CELGENE CORP /DE/
Form 10-K
February 20, 2008

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

Form 10-K

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2007
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 No. 0-16132
CELGENE CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**22-2711928**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification)*
86 Morris Avenue	**07901**
Summit, New Jersey	*(Zip Code)*
(Address of principal executive offices)	

(908) 673-9000

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
Common Stock, par value $.01 per share
(Title of Class)

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 þ No o

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 o No þ

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 þ No o

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. o

Indicate by check mark whether the registrant is a large accelerated filer, and 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 Ruler 12b-2 of the Exchange Act. (Check one):

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

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

The aggregate market value of voting stock held by non-affiliates of the registrant on June 30, 2007, the last business day of the registrant s most recently completed second quarter, was $21,930,005,924 based on the last reported sale price of the registrant s Common Stock on the NASDAQ Global Select Market on that date. There were 403,759,078 shares of Common Stock outstanding as of February 12, 2008.

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, 2007. The proxy statement is incorporated herein by reference into the following parts of the Form 10K:

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 and its subsidiaries (collectively we or our) is a global integrated biopharmaceutical company primarily engaged in the discovery, development and commercialization of innovative therapies designed to treat cancer and immune-inflammatory related diseases. Our primary commercial stage products are REVLIMID® (lenalidomide) and THALOMID® (thalidomide). REVLIMID® was approved by the U.S. Food and Drug Administration, or FDA, the European Commission, or EC, Swiss Agency for Therapeutic Products, or Swissmedic and Australian Therapeutic Goods Administration, for treatment in combination with dexamethasone for multiple myeloma patients who have received at least one prior therapy. In addition, REVLIMID® was approved by the FDA and the Canadian Therapeutic Products Directorate for treatment of patients with 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. THALOMID® was approved by the FDA for treatment in combination with dexamethasone of patients with newly diagnosed multiple myeloma and is also approved for the treatment and suppression of cutaneous manifestations of erythema nodosum leprosum, or ENL, an inflammatory complication of leprosy. We also sell ALKERAN®, which we obtain through a supply and distribution agreement with GlaxoSmithKline, or GSK, and FOCALIN™, which we sell exclusively to Novartis Pharma AG, or Novartis. We continue to develop our international operations and expect them to provide a significant contribution to future financial results as our products obtain additional regulatory approval for sale in foreign markets. Other sources of revenue include royalties which we primarily receive from Novartis on its sales of the entire family of RITALIN® drugs and FOCALIN XR™, in addition to revenues from collaborative agreements and licensing fees. Our broad portfolio of drug candidates in our product pipeline includes IMiDs® compounds, which are proprietary to us and have demonstrated certain immunomodulatory and other biologically important properties. We believe that the catalysts for future growth include: continued success of REVLIMID® and THALOMID®; depth of our product pipeline; favorable clinical data reported at major medical conferences and in peer-reviewed publications; additional product approvals from regulatory agencies; continued international market expansion; successful integration of any future product or business acquisitions.

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, such as intracellular signaling, immunomodulation and placental stem cell research. The therapies (drugs and cell therapies) we develop are designed to treat life-threatening diseases or chronic debilitating conditions where patients are poorly served by current therapies. Building on our growing knowledge of the biology underlying hematological and solid tumor cancers and immune-inflammatory diseases, we are investing in a range of innovative therapeutic programs that are investigating ways to treat and chronically manage diseases by targeting the disease source through multiple mechanisms of action.

Our future growth and operating results will depend on continued acceptance of our currently marketed products, regulatory approvals of both new products and the expanded use of existing products, depth of our product pipeline and ability to commercialize these products, competition to our marketed products and challenges to our intellectual property. We will continue to expand our international infrastructure in anticipation of additional international regulatory approvals and commercialization of our products. See also Risk Factors contained in Part I, Item 1A of this Annual Report.

For the year ended December 31, 2007, we reported revenue of $1.406 billion, net income of $226.4 million and diluted earnings per share of $0.54, representing increases of 56.4%, 228.3% and 200.0%, respectively, compared to

the year ended December 31, 2006. This increase primarily reflects the expanded use of REVLIMID®, partly offset by increased operating expenses required to support our on-going research, commercial operations and continued expansion into international markets.

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ACQUISITIONS

In August 2000, we acquired Signal Pharmaceuticals, Inc., d/b/a Celgene Research San Diego, a privately held biopharmaceutical company focused on the discovery and development of drugs that regulate genes associated with disease.

In December 2002, we acquired Anthrogenesis Corp., which was a privately held New Jersey-based biotherapeutics company and cord blood banking business, developing technologies for the recovery of stem cells from human placental tissues following the completion of full-term, successful pregnancies. Anthrogenesis d/b/a Celgene Cellular Therapeutics, or CCT, now operates as a wholly owned subsidiary of Celgene Corporation engaged in the research, recovery culture-expansion, preservation, development and distribution of placental stem cells as therapeutic agents.

In October 2004, we acquired all of the outstanding shares of Penn T Limited, a UK-based global supplier of THALOMID®. This acquisition expanded our corporate capabilities and enabled us to control manufacturing for THALOMID® worldwide. Through supply contracts acquired in this purchase, we also increased our participation in the potential growth of THALOMID® revenues in key international markets.

In December 2006, we purchased an active pharmaceutical ingredient, or API, manufacturing facility from Siegfried Ltd. and Siegfried Dienste AG (together Siegfried) located in Zofingen, Switzerland. The manufacturing facility has the capability to produce multiple drug substances and is being used to produce REVLIMID® and THALOMID® API to supply global markets. The facility may also be used to produce drug substance for our future drugs and drug candidates. This asset acquisition expanded our manufacturing capabilities and enabled us to control the production of REVLIMID® and THALOMID® worldwide.

In November 2007, we announced the signing of a definitive merger agreement pursuant to which we agreed to acquire Pharmion Corporation, or Pharmion. Under the terms of the merger agreement, we will acquire all of the outstanding shares of Pharmion common stock for $72.00 per share payable in a combination of cash and shares of Celgene common stock. The transaction has been unanimously approved by the Boards of Directors of both companies and is subject to customary closing conditions including the approval of the acquisition by Pharmion stockholders and receipt of antitrust clearances. The Hart-Scott-Rodino Act, or HSR, thirty day waiting period has expired without the United States Federal Trade Commission, or FTC, requesting additional information with regard to the merger. In addition, the Bundeskartellamt, Germany s Federal Cartel Office in charge of reviewing the antitrust aspects of mergers and acquisitions, has cleared Celgene s pending acquisition of Pharmion. On February 5, 2008 the Form S-4 relating to the merger of Pharmion and Celgene was declared effective by the United States Securities and Exchange Commission, or SEC. The merger is expected to be completed in March 2008. Refer to Note 2 Proposed Merger with Pharmion Corporation contained within the consolidated financial statements for additional information.

COMMERCIAL STAGE PRODUCTS:

REVLIMID® (lenalidomide): REVLIMID® is an oral immunomodulatory drug approved by the FDA, the EC, Swissmedic, and the Australian Therapeutic Goods Administration for treatment in combination with dexamethasone for patients with multiple myeloma who have received at least one prior therapy. REVLIMID® is also approved by the FDA and Canadian Therapeutic Products Directorate for treatment of patients with 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 primarily through contracted pharmacies under the RevAssist® program, which is a proprietary risk-management distribution program tailored specifically to help ensure, to the maximum extent possible, the safe use of REVLIMID® and is being distributed in additional countries where approval has been obtained as pricing, reimbursement and details of controlled distribution in each market are determined.

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, non-Hodgkin s lymphoma, or NHL, chronic lymphocytic leukemia, or CLL, other cancers and other diseases.

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A Marketing Authorization Application, or MAA, seeking approval to market REVLIMID® for treatment of transfusion-dependent anemia due to low-or-intermediate-1 risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities was evaluated by the European Medicines Agency s, or EMEA, Committee for Medicinal Products for Human Use, or CHMP, and a negative opinion was issued in January 2008. The CHMP concluded that lenalidomide is efficacious in patients suffering from deletion 5q MDS. However, based on information available to the CHMP from the uncontrolled, open-label, 148-patient Phase II study (MDS-003), the CHMP was not convinced the data were sufficient to assure safety. We intend to apply for a re-examination of the CHMP opinion in accordance with relevant EMEA procedures. Other international regulatory initiatives include MAAs currently being evaluated in New Zealand and Israel.

In April 2007, the Eastern Cooperative Oncology Group reported that its Data Monitoring Committee s review of preliminary results from a large, randomized clinical trial for patients with newly diagnosed multiple myeloma found that the use of a lower-dose of dexamethasone in combination with REVLIMID® suggests survival advantage for patients when compared to the higher, standard-dose of dexamethasone that is used in combination with REVLIMID® to treat the disease. These results were also presented at the June 2007 annual American Society of Clinical Oncology medical conference and updated at the December 2007 annual American Society of Hematology meeting. The regulatory utility of these findings will be discussed with the FDA.

THALOMID® (thalidomide): THALOMID® was approved by the FDA in May 2006 for use in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma and in July 1998 for the treatment of acute cutaneous manifestations of moderate to severe erythema nodosum leprosum, or ENL, and as maintenance therapy for prevention and suppression of the cutaneous manifestation of ENL recurrence.

THALOMID® is distributed under our *System for Thalidomide Education and Prescribing Safety*, or S.T.E.P.S.® program which we developed and is a proprietary strategic comprehensive education and risk-management distribution program with the objective of providing for the safe and appropriate distribution and use of THALOMID®. Among other things, S.T.E.P.S.® requires prescribers, patients and dispensing pharmacies to participate in a registry and an order cannot be filled unless the physicians, patients and pharmacies have been registered, trained and meet all qualification criteria.

ALKERAN® (melphalan): ALKERAN® is licensed from GSK, and sold under the Celgene label. ALKERAN® was approved by the FDA for the palliative treatment of multiple myeloma and of carcinoma of the ovary. Under terms of the licensing agreement, we purchase ALKERAN® tablets and ALKERAN® for injection from GSK and distribute the products in the United States. The agreement, which has been extended through March 31, 2009, requires us to purchase certain minimum quantities of ALKERAN® each year under a take-or-pay arrangement.

RITALIN® Family of Drugs: In April 2000, we licensed to Novartis the worldwide rights (excluding Canada) to FOCALIN™ and FOCALIN XR™, which are approved for the treatment of attention deficit hyperactivity disorder, or ADHD. We retained the rights to these products for the treatment of oncology-related disorders. We sell FOCALIN™ exclusively to Novartis and also supply them with FOCALIN XR™, for which we receive a royalty.

FOCALIN™ is formulated by isolating the active d-isomer of methylphenidate and contains only the more active isomer responsible for the effective management of the symptoms of ADHD. FOCALIN™ provides favorable tolerability and dosing flexibility at half the dose of RITALIN®.

PRECLINICAL AND CLINICAL STAGE PIPELINE:

Our preclinical and clinical-stage pipeline of new drug candidates, in addition to our cell therapies, is highlighted by multiple classes of small molecule, orally administered therapeutic agents designed to selectively regulate

disease-associated genes and proteins. The product candidates in our pipeline are at various

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stages of preclinical and clinical development. Successful results in preclinical or Phase I/II clinical studies may not be an accurate predictor of the ultimate safety or effectiveness of a drug or product candidate.

Phase I Clinical Trials

If the FDA allows a request to initiate clinical investigations of a new drug or product candidate to become effective, Phase I human clinical trials can begin. These tests usually involve between 20 to 80 healthy volunteers or patients. The tests study a drug s safety profile, and may include preliminary determination of a drug or product candidate s safe dosage range. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action.

Phase II Clinical Trials

In Phase II clinical trials, studies are conducted on a limited number of patients with the targeted disease. An initial evaluation of the drug s effectiveness on patients is performed and additional information on the drug s safety and dosage range is obtained.

Phase III Clinical Trials

This phase typically includes controlled multi-center trials and involves a larger target patient population to ensure that study results are statistically significant. During the Phase III clinical trials, physicians monitor patients to determine efficacy and to gather further information on safety.

IMiDs®: IMiDs® compounds are proprietary novel small molecule, orally available compounds that modulate the immune system and other biologically important targets through multiple mechanisms of action. We have marketed REVLIMID® and have advanced two other IMiDs® compounds into clinical development, CC-4047 and CC-11006. Additional compounds, including CC-10015, are in preclinical development.

Our IMiDs® compounds are covered by an extensive and comprehensive intellectual property estate of U.S. and foreign-issued patents and pending patent applications including composition-of-matter, use and other patents and patent applications.

CC-4047: CC-4047 (pomalidomide) is one of the most potent IMiDs® compounds that we are developing. We opened our investigational new drug, or IND, application to evaluate CC-4047 in a U.S. proof-of-principle study in sickle cell anemia. We are also evaluating CC-4047 for treatment in other diseases including myelofibrosis, multiple myeloma and solid tumor cancers.

CC-11006: CC-11006 is another molecule with activities distinct from those of REVLIMID® and CC-4047. Following successful completion of Phase I human clinical trials, we are currently evaluating conditions where this profile will have best therapeutic application including an ongoing Phase I clinical trial in MDS.

ORAL ANTI-INFLAMMATORY AGENTS: In May 2007, we announced plans to advance the development of leading oral anti-inflammatory candidates across a broad range of inflammatory diseases. Our oral PDE-4 inhibitor, CC-10004 (apremilast), is a member of a proprietary pipeline of novel small molecules with anti-inflammatory activities that impede the production of multiple proinflammatory mediators by inhibiting PDE-4 resulting in reductions in TNF- as well as interleukin-2 (IL-2), IL-17 and IL-23, interferon-gamma, leukotrienes and nitric oxide synthase. Apremilast is our lead investigational drug in this class of anti-inflammatory compounds. Based on results from proof-of-mechanism studies, we are accelerating clinical and regulatory strategies for apremilast in psoriasis and psoriatic arthritis, as well as embarking on exploratory clinical trials in rheumatoid arthritis and additional rheumatic,

dermatologic and inflammatory diseases to determine the potential of apremilast across a broad range of debilitating inflammatory diseases. We believe that our second oral PDE-4 inhibitor, CC-11050, which has completed Phase I trials, will also prove to be effective in a number of inflammatory conditions and is moving forward with its development.

KINASE INHIBITORS: We have generated valuable intellectual property in the identification of kinases that regulate pathways critical in inflammation and oncology. Our kinase inhibitor platform includes inhibitors

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of the c-Jun N-terminal kinase, or JNK, pathway, and inhibitors of the NFkB pathway. The JNK inhibitor, CC-401, has successfully completed a Phase I trial in healthy volunteers and in acute myelogenous leukemia, or AML, patients to determine safety and tolerability. No further studies are planned at this time as we intend to advance other JNK inhibitors. An investigational new drug application was filed for CC-930 on December 18, 2007 and the application was approved in January 2008. Phase I testing is scheduled to begin in February 2008.

LIGASE INHIBITORS: Our work has defined ubiquitin ligases that regulate the degradation of intracellular proteins. These ligases, as a class of targets, have broad potential for drug discovery in oncology. By identifying drug targets and compounds that regulate ligase pathways, we are addressing the potential to develop an important new class of anti-cancer and anti-inflammatory therapeutics.

PLEIOTROPIC PATHWAY MODIFIERS: Based upon our observations about the effect of therapeutics to modify multiple intracellular signaling pathways in distinct cell types, we have identified a new class of molecules that impact activity of several key pathways of therapeutic relevance. The first of these, CC-16057, has moved into preclinical development for inflammatory conditions.

STEM CELLS: 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 state-of-the-art research and development division dedicated to fulfilling the promise of cellular technologies by developing cutting-edge products and therapies that will 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 which today 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, including Crohn s disease and multiple sclerosis, neurological disorders including stroke and ALS, graft-versus-host disease and other immunological and rheumatilogical disorders. Our studies of the placenta indicate that it is a rich source of potential products with biological activity and therapeutic promise. Our lead product, PDA-001, is completing preclinical studies. We plan to submit our first IND in the second half of 2008.

In December 2006, CCT submitted an IND for our human placental derived stem cell, or HPDSC, product. We also maintain an IND with the FDA for a trial with cord blood in sickle cell anemia. Additional preclinical research to define further the potential of placental-derived stem cells and to characterize other placental-derived products is continuing.

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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
IMiDs Compounds:		
CC-4047	Solid tumor cancers	Phase II trials initiated
	Myelofibrosis	Phase II trial ongoing
	Hemoglobinopathies	Phase I-II trial initiated
	Multiple myeloma	Phase II trial planned
CC-11006	Hematological malignances	Phase I/II trial ongoing in MDS
CC-10015	Inflammatory diseases	Pre-clinical studies ongoing
CC-0478765	Inflammatory diseases	Pre-clinical studies ongoing
CC-0478995	Inflammatory diseases	Pre-clinical studies ongoing
Oral Anti-Inflammatory:		
CC-10004	Psoriasis Psoriatic arthritis	Phase II trial in severe psoriasis
	Inflammatory diseases	ongoing and IIb trial in moderate to severe psoriasis planned
		Phase II trials ongoing
		Phase II trials planned
CC-11050	Inflammatory diseases	Phase II trials planned
PPM (Pleiotropic Pathway Modifiers):		
CC-16057	Inflammatory diseases	Pre-clinical studies ongoing
Kinase Inhibitors:		
JNK 930	Fibrotic diseases	Phase I trial initiating
Stem Cell:		
HPDSC	Transplants, hematological disorders	Phase I trials initiating
	Orthopedics	Preclinical studies ongoing
PDA-001	Autoimmune/cancer	Pre-clinical studies ongoing
	Crohn s disease	Pre-clinical studies ongoing
	Multiple sclerosis	Pre-clinical studies ongoing
	ALS	Pre-clinical studies ongoing
	GVHD	Pre-clinical studies ongoing
	Stroke	Pre-clinical studies ongoing

PATENTS AND PROPRIETARY TECHNOLOGY

Patents and other proprietary rights are important to our business. It is our policy to seek patent protection for our inventions, and also to rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We own or have exclusively licensed at least 155 issued U.S. patents and at least 285 additional U.S. patent applications are pending. While we have a policy to seek worldwide patent protection for our inventions, we have foreign patent rights corresponding to most of our U.S. patents. Further, although THALOMID® is approved for use

associated with ENL, we do not have patent protection relating to the use of THALOMID® to treat ENL.

In August 2001, we entered into an agreement, termed the New Thalidomide Agreement, with EntreMed, Inc., Children s Medical Center Corporation, or CMCC, and Bioventure Investments, KFT relating to patents and patent applications owned by CMCC, which agreement superceded several agreements already

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in place between CMCC, EntreMed and us. Pursuant to the New Thalidomide Agreement, CMCC directly granted to us an exclusive worldwide license under the relevant patents and patent applications relating to thalidomide. Several U.S. patents have been issued to CMCC in this patent family and certain of these patents expire in 2013 and 2014. Corresponding foreign patent applications and additional U.S. patent applications are still pending.

In addition to the New Thalidomide Agreement, we entered into an agreement, entitled the New Analog Agreement, with CMCC and EntreMed in December 2002, pursuant to which we have been granted an exclusive worldwide license to certain CMCC patents and patent applications relating to thalidomide analogs. The New Analog Agreement was executed in connection with the settlement of certain pending litigation by and among us, EntreMed and the U.S. Patent and Trademark Office relating to the allowance of certain CMCC patent applications covering thalidomide analogs. These patent applications had been licensed exclusively to EntreMed in the field of thalidomide analogs. In conjunction with the settlement of these suits, we acquired equity securities in EntreMed, and EntreMed terminated its license agreements with CMCC relating to thalidomide analogs. In turn, under the New Analog Agreement, CMCC exclusively licensed to Celgene these patents and patent applications, which relate to analogs, metabolites, precursors and hydrolysis products of thalidomide, and stereoisomers thereof. Under the New Analog Agreement, we are obligated to comply with certain milestones and other obligations, including those relating to REVLIMID® approval and sales.

The New Analog Agreement grants us control over the prosecution and maintenance of the licensed thalidomide analog patent rights. The New Analog Agreement also granted us an option to inventions in the field of thalidomide analogs that may be developed at CMCC in the laboratory of Dr. Robert D Amato, pursuant to the terms and conditions of a separate Sponsored Research Agreement negotiated between CMCC and us.

Our research led 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. As of December 2007, included in those inventions described above, we owned, in whole or in part, 49 issued U.S. patents and approximately 57 U.S. pending patent applications, including pending provisional applications. An increasing percentage of our San Diego subsidiary s recent patent applications have been related to potential product candidates or compounds. It also holds licenses to U.S. patents and U.S. patent applications, some of which are licensed exclusively or sub-licensed to third parties in connection with sponsored or collaborative research relationships.

CCT, our cellular therapeutics subsidiary, 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 2007, CCT owned, in whole or in part, five U.S. patents, and more than 48 U.S. patent applications, including pending provisional applications, and holds licenses to U.S. patents and U.S. patent applications, including certain patents and patent applications related to cord blood collection and storage.

Our success will depend, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties where it is necessary to conduct our business without infringing upon the proprietary rights of others. The patent positions of pharmaceutical and biotechnology firms, including ours, can be uncertain and involve complex legal and factual questions. 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 or infringed by others. Finally, we are also aware of third-party U.S. patents that relate to the use of certain stem cell technologies and cannot guarantee that our patents or pending applications will not be involved in, or be defeated as a result of,

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opposition proceedings before a foreign patent office or any interference proceedings before the U.S. Patent and Trademark Office.

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, either with respect to thalidomide or thalidomide analogs, 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. Any termination of the licenses granted to Celgene by CMCC 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 U.S. on or after November 29, 2000 are not published until approximately 18 months after their earliest claimed priority date and 3) 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 U.S. Patent and Trademark Office 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.

We are aware of U.S. patents that have been issued to third parties claiming subject matter relating to the NF B pathway, including U.S. patents which could overlap with technology claimed in some of our owned or licensed NF B patents or patent applications, and a U.S. patent that has been asserted against certain pharmaceutical companies. With respect to those patents that overlap with our applications, we believe that one or more interference proceedings may be initiated by the U.S. Patent and Trademark Office to determine priority of invention for this subject matter. While we cannot predict the outcome of any such proceedings, in the event we do not prevail, we believe that we can use alternative methods for our NF B drug discovery program for which we have issued U.S. patents that are not claimed by the subject matter of the third-party patents. We are also aware of third-party U.S patents that relate to the use of certain TNF- inhibitors to treat inflammation or conditions such as asthma.

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 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 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, 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 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

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enforceable, there can be no assurance that competitors will not be able 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.

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 commercialization. In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by 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 indicated uses for which a product may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing review and discovery of previously unknown problems with such products or the manufacturing or quality control procedures used in their production may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Any failure by us, our suppliers of manufactured drug product, collaborators or licensees to obtain or maintain, or any delay 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.

The activities required before a product may be marketed in the United States begin with preclinical testing not involving human subjects. Preclinical tests include laboratory evaluation of a product candidate s chemistry and its biological activities and the conduct of animal studies to assess the potential safety and efficacy of a product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an investigational new drug application, or IND, which must be reviewed by the FDA primarily for safety considerations before proposed clinical trials in humans can begin.

Typically, clinical trials involve a three-phase process as previously described. In some cases, further studies (Phase IV) are required as a condition for new drug application, or NDA, or biologics license application, or BLA, approval, to provide additional information concerning the drug or product. 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. After approval, we have ongoing reporting obligations concerning adverse reactions associated with the drug, including expedited reports for serious and unexpected adverse events. Additionally, we may have limited control over studies conducted with our proprietary compounds or biologics if such studies are performed by others (e.g., cooperative groups and the like).

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 the product is sufficiently safe and effective for approval to commence commercial sales. In responding to an NDA or BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its

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regulatory approval criteria. When an NDA or BLA is approved, the NDA or BLA holder must a) employ a system for obtaining reports of 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 internal manufacturing procedures.

Pursuant to the 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 such drug or product containing the active ingredient 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 other labeled indications. The period of orphan exclusivity is concurrent with any patent exclusivity that relates to the drug or biologic. Orphan drugs may also be eligible for federal income tax credits for costs associated with the drug s development. Possible amendment of the Orphan Drug Act by the U.S. Congress and possible reinterpretation by the FDA has been discussed by regulators and legislators. FDA regulations reflecting certain definitions, limitations and procedures for orphan drugs initially went into effect in January 1993 and were amended in certain respects in 1998. Therefore, there is no assurance as to the precise scope of protection that may be afforded by orphan drug status in the future or that the current level of exclusivity and tax credits will remain in effect. Moreover, even if we have an orphan drug designation for a particular use of a drug, there can be no assurance that another company also holding orphan drug designation will not receive approval prior to us for the same indication. If that were to happen, our applications for that indication could not be approved until the competing company s seven-year period of exclusivity expired. Even if we are the first to obtain approval for the orphan drug indication, there are certain circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity. First, particularly in the case of large molecule drugs or biologics, a question can be raised whether the competing product is really the same drug as that which was approved. In addition, even in cases in which two products appear to be the same drug, the agency may approve the second product based on a showing of clinical superiority compared to the first product. REVLIMID® has been granted orphan medicinal product designation by the EC for treatment of chronic lymphocytic leukemia following the favorable opinion of the EMEA s Committee for Orphan Medicinal Products.

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, 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 recall of products previously shipped from the facility.

Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, products covered by approved NDAs or supplemental NDAs may be protected by periods of patent and/or non-patent exclusivity. During the exclusivity periods, the FDA is generally prevented from granting effective approval of an abbreviated NDA, or ANDA. Further, NDAs submitted under 505(b)(2) of the Food, Drug and Cosmetic Act may not reference data contained in the NDA for a product protected by an effective and unexpired exclusivity. 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

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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. While the Food, Drug and Cosmetic Act provides for ANDA and 505(b)(2) abbreviated approval pathways for drugs submitted as NDAs and approved under section 505 of the Act, there are no similar provisions for biologics submitted as BLAs and approved under the Public Health Service, or PHS, Act. That is, there is currently no abbreviated application that would permit approval of a generic or follow-on biologic based on the Agency s earlier approval of another manufacturer s application under section 351 of the PHS Act.

Failure to comply with applicable FDA regulatory requirements can result in enforcement actions such as warning letters, recalls or adverse publicity issued by the FDA or in legal actions such as seizures, injunctions, fines based on the equitable remedy of disgorgement, restitution and criminal prosecution.

Approval procedures similar to those in the United States must be undertaken in virtually every other country comprising the market for our products before any such product can be commercialized in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. There can be no assurance that approvals will be granted on a timely basis or at all. In addition, regulatory approval of drug and biologics pricing is required in most countries other than the United States. There can be no assurance that the resulting pricing of our products would be sufficient to generate an acceptable return to us.

COMPETITION

The pharmaceutical and biotechnology industries in which we compete are each highly competitive. Our competitors include major pharmaceutical and biotechnology companies, many of which have considerably greater financial, scientific, technical and marketing resources than us. We also experience competition in the development of our products and processes from universities and other research institutions and, in some instances, compete with others in acquiring technology from such sources.

Competition in the pharmaceutical industry, and specifically in the oncology and immune-inflammatory areas being addressed by us, is particularly intense. Numerous pharmaceutical, biotechnology and generic companies have extensive anti-cancer and anti-inflammatory drug discovery, development and commercial resources. Bristol-Myers Squibb Co., Amgen Inc., Genentech, Inc., Sanofi-Aventis SA., Novartis AG, AstraZeneca PLC., Eli Lilly and Company, F. Hoffmann-LaRoche Ltd, Millennium Pharmaceuticals, Inc., Eisai Co., Ltd., Biogen Idec Inc., Merck and Co., Inc., Johnson and Johnson and Pfizer Inc. are among some of the companies researching and developing new compounds in the oncology, inflammation and immunology fields.

The pharmaceutical and biotechnology industries have undergone, and are expected to continue to undergo, rapid and significant technological change. Also, 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. An important factor in competition will be the timing of market introduction of our or our competitors products. Accordingly, the relative speed with which we can develop products, complete clinical trials and regulatory approval processes, receive pricing and reimbursement in certain markets and supply commercial quantities of products to the market are expected to be important competitive factors. Competition among products approved for sale will be based, among other things, on product efficacy, safety,

convenience, reliability, availability, price, third-party reimbursement and patent and non-patent exclusivity.

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SIGNIFICANT ALLIANCES

From time to time we enter into strategic alliances with third parties whereby we either grant rights to certain of our compounds in exchange for rights to receive payments, or acquire rights to compounds owned by other pharmaceutical or biotechnology companies in exchange for obligations to make payments to the partnering companies. Payments either to or from third parties may be in the form of upfront payments, milestone payments contingent upon the achievement of pre-determined criteria and/or research and development funding. Under these arrangements, one of the parties may also purchase product and pay royalties on product sales. The following are our most significant alliances:

NOVARTIS: In April 2000, we entered into a development and license agreement with Novartis in which we granted to Novartis an exclusive worldwide license (excluding Canada) to further develop and market FOCALIN™ and FOCALIN XR™, the extended release drug formulation (*d-methylphenidate, or d-MPH*). We have retained the exclusive commercial rights to FOCALIN™ IR and FOCALIN XR™ for oncology-related disorders. We also granted Novartis rights to all of our related intellectual property and patents, including new formulations of the currently marketed RITALIN®. Under the agreement, we have received upfront and regulatory achievement milestone payments totaling $55.0 million through December 31, 2007 and are entitled to additional payments upon attainment of certain other milestone events. We also sell FOCALIN™ to Novartis and receive royalties on all of Novartis sales of FOCALIN XR™ and RITALIN® family of ADHD-related products.

PHARMION: In November 2001, we licensed to Pharmion Corporation exclusive rights relating to the development and commercial use of our intellectual property covering thalidomide and S.T.E.P.S®. Under the terms of the agreement, as amended in December 2004, we receive royalties of 8% of Pharmion s net thalidomide sales in countries where Pharmion has received regulatory approval and S.T.E.P.S® licensing fees of 8% of net sales in all other licensed territories. In December 2004, following our acquisition of Penn T Limited in which, among other things, we acquired a product supply agreement to exclusively supply Pharmion with thalidomide, we entered into an amended thalidomide supply agreement whereby in exchange for a reduction in Pharmion s purchase price to 15.5% of its net sales of thalidomide, we received a one-time payment of $77.0 million. Pursuant to a separate December 2004 agreement, we also received a one-time payment of $3.0 million in return for granting license rights to Pharmion to develop and market thalidomide in additional territories and eliminating certain of our license termination rights. Under the agreements, as amended, the territory licensed to Pharmion is for all countries other than the United States, Canada, Mexico, Japan and China, with the exception of Hong Kong. The agreements with Pharmion terminate upon the ten-year anniversary following receipt of the first regulatory approval for thalidomide in the United Kingdom.

To support the further clinical development of thalidomide, Pharmion has also provided research funding under various agreements of approximately $16.0 million through December 31, 2007.

As of December 31, 2007, we held 1,939,598 shares of Pharmion common stock received in connection with the conversion of a five-year Senior Convertible Promissory Note and the exercise of warrants purchased in April 2003 under a Securities Purchase Agreement and the exercise of warrants received in connection with the November 2001 thalidomide and S.T.E.P.S® license agreement.

On November 18, 2007, we entered into a merger agreement with Pharmion under which Pharmion will be acquired and become a wholly owned subsidiary of Celgene. The transaction will be accounted for as a purchase and we anticipate that the transaction will close in March 2008, subject to customary closing conditions including the approval of the acquisition by Pharmion stockholders. Refer to Note 2 Proposed Merger with Pharmion Corporation contained within the consolidated financial statements for additional information.

GLAXOSMITHKLINE: In March 2003, we entered into a supply and distribution agreement with GSK to distribute, promote and sell ALKERAN® (*melphalan*), a therapy approved by the FDA for the palliative treatment of multiple myeloma and carcinoma of the ovary. Under the terms of the agreement, we purchase ALKERAN® tablets and ALKERAN® for injection from GSK and distribute the products in the United States under the Celgene label. The agreement requires us to purchase certain minimum quantities each year under a

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take-or-pay arrangement. The agreement has been extended through March 31, 2009. As of December 31, 2007, the remaining minimum purchase requirements under the agreement totaled $38.2 million, including $30.5 million in 2008 and $7.7 million in 2009.

MANUFACTURING

We own and operate an FDA approved active pharmaceutical ingredient, or API, manufacturing facility in Zofingen, Switzerland. The API facility is used to produce REVLIMID® and THALOMID® API. We have contracted with third party manufacturing service providers in order to provide backup manufacturing capabilities. These manufacturing service providers manufacture API in accordance with our specifications and are required to meet the FDA s and foreign regulatory authorities cGMP regulations and guidelines. Our backup API manufacturing service providers are Aptuit Inc. UK (previously Evotec) with respect to REVLIMID® and Aptuit Inc. with respect to THALOMID®.

We have constructed a drug product manufacturing facility in Neuchatel, Switzerland to perform formulation, encapsulation, packaging, warehousing and distribution, and expect European and FDA approval in 2008. We maintain backup FDA drug product manufacturing service providers for the manufacture of REVLIMID® and THALOMID®. These drug product manufacturing service providers include Penn Pharmaceutical Ltd, Institute of Drug Technology Australia Ltd and OSG Norwich Pharmaceuticals. Our packaging service providers include Sharp Corporation for worldwide packaging, Norwich Pharmaceuticals and Cimex AG for US packaging and non US packaging respectively.

The API for FOCALIN™ and FOCALIN XR™ is currently obtained from two suppliers, Johnson Matthey Inc. and Siegfried USA Inc., and we rely on a single manufacturer, Mikart, Inc., for the tabletting and packaging of FOCALIN™ finished product.

CCT currently operates an FDA compliant facility for the recovery and storage of cordblood and placental stem cells for LifeBank USA. We are also implementing in-house capability for production of culture expanded placenta derived stem cells under GMP, to supply clinical studies of PDA001 and other future stem cell products.

INTERNATIONAL OPERATIONS

Our international headquarters are located in Neuchatel, Switzerland and in 2007, we completed construction of a drug product manufacturing facility to perform formulation, encapsulation, packaging, warehousing and distribution. We purchased an API manufacturing facility located in Zofingen, Switzerland which has the capability to produce multiple drug substances, expanding our global commercial manufacturing capabilities. We continue to expand our international regulatory, clinical and commercial infrastructure in various parts of the world. REVLIMID® has been granted approval by the EC, Swissmedic and Australian Therapeutic Goods Administration as a treatment for multiple myeloma who received at least one prior therapy. REVLIMID® has also been approved by the Canadian Therapeutic Products Directorate for treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk MDS, associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

We granted Pharmion Corporation a license to expand the THALOMID® franchise in certain parts of the world, accelerating the establishment of THALOMID® as an important therapy in the international markets. In October 2004, we acquired Penn T Limited, a supplier of THALOMID®. This acquisition has enabled us to manage the manufacturing for THALOMID® worldwide.

SALES AND COMMERCIALIZATION

We have a global pharmaceutical commercial organization that has considerable experience in the pharmaceutical industry, and many of our employees have experience with oncological and immunological products. We will continue to expand our sales and commercialization group to support products we develop to treat oncological and immunological diseases. We intend to market and sell the products we develop for indications with accessible patient populations. For products with indications involving larger patient

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populations, we may partner with other pharmaceutical companies. In addition, we are positioned to accelerate the expansion of these sales and marketing resources as appropriate to take advantage of product in-licensing and product acquisition opportunities.

EMPLOYEES

As of December 31, 2007, we had 1,685 full-time employees, 921 of whom were engaged primarily in research and development activities, 428 who were engaged in sales and commercialization activities and the remainder of which were engaged in executive and general and administrative activities. The number of international full-time employees included above has grown to 436 as of December 31, 2007. 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 in Europe and the United States.

FORWARD-LOOKING STATEMENTS

Certain statements contained or incorporated by reference in this Annual Report are forward-looking statements concerning our business, results of operations, economic performance and financial condition based on our current expectations. Forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and within the meaning of Section 21E of the Securities Exchange Act of 1934 are included, for example, in the discussions about:

- strategy;
- new product discovery, development or product introduction;
- product manufacturing;
- product sales, royalties and contract revenues;
- expenses and net income;
- credit risk management;
- liquidity;
- asset and liability risk management; and
- operational and legal risks.

These and other forward-looking statement are not guarantees of future performance and involve risks and uncertainties that could cause actual results to differ materially from those implied by such forward-looking statements. Given these risks and uncertainties, you are cautioned not to place undue reliance on any forward-looking statements.

You can identify these forward-looking statements by their use of words such as forecast, project, plan, strategy, intend, potential, outlook, target, seek, continue, believe, could, estimate, expect, may, proba words of similar meaning in conjunction with, among other things, discussions of future operations, financial performance, our strategy for growth, product development, regulatory approval and market position. You also can identify them by the fact that they do not relate strictly to historical or current facts.

Reference is made, in particular, to forward-looking statements regarding the results of current or pending clinical trials, our products ability to demonstrate efficacy or an acceptable safety profile, actions by the FDA, the financial conditions of suppliers including their solvency and ability to supply product, and other factors detailed in Item 1A. Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations . We note these factors as permitted by the Private Securities Litigation Reform Act of 1995.

Except as required under the federal securities laws and the rules and regulations of the Securities and Exchange Commission, we disclaim and do not undertake any obligations to update or revise publicly any

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forward-looking statements in this report, whether as a result of new information, future events, changes in assumptions, or otherwise.

Item 1A. *RISK FACTORS*

We may experience significant fluctuations in our quarterly operating results.

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 for our products;
- pricing decisions, and those of our competitors, including decisions to increase or decrease prices;
- regulatory approvals for our products;
- timing and levels of spending for research and development; sales and marketing;
- timing and levels of reimbursement from third-party payors for our products;
- timing and market acceptance of new product introductions by us and/or competitors;
- development or expansion of business infrastructure in new clinical and geographic markets;
- 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; and
- fluctuations in foreign currency exchange rates.

If we are unsuccessful in developing and commercializing our products, our business, financial condition, results of operations and liquidity could be materially adversely affected which could have a negative impact on the value of our securities.

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. Moreover, our commercially available products may require additional studies with respect to approved indications as well as new indications pending approval. If it becomes too expensive to sustain our present commitment of resources on a long-term basis, we will be unable to continue certain necessary research and development activities. Furthermore, we cannot be certain that our clinical testing will render satisfactory results, or that we will receive required regulatory approvals for our new products or new indications. If any of our products, even if developed and approved, cannot be successfully commercialized, our business, financial condition, results of operations and liquidity could be materially adversely affected which could have a negative impact on the value of our common stock or debt securities obligations.

During the next several years, we will be very dependent on the continued commercial success of our primary products REVLIMID® and THALOMID®.

During the next several years, the growth of our business will be largely dependent on the commercial success of REVLIMID® and our other products. REVLIMID® was approved by the FDA, EC, Swissmedic and Australia for treatment in combination with dexamethasone for multiple myeloma patients who have received at least one prior therapy. In addition, REVLIMID® was approved by the FDA and Canada for treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. We do not have long-term data on the use of the product and cannot predict whether REVLIMID® will continue to gain the acceptance

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of regulators, physicians, patients and other key opinion leaders as a relatively safe and effective drug that has certain advantages as compared to existing or future therapies. We are also seeking to introduce REVLIMID® in additional international markets as well as obtaining approvals for additional indications both in the U.S. and internationally. A delay in gaining the requisite regulatory approvals could negatively impact our growth plans and the value of our common stock or debt securities obligations.

THALOMID® in combination with dexamethasone was approved by FDA in May 2006 for the treatment of patients with newly diagnosed multiple myeloma. In addition, THALOMID® is currently approved as a therapy for the treatment of ENL, although the market for the use of THALOMID® in patients suffering from ENL is very small. If unexpected adverse experiences are reported in connection with the use of THALOMID® by patients, this could undermine physician and patient comfort with the product, could limit the commercial success of the product and could even impact the acceptance of our other products, including REVLIMID®.

Our revenues and profits would be negatively impacted if adverse experiences were reported in connection with any of these two products or generic versions were to be approved and launched. See *We may not be able to protect our intellectual property and our products may be subject to generic competition* for additional discussion related to possible generic competition for THALOMID®.

If our products are not accepted by the market, demand for our products will deteriorate or not materialize at all.

It is necessary that REVLIMID®, THALOMID®, ALKERAN®, FOCALIN™ and FOCALIN XR™, and the RITALIN® family of drugs achieve and maintain market acceptance. A number of factors can render the degree of market acceptance of our products uncertain, including the products efficacy, safety and advantages, if any, over competing products, as well as the reimbursement policies of third-party payors, such as government and private insurance plans. In particular, thalidomide, when used by pregnant women, has resulted in serious birth defects, and the negative history associated with thalidomide and birth defects may decrease the market acceptance of THALOMID®. In addition, the stem cell products that we are attempting to develop through our Celgene Cellular Therapeutics 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. If our products are not accepted by the market, demand for our products will deteriorate or not materialize at all.

We have grown rapidly, and if we fail to adequately manage that growth our business could be adversely impacted.

We have an aggressive growth plan that has included substantial and increasing investments in research and development, sales and marketing, and facilities. We plan to continue to grow and our plan has a number of risks, some of which we cannot control. For example:

- we will need to generate higher revenues to cover a higher level of operating expenses (including clinical trial costs, expenses associated with the regulatory approval process and commercialization of our products), and our ability to do so may depend on factors that we do not control;

- we will need to manage complexities associated with a larger and faster growing multinational organization; and

- we will need to accurately anticipate demand for the products we manufacture and maintain adequate manufacturing, marketing and distribution capacity, and our ability to do so may depend on factors that we do

not control.

If the third parties upon whom we rely fail to produce on a timely basis the encapsulation, finishing and packaging services in the volumes that we require or fail to meet quality standards and maintain

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necessary licensure from regulatory authorities, we may be unable to meet demand for our products, potentially resulting in lost revenues.

We have contracted with third party manufacturers to provide encapsulation, finishing services and packaging to meet our needs. We intend to continue to utilize third parties as needed to produce certain of our products on a commercial scale.

The active pharmaceutical ingredient, or API, for THALOMID® is primarily obtained from our Zofingen, Switzerland, manufacturing facility and from Aptuit, Inc. Two additional suppliers are currently progressing through the qualification process. With regard to drug product manufacturing, we rely on two manufacturing service providers, Penn Pharmaceuticals Services Limited and Institute of Drug Technology Australia Limited, for the formulation and encapsulation of the finished dosage form of THALOMID® capsules, and on one contract packager, Sharp Corporation, for the packaging of the final product.

The API for REVLIMID® is manufactured primarily by our Zofingen, Switzerland, manufacturing facility and by Aptuit Inc. UK (previously Evotec). We have also contracted and registered two manufacturing service providers, Penn Pharmaceuticals Services Limited and OSG Norwich Pharmaceuticals, for the formulation and encapsulation of the finished dosage form of REVLIMID® capsules. Sharp and Norwich are the contractors approved for supplying the packaging for the final product in the U.S. and Sharp, located in the U.S., and Cimex AG located in Liesberg, Switzerland for the non-U.S. supply.

The API for FOCALIN™ is currently obtained from two suppliers, Johnson Matthey Inc. and Siegfried USA, Inc., and we rely on a single manufacturer, Mikart, Inc., for the tableting and packaging of FOCALIN™ finished product. The API for FOCALIN XR™ is supplied by both Siegfried and Johnson Matthey Inc. on behalf of Novartis for the manufacture of FOCALIN XR™.

In all the countries where we sell our products, governmental regulations exist to define standards for manufacturing, packaging, labeling and storing. All of our suppliers of raw materials and contract manufacturers must comply with these regulations. Failure to do so could result in supply interruptions. 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 cGMP regulations and guidelines. 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, demand for our products or our ability to continue supplying such products could substantially decline.

We are in the process of establishing foreign marketing and distribution capabilities.

We are establishing 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. In addition, we have contracted with Ivers Lee Corporation, d/b/a Sharp, a

specialty distributor, to distribute THALOMID® and REVLIMID® in the United States. If Sharp does not perform its obligations, our ability to distribute THALOMID® and REVLIMID® in the United States may be impacted for a limited period of time.

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We have entered into a definitive agreement to acquire Pharmion, subject to certain closing conditions, including the appropriate affirmative vote of Pharmion stockholders. The integration of Pharmion and other acquired businesses may present significant challenges to us.

Achieving the anticipated benefits of our pending acquisition of Pharmion will depend in part upon whether we and Pharmion can integrate our businesses in an efficient and effective manner. In addition, we may acquire additional businesses from time to time. The integration of Pharmion and any future businesses that we may acquire 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, 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 Pharmion or other acquired businesses, we may experience material negative consequences to our business, financial condition or results of operations. Successful integration of Pharmion and other acquired businesses will depend on our ability to manage these operations, to realize opportunities for revenue growth presented by offerings and expanded geographic market coverage and, to some degree, to eliminate redundant and excess costs. Because of difficulties in combining geographically distant operations, we may not be able to achieve the benefits that we hope to achieve as a result of the merger with Pharmion or other acquired businesses.

We may be unable to retain skilled personnel and maintain key relationships.

The success of our business depends, in large part, on our continued ability to (i) attract and retain highly qualified management, scientific, manufacturing and sales and marketing 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. In particular, the success of the combined operations after our pending acquisition of Pharmion will depend in part upon our ability to retain key employees of Pharmion. Key employees may depart because of issues relating to the difficulty of integration or accelerated retirement as a result of change in control severance provisions in their employment agreements with Pharmion.

Among other benefits, we use stock options to attract and retain personnel. Stock option accounting rules require us to recognize all stock-based compensation costs as expenses. These or other factors could reduce the number of shares management and our board of directors grants under our stock option plans. We cannot be sure that we will be able to attract or retain skilled personnel or maintain key relationships, including key employees of Pharmion, or that the

costs of retaining such personnel or maintaining such relationships will not materially increase.

The hazardous materials we use in our research, development and other business operations could result in significant liabilities, which could exceed our insurance coverage and financial resources.

We use certain hazardous materials in our research, development and general business activities. While we believe we are currently in substantial compliance with the federal, state and local laws and regulations

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governing the use of these materials, we cannot be certain that accidental injury or contamination will not occur. Any such accident or contamination 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.

The pharmaceutical industry is subject to extensive government regulation which presents numerous risks to us.

The discovery, preclinical development, clinical trials, manufacturing, marketing and labeling of pharmaceuticals and biologics are all subject to extensive regulation by numerous governmental authorities and agencies in the United States and other countries. If we or our contractors and collaborators are delayed in receiving, or are unable to obtain at all, necessary governmental approvals, we will be unable to effectively market our products.

The testing, marketing and manufacturing of our products require regulatory approval, including approval from the FDA and, in some cases, from the U.S. Environmental Protection Agency, or the EPA, or governmental authorities outside of the United States that perform roles similar to those of the FDA and EPA. Certain of our pharmaceutical products, such as FOCALIN™, 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 several risks to us:

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, or upon the failure of the product to meet, 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;

Pricing and reimbursement controls;

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;

Guidelines and recommendations published by various 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

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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 study commitments are not completed with due diligence, 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 labeling and promotional activities relating to our products are regulated by the FDA and state regulatory agencies and, in some circumstances, by the DEA, and are subject to associated risks. If we fail to comply with FDA regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained, the FDA, or the Office of the Inspector General of the Department of Health and Human Services or the state Attorneys General could bring an enforcement action against us that could inhibit our marketing capabilities as well as result in significant penalties.

Additionally, the FDA approval process would allow for the approval of an 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. ANDAs and 505(b)(2) applications are generally less burdensome than full NDAs in that, in lieu of clinical data, these applications rely in whole, or in part, upon the safety and efficacy findings of the referenced approved product in conjunction with bridging data, typically bioequivalence data.

The FDA s Center for Biologics Evaluation and Research currently regulates under 21 CFR Parts 1270 and 1271 human tissue intended for transplantation that is recovered, processed, stored or distributed by methods that do not change tissue function or characteristics and that is not currently regulated as a human drug, biological product or medical device. Certain stem cell-related activities fall within this category. Part 1270 requires tissue establishments to screen and test donors, to prepare and follow written procedures for the prevention of the spread of communicable disease and to maintain records. It also provides for inspection by the FDA of tissue establishments. Part 1271 requires human cells, tissue and cellular and tissue-based product establishments (HCT/Ps) to register with the agency and list their HCT/Ps.

Currently, we are required to be, and are, licensed to operate in New York, New Jersey, Maryland and Delaware, four of the states in which we currently collect placentas and umbilical cord blood for our allogeneic and private stem cell banking businesses, and we are in process of obtaining a license in the state of California. If other states adopt similar licensing requirements, we would need to obtain such licenses to continue operating. 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 would impact negatively on our revenues.

We may not be able to protect our intellectual property and our products may be subject to generic competition.

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 firms, including ours, can be uncertain and involve complex legal and factual questions.

Under the current U.S. patent laws, patent applications filed in the United States on or before November 28, 2000 are maintained in secrecy until patents issue. Patent applications filed in the U.S. on or after November 29, 2000 are not published until approximately 18 months after their earliest claimed priority date, and publication of discoveries in the scientific and patent literature often lag behind actual discoveries.

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Thus, we may discover sometime in the future that we, or the third parties from whom we have licensed patents or patent applications, were not the first to make and/or file the inventions covered by the patents and patent applications in which we have or seek rights. In the event that a third party has also filed a patent application for any of the inventions claimed in our patents or patent applications, or those we have licensed-in, we could become involved in an interference proceeding declared by the U.S. Patent and Trademark Office, or the PTO, to determine priority of invention or an opposition proceeding in other places such as Europe. Such an interference or opposition could result in the loss of an issued U.S. or foreign patent, respectively, or loss of any opportunity to secure U.S. patent protection for that invention. Even if the eventual outcome is favorable to us, such proceedings could result in substantial cost and delay to us and limit the scope of the claimed subject matter.

In addition, the coverage sought in a patent application may not be obtained or may be significantly reduced before the patent is issued. Consequently, if our pending applications, or pending application that we have licensed-in from third parties, do not result in the issuance of patents or if any patents that are issued do not provide significant proprietary protection or commercial advantage, our ability to sustain the necessary level of intellectual property rights upon which our success depends may be restricted.

Moreover, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensors, in a given country, of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in other countries may be limited.

Furthermore, even if our patent applications, or those we have licensed-in, are issued, our competitors may still challenge the scope, validity or enforceability of such patents in court, requiring us to engage in complex, lengthy and costly litigation. Alternatively, our competitors may be able to design around such patents and compete with us using the resulting alternative technology. If any of our issued or licensed patents are infringed, we may not be successful in enforcing our or our licensor s intellectual property rights or defending the validity or enforceability of our issued patents and subsequently not be able to develop or market applicable product exclusively.

We rely upon unpatented proprietary and trade secret technology that we try to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. If these agreements are breached, we may not have adequate remedies for any such breach. Despite precautions taken by us, others may obtain access to or independently develop our proprietary technology or such technology may be found to be non-proprietary or not a trade secret.

Our right to practice the inventions claimed in certain patents that relate to THALOMID® arises under licenses granted to us by others, including The Rockefeller University and Children s Medical Center Corporation, or CMCC. In addition to these patents, which relate to thalidomide, we have also licensed from CMCC certain patents relating to thalidomide analogs. In December 2002, we entered into an exclusive license agreement with CMCC and EntreMed Inc. pursuant to which CMCC exclusively licensed to us certain patents and patent applications that relate to analogs, metabolites, precursors and hydrolysis products of thalidomide, and all stereoisomers thereof. Our license under the December 2002 agreement is worldwide and royalty-bearing, and we have complete control over the prosecution of the licensed thalidomide analog patent rights. Under this December 2002 agreement, we are obligated to comply with certain milestones for a REVLIMID® approval and royalties with respect to sales of REVLIMID®. The December 2002 agreement also grants us an option for a certain time period to inventions in the field of thalidomide analogs that may be developed at CMCC in the laboratory of Dr. Robert D Amato, pursuant to the terms and conditions of a separate Sponsored Research Agreement negotiated between CMCC and us.

Further, while we believe these confidentiality agreements and license agreements to be valid and enforceable, our rights under these agreements may not continue or disputes concerning these agreements may

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arise. If any of the foregoing should occur, we may be unable to rely upon our unpatented proprietary and trade secret technology, or we may be unable to use the third-party proprietary technology we have licensed-in, either of which may prevent or hamper us from successfully pursuing our business.

It is also possible that third-party patent applications and patents could issue with claims that broadly cover certain aspects of our business or of the subject matter claimed in the patents or patent applications owned or optioned by us or licensed to us, which may limit our ability to conduct our business or to practice under our patents, and may impede our efforts to obtain meaningful patent protection of our own. If patents are issued to third parties that contain competitive or conflicting claims, we may be legally prohibited from pursuing research, development or commercialization of potential products or be required to obtain licenses to these patents or to develop or obtain alternative technology. We may be legally prohibited from using patented technology, may not be able to obtain any license to the patents and technologies of third parties on acceptable terms, if at all, or may not be able to obtain or develop alternative technologies. Consequently, if we cannot successfully defend against any patent infringement suit that may be brought against us by a third-party, we may lose the ability to continue to conduct our business as we presently do, or to practice certain subject matter delineated by patent claims that we have exclusive rights to, whether by ownership or by license, and that may have a material adverse effect on our business.

We rely upon trademarks and service marks to protect our rights to the intellectual property used in our business.

Litigation on a variety of matters may subject us to significant legal expenses and liability.

From time to time, we may be subject to litigation on a variety of matters, including, as discussed above, intellectual property, licensing arrangements with other persons and product liability. Litigation requires the expenditure of significant time and resources, and is inherently unpredictable. If any litigation were to have an unanticipated adverse result, there could be a material impact on our results of operations or financial position.

The pharmaceutical and biotech industry is highly competitive and subject to rapid and significant technological change.

The pharmaceutical industry in which we operate is 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:

Amgen, which potentially competes with our TNF- and kinase inhibitors;

Novartis, which potentially competes with our IMiDs® compounds and kinase programs;

Bristol Myers Squibb Co., which potentially competes in clinical trials with our IMiDs® compounds and TNF-inhibitors;

Genentech, Inc., which potentially competes in clinical trials with our IMiDs® compounds and TNF- inhibitors;

AstraZeneca plc, which potentially competes in clinical trials with our IMiDs® compounds and TNF-inhibitors;

Millennium Pharmaceuticals Inc. and Johnson & Johnson, which compete with REVLIMID® and THALOMID® in the treatment of multiple myeloma and in clinical trials with our IMiDs® compounds;

Pfizer Inc., which potentially competes in clinical trials with our kinase inhibitors;

Biogen Idec Inc. and Genzyme Corporation, both of which are generally developing drugs that address the oncology and immunology markets; and

Johnson & Johnson, which potentially competes with certain of our proprietary programs including our oral anti-inflammatory programs.

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Many of these companies have considerably greater financial, technical and marketing resources than we do. 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.

Sales of our products are dependent on third-party reimbursement.

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 payors. These health care management organizations and third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. If these organizations and third-party payors 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.

Changes in our effective income tax rate could impact our earnings.

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 payments, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, future levels of capital expenditures, changes in the mix of earnings in the various tax jurisdictions in which we operate, the outcome of IRS exams and changes in overall levels of pre-tax earnings. The impact on our income tax provision resulting from the above-mentioned factors may be significant and could have an impact on our results of operations.

Our operations may be impacted by currency fluctuations that may cause our earnings to fluctuate.

Fluctuations in the value of the U.S. dollar against foreign currencies could impact our earnings. We anticipate utilizing foreign currency forward contracts to manage foreign currency risk and not to engage in currency speculation. We would use these forward contracts to hedge certain forecasted transactions denominated in foreign currencies. Our hedging efforts would reduce but not eliminate our anticipated exposure to currency fluctuations. Any significant foreign exchange rate fluctuations within a short period of time could still adversely affect our financial condition and results of operations.

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

As our Company continues to expand at a rapid pace, the development of new and improvements to existing 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 or debt securities obligations.

The price of our common stock may fluctuate significantly, which may make it difficult for you to sell the common stock when you want or at prices you find attractive.

There has been significant volatility in the market prices for publicly traded shares of biopharmaceutical companies, including ours. We expect that the market price of our common stock will continue to fluctuate. The intra-day price of our common stock fluctuated from a high of $75.44 per share to a low of $41.26 per share in 2007. On December 31, 2007, our common stock closed at a price of $46.21 per share. The price of

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our common stock may not remain at or exceed current levels. 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;
- announcements of technical or product developments by our competitors;
- market conditions for pharmaceutical and biotechnology stocks;
- market conditions generally;
- governmental regulation;
- new accounting pronouncements or regulatory rulings;
- health care legislation;
- 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;
- fluctuations in our operating results;
- the outcome of litigation involving our products or processes related to production and formulation of those products or uses of those products;
- competition;
- investor reaction to announcements regarding business or product acquisitions.

The market price of our common stock may also decline as a result of the pending acquisition of Pharmion if the integration with Pharmion is unsuccessful or takes longer than expected; the perceived benefits of the merger are not achieved as rapidly as anticipated or, to the extent anticipated, by financial analysts or investors; or the effect of the merger on our financial results is not consistent with the expectations of financial analysts or investors.

In addition, the stock market in general and the biotechnology sector in particular has experienced extreme volatility that has often been unrelated to the operating performance of a particular company. These broad market fluctuations may adversely affect the market price of our common stock.

The number of shares of our common stock eligible for future sale could adversely affect the market price of our common stock.

Future sales of substantial amounts of our common stock or debt or other securities convertible into common stock could adversely affect the market price of our common stock. As of December 31, 2007, there were outstanding stock options and warrants for 33,096,086 shares of common stock, of which 22,320,094 were currently vested and exercisable at an exercise price between $0.04 per share and $73.55 per share, with a weighted average exercise price of $18.97 per share. In addition, in June 2003, we issued $400.0 million of unsecured convertible notes that are

currently convertible into 16,227,441 shares of our common stock at the conversion price of $12.1125. These notes will mature in June 2008. The conversion of some or all of these notes will dilute the ownership interest of our stockholders. In addition, we will issue between 24,000,000 and 32,000,000 shares of our common stock in the merger, all of which may be immediately resold.

Our shareholder rights plan and certain charter and by-law provisions 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 adopted a shareholder rights plan, the purpose of which is to protect stockholders against unsolicited attempts to acquire control of us that do not offer a fair price to all of our

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stockholders. The rights plan may have the effect of dissuading a potential acquirer from making an offer for our common stock at a price that represents a premium to the then current trading price.

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 board of directors has adopted certain amendments to our by-laws 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.

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 Securities and Exchange Commission, or 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. 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, which is located in Summit, New Jersey on approximately 45 acres of land, was purchased in 2004 and consists of several buildings, which house our administrative, sales, marketing and research functions.

Construction of our international headquarters in Neuchatel, Switzerland was completed in 2007 and includes a drug product manufacturing facility to perform formulation, encapsulation, packaging, warehousing and distribution. In December 2006, we purchased an API manufacturing facility located in Zofingen, Switzerland which has the capability to produce multiple drug substances. The facility is being used to produce REVLIMID® and THALOMID® API to supply global markets and may also be used to produce drug substance for our future drugs and drug candidates.

We occupy the following facilities under operating lease arrangements that have remaining lease terms greater than one-year. Under these lease arrangements, we also are required to reimburse the lessors for real estate taxes, insurance, utilities, maintenance and other operating costs. All leases are with unaffiliated parties.

73,500-square feet of laboratory and office space in Warren, New Jersey. The two leases for this facility extend through May 2012 and July 2010, respectively, and contain five-year renewal options. Annual rent for these facilities is approximately $1.1 million.

78,200-square feet of laboratory and office space in San Diego, California. The lease for this facility has a term ending in August 2012 with one five-year renewal option. Annual rent for this facility is approximately $2.1 million and is subject to specified annual rental increases.

20,800-square feet of office and laboratory space in Cedar Knolls, New Jersey. The lease for this facility has a term ending at the end of October 2010 with renewal options for additional five-year terms. Annual rent for this facility is approximately $0.3 million and is subject to specified annual rental increases.

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11,000-square feet of office and laboratory space in Baton Rouge, Louisiana. The lease for this facility has a term ending in May 2011. Annual rent for this facility is approximately $0.1 million.

We also lease a number of offices under various lease agreements in Europe, Canada, Australia and Japan. The minimum annual rents may be subject to specified annual rent increases. At December 31, 2007, the non-cancelable lease terms for these operating leases expire at various dates between 2008 and 2016 and in some cases include renewal options.

ITEM 3. ***LEGAL PROCEEDINGS***

Barr Laboratories, Inc., (Barr) a generic drug manufacturer located in Pomona, New York, filed an ANDA for the treatment of ENL in the manner described in our label and seeking permission from the FDA to market a generic version of 50mg, 100mg and 200mg THALOMID®. Under the federal Hatch-Waxman Act of 1984, any generic manufacturer may file an ANDA with a certification (a Paragraph IV certification) challenging the validity or infringement of a patent listed in the FDA s Orange Book four years after the pioneer company obtains approval of its New Drug Application, or an NDA. On or after December 5, 2006, Barr mailed notices of Paragraph IV certifications alleging that the following patents listed for THALOMID® in the Orange Book are invalid, unenforceable, and/or not infringed: U.S. Patent Nos. 6,045,501 (the 501 patent), 6,315,720 (the 720 patent), 6,561,976 (the 976 patent), 6,561,977 (the 977 patent), 6,755,784 (the 784 patent), 6,869,399 (the 399 patent), 6,908,432 (the 432 patent) 7,141,018 (the 018 patent). The 501, 976, and 432 patents do not expire until August 28, 2018, while the remaining patents do not expire until October 23, 2020. On January 18, 2007, we filed an infringement action in the United States District Court of New Jersey against Barr. By bringing suit, we are entitled up to a maximum 30-month stay, from the date of Celgene s receipt of a Paragraph IV certification, against the FDA s approval of a generic applicant s application to market a generic version of THALOMID®. In June 2007, United States Patent No. 7,230,012, or 012 patent, was issued to us claiming formulations of thalidomide and was then timely listed in the Orange Book. Barr sent us a supplemental Paragraph IV certification against the 012 patent and alleged that the claims of the 012 patent, directed to formulations which encompass THALOMID®, were invalid. On August 23, 2007, we filed an infringement action in the United States District Court of New Jersey with respect to the 012 patent. On or after October 4, 2007, Barr filed a second supplemental notice of Paragraph IV certifications relating to the 150mg dosage strength of THALOMID® alleging that the 501 patent, 720 patent, 976 patent, 977 patent, 784 patent, 399 patent, 432 patent and the 018 patent are invalid, unenforceable, and/or not infringed. On November 14, 2007, we filed an infringement action in the United States District Court of New Jersey against Barr. All three actions have subsequently been consolidated. We intend to enforce our patent rights. If the ANDA is approved by the FDA, and Barr is successful in challenging our patents listed in the Orange Book for THALOMID®, Barr would be permitted to sell a generic thalidomide product.

On August 19, 2004, we, together with our exclusive licensee Novartis, filed an infringement action in the United States District Court of New Jersey against Teva Pharmaceuticals USA, Inc., (Teva) in response to notices of Paragraph IV certifications made by Teva in connection with the filing of an ANDA for FOCALIN®. The notification letters from Teva contend that United States Patent Nos. 5,908,850, or 850 patent, and 6,355,656, or 656 patent, are invalid. After the suit was filed, Novartis listed another patent, United States Patent No. 6,528,530, or 530 patent, in the Orange Book in association with the FOCALIN® NDA. The original 2004 action asserted infringement of the 850 patent. Teva amended its answer during discovery to contend that the 850 patent was not infringed by the filing of its ANDA, and that the 850 patent is not enforceable due to an allegation of inequitable conduct. Fact discovery in the original 2004 action expired on February 28, 2006. At about the time of the filing of the 850 patent infringement action, reexamination proceedings for the 656 patent were initiated in the U.S. PTO. On September 28, 2006, the U.S. PTO issued a Notice of Intent to Issue Ex Parte Reexamination Certificate, and on March 27, 2007, the Reexamination Certificate for the 656 patent issued. On December 21, 2006, Celgene and Novartis filed an action in

the United States District Court of New Jersey against Teva for infringement of the 656 patent. Teva filed an amended answer and counterclaim on March 23, 2007. The amended counterclaim seeks a declaratory judgment of patent invalidity, noninfringement, and unenforceability. The statutory 30-month stay of FDA approval of Teva s ANDA expired on January 9, 2007, and Teva proceeded to market with a generic version

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of FOCALIN®. Novartis sales of FOCALIN® have been significantly reduced in the United States by the entrance of a generic FOCALIN® product, consequently reducing our revenue from royalties associated with these sales. A claim has been made for damages resulting from Teva s sales and for a permanent injunction prohibiting future sales by Teva. The parties currently are engaged in fact discovery with respect to the 656 patent and other issues related to Teva s product launch. No trial date has been set. The 530 patent is not part of this patent infringement action against Teva.

On September 14, 2007, we, together with our exclusive licensee Novartis, filed an infringement action in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. in response to a notice of a Paragraph IV certification made by Teva in connection with the filing of an ANDA for FOCALIN XR®. The notification letter from Teva contends that claims in United States Patent Nos. 5,908,850 and 6,528,530 are invalid, unenforceable, and not infringed by the proposed Teva products, and it contends that United States Patent Nos. 5,837,284 and 6,635,284 are invalid and not infringed by the proposed Teva products. Celgene and Novartis asserted each of these patents and additionally asserted United States Patent No. 6,355,656 in their complaint against Teva. Teva filed an answer and counterclaim on November 5, 2007. The counterclaim seeks a declaratory judgment of patent invalidity, noninfringement, and unenforceability with respect to the patents-in-suit. No trial date has been set. If we are unsuccessful in proving infringement or defending our patents, Novartis sales of FOCALIN XR® could be significantly reduced in the United States by the entrance of a generic FOCALIN XR® product, consequently reducing our revenue from royalties associated with these sales.

On October 5, 2007, we, together with our exclusive licensee Novartis, filed an infringement action in the United States District Court for the District of New Jersey against IntelliPharmaCeutics Corp. (IPC) in response to a notice of a Paragraph IV certification made by IPC in connection with the filing of an ANDA for FOCALIN XR®. The notification letter from IPC contends that claims in United States Patent Nos. 5,908,850, 5,837,284, and 6,635,284 are not infringed by the proposed IPC products. The notification letter also contends that claims in United States Patent Nos. 5,908,850, 6,355,656, 6,528,530, 5,837,284, and 6,635,284 are invalid, and that claims in United States Patent Nos. 5,908,850, 6,355,656 and 6,528,530 are unenforceable. In their complaint against IPC, Celgene and Novartis asserted United States Patent Nos. 5,908,850, 6,355,656, 6,528,530, 5,837,284, and 6,635,284. IPC filed an answer and counterclaim on November 20, 2007. The counterclaim seeks a declaratory judgment of patent invalidity, noninfringement, and unenforceability with respect to Patent Nos. 5,908,850, 6,355,656, and 6,528,530, and it seeks a declaratory judgment of patent invalidity and noninfringement with respect to Patent Nos. 5,837,284 and 6,635,284. No pretrial or trial dates have been set. If we are unsuccessful in proving infringement or defending our patents, Novartis sales of FOCALIN XR® could be significantly reduced in the United States by the entrance of a generic FOCALIN XR® product, consequently reducing our revenue from royalties associated with these sales.

On November 8, 2007, we, together with our exclusive licensee Novartis, filed an infringement action in the United States District Court for the District of New Jersey against Actavis South Atlantic LLC and Abrika Pharmaceuticals, Inc. (collectively, Abrika) in response to a notice of a Paragraph IV certification made by Abrika in connection with the filing of an ANDA for FOCALIN XR®. The notification letter from Abrika contends that claims in United States Patent Nos. 5,908,850, 6,355,656, 5,837,284, and 6,635,284 are not infringed by the proposed Abrika products, and it contends that claims in United States Patent Nos. 5,908,850, 6,355,656, 6,528,530, 5,837,284 and 6,635,284 are invalid. In their complaint against Abrika, Celgene and Novartis asserted United States Patent Nos. 5,908,850, 6,355,656, 6,528,530, 5,837,284, and 6,635,284. No pretrial or trial dates have been set. If we are unsuccessful in proving infringement or defending our patents, Novartis sales of FOCALIN XR® could be significantly reduced in the United States by the entrance of a generic FOCALIN XR® product, consequently reducing our revenue from royalties associated with these sales.

On November 16, 2007, we, together with our exclusive licensee Novartis, filed an infringement action in the United States District Court for the District of New Jersey against Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. in

response to a notice of a Paragraph IV certification made by Barr in connection with the filing of an ANDA for FOCALIN XR®. The notification letter from Barr contends that claims in United States Patent Nos. 5,908,850, 6,355,656, 5,837,284, and 6,635,284 are not infringed by the proposed Barr products, and it contends that claims in United States Patent Nos. 5,908,850, 6,355,656, 6,528,530, 5,837,284 and 6,635,284 are invalid. In their complaint against Barr, Celgene and Novartis asserted United States Patent

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Nos. 5,908,850, 6,355,656, 6,528,530, 5,837,284, and 6,635,284. No pretrial or trial dates have been set. If we are unsuccessful in proving infringement or defending our patents, Novartis sales of FOCALIN XR® could be significantly reduced in the United States by the entrance of a generic FOCALIN XR® product, consequently reducing our revenue from royalties associated with these sales.

On December 4, 2006, we, together with our exclusive licensee Novartis, filed an infringement action in the United States District Court for the District of New Jersey against Abrika Pharmaceuticals, Inc. and Abrika Pharmaceuticals, LLP, in response to a notice of a Paragraph IV certification made by Abrika in connection wi