INFINITY PHARMACEUTICALS, INC.
Form 10-K
February 25, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2013

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

For the transition period from to

Commission file number: 000-31141

INFINITY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	33-0655706
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

780 Memorial Drive, Cambridge, Massachusetts 02139

(Address of principal executive offices) (zip code)

Registrant s telephone number, including area code: (617) 453-1000

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

Common Stock, $.001 par value	NASDAQ Global Select Market
(Title of each class)	(Name of each exchange on which listed)

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

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

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

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 x No ¨

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

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

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

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

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

The aggregate market value of voting Common Stock held by non-affiliates of the registrant as of June 28, 2013 was $756,105,453 based on the last reported sale price of the registrant s Common Stock on the NASDAQ Global Select Market on that date.

Number of shares outstanding of the registrant s Common Stock as of February 14, 2014: 48,281,015

Documents incorporated by reference:

Portions of our definitive proxy statement to be filed with the Securities and Exchange Commission no later than April 30, 2014 in connection with our 2014 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Forward-Looking Information

This Annual Report on Form 10-K contains forward-looking statements regarding our expectations with respect to the possible achievement of discovery and development milestones in 2014, our future discovery and development efforts, our collaborations, our future operating results and financial position, our business strategy and other objectives for future operations. We often use words such as anticipate, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, should, continue, and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. You also can identify these forward-looking statements by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause actual results or events to differ materially from those indicated by forward-looking statements. These risks and uncertainties include those inherent in pharmaceutical research and development, such as adverse results in our drug discovery and clinical development activities, decisions made by the U.S. Food and Drug Administration and other regulatory authorities with respect to the development and commercialization of our product candidates, our ability to obtain, maintain and enforce intellectual property rights for our product candidates, our dependence on our alliance partners, competition, our ability to obtain any necessary financing to conduct our planned activities and other risk factors. Please refer to the section entitled Risk Factors in Part I of this report for a description of these risks and uncertainties. Unless required by law, we do not undertake any obligation to update any forward-looking statements.

PART I

Item 1. Business

Overview

We are an innovative biopharmaceutical company dedicated to discovering, developing and delivering best-in-class medicines to people with difficult-to-treat diseases. We combine proven scientific expertise with a passion for developing novel small molecule drugs that target emerging disease pathways. We have worldwide development and commercialization rights to all of our development candidates and early discovery programs, subject to certain financial obligations to our current licensor and former development partners.

IPI-145, our lead product candidate, is a potent, oral inhibitor of Class I delta and gamma isoforms of phosphoinositide-3-kinase, or PI3K, which we are investigating in both hematologic malignancies and inflammatory diseases. The PI3Ks are a family of enzymes involved in multiple cellular functions, including cell proliferation and survival, cell differentiation, cell migration and immunity. The PI3K-delta and PI3K-gamma isoforms are preferentially expressed in white blood cells, where they have distinct and mostly non-overlapping roles in immune cell development and function. Targeting PI3K-delta and PI3K-gamma may provide multiple opportunities to develop differentiated therapies for the treatment of hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the most advanced PI3K-delta,gamma inhibitor in clinical development. The following is a summary of the clinical development of IPI-145 and 2014 goals:

Hematologic Malignancies

We have launched DUETTS™, a worldwide investigation of IPI-145 in blood cancers. As part of the DUETTS™ program, we are conducting DYNAMO™, a Phase 2, open-label, single arm study evaluating the safety and efficacy of IPI-145 dosed at 25mg BID in approximately 120 patients with indolent non-Hodgkin lymphoma, or iNHL, including follicular lymphoma (or FL), marginal zone lymphoma and small lymphocytic lymphoma (or SLL), whose disease is refractory to radioimmunotherapy or both rituximab and chemotherapy. The FDA has granted orphan drug designation to IPI-145 for the potential treatment of FL, the most common subtype of iNHL.

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Also under the DUETTS™ program, we are also conducting DUO™, a randomized, monotherapy Phase 3 study of IPI-145 in approximately 300 patients with relapsed/refractory chronic lymphocytic leukemia, or CLL.

We are also conducting an ongoing Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies. The dose escalation portion of the trial is complete, with the maximum tolerated dose defined as 75 mg twice daily, or BID. We are continuing to evaluate IPI-145 across two 25mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and mantle cell lymphoma, MCL, and treatment-naïve CLL in high-risk patients (those patients who are over age 65 or who have one of two genomic alterations known as a 17p deletion or a p53 mutation). Additionally, we are continuing to evaluate IPI-145 across five 75mg BID expansion cohorts in patients with relapsed/refractory CLL, iNHL and MCL; T-cell lymphomas; aggressive B-cell lymphomas; myeloid neoplasms; and T-cell or B-cell acute lymphoblastic leukemia/lymphoma.

In 2014, we intend to initiate DYNAMO+R, a Phase 3 study of IPI-145 dosed at 25 mg BID in combination with rituximab in patients with relapsed/refractory iNHL, as well as a Phase 2 study of IPI-145 in treatment-naïve patients with iNHL. We also expect to initiate at least one additional clinical trial in patients with hematologic malignancies in 2014.

Inflammation and Autoimmune Diseases

We have completed a Phase 1, randomized, double-blind, placebo-controlled trial of IPI-145 in healthy adult subjects designed to support the development of IPI-145 in inflammatory and autoimmune diseases.

We are conducting a Phase 2, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety and pharmacokinetics of IPI-145 in patients with rheumatoid arthritis, or RA, which we refer to as the ASPIRA trial. We intend to report topline data from this study in 2014.

We are also conducting a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in patients with mild, allergic asthma. We intend to report topline data from this study in 2014.

We are also developing our second PI3K product candidate, a potent, oral inhibitor of PI3K-delta and gamma which we refer to as IPI-443. The nonclinical studies of IPI-443 required for Phase 1 development have been completed, and the data from the two Phase 2 studies of IPI-145 in inflammatory and autoimmune diseases will guide the next steps for the development of IPI-443.

In September 2013 we announced topline data from our Phase 2 study evaluating retaspimycin hydrochloride, or HCl, a novel, potent and selective inhibitor of heat shock protein 90, or Hsp90, in combination with docetaxel, a chemotherapy, in 226 patients with second or third-line non-small cell lung cancer, or NSCLC, who are naïve to docetaxel treatment and have a history of heavy smoking. In this randomized, double-blind, placebo-controlled study, retaspimycin HCl did not meet its pre-specified efficacy endpoints for demonstrating an improvement in overall survival in the total patient population or in patients with squamous cell carcinoma, despite observing partial responses in patients with squamous cell carcinoma during the Phase 1b testing. Additionally, the combination of retaspimycin HCl plus docetaxel did not show a treatment benefit in patient populations defined by pre-specified biomarkers, including KRAS, p53 and plasma levels of Hsp90-alpha. We expect to present final data in a peer-reviewed setting after all analyses are complete.

We completed enrollment of the final cohort of patients in our separate, exploratory study of retaspimycin HCl in combination with everolimus (an mTOR inhibitor) in NSCLC patients with a KRAS mutation. Completing enrollment has concluded our development of retaspimycin HCl, and we will not initiate any new trials with retaspimycin HCl.

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Recent Development

Facility Agreement

On February 24, 2014, or Effective Date, we entered into a Facility Agreement with affiliates of Deerfield Management Company, L.P., or Deerfield, pursuant to which Deerfield agreed to loan to us up to $100,000,000, subject to the terms and conditions set forth in the Facility Agreement. Under the Facility Agreement, we may draw down on the facility in $25,000,000 increments at any time during the 12 months following the Effective Date. Our ability to draw down under the Facility Agreement is subject to various customary conditions, including the entry into a Guaranty and Security Agreement, or Guaranty, with Deerfield and Infinity Discovery, Inc., or IDI, our a wholly-owned subsidiary, pursuant to which, as security for the repayment of our obligations under the Facility Agreement, IDI will guaranty all of our obligations under the Facility Agreement and, to secure the obligations under the Facility Agreement and the Guaranty, both we and IDI will grant to Deerfield a security interest in substantially all of our assets including intellectual property.

Any amounts drawn under the Facility Agreement accrue interest at a rate of 7.95% per annum, payable quarterly in arrears beginning on June 1, 2014, provided that, during the first five interest payment dates of any draw under the Facility Agreement, we may elect to pay all or a portion of such accrued interest by adding it to the principal amount outstanding. All such accrued interest will, regardless of which draw it applies to, be payable on the last business day of the sixth calendar quarter following the date of the first draw. We have the right to terminate the Facility Agreement and/or to prepay amounts owed under the Facility Agreement at any time, provided that, to the extent that any amount was drawn less than three years before such early termination or prepayment, we will be required to pay an additional amount equal to three years of interest less the amount of interest previously paid. We will be required to repay Deerfield one-third of the total principal amount drawn under the Facility Agreement on each of the third, fourth and fifth anniversaries of the first draw, however the final payment must be made by December 15, 2019. On February 27, 2015, or upon the earlier termination or acceleration of the facility, we are required to pay a fee equal to 3% of the then undrawn portion of the $100,000,000 commitment.

Deerfield will have the right to accelerate payment of the facility in the event that we consummate a major transaction, which is generally defined as a change in control, a sale of all or substantially all of our assets, a tender or exchange offer for our common stock, a liquidation, bankruptcy, insolvency, dissolution or wind up, a delisting and/or the common stock ceases to be registered under the Securities Exchange Act of 1934, or the Exchange Act.

Any amounts drawn under the Facility Agreement may become immediately due and payable upon (i) customary events of default, as defined in the Facility Agreement, or (ii) the consummation of certain major transactions, in which case Deerfield would have the right to require us to repay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, plus any applicable additional amounts relating to a prepayment or termination, as described above.

Principal and interest under the Facility may be paid in cash or freely tradable shares of common stock at our election, subject to specified conditions at any time of conversion.

The Facility Agreement contains various representations and warranties, and affirmative and negative covenants, customary for financings of this type, provided that the negative covenants are not applicable until the first draw under the Facility Agreement.

Warrants

In connection with the execution of the Facility Agreement, we issued to Deerfield warrants to purchase an aggregate of 1,000,000 shares of common stock at an exercise price of $13.83 per share, or the Initial Warrants. As noted above, pursuant to the Facility Agreement, we have the right to request from Deerfield one or more

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cash disbursements in the minimum amount of $25,000,000 per disbursement, which disbursements shall be accompanied by the issuance to Deerfield of warrants to purchase an aggregate number of shares of common stock equal to (A) a quotient derived by dividing (x) the aggregate amount of such disbursement by (y) the volume weighted average closing price per share of the common stock during the 20 trading days following Deerfield s receipt of the applicable draw notice, or the 20-Day VWAP, multiplied by (B) 50%, or the Draw Warrants. We refer to the Initial Warrants and the Draw Warrants individually as a Warrant or together as the Warrants. The exercise price of the Draw Warrants will be the applicable 20-Day VWAP for each disbursement. The number of shares of common stock into which a Warrant is exercisable and the exercise price of any Warrant will be adjusted to reflect any stock splits, recapitalizations or similar adjustments in the number of outstanding shares of common stock.

Each Warrant issued under the Facility Agreement expires on the seventh anniversary of its issuance. Subject to certain exceptions, the Warrants and the Facility Agreement contain certain limitations such that we may not issue shares of common stock to Deerfield pursuant to the Warrants or the Facility Agreement if such issuance would result in Deerfield beneficially owning in excess of 9.985% of the total number of shares of our common stock of then issued and outstanding.

The holder of a Warrant may exercise the Warrant either for cash or on a cashless basis. In connection with certain major transactions, the holder may have the option to receive, upon exercise of the Warrant in whole or in part, either cash or a number of shares of common stock equal to the Black-Scholes value of the Warrant, as defined in the Warrant.

Registration Rights Agreement

In connection with the entry into the Facility Agreement and issuance of the Initial Warrants, we entered into a Registration Rights Agreement with Deerfield dated February 24, 2014. Pursuant to the terms of the Registration Rights Agreement, we have agreed to file a registration statement on Form S-3 with the SEC on or prior to 30 days from the Effective Date, to register for resale the shares of common stock issuable upon the exercise of the Initial Warrants. Additionally, pursuant to the terms of the Registration Rights Agreement, we have agreed to file one or more additional registration statements with the SEC to register for resale the shares of common stock issuable upon the exercise of the applicable Draw Warrants, on or prior to 30 days after issuance of each of the Draw Warrants.

Corporate Information

We were incorporated in California on March 22, 1995 under the name IRORI and, in 1998, we changed our name to Discovery Partners International, Inc., or DPI. In July 2000, we reincorporated in Delaware. On September 12, 2006, DPI completed a merger with Infinity Pharmaceuticals, Inc., or IPI, pursuant to which a wholly-owned subsidiary of DPI merged with and into IPI. IPI, the surviving corporation in the merger, changed its name to Infinity Discovery, Inc., or IDI, and became a wholly owned subsidiary of DPI. In addition, we changed our corporate name from Discovery Partners International, Inc. to Infinity Pharmaceuticals, Inc., and our ticker symbol on the NASDAQ Global Market to INFI. Our common stock currently trades on the NASDAQ Global Select Market.

Our principal executive offices are located at 780 Memorial Drive, Cambridge, Massachusetts 02139, and our telephone number at that address is (617) 453-1000.

The Infinity logo and all other Infinity product names are trademarks of Infinity or its subsidiary in the United States and in other select countries. We may indicate U.S. trademark registrations and U.S. trademarks with the symbols ® and , respectively. Other third-party logos and product/trade names are registered trademarks or trade names of their respective owners.

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Product Development Pipeline

Historically, our product development programs have arisen from a combination of internally developed programs and strategic licensing arrangements. Whether our programs are developed internally or obtained from a third party, we focus on targets that have the potential to represent fundamentally new approaches to how disease is treated and where we believe we can use our scientific capabilities to identify differentiated product candidates with well-defined development paths. We seek to leverage what we believe to be our innovative approaches to drug discovery and translational medicine and our robust internal capabilities across all of the relevant scientific disciplines, including medicinal chemistry, cell biology, biochemistry, pharmacology and molecular pathology. Our goal is to integrate these disciplines to rapidly identify product candidates and to better understand which populations of patients may benefit most from our product candidates. We view biomarkers as a key component of our drug development strategy and are actively researching biomarkers in our PI3K programs.

IPI-145, our clinical candidate directed to the inhibition of PI3K, arose out of our strategic licensing arrangement with Intellikine, Inc., or Intellikine, which was acquired in January 2012 by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit, or Millennium. We also have multiple innovative projects in earlier stages of development.

In building our product development pipeline, we have intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us multiple product opportunities in oncology and inflammatory disease, which are areas with broad commercial potential. This strategy also ensures that our success is not dependent on any single product candidate or indication, allowing us to optimize our portfolio on several dimensions in response to new data.

We also believe that the ability to deliver innovative new medicines to patients is an essential component of our mission. To this end, we have worldwide rights to all product candidates in our portfolio subject to certain financial obligations to Millennium, Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue.

Our product development programs as of February 1, 2014 are illustrated in the following chart:

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PI3K Inhibitor Program

The phosphoinositide-3-kinases, or PI3Ks, are key cellular signaling proteins that act as a central node for relaying signals from cell surface receptors to modulate downstream biochemical events. The PI3K-delta and PI3K-gamma isoforms are preferentially expressed in white blood cells, where they have distinct and non-overlapping roles in key cellular functions, including cell proliferation, cell differentiation, cell migration and immunity. Targeting PI3K-delta and PI3K-gamma may provide multiple opportunities to develop differentiated therapies for the treatment of inflammatory diseases as well as hematologic malignancies.

Our lead development candidate in this program is IPI-145, a potent, oral inhibitor of Class I PI3K-delta,gamma, for which we are conducting clinical trials in both hematologic malignancies and inflammatory diseases. We believe that IPI-145 is the most advanced PI3K-delta,gamma inhibitor in clinical development.

Hematologic Malignancies

Hematologic malignancies are cancers of the blood or bone marrow and include leukemia and lymphoma, such as CLL, Hodgkin lymphoma and non-Hodgkin lymphoma, or NHL. It is estimated that there will be approximately 130,000 newly diagnosed incident cases of NHL in the seven major pharmaceutical markets (France, Germany, Italy, Japan, Spain, UK and US) in 2014. The distribution of NHL subtypes differs by country. In the United States and major European countries, diffuse large B-cell lymphoma, or DLBCL, accounts for the majority of NHL cases ranging from 40-43 percent, while CLL accounts for 25-33 percent and FL for 17-22 percent. MCL is the rarest subtype, accounting for 5-6 percent of cases. Even with advances in treatment options for these diseases, the clinical outlook still remains poor for patients. A significant proportion of patients relapses following treatment and become refractory to current agents, representing a significant unmet medical need.

Our Phase 1, open-label, dose-escalation study designed to evaluate the safety, pharmacokinetics and clinical activity of IPI-145 in patients with advanced hematologic malignancies is ongoing (ClinicalTrials.gov Identifier NCT01476657). Data from this study, presented in December 2013 at the Annual Meeting of the American Society for Hematology, or ASH, and in January 2014 at the 6th Annual T-Cell Lymphoma Forum, showed that IPI-145 is clinically active in CLL, iNHL, T-Cell lymphoma and other hematologic malignancies.

Indolent Non-Hodgkin Lymphoma

IPI-145 is clinically active in patients with iNHL, with a 73 percent overall response rate, or ORR, (11 of 15 evaluable patients) and a 20 percent complete response rate (3 of 15 patients). Eight patients (53 percent) remain progression-free for over one year. IPI-145 was generally well tolerated, and the majority of side effects were low-grade, asymptomatic and transient. The most common ³ Grade 3 side effects were increases in ALT or AST (two liver enzymes) (38 percent), neutropenia (31 percent) and diarrhea (13 percent).

We have initiated DYNAMO, a Phase 2, open-label, single arm study evaluating the safety and efficacy of IPI-145 dosed at 25mg BID in approximately 120 patients with iNHL, including FL, marginal zone lymphoma and SLL, whose disease is refractory to radioimmunotherapy or both rituximab and chemotherapy. The FDA has granted orphan drug designation to IPI-145 for the potential treatment of FL, the most common subtype of iNHL. We intend to initiate DYNAMO+R, a Phase 3 study in combination with rituximab in patients with relapsed/refractory iNHL in 2014, as well as initiate a Phase 2 study in treatment-naïve patients with iNHL.

Chronic Lymphocytic Leukemia

IPI-145 is clinically active in patients with relapsed/refractory CLL, with a nodal response rate of 89 percent and an overall response rate of 48 percent as defined by criteria established by the International Workshop on Chronic Lymphocytic Leukemia, or IWCLL criteria, including one complete response and 12 partial responses, among patients receiving IPI-145 at doses £ 25 mg BID. Onset of activity was rapid, with the majority of

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responses occurring in less than two months. Among 12 patients evaluable with 17p deletions or p53 mutations who received IPI-145 at doses £ 25 mg BID, there were six partial responses, five patients with stable disease and one disease progression due to Richter transformation, an aggressive disease. Patients with CLL with 17p deletions or p53 mutations generally have a poor response to chemotherapy and worse prognosis. Preliminary data in treatment-naïve patients showed a decrease in the size of lymph nodes, in all six patients. Three of these six patients had nodal responses, a different way of measuring of clinical activity, including nodal responses in two patients with p53 mutations.

Data showed that IPI-145 was generally well tolerated, with a safety profile consistent with co-morbidities seen in patients with advanced hematologic malignancies. The majority of side effects were low-grade and/or asymptomatic. The most common ³ Grade 3 side effects in patients with relapsed/refractory CLL were neutropenia (30 percent), anemia (12 percent), diarrhea (6 percent) and increases in ALT or AST (6 percent). Fewer side effects were observed in treatment-naïve patients, which is consistent with the co-morbidities of patients with less advanced disease.

We are conducting DUO ™, a Phase 3 monotherapy study designed to evaluate the safety and efficacy of IPI-145 in patients with relapsed/refractory CLL. This randomized study is designed to evaluate the safety and efficacy of IPI-145 dosed at 25 mg BID compared to ofatumumab in approximately 300 patients with relapsed or refractory CLL. The primary endpoint of the study is progression-free survival. The FDA and the European Medicines Agency, or EMA, have granted orphan drug designation to IPI-145 for the potential treatment of CLL and SLL. We are also continuing to evaluate patients from our Phase 1 study with relapsed or refractory CLL and patients with CLL over the age of 65 or have a 17p deletion or p53 mutation and are treatment naïve.

T-Cell Lymphoma and Other Lymphomas

IPI-145 is clinically active in advanced T-cell lymphomas. Treatment with IPI-145 in patients with T-cell lymphomas led to an overall response rate of 38 percent (10 of 26 patients), including one complete response and nine partial responses. Among the 11 patients with peripheral T-cell lymphoma, or PTCL, evaluable for activity, IPI-145 led to one complete response and five partial responses (ORR of 55 percent). Among the 15 patients with cutaneous T-cell lymphoma, or CTCL, evaluable for activity, IPI-145 led to four partial responses (ORR of 27 percent). Stable disease was observed in seven patients with CTCL. The onset of activity was rapid, with a median time to response of 1.9 months (range: 1.5 2.7) for patients with PTCL and 2.4 months (range: 1.7 3.8) for patients with CTCL. The median number of treatment cycles for the 13 patients with PTCL was 2.2 (range 0.5-8) and the median number of treatment cycles for the 17 patients with CTCL was 3.1 (range: 0.4-11).

IPI-145 was generally well tolerated in this patient population with the majority of T-cell lymphoma patients (20 of 30) receiving 75 mg BID IPI-145. The most common Grade 3 side effects were increases in ALT or AST (10 of 30 patients, 33 percent), rash (4 of 30 patients, 13 percent) and fatigue (3 of 30 patients, 10 percent). One patient (3%) had grade 4 ALT or AST increases.

Additionally, early clinical data in patients with aggressive non-Hodgkin lymphoma, or aNHL, and T-cell acute lymphoblastic leukemia, or T-ALL, were reported, with reductions in adenopathy, or decrease in the size of lymph nodes, observed in patients with DLBCL and Richter transformation, an aggressive disease, as well as a partial response in one patient with transformed FL. Translational data showed that IPI-145 effects key signaling molecules in the tumor microenvironment, providing a potential mechanistic rationale for the clinical activity of IPI-145 observed in patients with iNHL and CLL.

An investigator-sponsored Phase 1b, open-label study of IPI-145 in patients with B-cell NHL, CLL and T-cell lymphoma in combination with rituximab (a monoclonal antibody therapy), bendamustine (a chemotherapy) or both rituximab and bendamustine is also open for enrollment (NCT01871675).

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Inflammatory and Autoimmune Diseases

Inflammatory and autoimmune diseases are a group of disorders characterized by the immune system attacking the body s own tissues, which can result in increased inflammation and organ dysfunction. Two examples of autoimmune and inflammatory diseases in particular, RA and asthma, affect large sections of the population with an estimated annual number of prevalent cases in the seven major markets in 2013 of 5.3 million and 76.5 million, respectively. Symptoms of RA include painful swelling and stiffness of the joints and surrounding tissues, while asthma is characterized by inflammation in the lungs leading to wheezing, shortness of breath, chest tightness and coughing. With inadequate treatment, either disease can lead to a poor quality of life, disability and increased mortality. In preclinical studies, IPI-145 has demonstrated activity in an allergen challenge model of asthma and in multiple models of RA. IPI-145 has also demonstrated activity in preclinical models of other inflammatory and autoimmune diseases including Crohn s disease, lupus and multiple sclerosis.

Within inflammatory diseases, IPI-145 is currently being evaluated in two Phase 2 trials. The first trial, which we refer to as the ASPIRA trial, is a Phase 2, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy, safety and pharmacokinetics of IPI-145 in patients with RA. The study is expected to enroll approximately 316 adults with moderate-to-severe RA and is designed to examine three dose levels of IPI-145 given twice daily for 12 weeks in combination with methotrexate compared to treatment with methotrexate alone. The primary efficacy endpoint of the study is the American College of Rheumatology 20 response rate, or ACR20, which is defined as the proportion of people who achieve at least a 20 percent improvement in ACR response criteria. The second is a Phase 2a randomized, double-blind, placebo-controlled trial of IPI-145 in patients with mild, allergic asthma. Endpoints of this multi-dose, two-way crossover study include safety, pharmacokinetics and FEV1, a measure of lung function. We expect to provide an update on this trial in 2014.

Pipeline Expansion

We are also developing our second PI3K product candidate, a potent, oral inhibitor of PI3K-delta and gamma which we refer to as IPI-443. The nonclinical studies of IPI-443 required for Phase 1 development are complete, and the data from the two Phase 2 studies of IPI-145 in inflammatory and autoimmune diseases will guide the next steps for the development of IPI-443.

Other Programs

In addition to our clinical stage programs, we have multiple innovative projects in earlier stages of development. Through our internal discovery efforts, we discovered IPI-940, a novel, orally available inhibitor of fatty acid amide hydrolase, or FAAH. It is believed that inhibition of FAAH may enable the body to bolster its own analgesic and anti-inflammatory response and may have applicability in a broad range of painful or inflammatory conditions. We are currently seeking potential partnering opportunities for our FAAH program.

Strategic Alliances

Since our inception, strategic alliances have been integral to our growth. These alliances have provided access to breakthrough science, significant research support and funding and innovative drug development programs, all intended to help us realize the full potential of our product pipeline. Since our inception, all of our revenue has been derived from our strategic alliances, and all of our revenue during 2012 and 2011 was derived from our former strategic alliance with Mundipharma and Purdue.

Millennium

In July 2010, we entered into a development and license agreement with Intellikine, Inc., or Intellikine, under which we obtained rights to discover, develop and commercialize pharmaceutical products targeting the delta and/or gamma isoforms of PI3K, including IPI-145 and we paid Intellikine a $13.5 million up-front license

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fee. In January 2012, Intellikine was acquired by Takeda Pharmaceutical Company Limited, or Takeda, acting through its Millennium business unit. We refer to our PI3K program licensor as Millennium. In December 2012, we amended and restated our development and license agreement with Millennium.

Under the terms of the amended and restated agreement, we retained worldwide development and commercialization rights for products arising from the agreement for all therapeutic indications, and we are solely responsible for research conducted under the agreement. Additionally, under the amended and restated agreement, Millennium waived certain commercial rights and, in consideration of such waiver, we agreed to pay to Millennium $15 million, payable in installments.

In addition to developing IPI-145, we are seeking to develop our second potent, oral PI3K-delta,gamma inhibitor product candidate, IPI-443, and we are seeking to identify additional novel inhibitors of PI3K-delta and/or PI3K-gamma for future development. We are obligated to pay to Millennium up to $5 million in remaining success-based milestone payments for the development of two distinct product candidates and up to $450 million in success-based milestones for the approval and commercialization of two distinct products. In February 2014, we paid Millennium a $10 million milestone payment in connection with the initiation of our Phase 3 study of IPI-145 in patients with relapsed or refractory CLL. In addition, we are obligated to pay Millennium tiered royalties on worldwide net sales ranging from 7 percent to 11 percent upon successful commercialization of products described in the agreement. Such royalties are payable until the later to occur of the expiration of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, subject to reduction and limits on the number of products, in certain circumstances.

The amended and restated agreement expires on the later of the expiration of certain patents and the expiration of the royalty payment terms for the products, unless earlier terminated. Either party may terminate the agreement on 75 days prior written notice if the other party materially breaches the agreement and fails to cure such breach within the applicable notice period, provided that the notice period is reduced to 30 days where the alleged breach is non-payment. Millennium may also terminate the agreement if we are not diligent in developing or commercializing the licensed products and do not, within three months after notice from Millennium, demonstrate to Millennium s reasonable satisfaction that we have not failed to be diligent. The foregoing periods are subject to extension in certain circumstances. Additionally, Millennium may terminate the agreement upon 30 days prior written notice if we or a related party bring an action challenging the validity of any of the licensed patents, provided that we have not withdrawn such action before the end of the 30-day notice period. We may terminate the agreement at any time upon 180 days prior written notice. The agreement also provides for customary reciprocal indemnification obligations of the parties.

Mundipharma and Purdue

Strategic Alliance Termination Agreements

On July 17, 2012, we terminated our strategic alliance with Mundipharma and Purdue and entered into termination and revised relationship agreements with each of those entities, which we refer to as the 2012 termination agreements. The alliance was previously governed by strategic alliance agreements that we entered into with each of Mundipharma and Purdue in November 2008. The strategic alliance agreement with Purdue was focused on the development and commercialization in the United States of products targeting FAAH. The strategic alliance agreement with Mundipharma was focused on the development and commercialization outside of the United States of all products and product candidates that inhibit or target the Hedgehog pathway, FAAH, PI3K and product candidates arising out of our early discovery projects in all disease fields. Our Hsp90 program was expressly excluded from the alliance.

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Under the terms of the 2012 termination agreements:

- All intellectual property rights that we had previously licensed to Mundipharma and Purdue to develop and commercialize products under the previous strategic alliance agreements terminated, with the result that we have worldwide rights to all product candidates that had previously been covered by the strategic alliance.

- We have no further obligation to provide research and development services to Mundipharma and Purdue as of July 17, 2012.

- Mundipharma and Purdue have no further obligation to provide research and development funding to us. Under the alliance, Mundipharma was obligated to reimburse us for research and development expenses we incurred, up to an annual aggregate cap for each alliance program other than FAAH.

- We are obligated to pay Mundipharma and Purdue a four percent royalty in the aggregate, subject to reduction as described below, on worldwide net sales of products that were covered by the alliance until such time as they have recovered approximately $260 million, representing the research and development funding paid to us for research and development services performed by us through the termination of the strategic alliance. After this cost recovery, our royalty obligations to Mundipharma and Purdue will be reduced to a one percent royalty on net sales in the United States of products that were previously subject to the strategic alliance.

Royalties are payable under these agreements until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country, provided that if royalties are payable solely on the basis of non-patent regulatory exclusivity, each of the royalty rates is reduced by 50 percent. In addition, royalties payable under these agreements after Mundipharma and Purdue have recovered all research and development expenses paid to us are subject to reduction on account of third party royalty payments or patent litigation damages or settlements which might be required to be paid by us if litigation were to arise, with any such reductions capped at 50 percent of the amounts otherwise payable during the applicable royalty payment period.

Intellectual Property

Our intellectual property consists of patents, trademarks, trade secrets and know-how. Our ability to compete effectively depends in large part on our ability to obtain patents and trademarks for our technologies and products, maintain trade secrets, operate without infringing the rights of others and prevent others from infringing our proprietary rights. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, or are effectively maintained as trade secrets. As a result, patents or other proprietary rights are an essential element of our business.

We have five issued or allowed U.S. patents covering IPI-145 and/or other molecules related to our PI3K program, which expire on various dates between 2029 and 2031, excluding any patent term extension. In addition, we have approximately 170 patents and patent applications pending worldwide related to our PI3K program. Any patents that may issue from our pending patent applications would expire between 2029 and 2034, excluding any patent term extension. These patents and patent applications disclose compositions of matter, pharmaceutical compositions, methods of use and synthetic methods.

Our policy is to obtain and enforce the patents and proprietary technology rights that are commercially important to our business, and we intend to continue to file patent applications to protect such technology and compounds in countries where we believe it is commercially reasonable and advantageous to do so. We also rely on trade secrets to protect our technology where patent protection is deemed inappropriate or unobtainable. We protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, collaborators and contractors.

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Competition

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in research and development of drugs for the treatment of the same diseases and conditions as our current and potential future product candidates. Many of these companies have substantially greater financial and other resources, larger research and development staffs and more extensive marketing and manufacturing organizations than we do. In addition, some of them have considerably more experience than us in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also develop products that may be competitive with our product candidates, either on their own or through collaborative efforts.

We expect to encounter significant competition for any drugs we develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage. We are aware that many other companies or institutions are pursuing the development of drugs in the areas in which we are currently seeking to develop our own product candidates, and there may be other companies working on competitive projects of which we are not aware.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals and begin commercialization of their products sooner than we may for our own product candidates. These competitive products may have superior safety or efficacy, or be manufactured less expensively, than our product candidates. If we are unable to compete effectively against these companies on the basis of safety, efficacy or cost, then we may not be able to commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our business.

PI3K Inhibitor Program

We believe that the following companies, among others, are in the clinical stage of development of compounds targeting the delta and/or gamma isoforms of PI3K:

- Gilead Sciences, Inc., which we believe is conducting multiple late stage clinical trials of idelalisib and is conducting a Phase 1b clinical trial of GS-9820;
- Amgen, Inc., which we believe is conducting a Phase 1 clinical trial of AMG-319;
- TG Therapeutics, Inc., which we believe is conducting a Phase 1 clinical trial of TGR-1202;
- Rhizen Pharmaceuticals S.A., which we believe is conducting a Phase 1 clinical trial of RP-6530; and
- GlaxoSmithKline, which we believe has completed Phase 1 clinical trials of GSK-2269557.

In addition, many companies are developing product candidates directed to disease targets such as Bruton s Tyrosine Kinase (or BTK), Janus Kinase (or JAK), Spleen Tyrosine Kinase (or Syk) and B-cell lymphoma 2 (or Bcl-2) in the fields of hematology-oncology and inflammation, including in the specific diseases for which we are currently developing IPI-145, or for which we may develop IPI-145, IPI-443, or other PI3K inhibitors in the future. Such companies include:

- Pharmacyclics, Inc., which has received approval with the U.S. Food and Drug Administration, or FDA, of ibrutinib, a BTK inhibitor, for the treatment of people with MCL or CLL and is conducting multiple late stage clinical studies of ibrutinib in additional hematologic malignancies;

Incyte Corporation which has received FDA approval of ruxolitinib, a JAK inhibitor, in patients with intermediate or high-risk myelofibrosis;

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Rigel Pharmaceuticals, Inc. which has completed a Phase 2 clinical trial of fostamatinib, a Syk inhibitor, in patients with immune thrombocytopenic purpura; and

AbbVie, Inc., which we believe is conducting multiple Phase 1 clinical trials of ABT-199, a Bcl-2 inhibitor, in hematologic malignancies.

Research and Development

As of February 1, 2014, our research and development group consisted of 151 employees, of whom over 34 percent hold Ph.D. or M.D. degrees and an additional 25 percent hold other advanced degrees. Our research and development group is focusing on drug discovery, preclinical research, clinical trials and manufacturing technologies. Our research and development expense for the years ended December 31, 2013, 2012 and 2011 was approximately $99.8 million, $118.6 million and $108.6 million, respectively. Reimbursement for our strategic collaborator-sponsored research and development expenses for the years ended December 31, 2013, 2012 and 2011 totaled approximately $0, $45.0 million, and $88.5 million, respectively. In calculating strategic collaborator-sponsored research and development expenses, we have included all reimbursement for our research and development efforts and excluded license fees. Our remaining research and development expense is company-sponsored.

Manufacturing and Supply

We rely primarily on third parties, and in some instances we rely on only one third party, to manufacture critical raw materials, drug substance and final drug product for our research, preclinical development and clinical trial activities. Commercial quantities of any drugs we seek to develop will have to be manufactured in facilities and by processes that comply with the FDA and other regulations, and we plan to rely on third parties to manufacture commercial quantities of any products we successfully develop.

Sales and Marketing

We currently have limited marketing and no commercial sales or distribution capabilities. We do, however, currently have worldwide development and commercialization rights for products arising out of all of our programs. In order to commercialize any of these drugs if and when they are approved for sale, we will need to, and we intend to, develop the necessary marketing, sales and distribution capabilities.

Government Regulation

Government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, storage, recordkeeping, approval, promotion, labeling, advertising, distribution, marketing, post-approval monitoring and reporting, sampling and export and import of pharmaceutical products such as those we are developing. We cannot provide assurance that any of our product candidates will prove to be safe or effective, will receive regulatory approvals or will be successfully commercialized.

New Drug Approval in the United States

In the United States, drugs and drug testing are regulated by the FDA and other federal agencies, as well as by state and local government authorities. Before any of our products may be marketed for commercial sale and/or shipment in the United States, we must comply with the requirements of the Federal Food, Drug and Cosmetic Act (FFD&C Act), which generally involves the following:

preclinical laboratory and animal tests performed in compliance with the FDA s Good Laboratory Practices, or GLP, regulations;

development of manufacturing processes which conform to FDA-mandated current Good Manufacturing Practices, or cGMPs;

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submission and acceptance of an investigational new drug application, or IND, which must become effective before clinical trials may begin in the United States;

conduct of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use; and

the submission to and review and approval by the FDA of a New Drug Application, or NDA, prior to any commercial sale or shipment of a product.

The testing and marketing approval process requires substantial time, effort and financial resources. We cannot be certain that any approval will be granted on a timely basis, if at all.

Preclinical testing. Preclinical tests include laboratory evaluation of a product candidate, its chemistry, formulation, safety and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. We must submit the results of the preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol to the FDA as part of an IND. An IND is an exemption from the FFD&C Act that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. Preclinical tests and studies can take several years to complete, and despite completion of those tests and studies, the FDA may not permit clinical testing to begin.

The IND process. The FDA requires a 30-day waiting period after the filing of each IND application before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin or continue. The IND application process may become extremely costly and substantially delay development of our product candidates. Moreover, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Prior to the initiation of clinical studies, an independent Institutional Review Board, or IRB, at each clinical site proposing to conduct the clinical trial must review and approve each study protocol, and study subjects must provide informed consent. During clinical studies the FDA requires the submission of serious adverse event reports and other periodic reports.

Clinical trials. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the disease being investigated and tested for safety, dosage tolerance, bioavailability, absorption, distribution, excretion and metabolism. These studies may be conducted in healthy volunteers or patients with the disease being studied.

Phase 2: The product candidate is introduced into a limited patient population to: (1) assess the efficacy of the candidate in specific, targeted indications; (2) assess dosage tolerance and optimal dosage; and (3) identify possible adverse effects and safety risks.

Phase 3: These are commonly referred to as pivotal studies. If a product candidate is found to have an acceptable safety profile and to be potentially effective in Phase 1 and 2 trials, Phase 3 clinical trials will be initiated to further demonstrate clinical efficacy and safety within a larger number of patients at geographically dispersed clinical study sites.

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We cannot be certain that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of our product candidates within any specific time period, if at all. Clinical testing must meet requirements for IRB oversight, informed consent and Good Clinical Practices (GCP). The FDA and the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

The NDA process. If clinical trials are successful, the next step in the drug development process is the preparation and submission to the FDA of an NDA. The NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for marketing and sale in the United States. The NDA must contain a description of the manufacturing process and quality control methods, as well as results of preclinical tests, toxicology studies, clinical trials and proposed labeling, among other things. A substantial user fee must also be paid with the NDA, unless an exemption applies. Every new drug must be the subject of an approved NDA before commercialization in the United States.

Upon submission of the NDA, the FDA will make a threshold determination of whether the application is sufficiently complete to permit review, and, if not, will issue a refuse-to-file letter. If the application is accepted for filing, the FDA will attempt to review and take action on the application in accordance with performance goal commitments the FDA has made in connection with the prescription drug user fee act, or PDUFA, in effect at that time. Current timing commitments under PDUFA vary depending on whether an NDA qualifies for a priority or standard review. FDA acceptance of an NDA for review regardless of the review classification does not guarantee that an application will be approved or even acted upon by any specific deadline. The review process can be significantly extended by FDA due to requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug. In addition, the FDA may approve a product candidate subject to the completion of post-marketing commitment studies, commonly referred to as Phase 4 trials, to monitor the safety and/or effect of the approved product. The FDA may also grant approval with restrictive product labeling, or may impose other restrictions on marketing or distribution such as the adoption of a special risk management plans. The FDA has broad post-marketing regulatory and enforcement powers, including the ability to issue warning letters, levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals.

Manufacturing and post-marketing requirements. If approved, a drug may only be marketed in the dosage forms and for the indications approved in the NDA. Special requirements also apply to any drug samples that are distributed in accordance with the Prescription Drug Marketing Act. The manufacturers of approved products and their manufacturing facilities are subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing requirements, including the FDA s cGMP requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA and make certain other required reports. Product and labeling changes, as well as certain changes in a manufacturing process or facility or other post-approval changes, may necessitate additional FDA review and approval. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as untitled letters, warning letters, suspension of manufacturing, seizure of product, voluntary recall of a product, injunctive action or possible criminal or civil penalties. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval. Because we intend to contract with third parties for manufacturing of our products, our ability to control third party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. Failure of third party manufacturers to comply with cGMP or other FDA requirements applicable to our products may result in, among other things, total or partial suspension of production, failure of the government to grant approval for marketing and withdrawal, suspension, or revocation of marketing approvals.

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With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug s approved labeling (known as off-label use), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors and civil or criminal penalties. Although physicians may prescribe FDA-approved products for off-label uses, manufacturers may not market or promote such off-label uses.

The FDA s policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

New Drug Approval Outside of the United States

Approval of a drug in the United States does not guarantee approval in any other country and vice versa. Thus, we will have to complete approval processes that are similar to those in the United States in virtually every foreign market in order to conduct clinical or preclinical research and to commercialize our product candidates in those countries. The approval procedures and the time required for approvals vary from country to country, may involve additional testing and may take longer than in the United States. Foreign approvals may not be granted on a timely basis, or at all. In addition, regulatory approval of drug prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us.

In common with the United States, the various phases of preclinical and clinical research are subject to significant regulatory controls within the European Union. Variations in the national regimes exist. Most jurisdictions, however, require regulatory and IRB/ethics committee (EC) approval of interventional clinical trials. Most European regulators also require the submission of serious adverse event reports during a study and a copy of the final study report. Under European Union regulatory systems, for products that have an Orphan Drug designation or which target cancer, such as the product candidates we are currently developing, marketing authorizations must be submitted under a centralized procedure that provides for the granting of a single marketing authorization that is valid for all European Union member states.

Orphan Drug Designation

Under the Orphan Drug Act and corresponding European Union orphan regulations, the FDA and European Union regulatory authorities may grant Orphan Drug designation to drugs intended to treat a rare disease or condition. In the United States, a rare disease or condition is one that affects fewer than 200,000 individuals, or more than 200,000 individuals but for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States of that drug. In the European Union, a rare disease or condition is one that affects fewer than 5 in 10,000 individuals.

In the United States, Orphan Drug designation must be requested before submitting an NDA. After the FDA grants Orphan Drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, nor does it assure approval.

In the United States, if a product that has Orphan Drug designation receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that

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the FDA may not approve any other applications to market the same drug (sameness defined as same active moiety) for the same indication, except in very limited circumstances, for seven years. In the European Union, the period of product exclusivity is ten years.

Orphan Drug exclusivity, however, also could block the approval of one of our products in the United States for seven years for an Orphan Drug indication if a competitor obtains approval of the same drug, as defined by the FDA, for such Orphan Drug indication or if our product candidate is determined to be contained within the competitor s product for the same indication or disease. We intend to seek Orphan Drug status for our product candidates as appropriate, but even if an Orphan Drug designation is granted it may not provide us with a material commercial advantage.

Other Regulatory Matters

In the United States, manufacturing, sales, promotion and other activities following the approval of a new drug are subject to regulation by regulatory authorities in addition to the FDA, including the Federal Trade Commission, the Department of Justice, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. Among other laws and requirements, our sales, marketing and scientific/educational programs would need to comply with the anti-kickback provisions of the Social Security Act, the False Claims Act and similar state laws. Our pricing and rebate programs would need to comply with pricing and reimbursement rules. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Finally, certain jurisdictions have other trade regulations from time to time to which our business is subject such as technology or environmental export controls and political trade embargoes. Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into supply contracts, including government contracts.

In addition to regulations enforced by the FDA, we also are subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future foreign, federal, state and local laws and regulations. Our research and development involves the controlled use of hazardous materials, including corrosive, explosive and flammable chemicals, various radioactive compounds and compounds known to cause birth defects. Although we believe that our safety procedures for storing, handling, using and disposing of such materials comply with the standards prescribed by applicable regulations, the risk of contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any such liability could materially affect our ongoing business.

Employees

As of February 1, 2014, we had 180 full-time employees, 151 of whom were engaged in research and development and 29 of whom were engaged in general business management, administration and finance. Over 57 percent of our employees hold advanced degrees. Our success depends, in part, on our ability to recruit and retain talented and trained scientific and business personnel and senior leadership. We believe that we have been successful to date in obtaining and retaining these individuals, but we do not know whether we will be successful in doing so in the future. None of our employees are represented by a labor union or covered by a collective bargaining agreement, nor have we experienced work stoppages. We believe that relations with our employees are good.

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Executive Officers

The following table lists the positions, names and ages of our executive officers as of February 15, 2014:

Name	Age	Position
Adelene Q. Perkins	54	President and Chief Executive Officer
Julian Adams, Ph.D.	59	President of Research & Development
Lawrence E. Bloch, M.D., J.D.	48	Executive Vice President, Chief Financial Officer and Chief Business Officer
Vito J. Palombella, Ph.D.	51	Chief Scientific Officer
David A. Roth, M.D.	51	Chief Medical Officer

Adelene Q. Perkins has served as our President and Chief Executive Officer since January 2010, President and Chief Business Officer from October 2008 through December 2009 and as our Executive Vice President and Chief Business Officer between September 2006 and October 2008. Ms. Perkins served as Executive Vice President of IPI from February 2006 until its merger with DPI in September 2006 and Chief Business Officer of IPI from June 2002 until the DPI merger. Prior to joining IPI, Ms. Perkins served as Vice President of Business and Corporate Development of TransForm Pharmaceuticals, Inc., a private pharmaceutical company, from 2000 to 2002. From 1992 to 1999, Ms. Perkins held various positions at Genetics Institute, most recently serving as Vice President of Emerging Business and General Manager of the DiscoverEase® business unit. From 1985 to 1992, Ms. Perkins held a variety of positions at Bain & Company, a strategy consulting firm. Ms. Perkins received a B.S. in Chemical Engineering from Villanova University and an M.B.A. from Harvard Business School.

Julian Adams, Ph.D., has served as our President of Research & Development since October 2007, our Chief Scientific Officer between September 2006 and May 2010, as Chief Scientific Officer of IPI from October 2003 until the merger with DPI in September 2006, as our President between September 2006 and October 2007 and as President of IPI from February 2006 until September 2006. Prior to joining Infinity, Dr. Adams served as Senior Vice President, Drug Discovery and Development at Millennium Pharmaceuticals, Inc. from 1999 to 2001, where he led the development of Velcade®. Dr. Adams served as Senior Vice President, Research and Development at LeukoSite Inc., a private biopharmaceutical company, from July 1999 until its acquisition by Millennium in December 1999. Dr. Adams served as a director and Executive Vice President of Research and Development at ProScript, Inc., a private biopharmaceutical company, from 1994 until its acquisition by LeukoSite in 1999. Prior to joining ProScript, Dr. Adams held a variety of positions with Boehringer Ingelheim, a private pharmaceutical company, and Merck & Co., Inc., a publicly traded pharmaceutical company. Dr. Adams has served as a director of Aileron Therapeutics, Inc., a privately held biopharmaceutical company, since May 2011. Dr. Adams received a B.S. from McGill University and a Ph.D. from the Massachusetts Institute of Technology in the field of synthetic organic chemistry.

Lawrence E. Bloch, M.D., J.D., has served as our Chief Financial Officer and Chief Business Officer since July 2012. Prior to joining Infinity, Dr. Bloch served as Chief Executive Officer of NeurAxon, Inc., a privately-held biopharmaceutical company, from 2007 to 2011. Previously, he served as Chief Financial Officer and Chief Business Officer of NitroMed, Inc., a publicly-held biopharmaceutical company, from 2004 to 2006. From 2000 to 2004, Dr. Bloch served as Chief Financial Officer, and from 1999 to 2002 as Vice President of Business Development, of Applied Molecular Evolution, Inc., a publicly-held biopharmaceutical company. Dr. Bloch began his career as an emergency medicine resident physician at Massachusetts General Hospital and Brigham & Woman s Hospital. He holds a J.D. from Harvard Law School, an M.D. from Harvard Medical School and an M.B.A. from Harvard Business School.

Vito J. Palombella, Ph.D., has served as our Chief Scientific Officer since May 2010. He is responsible for our drug discovery and preclinical development activities. Prior to his role as Chief Scientific Officer, Dr. Palombella was Vice President, Drug Discovery from September 2006 to May 2010 and Vice President, Biology of IPI from January 2004 to September 2006. Prior to joining Infinity, Dr. Palombella was Director of

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Molecular Biology and Protein Chemistry at Syntonix Pharmaceuticals where he was responsible for improving and expanding its core Fc receptor-mediated drug delivery technology. Before joining Syntonix, Dr. Palombella was Senior Director of Cell and Molecular Biology at Millennium Pharmaceuticals, which he joined through its acquisition of LeukoSite, at which he held the same title, in 1999. Prior to its acquisition by LeukoSite, Dr. Palombella held a number of positions at ProScript, Inc. between 1994 and 1999. While at ProScript, LeukoSite and Millennium, Dr. Palombella was involved in the discovery and development of Velcade® (bortezomib), a proteasome inhibitor for cancer therapy. He also managed a number of additional projects, including research into NF-kB regulation. Dr. Palombella received a B.S. in Microbiology from Rutgers University and an M.S. and Ph.D. in Viral Oncology and Immunology from the New York University Medical Center. He was also a post-doctoral fellow at Harvard University in the laboratory of Dr. Tom Maniatis.

David A. Roth, M.D., has served as our Chief Medical Officer since January 2014. In this role, he provides strategic leadership for our clinical development activities, including responsibility for the company s medical affairs, pharmacovigilance and clinical operations functions. Prior to his role as Chief Medical Officer, Dr. Roth served as our Senior Vice President of Clinical Development and Medical Affairs from the time he joined Infinity in September 2013. Prior to joining Infinity, Dr. Roth was with Pfizer Inc. and Wyeth Pharmaceuticals, publicly traded pharmaceutical companies, from 2003 to 2013 where he contributed to the successful regulatory approval of several products, including Bosulif® (bosutinib), a dual Src/Abl tyrosine kinase inhibitor for the treatment of chronic myelogenous leukemia; Xyntha® and ReFacto AF® for the treatment of hemophilia A; and BeneFIX® for the treatment of hemophilia B. Dr. Roth also led the early development of palbociclib, a CDK 4/6 inhibitor, to Phase 3 evaluation in women with ER positive advanced breast cancer. Among other leadership positions, Dr. Roth served as Vice President and Head of the Early Development, Oncology Business Unit at Pfizer from 2009 to 2013. While at Wyeth, he held the role of Assistant Vice President, Clinical Research & Development and Global Therapeutic Area Director of Hematology from 2007 until Pfizer s acquisition of Wyeth in 2009. During his tenure at Pfizer and Wyeth, Dr. Roth also co-chaired Pfizer s oncology research and development board and served on several oncology and hematology R&D leadership teams and governance committees. Prior to joining the pharmaceutical industry, Dr. Roth s experience included over 10 years in research and clinical practice as an academic hematologist, and he served on the full time faculty at Harvard Medical School and Beth Israel Deaconess Medical Center in Boston. Dr. Roth received his B.S. from the Massachusetts Institute of Technology and his M.D. from Harvard Medical School in the Harvard-M.I.T. Division of Health Sciences and Technology, where he remains on the Affiliated Faculty.

Available Information

Our Internet website is http://www.infi.com. We make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the U.S. Securities and Exchange Commission. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled Investors/Media, as a source of information about us.

Our Code of Conduct and Ethics and the charters of the Audit, Compensation, Nominating & Corporate Governance and Research & Development Committees of our board of directors are all available on our website at http://www.infi.com at the Investors/Media section under Corporate Governance. Stockholders may request a free copy of any of these documents by writing to Investor Relations, Infinity Pharmaceuticals, Inc., 780 Memorial Drive, Cambridge, Massachusetts 02139, U.S.A.

The foregoing references to our website are not intended to, nor shall they be deemed to, incorporate information on our website into this report by reference.

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Item 1A. Risk Factors

Risks Related to Our Stage of Development as a Company

Our results to date do not guarantee that any of our product candidates will be safe or effective, or receive regulatory approval.

The risk of failure of our current product candidates is high. To date, the data supporting our clinical development strategy for our product candidates are derived solely from laboratory and preclinical studies and limited early-to-mid-stage clinical trials. Later clinical trials may not yield data consistent with earlier clinical trials, as was the case with our randomized Phase 2 clinical trial of retaspimycin hydrochloride in combination with docetaxel in patients with non-small cell lung cancer, which did not yield results consistent with results obtained from an earlier Phase 1b study. Similarly, clinical responses seen in patients enrolled at early stages of a clinical trial may not be replicated in patients enrolled in that trial at a later time. In addition, adverse events not observed in early clinical trials may be seen for the first time in later studies, or adverse events observed in a small number of patients in early trials may be seen in a greater number of patients in later studies and have greater statistical significance than previously anticipated. In the event that our clinical trials do not yield data consistent with earlier experience, it may be necessary for us to change our development strategy or abandon development of that product candidate, either of which could result in delays, additional costs and a decrease in our stock price. It is impossible to predict when or if any of our product candidates will prove safe or effective in humans or receive regulatory approval. These product candidates may not demonstrate in patients the chemical and pharmacological properties ascribed to them in laboratory studies or early-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. If we are unable to discover or successfully develop drugs that are safe and effective in humans, we will not have a viable business.

We have a history of operating losses, expect to incur significant and increasing operating losses in the future, may never become profitable, or if we become profitable we may not remain profitable.

We have a limited operating history for you to evaluate our business. We have no approved products and have generated no product revenue from sales. We have primarily incurred operating losses. As of December 31, 2013, we had an accumulated deficit of $449.8 million. We expect to continue to spend significant resources to fund the research and development of IPI-145 and our other product candidates. While we may have net income in future periods as the result of non-recurring collaboration revenue, we expect to incur substantial operating losses over the next several years as our clinical trial and drug manufacturing activities increase. As a result, we expect that our accumulated deficit will also increase significantly.

Our product candidates are in varying stages of preclinical and clinical development and may never be approved for sale or generate any revenue. We will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials and receives regulatory approval. Since even our most advanced product candidate requires substantial additional clinical development, we do not expect to receive revenue from our product candidates for several years, if ever. Even if we eventually generate revenues, we may never be profitable, and if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We may be unable to raise the substantial additional capital that we will need to sustain our operations.

We will need substantial additional funds to support our planned operations. In the absence of additional funding or business development activities and based on our current operating plans, we expect that our current cash and investments are sufficient to fund our current operating plans into 2015. In the absence of changes to our current operating plans, we will need to raise additional funds by that date. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectation, if we acquire a

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third party or if we acquire or license rights to additional product candidates or new technologies from one or more third parties. Our need to raise additional funds may also be accelerated for other reasons, including without limitation if:

- our product candidates require more extensive clinical or preclinical testing than we currently expect;
- we advance our product candidates into clinical trials for more indications than we currently expect;
- we advance more of our product candidates than expected into costly later stage clinical trials;
- we advance more preclinical product candidates than expected into early stage clinical trials;
- we acquire additional business, technologies, products or product candidates;
- the cost of acquiring raw materials for, and of manufacturing, our product candidates is higher than anticipated;
- we are required, or consider it advisable, to acquire or license intellectual property rights from one or more third parties; or
- we experience a loss in our investments due to general market conditions or other reasons.

Historically, we relied on our previous strategic alliance with Mundipharma International Corporation Limited, or Mundipharma, and Purdue Pharmaceutical Products L.P., or Purdue, for a significant portion of our research and development funding needs. Mundipharma and Purdue provided us with approximately $260 million in research and development funding during the term of our strategic alliance. Following the termination of the strategic alliance agreements with Mundipharma and Purdue on July 17, 2012, we no longer receive such funding and must use other resources available to us to fund our research and development expenses. Our efforts to raise sufficient capital to replace the funding we previously received under the terminated strategic alliance agreements may not be successful.

We may seek to satisfy our need for additional funds by drawing down funds under the debt Facility Agreement we entered into with affiliates of Deerfield Management Company, L.P., or Deerfield, in February 2014. Under the Facility Agreement, Deerfield agreed to loan to us up to $100 million subject to the terms and conditions of the Facility Agreement. Our ability to draw down under the Facility Agreement is subject to various customary conditions, however, there is no assurance that we will be able to satisfy these conditions and draw down any funds. If we draw down under the Facility Agreement, we will be required to grant to Deerfield a security interest in substantially all of our assets including intellectual property, issue additional warrants to Deerfield, and repay any amounts borrowed together with interest accruing at a rate of 7.95% per annum no later than December 15, 2019. Any amounts drawn under the Facility Agreement may become immediately due and payable upon customary events of default or the consummation of certain major transactions, in which case Deerfield would have the right to require us to repay 100% of the principal amount of the loan, plus any accrued and unpaid interest thereon, plus any applicable additional amounts relating to a prepayment or termination. Principal and interest under the Facility may be paid in cash or freely tradable shares of common stock at our election, subject to specified conditions at any time of conversion. There is no assurance that the conditions to our ability to repay the loan in shares of our common stock would be satisfied at the time that any outstanding principal and interest under the loan is due, in which case we would be obligated to repay the loan in cash, or that events permitting acceleration of the loan will not occur, in which event we would be required to repay any outstanding principal and interest sooner than anticipated.

We may also seek additional funding through public or private financings of equity or debt securities, but such financing may not be available on acceptable terms, or at all. In addition, the terms of such financings may result in, among other things, dilution for stockholders or the incurrence of indebtedness that may impact our ability to make capital expenditures or incur additional debt as would be the case if we decided to draw down under the Facility Agreement with Deerfield. We may also seek additional funds through arrangements with collaborators or other third parties, or through project financing. These arrangements would generally require us

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to relinquish or encumber rights to some of our technologies or product candidates, and we may not be able to enter into such arrangements on acceptable terms, if at all. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our product development programs or to scale back, suspend or terminate our business operations.

If we are not able to attract and retain key personnel and advisors, we may not be able to operate our business successfully.

We are highly dependent on our executive leadership team. All of these individuals are employees-at-will, which means that neither Infinity nor the employee is obligated to a fixed term of service and that the employment relationship may be terminated by either Infinity or the employee at any time, without notice and whether or not cause or good reason exists for such termination. The loss of the services of any of these individuals might impede the achievement of our research, development and commercialization objectives. We do not maintain key person insurance on any of our employees.

Recruiting and retaining qualified scientific and business personnel is also critical to our success. We may not be able to attract or retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. This competition is particularly intense near our headquarters in Cambridge, Massachusetts. We also experience competition for the hiring of scientific personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by other entities, have commitments under consulting or advisory contracts with third parties that limit their availability to us, or both.

We may not be able to execute our business strategy if we are unable to enter into alliances with other companies that can provide capabilities or funding for the development and commercialization of our product candidates.

As part of our business strategy, we have historically entered into, and expect to enter into in the future, alliances with major biotechnology or pharmaceutical companies to jointly develop specific product candidates and to jointly commercialize them if they are approved. In these alliances, we would expect our alliance partner to provide substantial funding, as well as significant capabilities in development, marketing and sales. We may not be successful in entering into any such alliances on favorable terms, if at all. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved drug are disappointing. Furthermore, any delay in entering into alliances could delay the development and commercialization of our product candidates and reduce their competitiveness, even if they reach the market. Any such delay related to our alliances could adversely affect our business.

If an alliance partner terminates or fails to perform its obligations under agreements with us, the development and commercialization of our product candidates could be delayed or terminated.

If any future alliance partner does not devote sufficient time and resources to its alliance arrangements with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be adversely affected. In addition, if any alliance partner were to breach or terminate its arrangements with us, the development and commercialization of the affected product candidate could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of the product candidate on our own, and we may find it difficult to attract a new alliance partner for such product candidate.

Much of the potential revenue from any alliance we may enter into in the future will likely consist of contingent payments, such as royalties payable on sales of any successfully developed drugs. Any such contingent revenue will depend upon our, and our alliance partner s, ability to successfully develop, launch,

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market and sell new drugs. In some cases, we will not be involved in some or all of these processes, and we will depend entirely on our alliance partners. Any of our future alliance partners may fail to develop or effectively commercialize these drugs because it:

- decides not to devote the necessary resources because of internal constraints, such as limited personnel with the requisite scientific expertise, limited cash resources or specialized equipment limitations, or the belief that other product candidates may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;
- does not have sufficient resources necessary to carry the product candidate through clinical development, regulatory approval and commercialization; or
- cannot obtain the necessary regulatory approvals.

If any future alliance partner fails to develop or effectively commercialize our product candidates, we may not be able to develop and commercialize that product candidate independently, and our financial condition and operations would be negatively impacted.

Our competitors and potential competitors may develop products that make ours less attractive or obsolete.

In building our product development pipeline, we have intentionally pursued targets with applicability across multiple therapeutic areas and indications. This approach gives us several product opportunities in oncology and inflammatory diseases, which are highly competitive and rapidly changing segments of the pharmaceutical industry. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are pursuing the development of novel drugs that target various diseases in these segments. We currently face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. Moreover, there are a number of large pharmaceutical companies currently marketing and selling products in these segments including Bristol-Myers Squibb Company, the Roche Group and its subsidiary Genentech, Novartis AG and Pfizer, Inc. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of various forms of cancer and inflammatory diseases.

We are also aware of a number of companies seeking to develop product candidates directed to the same biological targets that our own product candidates are designed to inhibit. Specifically:

- we believe that Gilead Sciences, Inc., Amgen Inc., Rhizen Pharmaceuticals S.A, TG Therapeutics, Inc., and GlaxoSmithKline, are conducting clinical trials of drugs that target the delta and/or gamma isoforms of phosphoinositide-3-kinase, or PI3K, which is the target of IPI-145; and
- many companies are developing product candidates directed to disease targets such as Bruton s Tyrosine Kinase (or BTK), Janus Kinase (or JAK), Spleen Tyrosine Kinase (or Syk) and B-cell lymphoma 2 (or Bcl-2) in the fields of hematology-oncology and inflammation, including in the specific diseases for which we are currently developing IPI-145, or for which we may develop IPI-145, IPI-443 or other PI3K inhibitors in the future, including Pharmacyclics, Inc., Incyte Corporation, Rigel Pharmaceuticals, Inc., and AbbVie, Inc.

Many of our competitors have:

- significantly greater financial, technical and human resources than we have, and may be better equipped to discover, develop, manufacture and commercialize product candidates than we are;

more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing products than we do; and/or

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product candidates that have been approved, such as ibrutinib, a BTK inhibitor being developed and commercialized by Pharmacyclics, Inc. for the treatment of people with mantle cell lymphoma or chronic lymphocytic leukemia, or are in later-stage clinical development than our own product candidates.

Our competitors may commence and complete clinical testing of their product candidates, obtain regulatory approvals and begin commercialization of their products sooner than we and/or our strategic alliance partners may for our own product candidates. These competitive products may have superior safety or efficacy, have more attractive pharmacologic properties, or may be manufactured less expensively than our future products. If we are unable to compete effectively against these companies on the basis of safety, efficacy or cost, then we may not be able to commercialize our future products or achieve a competitive position in the market. This would adversely affect our ability to generate revenues.

We may encounter difficulties in managing organizational change, which could adversely affect our operations.

Our ability to effectively manage changes to our organization, including organizational growth, depends upon the continual improvement of our processes and procedures and the preservation of our corporate culture. We may not be able to implement improvements in an efficient or timely manner, or maintain our corporate culture during periods of organizational change. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may give rise to inefficiencies that would increase our losses or delay our programs.

We may undertake strategic acquisitions in the future, and any difficulties from integrating acquired businesses, products, product candidates and technologies could adversely affect our business and our stock price.

We may acquire additional businesses, products, product candidates, or technologies that complement or augment our existing business. We may not be able to integrate any acquired business, product, product candidate or technology successfully or operate any acquired business profitably. Integrating any newly acquired business, product, product candidate, or technology could be expensive and time-consuming. Integration efforts often place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we expect. The diversion of the attention of our management to, and any delay or difficulties encountered in connection with, any future acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards, controls, procedures and policies that could adversely affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. We may need to raise additional funds through public or private debt or equity financings to acquire any businesses, products, product candidates, or technologies which may result in, among other things, dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire businesses, products, product candidates and technologies or to enter into other significant transactions, we conduct business, legal and financial due diligence in an effort to identify and evaluate material risks involved in the transaction. We will also need to make certain assumptions regarding acquired product candidates, including, among other things, development costs, the likelihood of receiving regulatory approval and the market for such product candidates. If we are unsuccessful in identifying or evaluating all such risks or our assumptions prove to be incorrect, we might not realize some or all of the intended benefits of the transaction. If we fail to realize intended benefits from acquisitions we may consummate in the future, our business and financial results could be adversely affected.

In addition, we will likely incur significant expenses in connection with our efforts, if any, to consummate acquisitions. These expenses may include fees and expenses for investment bankers, attorneys, accountants and other advisers in connection with our efforts, and could be incurred whether or not an acquisition is consummated. Even if we consummate a particular acquisition, we may incur as part of such acquisition

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substantial closure costs associated with, among other things, elimination of duplicate operations and facilities. In such case, the incurrence of these costs could adversely affect our financial results for particular quarterly or annual periods.

Our investments are subject to risks that may cause losses and affect the liquidity of these investments.

As of December 31, 2013, we had approximately $214 million in cash, cash equivalents and available-for-sale securities. We historically have invested these amounts in money market funds, corporate obligations, U.S. government-sponsored enterprise obligations, U.S. Treasury securities and mortgage-backed securities meeting the criteria of our investment policy, which prioritizes the preservation of our capital. Corporate obligations may include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. Our investments are subject to general credit, liquidity, market and interest rate risks and instability in the global financial markets. We may realize losses in the fair value of these investments or a complete loss of these investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have a material adverse effect on our financial results and the availability of cash to fund our operations.

The estimates and judgments we make, or the assumptions on which we rely, in preparing our consolidated financial statements could prove inaccurate.

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include those related to revenue recognition, accrued expenses, assumptions in the valuation of stock-based compensation and income taxes. We base our estimates and judgments on historical experience, facts and circumstances known to us and on various assumptions that we believe to be reasonable under the circumstances. These estimates and judgments, or the assumptions underlying them, may change over time or prove inaccurate. If this is the case, we may be required to restate our financial statements as we did in 2011, which could in turn subject us to securities class action litigation. Defending against such potential litigation relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our financial results and cause our stock price to decline.

Under our strategic alliance termination agreements, Mundipharma and Purdue continue to have the right to audit research and development expenses incurred by us during the term of our former strategic alliance, in order to verify the research and development funding amounts previously paid by Mundipharma and Purdue and have, in the past, exercised such rights. If, as a result of any audit, it is determined that Mundipharma and Purdue have overpaid research and development expenses, we will be required to refund the amount of such overpayment, plus interest, and if such amount is material it could adversely impact our financial results and available cash and we may be required to restate prior period revenue.

If we are not able to maintain effective internal controls under Section 404 of the Sarbanes-Oxley Act, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls, and requires our independent auditors to attest to the effectiveness of our internal controls. Any failure by us to maintain the effectiveness of our internal controls in accordance with the requirements of Section 404 of the Sarbanes-Oxley Act, as such requirements exist today or may be modified, supplemented or amended in the future, could have a material adverse effect on our business, operating results and stock price.

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Risks Related to the Development and Commercialization of Our Product Candidates

All of our product candidates remain subject to clinical testing and regulatory approval. This process is highly uncertain, and we may never be able to obtain marketing approval for any of our product candidates.

To date, we have not obtained approval from the Food and Drug Administration, or FDA, or any foreign regulatory authority to market or sell any of our product candidates. Our product candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of medicinal products like our product candidates. For example, we are evaluating IPI-145, the lead compound in our PI3K inhibitor program, in all phases of clinical development and we anticipate initiating multiple additional trials of IPI-145 in 2014. If any of these trials or other trials of our product candidates are successful, we may need to conduct further clinical trials and will need to apply for regulatory approval before we may market or sell any of our future products. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we are developing, or may in the future develop, either alone or in collaboration with strategic alliance partners, will obtain marketing approval. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA and comparable foreign regulatory agencies. The time required to complete clinical trials and for regulatory review by the FDA and other countries regulatory agencies is uncertain and typically takes many years. Some of our product candidates may be eligible for the FDA s programs that are designed to facilitate the development and expedite the review of certain drugs, but we cannot provide any assurance that any of our product candidates will qualify for one or more of these programs. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification.

Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to changes in government regulation from future legislation or administrative action or changes in FDA and other regulatory policy during the period of product candidate development, clinical trials and FDA and other regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenues from the particular product candidate. Furthermore, the uses for which any regulatory authority may grant approval to market a product may be limited, thus placing constraints on the manner in which we may market the product and curtailing its market potential.

Our product candidates must undergo rigorous clinical trials prior to receipt of regulatory approval. Any problems in these clinical trials could delay or prevent commercialization of our product candidates.

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend, or discontinue clinical trials or to delay the analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of our product candidates:

- unfavorable results of discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;

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- the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;

- inadequate supply, delays in distribution or deficient quality of, or inability to purchase or manufacture drug product, comparator drugs or other materials necessary to conduct our clinical trials;

- unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

- serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;

- a finding that the trial participants are being exposed to unacceptable health risks;

- the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial; or

- any restrictions on, or post-approval commitments with regard to, any regulatory approval we ultimately obtain that render the product candidate not commercially viable.

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a product candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

The delay, suspension or discontinuation of any of our clinical trials, or a delay in the analysis of clinical data for our product candidates, for any of the foregoing reasons, could adversely affect our efforts to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our financial results.

Our inability to enroll sufficient numbers of patients in our clinical trials, or any delays in patient enrollment, can result in increased costs and longer development periods for our product candidates.

Clinical trials require sufficient patient enrollment, which is a function of many factors, including:

- the size of the patient population;

- the nature of the trial protocol, including eligibility criteria for the trial;

- the number of clinical trial sites and the proximity of patients to those sites;

- the commitment of clinical investigators to identify eligible patients; and

- competing studies or trials.

Additionally, the availability of safe and effective treatments for the relevant disease being studied may impact patient enrollment in our clinical trials. For example, Pharmacyclics, Inc. has received approval to manufacture and market, ibrutinib, a BTK inhibitor for the treatment of CLL, an indication in which we are currently evaluating IPI-145 in a Phase 3 clinical trial.

Our failure to enroll patients in a clinical trial could delay the initiation or completion of the clinical trial beyond current expectations. In addition, the FDA or other foreign regulatory authorities could require us to conduct clinical trials with a larger number of patients than has been projected for any of our product candidates. As a result of these factors, we may not be able to enroll a sufficient number of patients in a timely or cost-effective manner.

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Furthermore, enrolled patients may drop out of a clinical trial, which could impair the validity or statistical significance of the clinical trial. A number of factors can influence the patient discontinuation rate, including, but not limited to:

- the inclusion of a placebo arm in a trial;
- possible inactivity or low activity of the product candidate being tested at one or more of the dose levels being tested;
- the occurrence of adverse side effects, whether or not related to the product candidate; and
- the availability of numerous alternative treatment options, including clinical trials evaluating competing product candidates, that may induce patients to discontinue their participation in the trial.

A delay in our clinical trial activities could adversely affect our efforts to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

If we are unable to successfully develop companion diagnostics for our product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our product candidates.

There has been limited success to date industry-wide in developing companion diagnostics. To be successful in developing a companion diagnostic, we will need to address a number of scientific, technical and logistical challenges. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization. We have limited experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our product candidates that receive marketing approval. Given our limited experience in developing diagnostics, we expect to rely, in part, on third parties for their design and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostics for our product candidates or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not receive marketing approval and we may not realize the full commercial potential of any product candidates that receive marketing approval.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily.

We rely on third parties such as contract research organizations, medical institutions and external investigators to enroll qualified patients, conduct our clinical trials and provide services in connection with such clinical trials, and we intend to rely on these and other similar entities in the future. Our reliance on these third parties for clinical development activities reduces our control over these activities. Accordingly, these third party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or the trial design. If these third parties do not successfully carry out their contractual obligations or meet expected deadlines, we may be required to replace them. Replacing a third party contractor may result in a delay of the affected trial and unplanned costs. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our product candidates may be delayed.

In addition, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocol for the trial. The FDA requires us to comply with certain standards, referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If any of our trial investigators or third party contractors does not comply with good clinical practices, we may not be able to use the data and reported results from the trial. If this were to occur, our efforts to obtain regulatory approval for and to commercialize our product candidates may be delayed.

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Manufacturing difficulties could delay or preclude commercialization of our product candidates and substantially increase our expenses.

Our product candidates require precise, high quality manufacturing. The third party manufacturers on which we rely may not be able to comply with the FDA s current good manufacturing practices, or cGMPs, and other applicable government regulations and corresponding foreign standards. These regulations govern manufacturing processes and procedures and the implementation and operation of systems to control and assure the quality of products. The FDA and foreign regulatory authorities may, at any time, audit or inspect a manufacturing facility to ensure compliance with cGMPs and other quality standards. Any failure by our contract manufacturers to achieve and maintain high manufacturing and quality control standards could result in the inability of our product candidates to be released for use in one or more countries. In addition, such a failure could result in, among other things, patient injury or death, product liability claims, penalties or other monetary sanctions, the failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecution, any of which could significantly and adversely affect supply of our product candidates and seriously hurt our business.

Contract manufacturers may also encounter difficulties involving production yields or delays in performing their services. We do not have control over third party manufacturers performance and compliance with applicable regulations and standards. If, for any reason, our manufacturers cannot perform as agreed, we may be unable to replace such third party manufacturers in a timely manner, and the production of our product candidates would be interrupted, resulting in delays in clinical trials and additional costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited and, depending on the type of material manufactured at the contract facility, the change in contract manufacturer must be submitted to and/or approved by the FDA and comparable regulatory authorities outside of the United States. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates after receipt of regulatory approval. It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all.

To date, our product candidates have been manufactured for preclinical testing and clinical trials primarily by third party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third party manufacturers to produce commercial quantities of our approved product candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product candidates in a timely or economical manner, or at all. Significant scale-up of manufacturing might entail changes in the manufacturing process that have to be submitted to or approved by the FDA or other regulatory agencies. If contract manufacturers engaged by us are unable to successfully increase the manufacturing capacity for a product candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

We have commercialization rights to all product candidates in our portfolio, but we currently have limited marketing, sales and distribution experience and capabilities.

We have global commercialization rights for products arising out of our all of our development programs. In order to successfully commercialize our product candidates, we will need to, and we intend to, establish adequate marketing, sales and distribution capabilities for commercialization in the United States, and to seek a qualified partner with these capabilities for commercialization outside the United States. We may not successfully establish these capabilities or have sufficient resources to do so. If we do not establish adequate marketing, sales and distribution capabilities or engage a qualified partner, our ability to successfully commercialize any product candidates that we successfully develop will be adversely affected, as will our financial results. Even if we do develop such capabilities, we will compete with other companies that have more experienced and well-funded marketing, sales and distribution operations.

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If physicians and patients do not accept our future drugs, we may not be able to generate significant revenues from product sales.

Even if any of our product candidates obtains regulatory approval, that product may not gain market acceptance among physicians, patients and the medical community for a variety of reasons including:

- timing of our receipt of any marketing approvals, the terms of any such approvals and the countries in which any such approvals are obtained;
- timing of market introduction of competitive products;
- lower demonstrated clinical safety or efficacy, or less convenient route of administration, compared to competitive products;
- lack of cost-effectiveness;
- lack of reimbursement from managed care plans and other third-party payors;
- inconvenient or difficult administration;
- prevalence and severity of side effects;
- potential advantages of alternative treatment methods;
- safety concerns with similar products marketed by others;
- the reluctance of the target population to try new therapies and of physicians to prescribe those therapies;
- the lack of success of our physician education programs; and
- ineffective sales, marketing and distribution support.

If any of our approved drugs fails to achieve market acceptance, we would not be able to generate significant revenue from those drugs, which may adversely impact our ability to become profitable.

Even if we receive regulatory approvals for marketing our product candidates, we could lose our regulatory approvals and our business would be adversely affected if we, our strategic alliance partners, or our contract manufacturers fail to comply with continuing regulatory requirements.

The FDA and other regulatory agencies continue to review products even after they receive initial approval. If we receive approval to commercialize any of our product candidates, the manufacturing, marketing and sale of these drugs will be subject to continuing regulation, including compliance with quality systems regulations, cGMPs, adverse event requirements and prohibitions on promoting a product for

unapproved uses. Enforcement actions resulting from our failure to comply with government and regulatory requirements could result in fines, suspension of approvals, withdrawal of approvals, product recalls, product seizures, mandatory operating restrictions, criminal prosecution, civil penalties and other actions that could impair the manufacturing, marketing and sale of our product candidates and our ability to conduct our business.

If our product candidates exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could become subject to costly and damaging product liability claims.

Even if we receive regulatory approval for any of our product candidates, we will have tested them in only a small number of patients and over a limited period of time during our clinical trials. If our applications for marketing are approved and more patients begin to use our products, or patients use our products for a longer period of time, new risks and side effects associated with our products may be discovered or previously observed risks and side effects may become more prevalent and/or clinically significant. In addition, supplemental clinical trials that may be conducted on a drug following its initial approval may produce findings that are inconsistent with the trial results previously

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submitted to regulatory authorities. As a result, regulatory authorities may revoke their approvals, or we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers manufacturing facilities. We also might have to withdraw or recall our products from the marketplace. Any safety concerns with respect to a product may also result in a significant drop in the potential sales of that product, damage to our reputation in the marketplace, or result in us becoming subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

We are subject to uncertainty relating to reimbursement policies that could hinder or prevent the commercial success of our product candidates.

Our ability to commercialize any future products successfully will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors in the U.S. generally require that product candidates have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for our future products, or we may be required to sell our future products at prices that are below our expectations.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of our future products in determining whether, and at what level, to approve reimbursement for our future products. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of our future products from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare and Medicaid programs or other reimbursing bodies or payors limit the indications for which our future products will be reimbursed to a smaller set than we believe our future products are effective in treating.

In some foreign countries, particularly Canada and European Union member states, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies. If reimbursement for our products is unavailable in any country in which reimbursement is sought or is limited in scope or amount, or if pricing is set at unsatisfactory levels, our business would be materially harmed.

We expect to experience pricing pressures in connection with the sale of our future products, if any, due to the potential healthcare reforms discussed below, as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

Healthcare reform measures could hinder or prevent our future products commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the passing of the Patient Protection and Affordable Healthcare Act and the Health Care and Education Reconciliation Act. This healthcare reform law increases the number of individuals who receive health insurance coverage and closes a gap in drug coverage under Medicare Part D as established under the Medicare Prescription Drug Improvement Act of 2003. Each of these reforms could potentially increase our future revenue from any of our product candidates that are approved for sale. The law, however, also implements cost containment measures that could adversely affect our future revenue. These measures include increased drug rebates under Medicaid for brand name prescription drugs and extension of these rebates to Medicaid managed care. The legislation also extends certain discounted pricing on outpatient drugs to children s hospitals, critical access hospitals and rural health centers. This expansion reduces the amount of reimbursement received for drugs purchased by these newly covered entities.

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Additional provisions of the health care reform law may negatively affect our future revenue and prospects for profitability. Along with other pharmaceutical manufacturers and importers of brand name prescription drugs, we would be assessed a fee based on our proportionate share of sales of brand name prescription drugs to certain government programs, including Medicare and Medicaid. As part of the health care reform law s provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), we will also be required to provide a 50 percent discount on brand name prescription drugs sold to beneficiaries who fall within the donut hole.

In the aftermath of the healthcare reform law, private health insurers and managed care plans are likely to continue challenging the prices charged for medical products and services. These cost-control initiatives could decrease the price we might establish for any of our future products, which would result in lower product revenue or royalties payable to us.

In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our future products profitably. These proposed reforms could result in reduced reimbursement rates for any of our future products, which would adversely affect our business strategy, operations and financial results.

Our business could be harmed if we are unable to comply with applicable fraud and abuse and other laws and regulations where our product candidates may ultimately be sold.

As our pipeline of product candidates matures, we are becoming increasingly subject to extensive and complex laws and regulations, including but not limited to healthcare fraud and abuse and patient privacy laws and regulations by both the federal government and the states in which we conduct our business. These laws and regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug marketing, prohibits manufacturers from marketing drugs for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring

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of our operations could adversely affect our financial results. We are developing and implementing a corporate compliance program designed to ensure that we will market and sell any future products that we successfully develop from our product candidates in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Our Field

We may have significant product liability exposure that may harm our business and our reputation.

We face exposure to significant product liability or other claims if any of our product candidates is alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of human medicinal products. Although we do not currently commercialize any products, claims could be made against us based on the use of our product candidates in clinical trials. We currently have clinical trial insurance and will seek to obtain product liability insurance prior to the commercial launch of any of our product candidates. Our insurance may not, however, provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost. If we are sued for any injury caused by our product candidates or future products, our liability could exceed our insurance coverage and our total assets, and we would need to divert management attention to our defense. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to recruit investigators and patients to our clinical trials, obtain physician acceptance of our future products, or expand our business.

We work with hazardous materials that may expose us to liability.

Our activities involve the controlled storage, use and disposal of hazardous materials, including infectious agents, corrosive, explosive and flammable chemicals and various radioactive compounds. We are subject to certain federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We incur significant costs to comply with these laws and regulations. In addition, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, regulatory authorities may curtail our use of these materials, and we could be liable for any civil damages that result. These damages may exceed our financial resources or insurance coverage and may seriously harm our business. Additionally, an accident could damage, or force us to shut down, our operations.

Security breaches may disrupt our operations and harm our operating results.

Our network security and data recovery measures may not be adequate to protect against computer viruses, break-ins and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including research or clinical data, could have a material adverse impact on our business, operating results and financial condition. Additionally, any break-in or trespass of our facilities that results in the misappropriation, theft, sabotage or any other type of security breach with respect to our proprietary and confidential information, including research or clinical data, or that results in damage to our research and development equipment and assets, could have a material adverse impact on our business, operating results and financial condition.

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Risks Related to Intellectual Property

Our success depends substantially upon our ability to obtain and maintain intellectual property protection for our product candidates.

We own or hold exclusive licenses to a number of U.S. and foreign patents and patent applications directed to our product candidates. Our success depends on our ability to obtain patent protection both in the United States and in other countries for our product candidates, their methods of manufacture and their methods of use. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends substantially on our ability to obtain and enforce our patents.

Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and molecular diagnostics and the claim scope of these patents, our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. The standards that the United States Patent and Trademark Office, or PTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and are subject to change. To date, no consistent policy has emerged regarding the breadth of claims allowed in pharmaceutical or molecular diagnostics patents. Thus, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot guarantee that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competitive products or will afford us a commercial advantage over competitive products.

The U.S. Congress passed the Leahy-Smith America Invents Act, or the America Invents Act, which became effective in March 2013. The America Invents Act reforms United States patent law in part by changing the standard for patent approval for certain patents from a first to invent standard to a first to file standard and developing a post-grant review system. This new law changes United States patent law in a way that may severely weaken our ability to obtain patent protection in the United States. Additionally, recent judicial decisions establishing new case law and a reinterpretation of past case law, as well as regulatory initiatives, may make it more difficult for us to protect our intellectual property.

If we do not obtain adequate intellectual property protection for our products in the United States, competitors could duplicate them without repeating the extensive testing that we will have been required to undertake to obtain approval by the FDA. Regardless of any patent protection, under the current statutory framework the FDA is prohibited by law from approving any generic version of any of our products for up to five years after it has approved our product. Upon the expiration of that period, or if that time period is altered, the FDA could approve a generic version of our product unless we have patent protection sufficient for us to block that generic version. Without sufficient patent protection, the applicant for a generic version of our product would only be required to conduct a relatively inexpensive study to show that its product is bioequivalent to our product, and would not have to repeat the studies that we conducted to demonstrate that the product is safe and effective.

In the absence of adequate patent protection in other countries, competitors may similarly be able to obtain regulatory approval in those countries for products that duplicate our products. The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States. Many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. Some of our development efforts are performed in China, India and other countries outside of the United States through third party contractors. We may not be able to monitor and assess intellectual property developed by these contractors effectively; therefore, we may not be able to appropriately protect this intellectual property and could thus lose valuable intellectual property rights. In addition, the legal protection afforded to inventors andze="2">

1,922

1,392

1,398

351

Total costs and operating expenses

112,433

96,383

103,192

74,027

	50,074
Income (loss) from operations of continuing operations	
	7,624
	(1,874)
	(40,047)
	(29,724)
	(38,780)

Other income (expense) - net	34
	(6,368)
	(1,602)
	(913)
	3,053
Equity in net loss of affiliate	(164)

Income (loss) from continuing operations before income taxes			
	7,494		
	(8,242	)	
	(41,649	)	
	(30,637		

)

(35,727

)

Income tax benefit (provision)

(1,145

)

7

(368

)

(345

)

(257

)

Net income (loss) from continuing operations				
	6,349			
	(8,235	)		
	(42,017	)		
	(30,982	)		
	(35,984	)		
Net loss from operations of discontinued operation				
	(763	)		
	(2,342	)		

(2,025

)

(2,480

)

Net loss from disposal of discontinued operation

(381

)

Net income (loss)	$	6,349	$	(9,379)	$ (44,359)	$ (33,007)	$ (38,464)

Net income (loss) per share - basic (1)

Continuing operations

$

0.25

$

(0.40

)

$

(2.35

)

$

(1.83

)

$

(2.24

)

Discontinued operation

(0.06

)

(0.13

)

(0.12

)

(0.15

)

$	0.25
$	(0.46)
$	(2.48)
$	(1.95)
$	(2.39)

Net income (loss) per share - diluted (1)

Continuing operations

$

0.24

$

(0.40

)

$

(2.35

)

$

(1.83

)

$

(2.24

)

Discontinued operation

(0.06

)

(0.13

)

(0.12

)

(0.15

)

$

0.24

$

(0.46

)

$

(2.48

)

$

(1.95

)

$

(2.39

)

Shares used in per share computations - basic (1)				
	25,824			
	20,216			
	17,910			
	16,888			
	16,080			
Shares used in per share computations - diluted (1)				
	26,466			

20,216

17,910

16,888

16,080

	December 31,				
	2002	2001	2000	1999	1998
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 97,512	$ 32,822	$ 20,607	$ 26,519	$ 29,660
Working capital	113,530	33,266	39,774	63,991	46,828
Total assets	192,437	114,559	114,316	117,297	107,327
Long-term obligations, excluding current portion	15,920	30,539	35,214	40,192	16,402
Deferred revenue	3,158	6,317	9,475	9,304	
Accumulated deficit	(180,666)	(187,015)	(177,636)	(133,277)	(100,270)
Total stockholders equity	129,920	32,359	21,924	41,009	59,587

(1) For a description of the computation of net income (loss) per common share see Note 1 of Notes to Consolidated Financial Statements.

(2) Includes product recall charges of $872,000, $11,774,000, $50,000 and $379,000 for net product sales returns, cost of product sales, research and development expenses and selling, general and administrative expenses respectively.

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

The following discussion and analysis should be read in conjunction with Selected Consolidated Financial Data and our Consolidated Financial Statements and Notes thereto included elsewhere in this Report on Form 10-K. Except for the historical information contained herein, the discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the

Securities Exchange Act of 1934, which are subject to the safe harbor created by those sections. The forward-looking statements are based on the Registrant s current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as may, will, should, could, predicts, potential, continue, expects, anticipates, future, intends, plans, believes, estimates, and similar expressions. In particular, we have included forward-looking statements regarding the following: (i) our anticipated financial results for 2003; (ii) the timeline and potential results of preclinical development and clinical trials; (iii) potential outcomes of our and Abbott s litigation with Novartis; (iv) our plans for marketing a cyclosporine capsule in Europe; (v) anticipated expenditures and timing relating to FDA and foreign approval of our products and facilities; and (vi) anticipated potential strategic collaborations with others. These forward-looking statements are made as of the date of this Report on Form 10-K. These forward-looking statements are based on current beliefs, expectations and assumptions and involve certain risks and uncertainties that could cause actual results, levels of activity, performance, achievements and events to differ materially from those implied by such forward-looking statements. The cautionary statements made in this Report on Form 10-K should be read as being applicable to all related forward-looking statements wherever they appear. Our actual results could differ materially from those discussed here. Factors that could cause or contribute to such differences include those discussed in Risk Factors, as well as those discussed elsewhere herein. The Registrant disclaims any obligation to update these forward-looking statements.

Critical Accounting Policies

In December 2001, the SEC issued Financial Reporting Release No. 60, Cautionary Advice Regarding Disclosure About Critical Accounting Policies, or FR 60, suggesting that companies provide additional disclosure and commentary on those accounting policies considered most critical. FR 60 considers an accounting policy to be critical if it is important to the Company s financial condition and results and requires significant judgment and estimates on the part of management in its application. Our critical accounting estimates and the related assumptions are evaluated periodically as conditions warrant, and changes to such estimates are recorded as new information or changed conditions require revision. Application of the critical accounting policies requires management s significant judgments, often as the result of the need to make estimates of matters that are inherently uncertain. If actual results were to differ materially from the estimates made, the reported results could be materially affected. Our senior management has reviewed these critical accounting policies and estimates with our audit committee. We believe that the following represents our critical accounting policies as contemplated by FR 60. For a summary of all of our significant accounting policies, including critical accounting policies discussed below, see note 1 to our consolidated financial statements.

Revenue Recognition

Revenue from product sales, net of estimated sales allowances and rebates, is recognized upon receipt by the customer, when a purchase order has been received, the sales price is fixed or determinable and collection of the resulting receivable is reasonably assured. We record estimated reductions to revenue for customer programs, including contract pricing agreements, promotions, other volume based incentives and estimated future returns, in the same period as the related revenues are recorded. The estimates for returns are adjusted periodically based upon historical rates of return, and other related factors. The estimates and reserves for rebates and price protection are based on historical rates. In addition, our revenue recognition policy determines the timing of certain expenses, such as commissions and royalties that are recorded in the same period as the related revenue. While we believe we can make reliable estimates for these revenue adjustments, it is possible that actual amounts realized could vary from our estimates and that the amounts of such changes could affect our operating results.

Revenue from sales of Gengraf, which we co-promote with Abbott Laboratories, is recorded on a gross basis, in accordance with Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent.* Abbott s share of the gross profit, as defined, resulting from the sale is recorded as cost of product sales.

Revenue from collaborative agreements is recognized in accordance with the related contract terms. Upfront or milestone payments received under such agreements are generally recognized as revenues ratably over the life of the agreement where significant obligations for future services or the Company s participation exist or as milestones are met and no significant obligation for future services exists.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. We classify inventory not expected to be utilized within the next twelve months as long-term assets. We evaluate our inventory levels based on our estimates of marketing approval and forecasts of future sales, among other things. If these estimates or forecasts change at some time in the future we may be required to record additional charges for the write-down of excess or obsolete inventories. At December 31, 2002 we classified approximately $17.5 million of bulk cyclosporine raw materials inventory, net of reserves, as other long-term assets. We filed for marketing approval of the cyclosporine capsule product in a European country in January 2003. We intend to follow the European Community Mutual Recognition Procedure for obtaining marketing authorization in multiple member states following initial approval and to launch in these countries shortly after obtaining approval. The use of

such inventory is dependent upon the successful approval and launch of the cyclosporine capsule in the major European markets.

Foreign currency gains and losses

Many of our foreign sales are invoiced in local currencies, creating receivables denominated in currencies other than the U.S. dollar, primarily in the Euro and the Japanese yen but also in the U.K. pound. The risk due to foreign currency fluctuations associated with these receivables is partially reduced by local payables denominated in the same currencies, and presently we do not consider it necessary to hedge these exposures. However, we may revise our hedging policy from time to time as our foreign operations change. Gains and losses resulting from foreign currency transactions are included in other income (expense) net in our statement of operations.

Income taxes

SangStat has operations in several countries other than the United States, including France, where we manufacture Thymoglobulin. This product is then sold to other SangStat entities in other countries, including the United States. We believe that we record these sales at an appropriate transfer price; however it is possible that the tax authorities could challenge these transfer prices and assess additional taxes on prior period transactions. Any such assessment could require us to record an additional tax provision in our statement of operations.

We have substantial deferred tax assets that relate to prior period losses, primarily in the United States. We evaluate these deferred tax assets in each tax jurisdiction by estimating the likelihood of generating future profits to realize these assets. In most cases, we have assumed that we will not be able to generate sufficient future taxable income to realize these assets and have created valuation reserves to reduce the net asset values to zero. If these estimates and assumptions change in the future, we may be required to record additional valuation allowances against the net deferred tax assets resulting in additional income tax expense in our consolidated statement of operations. Conversely, we may be able to reverse the valuation allowances in future periods should the Company generate taxable income. At December 31, 2002, we had approximately $71.0 million of valuation allowances related to our net deferred tax assets.

Results of Operations

Revenues. Total revenues for the year ended December 31, 2002 were $120,057,000, an increase of $25,548,000 or 27% over total revenues of $94,509,000 for the year ended December 31, 2001. The increase was due primarily to increased sales of Thymoglobulin and Gengraf in the U.S., which accounted for $18,109,000 and $7,521,000 of the increase, respectively.

Total revenues for the year ended December 31, 2001 were $94,509,000, an increase of $31,364,000 or 50% over total revenues of $63,145,000 for the year ended December 31, 2000. The increase was due primarily to increased sales of Gengraf and Thymoglobulin in the U.S., which accounted for $18,167,000 and $13,551,000 of the increase, respectively. This increase was partially offset by lower sales of other products. Net product sales in fiscal 2001 included a full year of sales of Gengraf, which was launched in the U.S. in May 2000, compared with only eight months of sales in fiscal 2000.

On June 29, 2000 we, concluded that a recall of SangCya Oral Solution from the U.S. market would be required. Following discussions with the FDA as to the type of recall and mechanism for conducting it, we announced this decision on July 10, 2000. As a result, net sales for the year ended December 31, 2000 were reduced by $872,000

for returns of SangCya Oral Solution from customers following the product recall.

Included in total revenues was revenue from collaborative agreements of $3,208,000 and $3,207,000 in 2002 and 2001, respectively. Revenue from these agreements in fiscal 2001 represented an increase of $509,000 or 19% over revenue of $2,698,000 for the year ended December 31, 2000. In 2002, 2001 and 2000, we recognized revenue of $3,158,000, $3,157,000 and $2,698,000, respectively, from milestone payments from Abbott Laboratories under the co-promotion agreement for cyclosporine. The unamortized portion of these milestone payments is shown as deferred revenue on our consolidated balance sheet and is being recognized as revenue on a straight-line basis over the remaining term of the co-promotion agreement, which expires December 31, 2004.

Cost of product sales. Cost of product sales was $56,723,000 for the year ended December 31, 2002, an increase of $13,907,000 or 32% over cost of product sales of $42,816,000 for the year ended December 31, 2001. The increase in cost of product sales for the year ended December 31, 2002 was due to the overall increase in sales and the higher cost of Gengraf compared to our other products as well as an increase in royalties payable to Aventis on sales of Thymoglobulin that started on October 1, 2001.

Cost of product sales was $42,816,000 for the year ended December 31, 2001, an increase of $3,570,000 or 9% over cost of product sales of $39,246,000 for the year ended December 31, 2000. The increase in cost of product sales for the year ended December 31, 2001 was due to the overall increase in sales and the higher cost of Gengraf compared to our other products partially offset by cost of product recall in 2000 that did not recur in 2001.

Research and development. Research and development expenses were $18,913,000 for the year ended December 31, 2002, an increase of $1,050,000 or 6% over research and development expenses of $17,863,000 for the year ended December 31, 2001. These expenditures were necessary to support the advancement of potential drug candidates in all stages of development programs and included a payment of a $500,000 technology access fee to THP.

Research and development expenses were $17,863,000 for the year ended December 31, 2001, a decrease of $2,925,000 or 14% over research and development expenses of $20,788,000 for the year ended December 31, 2000. The decrease in spending on research and development mainly relates to payments to Abgenix for a license fee and SangStat s negotiated share of prior development costs incurred by Abgenix for ABX-CBL totaling $2,900,000, which did not recur in 2001, and a decrease in spending on SangCya Oral Solution and related products. This decrease in spending was partially offset by an increase in spending on RDP58 and the ongoing development of ABX-CBL for the year ended December 31, 2001.

While we allocate scientists and track resources when required pursuant to the terms of a partnering or similar arrangement, members of our research team typically work on a number of products concurrently, and our equipment and intellectual property resources often are deployed over a range of products with a view to maximizing the benefit of our investment. Accordingly, we have not and do not intend to separately track the costs incurred to date for each of our research projects on a product- by-product basis. For the year ended December 31, 2002, however, we estimate that the majority of research and development expense was associated with our three product candidates: RDP58, ABX-CBL and cyclosporine capsules. The balance of our expense was associated primarily with ongoing development of our marketed products, clinical trials for Thymoglobulin, and early-stage product candidates.

In Europe, we completed Phase I clinical trials for RDP58 and subsequently started Phase IIa trials in October 2001 and two additional Phase IIa trials in August 2002. The Phase II trials are prospective, randomized, blinded trials in patients with mild-to-moderate ulcerative colitis or Crohn s disease. We completed patient enrollment and expect to announce the results of these studies in the second quarter of 2003. We conducted a multi-center, randomized, and controlled Phase II/III study of ABX-CBL. In this study, patients were randomized to receive the polyclonal equine antibody, ATGAM, in the control group versus patients who received ABX-CBL in the treatment arm. Our primary endpoint of this study was patient survival at 180 days. On February 18, 2003, we announced preliminary results from this study that indicated that survival with ABX-CBL was similar to ATGAM. Based on these results, we do not plan to pursue further development of ABX-CBL We completed bioequivalence studies and stability studies for a cyclosporine capsule. We filed regulatory application for marketing approval in a European country in January 2003. We intend to follow the European Community Mutual Recognition Procedure for obtaining marketing authorization in multiple member states following initial approval. We also have under way two clinical trials

involving Thymoglobulin. One trial compares Thymoglobulin with Simulect. The study was closed early in March 2002, with a total enrollment of 279 participants out of a planned 340, after an interim analysis revealed significantly fewer acute rejections of implanted kidneys in patients treated with Thymoglobulin versus Simulect.

The second trial investigates the use of Thymoglobulin in myelodysplastic syndrome, or MDS. This trial was closed to further enrollment on November 1, 2002 based on a review by a data safety monitoring board. The board found no safety issues with patients treated with Thymoglobulin but recommended the study be closed based on poor patient accrual. The board noted that response rate in the treatment arm was less then expected and that the Thymoglobulin study may be enrolling a population subset that is less likely to respond. We intend to review the data from this study and determine whether further Thymoglobulin trials in MDS are justified. The patients treated in the protocol will be followed for safety and efficacy as mandated in the original protocol in accordance with ICH and FDA guidelines.

Of course, our timelines are estimates that are subject to change. Due to the inherent risks and uncertainties associated with the development of our proposed drugs, we are unable to further specify with meaningful certainty the estimated completion date or estimated cost of completion of our proposed products, or whether any of our products will eventually be successfully developed. For a discussion of the risks and uncertainties surrounding the development and cost of these products, see Risk Factors - If we do not develop and market new products, our business will be harmed and Risk Factors - If our preclinical and clinical testing of potential products is unsuccessful, our business will be harmed.

***Selling, general and administrative*.** Selling, general and administrative expenses for the year ended December 31, 2002 were $35,797,000, an increase of $2,015,000 or 6% over selling, general and administrative expenses of $33,782,000 for the year ended December 31, 2001. The increase in selling, general and administrative expenses in 2002 as compared with 2001, was as a result of severance and fringe benefits for work

force restructuring costs; continued growth in headcount-related costs principally in the sales and marketing organization; and bad debt expense reserve for a bankrupt customer in Europe.

Selling, general and administrative expenses for the year ended December 31, 2001 were $33,782,000, a decrease of $7,984,000 or 19% over selling, general and administrative expenses of $41,766,000 for the year ended December 31, 2000. The decrease in expenses for the year ended December 31, 2001 reflects the results of our cost control efforts through the continuation of our cost-containment program, including a reduction in launch and marketing expenses for Gengraf, a reduction in our share of Phase IV Gengraf study expenses, and a reduction in legal expenses associated with the Novartis lawsuits.

Amortization of intangible assets. Amortization expense for the IMTIX acquisition-related intangible assets was $1,000,000, $1,922,000 and $1,392,000 for the years ended December 31, 2002, 2001 and 2000, respectively. Amortization expense in 2001 included the write-off of $482,000 representing the net book value of the intangible assets related to distribution rights for two minor products formerly sold in Europe. Sales of these two products were discontinued in the fourth quarter of 2001. We adopted SFAS 142 on January 1, 2002. In accordance with SFAS 142, we ceased amortizing $1,652,000 of assembled workforce intangibles with a remaining net book value of $578,000 that were previously classified as purchased intangible assets, resulting in a lower amortization expense in 2002.

The following table presents the impact of SFAS 142 on net income (loss) and net income (loss) per share had the accounting standard been in effect for fiscal 2001 and 2000 (in thousands, except per-share amounts):

	Year Ended December 31,		
	2002	**2001**	**2000**
Net income (loss) - as reported	$ 6,349	$ (9,379)	$ (44,359)
Adjustments:			
Amortization of assembled workforce intangible previously classified as intangible assets		331	331
Net income (loss) - adjusted	$ 6,349	$ (9,048)	$ (44,028)
Basic net income (loss) per share - as reported	$ 0.25	$ (0.46)	$ (2.48)
Basic net income (loss) per share - adjusted	$ 0.25	$ (0.45)	$ (2.46)
Diluted net income (loss) per share- as reported	$ 0.24	$ (0.46)	$ (2.48)
Diluted net income (loss) per share- adjusted	$ 0.24	$ (0.45)	$ (2.46)

Interest income. Interest income for the year ended December 31, 2002 was $2,617,000 compared to $1,203,000 for the year ended December 31, 2001, and $2,016,000 for the year ended December 31, 2000. For each year, the change in interest income versus the prior year primarily reflected the change in the average cash balances available for investment and the reduction in interest rates over that period.

Interest expense. Interest expense for the year ended December 31, 2002 was $2,898,000 compared to $4,830,000 for the year ended December 31, 2001 and $4,368,000 for the year ended December 31, 2000. The decrease in interest expense in fiscal 2002 over 2001 was due primarily to the reduction in the amount of the note payable to Abbott Laboratories and the expense relating to the FINOVA loan termination agreement that was signed in June 2001 that did not recur in 2002. The increase in interest expense in fiscal 2001 over 2000 reflected the expenses incurred in 2001 relating to the FINOVA loan termination agreement.

Other income (expense) - net. Other income (expense) - net for the year ended December 31, 2002 was an income of $315,000 compared to an expense of $2,741,000 and an income of $750,000, for the years ended December 31, 2001 and 2000, respectively. The other income (expense) net in 2002 includes, $375,000 compensation received for termination of a manufacturing agreement, $300,000 gains on sales of SangCya manufacturing equipment partially offset by unfavorable foreign exchange effects resulting from the impact of currency movements. The increase in other expense in fiscal 2001 was due primarily to the expenses of $3,454,000 related to a breach of contract suit in Europe, partially offset by an $856,000 reimbursement claim we received from a supplier.

Equity in net loss of affiliate. Equity in net loss of affiliate for the year ended December 31, 2002 includes SangStat s proportionate share of the net loss of THP and the amortization of intangible assets, representing the difference between the Company s carrying value and its interest in the underlying net assets of THP. Such intangible assets are being amortized on a straight-line basis over two years.

Income taxes. For the years ended December 31, 2002, 2001 and 2000, we recorded a tax provision of $1,145,000, a benefit of $7,000 and a provision of $368,000, respectively, for European income taxes based upon the financial results of our European affiliates.

Net income (loss) from continuing operations. Net income from continuing operations for the year ended December 31, 2002 was $6,349,000, an increase of $14,584,000 or 177% compared to the net loss of $8,235,000 for the year ended December 31, 2001. The increase in net income for the year ended December 31, 2002 was primarily due to higher product sales partially offset by increases in selling, general and administration and research and development expenses and higher cost of product sales, resulting primarily from the higher product sales.

Net loss from continuing operations for the year ended December 31, 2001 was $8,235,000, a decrease of $33,782,000 or 80% compared to the net loss of $42,017,000 for the year ended December 31, 2000. The decrease in net loss for the year ended December 31, 2001 was primarily due to higher product sales and lower selling, general and administration and research and development expenses, partially offset by higher cost of product sales, resulting primarily from the higher product sales. In addition, the year ended December 31, 2000 included product

recall returns and charges totaling $13,075,000 that did not recur in 2001.

Net loss from operations of discontinued operation. Net sales of transplantation services for the year ended December 31, 2001 were $5,233,000, a decrease of $12,269,000 or 70% from sales of $17,502,000 for the year ended December 31, 2000. The decrease in net sales reflects the sale of our transplantation services business, The Transplant Pharmacy, which closed on April 20, 2001. Net sales for all periods consisted entirely of drug sales to transplant patients.

Net loss for transplantation services for the year ended December 31, 2001 was $763,000, compared to a net loss of $2,342,000 for the year ended December 30, 2000. The decrease in net loss reflects the sale of our transplantation services business, The Transplant Pharmacy, which closed on April 20, 2001.

Net loss from disposal of discontinued operation. Net loss on disposal of discontinued operation of $381,000 represents sale proceeds of $1,800,000 less estimated expenses of $2,181,000 incurred for the discontinued operation. These expenses primarily related to the costs associated with the closure of The Transplant Pharmacy operation including employee severance and the estimated future lease obligations for the facilities supporting The Transplant Pharmacy.

Liquidity and Capital Resources

From inception through December 31, 2002, we financed our operations primarily from proceeds of approximately $222,123,000 from public offerings of our common stock, $76,398,000 from private placements of equity securities and $25,550,000 from the convertible note and the note payable to Abbott Laboratories. As of December 31, 2002, we had cash, cash equivalents and short-term investments of $97,512,000 and total assets of $192,437,000.

During the year ended December 31, 2002, net cash used in operating activities was approximately $2,690,000 as compared to net cash provided by continuing operating activities of $4,407,000 for the year ended December 31, 2001 and net cash used in operating activities of $25,610,000 for the year ended December 31, 2000. The increase in net cash used in operating activities in 2002 resulted from increases in accounts receivable (net), other receivables, inventory, prepaid and other current assets and accounts payable partially offset by decreases in accrued liabilities. Accounts receivable (net) increased to $22,847,000 at December 31, 2002 from $19,872,000 at December 31, 2001. The increase was primarily due to the increase in sales. Inventory increased to $27,161,000 at December 31, 2002 from $22,942,000 at December 31, 2001. The decrease in net cash used in operating activities in 2001 was due substantially to a significant reduction in net loss and a reduction in other current assets due to the reclassification of $5,000,000 to cash and cash equivalents. This cash had previously been treated as restricted since it served as collateral for the loan with FINOVA. However, the loan was repaid in June 2001 and therefore the restriction was released. Other factors contributing to the net cash provided by operating activities included an increase in accounts payable and accrued liabilities and a decrease in other receivables. Net cash used in operating activities in 2000 was substantially due to a reduction in net inventories and increases in accounts payable and accrued liabilities, partially offset by an increase in net loss. The reduction in inventories is primarily due to provisions of $11,774,000 relating to the SangCya Oral Solution product recall, which resulted in a corresponding increase in net loss for 2000. Net cash used in 2000 also included an increase in other current assets reflecting $5,000,000 cash used as collateral for the note payable to FINOVA.

Net cash used in investing activities totaled $18,586,000 during the year ended December 2002. This primarily represents the purchase of short-term investments net of maturities and investment in affiliate and purchase of properties and equipment. Net cash provided by investing activities totaled $5,438,000 and $3,694,000 during the years ended December 31, 2001 and 2000 respectively. The amount for fiscal 2001 is primarily the result of a decrease in other assets, proceeds from the sale of The Transplant Pharmacy and maturities of short term investments, partially offset by purchases of property and equipment. In fiscal years 2000 and 1999, cash was provided by maturities of short-term investments, partially offset by purchases of property and equipment and purchases of short-term investments.

Net cash provided by financing activities totaled $70,956,000, $7,699,000 and $27,221,000 during the years ended December 31, 2002, 2001 and 2000 respectively. In fiscal year 2002 and 2001 net cash was provided primarily by the sale of common stock, partially offset by repayments of notes and capital lease obligations. In fiscal year 2000,

cash was provided by the issuance of notes payable and the sale of common stock which are described in more detail in the following paragraphs.

On April 21, 2000 we signed an agreement with FINOVA to provide a line of credit of up to $30 million (the Loan Agreement). At December 31, 2000 we had drawn down $5.0 million under the line of credit and had set aside a corresponding compensating balance, which was included in Other Current Assets on our consolidated balance sheet. Subsequently, we repaid the loan balance of $5.0 million on June 29, 2001, and terminated the Loan Agreement. Since the loan has been repaid, the $5.0 million compensating cash balance previously classified as other current assets has now been classified as cash in the accompanying consolidated balance sheet. In connection with this financing, we issued a warrant to purchase 50,000 shares of our common stock at an exercise price of $23.438. This warrant was valued using the Black-Scholes pricing model with the following weighted average assumptions: expected life, five years; stock volatility, 72%; risk free interest rate, 6.0%; and no dividend payments during the expected term. The calculated value of the warrant of $744,000 and the additional financing fees of $750,000 were reflected as additional interest expense over the life of the loan.

In August 2000, we entered into a global co-development, supply and license agreement for ABX-CBL with Abgenix under which we obtained an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD147 monoclonal antibody for the treatment of steroid resistant GVHD. Under the terms of the agreement, we made an initial license fee payment of $1.0 million and an additional payment to Abgenix of $1.0 million as partial reimbursement of one-half of the development costs incurred by Abgenix between January 1, 2000 and August 8, 2000. We subsequently paid an additional $900,000 as reimbursement of these development costs in two equal installments at the end of June 2001 and 2002. Development costs incurred after August 8, 2000 are being shared equally. We conducted a multi-center, randomized, and controlled Phase II/III study of ABX-CBL. On February 18, 2003, we announced preliminary results from this study that indicated that survival with ABX-CBL was similar to the control arm. Based on these results, we do not plan to pursue further development of ABX-CBL.

In November 2002, we entered into a collaboration with Therapeutic Human Polyclonals, Inc. for the development of humanized polyclonal therapeutic products to be generated by the immune systems of transgenic animals. THP is a private research stage company that was formed by two scientists, one of whom, Dr. Roland Buelow, was our Senior Vice President of Discovery Research from April 1, 2000 to November 8, 2002. We made an equity investment of $3,200,000 in THP that is being accounted for under the equity method. The difference between the initial investment and the $1,352,000 (or 28%) of the underlying equity in the net assets of THP at the date of investment was attributed to intangible assets, including technical know-how. This excess amount of $1,848,000 is being amortized on a straight-line basis over two years. We intend to review the remaining balance of these intangible assets annually for impairments. In addition we made a one-time technology access fee payment to THP of $500,000 under the terms of the agreement and recorded $10,000 in the fourth quarter of 2002 representing its proportionate share of the net loss. We are committed to make a second investment of $3.2 million when THP has produced the proof-of-principle engineered rabbit, unless that milestone is unduly delayed. The total of these investments would represent approximately twenty percent (20%) of THP s issued share capital. The investments are made in conjunction with investments by Research Corporation Technologies, Inc., which provided start-up financing for THP and is the majority shareholder. When THP has produced the commercial-grade engineered rabbit, we have an option to make an additional equity investment of $15.0 million, which would give us ownership of approximately 40% of THP s issued share capital. We do not have an option to acquire full ownership of THP.

Notes payable include $3,824,000 and $8,273,000 at December 31, 2002 and 2001, respectively, representing the current accreted value of the non-interest bearing note issued in connection with the acquisition of IMTIX. The note was discounted at a rate of 9.25% and the remaining unpaid balance of $4,000,000 at December 31, 2002 is payable in 2003.

In 2002, 2001 and 2000 we purchased $1,934,000, $1,146,000 and $3,790,000, respectively, of new property and equipment. In 2002 and 2001 purchases consisted primarily of manufacturing and other equipment. In 2000 this purchasing consisted primarily of manufacturing equipment, leasehold improvements for our new corporate headquarters in Fremont, California and expenditures associated with the implementation of a global enterprise resource planning system.

At December 31, 2002, we had federal, state and foreign net operating loss, or NOL, carryforwards of

approximately $134,219,000, $13,937,000 and $641,000, respectively, available to reduce future taxable income. Such carryforwards expire beginning in 2004 through 2021. In addition, we had available research and experimentation credit carryforwards of approximately $6,155,000 and $3,650,000 for federal and state tax purposes respectively. The federal tax credit carryforwards expire beginning in 2004 through 2022 and the state tax credit carryforwards have no expiration dates. Our ability to realize the benefits of the NOL and credit carryforwards is dependent upon the generation of sufficient taxable income in the respective taxing jurisdictions prior to their expiration. We may be unable to generate sufficient taxable income to avail ourselves of these benefits. Furthermore, utilization of the net operating losses and credits may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

We believe we have sufficient funds to continue operations for at least the next twelve months. However, we may need to raise additional funds through additional financings, including private or public equity and/or debt offerings and collaborative research and development arrangements with corporate partners in order to pursue new business opportunities. Our future capital requirements will depend on many factors, including our research and development programs, the scope and results of clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property, the status of competitive products, the maintenance of our manufacturing facility and the establishment of third-party manufacturing arrangements, the maintenance of sales and marketing capabilities, the establishment of collaborative relationships with other parties, and the costs of manufacturing scale-up and working capital requirements for inventory and financing of accounts receivable.

Recently Issued Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board, or FASB issued Statement of Financial Accounting Standards, or SFAS No. 143, *Accounting for Asset Retirement Obligations*. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development, and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The provisions of SFAS No. 143 will be effective for fiscal years beginning after June 15, 2002. We are currently in the process of evaluating the impact of this Statement on our financial condition and operating results. The adoption of this statement is not expected to have an impact on our financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement is effective for fiscal years beginning after December 15, 2001. We adopted SFAS No. 144 on January 1, 2002. The adoption of this statement did not have an impact on our financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated With Exit or Disposal Activities.* SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3. *Liability Recognition for Certain Employer Termination Benefits and other Costs to an Exit Activity (Including Certain Costs in a Restructuring)* SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost was recognized at the date of the Company s commitment to an exit plan. SFAS No.146 also establishes that the liability should initially be measured and recorded at fair value. We will adopt the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002. We do not expect the adoption of this Statement to have a significant impact on our financial position and results of operations.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure* . SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation* to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation to require more prominent disclosures about the method of accounting

for stock-based employee compensation and the effect of the method used on reported results in both annual and interim financial statements. We adopted the disclosure provisions of SFAS No. 148 for our annual period ended December 31, 2002.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 requires that upon issuance of a guarantee, a guarantor must recognize a liability for the fair value of an obligation assumed under a guarantee. FIN 45 also requires additional disclosures by a guarantor in its interim and annual financial statements about the obligations associated with guarantees issued. The recognition provisions of FIN 45 are effective for any guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. We adopted the disclosure requirements for the financial statements included in this Form 10-K. We are currently evaluating the effects of FIN 45, however does not expect that the adoption of FIN 45 will have a material effect on our financial position, results of operations, or cash flows.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates and foreign currency exchange rates. All of the potential changes noted below are based on sensitivity analyses performed on our financial position at December 31, 2002. Actual results may differ materially.

Interest Rate Sensitivity. Our short-term investment portfolio consists primarily of corporate bonds with an average maturity of less than one year as of December 31, 2002. The primary objective of our investments in debt securities is to preserve principal while maximizing yields, without significantly increasing risk. These available-for-sale securities are subject to interest rate risk. The fair market value of these securities may fluctuate with changes in interest rates. The fair market value of current and long-term debt at December 31, 2002, and 2001, amounted to $19,210,000 and $36,680,000, respectively, and consisted primarily of fixed-rate debt with maturities through 2004. Approximately 95% of our current and long-term debt as of December 31, 2002 and 2001, respectively, had fixed interest rates, while the remaining had variable interest rates. A hypothetical 100-basis point change in interest rates would not have a material effect on cash flows, income or market values.

	December 31, 2002			
	Expected Maturity Date			
	2003	2004	Total	Fair Value
				in thousands
Liabilities				
Long-term Debt				
Fixed Rate denominated	$ 3,784	$ 14,981	$ 18,765	$ 18,389
Average interest rate	7.9%	7.3%	7.6%	
Variable Rate denominated	330	491	821	821
Average interest rate	3.1%	3.1%	3.1%	
Total	$ 4,114	$ 15,472	$ 19,586	$ 19,210

Foreign Currency Risk. Many of our foreign sales are invoiced in local currencies, creating receivables denominated in currencies other than the U.S. dollar, primarily in the Euro and the Japanese yen. The risk due to foreign currency fluctuation associated with these receivables is partially reduced by local payables denominated in the same currencies, and presently we do not consider it necessary to hedge these exposures. We intend to re-assess our hedging policy from time to time as our foreign operations change. A 10% movement in the currency exchange rate would not have a material impact on our financial position or our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Reference is made to item 15(a) of this Report on Form 10- K.

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

None.

PART III

The information required by this item, insofar as it relates to our directors, will be contained under the captions Election of Directors and Section 16 Beneficial Ownership Reporting Compliance in the Proxy Statement and is incorporated herein by reference. The information relating to our executive officers as of December 31, 2002, is contained in the following table:

Name	Age	Position
Richard D. Murdock	55	Chairman of the Board, Chief Executive Officer and President
Steve Aselage	51	Senior Vice President, North American Sales and Marketing
Stephen G. Dance	51	Chief Financial Officer
Raymond J. Tesi, M.D.	47	Senior Vice President, Clinical Development and Medical Affairs
Ralph E. Levy	54	Senior Vice President, Operations
Rayasam S. Prasad	50	Senior Vice President, Worldwide Regulatory Affairs and Compliance
Adrian Arima	52	Senior Vice President, General Counsel and Secretary

Richard D. Murdock was appointed our Chairman, President and Chief Executive Officer in November 2002. The appointment was made on an interim basis while the Company conducts a search for a permanent Chairman, President and Chief Executive Officer. Mr. Murdock has been a director since October 1993. Previously, Mr. Murdock was a biotechnology management consultant. From October 2001 to March 2002, Mr. Murdock was the President, Chief Executive Officer and Director of InPro Biotechnology, a biotechnology company involved in the diagnosis and treatment of neurodegenerative diseases. From December 1998 until March 2001, Mr. Murdock was the President and Chief Executive Officer and a director of Kyphon, Inc., an orthopedic medical device company. From September 1991 to October 1998, Mr. Murdock served as the Chief Executive Officer and a director of CellPro, Incorporated, a public biotechnology company. Mr. Murdock received his B.S. in Zoology from the University of California at Berkeley.

Steve Aselage joined us in February 1999 and currently is our Senior Vice President, North American Sales and Marketing. From 1995 to December 1998, Mr. Aselage was the Director of Sales and Marketing at Advanced Tissue Sciences, a tissue engineering company. Mr. Aselage received a B.S. in biology from the University of Notre Dame.

Stephen G. Dance has been our Chief Financial Officer since December 2002. Before that, he was our Senior Vice President, Finance since joining Sangstat in April 1999. From July 1998 to April 1999, Mr. Dance was Director of Financial Accounting, Planning and Reporting at Plantronics, Inc., a telecommunications company. From 1983 to July 1998, Mr. Dance held various positions with Syntex Corporation, a pharmaceutical company, which was acquired by Roche Holding Ltd., also a pharmaceutical company, in 1994, serving most recently as Controller, Syntex Laboratories, Inc. Mr. Dance holds a B.A. in French from Leeds University in England, is a Certified Public Accountant in the State of California and a fellow of the Institute of Chartered Accountants in England and Wales.

Raymond J. Tesi, M.D., joined us in May 1997 and currently is our Senior Vice President, Clinical Development

and Medical Affairs. From 1994 until 1997, Dr. Tesi was an associate professor of surgery and director of the extra-renal transplantation program at Tulane Medical School in New Orleans, Louisiana. He was a transplantation surgical fellow at the Ohio State University Hospital. Dr. Tesi received an M.D. from the Washington University School of Medicine in St. Louis, Missouri.

Ralph E. Levy joined us in 1990 and currently is our Senior Vice President, Operations. Mr. Levy received a B.S. in chemistry from the City College of New York and an M.S. in chemistry from Seton Hall University.

Rayasam S. Prasad joined us in June 2002 as our Senior Vice President, Worldwide Regulatory Affairs and Compliance. Mr. Prasad was employed by Aviron from 1999 to 2002, and in 2000 became its Senior Vice President, Technical Affairs. From 1994 to 1999, he was Head of Regulatory, Quality and Drug Safety for Chiron Vaccines. Mr. Prasad holds a B.S in Pharmacy from Andhra University, India.

Adrian Arima joined us in September 2001 and currently is our Senior Vice President, General Counsel and Secretary. From 1997 until 2000, he was with the gene and cell therapy subsidiaries of Novartis AG, including SyStemix, Inc. and Genetic Therapy, Inc., rising to Vice President and General Counsel. From 1995 to 1997, he was Counsel to Gray Cary Ware & Freidenrich, a law firm in Palo Alto, California. Mr. Arima received his B.A and M.S. from Stanford University and his J.D. from the University of California, Berkeley.

Item 11 Executive Compensation.

The information required by this item will be contained in the Proxy Statement under the caption Executive Compensation and is incorporated herein by reference.

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

The information required by this item will be contained in the Proxy Statement under the caption Security Ownership of Certain Beneficial Owners and Management and is incorporated herein by reference.

Item 13 Certain Relationships and Related Transactions.

The information required by this item will be contained in the Proxy Statement under the caption Certain Relationships and Related Transactions and is incorporated herein by reference.

Item 14 Controls and Procedures

(a) Evaluation of disclosure controls and procedures.

Our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-14(c) and 15(d)-14(c) under the Securities Exchange Act of 1934, as amended) within 90 days of the filing of this Form 10-K (the Evaluation Date) and, based on that evaluation, concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective to timely alert management to material information relating to SangStat Medical Corporation during the period when our periodic reports are being prepared.

(b) Changes in internal controls.

Since the Evaluation Date, there have not been any significant changes to our internal controls or in other factors that could significantly affect these controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) The following documents are filed as a part of this Report on Form 10-K:

1. Financial Statements.

All other schedules are omitted because they are not required, are not applicable or the information is included in the consolidated financial statements and notes thereto.

3. Exhibits. Reference is made to Item 14(c) of this Annual Report on Form 10-K.

(b) Reports on Form 8-K.

On October 21, 2002, we filed a report on Form 8-K, reporting that the Board of Directors of the Company had appointed Richard D. Murdock as interim President, Chief Executive Officer and Chairman of the Board of Directors, succeeding Jean-Jacques Bienaimé.

On November 11, 2002, we filed a report on Form 8-K, reporting that we had entered into a strategic collaboration with Therapeutic Human Polyclonals, Inc. to develop and commercialize humanized polyclonal antibodies. In addition, the Company announced that Roland Buelow, Ph.D., Senior Vice President of Discovery Research, was resigning from the Company to assume the position as Chief Scientific Officer for this Company.

(c) Exhibits.

Exhibits	Description of Exhibit
2.2	Master Agreement between SangStat Medical Corporation and Pasteur Merieux Serums & Vaccins, S.A., dated June 10, 1998, including Exhibit 8 thereto (filed as Exhibit 2.1 to the Registrant s Current Report on Form 8-K, filed on October 15, 1998 and as amended on December 14, 1998, and incorporated herein by reference).
3.1	Restated Certificate of Incorporation, filed with the Delaware Secretary of State on July 9, 2002 (filed as Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30,2002, filed on August 14, 2002, and incorporated herein by reference).

Exhibits	Description of Exhibit
3.4	Second Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2000, filed on May 15, 2000, and incorporated herein by reference).
4.1	Specimen Common Stock Certificate of Registrant (filed as Exhibit 4.5 to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.1*	2002 Stock Option Plan effective as of March 6, 2002.

10.2	Form of Indemnification Agreement between the Registrant and its directors, officers and certain other employees (filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2001, filed on November 14, 2001, and incorporated herein by reference).
10.3**	License Agreement, dated November 15, 1993, between the Registrant and the Board of Trustees of Leland Stanford Junior University (filed as Exhibit 10.19to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.4	Rights Agreement, dated as of August 14, 1995, between the Registrant and First National Bank of Boston (filed as Exhibit 2 to the Registrant s Registration Statement on Form 8-A, filed on August 25, 1995, and incorporated herein by reference).
10.5	First Amendment to Rights Agreement, dated as of October 8, 2001, among the Registrant, Fleet National Bank (f/k/a The First National Bank of Boston) and EquiServe Trust Company, N.A. (filed as Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed on October 9, 2001, and incorporated herein by reference).
10.6	Real Property Sub-Lease, dated March 8, 1999, between the Registrant and Kelley-Clarke, Inc. to the Real Property lease, dated September 1, 1988, between Kelly-Clarke Inc. and Kaiser Development Company, as amended on February 26, 1990, May 1, 1990, May 5, 1990, and April 19, 1995 (filed as Exhibit 10.26 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1998, filed on March 31, 1999, and incorporated herein by reference).
10.7**	Co-Promotion Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.28 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000, filed on March 30, 2001,and incorporated herein by reference).
10.8	Right of First Refusal Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.28 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed on August 16, 1999,and incorporated herein by reference).
10.10	Convertible Promissory Note, dated March 1999, for $10,000,000 with Warburg Dillon Read LLC (filed as Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999, filed on April 14, 2000, and incorporated herein by reference).

Exhibits	Description of Exhibit
10.11**	Co-Development, Supply and License Agreement, dated as of August 8, 2000, between the Registrant and Abgenix, Inc. (filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000, and incorporated herein by reference).
10.17**	Option Agreement dated as of November 8, 2002 among the Registrant, Research Corporation Technologies, Inc. and Therapeutic Human Polyclonals, Inc.
10.18**	Hematology Alliance Agreement dated as of November 8, 2002 between the Registrant and Therapeutic Human Polyclonals, Inc.
10.19**	hTG Collaboration Agreement dated as of November 8, 2002 between the Registrant and Therapeutic Human Polyclonals, Inc.
10.20*	Separation Agreement and General Release of Claims dated as of November 8, 2002 between the Registrant and Roland Buelow.

21.1	Subsidiaries of Registrant.
23.1	Independent Auditors Consent.
24.1	Power of Attorney (reference is made to the signature page hereof).
99.1	Certification of Richard D. Murdock, Chief Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.2	Certification of Stephen G. Dance, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Management contract or compensatory plan or arrangement.

** Confidential treatment has been requested for certain portions omitted from this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Confidential portions of this Exhibit have been separately filed with the Securities and Exchange Commission. Confidential treatment has not yet been granted.

INDEPENDENT AUDITORS REPORT

To the Board of Directors and Stockholders
of SangStat Medical Corporation:

We have audited the accompanying consolidated balance sheets of SangStat Medical Corporation and subsidiaries (collectively, the Company) as of December 31, 2002 and 2001, and the related consolidated statements of operations, comprehensive income (loss), stockholders equity, and cash flows for each of the three years in the period ended December 31, 2002. Our audits also included the consolidated financial statement schedule listed in Item 14(a)2. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule referenced above, when considered in relation to the basic consolidated financial statements as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 5 to the consolidated financial statements, the Company changed its method of accounting for goodwill and other intangible assets to conform to Statement of Financial Accounting Standard No. 142, Goodwill and Other Intangible Assets effective January 1, 2002.

DELOITTE & TOUCHE LLP

San Jose, California
February 10, 2003

SANGSTAT MEDICAL CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands)

	December 31,	
	2002	**2001**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 85,412	$ 32,822
Short-term investments	12,100	
Accounts receivable (net of allowances of $4,150 in 2002 and $4,072 in 2001)	22,847	19,872
Other receivables	1,948	480
Inventories	27,161	22,942
Prepaid expenses and other current assets	7,501	2,494
Total current assets	156,969	78,610
PROPERTY AND EQUIPMENT -- net	5,824	5,469
INVESTMENT IN AFFILIATE	3,036	
INTANGIBLE ASSETS (net of accumulated amortization of $4,250 in 2002 and $4,324 in 2001)	7,642	9,220
OTHER ASSETS	18,966	21,260
TOTAL	$ 192,437	$ 114,559
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 22,447	$ 22,019
Accrued liabilities	13,485	14,375
Capital lease obligations -- current portion	235	177
Deferred revenue -- current portion	3,158	3,158
Notes payable -- current portion	4,114	5,615
Total current liabilities	43,439	45,344
CAPITAL LEASE OBLIGATIONS	448	326
DEFERRED REVENUE	3,158	6,317
NOTES PAYABLE	15,472	30,213
COMMITMENTS AND CONTINGENCIES (Notes 10, 11 and 18)		
STOCKHOLDERS EQUITY:		
Preferred stock, $.001 par value 5,000 shares authorized; none outstanding		
Common stock. $.001 par value, 40,000 shares authorized; outstanding: 2002, 26,443 shares; 2001, 20,961 shares	310,495	222,521
Accumulated deficit	(180,666)	(187,015)
Accumulated other comprehensive income (loss)	91	(3,147)
Total stockholders equity	129,920	32,359
TOTAL	$ 192,437	$ 114,559

See notes to Consolidated Financial Statements.

SANGSTAT MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2002	**2001**	**2000**
REVENUES:			
Net product sales	$ 116,849	$ 91,302	$ 61,319
Product recall returns			(872)
Revenue from collaborative agreements (Note 10)	3,208	3,207	2,698
Total revenues	120,057	94,509	63,145
COSTS AND OPERATING EXPENSES:			
Cost of sales:			
Cost of product sales	56,723	42,816	27,472
Product recall charges			11,774
Research and development (incl. product recall expenses of $50 for the year ended December 31, 2000)	18,913	17,863	20,788
Selling, general and administrative (incl. product recall expenses of $379 for the year ended December 31, 2000)	35,797	33,782	41,766
Amortization of intangible assets	1,000	1,922	1,392
Total costs and operating expenses	112,433	96,383	103,192
Income (loss) from operations of continuing operations	7,624	(1,874)	(40,047)
OTHER INCOME (EXPENSE), NET:			
Interest income	2,617	1,203	2,016
Interest expense	(2,898)	(4,830)	(4,368)
Other income (expense), net	315	(2,741)	750
Equity in net loss of affiliate	(164)		
Other income (expense), net	(130)	(6,368)	(1,602)
INCOME (LOSS) FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	7,494	(8,242)	(41,649)
INCOME TAX BENEFIT (PROVISION)	(1,145)	7	(368)
NET INCOME (LOSS) FROM CONTINUING OPERATIONS	6,349	(8,235)	(42,017)
NET LOSS FROM OPERATIONS OF DISCONTINUED OPERATION		(763)	(2,342)
NET LOSS FROM DISPOSAL OF DISCONTINUED OPERATION		(381)	

NET INCOME (LOSS)	$ 6,349	$ (9,379)	$ (44,359)
NET INCOME (LOSS) PER SHARE - BASIC			
Continuing operations	$ 0.25	$ (0.40)	$ (2.35)
Discontinued operation		(0.06)	(0.13)
Net income (loss)	$ 0.25	$ (0.46)	$ (2.48)
NET INCOME (LOSS) PER SHARE - DILUTED			
Continuing operations	$ 0.24	$ (0.40)	$ (2.35)
Discontinued operation		(0.06)	(0.13)
Net income (loss)	$ 0.24	$ (0.46)	$ (2.48)
Shares Used in Per Share Computations - Basic	25,824	20,216	17,910
Shares Used in Per Share Computations - Diluted	26,466	20,216	17,910

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Year Ended December 31,		
	2002	**2001**	**2000**
Net income (loss)	$ 6,349	$ (9,379)	$ (44,359)
Reversal of unrealized gain on marketable securities sold during the period		(6)	(644)
Unrealized gains (losses) on marketable securities classified as available for sale in the current period	(6)		40
Foreign currency translation adjustments	3,244	(935)	(898)
Total comprehensive Income (loss)	$ 9,587	$ (10,320)	$ (45,861)

See notes to Consolidated Financial Statements

SANGSTAT MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
(in thousands, except share data)

	Common stock				
	Shares	**Amount**	**Accumulated Deficit**	**Accumulated Other Comprehensive Loss**	**Total**
Balances, January 1, 2000	17,353,774	$ 174,990	$ (133,277)	$ (704)	$ 41,009
Issuance of common stock	1,345,928	23,401			23,401
Exercise of stock options	242,644	2,631			2,631
Warrant issued in connection with financing		744			744

Foreign currency translation adjustment				(898)	(898)
Reversal of unrealized gain on marketable securities sold during the period, net				(604)	(604)
Net loss			(44,359)		(44,359)
Balances, December 31, 2000	18,942,346	201,766	(177,636)	(2,206)	21,924
Issuance of common stock	1,784,635	18,774			18,774
Exercise of stock options	233,693	1,931			1,931
Stock option compensation expense		50			50
Foreign currency translation adjustment				(935)	(935)
Reversal of unrealized gain on marketable securities sold during the period, net				(6)	(6)
Net loss			(9,379)		(9,379)
Balances, December 31, 2001	20,960,674	222,521	(187,015)	(3,147)	32,359
Issuance of common stock	5,175,000	83,473			83,473
Exercise of stock options	307,332	4,501			4,501
Foreign currency translation adjustment				3,244	3,244
Unrealized loss on investments				(6)	(6)
Net income			6,349		6,349
Balances, December 31, 2002	26,443,006	$ 310,495	$ (180,666)	$ 91	$ 129,920

See notes to Consolidated Financial Statements

SANGSTAT MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2002	**2001**	**2000**
OPERATING ACTIVITIES:			
Net income (loss) from continuing operations	$ 6,349	$ (8,235)	$ (42,017)
Adjustments to reconcile net income (loss) from continuing operations to net cash provided by (used in) continuing operating activities:			
Depreciation and amortization	2,790	3,777	3,780
Non-cash interest expense	645	1,069	1,365
Equity in net loss of affiliate	164		
Loss on disposal of property and equipment	134	249	836
Stock compensation expense		50	
Deferred income taxes	(559)	84	130

Changes in assets and liabilities:			
Accounts receivable	(2,975)	(2,303)	(4,787)
Other receivables	(1,468)	1,853	573
Inventories	(4,219)	1,784	6,214
Prepaid expenses and other current assets	(489)	4,418	(4,606)
Accounts payable	428	4,466	5,702
Accrued liabilities	(331)	353	8,297
Deferred revenue	(3,159)	(3,158)	(1,097)
Net cash provided by (used in) continuing operating activities	(2,690)	4,407	(25,610)
Net cash used in discontinued operation		(2,944)	(2,223)
INVESTING ACTIVITIES:			
Purchases of property and equipment	(1,934)	(1,146)	(3,790)
Proceeds from the sale of equipment	300		
Maturities of short-term investments	41,158	1,556	7,492
Purchase of short-term investments	(53,264)		
Investment in Affiliate	(3,200)		
Proceeds from the sale of discontinued operation		1,800	
Other assets	(1,646)	3,228	(8)
Net cash provided by (used in) investing activities	(18,586)	5,438	3,694
FINANCING ACTIVITIES:			
Sale of common stock	87,974	20,705	26,032
Notes payable borrowings	1,488	465	6,574
Notes payable repayments	(18,375)	(13,182)	(4,834)
Repayment of capital lease obligations	(131)	(289)	(551)
Net cash provided by financing activities	70,956	7,699	27,221
EFFECT OF EXCHANGE RATE CHANGES ON CASH	2,910	(824)	(898)
NET INCREASE IN CASH AND EQUIVALENTS	52,590	13,776	2,184
CASH AND EQUIVALENTS, Beginning of year	32,822	19,046	16,862
CASH AND EQUIVALENTS, End of year	$ 85,412	$ 32,822	$ 19,046
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid during the period for interest	$ 980	$ 4,260	$ 1,158
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Warrants issued in connection with financing	$	$	$ 744

Property acquired under capital leases	$ 311	$	$ 518
Unrealized gain (loss) on investments	$ (6)	$ (5)	$ 604

See notes to Consolidated Financial Statements

SANGSTAT MEDICAL CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2002, 2001 and 2000

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Organization- SangStat Medical Corporation and subsidiaries (collectively, the Company) is a global Biopharmaceutical company focused on immunology and working to discover, develop and market high-value therapeutic products in transplantation medicine, hematology/oncology, immunology and auto-immune disorders.

Principles of Consolidation-The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany accounts and transactions are eliminated.

Revenue Recognition- Revenue from product sales, net of estimated sales allowances and rebates, is recognized upon receipt by the customer, when a purchase order has been received, the sales price is fixed or determinable and collection of the resulting receivable is reasonably assured.Revenue from collaborative agreements is recognized in accordance with the related contract terms. Up-front or milestone payments received under such agreements are generally recognized as revenue ratably over the life of the agreement where significant obligations for future services or Company participation exist or as milestones are met and no significant obligation for future services exists.

Revenue from sales of Gengraf, which we co-promote with Abbott Laboratories, is recorded on a gross basis, in accordance with Emerging Issues Task Force Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent.* Abbott s share of the gross profit, as defined, resulting from the sale is recorded as cost of product sales.

Research and Development- Research and development costs are expensed as incurred and include expenses associated with new product research, clinical trials of existing technologies, regulatory affairs activities associated with product candidates and costs incurred under our co-development agreements.

Advertising Expenses- Advertising costs, which also include promotional expenses, are expensed as incurred. Advertising expenses for the years ended December 31, 2002, 2001 and 2000 were approximately $1.6 million, $2.4 million, and $4.5 million, respectively.

Cash and Cash Equivalents- The Company considers all highly liquid debt instruments with a remaining maturity date of three months or less when purchased to be cash equivalents.

Short-Term Investments- The Company has classified all of its investments as available-for-sale securities. While the Company s practice is to hold debt securities to maturity, the Company has classified all debt securities as available-for-sale securities, as the sale of such securities may be required prior to maturity to implement management strategies. The carrying value of all securities is adjusted to fair market value, with unrealized gains and losses, net of deferred taxes, being excluded from earnings and reported as separate component of stockholders equity and included in accumulated other comprehensive income / loss. Cost is based on the specific identification method for purposes of computing realized gains or losses.

Inventories- Inventories are stated at the lower of cost (first-in, first-out) or market. The Company classifies inventory not expected to be utilized within the next twelve months as Other Assets (See Notes 3 and 6).

Property and Equipment- Property and equipment are stated at cost. Depreciation is calculated using the straight-line method over estimated useful lives of three to ten years. Leasehold improvements and assets under capital leases are amortized over the shorter of their lease term or estimated useful life.

Valuation of Long-lived Assets- The carrying value of the Company s long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that an asset may not be recoverable. The Company looks to current and future undiscounted cash flows, excluding financing costs, as primary indicators of recoverability. If an impairment is determined to exist, any related impairment loss is calculated based on fair value.

Investment in Affiliate- The equity investment in affiliate is accounted for under the equity method. The excess of the investment in affiliate represented by the difference between the investment and the Company s interest in the underlying net assets of the affiliate were attributed to intangible assets. Such intangible assets are being amortized on a straight-line basis over two years (See Note 10).

Foreign Currency Translation- Operations for the majority of the Company s foreign subsidiaries are measured using local currency as the functional currency. Assets and liabilities of such subsidiaries are translated into US dollars at the exchange rates in effect as of the balance sheet dates, and results of operations for each subsidiary are translated using average rates in effect for the periods presented. Gains or losses resulting from foreign currency translation are included as a component of accumulated other comprehensive loss.

The Company s subsidiary SangStat Atlantique uses the US dollar as its functional currency. Foreign currency denominated assets and liabilities are translated at the year-end exchange rates except for inventories, prepaid expenses, and property and equipment, which are translated at historical exchange rates. Gains or losses resulting from foreign currency translation and other foreign currency transaction gains and losses are included in other income (expense) - net in the consolidated statements of operations and were not significant for any period presented.

Stock-Based Compensation- The Company accounts for stock-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board (APB) No. 25, *Accounting for Stock Issued to Employees* (APB 25) *and* the Financial Accounting Standards Board (FASB) Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*. The Company accounts for stock based awards to non-employees in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation.*

SFAS No. 123 requires the disclosure of pro forma net income (loss) and earnings (loss) per share as though the Company had adopted the fair value method. Under SFAS No. 123, the fair value of stock-based awards to employees is calculated through the use of option pricing models, even though such models were developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from the Company s stock option awards. These models also require subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. The Company s calculations were made using the Black-Scholes option pricing model with the following weighted average assumptions: expected life, five and a half years; stock volatility, 69% in 2002, 64% in 2001 and 108% in 2000; risk free interest rate, approximately 4.5% in 2002, 5.0% in 2001 and 5.50% in 2000; and no dividend payments during the expected term. The Company s calculations are based on a single option valuation approach and forfeitures are recognized as they occur. If the fair values of the options granted during a fiscal year had been recognized as compensation expense on a straight-line basis over the vesting period of the grant, stock-based compensation costs would have impacted our pretax income (loss) and earnings per share for the fiscal years ended at December 31, as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2002	**2001**	**2000**
Pro forma net income (loss):			
Net income (loss) - as reported	$ 6,349	$ (9,379)	$ (44,359)
Stock option compensation expense	(1,038)	(1,924)	(2,763)
Net income (loss) - pro forma	$ 5,311	$ (11,303)	$ (47,122)
Basic net income (loss) per share - as reported	$ 0.25	$ (0.46)	$ (2.48)
Diluted net income (loss) per share- as reported	$ 0.24	$ (0.46)	$ (2.48)
Basic net income (loss) per share - pro forma	$ 0.21	$ (0.56)	$ (2.63)
Diluted net income (loss) per share- pro forma	$ 0.20	$ (0.56)	$ (2.63)

Net Income (Loss) Per Share- Basic EPS excludes dilution and is computed by dividing net income / loss by the

weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock. For the year ended December 31, 2002 common share equivalents for stock options aggregating 641,702, as determined using the treasury stock method, are included in the diluted EPS calculation. Common share equivalents including stock options and convertible notes payable, aggregating 337,875 shares and 1,215,203 shares for the years ended December 31, 2001 and 2000, respectively, have been excluded from diluted EPS, as their effect would be antidilutive.

The following is a reconciliation of the numerators and denominators of the basic and diluted net loss per share computations (in thousands, except per share data):

	Year Ended December 31,		
	2002	2001	2000
Numerator:			
Net income (loss)			
Continuing operations	$ 6,349	$ (8,235)	$ (42,017)
Discontinued operation		(1,144)	(2,342)
Net income (loss)	$ 6,349	$ (9,379)	$ (44,359)
Denominator:			
Basic:			
Weighted average number of common shares outstanding	25,824	20,216	17,910
Diluted:			
Weighted average number of common shares outstanding	25,824	20,216	17,910
Common share equivalents - stock options	642		
Weighted average number of common shares and common share equivalents	26,466	20,216	17,910
Basic net income (loss) per share :			
Continuing operations	$ 0.25	$ (0.40)	$ (2.35)
Discontinued operation		(0.06)	(0.13)
Net income (loss) per share	$ 0.25	$ (0.46)	$ (2.48)
Diluted net income (loss) per share :			
Continuing operations	$ 0.24	$ (0.40)	$ (2.35)
Discontinued operation		(0.06)	(0.13)
Net income (loss) per share	$ 0.24	$ (0.46)	$ (2.48)

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

The Company sells its products primarily to organizations in the healthcare industry in the U.S., Canada and Europe, and does not require its customers to provide collateral or other security to support accounts receivable. The Company maintains allowances for estimated bad debt losses.

The Company participates in the dynamic biopharmaceutical industry. The Company believes that changes in any of the following areas could have a negative impact on the Company in terms of its future financial position and results

of operations: ability to obtain additional financing; successful product development; manufacturing and marketing capabilities; ability to negotiate acceptable collaborative relationships; obtaining necessary FDA and foreign regulatory approvals; ability to attract and retain key personnel; litigation and other claims against the Company, including, but not limited to, patent claims; increased competition; uncertainty regarding health care reimbursement and reform; and potential exposure for product liability and hazardous materials.

Accumulated Other Comprehensive Income (Loss)- The following are the components of accumulated other comprehensive income (loss) (in thousands):

	December 31,		
	2002	**2001**	**2000**
Unrealized gain (loss) on investments	$ (6)	$	$ 6
Foreign currency translation adjustments	97	(3,147)	(2,212)
Total	$ 91	$ (3,147)	$ (2,206)

Recently Issued Accounting Pronouncements- In July 2001, the FASB issued SFAS No.143, *Accounting for Asset Retirement Obligations*. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development, and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The provisions of SFAS No. 143 will be effective for fiscal years beginning after June 15, 2002. The Company is currently in the process of evaluating the impact of this Statement on its financial condition and results of operations. The adoption of this statement is not expected to have an impact on the Company s financial position or results of operations.

In August 2001, the FASB issued SFAS No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*. SFAS No. 144 supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, and addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The Company adopted SFAS No. 144 on January 1, 2002. Adoption of this Statement did not have an impact on the Company s financial position or results of operations.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated With Exit or Disposal Activities.* SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3. *Liability Recognition for Certain Employer Termination Benefits and other Costs to an Exit Activity (Including Certain Costs in a Restructuring)* SFAS No. 146 requires that the liability for costs associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost was recognized at the date of the Company s commitment to an exit plan. SFAS No.146 also establishes that the liability should initially be measured and recorded at fair value. The Company will adopt the provisions of SFAS No. 146 for restructuring activities initiated after December 31, 2002. The Company does not expect the adoption of this Statement to have a significant impact on its financial position and results of operations.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure* . SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation* to provide alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation to require more prominent disclosures about the method of accounting for stock-based employee compensation and the effect of the method used on reported results in both annual and interim financial statements. The Company adopted the disclosure provisions of SFAS No. 148 for its annual period ended December 31, 2002.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 requires that upon issuance of a guarantee, a guarantor must recognize a liability for the fair value of an obligation assumed

under a guarantee. FIN 45 also requires additional disclosures by a guarantor in its interim and annual financial statements about the obligations associated with guarantees issued. The recognition provisions of FIN 45 are effective for any guarantees issued or modified after December 31, 2002. The disclosure requirements are effective for financial statements of interim or annual periods ending after December 15, 2002. The Company has adopted the disclosure requirements for the financial statements included in this Form 10-K. The Company is currently evaluating the effects of FIN 45, however does not expect that the adoption of FIN 45 will have a material effect on the Company s financial position, results of operations, or cash flows.

2. INVESTMENTS

Available-for-sale securities consist of the following (in thousands):

	December 31, 2002			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate notes and bonds				
Less than 90 days	$ 29,196	$ 3	$ 9	$ 29,190
Less than one year	12,100			12,100
Total	$ 41,296	$ 3	$ 9	$ 41,290
Reported as:				
Cash and cash equivalents				$ 29,190
Short-term investments				12,100
Total				$ 41,290

At December 31, 2001 there were no available-for-sale securities.

3. INVENTORIES

Inventories consist of (in thousands):

	December 31,	
	2002	2001
Raw materials	$ 830	$ 2,976
Work in process	16,896	13,868
Finished goods	9,435	6,098
Total	$ 27,161	$ 22,942

In addition to these inventories, the Company has classified approximately $17.5 million and $15.0 million of raw materials inventory as other assets in the accompanying consolidated balance sheet at December 31, 2002 and 2001 respectively, as it is not expected that any significant

portion of the inventory will be utilized in operations during the next twelve months. The Company filed for marketing approval of the cyclosporine capsule product in a European country in January 2003. The Company intends to follow the European Community Mutual Recognition Procedure for obtaining marketing authorization in multiple member states following initial approval and to launch

in these countries shortly after obtaining approval. The use of such inventory is dependent upon the successful approval and launch of the cyclosporine capsule in the major European markets.

4. PROPERTY AND EQUIPMENT

Property and equipment consist of (in thousands):

	December 31,	
	2002	**2001**
Machinery and equipment	$ 7,651	$ 8,176
Capitalized software	3,405	3,135
Furniture and fixtures	334	401
Projects in process	361	249
Leasehold improvements	1,488	1,464
Total	13,239	13,425
Accumulated depreciation and amortization	(7,415)	(7,956)
Property and equipment - net	$ 5,824	$ 5,469

Included in machinery and equipment at December 31, 2002 and 2001 are assets leased under capital leases of $1,815,000 and $2,236,000 (net of accumulated amortization of $1,185,000 and $1,784,000), respectively. Depreciation and amortization expense of property and equipment totaled $1,790,000, $1,774,000 and $2,507,000 for the years ended December 31, 2002, 2001 and 2000, respectively.

5. GOODWILL AND INTANGIBLE ASSETS

The Company adopted Statement of Financial Accounting Standard No. 142, *Goodwill and Other Intangible Assets* on January 1, 2002. SFAS No. 142 required that the net book value of assembled workforce intangibles be reclassified to goodwill on January 1, 2002. Accordingly, the Company ceased amortizing $1,652,000 of assembled workforce intangible previously classified as purchased intangible assets and reclassified the remaining net book value of $578,000 as goodwill which is included in Other Assets in the accompanying Consolidated Balance Sheet. Further, as required by SFAS No. 142, the Company performed a transitional impairment test as of January 1, 2002 and concluded that no impairment of goodwill was indicated. Intangible assets consist of (in thousands):

		December 31, 2002			December 31, 2001		
	Amortization Period (years)	**Gross Carrying Amount**	**Accumulated Amortization**	**Net Amount**	**Gross Carrying Amount**	**Accumulated Amortization**	**Net Amount**
Developed technology	14	$ 7,613	$ 2,311	$ 5,302	$ 7,613	$ 1,767	$ 5,846
Avoided royalties	14	2,514	763	1,751	2,514	584	1,930
Trademarks	10	763	324	439	763	248	515
Customer list	5	1,002	852	150	1,002	651	351
Assembled workforce	5				1,652	1,074	578

Total	$ 11,892	$ 4,250	$ 7,642	$ 13,544	$ 4,324	$ 9,220

Following the adoption of SFAS No. 142 all of the Company s identifiable intangible assets are subject to amortization. The Company evaluated the useful lives of its acquired intangible assets in connection with the adoption of SFAS No. 142 and determined that no changes to the useful lives were necessary. Intangible assets are stated at cost. Amortization is calculated using the straight-line method over the estimated useful lives ranging from five to fourteen years. Amortization expense totaled $1,000,000, $1,922,000 and $1,392,000 for the years ended

December 31, 2002, 2001 and 2000, respectively. Amortization expense in 2001 includes the write-off of $482,000 representing the net book value of the intangible assets related to distribution rights for Multitest and Celiptium, two minor products formerly sold in Europe. Sales of these two products were discontinued in the fourth quarter of 2001.

The following table presents the impact of SFAS 142 on net income (loss) and net income (loss) per share had the accounting standard been in effect for fiscal 2001 and 2000 (in thousands, except per-share amounts):

	Year Ended December 31,		
	2002	**2001**	**2000**
Net income (loss) - as reported	$ 6,349	$ (9,379)	$ (44,359)
Adjustments:			
Amortization of assembled workforce intangible previously classified as intangible assets		331	331
Net income (loss) - adjusted	$ 6,349	$ (9,048)	$ (44,028)
Basic net income (loss) per share - as reported	$ 0.25	$ (0.46)	$ (2.48)
Basic net income (loss) per share - adjusted	$ 0.25	$ (0.45)	$ (2.46)
Diluted net income (loss) per share- as reported	$ 0.24	$ (0.46)	$ (2.48)
Diluted net income (loss) per share- adjusted	$ 0.24	$ (0.45)	$ (2.46)

The estimated annual amortization expense for intangible assets for the next five years ending December 31 is as follows (in thousands): 2003-$950; 2004-$800; 2005-$800; 2006-$800; and 2007-$800.

6. OTHER ASSETS

Other assets consist of (in thousands):

	December 31,	
	2002	**2001**
Inventory-raw materials (Note 3)	$ 17,527	$ 15,263
Advance - Gensia Sicor	1,000	1,000
Restricted cash		4,000
Other	439	997
Total	$ 18,966	$ 21,260

The Company reclassed approximately $4,000,000 of restricted cash that serves as a collateral for a standby letter of credit in favor of Aventis to other current assets during 2002.

7. ACCRUED LIABILITIES

Accrued liabilities consist of (in thousands):

	December 31,	
	2002	2001
Salaries & related benefits	$ 5,199	$ 4,483
Interest payable	633	186
Research and development expenses (Note 10)	1,384	1,550
Marketing and development expenses (Note 10)	221	2,047
Other accrued liabilities	6,048	6,109
Total	$ 13,485	$ 14,375

Included in other accrued liabilities at December 31, 2002 and 2001 was $128,000 and $296,000, respectively, in reserves for residual expenses of the discontinued operation pertaining primarily to building lease obligations.

8. NOTES PAYABLE

Notes payable consist of (in thousands):

	December 31,	
	2002	2001
Note payable to Aventis	$ 4,000	$ 9,000
Discount on note payable to Aventis	(176)	(727)
Convertible note	9,874	9,779
Note payable to Abbott Laboratories	5,000	16,000
Other debt	888	1,776
Total	19,586	35,828
Less current portion	(4,114)	(5,615)
Long-term	$ 15,472	$ 30,213

In connection with the acquisition of IMTIX from Aventis in September 1998, the Company issued a $21.0 million non-interest bearing note payable over five years with two remaining payments totaling $4 million payments due in 2003. The note payable was discounted at a rate of 9.25%, which the Company believes was consistent with its normal borrowing rate at that time. The resulting discount of approximately $4.8 million is being accreted as an addition to interest expense over the term of the note. During the years ended December 31, 2002, 2001 and 2000, $551,000, $980,000 and $1,282,000, respectively, of amortization was recognized. The Company had approximately $4.0 million of restricted cash at December 31, 2002 and 2001, respectively, that serves as a collateral for a standby letter of credit in favor of Aventis.

In March 1999, the Company issued a $10.0 million convertible note due March 30, 2004. This note bears interest at the rate of 6.5% through March 30, 2004 and thereafter at the rate of 8.5% on any overdue amount. The interest is payable semi-annually in September and March. The note, or any portion thereof, is convertible at the option of the holder at any time before March 30, 2004 into shares of common stock of the Company at the rate of 50.0773 shares of common stock for each $1,000 principal amount. The net proceeds received by the Company were $9,550,000. The note is being accreted to its face amount over the five-year term. As of December 31, 2002 there has been no conversion into

common stock.

In May 1999, the Company received a loan of $16.0 million from Abbott Laboratories. The loan bears interest at 8.75%, payable annually, and is secured by a security interest in the US marketing rights for SangCya Oral Solution. The loan matures on December 31, 2004, and can be pre-paid by the Company without penalty at any time prior to maturity. The Company has repaid $11.0 million of the loan and at December 31, 2002, $5.0 million remains

outstanding.

On April 21, 2000 the Company signed an agreement with FINOVA to provide a line of credit of up to $30 million (the Loan Agreement). The Loan Agreement had an initial three-year term. The line of credit consisted of two elements: a $15 million line of credit bearing interest at the prime rate (9.0% at December 31, 2000) and secured by a matching compensating cash balance, and a $15.0 million line of credit bearing interest at the prime rate plus 1.5% and based on eligible domestic accounts receivable and inventory, as defined in the Loan Agreement. Under the terms of the Loan Agreement, the Company was required to maintain a loan balance of at least $5 million. As collateral for the line of credit, the Company granted FINOVA a first priority security interest in certain of its tangible and intangible assets and pledged the stock of its two French subsidiaries, IMTIX-SangStat SAS and SangStat Atlantique SA. In addition, the Company was required to meet certain financial covenants. At December 31, 2000, the Company had drawn down $5.0 million under the line of credit and had set aside a corresponding compensating balance, which is included in Other Current Assets on the consolidated balance sheet. As of December 31, 2000, the Company was in default of the Tangible Net Worth covenant under the Loan Agreement as a result of the reserve the Company took against inventory due to the SangCya Oral Solution recall. The Loan Agreement did not provide for a cure period for such a default. The parties entered into an Amendment dated May 11, 2001, which provided that the Loan Agreement would terminate as of December 31, 2001, the portion of the line of credit collateralized by accounts receivable and inventory would be eliminated, and FINOVA would waive the existing default and all early termination penalties with respect to the Loan Agreement. Subsequently, the Company repaid the loan balance of $5.0 million on June 29, 2001, thereby terminating the Loan Agreement. Since the loan was repaid, the $5.0 million compensating cash balance previously classified as other current assets was classified as cash in the accompanying consolidated balance sheet. In connection with this financing, the Company issued a warrant to purchase 50,000 shares of the Company s common stock at an exercise price of $23.438. This warrant was valued using the Black-Scholes pricing model with the following weighted average assumptions: expected life, five years; stock volatility, 72%; risk free interest rate, 6.0%; and no dividend payments during the expected term. The calculated value of the warrant of $744,000 and the additional financing fees of $750,000 were amortized as additional interest expense of $1,327,000 in 2001 and $167,000 in 2000.

Other debt at December 31, 2002 consisted primarily of borrowings by IMTIX against four revolving lines of credit from French banks. These lines of credit, which are renegotiable annually, bear interest at variable rates based on Eonia (Euro Over Night Index Average, 3.10 % at December 31, 2002).

As of December 31, 2002, future principal payments of notes payable (net of discounts) are as follows (in thousands):

Years Ending December 31,	
2003	$ 4,114
2004	15,472
Total	$ 19,586

9. FINANCIAL INSTRUMENTS

The following methods and assumptions were used to estimate the fair value of each class of financial instruments for which it is practicable to estimate fair value.

Short-term investments and corporate equity securities are recorded at fair value based on quoted market prices (see Note 2).

The fair value of the convertible note is based on market quotations, the major element of which is a comparison of the fixed conversion price and the closing price of the Company s common stock at December 31, 2002 and 2001. The fair value of the notes payable to Aventis and Abbott Laboratories is based on the present value of future cash flows discounted at an interest rate of 10.0% at December 31, 2002 and 2001, respectively. These estimates are approximate since no liquid market exists for these notes. The fair value of the Company s other debt is based

on carrying value as those obligations have short-term variable interest rates.

The estimated fair values of the Company s debt, including current portion, are as follows (in thousands):

	December 31, 2002		December 31, 2001	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Note payable to Aventis	$ 3,824	$ 3,636	$ 8,273	$ 7,851
Note payable to Abbott Laboratories	5,000	4,845	16,000	15,503
Convertible debt	9,874	9,841	9,779	11,550
Other debt	888	888	1,776	1,776
Total	$ 19,586	$ 19,210	$ 35,828	$ 36,680

10. COLLABORATIVE AGREEMENTS

In May 1999, the Company and Abbott Laboratories (Abbott) signed a multi-year co-promotion, distribution and research agreement for Gengraf cyclosporine capsules (the product) in the US. The Company is the exclusive distributor for the products and shares marketing, promotional and development expenses as well as the profits from the co-promotion of the product with Abbott. The agreement ends December 31, 2004 unless both parties agree to extend it. Pursuant to this agreement, Abbott made an equity investment of $14 million during 1999 in exchange for approximately 894,000 shares of common stock, representing a premium to fair market value at that time aggregating to $1.3 million. In addition, Abbott made a series of up-front and milestone payments totaling $20.8 million through May 2000, and a long-term loan of $16.0 million (see Note 8) to the Company. In January 2000, the Company made a milestone payment to Abbott of $4.0 million under the terms of the agreement. No further milestone payments are required from either party. All up-front and milestone payments received, net of milestone payments made, and the premium received on the sale of the common stock to Abbott are recorded as deferred revenue and are being recognized ratably over the term of the agreement. For the years ended December 31, 2002, 2001, 2000 and 1999, the Company amortized $3.2 million, $3.2 million, $2.7 million and $1.5 million, respectively, to revenue. In May 2000, the Company and Abbott launched the cyclosporine capsule developed by Abbott under the brand name Gengraf®. In connection with the equity investment, Abbott and the Company entered into a Right of First Refusal Agreement and a Registration Rights Agreement, and amended and restated their existing Supply Agreement. At December 31, 2002 the Company has repaid $11.0 million of the loan and $5.0 million remains outstanding. Our ability to continue marketing Gengraf may be limited as a result of a recent judgment that Gengraf infringed a Novartis patent.

In August 2000, the Company entered into a global co-development, supply and license agreement for ABX-CBL with Abgenix under which the Company obtained an exclusive worldwide license for the marketing and sale of ABX-CBL. ABX-CBL is an anti-CD147 monoclonal antibody for the treatment of steroid resistant GVHD. The Company conducted a multi-center, randomized, and controlled Phase II/III study of ABX-CBL. On February 18, 2003, the Company announced preliminary results from this study that indicated that survival with ABX-CBL was similar to the control arm. Based on these results, the Company and Abgenix decided to discontinue further development of ABX-CBL. As a result the Company will not have to pay Abgenix two additional milestone payments of $1.0 million which were contingent on achievement of certain milestones. Under the terms of the agreement, the Company made an initial license fee payment of $1.0 million and an additional payment to Abgenix of $1.0 million as partial reimbursement of one-half of the development costs incurred by Abgenix between January 1, 2000 and August 8, 2000. The Company subsequently paid an additional $900,000 as reimbursement of these development costs in two equal installments at the end of June 2001 and 2002. Development costs incurred after August 8, 2000 are being shared equally. The Company and Abgenix share responsibility for the expense of the clinical trial. For the years ended December 31, 2002, 2001 and 2000, the Company paid approximately $2,000,000, $2,800,000 and $1,500,000 as its share of the development costs incurred after August 8, 2000.

The Company entered into a Distribution Agreement with Aventis in May 1999 that appointed Aventis as the Company s exclusive distributor outside North America and Western Europe. The agreement automatically extends for additional annual periods unless either party gives notice of termination, and the current expiration date is March 31, 2004. Aventis sells the Company s products either through its local subsidiaries or through third party distributors that often distribute other Aventis products. The Company is in the process of renegotiating the Aventis

contract to remove territories from the contract. The Company then would contract directly with a local distributor in that territory, which may be the local Aventis subsidiary in that territory. The Company has contracted directly with local distributors in Israel and certain countries in Eastern Europe, South and Central America, and Asia.

Aventis also performs some of the steps in the manufacturing process of Thymoglobulin and Lymphoglobuline. The Company pays Aventis royalties on Thymoglobulin and Lymphoglobuline contingent upon the sales of these products. In the years ended December 31, 2002, 2001and 2000, royalty payments on Thymoglobulin and Lymphoglobuline to Aventis totaled approximately $7.6 million, $2.2 million, and $622,000, respectively. The Company began paying royalties on sales of Thymoglobulin commencing on the third anniversary of the purchase of IMTIX (October 1, 2001). The royalty rate on Thymoglobulin sales will decrease substantially on October 1, 2004.

Synt:em

In July 2001, the Company entered into a three-year research collaboration agreement for the discovery of next generation RDP58 molecules with Synt:em, a French biopharmaceutical company. The aim of this collaboration is to design novel RDP58-like compounds for the inhibition of inflammation in new *in vivo* applications using Synt:em s proprietary rational design technology, Acti:mapThe agreement builds on earlier development efforts between SangStat and Synt:em with Allotrap peptides that led to the original discovery of RDP58. Under the terms of the agreement the Company performs *in vitro* and *in vivo* testing of peptides and novel rationally designed peptides while Synt:em uses its Acti:map technology to perform the rational design work.

In late 2001, the European Community, or EC issued a research contract to a consortium consisting of the Company s wholly owned French subsidiary, Imtix-SangStat SAS, and seven academic research centers. The grant covered a term of three years and will provide up to approximately $2,755,600 (2,628,567 Euros)to the consortium to fund research in the role of heme oxygenase-1, or HO-1 in inflammation. Since RDP58 regulates HO-1, the research was of interest to Imtix-SangStat . A consortium agreement is being negotiated under which it is anticipated that the academic members of the consortium would convey to Imtix-SangStat the rights to commercialize any inventions arising in the course of the research. Under the EC research contract, Imtix-SangStat committed to funding approximately $472,000 (450,000 Euros) of research, with the EC matching that amount. Imtix-SangStat intended that a portion of its research would be subcontracted to Synt:em. Since the research of Synt:em currently being conducted under the SangStat-Synt:em Agreement is included under the EC contract, the Company is working with Imtix-SangStat and Synt:em to assign the SangStat-Synt:em Agreement to Imtix-SangStat.

Therapeutic Human Polyclonals

In November 2002, the Company entered into a collaboration with Therapeutic Human Polyclonals, Inc. for the development of humanized polyclonal therapeutic products to be generated by the immune systems of transgenic animals. THP is a private research stage company that was formed by two scientists, one of whom, Dr. Roland Buelow, was our Senior Vice President of Discovery Research from April 1, 2002 to November 8, 2002. . Dr. Buelow is transitioning from employment with us to becoming the full-time Chief Scientific Officer of THP.

The Company has options from THP to obtain exclusive licenses to the THP technology to produce humanized polyclonal antibody products. One option is for a humanized version of our current Thymoglobulin product. We also have options to obtain exclusive licenses to products to treat hematology (blood related) diseases, such leukemia and lymphoma. The options have an exercise period that commences when THP has produced a genetically engineered rabbit capable of producing commercial-grade humanized antibodies. Each license would have an up-front fee, milestone payments based on progression through clinical trials to product approval, and royalties. THP has the right to contribute to the development costs for hematology products and receive a commensurate share of profits from commercial sales. The Company share s antibody purification know-how with THP. In November 2002, the Company made a one-time technology access fee payment to THP of $500,000 under the terms of the agreement.

The Company made an equity investment of $3.2 million in THP. The Company is accounting for this investment under the equity method in accordance with APB 18 The Equity Method of Accounting for Investments in Common Stock because it believes that conditions exist that indicate an ability to exercise significant influence over THP. The difference between the Company s initial investment and the $1,352,000 (or 28%) of the underlying

equity in the net assets of THP at the date of investment was attributed to intangible assets, including technical know-how. This excess amount of $1,848,000 is being amortized on a straight-line basis over a period of two years. The $1,352,000 underlying equity in the net assets of THP and the Company s equity in net losses of THP from the date of investment have been determined in accordance with EITF 99-10 Percentage

Used to Determine the Amount of Equity Method Losses , using the hypothetical liquidation at book value method. The equity in net loss of affiliate for the year ended December 31, 2002, is comprised of the Company s equity in the net loss of THP from the date of investment of $10,000 and the amortization of amounts attributed to THP intangibles of $154,000. The Company is committed to make a second investment of $3.2 million when THP has produced the proof-of-principle engineered rabbit, unless that milestone is unduly delayed. The total of these investments would represent approximately twenty percent (20%) of THP s issued share capital. The investments are made in conjunction with investments by Research Corporation Technologies, Inc., which provided start-up financing for THP and is the majority shareholder. When THP has produced the commercial-grade engineered rabbit, the Company has an option to make an additional equity investment of $15.0 million, which would give the Company ownership of approximately 40% of THP s issued share capital. The Company does not have an option to acquire full ownership of THP.

11. LEASING ARRANGEMENTS

The Company leases administrative facilities under operating leases and machinery and equipment under capital leases expiring through 2013. The Company also leases manufacturing facilities from Aventis in Lyon, France under a lease that expires in 2013. This lease may be terminated at the Company s option with one year s notice. As of December 31, 2002, future minimum annual payments under capital and operating leases are as follows (in thousands):

Years Ending December 31,	Capital Leases	Operating Leases
2003	$ 255	$ 1,596
2004	299	1,495
2005	70	1,103
2006	69	730
2007	52	730
Thereafter		3,198
Total minimum lease payments	745	$ 8,852
Less amounts representing interest	(62)	
Present value of minimum lease payments	683	
Less current portion	(235)	
Capital lease obligations	$ 448	

Rent expense for the years ended December 31, 2002, 2001 and 2000 was $1,492,000, $1,642,000 and $1,493,000, respectively.

12. STOCKHOLDERS EQUITY

Issuance of Common Stock On February 20, 2002, the Company completed the issuance of 5,175,000 shares of common stock in a public offering for proceeds net of underwriting discounts of approximately $84.1 million. On January 5, 2001, the Company completed a private placement of approximately 1.3 million shares of common stock for aggregate proceeds of approximately $12.5 million with a group of institutional investors. Shares were purchased

at a discount to the closing market price on the date the agreements were signed. The transaction occurred in two tranches, of approximately $8.5 million (894,800 shares) and $4.0 million (421,000 shares) respectively, the first of which closed December 29, 2000, the second of which closed January 5, 2001. The Company did not pay any investment banking fees and did not issue any warrants with respect to this placement.

In June 2001, the Company sold 1,363,635 shares of common stock to the same group of investors for net proceeds of approximately $15.0 million.

Stockholder Rights Plan- The Company has a stockholder rights plan to protect stockholders rights in the event of a proposed takeover of the Company. Under the plan a preferred share purchase right is attached to each share of common stock. The Rights are exercisable only if a person or group acquires 15% or more of the Company s common stock or announces a tender offer, the consummation of which would result in ownership by a person or group of 15% or more of the Company s common stock. Each right will entitle stockholders to buy one one-hundredth of a share of a new series of junior participating preferred stock at an exercise price of $45 upon certain events. If, after the rights become exercisable, the Company is acquired in a merger or other business combination transaction, or sells 50% or more of its assets or earnings power, each right will entitle its holder to purchase, at the right s then-current price, a number of the acquiring company s common shares having a market value at the time of twice the right s exercise price. If a person or group acquires 15% or more of the Company s outstanding common stock, each right will entitle its holder (other than such person or members of such group) to purchase, at the right s then-current exercise price, a number of the Company s common shares (or cash, other securities or property) having a market value twice the right s exercise price. At any time within ten days after a person or group has acquired beneficial ownership of 15% or more of the Company s common stock, the rights are redeemable for $.01 per right at the option of the Board of Directors. The rights expire on August 25, 2005, unless earlier redeemed or exchanged. On October 8, 2001, the plan was amended to appoint EquiServe Trust Company, N.A., as successor rights agent to the plan and to conform the plan to current Delaware law regarding the use of continuing director provisions.

Stock Option Plans- On May 14, 2002, the stockholders approved the Company s 2002 Stock Option Plan (the 2002 Plan) that was adopted by the Board of Directors effective March 6, 2002. The 2002 Plan serves as the successor to the Company s 1993 Stock Option Plan (the Predecessor Plan). The Predecessor Plan terminated upon stockholder approval of the 2002 Plan, and no further stock option grants were or will be made from the Predecessor Plan from and after the date of stockholder approval of the 2002 Plan. All options outstanding under the Predecessor Plan immediately prior to the termination of the Predecessor Plan were incorporated into the 2002 Plan and are treated as outstanding options under the 2002 Plan. However, each outstanding option so incorporated will continue to be governed solely by the express terms and conditions of the instrument evidencing such grant, and no provision of the 2002 Plan will be deemed to affect or otherwise modify the rights or obligations of the holders of such incorporated options with respect to their acquisition of shares under such options. Employees of the Company or any parent or subsidiary, non-employee members of the Board or the board of directors of any parent or subsidiary corporation, and consultants and other independent advisors in the service of the Company or its parent or subsidiary corporations are eligible to participate in the 2002 Plan.

In addition to the 2002 Plan, the Company also grants options to non-employee directors of the Company under the 1996 Non-Employee Directors Stock Option Plan (the Directors Plan). Under the Company s stock option plans, incentive or non-statutory stock options to purchase up to 7,342,200 shares of common stock may be granted to employees, directors, and consultants.

A summary of stock option activity is as follows:

	Number of Shares	Weighted Average Exercise Price
Balances, January 1, 2000	2,810,959	$ 19.43
Options granted (weighted average fair value of $18.11).	1,331,725	21.19
Options exercised	(242,644)	10.84
Options canceled	(702,266)	23.15
Balances, December 31, 2000 (1,305,037 vested at a weighted average exercise price of $19.77)	3,197,774	19.97
Options granted (weighted average fair value of $12.07)	1,320,544	12.36
Options exercised	(233,693)	8.26
Options canceled	(849,048)	19.13
Balances, December 31, 2001 (1,575,544 vested at a weighted average exercise price of $20.57)	3,435,577	18.05
Options granted (weighted average fair value of $20.04).	1,262,929	20.04

Options exercised	(307,332)	14.65
Options canceled	(764,328)	22.33
Balances, December 31, 2002	3,626,846	$ 18.22

Under the 2002 Plan, options to purchase common stock generally vest over a period of four years, are exercisable upon vesting and expire ten years from the date of grant. As of December 31, 2002, 1,957,981 shares were available under the 2002 Plan for future grants.

Under the Directors Plan, up to a total 500,000 options to purchase shares of the Company s common stock may be issued. Also in accordance with the Directors Plan, during 2002, 2001 and 2000, each of the non-employee Directors was granted options to purchase 8,000, 8,000 and 4,000 shares of the Company s common stock, respectively. All options granted under the Directors Plan are immediately exercisable, but the Company may repurchase at the exercise price any unvested shares held by a non-employee Board member when his or her service terminates. The first 25% of the shares acquired under the Directors Plan vest when the non-employee director completes the first 12 months of service after the date of grant, and the balance vests in equal monthly installments as the non-employee director completes each of the next 36 months of service. The shares vest in full if the non-employee Board member s service terminates due to death or permanent disability or if the Company is subject to a change in control or a party to a merger or certain other transactions. In addition, the Directors Plan permits non-employee directors to receive all or part of his or her basic retainer payments from the Company in the form of non-statutory stock options. If a Board member makes an election to receive options in lieu of cash retainer, then options will automatically be granted to him or her under the Directors Plan. As of December 31, 2002, there were no outstanding shares subject to repurchase rights and 175,322 shares were available under the Directors Plan for future grants. Options granted under the Directors Plan are also included in the above table.

Additional information regarding options outstanding as of December 31, 2002 is as follows:

	Options Outstanding				Vested Options	
Range of Exercise Price	Number Outstanding	Weighted Avg. Remaining Contractual Life (yrs)	Weighted Avg. Exercise Price	Number vested	Weighted Avg. Exercise Prices
$ 0 .00 -5.00	22,950	1.5	$ 4.24	22,950	$ 4.24
5.01 -10.00	92,333	5.5	7.44	55,421	6.96
10.01 -15.00	1,044,544	7.8	11.54	550,512	11.82
15.01 - 20.00	1,348,021	8.0	18.79	377,682	18.99
20.01 - 25.00	629,774	7.3	22.35	281,234	22.88
25.01 - 30.00	364,081	6.6	26.30	223,206	26.50
30.01 - 35.00	89,143	6.0	32.03	82,273	32.04
35.01 - 45.00	36,000	7.1	39.60	19,538	40.84
	3,626,846	7.5	18.22	1,612,816	18.57

13. INCOME TAXES

Income (loss) before income taxes and the provision for income taxes consists of the following (in thousands):

	December 31,		
	2002	2001	2000

Income (loss) from continuing operations before income taxes			
Domestic	$ 12,338	$ 957	$ (38,448)
Foreign	(4,844)	(9,199)	(3,201)
Net loss from discontinued operation			
Domestic		(1,144)	(2,342)
Income tax benefit (provision)			
Domestic	(5)		
Foreign	(1,140)	7	(368)
Net Income (Loss)	$ 6,349	$ (9,379)	$ (44,359)

The difference between the Company s effective tax rate and the Federal statutory rate of 35% is attributable primarily to the recording of valuation allowances on certain net deferred tax assets during the respective periods. The effective income tax rate reconciliation is as follows (in millions):

	December 31,		
	2002	2001	2000
Expected benefit (provision) at U.S. statutory of 35%	$ (2,623)	$ 2,885	$ 14,577
Change resulting from:			
Valuation Allowance	4,155	(2,592)	(19,592)
Foreign and Other	(2,677)	(300)	5,383
Total	$ (1,145)	$ (7)	$ 368
Effective Income Tax Rate	15.3%	0%	0.7%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, as well as operating loss and tax credit carryforwards.

Significant components of the Company s deferred income tax assets are as follows (in thousands):

	December 31,	
	2002	2001
Deferred tax assets:		
Net operating loss carryforwards	$ 46,668	$ 48,987
General business credits	8,564	7,536
Revenue recognized in different periods	3,094	3,774
Capitalized research and development	3,903	4,576
Accruals and reserves deductible in different periods	7,196	8,607
Depreciation / Amortization	2,904	2,244
	72,329	75,724
Valuation allowance	(71,176)	(75,331)

Total	$ 1,153	$ 393

Based on its history of US operating losses, the Company has placed a valuation allowance of $71,176,000 and $75,331,000 against its otherwise recognizable domestic net deferred tax assets at December 31, 2002 and 2001, respectively, due to the uncertainty surrounding the realizability of these benefits. Net foreign deferred tax assets of $1,153,000 and $393,000 have been recognized at December 31, 2002 and 2001, respectively.

At December 31, 2002, the Company had federal, California and foreign net operating loss carryforwards of approximately $134,219,000, $13,937,000 and $641,000 respectively, available to reduce future taxable income. Such carryforwards expire beginning in 2004 through 2021. Also at December 31, 2002, the Company had research and experimentation credit carryforwards available of approximately $6,155,000 and $3,650,000 for federal and state tax purposes, respectively. The federal tax credit carryforwards expire beginning in 2004 through 2022 and the state tax credit carryforwards have no expiration date.

Utilization of the above domestic net operating loss and credit carryforwards may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating loss and credit carryforwards before utilization.

Included in the deferred tax assets at December 31, 2001 is approximately $5,878,000 of cumulative tax benefits related to equity transactions which will be credited to stockholders equity, if and when realized after the other tax deductions in the carryforwards have been realized.

14. EMPLOYEE BENEFIT PLAN

The Company sponsors the SangStat Medical Corporation 401(k) Plan, or the Plan to provide retirement benefits for its employees. As allowed under Section 401(k) of the internal revenue code, the Plan provides tax-deferred salary deductions for eligible employees.

Employees may contribute up to 20% (changed to 75% for 2003) of their annual compensation to the Plan. Employee contributions are limited to a maximum annual amount as set periodically by the Internal Revenue Service. Through December 31, 2001, the Company had not made any contributions to the Plan. Effective January 1, 2002, the Company matches employee contributions in an amount equal to 100% of the amount of the elective deferrals that do not exceed 3% of compensation and 50% of the amount of the elective deferrals that exceed 3% of compensation but that do not exceed 5% of compensation. All contributions are 100% vested when made. For the year ended December 31, 2002, the Company contributions were approximately $392,000.

Effective January 1, 2002, the Company established the Sangstat Medical Corporation Non-qualified Deferred Compensation Plan, or the Deferred Compensation Plan, for certain of its employees. The purpose of the Deferred Compensation Plan is to offer those employees an opportunity to elect to defer the receipt of compensation in order to provide post-employment and related benefits. The Deferred Compensation Plan is intended to be a top hat plan (i.e., an unfunded deferred compensation plan maintained for a select group of management or highly-compensated employees) under sections 201(2), 301(a)(3) and 401(a)(1) of the Employee Retirement Income Security Act of 1974. The Company has not made any contributions to the Deferred Compensation Plan.

15. MAJOR CUSTOMERS

For the year ended December 31, 2002, the Company had four customers that accounted for approximately 28%, 19%, 15% and 14%, respectively, of total revenues. For the year ended December 31, 2001, the Company had four customers that accounted for approximately 26%, 18%, 12% and 11%, respectively, of total revenues. For the year ended December 31, 2000, the Company had two customers that accounted for approximately 15% and 13%, respectively, of total revenues.

16. BUSINESS SEGMENT DATA

The Company s continuing operations are organized and operate in one business segment: pharmaceutical products. Pharmaceutical products consist primarily of therapeutic products for preventing and treating organ rejection.

The Company is engaged in the business of developing and marketing products in the areas of immunology, hematology/oncology and auto-immune disease. The Company s operations in Europe primarily relate to the manufacture, marketing and selling, research and development

and clinical study of therapeutic products for transplantation. The Company s operations in the rest of the world are principally sales and marketing related.

Summarized data for the Company s domestic and foreign revenues and long-lived assets are as follows (in thousands):

	United States	Europe	Canada	Rest of the World	Consolidated
Year ended December 31, 2002:					
Sales to unaffiliated customers	$ 94,013	$ 17,441	$ 2,071	$ 6,532	$ 120,057
Long-lived assets	$ 3,406	$ 10,636	$ 2	$	$ 14,044
Year ended December 31, 2001:					
Sales to unaffiliated customers	$ 70,388	$ 15,820	$ 1,372	$ 6,929	$ 94,509
Long-lived assets	$ 3,776	$ 10,910	$ 3	$	$ 14,689
Year ended December 31, 2000:					
Sales to unaffiliated customers	$ 41,272	$ 14,667	$ 1,289	$ 5,917	$ 63,145
Long-lived assets	$ 5,003	$ 12,669	$ 9	$	$ 17,681

17. RECALL OF SANGCYA ORAL SOLUTION

On June 29, 2000, the Company recalled of SangCya Oral Solution from the U.S. Following discussions with the FDA as to the type of recall and mechanism for conducting it, this decision was announced on July 10, 2000. The Company no longer sells SangCya Oral Solution.

The Company included in its financial results for the year ended December 31, 2000, charges to cover the losses resulting from the recall. These charges, which are reported in the consolidated statements of operations under revenues, cost of sales, research and development expenses and selling, general and administrative expenses, include $872,000 for sales returns, $11,774,000 for the write-off of all SangCya Oral Solution and CycloTech finished goods and components and a partial write-down of bulk cyclosporine inventories, and $429,000 for costs to terminate ongoing marketing and clinical programs, and to administer the recall. The inventory reserves are non-cash in nature since the inventories in question have already been paid for.

18. LITIGATION

Novartis Patent Litigation with Respect to Gengraf

Novartis sued Abbott in United States District Court in Delaware claiming that Gengraf® infringes its patents. On August 19, 2002 a judgment was entered finding that Gengraf infringed one of the Novartis patents and awarding Novartis $5.0 million in damages. Novartis filed for an injunction to prevent the sale of Gengraf in the U.S., but the judge has not yet ruled on the injunction. The Company has not been named a defendant in this lawsuit,and the Company is not liable for the damages awarded by the jury. Under our agreement with Abbott, Abbott is obligated to indemnify the Company against such suits, but their indemnity may not cover lost sales, if any. The course of litigation is inherently uncertain, Novartis may choose to sue the Company directly, Abbott may not prevail on its motions or on appeal, Abbott may elect to withdraw Gengraf from the market or Abbott may choose to settle on terms adverse to the Company s interests. Should the Company be sued by Novartis, it may incur expenses prior to reimbursement, if any, by Abbott pursuant to its indemnity obligation. Should Novartis succeed in obtaining a preliminary or permanent injunction, Abbott and the Company may be forced or elect to remove Gengraf from the market before its

co-promotion agreement with Abbott expires on December 31, 2004, its customers might return unsold inventory to the Company for credit or refund and the Company could be holding inventory of Gengraf that it may be unable to sell. In that event, its revenues would decrease significantly and its operating results would be materially adversely affected. The Company might also be required to write-off all or a portion of its Gengraf inventory.

Novartis Regulatory Litigation

U.S. Regulatory Litigation. Novartis U.S. sued the FDA on February 11, 1999 in the United States District Court for the District of Columbia alleging that the FDA did not follow its own regulations in approving SangCya Oral Solution in October 1998. The lawsuit alleges that because Neoral Oral Solution and SangCya Oral Solution are based on different formulation technologies, they should be classified as different dosage forms. Novartis initially asked the Court to (i) allow Novartis to keep its microemulsion labeling; (ii) declare microemulsion to be a separate dosage form; and (iii) rescind the AB rating that was given to SangCya Oral Solution. The Company intervened in this lawsuit. The Court granted the Company s motion to dismiss the counts that relate specifically to the approval of SangCya Oral Solution, but Novartis may appeal this decision. The Company may remain a party in the case. On July 11, 2002, the judge ordered Novartis, the FDA and the Company to file motions for summary judgment and set a schedule for briefs to be filed through December 20, 2002. The Company permanently withdrew SangCya Oral Solution from the U.S. market in July 2000, and receives no revenue from SangCya, but if the court were to declare microemulsion to be a separate dosage form, this ruling would require rescission of the AB rating for Gengraf, which would have a material adverse effect on its Gengraf revenues.

U.K. Regulatory Litigation SangCya Oral Solution. On October 18, 1999, Novartis U.K. was granted leave to seek judicial review of the decision by the Medicines Control Agency, or MCA, to approve SangCya Oral Solution. On March 30, 2000, the High Court in London dismissed Novartis s application for judicial review and ruled that the MCA acted properly in granting the SangCya Oral Solution marketing authorization. Novartis appealed the High Court s decision, and the hearing was held before the Court of Appeal on November 13 and 14, 2000. The Court of Appeal has stayed ruling on this matter pending the answer of certain questions of law to be submitted to the European Court of Justice, or ECJ. The ECJ hearing was held on November 7, 2002, and the Advocate General issued an opinion in January 2003. The Company expects the ECJ s decision approximately six to twelve months thereafter. Following the ECJ ruling, the parties would go back to the Court of Appeal, which will then apply the ECJ ruling on the law to the facts of this case. The Company no longer market SangCya Oral Solution, but the outcome of the case may affect the timing of regulatory approvals for our cyclosporine capsule product.

U.K. Regulatory Litigation Cyclosporine Capsules. In November 1999, Novartis filed a request with the High Court in London for judicial review of the refusal by MCA to state that it would not reference Neoral data in approving any generic copies of Novartis s cyclosporine capsule. An agreement was reached between the parties in which Novartis agreed to stay the judicial review until the earlier of (i) the decision on the judicial review of SangCya Oral Solution or (ii) MCA s approval of SangStat s marketing authorization for its cyclosporine capsule product; in return, the Company agreed that it would not launch or commence mutual recognition procedures in relation to the cyclosporine capsule marketing authorization (including a request to MCA to prepare an assessment report) for a period of 28 days commencing on the day on which the Company notifies Novartis s solicitors of capsule approval. The parties have agreed to continue the stay until the appeal of the High Court decision with respect to the judicial review of SangCya Oral Solution. The stay of this application for judicial review will remain in place pending the ECJ ruling on the questions of law and resulting Court of Appeal judgment.

Novartis has also indicated that it will seek an injunction to prevent our cyclosporine capsule from being sold in the United Kingdom until final resolution of the judicial review relating to our cyclosporine oral solution. Because the High Court ruled in favor of the MCA with respect to the SangCya Oral Solution marketing authorization and the Court of Appeal has referred questions of law to the ECJ, the Company believes that it is unlikely that a court would grant Novartis a preliminary injunction with respect to our cyclosporine capsule marketing authorization. If the Court of Appeals reverses the High Court s ruling following the ECJ s decisions on questions of law, either the MCA could still approve our cyclosporine capsule as supra-bioavailable to Sandimmune without referencing Neoral data or the MCA could decide not to approve the Company s cyclosporine capsule marketing authorization until the expiration of the ten year data exclusivity period for Neoral capsules (May 2004).

Italian Regulatory/Trade Secret Litigation. On May 5, 2000, Novartis Farma S.p.a. (Novartis Italy) served IMTIX-SangStat S.r.l., an Italian SangStat subsidiary, and IMTIX-SangStat Ltd. with a summons to the Milan Tribunal in a lawsuit concerning our application for approval by the Italian Health Authorities of the SangCya Oral Solution. In December 2002, Novartis Italy agreed to withdraw the lawsuit and the Company agreed not to file for approval of a cyclosporine oral solution before May 2004. Consequently, the Company does not expect any adverse consequences from this lawsuit.

IFFA CREDO and Elevage Scientifique des Dombes Breach of Contract Suit

In August 2000, two affiliated suppliers, IFFA CREDO and Elevage Scientifique des Dombes, sued the Company s French subsidiary, IMTIX-SangStat SAS, for breach of contract in the Commercial Court of Lyon, France. The suppliers won in the trial court and appeals court and the Company paid approximately $3.6 million in damages plus interest. IMTIX-SangStat recorded charges of $3,250,000 and $204,000 to other expense net for the year ended December 31, 2001, which, combined with reserves recorded in fiscal 2000, fully provided for the court award. The Company appealed the case to the French Cours de Cassation, and is negotiating with the parent of the suppliers to settle the lawsuit in return for a refund of some of the damages paid.

Summary

The course of litigation is inherently uncertain. With respect to Novartis s lawsuit against Abbott, Novartis is seeking to remove Gengraf from the market. If Novartis succeeds, the loss of Gengraf sales would have a significant and material adverse effect on the Company s business and operating results. The Company might also be required to write-off all or a portion of our cyclosporine inventory. With respect to the European regulatory and trade secret lawsuits, Novartis s requested relief, if granted, could have a negative material adverse effect on the Company if the European Court of Justice ruling prevents the Company from filing for marketing authorization of our cyclosporine capsule product currently under development until after the expiration of the data exclusivity period for Novartis Neoral cyclosporine product. (That data exclusivity period expires in May 2004 for most European countries, including Germany, France, Italy and the United Kingdom.) If the Company cannot obtain approval of our cyclosporine capsule in Europe until 2004, this could have a material adverse impact on the Company s future operating results because of (i) the loss of potential revenue and (ii) the need to write-off some or all of its bulk cyclosporine inventory. With respect to the FDA lawsuit, Novartis s requested relief, if granted could mean that Gengraf and all other generic cyclosporine products that are not microemulsions would lose their AB rating. If Gengraf were no longer AB-rated to Neoral capsules, pharmacists could not automatically substitute Gengraf for Neoral capsules and this would harm the Company s operating results. The litigation, if not resolved favorably to the Company, could have a material adverse effect on its business and operating results. Of the foregoing litigation matters, only the Novartis patent lawsuit against Abbott is likely to require significant time and expense to the extent it becomes involved in the dispute.

19. UNAUDITED QUARTERLY FINANCIAL INFORMATION

Selected Quarterly Consolidated Financial Data:

	(In thousands, except per share data)			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year ended December 31, 2002:				
Total revenues	$ 24,144	$ 30,917	$ 33,300	$ 31,696
Gross profit	$ 13,521	$ 15,651	$ 16,632	$ 17,530
Net income	$ 678	$ 1,808	$ 2,608	$ 1,255
Net income per share - basic	$ 0.03	$ 0.07	$ 0.10	$ 0.05
Net income per share - diluted	$ 0.03	$ 0.07	$ 0.09	$ 0.05
Cash and cash equivalents and total investments	$ 108,540	$ 105,632	$ 106,946	$ 97,512
Year ended December 31, 2001:				
Total revenues	$ 20,325	$ 21,784	$ 25,100	$ 27,300
Gross profit	$ 11,704	$ 12,462	$ 13,459	$ 14,068
Net income (loss):				
Continuing operations	$ (5,709)	$ (2,622)	$ (329)	$ 425

Discontinued operation	(763)		(381)	
	$ (6,472)	$ (2,622)	$ (710)	$ 425
Net income (loss) per share - basic and diluted				
Continuing operations	$ (0.29)	$ (0.13)	$ (0.01)	$ 0.02
Discontinued operation	(0.04)		(0.02)	
	$ (0.33)	$ (0.13)	$ (0.03)	$ 0.02
Cash and cash equivalents and total investments	$ 16,439	$ 32,297	$ 25,542	$ 32,822

Schedule II

SANGSTAT MEDICAL CORPORATION
Valuation and Qualifying Accounts

(In thousands)

	Balance at at beginning of period	Additions charged to costs and expenses	Deductions	Other	Balance at end of period
2000					
Allowances	$ 1,469	$ 3,789	$ 2,130	(1)$	$ 3,128
2001					
Allowances	$ 3,128	$ 6,611	$ 5,667	(1)$	$ 4,072
2002					
Allowances	$ 4,072	$ 8,899	$ 8,821	(1)$	$ 4,150

(1) Accounts written off, net of recoveries

SANGSTAT MEDICAL CORPORATION
SIGNATURES

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

Date: March 26, 2003 SANGSTAT MEDICAL CORPORATION

By: /s/ RICHARD D. MURDOCK

Richard D. Murdock
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Richard D. Murdock and Stephen G. Dance, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ RICHARD D. MURDOCK **Richard D. Murdock**	Chairman of the Board of Directors, President & Chief Executive Officer (Principal Executive Officer)	March 26, 2003
/s/ STEPHEN G. DANCE **Stephen G. Dance, CPA, FCA**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 26, 2003
/s/ JEAN-JACQUES BIENAIMÉ **Jean-Jacques Bienaimé**	Director	March 26, 2003
/s/ FREDRIC J. FELDMAN **Fredric J. Feldman, Ph.D.**	Director	March 26, 2003
/s/CORINNE H. LYLE **Corinne H. Lyle**	Director	March 26, 2003
/s/ ANDREW PERLMAN **Andrew Perlman, M.D., Ph.D**	Director	March 26, 2003
/s/HOLLINGS C. RENTON III **Hollings C. Renton III**	Director	March 26, 2003
/s/ NICHOLAS SIMON **Nicholas Simon**	Director	March 26, 2003
/s/ VINCENT WORMS	Director	March 26, 2003

Vincent Worms

CERTIFICATIONS

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Richard D. Murdock, certify that:

1. I have reviewed this annual report on Form 10-K of SangStat Medical Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) Evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

   c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Signature	Title	Date
/s/ RICHARD D. MURDOCK	Chairman of the Board of Directors, President and Chief Executive Officer (Principal	March 26, 2003

Richard D. Murdock Executive Officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Stephen G. Dance, certify that:

1. I have reviewed this annual report on Form 10-K of SangStat Medical Corporation;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

   a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) Evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

   c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Signature	Title	Date
/s/ STEPHEN G. DANCE	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 26, 2003

Stephen G. Dance, CPA, FCA

EXHIBIT INDEX

Exhibits	Description of Exhibit
2.2	Master Agreement between SangStat Medical Corporation and Pasteur Merieux Serums & Vaccins, S.A., dated June 10, 1998, including Exhibit 8 thereto (filed as Exhibit 2.1 to the Registrant s Current Report on Form 8-K, filed on October 15, 1998 and as amended on December 14, 1998, and incorporated herein by reference).
3.1	Restated Certificate of Incorporation, filed with the Delaware Secretary of State on July 9, 2002 (filed as Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30,2002, filed on August 14, 2002, and incorporated herein by reference).
3.4	Second Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2000, filed on May 15, 2000, and incorporated herein by reference).
4.1	Specimen Common Stock Certificate of Registrant (filed as Exhibit 4.5 to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.1*	2002 Stock Option Plan effective as of March 6, 2002.
10.2	Form of Indemnification Agreement between the Registrant and its directors, officers and certain other employees (filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2001, filed on November 14, 2001, and incorporated herein by reference).
10.3**	License Agreement, dated November 15, 1993, between the Registrant and the Board of Trustees of Leland Stanford Junior University (filed as Exhibit 10.19to the Registrant s Registration Statement on Form S-1, file no. 033-70436, and incorporated herein by reference).
10.4	Rights Agreement, dated as of August 14, 1995, between the Registrant and First National Bank of Boston (filed as Exhibit 2 to the Registrant s Registration Statement on Form 8-A, filed on August 25, 1995, and incorporated herein by reference).
10.5	First Amendment to Rights Agreement, dated as of October 8, 2001, among the Registrant, Fleet National Bank (f/k/a The First National Bank of Boston) and EquiServe Trust Company, N.A. (filed as Exhibit 99.1 to the Registrant s Current Report on Form 8-K, filed on October 9, 2001, and incorporated herein by reference).
10.6	Real Property Sub-Lease, dated March 8, 1999, between the Registrant and Kelley-Clarke, Inc. to the Real Property lease, dated September 1, 1988, between Kelly-Clarke Inc. and Kaiser Development Company, as amended on February 26, 1990, May 1, 1990, May 5, 1990, and April 19, 1995 (filed as Exhibit 10.26 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1998, filed on March 31, 1999, and incorporated herein by reference).
10.7**	Co-Promotion Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.28 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2000, filed on March 30, 2001,and incorporated herein by reference).

Exhibits	Description of Exhibit
10.8	Right of First Refusal Agreement, dated as of May 7, 1999, between the Registrant and Abbott Laboratories, Inc. (filed as Exhibit 10.28 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, filed on August 16, 1999,and incorporated herein by reference).
10.10	Convertible Promissory Note, dated March 1999, for $10,000,000 with Warburg Dillon Read LLC (filed as Exhibit 10.32 to the Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 1999, filed on April 14, 2000, and incorporated herein by reference).

10.11**	Co-Development, Supply and License Agreement, dated as of August 8, 2000, between the Registrant and Abgenix, Inc. (filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, filed on November 14, 2000, and incorporated herein by reference).
10.17**	Option Agreement dated as of November 8, 2002 among the Registrant, Research Corporation Technologies, Inc. and Therapeutic Human Polyclonals, Inc.
10.18**	Hematology Alliance Agreement dated as of November 8, 2002 between the Registrant and Therapeutic Human Polyclonals, Inc.
10.19**	hTG Collaboration Agreement dated as of November 8, 2002 between the Registrant and Therapeutic Human Polyclonals, Inc.
10.20*	Separation Agreement and General Release of Claims dated as of November 8, 2002 between the Registrant and Roland Buelow.
21.1	Subsidiaries of Registrant.
23.1	Independent Auditors Consent.
24.1	Power of Attorney (reference is made to the signature page hereof).
99.1	Certification of Richard D. Murdock, Chief Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.2	Certification of Stephen G. Dance, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Management contract or compensatory plan or arrangement.

** Confidential treatment has been requested for certain portions omitted from this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Confidential portions of this Exhibit have been separately filed with the Securities and Exchange Commission. Confidential treatment has not yet been granted.