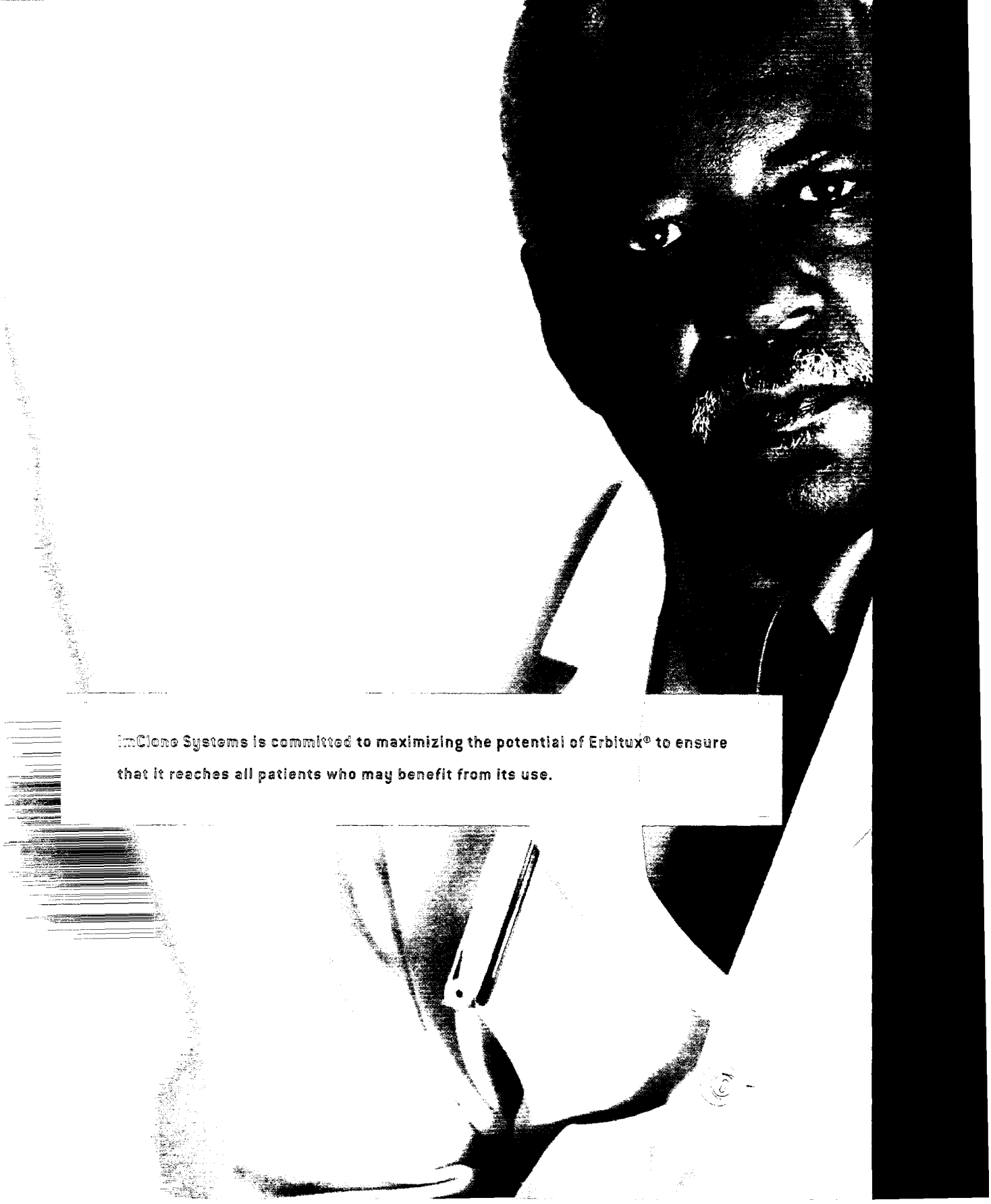


Erbitux® is approved for two uses in patients with EGFR-expressing, metastatic colorectal cancer: 1) in combination with irinotecan in patients refractory to irinotecan-based chemotherapy and 2) as a single agent in patients intolerant to irinotecan-based chemotherapy.*

FINANCIAL STRENGTH AND PROFITABILITY

This accomplishment set in motion a year of transformation, growth and profitability for the Company. Thanks to the economics of our partnership with Bristol-Myers Squibb and a successful product launch, we were able to achieve profitability in the quarter in which we launched Erbitux and for the full year of 2004. For a company in our position, having reported losses in every year of the Company's twenty-year history, this rapid transition to profitability was a rare accomplishment among our biotechnology peers. We were also able to significantly improve our balance sheet over the year, earning a $250 million milestone from Bristol-Myers Squibb for the approval of Erbitux, raising $600 million at very favorable terms in a convertible note offering and converting nearly $240 million of debt into equity.

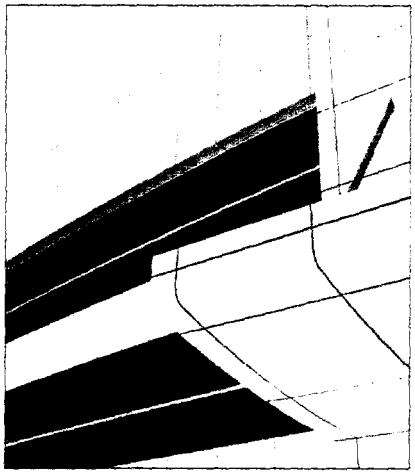
* See package insert at www.erbitux.com for full indication and important safety information



ImClone Systems is committed to maximizing the potential of Erbitux® to ensure that it reaches all patients who may benefit from its use.

A BEGINNING

We have begun to fulfill the promise of our mission to develop and commercialize novel oncology products for the benefit of the oncology community and our employees and investors. And yet our current success is only that: a beginning. With the progress made over the course of this past year and the efforts planned in 2005 and beyond, ImClone Systems' evolution into a mature, fully integrated company continues. In the months and years to come, we intend to leverage our current successes to accomplish even greater goals.



BB36
FDA approved for commercial supply of Erbitux® in 2004

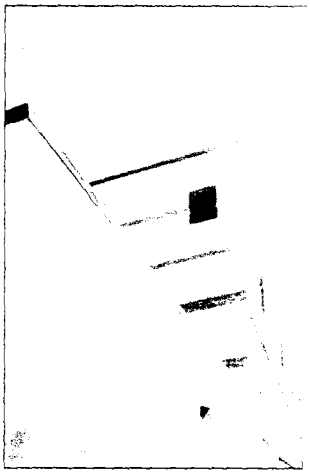
Peak capacity: 2,500,000 doses of Erbitux per annum

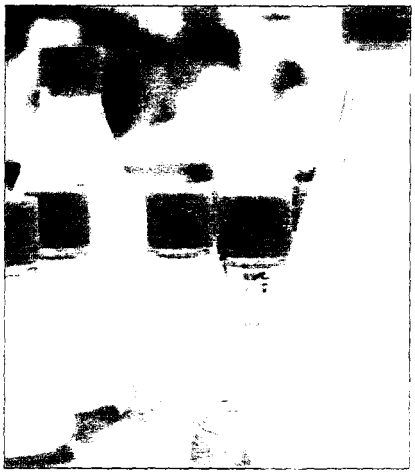
Bioreactor volume: 30,000 liters

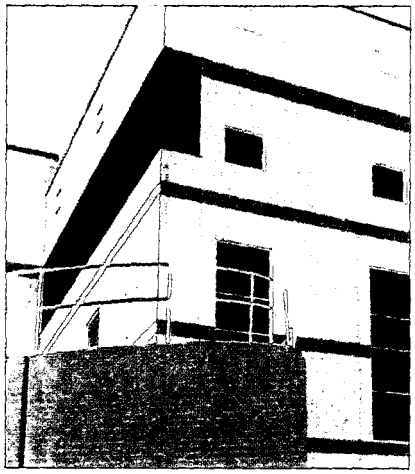
BB50
Multi-product capability

Full bioreactor volume: 110,000 liters

Scheduled mechanical completion: End of 2005

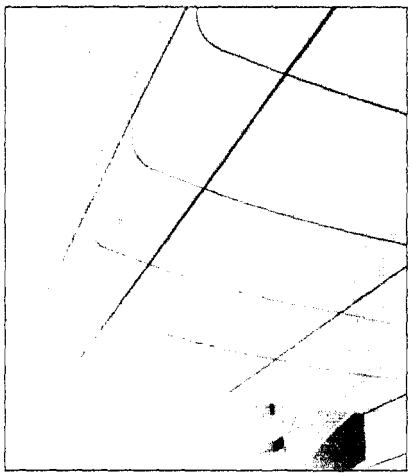
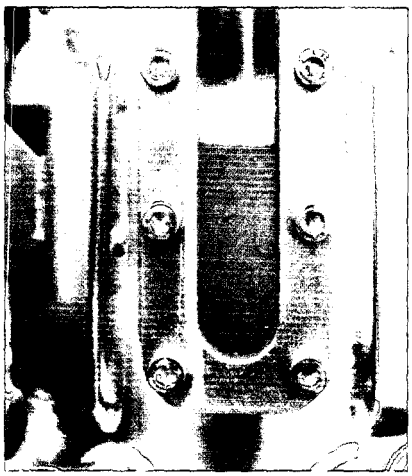
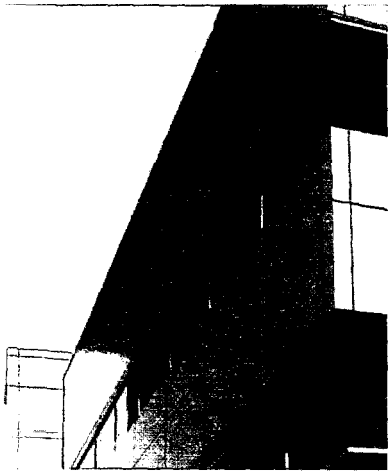


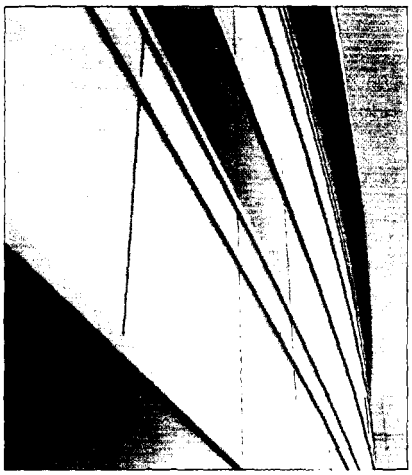




MAXIMIZING ERBITUX®

In the coming year, we expect to invest heavily in maximizing the potential of Erbitux — both from a market perspective, using our newly formed sales organization and the commercial resources of our Erbitux partners, and from a clinical and regulatory perspective, working with our partners Bristol-Myers Squibb and Merck KGaA.



PHYSICAL PLANT

We also plan to invest in our physical plant, which includes process improvements at the BB36 Erbitux manufacturing facility; the completion of our second commercial-scale manufacturing facility, BB50; and the groundbreaking on a new, consolidated research facility in New York City. Lastly, we will continue to invest in people to achieve our near- and long-term goals as an integrated company by adding to our current base of more than 850 employees.

CHAPTER

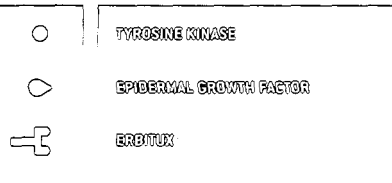
ERBITUX® – A NEW CHAPTER

Erbitux has made rapid and significant market inroads in the later stages of colorectal cancer since its launch last year. In-market sales in 2004, which included less than a full year of shipments, reached over $260 million in the U.S. and over $360 million worldwide, making Erbitux one of the most successful oncology product launches to date. This accomplishment was achieved at a very dynamic time in the colorectal cancer market, as several new therapies were working their way into physicians' treatment regimens.

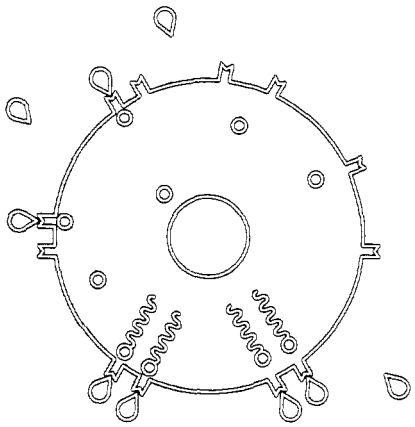
Because of this ongoing evolution in the market, we believe there is significantly greater opportunity for Erbitux use within its approved indications.

To capture this opportunity, this past fall we announced the formation of a sales organization and, by the end of the year, had assembled the full team. This team, comprising 43 sales professionals with an average of at least ten years of sales experience in oncology products, is today working side by side with the Bristol-Myers Squibb sales force, assisting physicians in a new and exciting market environment that is eager to integrate biologics into treatment regimens. These sales forces will work diligently to further the Erbitux commercial strategy, which is to expand our base within our indication in the second-line setting and to capture and ultimately own the growing third line of patients who do not respond to oxaliplatin and irinotecan.

In addition to our sales force, we continue to maintain six Scientific Services Liaisons in the field to further enhance the base of pre-clinical knowledge and studies supporting Erbitux. Beyond its currently indicated use, we believe Erbitux has potential in a number of other settings and, accordingly, have adopted a comprehensive development and regulatory strategy.

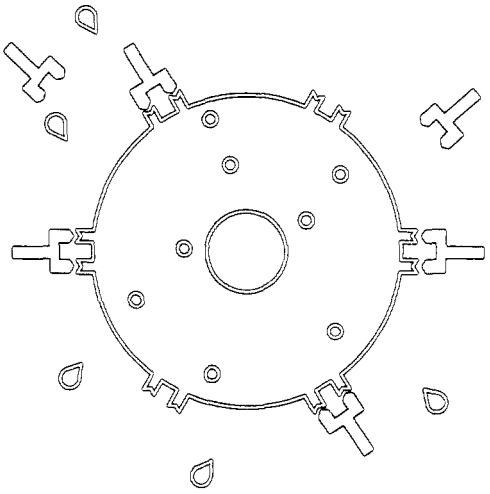


ERBITUX® – MECHANISM OF ACTION

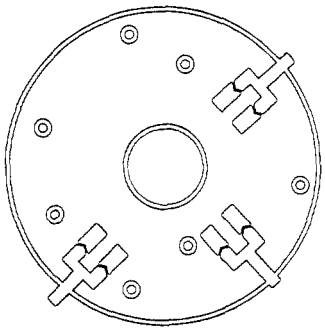


CANCER CELL

- EGF binding causes receptor conformation changes, resulting in receptor dimerization and activation and cell division.



- Erbitux® binding to receptor prevents ligand binding and all subsequent receptor activation steps.



- Erbitux® also leads to the internalization of EGFR, effectively reducing receptor expression on the cell surface and preventing future receptor activation.

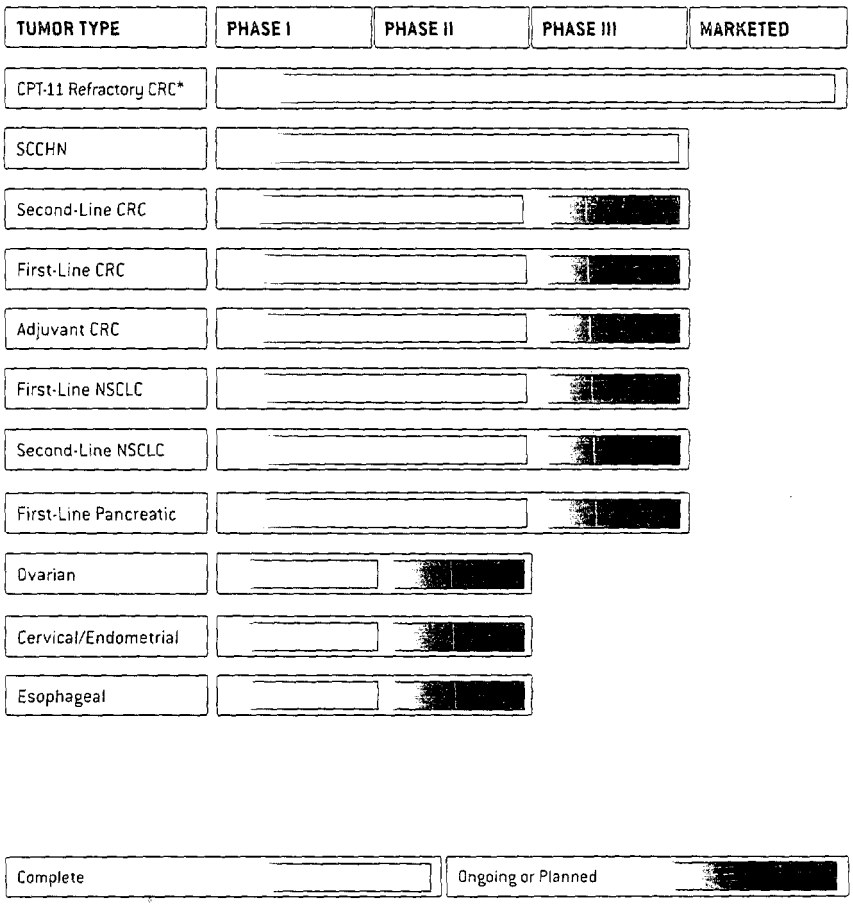
REASON TO BELIEVE

First, in squamous cell carcinoma of the head and neck, we presented a randomized Phase III study which tested the addition of Erbitux to high-dose radiation in 424 patients with locally advanced head and neck cancer at the American Society of Clinical Oncology (ASCO) annual meeting in 2004*. As we announced, the study met both its primary endpoint of locoregional control and its secondary endpoint of overall survival.

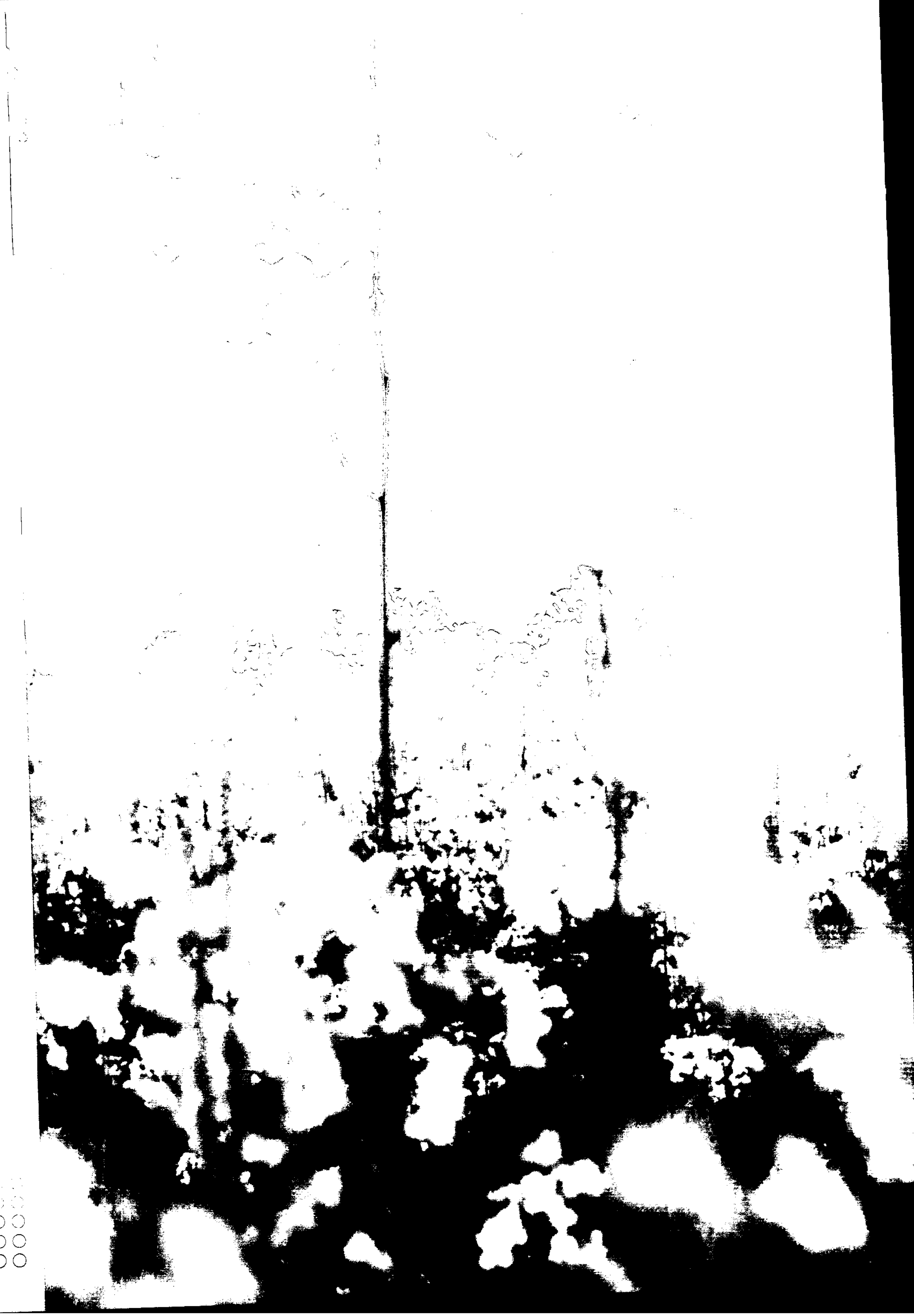
In total, Erbitux has been tested in over 1,000 patients with head and neck cancer, including testing as a single agent in patients refractory to platinum-based chemotherapy. This body of data allowed us to establish a plan with the FDA for the filing of a supplemental Biologics License Application to seek approval for use of Erbitux as a single agent and in combination with radiation in this disease. Because over 40,000 people are diagnosed with head and neck cancer every year in the United States and no new therapies for this disease have been introduced in over a decade, we will request priority review of the submission in order to reach these patients as soon as possible.

* Investigator data. Please see Bonner et al., ASCO 2004.

BECAUSE ERBITUX® IS BEING, OR HAS BEEN, TESTED IN MULTIPLE TUMOR TYPES IN MULTIPLE STAGES OF DISEASE, WE CONSIDER IT A "PIPELINE" OF ITS OWN.

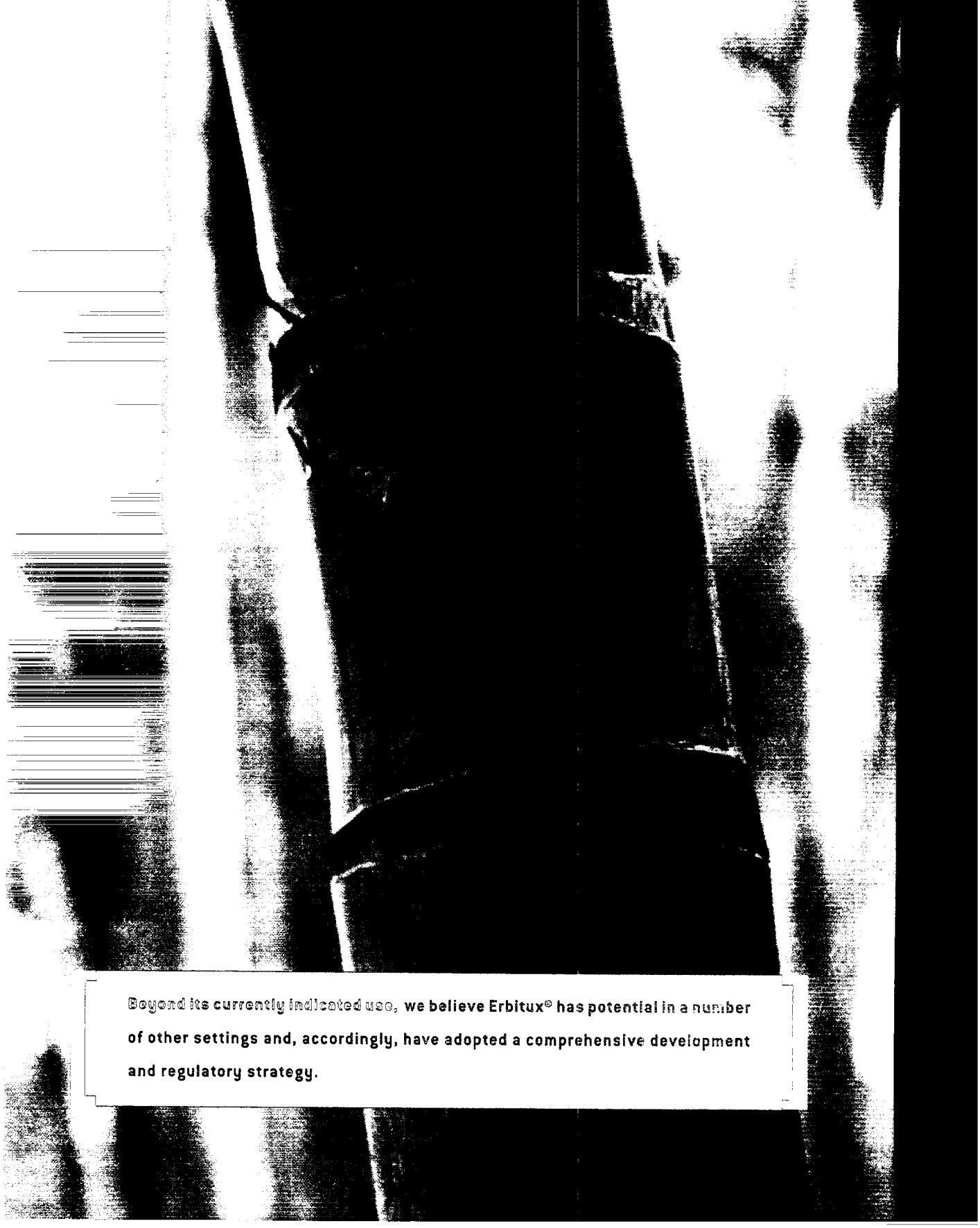


* Erbitux®, used in combination with irinotecan, is indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma patients who are refractory to irinotecan-based chemotherapy. Erbitux, administered as a single agent, is indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma patients who are intolerant to irinotecan-based chemotherapy. For full Erbitux prescribing information, please visit www.erbitux.com.



Second, we continue to explore the potential benefit of Erbitux in earlier-stage colorectal cancer. We have ongoing Phase II and III studies exploring the various combinations of Erbitux and the numerous treatment options in the first- and second-line stages of disease. By the summer of 2005, we anticipate that the National Cancer Institute will have replaced a first-line Phase III trial testing chemotherapy with and without Erbitux with a similar Phase III comparative trial that better reflects the emerging first-line standard of care in colorectal cancer. The replacement study will both compare and combine Erbitux and the anti-angiogenic antibody Avastin® in patients who will also receive chemotherapy. This trial design is particularly compelling, as it will be the first Phase III study of two monoclonal antibodies used in combination with chemotherapy in colorectal cancer and may have a significant impact on future usage of Erbitux. In addition to the first-line studies, Erbitux is also being tested in Phase III studies in the adjuvant and second-line settings.

Next, based on encouraging clinical results from Phase II studies in first- and second-line non-small-cell lung cancer, this past fall we embarked on a comprehensive clinical development program of Erbitux in this tumor type. To date we have initiated several studies, including a randomized Phase III clinical trial evaluating chemotherapy used alone or in combination with Erbitux in 800 patients with second-line non-small-cell lung cancer. Based on a special protocol assessment, this study could serve as the basis for an accelerated approval of Erbitux in this disease setting.

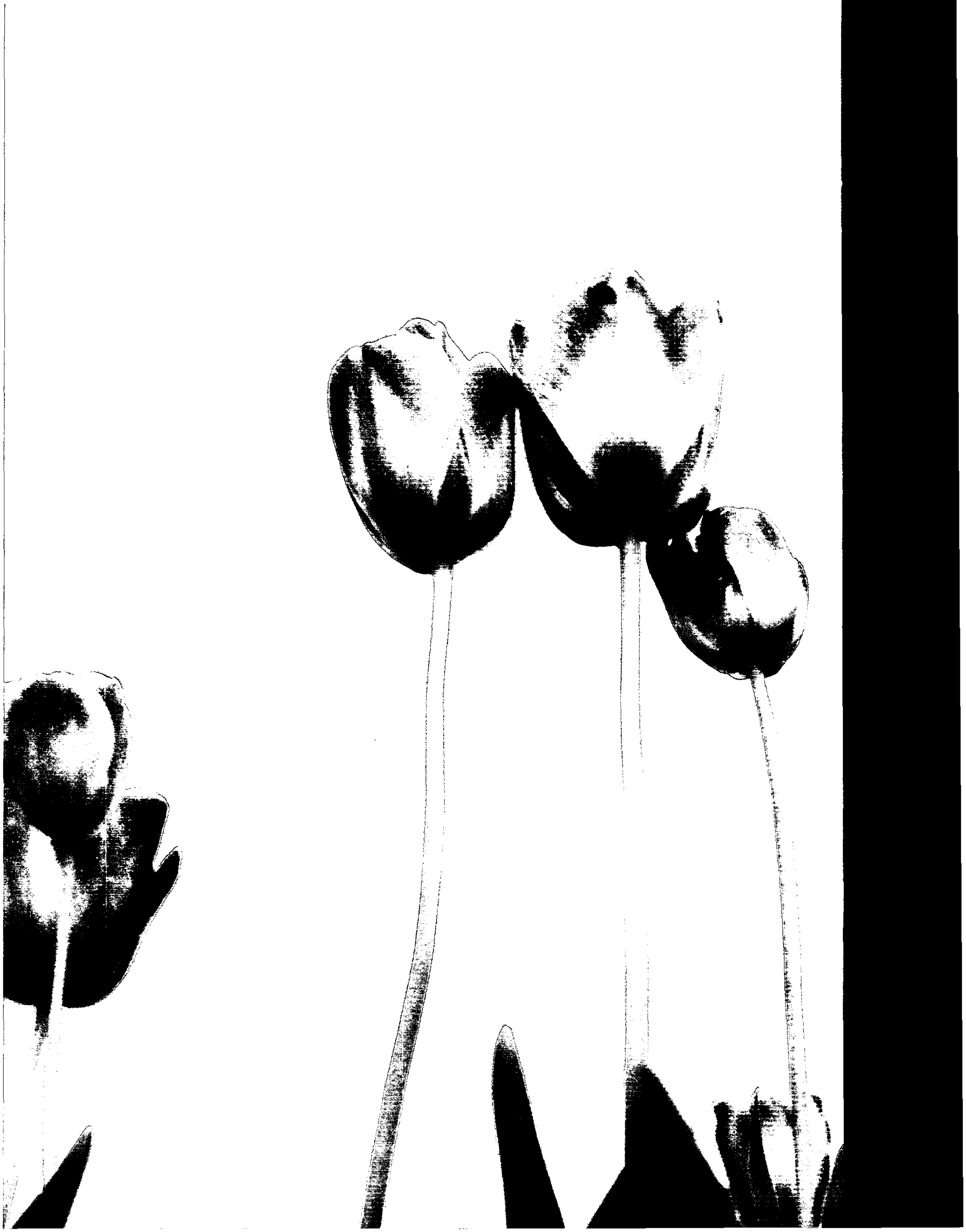


Beyond its currently indicated use, we believe Erbitux® has potential in a number of other settings and, accordingly, have adopted a comprehensive development and regulatory strategy.

In addition, our partner Merck KGaA initiated a randomized Phase III clinical trial testing a platinum-based chemotherapy and vinorelbine alone or in combination with Erbitux in 1,100 patients with first-line non-small-cell lung cancer. This study will be supplemented by two U.S. supportive first-line randomized clinical studies using common U.S. chemotherapy regimens to allow ImClone Systems and its partners to seek a broad-based indication in first-line treatment with platinum-based chemotherapy.

We also continue to evaluate Erbitux in various stages of clinical testing in pancreatic, ovarian, cervical/endometrial and esophageal cancers, in what is clearly a very broad and ambitious clinical program.

As all of the tumor types in which we are conducting clinical trials express the epidermal growth factor receptor (EGFR), Erbitux's key target in the EGF signaling pathway, we are also studying the correlation between expression levels of this receptor and tumor response under treatment. Specifically, because the Erbitux label requires that patients be deemed EGFR-expressing using immunohistochemistry, we are conducting a study as part of our post-marketing commitments in patients whose EGFR expression level is deemed "undetectable" to determine whether EGFR testing is a relevant screening criterion for patients who could potentially benefit from the use of Erbitux. Early investigational data published to date suggest that there may be no correlation between response rates and EGFR expression levels as assessed by immunohistochemistry.



CHAPTER

BEYOND ERBITUX®

Because Erbitux is being or has been tested in various stages of disease in over half a dozen tumor types, we consider it a "pipeline" of its own. But while Erbitux presents many compelling opportunities in and of itself, we are very excited about the potential represented in ImClone Systems' next generation of product candidates.

ImClone Systems' pipeline made significant progress over the course of the past year, with two antibodies advancing to human testing and two additional compounds nearing this stage.

The most important of these antibodies is IMC-1121B, a fully human monoclonal antibody that is designed to bind to a signaling pathway responsible for the development of blood vessels in tumors (angiogenesis), the vascular endothelial growth factor receptor (VEGFR). IMC-1121B is designed to bind to VEGFR-2, also known as KDR, causing an anti-angiogenic effect that has been shown to starve tumors of their nutrient supply and result in significant tumor growth inhibition in pre-clinical models.

The second antibody now in clinical testing is IMC-11F8, a fully human monoclonal antibody that is designed to bind to the EGFR, as Erbitux does, thereby inhibiting certain growth factors from binding to and activating the receptor. IMC-11F8 entered the clinic in November 2004 in a Phase I study testing its safety and pharmacology in patients with solid tumors. The two-center study is being conducted in Europe, the primary region in which we plan to develop IMC-11F8 at this stage in its lifecycle.

A third antibody, working in a manner similar to IMC-1121B but targeting VEGFR-1, IMC-18F1 is scheduled to enter the clinic in 2005. Because VEGFR-1 is present in tumor vasculature, IMC-18F1 has an anti-angiogenic effect. VEGFR-1 is also present on many tumor cells, so targeting this receptor has resulted in augmented tumor growth inhibition in pre-clinical models. As with all of ImClone Systems' current product candidates, IMC-18F1 is a fully human monoclonal antibody.

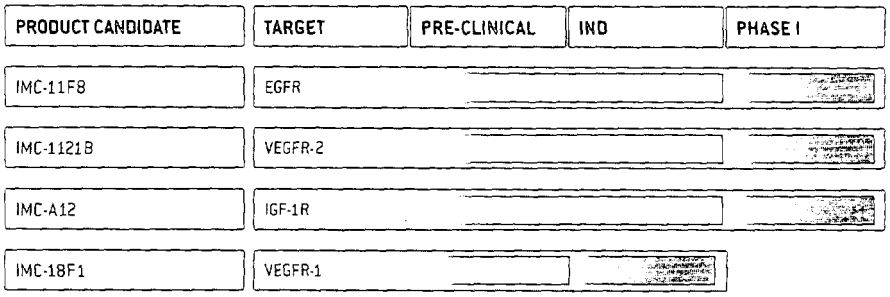
Importantly, ImClone Systems recently received a U.S. Patent that covers the therapeutic use of any VEGFR antibody when combined with either radiation or a chemotherapeutic agent in the treatment of cancer. IMC-18F1 and IMC-1121B, if proven to be effective in combination with these cytotoxic agents, would both be protected by this patent if they reach the commercial setting.

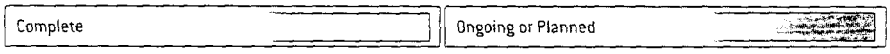
The final antibody we expect to enter the clinic in 2005 is IMC-A12, a fully human monoclonal antibody targeting insulin-like growth factor-1 receptor (IGF-1R). IGF-1R leads to the inhibition of ligand-dependent signals to the cell in human breast, colon and pancreatic tumor cell lines, which, in pre-clinical models, demonstrated a significant reduction of cancer cell proliferation and survival.

Beyond the pathways targeted by these new antibodies, ImClone Systems' researchers continue to explore both known and less well-studied tumor cell activities on a molecular level in an effort to understand the causes of tumor proliferation and metastases and, subsequently, to develop means of shutting these functions down. Research at this level is the true heritage of ImClone Systems, and it continues to be a significant function of the Company.

To ensure that this functional area has all the right resources to continue conducting its basic and applied research, we also announced last year our plans to develop a 100,000-square foot, state-of-the-art research facility near our corporate headquarters in downtown Manhattan. This building will house both our small molecule and antibody research functions, and will provide the space and equipment necessary for this group to continue producing results well into the future.

IMCLONE SYSTEMS' FULLY-HUMAN PIPELINE ANTIBODIES ALL TARGET GROWTH FACTOR RECEPTORS, AN APPROACH OUR SCIENTISTS BELIEVE HAS THE GREATEST LIKELIHOOD OF INHIBITING CELL MALIGNANCY AND METASTASIS.





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CHAPTER

ENABLING THE ORGANIZATION

In addition to our research facilities, our manufacturing capabilities continue to expand. There is little doubt today that antibodies will play a significant role in the future treatment of not only cancer but many other diseases, so we consider our investment in biologics manufacturing an investment in the future and a key to enabling the organization's long-term goals.

Unlike manufacturing chemical compounds, biologics manufacturing is a very complex process involving the replication of millions of cells and the harvesting of the antibodies they produce. Because of this, a significant investment in time and money is needed to engineer and build these facilities, and any antibody company must plan its supply needs many years in advance.

With this in mind, ImClone Systems continues the build-out of its second commercial-scale manufacturing facility, BB50. BB50 will have over three times the bioreactor capacity of BB36, the current Erbitux commercial supply facility, and will have the ability to produce different antibodies in each of its three suites. Construction remains on schedule and mechanical completion of the facility is expected by year-end 2005.

Once this facility is licensed and operational, ImClone Systems will be one of the largest volume manufacturers of mammalian cell production — an indication of what we expect to accomplish in the coming years.

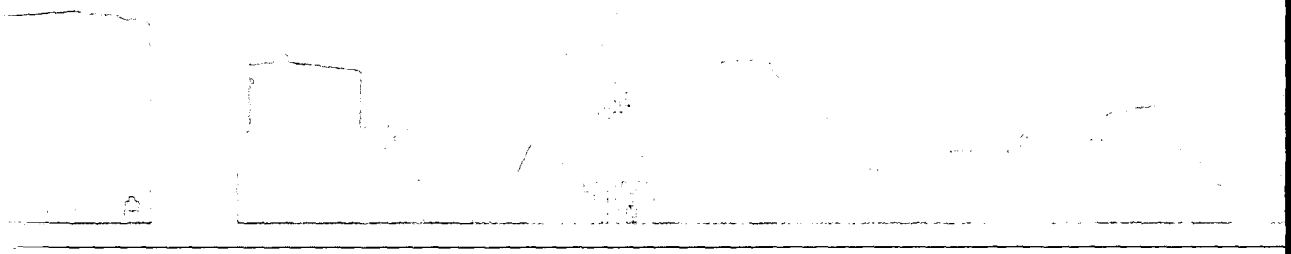
ImClone Systems will be one of the largest volume manufacturers of mammalian cell production — an indication of what we expect to accomplish in the coming years.

Another way in which we expect to enable the organization is by having the right human resources throughout the Company. This begins with leadership, as exemplified in the recent appointments of highly regarded individuals like Philip Frost, M.D., Ph.D., our Chief Scientific Officer, and Eric Rowinsky, M.D., our Chief Medical Officer. And it extends to the individuals within all of our functional areas, through leadership and technical training as well as the fostering of a productive and forward-thinking environment.

Finally, because we have many of the resources of a fully integrated company, significant financial strength and the drive of a dynamic biotechnology company, we believe we are well positioned to successfully move Erbitux and our pipeline forward as well as look for strategic opportunities outside the Company.

THANK YOU

We thank our shareholders for your ongoing dedication to the Company and your patience in awaiting the achievements of the past year. For a number of you, confidence in your investment in ImClone Systems stemmed from the belief in a drug with the potential to help so many. We are grateful to have delivered on this promise, and intend to continue doing so in the future. We also thank our employees, who are personally and professionally driven by the urge to help fight cancer, for allowing ImClone Systems to achieve great success in 2004 and for their continued diligence in seeking out our future successes.



Thanks to drugs like Erbitux, cancer will some day be a manageable disease. We further our own efforts and continue our collaborations with others working toward this end with the intention of making that day come a little sooner. We work diligently to remain at the forefront of this cause because, ultimately, cancer affects us all.

Sincerely,

David M. Kies, Chairman of the Board

Daniel S. Lynch, Chief Executive Officer

APPENDIX

CORPORATE HEADQUARTERS

[redacted] Varick Street, New York, NY 10014, Tel: 212.645.1405, Fax: 212.645.2054

NEW JERSEY CAMPUS HEADQUARTERS

[redacted] InterClone Drive, Branchburg, NJ 08876, Tel: 908.218.9588, Fax: 908.704.8325

TRANSFER AGENT AND REGISTRAR

[redacted] Transfer Agent and Registrar stockholder inquiries should be directed to:

EquiServe Trust Company, N.A., P.O. Box 219045, Kansas City, MO 64121-9045

[redacted] 816.843.4299, www.equiserve.com

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

[redacted] LLP, Princeton, NJ

COMMON STOCK

[redacted] Systems Incorporated is traded on the NASDAQ National Market under the symbol: IMCL.

The following table sets forth prices for the indicated periods for the fiscal year ended December [redacted], 2004.

	[redacted]	Low
[redacted] Quarter	$50.75	$34.00
[redacted] Quarter	$85.79	$53.00
[redacted] Quarter	$86.79	$49.08
[redacted] Quarter	$56.34	$41.20

COMPANY REPORTS

[redacted] additional information concerning the Company, including copies of any exhibits listed in the Annual Report (upon payment to the Company of its reasonable expenses in so furnishing the exhibits), please contact:

[redacted] Rabney, Esq.
Vice President, Corporate Communications
[redacted] Systems Incorporated
[redacted] Varick Street, New York, NY 10014
[redacted] 212.645.1405, Fax: 212.645.2054

ANNUAL MEETING

The Annual Meeting of Stockholders will be held at:
[redacted] Systems Incorporated
New Jersey Campus, 33 InterClone Drive, Branchburg, NJ 08876
[redacted], 2005, at 9:00 a.m.

[redacted] Annual Report contains certain forward-looking statements. Actual results may differ materially from those predicted herein due to certain risks and uncertainties inherent in the Company's business. This provision is not a complete disclosure regarding forward-looking statements and is qualified in its entirety by the full text in the Company's Form [redacted] (See "Disclosure Regarding Forward Looking Statements" and "Risk Factors").

www.interclone.com

2004 SELECT FINANCIAL INFORMATION

FINANCIAL HIGHLIGHTS

(Thousands, expect per-share data)

	2004	2003	2002
REVENUES			
License Fees and Milestone Revenue	$ 129,386	$ 42,970	$ 21,051
Manufacturing Revenue	99,041		
Profit Revenue	106,224	$25	1,353
Collaborative Agreement Revenue	53,999	32,285	32,601
TOTAL REVENUES	388,690	80,830	60,005
NET INCOME (LOSS)	$ 113,653	$ (112,502)	$ (157,949)
INCOME (LOSS) PER COMMON SHARE:			
Basic	$ 1.33	$ (1.52)	$ (2.15)
Income Diluted*	$ 1.94		
SHARES USED IN CALCULATION OF INCOME (LOSS) PER SHARE:			
Basic	85,193	74,250	73,408
CASH & MARKETABLE SECURITIES	$ 919,222	$ 106,348	$ 247,655

Diluted shares include the weighted average number of shares underlying the $600 million convertible notes outstanding.

* Income figure excludes a one-time settlement charge of $55.4 million taken in the fourth quarter of 2004.

2004 ERBITUX U.S. IN-MARKET SALES

(Millions)

Q1	Q2	Q3	Q4	FULL YEAR
$12.5	$ 21.4	$ 84.1	$ 87.8	$ 260.8

CONSOLIDATED BALANCE SHEETS

(In Thousands)

ASSETS	DECEMBER 31, 2004	DECEMBER 31, 2003
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 29,321	$ 30,865
Securities Available for Sale	840,451	25,483
Other Current Assets	142,665	16,222
TOTAL CURRENT ASSETS	1,062,437	122,570
PROPERTY, PLANT AND EQUIPMENT, NET	339,293	245,901
OTHER ASSETS	32,046	13,124
	$ 1,434,776	$ 381,595

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts Payable & Accrued Expenses	$ 99,669	46,579
Patent Settlement	25,900	–
Unrecognized Tax Liability	18,096	20,987
Current Portion of Deferred Revenue	108,994	50,820
Other Current Liabilities	1,031	4,411
TOTAL CURRENT LIABILITIES	303,690	122,842
Deferred Revenue, Less Current Portion	348,814	286,362
Long-term Debt	600,000	240,000
Deferred Rent, Less Current Portion	3,434	2,938
Other Long-term Liabilities, Less Current Portion	–	41
TOTAL LIABILITIES	1,255,938	652,188
COMMITMENTS AND CONTINGENCIES		
Total Stockholders' Equity (Deficit)	178,838	(270,593)
	$ 1,434,776	$ 381,595

BOARD OF DIRECTORS

CHAIRMAN OF THE BOARD

David M. Kies, Esq. Partner, Sullivan & Cromwell

DIRECTORS

Andrew G. Bodnar, M.D., J.D. Senior Vice President, Strategy and Medical & External Affairs, Bristol-Myers Squibb Company

William W. Crouse Managing Director and General Partner, HealthCare Ventures LLC

Vincent T. DeVita, Jr., M.D. Amy and Joseph Perella Professor of Medicine, Professor of Epidemiology, Public Health, Yale Cancer Center

John A. Fazio Former Senior Partner, PriceWaterhouseCoopers LLP

Joseph L. Fischer Former Group President and Corporate Controller, Johnson & Johnson

Daniel S. Lynch Chief Executive Officer, ImClone Systems Incorporated

William R. Miller Former Vice Chairman of the Board, Bristol-Myers Squibb Company

David Sidransky, M.D. Professor of Otolaryngology, Oncology, Urology, Genetics, Pediatrics, and Cellular and Molecular Medicine; Director, Head and Neck Cancer Research, Johns Hopkins University

OFFICERS

Daniel S. Lynch Chief Executive Officer

Philip Frost, M.D., Ph.D. Executive Vice President, Chief Scientific Officer

Michael J. Howerton Senior Vice President, Chief Financial Officer

Eric Rowinsky, M.D. Senior Vice President, Chief Medical Officer

Peter R. Borzillieri, CPA Vice President, Internal Audit

Lisa M. Cammy Vice President, Human Resources

Ronald A. Martell Senior Vice President, Commercial Operations

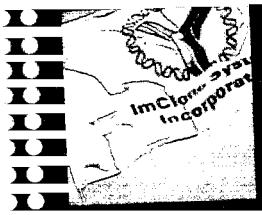
Andrea F. Rabney, Esq. Vice President, Corporate Communications

Erik D. Ramanathan, Esq. Vice President, General Counsel

Ana I. Stancic, CPA Vice President, Controller and Chief Accounting Officer

S. Joseph Tarnowski, Ph.D. Senior Vice President, Manufacturing Operations and Product Development

Larry D. Witte, Ph.D. Vice President, Research



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Concept & Design: 1919 Agency for Visual Communication, Tel: 212.982.6400
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180 VARICK STREET, NEW YORK, NY 10014
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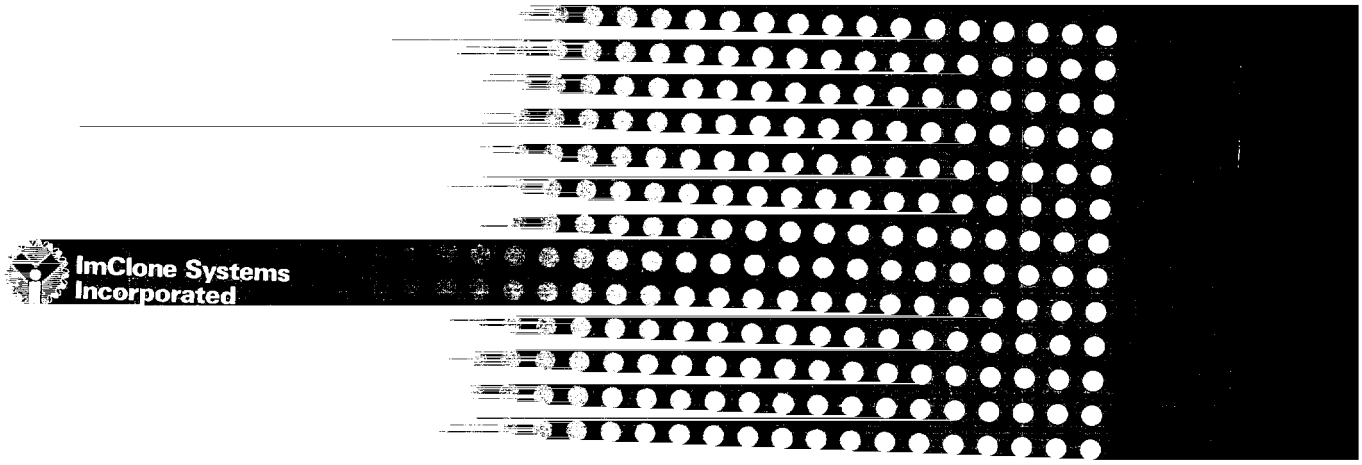

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended December 31, 2004

or

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

Commission file number 0-19612

IMCLONE SYSTEMS INCORPORATED

(Exact name of registrant as specified in its charter)

DELAWARE	**04-2834797**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
180 Varick Street, New York, NY	**10014**
(Address of principal executive offices)	(Zip Code)

(212) 645-1405

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:
Common stock, par value $.001 and the associated preferred stock purchase rights.

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

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

Indicate by check mark whether registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No ☐

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2004 was $7,055,510,896.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class	Outstanding as of March 9, 2005
Common stock, par value $.001	**83,338,025**

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement in connection with its 2005 Annual Meeting of Stockholders, scheduled to be held on June 15, 2005, are incorporated by reference in Parts II and III of this report.

IMCLONE SYSTEMS INCORPORATED

2004 Form 10-K Annual Report

TABLE OF CONTENTS

As used in this Form 10-K, "ImClone Systems," "ImClone," "Company," "we," "ours," and "us" refer to ImClone Systems Incorporated, except where the context otherwise requires or as otherwise indicated.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

The Company considers portions of the information in this Form 10-K to be "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. The Company intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Exchange Act and the Private Securities Litigation Reform Act of 1995. Such forward-looking statements relate to, without limitation, the Company's future economic performance, plans and objectives for future operations and projections of revenue and other financial items. Forward-looking statements can be identified by the use of words such as "may," "will," "should," "expect," "anticipate," "estimate," "continue" or comparable terminology. Forward-looking statements are inherently subject to risks, trends and uncertainties, many of which are beyond the Company's ability to control or predict with accuracy and some of which the Company might not even anticipate. Although the Company believes that the expectations reflected in such forward-looking statements are based upon reasonable assumptions at the time made, it can give no assurance that its expectations will be achieved. Future events and actual results, financial and otherwise, may differ materially from the results discussed in the forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements.

Important factors that may cause actual results to differ materially from forward-looking statements include, but are not limited to, the risks and uncertainties associated with completing pre-clinical and clinical studies of our compounds that demonstrate such compounds' safety and effectiveness; manufacturing losses and risks associated therewith; obtaining additional financing to support our operations; obtaining and maintaining regulatory approval for such compounds and complying with other governmental regulations applicable to our business; obtaining the raw materials necessary in the development of such compounds; consummating and maintaining collaborative arrangements with corporate partners for product development; achieving milestones under collaborative arrangements with corporate partners; developing the capacity to, and overcoming difficulties or delays that arise as we, manufacture, market and sell our products, either directly or with collaborative partners; developing market demand for and acceptance of such products; earning royalty revenues on commercial sales of ERBITUX®, both within and outside of the United States, by our collaborative partners; satisfactorily addressing factors impacting the commercial viability of ERBITUX; competing effectively with other pharmaceutical and biotechnological products; obtaining adequate reimbursement from third party payers; attracting and retaining key personnel; legal costs and the duration and outcome of legal proceedings and investigations, including, but not limited to, our investigations pertaining to tax withholding issues; complying with covenants in the indenture for the company's Convertible Notes and with the terms of other contractual obligations; obtaining patent protection for discoveries and risks associated with commercial limitations imposed by patents owned or controlled by third parties; and those other factors set forth in this report in Item 1 "Business" and Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations". The Company assumes no obligation to update and supplement any forward-looking statements, that may become untrue because of subsequent events whether as a result of new information, future events or otherwise.

We do not undertake to discuss matters relating to certain completed clinical studies or our regulatory strategies beyond those which have already been made public or discussed herein.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a biopharmaceutical company whose mission is to advance oncology care by developing a portfolio of targeted biologic treatments designed to address the medical needs of patients with cancer. We focus on what we believe are two promising strategies for treating cancer:

- growth factor blockers; and
- angiogenesis inhibitors.

We were incorporated under the laws of the State of Delaware on April 26, 1984. Our corporate headquarters and research facility are located at 180 Varick Street, New York, New York 10014 and our telephone number is (212) 645-1405. We make available free of charge on our Internet website (http://www.imclone.com) our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. In addition, our Internet website includes other items related to corporate governance matters, including among other things, our corporate governance guidelines, charters of the various committees of the Board of Directors, and our code of business conduct and ethics.

Our commercially available product, ERBITUX® (Cetuximab), is a first-of-its-kind antibody approved by the United States Food and Drug Administration ("FDA") for use in combination with irinotecan in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy. Please see full prescribing information, available at www.ERBITUX.com for important safety information relating to ERBITUX, including a box warning regarding infusion reactions. ERBITUX binds specifically to the epidermal growth factor receptor (EGFR, HER1, c-ErbB-1) on both normal and tumor cells, and competitively inhibits the binding of the epidermal growth factor (EGF) and other ligands, such as transforming growth factor-alpha. The EGFR is constitutively expressed in many normal epithelial tissues, including the skin and hair follicle. Expression of EGFR is also detected in many human cancers including those of the colon and rectum. We are conducting, and in some cases have completed, clinical studies evaluating ERBITUX for broader use in colorectal cancer, for the potential treatment of head and neck, lung and pancreatic cancers, as well as other potential indications.

On February 12, 2004, the FDA approved ERBITUX Injection for use in combination with irinotecan in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy. The FDA also approved Lonza Biologics plc's ("Lonza") manufacturing facility. ERBITUX inventory previously produced at Lonza's facility served as supply for the initial demand for ERBITUX. On June 18, 2004 the FDA approved our Chemistry Manufacturing and Controls (CMC) supplemental Biologics License Application (sBLA) for licensure of our manufacturing facility dedicated to the production of ERBITUX, referred to as BB36.

On December 1, 2003, Swissmedic, the Swiss agency for therapeutic products, approved ERBITUX in Switzerland for the treatment of patients with colorectal cancer who no longer respond to standard chemotherapy treatment with irinotecan. Merck KGaA licensed the right to market ERBITUX outside the United States and Canada from the Company in 1998. In Japan, Merck KGaA has marketing rights

to ERBITUX, which are co-exclusive to the co-development rights of the Company and Bristol-Myers Squibb Company ("BMS"). On June 30, 2004, Merck KGaA received marketing approval by the European Commission to sell ERBITUX for use in combination with irinotecan for the treatment of patients with EGFR-expressing, metastatic colorectal cancer after failure of irinotecan including cytotoxic therapy in all 25 member states of the newly expanded European Union, as well as Iceland and Norway in accordance with local regulations. In addition, ERBITUX has been approved in Australia, Argentina, Chile and Mexico.

We are co-promoting and otherwise supporting the commercial launch of ERBITUX in the United States and Canada together with our development, promotion and distribution partner BMS through its wholly-owned subsidiary E.R. Squibb & Sons, L.L.C. ("E.R. Squibb"). We are manufacturing ERBITUX for clinical studies and for commercial sales. According to our agreements with BMS and Merck KGaA, each will be obligated to pay us certain royalties on their sales of ERBITUX.

In addition to achieving approval in the above advanced colorectal cancer indications, we also have undertaken a comprehensive clinical development program to evaluate the broader use of ERBITUX in colorectal cancer, including two Phase III randomized studies known as BMS-006 and BMS-025. We have begun enrollment in both of these randomized studies. In collaboration with the National Cancer Institute Cooperative groups, studies in first line colorectal cancer (CALGB 80203) and first line pancreatic cancer (SWOG 0205) enrolled patients in 2004. Subsequently CALGB 80203 was closed to enrollment after accruing 238 patients and a new first line colorectal cancer protocol including both ERBITUX and Avastin® is in development by CALGB. Numerous pilot studies are underway or planned to further evaluate opportunities for the development of ERBITUX for other indications and tumor types. Additionally, enrollment started in 2004 in a Phase I study of 11F8, a fully human EGFR antibody, in patients with solid tumors who have failed standard therapy.

In addition to our work developing and commercializing ERBITUX, we also are developing investigational inhibitors of angiogenesis, which could be used to treat various kinds of cancer and other diseases. We have identified potential monoclonal antibody-based inhibitors, collectively known to us as IMC-KDR antibodies. Investigational data available to date indicate that the IMC-KDR antibodies bind selectively and with high affinity to the kinase insert domain-containing receptor ("KDR"), a principal vascular endothelial growth factor ("VEGF") receptor, thereby, we believe, inhibiting angiogenesis. A Phase I study of 1121B, a fully human anti-vascular endothelial growth factor receptor 2 (VEGFR-2) antibody, in patients with advanced solid tumors was initiated in 2004.

We also continue to work with cancer vaccines, including an ongoing Phase I study of GP75 in melanoma. No further clinical studies of BEC2, a monoclonal antibody we were developing as a cancer vaccine, will be sponsored by ImClone subsequent to the failure of the SILVA study to meet its endpoints in small cell lung cancer. Following the analysis of this Phase III data in small cell lung cancer, we and Merck KGaA agreed to discontinue further development of BEC2.

In addition to the development and commercialization of ERBITUX and the development of our lead product candidates, we continue to conduct research, both independently and in collaboration with academic and corporate partners, in a number of areas related to our core focus of tumor cell growth factor inhibitors and angiogenesis inhibitors. We also have developed diagnostic products and vaccines for certain infectious diseases, and we have licensed the rights to these products and vaccines to corporate partners. However, we are no longer actively developing product candidates in the areas of diagnostic and certain infectious diseases.

CLINICAL DEVELOPMENT PROGRAMS

ERBITUX Cancer Therapeutic

ERBITUX is an IgG1 chimerized (part human, part mouse) monoclonal antibody that selectively binds to the EGF receptor and thereby inhibits growth of tumors dependent upon activation of the EGF receptor for cell division and survival. The activation of the EGF receptor is believed to play a critical role in the growth and survival of certain types of tumor cells and select normal cells. Certain cancer types are characterized by the expression of the EGF receptor. For example, according to the American Cancer Society, an estimated 145,290 cases of colorectal cancer will be diagnosed in the United States in 2005. IMCL-9923 and other studies conducted by us have indicated that approximately 72% of advanced stage refractory colorectal cancer cases have been shown to express the EGF receptor in tumor cells. Also, according to the American Cancer Society, an estimated 29,370 cases of head and neck cancer will be diagnosed in the United States in 2005. Similarly, according to the literature in this area, approximately 95% to 100% of squamous cell head and neck cancer cases have been shown to express the EGF receptor on the surface of the tumor cells. Other types of cancer are also characterized, in certain patients, by expression of the EGF receptor, including non-small cell lung, renal, and pancreatic cancers. By preventing the binding of critical growth factors to the EGF receptor, we believe it is possible to inhibit the growth and survival of these tumors.

ERBITUX Clinical Studies

The charts presented below reflect studies in selected tumor types that we and our partners, Merck KGaA and BMS, are developing or collaborating on with National Cancer Institute cooperative groups, and are designed both for registration purposes and exploratory development in these indications.

Colorectal Cancer

Study	Description	Population	Target Enrollment
CP02-0451 (Ongoing)	Phase II Single Agent Study in EGFR non-detectable patients	Refractory	60
IMCL-0144 (Completed)	Phase II Single Agent Study	Refractory	350
EMR-007 (Completed)	Phase II Randomized Study (ERBITUX +/- Irinotecan)	Refractory	329
BMS-006 (Enrollment started 2Q2003)	Phase III Randomized Study (Irinotecan +/- ERBITUX)	Second Line (previously treated with Oxaliplatin)	1300
BMS-014 (Enrollment closed)	Phase III Randomized Study (FOLFOX +/- ERBITUX)	Second Line (previously treated with Irinotecan)	1100
CALGB 80203 (Enrollment closed)	Phase III Randomized Study (FOLFOX +/- ERBITUX) (Saltz +/- ERBITUX)	First line	2200
NCI-6444 (Enrollment closed)	Phase II Single Study (Avastin® + ERBITUX + Irinotecan vs. Avastin + ERBITUX)	Refractory	150

As part of our confirmatory obligation to the FDA in regard to the approval of ERBITUX, we initiated a Phase II study enrolling 60 patients with refractory, EGFR-non-detectable, metastatic colorectal cancer. This study is designed to estimate the overall response rate and duration obtained with single agent ERBITUX use and is targeted to complete in the fourth quarter of 2005.

The results of IMCL-0144, our Phase II single agent study, were presented at the June 2004 American Society for Clinical Oncology ("ASCO") conference.

The most commonly encountered adverse events were an acne-like skin rash (85% any grade, 6% grade 3) and fatigue/malaise (40% any grade, 8% grade 3). One patient experienced a grade 3 allergic reaction requiring discontinuance of study treatment. Partial responses (PR) were observed in 12% of patients (28/235; 95% CI: 8-17). 34% of patients had stable disease for at least 6 weeks bringing the disease control rate to 46%. Prior to an amendment to the protocol, 9 patients with EGFR-negative CRC were enrolled, 2 of whom had a PR.

Merck KGaA colorectal cancer phase I/II studies EMR-010 and EMR-018 (not summarized in the preceding table) were also presented at the June 2004 ASCO conference.

EMR-010, a first line Phase I/II study conducted by Merck KGaA, evaluated ERBITUX given in combination with FOLFIRI (irinotecan plus infusional 5-FU and folinic acid) in patients with EGFR positive metastatic colorectal cancer. Two dose levels of 5-FU were used: dose level 1, 300mg/m^2 bolus, 2000mg/m^2 infusion; dose level 2, 400mg/m^2 bolus, 2400mg/m^2 infusion. Ten patients received dose level 1, and forty-two patients received dose level 2. The findings showed that zero patients in dose level 1 had dose limiting toxicities, and 2 patients (15%) in dose level 2 had dose limiting toxicities (diarrhea, neutropenia). The forty-two patients who received dose level 2 were evaluated for safety and efficacy. Grade ¾toxicities were as follows: leucopenia (17%), diarrhea (14%), vomiting (11%), asthenia (7%), and skin (7%). 43% of patients had a partial response, and 45% had stable disease.

Merck KGaA conducted EMR-018, a Phase II study of ERBITUX in combination with oxaliplatin/5-flurouracil (5-FU)/folinic acid (FA) (FOLFOX-4) in the first line treatment of patients with metastatic colorectal cancer. The major grade ¾ toxicities were diarrhea, neutropenia, and acne-like rash. Overall response rate of 81% was achieved consisting of 2 complete responses (CR) and 32 partial responses (PR). Disease control rate (CR+PR+Stable Disease) was 98%.

The FDA-approved BLA for ERBITUX included data from EMR-007, a randomized two-arm Phase II clinical study conducted by Merck KGaA evaluating ERBITUX as a single agent and the combination of ERBITUX and irinotecan in 329 patients with EGFR-expressing metastatic colorectal cancer who were refractory to irinotecan-based chemotherapy. The findings showed that ERBITUX given in combination with irinotecan (n=218) had an objective response rate of 22.9 percent, a median duration of response of 5.7 months and a median time to disease progression of 4.1 months. Results of the ERBITUX single agent treatment group (n=111) showed a 10.8 percent objective response rate, a median duration of response of 4.2 months and a median time to disease progression of 1.5 months.

In conjunction with our U.S. partner, BMS, we have opened or expect to open additional studies in colorectal cancer, including randomized studies in first-line and second-line therapy settings for metastatic colorectal cancer. In the second-line therapy setting, one study, BMS-006, which opened for patient enrollment in May 2003, tests the addition of ERBITUX to irinotecan in patients who have failed oxaliplatin, 5-fluorouracil, and leucovorin in the first line of therapy. BMS-006 is being conducted in collaboration with Merck KGaA. A second study, BMS-014, which opened for patient enrollment and treatment in March 2003 and which is now currently closed to accrual, tests the addition of ERBITUX and the combination of oxaliplatin, 5-fluorouracil, and leucovorin (FOLFOX-4) in patients who have failed irinotecan, 5-fluorouracil, and leucovorin.

Upon the approval of ERBITUX under the accelerated approval mechanism, studies BMS-006 and BMS-014 were designated as studies to confirm the clinical benefit of ERBITUX. BMS-006 is targeted

to complete in the fourth quarter of 2006, and enrollment in BMS-014 was closed with FDA approval due to decreased feasibility of the study and was removed from the list of post-approval commitments. Preliminary safety results from BMS colorectal cancer Phase III study BMS-014 were presented at the June 2004 ASCO conference.

In this pooled analysis the incidence of the characteristic ERBITUX and FOLFOX4 toxicities does not seem to be increased as compared to the reported incidences in the ERBITUX and Eloxatin package inserts. Based on our limited experience the combination of FOLFOX-4 and ERBITUX appears to be a feasible and safe regimen.

Head and Neck Cancer

Study	Description	Population	Target Enrollment
IMCL-9815 (Completed)	Phase III Randomized Study (Radiation +/- ERBITUX)	First line	424
EMR-016 (Completed)	Phase II Single Agent Study	Recurrent/ Refractory or Metastatic	103
EMR-001 (Enrollment completed)	Phase II Study (Platinum + ERBITUX)	Recurrent/ Refractory or Metastatic	96
EMR-008 (Enrollment completed)	Phase I/II Study ERBITUX + Platinum (Carboplatin or Cisplatin) + 5FU (Low, Medium or High Dose)	Recurrent or Metastatic	53
ECOG-5397 (Enrollment completed)	Phase III Randomized Study (Cisplatin + Placebo vs. Cisplatin + ERBITUX)	Recurrent or Metastatic	123

Preliminary results from IMCL-9815, our Phase III locally advanced head and neck cancer study, conducted in cooperation with Merck KGaA, were presented at the June 2004 ASCO conference. Preliminary data showed a significant increase in median and overall survival.

Merck KGaA's squamous cell carcinoma of the head and neck Phase I study EMR-008 and the Phase II single agent study, EMR-016, were presented at the June 2004 ASCO conference.

Merck KGaA conducted EMR-008, a Phase I study of ERBITUX in combination with cisplatin or carboplatin, and 5-fluorouracil in patients with recurrent SCCHN. 5-flourouracil was administered at doses of 600 mg/m2, 800 mg/m2, and 1000 mg/m2 every three weeks. The main adverse events observed were acne-like rash, mucositis, nausea/vomiting, asthenia, and leucopenia. There was an overall response rate of 35.9%, and disease control (CR+PR+SD) was observed in 69.8% of the patients. There was a median time to progression of 155 days, and a median survival time of 297 days.

Merck KGaA conducted EMR-016, a Phase II study of ERBITUX in 103 patients with platinum-refractory recurrent/metastatic SCCHN. The results showed that ERBITUX had a partial response of 12.6% and demonstrated stable disease in 33% of the patient population. Furthermore, ERBITUX demonstrated a median time to disease progression, median survival, and one-year survival of 2.3 months, 5.9 months, and 12.7%, respectively.

Non-Small Cell Lung Cancer

Study	Description	Population	Target Enrollment
CP02-0452 (Ongoing)	Phase III, randomized study of ERBITUX in combination with docetaxel or pemetrexed compared to docetaxel or pemetrexed alone	Recurrent or progressive	800
EMR-011 (Enrollment completed)	Phase II randomized, chemotherapy-naïve, advanced non-small cell lung cancer (ERBITUX + Cisplatin + Vinorelbine vs. Cisplatin + Vinorelbine)	Stage IIIb or IV	86
BMS-012 (Ongoing)	Phase II single-arm study (ERBITUX)	Recurrent or progressive	100
EMR-046 (FLEX) (Ongoing)	Phase III Cisplatin/Vinorelbine or Cisplatin/Gemcitabine +/- ERBITUX	First line	1100
BMS-099 (Ongoing)	Phase II Taxane/Carbo or Cisplatin +/- ERBITUX	First line	300
BMS-100 (Ongoing)	Phase II Gemcitabine/Carbo or Cisplatin +/- ERBITUX	First line	300

Findings from our partner Merck KGaA reported at the same ASCO conference that in a randomized Phase II study, EMR-011, of 61 evaluable patients with chemotherapy-naïve advanced non-small cell lung cancer, the addition of ERBITUX to cisplatin and vinorelbine signixficantly increased tumor response rates (53.3% versus 32.3%). Merck KGaA presented further results of this study at the June 2004 ASCO conference.

A Phase II study (EMR-011) conducted by Merck KGaA evaluated cisplatin (C) + vinorelbine (V) with or without ERBITUX in 86 EGFR positive, Stage IV/IIIb with pleural effusions non-small cell lung cancer patients. The results of this first line study demonstrate disease control (CR+PR+SD) of 84% for CV plus ERBITUX and 68% for CV alone. Median survival for CV plus ERBITUX and CV alone was 8.3 and 7.0 months, respectively. CV plus ERBITUX had a progression free survival of 4.8 months, compared with 4.2 months for CV alone. No data were statistically significant.

In 2003, in conjunction with our U.S. partner BMS, we opened an ERBITUX monotherapy study as a third-line therapy for patients with non-small cell lung cancer, BMS-012, for which preliminary results were presented at the June 2004 ASCO conference. At a planned interim analysis of the first 29 EGFR positive patients, there were 2 confirmed partial responses and five patients with stable disease. The mean number of cycles received was 3 (range 1-6). Reported grade ¾ adverse events deemed possibly related to ERBITUX include rash, cellulitis, fatigue, nausea, and vomiting (1 patient each).

Pancreatic Cancer

Study	Description	Population	Target Enrollment
SWOG-0205 (Enrollment started 1Q2004)	Phase III Randomized Study (ERBITUX + Gemcitabine vs. Gemcitabine)	First line Stage IV Pancreatic Cancer	720

The Southwest Oncology Group activated S0205, a first line study in pancreatic cancer in January 2004. This study is a randomized comparative study comparing ERBITUX plus gemcitabine versus gemcitabine alone in first-line, stage IV, pancreatic cancer patients.

Safety and Other General Information

Severe infusion reactions, rarely fatal and characterized by rapid onset of airway obstruction (bronchospasm, stridor, hoarseness), urticaria, and hypotension, have occurred (3%) with the administration of ERBITUX. Most reactions (90%) are associated with the first infusion of ERBITUX.

Severe cases of interstitial lung disease (ILD), which was fatal in one case, occurred in less than 0.5% of patients receiving ERBITUX.

Dermatologic toxicities, including acneform rash (11% grade 3-4), skin drying and fissuring, and inflammatory or infectious sequelae (e.g., blepharitis, cheilitis, cellulitis, cyst) were reported. Sun exposure may exacerbate these effects.

Other serious adverse events associated with ERBITUX in clinical studies were fever (5%), sepsis (3%), kidney failure (2%), pulmonary embolus (1%), dehydration (5% in patients receiving ERBITUX plus irinotecan, 2% receiving monotherapy) and diarrhea (6% in patients receiving ERBITUX plus irinotecan, 0.2% with monotherapy).

Additional common adverse events seen in patients receiving ERBITUX plus irinotecan (n=354) or ERBITUX monotherapy (n=420) were acneform rash (88%/90%), asthenia/malaise (73%/49%), diarrhea (72%/25%), nausea (55%/29%), abdominal pain (45%/26%), vomiting (41%/25%), fever (34%/27%) and constipation (30%/26%).

Patients should be screened for EGFR expression using immunohistochemistry (IHC) to determine if they are appropriate candidates for treatment with ERBITUX. On February 12, 2004, the FDA approved an EGF receptor screening kit, manufactured by DakoCytomation A/S (formerly DAKO Corporation), in parallel with marketing approval of ERBITUX. ERBITUX is also being studied in earlier stages of colorectal cancer, as well as in other types of cancer that express the EGF receptor. Please see full prescribing information, available at www.ERBITUX.com for important safety information relating to ERBITUX, including a box warning regarding infusion reactions.

Human Monoclonal EGFR Inhibitor

We have developed a fully human monoclonal antibody, referred to as IMC-11F8, which targets the human EGFR. IMC-11F8 is a high affinity antibody that blocks ligand-dependent activation of the EGFR. Pre-clinical *in vitro* studies have shown that IMC-11F8 inhibits EGFR activation, downstream signaling pathways and growth of human tumor cells. In pre-clinical human tumor xenograft models, IMC-11F8 suppresses the growth of EGFR-positive tumors and enhances the activity of chemotherapeutic drugs when used in combination. We intend to commercialize this antibody in Europe and we believe that we have rights to do so under our agreements with BMS and Merck KGaA. However, Merck KGaA has advised us that it believes that IMC-11F8 could be covered under our existing developmental and license agreement with Merck KGaA and that it could therefore have the exclusive rights to market IMC-11F8 outside the United States and Canada and co-exclusive developmental rights in Japan, for which it would pay the same royalty as it pays for ERBITUX. See "Corporate Collaborations—Collaborations with Merck KGaA". We believe that IMC-11F8 is not covered under the Merck KGaA development and license agreement. We are discussing with Merck KGaA submitting this dispute to binding arbitration through an expedited process outside of the provisions of the development and license agreement. While we intend to vigorously defend our position as it relates to IMC-11F8 in any such proceeding, there is no assurance that our position would prevail in any arbitration proceeding. Commercial rights to this antibody in the U.S. and Canada fall within the scope of our agreement with BMS regarding Erbitux.

The Company received approval to begin Phase I clinical trials of IMC-11F8 from the National Institute for Public Health and the Environment (RIVM), the Dutch regulatory agency. The first patient began treatment in fourth quarter of 2004 in a Phase I clinical trial of patients with solid

tumors. The two-center study is being conducted at the Free University in Amsterdam and Utrecht University in Utrecht, and is designed to evaluate the safety and pharmacology of IMC-11F8 administered weekly or bi-weekly by intravenous infusion. The trial is expected to enroll up to 40 patients.

Monoclonal Antibody Inhibitors of Angiogenesis

Our general experience with growth factors, particularly the use of ERBITUX to block the EGF receptor, is mirrored in our pursuit of what may be another promising approach for the treatment of cancer, the inhibition of angiogenesis. Angiogenesis is the natural process of new blood vessel growth. VEGF is one of a group of molecules that helps regulate angiogenesis. Tumor cells, as well as normal cells, produce VEGF. Once produced by the tumor cells, VEGF stimulates the production of new blood vessels and ensures an adequate blood supply to the tumor, enabling the tumor to grow. KDR is a growth factor receptor found almost exclusively on the surface of human endothelial cells, which are the cells that line all blood vessels. VEGF must recognize and bind to this KDR receptor in order to stimulate the endothelial cells to grow and cause new blood vessels to form. We believe that interference with the binding of VEGF to the KDR receptor inhibits angiogenesis and potentially can be used to slow or halt tumor growth. We have identified potential inhibitors collectively known by us as IMC-KDR antibodies.

In 2001, we concluded a Phase I clinical study with a chimeric (part human, part murine) anti-KDR antibody known as IMC-1C11. In 2002, we identified several fully human monoclonal anti-KDR antibodies with potent anti-KDR activity. In 2003, we initiated pre-clinical development of one of these antibodies, IMC-1121B. We filed an Investigational New Drug Application ("IND") for IMC-1121B in July 2004 and have initiated clinical studies assessing its potential for angiogenesis inhibition in cancer patients during the fourth quarter of 2004. This fully human antibody has replaced IMC-1C11 in our development pipeline.

Subject to further investigation, we believe that such inhibitors could be effective in treating many solid and liquid tumors and may also be useful in treating other diseases, such as diabetic retinopathy and age-related macular degeneration that, like cancer, depend on the growth of new blood vessels.

Study	Description	Population	Target Enrollment
CP12-0401	Phase I Study of Weekly Anti-Vascular Endothelial Growth Factor Receptor 2 Monoclonal Antibody	In Patients with Advanced Solid Tumors who have not responded to Standard Therapy	33

Cancer Vaccines

BEC2

A cancer vaccine is proposed to work by the administration of an antigen or the mimic of an antigen that is found on the surface of certain types of cancer cells. Such treatment is intended to activate immune responses and in turn to protect against metastasis or recurrence of the tumor. A cancer vaccine generally will be given after the tumor has responded to initial treatment. Often, an antigen mimic can produce a stronger immune response than that produced by the original antigen that it resembles.

BEC2 is a monoclonal antibody that we were developing as a cancer vaccine. BEC2 mimics GD3, a molecule expressed on the surface of several types of cancer cells. By mimicking GD3, BEC2 stimulates an immune response against cells expressing GD3.

In conjunction with Merck KGaA, we have completed a 570-patient multinational pivotal Phase III study for BEC2 in the treatment of limited disease small-cell lung cancer. Limited disease small-cell lung carcinoma is limited to the lungs. The study examined patient survival two years after a course of therapy. Enrollment was completed in the third quarter of 2002. Data from this study was presented at the June 2004 ASCO conference.

The study demonstrated no improvement in survival, progression-free survival or quality of life was provided by the vaccination. There was no indication that any subgroup of patients benefited from vaccination. Following the analysis of the Phase III data in small cell lung cancer, we and Merck KGaA agreed to discontinue further development of BEC2.

gp75

We are conducting research on a murine DNA-based melanoma vaccine against the human melanoma antigen gp75. Melanoma is a tumor of the skin. Animal studies have shown that a gp75 cancer vaccine is effective in creating an immune response in the body of the animal against melanoma cells, and may prevent or inhibit growth of experimental melanoma tumors in mice. We submitted an IND for a gp75 DNA vaccine, referred to as IMC-GP75, and commenced Phase I human clinical studies with this vaccine in March 2002. This dose finding and proof of principle study has completed enrollment. The primary objective of the study is to establish the antigenicity of the vaccine, as measured by the production of antibodies to gp75 resulting from vaccination.

RESEARCH PROGRAMS

General

In addition to concentrating on our products in development, we perform ongoing research, including research in each of the areas of our ongoing clinical programs of growth factor blockers, other tumor cell growth inhibitors and angiogenesis inhibitors. We have assembled a scientific staff with expertise in a variety of disciplines, including oncology, immunology, molecular and cellular biology, antibody engineering, bioinformatics, protein chemistry, medicinal chemistry, computational chemistry and high-throughput screening. In addition to pursuing research programs in-house, we collaborate with academic institutions and corporations to support our research and development efforts.

Research on Growth Factor Blockers

We are conducting a research program to develop blockers of the cell-signal transduction pathways of a class of enzymes referred to as tyrosine kinases. Like those based on KDR and EGF receptors, these pathways have been shown to be involved in the rapid proliferation of tumor cells. We are developing monoclonal antibodies to block the binding of growth factors to a number of cellular receptors that trigger these pathways, thereby potentially inhibiting cell division and tumor growth. The more mature projects are briefly outlined in the following section. We also are developing small molecule inhibitors to tyrosine kinase pathways. Our small molecule program is discussed below.

Research on modulators of apoptosis (programmed cell death): We are developing antibody therapeutics that interfere with anti-apoptotic signaling and survival mechanisms of cancer cells. One mechanism involves the insulin-like growth factor-1 receptor (IGF1R) which is frequently over-expressed in diverse human tumor types. Activation of IGF1R in cancer cells increases the cells' ability to survive, especially under conditions of chemotherapy or radiotherapy, and it also contributes to cancer cell growth. We have developed and evaluated an antibody to IGF1R, designated IMC-A12, that blocks binding of insulin-like growth factor-1 to the receptor, thus preventing its activation and triggering of survival and growth mechanisms in cancer cells. The antibody also causes rapid internalization (removal from the cell surface) of IGF1R, thus further interfering with cancer growth-

supporting properties of the receptor. We anticipate filing an IND and initiating clinical studies for IMC-A12 in the first half of 2005.

Research on VEGFR-1 inhibitors: We are investigating the activities of antibodies that block the function of VEGFR-1 *(flt-1)*, another receptor to which VEGF binds. Like VEGFR-2, the target of our anti-KDR antibodies, the VEGFR-1 receptor is believed to be involved in blood vessel formation, but recent data suggest that it may function in novel ways unrelated to angiogenesis. We have discovered that VEGFR-1 is expressed by a number of human tumors, most notably breast and colorectal cancer. We have developed specific antibodies that block the function of VEGFR-1 and have conducted pre-clinical studies showing that these antibodies can inhibit the growth of human breast and colorectal tumors in pre-clinical models. It is believed that VEGFR-1 inhibitors could be useful in the treatment of VEGFR1-positive tumors, such as breast or colorectal cancer and we are developing therapeutic antibodies against this target for future clinical studies. One such agent, IMC-18F1, is a fully human monoclonal antibody for which we anticipate an IND filing and beginning of a phase 1 study in the third and fourth quarters of 2005, respectively.

We also have discovered that antibodies against VEGFR-1 may block inflammatory processes in such diseases as atherosclerosis and arthritis. Pre-clinical studies have demonstrated significant inhibition of atherosclerosis or arthritis disease processes by treatment with VEGFR-1 antibodies in mouse models. We are continuing research in this area to evaluate the therapeutic potential of VEGFR-1 antibodies in inflammatory diseases.

Research on PDGFR alpha inhibitors: Platelet-derived growth factor receptor alpha (PDGFRa) is a receptor tyrosine kinase that is activated by the binding of platelet-derived growth factors. Studies have shown that PDGFRa is expressed on ovarian, prostate, breast, lung, glial, skin and bone tumors. We have developed a fully human antibody, designated IMC-3G3 that effectively blocks the function of PDGFRa and inhibits the growth of glioblastoma and leiomyosarcoma tumors in animal models. We are conducting additional pre-clinical studies to evaluate if our antibody can also inhibit the growth of other cancers. We expect to file an IND for IMC-3G3 in the fourth quarter of 2005 or early in 2006.

Research on other growth factor receptor inhibitors: We are continually evaluating function-blocking antibodies against additional growth factor receptors known to be involved in the growth of certain cancers. We have reported promising results on solid tumor growth inhibition in animal models with antibodies against various fibroblast growth factor ("FGF") receptors and the recepteur d'origine Nantais ("RON"), and on leukemia inhibition with antibodies against the FLT3 receptor. We are further investigating these antibodies to define their potential clinical utility.

Research on Angiogenesis Inhibitors

Research on VEGFR-2 inhibitors: We are continuing to work with an experimental antibody known as DC101 in animal models in order to support the clinical development of our IMC-KDR monoclonal antibody known as IMC-1121B. DC101 neutralizes the *flk-1* receptor, which is the mouse receptor to VEGF that corresponds to KDR in humans. Tumor models in mice have shown that DC101 inhibits tumor growth as a single agent or in combination with chemotherapy or radiation therapy. We filed an IND for IMC-1121B in August 2004 and have since started a clinical phase 1 trial to study its potential for angiogenesis inhibition in cancer patients.

Research on VE-cadherin inhibitors: In another approach to angiogenesis inhibition, we are exploring the therapeutic potential of antibodies against vascular-specific cadherin ("VE-cadherin"). Cadherins are a family of cell surface molecules that help organize tissue structures. VE-cadherin is believed to play an important role in angiogenesis by organizing endothelial cells into vascular tubes, which is a necessary step in the formation of new blood vessels. Advanced tumor growth is dependent on the formation of a capillary blood vessel network in the tumor to ensure an adequate blood supply to the tumor. Therefore, antibodies that inhibit VE-cadherin may inhibit such capillary formation in

tumors, and help fight cancer by cutting off adequate blood supply to the tumor. Pre-clinical studies using monoclonal antibodies against VE-cadherin have demonstrated that inhibition of angiogenesis, tumor growth and metastasis occurs as a consequence of interfering with the ability of VE-cadherin to form tubular structures. We are evaluating in pre-clinical studies antibodies that are efficacious in inhibiting angiogenesis and tumor growth without negatively affecting existing vessels.

In connection with our VE-cadherin research program, we have an exclusive license from ICOS Corporation to certain patent rights pertaining to VE-cadherin and antibodies thereto for the treatment of cancer in humans.

Research on VEGFR-3 inhibitors: In connection with our research to block the binding of certain growth factors to their receptors, we have an exclusive license from the Ludwig Institute for Cancer Research to patent rights pertaining to VEGFR-3 inhibitors and the treatment of cancer. VEGFR-3 is thought to be involved in the metastatic spread of tumors via the lymphatic vessels.

Small Molecule Drug Discovery

We have established a chemistry department, which operates at our facility in Brooklyn, New York, with capabilities in medicinal chemistry, computational chemistry, and high-throughput screening. We also have established our own chemical compound library and infrastructure to perform high-throughput screening. This department, working together with our other research groups, is concerned with the discovery of small molecules that act on established or promising cancer targets residing inside the cancer cell where they are not reachable by antibodies. Examples of small molecule targets of interest to us are (1) signaling pathways that can promote uncontrolled growth of cancer cells that have lost normal growth control mechanisms, (2) the mechanisms that convey ability to cancer cells to resist cell death, (3) mechanisms of cell cycle progression, and (4) mechanisms that enable vascular function in tumor tissues.

CORPORATE COLLABORATIONS

In addition to our collaborations in the research and clinical areas with academic institutions, we have a number of collaborations with other corporations, the most significant of which are discussed below.

Collaborations with Bristol-Myers Squibb Company

On September 19, 2001, we entered into an acquisition agreement (the "Acquisition Agreement") with BMS and Bristol-Myers Squibb Biologics Company, a Delaware corporation ("BMS Biologics"), which is a wholly-owned subsidiary of BMS, providing for the tender offer by BMS Biologics to purchase up to 14,392,003 shares of our common stock for $70.00 per share, net to the seller in cash. In connection with the Acquisition Agreement, we entered into a stockholder agreement with BMS and BMS Biologics, dated as of September 19, 2001 (the "Stockholder Agreement"), pursuant to which all parties agreed to various arrangements regarding the respective rights and obligations of each party with respect to, among other things, the ownership of shares of our common stock by BMS and BMS Biologics. Concurrent with the execution of the Acquisition Agreement and the Stockholder Agreement, we entered into a commercial agreement (the "Commercial Agreement") with BMS and E.R. Squibb relating to ERBITUX, pursuant to which, among other things, BMS and E.R. Squibb are co-developing and co-promoting ERBITUX in the United States and Canada with us, and are co-developing and co-promoting ERBITUX in Japan with us and either together or co-exclusively with Merck KGaA.

On March 5, 2002, we amended the Commercial Agreement with E.R. Squibb and BMS. The amendment changed certain economics of the Commercial Agreement and expanded the clinical and strategic roles of BMS in the ERBITUX development program. One of the principal economic changes

to the Commercial Agreement is that we received payments of $140,000,000 on March 7, 2002 and $60,000,000 on March 5, 2003. Such payments are in lieu of the $300,000,000 milestone payment we would have received upon acceptance by the FDA of the ERBITUX BLA under the original terms of the Commercial Agreement. In addition, we agreed to resume and have resumed construction of our multiple product manufacturing facility located at 50 ImClone Drive on our Branchburg, New Jersey campus ("BB50"). The terms of the Commercial Agreement, as amended on March 5, 2002, are set forth in more detail below.

Commercial Agreement

Rights Granted to E.R. Squibb—Pursuant to the Commercial Agreement, as amended on March 5, 2002, we granted to E.R. Squibb (1) the exclusive right to distribute, and the co-exclusive right to develop and promote (together with us) any prescription pharmaceutical product using the compound ERBITUX (the "product") in the United States and Canada, (2) the co-exclusive right to develop, distribute and promote (together with us and together or co-exclusively with Merck KGaA and its affiliates) the product in Japan, and (3) the non-exclusive right to use our registered trademarks for the product in the United States, Canada and Japan (collectively, the "territory") in connection with the foregoing. In addition, we agreed not to grant any right or license to any third party, or otherwise permit any third party, to develop ERBITUX for animal health or any other application outside the human health field without the prior consent of E.R. Squibb (which consent may not be unreasonably withheld).

Rights Granted to the Company—Pursuant to the Commercial Agreement, E.R. Squibb has granted to us and our affiliates a license, without the right to grant sublicenses (other than to Merck KGaA and its affiliates for use in Japan and to any third party for use outside the territory), to use solely for the purpose of developing, using, manufacturing, promoting, distributing and selling ERBITUX or the product, any process, know-how or other invention developed solely by E.R. Squibb or BMS that has general utility in connection with other products or compounds in addition to ERBITUX or the product ("E.R. Squibb Inventions").

Up-Front and Milestone Payments—The Commercial Agreement provides for up-front and milestone payments by E.R. Squibb to us of $900,000,000 in the aggregate, of which $200,000,000 was paid on September 19, 2001, $140,000,000 was paid on March 7, 2002, $60,000,000 was paid on March 5, 2003 and $250,000,000 was paid on March 12, 2004. An additional $250,000,000 would become payable upon receipt of marketing approval from the FDA with respect to a second tumor type for ERBITUX. All such payments are non-refundable and non-creditable.

Distribution Fees—The Commercial Agreement provides that E.R. Squibb shall pay us distribution fees based on a percentage of "annual net sales" of the product (as defined in the Commercial Agreement) by E.R. Squibb in the United States and Canada. The distribution fee is 39% of net sales in the United States and Canada. During the year ended December 31, 2004, we have recorded royalty revenues of $101,703,000, representing 39% of net sales of ERBITUX by BMS.

The Commercial Agreement also provides that the distribution fees for the sale of the product in Japan by E.R. Squibb or ImClone Systems shall be equal to 50% of operating profit or loss with respect to such sales for any calendar month. In the event of an operating profit, E.R. Squibb shall pay us the amount of such distribution fee, and in the event of an operating loss, we shall credit E.R. Squibb the amount of such distribution fee.

Development of the Product—Responsibilities associated with clinical and other ongoing studies are apportioned between the parties as determined by the product development committee described below. The Commercial Agreement provides for the establishment of clinical development plans setting forth the activities to be undertaken by the parties for the purpose of obtaining marketing approvals, providing market support and developing new indications and formulations of the product. After transition of responsibilities for certain clinical and other studies, each party is primarily responsible for performing the studies designated to it in the clinical development plans. In the United States and Canada, the Commercial Agreement provides that E.R. Squibb is responsible for 100% of the cost of all clinical studies other than those studies undertaken post-launch which are not pursuant to an IND (e.g. Phase IV studies), the cost of which is shared equally between E.R. Squibb and ImClone Systems. As between E.R. Squibb and ImClone Systems, each is responsible for 50% of the costs of all studies in Japan. We have also agreed, and may agree in the future, to share with E.R. Squibb, on terms other than the foregoing, costs of clinical studies that we believe are not potentially registrational but should be undertaken prior to launch in the United States, Canada or Japan. We have incurred $9,096,000, $2,262,000 and $4,093,000 pursuant to such cost sharing for the years ended December 31, 2004, 2003 and 2002, respectively. In addition, to the extent that BMS and us, in 2005, exceed the contractual maximum registrational costs for clinical development, we have agreed to share such costs with BMS. We have also incurred $721,000, $663,000 and $377,000 related to the agreement with respect to development in Japan for the years ended December 31, 2004, 2003 and 2002, respectively. Except as otherwise agreed upon by the parties, the Company owns all registrations for the product and is primarily responsible for the regulatory activities leading to registration in each country. E.R. Squibb is primarily responsible for the regulatory activities in each country after the product has been registered in that country. Pursuant to the terms of the Commercial Agreement, as amended, Andrew G. Bodnar, M.D., J.D., Senior Vice President, Strategy and Medical & External Affairs of BMS, and a member of the Company's Board of Directors, is entitled to oversee the implementation of the clinical and regulatory plan for ERBITUX.

Distribution and Promotion of the Product—Pursuant to the Commercial Agreement, E.R. Squibb has agreed to use all commercially reasonable efforts to launch, promote and sell the product in the territory with the objective of maximizing the sales potential of the product and promoting the therapeutic profile and benefits of the product in the most commercially beneficial manner. In connection with its responsibilities for distribution, marketing and sales of the product in the territory, E.R. Squibb is performing all relevant functions, including but not limited to the provision of all sales force personnel, marketing (including all advertising and promotional expenditures), warehousing and physical distribution of the product.

However, we have the right, at our election and sole expense, to co-promote with E.R. Squibb the product in the territory. Pursuant to this co-promotion option, which we have exercised, we are entitled on or after April 11, 2002 (at our sole expense) to have our field organization participate in the promotion of the product consistent with the marketing plan and development plans agreed upon by the parties, provided that E.R. Squibb retains the exclusive rights to sell and distribute the product. Except for our expenses incurred pursuant to the co-promotion option, E.R. Squibb is responsible for 100% of the distribution, sales and marketing costs in the United States and Canada, and as between E.R. Squibb and ImClone Systems, each is responsible for 50% of the distribution, sales, marketing costs and other related costs and expenses in Japan. During the third quarter of 2004, we decided to establish a sales force to maximize the potential commercial opportunities for ERBITUX and to serve as a foundation for the marketing of future products derived either from within our pipeline or through business development opportunities.

Manufacture and Supply—The Commercial Agreement provides that we are responsible for the manufacture and supply of all requirements of ERBITUX in bulk form ("API") for clinical and commercial use in the territory, and that E.R. Squibb must purchase all of its requirements of API for

commercial use from us. We supply API for clinical use at our fully burdened manufacturing or purchase cost, and supply API for commercial use at our fully burdened manufacturing or purchase cost plus a mark-up of 10%. Upon the expiration, termination or assignment of any existing agreements between ImClone Systems and third party manufacturers, E.R. Squibb will be responsible for processing API into the finished form of the product.

Management—The parties have formed the following committees for purposes of managing their relationship and their respective rights and obligations under the Commercial Agreement:

- a Joint Executive Committee (the "JEC"), which consists of certain senior officers of each party. The JEC is co-chaired by a representative of BMS and us. The JEC is responsible for, among other things, managing and overseeing the development and commercialization of ERBITUX pursuant to the terms of the Commercial Agreement, approving the annual budgets and multi-year expense forecasts, and resolving disputes, disagreements and deadlocks arising in the other committees;

- a Product Development Committee (the "PDC"), which consists of members of senior management of each party with expertise in pharmaceutical drug development and/or marketing. The PDC is chaired by our representative. The PDC is responsible for, among other things, managing and overseeing the development and implementation of the clinical development plans, comparing actual versus budgeted clinical development and regulatory expenses, and reviewing the progress of the registrational studies;

- a Joint Commercialization Committee (the "JCC"), which consists of members of senior management of each party with clinical experience and expertise in marketing and sales. The JCC is chaired by a representative of BMS. The JCC is responsible for, among other things, overseeing the preparation and implementation of the marketing plans, coordinating the sales and commercial support efforts of E.R. Squibb and us, and reviewing and approving the marketing and promotional plans for the product in the territory; and

- a Joint Manufacturing Committee (the "JMC"), which consists of members of senior management of each party with expertise in manufacturing. The JMC is chaired by our representative (unless a determination is made that a long-term inability to supply API exists, in which case the JMC will be co-chaired by representatives of E.R. Squibb and us). The JMC is responsible for, among other things, overseeing and coordinating the manufacturing and supply of API and the product, and formulating and directing the manufacturing strategy for the product.

Any matter that is the subject of a deadlock (i.e., no consensus decision) in the PDC, the JCC or the JMC will be referred to the JEC for resolution. Subject to certain exceptions, deadlocks in the JEC will be resolved as follows: (1) if the matter was also the subject of a deadlock in the PDC, by the co-chairperson of the JEC designated by us, (2) if the matter was also the subject of a deadlock in the JCC, by the co-chairperson of the JEC designated by BMS, or (3) if the matter was also the subject of a deadlock in the JMC, by the co-chairperson of the JEC designated by us. All other deadlocks in the JEC will be resolved by arbitration.

Right of First Offer—E.R. Squibb has a right of first offer with respect to our investigational IMC-KDR monoclonal antibodies should we decide to enter into a partnering arrangement with a third party with respect to IMC-KDR antibodies at any time prior to the earlier to occur of September 19, 2006 and the first anniversary of the date which is 45 days after any date on which BMS's ownership interest in ImClone Systems is less than 5%. If we decide to enter into a partnering arrangement during such period, we must notify E.R. Squibb. If E.R. Squibb notifies us that it is interested in such an arrangement, we will provide proposed terms to E.R. Squibb and the parties will negotiate in good faith for 90 days to attempt to agree on the terms and conditions of such an arrangement. If the parties

do not reach agreement during this period, E.R. Squibb must propose the terms of an arrangement which it is willing to enter into, and if we reject such terms we may enter into an agreement with a third party with respect to such a partnering arrangement (provided that the terms of any such agreement may not be more favorable to the third party than the terms proposed by E.R. Squibb).

Right of First Negotiation—If at any time during the restricted period (as defined below), we are interested in establishing a partnering relationship with a third party involving certain compounds or products not related to IMC-KDR antibodies, we must notify E.R. Squibb and E.R. Squibb will have 90 days to enter into a non-binding agreement with us with respect to such a partnering relationship. In the event that E.R. Squibb and ImClone Systems do not enter into a non-binding agreement, we are free to negotiate with third parties without further obligation to E.R. Squibb. The "restricted period" means the period from September 19, 2001 until the earliest to occur of (1) September 19, 2006, (2) a reduction in BMS's ownership interest in ImClone Systems to below 5% for 45 consecutive days, (3) a transfer or other disposition of shares of our common stock by BMS or any of its affiliates such that BMS and its affiliates own or have control over less than 75% of the maximum number of shares of our common stock owned by BMS and its affiliates at any time after September 19, 2001, (4) an acquisition by a third party of more than 35% of the outstanding Shares, (5) a termination of the Commercial Agreement by BMS due to significant regulatory or safety concerns regarding ERBITUX, or (6) our termination of the Commercial Agreement due to a material breach by BMS.

Restriction on Competing Products—During the period from the date of the Commercial Agreement until September 19, 2008, the parties have agreed not to, directly or indirectly, develop or commercialize a competing product (defined as a product that has as its only mechanism of action an antagonism of the EGF receptor) in any country in the territory. In the event that any party proposes to commercialize a competing product or purchases or otherwise takes control of a third party which has developed or commercialized a competing product, then such party must either divest the competing product within 12 months or offer the other party the right to participate in the commercialization and development of the competing product on a 50/50 basis (provided that if the parties cannot reach agreement with respect to such an agreement, the competing product must be divested within 12 months).

Ownership—The Commercial Agreement provides that we own all data and information concerning ERBITUX and the product, and except for E.R. Squibb Inventions, all processes, know-how and other inventions relating to the product and developed by either party or jointly by the parties. E.R. Squibb, however, has the right to use all such data and information, and all such processes, know-how or other inventions, in order to fulfill its obligations under the Commercial Agreement.

Product Recalls—If E.R. Squibb is required by any regulatory authority to recall the product in any country in the territory (or if the JCC determines such a recall to be appropriate), then E.R. Squibb and ImClone Systems shall bear the costs and expenses associated with such a recall (1) in the United States and Canada, in the proportion of 39% for ImClone Systems and 61% for E.R. Squibb and (2) in Japan, in the proportion for which each party is entitled to receive operating profit or loss (unless, in the territory, the predominant cause for such a recall is the fault of either party, in which case all such costs and expenses shall be borne by such party).

Mandatory Transfer—Each of BMS and E.R. Squibb has agreed under the Commercial Agreement that in the event it sells or otherwise transfers all or substantially all of its pharmaceutical business or pharmaceutical oncology business, it must also transfer to the transferee its rights and obligations under the Commercial Agreement.

Indemnification—Pursuant to the Commercial Agreement, each party has agreed to indemnify the other for (1) its negligence, recklessness or wrongful intentional acts or omissions, (2) its failure to

perform certain of its obligations under the agreement, and (3) any breach of its representations and warranties under the agreement.

Termination—Unless earlier terminated pursuant to the termination rights discussed below, the Commercial Agreement expires with regard to the product in each country in the territory on the later of September 19, 2018 and the date on which the sale of the product ceases to be covered by a validly issued or pending patent in such country. The Commercial Agreement may also be terminated prior to such expiration as follows:

- by either party, in the event that the other party materially breaches any of its material obligations under the Commercial Agreement and has not cured such breach within 60 days after notice;
- by E.R. Squibb, if the JEC determines that there exists a significant concern regarding a regulatory or patient safety issue that would seriously impact the long-term viability of all products.

Acquisition Agreement

On October 29, 2001, pursuant to the Acquisition Agreement, BMS Biologics accepted for payment pursuant to the tender offer 14,392,003 shares of the Company's common stock on a pro rata basis from all tendering shareholders and those conditionally exercising stock options.

Stockholder Agreement

Pursuant to the Stockholder Agreement, our Board was increased from ten to twelve members in October 2001. BMS received the right to nominate two directors to our Board (each a "BMS director") so long as its ownership interest in ImClone Systems is 12.5% or greater. If BMS' ownership interest is 5% or greater but less than 12.5%, BMS will have the right to nominate one BMS director, and if BMS' ownership interest is less than 5%, BMS will have no right to nominate a BMS director. If the size of the Board is increased to a number greater than twelve, the number of BMS directors would be increased, subject to rounding, such that the number of BMS directors is proportionate to the lesser of BMS' then-current ownership interest and 19.9%. Notwithstanding the foregoing, BMS will have no right to nominate any BMS directors if (1) we have terminated the Commercial Agreement due to a material breach by BMS or (2) BMS' ownership interest were to remain below 5% for 45 consecutive days.

Based on the number of shares of common stock acquired pursuant to the tender offer, BMS has the right to nominate two directors. BMS designated Andrew G. Bodnar, M.D., J.D., BMS' Senior Vice President, Strategy and Medical & External Affairs, as one of the initial BMS directors. The nomination of Dr. Bodnar was approved by the Board on November 15, 2001. The other BMS director position was initially filled by Peter S. Ringrose, M.A, Ph.D. Dr. Ringrose retired in 2002 from his position of Chief Scientific Officer and President, Pharmaceutical Research Institute at BMS, and also resigned from his director position with us. BMS has not yet designated a replacement to fill Dr. Ringrose's vacated Board seat.

Voting of Shares—During the period in which BMS has the right to nominate at least one BMS director, BMS and its affiliates are required to vote all of their shares in the same proportion as the votes cast by all of our other stockholders with respect to the election or removal of non-BMS directors.

Committees of the Board of Directors—During the period in which BMS has the right to nominate at least one BMS director, BMS also has the right, subject to certain exceptions and limitations, to have one member of each committee of the Board be a BMS director. In order to maintain

independence of the Audit, Nominating & Corporate Governance, and Compensation and Stock Option Committees, no BMS director is serving on these committees.

Approval Required for Certain Actions—We may not take any action that constitutes a prohibited action under the Stockholder Agreement without the consent of the BMS directors, until September 19, 2006 or earlier, if any of the following occurs: (1) a reduction in BMS's ownership interest to below 5% for 45 consecutive days, (2) a transfer or other disposition of shares of our common stock by BMS or any of its affiliates such that BMS and its affiliates own or have control over less than 75% of the maximum number of shares of our common stock owned by BMS and its affiliates at any time after September 19, 2001, (3) an acquisition by a third party of more than 35% of the outstanding shares of our common stock, (4) a termination of the Commercial Agreement by BMS due to significant regulatory or safety concerns regarding ERBITUX, or (5) a termination of the Commercial Agreement due to a material breach by BMS. Such prohibited actions include (1) issuing additional shares or securities convertible into shares in excess of 21,473,002 shares of our common stock in the aggregate, subject to certain exceptions; (2) incurring additional indebtedness if the total of (A) the principal amount of indebtedness incurred since September 19, 2001 and then-outstanding, and (B) the net proceeds from the issuance of any redeemable preferred stock then-outstanding, would exceed our amount of indebtedness for borrowed money outstanding as of September 19, 2001 by more than $500 million; (3) acquiring any business if the aggregate consideration for such acquisition, when taken together with the aggregate consideration for all other acquisitions consummated during the previous twelve months, is in excess of 25% of our aggregate value at the time the binding agreement relating to such acquisition was entered into; (4) disposing of all or any substantial portion of our non-cash assets; (5) entering into non-competition agreements that would be binding on BMS, its affiliates or any BMS director; (6) taking certain actions that would have a discriminatory effect on BMS or any of its affiliates as a stockholder; and (7) issuing capital stock with more than one vote per share.

Limitation on Additional Purchases of Shares and Other Actions—Subject to the exceptions set forth below, until September 19, 2006 or, if earlier, the occurrence of any of (1) an acquisition by a third party of more than 35% of our outstanding shares, (2) the first anniversary of a reduction in BMS's ownership interest in us to below 5% for 45 consecutive days, or (3) our taking a prohibited action under the Stockholder Agreement without the consent of the BMS directors, neither BMS nor any of its affiliates will acquire beneficial ownership of any shares of our common stock or take any of the following actions: (1) encourage any proposal for a business combination with us or an acquisition of our shares; (2) participate in the solicitation of proxies from holders of shares of our common stock; (3) form or participate in any "group" (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934) with respect to shares of our common stock; (4) enter into any voting arrangement with respect to shares of our common stock; or (5) seek any amendment to or waiver of these restrictions.

The following are exceptions to the standstill restrictions described above: (1) BMS Biologics may acquire beneficial ownership of shares of our common stock either in the open market or from us pursuant to the option described below, so long as, after giving effect to any such acquisition of shares, BMS' ownership interest would not exceed 19.9%; (2) BMS may make, subject to certain conditions, a proposal to the Board to acquire shares of our common stock if we provide material non-public information to a third party in connection with, or begin active negotiation of, an acquisition by a third party of more than 35% of the outstanding shares; (3) BMS may acquire shares of our common stock if such acquisition has been approved by a majority of the non-BMS directors; and (4) BMS may make, subject to certain conditions, including that an acquisition of shares be at a premium of at least 25% to the prevailing market price, non-public requests to the Board to amend or waive any of the standstill restrictions described above. Certain of the exceptions to the standstill provisions described above will terminate upon the occurrence of: (1) a reduction in BMS's ownership interest in us to below 5% for 45 consecutive days, (2) a transfer or other disposition of shares of our common stock by BMS or any

of its affiliates such that BMS and its affiliates own or have control over less than 75% of the maximum number of shares owned by BMS and its affiliates at any time after September 19, 2001, (3) a termination of the Commercial Agreement by BMS due to significant regulatory or safety concerns regarding ERBITUX, or (4) a termination of the Commercial Agreement by us due to a material breach by BMS.

Option to Purchase Shares in the Event of Dilution—BMS Biologics has the right under certain circumstances to purchase additional shares of common stock from us at market prices, pursuant to an option granted to BMS by us, in the event that BMS's ownership interest is diluted (other than by any transfer or other disposition by BMS or any of its affiliates). BMS can exercise this right (1) once per year, (2) if we issue shares of common stock in excess of 10% of the then-outstanding shares in one day, and (3) if BMS's ownership interest is reduced to below 5% or 12.5%. BMS Biologics' right to purchase additional shares of common stock from us pursuant to this option will terminate on September 19, 2006 or, if earlier, upon the occurrence of (1) an acquisition by a third party of more than 35% of the outstanding shares, or (2) the first anniversary of a reduction in BMS's ownership interest in us to below 5% for 45 consecutive days.

Transfers of Shares—Until March 19, 2005, neither BMS nor any of its affiliates may transfer any shares of our common stock or enter into any arrangement that transfers any of the economic consequences associated with the ownership of shares. After March 19, 2005, neither BMS nor any of its affiliates may transfer any shares or enter into any arrangement that transfers any of the economic consequences associated with the ownership of shares, except (1) pursuant to registration rights granted to BMS with respect to the shares, (2) pursuant to Rule 144 under the Securities Act of 1933, as amended or (3) for certain hedging transactions. Any such transfer is subject to the following limitations: (1) the transferee may not acquire beneficial ownership of more than 5% of the then-outstanding shares of common stock; (2) no more than 10% of the total outstanding shares of common stock may be sold in any one registered underwritten public offering; and (3) neither BMS nor any of its affiliates may transfer shares of common stock (except for registered firm commitment underwritten public offerings pursuant to the registration rights described below) or enter into hedging transactions in any twelve-month period that would, individually or in the aggregate, have the effect of reducing the economic exposure of BMS and its affiliates by the equivalent of more than 10% of the maximum number of shares of common stock owned by BMS and its affiliates at any time after September 19, 2001. Notwithstanding the foregoing, BMS Biologics may transfer all, but not less than all, of the shares of common stock owned by it to BMS or to E.R. Squibb or another wholly-owned subsidiary of BMS.

Registration Rights—We granted BMS customary registration rights with respect to shares of common stock owned by BMS or any of its affiliates.

We incurred approximately $2,250,000 during the year ended December 31, 2002 in legal and other advisor fees associated with the amendment to the Commercial Agreement with BMS and affiliates, and $16,055,000 during the year ended December 31, 2001, in legal and other advisor fees associated with consummating the Acquisition Agreement, the Stockholder Agreement and the Commercial Agreement with BMS and affiliates. These costs have been expensed and included in operating expenses in the Consolidated Statements of Operations.

In June 2002, BMS and ImClone agreed that certain ERBITUX clinical study costs incurred by us but billed to BMS under the Commercial Agreement would in fact be borne by us due to such studies' non-registrational nature. This resulted in the issuance of credit memos to BMS during the year ended December 31, 2002 totaling approximately $2,949,000, which ultimately reduced collaborative agreement revenue and license fee revenue in the year ended December 31, 2002.

Collaborations with Merck KGaA

ERBITUX Development and License Agreement—In December 1998, the Company entered into a development and license agreement with Merck KGaA with respect to ERBITUX. In exchange for granting Merck KGaA exclusive rights to market ERBITUX outside of the United States and Canada and co-exclusive development rights in Japan, the Company has received $30,000,000 through December 31, 2004 in up-front cash fees and early cash payments based on the achievement of defined milestones. An additional $30,000,000 has been received through December 31, 2004 based upon the achievement of further milestones for which Merck KGaA received equity in the Company. All amounts received in 2004 and 2003 were recorded as equity transactions.

The chart below details the equity milestone payments received from Merck KGaA during the three years ended December 31, 2004:

Date	Amount of Milestone	Revenue Recognized	Number of common shares issued to Merck KGaA	Price per share
May 2003	$6,000,000	—	334,471	$17.94
June 2003	$3,000,000	—	150,007	$20.00
July 2003	$3,000,000	—	92,276	$32.51
July 2003	$3,000,000	—	90,944	$32.99
December 2003 .	$5,000,000	—	127,199	$39.31
July 2004	$5,000,000	—	58,807	$58.18

The equity interests underlying the milestone payments were priced at varying premiums to the then-market price of the common stock depending upon the timing of the achievement of the respective milestones. Merck KGaA pays us a royalty on sales of ERBITUX outside of the United States and Canada. In August 2001, Merck KGaA and we amended this agreement to provide, among other things, that Merck KGaA may manufacture ERBITUX for supply in its territory and may utilize a third party to do so upon our reasonable acceptance. The amendment further released Merck KGaA from its obligations under the agreement relating to providing a guaranty under a $30,000,000 credit facility relating to the build-out of BB36. In addition, the amendment provides that the companies have co-exclusive rights to ERBITUX in Japan, including the right to sublicense and Merck KGaA waived its right of first offer in the case of a proposed sublicense by us of ERBITUX in our territory. In consideration for the amendment, we agreed to a reduction in royalties payable by Merck KGaA on sales of ERBITUX in Merck KGaA's territory.

In September 2002, the Company entered into a binding term sheet, effective as of April 15, 2002, for the supply of ERBITUX to Merck KGaA, which replaces previous supply arrangements. The term sheet provides for Merck KGaA to purchase bulk and finished ERBITUX ordered from us during the term of the December 1998 development and license agreement at a price equal to our fully loaded cost of goods. The term sheet also provided for Merck KGaA to use reasonable efforts to enter into its own contract manufacturing agreements for supply of ERBITUX and obligates Merck KGaA to reimburse us for costs associated with transferring technology and any other services requested by Merck KGaA relating to establishing its own manufacturing or contract manufacturing capacity.

In June 2003, we agreed to supply a fixed quantity of ERBITUX for use in Merck KGaA's medical affairs program on different ordering and pricing terms than those provided in the binding term sheet, including prepayment by Merck KGaA for a portion of such supply. We have recorded this prepayment as deferred revenue on the Consolidated Balance Sheet until such time as the product is shipped to Merck KGaA. During 2004, the Company shipped some products under this agreement and based on a current demand schedule, it is expected that the remaining quantity will be shipped during 2005.

BEC2 Research and License Agreement—Effective April 1990, we entered into an agreement with Merck KGaA relating to the development and commercialization of BEC2 and the recombinant gp75 antigen. Under this agreement:

- we granted Merck KGaA a license, with the right to sublicense, to make, have made, use, sell, or have sold BEC2 and gp75 antigen outside North America;
- we granted Merck KGaA a license, without the right to sublicense, to use, sell, or have sold, but not to make, BEC2 within North America in conjunction with ImClone Systems;
- we retained the rights, (1) without the right to sublicense, to make, have made, use, sell, or have sold BEC2 in North America in conjunction with Merck KGaA and (2) with the right to sublicense, to make, have made, use, sell, or have sold gp75 antigen in North America;
- we are required to give Merck KGaA the opportunity to negotiate a license in North America to gp75 antigen before granting such a license to any third party.

In return, Merck KGaA:

- has made research support payments to us totaling $4,700,000;
- is required to make milestone payments to us of up to $22,500,000, of which $4,000,000 has been received through December 31, 2004, based on milestones achieved in the product development of BEC2;
- is required to make royalty payments to us on all sales of the licensed products outside North America, if any, with a portion of the earlier funding received under the agreement being creditable against the amount of royalties due.

Merck KGaA is responsible for conducting the clinical studies and regulatory submissions outside North America, and we are responsible for conducting those within North America. We are responsible for providing the supply of the active agent outside of North America at the expense of Merck KGaA, and the parties intend that the cost of goods sold in North America be paid out of gross sales of any licensed product in North America in accordance with a co-promotion agreement to be negotiated.

The agreement terminates upon the later of (1) the last to expire of any patents issued and covered by the technology or (2) fifteen years from the date of the first commercial sale. After termination, the license will survive without further royalty payment and is irrevocable. The agreement may be terminated earlier by us in the event Merck KGaA fails to pursue in a timely fashion regulatory approval or sale of a licensed product in a country in which it has the right to do so. It also may be terminated earlier by Merck KGaA if milestones are not achieved.

On June 7, 2004, we and Merck KGaA announced that the international, randomized Phase III clinical trial of our IMC-BEC2 cancer vaccine did not meet its primary endpoint of survival. Following the analysis of the Phase III data in small cell lung cancer, we and Merck KGaA agreed to discontinue further development of BEC2.

MANUFACTURING

ImClone Systems Manufacturing Facilities

We own and operate a pilot manufacturing facility ("BB22") for biologics in Branchburg, New Jersey for the manufacture of clinical study materials. At our pilot facility, we previously manufactured a portion of the ERBITUX utilized for clinical studies. We now are using our pilot facility for ERBITUX manufacturing process improvements, to develop the cell culture and purification process for IMC-KDR antibodies and to produce IMC-KDR antibodies for anticipated clinical studies. We also

plan to use the pilot manufacturing facility for the manufacture of other monoclonal antibodies in early development. Our pilot facility is operated in accordance with current Good Manufacturing Practices ("cGMP"), which is a requirement for product manufactured for use in clinical studies and for commercial sale.

Production of ERBITUX in commercial quantities required the expansion of our manufacturing capabilities and the hiring and training of additional personnel. In July 2001, we completed construction of an 80,000 square foot manufacturing facility, BB36, on our Branchburg, New Jersey campus. BB36 contains three 10,000 liter (production volume) fermenters and is dedicated to the clinical and commercial production of ERBITUX. The construction of BB36 cost a total of approximately $53,000,000, excluding capitalized interest of approximately $1,966,000. BB36 was ready for its intended use and was put into operation in July 2001. On June 18, 2004 the FDA granted a license to the BB36 facility for U.S. commercial supply. Additionally, BB36 had a satisfactory cGMP inspection by the Regierungspräsidium Darmstadt that resulted in a Product Import license being granted to Merck KGaA in April 2003, covering the period November 2003 to October 2004. The Regierungspräsidium reinspection has been scheduled for the first Quarter 2005. In December 2003, Swissmedic approved ERBITUX manufactured at BB36 for commercial use in Switzerland, in addition to ERBITUX manufactured at a European contract manufacturing site (Boehringer Ingelheim).

We are building a multiple product manufacturing facility ("BB50") in Branchburg, New Jersey with capacity of up to 110,000 liters (production volume). Management estimates that the 250,000 square foot facility will cost approximately $290,000,000, which is higher than a previously disclosed estimate of $260,000,000. The increase is due to the inclusion of incremental costs associated with the commissioning and validation work needed in order to bring this asset to its intended use. The actual cost of the new facility may change depending on various factors. We have incurred approximately $227,452,000 in conceptual design, engineering, pre-construction and construction costs, excluding capitalized interest of approximately $14,760,000, through December 31, 2004. As of December 31, 2004, committed purchase orders totaling approximately $177,414,000 have been placed with subcontractors for equipment related to this project and $69,231,000 for engineering, procurement, construction management and validation costs. Through December 31, 2004, $218,347,000 has been paid relating to these committed purchase orders.

Contract Manufacturing

In September 2000, we entered into a three-year commercial manufacturing services agreement with Lonza relating to ERBITUX. This agreement was amended in June 2001, September 2001, and August 2003 to include additional services and potentially to extend the term of the agreement. The total cost for services to be provided under the commercial manufacturing services agreement was approximately $86,913,000. We did not incur any costs during 2004 and had incurred costs of $23,189,000 and $51,520,000 for the years ended December 31, 2003 and 2002, respectively, and $85,022,000 was incurred from inception through December 31, 2004, for services provided under the commercial manufacturing services agreement. As of December 31, 2004, our commitment to Lonza under this agreement has been completed. The entire ERBITUX inventory produced by Lonza was consumed in clinical trials and used for commercial distribution during 2004.

Under the September 2000 agreement, Lonza manufactured ERBITUX at the 5,000-liter scale under cGMP and delivered it to us. The costs associated with this agreement are included in research and development expenses when incurred. During the term of the agreement, certain batches were cancelled at negotiated rates agreed to by the parties. All existing commitments under this agreement were completed during the year ended December 31, 2003, but an August 2003 amendment to the agreement allows for potential manufacture of a limited number of additional batches.

We rely entirely on a third party manufacturer for filling and finishing services with respect to ERBITUX. If our current third party manufacturers or critical raw material suppliers fail to meet our expectations, we cannot be assured that we will be able to enter into new agreements with other suppliers or third party manufacturers without an adverse effect on our business.

MARKETING AND SALES

Pursuant to the terms of the Commercial Agreement, E.R. Squibb has primary responsibility for distribution, marketing and sales of ERBITUX in the United States and Canada and will provide sales force personnel and marketing services for ERBITUX. We have the right, at our election and sole expense, to co-promote ERBITUX with E.R. Squibb. As part of our strategy to develop the capacity to market our cancer therapeutic products, we have exercised this co-promotion right and are therefore entitled to have our field organization participate in activities supporting the commercial launch of ERBITUX. Pursuant to the terms of the Commercial Agreement, E.R. Squibb retains the exclusive rights to sell and distribute the product. Pursuant to our co-promotion rights, during the third quarter of 2004 the Company decided to establish a field force of oncology sales professionals to increase the Company's presence and prominence within the oncology community and help maximize the market potential for ERBITUX in its applied indication.

We will continue to evaluate future arrangements and opportunities with respect to other products we may develop in order to optimize our profits and our distribution, marketing and sales capabilities.

PATENTS AND TRADEMARKS

General

We seek patent protection for our proprietary technology and products in the United States and abroad. Patent applications have been submitted and are pending in the United States, Canada, Europe and Japan, as well as other countries. The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. Our success will depend, in part, on whether we can:

- obtain patents to protect our own products;
- obtain licenses to use the technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how; and
- operate without infringing the intellectual property and proprietary rights of others.

Patent Rights; Licenses

We currently have exclusive licenses or assignments to 99 issued patents worldwide that relate to our proprietary technology in the United States and foreign countries, 51 of which are issued United States patents. In addition, we currently have exclusive licenses or assignments to approximately 79 families of patent applications.

ERBITUX. We have an exclusive license from the University of California to an issued United States patent for the murine form of ERBITUX, our EGF receptor antibody product. We believe that this patent's scope should be its literal claim scope as well as other antibodies not literally embraced but potentially covered under the patent law doctrine of equivalents. Whether or not a particular antibody is found to be an equivalent to the antibodies literally covered by the patent can only be determined at the time of a potential infringement, and in view of the technical details of the potentially infringing antibody in question. Our licensor of this patent did not obtain patent protection outside the United States for this antibody.

We are pursuing additional patent protection relating to the field of EGF receptor antibodies in the treatment of cancer that may limit the ability of third parties to commercialize EGF receptor antibodies for such use. Specifically, we are pursuing patent protection for the use of EGF receptor antibodies in combination with chemotherapy to inhibit tumors or tumor growth. We have exclusively licensed from Rhone-Poulenc Rorer Pharmaceuticals, now known as Aventis, patent applications seeking to cover the therapeutic use of antibodies to the EGF receptor in conjunction with anti-neoplastic agents. A U.S. patent, a Canadian patent and a European patent were issued in this family. In December 2002, Opposition Proceedings seeking to revoke the European patent were brought by the Scripps Research Institute, Amgen Inc., Abgenix, Inc., and YM Biosciences Inc. An Opposition Proceeding is an administrative process, the outcome of which may be that our European patent will be revoked. The Company has vigorously defended its position in this matter, which is suspended pending the outcome of the Yeda matter discussed under Item 3; "Legal Proceedings". We have filed additional patent applications, based in part on our own research, that would cover the use of ERBITUX and other EGF receptor antibodies in conjunction with radiation therapy, and the use of ERBITUX and other EGF receptor inhibitors in refractory patients, either alone or in combination with chemotherapy or radiation therapy. We have also filed patent applications that include claims on the use of conjugated forms of ERBITUX, as well as humanized forms of the antibody and fragments.

Our license agreements with the University of California and Aventis require us to pay royalties on sales of ERBITUX that are covered by these licenses. The Company has recently concluded license negotiations with Genentech and Centocor for patents relating to the use and manufacture of ERBITUX. We have entered license agreements with Genentech for rights to patents covering certain use of epidermal growth factor receptor antibodies and with both Genentech and Centocor for rights to patents covering various aspects of antibody technology. Our agreements with both Genentech and Centocor require us to pay royalties on the sale of ERBITUX that are covered by these licenses.

There can be no assurance that patent applications related to the field of antibodies in the treatment of cancer to which we hold rights will result in the issuance of patents, that any patents issued or licensed to our company related to ERBITUX or its use will not be challenged and held to be invalid or of a scope of coverage that is different from what we believe the patent's scope to be, or that our present or future patents related to these technologies will ultimately provide adequate patent coverage for or protection of our present or future EGF receptor antibody technologies, products or processes. Until recently, patent applications were secret until patents were issued in the U.S., or corresponding applications were published in foreign countries, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions, or that we were the first to file patent applications for such inventions. In addition, patents do not give the holder the right to commercialize technology covered by the patents, should our production or our use be found by a court to be embraced by the patent of another.

In the event that we are called upon to defend and/or prosecute patent suits and/or related legal or administrative proceedings, such proceedings are costly and time consuming and could result in loss of our patent rights, infringement penalties or both. Litigation and patent interference proceedings could result in substantial expense to us and significant diversion of efforts by our technical and management personnel. An adverse determination in any such interference proceedings or in patent litigation, particularly with respect to ERBITUX, to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties. If required, the necessary licenses may not be available on acceptable financial or other terms or at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us, in whole or in part, from commercializing our products, which could have a material adverse effect on our business, financial condition and results of operations.

In the event that there is patent litigation involving one or more of the patents issued to us, there can be no guarantee that the patents will be held valid and enforceable. The scope of patents may be called into question and could result in a decision by a court that the claims have a different scope than we believe them to have. Further, the outcome of patent litigation is subject to intangibles that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses that will be called to testify and the identity of the adverse party. This is especially true in biotechnology-related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

There can be no assurance that we will not be subject to claims in patent suits, that one or more of our products or processes infringe third parties' patents or violate the proprietary rights of third parties. Defense and prosecution of such patent suits can result in the diversion of substantial financial, management and other resources from our other activities. An adverse outcome could subject us to significant liability to third parties, require us to obtain licenses from third parties, or require that we cease any related product development activities or product sales.

An adverse determination by a court in any such patent litigation, or by the U.S. Patent and Trademark Office in a patent interference proceeding, particularly with respect to ERBITUX, to which we may become a party, could subject us to significant liabilities to third parties or require us to seek licenses from third parties, or result in loss in whole or part of our ability to continue to sell our product. If required, the necessary licenses may not be available on acceptable terms or at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us, in whole or in part, from commercializing our products, which could have a material adverse effect on our business, financial condition and results of operations.

Angiogenesis Inhibitors. With respect to our research on inhibitors to angiogenesis based on the *flk-1* receptor (VEGFR2), we are the exclusive licensee from Princeton University of a family of patents and patent applications covering recombinant nucleic acid molecules that encode the murine *flk-1* receptor and antibodies to extracellular portions of the receptor and its human homolog, KDR. We are also the assignee of a family of patents and patent applications filed by our scientists generally related to angiogenesis-inhibiting antibodies to receptors that bind VEGF, for example human flt-1 (VEGFR1) and KDR (VEGFR2). One of the patents licensed from Princeton University claims the use of *flk-1* receptor antibodies to isolate cells expressing the *flk-1* receptor on their cell surfaces. Additionally, we are a co-owner of a patent application claiming the use of *flk-1*/KDR receptor antibodies to isolate endothelial stem cells that express *flk-1*/KDR on their cell surfaces. At present, we are seeking exclusive rights to this invention from the co-owners. We have an exclusive license from the Ludwig Institute for Cancer Research for patent rights pertaining to antibodies that specifically bind FLT-4 (VEGFR-3) and their use in cancer.

Our license from Princeton University requires us to pay royalties on sales that would otherwise infringe the licensed patents, which cover antibodies to the *flk-1*/KDR receptor.

IMC-1121B and other antibodies of the IMC-KDR family are fully human monoclonal antibodies. Patents have been issued to other biotechnology companies that relate to the selection of fully human antibodies or their manufacture. Therefore, though we have licensed such patents from certain companies in this field we may be required to obtain additional licenses before we can commercialize our own fully human monoclonal antibodies, including IMC-1121B.

We cannot be certain that we will ever be able to obtain such additional patent licenses related to fully human and/or phage-derived monoclonal antibodies in the U.S. or in other territories of the world where we would want to commercialize such IMC-KDR antibodies. Even if we are able to obtain other licenses as requested, there can be no assurance that we would be able to obtain a license on financial or other terms acceptable to us or that we would be able to successfully redesign our products or processes to avoid the scope of such patents. In either such case, such inability could have a material

adverse effect on our business, financial condition and results of operations. We cannot guarantee that the cost of such licenses would not materially affect the ability to commercialize IMC-KDR antibodies.

There can be no assurance that others will not be, or have not been, issued patents that may prevent the sale of one or more of our products or the practice of one or more of our processes, or require licensing and the payment of significant fees or royalties by us to third parties in order to enable us to conduct business.

There can be no assurance that we will not be subject to claims that one or more of our products or processes infringe other patents or violate the proprietary rights of third parties. In the event that we are called upon to defend and/or prosecute patent suits, the related legal and administrative proceedings would be costly and time consuming and could result in loss of patent rights, infringement penalties or both. In addition, defense and prosecution of patent suits can result in the diversion of substantial financial, management and other resources from our other activities. An adverse outcome could subject us to significant liability to third parties, require us to obtain licenses from third parties, or require us to cease any related product development activities or product sales and might have a material adverse effect on our business.

VE-Cadherin. We have obtained an exclusive license from ICOS Corporation to certain patent rights pertaining to VE-cadherin and antibodies thereto for the treatment of cancer in humans. We are also the assignee of a family of patent applications filed by an employee related to methods of generating therapeutically valuable antibodies that bind VE-cadherins. These two families of patent applications cover cadherin molecules that are involved in endothelial cell interactions. These interactions are believed to be involved in angiogenic processes. The subject patents and patent applications also cover antibodies that bind to, and affect the cadherin molecules.

Our license from ICOS requires us to pay royalties on the sale of certain VE-cadherin antibodies.

BEC2. We have exclusively licensed from Memorial Sloan-Kettering Cancer Center a family of patents and patent applications relating to our BEC2 monoclonal anti-idiotypic antibody. We know that others have been issued patents in the U.S. and Europe relating to anti-idiotypic antibodies or their use for the treatment of tumors. These patents could be alleged by the third party patent holders in a suit for patent infringement to be valid and to cover BEC2 or certain uses of BEC2. We have entered into a license agreement with Merck KGaA, which entitles Merck KGaA to market BEC2 worldwide, with the exception of North America, where we are entitled to co-promote BEC2 in North America with Merck KGaA. Merck KGaA has informed us that it has obtained non-exclusive, worldwide licenses to some of these patents in order for Merck KGaA to market BEC2 within its territory.

Our license from Memorial Sloan-Kettering Cancer Center requires us to pay royalties on sales of BEC2, though the Company does not intend to continue clinical development of BEC2.

gp75 Cancer Vaccine. We have exclusively licensed from Memorial Sloan-Kettering Cancer Center a family of patents and patent applications relating to our work with the melanotic protein, gp75. We have exclusively licensed patents and patent applications that relate to both the human protein gp75 and the gene encoding human protein gp75, as well as the use of murine gp75 protein and nucleic acids used to elicit an immune response in humans. We have entered into a license agreement with Merck KGaA, which entitles Merck KGaA to market human gp75 protein as a vaccine. In Europe, Aventis Pasteur Ltd. has brought an Opposition Proceeding seeking to revoke a granted European patent claiming aspects of a gene encoding human gp75 protein.

Our license agreements with Memorial Sloan-Kettering Cancer Center require us to pay royalties on future sales of products covered by these licenses.

Phage Display Technology. A number of antibodies that we are developing, including our fully human anti-EGFR monoclonal antibody IMC-11F8 and our fully human anti-KDR monoclonal

antibody IMC-1121B are phage-derived antibodies, which means they are made using phage technology. Since patents have been issued to biotechnology companies that relate to phage-derived antibodies and their manufacture, we may be required to obtain licenses under these patents before we can commercialize certain phage-derived antibodies. In March 2003, we entered into a license with Dyax Corp. ("Dyax") for certain of Dyax's patent rights and know-how covering certain phage display technology and a proprietary phage display library. This license also includes sublicense or non-enforcement covenant rights from other companies that possess patent and other intellectual property rights relating to phage display technology. We believe, though we cannot be certain, that this license will provide us with the freedom to operate in the development of IMC-11F8 and IMC-1121B as well as certain other phage-derived antibodies.

Trademarks. ERBITUX, ERBITUX/cetuximab & antibody design logo, IMCLONE, IMCLONE SYSTEMS, IMCLONE SYSTEMS INCORPORATED, TARGETED ONCOLOGY and the ANTIBODY DESIGN (pantone #172 "Orange"), our corporate icon, are trademarks and/or service marks of ImClone Systems Incorporated. Applications are pending or registrations have been issued for various of these marks in the United States and/or foreign jurisdictions. In October 2003, Exxon Mobil Corporation filed a Notice of Opposition against our ERBITUX/cetuximab & antibody design logo. An Opposition in the U.S. Patent and Trademark Office is an administrative process, the outcome of which may be the rejection of the Company's federal trademark application. The Company is negotiating with Exxon Mobil to resolve this matter.

Trade Secrets. With respect to certain aspects of our technology, we rely, and intend to continue to rely, on our confidential trade secrets, unpatented proprietary know-how and continuing technological innovation to protect our competitive position. Such aspects of our technology include methods of isolating and purifying antibodies and other proteins, collections of plasmids in viable host systems, and antibodies that are specific for proteins that are of interest to us. We cannot be certain that others will not independently develop substantially equivalent proprietary information or techniques, or that we are free of the patent or other rights of third parties to commercialize this technology.

Relationships between us and our employees, scientific consultants and collaborators provide these persons with access to our trade secrets, know-how and technological innovation under confidentiality agreements with the parties involved. Similarly, our employees and consultants enter into agreements with us that require that they do not disclose confidential information of ours and that they assign to us all rights to any inventions relating to our activities made while in our employ or while consulting for us.

GOVERNMENT REGULATION

The research and development, manufacture and marketing of human therapeutic and diagnostic products are subject to regulation, primarily by the FDA in the United States and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, research and development activities (including testing in animals and in humans) and the testing, manufacturing, handling, labeling, storage, distribution, import, export, record keeping, reporting, approval, advertising and promotion of the products that we are developing. Noncompliance with applicable requirements can result in various adverse consequences, including delay in approval or refusal to approve product licenses or other applications, suspension or termination of clinical investigations, revocation of approvals previously granted, fines, criminal prosecution, recall or seizure of products, injunctions against shipping products and total or partial suspension of production and/or refusal to allow a company to enter into governmental supply contracts.

The process of obtaining requisite FDA approval has historically been costly, time consuming, and uncertain. Current FDA requirements for a new human drug or biological product to be marketed in the United States include: (1) the successful conclusion of pre-clinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND, to conduct human clinical studies for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; (4) filing by a company and acceptance and approval by the FDA of a New Drug Application ("NDA") for a drug product or a BLA for a biological product to allow commercial distribution of the drug or biologic, and (5) FDA review of whether the facility in which the drug or biologic is manufactured, processed, packed or held meets standards designed to assure the product's continued quality. Overall, conducting clinical studies is a lengthy, time-consuming and expensive process.

Pre-clinical tests include the evaluation of the product in the laboratory and in animal studies to assess the potential safety and efficacy of the product and its formulation. The results of the pre-clinical tests are submitted to the FDA as part of an IND to support the evaluation of the product in human patients. Historically, the results from pre-clinical testing and early clinical studies have often not been predictive of results obtained in later clinical studies. A number of new drugs and biologics have shown promising results in early clinical studies, but for which there was a subsequent failure to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may encounter regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of pre-clinical and clinical development.

Clinical studies involve administration of the product to patients under supervision of a qualified principal investigator. Such studies are typically conducted in three sequential phases, although the phases may overlap. In Phase I, the initial introduction of the drug into human patients, the product is generally tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion. Phase II typically involves studies in a limited patient population to: (1) determine the biological or clinical activity of the product for specific, targeted indications; (2) determine dosage tolerance and optimal dosage; and (3) identify possible adverse effects and safety risks. If Phase II evaluations indicate that a product is effective and has an acceptable benefit-to-risk relationship, Phase III studies may be undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population. Phase III studies are often the pivotal studies upon which commercial approval is sought, although earlier phase studies can sometimes support approval, particularly in the case of products approved on an accelerated or fast track basis. Phase IV studies, or post-regulatory approval studies, may also be required to provide additional data on safety or efficacy.

United States law requires that studies conducted to support approval for product marketing be "adequate and well controlled." In general, this means that either a placebo or a product already approved for the treatment of the disease or condition under study must be used as a reference control. Studies must also be conducted in compliance with all applicable laws and regulations including good clinical practice, or GCP, and informed consent requirements.

The FDA may prevent clinical studies from beginning if, among other reasons, it concludes that clinical subjects would be exposed to an unacceptable health risk. Studies may also be prevented from beginning by institutional review boards, who must review and approve all research involving human subjects. The FDA and institutional review boards review the results of the clinical studies and may order the temporary or permanent discontinuation of clinical studies at any time if they believe the product candidate exposes clinical subjects to an unacceptable health risk. Investigational products used in clinical studies must be produced in compliance with cGMP pursuant to FDA regulations.

Side effects or adverse events that are reported during clinical studies can delay, impede, or prevent regulatory approval. Similarly, adverse events that are reported after regulatory approval can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing authorization, can result in product liability claims against the Company.

During the course of, and following the completion of clinical studies, the data are analyzed to determine whether the studies successfully demonstrated safety and effectiveness, and whether a product approval application may be submitted. In the United States, if the product is regulated as a drug, a New Drug Application, or NDA, must be submitted and approved before commercial marketing may begin. If the product is regulated as a biologic, such as antibodies, a Biologics License Application, or BLA, must be submitted and approved before commercial marketing may begin. The FDA Center for Drug Evaluation and Research, or CDER, has responsibility for the review and approval of drugs, and, following a recent reorganization at FDA, also has responsibility for the review and approval of certain therapeutic biologics such as monoclonal antibodies, cytokines, growth factors, enzymes, interferons and certain proteins. The FDA Center for Biologics Evaluation and Research, or CBER, has responsibility for other biologics. Based on this recent re-distribution of responsibility, we expect that most of our products will be reviewed by CDER. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness (and, in the case of a biologic, purity and potency) of the compound from laboratory, animal and clinical testing, as well as data and information on manufacturing, product stability, and proposed product labeling.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing an NDA or BLA and supplements thereto, as well as annual fees for commercial manufacturing establishments and for approved products. These fees can be significant. The NDA or BLA review fee alone can exceed $500,000, although certain limited deferrals, waivers and reductions may be available.

Under applicable laws and FDA regulations, each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will "file" the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable. If the FDA refuses to file an application, the FDA will retain 25% percent of the user fee as a penalty. The FDA has established performance goals for the review of NDAs and BLAs—six months for priority applications and 10 months for regular applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. Moreover, the outcome of the review, even if generally favorable, typically is not an actual approval but an "action letter" that describes additional work that must be done before the application can be approved. The FDA's review of an application may involve review and recommendations by an independent FDA advisory committee. Even if the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that warning statements be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval.

Some of our cancer treatments require the use of *in vitro* diagnostic products to test patients for particular traits. *In vitro* diagnostic products are generally regulated by the FDA as medical devices. Before a medical device may be marketed in the United States, the manufacturer generally must obtain either clearance through a 510(k) pre-market notification ("510(k)") process or approval through the pre-market approval application ("PMA") process. Section 510(k) notifications may be filed only for those devices that are "substantially equivalent" to a legally marketed predicate device. If a device is not "substantially equivalent" to a legally marketed predicate device, a PMA must be filed. The

pre-market approval procedure generally involves more complex and lengthy testing, and a longer review process than the 510(k) process.

Under current law, each domestic and foreign drug and device product-manufacturing establishment must be registered with the FDA before product approval. Domestic and foreign manufacturing establishments must meet strict standards for compliance with cGMP regulations and licensing specifications after the FDA has approved an NDA, BLA or PMA for a product manufactured at such facility. The FDA and foreign regulatory authorities periodically inspect domestic and foreign manufacturing facilities where applicable.

Significant additional legal and regulatory requirements also apply after FDA approval to market under an NDA or BLA. Along with the requirement for ongoing adherence to cGMPs these requirements include, among other things, requirements related to adverse events and other reporting, product advertising and promotion, and the need to submit appropriate new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. The FDA also enforces the requirements of the Prescription Drug Marketing Act, or PDMA, which, among other things, imposes various requirements in connection with the distribution of product samples to physicians.

In the United States, the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), and state and local governments. For example, sales and marketing and scientific/educational grant programs must comply with the Medicare-Medicaid Anti-Fraud and Abuse Act, as amended, the False Claims Act, also as amended, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Moreover, we are now, and may become subject to, additional federal, state and local laws, regulations and policies relating to safe working conditions, laboratory practices, the experimental use of animals, and/or the use, storage, handling, transportation and disposal of human tissue, waste and hazardous substances, including radioactive and toxic materials and infectious disease agents used in conjunction with our research work.

Sales outside the United States of products we develop will also be subject to regulatory requirements governing human clinical studies and marketing for drugs and biological products and devices. The requirements vary widely from country to country, but typically the registration and approval process takes several years and requires significant resources. In most cases, if the FDA has not approved a product for sale in the United States the product may be exported to any country if it complies with the laws of that country and has valid marketing authorization by the appropriate authority (1) in Canada, Australia, New Zealand, Japan, Israel, Switzerland or South Africa, or (2) in the European Union or a country in the European Economic Area if the drug is marketed in that country or the drug is authorized for general marketing in the European Economic Area. There are specific FDA regulations that govern this process.

Our ability to earn sufficient returns on our products may depend in part on the extent to which government health administration authorities, private health coverage insurers and other organizations will provide reimbursement for the costs of such products and related treatments. Significant

uncertainty exists as to the reimbursement status of newly approved health care products, and there can be no assurance that adequate third-party coverage will be available.

In the United States, debate over the reform of the health care system has resulted in an increased focus on pricing. Although there are currently no government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under certain public health care programs. Various states have adopted mechanisms under Medicaid and otherwise that seek to control drug prices, including by disfavoring certain higher priced drugs and by seeking supplemental rebates from manufacturers. In the absence of new government regulation, managed care has become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. New federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs covered by Medicare are reimbursed, generally leading to lower reimbursement for physicians. As of January 1, 2005, physicians are reimbursed for physician-administered drugs, such as ERBITUX, based on the Average Sales Price of the drug plus six (6) percent. The Average Sales Price is the average net price of a drug to all non-federal purchasers. Price discounts will affect the drug reimbursement rates. To date, the Company has not discounted the sale of ERBITUX to non-federal purchasers, other than routine prompt payment discounts.

This focus on pricing has led to other adverse government action, and may lead to other action in the future. For example, in December 2003 federal legislation was enacted to change United States import laws and expand the ability to import lower priced versions of pharmaceutical products from Canada, where there are government price controls. These changes to the import laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The current Secretary of Health and Human Services has indicated that there is not a basis to make such a certification at this time. However, it is possible that this Secretary or a subsequent Secretary could make the certification in the future. In addition, legislative proposals have been made to implement the changes to the import laws without any certification, and to broaden permissible imports in other ways. Even if the changes to the import laws do not take effect, and other changes are not enacted, imports from Canada and elsewhere may increase due to market and political forces, and the limited enforcement resources of the FDA, the Customs Service, and other government agencies. For example, numerous states and localities have proposed programs to facilitate Canadian imports, and at least one locality has already begun such a program, notwithstanding questions raised by FDA about the legality of such actions. We expect that pressures on pricing results will continue.

In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the National Institute for Clinical Excellence in the UK (the "United Kingdom") which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

In Japan, the National Health Ministry biannually reviews the pharmaceutical prices of individual products. In the past, these reviews have resulted in price reductions.

ENVIRONMENTAL AND SAFETY MATTERS

We use hazardous chemicals, biological agents and various radioactive isotopes and compounds in our research and development and our manufacturing activities. Accordingly, we are subject to and seek to comply with, applicable regulations under federal, state and local laws regarding employee safety, environmental protection and hazardous substance control. We have made and will continue to make expenditures for environmental compliance, environmental protection and employee safety. Such expenditures have not had, and in the opinion of management are not expected to have a material effect on our financial position, results of operation, capital expenditures or competitive position. However, these laws may change, our processes may change, or other facts may emerge which could affect our operations, business or assets and therefore the amount and timing of expenditures in the future may vary substantially from those currently anticipated.

COMPETITION

Competition in the biopharmaceutical industry is intense and based significantly on scientific, technological and market factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical and large pharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. Further, such companies have substantially greater financial resources and greater access to the capital markets than we do. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific, technical and professional personnel and consultants.

We are aware of certain products under development or manufactured by competitors that are used for the prevention, diagnosis, or treatment of certain diseases that we have targeted for product development. Various companies are developing biopharmaceutical products that potentially compete directly with our commercial product and other product candidates. These include areas such as: (1) the use of biopharmaceutical and pharmaceutical products targeted to the EGF receptor or antibodies to that receptor to treat cancer; (2) the development of inhibitors to angiogenesis; and (3) the use of anti-idiotypic antibody or recombinant antigen approaches to cancer vaccines. On November 18, 2004 OSI Pharmaceuticals, Inc. and Genentech, Inc. received approval from the FDA for Tarceva™ (erlotinib) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. On May 5, 2003 AstraZeneca Pharmaceuticals received approval from the FDA for IRESSA® (gefitinib), a small molecule EGF receptor inhibitor indicated as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based and docetaxel chemotherapies. In addition, several product candidates are in advanced stages of clinical studies. We are aware of several companies that have potential antibody or other product candidates in clinical testing that target the EGF receptor and therefore may compete with our lead product, ERBITUX. These companies include, but are not limited to: (1) Abgenix, Inc. in collaboration with Amgen, Inc.; (2) Pfizer, Inc.; (3) GlaxoSmithKline plc; (4) Novartis; (5) Merck KGaA; (6) Wyeth; (7) Medarex; and (8) YM Bioscience Inc.

On February 26, 2004, Genentech announced that Avastin® was approved by the FDA for treatment in first line metastatic colorectal cancer. Avastin is an approved therapeutic antibody designed to inhibit vascular endothelial growth factor (VEGF), a protein that plays a role in tumor angiogenesis (the formation of new blood vessels to the tumor) and maintenance of existing tumor blood vessels. While Avastin does not target the EGF receptor and is indicated for a patient population different than the patient population in the pivotal studies we submitted as the basis of the FDA's approval for ERBITUX (i.e., previously-untreated metastatic colorectal cancer patients versus irinotecan-refractory metastatic colorectal cancer patients), it is competing significantly with ERBITUX as a treatment for colorectal cancer and may compete significantly with ERBITUX as a treatment for other cancers. We believe that, notwithstanding the fact that the FDA has approved Avastin® and ERBITUX for the treatment of metastatic colorectal cancer in different indications, physicians have prescribed Avastin® outside of its approved indication and within ERBITUX's approved indications. If physicians continue or accelerate such prescription of Avastin® outside of its approved indication, the prescription volume or market share of ERBITUX within its approved indication may be limited or may diminish.

We expect that our products under development and in clinical studies will address major markets within the cancer sector, and potentially markets in other therapeutic areas. Our competition will be determined in part by the potential indications for which drugs are developed and ultimately approved by regulatory authorities. Additionally, the timing of market introduction of some of our potential products or of competitors' products may be an important competitive factor. Accordingly, the relative speed with which we can develop products, complete pre-clinical testing, clinical studies and approval processes and supply commercial quantities to market are expected to be important competitive factors. We expect that competition among products approved for sale will be based on various factors, including product efficacy, safety, reliability, availability, price, patent position, manufacturing capacity and capability, distribution capability and government action.

OUR EMPLOYEES

We have assembled a qualified business, professional and scientific staff with a variety of complementary skills in a broad base of areas, including legal, finance, advanced research technologies, oncology, immunology, molecular and cell biology, antibody engineering, protein and medicinal chemistry and high-throughput screening. We believe that we have been successful to date in attracting and retaining skilled and experienced business and scientific professionals. We have also recruited a staff of technical and professional employees to carry out manufacturing at our Branchburg, New Jersey facilities. Of our 866 full-time personnel on January 28, 2005, 664 were employed at our New Jersey facilities, 160 were employed at our New York headquarters and 42 were employed at our Brooklyn facility. Our staff includes 64 persons with PhD's and 6 with MD's.

INDUSTRY SEGMENT

We operate in only one industry segment—biotechnology. We do not have any foreign operations, and our business is not seasonal.

RISK FACTORS

Risks Relating to Our Business

Royalty and manufacturing revenue from sales of ERBITUX represents a substantial portion of our revenues. If ERBITUX does not receive continued market acceptance, sales may not continue and we may not earn sufficient revenues.

Our future growth and a significant portion of our future revenues will depend on the continued commercial success, of ERBITUX, which is our only product that has received FDA approval. We cannot be certain that ERBITUX will continue to be accepted in the United States or in any foreign

markets. A number of factors may affect the rate and level of market acceptance of ERBITUX including:

- The perception by physicians and other members of the healthcare community of ERBITUX's safety or efficacy or that of competing products;
- The effectiveness of BMS' sales and BMS' and our marketing efforts in the United States and the effectiveness of Merck KGaA's sales and marketing efforts outside the United States;
- Any unfavorable publicity concerning ERBITUX or competitive drugs;
- The price of ERBITUX relative to other drugs or competing treatments;
- The availability and level of third-party reimbursement for sales of ERBITUX;
- The continued availability of adequate supplies of ERBITUX to meet demand; and
- Regulatory developments related to the manufacture or continued use of ERBITUX.

If the acceptance of ERBITUX does not continue it will reduce our revenues which may impact the success of our business, the price of our common stock and our ability to meet our obligations with respect to our outstanding convertible notes.

We depend on BMS and Merck KGaA to co-promote, market and sell ERBITUX. If BMS and Merck KGaA are unable to meet their obligations it would impact our revenues and harm our business.

Under our agreement with BMS, BMS has the exclusive right to distribute ERBITUX in the United States and Canada, in exchange for which we receive royalty payment of 39% of BMS' net sales of ERBITUX in the United States and Canada. Under our agreement with Merck KGaA, Merck has the exclusive right to market ERBITUX outside of the United States, Canada and Japan, in exchange for which we receive royalty payments based on Merck's gross profit from ERBITUX sales. These royalty payments from BMS and Merck represent a significant portion of our current revenues. In addition, we also receive milestone payments and reimbursements of various regulatory and clinical expenses as well as certain marketing and administrative expenses from BMS and Merck. If BMS and Merck are unable to sell sufficient quantities of ERBITUX or are otherwise unable to meet their contractual obligations, our revenues would be negatively impacted and it would harm our business.

We are subject to extensive governmental regulation. If we are unable to obtain or maintain regulatory approvals for our product or product candidates, we will not be able to market our product or further develop our product candidates.

We are subject to stringent regulation with respect to product safety and efficacy by various international, federal, state and local authorities. Of particular significance are the FDA's requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use. Any biopharmaceutical that we may develop cannot be marketed in the United States until it has been approved by the FDA, and then can only be marketed for the indications and claims approved by the FDA. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a New Drug Application (or NDA) or a Biologics License Application (or BLA), are substantial and can require a number of years, and the ability to obtain regulatory approval is uncertain. In addition, after any of our products receive regulatory approval, they remain subject to ongoing FDA regulation, including, for example, changes to the product, manufacturing, or product label, new or revised regulatory requirements for manufacturing practices, additional clinical study requirements, restricted distribution, written warnings to physicians, a product recall, and withdrawal of a previously obtained approval.

We cannot be sure that we can obtain necessary regulatory approvals on a timely basis, if at all, for any of the product candidates we are developing or that we can maintain necessary regulatory approvals or obtain additional approved indications for ERBITUX, and any delay in obtaining such approval or failure to maintain regulatory approvals could prevent us from marketing our product and would have a material adverse effect on our business.

Moreover, it is possible that the current regulatory framework could change or additional regulations could arise at any stage during our product development or marketing process, which may affect our ability to obtain or maintain approval of our products.

Our potential revenues will diminish if our collaborators fail to obtain acceptable prices or adequate reimbursement for ERBITUX from third-party payors.

All our revenues from ERBITUX are based on sales of the product by our two collaborators. The continuing efforts of government and third-party payors to contain or reduce the costs of health care may limit the revenues that we earn from sales of ERBITUX. If government and other third-party payors do not provide adequate coverage and reimbursement for our product, physicians may not prescribe it. In some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. In addition, managed care initiatives in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that our collaborators receive for any of our products in the future. Further, cost control initiatives could impair or diminish our ability or incentive, or the ability or incentive of our partners or potential partners, to commercialize our other product candidates, and accordingly, our ability to earn revenues.

Our ability to commercialize any other product candidates, alone or with collaborators, may depend in part on the availability of reimbursement from:

- government and health administration authorities;
- private health insurers; and
- other third-party payors, including Medicare and Medicaid.

Third-party payors, including Medicare, are increasingly challenging the prices charged for medical products and services. Government and other third-party payors increasingly are limiting obth coverage and the level of reimbursement for new drugs and, in some cases, refusing to provide coverage for a patient's use of an approved drug for purposes not approved by the FDA.

Our royalty and collaborative agreement revenues could vary significantly and may adversely impact our business.

Royalty and collaborative agreement revenues in future periods could vary significantly. Major factors affecting these revenues include, but are not limited to:

- Variations in BMS' and Merck KGaA's and other licensees' sales of licensed products;
- The expiration or termination of existing arrangements with our collaborative partners, particularly Merck KGaA and BMS, which may include development and marketing arrangements for our products in the U.S., Europe and other countries outside the United States;
- The timing of U.S. and non-U.S. approvals, if any, for products licensed to BMS, Merck KGaA and other licensees;
- The initiation of new collaborative agreements with other companies;
- Whether and when collaborative agreement benchmarks and milestones are achieved;
- The failure of or refusal of a licensee to pay royalties;
- The expiration or invalidation of our patents or licensed intellectual property
- Decreases in licensees' sales of our products due to competition, manufacturing difficulties or other factors that affect the sales of products; and
- Disputes arising with respect to the interpretation of provisions in existing or future agreements with our collaborative partners.

If we are unable to earn sufficient revenues from ERBITUX, our operating results or financial condition could be adversely affected.

We will be required to expend significant resources for research and development of our products in development and these products may not be developed successfully.

Our only approved product is ERBITUX. Our product candidates are still undergoing clinical trials or are in the early stages of development. All of our product candidates under development will require significant additional research and development resources prior to their commercialization. Even if we spend substantial amounts on research and development, our potential products may not be developed successfully. If our product candidates on which we have expended significant amounts for research and development are not commercialized, we will not earn a return on our research and development expenditures, which may harm our business.

Competition from Avastin® could adversely affect the market share of ERBITUX in its approved indications, diminishing our revenues derived from ERBITUX sales.

We have experienced significant competition for ERBITUX from Avastin® (bevacizumab). Avastin®, a non-chemotherapeutic biopharmaceutical product manufactured by Genentech, Inc., has been approved by the FDA as a first-line treatment for patients with metastatic colorectal cancer. In contrast, ERBITUX has been approved as a second-line and third-line therapy in the indications described under "Prospectus Summary—ImClone—Overview." We believe that, notwithstanding the fact that the FDA has approved Avastin® and ERBITUX for the treatment of metastatic colorectal cancer in different indications, physicians have prescribed Avastin® outside of its approved indication and within ERBITUX's approved indications. If physicians continue or accelerate such prescription of Avastin® outside of its approved indication, the prescription volume or market share of ERBITUX within its approved indications may be limited or may diminish. Because a significant portion of our revenues depends on the commercial success of ERBITUX within its approved indications, this would negatively impact our revenues and harm our business.

Difficulties or delays in product manufacturing and finishing could cause shortfalls in the supply of ERBITUX or our product candidates currently being developed which would harm our business and, in the case of ERBITUX, our ability to meet our financial obligations.

Cardinal Health, Inc. is currently our sole provider of filling and finishing services—the final stage of manufacturing for ERBITUX. In addition, we currently manufacture ERBITUX at our BB36 manufacturing facility and through Cardinal Health, Inc. Any prolonged interruption in the operations of our or our contractors' manufacturing and finishing facilities could result in cancellations of shipments, loss of product in the process of being manufactured, or a shortfall of available product inventory. A number of factors could cause interruptions, including a failure of our or our contractors' manufacturing and finishing facilities to obtain FDA approval and maintain compliance with current good manufacturing practice requirements, changes in the FDA's regulatory requirements or standards that require modifications to our manufacturing processes, action by the FDA that results in the halting of production of one or more of our products or product candidates due to regulatory issues or a contract manufacturer going out of business or other similar factors. Because our manufacturing and finishing processes and those of our contractors are highly complex and are subject to a lengthy FDA approval process and extensive ongoing regulation, alternative qualified production capacity may not be available on a timely basis or at all. We may also experience insufficient available capacity to manufacture existing or new products which could cause shortfalls of available product inventory. Difficulties or delays in our and our contractors' manufacturing and supply of existing or new products could increase our costs, cause us to lose revenue or market share and damage our reputation.

Our marketing partners may experience pressure to lower the price of ERBITUX because of new and/or proposed federal legislation, which would reduce our royalty revenue and may harm our business.

New federal legislation, enacted in December 2003, has altered the way in which physician administered drugs covered by Medicare, such as ERBITUX are reimbursed, generally leading to lower reimbursement levels. The new legislation has also added an outpatient prescription drug benefit to Medicare, effective January 2006. In the interim, Congress has established a discount drug card program for Medicare beneficiaries. Both benefits will be provided primarily through private entities, which will attempt to negotiate price concessions from pharmaceutical manufacturers, including our collaborators. These negotiations may increase pressures to lower pricing for ERBITUX. While the new law specifically prohibits the United States government from interfering in price negotiations between manufacturers and Medicare drug plan sponsors, some members of Congress are pursuing legislation that would permit the United States government to use its enormous purchasing power to demand discounts from pharmaceutical companies, thereby creating de facto price controls on prescription drugs, such as ERBITUX. In addition, the new law contains triggers for Congressional consideration of cost containment measures for Medicare in the event Medicare cost increases exceed a certain level. These cost containment measures could include some sorts of limitations on prescription drug prices that our collaborators charge for ERBITUX which would reduce our royalty revenue and harm our business.

If we become subject to importation of products from Canada and other countries, it will affect our profitability and harm our business.

ERBITUX and other products that we may develop may become subject to competition from the importation of lower priced imports from Canada, Mexico, and other countries where there are government price controls or other market dynamics that may make the products lower priced. The ability of patients and other customers to obtain these lower priced imports has grown significantly as a result of the Internet, an expansion of pharmacies in Canada and elsewhere targeted to American purchasers, the increase in U.S.-based businesses affiliated with Canadian pharmacies marketing to American purchasers, and other factors. Many of these foreign imports are illegal under current law. However, the volume of imports continues to rise due to the limited enforcement resources of the FDA and the U.S. Customs Service, and the pressure in the current political environment to permit the imports as a mechanism for expanding access to lower priced medicines.

In addition, in December 2003 federal legislation was enacted to change United States import laws and expand the ability to import lower priced imports of pharmaceutical products from Canada, where there are government price controls. These changes to the import laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will lead to substantial savings for consumers and will not create a public health safety issue. The current Secretary of Health and Human Services has indicated that there is not a basis to make such a certification at this time.

However, it is possible that this Secretary or a subsequent Secretary could make the certification in the future. In addition, legislative proposals have been made to implement the changes to the import laws without any certification, and to broaden permissible imports in other ways. Even if the changes to the import laws do not take effect, and other changes are not enacted, lower priced imports of our products from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, the Customs Service, and other government agencies. For example, state and local governments have suggested that they may import drugs from Canada for employees covered by state health plans or others, and some have already put such plans in place.

The importation of lower priced imports will adversely affect our profitability. This impact could become more significant in the future, and the impact could be even greater if there is a further change in the law or if state or local governments take further steps to import lower-priced products from abroad.

We depend on key employees in a competitive market for skilled personnel, and the loss of the services of any of our key employees would affect our ability to develop our business.

We are highly dependent on the principal members of our management, operations and scientific staff. We experience intense competition for qualified personnel. Our future success depends in part on the continued service of our executive management and scientific personnel and our ability to recruit, train and retain highly qualified management, scientific, manufacturing and sales and marketing personnel. If we lose the services of these personnel, our research and product development and marketing goals, including the maintenance of relationships with leading research institutions and key collaborators could be delayed or curtailed. We currently have employment contracts with only one of our key employees—our chief executive officer. We do not maintain "key man" life insurance on any of our employees.

The law or FDA policy could change and expose us to competition from "generic" or "follow-on" versions of our products, which may impact our market share and harm our business.

Under current U.S. law and FDA policy, generic versions of conventional chemical drug compounds, sometimes referred to as small molecule compounds, may be approved through an abbreviated approval process. In general terms, the generic applicant references an approved innovator product for which full clinical data demonstrating safety and effectiveness exist for the approved conditions of use. The generic applicant in turn need only demonstrate that its product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as the referenced innovator drug, and that the generic product is absorbed in the body at the same rate and to the same extent as the referenced innovator drug (this is known as bioequivalence). In addition, the generic application must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the referenced innovator drug.

There is no such abbreviated approval process under current law for biological products approved under the Public Health Service Act through a BLA, such as monoclonal antibodies, cytokines, growth factors, enzymes, interferons and certain other proteins. However, various proposals have been made to establish an abbreviated approval process to permit approval of generic or follow-on versions of these types of biological products. The proposals include proposals for legislation, and proposals for the FDA to extend its existing authority to this area. For example, some have proposed that the FDA allow a generic or follow-on copy of certain therapeutic biologics to be approved under an existing mechanism known as a 505(b)(2) application. A 505(b)(2) application is a form of an NDA, where the applicant does not have a right to reference some of the data being relied upon for approval. Under current regulations, 505(b)(2) applications can be used where the applicant is relying in part on published literature or on findings of safety or effectiveness in another company's NDA. 505(b)(2) applications have not been used to date for therapeutic biologic products. In addition, the use of 505(b)(2) applications even for conventional chemical drug products is the subject of ongoing legal challenge. It is thus not clear what the permitted use of a 505(b)(2) application might be in the future for biologics products, or whether any other proposals on generic or follow-on biologics will be adopted. However, if the law is changed or if the FDA somehow extends its existing authority in new ways, and third parties are permitted to obtain approvals of versions of our products through an abbreviated approval mechanism, and without conducting full clinical studies of their own, it could adversely affect our business. Such products would be significantly less costly than ours to bring to market, and could lead to the existence of multiple lower priced competitive products. This would substantially limit our ability to obtain a return on the investments we have made in those products.

Risks Relating to Intellectual Property and Legal Matters

Protecting our proprietary rights is difficult and costly. If we fail to adequately protect or enforce our proprietary rights, we could lose revenue.

Our success depends in large part on our ability to obtain, maintain and enforce our patents. Our ability to commercialize any product successfully will largely depend on our ability to obtain and

maintain patents of sufficient scope to prevent third parties from developing similar or competitive products. In the absence of patent protection, competitors may impact our business by developing and marketing substantially equivalent products and technology.

Patent disputes are frequent and can preclude the commercialization of products. We have in the past been, are currently, and may in the future be, involved in material patent litigation, such as the matters discussed under "Part I—Item 3. Legal Proceedings". Patent litigation is time-consuming and costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute.

The existence of patents or other proprietary rights belonging to other parties may lead to our termination of the research and development of a particular product or cause us to obtain third-party licenses at potentially material costs. We believe that we have strong patent protection or the potential for strong patent protection for our product and product candidates. However, it is for the courts and/or other governmental agencies in the U.S. and in other jurisdictions ultimately to determine the strength of that patent protection. We hold patents or licenses to patents relating to murine antibodies as well as patents and licenses relating to the therapeutic use of EGFR antibodies. These patents expire on various dates, the earliest of which is in 2007. Risks related to our patent position with respect to ERBITUX and our product candidates are more fully discussed under "Item 1—Business—Patents and Trademarks".

Several lawsuits have been filed against us which may result in litigation that is costly to defend and the outcome of which is uncertain and may harm our business.

Litigations to which we are currently or have been subjected relate to, among other things, our patent and other intellectual property rights, licensing arrangements with other persons, securities law claims, derivative actions and those other claims more fully described under "Part I—Item 3. Legal Proceedings".

We cannot provide any assurance as to the outcome of these pending lawsuits. Any conclusion of these matters in a manner adverse to us could have a material adverse effect on our business and operating results. In addition, the costs to us of defending these claims or any other proceedings, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of any litigation or other proceedings could also harm our ability to compete in the marketplace.

Our operations use hazardous materials, which may lead to environmental liability, and may harm our business.

We use certain hazardous materials in connection with our research and manufacturing activities. These hazardous materials include various flammable solvents, corrosives, oxidizers and toxics. We also use radioactive isotopes in our scientific research. In the event such hazardous materials are stored, handled or released into the environment in violation of law or any permit, or in a manner that adversely affects the environment, we could be subject to loss of our permits, government fines or penalties and/or other adverse governmental or third party action. We do not maintain any specific insurance to cover any accidents associated with the hazardous materials that we use in our manufacturing and research activities. The levy of a substantial fine or penalty, the payment of significant environmental remediation costs or the loss of a permit or other authorization to operate or engage in our ordinary course of business could materially adversely affect our business.

We could be exposed to material product liability claims that could prevent or interfere with the commercialization of any other products that we may develop.

The testing, manufacturing, marketing and sale of medical products entail an inherent risk of product liability. Liability exposures for biopharmaceuticals, such as ERBITUX, could expose us to significant liabilities that could prevent or interfere with continued sales of ERBITUX or the

commercialization of any other products that we may develop. Product liability claims could require us to spend significant time and money in litigation or to pay significant damages. We currently have $30 million of aggregate product liability insurance coverage. Our business may be materially and adversely affected by a successful product liability claim or claims in excess of our insurance coverage.

Risks Relating to our Common Stock

Our stock price is highly volatile. It may be difficult for you to resell our common stock.

Over the past two years our common stock price has ranged from a high of $86.79 per share to a low of $6.11 per share. The market price of our common stock has been and may continue to be volatile.

In addition, the following factors may have a significant impact on the market price of our common stock:

- Announcements of technological innovations or new commercial products by us or our competitors;
- Publicity regarding actual or potential medical results relating to products under development or being commercialized by us or our competitors;
- Developments or outcome of investigations and litigation generally, including litigation relating to proprietary rights and patents;
- Regulatory developments or delays concerning our products in the United States and foreign countries;
- Issues concerning the safety of our products or of biotechnology products generally;
- Economic and other external factors or a disaster or crisis; and
- Period-to-period fluctuations in our financial results.

Certain provisions of Delaware law, our charter and bylaws and our stockholder rights plan could hinder, delay or prevent changes in control.

Certain provisions of Delaware law, our charter and our bylaws, as well as our stockholder rights plan have the effect of discouraging, delaying or preventing transactions that involve an actual or threatened change in control. These provisions include the following:

Stockholder Rights Plan. We adopted a stockholder rights plan on February 15, 2002. Our stockholder rights plan may discourage any potential acquirer from acquiring more than 15 percent of our outstanding common stock since, upon this type of acquisition without approval of our board of directors, all other common stockholders will have the right to purchase a specified amount of our common stock at a substantial discount from market price, thus significantly increasing the acquisition cost to a potential acquirer.

Special Meetings. According to our bylaws, special meetings of stockholders may be called only by our board of directors.

Removal of Directors. Subject to the rights of BMS to elect at least one director, our bylaws provide that a director can be removed only for cause by the affirmative vote of at least a majority of all votes entitled to be cast.

Advance Notice Provisions for Stockholder Nominations and Proposals. Our bylaws require advance written notice for stockholders to nominate persons for election as directors at, or to bring other business before, any meeting of stockholders. This bylaw provision limits the ability of stockholders to make nominations of persons for election as directors or to introduce other proposals unless we are notified in a timely manner prior to the meeting.

Preferred Stock. Under our charter, our Board of Directors has authority to issue preferred stock from time to time in one or more series and to establish the terms, preferences and rights of any such series of preferred stock, all without approval of our stockholders.

Delaware Business Combinations. We are subject to Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, restricts certain transactions and business combinations between a corporation and a stockholder owning 15% or more of the corporation's outstanding voting stock for a period of three years from the date the stockholder becomes a 15% stockholder. In addition to discouraging a third party from acquiring control of us, the foregoing provisions could impair the ability of existing stockholders to remove and replace our management and/or our board of directors.

ITEM 2. PROPERTIES

180 Varick Street, New York, New York

We have occupied two contiguous leased floors at 180 Varick Street in New York City since 1986. The property currently serves as our corporate headquarters and biologics research facility. The most recent lease for the original two floors (sixth and seventh, totaling 45,000 square feet) was effective as of January 1, 1999 and was due to expire in December 2004. From 1999 to 2003 we have added additional space on the fifth and eighth floors of approximately 11,786 square feet. In August 2004, we modified our existing operating lease. The modification extends the term of the lease, which was to expire on December 31, 2004, for an additional ten years (with renewal rights) for a portion of the premises and by an additional three years (with renewal rights) for the space that currently houses our Research department. The modification also adds additional space on the fifth and eighth floors of approximately 4,286 square feet in 2004 and grants us the right to add additional space in the future. We plan to consolidate our Research departments at our 325 Spring Street, New York location. Our rent expense for the Varick Street location was approximately $1,322,000 for the year ended December 31, 2004.

Brooklyn, New York

On May 1, 2001, we leased a 4,000 square foot portion of a 15,000 square foot building known as 710 Parkside Avenue, Brooklyn, New York and an adjacent 6,250 square foot building known as 313-315 Clarkson Avenue, Brooklyn, New York (collectively the "Brooklyn facility"). The term of the lease is for five years with five successive one-year extensions at our option. The initial annual lease rate was $92,250 until six months after we have received all necessary permits for our improvements to the Brooklyn facility, at which time the annual base rent became $184,500. The Brooklyn facility was ready for its intended use and put in operation as our chemistry and high-throughput screening facility in December 2002. In the year ended December 31, 2004, we incurred rent expense for the premises of approximately $171,000. We plan to consolidate our Research department at our 325 Spring Street, New York location.

Effective February 1, 2005, the Company entered into an operating lease for approximately 2,269 square feet of a building known as 760 Parkside Avenue in Brooklyn, New York. The term of the lease is for fifteen months, to coincide with the term of the Brooklyn facility lease. The future minimum lease payments are $71,000.

325 Spring Street, New York, New York

On October 5, 2001, we entered into a sublease for a four-story building at 325 Spring Street, New York, New York, which includes between 75,000 and 100,000 square feet of usable space. The sublease has a term of just under 22 years, expiring on April 29, 2023, followed by two five-year renewal option periods. The future minimum lease payments remaining at December 31, 2004, are approximately

$47,153,000 over the term of the sublease. In order to induce the sublandlord to enter into the sublease, we made a loan to the sublandlord in the principal amount of a $10,000,000 note receivable, of which $9,213,000 is outstanding as of December 31, 2004. The loan is secured by a leasehold mortgage on the prime lease as well as a collateral assignment of rents by the sublandlord. The loan is payable by the sublandlord over 20 years and bears interest at 5½% in years one through five, 6½% in years six through ten, 7½% in years eleven through fifteen and 8½% in years sixteen through twenty. In addition, we paid the owner a consent fee in the amount of $500,000. We spent significant time analyzing our options with respect to this sublease and in June 2004, we concluded that we will move forward with plans to develop the property for occupancy. We plan to house at this location our research department, which currently include both antibody and small molecule research teams. In the year ended December 31, 2004, we incurred rent expense of approximately $1,905,000 for this sublease.

22 ImClone Drive, Branchburg, New Jersey

In 1992, we acquired a 5.1 acre parcel of land and a 54,400 square foot building located at 22 ImClone Drive (formerly known as Chubb Way), Branchburg, New Jersey at a cost to us of approximately $4,665,000, including expenses. We have retrofitted the building to serve as our pilot facility for biologics manufacturing. When purchased, the facility had in place various features, including clean rooms, air handling, electricity, and water for injection systems and administrative offices. The cost for completion of facility modifications was approximately $5,400,000. We currently operate the facility to develop and manufacture biologics for a portion of our clinical studies. Under certain circumstances, we also may use the facility for the manufacturing of commercial products. In January 1998, we completed the construction and commissioning of a 1,750 square foot process development center at this facility dedicated to manufacturing process optimization for existing products and the pre-clinical and Phase I development of new biological therapeutics. The cost of this construction activity was approximately $1,730,000.

33 ImClone Drive, Branchburg, New Jersey

On May 20, 2002, we purchased a 45,800 square foot warehouse on 6.94 acres of property located at 33 ImClone Drive. The purchase price for both land and building was approximately $4,515,000. Extensive site work and exterior and interior renovations began in late June 2002. The newly renovated location houses the clinical, regulatory, field operations, marketing, finance, human resources, legal, project management and MIS departments, as well as certain executive offices and other campus amenities. We have incurred approximately $4,486,000, for the renovation and fit-out of this facility. The administrative facility was ready for its intended use and put in operation in December 2002.

36 ImClone Drive, Branchburg, New Jersey

In July 2001, we completed the construction of our 80,000 square foot manufacturing facility, BB36, adjacent to the pilot facility in Branchburg, New Jersey. BB36 was built on a 5.7 acre parcel of land we purchased in December 1999 for approximately $700,000. BB36 contains three 10,000 liter (production volume) fermenters and is dedicated to the production of ERBITUX. BB36 was ready for its intended use and put in operation in July 2001. BB36 cost a total of approximately $53,000,000, excluding capitalized interest of approximately $1,966,000.

50 ImClone Drive, Branchburg, New Jersey

We have completed detailed design plans for, and are proceeding with construction of, the BB50 facility. The BB50 facility will have a capacity of up to 110,000 liters (production volume). The facility is being built on a 7.12 acre parcel of land that we purchased in July 2000 for approximately $950,000, which is the parcel immediately to the west of 36 ImClone Drive. The cost of this facility, for two completely fitted out suites and a third suite with utilities only, is expected to be approximately

$290,000,000, excluding capitalized interest, with anticipated mechanical completion by the end of 2005. We have incurred approximately $227,452,000, excluding capitalized interest of approximately $14,760,000 in costs through December 31, 2004.

41 ImClone Drive, Branchburg, New Jersey

In September 2000, we entered into a one-year lease with GM Stainless, Inc. for approximately 7,600 square feet of office space at 41 ImClone Drive, in order to house the additional personnel being hired in connection with our expansion of our clinical, medical and regulatory affairs functions. Following transfer of these functional departments to our 33 ImClone Drive facility, we are using this facility to house personnel required for the start-up of the BB50 facility located at 50 ImClone Drive. The lease was renewed each year for three years, to August 31, 2004. We amended the lease effective as of September 1, 2004 to extend to a fourth renewal term of one year to August 31, 2005. The amendment also gave us the option to renew for four successive one-year terms, so the lease will automatically renew each year for up to four additional years, unless terminated by our notice three months prior to the expiration of that year. In the year ended December 31, 2004, we incurred rent expense of approximately $91,000 for this lease.

59-61 ImClone Drive, Branchburg, New Jersey

In June 2004, we entered into an operating lease for a 54,247 square foot facility located at 59-61 ImClone Drive in Branchburg, New Jersey. Extensive interior renovations of approximately 24,000 square feet of the facility began in August 2004. The newly renovated areas house various laboratories used by our Quality Control and Clinical Pharmacology departments, as well as office space occupied by the Quality Assurance organization. As of December 31, 2004, we have incurred approximately $5,644,000 for the phase I renovation and fit-out of this facility. The administrative area of the facility and the laboratories were put in operation in December 2004. In the year ended December 31, 2004, we incurred rent expense of approximately $259,000 for this lease.

Corner of ImClone Drive and Chubb Way, Branchburg, New Jersey

On May 2, 2001, we purchased a 4.45 acre parcel of land on the corner of ImClone Drive and Chubb Way, for approximately $597,000, which is the parcel immediately to the east of 22 ImClone Drive. We are currently using this parcel for our construction parking and as a material and equipment lay-down area to support our construction at 50 ImClone Drive.

1181 Route 202N, Branchburg, New Jersey

On January 31, 2002, we purchased a 7.36 acre parcel of land located at 1181 Route 202, which is the parcel immediately to the north of 36 ImClone Drive and immediately to the east of 50 ImClone Drive. The parcel includes a 51,400 square foot building, approximately 39,000 square feet of which is warehouse space and approximately 12,000 square feet of which is office space. The purchase price for the property and improvements was approximately $7,020,000. We are currently using this property for warehousing and logistics for our Branchburg campus. Extensive renovations to the 12,000 square feet of office area were completed in the first quarter of 2003 to accommodate the relocation and consolidation of engineering, warehousing, logistics and quality assurance personnel from other campus locations. Interior renovations included office space, as well as the construction of a raw materials sampling laboratory, associated temperature-controlled storage locations and the addition of emergency power generation. Extensive site work at the recently occupied facility allowed for the physical connection of this location to the campus' other buildings to facilitate the use of this location as our central warehouse. We have incurred approximately $1,050,000 for the renovation of this facility.

ITEM 3. LEGAL PROCEEDINGS

A. Litigation

1. Federal Securities Actions

As previously reported, beginning in January 2002, a number of complaints asserting claims under the federal securities laws against the Company and certain of the Company's directors and officers were filed in the U.S. District Court for the Southern District of New York. Those actions were consolidated under the caption Irvine v. ImClone Systems Incorporated, et al., No. 02 Civ. 0109 (RO). In the corrected consolidated amended complaint, filed on October 22, 2002, plaintiffs asserted claims against the Company, its former President and Chief Executive Officer, Dr. Samuel D. Waksal, its former Chief Scientific Officer and then-President and Chief Executive Officer, Dr. Harlan W. Waksal, and several of the Company's other present or former officers and directors, for securities fraud under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b5-1, on behalf of a purported class of persons who purchased the Company's publicly traded securities between March 27, 2001 and January 25, 2002. The complaint also asserted claims against Dr. Samuel D. Waksal under section 20A of the Exchange Act on behalf of a separate purported sub-class of purchasers of the Company's securities between December 27, 2001 and December 28, 2001. The complaint generally alleged that various public statements made by or on behalf of the Company or the other defendants during 2001 and early 2002 regarding the prospects for FDA approval of ERBITUX® were false or misleading when made, that the individual defendants were allegedly aware of material non-public information regarding the actual prospects for ERBITUX at the time that they engaged in transactions in the Company's common stock and that members of the purported stockholder class suffered damages when the market price of the Company's common stock declined following disclosure of the information that allegedly had not been previously disclosed. The complaint sought to proceed on behalf of the alleged classes described above, sought monetary damages in an unspecified amount and sought recovery of plaintiffs' costs and attorneys' fees. On June 3, 2003, the court granted, in part, a motion to dismiss filed by all defendants and dismissed plaintiff's claims except those asserted against the Company, Dr. Samuel D. Waksal, and Dr. Harlan W. Waksal. On April 14, 2004, the court granted plaintiffs' motion for class certification. On January 24, 2005, the Company announced that it had reached an agreement in principle to settle the consolidated class action for a cash payment of $75 million, a portion of which will be paid by the Company's insurers. The settlement is subject to the negotiation and execution of definitive settlement documents and to Court approval. The Company anticipates that a hearing to consider approval of the settlement will be held in late April or early May 2005.

As previously reported, separately, on September 17, 2002, an individual purchaser of the Company's common stock filed an action (Flynn v. ImClone Systems Incorporated, et al., No. 02 Civ 7499 (RO)) on his own behalf in the U.S. District Court for the Southern District of New York asserting claims against the Company, Dr. Samuel D. Waksal and Dr. Harlan W. Waksal under sections 10(b) and 20(a) of the Exchange Act and Securities and Exchange Commission Rule 10b-5-1. The Company and the other defendants have reached an agreement in principle with the plaintiff to settle this matter. The Company has recorded a liability of $25,000 in the fourth quarter of 2004 related to this action.

2. Derivative Actions

As previously reported, beginning on January 13, 2002, and continuing thereafter, nine separate purported shareholder derivative actions were filed against members of the Company's board of directors, certain of the Company's present and former officers, and the Company, as nominal defendant, advancing claims based on allegations similar to the allegations in the federal securities class action complaints. Four of these derivative cases were filed in the Delaware Court of Chancery and

have been consolidated in that court under the caption In re ImClone Systems Incorporated Derivative Litigation, Cons. C.A. No. 19341-NC. Three of these derivative actions were filed in New York State Supreme Court in Manhattan and have been consolidated under the caption In re ImClone Systems, Inc. Shareholder Derivative Litigation, Index No. 02-100759. All of these state court actions have been stayed in deference to the proceedings in the U.S. District Court for the Southern District of New York, which have been consolidated under the caption In re ImClone Systems, Inc. Shareholder Derivative Litigation, Master File No. 02 CV 163 (RO). A supplemental verified consolidated amended derivative complaint in these consolidated federal actions was filed on August 8, 2003. It asserted, purportedly on behalf of the Company, claims including breach of fiduciary duty by certain current and former members of the Company's board of directors, among others, based on allegations including that they failed to ensure that the Company's disclosures relating to the regulatory and marketing prospects for ERBITUX were not misleading and that they failed to maintain adequate controls and to exercise due care with regard to the Company's ERBITUX application to the FDA. On January 9, 2004, the Company filed a motion to dismiss the complaint due to plaintiffs' failure to make a pre-suit demand on the Company's board of directors to institute suit or to allege grounds for concluding that such a demand would have been futile. The individual defendants filed motions on the same date, both joining in the Company's motion and seeking to dismiss the complaint for failure to state a claim. On January 24, 2005, the Company announced that it had reached an agreement in principle to settle the consolidated derivative action. Under the settlement, the Company will be paid $8.75 million by its insurers, which the Company intends to contribute toward the settlement of the Irvine securities class action described above after deducting amounts awarded by the Court in the derivative action for plaintiffs' attorney's fees and expenses in that action, which the Company has agreed not to oppose in an amount up to $875,000. The proposed settlement is subject to negotiation and execution of definitive settlement documents, the approval and consummation of the settlement of the Irvine class action and Court approval.

3. Bristol-Myers Action

As previously reported, on October 8, 2003, certain mutual funds that are past or present common stockholders of BMS filed an action in New York State court against BMS, certain present or former officers and directors of BMS and the Company asserting that they were misled into purchasing or holding their shares of BMS common stock as a result of various public statements by BMS and certain present or former officers or directors of BMS, and that the Company allegedly aided and abetted certain of these misstatements. The action is styled FSS Franklin Global Health Care Fund, et al. v. Bristol-Myers Squibb Co., et al., Index No. 603168/03. On January 9, 2004, the Company and all of the other defendants served motions to dismiss the complaint for failure to state a cause of action. Argument on the motions was held on April 6, 2004. The court has not yet ruled upon the motions, and discovery has been stayed during the pendency of the motions.

The Company intends to vigorously defend against the claims asserted in this action. The Company is unable to predict the outcome of this action at this time. No reserve has been established in the financial statements because the Company does not believe that such a reserve is required to be established at this time under Statement of Financial Accounting Standards No. 5.

B. Government Inquiries and Investigations

As previously reported, the Company received subpoenas and requests for information in connection with an investigation by the SEC relating to the circumstances surrounding the disclosure of the FDA "refusal to file" letter dated December 28, 2001, and trading in the Company's securities by certain ImClone Systems insiders in 2001. The Company also received subpoenas and requests for information pertaining to document retention issues in 2001 and 2002, and to certain communications regarding ERBITUX in 2000. On June 19, 2002, the Company received a written "Wells Notice" from

the staff of the SEC, indicating that the staff of the SEC is considering recommending that the SEC bring an action against the Company relating to the Company's disclosures immediately following the receipt of a "refusal to file" letter from the FDA on December 28, 2001 for the Company's BLA for ERBITUX. The Company filed a Wells submission on July 12, 2002 in response to the staff's Wells Notice. There have been no recent developments in connection with this SEC investigation.

In January 2003, New York State notified the Company that the Company was liable for the New York State and City income taxes that were not withheld because one or more the Company's employees who exercised certain non-qualified stock options in 1999 and 2000 failed to pay New York State and City income taxes for those years. On March 13, 2003, the Company entered into a closing agreement with New York State, paying $4,500,000 to settle the matter. The Company believes that substantially all of the underpayment of New York State and City income tax identified by New York State is attributable to the exercise of non-qualified stock options by the Company's former President and Chief Executive Officer, Dr. Samuel D. Waksal. At the same time, the Company informed the IRS, the SEC and the United States Attorney's Office, responsible for the prosecution of Dr. Samuel D. Waksal, of this issue. In order to confirm whether the Company's liability in this regard was limited to Dr. Samuel D. Waksal's failure to pay income taxes, the Company contacted current and former officers and employees who had exercised non-qualified stock options to confirm that those individuals had properly reported and paid their personal income tax liabilities for the years 1999 and 2000 in which they exercised options, which would reduce or eliminate the Company's potential liability for failure to withhold income taxes on the exercise of those options. In the course of doing so, the Company became aware of another potential income and employment tax withholding liability associated with the exercise of certain warrants granted in the early years of the Company's existence that were held by certain former officers, directors and employees, including the Company's former President and Chief Executive Officer, Samuel D. Waksal, the Company's former General Counsel, John B. Landes, the Company's former Chief Scientific Officer, Harlan W. Waksal, and the Company's former director and Chairman of the Board, Robert F. Goldhammer. Again, the Company promptly informed the IRS, the SEC and the United States Attorney's Office of this issue. The Company also informed New York State of this issue. On June 17, 2003, New York State notified the Company that based on this issue, they were continuing a previously conducted audit and were evaluating the terms of the closing agreement to determine whether it should be re-opened. On March 31, 2004, the Company entered into a new closing agreement pursuant to which the Company paid New York State an additional $1,000,000 in full satisfaction of all the deficiencies and determinations of withholding taxes for the years 1999-2001. Therefore, the Company has eliminated the liability of $2,815,000 primarily attributable to New York State withholding taxes on stock options and warrants exercised by Dr. Samuel D. Waksal and has recognized a benefit of $1,815,000 as a recovery in the Consolidated Statements of Operations in the first quarter of 2004.

The IRS has commenced audits of the Company's income tax and employment tax returns for tax years 1999 through 2001. The Company has responded to all requests for information and documents received to date from the IRS and is awaiting further requests or action from the IRS.

On March 31, 2003, the Company received notification from the SEC that it was conducting an informal inquiry into the matters discussed above and on April 2, 2003, the Company received a request from the SEC for the voluntary production of related documents and information. The Company is cooperating fully with this SEC inquiry. There have been no recent developments in connection with this SEC investigation.

C. Actions Against Dr. Samuel D. Waksal

As previously reported, on August 14, 2002, after the federal grand jury indictment of Dr. Samuel D. Waksal had been issued but before Dr. Samuel D. Waksal's guilty plea to certain counts of that indictment, the Company filed an action in New York State Supreme Court seeking recovery of certain

compensation, including advancement of certain defense costs, that the Company had paid to or on behalf of Dr. Samuel D. Waksal and cancellation of certain stock options. That action was styled ImClone Systems Incorporated v. Samuel D. Waksal, Index No. 02/602996. On July 25, 2003, Dr. Samuel D. Waksal filed a Motion to Compel Arbitration seeking to have all claims in connection with the Company's action against him resolved in arbitration. By order dated September 19, 2003, the Court granted Dr. Samuel D. Waksal's motion and the action was stayed pending arbitration. On September 25, 2003, Dr. Samuel D. Waksal submitted a Demand for Arbitration with the American Arbitration Association (the "AAA"), by which Dr. Samuel D. Waksal asserts claims to enforce the terms of his separation agreement, including provisions relating to advancement of legal fees, expenses, interest and indemnification, for which Dr. Samuel D. Waksal claims unspecified damages of $10 million. The Demand for Arbitration also seeks to resolve the claims that the Company asserted in the New York State Supreme Court action. On November 7, 2003, the Company filed an Answer and Counterclaims by which the Company denied Dr. Samuel D. Waksal's entitlement to advancement of legal fees, expenses and indemnification, and asserted claims seeking recovery of certain compensation, including stock options, cash payments and advancement of certain defense costs that the Company had paid to or on behalf of Dr. Samuel D. Waksal. In response, on December 15, 2003, Dr. Samuel D. Waksal filed a Reply to Counterclaims. Arbitration hearings in this matter are scheduled to occur in October and November 2005.

The Company intends to vigorously defend against the claims asserted in this matter and to vigorously pursue its counterclaims. The Company is unable to predict the outcome of this action at this time. No reserve has been established in the financial statements because the Company does not believe that such a reserve is required to be established at this time under Statement of Financial Accounting Standards No. 5.

As previously reported, on March 10, 2004, the Company commenced a second action against Dr. Samuel D. Waksal in the New York State Supreme Court. That action is styled ImClone Systems Incorporated v. Samuel D. Waksal, Index No. 04/600643. By this action, the Company seeks the return of more than $21 million that the Company paid to Dr. Samuel D. Waksal, as proceeds from stock option exercises, which the Company alleges he was expected to pay over to federal, state and local tax authorities in satisfaction of his tax obligations arising from certain exercises between 1999 and 2001 of warrants and non-qualified stock options. Specifically, by this action, the Company seeks to recover: (a) $4.5 million that the Company paid to the State of New York in respect of exercises of non-qualified stock options and certain warrants in 2000; (b) at least $16.6 million that the Company paid to Samuel D. Waksal in the form of ImClone common stock, in lieu of withholding federal income taxes from exercises of non-qualified stock options and certain warrants in 2000; and (c) approximately $1.1 million that the Company paid in the form of ImClone common stock to Samuel D. Waksal and his beneficiaries, in lieu of withholding federal, state and local income taxes from certain warrant exercises in 1999-2001. The complaint asserts claims for unjust enrichment, common law indemnification, moneys had and received and constructive trust. On June 18, 2004, Dr. Samuel D. Waksal filed an Answer to the Company's Complaint. Fact discovery in this matter is underway.

D. Intellectual Property Litigation

As previously reported, on October 28, 2003, a complaint was filed by Yeda Research and Development Company Ltd. ("Yeda") against ImClone Systems and Aventis Pharmaceuticals, Inc. in the U.S. District Court for the Southern District of New York (03 CV 8484). This action alleges and seeks that three individuals associated with Yeda should also be named as co-inventors on U.S. Patent No. 6,217,866. On February 9, 2005, Yeda indicated that they intend to amend their U.S. complaint to seek sole inventorship of the subject patent. The Company is vigorously defending against the claims asserted in this action. The Company is unable to predict the outcome of this action at the present time.

As previously reported, on March 25, 2004, an action was filed in the United Kingdom Patent Office entitled Referrer's Statement requesting transfer of co-ownership and amendment of patent EP (UK) 0 667 165 to add three Yeda employees as inventors. Also on March 25, 2004, a German action entitled Legal Action was filed in the Munich District Court I, Patent Litigation Division, seeking to add three Yeda employees as inventors on patent EP (DE) 0 667 165. The Company was not named as a party in these actions that relate to the European equivalent of U.S. Patent No. 6,217,866 discussed above; accordingly, the Company has intervened in both the German and the U.K. actions.

As previously reported, on May 4, 2004, a complaint was filed against the Company by Massachusetts Institute of Technology ("MIT") and Repligen Corporation ("Repligen") in the U.S. District Court for the District of Massachusetts (04-10884 RGS). This action alleges that ERBITUX infringes U.S. Patent No. 4,663,281, which is owned by MIT and exclusively licensed to Repligen. The Company intends to defend vigorously against claims asserted in this action, which is in its early stages. The Company is unable to predict the outcome of this action at the present time.

No reserve has been established in the financial statements for any of the Yeda or MIT and Repligen actions because the Company does not believe that such a reserve is required to be established at this time under Statement of Financial Accounting Standards No. 5.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

MARKET INFORMATION

Our common stock is traded in the over-the-counter market and prices are reported on the Nasdaq National Market tier of The Nasdaq Stock Market ("Nasdaq") under the symbol "IMCL".

The following table sets forth, for the periods indicated, the range of high and low sale prices for our common stock on the Nasdaq National Market, as reported by Nasdaq. The quotations shown represent inter-dealer prices without adjustment for retail mark-ups, mark-downs or commissions, and may not necessarily reflect actual transactions.

Year ended December 31, 2004	High	Low
First Quarter	$50.75	$34.00
Second Quarter	$85.79	$53.00
Third Quarter	$86.79	$49.08
Fourth Quarter	$56.34	$41.20

Year ended December 31, 2003	High	Low
First Quarter	$18.36	$ 9.00
Second Quarter	$38.53	$14.59
Third Quarter	$48.13	$31.95
Fourth Quarter	$42.58	$32.54

On March 9, 2005, the closing price of our common stock as reported by Nasdaq was $40.60.

STOCKHOLDERS

As of the close of business on March 9, 2005, there were approximately 361 holders of record of our common stock. We estimate that there are approximately 32,157 beneficial owners of our common stock.

DIVIDENDS

We have never declared cash dividends on our common stock and have no present intention to declare any cash dividends in the foreseeable future.

RECENT SALES BY THE COMPANY OF UNREGISTERED SECURITIES; PURCHASES OF EQUITY SECURITIES

We did not sell any unregistered securities in the years ended December 31, 2004, 2003 or 2002. We did not repurchase any of our common stock in the fourth quarter of 2004.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The information regarding securities authorized for issuance under our equity compensation plans is disclosed in Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

ITEM 6. SELECTED FINANCIAL DATA

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share data)				
Revenues	$ 388,690	$ 80,830	$ 60,005	$ 50,237	$ 6,253
Operating expenses:					
Research and development	82,658	121,111	142,862	78,036	44,291
Clinical and regulatory	30,254	30,154	20,439	32,943	17,910
Marketing, general and administrative	59,800	41,947	45,815	25,196	16,674
Royalty expense	36,065	—	—	—	—
Litigation settlement	55,363	—	—	—	—
Cost of manufacturing revenue	1,099	—	—	—	—
(Recovery) write-down of withholding tax asset	(1,815)	(3,384)	3,390	25,269	—
Other, net	—	(147)	2,348	16,153	98
Total operating expenses	263,424	189,681	214,854	177,597	78,973
Operating income (loss)	125,266	(108,851)	(154,849)	(127,360)	(72,720)
Other (income) expense, net	(5,748)	3,160	2,375	247	(4,847)
Income (loss) before income taxes and cumulative effect of change in accounting policy	131,014	(112,011)	(157,224)	(127,607)	(67,873)
Provision for income taxes	17,361	491	725	—	—
Income (loss) before cumulative effect of change in accounting policy	113,653	(112,502)	(157,949)	(127,607)	(67,873)
Cumulative effect of change in accounting policy for the recognition of up-front non-refundable fees	—	—	—	—	2,596
Net income (loss)	113,653	(112,502)	(157,949)	(127,607)	(70,469)
Preferred dividends	—	—	—	—	6,773
Net income (loss) to common stockholders	$ 113,653	$(112,502)	$(157,949)	$(127,607)	$ (77,242)
Income (loss) per common share:					
Basic:					
Income (loss) before cumulative effect of change in accounting policy	$ 1.43	$ (1.52)	$ (2.15)	$ (1.84)	$ (1.19)
Cumulative effect of change in accounting policy	—	—	—	—	(0.04)
Basic income (loss) per common share	$ 1.43	$ (1.52)	$ (2.15)	$ (1.84)	$ (1.23)
Diluted:					
Income (loss) before cumulative effect of change in accounting policy	$ 1.33	$ (1.52)	$ (2.15)	$ (1.84)	$ (1.19)
Cumulative effect of change in accounting policy	—	—	—	—	(0.04)
Diluted income (loss) per common share	$ 1.33	$ (1.52)	$ (2.15)	$ (1.84)	$ (1.23)
Shares used in calculation of income (loss) per share:					
Basic	79,500	74,250	73,408	69,429	63,030
Diluted	91,193	74,250	73,408	69,429	63,030
Balance Sheet Data:					
Cash and securities	$ 919,772	$ 106,348	$ 247,655	$ 333,986	$ 297,169
Total assets	1,434,776	381,595	484,506	487,712	402,978
Long-term obligations	603,434	242,979	241,972	242,281	242,779
Deferred revenue	457,808	337,232	322,504	203,496	2,434
Accumulated deficit	(528,955)	(642,608)	(530,106)	(372,157)	(244,550)
Stockholders' equity (deficit)	$ 178,838	$(270,593)	$(185,629)	$ (31,294)	$ 42,690

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis is provided to further the reader's understanding of the consolidated financial statements, financial condition and results of operations of ImClone Systems. This discussion should be read in conjunction with the consolidated financial statements and the accompanying notes included in this Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current expectations that involve risk and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below and under "Risk Factors" set forth in Item 1 and elsewhere in this Annual Report on Form 10-K.

OVERVIEW

ImClone Systems is a biopharmaceutical company whose mission is to advance oncology care by developing and commercializing a portfolio of targeted treatments designed to address the medical needs of patients with cancer. Our lead product, ERBITUX is a first-of-its-kind antibody approved by the FDA for use in combination with irinotecan in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy. ERBITUX binds specifically to epidermal growth factor receptor (EGFR, HER1, c-ErbB-1) on both normal and tumor cells, and competitively inhibits the binding of epidermal growth factor (EGF) and other ligands, such as transforming growth factor-alpha. We are conducting, and in some cases have completed, potential registration studies evaluating ERBITUX for the treatment of colorectal, head and neck and pancreatic cancers, as well as other indications.

On February 12, 2004, the FDA approved ERBITUX for use in combination with irinotecan in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy. On June 18, 2004 the FDA approved our Chemistry Manufacturing and Controls (CMC) supplemental Biologics License Application (sBLA) for licensure of our manufacturing facility referred to as BB36.

On December 1, 2003, Swissmedic, the Swiss agency for therapeutic products, approved ERBITUX in Switzerland for the treatment of patients with colorectal cancer who no longer respond to standard chemotherapy treatment with irinotecan. On June 30, 2004 Merck KGaA received marketing approval by the European Commission to sell ERBITUX for use in combination with irinotecan for the treatment of patients with EGFR-expressing metastatic colorectal cancer after failure of irinotecan including cytotoxic therapy in all members of the European Union, as well as Iceland and Norway in accordance with local legal regulations. In addition, ERBITUX has been approved in Argentina, Chile and Mexico.

Our revenues, as well as our results of operations, have fluctuated and are expected to continue to fluctuate significantly from period to period due to several factors, including but not limited to:

- the amount and timing of revenues earned from commercial sales of ERBITUX;
- the timing of when we begin to reflect full absorption cost of goods sold on sales of ERBITUX to our corporate partners;

- the timing of recognition of license fees and milestone revenues;
- the status of development of our various product candidates;
- whether or not we achieve specified research or commercialization milestones;
- timely payment by our corporate partners of amounts payable to us;
- legal costs and the outcome of outstanding legal proceedings and investigations; and
- the addition or termination of research programs or funding support and variations in the level of expenses related to our proprietary product candidates during any given period.

As a result of our substantial investment in research and development, we have incurred significant operating losses and have an accumulated deficit of $529.0 million as of December 31, 2004. We anticipate that our accumulated deficit will continue to decrease in the future as we earn revenues on commercial sales of ERBITUX and generate net income. Although we have historically devoted most of our efforts and resources to research and development, we expect to devote greater efforts and resources to the manufacturing, marketing, and commercialization of ERBITUX. There is no assurance that we will be able to continue to successfully manufacture, market or commercialize ERBITUX or that potential customers will buy ERBITUX. We rely entirely on third party manufacturers for filling and finishing services with respect to ERBITUX. If our current third party manufacturers or critical raw material suppliers fail to meet our expectations, we cannot be assured that we will be able to enter into new agreements with other suppliers or third party manufacturers without an adverse effect on our business.

HIGHLIGHTS AND OUTLOOK

2004 was very much a year of transition, growth and profitability for us at ImClone Systems. ERBITUX was approved for use in certain patients with EGFR-expressing, metastatic colorectal cancer just over a year ago. Thanks to the economics of our partnership with BMS and a successful product launch, we were able to achieve profitability within the launch quarter and in the subsequent two quarters. For a company that had been generating losses for almost its entire 20 year history and given the typical growing pains experienced by companies making such a transformation, this rapid transition to sustained profitability was no small achievement. With this rapid success has come a higher level of complexity from a financial standpoint.

For the year, we recorded a total of $113.7 million in net income on revenues of $388.7 million—or 29% of total revenues—translating into earnings per diluted share of $1.33. ERBITUX domestic sales in 2004 reached $260.8 million, making it one of the most successful oncology product launches to date. Expenses for the fourth quarter included some one-time items, including royalty expenses of approximately $3.9 million, reflecting the difference between royalty expenses accrued in prior periods and actual obligations resulting from final agreements. Operating expenses also includes a one-time charge of $55.4 million, net of insurance reimbursement, reflecting our settlement of outstanding shareholder and derivative litigation originating from 2002. The resolution of these outstanding uncertainties will contribute to a more stable landscape for the Company from a financial standpoint.

ERBITUX has made rapid and significant market inroads in later stages of the disease since its launch less than a year ago. Our data indicate that the market has accepted ERBITUX as a second and third line therapy and that oncologists have been eager to integrate biologics into their patients' treatment regimens. However, it is still too early to say that the market has settled into a predictable pattern of treatment. In order to increase our presence and prominence within the oncology community and to help maximize the market potential for ERBITUX in its approved indications, we established a sales force of oncology sales professionals during the fourth quarter of 2004. Our sales group will focus on the top 17 or so percent of ERBITUX prescribers who together represent a total of 60% of all the colorectal cancer market. We believe that, given the rapidly evolving landscape in colorectal cancer treatment, these individuals will serve as a helpful resource to physicians.

Building on this successful launch for ERBITUX, we continue to make significant advances in clinical and regulatory. On the regulatory front, we remain on track to file a supplemental biologics license application for ERBITUX in Head and Neck cancer in the second quarter of 2005. On the clinical front, our comprehensive testing program for ERBITUX in first- and second- line non-small cell lung cancer announced in the fourth quarter of 2004 is now well under way. Beyond ERBITUX, two new antibodies have begun Phase I testing. These are IMC-11F8, a fully human monoclonal antibody targeting the epidermal growth factor receptor, and IMC-1121B, a fully human monoclonal antibody designed to bind to the vascular endothelial growth factor receptor 2 found on tumor vasculature. By year end of 2005 we expect that we will be testing five antibodies in the clinic, with two additional antibodies to enter the clinic this year, these are: IMC-A12, which targets the insulin-like growth factor receptor, and IMC-18F1, which targets the VEGFR1 receptor.

From a financial perspective, we anticipate that our results in 2005 will reflect the following: Royalty revenue will continue to reflect 39% of BMS' in-market sales and a range of 4.0%–4.5% of Merck KGaA's in-market sales until such time as a contractual minimum of cumulative sales has been reached; thereafter the royalty rate will increase. License fees and milestone revenue in 2005 will include the continuing amortization, based on clinical development spending, of the $650 million received thus far from BMS. At comparable or slightly increased rates of spending from the most recent quarterly amounts, amortization of milestones received to date should approximate $100 million in 2005. However, should we receive an additional milestone in the fourth quarter of $250 million, license fees and milestone revenue would increase by approximately $125 million reflecting the "catch-up" effect of receipt of this final milestone. The selling price to our partners for Manufacturing revenue in 2005 will be approximately one-half of the price in 2004, since the 2004 price reflected a significant component of materials sourced from Lonza at significantly higher costs than our own manufacturing costs. Collaborative agreement revenue will continue to include the purchase of ERBITUX for clinical use by our partners, as well as reimbursement by BMS of certain regulatory and clinical expenses incurred on behalf of ERBITUX (and such expenses are expected to increase in 2005), and reimbursement for royalty expenses which will approximate 4.5% of US in-market sales, and approximately 1% of sales outside the U.S.

Research and development expenses are expected to increase by approximately 20% in 2005, reaching an annual total of approximately $100 million. The increase versus 2004 reflects significant additional efforts in support of our non-ERBITUX pipeline development and costs associated with producing clinical supplies of ERBITUX for use by ImClone and our partners. Clinical and regulatory expenses in 2005 are expected to increase significantly versus 2004, as we embark on a number of studies in support of expanded use of ERBITUX as well as Phase I clinical development programs for four pipeline products. Total expenses are expected to reach approximately $50 million for the full year. Marketing, general and administrative expenses should approximate $68 million in 2005, an $8 million increase versus 2004. Except for the incremental costs in support of our recently implemented field force, we are managing the total of all other administrative costs to a net year-to-year reduction versus 2004. Gross royalty expenses in 2005 for ERBITUX will include approximately 12.75% of US in-market sales; of which approximately 4.5% of US in-market sales is reimbursed as a component of collaborative agreement revenue, resulting in a net royalty burden to ImClone of 8.25%. Cost of manufacturing revenue will not be fully reflected on our statement of operations until such time as all previously expensed ERBITUX has been sold through to our partners for either commercial or clinical use. Based on our current expectations of purchases by our partners, we expect to begin to reflect full cost of manufacturing revenue during the third quarter of 2005. New accounting rules will require that we include expenses associated with equity-based compensation plans as a component of operating expenses beginning in the third quarter of 2005. We are currently analyzing the impact to our financial statements.

The single most important determinant in estimating our tax rate for 2005 is the assumption made with respect to the potential receipt of a $250 million milestone payment during the calendar year. If

an assumption is made that the milestone is earned this year, we would expect our effective tax rate to be approximately 35%. Conversely, if no milestone is received, we would expect the effective tax rate to be in the low single digits.

CRITICAL ACCOUNTING POLICIES

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. We base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Estimates are deemed critical when a different methodology could have reasonably been used or where changes in the estimate from period to period may have a material impact on the Company's financial condition or results of operations. The Company's critical accounting policies that require management to make significant judgments, estimates, and assumptions are set forth below. The development and selection of the critical accounting policies, and the related disclosure below have been reviewed with the Audit Committee of the Company's Board of Directors.

Revenue Recognition—Our revenues are derived from four primary sources: license fees and milestone payments, manufacturing revenue, royalty revenue, and collaborative agreement revenue.

Revenues from license fees and milestone payments primarily consist of up-front license fees and milestone payments received under the Commercial Agreement with BMS and E.R. Squibb, relating to ERBITUX, and milestone payments received under the development and license agreement with Merck KGaA. We recognize all non-refundable up-front license fees as revenues in accordance with the guidance provided in the Securities and Exchange Commission's Staff Accounting Bulletins No. 101 and 104. Our most critical application of this policy, to date, relates to the $650,000,000 in license fees received from BMS and E.R. Squibb under the Commercial Agreement which are being deferred and recognized as revenue based upon the actual product research and development costs incurred since September 19, 2001 to date by BMS and E.R. Squibb and ImClone as a percentage of the estimated total of such costs to be incurred over the 17 year term of the Commercial Agreement. The estimated total of such cost is based on the clinical development budget which establishes joint responsibilities that will be carried out by both the Company and BMS and E.R. Squibb for certain clinical and other studies. Of the $650,000,000 in payments received through December 31, 2004, $128,943,000 was recognized as revenue during 2004 and $199,631,000 from the commencement of the Commercial Agreement in 2001 through December 31, 2004. The methodology used to recognize deferred revenue involves a number of estimates and judgments, such as the estimate of total product research and development costs to be incurred under the Commercial Agreement. Changes in these estimates and judgments can have a significant effect on the size and timing of revenue recognition. In addition, if management had chosen a different methodology to recognize the license fee and milestone payments received under the Commercial Agreement, the Company's financial position and results of operations could have differed materially. For example, if the Company were to recognize the revenues earned from the Commercial Agreement on a straight-line basis over the life of the agreement, the Company would have recognized approximately $40,300,000 and $86,400,000 as revenue for the twelve months and from the commencement of the Commercial Agreement, respectively, through December 31, 2004. Management believes that the current methodology used to recognize revenues under the Commercial Agreement, which reflects the level of effort consistent with the product development activities, is the most appropriate methodology because it reflects the level of expenditure and activity in the period in which it is being spent as compared to the total expected expenditure over the life of the Commercial Agreement. This cost to cost approach is systematic and rational, it provides a factually supportable pattern to track progress, and is reflective of the level of effort, which varies over time.

Non-refundable upfront payments received from Merck KGaA were deferred due to our significant continuing involvement and are being recognized as revenue on a straight-line basis over the estimated

service period because the activities specified in the agreement between the Company and Merck KGaA will be performed over the estimated service period and there is no other pattern or circumstances that indicate a different way in which the revenue is earned. In addition, the development and license agreement with Merck KGaA does not contain any provisions for establishing a clinical budget and none has been established between the parties. This agreement does not call for co-development with the Company in Merck KGaA's territory, rather Merck KGaA is solely responsible for regulatory efforts in its territory. Non-refundable milestone payments, which represent the achievement of a significant step in the research and development process, pursuant to collaborative agreements other than the Commercial Agreement, are recognized as revenue upon the achievement of the specified milestone. This is because each milestone payment represents the achievement of a substantive step in the research and development process and Merck KGaA has the right to evaluate the technology to decide whether to continue with the research and development program as each milestone is reached.

Manufacturing revenue consists of revenue earned on the sale of ERBITUX to our corporate partners for subsequent commercial sale. The Company recognizes manufacturing revenue when the product is shipped, which is when our partners take ownership and title has passed, collectibility is reasonably assured, the sales price is fixed and determinable, and there is persuasive evidence of an agreement. We are contractually obligated to sell ERBITUX to BMS at our cost of production plus a 10% markup. We sell bulk inventory to Merck KGaA at our full absorption cost of production. The selling price for ERBITUX to BMS during 2004 reflected the weighted average costs of production for inventory previously produced by Lonza and at our BB36 manufacturing plant. During 2004, we sold all inventory produced by Lonza and we anticipate that all production of ERBITUX in 2005 will be performed at our BB36 manufacturing facility. Therefore, the sales price to our corporate partners in 2005 is expected to be significantly lower (i.e. roughly one-half) than the costs we charged our partner in 2004 since our unit cost to manufacture ERBITUX is significantly lower than the cost paid to Lonza for manufacturing ERBITUX. The continuing level of manufacturing revenue in future periods may fluctuate significantly based on market demand, our cost of production, as well as BMS's required level of safety stock inventory for ERBITUX.

Royalty revenues from licensees, which are based on third-party sales of licensed products and technology, are recorded as earned in accordance with contract terms when third-party sales can be reliably measured and collection of funds is reasonably assured.

Collaborative agreement revenue consists of reimbursements received from BMS and E.R. Squibb and Merck KGaA related to clinical and regulatory studies, ERBITUX provided to them for use in clinical studies, reimbursement of a portion of royalty expense and certain marketing and administrative costs. Collaborative agreement revenue is recorded as earned based on the performance requirements under the respective contracts.

Withholding Taxes—In January 2003, New York State notified the Company that it was liable for the New York State and City income taxes that were not withheld because one or more of the Company's employees who exercised certain non-qualified stock options in 1999 and 2000 failed to pay New York State and City income taxes for those years. On March 13, 2003, the Company entered into a closing agreement with New York State, paying $4,500,000 to settle the matter. Subsequently, the Company became aware of another potential income and employment tax withholding liability associated with the exercise of certain warrants granted in the early years of the Company's existence that were held by certain former officers, directors and employees. After the Company informed New York State of the issue relating to the warrants, New York State, in June 2003, notified the Company that it was continuing the previously conducted audit of the Company and was evaluating the terms of the closing agreement to determine whether or not it should be re-opened. On March 31, 2004, the Company entered into a new closing agreement pursuant to which the Company paid New York State an additional $1,000,000 in full satisfaction of all the deficiencies and determinations of withholding taxes for the years 1999-2001. As a result, we have utilized $1,000,000 of the liability of $2,815,000 that

we previously established for New York withholding taxes on stock options and warrants exercised and have recognized a benefit of $1,815,000 as a recovery in the Consolidated Statements of Operations for the year ended December 31, 2004.

On March 13, 2003, the Company initiated discussions with the Internal Revenue Service (the "IRS") relating to the federal income taxes applicable to the above noted issues. Although the IRS has not yet asserted that the Company is required to make a payment with respect to such failure to withhold, the IRS may assert that such a liability exists, and may further assert that the Company is liable for interest and penalties. The IRS has commenced audits of the Company's income tax and employment tax returns for tax years 1999 through 2001. The Company is cooperating fully with the IRS with respect to these audits, and intends to continue to do so.

The Company has not recognized withholding tax liabilities in respect of exercises of certain warrants by Robert F. Goldhammer, one of the four former officers or directors to whom warrants were issued and previously treated as non-compensatory warrants. Based on the Company's investigation, it believes that, although such warrants were compensatory, such warrants were received by Mr. Goldhammer in connection with the performance of services by him in his capacity as a director, rather than as an employee, and, as such, is not subject to tax withholding requirements. In addition, in 1999, Mr. Goldhammer erroneously received a portion of a stock option grant in the form of incentive stock options, which under federal law may only be granted to employees. There can be no assurance, however, that the IRS will agree with the Company's position and will not assert that the Company is liable for the failure to withhold income and employment taxes with respect to the exercise of such warrants and any stock options by Mr. Goldhammer. If the Company became liable for the failure to withhold taxes on the exercise of such warrants and any stock options by Mr. Goldhammer, the aggregate potential liability, exclusive of any interest or penalties, would be approximately $8,300,000.

The Company has not recognized accruals for penalties and interest that may be imposed with respect to the withholding tax issues previously described and other related contingencies, including the period covered by the statute of limitations and the Company's determination of certain exercise dates, because it does not believe that losses from such contingencies are probable, or in the event that any taxing authority makes a claim for penalties or interest, the Company believes that it will be able to settle the total amount asserted (including any liability for taxes) for an amount not in excess of the liability for taxes already accrued with respect to the relevant withholding tax issue. With respect to the statute of limitations and the Company's determination of certain exercise dates, while the Company does not believe a loss is probable, there is a potential additional liability with respect to these issues that may be asserted by a taxing authority. If taxing authorities assert such issues and prevail related to these withholding tax issues and other related contingencies, including penalties, the liability that could be imposed by taxing authorities would be substantial. The potential interest on the withholding tax liabilities recorded on the Consolidated Balance Sheets could be up to a maximum amount of approximately $8,000,000 at December 31, 2004. Potential additional withholding tax liability on other related contingencies amounts to approximately $8,000,000, exclusive of any interest or penalties, and excluding the amount potentially attributable to Mr. Goldhammer noted above.

Inventories—Until February 12, 2004, all costs associated with the manufacturing of ERBITUX were included in research and development expenses when incurred. Effective February 13, 2004, the date after the Company received approval from the FDA for ERBITUX, we began to capitalize in inventory the cost of manufacturing ERBITUX for commercial sale and will expense such cost as cost of manufacturing revenue at the time of sale. However, as we sell our existing inventory that was previously expensed, there will be a period of time whereby the Company will reflect manufacturing revenue with minimal cost. Therefore, we anticipate that our margin on sales of ERBITUX to our corporate partners will fluctuate from quarter to quarter during 2005. For example, effective February 13, 2004, we began to capitalize the cost of producing ERBITUX including the costs of packaging and labeling bulk inventory previously produced, some of which we subsequently sold and

reflected in our Consolidated Statement of Operations during 2004 as cost of manufacturing revenue. The cost of manufacturing revenue reflected in the Company's operating expenses during 2004 therefore, does not reflect full absorption cost of production because the raw materials, labor and overhead costs incurred to produce the product sold, were previously expensed. If the Company had capitalized inventory prior to obtaining FDA approval of ERBITUX, the cost basis of the inventory sold would be at least 90% of manufacturing revenue or a gross margin of approximately 10%, depending on the relative level of sales to BMS and Merck KGaA. We expect that, consistent with 2004, there will be periods in 2005 whereby the cost of manufacturing revenue reflected in our operating expenses will primarily reflect costs associated with packaging, labeling and shipping inventory that has been previously expensed. We also anticipate that there may be a reporting period in 2005 that may include a combination of partial cost, and full absorption cost of manufacturing revenue. Therefore, we believe that our manufacturing revenue margin will be distorted for comparison purposes for a significant period after February 12, 2004 depending on market demand for ERBITUX.

Litigation—The Company is currently involved in certain legal proceedings as fully disclosed in the Notes to the Consolidated Financial Statements. In accordance with Statement of Financial Accounting Standards No. 5, no reserve has been established in our financial statements for certain legal proceedings because we do not believe that such a reserve is required to be established at this time. However, if in a future period, events in any such legal proceedings render it probable that a loss will be incurred, and if such loss is reasonably estimable at that time, we will establish such a reserve. Thus, it is possible that legal proceedings may have a material adverse impact on the operating results for that period, on our balance sheet or both.

Long-Lived Assets—We review long-lived assets for impairment when events or changes in business conditions indicate that their full carrying value may not be recovered. Assets are considered to be impaired and written down to fair value if expected associated undiscounted cash flows are less than carrying amounts. Fair value is generally determined as the present value of the expected associated cash flows. We have built BB36 and are building BB50, and purchased a material logistics and warehousing facility and an administrative facility. BB36 is dedicated to the clinical and commercial production of ERBITUX and BB50 will be a multi-use production facility. ERBITUX is currently being produced for clinical studies and commercialization at BB36. The material logistics and warehousing facility includes office space, a storage location and sampling laboratory for ERBITUX. A newly renovated administrative facility houses the clinical, regulatory, sales, marketing, finance, human resources, project management and MIS departments, as well as certain executive and legal offices and other necessities. Based on management's current estimates, we expect to recover the carrying value of such assets. Changes in regulatory or other business conditions in the future could change our judgments about the carrying value of these facilities, which could result in the recognition of material impairment losses.

Income Taxes—Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Significant estimates are required in determining our provision for income taxes. As of December 31, 2004, the Company continues to reflect a valuation allowance against its total net deferred tax assets because, more likely than not, its net deferred tax assets will not be realized. Although management believes that the valuation allowance as of December 31, 2004 is appropriate, we expect that as we continue to sell ERBITUX to our corporate partners for commercial use and earn royalties and income from operations from the expected commercial sales of ERBITUX, we will need to revise our conclusions regarding the realization of our deferred tax assets due to expected changes in overall levels of pretax earnings. In addition, there may be other factors such as changes in tax laws and future levels of research and development spending that may impact our effective tax rate in the future.

RECENTLY ISSUED STATEMENTS OF FINANCIAL ACCOUNTING STANDARDS

On November 24, 2004 the Financial Accounting Standards Board (FASB) issued FASB Statement No. 151, *Inventory Costs*, an amendment of ARB No. 43. This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing", to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). The provisions of this Statement are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of this accounting pronouncement is not expected to have a material effect on the Company's consolidated statements.

On December 16, 2004 the FASB issued Statement No. 153, *Exchanges of Nonmonetary Transactions.* This Statement provides that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The Statement is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The provisions of this Statement are not expected to have a material effect on the Company's consolidated statements.

On December 16, 2004 the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment.* This Statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements and establishes fair value as the measurement objective in accounting for all share-based payment arrangements. This Statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. The adoption of this Statement will have a material effect on the Company's financial statements.

RESULTS OF OPERATIONS

Selected financial and operating data for the three years ended December 31, 2004, 2003 and 2002 are as follows: (in thousands)

	Years Ended December 31,			Variance	
	2004	2003	2002	2004 vs. 2003	2003 vs. 2002
Results of Operations:					
License fees and milestone revenue	$129,386	$ 47,970	$ 21,051	$ 81,416	$ 26,919
Manufacturing revenue	99,041	—	—	99,041	—
Royalty revenue	106,274	575	1,353	105,699	(778)
Collaborative agreement revenue	53,989	32,285	37,601	21,704	(5,316)
Total revenues	388,690	80,830	60,005	307,860	20,825
Operating Expenses:					
Research and development	82,658	121,111	142,862	(38,453)	(21,751)
Clinical and regulatory	30,254	30,154	20,439	100	9,715
Marketing, general and administrative	59,800	41,947	45,815	17,853	(3,868)
Royalty expense	36,065	—	—	36,065	—
Cost of manufacturing revenue	1,099	—	—	1,099	—
Litigation settlement	55,363	—	—	55,363	—
(Recovery) write-down of withholding taxes	(1,815)	(3,384)	3,390	1,569	(6,774)
Other	—	(147)	2,348	147	(2,495)
Total operating expenses	$263,424	$189,681	$214,854	$ 73,743	$(25,173)

Years Ended December 31, 2004 and 2003

Revenues

License Fees and Milestone Revenue

License fees and milestone revenue in 2004 of $129,386,000 consists of recognition of up-front and milestone payments received under the Commercial Agreement with BMS and E.R. Squibb of $128,943,000, recognition of payments received under the development and license agreements with Merck KGaA of $385,000 and license fees from GlaxoSmithKline plc. of $58,000. The increase of $81,416,000 in license fees and milestone revenue from the comparable period in 2003 is due to an increase in revenue recognized under the Commercial Agreement with BMS and E.R. Squibb primarily as a result of the $250,000,000 received in the first quarter of 2004, when we obtained FDA approval of ERBITUX and due to increases in clinical development spending by BMS and ImClone. License fees and milestone revenue in 2005 will include the continuing amortization, based on clinical development spending, of the $650 million received thus far from BMS. At comparable or slightly increased rates of spending from the most recent quarterly amounts, amortization of milestones received to date should approximate $100 million for the full year. However, should we receive an additional milestone in the fourth quarter of 2005 of $250 million, license fees and milestone revenue would increase by approximately $125 million reflecting the "catch-up" effect of receipt of this final milestone.

Manufacturing Revenue

Manufacturing revenue of $99,041,000 in 2004 consists of sales of ERBITUX to our corporate partners for commercial use. In accordance with the Commercial Agreement, we are contractually obligated to sell ERBITUX to BMS at our cost of production plus a 10% markup. We sell bulk inventory to Merck KGaA at our full absorption cost of production. There were no sales of ERBITUX to Merck KGaA during 2004. The selling price for ERBITUX to our corporate partners is based on the full absorption costs of production incurred, which during 2004 reflected the weighted average costs of production for inventory previously produced by Lonza and at our BB36 manufacturing plant. During 2004, we sold all inventory produced by Lonza and we anticipate that all production of ERBITUX in 2005 will be performed at our BB36 manufacturing facility. Therefore, the sales price to our corporate partners in 2005 is expected to be significantly lower than the price we charged our partner in 2004 since our unit cost to manufacture ERBITUX is significantly lower than the cost paid to Lonza for manufacturing ERBITUX. The continuing level of manufacturing revenue in future periods may fluctuate significantly based on market demand, our cost of production, as well as BMS's required level of safety stock inventory for ERBITUX.

Royalty Revenue

Royalty revenue consists primarily of royalty payments earned on the sale of ERBITUX by our partners, BMS and Merck KGaA. Under our agreement with BMS, we are entitled to royalty payments equal to 39% of BMS's net sales of ERBITUX in the United States and Canada. Under our agreement with Merck KGaA, we are entitled to royalty payments based on a percentage of gross margin of Merck KGaA's sales of ERBITUX outside the United States and Canada. During 2004, we earned royalties from BMS of $101,703,000 on net sales of ERBITUX of approximately $260.8 million and royalties from Merck KGaA of $4,314,000 on net sales of ERBITUX of approximately $100.0 million. Royalty revenue in 2005 will continue to reflect 39% of BMS' net in-market sales and a range of 4.0%–4.5% of Merck KGaA's in-market sales until such time as a contractual minimum of cumulative sales has been reached, thereafter the royalty rate will increase.

Collaborative Agreement Revenue

Collaborative agreement revenue consists primarily of reimbursements from our partners BMS and E.R. Squibb and Merck KGaA under our collaborative agreements. There are certain categories for which we receive reimbursement from our partners: clinical and regulatory expenses, the cost of ERBITUX supplied to our partners for use in clinical studies, certain marketing and administrative expenses and a portion of royalty expense. During 2004, we earned $53,989,000 in collaborative agreement revenue of which $38,919,000 represents amounts earned from BMS and E.R. Squibb and $15,018,000 represents amounts earned from Merck KGaA, as compared to $32,285,000 earned in the comparable period in 2003, of which $20,668,000 was earned from BMS and E.R. Squibb and $11,617,000 was earned from Merck KGaA. The increase in collaborative agreement revenue of $21,704,000 is principally due to royalty expense reimbursed by our corporate partners of approximately $12,738,000, and an increase in drug shipments to our partners of approximately $9,300,000, partly offset by a decrease in clinical and regulatory reimbursement. Collaborative agreement revenue in 2005 will continue to include the purchase of ERBITUX for clinical use by our partners, as well as reimbursement by BMS of certain regulatory and clinical expenses incurred on behalf of ERBITUX (and such expenses are expected to increase in 2005), and reimbursement for royalty expenses which will approximate 4.5% of US in-market sales, and approximately 1% of sales outside the U.S.

Research and Development

Research and development expenses in 2004 and 2003 were $82,658,000 and $121,111,000, respectively, a decrease of $38,453,000 or 32.0%. Research and development expenses include costs associated with our in-house and collaborative research programs, product and process development expenses, costs to manufacture ERBITUX (until February 12, 2004) and other product candidates (prior to any approval that we may obtain of a product candidate for commercial sale) and quality assurance and quality control costs. Research and development include costs that are reimbursable from our corporate partners. Approximately $24,508,000 and $15,232,000 of costs representing research and development expenses for the years ended December 31, 2004 and 2003, respectively, were reimbursed and included under collaborative agreement revenue since they represent inventory supplied to our partners for use in clinical studies.

The decrease in research and development expenses of $38,453,000 in 2004 was primarily attributable to a decrease of approximately $23,200,000 related to costs incurred in connection with the manufacturing of ERBITUX by Lonza, a contract manufacturer, and a decrease of approximately $28,000,000 reflecting the capitalization of inventory costs subsequent to February 12, 2004. These decreases were partially offset by an increase in salaries and benefits of approximately $12,200,000 due to a significant increase in headcount from the comparable period in 2003 and an overall increase in salary and benefit expenses.

Research and development expenses are expected to increase by approximately 20% in 2005, reaching an annual total of approximately $100 million. The increase versus 2004 reflects significant additional efforts in support of our non-ERBITUX pipeline development and costs associated with producing clinical supplies of ERBITUX for use by ImClone and our partners.

Clinical and Regulatory

Clinical and regulatory expenses in 2004 and 2003 were $30,254,000 and $30,154,000, respectively, an increase of $100,000 in 2004. Clinical and regulatory expenses consist of costs to conduct our clinical studies and associated regulatory activities. During 2004, there was an increase in salaries and benefits and other employee related expenses of approximately $3,300,000 due to increases in headcount, partially offset by a decrease in cost incurred related to contract clinical services of approximately $3,200,000. Approximately $13,858,000 and $15,071,000 of the costs included in this category for the year ended December 31, 2004 and 2003, respectively, are reflected as revenues under collaborative agreement revenue since they represent costs that are reimbursable by our corporate partners. Clinical and regulatory expenses in 2005 are expected to increase significantly versus 2004, as we embark on a number of studies in support of expanded use of ERBITUX as well as Phase 1 clinical development programs for four pipeline products. Total expenses are expected to reach approximately $50 million for the year ended December 31, 2005.

Marketing, General and Administrative

Marketing, general and administrative expenses include marketing and administrative personnel costs, including related facility costs, additional costs to develop internal marketing and field operations capabilities and expenses associated with applying for patent protection for our technology and products. Marketing, general and administrative expenses also include amounts reimbursable from our corporate partners.

Marketing, general and administrative expenses in 2004 amounted to $59,800,000, an increase of $17,853,000 or 43.0% from the comparable period in 2003. This increase is partly due to increases in personnel costs of approximately $10,900,000 due to increased headcount and marketing expenses incurred to support the commercialization of ERBITUX and an increase of approximately $12,200,000 in professional services fees related to legal, consulting and marketing research and marketing conventions, offset by a charge of approximately $5,000,000 in 2003 related to a termination agreement with a former officer of the company. Some expenses in this category are reimbursable from our corporate partners. Approximately $2,880,000 and $1,980,000 of costs representing marketing and general expenses for the years ended December 31, 2004 and 2003, respectively, were reimbursed and included in collaborative agreement revenue

In order to increase our presence and prominence within the oncology community and to help maximize the market potential for ERBITUX in its approved indications, we established a sales force of oncology sales professionals during the fourth quarter of 2004. Our sales group will focus on the top 17 or so percent of ERBITUX prescribers who together represent a total of 60% of all the CRC market. We believe that, given the rapidly evolving landscape in colorectal cancer treatment, these individuals will serve as a helpful resource to physicians. Marketing, general and administrative expenses should approximate $68 million in 2005, an $8 million increase versus 2004. Except for the incremental costs in support of our recently implemented field force, we are managing all other administrative costs to a net year-to-year reduction versus 2004.

Cost of Manufacturing Revenue

Effective February 13, 2004, the Company began to capitalize in inventory the costs of manufacturing of ERBITUX for commercial sale and will expense such costs as cost of manufacturing revenue at the time of sale. However, as we sell our existing inventory that was previously expensed, there will be a period of time in which the Company will reflect minimum cost of manufacturing revenue since the majority of the cost of such inventory has already been expensed in prior periods as research and development expenses. Cost of Manufacturing revenue for 2004 of approximately $1.1 million reflects primarily fill and finish costs. Consistent with 2004, we anticipate that our manufacturing revenue margin on sales of ERBITUX to our corporate partners will continue to fluctuate from quarter to quarter during 2005. We expect that during 2005, we will experience certain

quarters in which the cost of manufacturing revenue reflected in our operating expenses will primarily reflect costs associated with packaging, labeling and shipping inventory, for which all or a portion, have been previously expensed. We also anticipate that there may be a reporting period in 2005 that may include a combination of partial cost, and full absorption cost of manufacturing revenue. Therefore, full absorption costs of manufacturing revenue will not be reflected on our income statement until such time as all previously expensed or partially expensed ERBITUX has been sold through to our partners for either commercial or clinical use. Based on our current expectations of purchases by our partners, we expect to begin to reflect full cost of manufacturing revenue during the third quarter of 2005.

Royalty Expense

Royalty expense of $36,065,000 for the year ended December 31, 2004 consists of obligations related to certain licensing agreements related to ERBITUX. Approximately $12,700,000 of royalty expense is reimbursed by our corporate partners and included as collaborative agreement revenue for the year ended December 31, 2004. In January 2005, we finalized and signed license agreements with Genentech and Centocor, Inc. for the rights to patents covering various aspects of antibody technology and certain use of epidermal growth factor receptor (EGFR) antibodies. For ERBITUX use in combination with anti-neoplastic agents, ImClone Systems' gross royalty expense for all licenses, including Genentech, Centocor, Aventis and the University of California, is approximately 12.75 percent of North American sales. We receive reimbursements for a portion of these royalty expenses, resulting in a net royalty expense of approximately 8.25%. After the first quarter of 2006, gross royalty expense will decrease to 9.75% and net royalty expense will decrease to 7.25%. For ERBITUX monotherapy use, gross and net royalty expenses will be reduced by approximately 1% because certain licenses are not applicable. Fourth-quarter 2004 royalty expenses include charges of approximately $3.9 million required to bring estimated royalty expenses recorded through the first nine months of 2004 in line with actual obligations. Royalty expenses in 2005 for ERBITUX will include approximately 12.75% of US in-market sales; as previously mentioned, approximately 4.5% of US in-market sales is reimbursed as a component of collaborative agreement revenue, resulting in a net royalty burden to ImClone of 8.25%.

Litigation Settlement

In January 2002, a number of complaints asserting claims under the federal securities laws against the Company and certain of the Company's directors and officers were filed in the U.S. District Court for the Southern District of New York. Those actions were consolidated under the caption Irvine v. ImClone Systems Incorporated. The complaint generally alleged that various public statements made by or on behalf of the Company or the other defendants during 2001 and early 2002 regarding the prospects for FDA approval of ERBITUX were false or misleading when made, that the individual defendants were allegedly aware of material non-public information regarding the actual prospects for ERBITUX at the time that they engaged in transactions in the Company's common stock and that members of the purported stockholder class suffered damages when the market price of the Company's common stock declined following disclosure of the information that allegedly had not been previously disclosed. On January 13, 2002, and continuing thereafter, nine separate purported shareholder derivative actions were filed against members of the Company's board of directors, certain of the Company's present and former officers, and the Company, as nominal defendant, advancing claims based on allegations similar to the allegations in the federal securities class action complaints.

On January 24, 2005, we reached an agreement in principle to settle the consolidated class action described above for a cash payment of $75.0 million, a portion of which will be paid by our insurers. The settlement is subject to the negotiation and execution of definitive settlement documents and to Court approval. The Company anticipates that a hearing to consider approval of the settlement will be held in late April or early May 2005. We also reached an agreement in principle to settle the consolidated derivative action described above. Under the settlement, the Company will be paid $8.75 million by its insurers, which the Company intends to contribute toward the settlement of the

Irvine securities class action described above after deducting amounts awarded by the Court in the derivative action for plaintiffs' attorney's fees and expenses in that action, which the Company has agreed not to oppose in an amount up to $875,000. The proposed settlement is subject to negotiation and execution of definitive settlement documents, the approval and consummation of the settlement of the Irvine class action and Court approval. As a result, we have recorded in our Consolidated Balance Sheets at December 31, 2004 as Litigation settlement, a liability of $75.9 million and a receivable from our insurers of approximately $20.5 million, included in Other current assets. Net expense of $55.4 million, recorded in the fourth quarter of 2004, is reflected in the Consolidated Statement of Operations as Litigation settlement.

(Recovery) Write-down of Withholding Taxes

The amount for the year December 31, 2004 of $1,815,000 consists of the reversal of a liability related to withholding taxes that was settled at an amount less than was originally estimated. The recovery in the comparable period of 2003 of $3,384,000 is due to a recovery of a previous write-down related to a withholding tax matter attributable to a former executive of the Company.

Interest Income and Interest Expense

Interest income was $14,049,000 for the year ended December 31, 2004 compared with $4,121,000 in the comparable period in 2003, an increase of $9,928,000. This increase is attributable to the increase in the Company's cash and cash equivalents and our securities portfolio primarily as a result of the receipt of $250,000,000 in March of 2004 and the $600,000,000 of convertible debt issued in May 2004.

Interest expense was $8,432,000 and $8,881,000 for the year ended December 31, 2004 and 2003, respectively, a decrease of $449,000 or 5.0%. The decrease in interest expense is primarily attributable to the fact that the Company's cost of borrowing decreased with the issuance of $600 million of 1⅜% convertible debt in May of 2004, compared to the $240 million of 5½% convertible debt outstanding in the comparable period of 2003.

Provision for Income Taxes

The effective tax rate for the year ended December 31, 2004 amounted to approximately 13% which is lower than the amount previously indicated in our 2004 third quarter filing. The primary reason for the decline in the effective rate is due to the fact that the Company was able to utilize approximately $32.0 million of net operating losses that were previously believed to be limited based on a previous analysis conducted under Section 382 of the Internal Revenue Code of 1986. During the fourth quarter of 2004, we hired an external firm to conduct a study under Section 382 in order to verify if we had any limitations under this Section of the Code. Based on the results of such study, we learned that we do not have a limitation under Section 382, as previously believed. Therefore, we have utilized all available net operating losses in 2004 which has resulted in a lower actual effective rate than previously calculated in the third quarter of 2004. The effective tax rate in 2004 was also impacted by a $55.4 million litigation settlement expense taken in the fourth quarter of 2004. The difference from the statutory rate of 35% is due to the utilization of net operating losses, tax credit carryforwards and state taxes. A reconciliation of the statutory federal income tax rate to the effective income tax rate for each period is included in the notes to the consolidated financial statements. The single most important determinant in estimating our tax rate for 2005 is the assumption made with respect to the potential receipt of a $250 million milestone payment during the calendar year. If an assumption is made that the milestone is earned this year, we would expect our accounting tax rate to be approximately 35%. Conversely, if no milestone is received, we would expect the effective tax rate to be in the low single digits.

Net Income (Loss)

We had net income of $113,653,000 or $1.43 per basic common share and $1.33 per diluted common share for the year ended December 31, 2004, compared with a net loss of $112,502,000 or $1.52 per basic and diluted common share in the comparable period in 2003. The fluctuation in results was due to the factors noted above.

Years Ended December 31, 2003 and 2002

Revenues

Total revenues for the year ended December 31, 2003 amounted to $80,830,000, an increase of $20,825,000 or 34.7% from the comparable period in 2002. We derived our revenues from three primary sources: license fees and milestone revenue, royalty revenue, and collaborative agreement revenue.

License Fees and Milestone Revenue

Total license fees and milestone revenue in 2003 of $47,970,000 consist of recognition of up-front payments received under the Commercial Agreement with BMS and E.R. Squibb of approximately $47,527,000, recognition of payments received under the development and license agreements with Merck KGaA of $385,000 and license fees from GlaxoSmithKline plc. ("Glaxo") of $58,000. The increase in license fees and milestone revenue from 2002 of $26,919,000 is due to an increase in revenue recognized under the Commercial Agreement with BMS and E.R. Squibb as a result of increased expenditures in product research and development during 2003 by BMS and E.R. Squibb and ImClone Systems and the receipt of an additional payment of $60,000,000 from BMS during 2003.

Royalty Revenue

Royalty revenue consists primarily of royalty payments received from Abbott pursuant to the licensing of some of our diagnostic products and techniques on a worldwide basis. During 2003 we earned royalty payments of $557,000 primarily from Abbott, a decrease of $796,000 from the corresponding period in 2002. The decrease is due to the fact that Abbott discontinued the sales of these products during 2003, therefore we expect that any royalties in the future will be minimal as they exhaust their existing inventory. In addition, as a result of the approval by Swissmedic in December of 2003 of ERBITUX in Switzerland, we earned approximately $18,000 of royalty revenue on sales of ERBITUX by Merck KGaA in Switzerland during the month of December 2003.

Collaborative Agreement Revenue

Collaborative agreement revenue consists of reimbursements from our partners BMS and Merck KGaA under our collaborative agreements. There are three primary categories for which we receive reimbursement from our partners: clinical and regulatory expenses, the cost of ERBITUX supplied to our partners for use in clinical studies, and certain marketing and administrative expenses. During 2003, we earned $32,285,000 in collaborative agreement revenue of which $20,668,000 represents amounts earned from BMS and E.R. Squibb and $11,617,000 represents amounts earned from Merck KGaA as compared to $37,601,000 earned in 2002 of which $20,382,000 was earned from BMS and E.R. Squibb and $17,219,000 was earned from Merck KGaA. The decrease in collaborative agreement revenue in 2003 of $5,316,000 is primarily due to a decrease in product supplied to Merck KGaA during 2003 for use in clinical studies.

Operating Expenses

Total operating expenses for the year ended December 31, 2003 amounted to $189,681,000, a decrease of $25,173,000, or 11.7% from the corresponding period in 2002. This decrease is primarily due to a decrease in research and development expenses of $21,751,000, a decrease in marketing, general and administrative expenses of $3,868,000, a decrease of $6,774,000 due to a recovery of a

previous write-off in 2002 of $3,384,000 relating to a withholding tax liability and a decrease of $2,250,000 relating to expenses associated with the BMS acquisition, stockholder and amended commercial agreements. These decreases were partially offset by an increase in clinical and regulatory expenses of $9,715,000.

Research and Development

Research and development expenses for the year ended December 31, 2003 and 2002 were $121,111,000 and $142,862,000, respectively, a decrease of $21,751,000 or 15.2% in 2003. Research and development expenses include costs associated with our in-house and collaborative research programs, product and process development expenses, costs to manufacture ERBITUX and other product candidates (prior to any approval that we may obtain of a product candidate for commercial sale) and quality assurance and quality control costs. Research and development reflect costs that are reimbursable from our corporate partners. Approximately $15,232,000 and $23,162,000 of costs reflected in research and development for the years ended December 31, 2003 and 2002, respectively, are reflected under collaborative agreement revenue since they represent inventory supplied to our partners for use in clinical studies. With the approval of ERBITUX by the FDA on February 12, 2004, our research and development expenses will no longer reflect prospectively from that date the cost associated with manufacturing ERBITUX. Costs incurred in the production of ERBITUX for sale to our corporate partners will be included in inventory and expensed as cost of goods sold at the time of sale of such inventory.

The decrease in research and development expenses of $21,751,000 for the year ended December 31, 2003 was primarily attributable to a decrease of approximately $28,300,000 related to cost incurred in connection with the manufacturing of ERBITUX by Lonza, a contract manufacturer. For the years ended 2003 and 2002, research and development included approximately $23,189,000 and $51,521,000, respectively of inventory cost manufactured by Lonza under a service agreement that was completed by June of 2003. This decrease was partially offset by increased expenditures in discovery research and increased costs associated with the full-scale production of BB36.

The largest component of our total operating expenses is our ongoing investment in research and development and, in particular, the clinical development of our product pipeline. The process of conducting the clinical research necessary to obtain FDA approval is costly and time consuming. Current FDA requirements for a new human drug or biological product to be marketed in the United States include: (1) the successful conclusion of pre-clinical laboratory and animal tests, if appropriate, to gain preliminary information on the product's safety; (2) filing with the FDA of an IND, to conduct human clinical studies for drugs or biologics; (3) the successful completion of adequate and well-controlled human clinical investigations to establish the safety and efficacy of the product for its recommended use; and (4) filing by a company and acceptance and approval by the FDA of a NDA for a drug product or a BLA for a biological product to allow commercial distribution of the drug or biologic. Due to the inherent risks associated with candidate discovery and development, as well as the regulatory approval process, we, by necessity, manage our overall research, development and in-licensing efforts in a manner designed to generate new clinical candidates into development.

The actual probability of success for each candidate and clinical program may be impacted by a variety of factors, including, among others, the quality of the candidate, the validity of the target and disease indication, early clinical data, investment in the program, competition, manufacturing capability and commercial viability. Due to these factors, it is difficult to give accurate guidance on the anticipated proportion of our research and development investments assigned to any one program prior to the Phase III stage of development or the future cash inflows from these programs.

Clinical and Regulatory

Clinical and regulatory expenses for the year ended December 31, 2003 and 2002 were $30,154,000 and $20,439,000, respectively, an increase of $9,715,000 or 47.5% in 2003. Clinical and regulatory

expenses consist of costs to conduct our clinical studies and associated regulatory activities. The increase experienced in 2003 is primarily as a result of incremental costs incurred due to increased activity in our clinical programs including an increase of approximately $1,200,000 in salary and benefits based on increased headcount during 2003. Approximately $15,109,000 and $12,796,000 of the costs included in this category for the years ended December 31, 2003 and 2002, respectively is reflected as revenues under collaborative agreement since they represent costs that are reimbursable by our corporate partners.

Marketing, General and Administrative

Marketing, general and administrative expenses include marketing and administrative personnel costs, including related facility costs, additional costs to develop internal marketing and field operations capabilities, costs to pursue arrangements with strategic corporate partners and technology licensors, and expenses associated with applying for patent protection for our technology and products. Marketing, general and administrative expenses also include amounts reimbursable from our corporate partners.

Marketing, general and administrative expenses for the year ended December 31, 2003 amounted to $41,947,000, a decrease of $3,868,000, or 8.4% from the comparable period in 2002. This decrease is primarily due to a payment made in the second quarter of 2002 for separation compensation and other post-employment benefits of $7,283,000, associated with the resignation of our former President and Chief Executive Officer. In addition, during April 2003, BMS paid us $3,250,000, which represented the refund of a previously written-off deposit related to the exclusive right to negotiate a long-term supply agreement with Lonza, which was recognized as a decrease to marketing, general and administrative expenses in 2003. This decrease was partially offset by a payment of $4,189,000 in 2003 related to an employment agreement with a former executive officer and an increase in marketing expenses of approximately $2,200,000 incurred in order to support our marketing efforts going forward.

(Recovery) Write-down of Withholding Tax Assets and Industrial Development Revenue Bonds Tax Expense

In 2003, we recognized the recovery of the previous write-down of the withholding tax asset and the elimination of the withholding tax liability of $3,384,000 attributable to the exercise of warrants by our former General Counsel, John B. Landes, because Mr. Landes has represented to us that he has paid the taxes associated with this liability. The write-down of withholding tax assets in 2002 of $3,390,000 is primarily composed of the write-down that was reversed in 2003.

In April 2003, the Company discovered that we were in breach of certain covenants in our 11¼% Industrial Development Revenue Bonds due May 2004 issued by the New York Industrial Development Agency (the "1990 IDA Bonds"). We recorded additional tax expense of $98,000 for the year ended December 31, 2002 and $65,000 of additional tax expense for 2003. During the fourth quarter of 2003, we entered into a closing agreement with the Internal Revenue Service in settlement of our federal income tax liabilities associated with the 1990 IDA Bonds for an amount less than previous estimates of federal tax liability. As a result, the Company has recognized a benefit of $212,000 attributable to the recovery of tax expense attributable to the 1990 IDA Bonds.

Interest Income and Interest Expense

Interest income was $4,121,000 for the year ended December 31, 2003 compared with $9,301,000 for the year ended December 31, 2002, a decrease of $5,180,000, or 55.7% in 2003. The decrease was primarily attributable to a decrease in the average monthly cash and cash equivalents balance and a decrease in interest rates associated with our portfolio of marketable securities.

Interest expense was $8,881,000 and $13,179,000 for the year ended December 31, 2003 and 2002, respectively, a decrease of $4,298,000 or 32.6% in 2003. The overall decrease in interest expense from the year ended December 31, 2002 to 2003 was primarily attributable to an increase in the amount of

interest capitalized during the construction of BB50 in Branchburg, New Jersey, from $2,077,000 to $6,059,000. Interest expense for both periods included: (1) interest on the 5½% convertible subordinated notes due March 1, 2005 (the "Convertible Subordinated Notes") issued in February 2000; (2) interest on the 1990 IDA Bonds with a principal amount of $2,200,000, which were redeemed on June 30, 2003, (3) interest on financing our corporate insurance and (4) interest recorded on various capital lease obligations under a 1998 financing agreement with Finova Technology Finance, Inc. ("Finova") and with GE Capital Leasing.

We recorded gains on securities available for sale of $1,600,000 and $1,503,000 for the years ended December 31, 2003 and 2002, respectively. These amounts represent net realized gains from the sale of investments in our available-for-sale securities portfolio, which as of December 31, 2003 amounted to $49,498,000.

Provision for Income Taxes

Income taxes of $491,000 and $725,000 for the years ended December 31, 2003 and 2002, respectively, are the result of various tax law changes in the State of New Jersey, one of which is the establishment of the Alternative Minimum Assessment tax to which we are subject.

Net Losses

We had a net loss to common stockholders of $112,502,000 or $1.52 per share for the year ended December 31, 2003, compared with a net loss of $157,949,000 or $2.15 per share for the year ended December 31, 2002. The decrease in the net loss and net loss per share to common stockholders was due to the factors noted above.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2004, our principal sources of liquidity consisted of cash and cash equivalents and securities available for sale of approximately $920.0 million. Historically, we have financed our operations through a variety of sources, most significantly through the issuance of public and private equity and convertible notes, license fees and milestone payments and reimbursements from our corporate partners. Since the approval of ERBITUX on February 12, 2004, we began to generate royalty revenue and manufacturing revenue from the commercial sale of ERBITUX by our corporate partners and generated income from operations in 2004. As we continue to generate income, our cash flows from operating activities is expected to increase as a source to fund our operations. Therefore, we anticipate that our future financial condition and our future operating performance will continue to experience significant changes and that past performance will not likely be indicative of our future performance.

SUMMARY OF CASH FLOWS

	Years Ended December 31,			Variance	
(Thousands of dollars)	2004	2003	2002	2004 vs. 2003	2003 vs. 2002
Cash provided by (used in):					
Operating activities	$ 255,657	$(93,385)	$(4,532)	$ 349,042	$(88,853)
Investing activities	(872,249)	37,580	53,497	(909,829)	(15,917)
Financing activities	665,048	25,650	4,745	639,398	20,905
Net increase (decrease) in cash and cash equivalents	$ 48,456	$(30,155)	$53,710	$ 78,611	$(83,865)

Historically our cash flows from operating activities have fluctuated significantly due to the nature of our operations and the timing of our cash receipts. During the year ended December 31, 2004, net cash provided by operating activities was approximately $255.6 million, as compared to net cash used in operating activities of $93.4 million in the comparable period of 2003. The change in net cash provided

by operating activities in 2004 was primarily attributable to the receipt of a milestone payment of $250 million from BMS and E.R. Squibb on March 12, 2004 as a result of the FDA's approval of ERBITUX and from income generated from royalties earned on the sale of ERBITUX by our corporate partners. As we continue to earn revenues and operating income from the sale of ERBITUX in the future, we expect that our operating cash flows will continue to experience significant fluctuations from prior period results.

Our primary sources and uses of cash under investing activities consist of purchases and sales activity in our investment portfolio, which we manage based on our liquidity needs, possible business development transactions and amounts used for capital expenditures. During the year ended December 31, 2004, we used approximately $872.2 million in investing activities as compared to the comparable period in 2003, in which we generated $37.6 million from investing activities, or a net increase of cash used in investing activities of approximately $910 million. The increase in cash used in investing activities is mainly due to an increase of approximately $739.0 million in our investment portfolio and an increase in capital expenditures of approximately $32.5 million from the corresponding period in 2003 primarily related to construction of our multiple product manufacturing facility. During the second quarter of 2004, we raised net cash of approximately $581.0 million from the issuance of senior convertible notes. The proceeds generated from the issuance of these securities will be strategically invested in our business, however until such time as we decide the most beneficial use of this cash, we will continue to invest the money in securities in accordance with our investment policy.

Net cash flows provided by financing activities increased by approximately $639 million during the year ended December 31, 2004, primarily due to net proceeds of approximately $581 million received in May of 2004 from the issuance of senior convertible notes and an increase in cash from exercise of stock options.

We believe that our existing cash and cash equivalents and marketable securities and our cash provided by operating activities will provide us with sufficient liquidity to support our operations at least through the first quarter of 2006. We are also entitled to reimbursement for certain marketing, royalty expense, and research and development expenditures and certain other payments, some of which are payable contingent upon the achievement of research and development and regulatory milestones. There can be no assurance that we will achieve these milestones. Our future working capital and capital requirements will depend upon numerous factors, including, but not limited to:

- progress and cost of our research and development programs, pre-clinical testing and clinical studies;
- the amount and timing of revenues earned from the commercial sale of ERBITUX;
- our corporate partners fulfilling their obligations to us;
- timing and cost of seeking and obtaining additional regulatory approvals;
- level of resources that we devote to the development of marketing and field operations capabilities;
- costs involved in filing, prosecuting and enforcing patent claims; and legal costs associated with the outcome of outstanding legal proceedings and investigations;
- status of competition; and
- our ability to maintain existing corporate collaborations and establish new collaborative arrangements with other companies to provide funding to support these activities.

Below is a table that presents our contractual obligations and commercial commitments as of December 31, 2004: (in thousands)

	Payments due by Year(1)						
	Total	2005	2006	2007	2008	2009	2010 and Thereafter
Long-term debt	$600,000	$ —	$ —	$ —	$ —	$ —	$600,000
Operating leases	71,413	5,064	4,952	4,935	3,771	3,805	48,886
Purchase obligations	8,083	8,083	—	—	—	—	—
Construction commitments	28,298	28,298	—	—	—	—	—
Total contractual cash obligations	$707,794	$41,445	$4,952	$4,935	$3,771	$3,805	$648,886

(1) Amounts in the above table do not include milestone-type payments payable by us under collaborative agreements.

OFF-BALANCE SHEET ARRANGEMENTS

We have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our holdings of financial instruments comprise a mix of U.S. dollar denominated securities that may include U.S. corporate debt, foreign corporate debt, U.S. government debt, foreign government/agency guaranteed debt and commercial paper. All such instruments are classified as securities available for sale. Generally, we do not invest in portfolio equity securities, commodities, foreign exchange contracts or use financial derivatives for trading purposes. Our debt security portfolio represents funds held temporarily pending use in our business and operations. We manage these funds accordingly. We seek reasonable assuredness of the safety of principal and market liquidity by investing in investment grade fixed income securities while at the same time seeking to achieve a favorable rate of return. Our market risk exposure consists principally of exposure to changes in interest rates. Our holdings are also exposed to the risks of changes in the credit quality of issuers. We invest in securities that have a range of maturity dates. Typically, those with a short-term maturity are fixed-rate; highly liquid debt instruments and those with longer-term maturities are highly liquid debt instruments with fixed interest rates or with periodic interest rate adjustments.

The table below presents the principal amounts and related weighted average interest rates by year of maturity for our investment portfolio as of December 31, 2004: (in thousands, except interest rates)

	2005	2006	2007	2008	2009	2010 and Thereafter	Total	Fair Value
Fixed Rate	$165,233	$163,002	$194,627	$70,000	$35,000	$ —	$627,862	$627,040
Average Interest Rate	1.69%	2.92%	3.48%	3.80%	4.37%	—	2.95%	
Variable Rate	209,732(1)	—	—	1,805(1)	—	1,861(1)	213,398	213,411
Average Interest Rate	2.41%	—	—	1.37%	—	1.69%	2.39%	
	$374,965	$163,002	$194,627	$71,805	$35,000	$1,861	$841,260	$840,451

(1) These holdings primarily consist of U.S. corporate and foreign corporate floating rate notes. Interest on the securities is adjusted monthly, quarterly or semi-annually, depending on the instrument, using prevailing interest rates. These holdings are highly liquid and we consider the potential for loss of principal to be minimal.

Our outstanding 1⅜% fixed rate convertible senior notes in the principal amount of $600,000,000 due May 15, 2024 are convertible into our common stock at a conversion price of $94.69 per share,

subject to certain restrictions as outlined in the indenture agreement. The fair value of fixed interest rate instruments is affected by changes in interest rates and in the case of the convertible notes by changes in the price of our common stock as well. The fair value of the convertible senior notes was approximately $555,750,000 at December 31, 2004.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The response to this item is submitted as a separate section of this report as Part II commencing on Page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our "disclosure controls and procedures" (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information that we are required to disclose in the reports that we file or submit under the Exchange Act.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a—15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2004.

Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during our fourth fiscal quarter of 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
ImClone Systems Incorporated:

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting, that ImClone Systems Incorporated maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). ImClone Systems Incorporated's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that ImClone Systems Incorporated maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, ImClone Systems Incorporated maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of ImClone Systems Incorporated and subsidiary as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity (deficit) and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 15, 2005 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Princeton, New Jersey
March 15, 2005

ITEM 9B. OTHER INFORMATION.

Change in Control Plan

During 2004, the Board of Directors of the Company adopted a Change in Control Plan to maintain the focus of certain key employees of the Company on the business, mitigate the distractions that could be caused if the Company were to become the target of an acquisition strategy, and provide certain benefits to the covered employees if a change in control of the Company (as such term is defined in the plan) occurs and/or the employee's employment is terminated in connection with such change in control. Participants in the Change in Control Plan are determined by the Compensation and Stock Option Committee of the Board of Directors ("Compensation Committee") and include all the named executive officers.

In the event of a Change in Control, all equity-based compensation awards held by the plan participants will vest in full (unless the Compensation Committee determines that the participants' awards will be substituted for equity awards in the surviving entity of equivalent economic value) and any deferred compensation of participants will become nonforfeitable. In addition, if a participant in the Change in Control Plan is terminated in connection with a change in control by the Company without cause or by the participant for good reason (as such terms are defined in the plan), the Company will pay to the participant a cash payment equal to the participant's earned but unpaid base salary and bonus, unreimbursed expenses, any other accrued obligations, a pro rata bonus based on target bonus for the year of termination, and a multiple of base salary and bonus (with the multiplier ranging from 0.5 to three based on the tier assigned to the participant under the plan).

In connection with a termination described in the preceding sentence, if the participant signs a waiver and release of claims against the Company, each participant will vest in full in all long-term incentive arrangements he or she has with the Company and be entitled to continued health coverage for six to 18 months (based on the participant's plan tier) and outplacement services for six months. These benefits are reduced by any other severance amounts for which the participants are eligible under any other arrangement of the Company or its subsidiary. As a condition to receipt of these benefits, each participant agrees to be bound by noncompetition, nonsolicitation, confidentiality, return of Company property, and cooperation covenants contained in the plan. If a plan participant becomes subject to the change-in-control golden parachute excise tax under Section 4999 of the Code and the aggregate parachute payment exceeds the safe harbor amount by ten percent or more, the plan provides that the Company shall pay to the participant a tax gross-up payment such that after payment by the participant of all federal, state and local excise, income, employment, Medicare and other taxes resulting from the payment of the parachute payments and the tax gross-up payments, the participant retains an after-tax amount equal to the amount that he or she would have retained in the absence of the parachute excise tax.

Senior Executive Severance Plan

The Compensation Committee approved on February 10, 2005 a Senior Executive Severance Plan (the "Plan") to enhance the predictability of treatment for executives at the level of Vice President, Senior Vice President and Executive Vice President whose employment with the Company is terminated by the Company without cause (as such concept is explained in the Plan).

As a condition to receipt of benefits under the Plan, a participating employee must sign an agreement and general release in a form acceptable to the Plan administrator under which the participant agrees to certain confidentiality and non-solicitation provisions for a period of one year following his or her employment termination date, agrees to certain non-competition provisions for the duration of the employee's receipt of severance pay, and releases and discharges the Company and related entities (as well as any third party for whom the employee provides services on the Company's behalf) from any and all claims and liabilities relating to the employee's employment with the Company

or the termination of the employee's employment. Receipt of benefits under the Plan is also contingent upon the employee's continued employment through the employment termination date designated by the Company. The severance amounts payable to an employee under the Plan will be reduced, dollar-for-dollar, by the amount of any other termination payments paid or payable to the employee under any other plan, program or law (excluding any right to exercise stock options, any unemployment benefits payable in accordance with state law and payment for accrued but unused vacation).

The Senior Vice Presidents and Executive Vice Presidents who participate in the Plan and sign the above-described agreement and release upon their termination without cause are entitled to receive an amount equal to one year's base salary as severance and, if the employee would otherwise be eligible to elect employee-paid continued coverage under COBRA, Company-provided health insurance coverage for one year following a termination without Cause, subject to cessation upon the employee's becoming eligible for similar coverage offered by another employer. Senior Vice Presidents and Executive Vice Presidents would also be entitled continue their non-voluntary life insurance coverage provided by the Company with the premiums paid by the Company for 12 months after a termination without cause, subject to cessation when the employee becomes eligible for coverage under a life insurance plan or policy of another employer. Vice Presidents who meet the above criteria are entitled to the greater of six months' base salary or two weeks' base salary for each year of service with the Company, as well as six months' Company-paid health and life insurance coverage, subject to the conditions described above.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by Item 10 is incorporated into Part III of this Annual Report on Form 10-K by reference to our definitive Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on June 15, 2005.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is incorporated into Part III of this Annual Report on Form 10-K by reference to our definitive Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on June 15, 2005.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is incorporated into Part III of this Annual Report on Form 10-K by reference to our definitive Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on June 15, 2005.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by Item 13 is incorporated into Part III of this Annual Report on Form 10-K by reference to our definitive Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on June 15, 2005.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is incorporated into Part III of this Annual Report on Form 10-K by reference to our definitive Proxy Statement for the Annual Meeting of Stockholders scheduled to be held on June 15, 2005.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) and (2) The response to this portion of Item 15 is submitted as a separate section of this report commencing on page F-1.

(a)(3) Exhibits (numbered in accordance with Item 601 of Regulation S-K).

Exhibit No.	Description	Incorporation by Reference
3.1	Certificate of Incorporation, as amended through December 31, 1998	D (3.1)
3.2	Amendment dated June 4, 1999 to the Company's Certificate of Incorporation, as amended	H (3.1A)
3.3	Amendment dated June 12, 2000 to the Company's Certificate of Incorporation, as amended	K (3.1A)
3.4	Amendment dated August 9, 2002 to the Company's Certificate of Incorporation, as amended	Q (3.1C)
3.5	Amended and Restated By-Laws of the Company	S (3.2)
4.1	Rights Agreement dated as of February 15, 2002 between the Company and EquiServe Trust Company, N.A., as Rights Agent	M (99.2)
4.2	Stockholder Agreement, dated as of September 19, 2001, among Bristol-Myers Squibb Company, Bristol-Myers Squibb Biologics Company and the Company	L (99.2D2)
4.3	Indenture dated as of May 7, 2004 by and between the Company and The Bank of New York, as Trustee and Form of 1⅜% Convertible Notes Due 2024	V (4.5)
4.4	Registration Rights Agreement dates as of May 7, 2004 by and between the Company as Issuer, and Morgan Stanley & Co., Incorporated and UBS Securities LLC, as the Initial Purchasers	V (4.6)
10.1	Company's 1986 Employee Incentive Stock Option Plan, including form of Incentive Stock Option Agreement	A (10.1)
10.2	Company's 1986 Non-qualified Stock Option Plan, including form of Non-qualified Stock Option Agreement	A (10.2)
10.3	1996 Incentive Stock Option Plan, as amended	O (99.1)
10.4	1996 Non-Qualified Stock Option Plan, as amended	O (99.2)
10.5	ImClone Systems Incorporated 1998 Non-Qualified Stock Option Plan, as amended	O (99.2)
10.6	ImClone Systems Incorporated 2002 Stock Option Plan	Q (99.8)
10.7	ImClone Systems Incorporated 1998 Employee Stock Purchase Plan	I (99.4)
10.8	Option Agreement, dated as of September 1, 1998, between the Company and Ron Martell	F (99.3)
10.9	Option Agreement, dated as of January 4, 1999, between the Company and S. Joseph Tarnowski	J (99.4)

Exhibit No.	Description	Incorporation by Reference
10.10	License Agreement between the Company and the Regents of the University of California dated April 9, 1993	B (10.48)
10.11	Collaboration and License Agreement between the Company and the Cancer Research Campaign Technology, Ltd., signed April 4, 1994, with an effective date of April 1, 1994	B (10.50)
10.12	License Agreement between the Company and Rhone-Poulenc Rorer dated June 13, 1994	C (10.56)
10.13	Development and License Agreement between the Company and Merck KGaA dated December 14, 1998	E (10.70)
10.14	Lease dated as of December 15, 1998 for the Company's premises at 180 Varick Street, New York, New York	G (10.69)
10.15	Amendment dated March 2, 1999 to Development and License Agreement between the Company and Merck KGaA	G (10.71)
10.16	Acquisition Agreement dated as of September 19, 2001, among the Company, Bristol-Myers Squibb Company and Bristol-Myers Squibb Biologics Company	L (99.D1)
10.17	Development, Promotion, Distribution and Supply Agreement, dated as of September 19, 2001, among the Company, Bristol-Myers Squibb Company and E.R. Squibb & Sons, L.L.C	L (99.D3)
10.18	Employment Agreement, dated as of March 19, 2004, between the Company and Daniel S. Lynch	U (10.1)
10.19	Employment Agreement, dated as of September 19, 2001, between the Company and S. Joseph Tarnowski, PhD	L (99.D10)
10.20	Agreement of Sublease dated October 5, 2001, by and between 325 Spring Street LLC and the Company	O (10.86)
10.21	Promissory Note in the principal amount of $10,000,000, dated October 5, 2001, executed by 325 Spring Street LLC in favor of the Company	O (10.86.1)
10.22	Amendment No. 1 to Development, Promotion, Distribution and Supply Agreement, dated as of March 5, 2002, among the Company, Bristol-Myers Squibb Company and E.R. Squibb & Sons, L.L.C	N (99.2)
10.23	Amendment, dated as of August 16, 2001 to the Development and License Agreement between the Company and Merck KGaA	P (10.88)
10.24	Agreement of Sale and Purchase between 1/33 Building Associates, LP and ImClone Systems Incorporated pertaining to 33 ImClone Drive, Branchburg, New Jersey executed as of March 1, 2002	Q (10.92)
10.25	Target Price Contract, dated as of July 15, 2002, between ImClone Systems Incorporated and Kvaerner Process, a division of Kvaerner U.S. Inc., for the Architectural, Engineering, Procurement Assistance, Construction Management and Validation of a Commercial Manufacturing Project in Branchburg, New Jersey	R (10.93)

Exhibit No.	Description	Incorporation by Reference
10.26	Modifications Agreement dated as of December 15, 2000 by an between 180 Varick Street Corporation and the Company	S (10.94)
10.27	ImClone Systems Incorporated Annual Incentive Plan	T (A.C)
10.28*	Amendment number 4 to the Company's lease at 180 Varick Street dated August 13, 2004 by and between 180 Varick Street Corporation and the Company	W (10.28)
10.29*	ImClone Systems Incorporated Senior Executive Severance Plan	
10.30*	ImClone Systems Incorporated Change in Control Plan	
12.1*	Ratio of Earnings to Fixed Charges	
14.1*	Code of Ethics for Principal Executive and Senior Financial Officers	
21.1*	Subsidiaries of the Company	
23.1*	Consent of KPMG LLP, Independent Accountants	
31.1*	Certification of the Company's Chief Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002.	
31.2*	Certification of the Company's Chief Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002.	
32.1*	Certification of the Company's Chief Executive Officer and Chief Financial Officer pursuant to section 906 of the Sarbanes-Oxley Act of 2002.	

* Filed herewith.

(A) Previously filed with the Commission; incorporated by reference to Amendment No. 1 to Registration Statement on to Form S-1, File No. 33-61234.

(B) Previously filed with the Commission; incorporated by reference to the Company's Annual Report on Form 10-K, File No. 0-19612, for the fiscal year ended December 31, 1993. Confidential Treatment was granted for a portion of this Exhibit.

(C) Previously filed with the Commission; incorporated by reference to the Company's Annual Report on Form 10-K, File No. 0-19612, for the fiscal year ended December 31, 1994.

(D) Previously filed with the Commission; incorporated by reference to the Company's Quarterly Report on Form 10-Q, File No. 0-19612, for the quarter ended June 30, 1997.

(E) Previously filed with the Commission; incorporated by reference to the Company's Registration Statement on Form S-3, File No. 333-67335. Confidential treatment was granted for a portion of this Exhibit.

(F) Previously filed with the Commission; incorporated by reference to the Company's Registration Statement on Form S-8, File No. 333-64827.

(G) Previously filed with the Commission; incorporated by reference to the Company's Annual Report on Form 10-K, File No. 0-19612, for the fiscal year ended December 31, 1998.

(H) Previously filed with the Commission; incorporated by reference to the Company's Quarterly Report on Form 10-Q, File No. 0-19612, for the quarter ended June 30, 1999.

(I) Previously filed with the Commission; incorporated by reference to the Company's Annual Report on Form 10-K, File No. 0-19612, for the year ended December 31, 1999.

(J) Previously filed with the Commission; incorporated by reference to the Company's Registration Statement on Form S-8; File No. 333-30172.

(K) Previously filed with the Commission; incorporated by reference to the Company's Quarterly Report on Form 10-Q, File No. 0-19612, for the Quarter ended June 30, 2000.

(L) Previously filed with the Commission; incorporated by reference to the Company's Schedule 14D-9, File No. 05-42743, filed on September 28, 2001.

(M) Previously filed with the Commission; incorporated by reference to the Company's Current Report on Form 8-K, File No. 0-19612, dated February 19, 2002.

(N) Previously filed with the Commission; incorporated by reference to the Company's Current Report on Form 8-K, File No. 0-19612, dated March 6, 2002.

(O) Previously filed with the Commission; incorporated by reference to the Company's Annual Report on Form 10-K, File No. 0-19612, for the year ended December 31, 2001.

(P) Previously filed with the Commission; incorporated by reference to the Company's Annual Report on Form 10-K, File No. 0-19612, for the year ended December 31, 2001, and Confidential Treatment has been requested for a portion of this exhibit.

(Q) Previously filed with the Commission; incorporated by reference to the Company's Quarterly Report on Form 10-Q, File No. 0-19612, for the Quarter ended June 30, 2002.

(R) Previously filed with the Commission; incorporated by reference to the Company's Quarterly Report on Form 10-Q, File No. 0-19612, for the Quarter ended September 30, 2002.

(S) Previously filed with the Commission; incorporated by reference to the Company's Annual Report on Form 10-K, File No. 0-19612, for the year ended December 31, 2002.

(T) Previously filed with the Commission; incorporated by reference to the Company's definitive Proxy Statement for its Annual Meeting of Shareholders, File No. 0-19612, filed August 21, 2003, as appendix C.

(U) Previously filed with the Commission; incorporated by reference to the Company's Current Report on Form 8-K dated March 19, 2004.

(V) Previously filed with the Commission; incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004.

(W) Previously filed with the Commission; incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.

SIGNATURES

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

IMCLONE SYSTEMS INCORPORATED

March 16, 2005

By: /s/ DANIEL S. LYNCH
Daniel S. Lynch
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

Name	Title	Date
/s/ DANIEL S. LYNCH Daniel S. Lynch	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2005
/s/ MICHAEL J. HOWERTON Michael J. Howerton	Chief Financial Officer (Principal Financial Officer)	March 16, 2005
/s/ ANA I. STANCIC Ana I. Stancic	Vice President, Controller and Chief Accounting Officer (Principal Accounting Officer)	March 16, 2005
/s/ ANDREW G. BODNAR Andrew G. Bodnar	Director	March 16, 2005
/s/ WILLIAM W. CROUSE William W. Crouse	Director	March 16, 2005
/s/ VINCENT T. DEVITA, JR. Vincent T. DeVita, Jr.	Director	March 16, 2005
/s/ JOHN A. FAZIO John A. Fazio	Director	March 16, 2005

Name	Title	Date
/s/ JOSEPH L. FISCHER Joseph L. Fischer	Director	March 16, 2005
/s/ DAVID M. KIES David M. Kies	Director	March 16, 2005
/s/ WILLIAM R. MILLER William R. Miller	Director	March 16, 2005
/s/ DAVID SIDRANSKY David Sidransky	Director	March 16, 2005

INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
ImClone Systems Incorporated:

We have audited the consolidated financial statements of ImClone Systems Incorporated and subsidiary as listed in the accompanying index. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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 financial position of ImClone Systems Incorporated and subsidiary as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of ImClone Systems Incorporated's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2005 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Princeton, New Jersey
March 15, 2005

IMCLONE SYSTEMS INCORPORATED

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share and share data)

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 79,321	$ 30,865
Securities available for sale	840,451	75,483
Prepaid expenses	4,054	3,628
Amounts due from corporate partners less allowances of $430 in 2004	69,753	8,979
Inventories	40,618	—
Other current assets	28,240	3,615
Total current assets	1,062,437	122,570
Property, plant and equipment, net	339,293	245,901
Patent costs, net	1,321	1,482
Deferred financing costs, net	16,244	1,985
Note receivable, less current portion	8,763	9,213
Other assets	6,718	444
	$1,434,776	$ 381,595
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable (including $2,535 due Bristol-Myers Squibb Company ("BMS") at December 31, 2004)	$ 38,492	$ 28,722
Accrued expenses (including $3,187 and $3,729 due BMS at December 31, 2004 and 2003, respectively)	61,177	17,857
Litigation settlement	75,900	—
Withholding tax liability	18,096	20,987
Current portion of deferred revenue	108,994	50,870
Other current liabilities	1,031	4,411
Total current liabilities	303,690	122,847
Deferred revenue, less current portion	348,814	286,362
Long-term debt	600,000	240,000
Deferred rent, less current portion	3,434	2,938
Other long-term liabilities, less current portion	—	41
Total liabilities	1,255,938	652,188
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $1.00 par value; authorized 4,000,000 shares; reserved 1,200,000 series B participating cumulative preferred stock, none issued or outstanding	—	—
Common stock, $.001 par value; authorized 200,000,000 shares; issued 83,250,146 and 75,296,117 at December 31, 2004 and 2003, respectively; outstanding 83,056,888 and 75,106,867 at December 31, 2004 and 2003, respectively	83	75
Additional paid-in capital	712,819	375,731
Accumulated deficit	(528,955)	(642,608)
Treasury stock, at cost; 193,258 and 189,250 shares at December 31, 2004 and 2003, respectively	(4,300)	(4,100)
Accumulated other comprehensive income (loss):		
Unrealized (loss) gain on securities available for sale	(809)	309
Total stockholders' equity (deficit)	178,838	(270,593)
	$1,434,776	$ 381,595

See accompanying notes to consolidated financial statements.

IMCLONE SYSTEMS INCORPORATED
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2004	2003	2002
Revenues:			
License fees and milestone revenue	$129,386	$ 47,970	$ 21,051
Manufacturing revenue	99,041	—	—
Royalty revenue	106,274	575	1,353
Collaborative agreement revenue	53,989	32,285	37,601
Total revenues	388,690	80,830	60,005
Operating expenses:			
Research and development	82,658	121,111	142,862
Clinical and regulatory	30,254	30,154	20,439
Marketing, general and administrative	59,800	41,947	45,815
Royalty expense	36,065	—	—
Litigation settlement	55,363	—	—
Cost of manufacturing revenue	1,099	—	—
(Recovery) write-down of withholding tax asset	(1,815)	(3,384)	3,390
Other, net	—	(147)	2,348
Total operating expenses	263,424	189,681	214,854
Operating income (loss)	125,266	(108,851)	(154,849)
Other:			
Interest income	(14,049)	(4,121)	(9,301)
Interest expense	8,432	8,881	13,179
Gain on sale of securities, net	(131)	(1,600)	(1,503)
Other (income) expense, net	(5,748)	3,160	2,375
Income (loss) before income taxes	131,014	(112,011)	(157,224)
Provision for income taxes	17,361	491	725
Net income (loss)	$113,653	$(112,502)	$(157,949)
Income (loss) per common share:			
Basic	$ 1.43	$ (1.52)	$ (2.15)
Diluted	$ 1.33	$ (1.52)	$ (2.15)
Shares used in calculation of income (loss) per share:			
Basic	79,500	74,250	73,408
Diluted	91,193	74,250	73,408

See accompanying notes to consolidated financial statements

IMCLONE SYSTEMS INCORPORATED

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE INCOME (LOSS)

Years Ended December 31, 2004, 2003 and 2002

(in thousands, except share data)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount	Shares	Amount					
Balance at December 31, 2001	—	$—	73,348,271	$73	$341,735	$(372,157)	$(4,100)	$ 3,155	$ (31,294)
Options exercised			438,672	1	4,109				4,110
Issuance of shares through employee stock purchase plan			52,593	—	502				502
Compensation related to options granted to employees					41				41
Short-swing profit rule					565				565
Comprehensive loss:									
Net loss						(157,949)			(157,949)
Other comprehensive income (loss)									
Unrealized holding loss								(101)	(101)
Less: Reclassification adjustment for realized gain included in net loss								1,503	1,503
Total other comprehensive loss								(1,604)	(1,604)
Comprehensive loss									(159,553)
Balance at December 31, 2002	—	—	73,839,536	74	346,952	(530,106)	(4,100)	1,551	(185,629)
Options exercised			633,078	—	7,151				7,151
Issuance of shares through employee stock purchase plan			28,606	—	685				685
Compensation related to options granted to non-employees					851				851
Issuance of shares to Merck KGaA			794,897	1	19,999				20,000
Repayment of note from former officer					93				93
Comprehensive loss:									
Net loss						(112,502)			(112,502)
Other comprehensive income (loss)									
Unrealized holding gain								358	358
Less: Reclassification adjustment for realized gain included in net income								1,600	1,600
Total other comprehensive (loss)								(1,242)	(1,242)
Comprehensive loss									(113,744)
Balance at December 31, 2003	—	—	75,296,117	75	375,731	(642,608)	(4,100)	309	(270,593)
Options exercised			3,522,003	4	78,056				78,060
Issuance of shares on conversion of 5½% notes			4,356,468	4	239,993				239,997
Issuance of shares to Merck KGaA			58,807	—	5,000				5,000
Issuance of shares through employee stock purchase plan			16,751	—	802				802
Compensation related to options granted to non-employees					2,420				2,420
Tax benefit of stock options					9,982				9,982
Unamortized deferred financing costs on the 5½% notes					(1,193)				(1,193)
Compensation related to modifications of options granted to employees					2,028				2,028
Treasury shares							(200)		(200)
Comprehensive income:									
Net income						113,653			113,653
Other comprehensive income (loss)									
Unrealized holding loss								(987)	(987)
Less: Reclassification adjustment for realized gain included in net income								131	131
Total other comprehensive (loss)								(1,118)	(1,118)
Comprehensive income									112,535
Balance at December 31, 2004	—	$—	83,250,146	$83	$712,819	$(528,955)	$(4,300)	$ (809)	$ 178,838

See accompanying notes to consolidated financial statements

IMCLONE SYSTEMS INCORPORATED
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net income (loss)	$ 113,653	$(112,502)	$(157,949)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	13,062	11,478	10,073
Amortization of deferred financing costs	3,107	1,709	1,710
Expense associated with stock options	4,448	851	41
Recovery of withholding tax asset	(1,815)	(3,384)	3,390
Gain on securities available for sale, net	(131)	(1,600)	(1,503)
Other	1	200	57
Changes in:			
Prepaid expenses	(426)	(509)	772
Amounts due from corporate partners	(60,774)	3,384	(4,133)
Inventories	(40,618)	—	—
Other current assets	(24,252)	9,121	(8,051)
Withholding tax assets	77	9,799	(30)
Other assets	(6,274)	352	(412)
Accounts payable	9,770	5,005	6,798
Interest payable	(3,369)	(42)	(4)
Accrued expenses	43,320	(17,600)	23,649
Realized tax benefit from stock options	9,982	—	—
Withholding tax liability	(1,076)	(14,440)	32
Industrial Development Revenue Bonds tax liability	—	(953)	102
Litigation settlement	75,900	—	—
Deferred rent, less current portion	496	1,018	1,918
Deferred revenue	120,576	14,728	119,008
Net cash provided by (used in) operating activities	255,657	(93,385)	(4,532)
Cash flows from investing activities:			
Acquisitions of property, plant and equipment	(106,286)	(73,693)	(86,133)
Purchases of securities available for sale	(3,457,174)	(198,691)	(408,995)
Proceeds from sale of securities available for sale	1,967,058	206,834	296,917
Maturities of securities available for sale	724,161	103,366	252,018
Other	(8)	(236)	(310)
Net cash (used in) provided by investing activities	(872,249)	37,580	53,497
Cash flows from financing activities:			
Proceeds from exercise of stock options	77,860	7,151	4,110
Proceeds from issuance of common stock under the employee stock purchase plan	802	685	502
Proceeds from issuance of 1⅜% convertible notes	600,000	—	—
Deferred financing costs	(18,559)	—	—
Proceeds from issuance of common stock to Merck KGaA	5,000	20,000	—
Payment of Industrial Development Revenue Bond	—	(2,200)	—
Other	(55)	14	133
Net cash provided by financing activities	665,048	25,650	4,745
Net increase (decrease) in cash and cash equivalents	48,456	(30,155)	53,710
Cash and cash equivalents at beginning of period	30,865	61,020	7,310
Cash and cash equivalents at end of period	$ 79,321	$ 30,865	$ 61,020

See accompanying notes to consolidated financial statements.

(1) Business Overview and Basis of Preparation

ImClone Systems Incorporated (the "Company") is a biopharmaceutical company whose mission is to advance oncology care by developing and commercializing a portfolio of targeted treatments designed to address the medical needs of patients with cancer. A substantial portion of the Company's efforts and resources are devoted to research and development conducted on its own behalf and through collaborations with corporate partners and academic research and clinical institutions. The Company does not operate separate lines of business or separate business entities and does not conduct any of its operations outside of the United States. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas or by location and does not have separately reportable segments.

On February 12, 2004, the United States Food and Drug Administration ("FDA") approved ERBITUX® (Cetuximab) Injection for use in combination with irinotecan in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy. The FDA also approved Lonza Biologics plc's ("Lonza") manufacturing facility. ERBITUX inventory previously produced at Lonza's facility served as supply for the initial demand for ERBITUX. On June 18, 2004 the FDA approved the Company's Chemistry Manufacturing and Controls (CMC) supplemental Biologics License Application (sBLA) for licensure of its manufacturing facility, referred to as BB36.

On December 1, 2003, Swissmedic, the Swiss agency for therapeutic products, approved ERBITUX in Switzerland for the treatment of patients with colorectal cancer who no longer respond to standard chemotherapy treatment with irinotecan. Merck KGaA licensed the right to market ERBITUX outside the United States and Canada from the Company in 1998. In Japan, Merck KGaA has marketing rights to ERBITUX, which are co-exclusive to the co-development rights of the Company and BMS. On June 30, 2004 Merck KGaA received marketing approval by the European Commission to sell ERBITUX for use in combination with irinotecan for the treatment of patients with EGFR-expressing metastatic colorectal cancer after failure of irinotecan including cytotoxic therapy in all 25 member states of the newly expanded European Union, as well as Iceland and Norway in accordance with local legal regulations. In addition, ERBITUX has been approved in Argentina, Chile and Mexico.

The Company believes that our existing cash and cash equivalents and marketable securities and our cash provided from operating activities will provide us with sufficient liquidity to support our operations at least through the first quarter of 2006. The Company is also entitled to reimbursement for certain marketing and research and development expenditures and certain other payments, some of which are payable contingent upon the achievement of research and development or regulatory milestones. There can be no assurance that the Company will achieve these milestones.

We rely entirely on a third party manufacturer for filling and finishing services with respect to ERBITUX. If our current third party manufacturers or critical raw material suppliers fail to meet our expectations, we cannot be assured that we will be able to enter into new agreements with other suppliers or third party manufacturers without an adverse effect on our business.

(2) Summary of Significant Accounting Policies

(a) Principles of Consolidation

The consolidated financial statements include the financial statements of ImClone Systems Incorporated and its wholly-owned subsidiary, Endoclone Incorporated. All significant intercompany balances and transactions have been eliminated in consolidation.

(b) Cash Equivalents

Cash equivalents consist primarily of U.S. Government instruments, commercial paper and other readily marketable debt instruments. The Company considers all highly liquid debt instruments with original maturities at date of purchase not exceeding three months to be cash equivalents.

(c) Investments in Securities

The Company classifies its investments in debt and marketable equity securities as available-for-sale.

Available-for-sale securities are recorded at fair value. Unrealized holding gains and losses on available-for-sale securities are excluded from earnings and are reported as a separate component of accumulated comprehensive income (loss) until realized. Realized gains and losses from the sale of available-for-sale securities are determined on a specific identification basis.

A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary results in a reduction in carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Dividend and interest income are recognized when earned.

(d) Long-Lived Assets

Property, plant and equipment are stated at cost. Equipment under capital leases is stated at the present value of minimum lease payments. Leasehold improvements are amortized on the straight-line method over the related lease term or the useful life of the improvement, whichever is shorter. Depreciation of fixed assets is provided on the straight-line method over the estimated useful life of the asset. Estimated useful lives are generally as follows: buildings 20 years; machinery and equipment 3 to 8 years; furniture and fixtures 8 years.

Patent and patent application costs that have been capitalized are amortized on a straight-line basis over their respective expected useful lives, up to a 15-year period. Gross patents costs were $2,625,000 and $2,617,000 for the years ended December 31, 2004 and 2003, respectively. Accumulated amortization was $1,304,000 and $1,135,000 for the years ended December 31, 2004 and 2003, respectively. Amortization expense was $169,000, $182,000 and $173,000 for the three years ended December 31, 2004, 2003 and 2002, respectively. Amortization expense is estimated to be approximately $150,000 for each of the next five years.

The Company reviews long-lived assets for impairment when events or changes in business conditions indicate that their full carrying value may not be recovered. Assets are considered to be impaired and are written down to fair value if expected associated undiscounted cash flows are less than the carrying amounts. Fair value is generally the present value of the expected associated cash flows.

(2) Summary of Significant Accounting Policies (Continued)

(e) Deferred Financing Costs

Costs incurred in issuing the 1⅜% convertible senior notes and the 5½% convertible subordinated notes are amortized using the straight-line method over the shorter of: the term of the related instrument or the initial date on which the holders can require repurchase of the notes. The amortization of deferred financing costs is included in interest expense in the Consolidated Statements of Operations. Upon redemption of the Company's 5½% convertible subordinated notes in 2004, the remaining unamortized deferred financing costs of $1,193,000 were reclassified to equity.

(f) Revenue Recognition

The Company recognizes all non-refundable up-front license fees as revenues in accordance with the guidance provided in the Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"), Staff Accounting Bulletin No. 104, "Revenue Recognition, corrected copy" ("SAB 104") and Emerging Issues Task Force Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). Non-refundable fees received upon entering into license and other collaborative agreements where the Company has continuing involvement are recorded as deferred revenue and recognized over the estimated service period. Payments received under the Commercial Agreement are being deferred and recognized as revenue based on the percentage of actual product research and development costs incurred to date by both BMS and the Company to the estimated total of such costs to be incurred over the term of the agreement. Non-refundable milestone payments, which represent the achievement of a significant step in the research and development process, pursuant to collaborative agreements other than the Commercial Agreement, are recognized as revenue upon the achievement of the specified milestone.

Pursuant to the guidance in Emerging Issues Task Force ("EITF") Issue No. 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent," and No. 01-14, Income Statement Characterization of Reimbursements Received for "Out-of-Pocket" Expenses Incurred, the Company characterizes reimbursements received for research and development, clinical and regulatory, royalty expense and marketing and administrative expenses incurred as collaborative agreement revenue in the Consolidated Statements of Operations. In analyzing whether to categorize reimbursed expenses from our corporate partners as a) the gross amount billed or b) the net amount retained, the Company has analyzed the relevant facts and circumstances related to these expenses and considered the factors, as specified in the EITF Issues noted above. These expenses, which are associated with ERBITUX, are broader than would ordinarily result in our central ongoing operations. These expenses have been incurred as a result of entering into the collaborative agreements that the Company has in place with its partners. In assessing whether revenue should be reported gross or net, the Company considered various factors, among them: (1) the Company is the primary obligor with respect to all expenses incurred and reimbursed; (2) the Company bears credit risk and inventory risk; (3) the Company bears responsibility for manufacturing the product and its specification (4) the Company has pricing latitude and supplier discretion. Based on the factors considered, the Company has concluded that costs reimbursed by its corporate partners should be characterized as revenue in its Consolidated Statements of Operations.

Royalty revenue from licensees, which are based on third-party sales of licensed products and technology are earned in accordance with the contract terms when third-party sales can be reliably

(2) Summary of Significant Accounting Policies (Continued)

measured and collection of the funds is reasonably assured. Royalty revenue is recognized when earned and collection is probable.

Manufacturing revenue consists of revenue earned on the sale of ERBITUX to the Company's corporate partners for subsequent commercial sale. The Company recognizes manufacturing revenue when the product is shipped which is when the Company's partners take ownership and title has passed, collectibility is reasonably assured, the sales price is fixed and determinable, and there is persuasive evidence of an agreement.

Collaborative agreement revenue consists of reimbursements received from BMS and E.R. Squibb and Merck KGaA related to clinical and regulatory studies, ERBITUX provided for use in clinical studies, certain marketing and administrative costs and a portion of royalty expense. Collaborative agreement revenue is recorded as earned based on the performance requirements under the respective contracts.

Revenue recognized in the accompanying Consolidated Statements of Operations is not subject to repayment. Amounts received that are subject to repayment if certain specified goals are not met are classified as fees potentially refundable to corporate partner; revenue recognition of such amounts will commence upon the achievement of such specified goals. Payments received that are related to future performance are classified as deferred revenue and recognized when the revenue is earned.

(g) Foreign Currency Transactions

Gains and losses from foreign currency transactions, such as those resulting from the translation and settlement of receivables and payables denominated in foreign currencies, are included in the Consolidated Statements of Operations. The Company does not currently use derivative financial instruments to manage the risks associated with foreign currency fluctuations. The Company recorded losses on foreign currency transactions of approximately $26,000, $26,000 and $57,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Gains and losses from foreign currency transactions are included as a component of operating expenses.

(h) Stock-Based Compensation Plans

The Company has two types of stock-based compensation plans: a stock option plan and a stock purchase plan. The Company accounts for its stock-based compensation plans in accordance with the provisions of APB No. 25, and related interpretations including Statement of Financial Accounting Standards Board Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation—An Interpretation of APB Opinion No. 25" ("Interpretation No. 44"). Accordingly, compensation expense would be recorded on the date of grant of an option to an employee or member of the Board of Directors (the "Board") only if the market price of the underlying stock on the date of grant exceeds the exercise price. During the three years ended December 31, 2004, the Company's original stock option grants were based on the closing market price of its stock on the date of grant.

The fair value of stock options was estimated using the Black-Scholes option-pricing model. The Black-Scholes model considers a number of variables, including the exercise price and the expected life of the option, the current price of the common stock, the expected volatility and the dividend yield of

(2) Summary of Significant Accounting Policies (Continued)

the underlying common stock, and the risk-free interest rate during the expected term of the option. The following table summarizes the weighted average assumptions used:

	Year Ended December 31,		
	2004	2003	2002
Expected life (years)	4.47	4.00	3.03
Risk free interest rate	2.63%	2.28%	2.74%
Volatility factor	85.42%	87.18%	88.00%
Dividend yield	0%	0%	0%

Changes in assumptions used could have a material effect upon the pro-forma results.

The following table illustrates the effect on net income (loss) and net income (loss) per share if the compensation cost for the Company's stock option grants had been determined based on the fair value at the grant dates for awards consistent with the fair value method of Statement of Financial Accounting Standards No. 123 "Accounting for Stock-Based Compensation ("SFAS 123").

(in thousands, except per share amounts)	Year Ended December 31, 2004	2003	2002
Net income (loss) as reported	$113,653	$(112,502)	$(157,949)
Add: Stock-based employee compensation expense included in net income (loss), tax effected	1,759	128	41
Deduct: Total stock-based employee compensation expense determined under fair value based method, tax effected	(46,283)	(39,055)	(72,031)
Pro forma net income (loss)	$ 69,129	$(151,429)	$(229,939)
Net income (loss) per common share:			
Basic, as reported	$ 1.43	$ (1.52)	$ (2.15)
Basic, pro forma	$ 0.87	$ (2.04)	$ (3.13)
Diluted, as reported	$ 1.33	$ (1.52)	$ (2.15)
Diluted, pro forma	$ 0.85	$ (2.04)	$ (3.13)

The pro forma effect on the net income (loss) for the years ended December 31, 2004, 2003 and 2002 is not necessarily indicative of the pro forma effect on future years' operating results.

(i) Research and Development and Clinical and Regulatory

Research and development and clinical and regulatory expenses are comprised of the following types of costs: salaries and benefits, allocated overhead and occupancy costs, clinical trial and related clinical manufacturing costs, contract services and other outside costs. These expenses also include costs related to activities performed on behalf of corporate partners that are subject to reimbursement. Research and development and clinical and regulatory costs are expensed as incurred. The Company is currently producing clinical and commercial grade ERBITUX in its BB36 facility. Prior to the receipt of approval of ERBITUX for commercial sale on February 12, 2004, the Company had expensed all costs associated with the production of ERBITUX to research and development expense. Effective February 13, 2004, the Company began to capitalize the cost of manufacturing ERBITUX as inventories. Costs incurred in the production of ERBITUX is included in inventory and expensed at the time of sale of such inventory. Reference Note 4.

(2) Summary of Significant Accounting Policies (Continued)

(j) Interest

Interest costs are expensed as incurred, except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest costs capitalized for the years ended December 31, 2004, 2003 and 2002, were $6,087,000, $6,059,000, and $2,077,000, respectively. Interest expense includes the amortization of deferred financing costs associated with the Company's 1⅜% convertible senior notes and the 5½% convertible subordinated notes.

(k) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income or expense in the period that includes the enactment date of the rate change.

(l) Use of Estimates

Management of the Company has made a number of estimates and assumptions relating to the reporting of assets and liabilities and related revenue and expense accounts and the disclosure of contingent assets and liabilities to prepare these consolidated financial statements in conformity with U.S. generally accepted accounting principles. Actual results could differ materially from those estimates.

(m) Income (Loss) Per Common Share

Basic income (loss) per common share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the period. Diluted income (loss) per common share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the period increased to include all additional common shares that would have been outstanding assuming potentially dilutive common shares had been issued 1) on the exercise of stock options and any proceeds thereof used to repurchase common stock at the average market price during the period and 2) on conversion of convertible debt. In addition, in computing the dilutive effect of convertible debt, the numerator is adjusted to add back the after-tax amount of interest recognized in the period.

(n) Comprehensive Income (Loss)

SFAS No. 130, "Reporting Comprehensive Income," establishes standards for reporting and presentation of comprehensive income and its components in a full set of financial statements. Comprehensive income (loss) consists of net income (loss) and net unrealized gains (losses) on securities and is presented in the Consolidated Statements of Stockholders' Equity (Deficit). The tax benefit on the items included in Other comprehensive income (loss) assuming they were recognized in

(2) Summary of Significant Accounting Policies (Continued)

income would be approximately $148,000, $5,000 and $7,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

(o) Reclassification

Certain amounts previously reported have been reclassified to conform to the current year's presentation. Most notably, we reclassified master notes of approximately $26.0 million, $11.9 million and $30.8 million as of December 31, 2003, 2002 and 2001, respectively, from cash and cash equivalents to securities available for sale.

(p) Impact of Recent Accounting Pronouncements

On November 24, 2004 the Financial Accounting Standards Board (FASB) issued FASB Statement No. 151, *Inventory Costs*, an amendment of ARB No. 43. This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing", to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). The provisions of this Statement are effective for inventory costs incurred during fiscal years beginning after June 15, 2005 The adoption of this accounting pronouncement is not expected to have a material effect on the Company's consolidated statements.

On December 16, 2004 the FASB issued Statement No. 153, *Exchanges of Nonmonetary Transactions*. This Statement provides that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The Statement is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The provisions of this Statement are not expected to have a material effect on the Company's consolidated statements.

On December 16, 2004 the FASB issued Statement No. 123 (revised 2004), *Share-Based Payment*. This Statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements and establishes fair value as the measurement objective in accounting for all share-based payment arrangements. This Statement is effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. The Company currently accounts for its stock-based compensation plans in accordance with APB Opinion No. 25. Therefore, the adoption of this proposed statement will have a material effect on the Company's consolidated financial statements.

(3) Securities Available for Sale

The securities available for sale by major security type at December 31, 2004 and 2003 were as follows: (in thousands)

At December 31, 2004:

	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. government agency debt	$598,955	$196	$(1,251)	$597,900
U.S. corporate debt	228,691	213	(7)	228,897
Foreign corporate debt	13,614	47	(7)	13,654
	$841,260	$456	$(1,265)	$840,451

(3) Securities Available for Sale (Continued)

At December 31, 2003:

	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
U.S. government agency debt	$17,633	$ —	$—	$17,633
U.S. corporate debt	24,132	165	—	24,297
Foreign corporate debt	33,409	149	(5)	33,553
	$75,174	$314	$(5)	$75,483

Maturities of debt securities classified as available for sale were as follows at December 31, 2004: (in thousands)

	Amortized Cost	Fair Value
2005	$374,965	$374,976
2006	163,002	162,354
2007	194,627	194,415
2008	71,805	71,760
2009	35,000	35,089
2010 and thereafter	1,861	1,857
	$841,260	$840,451

Proceeds from the sale of investments in securities available for sale were $1,967,058,000, $206,834,000 and $296,917,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Gross realized gains included in income in the years ended December 31, 2004, 2003 and 2002 were $142,000, $1,612,000 and $1,757,000, respectively, and gross realized losses included in income in the years ended December 31, 2004, 2003 and 2002 were $11,000, $12,000 and $254,000, respectively. These gains and losses were determined on a specific identification basis. Interest on the securities is adjusted monthly, quarterly or semi-annually, depending on the instrument, using prevailing interest rates. These holdings are highly liquid and we consider the potential for loss of principal to be minimal. All holdings are denominated in U.S. currency.

(4) Inventories

Inventories are stated at the lower of cost, determined on the first-in-first-out method, or market. Inventories at December 31, 2004 consist of the following: (in thousands)

Raw materials and supplies	$ 9,536
Work in process	30,082
Finished goods	1,000
Total	$40,618

(4) Inventories (Continued)

Prior to receipt of approval of ERBITUX for commercial sale on February 12, 2004, the Company had expensed all costs associated with the production of ERBITUX to research and development expense. Effective February 13, 2004, the Company began to capitalize the cost of manufacturing ERBITUX as inventories, including the cost to label, package and ship previously manufactured bulk inventory whose costs had already been expensed as research and development. Although it is the Company's policy to state inventories reflecting full absorption costs, until the Company sells all of its existing inventories for which all or a portion of the costs were previously expensed, inventories will reflect costs incurred to process into finished goods previously expensed raw materials and work in process as well as full absorption costs to manufacture inventory subsequent to February 12, 2004. As the Company continues to process the inventory that was partially produced and expensed prior to February 13, 2004, the Company will continue to reflect in inventory only those incremental costs incurred to complete such inventory into finished goods.

At December 31, 2004, the costs reflected in finished goods inventory consist mainly of cost incurred to package and label work in process inventory previously expensed. In addition, approximately $25.7 million of cost reflected in work in process inventory consists of capitalized labor and overhead incurred subsequent to February 12, 2004 to process raw materials inventory, some of which were previously expensed as research and development.

(5) Property, Plant and Equipment

Property, plant and equipment are recorded at cost and consist of the following: (in thousands)

	December 31, 2004	December 31, 2003
Land	$ 4,899	$ 4,899
Building	67,083	66,615
Leasehold improvements	15,518	12,126
Machinery and equipment	55,430	46,075
Furniture and fixtures	4,265	3,478
Construction in progress	248,736	156,454
Total cost	395,931	289,647
Less accumulated depreciation and amortization	(56,638)	(43,746)
Property, plant and equipment, net	$339,293	$245,901

The Company is building a multiple product manufacturing facility ("BB50") in Branchburg, New Jersey with capacity of up to 110,000 liters (production volume). Management estimates that the 250,000 square foot facility will cost approximately $290,000,000, which is higher than a previously disclosed estimate of $260,000,000. The increase is due to the inclusion of incremental costs associated with the commissioning and validation work needed in order to bring this asset to its intended use. The actual cost of the new facility may change depending upon various factors. The Company has incurred approximately $227,452,000 in conceptual design, engineering, pre-construction, construction and start up costs (which are included in construction in progress in the preceding table), excluding capitalized interest of approximately $14,760,000, through December 31, 2004. As of December 31, 2004, committed purchase orders totaling approximately $177,414,000 have been placed with subcontractors for equipment related to this project and $69,231,000 for engineering, procurement, construction management and validation costs. Through December 31, 2004, $218,347,000 has been paid relating to

(5) Property, Plant and Equipment (Continued)

these committed purchase orders. All outstanding committed purchase orders as of December 31, 2004 require payment in 2005.

In January 2002, the Company purchased real estate consisting of a 7.36-acre parcel of land located adjacent to BB36 and a pilot facility in Branchburg, New Jersey. The real estate includes an existing 51,400 square foot building ("BB1181"), 39,000 square feet of which is warehouse space and 12,000 square feet of which is office space. The purchase price for the property and building was approximately $7,020,000, of which approximately $1,125,000 related to the purchase of the land and approximately $5,895,000 related to the purchase of the building. The Company is using this property for warehousing and material logistics for its Branchburg campus. The Company has incurred approximately $1,262,000 for the retrofit of this facility and it was put into operation in January 2003 and depreciation commenced at that time.

The process of preparing consolidated financial statements in accordance with U.S. generally accepted accounting principles requires the Company to evaluate the carrying values of its long-lived assets. The recoverability of the carrying values of long-lived assets depends on the Company's ability to earn sufficient returns on ERBITUX. Based on management's current estimates, the Company expects to recover the carrying value of such assets.

(6) Accrued Expenses

The following items are included in accrued expenses: (in thousands)

	December 31, 2004	December 31, 2003
Salaries and employee benefits	$12,119	$ 7,610
Research and development contract services	5,721	6,705
License fee and royalty expense	34,603	36
Other	8,734	3,506
	$61,177	$17,857

(7) Withholding Tax Assets and Liability

Federal and applicable state tax law requires an employer to withhold income taxes at the time of an employee's exercise of non-qualified stock options or warrants issued in connection with the performance of services by the employee. An employer that does not do so is liable for the taxes not withheld if the employee fails to pay his or her taxes for the year in which the non-qualified stock options or warrants are exercised. In 2000 and prior years, the Company generally did not require the withholding of federal, state or local income taxes and, in certain years, employment payroll taxes at the time of the exercise of non-qualified stock options or warrants. Prior to 1996, the Company did not comply with tax reporting requirements with respect to the exercise of non-qualified stock options or warrants.

In January 2003, the New York State Department of Taxation and Finance ("New York State") notified the Company that it was liable for the New York State and City income taxes that were not withheld because one or more of the Company's employees who exercised certain non-qualified stock options in 1999 and 2000 failed to pay New York State and City income taxes for those years. On March 13, 2003, the Company entered into a closing agreement with New York State, paying $4,500,000 by March 31, 2003, to settle the matter. On June 17, 2003, New York State notified the Company that

(7) Withholding Tax Assets and Liability (Continued)

based on the warrant issue identified below, it was continuing a previously conducted audit of the Company and was evaluating the terms of the closing agreement to determine whether or not it should be re-opened. On March 31, 2004, the Company entered into a new closing agreement pursuant to which the Company paid New York State an additional $1,000,000 in full satisfaction of all the deficiencies and determinations of withholding taxes for the years 1999-2001. The Company had an estimated liability related to this contingency of $2,815,000 as of December 31, 2003. Therefore the Company has eliminated such liability and has recognized a benefit of $1,815,000 as a recovery in the Consolidated Statements of Operations in the first quarter of 2004.

On March 13, 2003, the Company initiated discussions with the Internal Revenue Service (the "IRS") relating to federal income taxes on the exercise of non-qualified stock options on which income tax was not properly withheld. Although the IRS has not yet asserted that the Company is required to make a payment with respect to such failure to withhold, the IRS may assert that such a liability exists, and may further assert that the Company is liable for interest and penalties. The Company has determined that all but an insignificant amount of the potential liability for withholding taxes with respect to exercises of non-qualified stock options in 1999 and 2000 is attributable to those amounts related to Dr. Samuel D. Waksal, the Company's former Chief Executive Officer. In addition, in the course of the Company's investigation into its potential liability in respect of the non-qualified stock options described above, the Company identified certain warrants that were granted in 1991 and prior years to then current and former officers, directors and advisors that the Company previously treated as non-compensatory warrants and thus not subject to tax withholding and information reporting requirements upon exercise. Accordingly, when exercised in 2001 and prior years, the Company did not deduct income and payroll taxes upon exercise or report applicable information to the taxing authorities. The Company now believes that such treatment was incorrect, and that the exercise of such warrants by current and former officers of the Company should have been treated in the same manner for withholding and reporting purposes as the exercise of non-qualified stock options. The Company has informed the relevant authorities, including the IRS, of this matter and intends to resolve its liability, in conjunction with its resolution of the matter described above.

The Company has recognized assets at the time of exercise relating to certain individuals. These assets are based on the fact that individuals are required by law to pay their personal income taxes, which relieves the Company of its liability for such withholding taxes, but not interest and penalties, as well as the Company's determination that these individuals had the means and intention to satisfy their tax liabilities, and legal claims the Company has against these individuals both during and after their employment with the Company. As of December 31, 2004 and 2003 the Company had recorded $274,000 and $351,000, respectively, of withholding tax assets in its Consolidated Balance Sheets.

One former officer and director to whom warrants were issued and previously treated as non-compensatory warrants was the Company's former Chief Executive Officer, Dr. Samuel D. Waksal. The Company has made demands on Dr. Samuel D. Waksal to pay the taxes associated with the exercise of these warrants and certain non-qualified stock options and to indemnify the Company against any liability that it may incur to taxing authorities in respect of the warrants or non-qualified stock options that were previously exercised. The Company determined that subsequent to the Company's receipt of a "refusal to file" letter from the FDA on December 28, 2001, with respect to its rolling Biologics License Application for ERBITUX, Dr. Samuel D. Waksal's financial condition deteriorated and therefore the recoverability of the asset became doubtful. The Company has recorded $18,096,000 and $20,987,000 of withholding tax liability related to exercise of stock options and

(7) Withholding Tax Assets and Liability (Continued)

warrants and fringe benefits in its Consolidated Balance Sheets as of December 31, 2004 and 2003, respectively.

In 2003, we recognized the recovery of the previous write-down of the withholding tax asset and the elimination of the withholding tax liability of $3,384,000 attributable to the exercise of warrants by our former General Counsel, John B. Landes, because Mr. Landes has represented to us that he has paid the taxes associated with this liability. The write-down of withholding tax assets in 2002 of $3,390,000 is primarily composed of the write-down that was reversed in 2003.

(8) Long-Term Debt

The Company's long term debt was $600,000,000 and $240,000,000 at December 31, 2004 and 2003, respectively.

In May 2004, the Company completed a private placement of $600,000,000 in convertible senior notes due 2024. The notes bear interest at 1⅜% per annum payable semi-annually. The Company received net proceeds from this offering of approximately $581.4 million. Holders may convert the notes into shares of the Company's common stock at a conversion rate of 10.5613 shares per $1,000 principal amount of notes which is equivalent to a conversion price of approximately $94.69 per share, subject to adjustment, before the close of business on the business day immediately prior to May 15, 2024, subject to prior redemption or repurchase of the notes, only under the following circumstances: (1) on or prior to May 15, 2019 during any calendar quarter commencing after June 30, 2004, if the closing sale price of the Company's common stock exceeds 120% of the conversion price for at least 20 trading days in the 30 consecutive trading days ending on the last trading day of the preceding calendar quarter and after May 15, 2019 if the closing sale price of the Company's common stock exceeds 120% of the conversion price on the immediately preceding trading day; (2) during the five business day period after any five consecutive trading day period in which the trading price per note for each day of that period was less than 98% of the product of the closing sale price of the Company's common stock and the conversion rate; (3) if the notes have been called for redemption; or (4) upon the occurrence of certain corporate events. Beginning May 20, 2009, the Company may redeem all or any portion of the notes at a redemption price equal to 100% of the principal amount of the notes, plus accrued and unpaid interest, including additional interest, if any. On May 15 of 2009, 2014 and 2019, or upon the occurrence of certain designated events, holders may require the Company to repurchase the notes at a repurchase price equal to 100% of the principal amount of the notes plus accrued and unpaid interest, including additional interest, if any. The notes are unsubordinated unsecured debt and will rank on a parity with all of the Company's other existing and future unsubordinated unsecured debt and prior to all of the Company's existing and future subordinated debt. Deferred financing costs of approximately $18,600,000 associated with the issuance of this debt are being amortized over five years.

In February 2000, the Company completed a private placement of $240,000,000 in 5½% convertible subordinated notes due March 1, 2005. On May 19, 2004, the Company announced its intention to redeem all of the outstanding 5½% convertible subordinated notes due 2005 by June 18, 2004. All of the outstanding notes which amounted to $239,986,000 at the time of the announcement were converted, by June 17, 2004, into 4,356,000 shares of the Company's common stock. At the time of redemption there was $1,193,000 of unamortized deferred financing cost which was recorded against additional paid-in capital.

(9) Income (Loss) Per Common Share

Basic income (loss) per common share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the period. Diluted income (loss) per common share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the period increased to include all additional common shares that would have been outstanding assuming potentially dilutive common shares had been issued 1) on the exercise of stock options and any proceeds thereof used to repurchase common stock at the average market price during the period and 2) on conversion of convertible debt. In addition, in computing the dilutive effect of convertible debt, the numerator is adjusted to add back the after-tax amount of interest recognized in the period.

Potentially diluted common shares applicable to the 5½% convertible notes that were converted during 2004 have been weighted and included for the period the convertible securities were outstanding prior to conversion. The dilutive effect of the 1⅜% convertible notes issued in 2004 has been weighted and included in the diluted share computation.

Potentially dilutive common shares are not included in the diluted loss per share computation for the years ended December 31, 2003 and 2002, since the Company recognized a net loss for those periods and including potentially dilutive common shares in the diluted loss per share computation when there is a net loss will result in an anti-dilutive per share amount. At December 31, 2004, 2003, and 2002, there were an aggregate of 8,344,000, 19,231,000 and 17,870,000, respectively, potential common shares, excluded from the diluted loss per share computation because their inclusion would have had an anti-dilutive effect.

(9) Income (Loss) Per Common Share (Continued)

Basic and diluted income (loss) per common share (EPS) were computed using the following: (in thousands, except per share data)

	Year Ended December 31,		
	2004	2003	2002
EPS Numerator—Basic:			
Net income (loss)	$113,653	$(112,502)	$(157,949)
EPS Denominator—Basic:			
Weighted-average number of shares of common stock outstanding	79,500	74,250	73,408
EPS Numerator—Diluted:			
Net income (loss)	$113,653	$(112,502)	$(157,949)
Adjustment for interest, net of amounts capitalized and income tax effect	7,315	—	—
Net income (loss), adjusted	$120,968	$(112,502)	$(157,949)
EPS Denominator—Diluted:			
Weighted-average number of shares of common stock outstanding	79,500	74,250	73,408
Effect of dilutive securities:			
Stock options	5,589	—	—
Convertible subordinated notes	6,104	—	—
Dilutive potential common shares	11,693	—	—
Weighted-average common shares and dilutive potential common shares	91,193	74,250	73,408
Basic income (loss) per share	$ 1.43	$ (1.52)	$ (2.15)
Diluted income (loss) per share	$ 1.33	$ (1.52)	$ (2.15)

(10) Collaborative Agreements

(a) Merck KGaA

In April 1990, the Company entered into a development and commercialization agreement with Merck KGaA with respect to BEC2 and the recombinant gp75 antigen product candidate. The agreement has been amended a number of times, most recently in December 1997. The agreement grants Merck KGaA a license, with the right to sublicense, to make, have made, use, sell, or have sold BEC2 and gp75 antigen outside North America. The agreement also grants Merck KGaA a license, without the right to sublicense, to use, sell, or have sold, but not to make BEC2 within North America in conjunction with the Company. Pursuant to the terms of the agreement the Company has retained the rights, (1) without the right to sublicense, to make, have made, use, sell, or have sold BEC2 in North America in conjunction with Merck KGaA and (2) with the right to sublicense, to make, have made, use, sell, or have sold gp75 antigen in North America. In return, the Company has recognized research support payments totaling $4,700,000 and is not entitled to any further research support payments under the agreement. Merck KGaA is also required to make payments of up to $22,500,000, of which $4,000,000 has been received through December 31, 2004, based on milestones achieved in the licensed products' development. Merck KGaA is also responsible for worldwide costs of up to DM17,000,000 associated with a multi-site, multinational Phase III clinical trial for BEC2 in limited disease small-cell lung carcinoma. This expense level was reached during the fourth quarter of 2000 and all expenses incurred from that point forward are being shared 60% by Merck KGaA and 40% by the Company. The Company incurred approximately $333,000, $765,000 and $1,138,000 in the years ended December 31, 2004, 2003 and 2002, respectively, associated with this agreement. Merck KGaA is also required to pay royalties on the eventual sales of BEC2 outside of North America, if any. Revenues from sales, if any, of BEC2 in North America will be distributed in accordance with the terms of a co-promotion agreement to be negotiated by the parties.

(10) Collaborative Agreements (Continued)

On June 7, 2004, the Company and Merck KGaA announced that the international, randomized Phase III clinical trial of the Companies' IMC-BEC2 cancer vaccine did not meet its primary endpoint of survival. Following the analysis of the Phase III data in small cell lung cancer, the Company and Merck KGaA agreed to discontinue further development of BEC2.

In December 1998, the Company entered into a development and license agreement with Merck KGaA with respect to ERBITUX. In exchange for granting Merck KGaA exclusive rights to market ERBITUX outside of the United States and Canada and co-exclusive development rights in Japan, the Company has received $30,000,000 through December 31, 2004 in up-front cash fees and early cash payments based on the achievement of defined milestones. An additional $30,000,000 has been received through December 31, 2004 based upon the achievement of further milestones for which Merck KGaA received equity in the Company. All amounts received in 2004 and 2003 were recorded as equity transactions.

The chart below details the equity milestone payments received from Merck KGaA during the three years ended December 31, 2004:

Date	Amount of Milestone	Revenue Recognized	Number of common shares issued to Merck KGaA	Price per share
May 2003	$6,000,000	—	334,471	$17.94
June 2003	$3,000,000	—	150,007	$20.00
July 2003	$3,000,000	—	92,276	$32.51
July 2003	$3,000,000	—	90,944	$32.99
December 2003	$5,000,000	—	127,199	$39.31
July 2004	$5,000,000	—	58,807	$58.18

The equity interests underlying the milestone payments were priced at varying premiums to the then-market price of the common stock depending upon the timing of the achievement of the respective milestones. Merck KGaA pays the Company a royalty on sales of ERBITUX outside of the United States and Canada. In August 2001, the Company and Merck KGaA amended this agreement to provide, among other things, that Merck KGaA may manufacture ERBITUX for supply in its territory and may utilize a third party to do so upon the Company's reasonable acceptance. The amendment further released Merck KGaA from its obligations under the agreement relating to providing a guaranty under a $30,000,000 credit facility relating to the build-out of BB36. In addition, the amendment provides that the companies have co-exclusive rights to ERBITUX in Japan, including the right to sublicense and Merck KGaA waived its right of first offer in the case of a proposed sublicense by the Company of ERBITUX in the Company's territory. In consideration for the amendment, the Company agreed to a reduction in royalties' payable by Merck KGaA on sales of ERBITUX in Merck KGaA's territory.

In September 2002, the Company entered into a binding term sheet, effective as of April 15, 2002, for the supply of ERBITUX to Merck KGaA, which replaces previous supply arrangements. The term sheet provides for Merck KGaA to purchase bulk and finished ERBITUX ordered from the Company during the term of the December 1998 development and license agreement at a price equal to the Company's fully loaded cost of goods. The term sheet also provided for Merck KGaA to use reasonable efforts to enter into its own contract manufacturing agreements for supply of ERBITUX and obligates Merck KGaA to reimburse the Company for costs associated with transferring technology and any other services requested by Merck KGaA relating to establishing its own manufacturing or

(10) Collaborative Agreements (Continued)

contract manufacturing capacity. Amounts due from Merck KGaA related to these arrangements totaled approximately $8,096,000 and $2,553,000 at December 31, 2004 and December 31, 2003, respectively, and are included in amounts due from corporate partners in the Consolidated Balance Sheets. The Company recorded collaborative agreement revenue related to these arrangements in the Consolidated Statements of Operations totaling approximately $14,976,000, $11,575,000, and $16,864,000 for the years ended December 31, 2004, 2003, and 2002, respectively. Of these amounts, $11,446,000, $9,412,000 and $13,941,000 for the years ended December 31, 2004, 2003, and 2002, respectively, related to reimbursable costs associated with supplying ERBITUX to Merck KGaA for use in clinical trials. The related manufacturing costs, (or a portion in 2004) of the ERBITUX sold to Merck KGaA was produced in prior periods and have been expensed in prior periods when the related raw materials were purchased and the associated direct labor and overhead was consumed or, in the case of contract manufacturing, when such services were performed. Reimbursable clinical and regulatory expenses were incurred and totaled approximately $1,753,000, 1,742,000, and $2,494,000 for the years ended December 31, 2004, 2003, and 2002, respectively. These amounts have been recorded as clinical and regulatory expenses, and also as collaborative agreement revenue in the Consolidated Statements of Operations. Reimbursable general and administrative expenses and royalty expenses were incurred and totaled approximately $1,777,000, $421,000, and $429,000 for the years ended December 31, 2004, 2003, and 2002, respectively. These amounts have been recorded as marketing, general and administrative expenses, royalty expense, and also as collaborative agreement revenue in the Consolidated Statements of Operations. The Company has a liability due Merck KGaA of approximately $2,059,000, and $418,000 as of December 31, 2004 and 2003, respectively.

In June 2003, the Company agreed to supply a fixed quantity of ERBITUX for use in Merck KGaA's medical affairs program on different ordering and pricing terms than those provided in the binding term sheet, including prepayment by Merck KGaA for a portion of such supply. The Company has recorded this prepayment as deferred revenue on the Consolidated Balance Sheet until such time as the product is shipped to Merck KGaA. During 2004, the Company shipped some products under this agreement and based on a current demand schedule, it is expected that the remaining quantity will be shipped during 2005.

(b) Bristol-Myers Squibb Company

On September 19, 2001, the Company entered into an acquisition agreement (the "Acquisition Agreement") with BMS and Bristol-Myers Squibb Biologics Company, a Delaware corporation ("BMS Biologics"), which is a wholly-owned subsidiary of BMS, providing for the tender offer by BMS Biologics to purchase up to 14,392,003 shares of the Company's common stock for $70.00 per share, net to the seller in cash. In connection with the Acquisition Agreement, the Company entered into a stockholder agreement with BMS and BMS Biologics, dated as of September 19, 2001 (the "Stockholder Agreement"), pursuant to which all parties agreed to various arrangements regarding the respective rights and obligations of each party with respect to, among other things, the ownership of shares of the Company's common stock by BMS and BMS Biologics. Concurrent with the execution of the Acquisition Agreement and the Stockholder Agreement, the Company entered into the Commercial Agreement with BMS and E.R. Squibb, relating to ERBITUX, pursuant to which, among other things, BMS and E.R. Squibb are co-developing and co-promoting ERBITUX in the United States and Canada with the Company, and are co-developing and co-promoting ERBITUX in Japan with the Company and either together or co-exclusively with Merck KGaA.

(10) Collaborative Agreements (Continued)

On March 5, 2002, the Company amended the Commercial Agreement with E.R. Squibb and BMS. The amendment changed certain economics of the Commercial Agreement and expanded the clinical and strategic roles of BMS in the ERBITUX development program. One of the principal economic changes to the Commercial Agreement is that the Company received payments of $140,000,000 on March 7, 2002 and $60,000,000 on March 5, 2003. Such payments are in lieu of the $300,000,000 milestone payment the Company would have received upon acceptance by the FDA of the ERBITUX BLA under the original terms of the Commercial Agreement. In addition, the Company agreed to resume and has resumed construction of BB50. The terms of the Commercial Agreement, as amended on March 5, 2002, are set forth in more detail below.

Commercial Agreement

Rights Granted to E.R. Squibb—Pursuant to the Commercial Agreement, as amended on March 5, 2002, the Company granted to E.R. Squibb (1) the exclusive right to distribute, and the co-exclusive right to develop and promote (together with the Company) any prescription pharmaceutical product using the compound ERBITUX (the "product") in the United States and Canada, (2) the co-exclusive right to develop, distribute and promote (together with the Company and together or co-exclusively with Merck KGaA and its affiliates) the product in Japan, and (3) the non-exclusive right to use the Company's registered trademarks for the product in the United States, Canada and Japan (collectively, the "territory") in connection with the foregoing. In addition, the Company agreed not to grant any right or license to any third party, or otherwise permit any third party, to develop ERBITUX for animal health or any other application outside the human health field without the prior consent of E.R. Squibb (which consent may not be unreasonably withheld).

Rights Granted to the Company—Pursuant to the Commercial Agreement, E.R. Squibb has granted to the Company and the Company's affiliates a license, without the right to grant sublicenses (other than to Merck KGaA and its affiliates for use in Japan and to any third party for use outside the territory), to use solely for the purpose of developing, using, manufacturing, promoting, distributing and selling ERBITUX or the product, any process, know-how or other invention developed solely by E.R. Squibb or BMS that has general utility in connection with other products or compounds in addition to ERBITUX or the product ("E.R. Squibb Inventions").

Up-Front and Milestone Payments—The Commercial Agreement provides for up-front and milestone payments by E.R. Squibb to us of $900,000,000 in the aggregate, of which $200,000,000 was paid on September 19, 2001, $140,000,000 was paid on March 7, 2002, $60,000,000 was paid on March 5, 2003, and $250,000,000 was paid on March 12, 2004. An additional $250,000,000 would become payable upon receipt of marketing approval from the FDA with respect to a second tumor type for ERBITUX. All such payments are non-refundable and non-creditable.

Distribution Fees—The Commercial Agreement provides that E.R. Squibb shall pay the Company distribution fees based on a percentage of "annual net sales" of the product (as defined in the Commercial Agreement) by E.R. Squibb in the United States and Canada. The distribution fee is 39% of net sales in the United States and Canada. During the year ended December 31, 2004, the Company has recorded royalty revenues of $101,703,000, representing 39% of net sales of ERBITUX by BMS.

The Commercial Agreement also provides that the distribution fees for the sale of the product in Japan by E.R. Squibb or ImClone Systems shall be equal to 50% of operating profit or loss with respect to such sales for any calendar month. In the event of an operating profit, E.R. Squibb shall pay

(10) Collaborative Agreements (Continued)

the Company the amount of such distribution fee, and in the event of an operating loss, the Company shall credit E.R. Squibb the amount of such distribution fee.

Development of the Product—Responsibilities associated with clinical and other ongoing studies are apportioned between the parties as determined by the product development committee described below. The Commercial Agreement provides for the establishment of clinical development plans setting forth the activities to be undertaken by the parties for the purpose of obtaining marketing approvals, providing market support and developing new indications and formulations of the product. After transition of responsibilities for certain clinical and other studies, each party is primarily responsible for performing the studies designated to it in the clinical development plans. In the United States and Canada, the Commercial Agreement provides that E.R. Squibb is responsible for 100% of the cost of all clinical studies other than those studies undertaken post-launch which are not pursuant to an IND (e.g. Phase IV studies), the cost of which is shared equally between E.R. Squibb and ImClone Systems. As between E.R. Squibb and ImClone Systems, each is responsible for 50% of the costs of all studies in Japan. The Company has also agreed, and may agree in the future, to share with E.R. Squibb, on terms other than the foregoing, costs of clinical trials that the Company believes are not potentially registrational but should be undertaken prior to launch in the United States, Canada or Japan. The Company has incurred $9,096,000, $2,262,000, and $4,093,000 pursuant to such cost sharing for the years ended December 31, 2004, 2003, and 2002, respectively. In addition, to the extent that in 2005 the Company and BMS exceed the contractual maximum registrational costs for clinical development, the Company has agreed to share such cost with BMS. The Company has also incurred $721,000, $663,000, and $377,000 related to the agreement with respect to development in Japan for the years ended December 31, 2004, 2003, and 2002, respectively. Except as otherwise agreed upon by the parties, the Company will own all registrations for the product and is primarily responsible for the regulatory activities leading to registration in each country. E.R. Squibb will be primarily responsible for the regulatory activities in each country after the product has been registered in that country. Pursuant to the terms of the Commercial Agreement, as amended, Andrew G. Bodnar, M.D., J.D., Senior Vice President, Strategy and Medical & External Affairs of BMS, and a member of the Company's Board of Directors, is entitled to oversee the implementation of the clinical and regulatory plan for ERBITUX.

Distribution and Promotion of the Product—Pursuant to the Commercial Agreement, E.R. Squibb has agreed to use all commercially reasonable efforts to launch, promote and sell the product in the territory with the objective of maximizing the sales potential of the product and promoting the therapeutic profile and benefits of the product in the most commercially beneficial manner. In connection with its responsibilities for distribution, marketing and sales of the product in the territory, E.R. Squibb is performing all relevant functions, including but not limited to the provision of all sales force personnel, marketing (including all advertising and promotional expenditures), warehousing and physical distribution of the product.

However, the Company has the right, at its election and sole expense, to co-promote with E.R. Squibb the product in the territory. Pursuant to this co-promotion option, which the Company has exercised, the Company is entitled on and after April 11, 2002 (at the Company's sole expense) to have the Company's field organization participate in the promotion of the product consistent with the marketing plan agreed upon by the parties, provided that E.R. Squibb retains the exclusive rights to sell and distribute the product. Except for the Company's expenses incurred pursuant to the co-promotion option, E.R. Squibb is responsible for 100% of the distribution, sales and marketing costs in the United States and Canada, and as between E.R. Squibb and ImClone Systems, each is responsible for 50% of

(10) Collaborative Agreements (Continued)

the distribution, sales, marketing costs and other related costs and expenses in Japan. During the third quarter of 2004, the Company decided to establish a sales force to maximize the potential commercial opportunities for ERBITUX and to serve as a foundation for the marketing of future products derived either from within the Company's pipeline or through business development opportunities.

Manufacture and Supply—The Commercial Agreement provides that the Company is responsible for the manufacture and supply of all requirements of ERBITUX in bulk form ("API") for clinical and commercial use in the territory, and that E.R. Squibb will purchase all of its requirements of API for commercial use from the Company. The Company supplies API for clinical use at the Company's fully burdened manufacturing cost, and supplies API for commercial use at the Company's fully burdened manufacturing cost plus a mark-up of 10%. Upon the expiration, termination or assignment of any existing agreements between ImClone Systems and third party manufacturers, E.R. Squibb will be responsible for processing API into the finished form of the product.

Management—The parties have formed the following committees for purposes of managing their relationship and their respective rights and obligations under the Commercial Agreement:

- a Joint Executive Committee (the "JEC"), which consists of certain senior officers of each party. The JEC is co-chaired by a representative of each of BMS and the Company. The JEC is responsible for, among other things, managing and overseeing the development and commercialization of ERBITUX pursuant to the terms of the Commercial Agreement, approving the annual budgets and multi-year expense forecasts, and resolving disputes, disagreements and deadlocks arising in the other committees;
- a Product Development Committee (the "PDC"), which consists of members of senior management of each party with expertise in pharmaceutical drug development and/or marketing. The PDC is chaired by the Company's representative. The PDC is responsible for, among other things, managing and overseeing the development and implementation of the clinical development plans, comparing actual versus budgeted clinical development and regulatory expenses, and reviewing the progress of the registrational studies;
- a Joint Commercialization Committee (the "JCC"), which consists of members of senior management of each party with clinical experience and expertise in marketing and sales. The JCC is chaired by a representative of BMS. The JCC is responsible for, among other things, overseeing the preparation and implementation of the marketing plans, coordinating the sales efforts of E.R. Squibb and the Company, and reviewing and approving the marketing and promotional plans for the product in the territory; and
- a Joint Manufacturing Committee (the "JMC"), which consists of members of senior management of each party with expertise in manufacturing. The JMC is chaired by the Company's representative (unless a determination is made that a long-term inability to supply API exists, in which case the JMC will be co-chaired by representatives of E.R. Squibb and the Company). The JMC is responsible for, among other things, overseeing and coordinating the manufacturing and supply of API and the product, and formulating and directing the manufacturing strategy for the product.

Any matter that is the subject of a deadlock (i.e., no consensus decision) in the PDC, the JCC or the JMC will be referred to the JEC for resolution. Subject to certain exceptions, deadlocks in the JEC will be resolved as follows: (1) if the matter was also the subject of a deadlock in the PDC, by the

(10) Collaborative Agreements (Continued)

co-chairperson of the JEC designated by the Company, (2) if the matter was also the subject of a deadlock in the JCC, by the co-chairperson of the JEC designated by BMS, or (3) if the matter was also the subject of a deadlock in the JMC, by the co-chairperson of the JEC designated by the Company. All other deadlocks in the JEC will be resolved by arbitration.

Right of First Offer—E.R. Squibb has a right of first offer with respect to the Company's investigational IMC-KDR monoclonal antibodies should the Company decide to enter into a partnering arrangement with a third party with respect to IMC-KDR antibodies at any time prior to the earlier to occur of September 19, 2006 and the first anniversary of the date which is 45 days after any date on which BMS's ownership interest in ImClone Systems is less than 5%. If the Company decides to enter into a partnering arrangement during such period, the Company must notify E.R. Squibb. If E.R. Squibb notifies the Company that it is interested in such an arrangement, the Company will provide its proposed terms to E.R. Squibb and the parties will negotiate in good faith for 90 days to attempt to agree on the terms and conditions of such an arrangement. If the parties do not reach agreement during this period, E.R. Squibb must propose the terms of an arrangement which it is willing to enter into, and if the Company rejects such terms the Company may enter into an agreement with a third party with respect to such a partnering arrangement (provided that the terms of any such agreement may not be more favorable to the third party than the terms proposed by E.R. Squibb).

Right of First Negotiation—If at any time during the restricted period (as defined below), the Company is interested in establishing a partnering relationship with a third party involving certain compounds or products not related to IMC-KDR antibodies, the Company must notify E.R. Squibb and E.R. Squibb will have 90 days to enter into a non-binding agreement with the Company with respect to such a partnering relationship. In the event that E.R. Squibb and ImClone Systems do not enter into a non-binding agreement, the Company is free to negotiate with third parties without further obligation to E.R. Squibb. The "restricted period" means the period from September 19, 2001 until the earliest to occur of (1) September 19, 2006, (2) a reduction in BMS's ownership interest in ImClone Systems to below 5% for 45 consecutive days, (3) a transfer or other disposition of shares of the Company's common stock by BMS or any of its affiliates such that BMS and its affiliates own or have control over less than 75% of the maximum number of shares of the Company's common stock owned by BMS and its affiliates at any time after September 19, 2001, (4) an acquisition by a third party of more than 35% of the outstanding Shares, (5) a termination of the Commercial Agreement by BMS due to significant regulatory or safety concerns regarding ERBITUX, or (6) the Company's termination of the Commercial Agreement due to a material breach by BMS.

Restriction on Competing Products—During the period from the date of the Commercial Agreement until September 19, 2008, the parties have agreed not to, directly or indirectly, develop or commercialize a competing product (defined as a product that has as its only mechanism of action an antagonism of the EGF receptor) in any country in the territory. In the event that any party proposes to commercialize a competing product or purchases or otherwise takes control of a third party which has developed or commercialized a competing product, then such party must either divest the competing product within 12 months or offer the other party the right to participate in the commercialization and development of the competing product on a 50/50 basis (provided that if the parties cannot reach agreement with respect to such an agreement, the competing product must be divested within 12 months).

(10) Collaborative Agreements (Continued)

Ownership—The Commercial Agreement provides that the Company owns all data and information concerning ERBITUX and the product and (except for the E.R. Squibb Inventions) all processes, know-how and other inventions relating to the product and developed by either party or jointly by the parties. E.R. Squibb, however, has the right to use all such data and information, and all such processes, know-how or other inventions, in order to fulfill its obligations under the Commercial Agreement.

Product Recalls—If E.R. Squibb is required by any regulatory authority to recall the product in any country in the territory (or if the JCC determines such a recall to be appropriate), then E.R. Squibb and ImClone Systems shall bear the costs and expenses associated with such a recall (1) in the United States and Canada, in the proportion of 39% for ImClone Systems and 61% for E.R. Squibb and (2) in Japan, in the proportion for which each party is entitled to receive operating profit or loss (unless, in the territory, the predominant cause for such a recall is the fault of either party, in which case all such costs and expenses shall be borne by such party).

Mandatory Transfer—Each of BMS and E.R. Squibb has agreed under the Commercial Agreement that in the event it sells or otherwise transfers all or substantially all of its pharmaceutical business or pharmaceutical oncology business, it must also transfer to the transferee its rights and obligations under the Commercial Agreement.

Indemnification—Pursuant to the Commercial Agreement, each party has agreed to indemnify the other for (1) its negligence, recklessness or wrongful intentional acts or omissions, (2) its failure to perform certain of its obligations under the agreement, and (3) any breach of its representations and warranties under the agreement.

Termination—Unless earlier terminated pursuant to the termination rights discussed below, the Commercial Agreement expires with regard to the product in each country in the territory on the later of September 19, 2018 and the date on which the sale of the product ceases to be covered by a validly issued or pending patent in such country. The Commercial agreement may also be terminated prior to such expiration as follows:

- by either party, in the event that the other party materially breaches any of its material obligations under the Commercial Agreement and has not cured such breach within 60 days after notice;
- by E.R. Squibb, if the JEC determines that there exists a significant concern regarding a regulatory or patient safety issue that would seriously impact the long-term viability of all products.

Acquisition Agreement

On October 29, 2001, pursuant to the Acquisition Agreement, BMS-Biologics accepted for payment pursuant to the tender offer 14,392,003 shares of the Company's common stock on a pro rata basis from all tendering shareholders and those conditionally exercising stock options.

Stockholder Agreement

Pursuant to the Stockholder Agreement, the Company's Board was increased from ten to twelve members in October 2001. BMS received the right to nominate two directors to the Company's Board

(10) Collaborative Agreements (Continued)

(each a "BMS director") so long as its ownership interest in ImClone Systems is 12.5% or greater. If BMS' ownership interest is 5% or greater but less than 12.5%, BMS will have the right to nominate one BMS director, and if BMS' ownership interest is less than 5%, BMS will have no right to nominate a BMS director. If the size of the Board is increased to a number greater than twelve, the number of BMS directors would be increased, subject to rounding, such that the number of BMS directors is proportionate to the lesser of BMS' then-current ownership interest and 19.9%. Notwithstanding the foregoing, BMS will have no right to nominate any BMS directors if (1) the Company has terminated the Commercial Agreement due to a material breach by BMS or (2) BMS' ownership interest were to remain below 5% for 45 consecutive days.

Based on the number of shares of common stock acquired pursuant to the tender offer, BMS has the right to nominate two directors. BMS designated Andrew G. Bodnar, M.D., J.D., BMS' Senior Vice President, Strategy and Medical & External Affairs, as one of the initial BMS directors. The nomination of Dr. Bodnar was approved by the Board on November 15, 2001. The other BMS director position was initially filled by Peter S. Ringrose, M.A, and Ph.D. Dr. Ringrose retired in 2002 from his position of Chief Scientific Officer and President, Pharmaceutical Research Institute at BMS, and also resigned from his director position with the Company. BMS has not yet designated a replacement to fill Dr. Ringrose's vacated Board seat.

Voting of Shares—During the period in which BMS has the right to nominate up to two BMS directors, BMS and its affiliates are required to vote all of their shares in the same proportion as the votes cast by all of the Company's other stockholders with respect to the election or removal of non-BMS directors.

Committees of the Board of Directors—During the period in which BMS has the right to nominate up to two BMS directors, BMS also has the right, subject to certain exceptions and limitations, to have one member of each committee of the Board be a BMS director.

Approval Required for Certain Actions—The Company may not take any action that constitutes a prohibited action under the Stockholder Agreement without the consent of the BMS directors, until September 19, 2006 or earlier, if any of the following occurs: (1) a reduction in BMS's ownership interest to below 5% for 45 consecutive days, (2) a transfer or other disposition of shares of the Company's common stock by BMS or any of its affiliates such that BMS and its affiliates own or have control over less than 75% of the maximum number of shares of the Company's common stock owned by BMS and its affiliates at any time after September 19, 2001, (3) an acquisition by a third party of more than 35% of the outstanding shares of the Company's common stock, (4) a termination of the Commercial Agreement by BMS due to significant regulatory or safety concerns regarding ERBITUX, or (5) a termination of the Commercial Agreement due to a material breach by BMS. Such prohibited actions include (1) issuing additional shares or securities convertible into shares in excess of 21,473,002 shares of the Company's common stock in the aggregate, subject to certain exceptions; (2) incurring additional indebtedness if the total of (A) the principal amount of indebtedness incurred since September 19, 2001 and then-outstanding, and (B) the net proceeds from the issuance of any redeemable preferred stock then-outstanding, would exceed the Company's amount of indebtedness for borrowed money outstanding as of September 19, 2001 by more than $500 million; (3) acquiring any business if the aggregate consideration for such acquisition, when taken together with the aggregate consideration for all other acquisitions consummated during the previous twelve months, is in excess of 25% of the Company's aggregate value at the time the binding agreement relating to such acquisition

(10) Collaborative Agreements (Continued)

was entered into; (4) disposing of all or any substantial portion of the Company's non-cash assets; (5) entering into non-competition agreements that would be binding on BMS, its affiliates or any BMS director; (6) taking certain actions that would have a discriminatory effect on BMS or any of its affiliates as a stockholder; and (7) issuing capital stock with more than one vote per share.

Limitation on Additional Purchases of Shares and Other Actions—Subject to the exceptions set forth below, until September 19, 2006 or, if earlier, the occurrence of any of (1) an acquisition by a third party of more than 35% of the Company's outstanding shares, (2) the first anniversary of a reduction in BMS's ownership interest in the Company to below 5% for 45 consecutive days, or (3) the Company's taking a prohibited action under the Stockholder Agreement without the consent of the BMS directors, neither BMS nor any of its affiliates will acquire beneficial ownership of any shares of the Company's common stock or take any of the following actions: (1) encourage any proposal for a business combination with the Company's or an acquisition of our shares; (2) participate in the solicitation of proxies from holders of shares of the Company's common stock; (3) form or participate in any "group" (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934) with respect to shares of the Company's common stock; (4) enter into any voting arrangement with respect to shares of the Company's common stock; or (5) seek any amendment to or waiver of these restrictions.

The following are exceptions to the standstill restrictions described above: (1) BMS Biologics may acquire beneficial ownership of shares of the Company's common stock either in the open market or from the Company pursuant to the option described below, so long as, after giving effect to any such acquisition of shares, BMS' ownership interest would not exceed 19.9%; (2) BMS may make, subject to certain conditions, a proposal to the Board to acquire shares of the Company's common stock if the Company provides material non-public information to a third party in connection with, or begins active negotiation of, an acquisition by a third party of more than 35% of the outstanding shares; (3) BMS may acquire shares of the Company's common stock if such acquisition has been approved by a majority of the non-BMS directors; and (4) BMS may make, subject to certain conditions, including that an acquisition of shares be at a premium of at least 25% to the prevailing market price, non-public requests to the Board to amend or waive any of the standstill restrictions described above. Certain of the exceptions to the standstill provisions described above will terminate upon the occurrence of: (1) a reduction in BMS's ownership interest in the Company to below 5% for 45 consecutive days, (2) a transfer or other disposition of shares of the Company's common stock by BMS or any of its affiliates such that BMS and its affiliates own or have control over less than 75% of the maximum number of shares owned by BMS and its affiliates at any time after September 19, 2001, (3) a termination of the Commercial Agreement by BMS due to significant regulatory or safety concerns regarding ERBITUX, or (4) a termination of the Commercial Agreement by the Company due to a material breach by BMS.

Option to Purchase Shares in the Event of Dilution—BMS Biologics has the right under certain circumstances to purchase additional shares of common stock from the Company at market prices, pursuant to an option granted to BMS by the Company, in the event that BMS's ownership interest is diluted (other than by any transfer or other disposition by BMS or any of its affiliates). BMS can exercise this right (1) once per year, (2) if the Company issues shares of common stock in excess of 10% of the then-outstanding shares in one day, and (3) if BMS's ownership interest is reduced to below 5% or 12.5%. BMS Biologics' right to purchase additional shares of common stock from the Company pursuant to this option will terminate on September 19, 2006 or, if earlier, upon the occurrence of (1) an acquisition by a third party of more than 35% of the outstanding shares, or

(10) Collaborative Agreements (Continued)

(2) the first anniversary of a reduction in BMS's ownership interest in the Company to below 5% for 45 consecutive days.

Transfers of Shares—Until March 19, 2005, neither BMS nor any of its affiliates may transfer any shares of the Company's common stock or enter into any arrangement that transfers any of the economic consequences associated with the ownership of shares. After March 19, 2005, neither BMS nor any of its affiliates may transfer any shares or enter into any arrangement that transfers any of the economic consequences associated with the ownership of shares, except (1) pursuant to registration rights granted to BMS with respect to the shares, (2) pursuant to Rule 144 under the Securities Act of 1933, as amended or (3) for certain hedging transactions. Any such transfer is subject to the following limitations: (1) the transferee may not acquire beneficial ownership of more than 5% of the then-outstanding shares of common stock; (2) no more than 10% of the total outstanding shares of common stock may be sold in any one registered underwritten public offering; and (3) neither BMS nor any of its affiliates may transfer shares of common stock (except for registered firm commitment underwritten public offerings pursuant to the registration rights described below) or enter into hedging transactions in any twelve-month period that would, individually or in the aggregate, have the effect of reducing the economic exposure of BMS and its affiliates by the equivalent of more than 10% of the maximum number of shares of common stock owned by BMS and its affiliates at any time after September 19, 2001. Notwithstanding the foregoing, BMS Biologics may transfer all, but not less than all, of the shares of common stock owned by it to BMS or to E.R. Squibb or another wholly-owned subsidiary of BMS.

Registration Rights—The Company granted BMS customary registration rights with respect to shares of common stock owned by BMS or any of its affiliates.

The Company incurred approximately $2,250,000 during the year ended December 31, 2002 in legal and other advisor fees associated with the amendment to the Commercial Agreement with BMS and affiliates, which has been expensed and included in operating expenses in the Consolidated Statements of Operations.

Amounts due from BMS related to this agreement totaled approximately $61,621,000 and $6,407,000 at December 31, 2004 and 2003, respectively, and are included in amounts due from corporate partners in the Consolidated Balance Sheets. The Company recorded collaborative agreement revenue related to this agreement in the Consolidated Statements of Operations totaling approximately $38,919,000, $20,668,000 and $20,382,000 for the years ended December 31, 2004, 2003 and 2002, respectively. Of these amounts, $13,062,000, $5,820,000 and $9,221,000 for the years ended December 31, 2004, 2003 and 2002, respectively, related to reimbursable costs associated with supplying ERBITUX for use in clinical trials associated with this agreement. The majority of the related manufacturing costs have been expensed in prior years when the related raw materials were purchased and the associated direct labor and overhead was consumed or, in the case of contract manufacturing, when such services were performed. Reimbursable clinical and regulatory, marketing expenses and royalty expense were incurred and totaled approximately $25,857,000, $14,848,000 and $11,161,000 for the years December 31, 2004, 2003 and 2002, respectively. These amounts have been recorded as research and development, clinical and regulatory, marketing, general and administrative and royalty expenses and also as collaborative agreement revenue in the Consolidated Statements of Operations.

(10) Collaborative Agreements (Continued)

In June 2002, the Company and BMS agreed that certain ERBITUX clinical trial costs incurred by the Company but billed to BMS under the Commercial Agreement would in fact be borne by the Company due to such trials' non-registrational nature. This resulted in the issuance of credit memos to BMS during the year ended December 31, 2002 totaling approximately $2,949,000, which ultimately reduced collaborative agreement revenue and license fee revenue in the year ended December 31, 2002.

License fees and milestone revenue consists of the following: (in thousands)

	Year Ended December 31,		
	2004	2003	2002
BMS:			
ERBITUX license fee revenue	$128,943	$47,527	$20,608
Merck KGaA:			
ERBITUX and BEC2 license fee revenue	385	385	385
Other license fee revenue	58	58	58
Total license fees and milestone revenue	$129,386	$47,970	$21,051

Royalty revenue consists of the following: (in thousands)

	Year Ended December 31,		
	2004	2003	2002
BMS	$101,703	$ —	$ —
Merck KGaA	4,314	18	—
Other	257	557	1,353
Total royalty revenue	$106,274	$ 575	$ 1,353

Collaborative agreement revenue from corporate partners consists of the following: (in thousands)

	Year Ended December 31,		
	2004	2003	2002
BMS	$38,919	$20,668	$20,382
Merck KGaA	15,018	11,617	17,219
Other	52	—	—
Total collaborative agreement revenue	$53,989	$32,285	$37,601

Amounts due from corporate partners, net of allowance in 2004 of $430,000 consist of the following: (in thousands). There was no allowance recorded in 2003 or 2002 and there were no write-offs of amounts due from corporate partners in 2004.

	December 31, 2004	December 31, 2003
BMS:		
ERBITUX	$61,621	$6,407
Merck KGaA:		
ERBITUX and BEC2	8,132	2,572
Total amounts due from corporate partners	$69,753	$8,979

(10) Collaborative Agreements (Continued)

Deferred revenue consists of the following: (in thousands)

	December 31, 2004	December 31, 2003
BMS:		
ERBITUX commercial agreement	$ 450,368	$329,312
Merck KGaA:		
ERBITUX development and license agreement	3,111	3,333
Prepayment of ERBITUX supplied for medical affairs program	2,544	2,640
BEC2 development and commercialization agreement	1,785	1,947
Total deferred revenue	457,808	337,232
Less: current portion	(108,994)	(50,870)
Total long-term deferred revenue	$ 348,814	$286,362

The Company earned manufacturing revenue of $99,041,000 related to sales of ERBITUX to BMS for commercial use for the year ended December 31, 2004. There were no sales for commercial use during the years ended December 31, 2003 and 2002.

(11) Stockholder' Equity

(a) Common Stock

In June 2002, the stockholders approved the amendment of the Company's certificate of incorporation to increase the total number of shares of common stock the Company is authorized to issue from 120,000,000 shares to 200,000,000 shares.

(b) Stockholder Rights Plan

On February 15, 2002, the Company's Board of Directors approved a Stockholder Rights Plan and declared a dividend of one right for each share of the Company's common stock outstanding at the close of business on February 19, 2002. In connection with the Board of Directors' approval of the Stockholders Rights Plan Series B Participating Cumulative Preferred Stock was created. Under certain conditions, each right entitles the holder to purchase from the Company one-hundredth of a share of series B Participating Cumulative Preferred Stock at an initial purchase price of $175 per share. The Stockholder Rights Plan is designed to enhance the Board's ability to protect stockholders against, among other things, unsolicited attempts to acquire control of the Company which do not offer an adequate price to all of the Company's stockholders or are otherwise not in the best interests of the Company and the Company's stockholders.

Subject to certain exceptions, rights become exercisable (i) on the tenth day after public announcement that any person, entity, or group of persons or entities has acquired ownership of 15% or more of the Company's outstanding common stock, or (ii) 10 business days following the commencement of a tender offer or exchange offer by any person which would, if consummated, result in such person acquiring ownership of 15% or more of the Company's outstanding common stock, (collectively an "Acquiring Person").

In such event, each right holder will have the right to receive the number of shares of common stock having a then-current market value equal to two times the aggregate exercise price of such rights.

(11) Stockholder' Equity (Continued)

If the Company were to enter into certain business combination or disposition transactions with an Acquiring Person, each right holder will have the right to receive shares of common stock of the acquiring company having a value equal to two times the aggregate exercise price of the rights.

The Company may redeem these rights in whole at a price of $.001 per right. The rights expire on February 15, 2012.

(c) Stock Options

Stock Option Plans

In February 1986, the Company adopted and the shareholders thereafter approved an Incentive Stock Option Plan and a Non-Qualified Stock Option Plan (the "86 Plans"). Options may no longer be granted under the 86 Plans pursuant to the terms of the 86 Plans. In February 1996, the Company's Board of Directors adopted and the shareholders thereafter approved an additional Incentive Stock Option Plan and Non-Qualified Stock Option Plan (the "96 Plans"). In May 1998, the Company's Board of Directors adopted an additional Non-Qualified Stock Option Plan (the "98 Plan"), which shareholders were not required to approve. On June 11, 2002, the shareholders approved and the Company adopted the 2002 Stock Option Plan (the "02 Plan"). Effective with the adoption of the 02 Plan, the Company will not award new grants from the 96 Plans or the 98 Plan. The 02 Plan provides for the granting of both incentive stock options and non-qualified stock options to purchase, subject to adjustment under the plan, 3,300,000 shares of the Company's common stock to employees, directors, consultants and advisors of the Company. Any common stock subject to an option which is cancelled, forfeited or expires prior to exercise whether such option was granted under this plan or the 96 Plans or the 98 Plan, shall again become available for grant under the 02 Plan. Options granted under the 02 Plan generally vest over one to four year periods and unless earlier terminated, expire ten years from the date of grant. Options granted under the 02 Plan become fully vested and exercisable upon the occurrence of a change in control, as defined. Incentive stock options granted under the 02 Plan may not exceed 825,000 shares of common stock, may not be granted at a price less than the fair market value of the stock at the date of grant and may not be granted to non-employees. In September 2003, the shareholders approved an amendment to the 02 Plan that increased the maximum total number of shares of common stock currently available for grant of options under the plan from 3,300,000 shares to 6,600,000 shares, and increased the number of shares of common stock with respect to which incentive stock options may be granted under the plan from 825,000 shares to 1,650,000 shares.

In November 2001, the Board of Directors approved the amendment of the 96 Plans and the 98 Plan whereby upon the occurrence of a change in control, as defined in the amended plan documents, each outstanding option under the 96 Plans and the 98 Plan shall become fully vested and exercisable. In the event a change in control triggers the acceleration of vesting of stock option awards, the Company would be required to recognize compensation expense, in accordance with Interpretation No. 44, for those options that would have otherwise expired un-exercisable pursuant to the original terms.

Combined, the 86 Plans, the 96 Plans, as amended, the 98 Plan, as amended, and the 02 Plan, as amended, provide as of December 31, 2004 for the granting of options to purchase up to 33,900,000 shares of common stock to employees, directors, consultants and advisors of the Company. Incentive stock options may not be granted at a price less than the fair market value of the stock at the date of grant and may not be granted to non-employees. Options under all the plans, unless earlier terminated,

(11) Stockholder' Equity (Continued)

expire ten years from the date of grant. Options granted under these plans generally vest over one-to-four-year periods. At December 31, 2004, options to purchase 13,932,998 shares of common stock were outstanding and 763,819 shares were available for grant.

A summary of stock option activity follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Balance at December 31, 2001	11,061,052	$32.17
Granted	3,559,557	18.75
Exercised	(438,672)	9.37
Canceled	(668,804)	36.41
Balance at December 31, 2002	13,513,133	29.16
Granted	2,418,400	31.55
Exercised	(633,078)	11.30
Canceled	(423,899)	30.89
Balance at December 31, 2003	14,874,556	30.27
Granted	2,798,393	50.89
Exercised	(3,522,003)	22.16
Canceled	(217,948)	39.27
Balance at December 31, 2004	13,932,998	$36.33

The following table summarizes information concerning stock options outstanding at December 31, 2004:

Range of Exercise Price	Number Outstanding at 12/31/04	Weighted Average Remaining Contractual Term (years)	Weighted Average Exercise Price	Number Exercisable at 12/31/04	Weighted Average Exercise Price
$0.28–10.60	1,626,070	6.30	$ 6.91	1,435,701	$ 6.80
10.68–18.06	1,612,482	5.97	15.67	1,403,755	16.12
18.44–30.08	1,475,573	6.96	27.12	1,190,574	27.01
30.94–38.19	1,525,880	7.09	34.51	1,280,030	34.41
38.31–39.98	1,408,821	8.15	39.58	802,965	39.50
40.01–50.00	2,432,809	8.81	44.97	553,517	45.13
50.01–50.01	2,450,000	6.72	50.01	2,450,000	50.01
50.94–84.02	1,401,363	8.07	63.68	525,863	59.92
	13,932,998	7.29	$36.33	9,642,405	$33.12

In September 2001, and in connection with the Board of Directors' approval of certain employment the Company granted options to purchase, in the aggregate, 2,450,000 shares of its

(11) Stockholder' Equity (Continued)

common stock to its former President and Chief Executive Officer, Dr. Samuel D. Waksal, its then-current Chief Operating Officer, and now-former Chief Scientific Officer, Dr. Harlan W. Waksal and its then-current Senior Vice President, Finance, and Chief Financial Officer and current Chief Executive Officer, Daniel S. Lynch. The options have a per-share exercise price equal to $50.01, the last reported sale price of the common stock preceding the date Board of Director approval was obtained. The terms of the options granted to Dr. Samuel D. Waksal and Dr. Harlan W. Waksal provide that they vest in their entirety three years from the date of grant, but may vest earlier as to 33.33% of the shares if certain targets in the Company's common stock price are achieved. The options granted to Daniel S. Lynch vest equally over three years. In connection with the resignation of Dr. Samuel D. Waksal, and the associated May 24, 2002 Separation Agreement between the Company and Dr. Samuel D. Waksal, the Company amended Dr. Samuel D. Waksal's September 2001 stock option award such that the then unvested portion totaling 833,332 shares would vest immediately as of the date of termination. In August 2002, the Company filed an action against Dr. Samuel D. Waksal in New York State Supreme Court seeking, among other things the cancellation of all stock options that vested as a result of the separation agreement.

The Company's employee stock option plans generally permit option holders to pay for the exercise price of stock options and any related income tax withholding with shares of the Company's common stock that have been held by the option holders for at least six months. During the year ended December 31, 2004, 4,008 shares of common stock were delivered to the Company in payment of the aggregate exercise price and related to income tax withheld associated with the exercise of stock options to purchase an aggregate of 19,044 shares of common stock. The 4,008 shares delivered to the Company had a value of approximately $200,000 determined by multiplying the closing price of the common stock on the date of deliver for the number of shares presented for payment. These shares are included as treasury stock in the consolidated balance sheet at December 31, 2004.

The Company granted options to purchase 45,000 and 95,000 shares of its common stock to certain Scientific Advisory Board members and outside consultants in consideration for future services during the years ended December 31, 2003 and 2000, respectively. During 2004, the Company recognized compensation expense of $2,028,000 associated with the modification of stock options for a number of terminated employees. The Company recognized compensation expense associated with the options granted to Scientific Advisory Board members and outside consultants of approximately $2,420,000 and $722,000 in the years ended December 31, 2004 and 2003, respectively. No compensation expense was recognized in the year ended December 31, 2002 with respect to the options granted during the year ended December 31, 2000 because these grants were fully vested during 2001. At December 31, 2004, options to purchase 207,500 shares of the Company's common stock related to all grants of options to Scientific Advisory Board members and outside consultants were vested and outstanding. The fair value of these options was subject to remeasurement through the vesting date using the Black-Scholes option-pricing model using assumptions generally comparable to those disclosed in Note 2. During the years ended December 31, 2004, 2003 and 2002, the Company granted options to non-employee members of its Board of Directors to purchase approximately 352,000, 429,000 and 330,000 shares, respectively, of its common stock. During the year ended December 31, 2003, the options granted to the Board of Directors were modified such that the original quarterly vesting of the options was changed to daily prorated vesting for departing directors with respect to service during the quarter in which they depart the Board. Due to this modification, the Company recorded approximately $129,000 of compensation expense during the year ended December 31, 2003.

(11) Stockholder' Equity (Continued)

SFAS No. 123 Disclosures

The following table summarizes the weighted average fair value per share of stock options granted to employees and directors during the years ended December 31, 2004, 2003 and 2002:

	Option plans					
	2004		2003		2002	
	Shares	$	Shares(1)	$	Shares	$
Exercise price equals market value at date of grant	2,798,393	$50.89	2,373,400	$31.50	3,559,557	$10.51

(1) Does not include 45,000 shares in 2003 under options granted to certain Scientific Advisory Board members and outside consultants. The fair value of these grants has been recorded as compensation expense as prescribed by SFAS No. 123.

(d) Employee Stock Purchase Plan

In April 1998, the Company's Board of Directors adopted the ImClone Systems Incorporated 1998 Employee Stock Purchase Plan (the "ESPP"), subject to shareholders' approval, which was received in May 1998. The ESPP, as amended, allows eligible employees to purchase shares of the Company's common stock through payroll deductions at the end of quarterly purchase periods. To be eligible, an individual must be an employee, work more than 20 hours per week for at least five months per calendar year and not own greater than 5% of the Company's common stock. Pursuant to the ESPP, the Company has reserved 1,000,000 shares of common stock for issuance. Prior to the first day of each quarterly purchase period, each eligible employee may elect to participate in the ESPP. The participant is granted an option to purchase a number of shares of common stock determined by dividing each participant's contribution accumulated prior to the last day of the quarterly period by the purchase price. The participant has the ability to withdraw from the ESPP until the second-to-last day of the quarterly purchase period. The purchase price is equal to 85% of the market price per share on the last day of each quarterly purchase period. An employee may purchase stock from the accumulation of payroll deductions up to the lesser of 15% of such employee's compensation or $25,000 in aggregate purchase price, per year. Participating employees have purchased 16,751 shares of common stock at an aggregate price of $802,000 for the year ended December 31, 2004, 28,606 shares of common stock at an aggregate price of $685,000 for the year ended December 31, 2003, and 52,593 shares of common stock at an aggregate purchase price of $502,000 for the year ended December 31, 2002. As of December 31, 2004, 850,225 shares were available for future purchases. No compensation expense has been recorded in connection with the ESPP. Pro forma compensation expense of $141,000, $121,000 and $89,000 related to the discount given to employees is included in the pro forma operating results disclosed in Note 2 for the years ended December 31, 2004, 2003 and 2002, respectively.

(12) Income Taxes

Total income taxes for the years ended December 31, 2004, 2003 and 2002 were as follows: (in thousands)

	2004	2003	2002
Current:			
Federal	$ 5,947	$ —	$ —
State and local	11,414	491	725
Total provision for income taxes	$17,361	$491	$725

In 2004, the Company recorded as an increase to additional paid-in capital $9,982,000 of tax benefit from the exercise of stock options. The Company recognized state tax expense of $491,000 and $725,000 for the years ended December 31, 2003 and 2002, respectively, as a result of legislation in New Jersey, which resulted in Alternative Minimum Assessment tax.

Reconciliations between the total tax provision and the tax provision based on the federal statutory rate are presented below: (in thousands)

	2004	2003	2002
Pre-tax income (loss)	$131,014	$(112,011)	$(157,224)
Tax provision (benefit) at federal statutory rate of 35%	45,855	(39,204)	(55,028)
State and local income taxes	8,005	491	725
Change in valuation allowance	(33,023)	39,204	55,028
Research and development credits	(3,585)	—	—
Other	109	—	—
Provision for income taxes	$ 17,361	$ 491	$ 725

The tax effects of temporary differences that give rise to significant portions of the gross deferred tax assets and gross deferred tax liabilities at December 31, 2004, and 2003, are presented below: (in thousands)

	2004	2003
Gross deferred tax assets:		
Research and development credit carryforwards and other credits	$ 53,128	$ 38,303
Compensation relating to the issuance of stock options and warrants	2,567	1,661
Net operating loss carryforwards	151,481	222,441
Deferred revenue	185,616	152,789
Stock option withholding tax liability	7,226	11,198
Litigation settlement	22,447	—
Other	8,188	6,570
Total gross deferred tax assets	430,653	432,962
Less valuation allowance	(430,091)	(432,832)
Net deferred tax assets	562	130
Gross deferred tax liabilities:		
Other	562	130
Net deferred tax asset	$ —	$ —

(12) Income Taxes (Continued)

The Company has established a valuation allowance because, more likely than not, substantially all of its gross deferred tax assets will not be realized. The net change in the total valuation allowance for the year ended December 31, 2004 was a decrease of $2,741,000. Approximately $196,000,000 of the total valuation allowance pertains to tax deductions relating to stock option exercises for which any subsequently recognized tax benefit will be recorded as an increase to additional paid-in capital.

At December 31, 2004, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately $382,000,000, which expire at various dates from 2007 through 2023. At December 31, 2004, the Company had research credit carryforwards for federal and state purposes of approximately $49,747,000, which expire at various dates from 2007 through 2024. Under Section 382 of the Internal Revenue Code of 1986, as amended, a corporation's ability to use net operating loss and research credit carryforwards may be limited if the corporation experiences a change in ownership of more than 50 percentage points within a three-year period. During the fourth quarter of 2004, the Company hired an external firm to conduct a study under Section 382 in order to verify if we had any limitation under Section 382 of the Internal Revenue Code, as previously disclosed. Based on the results of such study, the Company has determined that no such ownership change has occurred subsequent to the Company's Initial Public Offering ("IPO"), and therefore any net operating loss or research credit incurred subsequent to the IPO is not limited under Section 382.

(13) Contingencies

Beginning in January 2002, a number of complaints asserting claims under the federal securities laws against the Company and certain of the Company's directors and officers were filed in the U.S. District Court for the Southern District of New York. Those actions were consolidated under the caption Irvine v. ImClone Systems Incorporated, et al., No. 02 Civ. 0109 (RO). In the corrected consolidated amended complaint, filed on October 22, 2002, plaintiffs asserted claims against the Company, its former President and Chief Executive Officer, Dr. Samuel D. Waksal, its former Chief Scientific Officer and then-President and Chief Executive Officer, Dr. Harlan W. Waksal, and several of the Company's other present or former officers and directors, for securities fraud under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b5-1, on behalf of a purported class of persons who purchased the Company's publicly traded securities between March 27, 2001 and January 25, 2002. The complaint also asserted claims against Dr. Samuel D. Waksal under section 20A of the Exchange Act on behalf of a separate purported sub-class of purchasers of the Company's securities between December 27, 2001 and December 28, 2001. The complaint generally alleged that various public statements made by or on behalf of the Company or the other defendants during 2001 and early 2002 regarding the prospects for FDA approval of ERBITUX® were false or misleading when made, that the individual defendants were allegedly aware of material non-public information regarding the actual prospects for ERBITUX at the time that they engaged in transactions in the Company's common stock and that members of the purported stockholder class suffered damages when the market price of the Company's common stock declined following disclosure of the information that allegedly had not been previously disclosed. The complaint sought to proceed on behalf of the alleged classes described above, sought monetary damages in an unspecified amount and sought recovery of plaintiffs' costs and attorneys' fees. On June 3, 2003, the court granted, in part, a motion to dismiss filed by all defendants and dismissed plaintiff's claims except those asserted against the Company, Dr. Samuel D. Waksal, and Dr. Harlan W. Waksal. On April 14, 2004, the court granted plaintiffs' motion for class certification.

(13) Contingencies (Continued)

Beginning on January 13, 2002, and continuing thereafter, nine separate purported shareholder derivative actions were filed against members of the Company's board of directors, certain of the Company's present and former officers, and the Company, as nominal defendant, advancing claims based on allegations similar to the allegations in the federal securities class action complaints. Four of these derivative cases were filed in the Delaware Court of Chancery and have been consolidated in that court under the caption In re ImClone Systems Incorporated Derivative Litigation, Cons. C.A. No. 19341-NC. Three of these derivative actions were filed in New York State Supreme Court in Manhattan and have been consolidated under the caption In re ImClone Systems, Inc. Shareholder Derivative Litigation, Index No. 02-100759. All of these state court actions have been stayed in deference to the proceedings in the U.S. District Court for the Southern District of New York, which have been consolidated under the caption In re ImClone Systems, Inc. Shareholder Derivative Litigation, Master File No. 02 CV 163 (RO). A supplemental verified consolidated amended derivative complaint in these consolidated federal actions was filed on August 8, 2003. It asserted, purportedly on behalf of the Company, claims including breach of fiduciary duty by certain current and former members of the Company's board of directors, among others, based on allegations including that they failed to ensure that the Company's disclosures relating to the regulatory and marketing prospects for ERBITUX were not misleading and that they failed to maintain adequate controls and to exercise due care with regard to the Company's ERBITUX application to the FDA. On January 9, 2004, the Company filed a motion to dismiss the complaint due to plaintiffs' failure to make a pre-suit demand on the Company's board of directors to institute suit or to allege grounds for concluding that such a demand would have been futile. The individual defendants filed motions on the same date, both joining in the Company's motion and seeking to dismiss the complaint for failure to state a claim.

On January 24, 2005, the Company reached an agreement in principle to settle the consolidated class action described above for a cash payment of $75.0 million, a portion of which will be paid by the Company's insurers. The settlement is subject to the negotiation and execution of definitive settlement documents and to Court approval. The Company anticipates that a hearing to consider approval of the settlement will be held in late April or early May 2005. The Company also reached an agreement in principle to settle the consolidated derivative action described above. Under the settlement, the Company will be paid $8.75 million by its insurers, which the Company intends to contribute toward the settlement of the Irvine securities class action described above after deducting amounts awarded by the Court in the derivative action for plaintiffs' attorney's fees and expenses in that action, which the Company has agreed not to oppose in an amount up to $875,000. The proposed settlement is subject to negotiation and execution of definitive settlement documents, the approval and consummation of the settlement of the Irvine class action and Court approval. As a result, the Company has recorded in its Consolidated Balance Sheets as of December 31, 2004 as Litigation settlement, a liability of $75.9 million and a receivable from our insurers of approximately $20.5 million, included in Other current assets. Net expense of $55.4 million was recorded in the fourth quarter of 2004 and reflected in the Consolidated Statement of Operations as Litigation settlement.

Separately, on September 17, 2002, an individual purchaser of the Company's common stock filed an action (Flynn v. ImClone Systems Incorporated, et al., No. 02 Civ 7499 (RO)) on his own behalf in the U.S. District Court for the Southern District of New York asserting claims against the Company, Dr. Samuel D. Waksal and Dr. Harlan W. Waksal under sections 10(b) and 20(a) of the Exchange Act and Securities and Exchange Commission Rule 10b-5-1. The Company and the other defendants have

(13) Contingencies (Continued)

reached an agreement in principle with the plaintiff to settle this matter. The Company has recorded a liability of $25,000 in the fourth quarter of 2004 related to this action.

The Company has recorded a receivable totaling $1,810,000 and $2,246,000 as of December 31, 2004 and December 31, 2003, respectively, for the portion of the legal fees related to the above matters that the Company believes are recoverable from its insurance carriers. This receivable is included in other current assets in the Consolidated Balance Sheets.

On October 8, 2003, certain mutual funds that are past or present common stockholders of BMS filed an action in New York State court against BMS, certain present or former officers and directors of BMS and the Company asserting that they were misled into purchasing or holding their shares of BMS common stock as a result of various public statements by BMS and certain present or former officers or directors of BMS, and that the Company allegedly aided and abetted certain of these misstatements. The action is styled FSS Franklin Global Health Care Fund, et al. v. Bristol-Myers Squibb Co., et al., Index No. 603168/03. On January 9, 2004, the Company and all of the other defendants served motions to dismiss the complaint for failure to state a cause of action. Argument on the motions was held on April 6, 2004. The court has not yet ruled upon the motions, and discovery has been stayed during the pendency of the motions.

The Company intends to vigorously defend against the claims asserted in this action. The Company is unable to predict the outcome of this action at this time. No reserve has been established in the financial statements because the Company does not believe that such a reserve is required to be established at this time under Statement of Financial Accounting Standards No. 5.

The Company received subpoenas and requests for information in connection with an investigation by the SEC relating to the circumstances surrounding the disclosure of the FDA "refusal to file" letter dated December 28, 2001, and trading in the Company's securities by certain ImClone Systems insiders in 2001. The Company also received subpoenas and requests for information pertaining to document retention issues in 2001 and 2002, and to certain communications regarding ERBITUX in 2000. On June 19, 2002, the Company received a written "Wells Notice" from the staff of the SEC, indicating that the staff of the SEC is considering recommending that the SEC bring an action against the Company relating to the Company's disclosures immediately following the receipt of a "refusal to file" letter from the FDA on December 28, 2001 for the Company's BLA for ERBITUX. The Company filed a Wells submission on July 12, 2002 in response to the staff's Wells Notice. There have been no recent developments in connection with this SEC investigation.

On August 14, 2002, after the federal grand jury indictment of Dr. Samuel D. Waksal had been issued but before Dr. Samuel D. Waksal's guilty plea to certain counts of that indictment, the Company filed an action in New York State Supreme Court seeking recovery of certain compensation, including advancement of certain defense costs, that the Company had paid to or on behalf of Dr. Samuel D. Waksal and cancellation of certain stock options. That action was styled ImClone Systems Incorporated v. Samuel D. Waksal, Index No. 02/602996. On July 25, 2003, Dr. Samuel D. Waksal filed a Motion to Compel Arbitration seeking to have all claims in connection with the Company's action against him resolved in arbitration. By order dated September 19, 2003, the Court granted Dr. Samuel D. Waksal's motion and the action was stayed pending arbitration. On September 25, 2003, Dr. Samuel D. Waksal submitted a Demand for Arbitration with the American Arbitration Association (the "AAA"), by which Dr. Samuel D. Waksal asserts claims to enforce the terms of his separation agreement, including provisions relating to advancement of legal fees, expenses, interest and indemnification, for which

(13) Contingencies (Continued)

Dr. Samuel D. Waksal claims unspecified damages of $10 million. The Demand for Arbitration also seeks to resolve the claims that the Company asserted in the New York State Supreme Court action. On November 7, 2003, the Company filed an Answer and Counterclaims by which the Company denied Dr. Samuel D. Waksal's entitlement to advancement of legal fees, expenses and indemnification, and asserted claims seeking recovery of certain compensation, including stock options, cash payments and advancement of certain defense costs that the Company had paid to or on behalf of Dr. Samuel D. Waksal. In response, on December 15, 2003, Dr. Samuel D. Waksal filed a Reply to Counterclaims. Arbitration hearings in this matter are scheduled to occur in October and November 2005.

The Company intends to vigorously defend against the claims asserted in this matter and to vigorously pursue its counterclaims. The Company is unable to predict the outcome of this action at this time. No reserve has been established in the financial statements because the Company does not believe that such a reserve is required to be established at this time under Statement of Financial Accounting Standards No. 5.

On March 10, 2004, the Company commenced a second action against Dr. Samuel D. Waksal in the New York State Supreme Court. That action is styled ImClone Systems Incorporated v. Samuel D. Waksal, Index No. 04/600643. By this action, the Company seeks the return of more than $21 million that the Company paid to Dr. Samuel D. Waksal, as proceeds from stock option exercises, which the Company alleges he was expected to pay over to federal, state and local tax authorities in satisfaction of his tax obligations arising from certain exercises between 1999 and 2001 of warrants and non-qualified stock options. Specifically, by this action, the Company seeks to recover: (a) $4.5 million that the Company paid to the State of New York in respect of exercises of non-qualified stock options and certain warrants in 2000; (b) at least $16.6 million that the Company paid to Samuel D. Waksal in the form of ImClone common stock, in lieu of withholding federal income taxes from exercises of non-qualified stock options and certain warrants in 2000; and (c) approximately $1.1 million that the Company paid in the form of ImClone common stock to Samuel D. Waksal and his beneficiaries, in lieu of withholding federal, state and local income taxes from certain warrant exercises in 1999-2001. The complaint asserts claims for unjust enrichment, common law indemnification, moneys had and received and constructive trust. On June 18, 2004, Dr. Samuel D. Waksal filed an Answer to the Company's Complaint. Fact discovery in this matter is underway.

The IRS has commenced audits of the Company's income tax and employment tax returns for tax years 1999 through 2001. The Company has responded to all requests for information and documents received to date from the IRS and is awaiting further requests or action from the IRS.

On March 31, 2003, the Company received notification from the SEC that it was conducting an informal inquiry into these matters and on April 2, 2003, the Company received a request from the SEC for the voluntary production of related documents and information. The Company is cooperating fully with this SEC inquiry. There have been no recent developments in connection with this SEC investigation.

On October 28, 2003, a complaint was filed by Yeda Research and Development Company Ltd. ("Yeda") against ImClone Systems and Aventis Pharmaceuticals, Inc. in the U.S. District Court for the Southern District of New York (03 CV 8484). This action alleges and seeks that three individuals associated with Yeda should also be named as co-inventors on U.S. Patent No. 6,217,866. On February 9, 2005, Yeda indicated that they intend to amend their U.S. complaint to seek sole

(13) Contingencies (Continued)

inventorship of the subject patent. The Company is vigorously defending against the claims asserted in this action. The Company is unable to predict the outcome of this action at the present time.

On March 25, 2004, an action was filed in the United Kingdom Patent Office entitled Referrer's Statement requesting transfer of co-ownership and amendment of patent EP (UK) 0 667 165 to add three Yeda employees as inventors. Also on March 25, 2004, a German action entitled Legal Action was filed in the Munich District Court I, Patent Litigation Division, seeking to add three Yeda employees as inventors on patent EP (DE) 0 667 165. The Company was not named as a party in these actions that relate to the European equivalent of U.S. Patent No. 6,217,866 discussed above; accordingly, the Company has intervened in both the German and the U.K. actions.

On May 4, 2004, a complaint was filed against the Company by Massachusetts Institute of Technology ("MIT") and Repligen Corporation ("Repligen") in the U.S. District Court for the District of Massachusetts (04-10884 RGS). This action alleges that ERBITUX infringes U.S. Patent No. 4,663,281, which is owned by MIT and exclusively licensed to Repligen. The Company intends to defend vigorously against claims asserted in this action, which is in its early stages. The Company is unable to predict the outcome of this action at the present time.

No reserve has been established in the financial statements for any of the Yeda or MIT and Repligen actions because the Company does not believe that such a reserve is required to be established at this time under Statement of Financial Accounting Standards No. 5.

The Company has not recognized withholding tax liabilities in respect of exercises of certain warrants by Robert F. Goldhammer, one of the four former officers or directors to whom warrants were issued and previously treated as non-compensatory warrants. Based on the Company's investigation, it believes that, although such warrants were compensatory, such warrants were received by Mr. Goldhammer in connection with the performance of services by him in his capacity as a director, rather than as an employee, and, as such, are not subject to tax withholding requirements. In addition, in 1999, Mr. Goldhammer erroneously received a portion of a stock option grant in the form of incentive stock options, which under federal law may only be granted to employees. There can be no assurance, however, that the taxing authorities will agree with the Company's position and will not assert that the Company is liable for the failure to withhold income and employment taxes with respect to the exercise of such warrants and any stock options by Mr. Goldhammer. If the Company became liable for the failure to withhold taxes on the exercise of such warrants and any stock options by Mr. Goldhammer, the aggregate potential liability, exclusive of any interest or penalties, would be approximately $8,300,000.

The Company has not recognized accruals for penalties and interest that may be imposed with respect to the withholding tax issues previously described and other related contingencies, including the period covered by the statute of limitations and the Company's determination of certain exercise dates, because it does not believe that losses from such contingencies are probable, or in the event that any taxing authority makes a claim for penalties or interest, the Company believes that it will be able to settle the total amount asserted (including any liability for taxes) for an amount not in excess of the liability for taxes already accrued with respect to the relevant withholding tax issue. With respect to the statute of limitations and the Company's determination of certain exercise dates, while the Company does not believe a loss is probable, there is a potential additional liability with respect to these issues that may be asserted by a taxing authority. If taxing authorities assert such issues and prevail related to these withholding tax issues and other related contingencies, including penalties, the liability that could

(13) Contingencies (Continued)

be imposed by taxing authorities would be substantial. The potential interest on the withholding tax liabilities recorded on the Consolidated Balance Sheets could be up to a maximum amount of approximately $8,000,000 at December 31, 2004. Potential additional withholding tax liability on other related contingencies amounts to approximately $8,000,000, exclusive of any interest or penalties, and excluding the amount potentially attributable to Mr. Goldhammer noted above.

(14) Commitments

Leases

The Company leases office, operating and laboratory space under various lease agreements. Rent expense was approximately $3,748,000, $3,421,000 and $3,376,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

In October 2001, the Company entered into a sublease for a four-story building at 325 Spring Street, New York, New York, which includes between 75,000 and 100,000 square feet of usable space. The sublease has a term of 22 years, followed by two five-year renewal option periods. The future minimum lease payments remaining at December 31, 2004, are approximately $47,153,000 over the term of the sublease. In order to induce the sublandlord to enter into the sublease, the Company made a loan to the sublandlord in the principal amount of a $10,000,000 note receivable, of which $9,213,000 is outstanding as of December 31, 2004. The loan is secured by a leasehold mortgage on the prime lease as well as a collateral assignment of rents by the sublandlord. The loan is payable by the sublandlord over 20 years and bears interest at 5½% in years one through five, 6½% in years six through ten, 7½% in years eleven through fifteen and 8½% in years sixteen through twenty. In addition, the Company paid the owner a consent fee in the amount of $500,000. The Company spent significant time analyzing its options with respect to this sublease and in June of 2004, the Company concluded that it will move forward with plans to develop the property for occupancy. The Company plans to house at this location its Research departments, which currently includes both antibody and small molecule research teams.

The Company leases its biologics research and corporate headquarters in New York City. In August 2004, the Company modified its existing operating lease for its corporate headquarters in New York City. The modification extends the term of the lease, which was to expire at December 31, 2004, for an additional ten years for a portion of the premises and by an additional four years for the space that houses its Research department. As noted above, the Company plans to consolidate its research departments to its 325 Spring Street, New York location. The future minimum lease payments remaining at December 31, 2004, are approximately $12,133,000 over the term of the lease.

In June 2004, the Company entered into an operating lease for a building located at 59-61 ImClone Drive in Branchburg, New Jersey. The building contains approximately 54,247 square feet of floor area. The lease expires on December 31, 2020 with no option to renew or extend beyond such date. The future minimum lease payments at December 31, 2004 are $10,928,000.

(14) Commitments (Continued)

In May 2001, the Company entered into an operating lease for a 4,000 square foot portion of a 15,000 square foot building and an adjacent 6,250 square foot building (collectively the "Brooklyn facility") in Brooklyn, New York. The Company has completed renovations to the premises and relocated its chemistry and high throughput screening personnel during November 2002, from its corporate headquarters and research facility in downtown New York. The term of the lease is for five years and contains five successive one-year extensions. The future minimum lease payments under this commitment are $246,000. Effective February 1, 2005, the Company entered into an operating lease for approximately 2,269 square feet of a building known as 760 Parkside Avenue in Brooklyn, New York. The term of the lease is for fifteen months, to coincide with the term of the Brooklyn facility lease. The future minimum lease payments are $71,000.

Future minimum lease payments under the operating leases are as follows: (in thousands)

Year ending December 31,	
2005	$ 5,064
2006	4,952
2007	4,935
2008	3,771
2009	3,805
2010 and thereafter	48,886
	$71,413

Employment Agreements

In September 2001 and February 2002, the Company entered into employment agreements with six senior executive officers, including, in September 2001, then-President and Chief Executive Officer, Dr. Samuel D. Waksal, and then-Chief Operating Officer, Dr. Harlan W. Waksal. The September 2001 agreements each had three-year terms and the February 2002 agreement had a one-year term. The February 2002 agreement was amended in April 2002 and is now expired. The employment agreements provided for stated base salaries, minimum bonuses and benefits aggregating $3,765,000 annually. Dr. Samuel D. Waksal resigned and entered into a separation agreement with the Company in May 2002 and Dr. Harlan W. Waksal was appointed President and Chief Executive Officer. Dr. Harlan W. Waksal resigned from the position of President and Chief Executive Officer and was named the Company's Chief Scientific Officer in April 2003. On July 18, 2003, Dr. Harlan W. Waksal provided the Company with notice of his termination effective July 22, 2003 in connection with his employment agreement. Pursuant to his employment agreement with the Company, Dr. Harlan W. Waksal received a lump sum payment totaling approximately $4,424,000 and is entitled to receive for defined periods of time the continuation of certain benefits including health care and life insurance coverage through July 2006, with an estimated cost of $38,000. The related expense of $4,462,000 is included in marketing, general and administrative expenses in the Consolidated Statements of Operations for the year ended December 31, 2003. In addition, all outstanding stock options held by Dr. Harlan W. Waksal, comprising options to purchase 1,000,000 shares of common stock of the Company at a per share exercise price of $50.01 that were granted on September 19, 2001, were deemed amended such that the 666,666 options that remained unvested as of the date of his resignation vested immediately on that date. The amended stock option awards can be exercised at any time until the end of the term of

(14) Commitments (Continued)

such awards. No compensation expense attributable to the stock options was recorded because the change in terms is in accordance with the terms of the original award and also because the fair market value of the Company's common stock was below the $50.01 exercise price on the date the option award was amended. In October 2002, the Company accepted the resignation and entered into a separation agreement with the Company's former General Counsel, John B. Landes, who held one of the aforementioned employment agreements. See Note 19 for discussion of the separation agreements.

On March 19, 2004, the Company entered into an employment agreement with Daniel S. Lynch in regards to his employment as Chief Executive Officer. The term of Mr. Lynch's employment agreement is three years, provided that the term will automatically renew for one-year periods on the third anniversary of this effective date and on each anniversary of the effective date thereafter, unless either party notifies the other of its intent not to renew.

Supported Research

The Company has entered into various research and license agreements with certain academic institutions and others to supplement the Company's research activities and to obtain rights to certain technologies. The agreements generally require the Company to fund the research, to pay milestones upon the achievement of defined events, such as the submission or approval of regulatory filings and to pay royalties based upon percentages of revenues, if any, on sales of products developed from technology arising under these agreements.

Consulting Agreements

The Company has consulting agreements with several of its Scientific Advisory Board members and other consultants. These agreements generally are for a term of one year and are terminable at the Company's option.

Contract Services

In December 1999, the Company entered into a development and manufacturing services agreement with Lonza. This agreement was amended in April 2001 to include additional services. Under the agreement, Lonza was responsible for process development and scale-up to manufacture ERBITUX in bulk form under current Good Manufacturing Practices ("cGMP"). These steps were taken to assure that the manufacturing process would produce bulk material that conforms with the Company's reference material and to support in part, the Company's regulatory filings with the FDA. The Company did not incur any costs during 2004 or 2003 and had incurred approximately $38,000 for the year ended December 31, 2002 and $7,068,000 from inception through December 31, 2004 under the development and manufacturing services agreement. As of December 31, 2002, Lonza completed its responsibilities under the development and manufacturing services agreement.

In September 2000, the Company entered into a three-year commercial manufacturing services agreement with Lonza relating to ERBITUX. This agreement was amended in June 2001, September 2001, and August 2003 to include additional services and potentially to extend the term of the agreement. The total cost for services to be provided under the commercial manufacturing services agreement was approximately $86,913,000. The Company did not incur any costs during 2004 and had

(14) Commitments (Continued)

incurred costs of $23,189,000 and $51,520,000 for the years ended December 31, 2003 and 2002, respectively, and $85,022,000 was incurred from inception through December 31, 2004, for services provided under the commercial manufacturing services agreement. All existing commitments under this agreement were completed during the year ended December 31, 2003, but an August 2003 amendment to the agreement allows for potential manufacture of a limited number of additional batches.

In December 2001, the Company entered into an agreement with Lonza to manufacture ERBITUX at the 2,000-liter scale for use in clinical trials by Merck KGaA. The costs associated with the agreement are reimbursable by Merck KGaA and accordingly are accounted for as collaborative agreement revenue and such costs are also included in research and development expenses in the Consolidated Statements of Operations. The Company did not incur any costs associated with this agreement during the year ended December 31, 2004 or 2003, and $4,700,000 was incurred in the year ended December 31, 2002. From inception to December 31, 2004, the Company incurred approximately $7,183,000 for services provided under this agreement. As of December 31, 2003, Merck KGaA had reimbursed the Company in full for all the services provided under this agreement and Lonza has completed its responsibilities under such agreement.

On January 2, 2002, the Company executed a letter of intent with Lonza to enter into a long-term supply agreement. The long-term supply agreement would have applied to a large scale manufacturing facility that Lonza is constructing, which would have been able to produce ERBITUX in 20,000-liter batches. The Company paid Lonza $3,250,000 upon execution of the letter of intent for the exclusive right to negotiate a long-term supply agreement for a portion of the facility's manufacturing capacity. In September 2002, the Company wrote-off the deposit as a charge to marketing, general and administrative expenses, because the exclusive negotiation period ended on September 30, 2002. In light of the assistance the Company provided to BMS with respect to preserving and then relinquishing the manufacturing capacity described above, BMS paid the Company $3,250,000 in April 2003 and this amount is recognized as a reduction to marketing, general and administrative expenses in the year ended December 31, 2003.

License Agreements

The Company has an exclusive license from the University of California to an issued United States patent for the murine form of ERBITUX, our EGF receptor antibody product. The Company has exclusively licensed from Rhone-Poulenc Rorer Pharmaceuticals, now known as Aventis, patent applications seeking to cover the therapeutic use of antibodies to the EGF receptor in conjunction with anti-neoplastic agents. The agreements with the University of California and Aventis require the Company to pay royalties on sales of ERBITUX that are covered by these licenses. In January 2005, the Company concluded license negotiations with Genentech and Centocor for patents relating to the use and manufacture of ERBITUX. The Company has license agreements with Genentech for rights to patents covering certain use of epidermal growth factor receptor antibodies and with both Genentech and Centocor for rights to patents covering various aspects of antibody technology. Our agreements with both Genentech and Centocor require us to pay royalties on the sale of ERBITUX that are covered by these licenses. For ERBITUX use in combination with anti-neoplastic agents, royalty expense for all licenses, including Genentech, Centocor, Aventis and the University of California, is approximately 12.75 percent of in-market net sales of Erbitux by our corporate partner in North

(14) Commitments (Continued)

America. The Company receives reimbursements, which is included in collaborative agreement revenue, for a portion of these royalty expenses resulting in a net royalty expense of approximately 8.25%. After the first quarter of 2006, gross royalty expense will decrease to approximately 9.75% and net royalty expense will decrease to approximately 7.25%. For ERBITUX monotherapy use, gross and net royalty expenses will be reduced by approximately 1% because certain licenses are not applicable.

(15) Employee Benefit Plans

Defined Contribution Plan

All employees of the Company who meet certain minimum age and period of service requirements are eligible to participate in a 401(k) defined contribution plan. The 401(k) plan allows eligible employees to defer up to 25 percent of their annual compensation, subject to certain limitations imposed by federal law. The amounts contributed by employees are immediately vested and non-forfeitable. Under the 401(k) plan, the Company, at management's discretion, may match employee contributions and/or make discretionary contributions. Neither the employee contributions nor voluntary matching contributions are invested in the Company's securities. Total expense incurred by the Company was $580,000, $392,000 and $314,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Change in Control Plan

During 2004, the Board of Directors of the Company adopted a Change in Control Plan to maintain the focus of certain key employees of the Company on the business, mitigate the distractions that could be caused if the Company were to become the target of an acquisition strategy, and provide certain benefits to the covered employees if a change in control of the Company (as such term is defined in the plan) occurs and/or the employee's employment is terminated in connection with such change in control. Participants in the Change in Control Plan are determined by the Compensation Committee and include all the named executive officers.

In the event of a Change in Control, all equity-based compensation awards held by the plan participants will vest in full (unless the Compensation Committee determines that the participants' awards will be substituted for equity awards in the surviving entity of equivalent economic value) and any deferred compensation of participants will become nonforfeitable. In addition, if a participant in the Change in Control Plan is terminated in connection with a change in control by the Company without cause or by the participant for good reason (as such terms are defined in the plan), the Company will pay to the participant a cash payment equal to the participant's earned but unpaid base salary and bonus, unreimbursed expenses, any other accrued obligations, a pro rata bonus based on target bonus for the year of termination, and a multiple of base salary and bonus (with the multiplier ranging from 0.5 to three based on the tier assigned to the participant under the plan).

In connection with a termination described in the preceding sentence, if the participant signs a waiver and release of claims against the Company, each participant will vest in full in all long-term incentive arrangements he or she has with the Company and be entitled to continued health coverage for six to 18 months (based on the participant's plan tier) and outplacement services for six months. These benefits are reduced by any other severance amounts for which the participants are eligible

(15) Employee Benefit Plans (Continued)

under any other arrangement of the Company or its subsidiary. As a condition to receipt of these benefits, each participant agrees to be bound by noncompetition, nonsolicitation, confidentiality, return of Company property, and cooperation covenants contained in the plan. If a plan participant becomes subject to the change-in-control golden parachute excise tax under Section 4999 of the Code and the aggregate parachute payment exceeds the safe harbor amount by ten percent or more, the plan provides that the Company shall pay to the participant a tax gross-up payment such that after payment by the participant of all federal, state and local excise, income, employment, Medicare and other taxes resulting from the payment of the parachute payments and the tax gross-up payments, the participant retains an after-tax amount equal to the amount that he or she would have retained in the absence of the parachute excise tax.

Senior Executive Severance Plan

The Compensation Committee approved on February 10, 2005 a Senior Executive Severance Plan (the "Plan") to enhance the predictability of treatment for executives at the level of Vice President, Senior Vice President and Executive Vice President whose employment with the Company is terminated by the Company without cause (as such concept is explained in the Plan).

As a condition to receipt of benefits under the Plan, a participating employee must sign an agreement and general release in a form acceptable to the Plan administrator under which the participant agrees to certain confidentiality and non-solicitation provisions for a period of one year following his or her employment termination date, agrees to certain non-competition provisions for the duration of the employee's receipt of severance pay, and releases and discharges the Company and related entities (as well as any third party for whom the employee provides services on the Company's behalf) from any and all claims and liabilities relating to the employee's employment with the Company or the termination of the employee's employment. Receipt of benefits under the Plan is also contingent upon the employee's continued employment through the employment termination date designated by the Company. The severance amounts payable to an employee under the Plan will be reduced, dollar-for-dollar, by the amount of any other termination payments paid or payable to the employee under any other plan, program or law (excluding any right to exercise stock options, any unemployment benefits payable in accordance with state law and payment for accrued but unused vacation).

The Senior Vice Presidents and Executive Vice Presidents who participate in the Plan and sign the above-described agreement and release upon their termination without cause are entitled to receive an amount equal to one year's base salary as severance and, if the employee would otherwise be eligible to elect employee-paid continued coverage under COBRA, Company-provided health insurance coverage for one year following a termination without Cause, subject to cessation upon the employee's becoming eligible for similar coverage offered by another employer. Senior Vice Presidents and Executive Vice Presidents would also be entitled continue their non-voluntary life insurance coverage provided by the Company with the premiums paid by the Company for 12 months after a termination without cause, subject to cessation when the employee becomes eligible for coverage under a life insurance plan or policy of another employer. Vice Presidents who meet the above criteria are entitled to the greater of six months' base salary or two weeks' base salary for each year of service with the Company, as well as six months' Company-paid health and life insurance coverage, subject to the conditions described above.

(16) Supplemental Cash Flow Information and Non-cash Investing and Financing Activities: (in thousands)

	Year Ended December 31,		
	2004	2003	2002
Cash paid for:			
Interest, net of amounts capitalized	$ 8,729	$ 7,460	$11,469
Taxes	6,167	550	420
Non-cash investing and financing activities:			
Change in net unrealized loss (gain) in securities available-for-sale	(1,118)	(1,242)	(1,604)
Capital asset and lease obligation addition	—	—	58
Options exercised and exchanged for mature shares of common stock	200	—	—
Common stock issued from conversion of 5½% subordinated convertible notes	239,997	—	—
Reclassification of unamortized deferred financing costs on the 5½% subordinated convertible notes to equity	1,193	—	—

(17) Certain Related Party Transactions

The Company used Concord Investment Management, a New York-based money management firm, to manage a substantial portion of the Company's debt security portfolio. The Company's former Chairman of the Board was a limited partner of Concord International Holdings, LP. Concord International Holdings, LP is a holding company that controls Concord Investment Management. The Company paid investment management fees to Concord Investment Management of approximately $95,000, $252,000 and $452,000 in the years ended December 31, 2004, 2003 and 2002, respectively. In May of 2004, the Company switched investment managers and no longer uses Concord Investment Management.

(18) Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, receivables from corporate partners, accounts payable, and other current liabilities at December 31, 2003 and 2002 approximate fair value because maturities are less than one year in duration. The fair value of the 1⅜% convertible senior notes of $600,000,000 was approximately $555,750,000 at December 31, 2004 based on their quoted market price. The fair value of the 5½% convertible subordinated notes of $240,000,000 at December 31, 2003 was $243,000,000 based on their quoted market price.

(19) Separation Agreements

On May 22, 2002, the Company accepted the resignation of its then-President and Chief Executive Officer, Dr. Samuel D. Waksal. In connection with the resignation, on May 24, 2002 the Company and Dr. Samuel D. Waksal executed a separation agreement whereby Dr. Samuel D. Waksal received a

(19) Separation Agreements (Continued)

lump sum payment totaling $7,000,000 and was entitled to receive for defined periods of time the continuation of certain benefits including health care and life insurance coverage with an estimated cost of $283,000. The related expense of $7,283,000 was included in Marketing, general and administrative expenses in the Consolidated Statements of Operations for the year ended December 31, 2002. In addition, 1,250,000 stock option awards granted to Dr. Samuel D. Waksal on September 19, 2001 which were exercisable at a per share exercise price of $50.01 and constituted all outstanding stock option awards held by Dr. Samuel D. Waksal, were deemed amended such that the unvested portion vested immediately as of the date of termination. The amended stock option awards can be exercised at any time until the end of the term of such awards. No compensation expense was recorded because the fair market value of the Company's common stock was below the $50.01 exercise price on the date the option award was amended.

In October 2002, the Company accepted the resignation of its then-General Counsel, John B. Landes. The Company and Mr. Landes executed a separation agreement whereby Mr. Landes was to receive his stated base salary from the date of termination through October 2003 and certain benefits including healthcare and life insurance coverage through December 2002. In May 2003, the Company suspended payments under this separation agreement in response to the withholding tax liabilities discussed in Note 8.

During 2004 the Company entered into separation agreements with six employees. The total severance paid in relation to these agreements was $330,000. In addition, some of these people were entitled to continue to vest in their stock options and as a result the Company recorded a stock compensation charge of $2,028,000.

(20) Annual Incentive Plan

In September 2003, the shareholders approved and the Company adopted the Annual Incentive Plan. The plan permits the Compensation Committee to grant performance awards based upon pre-established performance goals to executives of the Company and its subsidiaries selected by the Compensation Committee, whether or not such executives, at the time of grant, are subject to the limit on deductible compensation under Section 162(m) of the Internal Revenue Code. The Annual Incentive Plan became effective as of January 1, 2003.

(21) Quarterly Financial Data (Unaudited)

The tables below summarize the Company's unaudited quarterly operating results for 2004 and 2003 (in thousands, except per share data). The diluted income per share for all periods presented below has been restated to conform to EITF Issue No. 04-8 "The Effect of Contingently Convertible Debt on Diluted Earnings per Share." Revenues for the first, second and third quarters of 2004 have been reclassified to conform to the fourth quarter presentation. The reclassification relates to royalty expense for agreements that were under negotiations during these quarters and the estimated royalty obligation was recorded net of reimbursement. The Company finalized these agreements in January of

(21) Quarterly Financial Data (Unaudited) (Continued)

2005 and has reclassified prior quarters to reflect the reimbursed portion of the royalty expense in collaborative agreement revenue.

	Three months ended			
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004
Revenues	$110,164	$ 73,768	$ 97,461	$107,297
Net income (loss)	62,736	24,312	39,783	(13,178)
Basic net income (loss) per share allocable to common stockholders	0.83	0.31	0.48	(0.16)
Diluted net income (loss) per share allocable to common stockholders	$ 0.76	$ 0.29	$ 0.44	$ (0.16)

	Three months ended			
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
Revenues	$ 19,571	$ 17,875	$ 23,583	$ 19,801
Net loss	(34,811)	(34,828)	(16,520)	(26,343)
Basic and diluted net loss per share allocable to common stockholders	$ (0.47)	$ (0.47)	$ (0.22)	$ (0.35)