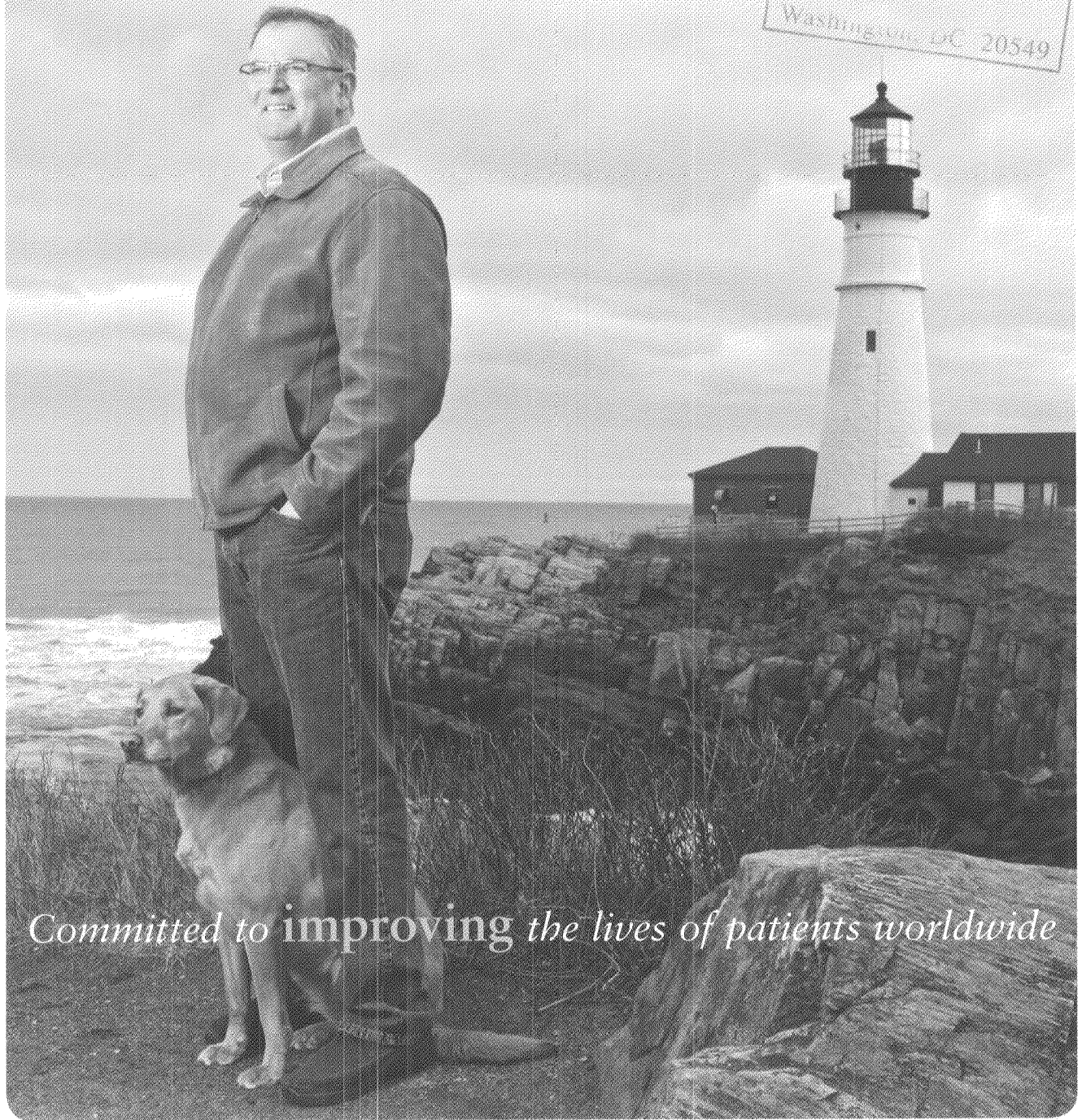




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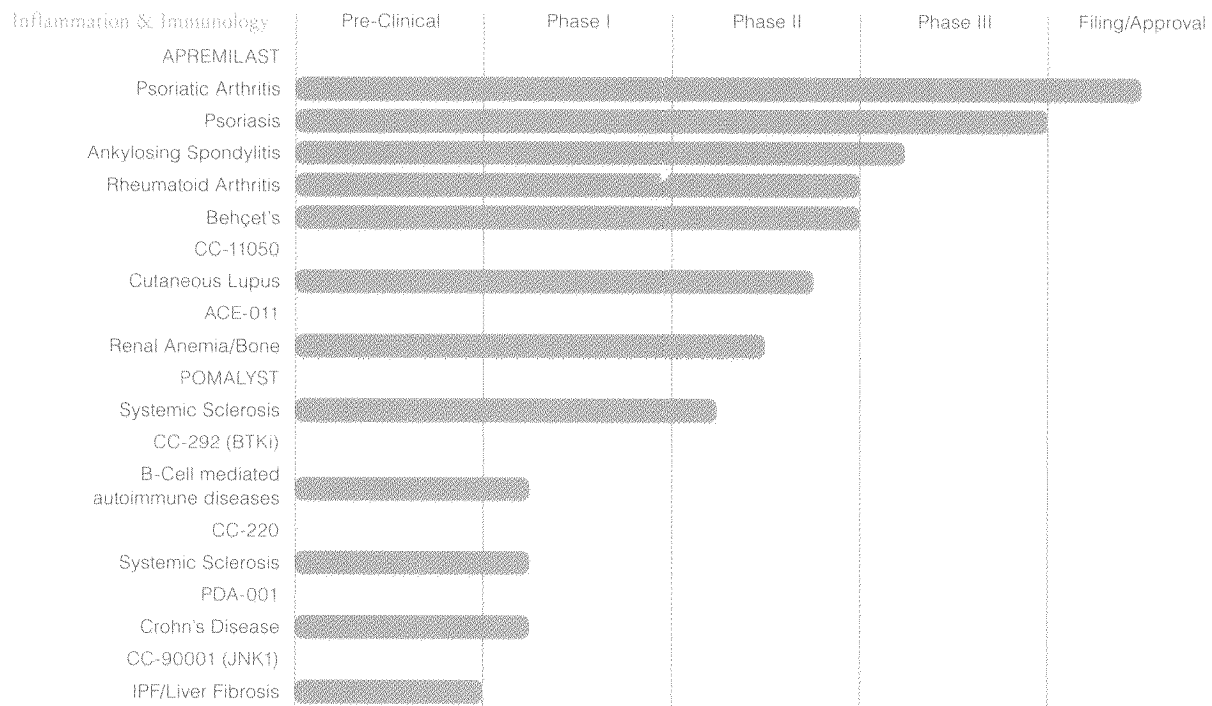
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*Committed to improving the lives of patients worldwide*

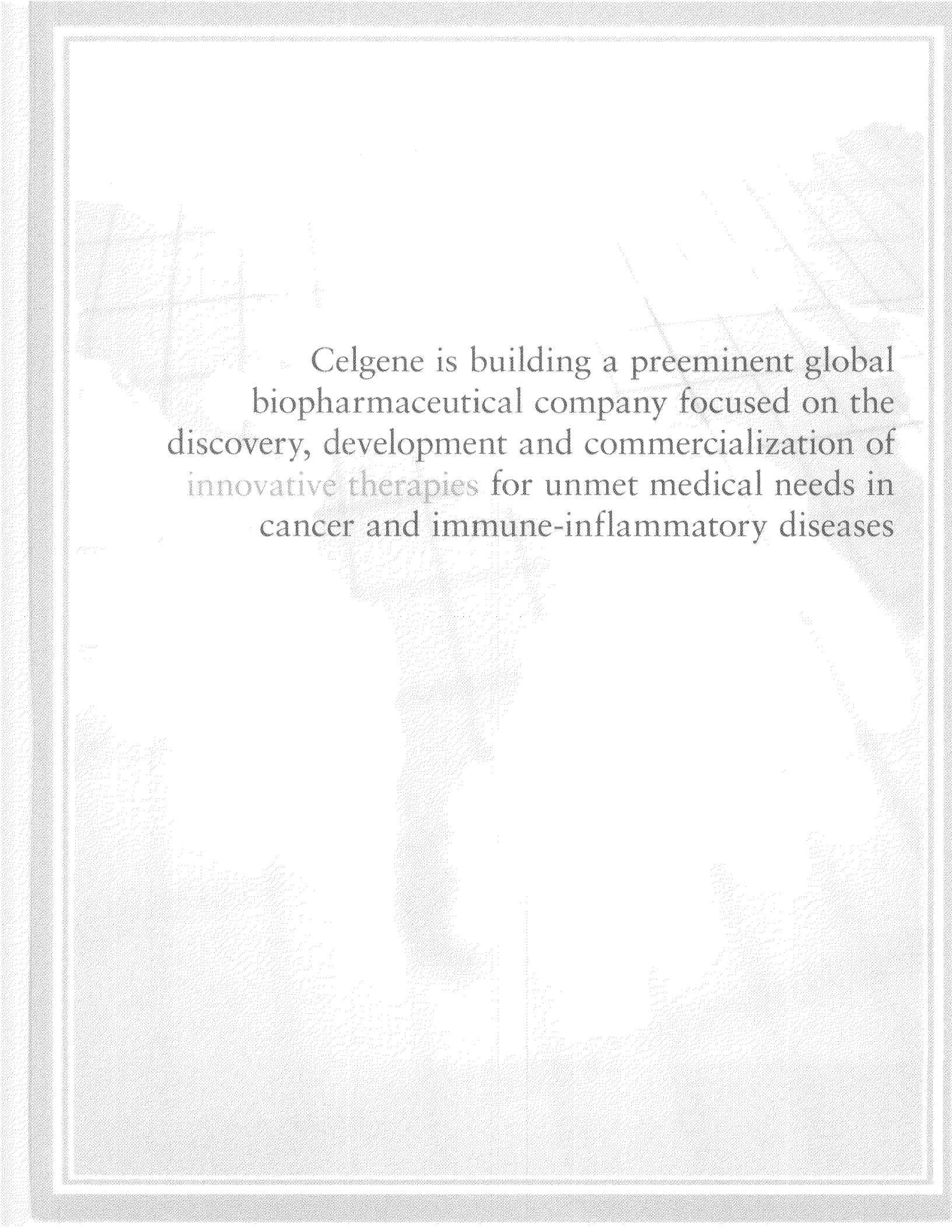


2012 Annual Report



RESEARCH & EARLY DEVELOPMENT



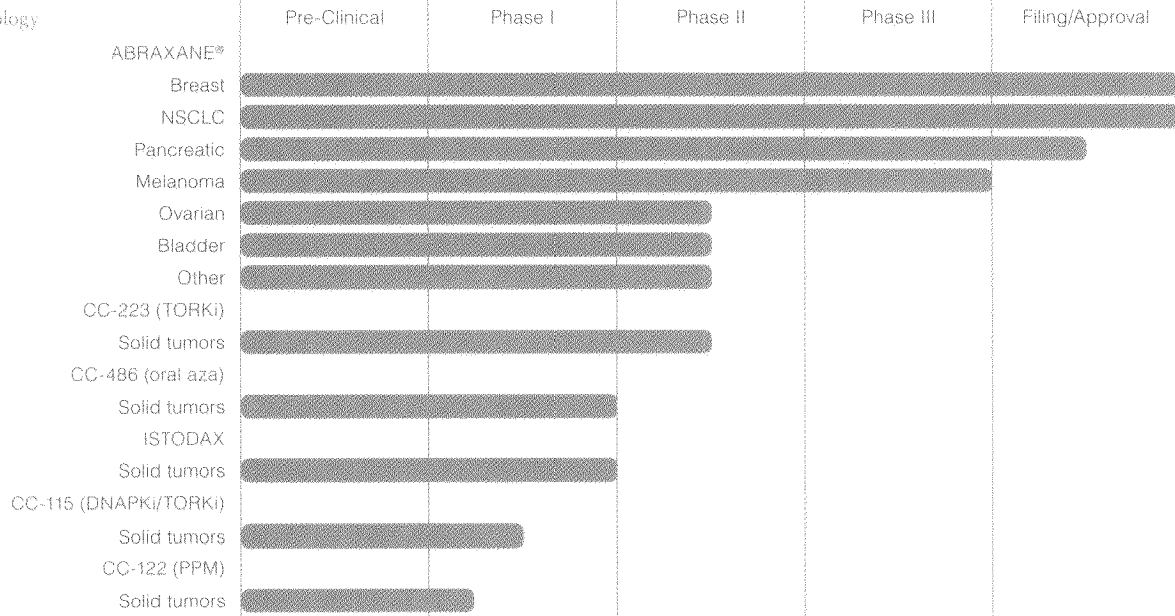


Celgene is building a preeminent global biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for unmet medical needs in cancer and immune-inflammatory diseases

Hematology



Oncology



## Our Four Strategic Imperatives

### Operational Excellence

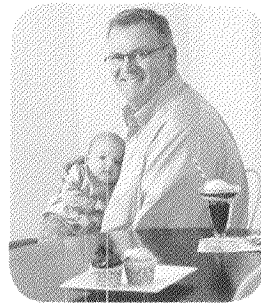
1



When **Mike Kacsor** was first diagnosed with multiple myeloma sixteen years ago, his first thought was of his fiancée, Karen. He told her that he would understand if she wanted to call off the wedding. Karen was having none of that, and two months later, they were married. An environmental engineer in Toronto, Mike underwent two bone marrow transplants, but the disease progressed. It was then that he started on REVLIMID in combination with dexamethasone. "I jumped at the chance," he says, and "it has been a successful drug for me." Mike credits Karen's unfailing support, strength and love—and REVLIMID—with the fact that his treatment has been successful. "I have a great life," Mike says.

### Capitalizing on Strengths in Hematology

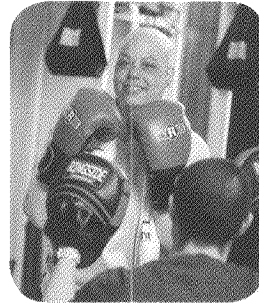
2



As a participant in a clinical trial for multiple myeloma, every two weeks **David Parrott**, of Portland, Maine, gets up before dawn for the two-hour drive to the Dana-Farber Cancer Institute in Boston for his treatment. But he doesn't mind at all. Quite the contrary. "I look forward to going," he says, "because the treatments are really helping." Those treatments include POMALYST—which has proven effective. The father of two daughters, he and wife, Janet, recently welcomed their first grandchild—Scarlette—for whom he enjoys babysitting. David is encouraged about how things are going. "I thank Celgene, Dana-Farber, and my doctor for helping me manage this and enabling me to enjoy my life."

### Building New Businesses in Oncology & Inflammation & Immunology

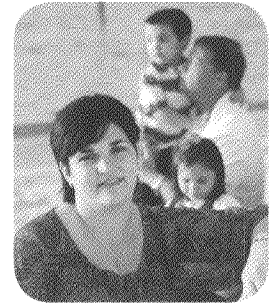
3



A health care professional, **Lynne Jacoby** knew something was wrong with how she was feeling. But even she was shocked when her doctor told her she had stage 4 pancreatic cancer, and that her life span would likely be measured in weeks. Lynne was fortunate that one of the nation's leading physicians in treating pancreatic cancer was right in her Phoenix backyard, and she wasted no time enrolling in a clinical trial for ABRAXANE. That was almost a year ago. Today, Lynne is enjoying a "happy life" with her spouse, Jennifer.

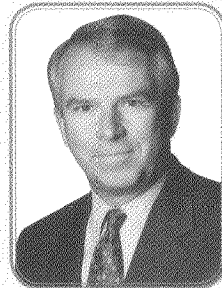
### Sustaining Innovation and Long-Term Growth

4



The mother of a 3-year-old boy and 5-year-old girl, **Wendy Ryder** works as an executive assistant to a corporate CEO in the Tampa Bay area. She had begun to experience joint pain and also noticed a cyst on her ring finger. When the pain started to become severe, she consulted a rheumatologist. Wendy was diagnosed with psoriatic arthritis, and put on a regimen of anti-inflammatory drugs and cortisone. After the treatment failed in providing much relief, her doctor was able to enroll her in a new trial of Apremilast. "I feel better and more able to fully participate in our family activities," Wendy reports.

## To Our Shareholders:



Robert J. Hugin

*Chairman and Chief Executive Officer*

2012 was an exceptional year for Celgene. Revenues were strong, earnings per share exceeded our initial expectations and operating margins improved significantly, highlighting the power and productivity of our business model. We actively managed our balance sheet and capital structure to enhance shareholder returns. As importantly, we achieved several transformational clinical milestones and advanced our key pipeline programs. We delivered substantial value for our stakeholders while fulfilling our promise to help the tens of thousands of patients globally who can benefit from our innovative therapies.

These results reflect strong operating momentum and execution worldwide, positioning us extraordinarily well for our next phase of growth. From 2013 to 2017 we are committed to delivering annual growth of 19 percent and 25 percent in net product sales and adjusted earnings, respectively. To achieve these targets, we are focused on four strategic imperatives that guide and direct what we do every day.

Specifically:

- Operational Excellence
- Capitalizing on Strengths in Hematology
- Building New Businesses in Oncology and Inflammation and Immunology
- Sustaining Innovation and Long-Term Growth

### Operational Excellence

In 2012, our performance was driven by strength across key operational and financial metrics. Total revenue grew by 14 percent to \$5.5 billion and adjusted earnings per share increased 30 percent to \$4.91. We achieved a higher rate of growth in earnings by leveraging our global infrastructure and improving operating efficiency. Our adjusted operating margin increased to 48.1 percent, a 300 basis point improvement over 2011. We captured these efficiency gains while continuing

to make substantial investments in Research and Development and advancing over 100 clinical trials evaluating our products in an expanding range of diseases.

Our commercial teams were focused on delivering strong product volume growth globally that resulted in net sales of \$5.4 billion, a 15 percent increase over the previous year. We gained market share for our core cancer therapeutics and launched ABRAXANE for a new indication in the U.S. Our top three therapies returned double-digit increases in sales from the previous year:

- REVLIMID full year sales were \$3,767 million, an increase of 17 percent.
- VIDAZA full year sales were \$823 million, an increase of 17 percent.
- ABRAXANE full year sales were \$427 million, an increase of 11 percent.

We continued to optimize our capital structure by taking advantage of the favorable interest rate environment and issuing \$1.5 billion in senior unsecured notes. In addition, we returned \$2.1 billion in capital to shareholders through our share repurchase program. Since implementing the program four years ago, we have repurchased over \$5 billion of our common stock.

Our company is stronger today than it has ever been. We are extremely well positioned to build on the important progress we achieved in 2012 and to seize the opportunities in 2013 and beyond.

#### Capitalizing on Strengths in Hematology

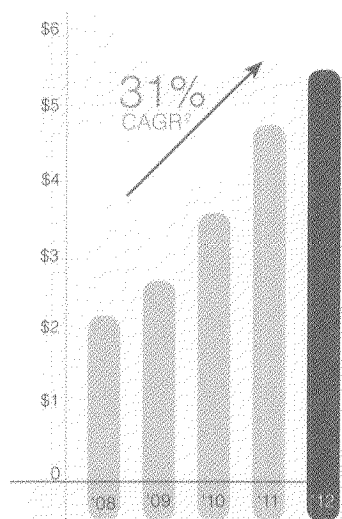
We are expanding our global leadership position in hematology as we continue to bring new therapies to treat patients with devastating diseases. Earlier this year, the U.S. Food and Drug Administration (FDA) approved POMALYST, our newest immunomodulatory agent, for patients with multiple myeloma who have progressed in their disease after receiving at least two prior therapies including REVLIMID and bortezomib. Our POMALYST regulatory submission to the European Medicines Agency (EMA) is under review with a decision expected later this year. Importantly, this submission is supported by a randomized Phase III study in which POMALYST demonstrated a statistically significant and clinically meaningful improvement in overall survival.

The addition of POMALYST represents an important new therapy for patients with heavily pre-treated disease and few remaining treatment options—complementing our existing portfolio of multiple myeloma treatments. Our flagship product, REVLIMID, is well established as a backbone of multiple myeloma therapy in our core markets. We continue to expand our geographic reach into emerging markets with the approval earlier this year in China. Gaining access in other markets, such as Brazil, Korea, Mexico and Russia, is a key focus. We expect these markets to make meaningful contributions to REVLIMID's long-term growth.

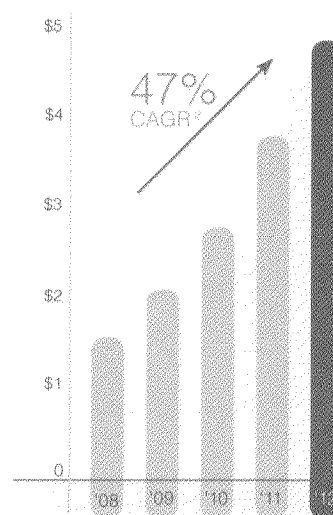
A top near-term priority is to advance REVLIMID in multiple myeloma to patients with previously untreated disease. Last year we experienced a delay in achieving this goal, as we withdrew our European marketing application for newly diagnosed multiple myeloma and maintenance therapy (NDMM). We made this decision to allow time for the datasets from MM-015, CALGB 104 and IMF 0502, the trials supporting the application, to

Our focus on operating excellence has produced a track record of outstanding financial results over the last five years. Total revenue has increased 31% annually with a corresponding 47% annual increase in adjusted earnings.

Total Revenue<sup>1</sup>  
(dollars in billions)



Earnings Per Share<sup>1</sup>  
(dollars per share)



Notes: 1) Adjusted, includes impact of acquisitions. 2) CAGR calculated using 2007 and 2012.

further mature. Throughout 2013 we expect updates to these trials, in addition to new data from the largest Phase III trial conducted to date in this setting—MM-020. Collectively, these data will shape our global NDMM regulatory strategy going forward.

We are making good progress advancing programs that evaluate REVLIMID in new diseases. The FDA recently granted priority review to our supplemental New Drug Application (NDA) for relapsed or refractory mantle-cell lymphoma. A decision is expected in June. Additional Phase III trials are either underway or planned to evaluate a variety of clinical strategies with REVLIMID in more common forms of lymphoma, such as diffuse large B-cell and follicular non-Hodgkin's lymphoma (NHL). Finally, earlier this year we completed enrollment in a Phase III trial in elderly patients with chronic lymphocytic leukemia (CLL). Our Phase III trial testing REVLIMID as maintenance therapy in CLL continues to enroll patients. With each and every completed study, we expand our understanding of how and in which settings REVLIMID can benefit patients.

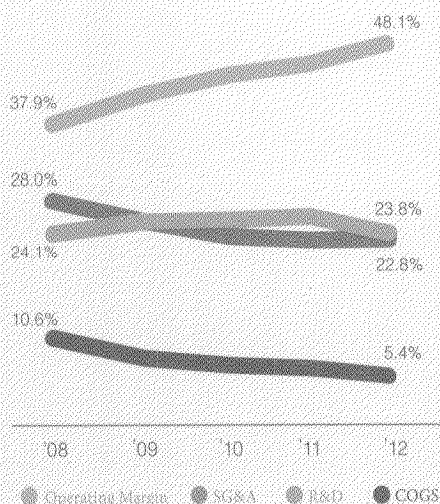
### Building New Businesses in Oncology and Inflammation and Immunology

The last 12 months bear witness to an unprecedented number of successful outcomes validating the potential of our Oncology and Inflammation and Immunology businesses. We expect these businesses to become meaningful contributors to our future growth leading to a further diversification of our revenue mix.

In Oncology, the FDA approved ABRAXANE for patients with advanced non-small cell lung cancer last fall. During the same period, ABRAXANE achieved the primary endpoint of progression-free survival in a Phase III trial for metastatic melanoma marking the first time in decades that a chemotherapeutic agent has shown a clinically superior result compared to a standard of care in that disease. Shortly after achieving these results, ABRAXANE in combination with gemcitabine demonstrated a statistically significant and clinically meaningful improvement in overall survival in a Phase III trial for metastatic pancreatic cancer. We believe these findings further differentiate

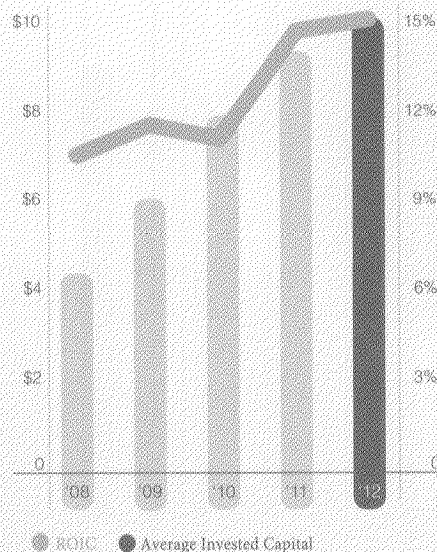
Our business model is delivering significant leverage off our global infrastructure and an increasing rate of return on our invested capital. We are making effective internal and external investments resulting in increased value to our shareholders.

Operating Margin<sup>1</sup>



Notes: <sup>1</sup> Adjusted

Return on Investment Capital  
(dollars in billions)





ABRAXANE from other chemotherapeutics and form the basis for future development in combination with novel agents across a range of cancers. Based on the results in pancreatic cancer, we are submitting for regulatory approvals globally that enable patients to begin benefiting from this therapy.

In Inflammation and Immunology (I&I), apremilast achieved positive results in five Phase III trials spanning over 3,000 patients with psoriatic arthritis (PsA) and moderate-to-severe psoriasis. These large, underserved markets are in need of new treatment options. Earlier this year, we submitted an NDA in the U.S. for PsA and plan to submit regulatory filings globally for PsA and psoriasis during the second half of the year. Beyond the initial indications, we are evaluating apremilast in a Phase III trial for ankylosing spondylitis and in other debilitating inflammatory conditions, such as Behçet's disease. We believe apremilast has significant commercial potential and will serve as the cornerstone for our emerging I&I business.

### Sustaining Innovation and Long-Term Growth

Every day we recognize the value and benefit of operating a science-based business in a favorable policy environment—creating a vital culture of innovation. This is truly fundamental to the success of Celgene and is supported by our powerful and unique Research and Development capability, with industry-leading expertise in hematology, oncology and immunology. We are focused on leveraging our core capabilities—IMiD® technology, epigenetics, kinase inhibitors, tumor progenitors, cellular therapeutics, and Avilomics™ protein silencing—with complementary strategic collaborations to accelerate drug discovery. Over the last two years alone we and our partners have filed seven investigational new drug (IND) applications.

Medical innovation is at the heart of what we do and is the embodiment of our actions that help patients live longer, better lives, while reducing the burden on the healthcare system. The continued progress of our research efforts has already brought about medical

We are positioned for sustainable growth with an increasingly diversified revenue mix through 2017 and beyond. Our financial commitment is to generate annual growth of 19% in net product sales and 25% in adjusted earnings through 2017.

Net Product Sales 2013-2017<sup>1</sup>  
(dollars in billions)



Earnings Per Share<sup>2</sup>  
(in dollars)



Notes: 1) Adjusted. 2) CAGR calculated using 2013E and 2017E midpoints.

advancements that have changed the treatment paradigm in critical blood cancers. That success has, in turn, enabled us to grow a rich pipeline consisting of 19 programs in preclinical development and 16 therapies being evaluated in over 100 clinical trials.

During the last year we advanced next-generation immunomodulatory candidates, CC-122 and CC-220, into human testing. We established an effective dose for CC-292, a highly selective Bruton's tyrosine kinase (Btk) inhibitor that could be complementary to our REVLIMID programs in NHL and CLL. Our oral epigenetic therapy, CC-486, advanced into Phase III programs for myelodysplastic syndromes and acute myeloid leukemia. During 2013, we will advance CC-486 into Phase II trials evaluating different priming strategies in solid tumors. In connection with our partner, Acceleron Pharma, Inc., multiple Phase II trials began with ACE-011 and ACE-536 in a variety of severe forms of anemia. We are excited about these programs and how they can produce the next breakthrough therapies.

#### Outlook to 2017

The remarkable positive results across multiple milestones achieved last year position Celgene to have three new products with blockbuster potential and two emerging businesses that will help serve as the engine for our continued growth for the next five years. Our increasingly diversified revenue mix provides the foundation for sustainable growth going forward. Each milestone accomplished strengthens our conviction in achieving the 2017 financial targets of over \$12 billion in net product sales and \$13.00 to \$14.00 in adjusted earnings per share.

#### Summary

At Celgene, we are excited by what has been accomplished and even more energized about what will be achieved over the next several years. We are focused

on the key success factors that validate our business model and lead to sustainable, long-term growth. We know what we do well, what our competitive advantages are, and how to leverage them to capture long-term value.

We are making exceptional progress building a leading global biopharmaceutical company focused on developing and discovering new innovative therapies in the areas of cancer and inflammatory diseases that make a real difference in the lives of patients. As Celgene grows, we have rigorous and robust discussions about how to retain the character and culture of our company—remaining bold, willing to take smart and appropriate risks and focused on applying our expertise to benefit patients. Every day, Celgene employees are thinking about what we can do better, how we can further expand on and improve our unique value proposition.

That is our mission. It unifies us and serves as our vision, as does our keen awareness that there is no success for Celgene if we do not continue to make an increasingly meaningful difference in the lives of the patients we serve. What Celgene does matters to people in a profound way. There is nothing more gratifying than when recipients of our therapies—some of whom you have read about in the preceding pages—say that we have given them their lives back.

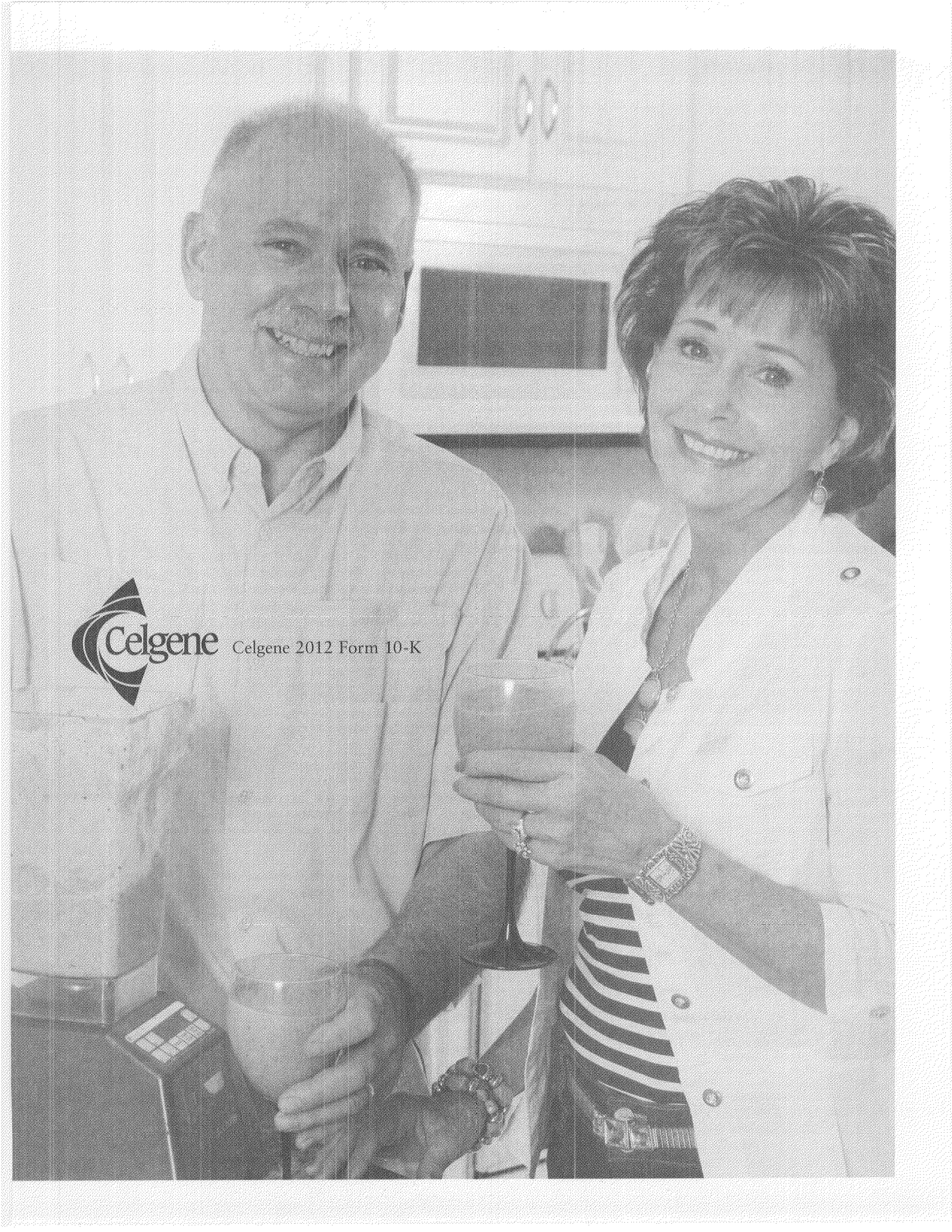
I have never been more optimistic about where our company is heading. *Celgene is on the move.*



Robert J. Hugin  
*Chairman and Chief Executive Officer*



Celgene 2012 Form 10-K



**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-K**

(Mark one)

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

For the fiscal year ended December 31, 2012

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-34912

**CELGENE CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**22-2711928**  
(I.R.S. Employer Identification No.)

**86 Morris Avenue**  
**Summit, New Jersey**  
(Address of principal executive offices)

**07901**  
(Zip Code)

**(908) 673-9000**

(Registrant's telephone number, including area code)

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

| Title of each class                     | Name of each exchange on which registered |
|---|---|
| Common Stock, par value \$.01 per share | NASDAQ Global Select Market               |
| Contingent Value Rights                 | NASDAQ Global Market                      |

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2012, the last business day of the registrant's most recently completed second quarter, was \$27,784,369,047 based on the last reported sale price of the registrant's Common Stock on the NASDAQ Global Select Market on that date.

There were 418,744,447 shares of Common Stock outstanding as of February 7, 2013.

**Documents Incorporated by Reference**

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2012. The proxy statement is incorporated herein by reference into the following parts of the Form 10-K:

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| Part III, Item 10. | Directors, Executive Officers and Corporate Governance.   |
| Part III, Item 11. | Executive Compensation.   |
| Part III, Item 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters. |
| Part III, Item 13. | Certain Relationships and Related Transactions, and Director Independence.                      |
| Part III, Item 14. | Principal Accountant Fees and Services.   |

**CELGENE CORPORATION**  
**ANNUAL REPORT ON FORM 10-K**

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## PART I

### ITEM 1. BUSINESS

Celgene Corporation (collectively with its subsidiaries, “we,” “our,” “us,” “Celgene” or the “Company”) is a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. We are dedicated to innovative research and development designed to bring new therapies to market and are involved in research in several scientific areas that may deliver proprietary next-generation therapies, targeting areas such as intracellular signaling pathways in cancer and immune cells, immunomodulation in cancer and autoimmune diseases, and therapeutic application of cell therapies. Celgene was incorporated in the State of Delaware in 1986.

Our primary commercial stage products include REVLIMID<sup>®</sup>, VIDAZA<sup>®</sup>, ABRAXANE<sup>®</sup>, THALOMID<sup>®</sup> (inclusive of Thalidomide Celgene<sup>®</sup>), and ISTODAX<sup>®</sup>. POMALYST<sup>®</sup> was approved by the U.S. Food and Drug Administration, or FDA, in February 2013 for patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and bortezomib, and have demonstrated disease progression on or within 60 days of completion of the last therapy. Additional sources of revenue include royalties from Novartis on their sales of FOCALIN XR<sup>®</sup> and the entire RITALIN<sup>®</sup> family of drugs, other licensing royalties, and the sale of services through our Celgene Cellular Therapeutics subsidiary.

We make significant investments in research and development in support of multiple ongoing proprietary clinical development programs which support both our existing products and our pipeline of new drug candidates. REVLIMID<sup>®</sup> is in several phase III trials across a range of hematological malignancies that include newly diagnosed multiple myeloma and maintenance, lymphomas, chronic lymphocytic leukemia, or CLL, and non-deletion 5q myelodysplastic syndromes, or MDS. Phase III trials for POMALYST<sup>®</sup> in myelofibrosis, VIDAZA<sup>®</sup> in acute myeloid leukemia, or AML, and CC-486 for MDS and AML are also underway. In solid tumors, we continue to evaluate ABRAXANE<sup>®</sup> in a phase III trial for metastatic melanoma and have recently completed a phase III trial for ABRAXANE<sup>®</sup> in pancreatic cancer. Our lead product candidate in Inflammation & Immunology, apremilast, is being evaluated in broad phase III programs for psoriatic arthritis, psoriasis, and ankylosing spondylitis.

Beyond our phase III programs, we have developed a growing early-to-mid-stage pipeline of novel therapies to address significant unmet medical needs, including CC-292 (BTK inhibitor), CC-223 (dual TORC inhibitor), CC-115 (dual TORC/DNA PK inhibitor), CC-122 (pleiotropic pathway modulator), CC-220 and CC-11050 (anti-inflammatory), PDA-001 and PDA-002 (cellular therapies), in addition to partnered molecules ACE-011 (ActR fusion protein), ACE-536 (GDF trap), and EPZ-5676 (DOT1L inhibitor). For more information, see “– Celgene Leading Product Candidates.”

We believe that the continued commercial success of our marketed products, our participation in research and development collaboration arrangements, the depth of our product pipeline, expected regulatory approvals of new products and expanded use of existing products will provide multiple catalysts for our future growth.

In recent years we have completed a number of strategic acquisitions that strengthened our research and manufacturing capabilities and enhanced our commercial product portfolio. Our most recent strategic acquisitions include the following:

- In January 2010, we acquired Gloucester Pharmaceuticals, Inc., or Gloucester, which developed new therapies to address unmet medical needs in the treatment of hematological cancers and other hematological malignancies. Gloucester added ISTODAX® to our product portfolio and advanced our leadership position in the development of disease-altering therapies through innovative approaches for patients with rare and debilitating blood cancers.
- In October 2010, we acquired Abraxis Bioscience Inc., or Abraxis, a fully integrated global biotechnology company. The acquisition of Abraxis accelerated our strategy to become a global leader in oncology and added ABRAXANE®, which is based on Abraxis' proprietary tumor-targeting platform known as nab® technology, to our portfolio of leading cancer products.
- In March 2012, we acquired Avila Therapeutics, Inc., or Avila, a clinical-stage biotechnology company focused on the design and development of targeted covalent drugs. The acquisition added Avila's proprietary Avilomics™ platform for developing targeted covalent drugs that treat diseases through protein silencing and augments our investment in the discovery and development of novel therapeutics.

## COMMERCIAL STAGE PRODUCTS

*REVLIMID® (lenalidomide):* REVLIMID® is an oral immunomodulatory drug marketed in the United States and many international markets, in combination with dexamethasone, for treatment of patients with multiple myeloma who have received at least one prior therapy. It is also marketed in the United States and certain international markets for the treatment of transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID® is distributed in the United States through contracted pharmacies under the RevAssist® program, which is a proprietary risk-management distribution program tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID®. Internationally, REVLIMID® is distributed under mandatory risk-management distribution programs tailored to meet local competent authorities' specifications to provide for the safe and appropriate distribution and use of REVLIMID®. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies.

REVLIMID® continues to be evaluated in numerous clinical trials worldwide either alone or in combination with one or more other therapies in the treatment of a broad range of hematological malignancies, including multiple myeloma, MDS, various lymphomas, CLL, other cancers and other diseases.

*VIDAZA® (azacitidine for injection):* VIDAZA® is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene

re-expression. VIDAZA® is a Category 1 recommended treatment for patients with intermediate-2 and high-risk MDS, according to the National Comprehensive Cancer Network and is marketed in the United States for the treatment of all subtypes of MDS. The U.S. regulatory exclusivity for VIDAZA® expired in May 2011. If a generic version of VIDAZA® is successfully launched, we may quickly lose a significant portion of our sales for this product in the United States. In Europe, VIDAZA® is marketed for the treatment of intermediate-2 and high-risk MDS, as well as AML with 30% blasts, and has been granted orphan drug designation for the treatment of MDS and AML. European regulatory exclusivity is expected to continue through 2018.

*ABRAXANE® (paclitaxel albumin-bound particles for injectable suspension):* ABRAXANE® is a solvent-free chemotherapy treatment option for metastatic breast cancer and non-small cell lung cancer which was developed using our proprietary nab® technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin. It is approved for the treatment of metastatic breast cancer in the United States and many international markets and for the treatment of non-small cell lung cancer in the United States. In January 2013, we announced the results from a phase III trial for ABRAXANE® in combination with gemcitabine in treatment-naïve patients with metastatic pancreatic cancer. The ABRAXANE® combination demonstrated a statistically significant improvement in overall survival compared to patients receiving gemcitabine alone. Based on these results, we plan to submit dossiers for registration in the U.S. and Europe during the first half of 2013 followed by submissions in other countries and regions during the second half of 2013. ABRAXANE® is currently in various stages of investigation for the treatment of the following cancers: expanded applications for metastatic breast, malignant melanoma, and bladder and ovarian. In October 2012, the FDA approved ABRAXANE® for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. The FDA approval was based on tumor response rates and the label did not include a progression-free survival claim. Accordingly, the Contingent Value Rights, or CVR, milestone payment, as described in Note 2 of the Notes to the Consolidated Financial Statements included elsewhere in this report, has not been achieved.

*THALOMID® (thalidomide):* In combination with dexamethasone, THALOMID® is marketed for patients with newly diagnosed multiple myeloma and for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum, or ENL, an inflammatory complication of leprosy, and as maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence.

THALOMID® is distributed in the United States under our “*System for Thalidomide Education and Prescribing Safety*,” or *S.T.E.P.S.*®, program, our proprietary comprehensive education and risk-management distribution program that we developed with the objective of providing for the safe and appropriate distribution and use of THALOMID®. Internationally, THALOMID® is also distributed under mandatory risk-management distribution programs tailored to meet local competent authorities’ specifications to provide for the safe and appropriate distribution and use of THALOMID®. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies.



*ISTODAX® (romidepsin):* ISTODAX® is approved in the United States for the treatment of cutaneous T-cell lymphoma, or CTCL, in patients who have received at least one prior systemic therapy and for the treatment of peripheral T-cell lymphoma, or PTCL, in patients who have received at least one prior therapy. ISTODAX® has received orphan drug designation for the treatment of non-Hodgkin's T-cell lymphomas, which includes CTCL and PTCL.

*POMALYST® (pomalidomide):* POMALYST® was approved by the FDA in February 2013 for patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and bortezomib, and have demonstrated disease progression on or within 60 days of completion of the last therapy, and is under review by the European Agency for the Evaluation of Medicinal Products, or EMA, for use in Europe. POMALYST® is a proprietary, small molecule that is administered orally and modulates the immune system and other biologically important targets. POMALYST® is also being evaluated in a phase III clinical trial for the treatment of myelofibrosis, in multiple trials in various phases for expanded usage in multiple myeloma and in a phase II trial for systemic sclerosis.

POMALYST® is distributed in the United States through contracted pharmacies under the POMALYST® REMS® program, which is a proprietary risk-management distribution program tailored specifically to provide for the safe and appropriate distribution and use of POMALYST®.

*FOCALIN®, FOCALIN XR® and RITALIN LA®:* We licensed the worldwide rights (excluding Canada) regarding certain chirally pure forms of methylphenidate for FOCALIN® and FOCALIN XR® to Novartis. We also licensed to Novartis the rights related to long-acting formulations of methylphenidate and dex-methylphenidate products which are used in FOCALIN XR® and RITALIN LA®. As a result of the grant of these licenses we receive royalties on sales of these products.

Current pivotal or phase III trials of our commercial stage products and their targeted disease indications are outlined in the following table:

| Product                     | Disease Indication                              | Status   | Trial Beginning Date |
|-----------------------------|---|--|----------------------|
| REVLIMID®                   | Newly diagnosed multiple myeloma                | Phase III ongoing  | August 2008          |
|                             | Maintenance therapy for multiple myeloma        | Phase III trials ongoing                                       | December 2004        |
|                             | MDS del 5q                                      | Submitted EU regulatory filing                                 |                      |
|                             | MDS non-del 5q                                  | Phase III ongoing  | February 2010        |
|                             | Mantle cell lymphoma for U.S. filing            | Phase II completed,<br>Submitted U.S. regulatory filing        |                      |
|                             | Mantle cell lymphoma for EU filing              | Phase II ongoing   | April 2009           |
|                             | Diffuse large B cell lymphoma                   | Phase II/III ongoing   | July 2010            |
|                             | Diffuse large B cell lymphoma maintenance       | Phase III enrolling  | May 2009             |
|                             | Follicular lymphoma consolidation & maintenance | Phase III enrolling  | December 2011        |
|                             | CLL first-line                                  | Phase III enrolling  | November 2009        |
| CLL maintenance             | Phase III enrolling                             | February 2009  |                      |
| VIDAZA®                     | AML   | Phase III enrolling  | October 2010         |
| ABRAXANE®                   | Pancreatic cancer                               | Phase III completed,<br>U.S. and EU regulatory filings pending |                      |
|                             | Melanoma  | Phase III ongoing  | April 2009           |
| POMALYST®<br>(pomalidomide) | Myelofibrosis                                   | Phase III ongoing  | September 2010       |
|                             | Multiple myeloma                                | Phase II completed,<br>Submitted EU regulatory filings         |                      |
|                             | Multiple myeloma                                | Phase III ongoing  | April 2011           |
|                             | Multiple myeloma                                | Additional phase I, II, III trials enrolling                   | March 2012           |
|                             | Systemic Sclerosis                              | Phase II enrolling   | June 2012            |

## PRODUCT DEVELOPMENT

We devote significant resources to research and development programs in an effort to discover and develop potential future product candidates. Research and development expenses amounted to \$1.724 billion in 2012, \$1.600 billion in 2011, and \$1.128 billion in 2010. The product candidates in our pipeline are at various stages of preclinical and clinical development. The path to regulatory approval includes three phases of clinical trials in which we collect data to support an application to regulatory authorities to allow us to market a product for treatment of a specified disease. There are many difficulties and uncertainties inherent in research and development of new products, resulting in a high rate of failure. To bring a drug from the discovery phase to regulatory approval, and ultimately to market, takes many years and significant cost. Failure can occur at any point in the process, including after the product is approved, based on post-market factors. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals, limited scope of approved uses, reimbursement challenges, difficulty or excessive costs of manufacture, alternative therapies or infringement of the patents or intellectual property rights of others. Uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunities. Consequently, it is very

difficult to predict which products will ultimately be submitted for approval, which have the highest likelihood of obtaining approval and which will be commercially viable and generate profits. Successful results in preclinical or clinical studies may not be an accurate predictor of the ultimate safety or effectiveness of a drug or product candidate.

#### Phase I Clinical Trials

Phase I clinical trials begin when regulatory agencies allow initiation of clinical investigation of a new drug or product candidate and usually involves up to 80 healthy volunteers or subjects. The tests study a drug's safety profile, and may include a preliminary determination of a drug or product candidate's safe dosage range. The phase I clinical trial also determines how a drug is absorbed, distributed, metabolized and excreted by the body, and therefore the potential duration of its action. Phase I clinical trials generally take from one to three years to complete.

#### Phase II Clinical Trials

Phase II clinical trials are conducted on a limited number of subjects with the targeted disease. An initial evaluation of the drug's effectiveness on subjects is performed and additional information on the drug's safety and dosage range is obtained. Phase II clinical trials normally include up to several hundred subjects and may take as many as two to three years to complete.

#### Phase III Clinical Trials

Phase III clinical trials typically include controlled multi-center sites and involve a larger target patient population that normally consists of from several hundred to several thousand subjects to ensure that study results are statistically significant. During phase III clinical trials, physicians monitor subjects to determine efficacy and to gather further information on safety. These trials are generally global in nature and are designed to generate all of the clinical data necessary to submit an application for marketing approval to regulatory agencies. Phase III testing varies by disease state, but can often last from two to seven years.

#### Regulatory Review

If a product candidate successfully completes phase III clinical trials and is submitted to governmental regulators, such as the FDA in the United States or the EMA in the European Union, the time to final marketing approval can vary from six months (for a U.S. filing that is designated for priority review by the FDA) to several years, depending on a number of variables, such as the disease state, the strength and complexity of the data presented, the novelty of the target or compound, risk-management approval and whether multiple rounds of review are required for the agency(ies) to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval, or that decisions on marketing approvals or treatment indications will be consistent across geographic areas.

### **PRECLINICAL AND CLINICAL – STAGE PIPELINE**

Our preclinical and clinical-stage pipeline of new drug candidates and cell therapies is highlighted by multiple classes of small molecule, therapeutic agents designed to selectively regulate disease-associated genes and proteins. These product candidates are at various stages of preclinical and clinical development.

*Oral anti-inflammatory agents:* We are developing novel, orally administered small molecules that specifically target PDE4, an intracellular enzyme that modulates the production of multiple pro-inflammatory and anti-inflammatory mediators including interleukin-2 (IL-2), IL-10, IL-12, IL-23, INF-gamma, TNF- $\alpha$ , leukotrienes and nitric oxide synthase. Apremilast (CC-10004), our lead product candidate in Inflammation & Immunology, has demonstrated statistically significant and clinically meaningful benefits in recent phase III trials in the treatment of psoriasis (ESTEEM 1 and 2 trials) and previously treated psoriatic arthritis (PALACE 1, 2, and 3 trials). Apremilast is being evaluated in phase III trials for psoriatic arthritis and ankylosing spondylitis and a phase II trial for the use of apremilast for Behçet's disease was recently completed. In addition, we are investigating our next generation oral PDE4 inhibitor, CC-11050, a unique anti-inflammatory compound with the potential to treat a variety of chronic inflammatory conditions such as cutaneous lupus erythematosus.

*Cellular therapies:* At Celgene Cellular Therapeutics, or CCT, we are researching stem cells derived from the human placenta as well as from the umbilical cord. CCT is our research and development division dedicated to fulfilling the promise of cellular technologies by developing products and therapies to significantly benefit patients. Our goal is to develop proprietary cell therapy products for the treatment of unmet medical needs.

Stem cell based therapies offer the potential to provide disease-modifying outcomes for serious diseases that lack adequate therapy. We have developed proprietary technology for collecting, processing and storing placental stem cells with potentially broad therapeutic applications in cancer, auto-immune diseases, and other inflammatory diseases.

We are developing our cellular therapies, PDA-001 (IV formulation) and PDA-002 (IM/SC injectable formulation), with the initiation of phase I safety and dose finding studies. We are also continuing research to define the potential of placental-derived stem cells and to characterize other placental-derived products.

*CC-486:* We have initiated two phase III trials of CC-486 that are currently enrolling to evaluate CC-486 in the treatment of MDS and AML. In addition, a phase I trial of CC-486 for the treatment of solid tumor indications is currently in progress.

*Sotatercept (ACE-011) and ACE-536:* We have collaborated with Acceleron Pharma, Inc., or Acceleron, to develop sotatercept and ACE-536 to treat anemia in patients with rare blood disorders. Several phase II trials are in progress to evaluate the use of sotatercept or ACE-536 in the treatment of anemia in patients with rare blood disorders.

## CELGENE LEADING PRODUCT CANDIDATES

The development of our leading new drug candidates and their targeted disease indications are outlined in the following table:

| Product                         | Disease Indication   | Status  | Trial Beginning Date   |
|---------------------------------|--|---|--|
| CC-486                          | Lower risk MDS<br>AML maintenance  | Phase III initiated<br>Phase III initiated  | December 2012<br>December 2012   |
| EPZ-5676                        | MLL-r Leukemia   | Phase I enrolling   | September 2012   |
| <i>Oral Anti-Inflammatory:</i>  |  |   |  |
| Apremilast (CC-10004)           | Psoriasis<br>Psoriatic arthritis<br>Rheumatoid arthritis<br>Ankylosing spondylitis<br>Behçet's disease | Phase III trials ongoing<br>Phase III trials ongoing<br>Phase II completed<br>Phase III enrolling<br>Phase II completed | September 2010<br>June 2010<br>December 2010<br>June 2012<br>August 2009 |
| CC-11050                        | Cutaneous lupus  | Phase II ongoing  | February 2011  |
| CC-220                          | Inflammation   | Phase I enrolling   | December 2012  |
| <i>Cellular Therapies:</i>      |  |   |  |
| PDA-001                         | Crohn's disease  | Phase I initiating  | February 2013  |
| PDA-002                         | Peripheral arterial disease  | Phase I initiating  | Q2 2013  |
| <i>Activin Biology:</i>         |  |   |  |
| Sotatercept (ACE-011)           | Renal anemia<br>Anemia with beta thalassemia<br>Anemia with MDS  | Phase II ongoing<br>Phase II enrolling<br>Phase II enrolling  | June 2010<br>April 2012<br>December 2012                                 |
| ACE-536                         | Beta thalassemia<br>Anemia with MDS  | Phase II enrolling<br>Phase II enrolling  | January 2013<br>January 2013   |
| <i>Novel Anti-tumor Agents:</i> |  |   |  |
| CC-223                          | Solid tumors, non-Hodgkin lymphoma, multiple myeloma<br>Non-small cell lung cancer                     | Phase I/II ongoing<br>Phase Ib ongoing  | July 2010<br>March 2012  |
| CC-115                          | Solid tumors, non-Hodgkin lymphoma, multiple myeloma   | Phase I ongoing   | April 2011   |
| CC-122                          | Solid tumors, non-Hodgkin lymphoma, multiple myeloma   | Phase I ongoing   | September 2011   |
| CC-486                          | Solid tumors   | Phase I/II ongoing  | November 2011  |
| CC-292                          | CLL, non-Hodgkin lymphoma  | Phase I and Ib trials ongoing   | August 2010  |

## PATENTS AND PROPRIETARY TECHNOLOGY

We consider intellectual property protection (including, but not limited to, patents and regulatory exclusivities) relative to certain products, particularly those products discussed below, to be critical to our operations. For many of our products, in addition to compound patents, we hold patents on manufacturing processes, formulations or uses that may extend exclusivity beyond the expiration of the compound patent.

*Key products table of exclusivities:*

The following table shows the expected expiration dates in the United States and in Europe of the last-to-expire period of exclusivity (regulatory or patent) related to the following approved drugs, which are subject to the challenges and risk factors as described herein:

|   | <u>U.S.</u> | <u>Europe</u>                                      |
|---|-------------|--|
| <b>REVLIMID® brand drug</b><br>(U.S. and European Patent Office, or EPO, drug substance patents)          | 2027        | 2024   |
| <b>THALOMID® brand drug</b><br>(Use and/or drug product patents)  | 2023        | 2019   |
| <b>VIDAZA® brand drug</b><br>(U.S. and EMA regulatory exclusivities only)                                 | 2011        | 2018   |
| <b>ABRAXANE® brand drug</b><br>(U.S. use and EPO use/drug product patents)                                | 2026        | 2022   |
| <b>ISTODAX® brand drug</b><br>(U.S. drug substance patents)<br>(EMA regulatory exclusivity upon approval) | 2021        | (10 years regulatory<br>exclusivity upon approval) |
| <b>POMALYST® brand drug</b><br>(U.S. use patent)<br>(EMA regulatory exclusivity upon approval)            | 2024        | (10 years regulatory<br>exclusivity upon approval) |
| <b>FOCALIN® brand drug</b><br>(U.S. use patents)  | 2015        | N/A  |
| <b>FOCALIN XR® brand drug</b><br>(U.S. use patents)<br>(EPO drug product patent)                          | 2015        | 2018   |

In the United States, the patents covering REVLIMID® include 17 patents that are listed in the U.S. Orange Book, all of which are assigned to us. The last-to-expire patent (2027), U.S. Patent No. 7,465,800, covers certain polymorphic forms of the pharmaceutically active ingredient of REVLIMID®.

REVLIMID® is also covered in foreign countries by certain patents and patent applications that correspond to certain of those listed in the U.S. Orange Book. For example, patents related to the active pharmaceutical ingredient, uses and pharmaceutical compositions have been granted in Europe. Although certain of the patents are currently scheduled to expire in 2017 or 2018, patents granted in certain European countries, such as Spain, France, Italy, Germany and the United Kingdom, will not expire until 2022 due to the Supplementary Protection Certificates, or SPCs, granted in these countries. In addition, as noted in the table above, patents in Europe that relate to certain polymorphic forms of the active pharmaceutical ingredient of REVLIMID® will not expire until 2024.

The patents covering THALOMID® in the United States include 18 patents that are listed in the U.S. Orange Book. The last-to-expire patent that is assigned to us (2023), U.S. Patent No. 7,230,012, covers marketed THALOMID® formulations.

In foreign countries, THALOMID® is also covered by certain patents and patent applications that correspond to certain of those listed in the U.S. Orange Book. Patents related to the approved uses of THALOMID® have been granted in Europe. Although certain of these patents are currently scheduled to expire in 2014 or 2017, patents granted in certain European countries, such as Spain, France and Italy, will not expire relative to certain uses of thalidomide, until 2019 due to the SPCs granted in these countries.

In the United States, orphan drug exclusivity with respect to VIDAZA® expired in May 2011. In Europe, new drug and orphan exclusivities relative to VIDAZA® will expire in December 2018.

The patents covering ABRAXANE® in the United States include 14 patents that are listed in the U.S. Orange Book. One patent, U.S. Patent No. 7,820,788, expiring in 2024, covers marketed ABRAXANE® formulations. The last-to-expire patent (2026), U.S. Patent No. 8,268,348, covers approved uses of ABRAXANE®. In Europe, new drug exclusivity relative to ABRAXANE® expires in 2018. We have applied for and received in certain European countries SPCs relative to EP 0 961 612 B1 that extend exclusivity for ABRAXANE® to 2022.

The last-to-expire patents relating to ISTODAX® that are listed in the U.S. Orange Book, expire in August 2021.

The patents related to POMALYST® in the United States include at least 10 patents that are anticipated to be listed in the U.S. Orange Book. One patent (2016), U.S. Patent No. 6,316,471, covers marketed POMALYST® formulations. The last-to-expire patent (2024) is U.S. Patent No. 8,198,262 which covers uses of POMALYST® referenced in the approved U.S. label. POMALYST® is expected to receive Orphan Drug exclusivity which will last until February 2020.

In the United States, the patents covering FOCALIN® include three patents that are listed in the U.S. Orange Book. All of these patents are assigned to us. The last-to-expire patents, listed in the U.S. Orange Book, all expire in December 2015.

In the United States, the patents covering FOCALIN XR® comprise six patents that are listed in the U.S. Orange Book. All of these patents are assigned to us. These patents all expire in December 2015. A relevant European patent, owned by us, expires in June 2018.

In the United States, the patents covering RITALIN LA® comprise three patents that are listed in the U.S. Orange Book. All of these patents are assigned to us. These last-to-expire patents, all listed in the U.S. Orange Book, expire in December 2015. A related European patent, owned by us, expires in June 2018.

With respect to our U.S. patents for FOCALIN®, FOCALIN XR® and RITALIN LA®, litigation with generic drug companies have been resolved pursuant to confidential settlements which allow for the entrance of their respective generic products in the United States prior to the 2015 patent expirations in the event their respective abbreviated new drug applications, or ANDAs, receive

FDA approval. In January 2012, Actavis Group, a generic manufacturer, announced the launch of a generic version of RITALIN LA®.

We have received SPCs in Europe relative to certain in-licensed thalidomide patents, which relate to THALOMID® and extend the terms of these patents relative to certain uses of thalidomide to 2019. Corresponding foreign patent applications and additional U.S. patent applications are still pending. Pursuant to certain agreements with the owners of the thalidomide patents, we are obligated to comply with certain milestones and other obligations, including those relating to REVLIMID® sales.

In 2001, Children's Medical Center Corporation, or CMCC, granted to us an exclusive worldwide license under certain patents and patent applications relating to thalidomide. In December 2002, CMCC granted to us an exclusive worldwide license to certain patents and patent applications relating to thalidomide analogs, metabolites, precursors and hydrolysis products of thalidomide, and stereoisomers thereof.

In addition, we have applied for and received SPCs to 2022 in Europe relative to both REVLIMID® and ABRAXANE®. In the United States, we have been granted a patent term extension of a REVLIMID® composition of matter patent to 2019. In the United States, we have been granted patent term adjustment with respect to a REVLIMID® polymorph patent; this patent is presently scheduled to expire in 2027.

Patent term extensions have been granted in other markets as well, including Australia and Korea, relative to certain of our patents related to REVLIMID®. Patent term extensions relative to lenalidomide have been granted in Japan. Further, patent term extensions relative to ABRAXANE® have been secured and/or are actively being sought in Australia, Japan, Russia and Korea. We are also considering alternative exclusivity strategies, mostly through international treaties, in a variety of countries throughout Latin America.

Trade secret strategies also are important to our success and related to many of our key products.

Our brand names, logos and trademarks are also important to our success. We maintain both registered and common law trademarks. Common law trademark protection typically continues where and for as long as the mark is used. Registered trademarks continue in each country for as long as the trademark is registered.

In total, we own or have exclusively licensed nearly 400 issued U.S. patents. In addition, approximately 550 additional pending U.S. patent applications are owned by or exclusively licensed to us. We have a policy to seek worldwide patent protection for our inventions and have foreign patent rights corresponding to most of our U.S. patents.

Our research leads us to seek patent protection for molecular targets and drug discovery technologies, as well as therapeutic and diagnostic products and processes. More specifically, proprietary technology has been developed for use in molecular target discovery, the identification of regulatory pathways in cells, assay design and the discovery and development of pharmaceutical product candidates. An increasing percentage of our recent patent applications have been related to potential product candidates or compounds.



CCT seeks patent protection for the collection, processing, composition, formulation and uses of mammalian placental and umbilical cord tissue and placental and umbilical cord stem cells, as well as cells and biomaterials derived from the placenta. As of December 2012 CCT owned, in whole or in part, 24 U.S. patents, including claims to novel cells and cellular compositions. In addition, CCT owns 92 U.S. patent applications, including pending provisional applications.

Our patents are regularly subject to challenge by generic drug companies. See Part I, Item 3, “Legal Proceedings.” We rely on several different types of patents to protect our products that may include, without limitation, compound, polymorph, formulation and method of use patents. We cannot be certain, however, whether any of these patents will be circumvented, invalidated or found unenforceable or infringing in challenges by generic companies. For a more detailed discussion of risks related to our patent portfolio, see Part I, Item 1A. “Risk Factors.”

## **GOVERNMENTAL REGULATION/EXCLUSIVITIES AFFORDED BY REGULATORY AUTHORITIES**

*Governmental Regulation:* Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. Most, if not all, of our therapeutic products require regulatory approval by governmental agencies prior to and after commercialization. Human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing and post-marketing approval requirements of the FDA and regulatory authorities in other countries. In the United States, various federal and, in some cases, state statutes and regulations also govern, or impact upon the manufacturing, testing for safety and effectiveness, labeling, storage, record-keeping and marketing of such products. The lengthy process of seeking required approvals, and the continuing need for compliance with applicable statutes and regulations, require the expenditure of substantial resources. Regulatory approval, if and when obtained, may be limited in scope which may significantly limit the uses for which a product may be promoted. Further, approved drugs, as well as their manufacturers, are subject to ongoing post-marketing review, inspection and discovery of previously unknown problems with such products or the manufacturing or quality control procedures used in their production, which may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Any failure or delay by us, our suppliers of manufactured drug product, collaborators or licensees, in obtaining regulatory approvals could adversely affect the marketing of our products and our ability to receive product revenue, license revenue or profit sharing payments.

*Clinical Development:* Before a product may be administered to human subjects, it must undergo preclinical testing. Preclinical tests include laboratory evaluation of a product candidate’s chemistry and its biological activities and animal studies to assess potential safety and efficacy. The results of these studies must be submitted to the FDA as part of an Investigational New Drug, or IND, application which must be reviewed by the FDA primarily for safety considerations before clinical trials in humans can begin.

In the United States, the FDA may grant “fast track” status (a process designed to facilitate the development and expedite the review of drugs) to products that treat serious diseases and fill an unmet medical need. In addition, most drugs with fast track status would be considered candidates for priority review, which generally means that the time it takes the FDA to review a New Drug Application, or NDA, is reduced.

The FDA can also assign a Breakthrough Therapy designation to a drug or biologic. A drug intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and that may be a substantial improvement over existing therapies, based on preliminary clinical evidence from one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development may be designated a Breakthrough Therapy. For drugs and biologics that have been designated as Breakthrough Therapies, robust FDA-Sponsor interaction and communication can help to identify the most efficient, expeditious path for clinical development while minimizing the number of patients placed in ineffective control regimens. A Breakthrough Therapy designation requires evidence of substantial improvement over current treatments in early clinical development.

Typically, clinical trials involve a three-phase process as previously described. In some cases, further studies are required as a condition for an NDA or biologics license application, or BLA, approval. The FDA requires monitoring of all aspects of clinical trials and reports of all adverse events must be made to the agency before drug approval and requires submission of post-marketing adverse event reports after approval. The FDA may also require the Sponsor to conduct pediatric studies for the drug and indication under review if the application is for a new active ingredient, indication, dosage form, dosing regimen, or route of administration.

*FDA Review and Approval:* The results of the preclinical testing and clinical trials are submitted to the FDA as part of an NDA or BLA for evaluation to determine if there is substantial evidence that the product is safe and effective for approval to commence commercial sales. In responding to an NDA or BLA, the FDA may grant marketing approval or deny approval by requesting additional information, even new clinical trials, if it determines that the application does not satisfy its regulatory approval criteria. When an NDA or BLA is approved, the NDA or BLA holder must (a) employ a system for obtaining reports of drug adverse experience and side effects associated with the drug and make appropriate submissions to the FDA and (b) timely advise the FDA if any marketed product fails to adhere to specifications established by the NDA or BLA.

The FDA may grant “accelerated approval” to products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments. For accelerated approval, the drug product must have an effect on a surrogate endpoint reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity.

The FDA may provide approval with restrictions to assure safe use. If the FDA concludes that a drug previously shown to be effective can be safely used only if distribution or use is restricted, the FDA will require post-marketing restrictions as necessary to assure safe use. The sponsor may be required to establish systems to assure use of the product under safe conditions. In 2007, the FDA was granted authority to require risk evaluation and mitigation strategies, or REMS, to ensure that benefits of a drug outweigh risks. There are financial and other penalties for non-compliance with a drug’s REMS.

For all products that receive accelerated approval, the FDA may withdraw approval after a hearing if a post-marketing clinical study fails to verify clinical benefit, if the applicant fails to perform the required post-marketing study with due diligence, if post-marketing restrictions are

inadequate to assure safe use of the product, if the applicant fails to adhere to agreed upon post-marketing restrictions, if promotional materials are false or misleading, or if other evidence demonstrates the product is not safe or effective under its conditions of use.

*Manufacturing Quality Control:* Among the conditions for NDA or BLA approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures continually conform with the FDA's current Good Manufacturing Practice, or cGMP, regulations (which are regulations established by the FDA governing the manufacture, processing, packing, storage and testing of drugs and biologics intended for human use). In complying with cGMP, manufacturers must devote extensive time, money and effort in the area of production and quality control and quality assurance to maintain full technical compliance. Manufacturing facilities and company records are subject to periodic inspections by the FDA to ensure compliance. If a manufacturing facility is not in substantial compliance with these requirements, regulatory enforcement action may be taken by the FDA, which may include seeking an injunction against shipment of products from the facility and/or recall of products previously shipped from the facility.

*FDA Review and Enforcement:* The FDA closely reviews and regulates the marketing and promotion of drug and biologic products. FDA approval for a specified indication is required before marketing or promoting a product for that indication. The FDA may take enforcement action against a company for promoting unapproved uses of a product ("off-label promotion") or for other violations of advertising and labeling laws and regulations.

The FDA may issue warning letters and untitled letters or non-compliance letters that are made public, which may require corrective actions including modification of advertising or other corrective communications to consumers or healthcare professionals. Failure to comply with applicable FDA regulatory requirements can result in enforcement actions, such as license revocation or suspension; orders for retention, recall, seizure or destruction of product; cessation of manufacturing; injunctions; inspection warrants; search warrants; civil penalties, including fines based on the equitable remedy of disgorgement; restitution; and criminal prosecution.

*Post-approval:* After approval, a sponsor of a drug product has ongoing reporting obligations concerning adverse reactions associated with the drug, including expedited reports for serious and unexpected adverse events. Following assessment of these reports, regulatory authorities can require product label updates to reflect new safety data or warnings. If the FDA becomes aware of new safety information, it can also require us to conduct studies or clinical trials at the time of approval or after approval to assess the potential for a serious risk. The FDA can also impose marketing restrictions, including the suspension of marketing or complete withdrawal of a product from the market.

*Markets Outside of the United States:* Approval procedures must be undertaken in virtually every other country comprising the market for our products. The approval procedure and the time required for approval vary from country to country and may involve additional testing.

*Exclusivities:* Pursuant to the United States Orphan Drug Act, a sponsor may request that the FDA designate a drug intended to treat a "rare disease or condition" as an "orphan drug." The term "orphan drug" can refer to either a drug or biologic. A rare disease or condition is defined as one which affects less than 200,000 people in the United States, or which affects more than 200,000 people, but for which the cost of developing and making available the product is not

expected to be recovered from sales of the product in the United States. Upon the approval of the first NDA or BLA for a drug designated as an orphan drug for a specified indication, the sponsor of that NDA or BLA is entitled to seven years of exclusive marketing rights in the United States for the orphan drug for the same indication unless the sponsor cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease. However, orphan drug status is particular to the approved indication and does not prevent another company from seeking approval of an off-patent drug that has other labeled indications that are not under orphan or other exclusivities. The period of orphan exclusivity is concurrent with any patent or other exclusivity that relates to the drug or biologic. Orphan drugs may also be eligible for federal income tax credits for costs associated with the drugs' development. In order to increase the development and marketing of drugs for rare disorders, regulatory bodies outside the United States have enacted regulations similar to the Orphan Drug Act.

Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, or the Act, products covered by approved NDAs or supplemental NDAs may be protected by periods of patent and/or non-patent exclusivity. During the three-year marketing exclusivity period granted for reports of new clinical investigations conducted by the sponsor essential for approval, the FDA is precluded from approving a potential competitor's Abbreviated New Drug Application, or ANDA, or a 505(b)(2) application. The FDA is also precluded from accepting an ANDA or 505(b)(2) application for a five-year marketing exclusivity period that is granted when an active moiety (which is a molecule or ion responsible for the physiological or pharmacological action of the drug) has not been previously approved. An applicant is permitted to submit an ANDA or 505(b)(2) after four years if it contains certification of invalidity or non-infringement to a patent listed for the approved drug, but such application does not affect any regulatory or appropriate patent exclusivity.

The FDA also grants an additional six months of market protection at the end of listed patents and/or exclusivity for the drug product's active moiety, when the drug sponsor has conducted pediatric studies in response to a written request from the FDA. To qualify for pediatric exclusivity, an applicant must have received a written request for pediatric studies from the FDA.

NDAs submitted under 505(b)(2) of the Act may not reference data contained in the NDA for a product protected by an effective and unexpired exclusivity and must include patent certifications. ANDAs and 505(b)(2) applications are generally less burdensome than full NDAs in that, in lieu of new clinical data, the applications rely in whole, or in part, upon the safety and efficacy findings of the referenced approved drug in conjunction with bridging data, typically bioequivalence data. Upon the expiration of the applicable exclusivities, through passage of time or successful legal challenge, the FDA may grant effective approval of an ANDA for a generic drug, or may accept reference to a previously protected NDA in a 505(b)(2) application. Depending upon the scope of the applicable exclusivities, any such approval could be limited to certain formulations and/or indications/claims, i.e., those not covered by any outstanding exclusivities.

An abbreviated pathway was established by the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), enacted in 2010, as part of the Patient Protection and Affordable Care Act. The BPCI Act creates an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product. Biological products

have 12 years of exclusivity, after which there may be biosimilar application approvals under the Public Health Service Act.

Manufacturers also have the opportunity to take advantage of the ability for the FDA to consider single enantiomer drugs as new chemical entities for a five-year new chemical entity exclusivity. For new chemical entity determination the new single enantiomer may not rely on clinical investigations from the racemic product's approval.

Under the Generating Antibiotic Incentives Now Act of 2011, an additional five years of marketing exclusivity is available for products approved and designated as qualified infectious disease products, or QIDPs. A QIDP is defined as "an antibacterial or drug for human use intended to treat serious or life-threatening infections, including those caused by (1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or (2) qualifying pathogens." A "qualifying pathogen" means a pathogen identified and listed by the FDA as such.

## **COMPETITION**

The pharmaceutical and biotechnology industries are highly competitive. We also compete with universities and research institutions in the development of products and processes, and in the acquisition of technology from outside sources.

Competition in the areas of oncology and inflammation and immunology areas, is particularly intense. Numerous pharmaceutical and biotechnology companies have extensive anti-cancer and anti-inflammatory drug discovery, development and commercial resources. AbbVie, Amgen, AstraZeneca, Biogen Idec, Bristol-Myers Squibb, Eisai, Ltd., F. Hoffmann-LaRoche, Johnson & Johnson, Merck, Novartis, Pfizer, Sanofi, and Takeda, are among the many companies researching and developing new compounds in the oncology and inflammation and immunology fields. We also have potential competition from generic drug manufacturers.

The pharmaceutical and biotechnology industries have undergone, and are expected to continue to undergo, rapid and significant technological change. Consolidation and competition are expected to intensify as technical advances in each field are achieved and become more widely known. In order to compete effectively, we will be required to continually upgrade and expand our scientific expertise and technology, identify and retain capable personnel and pursue scientifically feasible and commercially viable opportunities.

Our competition will be determined in part by the indications and geographic markets for which our products are developed and ultimately approved by regulatory authorities. The relative speed with which we develop new products, complete clinical trials, obtain regulatory approvals, receive pricing and reimbursement approvals, and finalize agreements with contract manufacturers, when needed, and market our products are critical factors in gaining a competitive advantage. Competition among approved products depends, among other things, on product efficacy, safety, convenience, reliability, availability, price, third-party reimbursement and patent and non-patent exclusivity.

## SIGNIFICANT ALLIANCES

We have entered into a variety of alliances in the ordinary course of our business. Although we do not consider any individual alliance to be material, the following is a brief description of certain of the more notable alliances:

*Novartis Pharma AG:* We licensed the worldwide rights (excluding Canada) regarding certain chirally pure forms of methylphenidate for FOCALIN® and FOCALIN XR® to Novartis. We also licensed to Novartis the rights related to long-acting formulations of methylphenidate and dex-methylphenidate products which are used in FOCALIN XR® and RITALIN LA®. As a result of the grant of these licenses we sell FOCALIN® to Novartis and receive royalties of between 30% and 35% on their sales of FOCALIN XR® and RITALIN LA®. Under the agreement, we have received upfront and regulatory achievement milestone payments totaling \$55.0 million.

The agreement will continue until the later of (i) the tenth anniversary of the first commercial launch on a country-by-country basis or (ii) when the last applicable patent expires with respect to that country. At the expiration date, we will grant Novartis a perpetual, non-exclusive, royalty-free license to make, have made, use, import and sell products using the dex-methylphenidate and long-acting formulation technology.

The agreement may be terminated by Novartis upon 12 months' prior written notice or by either party upon, among other things, the material breach of the other or in the event of withdrawal of the dex-methylphenidate product or RITALIN® product from the market because of regulatory mandate.

If the agreement is terminated by us, then all licenses granted to Novartis under the agreement will terminate and Novartis will grant us a non-exclusive license to certain of their intellectual property related to the compounds and products. If the agreement is terminated by Novartis then all licenses granted to Novartis under the agreement will terminate.

When generic versions of long-acting methylphenidate hydrochloride and dexmethylphenidate hydrochloride enter the market, we expect Novartis' sales of RITALIN LA® and FOCALIN XR® products to decrease and therefore its royalties under this agreement to also decrease. In January 2012, Actavis Group announced the launch of a generic version of RITALIN LA®.

*Array BioPharma Inc.:* We have a research collaboration agreement with Array BioPharma Inc., or Array, focused on the discovery, development and commercialization of novel therapeutics in cancer and inflammation. As part of this agreement, we made payments to date in the aggregate amount of \$59.0 million, which were recorded as research and development expense, in return for an option to purchase exclusive worldwide rights for compounds developed against up to two research targets defined in the agreement. Array will be responsible for all discovery and clinical development through phase I or phase IIa for each compound. Potential milestone payments for each compound of approximately \$200.0 million (most of which are payable subsequent to exercise of the relevant option) if certain discovery, development and regulatory milestones are achieved, and \$300.0 million if certain commercial milestones are achieved, as well as royalties on net sales.

During 2012 we exercised our option to extend the term of the agreement for an additional year. Our option will now terminate upon the earlier of (i) a termination of the agreement by its terms, (ii) the date we have exercised our options for compounds developed against two of the four research targets identified, or (iii) September 21, 2013. We may unilaterally extend the option term for an additional one-year term until September 21, 2014. During 2012, we made a \$3.0 million payment to Array in order to extend the research activities on one of the compounds.

If we exercise the options for each compound, upon the expiration of the research collaboration agreement under certain circumstances, Array will grant us a fully paid-up, royalty-free license to use certain intellectual property of Array to market and sell the compounds and products developed under the agreement.

*Acceleron Pharma:* We entered into a worldwide strategic collaboration agreement with Acceleron for the joint development and commercialization of sotatercept, or ACE-011, currently being studied for treatment of renal anemia. The collaboration agreement, as amended, combines both companies' resources and commitment to developing products for the treatment of cancer and cancer-related bone loss, and expands the joint development, manufacturing and commercialization of Acceleron's products to include anemia exclusivity. Under the terms of the ACE-011 agreement, we and Acceleron will jointly develop, manufacture and commercialize Acceleron's products for the treatment of bone loss. We made a payment to Acceleron in February 2008 of \$50.0 million, which included a \$5.0 million equity investment in Acceleron Series C-1 Convertible Preferred Stock, with the remainder recorded as research and development expense. In December 2011, we made a \$25.0 million equity investment in Acceleron Series F Convertible Preferred Stock. In the event of an initial public offering of Acceleron, we will purchase a minimum of \$7.0 million of Acceleron common stock. We have agreed to pay all development costs related to ACE-011 incurred after January 1, 2013.

Acceleron is eligible to receive development, regulatory approval and sales-based milestones of up to \$367.0 million for the ACE-011 program and up to an additional \$348.0 million for each of three specific discovery stage programs. The parties also agreed to co-promote the products under the ACE-011 agreement in North America. Acceleron will receive tiered royalties on worldwide net sales upon the commercialization of a development compound. We made a \$7.0 million development milestone payment to Acceleron in April 2011 for the initiation of enrollment into a phase II study for chemotherapy-induced anemia.

In August 2011, we also entered into a collaboration, license and option agreement with Acceleron, for the joint development and commercialization of ACE-536 for the treatment of anemia. The ACE-536 agreement also includes an option for future Acceleron anemia programs. The ACE-536 agreement provides us with an exclusive, worldwide, royalty-bearing license to the ACE-536 program and future Acceleron programs for the treatment of anemia. The parties also agreed to co-promote the products under the ACE-536 agreement in the United States, Canada and Mexico.

In connection with the ACE-536 agreement, we made a payment to Acceleron in the amount of \$25.0 million. We have also agreed to pay all development costs incurred after January 1, 2013. Acceleron is eligible to receive development, regulatory approval and sales-based milestones of up to \$217.5 million for the ACE-536 program and up to an additional \$170.8 million for the first

discovery stage program, \$148.8 million for the second discovery stage program and \$125.4 million for each additional discovery stage program thereafter. In October 2011, we made a \$7.5 million milestone payment for the initiation of a phase I clinical study of ACE-536. A \$10.0 million milestone payment will be made for the January 2013 initiation of a phase II clinical study to evaluate ACE-536 for the treatment of anemia in patients with myelodysplastic syndromes. Acceleron will receive tiered royalties on worldwide net sales upon the commercialization of a development compound.

The agreements for ACE-011 and ACE-536 may be terminated by us, at our sole discretion, at any time for the ACE-011 agreement, and, with respect to the ACE-536 agreement, after completion of the initial phase II clinical trials, or by either party, among other things, upon a material breach by the other party.

*GlobeImmune, Inc.:* We entered into a collaboration and option agreement with GlobeImmune, Inc., or GlobeImmune, as amended, focused on the discovery, development and commercialization of novel therapeutics in cancer. As part of this agreement, we made a payment in May 2009 of \$30.0 million, which was recorded as research and development expense, in return for the option to license certain compounds and products based on the GI-4000, GI-6200, GI-3000 and GI-6300 oncology drug candidate programs, as well as oncology compounds and products resulting from future programs controlled by GlobeImmune. If the option is exercised, GlobeImmune will be entitled to receive potential milestone payments of approximately \$230.0 million for the GI-4000 program, \$145.0 million for each of the GI-6200 and GI-3000 programs and \$161.0 million for each of the GI-6300 program and each additional future program if certain development, regulatory and sales-based milestones are achieved. GlobeImmune will also receive tiered royalties on worldwide net sales.

Our options with respect to the GI-4000, GI-6200, GI-3000 and GI-6300 oncology drug candidate programs will terminate if we do not exercise our respective options after delivery of certain reports from GlobeImmune on the completed clinical trials with respect to each drug candidate program. If we do not exercise our options with respect to any drug candidate program or future program, our option with respect to the oncology products resulting from future programs controlled by GlobeImmune will terminate three years after the last of the options with respect to the GI-4000, GI-6200, GI-3000 and GI-6300 oncology drug candidate programs terminates.

*Agios Pharmaceuticals, Inc.:* On April 14, 2010, we entered into a discovery and development collaboration and license agreement with Agios Pharmaceuticals, Inc., or Agios, which focuses on cancer metabolism targets and the discovery, development and commercialization of associated therapeutics. As part of the agreement, as amended, we paid Agios \$121.2 million, which was recorded by us as research and development expense. We also made an \$8.8 million equity investment in Agios Series B Convertible Preferred Stock. In October 2011, we made a \$20.0 million payment to Agios for a one year extension of our oncology collaboration and licensing agreement and in November 2011, made a \$28.7 million investment in Agios series C-2 Convertible Preferred Stock. With respect to each product in a program that we choose to license, Agios could receive up to \$120.0 million upon achievement of certain milestones plus royalties on sales, and Agios may also participate in the development and commercialization of certain products in the United States. Agios may also receive a one-time milestone payment of \$25.0 million upon dosing of the final human subject in a phase II study, such payment to be made only once with respect to only one program. Our option will terminate on April 14, 2014.



We have determined that Agios is a variable interest entity; however, we are not the primary beneficiary of Agios. Although we would have the right to receive the benefits from the collaboration and license agreement, we do not have the power to direct the activities under the collaboration and license agreement as Agios has the decision-making authority for the Joint Steering Committee and Joint Research Committee until we exercise our option to license a product. Our interest in Agios is limited to our equity ownership and we do not have any obligations or rights to the future losses or returns of Agios beyond this ownership.

*Epizyme:* In April 2012, we entered into a collaboration and license agreement with Epizyme, Inc., or Epizyme, to discover, develop and commercialize novel therapeutic compounds by inhibiting histone methyltransferases (HMTs), an important epigenetic target class.

Under the terms of the agreement, we made an upfront payment of \$65.0 million to Epizyme and also made a \$25.0 million equity investment in Epizyme Series C Preferred Stock. If the option is exercised, Epizyme could receive up to \$165.0 million in milestone payments associated with each Epizyme compound developed to inhibit each distinct HMT target under the collaboration plus royalties on sales. Under this agreement, we have the exclusive option to license rights to HMT targets outside the United States and each Epizyme compound associated with such target during the option term. Epizyme will have the sole responsibility to develop and commercialize compounds in the United States.

The option term expires on either July 9, 2015, or July 9, 2016 if we unilaterally extend the option term for a fourth year and pay an option extension fee. Further, if an HMT target or targets are selected then the agreement will expire upon the expiration of all applicable royalty terms under the agreement with respect to all licensed Epizyme compounds. Upon the expiration of the agreement, we will have a fully paid-up, royalty-free license to use Epizyme intellectual property to manufacture, market, use and sell such licensed Epizyme compounds developed under the agreement outside the United States.

*Other Collaboration Arrangements in 2012:* In addition to the collaboration arrangements described above, we entered into a number of collaborative arrangements during 2012 that resulted in \$34.5 million of assets for investments in equity or other assets and research and development expenses of \$113.5 million. These additional arrangements entered into during 2012 include the potential for future milestone payments of up to an aggregate \$1.420 billion related to the attainment of specified development and regulatory approval milestones over a period of several years. Our obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs.

## **MANUFACTURING**

We own and operate an FDA approved manufacturing facility in Zofingen, Switzerland which produces the active pharmaceutical ingredient, or API, for REVLIMID® and THALOMID® and have contracted with FDA approved third-party contract manufacturers to provide backup API manufacturing services for these products. Manufacturing services for REVLIMID® and THALOMID®, which consist of formulation, encapsulation, packaging, warehousing and distribution, are performed at our FDA approved drug product manufacturing facility in Boudry, Switzerland. We have contracted with a number of third-party drug product manufacturing

service providers and packaging service providers to provide backup manufacturing and packaging services. All of our third-party service providers are approved by the regulatory authorities for the geographies that they serve.

The API for ABRAXANE® is generally available from multiple sources and is normally available in quantities adequate to meet our needs. Manufacturing services for ABRAXANE® are performed at our manufacturing facility in Arizona and by an approved third party contract manufacturing facility.

The API for VIDAZA® is supplied by two suppliers, and the API for ISTODAX® is supplied by a single-source supplier. Manufacturing and packaging services for these products are provided by a number of third-party service providers.

The API for POMALYST® is supplied by a single-source supplier with primary manufacturing services being performed at our Boudry manufacturing facility. We expect to utilize third-party service providers for backup manufacturing and packaging services for this product.

The API for FOCALIN® and FOCALIN XR® is currently obtained from two suppliers, and we rely on a single manufacturer for the tableting and packaging of FOCALIN® finished product.

CCT currently operates an FDA registered facility in Cedar Knolls, New Jersey for the recovery and storage of cord blood and placental stem cells for LifeBankUSA®. In addition, our Warren, New Jersey facility is FDA registered for production of PDA-001, a culture-expanded placenta-derived stem cell under cGMP to supply clinical studies. This is a multi-purpose facility capable of supporting other products.

## **INTERNATIONAL OPERATIONS**

We have significant operations outside the United States conducted both through our subsidiaries and through distributors. Revenues from operations outside the United States were \$2.338 billion, or 42.4% of total revenues in 2012, \$1.981 billion, or 40.9% of total revenues in 2011, and \$1.437 billion, or 39.6% of total revenues in 2010. The increase in the percentage of total revenues from outside of the United States is the result of our ongoing efforts to increase the availability of our products to patients worldwide.

Our international headquarters and a drug product manufacturing facility which performs formulation, encapsulation, packaging, warehousing and distribution are located in Boudry, Switzerland. We continue to expand our international regulatory, clinical and commercial infrastructure and currently conduct our international operations in over 50 countries and have sales in over 70 countries and regions including Europe, Latin America, Middle East, Asia/Pacific and Canada.

Our international operations are subject to risks associated with operating on an international basis including currency fluctuations, price and exchange controls and other restrictive governmental actions. Our international operations are also subject to government-imposed constraints, including laws on pricing, reimbursement and access to our products. Depending on the direction of change relative to the U.S. dollar, foreign currency values can increase or decrease the reported dollar value of our net assets and results of operations. While we cannot

predict with certainty future changes in foreign exchange rates or the effect they will have, we attempt to mitigate their impact through operational means and by using foreign currency derivative instruments. See the discussions under “Item 7A Quantitative and Qualitative Disclosures About Market Risk.”

## **SALES AND COMMERCIALIZATION**

We promote our brands globally through our commercial organization which is comprised of highly trained individuals who have significant experience in the pharmaceutical industry, especially in the areas of oncology and immunology. Our commercial organization supports our currently marketed brands and prepares for the launches of new products, as well as new indications for existing products. We have a team of dedicated market access professionals to help physicians, patients and payers understand the value our products deliver. Given our goal to ensure that patients who might benefit from our therapies have the opportunity to do so and given the complex reimbursement environment in the United States, we offer the services of Celgene Patient Support<sup>®</sup>, a dedicated, central point of contact for patients and healthcare professionals who use or prescribe Celgene products. Celgene Patient Support<sup>®</sup> is a free service that helps patients and healthcare professionals navigate the challenges of reimbursement, providing information about co-pay assistance and answering questions about obtaining Celgene products.

In most countries, we sell our products through our own sales organizations. In some countries, particularly in Latin America, we partner with third-party distributors. See the section entitled “COMMERCIAL STAGE PRODUCTS” above. Generally, we distribute our products through the commonly used channels in local markets. However, REVLIMID<sup>®</sup>, POMALYST<sup>®</sup>, and THALOMID<sup>®</sup> are distributed under mandatory risk-management distribution programs tailored to meet local competent authorities’ specifications to provide for their safe and appropriate distribution and use.

## **EMPLOYEES**

As of December 31, 2012, we had 4,700 full-time employees, of whom 2,020 were engaged primarily in research and development activities, 1,451 engaged primarily in sales and commercialization activities, 452 engaged primarily in manufacturing, and the remaining 777 engaged primarily in executive and general and administrative activities. The number of full-time employees in our international operations has grown from 1,654 at the end of 2011 to 1,834 at the end of 2012. We also employ a number of part-time employees and maintain consulting arrangements with a number of researchers at various universities and other research institutions around the world.

## **FORWARD-LOOKING STATEMENTS**

Certain statements contained or incorporated by reference in this Annual Report on Form 10-K are considered forward-looking statements (within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended) concerning our business, results of operations, economic performance and/or financial condition, based on management’s

current expectations, plans, estimates, assumptions and projections. Forward-looking statements are included, for example, in the discussions about:

- strategy;
- new product discovery and development;
- current or pending clinical trials;
- our products' ability to demonstrate efficacy or an acceptable safety profile;
- actions by the FDA;
- product manufacturing, including our arrangements with third-party suppliers;
- product introduction and sales;
- royalties and contract revenues;
- expenses and net income;
- credit and foreign exchange risk management;
- liquidity;
- asset and liability risk management;
- the outcome of litigation;
- intellectual property rights and protection;
- economic factors;
- competition; and
- operational and legal risks.

Any statements contained in this report that are not statements of historical fact may be deemed forward-looking statements. Forward-looking statements generally are identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “aims,” “plans,” “may,” “could,” “will,” “will continue,” “seeks,” “should,” “predict,” “potential,” “outlook,” “guidance,” “target,” “forecast,” “probable,” “possible” or the negative of such terms and similar expressions. Forward-looking statements are subject to change and may be affected by risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under the U.S. securities laws and other applicable laws.

We caution you that a number of important factors could cause actual results or outcomes to differ materially from those expressed in, or implied by, the forward-looking statements, and therefore you should not place too much reliance on them. These factors include, among others, those described herein, under “Risk Factors” and elsewhere in this Annual Report and in our other public reports filed with the Securities and Exchange Commission, or SEC. It is not possible to predict or identify all such factors, and therefore the factors that are noted are not intended to be a complete discussion of all potential risks or uncertainties that may affect forward-looking statements. If these or other risks and uncertainties materialize, or if the assumptions underlying any of the forward-looking statements prove incorrect, our actual performance and future actions may be materially different from those expressed in, or implied by, such forward-looking statements. We can offer no assurance that our estimates or expectations will prove accurate or that we will be able to achieve our strategic and operational goals.

#### **ITEM 1A. RISK FACTORS**

The following statements describe the major risks to our business and should be considered carefully. Any of these factors could significantly and negatively affect our business, prospects, financial condition, operating results or credit ratings, which could cause the trading price of our common stock to decline. The risks described below are not the only risks we may face. Additional risks and uncertainties not presently known to us, or risks that we currently consider immaterial, could also negatively affect our business, financial results and operations.

*We may experience significant fluctuations in our quarterly operating results which could cause our financial results to be below expectations and cause our stock price to be volatile.*

We have historically experienced, and may continue to experience, significant fluctuations in our quarterly operating results. These fluctuations are due to a number of factors, many of which are outside our control, and may result in volatility of our stock price. Future operating results will depend on many factors, including:

- demand or lack of demand for our products, including demand that adversely affects our ability to optimize the use of our manufacturing facilities;
- the introduction and pricing of products competitive with ours, including generic competition;
- developments regarding the safety or efficacy of our products;
- regulatory approvals for our products and pricing determinations with respect to our products;
- regulatory approvals for our manufacturing facilities and those of our suppliers;
- timing and levels of spending for research and development, sales and marketing;
- timing and levels of reimbursement from third-party payers for our products;

- development or expansion of business infrastructure in new clinical and geographic markets;
- the acquisition of new products and companies;
- tax rates in the jurisdictions in which we operate;
- timing and recognition of certain research and development milestones and license fees;
- ability to control our costs;
- fluctuations in foreign currency exchange rates; and
- economic and market instability.

*We are dependent on the continued commercial success of our primary products REVLIMID®, VIDAZA®, THALOMID® and ABRAXANE®, and a significant decline in demand for or use of these products or our other commercially available products could materially and adversely affect our operating results.*

During the next several years, the growth of our business will be largely dependent on the commercial success of REVLIMID®, VIDAZA®, THALOMID® and ABRAXANE®. We cannot predict the extent to which these or our other existing or new products will be accepted by regulators, physicians, patients and other key opinion leaders as effective drugs with certain advantages over existing or future therapies. We are continuing to introduce our products in additional international markets and to obtain approvals for additional indications both in the United States and internationally. A delay in gaining the requisite regulatory approvals for these markets or indications could negatively impact our growth plans and the value of our stock.

Further, if unexpected adverse experiences are reported in connection with the use of any of our products, physician and patient comfort with the product could be undermined, the commercial success of such product could be adversely affected and the acceptance of our other products could be negatively impacted. We are subject to adverse event reporting regulations that require us to report to the Food and Drug Administration, or FDA, or similar bodies in other countries if our products are associated with a death or serious injury. These adverse events, among others, could result in additional regulatory controls, such as the performance of costly post-approval clinical studies or revisions to our approved labeling, which could limit the indications or patient population for our products or could even lead to the withdrawal of a product from the market. Similarly, the occurrence of serious adverse events known or suspected to be related to the products could negatively impact product sales. For example, THALOMID® is known to be toxic to the human fetus and exposure to the drug during pregnancy could result in significant deformities in the baby. REVLIMID® is also considered fetal toxic and there are warnings against use of VIDAZA® in pregnant women as well. While we have restricted distribution systems for both THALOMID® and REVLIMID® and we endeavor to educate patients regarding the potential known adverse events including pregnancy risks, we cannot ensure that all such warnings and recommendations will be complied with or that adverse events resulting from non-compliance will not have a material adverse effect on our business.

It is necessary that our primary products achieve and maintain market acceptance. A number of factors may adversely impact the degree of market acceptance of our products, including the products' efficacy, safety, price and benefits, if any, over competing products, as well as the reimbursement policies of third-party payers, such as government and private insurance plans, patent disputes and claims about adverse side effects.

***If we do not gain or maintain regulatory approval of our products we will be unable to sell our current products and products in development.***

Changes in law, government regulations or policies can have a significant impact on our results of operations. The discovery, preclinical development, clinical trials, manufacturing, risk evaluation and mitigation strategies (such as our S.T.E.P.S.<sup>®</sup> and RevAssist<sup>®</sup> programs), marketing and labeling of pharmaceuticals and biologics are all subject to extensive laws and regulations, including, without limitation, the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Public Health Service Act, Medicare Modernization Act, Food and Drug Administration Amendments Act, and other federal and state statutes, as well as similar laws in foreign jurisdictions. Changes in laws, government regulations or policies can have a significant adverse impact on our ability to continue to commercialize our products or introduce new products to the market, which would adversely affect our results of operations.

If we or our agents, contractors or collaborators are delayed in receiving, or are unable to obtain all, necessary governmental approvals, we will be unable to effectively market our products.

The testing, marketing and manufacturing of our products requires regulatory approval, including approval from the FDA and, in some cases, from the Environmental Protection Agency, or EPA, or governmental authorities outside of the United States that perform roles similar to those of the FDA and EPA, including the EMA, European Commission, the Japanese Pharmaceuticals and Medical Devices Agency, the Swissmedic, the Australian Therapeutic Goods Administration and Health Canada. Certain of our pharmaceutical products, such as FOCALIN<sup>®</sup>, fall under the Controlled Substances Act of 1970 that requires authorization by the U.S. Drug Enforcement Agency, or DEA, of the U.S. Department of Justice in order to handle and distribute these products.

The regulatory approval process presents a number of risks to us, principally:

- In general, preclinical tests and clinical trials can take many years, and require the expenditure of substantial resources, and the data obtained from these tests and trials can be susceptible to varying interpretation that could delay, limit or prevent regulatory approval;
- Delays or rejections may be encountered during any stage of the regulatory process based upon the failure of the clinical or other data to demonstrate compliance with a regulatory agency's requirements for safety, efficacy and quality or, in the case of a product seeking an orphan drug indication, because another designee received approval first or receives approval of other labeled indications;
- Requirements for approval may become more stringent due to changes in regulatory agency policy or the adoption of new regulations or legislation;

- The scope of any regulatory approval, when obtained, may significantly limit the indicated uses for which a product may be marketed and reimbursed and may impose significant limitations in the nature of warnings, precautions and contra-indications that could materially affect the sales and profitability of the drug;
- Approved products, as well as their manufacturers, are subject to continuing and ongoing review, and discovery of previously unknown problems with these products or the failure to adhere to manufacturing or quality control requirements may result in restrictions on their manufacture, sale or use or in their withdrawal from the market;
- Regulatory authorities and agencies of the United States or foreign governments may promulgate additional regulations restricting the sale of our existing and proposed products, including specifically tailored risk evaluation and mitigation strategies;
- Guidelines and recommendations published by various governmental and non-governmental organizations can reduce the use of our products;
- Once a product receives marketing approval, we may not market that product for broader or different applications, and the FDA may not grant us approval with respect to separate product applications that represent extensions of our basic technology. In addition, the FDA may withdraw or modify existing approvals in a significant manner or promulgate additional regulations restricting the sale of our present or proposed products. The FDA may also request that we perform additional clinical trials or change the labeling of our existing or proposed products if we or others identify side effects after our products are on the market;
- Products, such as REVLIMID®, that are subject to accelerated approval can be subject to an expedited withdrawal if the post-marketing restrictions are not adhered to or are shown to be inadequate to assure the safe use of the drug, or evidence demonstrates that the drug is not shown to be safe and effective under its conditions of use. Additionally, promotional materials for such products are subject to enhanced surveillance, including pre-approval review of all promotional materials used within 120 days following marketing approval and a requirement for the submissions 30 days prior to initial dissemination of all promotional materials disseminated after 120 days following marketing approval; and
- Our risk evaluation and mitigation strategies, labeling and promotional activities relating to our products as well as our post-marketing activities are regulated by the FDA, the Federal Trade Commission, the United States Department of Justice, the DEA, state regulatory agencies and foreign regulatory agencies and are subject to associated risks. In addition, individual states, acting through their attorneys general, have become active as well, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. If we fail to comply with regulations regarding the promotion and sale of our products, appropriate distribution of our products under our restricted distribution systems, off-label promotion and the promotion of unapproved products, such agencies may bring enforcement actions against us that could inhibit our commercial capabilities as well as result in significant penalties.



Other matters that may be the subject of governmental or regulatory action which could adversely affect our business include:

- changes in laws and regulations, including without limitation, patent, environmental, privacy, health care and competition laws;
- importation of prescription drugs from outside the United States at prices that are regulated by the governments of various foreign countries;
- additional restrictions on interactions with healthcare professionals; and
- privacy restrictions that may limit our ability to share data from foreign jurisdictions.

We collect placentas and umbilical cord blood for our unrelated allogeneic and private stem cell banking businesses. The FDA's Center for Biologics Evaluation and Research currently regulates human tissue or cells intended for transplantation, implantation, infusion or transfer to a human recipient under 21 CFR Parts 1270 and 1271. Part 1271 requires cell and tissue establishments to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease and to register the establishment with FDA. This part also provides for inspection by the FDA of cell and tissue establishments. Currently, we are required to be, and are, licensed to operate in New York, New Jersey, Maryland and California. If other states adopt similar licensing requirements, we would need to obtain such licenses to continue operating any stem cell banking businesses if we are deemed to be operating in those states. If we are delayed in receiving, or are unable to obtain at all, necessary licenses, we will be unable to provide services in those states and this could impact negatively on our revenue.

***Sales of our products will be significantly reduced if access to and reimbursement for our products by governmental and other third-party payers is reduced or terminated.***

Sales of our products will depend, in part, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. Generally, in Europe and other countries outside the United States, the government-sponsored healthcare system is the primary payer of healthcare costs of patients. These health care management organizations and third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the 2010 U.S. Health Care Reform Law, which became effective in January 2011, has provided sweeping health care reform in the United States, which may impact access to and reimbursement for our products. In addition to the federal legislation, state legislatures and foreign governments have also shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. The establishment of limitations on patient access to our drugs, adoption of price controls and cost-containment measures in new jurisdictions or programs, and adoption of more restrictive policies in jurisdictions with existing controls and measures, including the impact of the 2010 U.S. Health Care Reform Law, could adversely impact our business and future results. If these organizations and third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not reimburse

providers or consumers of our products or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors, and these negotiated prices are made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of that contractual arrangement. Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

We encounter similar regulatory and legislative issues in most countries outside the United States. International operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on access to and reimbursement for our products. Although we cannot predict the extent to which our business may be affected by future cost-containment measures or other potential legislative or regulatory developments, additional foreign price controls or other changes in pricing regulation could restrict access to and reimbursement for our current and future products, which could adversely affect our revenue and results of operations.

***Our long-term success depends, in part, on intellectual property protection.***

Our success depends, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties and to conduct our business without infringing upon the proprietary rights of others. The patent positions of pharmaceutical and biopharmaceutical companies, including ours, can be uncertain and involve complex legal and factual questions including those related to our risk evaluation and mitigation strategies (such as our S.T.E.P.S.<sup>®</sup> and RevAssist<sup>®</sup> programs). In addition, the coverage sought in a patent application can be significantly reduced before the patent is issued.

Consequently, we do not know whether any of our owned or licensed pending patent applications, which have not already been allowed, will result in the issuance of patents or, if any patents are issued, whether they will be dominated by third-party patent rights, whether they will provide significant proprietary protection or commercial advantage or whether they will be circumvented, opposed, invalidated, rendered unenforceable or infringed by others. Further, we are aware of third-party U.S. patents that relate to, for example, the use of certain stem cell technologies and cannot be certain as to any impact to our potential products, or guarantee that our patents or pending applications will not be involved in, or be defeated as a result of,

opposition proceedings before a foreign patent office or any interference proceedings before the United States Patent & Trademark Office, or PTO.

With respect to patents and patent applications we have licensed-in, there can be no assurance that additional patents will be issued to any of the third parties from whom we have licensed patent rights, or that, if any new patents are issued, such patents will not be opposed, challenged, invalidated, infringed or dominated or provide us with significant proprietary protection or commercial advantage. Moreover, there can be no assurance that any of the existing licensed patents will provide us with proprietary protection or commercial advantage. Nor can we guarantee that these licensed patents will not be either infringed, invalidated or circumvented by others, or that the relevant agreements will not be terminated. A termination of material licenses granted to us could have a material adverse effect on our business, financial condition and results of operations.

Because (1) patent applications filed in the United States on or before November 28, 2000 are maintained in secrecy until patents issue, (2) patent applications filed in the United States on or after November 29, 2000 are not published until approximately 18 months after their earliest claimed priority date, (3) United States patent applications that are not filed outside the United States may not publish at all until issued and (4) publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be certain that we, or our licensors, were the first to make the inventions covered by each of the issued patents or pending patent applications or that we, or our licensors, were the first to file patent applications for such inventions. In the event a third party has also filed a patent for any of our inventions, we, or our licensors, may have to participate in interference proceedings before the PTO to determine priority of invention, which could result in the loss of a U.S. patent or loss of any opportunity to secure U.S. patent protection for the invention. Even if the eventual outcome is favorable to us, such interference proceedings could result in substantial cost to us.

Our intellectual property rights will further be affected in ways that are difficult to anticipate at this time by the provisions of the America Invents Act, signed into law on September 16, 2011. The new patent law is the first major overhaul of the U.S. patent system since 1952, and includes a number of changes to established practices. The most significant changes in the new law include the transition to a first-to-file system, the availability of new post-grant review for issued patents, various procedural changes, including the submission of prior art and the availability of derivation proceedings and supplemental examination, and an expanded prior commercial user rights defense to a claim of patent infringement. The scope of these changes and the lack of experience with their practical implementation, suggest a transitional period with some uncertainty over the next few years. For example, while some provisions of the new patent law have already taken effect, others will take effect up to 18 months from enactment. The U.S. PTO is still in the process of publishing regulations concerning the implementation of the law. Several provisions of the new law will likely be tested in courts over time.

The changes in the new U.S. patent law will have an impact on our intellectual property rights and how business is conducted in general. For example, the first-to-file system places a premium on filing as early as possible and appears to increase what is available as prior art, by changing the applicable definitions. In the future, in addition to patents and printed publications, we may be required to deal with unfamiliar prior art categories such as art that is “otherwise available to the

public.” For patent applications filed on or after March 16, 2013, we may expect post-grant review challenges initiated up to nine months after the corresponding patent issues.

While the new patent law was intended to make the resolution of intellectual property disputes easier and less expensive, we may in the future have to prove that we are not infringing patents or we may be required to obtain licenses to such patents. However, we do not know whether such licenses will be available on commercially reasonable terms, or at all. Prosecution of patent applications, post-grant opposition proceedings and litigation to establish the validity and scope of patents, to assert patent infringement claims against others and to defend against patent infringement claims by others can be expensive and time-consuming. There can be no assurance that, in the event that claims of any of our owned or licensed patents are challenged by one or more third parties, any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation or post-grant proceeding could cause us to lose exclusivity relating to the subject matter delineated by such patent claims and may have a material adverse effect on our business. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using the products or processes covered by the disputed rights, be subject to significant liabilities to such third party and/or be required to license technologies from such third party. Also, different countries have different procedures for obtaining patents, and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. There can be no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention or that any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country will be similar to the judicial interpretation given to a corresponding patent issued in another country. Competitors have chosen and in the future may choose to file oppositions to patent applications, which have been deemed allowable by foreign patent examiners. Furthermore, even if our owned or licensed patents are determined to be valid and enforceable, there can be no assurance that competitors will not be able to challenge the validity or our patent claims in post-grant proceedings, or to design around such patents and compete with us using the resulting alternative technology. Additionally, for these same reasons, we cannot be sure that patents of a broader scope than ours may be issued and thereby create freedom to operate issues. If this occurs we may need to reevaluate pursuing such technology, which is dominated by others’ patent rights, or alternatively, seek a license to practice our own invention, whether or not patented.

We also rely upon unpatented, proprietary and trade secret technology that we seek to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach or that our trade secrets, proprietary know-how and technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology or that such technology will not be found to be non-proprietary or not a trade secret.

***Our products may face competition from lower cost generic or follow-on products and providers of these products may be able to sell them at a substantially lower cost than us.***

Generic drug manufacturers are seeking to compete with our drugs and present an important challenge to us. Even if our patent applications, or those we have licensed-in, are issued, innovative and generic drug manufacturers and other competitors may challenge the scope, validity or enforceability of such patents in court, requiring us to engage in complex, lengthy and costly litigation. Alternatively, innovative and generic drug manufacturers and other competitors may be able to design around our owned or licensed patents and compete with us using the resulting alternative technology. If any of our issued or licensed patents are infringed or challenged, we may not be successful in enforcing or defending our or our licensor's intellectual property rights and subsequently may not be able to develop or market the applicable product exclusively.

Upon the expiration or loss of patent protection for one of our products, or upon the "at-risk" launch (despite pending patent infringement litigation against the generic product) by a generic manufacturer of a generic version of one of our products, we can quickly lose a significant portion of our sales of that product, which can adversely affect our business. In addition, if generic versions of our competitors' branded products lose their market exclusivity, our patented products may face increased competition which can adversely affect our business.

The FDA approval process allows for the approval of an Abbreviated New Drug Application, or ANDA, or 505(b)(2) application for a generic version of our approved products upon the expiration, through passage of time or successful legal challenge, of relevant patent or non-patent exclusivity protection. Generic manufacturers pursuing ANDA approvals are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative companies who have incurred substantial expenses associated with the research and development of the drug product. Accordingly, while our products currently may retain certain regulatory and or patent exclusivity, our products are or will be subject to ANDA applications to the FDA in light of the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act. The ANDA procedure includes provisions allowing generic manufacturers to challenge the effectiveness of the innovator's patent protection prior to the generic manufacturer actually commercializing their products – the so-called "Paragraph IV" certification procedure. In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the applicability of Orange Book-listed patents on a wide array of innovative pharmaceuticals, and we expect this trend to continue. During the exclusivity periods, the FDA is generally prevented from granting effective approval of an ANDA. Upon the expiration of the applicable exclusivities, through passage of time or successful legal challenge, the FDA may grant effective approval of an ANDA for a generic drug, or may accept reference to a previously protected NDA in a 505(b)(2) application. Further, upon such expiration event, the FDA may require a generic competitor to participate in some form of risk management system which could include our participation as well. Depending upon the scope of the applicable exclusivities, any such approval could be limited to certain formulations and/or indications/claims, i.e., those not covered by any outstanding exclusivities.

If an ANDA filer or a 505(b)(2) applicant were to receive approval to sell a generic or follow-on version of one of our products, that product would become subject to increased competition and our revenues for that product would be adversely affected.

We received two Paragraph IV Certification Letters dated August 30, 2010 and June 12, 2012, respectively, advising us that Natco Pharma Limited of Hyderabad, India, or Natco, submitted an ANDA to the FDA with respect to REVLIMID®. See “Legal Proceedings” contained in Part I, Item 3 of this Annual Report on Form 10-K for further information.

*If we are not able to effectively compete our business will be adversely affected.*

The pharmaceutical and biotechnology industries in which we operate are highly competitive and subject to rapid and significant technological change. Our present and potential competitors include major pharmaceutical and biotechnology companies, as well as specialty pharmaceutical firms, including, but not limited to:

- Takeda and Johnson & Johnson, which compete with REVLIMID® and THALOMID® in the treatment of multiple myeloma and in clinical trials with our compounds;
- Eisai, SuperGen and Johnson & Johnson, which compete or may potentially compete with VIDAZA®, in addition Eisai potentially competes with ABRAXANE®, and in other oncology products in general;
- Amgen, which potentially competes with our TNF- $\alpha$  and kinase inhibitors;
- AstraZeneca, which potentially competes in clinical trials with our compounds and TNF- $\alpha$  inhibitors;
- Biogen Idec is generally developing drugs that address the oncology and immunology markets;
- Bristol Myers Squibb, which potentially competes with ABRAXANE®, and in clinical trials with our compounds and TNF- $\alpha$  inhibitors, in addition to other oncology products in general;
- F. Hoffman-La Roche, which potentially competes in clinical trials with our ®TNF- $\alpha$  inhibitors, in addition to other oncology products in general;
- Johnson & Johnson, Pfizer, and Abbott Laboratories also compete with our oral anti-inflammatory programs;
- Novartis, which potentially competes with our compounds and kinase programs;
- Pfizer, which potentially competes in clinical trials with our kinase inhibitors; and
- Sanofi, which competes with ABRAXANE®, in addition to other oncology products in general.

Many of these companies have considerably greater financial, technical and marketing resources than we do. This enables them, among other things, to make greater research and development investments and spread their research and development costs, as well as their marketing and promotion costs, over a broader revenue base. Our competitors may also have more experience and expertise in obtaining marketing approvals from the FDA, and other regulatory authorities. We also experience competition from universities and other research institutions, and in some instances, we compete with others in acquiring technology from these sources. The pharmaceutical industry has undergone, and is expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technical advances in the field are made and become more widely known. The development of products, including generics, or processes by our competitors with significant advantages over those that we are seeking to develop could cause the marketability of our products to stagnate or decline.

***A decline of global economic conditions could adversely affect our results of operations.***

Sales of our products are dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of global credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, U.S. federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may limit access to and reimbursement for our products. A reduction in the availability or extent of reimbursement could negatively affect our product sales, revenue and cash flows.

See our discussion of accounts receivable from Spain, Italy and Portugal in the Management Discussion and Analysis section of this Annual Report on Form 10-K, under the caption “Liquidity and Capital Resources” for details related to amounts receivable from the government owned or controlled hospitals in Spain, Italy and Portugal.

Due to tightened global credit, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. We rely on third parties for several important aspects of our business, including portions of our product manufacturing, royalty revenue, clinical development of future collaboration products, conduct of clinical trials and raw materials. If such third parties are unable to satisfy their commitments to us, our business could be adversely affected.

***We may be required to modify our business practices, pay fines and significant expenses or experience losses due to litigation or governmental investigations.***

From time to time, we may be subject to litigation or governmental investigation on a variety of matters in the United States or foreign jurisdictions, including, without limitation, regulatory, intellectual property, product liability, antitrust, consumer, false claims, whistleblower, Qui Tam, privacy, anti-kickback, anti-bribery, environmental, commercial, securities and employment litigation and claims and other legal proceedings that may arise from the conduct of our business.

Our activities relating to the sale and marketing and the pricing of our products are subject to extensive regulation in the United States and foreign jurisdictions. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of

information requests from government authorities, and we have been subject to claims and other actions related to our business activities.

We are also subject to significant product liability risks as a result of the testing of our products in human clinical trials and for products that we sell after regulatory approval. Although we have insurance coverage with respect to potential product liability claims, there can be no guarantee that insurance coverage will be adequate or continue to be available at sufficient levels to fully cover claims that may arise in the future.

In the fourth quarter of 2009, we received a Civil Investigative Demand (CID) from the U.S. Federal Trade Commission, or the FTC. The FTC requested documents and other information relating to requests by generic companies to purchase our patented REVLIMID® and THALOMID® brand drugs in order to evaluate whether there is reason to believe that we have engaged in unfair methods of competition. In the first quarter of 2010, the State of Connecticut referenced the same issues as those referenced in the 2009 CID and issued a subpoena. In the fourth quarter of 2010, we received a second CID from the FTC relating to this matter. We continue to respond to requests for information.

In the first quarter of 2011, the United States Attorney's Office for the Central District of California informed us that they are investigating possible off-label marketing and improper payments to physicians in connection with the sales of THALOMID® and REVLIMID®. In the third quarter of 2012, we learned that two other United States Attorneys' offices (the Northern District of Alabama and the Eastern District of Texas) and various state Attorneys General are conducting related investigations. We are cooperating with these investigations.

While the ultimate outcome of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters may have a material adverse effect on our results of operations, cash flows or financial condition and result in, among other things:

- rulings that are materially unfavorable to us, including significant damage awards, fines or penalties, and administrative remedies, such as exclusion and/or debarment from government programs, or other rulings that prevent us from operating our business in a certain manner;
- changes to our business operations to avoid perceived risks associated with such litigation or investigations;
- modification of our business practices;
- product recalls;
- reputational damage and decreased demand for our products; and
- expenditure of significant time and resources, which may divert the attention of our management and interfere with the pursuit of our strategic objectives.

While we maintain insurance for certain risks, the amount of our insurance coverage may not be adequate to cover the total amount of all insured claims and liabilities. It also is not possible to



obtain insurance to protect against all potential risks and liabilities. If any litigation or governmental investigation were to have a material adverse result, there could be a material impact on our results of operations, cash flows or financial condition. See also “Legal Proceedings” contained in Part I, Item 3 of this Annual Report on Form 10-K.

***The development of new biopharmaceutical products involves a lengthy and complex process, and we may be unable to commercialize any of the products we are currently developing.***

Many of our drug candidates are in the early or mid-stages of research and development and will require the commitment of substantial financial resources, extensive research, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. This process involves a high degree of risk and takes many years. Our product development efforts with respect to a product candidate may fail for many reasons, including the failure of the product candidate in preclinical studies; adverse patient reactions to the product candidate or indications or other safety concerns; insufficient clinical trial data to support the effectiveness or superiority of the product candidate; our inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-efficient manner; our failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate, the facilities or the process used to manufacture the product candidate; or changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer desirable. Moreover, our commercially available products may require additional studies with respect to approved indications as well as new indications pending approval.

The stem cell products that we are developing through our Celgene Cellular Therapeutics, or CCT, subsidiary may represent substantial departures from established treatment methods and will compete with a number of traditional products and therapies which are now, or may be in the future, manufactured and marketed by major pharmaceutical and biopharmaceutical companies. Furthermore, public attitudes may be influenced by claims that stem cell therapy is unsafe, and stem cell therapy may not gain the acceptance of the public or the medical community.

Due to the inherent uncertainty involved in conducting clinical studies, we can give no assurances that our studies will have a positive result or that we will receive regulatory approvals for our new products or new indications.

***Manufacturing and distribution risks including a disruption at certain of our manufacturing and distribution sites, would significantly interrupt our production capabilities, which could result in significant product delays and adversely affect our results.***

We have our own manufacturing facilities for many of our products and we have contracted with third-party manufacturers and distributors to provide active pharmaceutical ingredient, or API, encapsulation, finishing services, packaging and distribution services to meet our needs. These operations expose us to risks that include the possibility that our or our suppliers' manufacturing processes and distribution channels could be partially or completely disrupted by a fire, natural disaster, terrorist attack, governmental action or military action. In the case of a disruption, we may need to establish alternative manufacturing sources for these products. This would likely lead to substantial production delays as we build or locate replacement facilities and seek and

obtain the necessary regulatory approvals. If this occurs, and our finished goods inventories are insufficient to meet demand, we may be unable to satisfy customer orders on a timely basis, if at all. Further, our business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the uncovered cost of any disruption. For these reasons, a significant disruptive event affecting these manufacturing facilities or sites could materially and adversely affect our business and results of operations. In addition, if we inaccurately predict market demand for our products, we may be unable to sufficiently increase production capacity to satisfy demand or may incur costs associated with excess inventory that we manufacture.

In all the countries where we sell our products, governmental regulations exist to define standards for manufacturing, packaging, labeling, distribution and storing. All of our suppliers of raw materials, contract manufacturers and distributors must comply with these regulations, as applicable. In the United States, the FDA requires that all suppliers of pharmaceutical bulk material and all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA's current Good Manufacturing Practice regulations and guidelines. Our failure to comply, or failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications pre-approved by regulators for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

If our outside manufacturers do not meet our requirements for quality, quantity or timeliness, or do not achieve and maintain compliance with all applicable regulations, our ability to continue supplying such products at a level that meets demand could be adversely affected.

We have contracted with distributors, to distribute REVLIMID®, THALOMID®, VIDAZA®, ABRAXANE® and ISTODAX®. If our distributors fail to perform and we cannot secure a replacement distributor within a reasonable period of time, we may experience adverse effects to our business and results of operations.

We are continuing to establish marketing and distribution capabilities in international markets with respect to our products. At the same time, we are in the process of obtaining necessary governmental and regulatory approvals to sell our products in certain countries. If we have not successfully completed and implemented adequate marketing and distribution support services upon our receipt of such approvals, our ability to effectively launch our products in these countries would be severely restricted.

***The consolidation of drug wholesalers and other wholesaler actions could increase competitive and pricing pressures on pharmaceutical manufacturers, including us.***

We sell our pharmaceutical products in the United States primarily through wholesale distributors and contracted pharmacies. These wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation. As a result, a smaller number of large wholesale distributors and pharmacy chains control a significant share of the market. We expect that consolidation of drug wholesalers and pharmacy chains will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through fee-for-service arrangements, and their purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters. We cannot assure you that we can manage these pressures or that wholesaler purchases will not decrease as a result of this potential excess buying.

***Risks from the improper conduct of employees, agents or contractors or collaborators could adversely affect our business or reputation.***

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including without limitation, employment, foreign corrupt practices, environmental, competition and privacy laws. Such improper actions could subject us to civil or criminal investigations, monetary and injunctive penalties and could adversely impact our ability to conduct business, our results of operations and our reputation.

***The integration of acquired businesses may present significant challenges to us.***

We may face significant challenges in effectively integrating entities and businesses that we may acquire and we may not realize the benefits anticipated from such acquisitions. Achieving the anticipated benefits of our acquired businesses will depend in part upon whether we can integrate our businesses in an efficient and effective manner. Our integration of acquired businesses involves a number of risks, including, but not limited to:

- demands on management related to the increase in our size after the acquisition;
- the diversion of management's attention from the management of daily operations to the integration of operations;
- higher integration costs than anticipated;
- failure to achieve expected synergies and costs savings;
- difficulties in the assimilation and retention of employees;

- difficulties in the assimilation of different cultures and practices, as well as in the assimilation of broad and geographically dispersed personnel and operations; and
- difficulties in the integration of departments, systems, including accounting systems, technologies, books and records, and procedures, as well as in maintaining uniform standards and controls, including internal control over financial reporting required by the Sarbanes-Oxley Act of 2002 and related procedures and policies.

If we cannot successfully integrate acquired businesses we may experience material negative consequences to our business, financial condition or results of operations. Successful integration of acquired businesses will depend on our ability to manage these operations, to realize opportunities for revenue growth presented by product offerings and expanded geographic market coverage and, to some degree, to eliminate redundant and excess costs.

***An inability to continue to attract and retain key leadership, managerial, commercial and scientific talent could adversely affect our business.***

The success of our business depends, in large part, on our continued ability to (i) attract and retain highly qualified management, scientific, manufacturing and commercial personnel, (ii) successfully integrate large numbers of new employees into our corporate culture and (iii) develop and maintain important relationships with leading research and medical institutions and key distributors. Competition for these types of personnel and relationships is intense.

Among other benefits, we use share-based compensation to attract and retain personnel. Share-based compensation accounting rules require us to recognize all share-based compensation costs as expenses. These or other factors could reduce the number of share-based compensation awards we grant under our incentive plan. We cannot be sure that we will be able to attract or retain skilled personnel or maintain key relationships, or that the costs of retaining such personnel or maintaining such relationships will not materially increase.

***We could be subject to significant liability as a result of risks associated with using hazardous materials in our business.***

We use certain hazardous materials in our research, development, manufacturing and general business activities. While we believe we are currently in substantial compliance with the federal, state and local laws and regulations governing the use of these materials, we cannot be certain that accidental injury or contamination will not occur. If an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. This could result in substantial liabilities that could exceed our insurance coverage and financial resources. Additionally, the cost of compliance with environmental and safety laws and regulations may increase in the future, requiring us to expend more financial resources either in compliance or in purchasing supplemental insurance coverage.

***Changes in our effective income tax rate could adversely affect our results of operations.***

We are subject to income taxes in both the United States and various foreign jurisdictions, and our domestic and international tax liabilities are largely dependent upon the distribution of

income among these different jurisdictions. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, the accounting for stock options and other share-based compensation, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, the outcome of examinations by the U.S. Internal Revenue Service and other jurisdictions, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets, and changes in overall levels of pre-tax earnings. The impact on our income tax provision resulting from the above-mentioned factors and others may be significant and could have an impact on our results of operations.

***Currency fluctuations and changes in exchange rates could increase our costs and may cause our profitability to decline.***

We collect and pay a substantial portion of our sales and expenditures in currencies other than the U.S. dollar. Therefore, fluctuations in foreign currency exchange rates affect our operating results.

We utilize foreign currency forward contracts and option contracts, which are derivative instruments, to manage foreign currency risk, but not to engage in currency speculation. We use these derivative instruments to hedge certain forecasted transactions and balance sheet exposures denominated in foreign currencies. The use of these derivative instruments is intended to mitigate the exposure of these risks with the intent to reduce our risk or cost, but may not fully offset any change in operating results as a consequence of fluctuations in foreign currencies. Any significant foreign exchange rate fluctuations could adversely affect our financial condition and results of operations. For additional information, see Part II, Item 8, Note 5 of Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

***We may experience an adverse market reaction if we are unable to meet our financial reporting obligations.***

As we continue to expand at a rapid pace, the development of new and/or improved automated systems will remain an ongoing priority. During this expansion period, our internal control over financial reporting may not prevent or detect misstatements in our financial reporting. Such misstatements may result in litigation and/or negative publicity and possibly cause an adverse market reaction that may negatively impact our growth plans and the value of our common stock.

***The price of our common stock may fluctuate significantly and you may lose some or all of your investment in us.***

The market for our shares of common stock may be subject to conditions that cause prices to fluctuate significantly. The following key factors may have an adverse impact on the market price of our common stock:

- results of our clinical trials or adverse events associated with our marketed products;
- fluctuations in our commercial and operating results;

- announcements of technical or product developments by us or our competitors;
- market conditions for pharmaceutical and biotechnology stocks in particular;
- stock market conditions generally;
- changes in governmental regulations and laws, including, without limitation, changes in tax laws, health care legislation, environmental laws, competition laws, and patent laws;
- new accounting pronouncements or regulatory rulings;
- public announcements regarding medical advances in the treatment of the disease states that we are targeting;
- patent or proprietary rights developments;
- changes in pricing and third-party reimbursement policies for our products;
- the outcome of litigation involving our products or processes related to production and formulation of those products or uses of those products;
- other litigation or governmental investigations;
- competition; and
- investor reaction to announcements regarding business or product acquisitions.

In addition, our operations may be materially impacted by conditions affecting global markets generally. Global markets may be adversely affected by many factors beyond our control, including global, regional and industrial economic instability and market volatility, sovereign debt issues, rising interest rates or inflation, terrorism or political uncertainty. A market downturn in general and/or in the biopharmaceutical sector in particular, may adversely affect the market price of our securities, which may not necessarily reflect the actual or perceived value of our company.

***Our business could be adversely affected if we are unable to service our obligations under our incurred indebtedness.***

We have incurred various forms of indebtedness including senior notes, commercial paper, and a senior unsecured credit facility. Our ability to pay interest, principal amounts when due at maturity, to comply with debt covenants or to repurchase the senior notes if a change of control occurs will depend upon, among other things, continued commercial success of our products and other factors that affect our future financial and operating performance, including, without limitation, prevailing economic conditions and financial, business, and regulatory factors, many of which are beyond our control.

If we are unable to generate sufficient cash flow to service the debt service requirements under our incurred indebtedness, we may be forced to take actions such as:

- restructuring or refinancing our debt;
- seeking additional debt or equity capital;
- reducing or delaying our business activities, acquisitions, investments or capital expenditures, including research and development expenditures; or
- selling assets, businesses, products or other potential revenue streams.

Such measures might not be successful and might not enable us to service our obligations under our indebtedness. In addition, any such financing, refinancing or sale of assets might not be available on economically favorable terms, if at all.

***A breakdown or breach of our information technology systems could subject us to liability or interrupt the operation of our business.***

We rely upon our information technology systems and infrastructure for our business. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, data privacy breaches by employees and others who access our systems may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. While we believe that we have taken appropriate security measures to protect our data and information technology systems, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business.

***We have certain charter and by-law provisions that may deter a third-party from acquiring us and may impede the stockholders' ability to remove and replace our management or board of directors.***

Our board of directors has the authority to issue, at any time, without further stockholder approval, up to 5,000,000 shares of preferred stock, and to determine the price, rights, privileges and preferences of those shares. An issuance of preferred stock could discourage a third-party from acquiring a majority of our outstanding voting stock. Additionally, our by-laws contain provisions intended to strengthen the board's position in the event of a hostile takeover attempt. These provisions could impede the stockholders' ability to remove and replace our management and/or board of directors. Furthermore, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law, which may also dissuade a potential acquirer of our common stock.

***In addition to the risks relating to our common stock, holders of our contingent value right, or CVRs, are subject to additional risks.***

On October 15, 2010, we acquired all of the outstanding common stock of Abraxis and in connection with our acquisition, CVRs, were issued under a CVR Agreement entered into between us and American Stock Transfer & Trust Company, LLC, as trustee. Pursuant to the CVR Agreement, each holder of a CVR is entitled to receive a *pro rata* portion, based on the number of CVRs then outstanding, of certain milestone and net sales payments if certain

specified conditions are satisfied. For more information, see Part II, Item 8, Note 2 of Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

In addition to the risks relating to our common stock, CVR holders are subject to additional risks, including:

- an active public market for the CVRs may not continue to exist or the CVRs may trade at low volumes, both of which could have an adverse effect on the resale price, if any, of the CVRs;
- in the absence of an active public market for the CVRs, the market price and trading volume of the CVRs may be volatile;
- if the clinical approval milestones specified in the CVR Agreement are not achieved for any reason within the time periods specified therein, and if net sales do not exceed the thresholds set forth in the CVR Agreement for any reason within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire valueless;
- since the U.S. federal income tax treatment of the CVRs is unclear, any part of any CVR payment could be treated as ordinary income and required to be included in income prior to the receipt of the CVR payment;
- any payments in respect of the CVRs are subordinated to the right of payment of certain of our other indebtedness;
- we may under certain circumstances redeem the CVRs; and
- upon expiration of our obligations to achieve each of the CVR milestones and to commercialize ABRAXANE<sup>®</sup> or any of the other Abraxis pipeline products, we may discontinue such efforts, which would have an adverse effect on the value, if any, of the CVRs.

## **AVAILABLE INFORMATION**

Our Current Reports on Form 8-K, Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K are electronically filed with or furnished to the SEC, and all such reports and amendments to such reports filed have been and will be made available, free of charge, through our website (<http://www.celgene.com>) as soon as reasonably practicable after such filing. Such reports will remain available on our website for at least 12 months. The contents of our website are not incorporated by reference into this Annual Report on Form 10-K. The public may read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, NW, Washington, D.C. 20549.

The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site (<http://www.sec.gov>) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.



### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

### **ITEM 2. PROPERTIES**

Our corporate headquarters are located in Summit, New Jersey and our international headquarters are located in Boudry, Switzerland. Summarized below are the locations, primary usage and approximate square footage of the facilities we own worldwide:

| <u>Location</u>       | <u>Primary Usage</u>                | <u>Approximate Square Feet</u> |
|-----------------------|-------------------------------------|--------------------------------|
| Summit, New Jersey    | Administration, marketing, research | 400,000                        |
| Phoenix, Arizona      | Manufacturing and warehousing       | 247,000                        |
| Boudry, Switzerland   | Manufacturing and administration    | 148,000                        |
| Zofingen, Switzerland | Manufacturing                       | 12,000                         |

We occupy the following facilities, located in the United States, under operating lease arrangements, none of which are individually material to us. Under these lease arrangements, we may be required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs. All leases are with unaffiliated parties.

| <u>Location</u>              | <u>Primary Usage</u>                | <u>Approximate Square Feet</u> |
|------------------------------|-------------------------------------|--------------------------------|
| Berkeley Heights, New Jersey | Office space                        | 282,900                        |
| San Diego, California        | Research                            | 255,200                        |
| Warren, New Jersey           | Office space and research           | 177,500                        |
| Basking Ridge, New Jersey    | Office space                        | 95,900                         |
| San Francisco, California    | Office space and research           | 55,900                         |
| Durham, North Carolina       | Clinical trial management           | 36,000                         |
| Melrose Park, Illinois       | Research                            | 35,000                         |
| Overland Park, Kansas        | Office space                        | 29,600                         |
| Cedar Knolls, New Jersey     | Office space and stem cell recovery | 25,300                         |
| Bedford, Massachusetts       | Office space                        | 23,000                         |
| Los Angeles, California      | Office space                        | 6,000                          |
| Destin, Florida              | Office space                        | 1,600                          |

We also lease a number of offices under various lease agreements outside of the United States for which the minimum annual rents may be subject to specified annual rent increases. At December 31, 2012, the non-cancelable lease terms for our operating leases expire at various dates between 2013 and 2023 and in some cases include renewal options. The total amount of rent expense recorded for all leased facilities in 2012 was \$35.4 million.

### **ITEM 3. LEGAL PROCEEDINGS**

We and certain of our subsidiaries are involved in various patent, trademark, commercial and other claims; government investigations; and other legal proceedings that arise from time to time

in the ordinary course of business. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information requests from government authorities, and we have been subject to claims and other actions related to our business activities. While the ultimate outcome of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters may result in, among other things, modification of our business practices, product recalls, incurrence of costs and payment of significant penalties, which may have a material adverse effect on our results of operations, cash flows or financial condition.

Pending patent proceedings include challenges to the scope, validity or enforceability of our patents relating to certain of our products or processes. Although we believe we have substantial defenses to these challenges with respect to all our material patents, there can be no assurance as to the outcome of these matters, and a loss in any of these cases could result in a loss of patent protection for the drug at issue, which could lead to a significant loss of sales of that product and could materially affect future results of operations.

Among the principal matters pending to which we are a party are the following:

In the fourth quarter of 2009, we received a Civil Investigative Demand, or CID, from the U.S. Federal Trade Commission, or the FTC. The FTC requested documents and other information relating to requests by generic companies to purchase our patented REVLIMID® and THALOMID® brand drugs in order to evaluate whether there is reason to believe that we have engaged in unfair methods of competition. In the first quarter of 2010, the State of Connecticut referenced the same issues as those referenced in the 2009 CID and issued a subpoena. In the fourth quarter of 2010, we received a second CID from the FTC relating to this matter. We continue to respond to requests for information.

In the first quarter of 2011, the United States Attorney's Office for the Central District of California informed us that they are investigating possible off-label marketing and improper payments to physicians in connection with the sales of THALOMID® and REVLIMID®. In the third quarter of 2012, we learned that two other United States Attorneys' offices (the Northern District of Alabama and the Eastern District of Texas) and various state Attorneys General are conducting related investigations. We are cooperating with these investigations.

**REVLIMID®:** We have publicly announced that we received a Notice Letter dated August 30, 2010, sent from Natco Pharma Limited of India ("Natco") notifying us of Natco's Abbreviated New Drug Application, or ANDA, which contains Paragraph IV certifications against certain of Celgene's patents that are listed in the U.S. Federal Drug Administration's, or FDA, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book") for REVLIMID® (lenalidomide). Under the Hatch-Waxman Act of 1984, a generic manufacturer may file an ANDA containing a certification (a "Paragraph IV certification") challenging the validity or infringement of a patent listed in the Orange Book. Natco's Notice letter alleges, among other things, that certain claims of United States Patent Nos. 5,635,517 (the "'517 patent'"), 6,045,501 (the "'501 patent'"), 6,315,720 (the "'720 patent'"), 6,555,554 (the "'554 patent'"), 6,561,976 (the "'976 patent'"), 6,561,977 (the "'977 patent'"), 6,755,784 (the "'784 patent'"), 7,119,106 (the "'106 patent'") and 7,465,800 (the "'800 patent'") are invalid, unenforceable, and/or not infringed. Natco's Notice Letter was sent in connection with its filing of an ANDA seeking permission from the FDA to market a generic version of 25mg, 15mg, 10mg and 5mg REVLIMID® capsules.

On October 8, 2010, we filed an infringement action in the United States District Court of New Jersey against Natco in response to the Notice Letter with respect to the '517 patent, the '501 patent, United States Patent No. 6,281,230 (the "'230 patent'"), the '720 patent, the '554 patent, the '976 patent, the '977 patent, the '784 patent, the '106 patent and the '800 patent.

Natco responded to our infringement action on November 18, 2010, with its Answer, Affirmative Defenses and Counterclaims. Natco has alleged (through Affirmative Defenses and Counterclaims) that the patents are invalid, unenforceable, and/or not infringed by Natco's proposed generic products. After filing the infringement action, we learned the identity of Natco's U.S. partner, Arrow International Limited ("Arrow"), and filed an amended complaint on January 7, 2011, adding Arrow as a defendant. On March 25, 2011, We filed a second amended complaint naming Natco, Arrow and Watson Laboratories, Inc. (a wholly-owned subsidiary of Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc.), which is Arrow's parent) as defendants. Those three entities remain the current defendants in that action.

On June 12, 2012, we received a Second Notice Letter from Natco, notifying us of Natco's submission in its ANDA of new, additional Paragraph IV certifications against the '517 patent, the '230 patent and United States Patent Nos. 7,189,740 (the "'740 patent'"), 7,855,217 (the "'217 patent'") and 7,968,569 (the "'569 patent'"). On July 20, 2012, we filed a new infringement action in the United States District Court of New Jersey against Natco, Arrow, Watson Laboratories, Inc. and Actavis, Inc. in response to the Second Notice Letter with respect to the '517 patent, the '230 patent, the '740 patent, and the '569 patent, as well as two non-Orange Book listed patents, United States Patent Nos. 7,977,357 (the "'357 patent'") and 8,193,219 (the "'219 patent'"). Natco filed its Answer and Counterclaims on September 28, 2012. Natco's counterclaims in the second action are similar to its counterclaims in the first action. In the second action, Natco added counterclaims against United States Patent No. 8,204,763 (the "'763 patent'"), which Celgene has not asserted against Natco. Celgene has moved to dismiss those counterclaims related to the '763 patent for lack of subject matter jurisdiction.

A revised Scheduling Order was entered by the Court on November 9, 2012, setting the close for fact discovery on August 14, 2013. A Markman hearing is currently expected to be fully briefed by the end of July 2013. Dates for a Markman hearing and trial have yet to be set.

We believe that Natco's defenses and counterclaims are unlikely to be sustained and we intend to vigorously defend our patent rights. We believe it unlikely that Natco will prevail on each and every patent and patent claim subject to the lawsuits, and that all of the patent claims will be deemed to be invalid, unenforceable and/or not infringed. Accordingly, the ultimate outcome is not expected to have a material adverse effect on our financial condition or results of operations.

However, if Natco is successful in challenging our patents, and the FDA were to approve Natco's ANDA with a comprehensive education and risk management program for a generic version of lenalidomide and a generic product were to be introduced, sales of REVLIMID® could be significantly reduced in the United States, which would have a material adverse effect on our results of operations, cash flows and financial condition.

**ABRAXANE®:** On December 14, 2011, Cephalon, Inc. and Acusphere, Inc. filed a complaint against us in the United States District Court for the District of Massachusetts, alleging, among other things, that the making, using, selling, offering to sell, and importing of ABRAXANE®

brand drug infringes claims of United States Patent No. RE40,493. Plaintiffs are seeking damages and injunctive relief. We intend to vigorously defend against this infringement suit. If the suit against us is successful, we may have to pay damages, ongoing royalties and may have to license rights from plaintiffs. However, we believe that (a) it is unlikely that the plaintiffs in this matter will prevail and (b) the ultimate outcome will not have a material adverse effect on our financial condition or results of operations.

**VIDAZA®:** On September 28, 2012, we were named as a defendant in a complaint filed by Ivax LLC (formerly Ivax Corporation) in the United States District Court for the Southern District of Florida. Ivax LLC alleges that we have infringed the claims of United States Patent No. 7,759,481 by making, using, and selling VIDAZA® brand drug in the United States. We filed an answer to this complaint on October 19, 2012. We filed a motion for judgment on the pleadings on November 15, 2012, to which Ivax LLC filed an opposition on December 7, 2012. We intend to vigorously defend against this infringement suit. If the suit against us is successful, we may have to pay damages, ongoing royalties or license rights from the plaintiff. However, we believe (a) that it is unlikely that the plaintiff in this matter will prevail and (b) that the ultimate outcome will not have a material adverse effect on our financial condition or results of operations.

#### **ITEM 4. *MINE SAFETY DISCLOSURES***

Not applicable.

## PART II

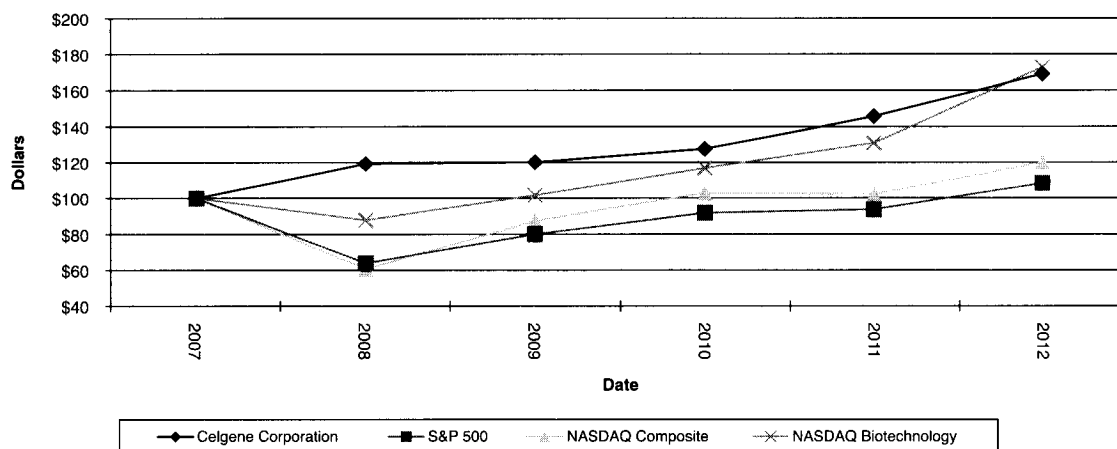
### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### (a) MARKET INFORMATION

Our common stock is traded on the NASDAQ Global Select Market under the symbol "CELG." The following table sets forth, for the periods indicated, the intra-day high and low prices per share of common stock on the NASDAQ Global Select Market:

|                | High     | Low      |
|----------------|----------|----------|
| 2012           |          |          |
| Fourth Quarter | \$ 82.78 | \$ 71.23 |
| Third Quarter  | 78.63    | 61.89    |
| Second Quarter | 80.42    | 58.53    |
| First Quarter  | 78.83    | 66.28    |
| 2011           |          |          |
| Fourth Quarter | \$ 68.25 | \$ 59.32 |
| Third Quarter  | 65.86    | 51.70    |
| Second Quarter | 61.70    | 54.83    |
| First Quarter  | 60.90    | 48.92    |

#### Comparison of Five Year Cumulative Total Returns\*



|                      | Cumulative Total Return |           |           |           |           |           |
|----------------------|-------------------------|-----------|-----------|-----------|-----------|-----------|
|                      | 12/07                   | 12/08     | 12/09     | 12/10     | 12/11     | 12/12     |
| Celgene Corporation  | \$ 100.00               | \$ 119.63 | \$ 120.49 | \$ 127.98 | \$ 146.29 | \$ 169.81 |
| S&P 500              | 100.00                  | 63.45     | 79.90     | 91.75     | 93.67     | 108.55    |
| NASDAQ Composite     | 100.00                  | 60.20     | 87.33     | 103.05    | 102.26    | 120.36    |
| NASDAQ Biotechnology | 100.00                  | 87.73     | 101.71    | 117.17    | 131.30    | 173.67    |

\* \$100 Invested on 12/31/07 in Stock or Index – Including Reinvestment of Dividends, Fiscal Year Ended December 31.

**(b) HOLDERS**

The closing sales price per share of common stock on the NASDAQ Global Select Market on February 7, 2013 was \$97.84. As of February 7, 2013, there were approximately 480 holders of record of our common stock.

**(c) DIVIDEND POLICY**

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

**(d) EQUITY COMPENSATION PLAN INFORMATION**

We incorporate information regarding the securities authorized for issuance under our equity compensation plan into this section by reference from the section entitled “Equity Compensation Plan Information” to be included in the proxy statement for our 2013 Annual Meeting of Stockholders.

**(e) REPURCHASE OF EQUITY SECURITIES**

Since April 2009, our Board of Directors has approved repurchases of up to an aggregate of \$6.500 billion of our common stock, including \$2.500 billion approved by our Board of Directors in June 2012. Approved amounts exclude share repurchase transaction fees.

As of December 31, 2012, an aggregate 74,465,418 common shares were repurchased under the program at an average price of \$62.62 per common share and cost of \$4.663 billion, excluding share repurchase transaction fees.

The following table presents the total number of shares purchased during the three-month period ended December 31, 2012, the average price paid per share, the number of shares that were purchased and the approximate dollar value of shares that still could have been purchased, pursuant to our publicly announced repurchase program:

| Period                   | Total Number of Shares Purchased | Average Price Paid per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs | Approximate Dollar Value of Shares That May Yet be Purchased Under the Plans or Programs |
|--------------------------|----------------------------------|------------------------------|--|--|
| October 1 - October 31   | 2,350,000                        | \$ 77.09                     | 2,350,000  | \$ 2,236,000,482   |
| November 1 - November 30 | 1,648,467                        | \$ 75.25                     | 1,648,467  | \$ 2,111,990,848   |
| December 1 - December 31 | 3,458,925                        | \$ 79.55                     | 3,458,925  | \$ 1,836,885,988   |

During the period covered by this report, we did not sell any of our equity shares that were not registered under the Securities Act of 1933, as amended.

## ITEM 6. SELECTED FINANCIAL DATA

The following Selected Consolidated Financial Data should be read in conjunction with our Consolidated Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included elsewhere in this Annual Report on Form 10-K. The data set forth below with respect to our Consolidated Statements of Income for the years ended December 31, 2012, 2011 and 2010 and the Consolidated Balance Sheet data as of December 31, 2012 and 2011 are derived from our Consolidated Financial Statements which are included elsewhere in this Annual Report on Form 10-K and are qualified by reference to such Consolidated Financial Statements and related Notes thereto. The data set forth below with respect to our Consolidated Statements of Income for the years ended December 31, 2009 and 2008 and the Consolidated Balance Sheet data as of December 31, 2010, 2009 and 2008 are derived from our Consolidated Financial Statements, which are not included elsewhere in this Annual Report on Form 10-K (amounts in thousands, except per share data).

|  | Years ended December 31, |              |              |              |                |
|--|--------------------------|--------------|--------------|--------------|----------------|
|  | 2012                     | 2011         | 2010         | 2009         | 2008           |
| <b>Consolidated Statements of Income:</b>                |                          |              |              |              |                |
| Total revenue  | \$ 5,506,713             | \$ 4,842,070 | \$ 3,625,745 | \$ 2,689,893 | \$ 2,254,781   |
| Costs and operating expenses                             | 3,760,271                | 3,399,317    | 2,636,110    | 1,848,367    | 3,718,999      |
| Operating income (loss)                                  | 1,746,442                | 1,442,753    | 989,635      | 841,526      | (1,464,218)    |
| Interest and investment income, net                      | 15,260                   | 25,860       | 44,757       | 76,785       | 84,835         |
| Interest (expense)                                       | (63,205)                 | (42,737)     | (12,634)     | (1,966)      | (4,437)        |
| Other income (expense), net                              | (17,006)                 | (6,354)      | (9,148)      | 59,358       | 14,995         |
| Income (loss) before tax                                 | 1,681,491                | 1,419,522    | 1,012,610    | 975,703      | (1,368,825)    |
| Income tax provision                                     | 225,311                  | 102,066      | 132,418      | 198,956      | 164,828        |
| Net income (loss)  | \$ 1,456,180             | \$ 1,317,456 | \$ 880,192   | \$ 776,747   | \$ (1,533,653) |
| Less: Net loss attributable to non-controlling interests | -                        | 694          | 320          | -            | -              |
| Net income (loss) attributable to Celgene                | \$ 1,456,180             | \$ 1,318,150 | \$ 880,512   | \$ 776,747   | \$ (1,533,653) |
| Net income (loss) per share attributable to Celgene:     |                          |              |              |              |                |
| Basic  | \$ 3.38                  | \$ 2.89      | \$ 1.90      | \$ 1.69      | \$ (3.46)      |
| Diluted  | \$ 3.30                  | \$ 2.85      | \$ 1.88      | \$ 1.66      | \$ (3.46)      |
| Weighted average shares:                                 |                          |              |              |              |                |
| Basic  | 430,927                  | 455,348      | 462,298      | 459,304      | 442,620        |
| Diluted  | 440,796                  | 462,748      | 469,517      | 467,354      | 442,620        |
| As of December 31,                                       |                          |              |              |              |                |
|  | 2012                     | 2011         | 2010         | 2009         | 2008           |
| <b>Consolidated Balance Sheets Data:</b>                 |                          |              |              |              |                |
| Cash, cash equivalents and marketable securities         | \$ 3,900,270             | \$ 2,648,154 | \$ 2,601,301 | \$ 2,996,752 | \$ 2,222,091   |
| Total assets   | 11,734,306               | 10,005,910   | 10,177,162   | 5,389,311    | 4,445,270      |
| Short-term borrowings                                    | 308,459                  | 526,684      | -            | -            | -              |
| Long-term debt, net of discount                          | 2,771,333                | 1,275,585    | 1,247,584    | -            | -              |
| Retained earnings (accumulated deficit)                  | 3,022,596                | 1,566,416    | 248,266      | (632,246)    | (1,408,993)    |
| Total equity   | 5,694,467                | 5,512,727    | 5,995,472    | 4,394,606    | 3,491,328      |

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

### **EXECUTIVE SUMMARY**

Celgene Corporation (collectively with its subsidiaries, “we,” “our,” “us,” “Celgene” or the “Company”) is a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. We are dedicated to innovative research and development, designed to bring new therapies to market and are involved in research in several scientific areas that may deliver proprietary next-generation therapies, targeting areas such as intracellular signaling pathways in cancer and immune cells, immunomodulation in cancer and autoimmune diseases, and therapeutic application of cell therapies. Celgene was incorporated in the State of Delaware in 1986.

Our primary commercial stage products include REVLIMID<sup>®</sup>, VIDAZA<sup>®</sup>, ABRAXANE<sup>®</sup>, THALOMID<sup>®</sup> (inclusive of Thalidomide Celgene<sup>®</sup>), and ISTODAX<sup>®</sup>. POMALYST<sup>®</sup> (pomalidomide) was approved by the U.S. Food and Drug Administration, or FDA, in February 2013 for patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and bortezomib, and have demonstrated disease progression on or within 60 days of completion of the last therapy.

- REVLIMID<sup>®</sup> is an oral immunomodulatory drug marketed in the United States and many international markets, in combination with dexamethasone, for treatment of patients with multiple myeloma who have received at least one prior therapy. It is also marketed in the United States and certain international markets for the treatment of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes, or MDS, associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
- VIDAZA<sup>®</sup> is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. VIDAZA<sup>®</sup> is a Category 1 recommended treatment for patients with intermediate-2 and high-risk MDS, according to the National Comprehensive Cancer Network, and is marketed in the United States for the treatment of all subtypes of MDS. The U.S. regulatory exclusivity for VIDAZA<sup>®</sup> expired in May 2011. If a generic version of VIDAZA<sup>®</sup> is successfully launched, we may quickly lose a significant portion of our sales for this product in the United States. In Europe, VIDAZA<sup>®</sup> is marketed for the treatment of intermediate-2 and high-risk MDS, as well as acute myeloid leukemia, or AML, with 30% blasts and has been granted orphan drug designation for the treatment of MDS and AML. European regulatory exclusivity is expected to continue through 2018.
- ABRAXANE<sup>®</sup> is a solvent-free chemotherapy treatment option for metastatic breast cancer which was developed using our proprietary nab<sup>®</sup> technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin. It is approved for the treatment of metastatic breast cancer in the United States and many international markets and for the treatment of non-small cell lung cancer in the United States. In January 2013, we announced the results from a phase III trial for ABRAXANE<sup>®</sup> in



combination with gemcitabine in treatment-naïve patients with metastatic pancreatic cancer. The ABRAXANE® combination demonstrated a statistically significant improvement in overall survival compared to patients receiving gemcitabine alone. Based on these results, we plan to submit dossiers for registration in the U.S. and Europe during the first half of 2013 followed by submissions in other countries and regions during the second half of 2013. ABRAXANE® is currently in various stages of investigation for the treatment of the following cancers: expanded applications for metastatic breast; malignant melanoma; and bladder and ovarian. In October 2012, the FDA approved ABRAXANE® for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, or NSCLC, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. The FDA approval was based on tumor response rates and did not result in the use of a marketing label that includes a progression-free survival claim, and accordingly, the Contingent Value Rights, or CVR, milestone payment, as described in Note 2 of the Notes to the Consolidated Financial Statements included elsewhere in this report, has not been achieved.

- THALOMID®, in combination with dexamethasone, is marketed for patients with newly diagnosed multiple myeloma and for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum, or ENL, an inflammatory complication of leprosy and as maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence.
- ISTODAX® is approved in the United States for the treatment of cutaneous T-cell lymphoma, or CTCL, in patients who have received at least one prior systemic therapy and for the treatment of peripheral T-cell lymphoma, or PTCL, in patients who have received at least one prior therapy. ISTODAX® has received orphan drug designation for the treatment of non-Hodgkin's T-cell lymphomas, which includes CTCL and PTCL. The European Medicines Agency, or EMA, has granted orphan drug designation for ISTODAX® for the treatment of both CTCL and PTCL.
- POMALYST® (pomalidomide) was approved by the FDA in February 2013 for patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and bortezomib, and have demonstrated disease progression on or within 60 days of completion of the last therapy, and is under review by the EMA for use in Europe. POMALYST® is a proprietary, distinct, small molecule that is administered orally and modulates the immune system and other biologically important targets. POMALYST® is also being evaluated in a phase III clinical trial for the treatment of myelofibrosis, in multiple trials in various phases for expanded usage in multiple myeloma, and in a phase II trial for systemic sclerosis.

Additional sources of revenue include royalties from Novartis on their sales of FOCALIN XR® and the entire RITALIN® family of drugs, the sale of services through our Celgene Cellular Therapeutics subsidiary, and other licensing agreements.

We continue to invest substantially in research and development in support of multiple ongoing clinical proprietary development programs which support our existing products and pipeline of new drug candidates. REVLIMID is in several phase III trials across a range of hematological

malignancies that include newly diagnosed multiple myeloma and maintenance, lymphomas, chronic lymphocytic leukemia, or CLL, and MDS. Phase III trials with POMALYST® in relapsed refractory multiple myeloma and myelofibrosis, in addition to VIDAZA for AML, and CC-486 for MDS and AML are also underway. In solid tumors, we are evaluating ABRAXANE in a phase III trial for metastatic melanoma. Our lead product candidate in Inflammation & Immunology, apremilast, is being evaluated in a broad phase III program for psoriatic arthritis, psoriasis, and ankylosing spondylitis.

Beyond our phase III programs is a growing early-to-mid-stage pipeline of novel therapies addressing significant unmet medical needs, including CC-292 (BTK inhibitor), CC-223 (dual TORC1 inhibitor), CC-115 (dual TORC1/DNA PK inhibitor), CC-122 (pleiotropic pathway modulator), CC-220 and CC-11050 (anti-inflammatory), PDA-001 and PDA-002 (cellular therapies), in addition to partnered molecules ACE-011 (ActR fusion protein), ACE-536 (GDF trap), and EPZ-5676 (DOT1L inhibitor).

We believe that continued acceptance of our primary commercial stage products, participation in research and development collaboration arrangements, depth of our product pipeline, regulatory approvals of new products, and expanded use of existing products will provide the catalysts for future growth.

The following table summarizes total revenue and earnings for the years ended December 31, 2012, 2011 and 2010 (dollar amounts in thousands, except per share data):

|  | Years Ended December 31, |             |             | % Change    |       |
|--|--------------------------|-------------|-------------|-------------|-------|
|  |                          |             |             | 2012        | 2011  |
|  | Total revenue            | \$5,506,713 | \$4,842,070 | \$3,625,745 | 13.7% |
| Net income attributable to Celgene                 | \$1,456,180              | \$1,318,150 | \$ 880,512  | 10.5%       | 49.7% |
| Diluted earnings per share attributable to Celgene | \$ 3.30                  | \$ 2.85     | \$ 1.88     | 15.8%       | 51.6% |

Revenue increased by \$664.6 million in 2012 compared to 2011 primarily due to the continued growth in sales of REVLIMID®, VIDAZA® and ABRAXANE® in both U.S. and international markets. The \$138.0 million increase in net income and \$0.45 increase in diluted earnings per share in 2012 compared to 2011 reflected a higher level of net product sales, reduction in amortization of acquired intangible assets, primarily due to certain intangible assets becoming fully amortized at the end of 2011, and a decrease in cost of goods sold resulting from the 2011 inclusion of inventory step-up amortization for sales of ABRAXANE®. These favorable items were partly offset by an increase in the fair value of our liability related to publicly traded CVRs that were issued as part of the acquisition of Abraxis, increase in payments related to research and development collaboration arrangements and increase in marketing activity, primarily related to prelaunch expenses for POMALYST® and ABRAXANE® for new indications.

## Results of Operations:

### Fiscal Years Ended December 31, 2012, 2011 and 2010

*Total Revenue:* Total revenue and related percentages for the years ended December 31, 2012, 2011 and 2010 were as follows (dollar amounts in thousands, except per share data):

|   | 2012               | 2011               | 2010               | % Change               |                        |
|---|--------------------|--------------------|--------------------|------------------------|------------------------|
|   |                    |                    |                    | 2012<br>versus<br>2011 | 2011<br>versus<br>2010 |
| <b>Net product sales:</b>                     |                    |                    |                    |                        |                        |
| REVLIMID®                                     | \$3,766,640        | \$3,208,153        | \$2,469,183        | 17.4%                  | 29.9%                  |
| VIDAZA®                                       | 823,191            | 705,327            | 534,302            | 16.7%                  | 32.0%                  |
| ABRAXANE®                                     | 426,675            | 385,905            | 71,429             | 10.6%                  | N/A                    |
| THALOMID®                                     | 302,136            | 339,067            | 389,605            | (10.9)%                | (13.0)%                |
| ISTODAX®                                      | 50,001             | 30,921             | 15,781             | 61.7%                  | 95.9%                  |
| Other   | 16,956             | 30,317             | 28,138             | (44.1)%                | 7.7%                   |
| Total net product sales                       | \$5,385,599        | \$4,699,690        | \$3,508,438        | 14.6%                  | 34.0%                  |
| Collaborative agreements and other<br>revenue | 10,711             | 19,500             | 10,540             | (45.1)%                | 85.0%                  |
| Royalty revenue                               | 110,403            | 122,880            | 106,767            | (10.2)%                | 15.1%                  |
| Total revenue                                 | <u>\$5,506,713</u> | <u>\$4,842,070</u> | <u>\$3,625,745</u> | <u>13.7%</u>           | <u>33.5%</u>           |

Total revenue increased by \$664.6 million, or 13.7%, to \$5.507 billion in 2012 compared to 2011, reflecting increases of \$309.1 million, or 10.8%, in the United States, and \$355.5 million, or 17.9%, in international markets. The \$1.216 billion, or 33.5%, increase in 2011 compared to 2010 included increases of \$672.4 million, or 30.7%, in the United States and \$544.0 million, or 37.8%, in international markets.

*Net Product Sales:* Total net product sales for 2012 increased by \$685.9 million, or 14.6%, to \$5.386 billion compared to 2011. The increase was comprised of net volume increases of \$559.1 million and price increases of \$162.2 million, partly offset by an unfavorable impact from foreign exchange of \$35.4 million. The increase in price was primarily due to price increases on REVLIMID®, VIDAZA® and THALOMID® in the U.S. market.

Total net product sales for 2011 increased by \$1.191 billion, or 34.0%, to \$4.7 billion compared to 2010. The increase was comprised of net volume increases of \$1.157 billion, price decreases of \$4.9 million and a favorable impact from foreign exchange of \$38.7 million. The decrease in prices was primarily due to increased Medicare Part D Coverage Gap rebates resulting from the Health Care Reform Act and an increase in rebates to U.S. and international governments resulting from their attempts to reduce health care costs, partly offset by product price increases.

REVLIMID® net sales increased by \$558.5 million, or 17.4%, to \$3.767 billion in 2012 compared to 2011, primarily due to increased unit sales in both U.S. and international markets. Increases in market penetration, treatment duration of patients using REVLIMID® in multiple myeloma and

price contributed to U.S. growth. The growth in international markets resulted from volume increases, primarily driven by increased duration of use and market share gains.

Net sales of REVLIMID® increased by \$739.0 million, or 29.9%, to \$3.208 billion in 2011 compared to 2010, primarily due to increased unit sales in both U.S. and international markets. Increased treatment duration of patients using REVLIMID® in multiple myeloma and an increase in market penetration contributed to U.S. growth. The growth in international markets reflects the expansion of our commercial activities in addition to product reimbursement approvals and the launch of REVLIMID® in Japan in the latter part of 2010.

VIDAZA® net sales increased by \$117.9 million, or 16.7%, to \$823.2 million in 2012 compared to 2011, reflecting increases in both U.S. and international markets. The U.S. growth reflects an increase in volume and price. The growth in international markets was partly due to the increase in treatment duration of patients using VIDAZA® and launches of VIDAZA® in new markets, including the United Kingdom and Japan. VIDAZA® retains orphan drug exclusivity in Europe through the end of 2018 and in Japan until January 2021.

Net sales of VIDAZA® increased by \$171.0 million, or 32.0%, to \$705.3 million in 2011 compared to 2010, with sales increases in both U.S. and international markets. The growth in the U.S. was the result of increased volume and price. The growth in international markets was primarily due to the increase in treatment duration of patients using VIDAZA® and product launches in multiple markets, including the United Kingdom and Japan.

ABRAXANE® net sales increased by \$40.8 million, or 10.6%, to \$426.7 million in 2012 compared to 2011, primarily due to increased unit volumes in both U.S. and international markets, reflecting increased acceptance of the product in the treatment of metastatic breast cancer and the October 2012 approval for NSCLC.

Net sales of ABRAXANE® increased by \$314.5 million to \$385.9 million in 2011 compared to 2010 due to the inclusion of a full year of sales in 2011 compared to the 2.5 month period in 2010 subsequent to the acquisition of Abraxis.

THALOMID® net sales decreased by \$36.9 million, or 10.9%, to \$302.1 million in 2012 compared to 2011, primarily due to lower unit volumes in the United States, partly resulting from the increased use of REVLIMID®, partially offset by an increase in price and lower gross to net adjustments.

Net sales of THALOMID® decreased by \$50.5 million, or 13.0%, to \$339.1 million in 2011 compared to 2010, primarily due to lower unit volumes in the United States.

ISTODAX® net sales increased by \$19.1 million, or 61.7%, to \$50.0 million in 2012 compared to 2011, primarily due to increased unit sales in the treatment of CTCL and the June 2011 FDA approval of ISTODAX® for the treatment of PTCL in patients who have received at least one prior therapy.

Net sales of ISTODAX® increased by \$15.1 million, or 95.9%, to \$30.9 million in 2011 compared to 2010. ISTODAX® was launched for the treatment of CTCL in March of 2010 and was

approved by the FDA for the treatment of PTCL in June 2011 in patients who have received at least one prior therapy.

The “other” net product sales category decreased by \$13.4 million, or 44.1%, to \$17.0 million in 2012 compared to 2011. The decrease was primarily due to the April 2011 sale of Abraxis non-core assets, resulting in the elimination of future Abraxis non-core product sales. Sales of Abraxis non-core products totaled \$21.3 million in 2011.

“Other” net product sales in 2011 primarily included \$21.3 million in Abraxis non-core product sales, \$5.4 million in sales of non-core Pharmion products to be exited and \$1.3 million in sales of FOCALIN®.

*Collaborative Agreements and Other Revenue:* Revenue from collaborative agreements and other sources decreased by \$8.8 million to \$10.7 million in 2012 compared to 2011. The decrease was primarily due to a \$6.3 million milestone payment received in 2011 related to VIDAZA® and a \$2.4 million reduction in certain manufacturing and management fees received in 2012.

Revenue from collaborative agreements and other sources increased by \$9.0 million to \$19.5 million in 2011 compared to 2010, primarily due to the \$6.3 million milestone payment received in February 2011 related to the approval of VIDAZA® in Japan and a \$2.2 million increase in certain manufacturing and management fees received in 2011.

*Royalty Revenue:* Royalty revenue decreased by \$12.5 million to \$110.4 million in 2012 compared to 2011, primarily due to reduced royalties earned from Novartis based upon its sales of RITALIN®, which was negatively impacted by generic competition in certain markets, partly offset by an increase in royalties from sales of FOCALIN XR®.

Royalty revenue increased by \$16.1 million to \$122.9 million in 2011 compared to 2010 primarily due to an increase in royalties earned from Novartis based upon its sales of FOCALIN XR® and the entire RITALIN® family of drugs. The increase was partly offset by a decrease in residual payments earned by us from the ALKERAN® revenues of GlaxoSmithKline plc, or GSK.

*Gross to Net Sales Accruals:* We record gross to net sales accruals for sales returns and allowances, sales discounts, government rebates, and chargebacks and distributor service fees.

REVLIMID® is distributed in the United States primarily through contracted pharmacies under the RevAssist® program, which is a proprietary risk-management distribution program tailored specifically to provide for the safe and appropriate distribution and use of REVLIMID®. Internationally, REVLIMID® is distributed under mandatory risk-management distribution programs tailored to meet local competent authorities’ specifications to provide for the product’s safe and appropriate distribution and use. These programs may vary by country and, depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies. THALOMID® is distributed in the United States under our proprietary “System for Thalidomide Education and Prescribing Safety,” or S.T.E.P.S.®, program which is a comprehensive education and risk-management distribution program with the objective of providing for the safe and appropriate distribution and use of THALOMID®. Internationally, THALOMID® is distributed under mandatory risk-management distribution programs tailored to meet local competent authorities’ specifications to provide for the safe and appropriate distribution and use of THALOMID®. These programs may vary by country and,

depending upon the country and the design of the risk-management program, the product may be sold through hospitals or retail pharmacies. VIDAZA<sup>®</sup>, ABRAXANE<sup>®</sup> and ISTODAX<sup>®</sup> are distributed through the more traditional pharmaceutical industry supply chain and are not subject to the same risk-management distribution programs as REVLIMID<sup>®</sup> and THALOMID<sup>®</sup>.

We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization initiatives conducted by major pharmacy chains, as applicable. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits, are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance. As noted above, REVLIMID<sup>®</sup> is distributed primarily through hospitals and contracted pharmacies, lending itself to tighter controls of inventory quantities within the supply channel and, thus, resulting in lower returns activity. THALOMID<sup>®</sup> is drop-shipped directly to the prescribing pharmacy and, as a result, wholesalers do not stock the product.

Sales discount accruals are based on payment terms extended to customers.

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. We have also analyzed actual billings received from certain states to further support the accrual rates. Subsequent to implementation of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, or collectively the 2010 U.S. Health Care Reform Law, certain states have not yet submitted actual Medicaid Managed Care Organization bills, resulting in an increasing accrual balance. Effective January 1, 2011, manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this coverage gap responsibility, we analyze data for eligible Medicare Part D patients against data for eligible Medicare Part D patients treated with our products as well as the historical invoices. This expense is recognized throughout the year as incurred. In addition, certain international markets have government-sponsored programs that require rebates to be paid based on program specific rules and, accordingly, the rebate accruals are determined primarily on estimated eligible sales.

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations and end-user customers, consistent with pharmaceutical industry practices.

Settlement of rebates and fees may generally occur from one to 15 months from the date of sale. We provide a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include level of wholesaler inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Distributor service fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. TRICARE is a health care program of the U.S. Department of Defense Military Health System that provides civilian health benefits for military personnel, military retirees and their dependents. TRICARE rebate accruals are based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

See Critical Accounting Estimates and Significant Accounting Policies below for further discussion of gross to net sales accruals.

Gross to net sales accruals and the balance in the related allowance accounts for the years ended December 31, 2012, 2011 and 2010 were as follows (in thousands):

|  | Returns<br>and<br>Allowances | Discounts | Government<br>Rebates | Chargebacks<br>and Distributor<br>Service Fees | Total      |
|--|------------------------------|-----------|-----------------------|--|------------|
| Balance at December 31, 2009                       | \$ 7,360                     | \$ 3,598  | \$ 18,111             | \$ 29,241                                      | \$ 58,310  |
| Abraxis balance at October 15,<br>2010             | 815                          | -         | 4,336                 | 7,253  | 12,404     |
| Allowances for sales during 2010                   | 6,440                        | 52,975    | 117,788               | 123,625  | 300,828    |
| Credits/deductions issued for<br>prior year sales  | (5,764)                      | (3,304)   | (14,437)              | (15,882)                                       | (39,387)   |
| Credits/deductions issued for<br>sales during 2010 | (4,072)                      | (44,997)  | (40,834)              | (96,870)                                       | (186,773)  |
| Balance at December 31, 2010                       | \$ 4,779                     | \$ 8,272  | \$ 84,964             | \$ 47,367                                      | \$ 145,382 |
| Allowances for sales during prior<br>periods       | -                            | -         | (5,366)               | 2,047  | (3,319)    |
| Allowances for sales during 2011                   | 16,757                       | 56,110    | 192,118               | 191,765  | 456,750    |
| Credits/deductions issued for<br>prior year sales  | (5,714)                      | (4,208)   | (34,344)              | (38,162)                                       | (82,428)   |
| Credits/deductions issued for<br>sales during 2011 | (6,848)                      | (51,450)  | (100,333)             | (138,708)                                      | (297,339)  |
| Balance at December 31, 2011                       | \$ 8,974                     | \$ 8,724  | \$ 137,039            | \$ 64,309                                      | \$ 219,046 |
| Allowances for sales during prior<br>periods       | (7,489)                      | -         | (13,254)              | (2,467)  | (23,210)   |
| Allowances for sales during 2012                   | 14,982                       | 64,865    | 208,709               | 212,550  | 501,106    |
| Credits/deductions issued for<br>prior year sales  | 1,748                        | (4,280)   | (60,182)              | (54,757)                                       | (117,471)  |
| Credits/deductions issued for<br>sales during 2012 | (4,945)                      | (58,089)  | (146,456)             | (158,451)                                      | (367,941)  |
| Balance at December 31, 2012                       | \$ 13,270                    | \$ 11,220 | \$ 125,856            | \$ 61,184                                      | \$ 211,530 |

A comparison of provisions for allowances for sales within each of the four categories noted above for 2012 and 2011 follows:

*2012 compared to 2011:* Returns and allowances decreased by \$9.3 million in 2012 compared 2011, primarily due to the reversal of approximately \$7.5 million in reserves established for certain products with quality issues which were resolved in 2012 and lower returns experience on all products, partially offset by a \$7.6 million increase in the returns allowance related to increased levels of VIDAZA® inventory held by distributors at the end of 2012.

Discounts increased by \$8.8 million in 2012 compared to 2011, primarily due to revenue increases in the U.S. and international markets, both of which offer different discount programs, and expansion into new international markets. These amounts were partly offset by rebates related to VIDAZA® sales in the Japanese market being included in the chargebacks and distributor service fees category in 2012.

Government rebates increased by \$8.7 million in 2012 compared to 2011, primarily due to an increase of approximately \$15.8 million in rebates related to various U.S. programs, partly offset by a \$7.0 million decrease in rebates in certain international markets. The U.S. programs increase was primarily attributable to volume increases and the refinement of accrual rates for Medicaid Managed Care Organizations and Medicare Part D Coverage Gap. The decrease in government rebates of \$7.0 million in international markets was primarily driven by the refinement of select government rebates during the third quarter of 2012.

Chargebacks and distributor service fees increased by \$16.3 million in 2012 compared to 2011. Chargebacks increased by approximately \$2.8 million primarily due to higher sales volumes. Distributor service fees increased by approximately \$13.5 million, primarily due to \$8.3 million in service fees associated with higher sales of ABRAXANE®, and \$7.7 million of rebates related to VIDAZA® sales in the Japanese market which were included within discounts during the 2011 period. The increases were partly offset by a \$4.1 million decrease in TRICARE rebates, reflecting lower utilization of THALOMID®.

*2011 compared to 2010:* Returns and allowances increased by \$10.3 million in 2011 compared to 2010, including approximately \$7.7 million related to provisions for products with quality issues from contract manufacturers.

Discounts increased by \$3.1 million in 2011 compared to 2010, primarily due to revenue increases in the United States and international markets, both of which offer discount programs, and expansion into new international markets.

Government rebates increased by \$69.0 million in 2011 compared to 2010. The increase was primarily due to an increase of \$52.5 million in rebate rates in certain international markets and \$23.9 million in increased costs associated with the Medicare Part D Coverage Gap, partly offset by a \$5.4 million benefit related to a refinement of prior year estimates for Medicaid Managed Care Organizations.

Chargebacks and distributor service fees increased by \$70.2 million in 2011 compared to 2010. Chargebacks increased by \$33.3 million, including \$23.2 million related to the inclusion of ABRAXANE® sales in 2011 and \$8.8 million related to sales of VIDAZA®, which included



\$2.1 million related to disputed claims from 2010. Distributor service fees increased by \$36.9 million, including \$22.8 million in service fees primarily attributable to sales of ABRAXANE®, \$7.8 million in rebates related to the launch of VIDAZA® in Japan and a \$3.6 million increase in TRICARE rebates.

*Cost of Goods Sold (excluding amortization of acquired intangible assets):* Cost of goods sold and related percentages for the years ended December 31, 2012, 2011 and 2010 were as follows (dollar amounts in thousands):

|   | 2012         | 2011       | 2010       |
|---|--------------|------------|------------|
| Cost of goods sold (excluding amortization of acquired intangible assets) | \$ 299,124   | \$ 425,859 | \$ 306,521 |
| Increase (decrease) from prior year                                       | \$ (126,735) | \$ 119,338 | \$ 90,232  |
| Percent increase (decrease) from prior year                               | (29.8)%      | 38.9%      | 41.7%      |
| Percent of net product sales  | 5.6%         | 9.1%       | 8.7%       |

*Cost of goods sold (excluding amortization of acquired intangible assets):* Cost of goods sold (excluding amortization of acquired intangible assets) decreased by \$126.7 million to \$299.1 million in 2012 compared to 2011. The decrease was primarily due to the 2011 inclusion of the following items: a \$90.3 million inventory step-up amortization adjustment related to sales of ABRAXANE®, an aggregate \$13.2 million in costs related to the sale of non-core Abraxis products which were divested in April 2011, \$8.6 million in higher costs related to former Pharmion products to be exited and a \$15.3 million higher allocation of prepaid royalties related to sales of VIDAZA®. These items were partly offset by an increase in 2012 product material costs resulting from a higher level of sales activity. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) decreased to 5.6% in 2012 compared to 9.1% in 2011. Excluding the inventory step-up amortization for ABRAXANE®, the cost of goods sold ratio in 2011 was 7.1%. The cost of goods sold ratio in 2012 was favorably impacted by 0.3% from a reduction in prepaid royalties expensed in 2012 related to sales of VIDAZA® and lower cost products, such as REVLIMID®, comprising a larger portion of total net sales.

Cost of goods sold (excluding amortization of acquired intangible assets) increased by \$119.3 million to \$425.9 million in 2011 compared to 2010. The increase was primarily due to the inclusion in 2011 of a \$90.3 million inventory step-up amortization adjustment related to sales of ABRAXANE® subsequent to the acquisition of Abraxis compared to a \$34.7 million step-up amortization adjustment included in 2010. The remainder of the increase was primarily due to an increase in material costs resulting from a higher level of sales activity. As a percent of net product sales, cost of goods sold (excluding amortization of acquired intangible assets) increased to 9.1% in 2011 compared to 8.7% in 2010 primarily due to the inventory step-up amortization adjustment for ABRAXANE®. Excluding the step-up amortization adjustments in both years, the cost of goods sold ratios were 7.1% and 7.7% in 2011 and 2010, respectively.

*Research and Development:* Research and development costs are expensed as incurred and primarily include salary and benefit costs, third-party grants and fees paid to clinical research organizations, supplies and upfront and milestone payments resulting from collaboration arrangements.

Research and development expenses and related percentages for the years ended December 31, 2012, 2011 and 2010 were as follows (dollar amounts in thousands):

|                                  | 2012         | 2011         | 2010         |
|----------------------------------|--------------|--------------|--------------|
| Research and development         | \$ 1,724,156 | \$ 1,600,264 | \$ 1,128,495 |
| Increase from prior year         | \$ 123,892   | \$ 471,769   | \$ 333,647   |
| Percent increase from prior year | 7.7%         | 41.8%        | 42.0%        |
| Percent of total revenue         | 31.3%        | 33.0%        | 31.1%        |

*Research and Development:* Research and development expenses increased by \$123.9 million to \$1.724 billion in 2012 compared to 2011. The increase was primarily due to a \$31.9 million increase in payments related to research and development collaboration arrangements, an increase in 2012 research and development project spending in support of multiple programs across a broad range of diseases and the inclusion of Avila expenses incurred subsequent to the March 2012 acquisition date. The expense for 2012 also includes a \$53.4 million in-process research and development, or IPR&D, asset impairment charge related to ISTODAX® for PTCL in Europe and a \$69.2 million impairment related to an adjustment to the probability weighted forecasted sales of CC-292 compared to prior estimates.

Research and development expenses increased by \$471.8 million to \$1.600 billion in 2011 compared to 2010. The increase in 2011 was partly due to an increase of \$230.1 million related to the Abraxis business, including a \$118.0 million impairment charge related to the IPR&D acquired intangible asset. The impairment charge resulted from a change in the probability of obtaining progression-free survival labeling for the treatment of non-small cell lung cancer for ABRAXANE® in the United States. The remainder of the increase was primarily due to an increase in research and development project spending in support of multiple programs across a broad range of diseases, with late stage clinical trials completing enrollment during 2011. Expenses for 2011 also included \$128.5 million in upfront payments related to research and development collaboration arrangements, a \$20.0 million payment to Agios for a one year extension of our collaboration agreement and \$14.5 million in milestone payments.

The following table provides a breakdown of research and development expenses (in thousands):

|  | 2012               | 2011               | 2010               | Increase<br>(Decrease) |                        |
|--|--------------------|--------------------|--------------------|------------------------|------------------------|
|  |                    |                    |                    | 2012<br>versus<br>2011 | 2011<br>versus<br>2010 |
| Human pharmaceutical clinical programs | \$ 781,032         | \$ 732,366         | \$ 480,491         | \$ 48,666              | \$251,875              |
| Other pharmaceutical programs (1)      | 428,261            | 406,094            | 374,342            | 22,167                 | 31,752                 |
| Drug discovery and development         | 166,586            | 159,409            | 120,362            | 7,177                  | 39,047                 |
| Cellular therapy                       | 30,918             | 21,416             | 22,124             | 9,502                  | (708)                  |
| Collaboration arrangements             | 194,850            | 162,979            | 131,176            | 31,871                 | 31,803                 |
| IPR&D impairments                      | 122,509            | 118,000            | -                  | 4,509                  | 118,000                |
| Total                                  | <u>\$1,724,156</u> | <u>\$1,600,264</u> | <u>\$1,128,495</u> | <u>\$123,892</u>       | <u>\$471,769</u>       |

(1) Other pharmaceutical programs include spending for toxicology, analytical research and development,

We make significant investments in research and development in support of multiple ongoing proprietary clinical proprietary development programs which support both our existing products and pipeline of new drug candidates. REVLIMID is in several phase III trials across a range of hematological malignancies that include newly diagnosed multiple myeloma and maintenance, lymphomas, CLL, and non-deletion 5q MDS. Phase III trials for POMALYST® in myelofibrosis, in addition to VIDAZA in AML, and CC-486 for MDS and AML are also underway. In solid tumors, we continue to evaluate ABRAXANE in a phase III trial for metastatic melanoma and have recently completed a phase III trial for ABRAXANE® in pancreatic cancer. Our lead product candidate in Inflammation & Immunology, apremilast, is being evaluated in broad phase III programs for psoriatic arthritis, psoriasis, and ankylosing spondylitis.

Beyond our phase III programs is a growing early-to-mid-stage pipeline of novel therapies addressing significant unmet medical needs, including CC-292 (BTK inhibitor), CC-223 (dual TORK inhibitor), CC-115 (dual TORK/DNA PK inhibitor), CC-122 (pleiotropic pathway modulator), CC-220 and CC-11050 (anti-inflammatory), PDA-001 and PDA-002 (cellular therapies), in addition to partnered molecules ACE-011 (ActR fusion protein), ACE-536 (GDF trap), and EPZ-5676 (DOT1L inhibitor).

We do not collect costs on a project basis or for any category of projects for the majority of costs involved in carrying out research projects. While we do perform cost calculations to facilitate our internal evaluation of individual projects, these calculations include significant estimations and allocations that are not relevant to, or included in, our external financial reporting mechanisms. As a consequence, we do not report research and development costs at the project level.

The following table presents significant developments in our phase III clinical trials and regulatory approval requests that occurred during the three-month period ended December 31, 2012, as well as developments that are expected to occur if the future occurrence is material and reasonably certain:

**New phase III trials**

| <u>Product</u> | <u>Disease Indication</u>                       |
|----------------|---|
| CC-486         | Lower Risk MDS <sup>1</sup><br>AML <sup>2</sup> |
| POMALYST®      | Maintenance<br>Multiple Myeloma                 |

**Regulatory approval requests in major markets**

| <u>Product</u> | <u>Disease Indication</u> | <u>Major Market</u> | <u>Regulatory Agency</u> | <u>Date of Submission</u> |
|----------------|---------------------------|---------------------|--------------------------|---------------------------|
| REVLIMID®      | MCL <sup>3</sup>          | U.S.                | FDA                      | Dec-12                    |

**Regulatory agency actions**

| <u>Product</u> | <u>Disease Indication</u> | <u>Major Market</u> | <u>Regulatory Agency</u> | <u>Action</u>                      |
|----------------|---------------------------|---------------------|--------------------------|------------------------------------|
| REVLIMID®      | RRMM                      | China               | SFDA <sup>6</sup>        | Approval                           |
| ABRAXANE®      | NSCLC <sup>4</sup>        | U.S.                | FDA                      | Approval                           |
| POMALYST®      | Multiple Myeloma          | U.S.                | FDA                      | Approval                           |
| ISTODAX®       | PTCL <sup>5</sup>         | E.U.                | CHMP <sup>7</sup>        | Negative opinion on re-examination |

<sup>1</sup> Myelodysplastic syndromes

<sup>2</sup> Acute myeloid leukemia

<sup>3</sup> Mantle cell lymphoma

<sup>4</sup> Non Small Cell Lung Cancer

<sup>5</sup> Peripheral T-Cell Lymphoma

<sup>6</sup> China State Food and Drug Administration

<sup>7</sup> European Medicines Agency's Committee for Medicinal Products for Human Use

*Selling, General and Administrative:* Selling, general and administrative expenses primarily include salary and benefit costs for employees included in our sales, marketing, finance, legal and administrative organizations, costs related to the launch of new products or those approved for new indications, outside legal and professional services, donations to non-profit foundations and facilities costs.

Selling, general and administrative expenses and related percentages for the years ended December 31, 2012, 2011 and 2010 were as follows (dollar amounts in thousands):

|                                     | 2012         | 2011         | 2010       |
|-------------------------------------|--------------|--------------|------------|
| Selling, general and administrative | \$ 1,373,541 | \$ 1,226,314 | \$ 950,634 |
| Increase from prior year            | \$ 147,227   | \$ 275,680   | \$ 196,807 |
| Percent increase from prior year    | 12.0%        | 29.0%        | 26.1%      |
| Percent of total revenue            | 24.9%        | 25.3%        | 26.2%      |

Selling, general and administrative expenses increased by \$147.2 million to \$1.374 billion in 2012 compared to 2011, partly due to a \$72.0 million increase in donations to non-profit foundations, a \$6.1 million increase in allowances for doubtful accounts related to our European operations and increased marketing activities related to the prelaunch of ABRAXANE® for first-line treatment of advanced NSCL in the United States and prelaunch activities for POMALYST® globally.

Selling, general and administrative expenses increased by \$275.7 million to \$1.226 billion in 2011 compared to 2010, partly due to higher marketing and sales-related expenses resulting from ongoing product launch activities, including REVLIMID® in Japan, preparation for the filing and launch of REVLIMID® in China, ISTODAX® in PTCL in the United States and ABRAXANE® in the United States and Europe. In addition, 2011 included an increase of \$72.1 million in expenses related to the Abraxis business, resulting from a full year's expense being included in 2011.

*Amortization of Acquired Intangible Assets:* Amortization of intangible assets acquired as a result of business combinations is summarized below for the years ended December 31, 2012, 2011 and 2010 (in thousands):

|                                     | 2012        | 2011       | 2010       |
|-------------------------------------|-------------|------------|------------|
| Avila                               | \$ 39,381   | \$ -       | \$ -       |
| Abraxis                             | 99,618      | 89,259     | 21,648     |
| Gloucester                          | 51,500      | 40,217     | 21,833     |
| Pharmion                            | 4,000       | 159,750    | 159,750    |
| Total amortization                  | \$ 194,499  | \$ 289,226 | \$ 203,231 |
| Increase (decrease) from prior year | \$ (94,727) | \$ 85,995  | \$ 119,828 |

Amortization of acquired intangible assets decreased by \$94.7 million to \$194.5 million in 2012 compared to 2011 primarily due to certain Pharmion intangible assets becoming fully amortized at the end of 2011, which reduced amortization expense by \$155.8 million. The decrease was partly offset by intangible assets obtained in the March 2012 acquisition of Avila, which increased amortization expense by \$39.4 million. In addition, the June 2011 FDA approval of ISTODAX® for treatment of PTCL in patients who have received at least one prior therapy and the October 2012 approval of ABRAXANE® in the U.S. for the treatment of NSCLC resulted in the commencement of amortization of the related intangible assets. The approval of ABRAXANE® increased amortization expense by \$16.3 million and is expected to result in annual amortization expense of approximately \$78.0 million over the 15 year estimated useful life of the associated intangible asset.

Amortization of acquired intangible assets increased by \$86.0 million to \$289.2 million in 2011 compared to 2010. The increase in amortization expense was primarily due to a full year's amortization of intangible assets obtained in the October 2010 acquisition of Abraxis being included in 2011. In addition, in June 2011, the FDA approved ISTODAX<sup>®</sup>, which was obtained in the January 2010 acquisition of Gloucester, for treatment of PTCL in patients who have received at least one prior therapy. As a result of the FDA approval, amortization of the intangible asset commenced with an 8.8 year expected useful life, increasing amortization expense by \$17.8 million.

*Acquisition Related (Gains) Charges and Restructuring, net:* Acquisition related (gains) charges and restructuring, net was a net charge of \$169.0 million in 2012 and a net gain of \$142.3 million in 2011. The net increase of \$311.3 million in 2012 compared to 2011 was primarily due to a \$368.3 million change in the income statement impact related to our publicly traded contingent value rights, or CVRs. We recorded a \$216.8 million charge in 2012 and a \$151.5 million favorable adjustment in 2011. In addition, we recorded a \$9.2 million accretion of the contingent consideration liability related to our acquisition of Avila. The increases were partly offset by a \$63.6 million reduction in the contingent consideration liability related to the approval of ISTODAX<sup>®</sup> for PTCL in Europe.

Acquisition related (gains) charges and restructuring, net was a net gain of \$142.3 million in 2011, primarily due to a \$151.5 million favorable adjustment to the fair value of our liability related to our publicly traded CVRs. The favorable adjustment was partly offset by \$4.0 million in accretion of contingent consideration related to U.S. and EU approval of ISTODAX<sup>®</sup> for treatment of PTCL and \$5.2 million in restructuring and other acquisition related charges.

*Interest and Investment Income, Net:* Interest and investment income, net is summarized below for the years ended December 31, 2012, 2011 and 2010 (dollar amounts in thousands):

|                                     | 2012        | 2011        | 2010        |
|-------------------------------------|-------------|-------------|-------------|
| Interest and investment income, net | \$ 15,260   | \$ 25,860   | \$ 44,757   |
| Decrease from prior year            | \$ (10,600) | \$ (18,897) | \$ (32,028) |
| Percentage decrease from prior year | (41.0)%     | (42.2)%     | (41.7)%     |

*Interest and Investment Income, Net:* Interest and investment income, net decreased by \$10.6 million to \$15.3 million in 2012 compared to 2011. The decrease was primarily due to a \$3.7 million reduction in interest income due to lower overall interest rates, a \$5.1 million net decrease in gains on sales of marketable securities and a \$1.9 million net increase in the cost of amortization of discounts and premiums related to marketable securities.

Interest and investment income, net decreased by \$18.9 million to \$25.9 million in 2011 compared to 2010. The decrease was primarily due to a \$14.2 million reduction in interest income due to lower overall yields, a \$7.4 million net reduction in gains on sales of marketable securities and a \$0.3 million decrease in dividend income, partly offset by a \$3.0 million net decrease in the amortization of premiums and discounts related to the purchase of marketable securities.

*Interest (Expense):* Interest (expense) is summarized below for the years ended December 31, 2012, 2011 and 2010 (dollar amounts in thousands):

|                          | <u>2012</u> | <u>2011</u> | <u>2010</u> |
|--------------------------|-------------|-------------|-------------|
| Interest expense         | \$ 63,205   | \$ 42,737   | \$ 12,634   |
| Increase from prior year | \$ 20,468   | \$ 30,103   | \$ 10,668   |

Interest (expense) increased by \$20.5 million to \$63.2 million in 2012 compared to 2011 primarily due to interest and fees associated with the issuance of an additional \$1.500 billion in senior notes in August 2012 and an increase in interest on Commercial Paper borrowings, which was in effect for full year 2012.

Interest expense increased by \$30.1 million to \$42.7 million in 2011 compared to 2010. The increase was primarily due to a \$29.6 million increase in interest accrued on the \$1.250 billion in senior notes issued in October 2010 and to the issuance of commercial paper beginning in September 2011.

*Other Income (Expense), Net:* Other income, net is summarized below for the years ended December 31, 2012, 2011 and 2010 (in thousands):

|                                     | <u>2012</u> | <u>2011</u> | <u>2010</u> |
|-------------------------------------|-------------|-------------|-------------|
| Other income (expense), net         | \$ (17,006) | \$ (6,354)  | \$ (9,148)  |
| Increase (decrease) from prior year | \$ (10,652) | \$ 2,794    | \$ (68,506) |

Other income (expense), net was a net expense of \$17.0 million in 2012 and primarily included \$25.5 million in impairment losses related to cost method investments and net foreign exchange losses/forward point amortization of \$8.4 million, partly offset by a \$7.4 million gain on the sale of equity securities, net gains of \$3.7 million related to the short period in June 2012 when certain treasury rate lock agreements were not designated as hedges and a \$3.7 million economic development grant from the State of New Jersey. Included in 2011 were net foreign exchange losses/forward point amortization of \$10.9 million and equity method investment losses of \$2.8 million, partly offset by a \$2.9 million gain on the sale of non-core assets and \$3.6 million in economic development grant proceeds received from the State of New Jersey.

*Income Tax Provision:* The income tax provision increased by \$123.2 million to \$225.3 million in 2012 compared to 2011. The full year 2012 underlying effective tax rate of 13.5% reflects the impact of our global business footprint. The increase in the underlying effective tax rate from 2011 reflects a decrease in tax benefits from certain acquisition-related items. The effective tax rate for 2012 was reduced by 0.1 percentage points as a result of discrete items, including tax benefits related to the settlement of tax examinations and expirations of statutes of limitations offset by an increase in deferred tax liabilities recorded on certain unremitted foreign earnings previously treated as permanently reinvested in such foreign jurisdictions and tax expense related to the filing of our 2011 income tax returns with certain items being less favorable than originally estimated. The U.S. research and development tax credit expired on December 31, 2011 and was retroactively reinstated in the first quarter of 2013. The tax benefit of our 2012 research credit will be recorded in the first quarter of 2013. This change in tax law does not have a significant impact on our income tax provisions.

The income tax provision decreased by \$30.4 million to \$102.1 million in 2011 compared to 2010. The full year 2011 underlying effective tax rate of 11.5% reflects the impact of our global business footprint, the favorable impact of a shift in earnings between the United States and lower tax foreign jurisdictions, and tax deductions related to our acquisitions. The decrease in the underlying effective tax rate also reflects benefits from an increase in acquisition-related charges, including an IPR&D asset impairment charge of \$118.0 million and a non-taxable gain from a decrease in the fair value of our liability under the CVR Agreement related to the acquisition of Abraxis of \$151.5 million. The effective tax rate was reduced by 4.3 percentage points in 2011 as a result of discrete items which included tax benefits related to a foreign tax credit, a decrease in unrecognized tax benefits for certain ongoing income tax audits and expirations of statutes of limitations, and a net tax benefit related to changes in state tax laws.

The income tax provision for 2010 included a full year underlying effective tax rate of 15.9%. The effective tax rate was reduced by 2.8 percentage points in 2010 as a result of discrete items which included tax benefits related to a settlement of a tax examination and a reduction in a valuation allowance related to certain tax carryforwards, partially offset by an increase in unrecognized tax benefits for certain ongoing income tax audits.

*Net Income:* Net income and per common share amounts for the years ended December 31, 2012, 2011 and 2010 were as follows (dollar amounts in thousands, except per share data):

|                                    | 2012         | 2011         | 2010       |
|------------------------------------|--------------|--------------|------------|
| Net income attributable to Celgene | \$ 1,456,180 | \$ 1,318,150 | \$ 880,512 |
| Per common share amounts:          |              |              |            |
| Basic                              | \$ 3.38      | \$ 2.89      | \$ 1.90    |
| Diluted                            | \$ 3.30      | \$ 2.85      | \$ 1.88    |
| Weighted average shares:           |              |              |            |
| Basic                              | 430,927      | 455,348      | 462,298    |
| Diluted                            | 440,796      | 462,748      | 469,517    |

The \$138.0 million increase in net income and \$0.45 increase in diluted earnings per share in 2012 compared to 2011 reflected a higher level of net product sales, reduction in amortization of acquired intangible assets primarily due to certain intangible assets becoming fully amortized at the end of 2011 and a decrease in cost of goods sold, resulting from the 2011 inclusion of inventory step-up amortization for sales of ABRAXANE®. These favorable items were partly offset by an increase in the fair value of our liability related to publicly traded CVRs, an increase in payments related to research and development collaboration arrangements and increase in marketing activity, primarily related to prelaunch expenses for POMALYST® and ABRAXANE® for new indications. Earnings per diluted share were also favorably impacted in 2012 by the repurchase of 28.6 million common shares under our common share repurchase program, reducing our outstanding share base.

Net income for 2011 reflects the earnings impact from higher sales of REVLIMID®, VIDAZA® and a full year's sales of ABRAXANE®. The favorable impact of higher revenues was partly offset by increased spending for new product launches, research and development activities, expansion of our international operations, increase in amortization of intangible assets related to



acquisitions and an increase in interest expense related to the issuance of senior notes in October 2010. Earnings per diluted share were also favorably impacted in 2011 by the repurchase of 38.3 million common shares under our common share repurchase program, reducing our outstanding share base.

### Liquidity and Capital Resources

The following table summarizes the components of our financial condition for the years ended December 31, 2012, 2011 and 2010 (in thousands):

|   | 2012               | 2011               | 2010               | Increase (Decrease)    |                        |
|---|--------------------|--------------------|--------------------|------------------------|------------------------|
|   |                    |                    |                    | 2012<br>versus<br>2011 | 2011<br>versus<br>2010 |
| <b>Financial assets:</b>                    |                    |                    |                    |                        |                        |
| Cash and cash equivalents                   | \$2,090,387        | \$1,859,464        | \$1,351,128        | \$ 230,923             | \$ 508,336             |
| Marketable securities<br>available for sale | <u>1,809,883</u>   | <u>788,690</u>     | <u>1,250,173</u>   | <u>\$1,021,193</u>     | <u>\$ (461,483)</u>    |
| Total financial assets                      | <u>\$3,900,270</u> | <u>\$2,648,154</u> | <u>\$2,601,301</u> | <u>\$1,252,116</u>     | <u>\$ 46,853</u>       |
| <b>Debt:</b>                                |                    |                    |                    |                        |                        |
| Short-term borrowings                       | \$ 308,459         | \$ 526,684         | \$ -               | \$ (218,225)           | \$ 526,684             |
| Long-term debt, net of<br>discount          | <u>2,771,333</u>   | <u>1,275,585</u>   | <u>1,247,584</u>   | <u>1,495,748</u>       | <u>28,001</u>          |
| Total debt                                  | <u>\$3,079,792</u> | <u>\$1,802,269</u> | <u>\$1,247,584</u> | <u>\$1,277,523</u>     | <u>\$ 554,685</u>      |
| Working capital (1)                         | <u>\$3,767,525</u> | <u>\$2,659,970</u> | <u>\$2,835,427</u> | <u>\$1,107,555</u>     | <u>\$ (175,457)</u>    |

(1) Includes cash, cash equivalents and marketable securities available for sale, accounts receivable, net of allowances, inventory and other current assets, less short-term borrowings, accounts payable, accrued expenses, income taxes payable and other current liabilities.

We rely primarily on positive cash flows from operating activities, proceeds from sales of available-for-sale marketable securities, and borrowings in the form of long-term notes payable and short-term Commercial Paper to provide for our liquidity requirements. We expect continued growth in our expenditures, particularly those related to research and development, clinical trials, commercialization of new products, international expansion and capital investments. However, we anticipate that existing cash and cash equivalent balances, marketable securities available for sale, cash generated from operations and existing sources of and access to financing are adequate to fund our operating needs, capital expenditures, debt service requirements and our plans to repurchase stock or pursue other strategic business initiatives for the foreseeable future.

Many of our operations are conducted outside the United States, and significant portions of our cash, cash equivalents and short-term investments are held internationally. As of December 31, 2012, we held approximately \$2.700 billion of these short-term funds in foreign tax jurisdictions. The amount of funds held in U.S. tax jurisdictions can fluctuate due to the timing of receipts and payments in the ordinary course of business and due to other reasons, such as repurchases of our

common stock and business-development activities. As part of our ongoing liquidity assessments, we regularly monitor the mix of domestic and international cash flows (both inflows and outflows). Repatriation of overseas funds can result in additional U.S. federal, state and local income tax payments. We record U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be permanently reinvested outside of the U.S., no accrual for U.S. taxes is provided. During 2012, we concluded that approximately \$900.0 million of our foreign earnings may not be required for use in offshore operations and may be available for use in the United States. These earnings are no longer treated as permanently reinvested, and accordingly, we recorded a deferred tax liability of \$316.5 million for the estimated U.S. federal and state income taxes that may be incurred should these earnings be repatriated. The remaining foreign earnings are unremitted and expected to be permanently reinvested outside the U.S. We do not rely on these unremitted earnings as a source of funds for our domestic business as we expect to have sufficient current cash resources combined with future cash flows in the United States to fund our U.S. operational and strategic needs.

*Share Repurchase Program:* Our Board of Directors has approved an aggregate \$6.500 billion stock repurchase program of which we have approximately \$1.837 billion remaining for future share repurchases. During 2012, we used \$2.044 billion for repurchases of our common stock, measured on a settlement date basis.

#### Components of Working Capital

*Cash, Cash Equivalents and Marketable Securities Available for Sale:* We invest our excess cash primarily in money market funds, U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government agency and Supranational securities and global corporate debt securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from the date of purchase are classified as marketable securities available for sale. We determine the appropriate classification of our investments in marketable debt and equity securities at the time of purchase. The \$1.252 billion increase in cash, cash equivalents and marketable securities available for sale at December 31, 2012 compared to 2011 was primarily due to the issuance of \$1.500 billion in senior notes in August 2012 and by cash generated from operations, partly offset by \$2.044 billion paid under our share repurchase program, \$352.2 million paid for the acquisition of Avila, and a net repayment of \$217.4 million in short-term borrowings.

Marketable securities available for sale are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other than temporary impairment charges, is included in interest and investment income, net. For more information related to the fair value and valuation of our marketable securities, see Note 4 to the Notes to the Consolidated Financial Statements included elsewhere in this report.

*Accounts Receivable, Net:* Accounts receivable, net increased by \$15.0 million to \$960.5 million at the end of 2012 compared to 2011. The impact of increased U.S. and international sales of

REVLIMID®, VIDAZA® and ABRAXANE® was partly offset by increased collections in certain markets. Sales made outside the United States typically have payment terms that are greater than 60 days, thereby extending collection periods beyond those in the United States. We expect our accounts receivable balance to continue to grow as our international sales continue to expand.

We continue to monitor economic conditions, including the volatility associated with international economies, the sovereign debt crisis in certain European countries and associated impacts on the financial markets and our business. Our current business model in these markets is typically to sell our products directly to principally government owned or controlled hospitals, which in turn directly deliver critical care to patients. Our products are used to treat life-threatening diseases and we believe this business model enables timely delivery and adequate supply of products. Many of the outstanding receivable balances are related to government-funded hospitals and we believe the receivable balances are ultimately collectible. Similarly, we believe that future sales to these customers will continue to be collectible.

The credit and economic conditions within Spain, Italy, Portugal and Greece, as well as increasing sales levels in those countries have resulted in, and may continue to result in, an increase in the average length of time it takes to collect accounts receivable. Our total net receivables in Spain, Italy and Portugal are composed almost entirely of amounts receivable from government-owned or controlled hospitals and the public sector and amounted to \$324.2 million in 2012 compared to \$396.1 million in 2011. Approximately \$51.9 million of the \$324.2 million receivable in 2012 was greater than one year past due. Our exposure to the sovereign debt crisis in Greece is limited, as we do not have a material amount of receivables in Greece. We maintain timely and direct communication with hospital customers in Spain, Italy and Portugal regarding both the current and past due receivable balances. We continue to receive payments from these countries, and closely monitor the plans for payment at the regional government level. Payments from customers in these countries are not received on regular intervals and several months could elapse between significant payments. This payment pattern was observed in Spain earlier in 2012, where a significant portion of aged receivables were paid in late June and early July 2012. We also regularly request and receive positive confirmation of the validity of our receivables from most of the regional governmental authorities. We have the option to pursue legal action against certain of our customers. In view of the protracted timeline associated with collecting the outstanding balances through legal action and the current direct communication with our customers, in many instances, we do not believe pursuing legal action to be the best approach for any of the parties involved.

In determining the appropriate allowance for doubtful accounts for Spain, Italy, and Portugal, we considered that the balance of past due receivables is related to sales made to government-owned or supported customers. We regularly monitor developments in Europe to assess whether the level of risk of default for any customers has increased and note the ongoing efforts by the European Union, European Monetary Union and International Monetary Fund to support countries with large public deficits and outstanding debt balances. We also monitor the efforts of individual countries to support their regions with large public deficits and outstanding debt balances. We have not experienced significant losses or write-offs with respect to the collection of our accounts receivable in these countries as a result of their economic difficulties and we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse impact on our financial position or results of operations.

*Inventory:* Inventory balances increased by \$69.9 million to \$259.5 million at the end of 2012 compared to 2011. The increase was primarily due to increases in REVLIMID®, VIDAZA® and ABRAXANE® inventories, attributable to higher anticipated sales levels.

*Other Current Assets:* Other current assets decreased by \$74.9 million to \$320.2 million at the end of 2012 compared to 2011 primarily due to a \$64.1 million decrease in prepaid taxes and a \$60.0 million decrease in the fair value of foreign currency forward contracts, partly offset by an increase in other prepaid accounts.

*Commercial Paper:* In September 2011, we entered into a commercial paper program, or the Program, under which we issue unsecured commercial paper notes, or Commercial Paper, on a private placement basis up to a maximum aggregate amount outstanding at any time of \$1.000 billion, the proceeds of which will be used for general corporate purposes. The maturities of the Commercial Paper may vary, but may not exceed 270 days from the date of issue. The Commercial Paper is sold under customary terms to a dealer or in the commercial paper market and is issued at a discount from par or, alternatively, is sold at par and bears varying interest rates on a fixed or floating basis. Borrowings under the Program are accounted for as short-term borrowings. As of December 31, 2012, \$308.5 million of Commercial Paper was outstanding bearing an effective interest rate of 0.5%.

*Senior Unsecured Credit Facility:* In September 2011, we entered into a senior unsecured revolving credit facility, or the Credit Facility, providing for revolving credit in the aggregate amount of \$1.000 billion. Subject to certain conditions, we have the right to increase the amount of the Credit Facility (but in no event more than one time per annum), up to a maximum aggregate amount of \$1.250 billion.

The Credit Facility has a five-year term and amounts may be borrowed for working capital, capital expenditures and other corporate purposes. The Credit Facility serves as backup liquidity for our Commercial Paper borrowings. As of December 31, 2012 there was no outstanding borrowing against the Credit Facility.

The Credit Facility contains affirmative and negative covenants including certain customary financial covenants. We were in compliance with all debt covenants as of December 31, 2012.

*Accounts Payable, Accrued Expenses and Other Current Liabilities:* Accounts payable, accrued expenses and other current liabilities increased by \$391.0 million to \$1.353 billion at the end of 2012 compared to 2011. The increase was primarily due to a \$277.4 million reclassification of the liability associated with our publicly traded CVRs from non-current to current, a \$51.5 million increase in clinical trial accruals, a \$17.4 million increase in the contingent consideration related to the January 2012 Avila acquisition and a \$16.6 million increase in accrued interest.

*Income Taxes Payable (Current and Non-Current):* Income taxes payable decreased by \$446.5 million to \$200.0 million at the end of 2012 compared to 2011, primarily from tax payments of \$469.6 million, the application of previously refundable prepaid income taxes of \$11.4 million, a tax benefit of stock options of \$43.4 million, net deferred intercompany credits of \$50.3 million offset by the current provision for income taxes of \$125.1 million, which includes a benefit related to tax settlements of \$373.0 million.

*Senior Notes:* In August 2012, we issued an additional \$1.500 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 1.90% Senior Notes due 2017, or the 2017 notes, and \$1.000 billion aggregate principal amount of 3.25% Senior Notes due 2022 (the “2022 notes” and, together with the 2017 notes, referred to herein as the “2012 issued notes”). The 2012 issued notes were issued at 99.786% and 99.949% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$11.7 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2013 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at our option, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2017 notes and 25 basis points in the case of the 2022 notes. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property. The carrying value of the senior notes was \$2.771 billion at December 31, 2012.

Cash flows from operating, investing and financing activities for the years ended December 31, 2012, 2011 and 2010 were as follows (in thousands):

|   | 2012          | 2011          | 2010          | Increase (Decrease)    |                        |
|---|---------------|---------------|---------------|------------------------|------------------------|
|   |               |               |               | 2012<br>versus<br>2011 | 2011<br>versus<br>2010 |
| Net cash provided by operating activities           | \$ 2,018,553  | \$ 1,776,110  | \$ 1,181,556  | \$ 242,443             | \$ 594,554             |
| Net cash provided by (used in) investing activities | \$(1,553,592) | \$ 377,696    | \$(2,107,305) | \$(1,931,288)          | \$ 2,485,001           |
| Net cash provided by (used in) financing activities | \$ (248,728)  | \$(1,622,030) | \$ 1,177,167  | \$ 1,373,302           | \$(2,799,197)          |

*Operating Activities:* Net cash provided by operating activities increased by \$242.4 million to \$2.019 billion in 2012 compared to 2011. The increase in net cash provided by operating activities was primarily attributable to an expansion of our operations and related increase in net earnings.

Net cash provided by operating activities in 2011 increased by \$594.6 million to \$1.776 billion as compared to 2010. The increase in net cash provided by operating activities was primarily attributable to an expansion of our operations and related increase in net earnings, partially

offset by the increase in accounts receivable associated with expanding international sales, which take longer to collect, and the timing of receipts and payments in the ordinary course of business.

*Investing Activities:* Net cash used in investing activities in 2012 changed to a net usage of \$1.554 billion compared to \$377.7 million of net cash provided by investing activities in 2011. The decrease in net cash provided by investing activities was principally related to a cash use of \$1.025 billion for net purchases of marketable securities available for sale during 2012 compared to net sales of \$481.8 million in 2011, plus usages of \$352.2 million for the acquisition of Avila and \$48.9 million for the purchase of intellectual property and other assets.

Net cash provided by investing activities in 2011 changed to a positive \$377.7 million compared to a net cash use of \$2.107 billion in 2010. The 2010 investing activities included net cash used in the acquisition of Abraxis of \$2.315 billion and the acquisition of Gloucester of \$337.6 million.

*Financing Activities:* Net cash used in financing activities in 2012 was \$248.7 million compared to a net cash use of \$1.622 billion in 2011. The \$1.373 billion decrease in net cash used in financing activities in 2012 was primarily attributable to \$1.487 billion of proceeds from the issuance of long-term debt, partially offset by \$217.4 million of net repayments of short-term borrowing in 2012 compared to \$525.7 million of net short-term borrowing in 2011. During 2012 and 2011, we used \$2.044 billion and \$2.189 billion, respectively, for repurchases of our common stock, measured on a settlement date basis.

Net cash used in financing activities in 2011 was \$1.622 billion compared to net cash provided of \$1.177 billion in 2010. The \$2.799 billion decrease in net cash provided by financing activities in 2011 was primarily attributable to proceeds from the issuance of long-term debt in 2010 that provided net cash of \$1.237 billion and the \$2.189 billion in common share repurchases in 2011 under the common share repurchase program.

### Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2012 (in thousands):

|                               | Payment Due By Period |                   |                   |                      |                    |
|-------------------------------|-----------------------|-------------------|-------------------|----------------------|--------------------|
|                               | Less than<br>1 Year   | 1 to 3 Years      | 3 to 5 Years      | More than<br>5 Years | Total              |
| Senior notes (1)              | \$ 88,250             | \$ 676,500        | \$ 652,000        | \$2,299,500          | \$3,716,250        |
| Short-term borrowings         | 308,459               | -                 | -                 | -                    | 308,459            |
| Operating leases              | 50,532                | 95,715            | 66,763            | 67,950               | 280,960            |
| Other contract<br>commitments | 67,710                | 15,644            | 6,054             | -                    | 89,408             |
| Total                         | <u>\$ 514,951</u>     | <u>\$ 787,859</u> | <u>\$ 724,817</u> | <u>\$2,367,450</u>   | <u>\$4,395,077</u> |

(1) The senior note obligation amounts include future principal and interest payments.

*Senior Notes:* In August 2012, we issued \$1.500 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 1.90% Senior Notes due 2017, and

\$1.000 billion aggregate principal amount of 3.25% Senior Notes due 2022. The 2012 issued notes were issued at 99.786% and 99.949% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$11.7 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2013 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at the option of the Company, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2017 notes and 25 basis points in the case of the 2022 notes. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

In October 2010, we issued a total of \$1.250 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.45% Senior Notes due 2015, \$500.0 million aggregate principal amount of 3.95% Senior Notes due 2020 and \$250.0 million aggregate principal amount of 5.7% Senior Notes due 2040.

*Short-term Borrowings:* Contractual obligations related to short-term borrowings included principal, interest and fees of \$308.5 million related to commercial paper outstanding at December 31, 2012.

*Operating Leases:* We lease office and research facilities under various operating lease agreements in the United States and various international markets. The non-cancelable lease terms for operating leases expire at various dates between 2013 and 2023 and include renewal options. In general, we are also required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs associated with the leases. For more information on the major facilities that we occupy under lease arrangements refer to Part I, Item 2, "Properties" of this Annual Report on Form 10-K.

*Other Contract Commitments:* Other contract commitments of \$89.4 million on December 31, 2012 include \$64.1 million in contractual obligations related to product supply contracts. In addition, we have committed to invest an aggregate \$25.0 million in two investment funds over a ten-year period, which is callable at any time. On December 31, 2012, our remaining investment commitment was \$5.4 million.

*Collaboration Arrangements:* We have entered into certain research and development collaboration agreements with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. Our obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the

programs. Due to the nature of these arrangements, the future potential payments related to the attainment of specified development and regulatory approval milestones over a period of several years are inherently uncertain, and accordingly, no amounts have been recorded for these future potential payments in our Consolidated Balance Sheets at December 31, 2012 and 2011 contained in this Annual Report on Form 10-K. Potential milestone payments total approximately \$6.202 billion, including approximately \$4.284 billion contingent on the achievement of various research, development and regulatory approval milestones and approximately \$1.918 billion in sales-based milestones. The most significant collaboration agreements are identified in Note 17 of the Notes to Consolidated Financial Statements contained in this Annual Report on Form 10-K.

### **New Accounting Principles**

In July 2012, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2012-02, “Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment,” or ASU 2012-02. ASU 2012-02 allows a company the option to first assess qualitative factors to determine whether it is necessary to perform a quantitative impairment test. Under that option, a company would no longer be required to calculate the fair value of an indefinite-lived intangible asset unless the company determines, based on that qualitative assessment, that it is more likely than not that the fair value of the indefinite-lived intangible asset is less than its carrying amount. ASU 2012-02 is effective for annual and interim indefinite-lived intangible asset impairment tests performed for periods beginning after September 15, 2012. Early adoption is permitted and we adopted this standard in the fourth quarter of 2012. The adoption of ASU 2012-02 did not have a material impact on our financial position or results of operations.

### **Critical Accounting Estimates and Significant Accounting Policies**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 1 of the Notes to Consolidated Financial Statements included in this Annual Report, we believe the following accounting estimates and policies to be critical:

*Revenue Recognition:* Revenue from the sale of products is recognized when title and risk of loss of the product is transferred to the customer. Provisions for discounts, early payments, rebates, sales returns and distributor chargebacks under terms customary in the industry are provided for in the same period the related sales are recorded. We record estimated reductions to revenue for volume-based discounts and rebates at the time of the initial sale. The estimated reductions to revenue for such volume-based discounts and rebates are based on the sales terms, historical experience and trend analysis.

We recognize revenue from royalties based on licensees’ sales of our products or products using our technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.



*Gross to Net Sales Accruals:* We record gross to net sales accruals for sales returns and allowances, sales discounts, government rebates, and chargebacks and distributor service fees.

We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization initiatives conducted by major pharmacy chains, as applicable. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits, are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance. REVLIMID® is distributed primarily through hospitals and contracted pharmacies, lending itself to tighter controls of inventory quantities within the supply channel and, thus, resulting in lower returns activity. THALOMID® is drop-shipped directly to the prescribing pharmacy and, as a result, wholesalers do not stock the product.

Sales discount accruals are based on payment terms extended to customers.

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. We have also analyzed actual billings received from certain states to further support the accrual rates. Subsequent to implementation of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, or collectively the 2010 U.S. Health Care Reform Law, certain states have not yet submitted actual Medicaid Managed Care Organization bills, resulting in an increase in the accrual balance. Effective January 1, 2011, manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this coverage gap responsibility, we analyze data for eligible Medicare Part D patients against data for eligible Medicare Part D patients treated with our products as well as the historical invoices. This expense is recognized throughout the year as incurred. In addition, certain international markets have government-sponsored programs that require rebates to be paid based on program specific rules and, accordingly, the rebate accruals are determined primarily on estimated eligible sales.

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to 15 months from the date of sale. We provide a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include level of wholesaler

inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Distributor service fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. TRICARE is a health care program of the U.S. Department of Defense Military Health System that provides civilian health benefits for military personnel, military retirees and their dependents. TRICARE rebate accruals are based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

*Allowance for Doubtful Accounts:* We estimate an allowance for doubtful accounts primarily based on the credit worthiness of our customers, historical payment patterns, aging of receivable balances and general economic conditions, including publicly available information on the credit worthiness of countries themselves and provinces or areas within such countries where they are the ultimate customers.

*Income Taxes:* We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We provide a valuation allowance when it is more likely than not that deferred tax assets will not be realized.

We account for interest and penalties related to uncertain tax positions as part of our provision for income taxes. These unrecognized tax benefits relate primarily to issues common among multinational corporations in our industry. We apply a variety of methodologies in making these estimates which include studies performed by independent economists, advice from industry and subject experts, evaluation of public actions taken by the U.S. Internal Revenue Service and other taxing authorities, as well as our own industry experience. We provide estimates for unrecognized tax benefits. If our estimates are not representative of actual outcomes, our results of operations could be materially impacted.

We periodically evaluate the likelihood of the realization of deferred tax assets, and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of deferred tax assets, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. Significant judgment is required in making this assessment and, to the extent future expectations change, we would have to assess the recoverability of our deferred tax assets at that time. At December 31, 2012, it was more likely than not that we would realize our deferred tax assets, net of valuation allowances.

*Share-Based Compensation:* The cost of share-based compensation is recognized in the Consolidated Statements of Income based on the fair value of all awards granted, using the Black-Scholes method of valuation for stock options. The fair values of restricted stock units and performance restricted stock units are based on the market value of our Common Stock on the date of grant. The fair value of each award is determined and the compensation cost is

recognized over the service period required to obtain full vesting. Compensation cost to be recognized reflects an estimate of the number of awards expected to vest after taking into consideration an estimate of award forfeitures based on actual experience.

*Other-Than-Temporary Impairments of Available-For-Sale Marketable Securities:* A decline in the market value of any available-for-sale marketable security below its cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security established. The determination of whether an available-for-sale marketable security is other-than-temporarily impaired requires significant judgment and requires consideration of available quantitative and qualitative evidence in evaluating the potential impairment. Factors evaluated to determine whether the investment is other-than-temporarily impaired include: significant deterioration in the issuer's earnings performance, credit rating, asset quality, business prospects of the issuer, adverse changes in the general market conditions in which the issuer operates, length of time that the fair value has been below our cost, our expected future cash flows from the security, our intent not to sell, an evaluation as to whether it is more likely than not that we will not have to sell before recovery of our cost basis, and issues that raise concerns about the issuer's ability to continue as a going concern. Assumptions associated with these factors are subject to future market and economic conditions, which could differ from our assessment.

*Derivatives and Hedging Activities:* All derivative instruments are recognized on the balance sheet at their fair value. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction and, if it is, the type of hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, we formally document the nature and relationships between the hedging instruments and hedged item. We assess, both at inception and on an on-going basis, whether the derivative instruments that are used in cash flow hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. We assess hedge effectiveness on a quarterly basis and record the gain or loss related to the ineffective portion of derivative instruments, if any, to current earnings. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in current earnings. We use derivative instruments, including those not designated as part of a hedging transaction, to manage our exposure to movements in foreign exchange and interest rates. The use of these derivative instruments modifies the exposure of these risks with the intent to reduce our risk or cost. We do not use derivative instruments for speculative trading purposes and are not a party to leveraged derivatives.

*Investments in Other Entities:* We hold a portfolio of investments in equity securities and certain investment funds that are accounted for under either the equity method or cost method. Investments in companies or certain investment funds over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in other income (expense), net. Our cost method and equity method investments are included in other assets on the Consolidated Balance Sheets.

All of our investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value and the decline is determined to be other-than-temporary, the investment is written down to its fair value. Such an evaluation is

judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value has occurred include: market value or exit price of the investment based on either market-quoted prices or future rounds of financing by the investee; length of time that the market value was below its cost basis; financial condition and business prospects of the investee; our intent and ability to retain the investment for a sufficient period of time to allow for recovery in market value of the investment; issues that raise concerns about the investee's ability to continue as a going concern; and any other information that we may be aware of related to the investment.

*Accounting for Long-Term Incentive Plans:* We have established a Long-Term Incentive Plan, or LTIP, designed to provide key officers and executives with performance-based incentive opportunities contingent upon achievement of pre-established corporate performance objectives covering a three-year period. We currently have three separate three-year performance cycles running concurrently ending December 31, 2013, 2014 and 2015. Performance measures for the performance cycle ending in 2013 are based on the following components in the last year of the three-year cycle: 25% on non-GAAP earnings per share; 25% on non-GAAP net income; and 50% on total non-GAAP revenue, as defined. The performance cycles ending in 2014 and 2015 are based on the following components: 37.5% on non-GAAP earnings per share; 37.5% on total non-GAAP revenue, as defined; and 25% on relative total shareholder return, which is a measurement of our stock price performance during the year compared with a group of other companies in the biopharmaceutical industry.

Payouts may be in the range of 0% to 200% of the participant's salary for the LTIPs. Such awards are payable in cash or common stock or a mixture of cash and common stock, which will be determined by the Compensation Committee at the time of award delivery. For awards payable in common stock, the number of shares is determined using the average closing price for the 30 trading days prior to the beginning of the cycle. Payments made in common stock are restricted from trading for a period of three years. We accrue the long-term incentive liability over each three-year cycle. Prior to the end of a three-year cycle, the accrual is based on an estimate of our level of achievement during the cycle. Upon a change in control, participants will be entitled to an immediate payment equal to their target award or, if higher, an award based on actual performance through the date of the change in control.

Accruals recorded for the LTIP entail making certain assumptions concerning future non-GAAP earnings per share, non-GAAP net income and non-GAAP revenues, as defined; the actual results of which could be materially different than the assumptions used. Accruals for the LTIP are reviewed on a regular basis and revised accordingly so that the liability recorded reflects updated estimates of future payouts. In estimating the accruals, management considers actual results to date for the performance period, expected results for the remainder of the performance period, operating trends, product development, pricing and competition.

*Valuation of Goodwill, Acquired Intangible Assets and IPR&D:* We have recorded goodwill, acquired intangible assets and IPR&D primarily through the acquisitions of Pharmion, Gloucester, Abraxis and Avila. When identifiable intangible assets, including in-process research and development, are acquired, we determine the fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations if quoted market prices

are not available, and the models require the use of significant estimates and assumptions including but not limited to:

- projecting regulatory approvals,
- estimating future cash flows from product sales resulting from completed products and in-process projects and
- developing appropriate discount rates and probability rates

Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination accounted for by the acquisition method of accounting and is not amortized, but subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. We test our goodwill annually for impairment each November 30. We are organized as a single reporting unit and therefore the goodwill impairment test is done using our overall market value, as determined by our traded share price, as compared to our book value of net assets.

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events occur. Intangible assets related to IPR&D product rights are treated as indefinite-lived intangible assets and not amortized until the product is approved for sale by regulatory authorities in specified markets. At that time, we will determine the useful life of the asset, reclassify the asset out of IPR&D and begin amortization. Impairment testing is also performed at least annually or when a triggering event occurs that could indicate a potential impairment. Such test entails completing an updated discounted cash flow model to estimate the fair value of the asset. Our existing IPR&D product rights were obtained in the acquisitions of Gloucester and Avila. The Gloucester related product rights will become definite-lived intangibles when marketing approval is received for ISTODAX® for treatment of PTCL in the European Union. The Avila related product rights will become definite-lived intangibles when marketing approval is received for CC-292 for any indication in any major market.

*Valuation of Contingent Consideration Resulting from a Business Combination:* We record contingent consideration resulting from a business combination at its fair value on the acquisition date, and for each subsequent reporting period revalue these obligations and record increases or decreases in their fair value as an adjustment to operating earnings in the consolidated statements of income. Changes to contingent consideration obligations can result from movements in publicly traded share prices of CVRs, adjustments to discount rates and periods, updates in the assumed achievement or timing of any development milestones or changes in the probability of certain clinical events and changes in the assumed probability associated with regulatory approval. The assumptions related to determining the value of a contingent consideration include a significant amount of judgment and any changes in the assumptions could have a material impact on the amount of contingent consideration expense recorded in any given period. Our contingent consideration liabilities were acquired in the acquisitions of Gloucester, Abraxis, and Avila. The fair values of the Gloucester and Avila contingent consideration liabilities are based on the discount rate, probability and estimated timing of cash milestone payments to the former shareholders or each company. The fair value of the Abraxis

contingent consideration liability is based on the quoted market price of the publicly traded CVRs.

**ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK***

The following discussion provides forward-looking quantitative and qualitative information about our potential exposure to market risk. Market risk represents the potential loss arising from adverse changes in the value of financial instruments. The risk of loss is assessed based on the likelihood of adverse changes in fair values, cash flows or future earnings.

We have established guidelines relative to the diversification and maturities of investments to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified depending on market conditions. Although investments may be subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. At December 31, 2012, our market risk sensitive instruments consisted of marketable securities available for sale, our long-term debt and certain foreign exchange contracts.

*Marketable Securities Available for Sale:* At December 31, 2012, our marketable securities available for sale consisted of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government, agency and Supranational securities, global corporate debt securities and a marketable equity security. U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by U.S. Government Sponsored Enterprises. U.S. government-sponsored agency MBS include mortgage backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Non-U.S. government, agency and Supranational securities consist of direct obligations of highly rated governments of nations other than the United States, obligations of sponsored agencies and other entities that are guaranteed or supported by highly rated governments of nations other than the United States. Corporate debt – global includes obligations issued by investment-grade corporations including some issues that have been guaranteed by governments and government agencies.

Marketable securities available for sale are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other than temporary impairment charges, is included in interest and investment income, net.

As of December 31, 2012, the principal amounts, fair values and related weighted-average interest rates of our investments in debt securities classified as marketable securities available for sale were as follows (in thousands):

|                                | Duration            |              |              |             |
|--------------------------------|---------------------|--------------|--------------|-------------|
|                                | Less than<br>1 Year | 1 to 3 Years | 3 to 5 Years | Total       |
| Principal amount               | \$580,241           | \$ 1,136,106 | \$ 61,355    | \$1,777,702 |
| Fair value                     | \$587,170           | \$ 1,159,017 | \$ 63,400    | \$1,809,587 |
| Weighted average interest rate | 0.4%                | 0.5%         | 1.0%         | 0.5%        |

*Long-Term Debt:* In August 2012, we issued a total of \$1.500 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 1.90% Senior Notes due 2017 and \$1.000 billion aggregate principal amount of 3.25% Senior Notes due 2022. The 2012 issued notes were issued at 99.786% and 99.949% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$11.7 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2013 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at our option, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2017 notes and 25 basis points in the case of the 2022 notes. If a change of control occurs accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

On October 7, 2010, we issued a total of \$1.250 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 2.45% Senior Notes due 2015, \$500.0 million aggregate principal amount of 3.95% Senior Notes due 2020 and \$250.0 million aggregate principal amount of 5.7% Senior Notes due 2040. The notes were issued at 99.854%, 99.745% and 99.813% of par, respectively, and the discount amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$10.5 million have been recorded as debt issuance costs on our consolidated balance sheet and are amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on April 15 and October 15 of each year and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at our option, in whole or in part, at any time at a redemption price equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid

interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

At December 31, 2012, the fair value of our senior notes outstanding was \$2.893 billion.

## **MARKET RISK MANAGEMENT**

Our revenue and earnings, cash flows and fair values of assets and liabilities can be impacted by fluctuations in foreign exchange rates and interest rates. We manage the impact of foreign exchange rate and interest rate movements through operational means and through the use of various financial instruments, including derivative instruments such as foreign currency options, foreign currency forward contracts, treasury rate lock agreements and interest rate swap contracts.

### ***Foreign Currency Risk Management***

We have established revenue hedging and balance sheet risk management programs to mitigate volatility in future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

Through our revenue hedging program, we endeavor to reduce the impact of possible unfavorable changes in foreign exchange rates on our future U.S. dollar cash flows that are derived from foreign currency denominated sales. To achieve this objective, we hedge a portion of our forecasted foreign currency denominated sales that are expected to occur in the foreseeable future, typically no more than three years into the future. We manage our anticipated transaction exposure principally with foreign currency forward contracts and occasionally foreign currency put and call options.

*Foreign Currency Forward Contracts:* We use foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies and to reduce exposures to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies.

We enter into foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at December 31, 2012 and 2011 had settlement dates within 36 months. These foreign currency forward contracts are designated as cash flow hedges and, to the extent effective, any unrealized gains or losses on them are reported in other comprehensive income (loss), or OCI, and reclassified to operations in the same periods during which the underlying hedged transactions affect operations. Any ineffectiveness on these foreign currency forward contracts is reported in other income



(expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at December 31, 2012 and 2011:

| <u>Foreign Currency</u> | <u>Notional Amount</u> |                    |
|-------------------------|------------------------|--------------------|
|                         | <u>2012</u>            | <u>2011</u>        |
| Australian Dollar       | \$ 5,076               | \$ 17,169          |
| British Pound           | 77,914                 | 53,764             |
| Canadian Dollar         | 134,366                | 67,281             |
| Euro                    | 969,296                | 714,446            |
| Japanese Yen            | 236,212                | 606,538            |
| Swiss Franc             | -                      | 49,182             |
| Total                   | <u>\$1,422,864</u>     | <u>\$1,508,380</u> |

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of December 31, 2012, credit risk did not materially change the fair value of our foreign currency forward contracts.

We also enter into foreign currency forward contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at December 31, 2012 and 2011 were \$795.4 million and \$916.9 million, respectively.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the December 31, 2012 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency forward contracts would change by approximately \$227.9 million. However, since the contracts either hedge specific forecasted intercompany transactions denominated in foreign currencies or relate to assets and liabilities denominated in currencies other than the entities' functional currencies, any change in the fair value of the contract would be either reported in other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the underlying asset or liability

*Foreign Currency Option Contracts:* During 2012, we began hedging a portion of our future foreign currency exposure by utilizing a strategy that involves both a purchased local currency put option and a written local currency call option that are accounted for as hedges of future sales denominated in Euros. Specifically, we sell (or write) a local currency call option and purchase a local currency put option with the same expiration dates and amounts but with different strike prices; this combination of transactions is generally referred to as a "collar". The expiration dates and notional amounts correspond to the amount and timing of forecasted future foreign currency sales. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value reduces to zero and we benefit from the increase in the U.S. dollar

equivalent value of our anticipated foreign currency cash flows, however this benefit would be capped at the strike level of the written call, which forms the upper end of the collar. The premium collected from the call option partially offsets the premium paid for the purchased put option, resulting in a net cost for the collars.

In order to fully offset the net cost of the collars, we also sold local currency put options with a lower strike price and the same expiration dates and amounts as the option contracts that were used to hedge sales. These written put options introduced risk of loss if the U.S. dollar were to strengthen beyond the strike price of the written put options. In December 2012, we entered into purchased put options that are not designated as hedges in order to partially offset the risk of loss that would be incurred on the written put options if the US dollar were to strengthen beyond the strike price of the written put. Gains and losses associated with the non-hedge put options have been recorded on the income statement as other income (expense), net.

Foreign currency option contracts entered into to hedge forecasted revenue and expenses were as follows at December 31, 2012:

| <u>Foreign Currency Option</u>      | <u>Notional Amount*</u><br><u>2012</u> |
|-------------------------------------|--|
| Designated as hedging activity:     |  |
| Purchased Put                       | \$ 228,779                             |
| Written Call                        | \$ 235,920                             |
| Not designated as hedging activity: |  |
| Purchased Put                       | \$ 160,493                             |
| Written Put                         | \$(215,952)                            |

\* U.S. Dollar notional amounts are calculated as the hedged local currency amount multiplied times the strike value of the foreign currency option. The local currency notional amounts of our purchased put, and written call that are designated as hedging activity are equal to each other.

Although not predictive in nature, we believe a hypothetical 10% threshold reflects a reasonably possible near-term change in foreign currency rates. Assuming that the December 31, 2012 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts that are designated as hedges would change by approximately \$24.1 million. However, since the foreign currency option contracts designated as hedges hedge specific forecasted intercompany transactions denominated in foreign currencies, any change in the fair value of the contract would be either reported in other comprehensive income and reclassified to earnings in the same periods during which the underlying hedged transactions affect earnings or re-measured through earnings each period along with the underlying asset or liability. Assuming that the December 31, 2012 exchange rates were to change by a hypothetical 10%, the fair value of the foreign currency option contracts that are not designated as hedges would decrease by approximately \$0.9 million if the U.S. Dollar were to strengthen, and would increase by approximately \$2.2 million if the U.S. Dollar were to weaken. This impact would be recorded to income during the period during which the change in currency rates occurred.

## ***Interest Rate Risk Management***

***Treasury Rate Lock Agreements:*** During 2012, we entered into treasury rate lock agreements, or treasury rate locks, in anticipation of issuing fixed-rate notes that were issued in August 2012. With the exception of a short period in June when certain outstanding treasury rate locks were not designated as hedges, our treasury rate locks are designated as cash flow hedges and, to the extent effective, any realized or unrealized gains or losses on them are reported in OCI and will be recognized in income over the life of the anticipated fixed-rate notes. Treasury rate locks were settled during 2012 which resulted in losses of \$35.3 million that were recorded to OCI. During the short period in June when we had outstanding treasury rate locks that were not considered hedging instruments, we recorded the change in fair value of \$3.7 million in other income (expense), net. No material amounts were recorded in income during 2012 or 2011 as a result of hedge ineffectiveness or hedge components excluded from the assessment of effectiveness. At December 31, 2012 we had no outstanding treasury rate locks.

***Interest Rate Swap Contracts:*** From time to time we hedge the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in interest rates. Since the specific terms and notional amount of the swap are intended to match those of the debt being hedged, it is assumed to be a highly effective hedge and all changes in fair value of the swaps are recorded on the Consolidated Balance Sheets with no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense.

In 2011, we settled outstanding interest rate swap contracts we entered into with respect to our \$500.0 million 2.45% fixed notes due in 2015 resulting in the receipt of \$34.3 million. The proceeds from the settlements are being accounted for as a reduction of current and future interest expense associated with these notes. During 2012, we terminated the hedging relationship on \$800.0 million notional amount of swap contracts that had been entered into earlier in 2012 as hedges of our 1.9% fixed rate notes due in 2017 and our 3.25% fixed rate notes due in 2022 by settling certain of the contracts and entering into offsetting contracts for those not settled. This resulted in gains of \$5.0 million that are being accounted for as a reduction of current and future interest expense associated with these notes.

At December 31, 2012, we were a party to pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. Our swap contracts outstanding at December 31, 2012 consisted of \$100.0 million aggregate notional amount maturing in 2017, which effectively convert a portion of our \$500.0 million, 1.90% fixed-rate notes due in 2017 to a floating rate and \$200.0 million aggregate notional amount maturing in 2022, which effectively converts a portion of our \$1.000 billion, 3.25% fixed-rate notes due in 2022 to a floating rate.

In January 2013 we entered into additional interest rate swap contracts with notional amounts of \$400.0 million related to our 1.90% fixed-rate notes due in 2017 and \$800.0 million related to our 3.25% fixed-rate notes due in 2022.

A sensitivity analysis to measure potential changes in the market value of our debt and interest rate swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2012 would have reduced the aggregate fair value of our net payable by \$169.3 million. A one percentage point decrease at December 31, 2012 would have increased the aggregate fair value of our net payable by \$188.7 million.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**CELGENE CORPORATION AND SUBSIDIARIES**

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders

Celgene Corporation:

We have audited the accompanying consolidated balance sheets of Celgene Corporation and subsidiaries (the Company) as of December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, cash flows, and stockholders' equity for each of the years in the three-year period ended December 31, 2012. In connection with our audits of the consolidated financial statements, we also have audited the consolidated financial statement schedule, "Schedule II – Valuation and Qualifying Accounts." These consolidated financial statements and consolidated financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and consolidated financial statement schedule 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 Celgene Corporation and subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 15, 2013 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Short Hills, New Jersey

February 15, 2013

**CELGENE CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
(Dollars in thousands, except per share amounts)

|   | December 31,  |               |
|---|---------------|---------------|
|   | 2012          | 2011          |
| <b>Assets</b>   |               |               |
| Current assets:   |               |               |
| Cash and cash equivalents   | \$ 2,090,387  | \$ 1,859,464  |
| Marketable securities available for sale  | 1,809,883     | 788,690       |
| Accounts receivable, net of allowances of \$32,988 and \$18,855 at December 31, 2012 and 2011, respectively   | 960,521       | 945,531       |
| Inventory   | 259,495       | 189,573       |
| Deferred income taxes   | 93,168        | 116,751       |
| Other current assets  | 320,211       | 395,094       |
| Assets held for sale  | -             | 58,122        |
| Total current assets  | 5,533,665     | 4,353,225     |
| Property, plant and equipment, net  | 578,362       | 506,042       |
| Intangible assets, net  | 3,100,423     | 2,844,698     |
| Goodwill  | 2,042,773     | 1,887,220     |
| Other assets  | 479,083       | 414,725       |
| Total assets  | \$ 11,734,306 | \$ 10,005,910 |
| <b>Liabilities and Stockholders' Equity</b>   |               |               |
| Current liabilities:  |               |               |
| Short-term borrowings   | \$ 308,459    | \$ 526,684    |
| Accounts payable  | 145,652       | 121,525       |
| Accrued expenses  | 775,724       | 701,707       |
| Income taxes payable  | 11,841        | 30,042        |
| Current portion of deferred revenue   | 17,263        | 14,346        |
| Other current liabilities   | 431,296       | 138,424       |
| Liabilities of disposal group   | -             | 7,244         |
| Total current liabilities   | 1,690,235     | 1,539,972     |
| Deferred revenue, net of current portion  | 16,178        | 12,623        |
| Income taxes payable  | 188,181       | 616,465       |
| Deferred income taxes   | 1,018,366     | 775,022       |
| Other non-current liabilities   | 355,546       | 273,516       |
| Long-term debt, net of discount   | 2,771,333     | 1,275,585     |
| Total liabilities   | 6,039,839     | 4,493,183     |
| <b>Commitments and Contingencies (Note 18)</b>  |               |               |
| <b>Stockholders' Equity:</b>  |               |               |
| Preferred stock, \$.01 par value per share, 5,000,000 shares authorized; none outstanding at December 31, 2012 and 2011, respectively                         | -             | -             |
| Common stock, \$.01 par value per share, 575,000,000 shares authorized; issued 498,427,951 and 487,381,255 shares at December 31, 2012 and 2011, respectively | 4,984         | 4,874         |
| Common stock in treasury, at cost; 78,676,097 and 49,889,078 shares at December 31, 2012 and 2011, respectively   | (4,823,153)   | (2,760,705)   |
| Additional paid-in capital  | 7,539,787     | 6,764,479     |
| Retained earnings   | 3,022,596     | 1,566,416     |
| Accumulated other comprehensive (loss)  | (49,747)      | (62,337)      |
| Total stockholders' equity  | 5,694,467     | 5,512,727     |
| Total liabilities and stockholders' equity  | \$ 11,734,306 | \$ 10,005,910 |

See accompanying Notes to Consolidated Financial Statements

**CELGENE CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF INCOME**  
(In thousands, except per share amounts)

|  | <b>Years Ended December 31,</b> |                     |                   |
|--|---------------------------------|---------------------|-------------------|
|  | <b>2012</b>                     | <b>2011</b>         | <b>2010</b>       |
| Revenue:   |                                 |                     |                   |
| Net product sales  | \$ 5,385,599                    | \$ 4,699,690        | \$ 3,508,438      |
| Collaborative agreements and other revenue                                   | 10,711                          | 19,500              | 10,540            |
| Royalty revenue  | 110,403                         | 122,880             | 106,767           |
| Total revenue  | <u>5,506,713</u>                | <u>4,842,070</u>    | <u>3,625,745</u>  |
| Expenses:  |                                 |                     |                   |
| Cost of goods sold (excluding amortization of<br>acquired intangible assets) | 299,124                         | 425,859             | 306,521           |
| Research and development   | 1,724,156                       | 1,600,264           | 1,128,495         |
| Selling, general and administrative  | 1,373,541                       | 1,226,314           | 950,634           |
| Amortization of acquired intangible assets                                   | 194,499                         | 289,226             | 203,231           |
| Acquisition related (gains) charges and<br>restructuring, net                | 168,951                         | (142,346)           | 47,229            |
| Total costs and expenses   | <u>3,760,271</u>                | <u>3,399,317</u>    | <u>2,636,110</u>  |
| Operating income   | 1,746,442                       | 1,442,753           | 989,635           |
| Other income and (expense):  |                                 |                     |                   |
| Interest and investment income, net  | 15,260                          | 25,860              | 44,757            |
| Interest (expense)   | (63,205)                        | (42,737)            | (12,634)          |
| Other income (expense), net  | (17,006)                        | (6,354)             | (9,148)           |
| Income before income taxes   | 1,681,491                       | 1,419,522           | 1,012,610         |
| Income tax provision   | 225,311                         | 102,066             | 132,418           |
| Net income   | 1,456,180                       | 1,317,456           | 880,192           |
| Net loss attributable to non-controlling interest                            | -                               | 694                 | 320               |
| Net income attributable to Celgene   | <u>\$ 1,456,180</u>             | <u>\$ 1,318,150</u> | <u>\$ 880,512</u> |
| Net income per share attributable to Celgene:                                |                                 |                     |                   |
| Basic  | \$ 3.38                         | \$ 2.89             | \$ 1.90           |
| Diluted  | \$ 3.30                         | \$ 2.85             | \$ 1.88           |
| Weighted average shares:   |                                 |                     |                   |
| Basic  | 430,927                         | 455,348             | 462,298           |
| Diluted  | 440,796                         | 462,748             | 469,517           |

See accompanying Notes to Consolidated Financial Statements

**CELGENE CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
(Dollars in thousands)

|   | <b>Years Ended December 31,</b> |                     |                   |
|---|---------------------------------|---------------------|-------------------|
|   | <b>2012</b>                     | <b>2011</b>         | <b>2010</b>       |
| Net income  | \$ 1,456,180                    | \$ 1,317,456        | \$ 880,192        |
| Other comprehensive income (loss):  |                                 |                     |                   |
| Foreign currency translation adjustments  | 25,905                          | (9,847)             | (18,181)          |
| Pension liability adjustment  | (4,739)                         | (1,546)             | (5,695)           |
| Change in functional currency of a foreign subsidiary   | 13,145                          | -                   | 57,668            |
| Net asset transfer of a common control foreign subsidiary   | 607                             | (51)                | (106)             |
| Net unrealized gains (losses) related to cash flow hedges:  |                                 |                     |                   |
| Unrealized holding gains (losses), net of tax expense (benefit) of (\$13,755), (\$28) and (\$197) for the years ended 2012, 2011 and 2010, respectively                                   | 52,958                          | 21,264              | 26,964            |
| Reclassification adjustment for (gains) losses included in net income, net of tax (expense) benefit of (\$1,933), (\$2,922) and \$0 for the years ended 2012, 2011 and 2010, respectively | (77,717)                        | 2,955               | (47,686)          |
| Net unrealized gains (losses) on marketable securities available for sale:  |                                 |                     |                   |
| Unrealized holding gains (losses), net of tax expense (benefit) of (\$135), \$1,445 and \$3,365 for the years ended 2012, 2011 and 2010, respectively                                     | 1,436                           | 2,919               | 10,409            |
| Reclassification adjustment for (gains) losses included in net income, net of tax (expense) benefit of \$79, \$256 and (\$3,638) for the years ended 2012, 2011 and 2010, respectively    | 995                             | (4,264)             | (7,715)           |
| Total other comprehensive income (loss)   | <u>12,590</u>                   | <u>11,430</u>       | <u>15,658</u>     |
| Comprehensive income  | 1,468,770                       | 1,328,886           | 895,850           |
| Comprehensive loss attributable to non-controlling interest   | -                               | 694                 | 320               |
| Comprehensive income attributable to Celgene  | <u>\$ 1,468,770</u>             | <u>\$ 1,329,580</u> | <u>\$ 896,170</u> |

See accompanying Notes to Consolidated Financial Statements



**CELGENE CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Dollars in thousands)

|   | Years Ended December 31, |                     |                     |
|---|--------------------------|---------------------|---------------------|
|   | 2012                     | 2011                | 2010                |
| Cash flows from operating activities:   |                          |                     |                     |
| Net income  | \$ 1,456,180             | \$ 1,317,456        | \$ 880,192          |
| Adjustments to reconcile net income to net cash provided by operating activities: |                          |                     |                     |
| Depreciation  | 84,874                   | 71,153              | 54,234              |
| Amortization  | 198,573                  | 291,698             | 204,855             |
| Allocation of prepaid royalties   | 1,444                    | 16,742              | 47,241              |
| Provision (benefit) for accounts receivable allowances                            | 12,453                   | 6,354               | (2,309)             |
| Deferred income taxes   | 100,199                  | (85,822)            | (103,923)           |
| Impairment charges  | 148,010                  | 118,000             | -                   |
| Change in value of contingent consideration                                       | 166,374                  | (147,463)           | 9,712               |
| Share-based compensation expense  | 231,043                  | 217,202             | 182,796             |
| Share-based employee benefit plan expense   | 19,324                   | 20,664              | 14,403              |
| Reclassification adjustment for cash flow hedges included in net income           | (79,650)                 | 33                  | (47,682)            |
| Unrealized change in value of derivative instruments                              | 71,682                   | (47,644)            | 57,652              |
| Realized (gains) losses on marketable securities available for sale               | 1,074                    | (3,842)             | (11,531)            |
| Other, net  | (3,193)                  | (648)               | 3,769               |
| Change in current assets and liabilities, excluding the effect of acquisitions:   |                          |                     |                     |
| Accounts receivable   | (30,052)                 | (263,130)           | (234,452)           |
| Inventory   | (69,680)                 | 70,980              | 18,723              |
| Other operating assets  | 92,887                   | (69,288)            | (45,674)            |
| Assets held for sale, net   | (1,176)                  | 2,361               | 2,999               |
| Accounts payable and other operating liabilities                                  | 68,191                   | 191,239             | 51,557              |
| Payment of contingent consideration   | -                        | (23,324)            | -                   |
| Income tax payable  | (455,485)                | 95,326              | 78,110              |
| Deferred revenue  | 5,481                    | (1,937)             | 20,884              |
| Net cash provided by operating activities   | <u>2,018,553</u>         | <u>1,776,110</u>    | <u>1,181,556</u>    |
| Cash flows from investing activities:   |                          |                     |                     |
| Proceeds from sales of marketable securities available for sale                   | 1,743,741                | 2,175,172           | 3,931,883           |
| Purchases of marketable securities available for sale                             | (2,768,798)              | (1,693,380)         | (3,272,225)         |
| Payments for acquisition of business, net of cash acquired                        | (352,245)                | -                   | (2,652,377)         |
| Purchases of intellectual property and other assets                               | (48,865)                 | -                   | -                   |
| Proceeds from the sale of assets, net   | 15,782                   | 93,185              | -                   |
| Capital expenditures  | (111,524)                | (132,119)           | (98,632)            |
| (Purchases) refunds of investment securities                                      | (30,046)                 | (59,248)            | (14,020)            |
| Other investing activities  | (1,637)                  | (5,914)             | (1,934)             |
| Net cash provided by (used in) investing activities                               | <u>(1,553,592)</u>       | <u>377,696</u>      | <u>(2,107,305)</u>  |
| Cash flows from financing activities:   |                          |                     |                     |
| Payment for treasury shares   | (2,043,570)              | (2,188,582)         | (183,116)           |
| Proceeds from short-term borrowing  | 4,494,787                | 1,878,784           | -                   |
| Principal repayments on short-term borrowing                                      | (4,712,174)              | (1,353,061)         | -                   |
| Payment of contingent consideration   | -                        | (156,676)           | -                   |
| Proceeds from the issuance of long-term debt                                      | 1,486,682                | -                   | 1,237,270           |
| Net proceeds from exercise of common stock options and warrants                   | 476,228                  | 166,451             | 86,889              |
| Excess tax benefit from share-based compensation arrangements                     | 49,319                   | 31,054              | 36,124              |
| Net cash provided by (used in) financing activities                               | <u>(248,728)</u>         | <u>(1,622,030)</u>  | <u>1,177,167</u>    |
| Effect of currency rate changes on cash and cash equivalents                      | 14,690                   | (23,440)            | (2,462)             |
| Net increase in cash and cash equivalents   | 230,923                  | 508,336             | 248,956             |
| Cash and cash equivalents at beginning of period                                  | 1,859,464                | 1,351,128           | 1,102,172           |
| Cash and cash equivalents at end of period  | <u>\$ 2,090,387</u>      | <u>\$ 1,859,464</u> | <u>\$ 1,351,128</u> |

See accompanying Notes to Consolidated Financial Statements

**CELGENE CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS – (Continued)**  
**(Dollars in thousands)**

|  | <b>Years Ended December 31,</b> |             |             |
|--|---------------------------------|-------------|-------------|
|  | <b>2012</b>                     | <b>2011</b> | <b>2010</b> |
| <b>Supplemental schedule of non-cash investing and financing activity:</b>       |                                 |             |             |
| Change in net unrealized (gain) loss on marketable securities available for sale | \$ (1,301)                      | \$ (3,651)  | \$ (13,808) |
| Matured shares tendered in connection with stock option exercises                | \$ (1,182)                      | \$ (4,912)  | \$ (8,245)  |
| <b>Supplemental disclosure of cash flow information:</b>                         |                                 |             |             |
| Interest paid  | \$ 48,421                       | \$ 50,192   | \$ 1,752    |
| Income taxes paid  | \$ 469,570                      | \$ 93,019   | \$ 121,976  |

See accompanying Notes to Consolidated Financial Statements

**CELGENE CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(Dollars in thousands)

|   | Celgene Corporation Shareholders |                   |                                  |                                   |   |                         |                                 |             |
|---|----------------------------------|-------------------|----------------------------------|-----------------------------------|---|-------------------------|---------------------------------|-------------|
|   | Common<br>Stock                  | Treasury<br>Stock | Additional<br>Paid-in<br>Capital | Retained<br>Earnings<br>(Deficit) | Accumulated<br>Other<br>Comprehensive<br>Income<br>(Loss) | Stockholders'<br>Equity | Non-<br>Controlling<br>Interest | Total       |
| <b>Years Ended December 31, 2012, 2011 and 2010</b>                             |                                  |                   |                                  |                                   |   |                         |                                 |             |
| Balances at December 31, 2009   | \$4,676                          | \$ (362,521)      | \$5,474,122                      | \$ (632,246)                      | \$(89,425)  | \$4,394,606             | \$ -                            | \$4,394,606 |
| Net income  |                                  |                   |                                  | 880,512                           |   | 880,512                 | (320)                           | 880,192     |
| Other comprehensive income  |                                  |                   | (57,562)                         |                                   | 15,658  | (41,904)                |                                 | (41,904)    |
| Mature shares tendered related to option exercise                               |                                  | (8,245)           | 7,335                            |                                   |   | (910)                   |                                 | (910)       |
| Exercise of stock options and warrants and conversion of restricted stock units | 39                               | (1,410)           | 91,039                           |                                   |   | 89,668                  |                                 | 89,668      |
| Shares purchased under share repurchase program                                 |                                  | (183,116)         |                                  |                                   |   | (183,116)               |                                 | (183,116)   |
| Issuance of common stock for employee benefit plans                             |                                  | 9,704             | 2,722                            |                                   |   | 12,426                  |                                 | 12,426      |
| Issuance of common stock related to Abraxis acquisition                         | 107                              |                   | 617,651                          |                                   |   | 617,758                 |                                 | 617,758     |
| Expense related to share-based compensation                                     |                                  |                   | 182,404                          |                                   |   | 182,404                 |                                 | 182,404     |
| Income tax benefit upon exercise of stock options                               |                                  |                   | 32,529                           |                                   |   | 32,529                  |                                 | 32,529      |
| Non-controlling interest resulting from acquisition of Abraxis, net             |                                  |                   |                                  |                                   |   | -                       | 11,819                          | 11,819      |
| Balances at December 31, 2010   | \$4,822                          | \$ (545,588)      | \$6,350,240                      | \$ 248,266                        | \$(73,767)  | \$5,983,973             | \$ 11,499                       | \$5,995,472 |
| Net income  |                                  |                   |                                  | 1,318,150                         |   | 1,318,150               | (694)                           | 1,317,456   |
| Other comprehensive income  |                                  |                   | 51                               |                                   | 11,430  | 11,481                  |                                 | 11,481      |
| Mature shares tendered related to option exercise                               |                                  | (4,912)           | 3,061                            |                                   |   | (1,851)                 |                                 | (1,851)     |
| Exercise of stock options and warrants and conversion of restricted stock units | 52                               | (3)               | 166,693                          |                                   |   | 166,742                 |                                 | 166,742     |
| Shares purchased under share repurchase program                                 |                                  | (2,221,157)       |                                  |                                   |   | (2,221,157)             |                                 | (2,221,157) |
| Issuance of common stock for employee benefit plans                             |                                  | 10,955            | 2,644                            |                                   |   | 13,599                  |                                 | 13,599      |
| Issuance of common stock related to Abraxis acquisition                         |                                  |                   | 72                               |                                   |   | 72                      |                                 | 72          |
| Expense related to share-based compensation                                     |                                  |                   | 216,628                          |                                   |   | 216,628                 |                                 | 216,628     |
| Income tax benefit upon exercise of stock options                               |                                  |                   | 25,090                           |                                   |   | 25,090                  |                                 | 25,090      |
| Disposal of non-controlling interest  |                                  |                   |                                  |                                   |   | -                       | (10,805)                        | (10,805)    |
| Balances at December 31, 2011   | \$4,874                          | \$(2,760,705)     | \$6,764,479                      | \$ 1,566,416                      | \$(62,337)  | \$5,512,727             | \$ -                            | \$5,512,727 |
| Net income  |                                  |                   |                                  | 1,456,180                         |   | 1,456,180               |                                 | 1,456,180   |
| Other comprehensive income  |                                  |                   | (13,752)                         |                                   | 12,590  | (1,162)                 |                                 | (1,162)     |
| Mature shares tendered related to option exercise                               |                                  | (1,182)           | 673                              |                                   |   | (509)                   |                                 | (509)       |
| Exercise of stock options and warrants and conversion of restricted stock units | 107                              | (10,535)          | 482,936                          |                                   |   | 472,508                 |                                 | 472,508     |
| Shares purchased under share repurchase program                                 |                                  | (2,050,731)       |                                  |                                   |   | (2,050,731)             |                                 | (2,050,731) |
| Issuance of common stock for employee benefit plans                             | 3                                |                   | 19,178                           |                                   |   | 19,181                  |                                 | 19,181      |
| Expense related to share-based compensation                                     |                                  |                   | 230,500                          |                                   |   | 230,500                 |                                 | 230,500     |
| Income tax benefit upon exercise of stock options                               |                                  |                   | 55,773                           |                                   |   | 55,773                  |                                 | 55,773      |
| Balances at December 31, 2012   | \$4,984                          | \$(4,823,153)     | \$7,539,787                      | \$ 3,022,596                      | \$(49,747)  | \$5,694,467             | \$ -                            | \$5,694,467 |

See accompanying Notes to Consolidated Financial Statements

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(Thousands of dollars, except per share amounts, unless otherwise indicated)

**1. Nature of Business and Basis and Summary of Significant Accounting Policies**

Celgene Corporation, together with its subsidiaries (collectively “we,” “our,” “us,” “Celgene” or the “Company”) is a global biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory diseases. We are dedicated to innovative research and development which is designed to bring new therapies to market and are involved in research in several scientific areas that may deliver proprietary next-generation therapies, targeting areas such as intracellular signaling pathways in cancer and immune cells, immunomodulation in cancer and autoimmune diseases, and therapeutic application of cell therapies.

Our primary commercial stage products include REVLIMID®, VIDAZA®, ABRAXANE®, THALOMID® (inclusive of Thalidomide Celgene®), and ISTODAX®. POMALYST® was approved by the U.S. Food and Drug Administration, or FDA, in February 2013 for patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and bortezomib, and have demonstrated disease progression on or within 60 days of completion of the last therapy. Additional sources of revenue include royalties from Novartis on their sales of FOCALIN XR® and the entire RITALIN® family of drugs, other licensing royalties, and the sale of services through our Celgene Cellular Therapeutics subsidiary.

The consolidated financial statements include the accounts of Celgene Corporation and its subsidiaries. Investments in limited partnerships and interests where we have an equity interest of 50% or less and do not otherwise have a controlling financial interest are accounted for by either the equity or cost method. We record net income (loss) attributable to non-controlling interest, if any, in our Consolidated Statements of Income equal to the percentage of ownership interest retained in the respective operations by the non-controlling parties. Certain prior year amounts have been reclassified to conform to the current year’s presentation.

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect reported amounts and disclosures. Actual results could differ from those estimates. We are subject to certain risks and uncertainties related to product development, regulatory approval, market acceptance, scope of patent and proprietary rights, competition, outcome of civil and governmental proceedings, European credit risk, technological change and product liability.

*Financial Instruments:* Certain financial instruments reflected in the Consolidated Balance Sheets, (e.g., cash, cash equivalents, accounts receivable, certain other assets, accounts payable, short-term borrowings and certain other liabilities) are recorded at cost, which approximates fair value due to their short-term nature. The fair values of financial instruments other than marketable securities are determined through a combination of management estimates and information obtained from third parties using the latest market data. The fair value of available-for-sale marketable securities is determined utilizing the valuation techniques appropriate to the type of security (See Note 4).

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

*Derivative Instruments and Hedges:* All derivative instruments are recognized on the balance sheet at their fair value. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction and, if it is, the type of hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, we formally document the nature and relationships between the hedging instruments and hedged item. We assess, both at inception and on an on-going basis, whether the derivative instruments that are used in cash flow hedging transactions are highly effective in offsetting the changes in cash flows of hedged items. We assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion of derivative instruments, if any, to current earnings. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in current earnings. We use derivative instruments, including those not designated as part of a hedging transaction, to manage our exposure to movements in foreign exchange and interest rates. The use of these derivative instruments modifies the exposure of these risks with the intent to reduce our risk or cost. We do not use derivative instruments for speculative trading purposes and are not a party to leveraged derivatives.

*Cash, Cash Equivalents and Marketable Securities Available for Sale:* We invest our excess cash primarily in money market funds, U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government, agency and Supranational securities and global corporate debt securities. All liquid investments with maturities of three months or less from the date of purchase are classified as cash equivalents and all investments with maturities of greater than three months from date of purchase are classified as marketable securities available for sale. We determine the appropriate classification of our investments in marketable debt and equity securities at the time of purchase. Marketable securities available for sale are carried at fair value, held for an unspecified period of time and are intended for use in meeting our ongoing liquidity needs. Unrealized gains and losses on available-for-sale securities, which are deemed to be temporary, are reported as a separate component of stockholders' equity, net of tax. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization, along with realized gains and losses and other-than-temporary impairment charges, is included in interest and investment income, net.

A decline in the market value of any available-for-sale security below its carrying value that is determined to be other-than-temporary would result in a charge to earnings and decrease in the security's carrying value down to its newly established fair value. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in earnings performance, credit rating, asset quality or business prospects of the issuer; adverse changes in the general market condition in which the issuer operates; our intent to hold to maturity and an evaluation as to whether it is more likely than not that we will not have to sell before recovery of its cost basis; our expected future cash flows from the security; and issues that raise concerns about the issuer's ability to continue as a going concern.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

*Concentration of Credit Risk:* Cash, cash equivalents and marketable securities are financial instruments that potentially subject the Company to concentration of credit risk. We invest our excess cash primarily in money market funds, U.S. Treasury fixed rate securities, U.S. government-sponsored agency fixed rate securities, U.S. government-sponsored agency mortgage-backed fixed rate securities and FDIC guaranteed fixed rate corporate debt, non-U.S. government issued securities and non-U.S. government guaranteed securities (See Note 6). We may also invest in unrated or below investment grade securities, such as equity in private companies. We have established guidelines relative to diversification and maturities to maintain safety and liquidity. These guidelines are reviewed periodically and may be modified to take advantage of trends in yields and interest rates.

We sell our products in the United States primarily through wholesale distributors and specialty contracted pharmacies. Therefore, wholesale distributors and large pharmacy chains account for a large portion of our U.S. trade receivables and net product revenues (See Note 19). International sales are primarily made directly to hospitals, clinics and retail chains, many of which in Europe are government owned and have extended their payment terms in recent years given the economic pressure these countries are facing. We continuously monitor the creditworthiness of our customers, including these governments, and have internal policies regarding customer credit limits. We estimate an allowance for doubtful accounts primarily based on the credit worthiness of our customers, historical payment patterns, aging of receivable balances and general economic conditions, including publicly available information on the credit worthiness of countries themselves and provinces or areas within such countries where they are the ultimate customers.

We continue to monitor economic conditions, including the volatility associated with international economies, the sovereign debt crisis in certain European countries and associated impacts on the financial markets and our business. Our current business model in these markets is typically to sell our products directly to principally government owned or controlled hospitals, who in turn directly deliver critical care to patients. Our products are used to treat life-threatening diseases and we believe this business model enables timely delivery and adequate supply of products. Many of the outstanding receivable balances are related to government-funded hospitals and we believe the receivable balances are ultimately collectible. Similarly, we believe that future sales to these customers will continue to be collectible.

The credit and economic conditions within Spain, Italy, Portugal and Greece, as well as increasing sales levels in those countries have resulted in, and may continue to result in, an increase in the average length of time it takes to collect accounts receivable. Our total net receivables in Spain, Italy and Portugal are composed almost entirely of amounts receivable from government-owned or controlled hospitals and the public sector and amounted to \$324.2 million at December 31, 2012 compared to \$396.1 million at December 31, 2011. Approximately \$51.9 million of the \$324.2 million receivable at December 31, 2012 was greater than one year past due. Our exposure to the sovereign debt crisis in Greece is limited, as we do not have a material amount of receivables in Greece. We maintain timely and direct communication with hospital customers in Spain, Italy and Portugal regarding both the current and past due

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

receivable balances. We continue to receive payments from these countries, and closely monitor the plans for payment at the regional government level. Payments from customers in these countries are not received on regular intervals and several months could elapse between significant payments. This payment pattern was observed in Spain, where a significant portion of aged receivables were paid in late June and early July 2012. We also regularly request and receive positive confirmation of the validity of our receivables from most of the regional governmental authorities. We have the option to pursue legal action against certain of our customers. In view of the protracted timeline associated with collecting the outstanding balances through legal action and the current direct communication with our customers, in many instances, we do not believe pursuing legal action to be the best approach for any of the parties involved.

In determining the appropriate allowance for doubtful accounts for Spain, Italy and Portugal, we considered that the balance of past due receivables is related to sales made to government-owned or supported customers. We regularly monitor developments in Europe to assess whether the level of risk of default for any customers has increased and note the ongoing efforts by the European Union, European Monetary Union and International Monetary Fund to support countries with large public deficits and outstanding debt balances. We also monitor the efforts of individual countries to support their regions with large public deficits and outstanding debt balances. We have not experienced significant losses or write-offs with respect to the collection of our accounts receivable in these countries as a result of their economic difficulties and we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse impact on our financial position or results of operations.

*Inventory:* Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. We periodically review the composition of inventory in order to identify obsolete, slow-moving or otherwise non-saleable items. If non-saleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the decline in value is first recognized. Included in inventory are raw materials used in the production of preclinical and clinical products, which are charged to research and development expense when consumed.

*Assets Held for Sale:* Assets to be disposed of were separately presented in the consolidated balance sheet and reported at the lower of their carrying amount or fair value less costs to sell, and were not depreciated. The assets and related liabilities of a disposal group classified as held for sale were presented separately in the current asset and current liability sections of the consolidated balance sheet.

*Property, Plant and Equipment:* Property, plant and equipment are stated at cost less accumulated depreciation. Depreciation of plant and equipment is recorded using the straight-line method. Building improvements are depreciated over the remaining useful life of the building. Leasehold improvements are depreciated over the lesser of the economic useful life

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

of the asset or the remaining term of the lease, including anticipated renewal options. The estimated useful lives of capitalized assets are as follows:

|                                       |           |
|---------------------------------------|-----------|
| Buildings                             | 40 years  |
| Building and operating equipment      | 15 years  |
| Manufacturing machinery and equipment | 10 years  |
| Other machinery and equipment         | 5 years   |
| Furniture and fixtures                | 5 years   |
| Computer equipment and software       | 3-7 years |

Maintenance and repairs are charged to operations as incurred, while expenditures for improvements which extend the life of an asset are capitalized.

*Capitalized Software Costs:* We capitalize software costs incurred in connection with developing or obtaining software. Capitalized software costs are included in property, plant and equipment, net and are amortized over their estimated useful life of three to seven years from the date the systems are ready for their intended use.

*Investments in Other Entities:* We hold a portfolio of investments in equity securities and certain investment funds that are accounted for under either the equity method or cost method. Investments in companies or certain investment funds over which we have significant influence but not a controlling interest are accounted for using the equity method, with our share of earnings or losses reported in other income (expense), net. Our cost method and equity method investments are included in other assets on the Consolidated Balance Sheets.

All investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value and the decline is determined to be other-than-temporary, the investment is written down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an other-than-temporary decline in value has occurred include: market value or exit price of the investment based on either market-quoted prices or future rounds of financing by the investee; length of time that the market value was below its cost basis; financial condition and business prospects of the investee; our intent and ability to retain the investment for a sufficient period of time to allow for recovery in market value of the investment; issues that raise concerns about the investee's ability to continue as a going concern; any other information that we may be aware of related to the investment.

*Other Intangible Assets:* Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Intangible assets which are not amortized include acquired in-process research and development, or IPR&D, and acquired intangible assets held for sale. Amortization is initiated for IPR&D intangible assets when their useful lives have been determined. IPR&D intangible assets which are determined to have had a drop in their fair value are adjusted downward and an expense recognized on the earnings statement. These are tested at least annually or when a triggering event occurs that could indicate a potential impairment.



**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

*Goodwill:* Goodwill represents the excess of purchase price over fair value of net assets acquired in a business combination accounted for by the acquisition method of accounting and is not amortized, but subject to impairment testing at least annually or when a triggering event occurs that could indicate a potential impairment. We test our goodwill annually for impairment each November 30.

*Impairment of Long-Lived Assets:* Long-lived assets, such as property, plant and equipment and certain other long-term assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset or asset group to the estimated undiscounted future cash flows expected to be generated by the asset or asset group. If the carrying amount of the assets exceed their estimated future undiscounted net cash flows, an impairment charge is recognized for the amount by which the carrying amount of the assets exceed the fair value of the assets.

*Contingent Consideration from Business Combinations:* Subsequent to the acquisition date, we measure contingent consideration arrangements at fair value for each period with changes in fair value recognized in operating earnings. Changes in fair values reflect new information about related IPR&D assets and the passage of time. In the absence of new information, changes in fair value reflect only the passage of time as development work towards the achievement of the milestones progresses, and is accrued based on an accretion schedule.

*Foreign Currency Translation:* Operations in non-U.S. entities are recorded in the functional currency of each entity. For financial reporting purposes, the functional currency of an entity is determined by a review of the source of an entity's most predominant cash flows. The results of operations for non-U.S. dollar functional currency entities are translated from functional currencies into U.S. dollars using the average currency rate during each month, which approximates the results that would be obtained using actual currency rates on the dates of individual transactions. Assets and liabilities are translated using currency rates at the end of the period. Adjustments resulting from translating the financial statements of our foreign entities into the U.S. dollar are excluded from the determination of net income and are recorded as a component of other comprehensive income (loss). Transaction gains and losses are recorded in other income (expense), net in the Consolidated Statements of Income. We had net foreign exchange losses of \$10.8 million in 2012, \$3.1 million in 2011 and \$9.8 million in 2010.

*Research and Development Costs:* Research and development costs are expensed as incurred. These include all internal and external costs related to services contracted by us. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Milestone payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product.

*Income Taxes:* We utilize the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. A valuation

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. We recognize the benefit of an uncertain tax position that it has taken or expects to take on income tax returns it files if such tax position is more likely than not to be sustained.

*Revenue Recognition:* Revenue from the sale of products is recognized when title and risk of loss of the product is transferred to the customer. Provisions for discounts, early payments, rebates, sales returns and distributor chargebacks under terms customary in the industry are provided for in the same period the related sales are recorded.

Sales discount accruals are based on payment terms extended to customers.

Government rebate accruals are based on estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. The Medicaid rebate percentage was increased and extended to Medicaid Managed Care Organizations in March 2010. The accrual of the rebates associated with Medicaid Managed Care Organizations is calculated based on estimated historical patient data related to Medicaid Managed Care Organizations. We have also analyzed actual billings received from certain states to further support the accrual rates. Subsequent to implementation of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, or collectively the 2010 U.S. Health Care Reform Law, certain states have not yet submitted actual Medicaid Managed Care Organization bills, resulting in an increase in the accrual balance. Effective January 1, 2011, manufacturers of pharmaceutical products are responsible for 50% of the patient's cost of branded prescription drugs related to the Medicare Part D Coverage Gap. In order to estimate the cost to us of this coverage gap responsibility, we analyze data for eligible Medicare Part D patients against data for eligible Medicare Part D patients treated with our products as well as the historical invoices. This expense is recognized throughout the year as incurred. In addition, certain international markets have government-sponsored programs that require rebates to be paid based on program specific rules and, accordingly, the rebate accruals are determined primarily on estimated eligible sales.

Rebates or administrative fees are offered to certain wholesale customers, group purchasing organizations and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to 15 months from the date of sale. We provide a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include level of wholesaler inventories, contract sales volumes and average contract pricing. We regularly review the information related to these estimates and adjust the provision accordingly.

We base our sales returns allowance on estimated on-hand retail/hospital inventories, measured end-customer demand as reported by third-party sources, actual returns history and other factors, such as the trend experience for lots where product is still being returned or inventory centralization and rationalization initiatives conducted by major pharmacy chains, as applicable. If the historical data we used to calculate these estimates does not properly reflect future returns,

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then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Under this methodology, we track actual returns by individual production lots. Returns on closed lots, that is, lots no longer eligible for return credits, are analyzed to determine historical returns experience. Returns on open lots, that is, lots still eligible for return credits, are monitored and compared with historical return trend rates. Any changes from the historical trend rates are considered in determining the current sales return allowance.

Chargeback accruals are based on the differentials between product acquisition prices paid by wholesalers and lower government contract pricing paid by eligible customers covered under federally qualified programs. Distributor service fee accruals are based on contractual fees to be paid to the wholesale distributor for services provided. TRICARE is a health care program of the U.S. Department of Defense Military Health System that provides civilian health benefits for military personnel, military retirees and their dependents. TRICARE rebate accruals are based on estimated Department of Defense eligible sales multiplied by the TRICARE rebate formula.

We record estimated reductions to revenue for free goods and volume-based discounts at the time of the initial sale. The estimated reductions to revenue for such free goods and volume-based discounts are based on the sales terms, historical experience and trend analysis. The cost of free goods is included in Cost of Goods Sold (excluding amortization of acquired intangible assets).

We recognize revenue from royalties based on licensees' sales of its products or products using its technologies. Royalties are recognized as earned in accordance with the contract terms when royalties from licensees can be reasonably estimated and collectability is reasonably assured. If royalties cannot be reasonably estimated or collectability of a royalty amount is not reasonably assured, royalties are recognized as revenue when the cash is received.

*Share-Based Compensation:* We utilize share based compensation in the form of stock options, restricted stock units, or RSUs, and performance-based restricted stock units, or PSUs. Compensation expense is recognized in the Consolidated Statements of Income based on the estimated fair value of the awards at grant date. Compensation expense recognized reflects an estimate of the number of awards expected to vest after taking into consideration an estimate of award forfeitures based on actual experience and is recognized on a straight-line basis over the requisite service period, which is generally the vesting period required to obtain full vesting. Management expectations related to the achievement of performance goals associated with PSU grants is assessed regularly and that assessment is used to determine whether PSU grants are expected to vest. If performance-based milestones related to PSU grants are not met or not expected to be met, any compensation expense recognized to date associated with grants that are not expected to vest will be reversed.

The fair values of stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model. The fair values of RSU and PSU grants are based on the market value of our Common Stock on the date of grant.

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*Earnings Per Share:* Basic earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period, assuming potentially dilutive common shares, resulting from option exercises, restricted stock units, warrants and other incentives had been issued and any proceeds thereof used to repurchase common stock at the average market price during the period. The assumed proceeds used to repurchase common stock is the sum of the amount to be paid to us upon exercise of options, the amount of compensation cost attributed to future services and not yet recognized and, if applicable, the amount of excess income tax benefit that would be credited to paid-in capital upon exercise.

*New Accounting Pronouncements:* In June 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-05, “Comprehensive Income (Topic 220),” or ASU 2011-05. ASU 2011-05 was issued to improve the comparability, consistency and transparency of financial reporting and to increase the prominence of items reported in other comprehensive income. The guidance in ASU 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders’ equity and requires that all non-owner changes in stockholders’ equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. We have adopted ASU 2011-05 during the first quarter of 2012 and have presented the components of other comprehensive income in separate Consolidated Statements of Comprehensive Income.

In July 2012, the FASB issued ASU No. 2012-02, “Intangibles — Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment,” or ASU 2012-02. ASU 2012-02 allows a company the option to first assess qualitative factors to determine whether it is necessary to perform a quantitative impairment test. Under that option, a company would no longer be required to calculate the fair value of an indefinite-lived intangible asset unless the company determines, based on that qualitative assessment, that it is more likely than not that the fair value of the indefinite-lived intangible asset is less than its carrying amount. ASU 2012-02 is effective for annual and interim indefinite-lived intangible asset impairment tests performed for periods beginning after September 15, 2012. Early adoption is permitted and we have adopted this standard in the fourth quarter of 2012. The adoption of ASU 2012-02 did not have a material impact on our financial position or results of operations.

## **2. Acquisitions and Divestitures**

### **Avila Acquisition**

On March 7, 2012, or the Acquisition Date, we acquired all of the outstanding common stock of Avila Therapeutics, Inc., subsequently renamed Celgene Avilomics Research, herein referred to as Avila. The acquisition resulted in Avila becoming our wholly-owned subsidiary. The results of operations for Avila are included in our consolidated financial statements from the Acquisition Date and the assets and liabilities of Avila have been recorded at their respective fair values on the Acquisition Date and consolidated with our other assets and liabilities. Avila’s results of

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operations prior to the Acquisition Date were determined to be immaterial to us; therefore, pro forma financial statements are not required to be presented.

We paid \$352.2 million in cash, net of cash acquired, and may make additional payments of up to an estimated maximum of \$595.0 million in contingent developmental and regulatory milestone payments.

Avila is a clinical-stage biotechnology company focused on the design and development of targeted covalent drugs to achieve best-in-class outcomes. Avila’s product pipeline has been created using its proprietary Avilomics™ platform for developing targeted covalent drugs that treat diseases through protein silencing. Avila’s most advanced product candidate, CC-292, formerly AVL-292, a potential treatment for cancer and autoimmune diseases, is currently in phase I clinical testing. We acquired Avila to enhance our portfolio of potential therapies for patients with life-threatening illnesses worldwide.

Our potential contingent consideration payments are classified as liabilities, which were measured at fair value as of the Acquisition Date. The range of potential milestone payments is from no payment if none of the milestones are achieved to an estimated maximum of \$595.0 million if all milestones are achieved. The potential milestones consist of developmental and regulatory achievements, including milestones for the initiation of phase II and phase III studies, investigational new drug, or IND, filings, and other regulatory events.

We estimated the fair value of potential contingent consideration using a probability-weighted income approach, which reflects the probability and timing of future potential payments. This fair value measurement is based on significant input not observable in the market and thus represents a Level 3 liability within the fair value hierarchy. The resulting probability-weighted cash flows were discounted using a discount rate based on a market participant assumption.

The acquisition has been accounted for using the acquisition method of accounting which requires that assets acquired and liabilities assumed be recognized at their fair values as of the Acquisition Date and requires the fair value of acquired IPR&D to be classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts.

The fair value of consideration transferred in the acquisition of Avila is shown in the table below:

|   | <u>Fair Value at the<br/>Acquisition Date</u> |
|---|---|
| Cash  | \$ 363,405                                    |
| Contingent consideration                      | 171,654                                       |
| Total fair value of consideration transferred | <u>\$ 535,059</u>                             |

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The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the Acquisition Date based upon their respective fair values summarized below:

|  | Amounts<br>Recognized as of<br>Acquisition Date |
|--|---|
| Working capital (1)                                | \$ 11,987                                       |
| Property, plant and equipment                      | 2,559   |
| Platform technology intangible asset (2)           | 330,800   |
| In-process research and development product rights | 198,400   |
| Net deferred tax liability (3)                     | <u>(164,993)</u>                                |
| Total identifiable net assets                      | 378,753   |
| Goodwill   | <u>156,306</u>                                  |
| Net assets acquired                                | <u>\$ 535,059</u>                               |

- (1) Includes cash and cash equivalents, accounts receivable, other current assets, accounts payable and other current liabilities.
- (2) Platform technology related to the Avilomics™ discovery platform which is being amortized over a useful life of seven years based on the estimated useful life of the platform.
- (3) Includes current deferred income tax asset of \$14.7 million and non-current deferred tax liability of \$179.7 million.

The fair values of current assets, current liabilities and property, plant and equipment were determined to approximate their book values.

The fair value of the platform technology intangible asset was based primarily on expected cash flows from future product candidates to be developed from the Avilomics™ platform and the fair value assigned to acquired IPR&D was primarily based on expected cash flows from the CC-292 product candidate which is in phase I testing. The values assigned to the platform technology intangible asset and the IPR&D asset were determined by estimating the costs to develop CC-292 and future product candidates into commercially viable products, estimating the resulting revenue from the potential products, and discounting the net cash flows to present value. The revenue and cost projections used were reduced based on the probability of developing new drugs. Additionally, the projections considered the relevant market sizes, growth factors and the nature and expected timing of new product introductions. The resulting net cash flows from such potential products are based on our estimates of cost of sales, operating expenses, and income taxes. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections described above. Acquired IPR&D will be accounted for as an indefinite-lived intangible asset until regulatory approval in specified markets or discontinuation of CC-292.

The excess of purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The goodwill

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recorded as part of the acquisition is largely attributable to full ownership rights to the Avilomics™ platform. We do not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the acquisition has been recorded as a non-current asset in our Consolidated Balance Sheets and is not amortized, but is subject to review for impairment annually.

Prior to the acquisition, Avila had a number of collaboration agreements in place which we are now party to. These agreements entitle us to receive potential milestone payments and reimbursement of expenses for research and development expenses incurred under the collaborations and our collaboration partners may receive intellectual property rights or options to purchase such rights related to products developed under the collaborations. We do not consider these collaboration arrangements to be significant.

***Abraxis BioScience, Inc.***

On October 15, 2010, or the Abraxis Acquisition Date, we acquired all of the outstanding common stock of Abraxis BioScience, Inc., or Abraxis, in exchange for consideration valued at the Abraxis Acquisition Date at approximately \$3.205 billion, consisting of cash, stock and contingent value rights, or CVRs. The transaction, referred to as the Merger, resulted in Abraxis becoming our wholly owned subsidiary.

As discussed further under “Contingent Value Rights” below, a holder of a CVR is entitled to receive a *pro rata* portion of cash payments that we are obligated to pay to all holders of CVRs, which is determined by achievement of certain net sales and U.S. regulatory approval milestones. Potential cash payments to CVR holders range from no payment, if no regulatory milestones or net sales thresholds are met, to a maximum of \$650.0 million in milestone payments plus payments based on annual net sales levels if all milestones are met at the earliest target dates and annual net sales exceed threshold amounts.

The Merger has been accounted for using the acquisition method of accounting which requires that most assets acquired and liabilities assumed be recognized at their fair values as of the Abraxis Acquisition Date and requires the fair value of IPR&D to be classified as indefinite-lived assets until the successful completion or abandonment of the associated research and development efforts. An aggregate \$1.290 billion was the recorded value of the IPR&D asset, of which \$118.0 million was subsequently recognized as impaired due to a change in the probability of obtaining progression-free survival labeling for the treatment of non-small cell lung cancer for ABRAXANE® in the United States. The remaining \$1.172 billion asset was reclassified in October 2012 from an acquired IPR&D intangible to an acquired developed product rights intangible asset upon the approval of ABRAXANE® for NSCLC.

***Contingent Value Rights***

In connection with the Merger on October 15, 2010, CVRs were issued under a Contingent Value Rights Agreement, or CVR Agreement, entered into between Celgene and American Stock Transfer & Trust Company, LLC, as trustee. The CVRs are registered for trading on the

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NASDAQ Global Market under the symbol “CELGZ.” The fair value of the liability of the Company related to payments under the CVR Agreement are subject to fluctuation based on trading prices for the publicly traded CVRs. Subsequent to the Abraxis Acquisition Date, we measured the contingent consideration represented by the CVRs at fair value with changes in fair value recognized in operating earnings.

Each holder of a CVR is entitled to receive a *pro rata* portion, based on the number of CVRs then outstanding, of each of the following contingent cash payments:

- *Milestone Payment #1.* \$250.0 million upon FDA approval of ABRAXANE® for use in the treatment of non-small cell lung cancer, or NSCLC, if such approval permits us to market ABRAXANE® with FDA approval that includes a progression-free survival, or PFS, claim, but only if this milestone is achieved no later than the fifth anniversary of the Merger.
- *Milestone Payment #2.* \$400.0 million (if achieved no later than April 1, 2013) or \$300.0 million (if achieved after April 1, 2013 and before the fifth anniversary of the Merger) upon FDA approval of ABRAXANE® for use in the treatment of pancreatic cancer, if such approval permits us to market ABRAXANE® with FDA approval that includes an overall survival claim.
- *Net Sales Payments.* For each full one-year period ending December 31 during the term of the CVR Agreement, which we refer to as a net sales measuring period (with the first net sales measuring period beginning January 1, 2011 and ending December 31, 2011):
  - 2.5% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$1.000 billion but are less than or equal to \$2.000 billion for such period, plus
  - an additional amount equal to 5% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$2.000 billion but are less than or equal to \$3.000 billion for such period, plus
  - an additional amount equal to 10% of the net sales of ABRAXANE® and the Abraxis pipeline products that exceed \$3.000 billion for such period.

No payments will be due under the CVR Agreement with respect to net sales of ABRAXANE® and the Abraxis pipeline products after December 31, 2025, which we refer to as the net sales payment termination date, unless net sales for the net sales measuring period ending on December 31, 2025 are equal to or greater than \$1.000 billion, in which case the net sales payment termination date will be extended until the last day of the net sales measuring period subsequent to December 31, 2025 during which net sales of ABRAXANE® and the Abraxis pipeline products are less than \$1.000 billion or, if earlier, December 31, 2030. The fair value of our liability related to the CVRs was \$277.4 million at the end of 2012 compared to \$60.6 million at the end of 2011.



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In October 2012, the FDA approved ABRAXANE® for the first-line treatment of locally advanced or metastatic NSCLC, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. The FDA approval was based on tumor response rates and did not result in the use of a marketing label that includes a progression-free survival claim, and accordingly, the CVR Milestone Payment #1, as described above, has not been achieved. This approval resulted in the related \$1.172 billion intangible asset obtained from the Abraxis acquisition being reclassified in October 2012 from an acquired IPR&D intangible to an acquired developed product rights intangible asset and amortization commenced in October 2012.

***Sale of Non-core Assets***

The purchase of Abraxis included a number of assets that are not associated with nab® technology or ABRAXANE®. These assets, or non-core assets, consisted of a number of subsidiaries, tangible assets, equity investments, joint venture partnerships and assets that supported research and sales of products not directly related to the nab® technology or ABRAXANE®. At the time of acquisition, we committed to a plan to divest certain non-core assets and they were classified on the Consolidated Balance Sheets as of December 31, 2010 as assets held for sale and the associated liabilities were classified as liabilities of disposal group. In April 2011, we sold these non-core assets to various entities that are owned or controlled by Dr. Patrick Soon-Shiong, the former majority shareholder and executive chairman of Abraxis.

We received cash consideration of \$110.0 million, 10% equity ownership in Active Biomaterials, LLC, which is an entity that was formed with certain of the non-core assets with revenue-producing potential, and a future royalty stream based on net sales of certain products of Active Biomaterials, LLC. The royalties, which commence in 2014 at the earliest and are not to exceed an annual amount of \$128.0 million, will be calculated based on a range of between 10% and 12.5% of net sales of certain future products. Dr. Patrick Soon-Shiong held an option to purchase the 10% equity ownership in Active Biomaterials, LLC from us for a price of \$15.0 million at any time prior to April 2013 and he exercised that option in 2012. We recorded the future royalty stream as an asset and assigned a value of \$170.0 million based on its fair market value calculated as the present value of estimated future net cash flows. The sale of the non-core assets resulted in a gain of \$2.9 million which was included in the Consolidated Statements of Income, in other income (expense), net. Our policy is to present gains and losses from sales of businesses as other income or expense.

Two manufacturing and research facilities located in Melrose Park, Illinois, and the equipment associated with operations at those facilities, were sold in June of 2012 to APP Pharmaceuticals, Inc. (now known as Fresenius Kabi USA, LLC), or APP, a subsidiary of Fresenius Kabi AG. APP manufactures ABRAXANE® at one of the facilities. In exchange for the facilities, we received rights to free and reduced cost manufacturing of specified quantities of ABRAXANE®, which we recorded as current or non-current assets based on anticipated timing of delivery, a five-year rent-free lease of a portion of one of the facilities, and a net cash payment of \$1.8 million. The transaction did not result in any gain or loss. The assets and liabilities related to these two facilities were included in assets held for sale and liabilities of disposal group on the 2011 Consolidated Balance Sheet.

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***Gloucester Pharmaceuticals, Inc.***

On January 15, 2010, we acquired all of the outstanding common stock and stock options of Gloucester Pharmaceuticals, Inc., or Gloucester. The assets acquired and liabilities assumed of Gloucester were recorded as of the acquisition date, at their respective fair values, and consolidated with our assets and liabilities. Gloucester's results of operations are included in the Company's consolidated financial statements from the date of acquisition.

We paid \$338.9 million in cash before milestone payments with potential additional future payments of up to \$300.0 million in contingent regulatory milestone payments. As part of the consideration for the Gloucester acquisition, we are contractually obligated to pay certain consideration resulting from the outcome of future events. We update our assumptions each reporting period based on new developments and records such amounts at fair value until such consideration is satisfied.

In June 2011, the FDA granted accelerated approval of the Supplemental New Drug Application for ISTODAX® for the treatment of peripheral T-cell lymphoma, or PTCL, in patients who have received at least one prior therapy. This FDA approval was the triggering event for the payment of one of the two contingent regulatory milestone payments associated with the Gloucester acquisition. We made a payment of \$180.0 million to the former shareholders of Gloucester in July 2011 in satisfaction of this milestone payment requirement. The single remaining contingent milestone payment is for a \$120.0 million cash payment upon the marketing approval for the European Union PTCL. At December 31, 2012 and 2011, the balance of the contingent consideration, which reflects the fair value of the single remaining continent milestone payment, was \$17.3 million and \$76.9 million, respectively, and is included in other non-current liabilities.

**3. Earnings Per Share**

| <i>(Amounts in thousands, except per share)</i>     | 2012               | 2011               | 2010             |
|---|--------------------|--------------------|------------------|
| Net income attributable to Celgene                  | <u>\$1,456,180</u> | <u>\$1,318,150</u> | <u>\$880,512</u> |
| Weighted-average shares:                            |                    |                    |                  |
| Basic   | 430,927            | 455,348            | 462,298          |
| Effect of dilutive securities:                      |                    |                    |                  |
| Options, restricted stock units, warrants and other | 9,869              | 7,400              | 7,219            |
| Diluted   | <u>440,796</u>     | <u>462,748</u>     | <u>469,517</u>   |
| Net income per share attributable to Celgene:       |                    |                    |                  |
| Basic   | \$ 3.38            | \$ 2.89            | \$ 1.90          |
| Diluted   | \$ 3.30            | \$ 2.85            | \$ 1.88          |

The total number of potential shares of common stock excluded from the diluted earnings per share computation because their inclusion would have been anti-dilutive was 12,665,529 in 2012, 25,864,186 in 2011 and 24,123,172 in 2010.

Since April 2009, our Board of Directors has approved repurchases of up to an aggregate of \$6.500 billion of our common stock, including \$2.500 billion approved by our Board of Directors

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during their June 2012 meeting. As of December 31, 2012, an aggregate of 74,465,418 shares of common stock were repurchased under the program, including 28,636,033 shares of common stock repurchased during 2012. As of December 31, 2012, we had a remaining open-ended repurchase authorization of \$1.837 billion.

**4. Financial Instruments and Fair Value Measurement**

The table below presents information about assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2012 and the valuation techniques we utilized to determine such fair value. Fair values determined based on Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Our Level 1 assets consist of marketable equity securities. Fair values determined based on Level 2 inputs utilize observable quoted prices for similar assets and liabilities in active markets and observable quoted prices for identical or similar assets in markets that are not very active. Our Level 2 assets consist primarily of U.S. Treasury securities, U.S. government-sponsored agency securities, U.S. government-sponsored agency mortgage-backed securities, non-U.S. government, agency and Supranational securities, global corporate debt securities, foreign currency forward contracts, purchased foreign currency options and interest rate swap contracts. Fair values determined based on Level 3 inputs utilize unobservable inputs and include valuations of assets or liabilities for which there is little, if any, market activity. We do not have any Level 3 assets. Our Level 1 liability relates to our publicly traded CVRs. Our Level 2 liability relates to written foreign currency options. Our Level 3 liabilities consists of contingent consideration related to undeveloped product rights resulting from the acquisition of Gloucester and contingent consideration related to the undeveloped product rights and the technology platform acquired from the Avila acquisition. The maximum potential payments related to the contingent consideration from the acquisitions of Gloucester and Avila are estimated to be \$120.0 million and \$595.0 million, respectively.

|  | Balance at<br>December 31, 2012 | Quoted Price in<br>Active Markets for<br>Identical Assets<br>(Level 1) | Significant<br>Other Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
|--|---------------------------------|--|--|--|
| <b>Assets:</b>                                     |                                 |  |  |  |
| Available-for-sale securities                      | \$1,809,883                     | \$ 296   | \$1,809,587  | \$ -   |
| Cash equivalents                                   | 27,000                          | -  | 27,000   | -  |
| Interest rate swaps                                | 1,751                           | -  | 1,751  | -  |
| Forward currency contracts                         | 17,759                          | -  | 17,759   | -  |
| Purchased currency options                         | 2,688                           | -  | 2,688  | -  |
| Total assets                                       | <u>\$1,859,081</u>              | <u>\$ 296</u>  | <u>\$1,858,785</u>                                     | <u>\$ -</u>  |
| <b>Liabilities:</b>                                |                                 |  |  |  |
| Contingent value rights                            | \$ (277,385)                    | \$(277,385)  | \$ -   | \$ -   |
| Written currency options                           | (5,130)                         | -  | (5,130)  | -  |
| Other acquisition related contingent consideration | (198,116)                       | -  | -  | (198,116)  |
| Total liabilities                                  | <u>\$ (480,631)</u>             | <u>\$(277,385)</u>   | <u>\$ (5,130)</u>                                      | <u>\$(198,116)</u>                                 |

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|  | Balance at<br>December 31, 2011 | Quoted Price in<br>Active Markets for<br>Identical Assets<br>(Level 1) | Significant<br>Other Observable<br>Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) |
|--|---------------------------------|--|--|--|
| <b>Assets:</b>                                     |                                 |  |  |  |
| Available-for-sale securities                      | \$ 788,690                      | \$ 560   | \$788,130  | \$ -   |
| Forward currency contracts                         | <u>48,561</u>                   | -  | <u>48,561</u>  | -  |
| Total assets                                       | <u>\$ 837,251</u>               | <u>\$ 560</u>  | <u>\$836,691</u>                                       | <u>\$ -</u>  |
| <b>Liabilities:</b>                                |                                 |  |  |  |
| Contingent value rights                            | \$ (60,583)                     | \$(60,583)   | \$ -   | \$ -   |
| Other acquisition related contingent consideration | <u>(76,890)</u>                 | -  | -  | <u>(76,890)</u>                                    |
| Total liabilities                                  | <u>\$ (137,473)</u>             | <u>\$ (60,583)</u>   | <u>\$ -</u>  | <u>\$ (76,890)</u>                                 |

There were no security transfers between Levels 1 and 2 during 2012. The following tables represent a roll-forward of the fair value of Level 3 instruments (significant unobservable inputs):

|                                    | 2012        | 2011        |
|------------------------------------|-------------|-------------|
| <b>Assets:</b>                     |             |             |
| Balance at beginning of period     | \$ -        | \$ 23,372   |
| Amounts acquired or issued         | -           | -           |
| Net realized and unrealized gains  | -           | 1,194       |
| Settlements                        | -           | (22,477)    |
| Transfers in and/or out of Level 3 | -           | (2,089)     |
| Balance at end of period           | <u>\$ -</u> | <u>\$ -</u> |

Settlements of \$22.5 million during 2011 consisted of Level 3 instruments that were considered non-core assets acquired in the acquisition of Abraxis and were included in the sale of the non-core assets in April 2011.

|                                    | 2012               | 2011               |
|------------------------------------|--------------------|--------------------|
| <b>Liabilities:</b>                |                    |                    |
| Balance at beginning of period     | \$ (76,890)        | \$(252,895)        |
| Amounts acquired or issued         | (171,654)          | -                  |
| Net change in fair value           | 50,428             | (3,995)            |
| Settlements                        | -                  | -                  |
| Transfers in and/or out of Level 3 | -                  | 180,000            |
| Balance at end of period           | <u>\$(198,116)</u> | <u>\$ (76,890)</u> |

Level 3 liabilities issued during 2012 consisted of contingent consideration related to the acquisition of Avila. The \$50.4 million net decrease in fair value of liabilities in 2012 was due to a \$59.6 million reduction in the contingent consideration liability related to the approval of

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ISTODAX® for PTCL in Europe, partly offset by a \$9.2 million increase in the accretion of the contingent consideration liability related to our acquisition of Avila.

Transfers out of Level 3 during 2011 consisted of a \$180.0 million milestone that was part of the contingent consideration in the Gloucester acquisition. This milestone was valued based on the contractually defined amount of the milestone and paid in July 2011.

**5. Derivative Instruments and Hedging Activities**

Our revenue and earnings, cash flows and fair values of assets and liabilities can be impacted by fluctuations in foreign exchange rates and interest rates. We manage the impact of foreign exchange rate and interest rate movements through operational means and through the use of various financial instruments, including derivative instruments such as foreign currency option contracts, foreign currency forward contracts, treasury rate lock agreements and interest rate swap contracts.

***Foreign Currency Risk Management***

We have established revenue hedging and balance sheet risk management programs to mitigate volatility in future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

Through our revenue hedging program, we endeavor to reduce the impact of possible unfavorable changes in foreign exchange rates on our future U.S. dollar cash flows that are derived from foreign currency denominated sales. To achieve this objective, we hedge a portion of our forecasted foreign currency denominated sales that are expected to occur in the foreseeable future, typically within the next three years. We manage our anticipated transaction exposure principally with foreign currency forward contracts and occasionally foreign currency put and call options.

*Foreign Currency Forward Contracts:* We use foreign currency forward contracts to hedge specific forecasted transactions denominated in foreign currencies and to reduce exposures to foreign currency fluctuations of certain assets and liabilities denominated in foreign currencies.

We enter into foreign currency forward contracts to protect against changes in anticipated foreign currency cash flows resulting from changes in foreign currency exchange rates, primarily associated with non-functional currency denominated revenues and expenses of foreign subsidiaries. The foreign currency forward hedging contracts outstanding at December 31, 2012 and 2011 had settlement dates within 36 months. These foreign currency forward contracts are designated as cash flow hedges and, to the extent effective, any unrealized gains or losses on them are reported in other comprehensive income (loss), or OCI, and reclassified to operations in the same periods during which the underlying hedged transactions affect operations. Any ineffectiveness on these foreign currency forward contracts is reported in other income

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(expense), net. Foreign currency forward contracts entered into to hedge forecasted revenue and expenses were as follows at December 31, 2012 and 2011:

| <u>Foreign Currency</u> | <u>Notional Amount</u> |                    |
|-------------------------|------------------------|--------------------|
|                         | <u>2012</u>            | <u>2011</u>        |
| Australian Dollar       | \$ 5,076               | \$ 17,169          |
| British Pound           | 77,914                 | 53,764             |
| Canadian Dollar         | 134,366                | 67,281             |
| Euro                    | 969,296                | 714,446            |
| Japanese Yen            | 236,212                | 606,538            |
| Swiss Franc             | -                      | 49,182             |
| Total                   | <u>\$1,422,864</u>     | <u>\$1,508,380</u> |

We consider the impact of our own and the counterparties' credit risk on the fair value of the contracts as well as the ability of each party to execute its obligations under the contract on an ongoing basis. As of December 31, 2012, credit risk did not materially change the fair value of our foreign currency forward contracts.

We also enter into foreign currency forward contracts to reduce exposures to foreign currency fluctuations of certain recognized assets and liabilities denominated in foreign currencies. These foreign currency forward contracts have not been designated as hedges and, accordingly, any changes in their fair value are recognized on the Consolidated Statements of Income in other income (expense), net in the current period. The aggregate notional amount of the foreign currency forward non-designated hedging contracts outstanding at December 31, 2012 and 2011 were \$795.4 million and \$916.9 million, respectively.

*Foreign Currency Option Contracts:* During 2012, we began hedging a portion of our future foreign currency exposure by utilizing a strategy that involves both a purchased local currency put option and a written local currency call option that are accounted for as hedges of future sales denominated in Euros. Specifically, we sell (or write) a local currency call option and purchase a local currency put option with the same expiration dates and amounts but with different strike prices; this combination of transactions is generally referred to as a "collar". The expiration dates and notional amounts correspond to the amount and timing of forecasted future foreign currency sales. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value reduces to zero and we benefit from the increase in the U.S. dollar equivalent value of our anticipated foreign currency cash flows, however this benefit would be capped at the strike level of the written call, which forms the upper end of the collar. The premium collected from the call option partially offsets the premium paid for the purchased put option, resulting in a net cost for the collars.

In order to fully offset the net cost of the collars, we also sold local currency put options with a lower strike price and the same expiration dates and amounts as the option contracts that were used to hedge sales. These written put options introduced risk of loss if the U.S. dollar were to strengthen beyond the strike price of the written put options. In December 2012, we entered into

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purchased put options that are not designated as hedges in order to partially offset the risk of loss that would be incurred on the written put options if the US dollar were to strengthen beyond the strike price of the written put. Gains and losses associated with the non-hedge put options have been recorded on the income statement as other income (expense), net.

Foreign currency option contracts entered into to hedge forecasted revenue and expenses were as follows at December 31, 2012.

| <u>Foreign Currency Option</u>      | <u>Notional Amount*</u> |
|-------------------------------------|-------------------------|
|                                     | <u>2012</u>             |
| Designated as hedging activity:     |                         |
| Purchased Put                       | \$ 228,779              |
| Written Call                        | \$ 235,920              |
| Not designated as hedging activity: |                         |
| Purchased Put                       | \$ 160,493              |
| Written Put                         | \$(215,952)             |

\* U.S. Dollar notional amounts are calculated as the hedged local currency amount multiplied times the strike value of the foreign currency option. The local currency notional amounts of our purchased put, and written call that are designated as hedging activity are equal to each other.

***Interest Rate Risk Management***

***Treasury Rate Lock Agreements:*** During 2012, we entered into treasury rate lock agreements, or treasury rate locks, in anticipation of issuing fixed-rate notes that were issued in August 2012. With the exception of a short period in June when certain outstanding treasury rate locks were not designated as hedges, our treasury rate locks were designated as cash flow hedges and, to the extent effective, any realized or unrealized gains or losses on them were reported in OCI and will be recognized in income over the life of the anticipated fixed-rate notes. Treasury rate locks were settled during 2012 which resulted in losses of \$35.3 million that were recorded to OCI. During the short period in June when we had outstanding treasury rate locks that were not considered hedging instruments, we recorded the favorable change in fair value of \$3.7 million in other income (expense), net. No material amounts were recorded in income during 2012 or 2011 as a result of hedge ineffectiveness or hedge components excluded from the assessment of effectiveness. At December 31, 2012 we had no outstanding treasury rate locks.

***Interest Rate Swap Contracts:*** From time to time we hedge the fair value of certain debt obligations through the use of interest rate swap contracts. The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in interest rates. Since the specific terms and notional amount of the swap are intended to match those of the debt being hedged, it is assumed to be a highly effective hedge and all changes in fair value of the swap is recorded on the Consolidated Balance Sheets with no net impact recorded in income. Any net interest payments made or received on interest rate swap contracts are recognized as interest expense.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

In 2011, we settled outstanding interest rate swap contracts we entered into with respect to our \$500.0 million 2.45% fixed notes due in 2015 resulting in the receipt of \$34.3 million. The proceeds from the settlements are being accounted for as a reduction of current and future interest expense associated with these notes. During 2012, we terminated the hedging relationship on \$800.0 million notional amount of swap contracts that had been entered into earlier in 2012 as hedges of our 1.9% fixed rate notes due in 2017 and our 3.25% fixed rate notes due in 2022 by settling certain of the contracts and entering into offsetting contracts for those not settled. This resulted in gains of \$5.0 million that are being accounted for as a reduction of current and future interest expense associated with these notes.

At December 31, 2012, we were a party to pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. Our swap contracts outstanding at December 31, 2012 consisted of \$100.0 million aggregate notional amount maturing in 2017, which effectively convert a portion of our \$500.0 million, 1.90% fixed-rate notes due in 2017 to a floating rate and \$200.0 million aggregate notional amount maturing in 2022, which effectively converts a portion of our \$1.000 billion, 3.25% fixed-rate notes due in 2022 to a floating rate.

In January 2013 we entered into additional interest rate swap contracts with notional amounts of \$400 million related to our 1.90% fixed-rate notes due in 2017 and \$800 million related to our 3.25% fixed-rate notes due in 2022.

The following table summarizes the fair value and presentation in the Consolidated Balance Sheets for derivative instruments as of December 31, 2012 and 2011:

| Instrument  | December 31, 2012             |                   |                               |                   |
|---|-------------------------------|-------------------|-------------------------------|-------------------|
|   | Asset Derivatives             |                   | Liability Derivatives         |                   |
|   | Balance Sheet Location        | Fair Value        | Balance Sheet Location        | Fair Value        |
| <i>Derivatives designated as hedging instruments:</i>     |                               |                   |                               |                   |
| Foreign exchange contracts*                               | Other current assets          | \$ 35,146         | Other current assets          | \$ 12,725         |
|   | Other current liabilities     | 9,069             | Other current liabilities     | 31,416            |
|   | Other non-current assets      | 30,486            | Other non-current assets      | 13,796            |
| Interest rate swap agreements                             | Other current assets          | 106               | Other current assets          | -                 |
|   | Other non-current assets      | 79                | Other non-current assets      | 188               |
|   | Other non-current liabilities | -                 | Other non-current liabilities | 620               |
| <i>Derivatives not designated as hedging instruments:</i> |                               |                   |                               |                   |
| Foreign exchange contracts*                               | Other current assets          | 45,819            | Other current assets          | 36,272            |
|   | Other current liabilities     | 10,408            | Other current liabilities     | 21,402            |
| Interest rate swap agreements                             | Other current assets          | 635               | Other current assets          | -                 |
|   | Other non-current assets      | 1,739             | Other non-current assets      | -                 |
| Total   |                               | <u>\$ 133,487</u> |                               | <u>\$ 116,419</u> |



**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

| December 31, 2011   |                               |            |                               |            |
|---|-------------------------------|------------|-------------------------------|------------|
| Instrument  | Asset Derivatives             |            | Liability Derivatives         |            |
|   | Balance Sheet Location        | Fair Value | Balance Sheet Location        | Fair Value |
| <i>Derivatives designated as hedging instruments:</i>     |                               |            |                               |            |
| Foreign exchange contracts*                               | Other current assets          | \$ 68,889  | Other current assets          | \$ 32,430  |
|   | Other current liabilities     | 129        | Other current liabilities     | 3,940      |
|   | Other non-current liabilities | -          | Other non-current liabilities | 24,832     |
| <i>Derivatives not designated as hedging instruments:</i> |                               |            |                               |            |
| Foreign exchange contracts*                               | Other current assets          | 66,639     | Other current assets          | 10,395     |
|   | Other current liabilities     | 2,462      | Other current liabilities     | 22,289     |
|   | Other non-current assets      | 36,684     | Other non-current assets      | 32,356     |
| Total   |                               | \$ 174,803 |                               | \$ 126,242 |

\* Derivative instruments in this category are subject to master netting arrangements and are presented on a net basis in the Consolidated Balance Sheets in accordance with ASC 210-20.

The following table summarizes the effect of derivative instruments designated as fair value hedging instruments on the Consolidated Statements of Income for the years ended December 31, 2012 and 2011:

| Instrument                    | 2012  |   |   |   |   |
|-------------------------------|---|---|---|---|---|
|                               | Amount of Gain/(Loss) Recognized in OCI on Derivative (1) | Location of Gain/(Loss) Reclassified from Accumulated OCI into Income | Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income | Location of Gain/(Loss) Recognized in Income on Derivative<br><i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i> | Amount of Gain/(Loss) Recognized in Income on Derivative<br><i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i> |
| Instrument                    | <i>(Effective Portion)</i>                                | <i>(Effective Portion)</i>  | <i>(Effective Portion)</i>  | <i>(Effective Portion)</i>  | <i>(Effective Portion)</i>  |
| Foreign exchange contracts    | \$ 74,458   | Net product sales   | \$ 80,915   | Other income, net   | \$ (6,578) (2)  |
| Treasury rate lock agreements | \$ (35,255)   | Interest Expense  | \$ (1,265)  |   |   |

- (1) Net losses of \$27,886 are expected to be reclassified from Accumulated OCI into income in the next 12 months.
- (2) The amount of net losses recognized in income represents \$9,037 in losses related to the ineffective portion of the hedging relationships and \$2,459 of gains related to amounts excluded from the assessment of hedge effectiveness.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

| Instrument                 | 2011  |   |   |   |   |
|----------------------------|---|---|---|---|---|
|                            | Amount of Gain/(Loss) Recognized in OCI on Derivative | Location of Gain/(Loss) Reclassified from Accumulated OCI into Income | Amount of Gain/(Loss) Reclassified from Accumulated OCI into Income | Location of Gain/(Loss) Recognized in Income on Derivative<br><i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i> | Amount of Gain/(Loss) Recognized in Income on Derivative<br><i>(Ineffective Portion and Amount Excluded From Effectiveness Testing)</i> |
|                            | <i>(Effective Portion)</i>                            | <i>(Effective Portion)</i>  | <i>(Effective Portion)</i>  |   |   |
| Foreign exchange contracts | \$ 21,236   | Net product sales   | \$ (33)   | Other income, net   | \$ (10,643) (1)   |

(1) The amount of net losses recognized in income represents \$2,837 in losses related to the ineffective portion of the hedging relationships and \$7,806 of losses related to amounts excluded from the assessment of hedge effectiveness.

The following table summarizes the effect of derivative instruments designated as fair value hedging instruments on the Consolidated Statements of Income for the years ended December 31, 2012 and 2011:

| Instrument | Location of Gain (Loss) Recognized in Income on Derivative | Amount of Gain (Loss) Recognized in Income on Derivative |                  |
|------------|--|--|------------------|
|            |  | 2012   | 2011             |
|            |  | Interest Rate Swaps                                      | Interest expense |

The following table summarizes the effect of derivative instruments not designated as hedging instruments on the Consolidated Statements of Income for the years ended December 31, 2012 and 2011:

| Instrument                    | Location of Gain (Loss) Recognized in Income on Derivative | Amount of Gain (Loss) Recognized in Income on Derivative |                   |
|-------------------------------|--|--|-------------------|
|                               |  | 2012   | 2011              |
|                               |  | Foreign exchange contracts                               | Other income, net |
| Treasury rate lock agreements | Other income, net  | \$ 3,718   | \$ -              |
| Interest rate swap agreements | Other income, net  | \$ 266   | \$ -              |

The impact of gains and losses on foreign exchange contracts not designated as hedging instruments are generally offset by net foreign exchange gains and losses, which are also included in other income (expense), net for all periods presented.

**6. Cash, Cash Equivalents and Marketable Securities Available-for-Sale**

Money market funds of \$1.160 billion and \$738.7 million at December 31, 2012 and 2011, respectively, were recorded at cost, which approximates fair value and are included in cash and cash equivalents.

**CELGENE CORPORATION AND SUBSIDIARIES**  
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The amortized cost, gross unrealized holding gains, gross unrealized holding losses and estimated fair value of available-for-sale securities by major security type and class of security at December 31, 2012 and 2011 were as follows:

| December 31, 2012   | Amortized<br>Cost   | Gross<br>Unrealized<br>Gain | Gross<br>Unrealized<br>Loss | Estimated<br>Fair<br>Value |
|---|---------------------|-----------------------------|-----------------------------|----------------------------|
| U.S. Treasury securities                                    | \$ 902,047          | \$ 488                      | \$ (7)                      | \$ 902,528                 |
| U.S. government-sponsored agency securities                 | 303,470             | 318                         | (8)                         | 303,780                    |
| U.S. government-sponsored agency MBS                        | 387,222             | 1,592                       | (1,831)                     | 386,983                    |
| Non-U.S. government, agency and<br>Supranational securities | 7,105               | 10                          | -                           | 7,115                      |
| Corporate debt – global                                     | 208,476             | 915                         | (210)                       | 209,181                    |
| Marketable equity securities                                | 408                 | -                           | (112)                       | 296                        |
| Total available-for-sale marketable securities              | <u>\$ 1,808,728</u> | <u>\$ 3,323</u>             | <u>\$ (2,168)</u>           | <u>\$ 1,809,883</u>        |

| December 31, 2011   | Amortized<br>Cost | Gross<br>Unrealized<br>Gain | Gross<br>Unrealized<br>Loss | Estimated<br>Fair<br>Value |
|---|-------------------|-----------------------------|-----------------------------|----------------------------|
| U.S. Treasury securities                                    | \$ 228,996        | \$ 58                       | \$ (38)                     | \$ 229,016                 |
| U.S. government-sponsored agency securities                 | 196,833           | 81                          | (69)                        | 196,845                    |
| U.S. government-sponsored agency MBS                        | 256,440           | 600                         | (1,901)                     | 255,139                    |
| Non-U.S. government, agency and<br>Supranational securities | 2,666             | 19                          | -                           | 2,685                      |
| Corporate debt – global                                     | 104,181           | 497                         | (233)                       | 104,445                    |
| Marketable equity securities                                | 407               | 153                         | -                           | 560                        |
| Total available-for-sale marketable securities              | <u>\$ 789,523</u> | <u>\$ 1,408</u>             | <u>\$ (2,241)</u>           | <u>\$ 788,690</u>          |

U.S. government-sponsored agency securities include general unsecured obligations either issued directly by or guaranteed by U.S. Government Sponsored Enterprises. U.S. government-sponsored agency mortgage-backed securities, or MBS, include mortgage-backed securities issued by the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation and the Government National Mortgage Association. Non-U.S. government, agency and Supranational securities consist of direct obligations of highly rated governments of nations other than the United States and obligations of sponsored agencies and other entities that are guaranteed or supported by highly rated governments of nations other than the United States. Corporate debt – global includes obligations issued by investment-grade corporations, including some issues that have been guaranteed by governments and government agencies. Net unrealized gains in the marketable debt securities primarily reflect the impact of decreased interest rates at December 31, 2012.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

The fair value of all available-for-sale securities, which have been in an unrealized loss position for less than and longer than 12 months at December 31, 2012, was as follows:

| December 31, 2012                              | Less than 12 months        |                             | 12 months or longer        |                             | Total                      |                             |
|--|----------------------------|-----------------------------|----------------------------|-----------------------------|----------------------------|-----------------------------|
|  | Estimated<br>Fair<br>Value | Gross<br>Unrealized<br>Loss | Estimated<br>Fair<br>Value | Gross<br>Unrealized<br>Loss | Estimated<br>Fair<br>Value | Gross<br>Unrealized<br>Loss |
| U.S. Treasury securities                       | \$ 49,830                  | \$ (7)                      | \$ -                       | \$ -                        | \$ 49,830                  | \$ (7)                      |
| U.S. government-sponsored<br>agency securities | 23,920                     | (8)                         | -                          | -                           | 23,920                     | (8)                         |
| U.S. government-sponsored<br>agency MBS        | 201,497                    | (1,571)                     | 8,984                      | (260)                       | 210,481                    | (1,831)                     |
| Corporate debt – global                        | 99,067                     | (210)                       | -                          | -                           | 99,067                     | (210)                       |
| Marketable equity securities                   | 407                        | (112)                       | -                          | -                           | 407                        | (112)                       |
| <b>Total</b>                                   | <b>\$ 374,721</b>          | <b>\$ (1,908)</b>           | <b>\$ 8,984</b>            | <b>\$ (260)</b>             | <b>\$ 383,705</b>          | <b>\$ (2,168)</b>           |

The Company believes that the decline in fair value of securities held at December 31, 2012 below their cost is temporary and intends to retain its investment in these securities for a sufficient period of time to allow for recovery in the market value of these investments.

Duration periods of available-for-sale debt securities at December 31, 2012 were as follows:

|                                      | Amortized<br>Cost   | Fair<br>Value       |
|--------------------------------------|---------------------|---------------------|
| Duration of one year or less         | \$ 587,358          | \$ 587,170          |
| Duration of one through three years  | 1,157,875           | 1,159,017           |
| Duration of three through five years | 63,087              | 63,400              |
| <b>Total</b>                         | <b>\$ 1,808,320</b> | <b>\$ 1,809,587</b> |

**7. Inventory**

A summary of inventories by major category at December 31, 2012 and 2011 follows:

|                 | 2012              | 2011              |
|-----------------|-------------------|-------------------|
| Raw materials   | \$ 79,201         | \$ 50,533         |
| Work in process | 86,544            | 115,170           |
| Finished goods  | 93,750            | 23,870            |
| <b>Total</b>    | <b>\$ 259,495</b> | <b>\$ 189,573</b> |

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

**8. Property, Plant and Equipment**

Property, plant and equipment at December 31, 2012 and 2011 consisted of the following:

|  | 2012       | 2011       |
|--|------------|------------|
| Land   | \$ 36,693  | \$ 34,718  |
| Buildings                                      | 228,348    | 141,188    |
| Building and operating equipment               | 30,003     | 18,559     |
| Leasehold improvements                         | 78,133     | 56,511     |
| Machinery and equipment                        | 175,226    | 137,133    |
| Furniture and fixtures                         | 41,179     | 35,630     |
| Computer equipment and software                | 239,487    | 205,426    |
| Construction in progress                       | 90,074     | 137,278    |
| Subtotal                                       | 919,143    | 766,443    |
| Less accumulated depreciation and amortization | 340,781    | 260,401    |
| Total  | \$ 578,362 | \$ 506,042 |

The balance of construction in progress at December 31, 2012 relates primarily to an expansion of our international headquarters in Boudry, Switzerland, expansion of our corporate headquarters in Summit, New Jersey and construction of our new research facilities in San Diego.

**9. Other Financial Information**

Accrued expenses at December 31, 2012 and 2011 consisted of the following:

|   | 2012       | 2011       |
|---|------------|------------|
| Rebates, distributor chargebacks and distributor services | \$ 187,040 | \$ 201,348 |
| Clinical trial costs and grants                           | 183,315    | 132,167    |
| Compensation  | 170,277    | 163,824    |
| Common share repurchases                                  | 40,979     | 33,818     |
| Interest  | 26,263     | 9,635      |
| Royalties, license fees and milestones                    | 19,370     | 20,924     |
| Sales returns   | 13,270     | 8,974      |
| Professional services                                     | 9,785      | 9,934      |
| Rent  | 9,534      | 6,758      |
| Other Taxes   | 8,334      | 7,212      |
| Canadian pricing settlement                               | -          | 10,000     |
| Other   | 107,557    | 97,113     |
| Total   | \$ 775,724 | \$ 701,707 |

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

Other current liabilities at December 31, 2012 and 2011 consisted of the following:

|   | <u>2012</u>       | <u>2011</u>       |
|---|-------------------|-------------------|
| Contingent value rights – Abraxis acquisition | \$ 277,385        | \$ -              |
| Sales, use and value added tax                | 56,862            | 73,978            |
| Foreign exchange contracts                    | 33,341            | 23,638            |
| Collaboration agreement                       | 17,000            | 17,000            |
| Contingent consideration – Avila acquisition  | 17,389            | -                 |
| Other   | 29,319            | 23,808            |
| Total   | <u>\$ 431,296</u> | <u>\$ 138,424</u> |

Other non-current liabilities at December 31, 2012 and 2011 consisted of the following:

|   | <u>2012</u>       | <u>2011</u>       |
|---|-------------------|-------------------|
| Contingent consideration – Avila acquisition      | \$ 163,470        | \$ -              |
| Deferred compensation and long-term incentives    | 99,162            | 71,262            |
| Deferred lease incentive                          | 31,420            | -                 |
| Contingent value rights – Abraxis acquisition     | -                 | 60,583            |
| Contingent consideration – Gloucester acquisition | 17,257            | 76,890            |
| Manufacturing facility purchase                   | 14,427            | 17,168            |
| Foreign exchange contracts                        | -                 | 24,832            |
| Collaboration agreement                           | -                 | 17,000            |
| Other   | 29,810            | 5,781             |
| Total   | <u>\$ 355,546</u> | <u>\$ 273,516</u> |

**10. Intangible Assets and Goodwill**

*Intangible Assets:* Our intangible assets consist of developed product rights obtained primarily from the Pharmion, Gloucester and Abraxis acquisitions, IPR&D product rights from the Gloucester and Avila acquisitions and technology obtained primarily from the Avila acquisition. Also included are contract-based licenses and other miscellaneous intangibles. The amortization periods related to non-IPR&D intangible assets range from one to 17 years. The following

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summary of intangible assets by category includes intangibles currently being amortized and intangibles not yet subject to amortization:

| <u>December 31, 2012</u>          | <u>Gross<br/>Carrying<br/>Value</u> | <u>Accumulated<br/>Amortization</u> | <u>Intangible<br/>Assets,<br/>Net</u> | <u>Weighted<br/>Average<br/>Life (Years)</u> |
|-----------------------------------|-------------------------------------|-------------------------------------|---------------------------------------|--|
| Amortizable intangible assets:    |                                     |                                     |                                       |  |
| Acquired developed product rights | \$ 3,400,417                        | \$ (814,507)                        | \$ 2,585,910                          | 13.0   |
| Technology                        | 333,333                             | (39,824)                            | 293,509                               | 7.0  |
| Licenses                          | 64,250                              | (9,945)                             | 54,305                                | 16.8   |
| Other                             | 43,434                              | (14,625)                            | 28,809                                | 8.5  |
|                                   | <u>3,841,434</u>                    | <u>(878,901)</u>                    | <u>2,962,533</u>                      | <u>12.5</u>                                  |
| Non-amortized intangible assets:  |                                     |                                     |                                       |  |
| Acquired IPR&D product rights     | 137,890                             | -                                   | 137,890                               |  |
| Total intangible assets           | <u>\$ 3,979,324</u>                 | <u>\$ (878,901)</u>                 | <u>\$ 3,100,423</u>                   |  |
|                                   |                                     |                                     |                                       |  |
| <u>December 31, 2011</u>          | <u>Gross<br/>Carrying<br/>Value</u> | <u>Accumulated<br/>Amortization</u> | <u>Intangible<br/>Assets,<br/>Net</u> | <u>Weighted<br/>Average<br/>Life (Years)</u> |
| Amortizable intangible assets:    |                                     |                                     |                                       |  |
| Acquired developed product rights | \$ 2,186,000                        | \$ (666,142)                        | \$ 1,519,858                          | 11.9   |
| Technology                        | 2,534                               | (190)                               | 2,344                                 | 10.0   |
| Licenses                          | 64,250                              | (6,108)                             | 58,142                                | 16.8   |
| Other                             | 40,600                              | (10,246)                            | 30,354                                | 8.8  |
|                                   | <u>2,293,384</u>                    | <u>(682,686)</u>                    | <u>1,610,698</u>                      | <u>11.9</u>                                  |
| Non-amortized intangible assets:  |                                     |                                     |                                       |  |
| Acquired IPR&D product rights     | 1,234,000                           | -                                   | 1,234,000                             |  |
| Total intangible assets           | <u>\$ 3,527,384</u>                 | <u>\$ (682,686)</u>                 | <u>\$ 2,844,698</u>                   |  |

The gross carrying value of intangible assets increased by \$451.9 million in 2012 compared to 2011 primarily due to the acquisition of Avila, which resulted in a net increase of \$460.0 million in the gross carrying value of intangible assets, after recognizing a \$69.2 million impairment charge related to an adjustment to the probability weighted forecasted sales of CC-292 compared to estimates at date of acquisition. The gross carrying value of intangible assets also included a \$42.4 million acquisition of intellectual property rights related to an approved product acquired from Deuteria Pharmaceuticals, Inc., or Deuteria, in 2012 and \$53.3 million in impairment charges related to the IPR&D product right for ISTODAX® for PTCL in Europe following a negative opinion issued by the European Medicines Agency's Committee for Medicinal Products for Human Use, or CHMP, for the Marketing Authorization Application submitted for ISTODAX® for the treatment of PTCL.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

Acquired developed product rights increased by \$1.214 billion primarily due to a \$1.172 billion reclassification of acquired IPR&D product right assets related to ABRAXANE® following the 2012 FDA approval of ABRAXANE® for the first-line treatment of locally advanced or metastatic NSCLC in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. Technology increased by \$330.8 million due to the acquisition of Avila and its Avilomics™ platform. The \$2.8 million increase in other intangible assets resulted from certain third-party agreements entered into during 2012. Acquired IPR&D rights decreased by \$1.096 billion primarily due to the \$1.172 billion transfer to acquired developed product rights and \$53.3 million of impairment charges related to the IPR&D product right for ISTODAX®. The decrease was partly offset by a net increase of \$129.2 million resulting from the acquisition of Avila, which included the impact of a \$69.2 million impairment charge related to an adjustment to the probability weighted forecasted sales of CC-292 compared to estimates at date of acquisition.

Amortization expense was \$196.2 million, \$290.3 million and \$204.5 million for the years ended December 31, 2012, 2011 and 2010, respectively. Amortization expense decreased in 2012 compared to 2011 primarily due to the 2011 inclusion of amortization related to Vidaza in the U.S., which became fully amortized during 2011, partly offset by amortization related to the Avila intangible assets acquired in 2012 and the initiation of amortization related to ABRAXANE® in late 2012 as noted above. Assuming no changes in the gross carrying amount of intangible assets, the amortization of intangible assets for years 2013 through 2017 is estimated to be in the range of approximately \$255.0 million to \$270.0 million annually.

*Goodwill:* At December 31, 2012, our goodwill related to the 2012 acquisition of Avila, the 2010 acquisitions of Abraxis and Gloucester, the 2008 acquisition of Pharmion and the 2004 acquisition of Penn T Limited.

The change in carrying value of goodwill is summarized as follows:

|   |                     |
|---|---------------------|
| Balance at December 31, 2011                                    | \$ 1,887,220        |
| Acquisition of Avila (see Note 2)                               | 156,306             |
| Tax benefit on the exercise of Pharmion converted stock options | (753)               |
| Balance at December 31, 2012                                    | <u>\$ 2,042,773</u> |

**11. Debt**

*Senior Notes:* Summarized below are the carrying values of our senior notes at December 31, 2012 and 2011:

|                              | 2012                | 2011                |
|------------------------------|---------------------|---------------------|
| 2.450% senior notes due 2015 | \$ 520,113          | \$ 527,191          |
| 1.900% senior notes due 2017 | 500,652             | -                   |
| 3.950% senior notes due 2020 | 498,965             | 498,854             |
| 3.250% senior notes due 2022 | 1,002,057           | -                   |
| 5.700% senior notes due 2040 | 249,546             | 249,540             |
| Total long-term debt         | <u>\$ 2,771,333</u> | <u>\$ 1,275,585</u> |



**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

At December 31, 2012, the fair value of our outstanding Senior Notes was \$2.893 billion and represented a Level 2 measurement within the fair value measurement hierarchy.

In August 2012, we issued an additional \$1.500 billion principal amount of senior notes consisting of \$500.0 million aggregate principal amount of 1.90% Senior Notes due 2017, or the 2017 notes, and \$1.000 billion aggregate principal amount of 3.25% Senior Notes due 2022 (the “2022 notes” and, together with the 2017 notes, referred to herein as the “2012 issued notes”). The 2012 issued notes were issued at 99.786% and 99.949% of par, respectively, and the discount is being amortized as additional interest expense over the period from issuance through maturity. Offering costs of approximately \$11.7 million have been recorded as debt issuance costs on our Consolidated Balance Sheets and are being amortized as additional interest expense using the effective interest rate method over the period from issuance through maturity. Interest on the notes is payable semi-annually in arrears on February 15 and August 15 each year beginning February 15, 2013 and the principal on each note is due in full at their respective maturity dates. The notes may be redeemed at the option of the Company, in whole or in part, at any time at a redemption price defined in a make-whole clause equaling accrued and unpaid interest plus the greater of 100% of the principal amount of the notes to be redeemed or the sum of the present values of the remaining scheduled payments of interest and principal discounted to the date of redemption on a semi-annual basis plus 20 basis points in the case of the 2017 notes and 25 basis points in the case of the 2022 notes. If we experience a change of control accompanied by a downgrade of the debt to below investment grade, we will be required to offer to repurchase the notes at a purchase price equal to 101% of their principal amount plus accrued and unpaid interest. We are subject to covenants which limit our ability to pledge properties as security under borrowing arrangements and limit our ability to perform sale and leaseback transactions involving our property.

During the year ended December 31, 2012, we entered into or treasury rate locks in anticipation of issuing the fixed-rate notes that were issued in August 2012. Losses related to these treasury rate locks of \$35.3 million have been recorded in OCI during the year ended December 31, 2012 and will be recognized as interest expense over the life of the 2017 notes and the 2022 notes.

At December 31, 2012, we were party to pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts matched the amount of the hedged fixed-rate notes. Our swap contracts outstanding at December 31, 2012 consist of \$100.0 million aggregate notional amount maturing in 2017, which effectively converts a portion of our \$500.0 million, 1.90% fixed-rate notes due in 2017 to a floating rate and \$200.0 million aggregate notional amount maturing in 2022, which effectively converts a portion of our \$1.000 billion, 3.25% fixed-rate notes due in 2022 to a floating rate. In August 2011, we settled outstanding interest rate swap contracts we entered into with respect to our \$500.0 million, 2.45% fixed-rate notes due in 2015 resulting in the receipt of \$34.3 million. The proceeds from the settlements are being accounted for as a reduction of current and future interest expense associated with these notes.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

*Commercial Paper:* The carrying value of Commercial Paper as of December 31, 2012 and 2011 was \$308.5 million and \$401.4 million, respectively, and approximated its fair value. The effective interest rate on the outstanding Commercial Paper balance at December 31, 2012 was 0.5%.

*Senior Unsecured Credit Facility:* We maintain a senior unsecured revolving credit facility, or the Credit Facility, that provides revolving credit in the aggregate amount of \$1.000 billion. Amounts may be borrowed in U.S. dollars for working capital, capital expenditures and other corporate purposes. The Credit Facility serves as backup liquidity for our Commercial Paper borrowings. As of December 31, 2012 and 2011, there was no outstanding borrowing against the Credit Facility.

The Credit Facility contains affirmative and negative covenants including certain customary financial covenants. We were in compliance with all financial debt covenants as of December 31, 2012.

*Credit Facility:* In November 2011, we entered into an uncommitted facility, or the Facility, not exceeding an aggregate \$125.0 million. As of December 31, 2011, \$125.0 million was outstanding under the Facility and accounted for as short-term borrowings. The outstanding balance was repaid in January 2012 and the Facility was canceled.

## **12. Stockholders' Equity**

*Preferred Stock:* Our Board of Directors is authorized to issue, at any time, without further stockholder approval, up to 5,000,000 shares of preferred stock, and to determine the price, rights, privileges, and preferences of such shares.

*Common Stock:* At December 31, 2012, we were authorized to issue up to 575,000,000 shares of common stock of which shares of common stock issued totaled 498,427,951.

*Treasury Stock:* Since April 2009, our Board of Directors has approved repurchases of up to an aggregate \$6.500 billion of our common stock, including \$2.500 billion approved by our Board of Directors during their June 2012 meeting. We repurchased \$2.050 billion, \$2.220 billion, and \$183.1 million of treasury stock under the program in 2012, 2011 and 2010, respectively, excluding transaction fees. As of December 31, 2012 an aggregate 74,465,418 common shares were repurchased under the program at an average price of \$62.62 per common share and total cost of \$4.663 billion.

Certain employees exercised stock options containing a reload feature and, pursuant to our stock option plan, tendered mature shares of 14,865 in 2012, 81,281 in 2011 and 152,361 in 2010 related to stock option exercises. Such tendered shares are reflected as treasury stock. In addition, when employee awards of restricted stock units, or RSUs, vest and are settled net in order to fulfill tax withholding requirements, the shares withheld are reflected as treasury stock.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

A summary of changes in common stock issued and treasury stock is presented below:

|   | <u>Common Stock</u>       | <u>Common Stock<br/>in Treasury</u> |
|---|---------------------------|-------------------------------------|
| December 31, 2009   | 467,629,433               | (8,337,961)                         |
| Issuance of common stock for the Abraxis acquisition                            | 10,660,196                | -                                   |
| Exercise of stock options, warrants and conversion of<br>restricted stock units | 3,874,724                 | -                                   |
| Issuance of common stock for employee benefit plans                             | -                         | 223,162                             |
| Treasury stock – mature shares tendered related to option<br>exercises          | -                         | (152,361)                           |
| Shares repurchased under share repurchase program                               | -                         | (3,508,876)                         |
| December 31, 2010   | <u>482,164,353</u>        | <u>(11,776,036)</u>                 |
| Exercise of stock options, warrants and conversion of<br>restricted stock units | 5,216,902                 | (64)                                |
| Issuance of common stock for employee benefit plans                             | -                         | 236,460                             |
| Treasury stock – mature shares tendered related to option<br>exercises          | -                         | (81,281)                            |
| Shares repurchased under share repurchase program                               | -                         | (38,268,157)                        |
| December 31, 2011   | <u>487,381,255</u>        | <u>(49,889,078)</u>                 |
| Exercise of stock options, warrants and conversion of<br>restricted stock units | 10,762,962                | (136,121)                           |
| Issuance of common stock for employee benefit plans                             | 283,734                   | -                                   |
| Treasury stock – mature shares tendered related to option<br>exercises          | -                         | (14,865)                            |
| Shares repurchased under share repurchase program                               | -                         | (28,636,033)                        |
| December 31, 2012   | <u><u>498,427,951</u></u> | <u><u>(78,676,097)</u></u>          |

**13. Accumulated Other Comprehensive Income (Loss)**

The components of other comprehensive income (loss) consist of changes in pension liability, changes in net unrealized gains (losses) on marketable securities classified as available-for-sale, net unrealized gains (losses) related to cash flow hedges and changes in foreign currency translation adjustments, which includes changes in a subsidiary's functional currency and net asset transfers of common control subsidiaries.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

The accumulated balances related to each component of other comprehensive income (loss), net of tax, are summarized as follows:

|                           | Pension<br>Liability | Net Unrealized<br>Gains (Losses) From<br>Marketable Securities | Net Unrealized<br>Gains (Losses)<br>From Hedges | Foreign<br>Currency<br>Translation<br>Adjustment | Total<br>Accumulated<br>Other<br>Comprehensive<br>Income (Loss) |
|---------------------------|----------------------|--|---|--|---|
| Balance December 31, 2010 | \$ (3,836)           | \$ 3,102   | \$ (15,556)                                     | \$ (57,477)                                      | \$ (73,767)   |
| Period change             | (1,546)              | (1,345)  | 24,219  | (9,898)  | 11,430  |
| Balance December 31, 2011 | (5,382)              | 1,757  | 8,663   | (67,375)   | (62,337)  |
| Period change             | (4,739)              | 2,431  | (24,759)  | 39,657   | 12,590  |
| Balance December 31, 2012 | <u>\$ (10,121)</u>   | <u>\$ 4,188</u>  | <u>\$ (16,096)</u>                              | <u>\$ (27,718)</u>                               | <u>\$ (49,747)</u>  |

**14. Share-Based Compensation**

We have a stockholder-approved stock incentive plan, the 2008 Stock Incentive Plan as amended and restated in 2009, and further amended in 2011 and 2012, or the Plan, which provides for the granting of options, restricted stock awards, stock appreciation rights, performance awards and other share-based awards to our employees and officers. The Management Compensation and Development Committee of the Board of Directors, or the Compensation Committee, may determine the type, amount and terms, including vesting, of any awards made under the Plan.

On June 13, 2012, our stockholders approved an amendment of the Plan, which included the following key modifications: adoption of an aggregate share reserve of 95,981,641 shares of Common Stock, which includes an increase in the share reserve by 14,000,000 shares; extension of the term of the plan through April 18, 2022; a change in the weighting of full-value awards such as restricted stock and restricted stock units such that the weighting of grants of full-value awards will be increased from 1.6 shares for every share granted to 2.1 shares for every share granted for purposes of determining usage of the aggregate share reserve.

With respect to options granted under the Plan, the exercise price may not be less than the market closing price of the common stock on the date of grant. In general, options granted under the Plan vest over periods ranging from immediate vesting to four-year vesting and expire ten years from the date of grant, subject to earlier expiration in case of termination of employment unless the participant meets the retirement provision under which the option would have a maximum of three additional years to vest. The vesting period for options granted under the Plan is subject to certain acceleration provisions if a change in control, as defined in the Plan, occurs. Plan participants may elect to exercise options at any time during the option term. However, any shares so purchased which have not vested as of the date of exercise shall be subject to forfeiture, which will lapse in accordance with the established vesting time period.

Shares of common stock available for future share-based grants under all plans were 19,524,592 at December 31, 2012.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

The following table summarizes the components of share-based compensation expense in the Consolidated Statements of Income for the years ended December 31, 2012, 2011 and 2010:

|   | 2012              | 2011              | 2010              |
|---|-------------------|-------------------|-------------------|
| Cost of goods sold                                      | \$ 12,413         | \$ 9,762          | \$ 6,776          |
| Research and development                                | 102,413           | 104,704           | 82,097            |
| Selling, general and administrative                     | 116,217           | 102,736           | 93,923            |
| Total share-based compensation expense                  | 231,043           | 217,202           | 182,796           |
| Tax benefit related to share-based compensation expense | 61,287            | 55,900            | 42,362            |
| Reduction in income                                     | <u>\$ 169,756</u> | <u>\$ 161,302</u> | <u>\$ 140,434</u> |

Included in share-based compensation expense for the years ended December 31, 2012, 2011 and 2010 was compensation expense related to non-qualified stock options of \$155.2 million, \$154.4 million and \$142.6 million, respectively. Share-based compensation cost included in inventory was \$1.2 million and \$2.0 million at December 31, 2012 and 2011, respectively. We do not recognize a deferred tax asset for excess tax benefits that have not been realized and have adopted the tax law method as its accounting policy regarding the ordering of tax benefits to determine whether an excess tax benefit has been realized.

**Stock Options:** Cash received from stock option exercises for the years ended December 31, 2012, 2011 and 2010 was \$476.2 million, \$166.5 million and \$86.9 million, respectively, and the excess tax benefit recognized was \$49.3 million, \$31.1 million and \$36.1 million, respectively. As of December 31, 2012, there was \$299.9 million of total unrecognized compensation cost related to stock options granted under the plans. That cost will be recognized over an expected remaining weighted-average period of 2.3 years.

The weighted-average grant date fair value of the stock options granted during the years ended December 31, 2012, 2011 and 2010 was \$19.33 per share, \$17.09 per share and \$18.59 per share, respectively. We estimated the fair value of options granted using a Black-Scholes option pricing model with the following assumptions:

|                                      | 2012          | 2011          | 2010          |
|--------------------------------------|---------------|---------------|---------------|
| Risk-free interest rate              | 0.21% - 1.23% | 0.21% - 2.20% | 0.73% - 2.50% |
| Expected volatility                  | 27% - 30%     | 27% - 33%     | 30% - 37%     |
| Weighted average expected volatility | 28%           | 29%           | 33%           |
| Expected term (years)                | 1.3 - 5.17    | 1.8 - 5.2     | 2.7 - 5.1     |
| Expected dividend yield              | 0%            | 0%            | 0%            |

The risk-free interest rate is based on the U.S. Treasury zero-coupon curve. Expected volatility of stock option awards is estimated based on the implied volatility of our publicly traded options with settlement dates of six months. The use of implied volatility was based upon the availability of actively traded options on our common stock and the assessment that implied volatility is more representative of future stock price trends than historical volatility. The expected term of an

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

employee share option is the period of time for which the option is expected to be outstanding. We made a determination of expected term by analyzing employees' historical exercise experience from its history of grants and exercises in our option database and management estimates. Forfeiture rates are estimated based on historical data.

The following table summarizes all stock option activity for the year ended December 31, 2012:

|   | Options           | Weighted<br>Average Exercise<br>Price Per Option | Weighted<br>Average Remaining<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic Value<br>(In Thousands) |
|---|-------------------|--|--|--|
| Outstanding at<br>December 31, 2011                                 | 44,526,748        | \$ 52.55   | 6.8  | \$ 684,389                                     |
| Changes during the<br>Year:   |                   |  |  |  |
| Granted   | 9,776,128         | 72.80  |  |  |
| Exercised   | (10,306,894)      | 46.93  |  |  |
| Forfeited   | (1,283,347)       | 60.48  |  |  |
| Expired   | (120,725)         | 53.62  |  |  |
| Outstanding at<br>December 31, 2012                                 | <u>42,591,910</u> | <u>\$ 58.31</u>                                  | <u>6.9</u>   | <u>\$ 860,305</u>                              |
| Vested at December 31,<br>2012 or expected to<br>vest in the future | <u>41,681,582</u> | <u>\$ 58.09</u>                                  | <u>6.9</u>   | <u>\$ 850,811</u>                              |
| Vested at December 31,<br>2012                                      | <u>20,253,954</u> | <u>\$ 52.26</u>                                  | <u>5.2</u>   | <u>\$ 530,796</u>                              |

The total fair value of shares vested during the years ended December 31, 2012, 2011 and 2010 was \$144.1 million, \$162.8 million and \$149.0 million, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2012, 2011 and 2010 was \$293.5 million, \$147.9 million and \$109.6 million, respectively. We primarily utilize newly issued shares to satisfy the exercise of stock options.

Stock options granted to executives at the vice-president level and above under the Plan, formerly the 1998 Stock Incentive Plan, after September 18, 2000, contained a reload feature which provided that if (1) the optionee exercises all or any portion of the stock option (a) at least six months prior to the expiration of the stock option, (b) while employed by the Company and (c) prior to the expiration date of the Plan and (2) the optionee pays the exercise price for the portion of the stock option exercised or the minimum statutory applicable withholding taxes by using common stock owned by the optionee for at least six months prior to the date of exercise, the optionee shall be granted a new stock option under the Plan on the date all or any portion of the stock option is exercised to purchase the number of shares of common stock equal to the number of shares of common stock exchanged by the optionee. The reload stock option is exercisable on the same terms and conditions as apply to the original stock option except that

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

(x) the reload stock option will become exercisable in full on the day which is six months after the date the original stock option is exercised, (y) the exercise price shall be the fair value (as defined in the Plan) of the common stock on the date the reload stock option is granted and (z) the expiration of the reload stock option will be the date of expiration of the original stock option. As of December 31, 2012, 65,144 options that contain the reload features noted above are still outstanding and are included in the tables above. The Plan was amended to eliminate the reload feature for all stock options granted on or after October 1, 2004.

*Restricted Stock Units:* We issue restricted stock units, or RSUs, under our equity program in order to provide an effective incentive award with a strong retention component. Equity awards may, at the option of employee participants, be divided between stock options and RSUs. The employee may choose between alternate Company defined mixes of stock options and RSUs, with the number of RSUs to be granted based on a three-to-one ratio of stock options to RSUs. Information regarding the Company's RSUs for the years ended December 31, 2012 and 2011 is as follows:

| Nonvested RSUs                 | Share<br>Equivalent | Weighted<br>Average<br>Grant Date<br>Fair Value |
|--------------------------------|---------------------|---|
| Nonvested at December 31, 2011 | 3,019,943           | \$ 57.23  |
| Changes during the period:     |                     |   |
| Granted                        | 2,092,994           | 73.77   |
| Vested                         | (435,871)           | 41.98   |
| Forfeited                      | (214,104)           | 62.95   |
| Nonvested at December 31, 2012 | <u>4,462,962</u>    | <u>\$ 66.20</u>                                 |

As of December 31, 2012, there was \$176.5 million of total unrecognized compensation cost related to non-vested awards of RSUs. That cost is expected to be recognized over a weighted-average period of 1.7 years. The Company primarily utilizes newly issued shares to satisfy the vesting of RSUs.

**Performance-Based Restricted Stock Units:** The Company's performance-based restricted stock units vest contingent upon the achievement of pre-determined performance-based milestones

**CELGENE CORPORATION AND SUBSIDIARIES**  
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typically related to product development. The following table summarizes the Company's performance-based restricted stock unit activity for the year ended December 31, 2012:

| Nonvested Performance-Based RSUs | Share<br>Equivalent | Weighted<br>Average<br>Grant Date<br>Fair Value |
|----------------------------------|---------------------|---|
| Nonvested at December 31, 2011   | 28,500              | \$ 60.81  |
| Changes during the period:       |                     |   |
| Granted                          | -                   | -   |
| Vested                           | -                   | -   |
| Forfeited                        | (3,000)             | 60.88   |
| Non-vested at December 31, 2012  | <u>25,500</u>       | <u>\$ 60.80</u>                                 |

As of December 31, 2012, there was \$0.7 million of total unrecognized compensation cost related to non-vested awards of performance-based RSUs that is expected to be recognized over a period of 1.0 years.

**15. Employee Benefit Plans**

We sponsor an employee savings and retirement plan, which qualifies under Section 401(k) of the Internal Revenue Code, as amended, or the Code, for its U.S. employees. Our contributions to the U.S. savings plan are discretionary and have historically been made in the form of our common stock (See Note 12). Such contributions are based on specified percentages of employee contributions up to 6% of eligible compensation or a maximum permitted by law. Total expense for contributions to the U.S. savings plans were \$19.3 million, \$20.7 million and \$14.4 million in 2012, 2011 and 2010, respectively. We also sponsor defined contribution plans in certain foreign locations.

Participation in these plans is subject to the local laws that are in effect for each country and may include statutorily imposed minimum contributions. The Company also maintains defined benefit plans in certain foreign locations for which the obligations and the net periodic pension costs were determined to be immaterial at December 31, 2012.

In 2000, the Company's Board of Directors approved a deferred compensation plan. The plan was frozen effective as of December 31, 2004, and no additional contributions or deferrals can be made to that plan. Accrued benefits under the frozen plan will continue to be governed by the terms under the tax laws in effect prior to the enactment of Section 409A. In February 2005, the Company's Board of Directors adopted the Celgene Corporation 2005 Deferred Compensation Plan, effective as of January 1, 2005, and amended the plan in February 2008. This plan operates as the Company's ongoing deferred compensation plan and is intended to comply with the American Jobs Creation Act of 2004, Section 409A. Eligible participants, which include certain top-level executives of the Company as specified by the plan, can elect to defer up to an amended 90% of the participant's base salary, 100% of cash bonuses and equity compensation allowed



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under Section 409A of the Code. Company contributions to the deferred compensation plan represent a match to certain participants' deferrals up to a specified percentage, which currently ranges from 10% to 20%, depending on the employee's position as specified in the plan, of the participant's base salary. The Company recorded expense of \$0.6 million, \$0.7 million and \$0.5 million related to the deferred compensation plans in 2012, 2011 and 2010, respectively. The Company's recurring matches are fully vested, upon contribution. All other Company contributions to the plan do not vest until the specified requirements are met. At December 31, 2012 and 2011, the Company had a deferred compensation liability included in other non-current liabilities in the Consolidated Balance Sheets of approximately \$59.8 million and \$50.8 million, respectively, which included the participant's elected deferral of salaries and bonuses, the Company's matching contribution and earnings on deferred amounts as of that date. The plan provides various alternatives for the measurement of earnings on the amounts participants defer under the plan. The measuring alternatives are based on returns of a variety of funds that offer plan participants the option to spread their risk across a diverse group of investments.

In 2003, the Company established a Long-Term Incentive Plan, or LTIP, designed to provide key officers and executives with performance-based incentive opportunities contingent upon achievement of pre-established corporate performance objectives covering a three-year period. We currently have three separate three-year performance cycles running concurrently ending December 31, 2013, 2014 and 2015. Performance measures for the performance cycle ending in 2013 are based on the following components in the last year of the three-year cycle: 25% on non-GAAP earnings per share; 25% on non-GAAP net income; and 50% on total non-GAAP revenue, as defined. The performance cycles ending in 2014 and 2015 are based on the following components: 37.5% on non-GAAP earnings per share; 37.5% on total non-GAAP revenue, as defined; and 25% on relative total shareholder return, which is a measurement of our stock price performance during the year compared with a group of other companies in the biopharmaceutical industry.

Payouts may be in the range of 0% to 200% of the participant's salary for the LTIPs. The estimated payout for the concluded 2012 Plan is \$8.8 million, which is included in accrued expenses at December 31, 2012, and the maximum potential payout, assuming maximum objectives are achieved for the 2013, 2014 and 2015 Plans are \$18.4 million, \$19.6 million and \$22.6 million, respectively. Such awards are payable in cash or common stock or a mixture of cash and common stock, which will be determined by the Compensation Committee at the time of award delivery. For awards payable in common stock, the number of shares is determined using the average closing price for the 30 trading days prior to the beginning of the cycle. Payments made in common stock are restricted from trading for a period of three years. We accrue the long-term incentive liability over each three-year cycle. Prior to the end of a three-year cycle, the accrual is based on an estimate of our level of achievement during the cycle. Upon a change in control, participants will be entitled to an immediate payment equal to their target award or, if higher, an award based on actual performance through the date of the change in control. For the years ended December 31, 2012, 2011 and 2010, we recognized expense related to the LTIP of \$10.1 million, \$12.0 million and \$8.1 million, respectively.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

**16. Income Taxes**

The income tax provision is based on income before income taxes as follows:

|                            | 2012                | 2011                | 2010                |
|----------------------------|---------------------|---------------------|---------------------|
| U.S.                       | \$ 279,562          | \$ 416,841          | \$ 233,635          |
| Non-U.S.                   | 1,401,929           | 1,002,681           | 778,975             |
| Income before income taxes | <u>\$ 1,681,491</u> | <u>\$ 1,419,522</u> | <u>\$ 1,012,610</u> |

For the years ended December 31, 2012, 2011, and 2010, U.S. income before income taxes reflects charges related to share-based compensation, up-front collaboration payments, and acquisitions. These charges were less significant outside the U.S.

The provision (benefit) for taxes on income is as follows:

|                                   | 2012              | 2011              | 2010              |
|-----------------------------------|-------------------|-------------------|-------------------|
| United States:                    |                   |                   |                   |
| Taxes currently payable:          |                   |                   |                   |
| Federal                           | \$ 101,505        | \$ 100,834        | \$ 184,730        |
| State and local                   | (31,803)          | 33,227            | 9,926             |
| Deferred income taxes             | 107,345           | (67,166)          | (99,581)          |
| Total U.S. tax provision          | <u>177,047</u>    | <u>66,895</u>     | <u>95,075</u>     |
| International:                    |                   |                   |                   |
| Taxes currently payable           | 55,411            | 53,827            | 41,685            |
| Deferred income taxes             | (7,147)           | (18,656)          | (4,342)           |
| Total international tax provision | <u>48,264</u>     | <u>35,171</u>     | <u>37,343</u>     |
| Total provision                   | <u>\$ 225,311</u> | <u>\$ 102,066</u> | <u>\$ 132,418</u> |

Amounts are reflected in the preceding tables based on the location of the taxing authorities. We do not provide for U.S. federal or state income taxes on unremitted earnings of our international subsidiaries that are indefinitely invested outside the United States. As of December 31, 2012, we have not made a U.S. tax provision on \$4.300 billion of unremitted earnings of our international subsidiaries. As these earnings are expected to be reinvested overseas indefinitely, it is not practicable to compute the estimated deferred tax liability on these earnings.

Deferred taxes arise because of different treatment between financial statement accounting and tax accounting, known as temporary differences. We record the tax effect on these temporary differences as deferred tax assets (generally items that can be used as a tax deduction or credit in future periods) or deferred tax liabilities (generally items for which we received a tax deduction but that have not yet been recorded in the Consolidated Statements of Income). We periodically evaluate the likelihood of the realization of deferred tax assets, and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We consider many factors when assessing the likelihood of future realization of deferred

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

tax assets, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, the carryforward periods available to us for tax reporting purposes, tax planning strategies and other relevant factors. Significant judgment is required in making this assessment. At December 31, 2012 and 2011, it was more likely than not that we would realize our deferred tax assets, net of valuation allowances. The principal valuation allowance relates to Swiss deferred tax assets.

During 2012, we concluded that approximately \$900.0 million of our foreign earnings may not be required for use in offshore operations and may be available for use in the United States. These earnings are no longer treated as permanently reinvested, and accordingly, we recorded a deferred tax liability of \$316.5 million for the estimated U.S. federal and state income taxes that may be incurred should these earnings be repatriated. In drawing this conclusion, we considered our future sources of funds as well as our global operating and strategic liquidity needs, including common share repurchase activities and expansion of our commercial, research, manufacturing and administrative infrastructure worldwide.

At December 31, 2012 and 2011 the tax effects of temporary differences that give rise to deferred tax assets and liabilities were as follows:

|   | 2012       |                     | 2011       |                     |
|---|------------|---------------------|------------|---------------------|
|   | Assets     | Liabilities         | Assets     | Liabilities         |
| Federal and state NOL carryforwards                           | \$ 12,630  | \$ -                | \$ 38,539  | \$ -                |
| Deferred revenue  | 2,313      | -                   | 20,423     | -                   |
| Capitalized research expenses                                 | 37,114     | -                   | 25,793     | -                   |
| Tax credit carryforwards                                      | 4,111      | -                   | 6,811      | -                   |
| Non-qualified stock options                                   | 164,416    | -                   | 132,617    | -                   |
| Plant and equipment, primarily<br>differences in depreciation | -          | (13,590)            | -          | (18,245)            |
| Inventory   | 6,271      | -                   | 9,744      | -                   |
| Other assets  | 26,749     | (9,260)             | 60,892     | (9,394)             |
| Intangibles   | 187,190    | (1,069,227)         | 222,395    | (1,175,765)         |
| Accrued and other expenses                                    | 116,068    | -                   | 93,503     | -                   |
| Unremitted earnings   | -          | (316,545)           | -          | -                   |
| Unrealized (gains) losses on securities                       | 17,319     | -                   | 1,576      | -                   |
| Subtotal  | 574,181    | (1,408,622)         | 612,293    | (1,203,404)         |
| Valuation allowance   | (41,709)   | -                   | (33,764)   | -                   |
| Total deferred taxes  | \$ 532,472 | \$ (1,408,622)      | \$ 578,529 | \$ (1,203,404)      |
| Net deferred tax asset (liability)                            |            | <u>\$ (876,150)</u> |            | <u>\$ (624,875)</u> |

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

At December 31, 2012 and 2011, deferred tax assets and liabilities were classified on the Company's balance sheet as follows:

|                                    | 2012         | 2011         |
|------------------------------------|--------------|--------------|
| Current assets                     | \$ 93,168    | \$ 116,751   |
| Other assets (non-current)         | 49,100       | 33,396       |
| Current liabilities                | (52)         | -            |
| Other non-current liabilities      | (1,018,366)  | (775,022)    |
| Net deferred tax asset (liability) | \$ (876,150) | \$ (624,875) |

Reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

| Percentages                         | 2012   | 2011   | 2010   |
|-------------------------------------|--------|--------|--------|
| U.S. statutory rate                 | 35.0 % | 35.0 % | 35.0 % |
| Foreign tax rate differences        | (28.0) | (21.1) | (21.8) |
| Unremitted earnings                 | 18.8   | -      | -      |
| State taxes, net of federal benefit | 1.1    | 0.7    | -      |
| Change in valuation allowance       | 0.4    | -      | (1.9)  |
| Acquisition related differences     | 3.8    | (3.5)  | 1.2    |
| Resolution of certain tax positions | (19.3) | (2.5)  | (1.2)  |
| Other                               | 1.6    | (1.4)  | 1.8    |
| Effective income tax rate           | 13.4 % | 7.2 %  | 13.1 % |

We have operations in many foreign tax jurisdictions, which impose income taxes at different rates than the U.S. The impact of these rate differences is included in the foreign tax rate differences that we disclose in our reconciliation of the U.S. statutory income tax rate to our effective tax rate. The benefit related to foreign tax rate differences primarily results from our commercial operations in Switzerland, which include significant research and development and manufacturing for worldwide markets. We operate under an income tax holiday in Switzerland through 2015 that exempts us from Swiss income taxes on most of our operations in Switzerland. The impact of the Swiss tax holiday is reflected in our effective tax rate. The difference between the maximum statutory Swiss income tax rate (approximately 21% in 2012, and 22% in 2011 and 2010) and our Swiss income tax rate under the tax holiday resulted in a reduction in the 2012, 2011 and 2010 effective tax rates of 26.6, 20.2 and 15.8 percentage points, respectively. The increase in benefits reflected in the foreign tax rate differences from 2010 to 2012 results from growth in our Non-US operations and an increase in the proportion of consolidated income before income taxes from Non-U.S. operations.

At December 31, 2012, we had federal net operating loss, or NOL, carryforwards of \$3.5 million and combined state NOL carryforwards of approximately \$380.8 million that will expire in the years 2013 through 2032. We also have research and experimentation credit carryforwards of

**CELGENE CORPORATION AND SUBSIDIARIES**  
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approximately \$13.9 million that will expire in the years 2017 through 2030. Excess tax benefits related to stock option deductions incurred after December 31, 2005 are required to be recognized in the period in which the tax deduction is realized through a reduction of income taxes payable. As a result, we have not recorded deferred tax assets for certain stock option deductions included in our state NOL carryforwards and research and experimentation credit carryforwards. At December 31, 2012, deferred tax assets have not been recorded on state NOL carryforwards of approximately \$137.8 million and for research and experimentation credits of approximately \$8.8 million. These stock option tax benefits will be recorded as an increase in additional paid-in capital when realized.

We realized stock option deduction benefits in 2012, 2011 and 2010 for income tax purposes and have increased additional paid-in capital in the amount of approximately \$55.8 million, \$25.1 million and \$32.5 million, respectively. We have recorded deferred income taxes as a component of accumulated other comprehensive income resulting in a deferred income tax asset at December 31, 2012 of \$17.3 million and a deferred income tax asset at December 31, 2011 of \$1.6 million.

Our tax returns are under routine examination in many taxing jurisdictions. The scope of these examinations includes, but is not limited to, the review of our taxable presence in a jurisdiction, our deduction of certain items, our claims for research and development credits, our compliance with transfer pricing rules and regulations and the inclusion or exclusion of amounts from our tax returns as filed. During 2012, we settled an examination with the U.S. Internal Revenue Service, or the IRS, for the years ended December 31, 2006, 2007 and 2008. Our U.S. federal income tax returns have now been audited by the IRS through the year ended December 31, 2008. Tax returns for the years ended December 31, 2009, 2010, and 2011 are currently under examination by the IRS. We are also subject to audits by various state and foreign taxing authorities, including, but not limited to, most U.S. states and major European and Asian countries where we have operations.

We regularly reevaluate our tax positions and the associated interest and penalties, if applicable, resulting from audits of federal, state and foreign income tax filings, as well as changes in tax law (including regulations, administrative pronouncements, judicial precedents, etc.) that would reduce the technical merits of the position to below more likely than not. We believe that our accruals for tax liabilities are adequate for all open years. Many factors are considered in making these evaluations, including past history, recent interpretations of tax law and the specifics of each matter. Because tax regulations are subject to interpretation and tax litigation is inherently uncertain, these evaluations can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. We apply a variety of methodologies in making these estimates and assumptions, which include studies performed by independent economists, advice from industry and subject experts, evaluation of public actions taken by the IRS and other taxing authorities, as well as our industry experience. These evaluations are based on estimates and assumptions that have been deemed reasonable by management. However, if management's estimates are not representative of actual outcomes, our results of operations could be materially impacted.

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Unrecognized tax benefits, generally represented by liabilities on the consolidated balance sheet and all subject to tax examinations, arise when the estimated benefit recorded in the financial statements differs from the amounts taken or expected to be taken in a tax return because of the uncertainties described above. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

|   | <u>2012</u>       | <u>2011</u>       |
|---|-------------------|-------------------|
| Balance at beginning of year                    | \$ 596,811        | \$ 540,340        |
| Increases related to prior year tax positions   | -                 | 1,623             |
| Decreases related to prior year tax positions   | -                 | (9,115)           |
| Increases related to current year tax positions | 38,068            | 91,171            |
| Settlements                                     | (450,595)         | -                 |
| Lapse of statute                                | <u>(9,571)</u>    | <u>(27,208)</u>   |
| Balance at end of year                          | <u>\$ 174,713</u> | <u>\$ 596,811</u> |

These unrecognized tax benefits relate primarily to issues common among multinational corporations. If recognized, unrecognized tax benefits of approximately \$157.9 million would have a net impact on the effective tax rate. We account for interest and penalties related to uncertain tax positions as part of our provision for income taxes. Accrued interest at December 31, 2012 and 2011 is approximately \$18.0 million and \$53.2 million, respectively.

During 2012, we settled examinations with various taxing authorities related to tax positions taken in prior years. The settlements resulted in a decrease in our gross unrecognized tax benefits of \$450.6 million, exclusive of interest, and a reduction to income tax expense of \$318.6 million. The decrease in unrecognized tax benefits and the reduction to income tax expense reflect the impact of the settlements on tax returns filed in various taxing jurisdictions for the years examined as well as certain adjustments to unrecognized tax benefits for years subsequent to the examination period. We have also recorded changes in the liability for unrecognized tax benefits for prior years related to ongoing income tax audits in various taxing jurisdictions.

The liability for unrecognized tax benefits is expected to increase in the next 12 months relating to operations occurring in that period. Any settlements of examinations with taxing authorities or statute of limitations expirations would likely result in a decrease in our unrecognized tax benefits. Our estimates of tax benefits and potential tax benefits may not be representative of actual outcomes, and variation from such estimates could materially affect our financial statements in the period of settlement or when the statutes of limitations expire.

**CELGENE CORPORATION AND SUBSIDIARIES**  
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**17. Collaboration Agreements**

We have entered into a variety of alliances in the ordinary course of our business. Although we do not consider any individual alliance to be material, the following is a brief description of certain of the more notable alliances:

*Novartis Pharma AG:* We licensed the worldwide rights (excluding Canada) regarding certain chirally pure forms of methylphenidate for FOCALIN® and FOCALIN XR® to Novartis. We also licensed to Novartis the rights related to long-acting formulations of methylphenidate and dex-methylphenidate products which are used in FOCALIN XR® and RITALIN LA®. As a result of the grant of these licenses we sell FOCALIN® to Novartis and receive royalties of between 30% and 35% on their sales of FOCALIN XR® and RITALIN LA®. Under the agreement, we have received upfront and regulatory achievement milestone payments totaling \$55.0 million.

The agreement will continue until the later of (i) the tenth anniversary of the first commercial launch on a country-by-country basis or (ii) when the last applicable patent expires with respect to that country. At the expiration date, we will grant Novartis a perpetual, non-exclusive, royalty-free license to make, have made, use, import and sell products using the dex-methylphenidate and long-acting formulation technology.

The agreement may be terminated by Novartis upon 12 months' prior written notice or by either party upon, among other things, the material breach of the other or in the event of withdrawal of the dex-methylphenidate product or RITALIN® product from the market because of regulatory mandate.

If the agreement is terminated by us, then all licenses granted to Novartis under the agreement will terminate and Novartis will grant us a non-exclusive license to certain of their intellectual property related to the compounds and products. If the agreement is terminated by Novartis then all licenses granted to Novartis under the agreement will terminate.

When generic versions of long-acting methylphenidate hydrochloride and dexmethylphenidate hydrochloride enter the market, we expect Novartis' sales of RITALIN LA® and FOCALIN XR® products to decrease and therefore its royalties under this agreement to also decrease. In January 2012, Actavis Group announced the launch of a generic version of RITALIN LA®.

*Array BioPharma Inc.:* We have a research collaboration agreement with Array BioPharma Inc., or Array, focused on the discovery, development and commercialization of novel therapeutics in cancer and inflammation. As part of this agreement, we made payments to date in the aggregate amount of \$59.0 million, which were recorded as research and development expense, in return for an option to purchase exclusive worldwide rights for compounds developed against up to two research targets defined in the agreement. Array will be responsible for all discovery and clinical development through phase I or phase IIa for each compound. Potential milestone payments for each compound of approximately \$200.0 million (most of which are payable subsequent to exercise of the relevant option) if certain discovery, development and regulatory milestones are

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

achieved, and \$300.0 million if certain commercial milestones are achieved, as well as royalties on net sales.

During 2012 we exercised our option to extend the term of the agreement for an additional year. Our option will now terminate upon the earlier of (i) a termination of the agreement by its terms, (ii) the date we have exercised our options for compounds developed against two of the four research targets identified, or (iii) September 21, 2013. We may unilaterally extend the option term for an additional one-year term until September 21, 2014. During 2012, we made a \$3.0 million payment to Array in order to extend the research activities on one of the compounds.

If we exercise the options for each compound, upon the expiration of the research collaboration agreement under certain circumstances, Array will grant us a fully paid-up, royalty-free license to use certain intellectual property of Array to market and sell the compounds and products developed under the agreement.

*Acceleron Pharma:* We entered into a worldwide strategic collaboration agreement with Acceleron for the joint development and commercialization of sotatercept, or ACE-011, currently being studied for treatment of renal anemia. The collaboration agreement, as amended, combines both companies' resources and commitment to developing products for the treatment of cancer and cancer-related bone loss, and expands the joint development, manufacturing and commercialization of Acceleron's products to include anemia exclusivity. Under the terms of the ACE-011 agreement, we and Acceleron will jointly develop, manufacture and commercialize Acceleron's products for the treatment of bone loss. We made a payment to Acceleron in February 2008 of \$50.0 million, which included a \$5.0 million equity investment in Acceleron Series C-1 Convertible Preferred Stock, with the remainder recorded as research and development expense. In December 2011, we made a \$25.0 million equity investment in Acceleron Series F Convertible Preferred Stock. In the event of an initial public offering of Acceleron, we will purchase a minimum of \$7.0 million of Acceleron common stock. We have agreed to pay all development costs related to ACE-011 incurred after January 1, 2013.

Acceleron is eligible to receive development, regulatory approval and sales-based milestones of up to \$367.0 million for the ACE-011 program and up to an additional \$348.0 million for each of three specific discovery stage programs. The parties also agreed to co-promote the products under the ACE-011 agreement in North America. Acceleron will receive tiered royalties on worldwide net sales upon the commercialization of a development compound. We made a \$7.0 million development milestone payment to Acceleron in April 2011 for the initiation of enrollment into a phase II study for chemotherapy-induced anemia.

In August 2011, we also entered into a collaboration, license and option agreement with Acceleron, for the joint development and commercialization of ACE-536 for the treatment of anemia. The ACE-536 agreement also includes an option for future Acceleron anemia programs. The ACE-536 agreement provides us with an exclusive, worldwide, royalty-bearing license to the ACE-536 program and future Acceleron programs for the treatment of anemia. The parties also agreed to co-promote the products under the ACE-536 agreement in the United States, Canada and Mexico.



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In connection with the ACE-536 agreement, we made a payment to Acceleron in the amount of \$25.0 million. We have also agreed to pay all development costs incurred after January 1, 2013. Acceleron is eligible to receive development, regulatory approval and sales-based milestones of up to \$217.5 million for the ACE-536 program and up to an additional \$170.8 million for the first discovery stage program, \$148.8 million for the second discovery stage program and \$125.4 million for each additional discovery stage program thereafter. In October 2011, we made a \$7.5 million milestone payment for the initiation of a phase I clinical study of ACE-536. A \$10.0 million milestone payment will be made for the January 2013 initiation of a phase II clinical study to evaluate ACE-536 for the treatment of anemia in patients with myelodysplastic syndromes. Acceleron will receive tiered royalties on worldwide net sales upon the commercialization of a development compound.

The agreements for ACE-011 and ACE-536 may be terminated by us, at our sole discretion, at any time for the ACE-011 agreement, and, with respect to the ACE-536 agreement, after completion of the initial phase II clinical trials, or by either party, among other things, upon a material breach by the other party.

*GlobeImmune, Inc.:* We entered into a collaboration and option agreement with GlobeImmune Inc., or GlobeImmune, as amended, focused on the discovery, development and commercialization of novel therapeutics in cancer. As part of this agreement, we made a payment in May 2009 of \$30.0 million, which was recorded as research and development expense, in return for the option to license certain compounds and products based on the GI-4000, GI-6200, GI-3000 and GI-6300 oncology drug candidate programs, as well as oncology compounds and products resulting from future programs controlled by GlobeImmune. If the option is exercised, GlobeImmune will be entitled to receive potential milestone payments of approximately \$230.0 million for the GI-4000 program, \$145.0 million for each of the GI-6200 and GI-3000 programs and \$161.0 million for each of the GI-6300 program and each additional future program if certain development, regulatory and sales-based milestones are achieved. GlobeImmune will also receive tiered royalties on worldwide net sales.

Our options with respect to the GI-4000, GI-6200, GI-3000 and GI-6300 oncology drug candidate programs will terminate if we do not exercise our respective options after delivery of certain reports from GlobeImmune on the completed clinical trials with respect to each drug candidate program. If we do not exercise our options with respect to any drug candidate program or future program, our option with respect to the oncology products resulting from future programs controlled by GlobeImmune will terminate three years after the last of the options with respect to the GI-4000, GI-6200, GI-3000 and GI-6300 oncology drug candidate programs terminates.

*Agios Pharmaceuticals, Inc.:* On April 14, 2010, we entered into a discovery and development collaboration and license agreement with Agios Pharmaceuticals, Inc., or Agios, which focuses on cancer metabolism targets and the discovery, development and commercialization of associated therapeutics. As part of the agreement, as amended, we paid Agios \$121.2 million, which was recorded by us as research and development expense. We also made an \$8.8 million equity investment in Agios Series B Convertible Preferred Stock. In October 2011, we made a \$20.0 million payment to Agios for a one year extension of our oncology collaboration and

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licensing agreement and in November 2011, made a \$28.7 million investment in Agios series C-2 Convertible Preferred Stock. With respect to each product in a program that we choose to license, Agios could receive up to \$120.0 million upon achievement of certain milestones plus royalties on sales, and Agios may also participate in the development and commercialization of certain products in the United States. Agios may also receive a one-time milestone payment of \$25.0 million upon dosing of the final human subject in a phase II study, such payment to be made only once with respect to only one program. Our option will terminate on April 14, 2014.

We have determined that Agios is a variable interest entity; however, we are not the primary beneficiary of Agios. Although we would have the right to receive the benefits from the collaboration and license agreement, we do not have the power to direct the activities under the collaboration and license agreement as Agios has the decision-making authority for the Joint Steering Committee and Joint Research Committee until we exercise our option to license a product. Our interest in Agios is limited to our equity ownership and we do not have any obligations or rights to the future losses or returns of Agios beyond this ownership.

*Epizyme:* In April 2012, we entered into a collaboration and license agreement with Epizyme, Inc., or Epizyme, to discover, develop and commercialize novel therapeutic compounds by inhibiting histone methyltransferases, or HMTs, an important epigenetic target class.

Under the terms of the agreement, we made an upfront payment of \$65.0 million to Epizyme and also made a \$25.0 million equity investment in Epizyme Series C Preferred Stock. If the option is exercised, Epizyme could receive up to \$165.0 million in milestone payments associated with each Epizyme compound developed to inhibit each distinct HMT target under the collaboration plus royalties on sales. Under this agreement, we have the exclusive option to license rights to HMT targets outside the United States and each Epizyme compound associated with such target during the option term. Epizyme will have the sole responsibility to develop and commercialize compounds in the United States.

The option term expires on either July 9, 2015, or July 9, 2016 if we unilaterally extend the option term for a fourth year and pay an option extension fee. Further, if an HMT target or targets are selected then the agreement will expire upon the expiration of all applicable royalty terms under the agreement with respect to all licensed Epizyme compounds. Upon the expiration of the agreement, we will have a fully paid-up, royalty-free license to use Epizyme intellectual property to manufacture, market, use and sell such licensed Epizyme compounds developed under the agreement outside the United States.

*Other Collaboration Arrangements in 2012:* In addition to the collaboration arrangements described above, we entered into a number of collaborative arrangements during 2012 that resulted in \$34.5 million of assets for investments in equity or other assets and research and development expenses of \$113.5 million. These additional arrangements entered into during 2012 include the potential for future milestone payments of up to an aggregate \$1.420 billion related to the attainment of specified development and regulatory approval milestones over a period of several years. Our obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the

**CELGENE CORPORATION AND SUBSIDIARIES**  
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discontinuance of the programs. We do not consider these collaboration arrangements to be significant.

**18. Commitments and Contingencies**

*Leases:* The Company leases offices and research facilities under various operating lease agreements in the United States and international markets. At December 31, 2012, the non-cancelable lease terms for the operating leases expire at various dates between 2013 and 2023 and include renewal options. In general, the Company is also required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs associated with the leases.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2012 are:

|                              | <u>Operating<br/>Leases</u> |
|------------------------------|-----------------------------|
| 2013                         | \$ 50,532                   |
| 2014                         | 51,315                      |
| 2015                         | 44,400                      |
| 2016                         | 36,515                      |
| 2017                         | 30,248                      |
| Thereafter                   | <u>67,950</u>               |
| Total minimum lease payments | <u>\$ 280,960</u>           |

Total rental expense under operating leases was approximately \$41.9 million in 2012, \$48.1 million in 2011 and \$36.4 million in 2010.

*Lines of Credit:* The Company maintains lines of credit with several banks to support its hedging programs and to facilitate the issuance of bank letters of credit and guarantees on behalf of its subsidiaries. Lines of credit supporting the Company's hedging programs as of December 31, 2012 allowed the Company to enter into derivative contracts with settlement dates through 2015. As of December 31, 2012, the Company has entered into derivative contracts with net notional amounts totaling \$3.400 billion. Lines of credit facilitating the issuance of bank letters of credit and guarantees as of December 31, 2012 allowed the Company to have letters of credit and guarantees issued on behalf of its subsidiaries totaling \$59.4 million.

*Other Commitments:* The Company's obligations related to product supply contracts totaled \$64.1 million at December 31, 2012. The Company also owns an interest in three limited partnership investment funds and has committed to invest an additional \$5.4 million, which is callable any time within a ten-year period from the date of original investment.

In addition, under an agreement with the Institute for Advanced Health, later renamed The Chan Soon-Shiong Institute for Advanced Health, or the CSS Institute, we are committed to

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

make certain payments, including future contingent matching contributions and an additional milestone-based contingent contribution. The CSS Institute is a non-profit organization dedicated to research and technology development in personalized molecular medicine of which Dr. Patrick Soon-Shiong is the Chairman and Chief Executive Officer. Under the terms of the agreement, we made an initial contribution during 2011 with a value of \$41.0 million. The agreement provides for two additional contributions of \$25.0 million to be made by us based on like amounts of other third-party contributions being received by the CSS Institute and a \$25.0 million milestone-based contribution contingent upon the CSS Institute achieving specified results related to the collection of DNA data and genomic sequences and the initiation of research and development alliances to be achieved before December 31, 2015. During 2012, we terminated an associated agreement with aggregate remaining payments of up to \$150 million, resulting in the forfeiture of our previous rights under the agreement with the CSS Institute. In the event that payment of these contributions becomes probable, they will be recorded as selling general and administrative expense. No additional contributions have been made as of December 31, 2012.

*Collaboration Arrangements:* We have entered into certain research and development collaboration agreements, as identified in Note 17, with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial targets. Our obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. Due to the nature of these arrangements, the future potential payments are inherently uncertain, and accordingly no amounts have been recorded for these future potential payments in our accompanying Consolidated Balance Sheets at December 31, 2012 and 2011.

*Contingencies:* We believe we maintain insurance coverage adequate for our current needs. Our operations are subject to environmental laws and regulations, which impose limitations on the discharge of pollutants into the air and water and establish standards for the treatment, storage and disposal of solid and hazardous wastes. We review the effects of such laws and regulations on our operations and modify our operations as appropriate. We believe we are in substantial compliance with all applicable environmental laws and regulations.

***Legal Proceedings:***

We and certain of our subsidiaries are involved in various patent, trademark, commercial and other claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of business. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information requests from government authorities, and we have been subject to claims and other actions related to our business activities. While the ultimate outcome of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters may result in, among other things, modification of our business practices, product recalls, incurrence of costs and payment of

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

significant penalties, which may have a material adverse effect on our results of operations, cash flows or financial condition.

Pending patent proceedings include challenges to the scope, validity or enforceability of our patents relating to certain of our products or processes. Although we believe we have substantial defenses to these challenges with respect to all our material patents, there can be no assurance as to the outcome of these matters, and a loss in any of these cases could result in a loss of patent protection for the drug at issue, which could lead to a significant loss of sales of that product and could materially affect future results of operations.

Among the principal matters pending to which we are a party are the following:

In the fourth quarter of 2009, we received a Civil Investigative Demand, or CID, from the U.S. Federal Trade Commission, or the FTC. The FTC requested documents and other information relating to requests by generic companies to purchase our patented REVLIMID® and THALOMID® brand drugs in order to evaluate whether there is reason to believe that we have engaged in unfair methods of competition. In the first quarter of 2010, the State of Connecticut referenced the same issues as those referenced in the 2009 CID and issued a subpoena. In the fourth quarter of 2010, we received a second CID from the FTC relating to this matter. We continue to respond to requests for information.

In the first quarter of 2011, the United States Attorney's Office for the Central District of California informed us that they are investigating possible off-label marketing and improper payments to physicians in connection with the sales of THALOMID® and REVLIMID®. In the third quarter of 2012, we learned that two other United States Attorneys' offices (the Northern District of Alabama and the Eastern District of Texas) and various state Attorneys General are conducting related investigations. We are cooperating with these investigations.

**REVLIMID®:** We have publicly announced that we received a Notice Letter dated August 30, 2010, sent from Natco Pharma Limited of India ("Natco") notifying us of Natco's Abbreviated New Drug Application, or ANDA, which contains Paragraph IV certifications against certain of Celgene's patents that are listed in the U.S. Federal Drug Administration's, or FDA, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book") for REVLIMID® (lenalidomide). Under the Hatch-Waxman Act of 1984, a generic manufacturer may file an ANDA containing a certification (a "Paragraph IV certification") challenging the validity or infringement of a patent listed in the Orange Book. Natco's Notice letter alleges, among other things, that certain claims of United States Patent Nos. 5,635,517 (the "517 patent"), 6,045,501 (the "501 patent"), 6,315,720 (the "720 patent"), 6,555,554 (the "554 patent"), 6,561,976 (the "976 patent"), 6,561,977 (the "977 patent"), 6,755,784 (the "784 patent"), 7,119,106 (the "106 patent") and 7,465,800 (the "800 patent") are invalid, unenforceable, and/or not infringed. Natco's Notice Letter was sent in connection with its filing of an ANDA seeking permission from the FDA to market a generic version of 25mg, 15mg, 10mg and 5mg REVLIMID® capsules.

On October 8, 2010, we filed an infringement action in the United States District Court of New Jersey against Natco in response to the Notice Letter with respect to the '517 patent, the '501

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

patent, United States Patent No. 6,281,230 (the “’230 patent”), the ’720 patent, the ’554 patent, the ’976 patent, the ’977 patent, the ’784 patent, the ’106 patent and the ’800 patent.

Natco responded to our infringement action on November 18, 2010, with its Answer, Affirmative Defenses and Counterclaims. Natco has alleged (through Affirmative Defenses and Counterclaims) that the patents are invalid, unenforceable, and/or not infringed by Natco’s proposed generic products. After filing the infringement action, we learned the identity of Natco’s U.S. partner, Arrow International Limited (“Arrow”), and filed an amended complaint on January 7, 2011, adding Arrow as a defendant. On March 25, 2011, We filed a second amended complaint naming Natco, Arrow and Watson Laboratories, Inc. (a wholly-owned subsidiary of Actavis, Inc. (formerly known as Watson Pharmaceuticals, Inc.), which is Arrow’s parent) as defendants. Those three entities remain the current defendants in that action.

On June 12, 2012, we received a Second Notice Letter from Natco, notifying us of Natco’s submission in its ANDA of new, additional Paragraph IV certifications against the ’517 patent, the ’230 patent and United States Patent Nos. 7,189,740 (the “’740 patent”), 7,855,217 (the “’217 patent”) and 7,968,569 (the “’569 patent”). On July 20, 2012, we filed a new infringement action in the United States District Court of New Jersey against Natco, Arrow, Watson Laboratories, Inc. and Actavis, Inc. in response to the Second Notice Letter with respect to the ’517 patent, the ’230 patent, the ’740 patent, and the ’569 patent, as well as two non-Orange Book listed patents, United States Patent Nos. 7,977,357 (the “’357 patent”) and 8,193,219 (the “’219 patent”). Natco filed its Answer and Counterclaims on September 28, 2012. Natco’s counterclaims in the second action are similar to its counterclaims in the first action. In the second action, Natco added counterclaims against United States Patent No. 8,204,763 (the “’763 patent”), which Celgene has not asserted against Natco. Celgene has moved to dismiss those counterclaims related to the ’763 patent for lack of subject matter jurisdiction.

A revised Scheduling Order was entered by the Court on November 9, 2012, setting the close for fact discovery on August 14, 2013. A Markman hearing is currently expected to be fully briefed by the end of July 2013. Dates for a Markman hearing and trial have yet to be set.

We believe that Natco’s defenses and counterclaims are unlikely to be sustained and we intend to vigorously defend our patent rights. We believe it unlikely that Natco will prevail on each and every patent and patent claim subject to the lawsuits, and that all of the patent claims will be deemed to be invalid, unenforceable and/or not infringed. Accordingly, the ultimate outcome is not expected to have a material adverse effect on our financial condition or results of operations.

However, if Natco is successful in challenging our patents, and the FDA were to approve Natco’s ANDA with a comprehensive education and risk management program for a generic version of lenalidomide and a generic product were to be introduced, sales of REVLIMID® could be significantly reduced in the United States, which would have a material adverse effect on our results of operations, cash flows and financial condition.

**ABRAXANE®:** On December 14, 2011, Cephalon, Inc. and Acusphere, Inc. filed a complaint against us in the United States District Court for the District of Massachusetts, alleging, among

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

other things, that the making, using, selling, offering to sell, and importing of ABRAXANE® brand drug infringes claims of United States Patent No. RE40,493. Plaintiffs are seeking damages and injunctive relief. We intend to vigorously defend against this infringement suit. If the suit against us is successful, we may have to pay damages, ongoing royalties and may have to license rights from plaintiffs. However, we believe that (a) it is unlikely that the plaintiffs in this matter will prevail and (b) the ultimate outcome will not have a material adverse effect on our financial condition or results of operations.

**VIDAZA®:** On September 28, 2012, we were named as a defendant in a complaint filed by Ivax LLC (formerly Ivax Corporation) in the United States District Court for the Southern District of Florida. Ivax LLC alleges that we have infringed the claims of United States Patent No. 7,759,481 by making, using, and selling VIDAZA® brand drug in the United States. We filed an answer to this complaint on October 19, 2012. We filed a motion for judgment on the pleadings on November 15, 2012, to which Ivax LLC filed an opposition on December 7, 2012. We intend to vigorously defend against this infringement suit. If the suit against us is successful, we may have to pay damages, ongoing royalties or license rights from the plaintiff. However, we believe (a) that it is unlikely that the plaintiff in this matter will prevail and (b) that the ultimate outcome will not have a material adverse effect on our financial condition or results of operations.

**19. Geographic and Product Information**

*Operations by Geographic Area:* Revenues primarily consisted of sales of REVLIMID®, VIDAZA®, ABRAXANE®, THALOMID®, and ISTODAX®. Additional sources of revenue included a licensing agreement with Novartis, which entitles us to royalties on FOCALIN XR® and the entire RITALIN® family of drugs, the sale of services through our Cellular Therapeutics subsidiary and other miscellaneous licensing agreements.

| Revenues       | 2012         | 2011         | 2010         |
|----------------|--------------|--------------|--------------|
| United States  | \$ 3,169,132 | \$ 2,860,935 | \$ 2,188,562 |
| Europe         | 1,911,055    | 1,571,088    | 1,266,791    |
| All other      | 426,526      | 410,047      | 170,392      |
| Total revenues | \$ 5,506,713 | \$ 4,842,070 | \$ 3,625,745 |

| Long-Lived Assets (1)   | 2012       | 2011       |
|-------------------------|------------|------------|
| United States           | \$ 343,330 | \$ 299,561 |
| Europe                  | 221,458    | 197,204    |
| All other               | 13,574     | 9,277      |
| Total long lived assets | \$ 578,362 | \$ 506,042 |

(1) Long-lived assets consist of net property, plant and equipment.

**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

*Revenues by Product:* Total revenues from external customers by product for the years ended December 31, 2012, 2011 and 2010 were as follows:

|  | 2012                | 2011                | 2010                |
|--|---------------------|---------------------|---------------------|
| REVLIMID®                                  | \$ 3,766,640        | \$ 3,208,153        | \$ 2,469,183        |
| VIDAZA®                                    | 823,191             | 705,327             | 534,302             |
| ABRAXANE®                                  | 426,675             | 385,905             | 71,429              |
| THALOMID®                                  | 302,136             | 339,067             | 389,605             |
| ISTODAX®                                   | 50,001              | 30,921              | 15,781              |
| Other                                      | 16,956              | 30,317              | 28,138              |
| Total net product sales                    | 5,385,599           | 4,699,690           | 3,508,438           |
| Collaborative agreements and other revenue | 10,711              | 19,500              | 10,540              |
| Royalty revenue                            | 110,403             | 122,880             | 106,767             |
| Total revenue                              | <u>\$ 5,506,713</u> | <u>\$ 4,842,070</u> | <u>\$ 3,625,745</u> |

*Major Customers:* We sell our products primarily through wholesale distributors and specialty pharmacies in the United States, which account for a large portion of our total revenues. International sales are primarily made directly to hospitals, clinics and retail chains, many of which are government owned. In 2012, 2011 and 2010, only Amerisource Bergen accounted for more than 10% of our total revenue in at least one of those years and is summarized below. The percentage of amounts due from this customer compared to total net accounts receivable is also summarized below as of December 31, 2012 and 2011.

| Customer                 | Percent of Total Revenue |       |      | Percent of Net Accounts Receivable |      |
|--------------------------|--------------------------|-------|------|------------------------------------|------|
|                          | 2012                     | 2011  | 2010 | 2012                               | 2011 |
| Amerisource Bergen Corp. | 11.5%                    | 12.6% | 9.8% | 9.6%                               | 3.9% |



**CELGENE CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS – (Continued)**

**20. Quarterly Results of Operations (Unaudited)**

| 2012  | 1Q           | 2Q           | 3Q           | 4Q           | Year         |
|---|--------------|--------------|--------------|--------------|--------------|
| Total revenue                                     | \$ 1,273,288 | \$ 1,366,764 | \$ 1,419,251 | \$ 1,447,410 | \$ 5,506,713 |
| Gross profit (1)                                  | 1,172,979    | 1,264,738    | 1,313,391    | 1,335,367    | 5,086,475    |
| Income tax provision                              | 72,465       | 73,311       | 52,347       | 27,188       | 225,311      |
| Net income attributable to Celgene                | 401,537      | 367,373      | 424,155      | 263,115      | 1,456,180    |
| Net income per share: (2)                         |              |              |              |              |              |
| Basic   | \$ 0.92      | \$ 0.84      | \$ 0.99      | \$ 0.62      | \$ 3.38      |
| Diluted   | \$ 0.90      | \$ 0.82      | \$ 0.97      | \$ 0.61      | \$ 3.30      |
| Weighted average shares (in thousands)            |              |              |              |              |              |
| Basic   | 438,349      | 436,703      | 427,209      | 421,592      | 430,927      |
| Diluted   | 448,598      | 445,379      | 436,272      | 432,310      | 440,796      |
| 2011  | 1Q           | 2Q           | 3Q           | 4Q           | Year         |
| Total revenue                                     | \$ 1,125,281 | \$ 1,183,155 | \$ 1,249,737 | \$ 1,283,897 | \$ 4,842,070 |
| Gross profit (1)                                  | 956,341      | 1,027,885    | 1,124,473    | 1,165,132    | 4,273,831    |
| Income tax (benefit) provision                    | 31,722       | 39,203       | 39,657       | (8,516)      | 102,066      |
| Net income attributable to Celgene                | 255,590      | 279,398      | 372,984      | 410,178      | 1,318,150    |
| Net income per share attributable to Celgene: (2) |              |              |              |              |              |
| Basic   | \$ 0.55      | \$ 0.60      | \$ 0.83      | \$ 0.93      | \$ 2.89      |
| Diluted   | \$ 0.54      | \$ 0.59      | \$ 0.81      | \$ 0.91      | \$ 2.85      |
| Weighted average shares (in thousands)            |              |              |              |              |              |
| Basic   | 465,993      | 462,625      | 452,019      | 441,064      | 455,348      |
| Diluted   | 472,235      | 469,962      | 459,530      | 449,747      | 462,748      |

- (1) Gross profit is computed by subtracting cost of goods sold (excluding amortization of acquired intangible assets) from net product sales.
- (2) The sum of the quarters may not equal the full year due to rounding. In addition, quarterly and full year basic and diluted earnings per share are calculated separately.

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**CONCLUSION REGARDING THE EFFECTIVENESS OF DISCLOSURE CONTROLS AND PROCEDURES**

As of the end of the period covered by this Annual Report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Exchange Act Rules 13a-15(e) and 15d-15(e)) (the “Exchange Act”). Based on the foregoing evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to our management (including our Chief Executive Officer and Chief Financial Officer) to allow timely decisions regarding required disclosures.

**CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING**

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with U.S. generally accepted accounting principles.

Our 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 our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated 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 connection with the preparation of our annual consolidated financial statements, management has undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2012.

KPMG LLP, the independent registered public accounting firm that audited our consolidated financial statements included in this report, has issued their report on the effectiveness of internal control over financial reporting as of December 31, 2012, a copy of which is included herein.

## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Celgene Corporation:

We have audited Celgene Corporation and subsidiaries' internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Celgene Corporation and subsidiaries' management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the effectiveness of Celgene Corporation and subsidiaries' 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, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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 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 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, Celgene Corporation and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control-Integrated Framework issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Celgene Corporation and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, cash flows, and stockholders' equity for each of the years in the three-year period ended December 31, 2012, and our report dated February 15, 2013 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Short Hills, New Jersey

February 15, 2013

**ITEM 9B. *OTHER INFORMATION***

None.

**PART III**

**ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

Pursuant to Paragraph G(3) of the General Instructions to Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our definitive proxy statement (or an amendment to our Annual Report on Form 10-K) to be filed with the SEC within 120 days of the end of the fiscal year ended December 31, 2012 in connection with our 2013 Annual Meeting of Stockholders.

**ITEM 11. *EXECUTIVE COMPENSATION***

See Item 10.

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

See Item 10.

**ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE***

See Item 10.

**ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES***

See Item 10.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

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*(a) 3. Exhibit Index*

The following exhibits are filed with this report or incorporated by reference:

| Exhibit No. | Exhibit Description   |
|-------------|---|
| 2.1         | Agreement and Plan of Merger, dated as of November 18, 2007, among Pharmion Corporation, Celgene Corporation and Cobalt Acquisition LLC (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on November 19, 2007).  |
| 2.2         | Agreement and Plan of Merger dated as of June 30, 2010, among Celgene Corporation, Artistry Acquisition Corp. and Abraxis Bioscience, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on July 1, 2010).  |
| 3.1         | Certificate of Incorporation of the Company, as amended through February 16, 2006 (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005).  |
| 3.2         | Bylaws of the Company (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, dated September 16, 1996), as amended effective May 1, 2006 (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006), as further amended effective December 16, 2009 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 17, 2009), and as further amended effective February 17, 2010 (incorporated by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009). |
| 4.1         | Contingent Value Rights Agreement, dated as of October 15, 2010, between Celgene Corporation and American Stock Transfer & Trust Company, LLC, as trustee, including the Form of CVR Certificate as Annex A (incorporated by reference to Exhibit 4.1 to the Company's Form 8-A12B filed on October 15, 2010).  |
| 4.2         | Indenture, dated as of October 7, 2010, relating to the 2.450% Senior Notes due 2015, 3.950% Senior Notes due 2020 and 5.700% Senior Notes due 2040, between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 7, 2010).   |
| 4.3         | Indenture, dated as of August 9, 2012, relating to the 1.900% Senior Notes due 2017 and 3.250% Senior Notes due 2022, between the Company and The Bank of New York Mellon Trust Company, N.A., as trustee (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on August 9, 2012).   |
| 4.4         | Form of 2.450% Senior Notes due 2015 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 7, 2010).   |
| 4.5         | Form of 3.950% Senior Notes due 2020 (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on October 7, 2010).   |
| 4.6         | Form of 5.700% Senior Notes due 2040 (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed on October 7, 2010).   |
| 4.7         | Form of 1.900% Senior Notes due 2017 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on August 9, 2012).  |



| Exhibit No. | Exhibit Description   |
|-------------|---|
| 4.8         | Form of 3.250% Senior Notes due 2022 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on August 9, 2012).  |
| 10.1        | 1992 Long-Term Incentive Plan (incorporated by reference to Exhibit A to the Company's Proxy Statement dated May 30, 1997), as amended by Amendment No. 1 thereto, effective as of June 22, 1999 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002).   |
| 10.2        | 1995 Non Employee Directors' Incentive Plan (incorporated by reference to Exhibit A to the Company's Proxy Statement, dated May 24, 1999), as amended by Amendment No. 1 thereto, effective as of June 22, 1999 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002), as further amended by Amendment No. 2 thereto, effective as of April 18, 2000 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002), as further amended by Amendment No. 3 thereto, effective as of April 23, 2003 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005), as further amended by Amendment No. 4 thereto, effective as of April 5, 2005 (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 (No. 333-126296)), as amended by Amendment No. 5 thereto (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007), as further amended by Amendment No. 6 thereto (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008). |
| 10.3        | Form of Indemnification Agreement between the Company and each officer and director of the Company (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 1996).   |
| 10.4        | Amended and Restated Employment Agreement effective May 1, 2006 between the Company and Robert J. Hugin (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006), as amended by Amendment No. 1 thereto, effective as of December 31, 2008 (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2008), as further amended by Amendment No. 2 thereto, effective as of June 16, 2010 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on June 18, 2010).  |
| 10.5        | Celgene Corporation 2008 Stock Incentive Plan, as amended and restated as of June 17, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 18, 2009), as further amended by Amendment No. 1 thereto, effective as of April 13, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 20, 2011), as further amended by Amendment No. 2 thereto, effective as of June 13, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 15, 2012).   |

| Exhibit No. | Exhibit Description   |
|-------------|---|
| 10.6        | Development and License Agreement between the Company and Novartis Pharma AG, dated April 19, 2000 (incorporated by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000).   |
| 10.7        | Collaborative Research and License Agreement between the Company and Novartis Pharma AG, dated December 20, 2000 (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 2000).   |
| 10.8        | Celgene Corporation 2005 Deferred Compensation Plan, effective as of January 1, 2005 (incorporated by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004), as amended and restated, effective January 1, 2008 (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed on May 12, 2008).                        |
| 10.9        | Anthrogenesis Corporation Qualified Employee Incentive Stock Option Plan (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002).   |
| 10.10       | Distribution and Supply Agreement between SmithKline Beecham Corporation, d/b/a GlaxoSmithKline and Celgene Corporation, dated as of March 31, 2003 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2003).  |
| 10.11       | Technical Services Agreement among the Company, Celgene UK Manufacturing II, Limited (f/k/a Penn T Limited), Penn Pharmaceutical Services Limited and Penn Pharmaceutical Holding Limited, dated October 21, 2004 (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004).  |
| 10.12       | Lease Agreement between the Company and Powder Horn Associates, with respect to the Warren, New Jersey property, dated January 16, 1987 (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 dated July 24, 1987) (incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004).   |
| 10.13       | Finished Goods Supply Agreement between the Company and Penn Pharmaceutical Services Limited, dated September 8, 2004 (certain portions of the agreement have been redacted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment, which has been granted) (incorporated by reference to Exhibit 10.52 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005). |
| 10.14       | Distribution Services and Storage Agreement between the Company and Sharp Corporation, dated January 1, 2005 (certain portions of the agreement have been redacted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment, which has been granted) (incorporated by reference to Exhibit 10.53 to the Company's Annual Report on Form 10-K for the year ended December 31, 2005).          |

| Exhibit No. | Exhibit Description   |
|-------------|---|
| 10.15       | Non-Competition, Non-Solicitation and Confidentiality Agreement between Celgene Corporation and Dr. Patrick Soon-Shiong, dated as of June 30, 2010 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on July 1, 2010).   |
| 10.16       | Stockholders' Agreement among Celgene Corporation, Dr. Patrick Soon-Shiong, California Capital LP, Patrick Soon-Shiong 2009 GRAT 1, Patrick Soon-Shiong 2009 GRAT 2, Michele B. Soon-Shiong GRAT 1, Michele B. Soon-Shiong GRAT 2, Soon-Shiong Community Property Revocable Trust, California Capital Trust and Michele B. Chan Soon-Shiong, dated as of June 30, 2010 (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on July 1, 2010). |
| 10.17       | Letter Agreement between the Company and Jacquelyn A. Fouse, dated August 18, 2010 (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed on August 27, 2010).  |
| 10.18       | Credit Agreement among Celgene Corporation, the lender parties named therein, and Citibank, N.A., as administrative agent, dated as of September 2, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 6, 2011).  |
| 10.19*      | Celgene Corporation Management Incentive Plan (MIP) and Performance Plan.   |
| 10.20*      | Form of Stock Option Agreement  |
| 10.21*      | Form of Restricted Stock Unit Agreement   |
| 14.1        | Code of Ethics (incorporated by reference to Exhibit 14.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004).  |
| 21.1*       | List of Subsidiaries.   |
| 23.1*       | Consent of KPMG LLP.  |
| 24.1*       | Power of Attorney (included in Signature Page).   |
| 31.1*       | Certification by the Company's Chief Executive Officer.   |
| 31.2*       | Certification by the Company's Chief Financial Officer.   |
| 32.1*       | Certification by the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350.  |
| 32.2*       | Certification by the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350.  |
| 101*        | The following materials from Celgene Corporation's Annual Report on Form 10-K for the year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Income, (iii) the Consolidated Statements of Cash Flows, (iv) the Consolidated Statements of Stockholders' Equity and (v) Notes to Consolidated Financial Statements.  |

\* Filed herewith.

## SIGNATURES AND POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person or entity whose signature appears below constitutes and appoints Robert J. Hugin its true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for it and in its name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all contents and purposes as it might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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.

### CELGENE CORPORATION

By: /s/ Robert J. Hugin

Robert J. Hugin  
Chief Executive Officer

Date: February 15, 2013

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 dates indicated.

| <u>Signature</u>                                    | <u>Title</u>   | <u>Date</u>       |
|---|--|-------------------|
| <u>/s/ Robert J. Hugin</u><br>Robert J. Hugin       | Chairman of the Board;<br>Chief Executive Officer                          | February 15, 2013 |
| <u>/s/ Jacquelyn A. Fouse</u><br>Jacquelyn A. Fouse | Chief Financial Officer<br>(principal financial and accounting<br>officer) | February 15, 2013 |
| <u>/s/ Richard W. Barker</u><br>Richard W. Barker   | Director   | February 15, 2013 |
| <u>/s/ Michael D. Casey</u><br>Michael D. Casey     | Director   | February 15, 2013 |

| <u>Signature</u>                                      | <u>Title</u> | <u>Date</u>       |
|---|--------------|-------------------|
| <u>/s/ Carrie S. Cox</u><br>Carrie S. Cox             | Director     | February 15, 2013 |
| <u>/s/ Rodman L. Drake</u><br>Rodman L. Drake         | Director     | February 15, 2013 |
| <u>/s/ Michael A. Friedman</u><br>Michael A. Friedman | Director     | February 15, 2013 |
| <u>/s/ Gilla Kaplan</u><br>Gilla Kaplan               | Director     | February 15, 2013 |
| <u>/s/ James Loughlin</u><br>James Loughlin           | Director     | February 15, 2013 |
| <u>/s/ Ernest Mario</u><br>Ernest Mario               | Director     | February 15, 2013 |

**Celgene Corporation and Subsidiaries**  
**Schedule II – Valuation and Qualifying Accounts**

| Year ended December 31,          | Balance at<br>Beginning of<br>Year | Additions Charged<br>to Expense or<br>Sales | Other<br>Additions    | Deductions       | Balance at<br>End of Year |
|----------------------------------|------------------------------------|---|-----------------------|------------------|---------------------------|
|                                  | (In thousands)                     |   |                       |                  |                           |
| <b>2012</b>                      |                                    |   |                       |                  |                           |
| Allowance for doubtful accounts  | \$ 10,131                          | \$ 12,453                                   |                       | \$ 816           | \$ 21,768                 |
| Allowance for customer discounts | 8,724                              | 64,865 <sup>(1)</sup>                       | -                     | 62,369           | 11,220                    |
| Subtotal                         | 18,855                             | 77,318                                      | -                     | 63,185           | 32,988                    |
| Allowance for sales returns      | 8,974                              | 7,493 <sup>(1)</sup>                        |                       | 3,197            | 13,270                    |
| Total                            | <u>\$ 27,829</u>                   | <u>\$ 84,811</u>                            | <u>\$ -</u>           | <u>\$ 66,382</u> | <u>\$ 46,258</u>          |
| <b>2011</b>                      |                                    |   |                       |                  |                           |
| Allowance for doubtful accounts  | \$ 4,832                           | \$ 6,354                                    |                       | \$ 1,055         | \$ 10,131                 |
| Allowance for customer discounts | 8,272                              | 56,110 <sup>(1)</sup>                       | -                     | 55,658           | 8,724                     |
| Subtotal                         | 13,104                             | 62,464                                      | -                     | 56,713           | 18,855                    |
| Allowance for sales returns      | 4,779                              | 16,757 <sup>(1)</sup>                       |                       | 12,562           | 8,974                     |
| Total                            | <u>\$ 17,883</u>                   | <u>\$ 79,221</u>                            | <u>\$ -</u>           | <u>\$ 69,275</u> | <u>\$ 27,829</u>          |
| <b>2010</b>                      |                                    |   |                       |                  |                           |
| Allowance for doubtful accounts  | \$ 7,189                           | \$ (2,309)                                  | \$ 262 <sup>(2)</sup> | \$ 310           | \$ 4,832                  |
| Allowance for customer discounts | 3,598                              | 52,975 <sup>(1)</sup>                       | -                     | 48,301           | 8,272                     |
| Subtotal                         | 10,787                             | 50,666                                      | 262                   | 48,611           | 13,104                    |
| Allowance for sales returns      | 7,360                              | 6,440 <sup>(1)</sup>                        | 815 <sup>(2)</sup>    | 9,836            | 4,779                     |
| Total                            | <u>\$ 18,147</u>                   | <u>\$ 57,106</u>                            | <u>\$ 1,077</u>       | <u>\$ 58,447</u> | <u>\$ 17,883</u>          |

(1) Amounts are a reduction from gross sales.

(2) Other Additions represent valuation account balances assumed in the 2010 acquisition of Abraxis.

## LIST OF SUBSIDIARIES

| Name  | State or Other Jurisdiction of Incorporation |
|---|--|
| Celgene Inc.  | Canada                                       |
| Abraxis Bioscience Australia Pty Ltd.                         | Australia                                    |
| Abraxis BioScience International Holding Company, Inc.        | Delaware                                     |
| Abraxis Bioscience Limited                                    | United Kingdom                               |
| Abraxis BioScience Puerto Rico, LLC                           | Puerto Rico                                  |
| Abraxis BioScience Service (Beijing) Co. Ltd. Beijing, P.R.C. | People's Republic of China                   |
| Abraxis BioScience, LLC                                       | Delaware                                     |
| Abraxis Health, Inc.  | Delaware                                     |
| Anthrogenesis Corporation                                     | New Jersey                                   |
| Cabrellis Pharmaceuticals Corp.                               | Delaware                                     |
| Celgene Alpine Investment. Co., LLC                           | Delaware                                     |
| Celgene Ab  | Finland                                      |
| Celgene AB  | Sweden                                       |
| Celgene ApS   | Denmark                                      |
| Celgene AS  | Norway                                       |
| Celgene BV  | Netherlands                                  |
| Celgene BVBA  | Belgium                                      |
| Celgene Chemicals Sarl  | Switzerland                                  |
| Celgene Co.   | South Korea                                  |
| Celgene Edinburgh Finance                                     | Scotland                                     |
| Celgene Europe, Limited                                       | United Kingdom                               |
| Celgene European Investment Co. LLC                           | Delaware                                     |
| Celgene Financing Company, LLC                                | Delaware                                     |
| Celgene GmbH  | Austria                                      |
| Celgene GmbH  | Germany                                      |
| Celgene GmbH  | Switzerland                                  |
| Celgene Holdings East Corp.                                   | New Jersey                                   |
| Celgene Holdings Sarl   | Switzerland                                  |
| Celgene International Holdings Corporation                    | Delaware                                     |
| Celgene International SARL                                    | Switzerland                                  |
| Celgene International, Inc.                                   | Delaware                                     |
| Celgene Kft   | Hungary                                      |
| Celgene KK  | Japan  |
| Celgene Limited   | Hong Kong                                    |
| Celgene Limited   | Ireland                                      |
| Celgene Limited   | Taiwan                                       |
| Celgene Limited   | United Kingdom                               |
| Celgene Ilac Pazarlama ve Tic.Ltd. Sti.                       | Turkey                                       |
| Celgene Logistics Sarl  | Switzerland                                  |
| Celgene Luxembourg Finance Company SARL                       | Luxembourg                                   |
| Celgene Luxembourg SARL                                       | Luxembourg                                   |
| Celgene Management Sarl                                       | Switzerland                                  |

|   |                |
|---|----------------|
| Celgene Netherlands BV                      | Netherlands    |
| Celgene Netherlands II BV                   | Netherlands    |
| Celgene Netherlands Investment, B.V.        | Netherlands    |
| Celgene NJ Investment Co                    | New Jersey     |
| Celgene Pharmaceuticals (Shanghai) Co. Ltd  | China          |
| Celgene PTE Ltd                             | Singapore      |
| Celgene Pty Limited                         | New Zealand    |
| Celgene Pty Limited                         | Australia      |
| Celgene Puerto Rico Distribution LLC        | Puerto Rico    |
| Celgene R&D Sarl                            | Switzerland    |
| Celgene Research and Investment Company LLC | Delaware       |
| Celgene Research, SL                        | Spain          |
| Celgene Sdn. Bhd.                           | Malaysia       |
| Celgene S.L.                                | Spain          |
| Celgene Sarl                                | France         |
| Celgene Sociedade Unipessoal Lda            | Portugal       |
| Celgene sp. zoo                             | Poland         |
| Celgene Srl                                 | Italy          |
| Celgene sro                                 | Czech Republic |
| Celgene sro                                 | Slovakia       |
| Celgene Summit Investment Co                | New Jersey     |
| Celgene Switzerland Holdings Sarl           | Switzerland    |
| Celgene Switzerland SA                      | Switzerland    |
| Celgene UK Distribution Limited             | United Kingdom |
| Celgene UK Holdings, Limited                | United Kingdom |
| Celgene UK Manufacturing II, Limited        | United Kingdom |
| Celgene UK Manufacturing III, Limited       | United Kingdom |
| Celgene UK Manufacturing, Limited           | United Kingdom |
| Celgro Corporation                          | Delaware       |
| Canomed BioSciences, LLC                    | Delaware       |
| CHT I LLC                                   | Delaware       |
| CHT II LLC                                  | Delaware       |
| CHT III LLC                                 | Delaware       |
| CHT IV LLC                                  | Delaware       |
| Global Strategic Partners, LLC              | Delaware       |
| Gloucester Pharmaceuticals Limited          | United Kingdom |
| Gloucester Pharmaceuticals, LLC             | Delaware       |
| Morris Avenue Investment II, LLC            | New Jersey     |
| Morris Avenue Investment LLC                | New Jersey     |
| Celgene Ltd                                 | Thailand       |
| Pharmion LLC                                | Delaware       |
| Resuscitation Technologies, LLC             | Delaware       |
| Seamair Risk Limited                        | Ireland        |
| Signal Pharmaceuticals, LLC                 | California     |
| VivoRx Autoimmune, Inc.                     | California     |
| Celgene Brasil Biofarmacêutica Ltda.        | Brazil         |
| Abraxis BioScience Limited                  | Hong Kong      |
| AHI Investment, LLC                         | Delaware       |
| Abraxis BioScience, Inc.                    | Delaware       |
| Celgene Logistics II Sarl                   | Switzerland    |
| Gloucester International, LLC               | Delaware       |
| Celgene Avilomics Research, Inc.            | Delaware       |
| Deuteria Pharmaceuticals, Inc.              | Delaware       |
| Celgene, S. de R.I. de C.V.                 | Mexico         |
| Celgene Research Investment Company II, LLC | Delaware       |



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors  
Celgene Corporation:

We consent to the incorporation by reference in the registration statements (Nos. 333-70083, 333-91977, 333-39716, 333-107980, 333-65908, 333-138497, 333-149603, 333-152655, 333-160955, 333-177669, 333-184634) on Form S-8, in the registration statements (Nos. 333-02517, 333-32115, 333-38861, 333-52963, 333-87197, 333-93759, 333-94915, 333-75636, 333-107977, 333-107978, 333-138395, 333-169731) on Form S-3, and in the registration statements (Nos. 333-101196, 333-42302, 333-148777 and 333-168369) on Form S-4 of Celgene Corporation of our reports dated February 15, 2013, with respect to the consolidated balance sheets of Celgene Corporation and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, cash flows, and stockholders' equity for each of the years in the three-year period ended December 31, 2012, the related consolidated financial statement schedule, and the effectiveness of internal control over financial reporting as of December 31, 2012, which reports appear in the December 31, 2012 annual report on Form 10-K of Celgene Corporation and subsidiaries.

/s/ KPMG LLP

Short Hills, New Jersey  
February 15, 2013

CERTIFICATION PURSUANT TO  
18 U.S.C. Sec. 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert J. Hugin, certify that:

1. I have reviewed this annual report on Form 10-K of Celgene Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit

committee of the registrant's Board of Directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 15, 2013

/s/ Robert J. Hugin

Robert J. Hugin  
Chief Executive Officer

CERTIFICATION PURSUANT TO  
18 U.S.C. Sec. 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jacquelyn A. Fouse, certify that:

1. I have reviewed this annual report on Form 10-K of Celgene Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit

committee of the registrant's Board of Directors (or persons performing the equivalent functions):

- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 15, 2013

/s/ Jacquelyn A. Fouse  
Jacquelyn A. Fouse, Ph.D.  
Executive Vice President  
Chief Financial Officer  
(principal financial and  
accounting officer)

CERTIFICATION PURSUANT TO  
18 U.S.C. §1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Annual Report on Form 10-K of Celgene Corporation (“the Company”) for the year ended December 31, 2012 (“the Periodic Report”), I, Robert J. Hugin, Chief Executive Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge that the Periodic Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934 and that the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 15, 2013

/s/ Robert J. Hugin

Robert J. Hugin  
Chief Executive Officer

CERTIFICATION PURSUANT TO  
18 U.S.C. §1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the accompanying Annual Report on Form 10-K of Celgene Corporation (“the Company”) for the year ended December 31, 2012 (“the Periodic Report”), I, Jacquelyn A. Fouse, Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge that the Periodic Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934 and that the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 15, 2013

/s/ Jacquelyn A. Fouse

Jacquelyn A. Fouse, Ph.D.  
Executive Vice President  
Chief Financial Officer  
(principal financial and  
accounting officer)

# Celgene Corporate Information

## Corporate Headquarters

Celgene Corporation  
86 Morris Avenue  
Summit, New Jersey 07901  
(908) 673-9000  
www.celgene.com

## Transfer Agent

American Stock Transfer and Trust Company  
59 Maiden Lane  
New York, New York 10039

## Independent Auditors

KPMG LLP  
51 John F. Kennedy Parkway  
Short Hills, New Jersey 07078

This document contains forward-looking statements. Forward-looking statements are statements that are not historical facts and are based on current plans, estimates, assumptions and projections, and therefore you should not place too much reliance on them. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update any forward-looking statement in light of new information or future events, although we intend to continue to meet our ongoing disclosure obligations under applicable laws. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. We caution you that actual results or outcomes may differ materially from those expressed in, or implied by, the forward-looking statements as a result of the impact of a number of important factors, as well as other known and unknown risks and uncertainties, or if the assumptions underlying any of these statements prove incorrect. Certain of these factors are discussed in more detail in our public reports filed with the Securities and Exchange Commission.

In addition to financial information prepared in accordance with U.S. GAAP (generally accepted accounting principles), this document also contains certain adjusted financial measures that we believe provide investors and management with supplemental measures of operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted measures should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. Other companies may define these measures in different ways. For further information relevant to the interpretation of

adjusted financial measures, please refer to the Financial Reports page posted in the Investor Relations section of our website at [www.celgene.com](http://www.celgene.com).

## Stockholder Information

Celgene common stock is traded on the NASDAQ GS (NASDAQ Global Select Market). NASDAQ Symbol: CELG. Celgene Contingent Value Rights (CVRs) are traded on the NASDAQ GM (NASDAQ Global Market). NASDAQ Symbol: CELGZ. Celgene options are listed on the Chicago Board Options Exchange. CBOE symbol: LQH.

As of March 13, 2013, there were 363,580 beneficial account holders of the Company's common stock.

The following table sets forth the intra-day high and low sales price of the common stock for the periods indicated, as reported by the NASDAQ.

|    | 2012    |         | 2011    |         |
|----|---------|---------|---------|---------|
|    | High    | Low     | High    | Low     |
| Q4 | \$82.78 | \$71.23 | \$68.25 | \$59.32 |
| Q3 | 78.63   | 61.89   | 65.86   | 51.70   |
| Q2 | 80.42   | 58.53   | 61.70   | 54.83   |
| Q1 | 78.83   | 66.28   | 60.90   | 48.92   |

The price quotations set forth above represent prices to dealers and do not include retail markups, markdowns or commissions. Celgene has not paid, and does not anticipate paying in the near future, dividends on its common stock. Anyone wishing more information about Celgene should direct their inquiries to:

Investor Relations  
Celgene Corporation  
86 Morris Avenue  
Summit, New Jersey 07901  
(908) 673-9000

## Annual Meeting

The annual meeting of stockholders of Celgene Corporation will be held on Wednesday, June 12, 2013 at Celgene headquarters in Summit, New Jersey, at 1:00 P.M.

## Form 10-K

Copies of the Form 10-K for the year ended December 31, 2012 may be obtained by stockholders without charge upon written inquiry to the Corporate Secretary at Celgene headquarters.

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