

RIBAPHARM INC  
Form 10-K  
March 31, 2003

---

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

### FORM 10-K

---

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

For the fiscal year ended December 31, 2002.

Commission File Number 1-31294

---

### RIBAPHARM INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

3300 Hyland Avenue, Costa Mesa, California  
(Address of principal executive offices)

95-4805655  
(I.R.S. Employer  
Identification No.)

92626  
(Zip Code)

Registrant's telephone number, including area code: (714) 427-6236

---

Edgar Filing: RIBAPHARM INC - Form 10-K

**Securities Registered Pursuant to Section 12(b) of the Act:**

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common stock, \$.01 par value	New York Stock Exchange

**Securities Registered Pursuant to Section 12(g) of the Act:**

**None**

---

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

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

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

The aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant on June 28, 2002 was \$271,791,000 based on a \$9.09 closing price for the common stock on such date. Shares of voting stock held by each executive officer and director and by each person who owns 5% or more of any voting stock have been excluded in that such persons may be deemed affiliates of the Registrant.

The number of outstanding shares of the Registrant's common stock as of March 21, 2003 was 150,000,000.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information contained in Ribapharm Inc.'s definitive Proxy Statement for the 2003 Annual Meeting of Stockholders, to be filed not later than 120 days after the end of the fiscal year covered by this report, is incorporated by reference into Part III hereof.

---

**TABLE OF CONTENTS**

**PART I**

1.	<u>Business</u>	3
2.	<u>Properties</u>	22
3.	<u>Legal Proceedings</u>	22
4.	<u>Submission of Matters to a Vote of Security Holders</u>	22

**PART II**

5.	<u>Market for Registrant's Common Equity and Related Stockholder Matters</u>	22
6.	<u>Selected Financial Data</u>	23
7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	25
7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	31
8.	<u>Financial Statements and Supplementary Data</u>	34
9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	57

**PART III**

10.	<u>Directors and Executive Officers of the Registrant</u>	57
11.	<u>Executive Compensation</u>	57
12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	57
13.	<u>Certain Relationships and Related Transactions</u>	57
14.	<u>Controls and Procedures</u>	57

**PART IV**

15.	<u>Exhibits, Financial Statement Schedules and Reports on Form 8-K</u>	57
-----	--	----

## PART I

### Item 1. *Business*

#### Overview

Ribapharm Inc. (the Company or Ribapharm) is a biopharmaceutical company that seeks to discover, develop, acquire and commercialize innovative products for the treatment of diseases with significant unmet medical needs, principally in the antiviral and anticancer areas. The Company's current research and development program focuses on hepatitis C, hepatitis B, cancer and HIV/AIDS, each of which affects a large number of patients. The Company seeks to capitalize on an extensive library of nucleoside analogs and other compounds that has already led to the discovery and development of ribavirin. Ribavirin is an antiviral drug that Schering-Plough Ltd. (together with its affiliates,

Schering-Plough) and F. Hoffmann-La Roche Ltd. (Roche) currently market in combination with other therapies under license from the Company for the treatment of hepatitis C in the United States, the European Union, Japan and other countries. Royalties from Schering-Plough's license contributed 100% of the Company's revenues of \$270,265,000 in 2002. Roche's license of ribavirin was executed in January of 2003.

The Company's internet address is [www.ribapharm.com](http://www.ribapharm.com). Posted links to the following filings are on the Company's website as soon as reasonably practical after they are electronically filed with or furnished to the Securities and Exchange Commission (SEC): annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendment to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities and Exchange Act of 1934. All such filings on the Company's website are available free of charge. Material that the Company files with the SEC may also be obtained directly from the SEC at its internet site (<http://www.sec.gov>) or by calling its Public Relations Room at 1-800-SEC-0330.

The Company has two next generation compounds of ribavirin as product candidates. These product candidates are Levovirin and Viramidine. The Company filed an investigational new drug application (IND) with the U.S. Food and Drug Administration (the FDA) for Levovirin in December 2000, and began Phase 1 clinical trials in the U.S. in February 2001. In June 2001, the Company licensed Levovirin to Roche. The Company initiated Phase 1 clinical trials on Viramidine in Europe in September 2001. The Company filed an IND for Viramidine with the FDA in December 2001, began additional Phase 1 clinical trials in the United States in late March 2002, and began Phase 2 clinical trials in the United States in December 2002.

To further expand the Company's pipeline, the Company has licensed two other compounds, Hepavir B and IL-12, from third parties. Hepavir B was licensed from Metabasis Therapeutics, Inc. in October 2001. The Company intends to develop Hepavir B for the treatment of hepatitis B. IL-12, a developmental compound for the treatment of cancer and allergies, was licensed from Roche under an agreement dated as of June 2001. The Company applied with the FDA to reactivate the IND to initiate human clinical trials of IL-12 during December 2002, and the IND has since been reactivated.

Ribavirin, Levovirin and Viramidine came from the Company's library of nucleoside analog chemical compounds. ICN Pharmaceuticals, Inc. (ICN), which owns 80.07% of the Company's common stock, originally discovered and developed these compounds from 1968 through 1988. Since March 2000, the Company discovered additional compounds using chemical methods known as combinatorial chemistry. In total, the Company presently has over 10,300 nucleoside analogs in its library. Nucleoside analogs are small-molecule chemicals that resemble the natural building blocks of human and viral genetic material, commonly known as DNA and RNA. The Company believes that its library contains one of the largest collections of nucleoside analogs in the world, and intends to combine its scientific expertise with advanced drug screening techniques in an effort to discover and develop new product candidates using its nucleoside analog library. During 2002, the Company acquired

## Edgar Filing: RIBAPHARM INC - Form 10-K

more than 113,000 diverse non-nucleoside analog compounds from third parties to complement its nucleoside analog library. These non-nucleoside compounds also target antiviral and anticancer areas. The Company intends to use these non-nucleoside compounds to facilitate its development of new products. To date, ribavirin is the only compound the Company has commercialized from the library.

The Company is committed to its research and development efforts. The Company spent approximately \$47.5 million, \$25.6 million, and \$12.6 million on research and development in 2002, 2001 and 2000, respectively. Beginning in April 2000, the Company expanded its research facilities and assembled an experienced research and development team. The Company has hired lead scientists in various areas of drug discovery, drug development, and clinical and regulatory affairs. The Company expanded its research team from 12 scientists on March 1, 2000 to approximately 83 and 100 scientists on December 31, 2001 and 2002, respectively. The Company spent approximately \$6 million in each of 2001 and 2000 and approximately \$3 million in 2002, to upgrade and modernize its research equipment. In addition, ICN spent approximately \$16 million in 2001 and \$12 million in 2000 on capital improvements to ICN's Costa Mesa, California headquarters, in which the Company's facility is located. A substantial portion of these improvements were to upgrade and modernize the Company's laboratories that it leases from ICN. This included the expansion of the Company's physical research and development facilities and the purchase of equipment for sophisticated drug discovery experiments. Furthermore, the Company intends to accelerate its drug discovery and development process by utilizing advanced screening techniques and equipment, biological assays, and computer-assisted drug design. As part of its effort to improve quality-control functions, the Company will continue to invest in new equipment and process and system improvements. In addition, the Company has made or is currently in the process of making extensive improvements to its research and development operations including:

recruitment and hiring of highly qualified executives, scientists and consultants in the areas of clinical research, regulatory affairs, biostatistics, data management and project management, to improve research and development and support systems;

installation of improved electronic document management and laboratory information management systems; and

formation of a Data Monitoring Committee, which includes prominent external consultants, to monitor clinical safety procedures and efficacy, as needed.

The Company has implemented and continues to take extensive measures intended to enhance its research and development processes and controls.

In 2002, the Company had revenues of \$270,265,000 and net income of \$129,241,000. Based on the closing price of the Company's common stock on the New York Stock Exchange on March 21, 2003, the Company has an equity market capitalization of approximately \$709,500,000.

### **Company Restructuring**

Until April 14, 2000, the Company was operated as a division of ICN. On April 14, 2000, ICN incorporated the Company in Delaware as a wholly owned subsidiary, and contributed to the new subsidiary the Company's operations and the assets used in the Company's business, including the following:

ICN's right, title and interest under the Schering-Plough ribavirin license;

all the chemical compounds contained in ICN's chemical compound library, along with all associated records, journals and data;

all intellectual property rights, including all patents, copyrights and trademarks, related to the Company's business, including all intellectual property rights held by ICN at the time of contribution in ribavirin and excluding existing approved indications for use other than as contemplated in the Schering-Plough ribavirin license, Tiazole, Adenazole, Levovirin, Viramidine and the chemical

## Edgar Filing: RIBAPHARM INC - Form 10-K

compounds in ICN's nucleoside analog library; and

all of the equipment and furniture contained in, and personnel employed in, the Company's research and development organization in the Costa Mesa facility.

With respect to the intellectual property rights to Tiazole and Adenazole, in an ongoing arbitration with certain Serbian governmental entities, ICN has taken the position that it has previously contributed its rights in

those compounds to ICN Yugoslavia, a Yugoslavian subsidiary. The validity of that transfer is one of the issues in dispute in that arbitration. Accordingly, whether or not the Company has rights to these compounds will be impacted by the outcome of this arbitration.

In anticipation of the Initial Public Offering ( IPO ) of the Company s common stock, on April 10, 2002, the Company effected a recapitalization of its common stock in the form of a 1,500,000 for 1.0 stock split. On April 17, 2002, ICN completed the sale, through an underwritten IPO, of 29,900,000 shares of common stock, representing 19.93% of the 150,000,000 outstanding shares of common stock. Shares sold in the IPO were owned by ICN, and the Company received no proceeds from the IPO. Upon consummation of the IPO, advances due from ICN of \$222,240,000 were treated similar to a dividend and recorded by the Company as a reduction of its retained earnings. The Company received no repayments of the advances. The Company and ICN also entered into certain intercompany agreements at the time of the IPO. See Note 7 of Notes to Financial Statements regarding Related Party Transactions . The terms of those agreements were agreed upon by ICN and the Company in a manner that both parties believed would be reasonable. The prices and other terms of those agreements may be more or less favorable to the Company than those it could have obtained in arms -length negotiations with unaffiliated third parties. The Company will also be included in ICN s consolidated group for federal income tax purposes for so long as ICN owns at least 80% of the Company s outstanding stock. Each member of the consolidated tax group is jointly and severally liable for the federal income tax liability of each other member of the consolidated group. Accordingly, although ICN and the Company have entered into a tax sharing agreement that allocates tax liabilities between the parties, the Company could be liable in the event that any federal tax liability is incurred, but not paid, by another member of ICN s consolidated group.

ICN owns 120,100,000 shares, or 80.07%, of the Company s outstanding common stock. As long as ICN owns a majority of the Company s outstanding common stock, it will be able to determine the outcome of most matters requiring approval by the Company s stockholders and to take certain actions by written consent.

Prior to the time of the IPO, ICN indicated that it would consider distributing its remaining 80.07% interest in the Company s common stock to ICN s stockholders in a tax-free spin-off within six months after completion of the IPO. In June 2002, ICN announced that, in light of changed circumstances and market conditions, ICN s newly reconstituted Board of Directors was reviewing certain strategic decisions, including the spin-off. In order for the spin-off to be tax free to ICN s stockholders, ICN must distribute to its stockholders at least 80% of the issued and outstanding common stock of the Company. Due to this requirement, at the time of the Company s restructuring, the Company agreed with ICN to limit the number of shares of common stock that can be sold by the Company. ICN has announced that it is continuing to explore its options with regard to the Company.

### **Management Disputes and Changes**

On December 20, 2002, the Company requested assurances from ICN regarding its intention to proceed with the tax-free spin-off. On December 23, 2002, ICN acted by written consent to remove Dr. Johnson Y.N. Lau, Kim Campbell, Arnold Kroll, Hans Thierstein and John Vierling (the Former Directors ) as directors of the Company, and to amend a bylaw provision adopted by the Board of Directors requiring advance notice of actions to be taken by written stockholder consent. In its letter to the Company, ICN expressed its concern over certain actions and inactions by the Board of Directors and management, including the Compensation Committee s grant of cash bonuses and stock option awards to senior management in December 2002. The disputes between ICN and the Former Directors are described in greater detail in the Information Statement on Form 14C filed by the Company on January 7, 2003. ICN also filed suit in the Court of Chancery of the State of Delaware against the directors it sought to remove. On January 22, 2003, in connection with the settlement of that litigation, the Former Directors resigned as directors of the Company. In addition, the executive officers of the Company, consisting of Dr. Lau, Thomas Stankovich and Roger Loomis, also resigned. On January 23, 2003, the Board, comprised of Roberts A. Smith, Ph.D., the sole remaining director, elected the following individuals to serve as directors effective immediately: Daniel J. Paracka, Santo J. Costa, Esquire, Gregory F. Boron and James J. Pieczynski. Mr. Paracka was also elected to serve as Chairman. The Board also appointed Kim D. Lamon, M.D.,



Ph.D., to the position of President and Chief Executive Officer, William M. Comer, Jr., CPA, to the position of Vice President and Chief Financial Officer, and Mel D. Deutsch, Esquire, to the position of Vice President, General Counsel and Secretary. A sixth Director, Andre C. Dimitriadis, Ph.D., was elected to the Board on February 21, 2003. The bylaw amendment adopted by ICN's written consent became effective January 27, 2003.

## Market Focus

The Company intends to focus its initial product discovery efforts on treatments for hepatitis C, hepatitis B, HIV/AIDS and cancer. The Company believes the hepatitis C, hepatitis B, HIV/AIDS and cancer markets are attractive, because these diseases are highly prevalent and there are few treatment alternatives. In addition, drugs that treat these diseases may qualify for accelerated FDA review procedures.

### *Hepatitis C:*

Hepatitis C virus ( HCV ) is a highly infectious and potentially fatal virus that can be contracted through blood and bodily fluid contact. It is one of the most prevalent chronic infectious diseases in the United States. The virus attacks the liver and can cause liver inflammation, liver scarring, liver failure and liver cancer. Most people infected with HCV have no symptoms and are unaware that they carry this potentially deadly virus. Because they are symptomless carriers, they can unknowingly infect others. HCV also has the ability to adapt rapidly to resist antiviral treatment and host immune responses. For this reason, mutants or quasispecies of the virus, which are resistant to treatment, can arise. In most cases, the body is not able to fight off the infection and the infected individual becomes a chronic carrier of HCV. According to the World Health Organization ( WHO ), as many as 170 million people worldwide are infected by the hepatitis C virus. Of these, it is estimated that approximately 10 million people are infected with HCV in the United States, Europe and Japan, with approximately 3.9 million in the United States (according to the Centers for Disease Control and Prevention ( CDC )) and 2 million in Japan. According to the CDC, approximately 25,000 people become infected and approximately 8,000 to 10,000 people die from complications of hepatitis C each year in the United States. HCV was not specifically identified until 1989. Approximately 20% of infected persons develop cirrhosis of the liver 10 to 30 years after infection. For others, the rate of disease progression is much slower and may extend over 30 to 40 years or more. Aside from the fact that this is a blood borne disease, the spread of HCV within a population is not fully understood. Currently, there is no approved vaccine to prevent hepatitis C.

The Company believes the hepatitis C market is important not only because of the potential size of the market, but because of the growing education and public awareness campaigns that are focusing the public's attention on the scale and severity of the disease. With this increasing awareness of HCV infection, the Company believes the market potential of hepatitis C will expand further and the demand for effective and safer treatments will increase.

The Company believes that a combination therapy consisting of pegylated interferon alfa-2b with ribavirin is currently one of the most effective treatments approved by the FDA for patients with chronic hepatitis C. Pegylated interferon differs from interferon in that a substance called polyethylene glycol is attached to the interferon protein. The presence of polyethylene glycol is believed to result in longer-acting, sustained activity of interferon. By prolonging the activity of interferon, patients could potentially take pegylated interferon only once a week, as opposed to the three times per week regimen followed with the interferon combination therapy. However, only approximately 54% of patients with chronic hepatitis C who were not previously treated with interferon alpha respond to the pegylated interferon alfa-2b combination therapy. In addition, pegylated interferon alfa-2b and interferon alfa-2b can cause flu-like symptoms and malaise, while ribavirin causes some patients to experience anemia. Therefore, the Company believes that safer and more effective treatments for hepatitis C will have significant market potential.

See Business Mature Product Ribavirin and Business Products in Development Levovirin and Virmidine .



**Hepatitis B:**

Hepatitis B virus ( HBV ) causes inflammation of the liver and is potentially fatal. It is one of the most common chronic infectious diseases in the world. HBV is transmitted through contaminated needles or blood and also through sexual contact. According to the American Liver Foundation, about 90-95% of patients who acquire hepatitis B as adults are able to defeat HBV infection on their own. However, approximately 5% of those infected will become chronic carriers of the virus. Children are particularly susceptible to the virus. According to the WHO, about 90% of infants infected during the first year of life, and 30-50% of children infected between one to four years of age, develop chronic infection. The risk of death from HBV-related liver cancer or cirrhosis for persons who become chronically infected during childhood is approximately 25%. The WHO estimates that approximately 2 billion people have evidence of past or current HBV infection and 400 million individuals worldwide, or approximately 5% of the world's population, are long term carriers of HBV in their blood. Most people who contract acute hepatitis B remain in good health, have no symptoms, and completely recover. However, chronic carriers of HBV have an increased chance of developing liver cancer, and a significant number develop cirrhosis of the liver.

A safe and effective vaccine against hepatitis B is available; however, the vaccine only benefits those who have not yet been infected by HBV. There are three FDA approved therapies for patients with hepatitis B: interferon alpha, lamivudine, and Adefovir Dipivoxil. Interferon alpha has the ability to reduce the amount of HBV in the blood for long periods of time in approximately 40% of patients, but has serious side effects such as flu-like symptoms, neutropenia, thrombocytopenia and malaise. Lamivudine, which is a nucleoside analog, suppresses the amount of HBV in the blood in a majority of patients. However, if lamivudine therapy is discontinued, HBV levels in the blood can rebound and liver disease can ensue. In addition, up to 70% of patients taking lamivudine will develop drug resistance within three years. Therefore, the Company believes that more effective drugs, including drugs that are effective against lamivudine resistant HBV, will have significant market potential.

The Company intends to develop the Hepavir B compound for the treatment of hepatitis B. See Business Products in Development Hepavir B.

**HIV:**

AIDS, acquired immune deficiency syndrome, is caused by the human immunodeficiency virus, or HIV. HIV attacks cells of the immune system. It thereby destroys the body's ability to fight infections and some cancers. Individuals diagnosed with AIDS are susceptible to life-threatening diseases, including opportunistic infections and cancer. The infections are caused by microbes that usually do not cause illness in healthy people. According to the WHO, the AIDS epidemic claimed more than 3 million lives in 2002. Moreover, an estimated 5 million people acquired HIV in 2002, bringing to 42 million the number of people globally living with the virus. Current projections suggest that, unless the world succeeds in mounting a drastically expanded prevention effort, an additional 45 million people will become infected with HIV in 126 low and middle-income countries between 2002 and 2010. More than 600,000 cases of AIDS have been reported in the United States since 1981. More than 900,000 Americans may be infected with HIV according to the WHO. HIV is spread most commonly by sexual contact with an infected partner. HIV is also spread through contact with contaminated blood, including by the sharing of needles or syringes with minute quantities of blood of someone infected with the virus.

The life cycle of HIV has been extensively investigated, but is still not fully understood. Researchers initially focused on an enzyme crucial to the replication of HIV, reverse transcriptase. This research has led to the development of several reverse transcriptase inhibitors as antiviral therapies. AZT and 3TC are the best known nucleoside analogs, while Efavirenz is the best known non-nucleoside inhibitor. These are some of the most widely used reverse transcriptase inhibitors. More recently, inhibitors of a second enzyme required for viral replication, HIV protease, have been approved as treatments for HIV infection. The market for HIV protease inhibitors is highly competitive. Five different protease inhibitors compete for a share of a \$1 billion U.S. market. According to IMS Health Incorporated, worldwide sales of HIV protease inhibitors were an estimated \$1.4 billion in 2002.



Initial treatments for HIV focused on monotherapies. Monotherapy involves treatment with only one drug at a time. However, in an effort to combat resistance to drugs, doctors now use a combination of two or more drugs. Often called a cocktail, combination therapy is used for a number of reasons. These include the fact that combination therapy reduces the likelihood of developing resistant strains and that the effect of the drugs may be synergistic or additive. Current combination therapy is usually composed of two nucleoside analogs and either a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor. The Company believes that novel potent antiviral drugs to treat HIV, and in particular treatments that are less susceptible to drug resistance, will have significant market potential if approved by regulatory authorities.

### ***Cancer:***

Cancer is characterized by uncontrolled division of cells and can occur in almost any tissue or organ in the body. Cancerous cells can grow into a mass known as a tumor. If not destroyed, cancer cells can spread throughout the body. Cancer is the second leading cause of death in the United States. The National Cancer Advisory Board reports that more than 8.9 million people in the United States have cancer.

The three most prevalent methods of treating patients with cancer are surgery, radiation therapy and chemotherapy. A cancer patient often receives a combination of two or all three of these treatment methods. Surgery and radiation therapy is particularly effective in patients in whom the disease has not yet spread to other tissues or organs. Chemotherapy is the principal treatment for tumors that have spread. These tumors are referred to as having metastasized. The purpose of chemotherapy is to interfere with the molecular and cellular processes that control the development, growth and survival of malignant tumor cells. Chemotherapy involves the administration of drugs designed to kill cancer cells or the administration of hormone analogs to either reduce the production of, or block the action of, some hormones, including estrogens and androgens. These hormones affect the growth of tumors. In many cases, chemotherapy consists of the administration of several different drugs in combination. Use of these agents often has adverse effects, since chemotherapeutic agents generally attack rapidly dividing cells indiscriminately. As a result, most chemotherapeutic agents damage both normal and cancerous cells.

Although several types of tumors can now be treated effectively with drugs, survival rates for the most common tumors have only begun to improve slightly. In recent years, however, there have been significant advances in molecular biology, immunology and other related fields of biotechnology. These advances have led to a better understanding of the processes that regulate the proliferation and metastasis of malignant cells and by which malfunctioning genes can result in the formation of tumors.

The anti-cancer pharmaceutical market is expanding due to aging demographics, early detection and new treatments. The Company intends to develop IL-12 as a treatment for cancer. See Business Products in Development IL-12.

### **The Company's Strategy**

The Company's objective is to be a leader in the discovery, development, acquisition and commercialization of novel drugs that can be effective in the treatment of viral diseases and cancer. The Company plans to pursue this objective by continuing to focus its drug discovery and development efforts on serious diseases that represent large potential markets for drug products, such as HCV, HCB, HIV/AIDS and cancer. The Company intends to retain control of its product candidates through preclinical development and as far into the clinical trial process as its resources permit, in order to obtain the maximum value for its research efforts. It believes that its royalty revenues from sales of ribavirin by Schering-Plough and Roche may give it the financial flexibility to develop product candidates through the clinical trial process without having to prematurely license product candidates to third parties. The Company may choose to market and sell its products on its own or in collaboration with other pharmaceutical companies. In addition to its in-house development efforts, the Company plans to selectively license or acquire product candidates, technologies and businesses from third parties that complement its



business. The Company believes its drug development expertise may allow it to recognize licensing opportunities and to capitalize on research initially conducted and funded by others. In addition, the Company's existing technologies and product pipeline may be expanded through acquisitions that present additional commercial opportunities. (Schering-Plough, Roche and ICN have retained certain rights to commercialize products being developed by the Company, as described elsewhere in this Form 10-K.)

## **Mature Product**

### ***Ribavirin***

Ribavirin is the Company's principal product. It is a nucleoside analog the Company discovered from its library of nucleoside analog compounds. Ribavirin was one of the first antiviral drugs ever discovered and was first approved by the FDA in 1985 for the treatment of a respiratory syncytial virus infection in children with respiratory distress via aerosol administration. In 1995, ICN entered into an Exclusive License and Supply Agreement (the Schering-Plough License Agreement) with Schering-Plough whereby Schering-Plough licensed all oral forms of ribavirin for the treatment of chronic HCV. Schering-Plough markets ribavirin in combination with its interferon alfa-2b under the trade name Rebetron®, in combination with its pegylated interferon alfa-2b under the trade name Peg-Intron®/Rebetol®, and as a separately packaged product under the trade name Rebetol for use in either of these combination therapies. It is not clear how ribavirin works in conjunction with interferon alpha and pegylated interferon for the treatment of hepatitis C. Published data suggest that ribavirin not only has an antiviral effect, but can also stimulate some aspects of the body's immune responses to fight the virus.

In January 2003, the Company granted a license authorizing Roche to market ribavirin under the trade name Copegus. Roche markets Copegus as a combination therapy with Pegasys, its pegylated interferon alfa-2a.

### ***Schering-Plough License and Approvals:***

The Schering-Plough License Agreement provides for royalty payments from sales of ribavirin by Schering-Plough, including certain minimum royalty rates. ICN retained the right to co-market ribavirin capsules in the European Union under its trademark Virazole. In 1998, ICN sold to Schering-Plough its rights to co-market oral ribavirin for the treatment of HCV in the European Union in exchange for increased royalty rates on sales of ribavirin worldwide. Accordingly, Schering-Plough currently has worldwide marketing rights for oral forms of ribavirin for HCV and is responsible for all clinical development and regulatory activities. As part of ICN's contribution of assets, ICN contributed its rights under the Schering-Plough License Agreement to the Company. Generally, the license continues on an exclusive basis until the earlier of the tenth anniversary of the first commercial sale or the fifteenth anniversary of the 1995 effective date of the Schering-Plough License Agreement, and thereafter in perpetuity on a non-exclusive basis, in each case unless earlier terminated by Schering-Plough or by either party for cause. Schering-Plough consented to the Company's grant of a license to Roche.

In June 1998, Schering-Plough received FDA approval to market its Rebetron combination therapy for the treatment of HCV in patients with compensated liver disease that had relapsed following interferon alpha therapy. In December 1998, Schering-Plough received FDA approval to market the combination therapy for the treatment of HCV in patients with compensated liver disease previously untreated with interferon alpha therapy. These patients are commonly referred to as treatment-naive patients. Clinical trials indicated that the combination therapy, as opposed to treatment with interferon alfa-2b alone, produced a greater sustained response to the hepatitis C virus. In two clinical trials involving relapsed hepatitis C patients, approximately 46% of the patients had no detectable hepatitis C virus in their blood after receiving the combination therapy, as compared to approximately 5% who received interferon alfa-2b alone. In two clinical trials involving treatment-naive hepatitis C patients, 41% of the patients who received combination therapy responded, compared to approximately 16% of the patients who received interferon alfa-2b alone. These results represented a significant advancement.





In May 1999, the European Union ( E.U. ) granted Schering-Plough authorization to market its Rebetron combination therapy -2b for the treatment of both relapsed and treatment-naive HCV patients. The E.U. approval was immediately valid in all 15 E.U. member states. The Company believes Schering-Plough markets ribavirin throughout the E.U. In March 2001, the E.U. granted Schering-Plough authorization to market its Peg-Intron/Rebetol combination therapy for both relapsed and treatment-naive HCV patients. This approval was immediately valid in all 15 E.U.-member states and Iceland and Norway.

In January 2001, the FDA granted Schering-Plough authorization to market pegylated interferon alfa-2b, a longer lasting form of interferon alfa-2b, as a monotherapy for treatment-naive HCV patients. In July 2001, the FDA granted Schering-Plough authorization to market Rebetol capsules for use in combination with interferon alfa-2b for both relapsed and treatment-naive HCV patients. In August 2001, the FDA granted Schering-Plough authorization to market its Peg-Intron/Rebetol combination therapy for treatment-naive HCV patients who are at least 18 years of age.

In November 2001, Schering-Plough received marketing approval from the Ministry of Health, Labor and Welfare of Japan for ribavirin in combination with interferon alfa-2b for the treatment of HCV. The combination therapy is the first combination therapy approved in Japan for treating HCV patients. In December 2001, Schering-Plough received pricing approval for this combination therapy in Japan.

Schering-Plough also markets the combination therapy in many other countries around the world based on the U.S. and E.U. regulatory approvals. Royalty revenues under the Schering-Plough License Agreement were \$270,265,000, \$138,622,000 and \$154,818,000 for 2002, 2001 and 2000, respectively, representing 100%, 97% and 100% of the Company's revenues in 2002, 2001 and 2000, respectively.

The Company and ICN are involved in a dispute with Schering-Plough over the payment of royalties on products distributed as part of Schering-Plough's indigent patient marketing program. Also, in February and March 2003, Schering-Plough entered into license agreements with three generic pharmaceutical companies, which granted to the three companies non-exclusive, non-sublicensable licenses to Schering-Plough's U.S. ribavirin patents. The outcome of the dispute regarding royalties from the indigent marketing program and Schering-Plough's licenses to the three generic pharmaceutical companies could have a material negative impact on the Company's future royalty revenues. See Management's Discussion and Analysis Results of Operations Royalties and Notes 3 and 11 of Notes to Financial Statements regarding Schering-Plough License Agreement and Commitments and Contingencies, respectively.

#### ***Roche Ribavirin License and Approvals***

Schering-Plough and Roche have each developed pegylated interferon. In August 2001, they settled an action under which Roche had alleged that Schering-Plough violated Roche's patents on pegylated interferon. The settlement provided for each company to manufacture and market worldwide its pegylated interferon products free from liability for infringement under the other's existing patent rights. Roche and Schering-Plough terminated all patent litigation against each other in the United States and Europe involving their pegylated interferon products. Schering-Plough advised the Company that, in connection with the settlement, it licensed its patents relating to ribavirin as part of a combination therapy for the treatment of HCV to Roche.

Roche had also conducted clinical trials of Pegasys, its form of pegylated interferon alfa-2b, in combination with ribavirin. In May 2001, Roche presented data that approximately 56% of treatment-naive HCV patients responded to the Pegasys combination therapy. In September 2002, the E.U. granted Roche authorization to market Copegus in combination with Pegasys, for both relapsed and treatment-naive adult HCV patients. In December 2002, the FDA granted Roche authorization to market Copegus in combination with Pegasys. Roche made various regulatory filings seeking to invalidate certain of the Company's patents relating to ribavirin, and the Company and Roche initiated various legal actions against each other in the United States and Europe relating to the Company's patents.



On January 6, 2003, the Company, ICN and Roche reached agreement on a settlement regarding these patent disputes. The companies agreed to stop all legal actions regarding ribavirin. See Note 13 of Notes to Financial Statements regarding Subsequent Events. The terms of this settlement agreement include a license by the Company of rights under the Company's ribavirin patents to Roche. The term of the license agreement ends upon expiration of the last to expire licensed patent. The license authorizes Roche to make or have made, and to sell Copegus on a global basis under the Company's patents. Roche will pay royalty fees to the Company on all sales of the combination product containing Copegus. No royalties under the Roche agreement were earned by or paid to the Company in fiscal year 2002. The Company understands that Roche may sell ribavirin at prices below those charged by Schering-Plough. If that were to occur, the Company could experience a decline in royalty revenues from Schering-Plough, and it is uncertain if royalty revenues from Roche will offset the effect of any such decline.

Roche, ICN and the Company co-operate on several other projects, including Roche's exclusive license from the Company of Levovirin. See Business Products in Development Levovirin.

### Products In Development

The following is a description of the Company's current product candidates. Each of these product candidates was derived from the Company nucleoside analog library, except for Hepavir B and IL-12. Levovirin, Tiazole, Adenazole, Viramidine and Hepavir B are the Company's trademarks. All other brand names, trademarks or service marks referred to in this Form 10-K are the property of their owners. Schering-Plough markets ribavirin under the trade name Rebetron as part of a combination therapy with its interferon alfa-2b and under the trade name Peg-Intron/Rebetol as part of a combination therapy with its pegylated interferon alfa-2b. Schering-Plough also markets ribavirin as a separately packaged product under the trade name Rebetol for use in either of these combination therapies. Roche also markets ribavirin under the trade name Copegus as a combination therapy with Roche's pegylated interferon alfa-2a, Pegasys.

As discussed in Business Licensing, Patents and Trademarks (Proprietary Rights), the Company's flexibility in maximizing commercialization opportunities for its compounds may be limited by Schering-Plough's rights under its November 2000 agreement with ICN and the Company.

#### *Levovirin:*

Levovirin is a nucleoside analog discovered by the Company. The Company is exploring whether Levovirin may stimulate an immune response to viral infections similar to ribavirin, but without a direct antiviral effect and without the anemia associated with ribavirin. The Company completed chemical development and formulation studies, as well as the ancillary pharmacology and short-term toxicology studies, on Levovirin, and filed an IND in December 2000. Based on this application, the Company began Phase 1 clinical trials on Levovirin in February 2001 in the United States.

On June 29, 2001, the Company licensed Levovirin to Roche on an exclusive basis, in exchange for the license of IL-12 to the Company by Roche, plus a payment by Roche of \$5 million. (See Business Products in Development IL-12). Roche is responsible for all future developmental costs of Levovirin. The Company is entitled to receive milestone payments from Roche in connection with drug development and regulatory approvals, and royalty payments from Roche upon commercialization of the product. In that case, it is expected that Levovirin will be used in combination therapy with Pegasys. Roche's exclusive license can be terminated by Roche without cause upon six months' prior written notice, or by either party for cause. The license agreement will expire 10 years after the first commercial sale of any human pharmaceutical product containing Levovirin, or after the expiration or invalidation of licensed patents used in connection with this agreement, whichever occurs later. Under the license agreement, the Company has the option or right of first refusal to develop, market, import, use, offer for sale or sell Levovirin in some Eastern European countries.



The Company has submitted patent applications in the United States and in many foreign countries for Levovirin relating both to the compound and for numerous indications, and has a composition of matter patent for Levovirin from the U.S. Patent and Trademark Office ( PTO ). This patent expires in October 2016.

***Viramidine:***

Viramidine is a nucleoside analog that the Company intends to develop in oral form for the treatment of hepatitis C. The Company expects to test Viramidine s effect on the hepatitis C virus both on its own and in combination with interferon alpha or pegylated interferon alpha.

Preclinical studies indicated that Viramidine, a liver-targeting prodrug of ribavirin, has antiviral and immunological activities (properties) similar to ribavirin. In an animal model of acute hepatitis, Viramidine showed biologic activity similar to ribavirin. The liver-targeting properties of Viramidine were also confirmed in two animal models. Short-term toxicology studies in an animal model also suggested that Viramidine might be safer than ribavirin at the same dosage levels. This data suggests that Viramidine, as a liver-targeting prodrug of ribavirin, may have the potential of having better efficacy and less side effects compared to ribavirin.

In September 2001, the Company initiated Phase 1 clinical trials on Viramidine in Europe. The Company filed an IND with the FDA in December 2001. In late March 2002, the Company began additional Phase 1 clinical trials on Viramidine in the United States, and Phase 2 clinical trials on Viramidine in the United States began in December 2002.

The Company has filed a number of patent applications for novel use of Viramidine and its related compounds. The structure of Viramidine was disclosed many years ago, and it cannot be patented as a new chemical entity. Patent efforts are therefore directed to claiming related compounds, dosing, liver targeting and novel indications including immunomodulatory activity and activity against specific viruses. The PTO allowed a broad method of use patent for Viramidine hydrochloride in October 2001, including for the treatment of hepatitis C. Another broad use patent application covering modifications of Viramidine was allowed in February 2002.

***Hepavir B:***

Hepavir B is a nucleoside analog that ICN licensed from Metabasis Therapeutics, Inc., in October 2001, for development of a treatment of hepatitis B. ICN contributed the Hepavir B license to the Company. The Company s exclusive license can be terminated by either party for cause, and will expire 10 years after the first commercial sale of any human pharmaceutical product containing Hepavir B or after the expiration or invalidation of licensed patents used in connection with this agreement, whichever occurs later. The Company paid a \$2 million nonrefundable license fee. In addition, Metabasis will receive milestone payments from the Company of up to \$18 million in connection with drug development and regulatory approvals, as well as royalty payments from the Company if the drug is commercialized. The Company is exploring the possibilities of developing this compound into an oral once a day monotherapy for patients with chronic hepatitis B.

The active molecule in this compound exhibits anti-hepatitis B activity against both the wild type and Lamivudine drug-resistant hepatitis B. Based on biologic and molecular modeling data, this compound binds to the active site of the hepatitis B replication enzyme so that the virus is prevented from utilizing the natural substrate from the host to replicate. A prodrug modification developed by Metabasis significantly improved the compound s physicochemical properties and ability to target the liver. In preliminary experiments in rodents, the active molecule was delivered in significantly greater proportion to the targeted organ, the liver, as compared to the non-targeted organ, the kidney. The kidney is the organ responsible for the dose-limiting toxicity. In these experiments, the amount of Metabasis-modified compound delivered to the liver versus kidneys was approximately 10 times greater than the amount of compound delivered by another well established process. The Company is

## Edgar Filing: RIBAPHARM INC - Form 10-K

working on large-scale synthesis of this compound, and has commenced formulation studies. The Company has also initiated additional biology, drug metabolism, pharmacokinetic, and toxicology studies. In August 2002, the Company initiated a Phase 1 clinical trial of Hepavir B in Europe, and filed an IND with the FDA in October 2002.

Metabasis has one U.S. patent on the structure of this compound and is in the process of preparing patent applications on this compound in other countries.

***IL-12:***

IL-12 is a developmental compound for the treatment of cancer and allergies. On June 29, 2001, Roche exclusively licensed to the Company and ICN both its own rights in IL-12 and the non-exclusive rights to IL-12 that Roche had previously licensed from Genetics Institute. At the time, Roche had completed Phase 1 clinical trials on IL-12. ICN contributed all of its rights under this license agreement to the Company. The June 2001 agreement contemplated that the parties would negotiate and execute a revised definitive agreement, which was completed in the third quarter of 2002. The Company applied with the FDA to reactivate the IND to initiate human clinical trials of IL-12 during December 2002. Although the Company has not received formal notification from the FDA regarding the status of the Company's application, the 30-day waiting period has elapsed, thus reactivating the IND. Under the license agreement, Roche is entitled to milestone payments from the Company of up to \$24 million in connection with drug development and regulatory approvals, and royalty payments from the Company if the drug is commercialized. The Company is responsible for the development costs of this compound. The patent applications underlying the licensed rights have not yet been issued. The Company has the right to terminate the agreement at any time without cause with six months' prior written notice. The license agreement will expire 10 years after the first commercial sale of any human pharmaceutical product containing IL-12 or after the expiration or invalidation of licensed patents used in connection with this agreement, whichever occurs later. The Company may also need to pursue a license agreement from Genetics Institute to proceed with development of this compound.

***Tiazole (Tiazofurin):***

Tiazole is a nucleoside analog the Company has evaluated for the treatment of chronic myelogenous leukemia in blast crisis and ovarian cancer. The Company has conducted Phase 3 testing in the United States for treatment of chronic myelogenous leukemia in blast crisis and Phase 2 testing in Russia for treatment of ovarian cancer through a Russian subsidiary of ICN. In May 2001, Novartis announced that it received FDA approval to market its product, Gleevec, for the treatment of chronic myelogenous leukemia, including blast crisis stage. As a result of this development and the uncertainty over the Company's rights to this compound pending the outcome of the ongoing arbitration between ICN and certain Serbian governmental entities which concerns rights in Tiazole, the Company has decided to terminate and cancel these clinical studies.

***Adenazole (8-CI cAMP, Toclasdenine):***

Adenazole is a nucleoside analog the Company evaluated for the treatment of colon cancer. The Company initiated a Phase 1 study in the United States in September 2000, following earlier clinical tests by ICN in Europe. However, the Company has no plans to further advance this compound unless this trial, which is in its final stage, yields favorable results and the ongoing arbitration against the Serbian governmental entities results in a recovery of ICN's rights in this compound, which ICN previously contributed to ICN Yugoslavia.

**Research and Development Programs**

The Company's research and development efforts seek to discover, develop, acquire and commercialize innovative products for the treatment of diseases with significant unmet medical needs, principally in the antiviral and anticancer areas. Its current program areas include HCV, HBV, HIV/AIDS and cancer.

*The Company's Chemical Library:*

The Company believes its nucleoside analog library contains one of the largest collections of nucleoside analogs in the world. The late Roland K. Robins, Ph.D., a prominent nucleoside chemist who worked in ICN's



Nucleic Acid Research Institute division, created the first collection of the compounds in the Company library. During his affiliation with ICN, Dr. Robins was responsible for the discovery and development of ribavirin and other compounds. Between 1970 and 1980, ICN screened a number of compounds in the nucleoside analog library for activity against the virus that causes the common cold, herpes viruses and adenoviruses. ICN selected ribavirin from a large panel of nucleoside analogs for development, because it demonstrated broad-spectrum antiviral activity and the financial resources of ICN at that time only permitted the development of one compound.

ICN contributed its chemical compound library to the Company in August of 2000. Since March 2000, ICN and the Company have discovered additional compounds using chemical methods known as combinatorial chemistry. In total, the Company presently has over 10,300 nucleoside analog compounds in its library. The Company intends to pursue U.S. and foreign patent protection with respect to compounds and uses of nucleoside analogs from the Company library that show promise for development. During 2002, the Company acquired more than 113,000 diverse non-nucleoside compounds from third parties to complement its nucleoside analog library. The Company intends to use both the nucleoside and non-nucleoside libraries to develop new products.

The Company has initiated screening of its chemical compound library for its target indications, hepatitis C, hepatitis B, HIV/AIDS and cancer. With the Company's investments in its research and development facilities and equipment, together with its royalty revenues from sales of ribavirin, the Company believes that it has the financial resources and technological equipment necessary to perform this screening.

The Company's future growth depends in large part of its ability to develop or obtain and commercialize new products and new formulations or indications of existing products. The process of developing and successfully commercializing product candidates is expensive, time-consuming and unpredictable. The Company may not be able to identify additional compounds from its chemical compound library or from third parties that warrant further development, or develop or obtain regulatory approvals for product candidates. Similarly, compounds developed by the Company may not prove to be patentable or subject to successful commercial development.

### **Sales and Marketing**

The Company currently does not have a marketing or sales force and, other than its agreements with Schering-Plough and Roche, currently has no agreements with third parties to sell, market or distribute its products. The Company may decide to build a sales and marketing force in the future, although it may also establish corporate collaborations with pharmaceutical and biotechnology companies to fill these needs. As part of the ordinary course of business, the Company may also consider forming arrangements or collaborations with strategic partners, including pharmaceutical companies, government organizations, academic institutions and others, to help develop and market its drug candidates, as it has with Schering-Plough and Roche. In addition, the Company may enter into marketing, sales and distribution arrangements with ICN and its affiliates. While the Company intends to carefully evaluate potential collaborators, it may have limited or no control over the activities of third parties, who may not be able to market or distribute the Company's products successfully.

### **Manufacturing**

The Company does not have manufacturing facilities. It contracts out its manufacturing requirements to third parties that have plants with a history of compliance with good manufacturing practices requirements. The Company obtains all compounds for its clinical trials from third-party contract manufacturers and other third parties. Relying on third parties for manufacturing capabilities presents many of the same risks presented by reliance on third parties for sales and marketing.

### **Competition**

The Company operates in an intensely competitive and rapidly changing environment. Competitive factors vary by product line and customer and include service, product availability and performance, price and technical

capabilities. The Company's competitors, many of whom have substantially greater financial and technical resources and marketing capabilities and larger research and development staffs and facilities, are actively engaged in marketing similar products and developing new products similar to those proposed to be developed by the Company. The Company does business in an industry characterized by extensive and ongoing research efforts. The Company believes that many of its competitors spend significantly more on research and development related activities. Others may succeed in developing products that are more effective than those presently marketed by the Company, including ribavirin, or proposed for development by the Company. Progress by other researchers in areas similar to those explored by the Company may result in further competitive challenges. The Company may also be affected by industry consolidation.

The Company may face increased competition from manufacturers of generic pharmaceutical products when its ribavirin patents expire. In addition, patent positions are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products. The effect on operations of patent disputes cannot be predicted. The Company recently settled litigation with Roche challenging the validity of the Company's ribavirin patents. See Business Roche Ribavirin License and Approvals. In addition, three generic pharmaceutical companies have filed Abbreviated New Drug Applications (ANDA) with the FDA to market generic forms of ribavirin for use as part of a combination therapy for the treatment of HCV. ICN and the Company have sued all three of these pharmaceutical companies to prevent these three companies from marketing a generic form of ribavirin. See Business Licenses, Patents and Trademarks (Proprietary Rights), and Notes 11 and 13 of Notes to Financial Statements regarding Commitments and Contingencies and Subsequent Events, respectively. If any other pharmaceutical company is able to obtain regulatory approval of a competing version of ribavirin for use in combination therapy for treatment of HCV without obtaining a license from the Company, the Company's royalties from sales by Schering-Plough and Roche may decrease significantly.

### **Pharmaceutical Pricing and Reimbursement**

In both domestic and foreign markets, sales of the Company's products will depend in part upon the availability of reimbursement from third-party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The Company may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of its products. These studies may require a significant amount of resources. If the Company's product candidates are not considered cost-effective, adequate third-party reimbursement may not be available for the Company to realize an appropriate return on its investment in product development. United States and foreign governments continue to propose and pass legislation designed to reduce the costs of healthcare. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals may change before the Company's proposed products are approved for marketing. Adoption of new legislation could further limit reimbursement for pharmaceuticals. The marketability and profitability of the Company's products may suffer if the government and third party payors fail to provide adequate coverage and reimbursement. In addition, an emphasis on managed care in the United States has increased, and will continue to increase, the pressure on pharmaceutical pricing.

In the United States, the marketing and sales of ribavirin products are subject to increasingly competitive pricing as managed care groups, institutions, government agencies and other groups seek price discounts. In most international markets, ribavirin sales occur in an environment of government-mandated cost-containment programs. In the U.S. market, statutorily defined rebates are required to various government agencies in order to participate in Medicaid, the veterans health care program and other government-funded programs. Several governments have placed restrictions on physician prescription levels and patient reimbursements, emphasized greater use of generic drugs and enacted across-the-board price cuts as methods to control costs.

A significant portion of ribavirin's net sales is made to major pharmaceutical and health care products distributors and major retail chains in the United States. Consequently, net sales and quarterly growth comparisons

may be affected by fluctuations in the buying patterns of major distributors, retail chains and other trade buyers. These fluctuations may result from seasonality, pricing, and wholesaler buying decisions or other factors.

Pharmaceutical products are sold to direct purchasers (e.g., wholesalers, retailers, and health maintenance organizations), and those entities are invoiced when the products are shipped. In addition, commercial rebate and discount arrangements exist with certain indirect purchasers and other market participants (e.g., managed care organizations that indemnify beneficiaries of health plans for the pharmaceutical cost, and pharmacy benefit managers) based upon the purchase or utilization of the Company's products. These are also governmental rebate obligations under certain federal and state programs. The Company estimates the amount of commercial and governmental rebates that will be paid in subsequent periods for those products sold during the current period, and accrues those estimated amounts as a liability.

### **Employees**

As of December 31, 2002, the Company employed 139 persons, none of whom are covered by collective bargaining agreements. These employees included 123 in research and development, and 16 in general and administrative matters. The Company currently considers its relations with its employees to be satisfactory and has not experienced any work stoppages, slowdowns or other serious labor problems that have materially impeded its business operations.

### **Licenses, Patents and Trademarks (Proprietary Rights)**

#### ***The Company's Approach:***

The Company's success will depend substantially on its ability to obtain patents for its technology to protect its intellectual property rights. As a general policy, the Company expects to seek patents, where available, on inventions concerning novel drugs, techniques, processes or other products that it may develop or acquire in the future. Patent positions in the biotechnology field are often uncertain and may involve complex legal, scientific and factual questions. There has been increasing litigation in the biotechnology industry with respect to the manufacture, use and sale of new therapeutic and diagnostic products that are the subject of conflicting patent rights. The validity and breadth of claims in biotechnology patents may involve complex factual and legal issues for which no consistent policy has emerged. Therefore, these patents are highly uncertain. Moreover, the patent laws of foreign countries differ from those of the United States. Hence, the degree of protection afforded by foreign patents may be different from the protection offered by U.S. patents. There can be no assurance that patent applications relating to products and technologies developed by the Company will result in patents being issued or that, if issued, the patents will have commercial value, provide a competitive advantage or will afford protection against competitors with similar technologies. There also can be no assurance that these patents will not be challenged successfully or circumvented by competitors. In addition, the PTO has a substantial backlog of biotechnology patent applications and the approval or rejection of patent applications may take several years.

In some instances, the Company intends to rely substantially on its unpatented proprietary know-how, but there can be no assurance that others will not develop substantially equivalent proprietary information or otherwise obtain access to the Company's know-how. Patents for pharmaceutical compounds are not available in certain countries in which the Company intends to market its products. Marketing approvals in certain foreign countries provide an additional level of protection for products approved for sale in such countries.

The Company's commercial success also will depend in part on its not infringing patents or proprietary rights of others. In some cases, litigation or other proceedings may be necessary to defend against or assert claims of infringement, to enforce the Company's patents to protect its trade secrets, know-how or other intellectual property rights, or to determine the scope and validity of the proprietary rights of third parties. Any

## Edgar Filing: RIBAPHARM INC - Form 10-K

potential litigation could result in substantial costs to the Company and diversion of its resources. The Company cannot be sure that any of its patents would ultimately be held valid or that efforts to defend any of its patents, trade secrets, know-how or other intellectual property rights would be successful. An adverse outcome in any litigation or

proceeding could subject the Company to significant liabilities, require it to cease using the subject technology or require it to license the subject technology from the third party, which license may not be available.

Much of the know-how of importance to the Company's technology and many of its processes depend upon the knowledge, experience and skills of key scientific and technical personnel. This experience and these skills are not patentable. To protect the Company's rights to and to maintain the confidentiality of trade secrets and proprietary information, the Company requires employees and consultants to execute confidentiality and invention assignment agreements. These agreements prohibit the disclosure of confidential information to anyone outside the Company, and require disclosure and assignment to the Company of ideas, developments, discoveries and inventions made by employees, advisors and consultants. The Company cannot be sure, however, that these agreements will not be breached or that its trade secrets or proprietary information will not otherwise become known or developed independently by others.

***Certain Rights and Disputes:***

The Company has three U.S. patents related to ribavirin. These patents claim uses of ribavirin, including treatment of HCV alone and in combination therapy with interferon alpha. These patents expire in 2016. The Company has licensed rights under these patents to Schering-Plough and Roche.

Schering-Plough has five U.S. patents covering specific formulations of ribavirin. These patents expire in 2017. Schering-Plough also has at least three U.S. patents covering the use of ribavirin with interferon alpha-2b in combination therapy for the treatment of HCV. These patents expire between 2015 and 2018.

The Company has a European Union patent claiming methods of using of ribavirin for medical treatment for arboviruses, including the virus responsible for hepatitis C. This patent expires in 2005. The Company has filed for an extension of this patent until 2010 in the relevant countries of the E.U., Switzerland and Japan.

The Company believes others cannot manufacture, import or sell ribavirin for the treatment of HCV in the U.S., designated countries of the European Union or Japan without infringing on the Company's patent rights unless those patents are invalidated or they obtain a license from the Company.

Three generic pharmaceutical companies have submitted ANDAs with the FDA to market generic forms of ribavirin in combination therapy for the treatment of HCV. ICN and the Company have sued all three companies to prevent them from marketing a generic form of ribavirin. See Notes 11 and 13 of Notes to Financial Statements regarding Commitments and Contingencies and Subsequent Events, respectively. The Federal Food, Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, generally prohibits the FDA from giving final marketing approval of these ANDAs for 30 months after the applicants notify the Company of their intent to seek approval from the FDA. However, the FDA could grant marketing approval prior to expiration of this 30-month stay if a court rules that the Company's patents are invalid or unenforceable or that a generic manufacturer of ribavirin would not infringe the Company's patents, or if a court determines that a party has unreasonably delayed the progress of the patent litigation. The defendants have asserted in the litigation that the Schering-Plough and Company patents are not infringed and that the claims of the patents are invalid.

Schering-Plough also sued all three generic pharmaceutical companies to prevent them from marketing a generic form of ribavirin. However, in February and March 2003, Schering-Plough announced it has entered into license agreements with each of the three companies that settled all

## Edgar Filing: RIBAPHARM INC - Form 10-K

litigation between them regarding Schering-Plough's U.S. patents for ribavirin and its use in treating HCV. Under terms of the agreements, Schering-Plough granted to each company a non-exclusive, non-sublicensable license to its U.S. ribavirin patents. The agreements do not affect the three companies' litigation with the Company. The Company believes its patent position to be unchanged by Schering-Plough's settlements with the three generic pharmaceutical companies. See Notes 3 and 11 of Notes to Financial Statements regarding Schering-Plough License Agreement and Commitments and Contingencies, respectively.

The Company filed a trademark registration application with the PTO for the mark RIBAPHARM. The Company's application was published in the Federal Register on January 8, 2002 and a notice of allowance was granted on April 2, 2002. Extensions have been filed with the PTO for a statement of use. Refer to Note 11 of Notes to Financial Statements regarding Commitments and Contingencies.

***November 2000 Schering-Plough Agreement:***

In November 2000, the Company and ICN entered into an agreement that provides Schering-Plough with certain rights to license various products the Company may develop. Under the terms of the agreement, Schering-Plough has the option to exclusively license on a worldwide basis up to three compounds that the Company may develop for the treatment of hepatitis C on terms specified in the agreement. The option does not apply to Levovirin or Viramidine. The option is exercisable as to a particular compound at any time prior to the start of Phase 2 clinical studies for that compound. Once it exercises the option with respect to a compound, Schering-Plough is required to take over all developmental costs and responsibility for regulatory approval for that compound. Under the agreement, the Company will receive royalty revenues based on the sales of licensed products. These rates will increase upon the achievement of different milestones and may be reduced upon the expiration of some of the Company's patent rights.

Under the terms of the agreement, the Company also granted Schering-Plough the right of first/last refusal to license compounds relating to the treatment of infectious diseases (other than hepatitis C) or cancer or other oncology indications as well as the right of first/last refusal with respect to Levovirin and Viramidine (collectively, the Refusal Rights). Under the terms of the Refusal Rights, the Company must notify Schering-Plough if it intends to offer a license or other rights for any of these compounds to a third party. At Schering-Plough's request, the Company is required to negotiate in good faith on an exclusive basis the terms of a mutually acceptable exclusive worldwide license or other form of agreement on commercial terms to be mutually agreed upon. If the Company cannot reach an agreement with Schering-Plough, the Company is permitted to negotiate a license agreement or other arrangement with a third party. Prior to entering into any final arrangement with the third party, the Company must offer substantially similar terms to Schering-Plough, which terms Schering-Plough has the right to match.

If Schering-Plough does not exercise its option or Refusal Rights as to a particular compound, the Company may continue to develop that compound or license that compound to other third parties. The agreement with Schering-Plough will terminate the later of 12 years from the date of the agreement or the termination of the License Agreement with Schering-Plough. The agreement was entered into as part of the resolution of claims asserted by Schering-Plough against the Company, including claims regarding the Company's alleged improper hiring of former Schering-Plough research and development personnel and claims that the Company was not permitted to conduct hepatitis C research. The Company also agreed not to hire or solicit directly for employment any employee of Schering-Plough or any of its corporate affiliates for the term of the agreement.

In June 2001, the Company licensed Levovirin to Roche. Although the Company believes it has complied with Schering-Plough's Refusal Rights, Schering-Plough may allege that the Company has not complied with the Refusal Rights as to Levovirin, although Schering-Plough has made no such claim to date.

**Government Regulation**

The Company is subject to licensing and other regulatory control by the FDA, the Nuclear Regulatory Commission, other Federal and state agencies, and comparable foreign governmental agencies. FDA approval must be obtained in the United States and approval must be obtained from comparable agencies in other countries prior to marketing or manufacturing new pharmaceutical products for use by humans. Obtaining FDA approval for new products and manufacturing processes can take a number of years and involve the expenditure of substantial resources.





***New Drug Development and Approval Process:***

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of the Company's products and in ongoing research and product development activities. All of the Company's pharmaceutical products, including biological and other drug candidates, will require regulatory approval by governmental agencies prior to commercialization. In particular, the Company's products are subject to rigorous preclinical and clinical testing and other premarket approval requirements by the FDA and regulatory authorities in other countries. In the United States, various statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. The Company believes it is currently in compliance with applicable statutes and regulations. Regulatory approval, when and if obtained, may be limited in scope. In particular, regulatory approvals will restrict the marketing of a product to specific indications. Further, approved drugs, as well as their manufacturers, are subject to ongoing review. Discovery of previously unknown problems with these products may result in restrictions on their manufacture, sale or use or in their withdrawal from the market. Failure to comply with regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, total or partial suspension of production or injunction, as well as other action affecting the Company and its potential products. Any failure to obtain and maintain, or any delay in obtaining, regulatory approvals could materially adversely affect the Company's business.

The process for new drug approval has many steps, including:

*(a) Preclinical Testing:* Once a drug candidate is identified for development, it enters the preclinical testing stage. During this stage, laboratory and animal studies are conducted on both healthy and diseased animals to show biological activity of the drug candidate in animals. These tests typically take approximately two years to complete.

*(b) Investigational New Drug Application:* After the safety and the scientific rationale for initial human studies have been demonstrated by preclinical testing, an investigational new drug application may be filed with the FDA for authorization to begin human testing. The application becomes effective if not rejected by the FDA within 30 days after filing. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations, including the informed consent of all subjects. In addition, an institutional review board must review, approve and monitor each human study. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur. The FDA may impose a clinical hold on proposed or ongoing clinical trials. In some instances, the investigational new drug application process can result in substantial delay and expense.

Limited human clinical testing may also occur under a physician's IND that allows a single individual to receive the drug. This application does not replace the more formal IND process, but may on occasion facilitate the more formal process.

*(c) Clinical Trials:* Clinical trials are typically conducted in three sequential phases, which may overlap. Phase 1 Clinical Trials usually involve between 20 and 80 healthy volunteers or patients and typically take one to two years to complete. The tests study a drug's safety profile, and may seek to establish the safe dosage range. The tests also determine how a drug candidate is absorbed, distributed, metabolized and excreted by the body, and the duration of its action. Phase 2 Clinical Trials involve controlled studies on an expanded population of patients with the targeted disease. The tests evaluate the effectiveness of the drug candidate and determine if there are any side effects or other risks associated with the drug. These studies generally take approximately two years, and may be conducted concurrently with Phase 1 clinical trials. Phase 3 Clinical Trials typically lasts two to three years and involve an even larger patient population, often with several hundred or even several thousand patients. These tests are intended to establish the overall risk-benefit ratio of the drug and provide, if appropriate, an adequate basis for product labeling.



*(d) New Drug Application:* After the successful completion of the clinical trials, a NDA may be submitted to the FDA. The NDA must contain all of the information on the drug candidate gathered to that date, including data from the clinical trials. NDAs are often over 100,000 pages in length.

The FDA reviews all NDAs before it accepts them for filing, and may request additional information. Once the submission is accepted, the FDA begins an in-depth review of the NDA. Under the Federal Food, Drug and Cosmetic Act, the FDA has 180 days in which to review the NDA and respond to the applicant. In practice, the review process is often significantly extended by FDA requests for additional information or clarification regarding submitted information. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. If the FDA's evaluations of the NDA and the applicant's manufacturing facilities are favorable, the FDA may issue an approval letter authorizing commercial marketing of the drug candidate for specified indications. The FDA could also issue an approval letter containing conditions of final approval. If the FDA's evaluation is not favorable, it may refuse to approve the NDA or issue a non-approval letter.

Among the conditions for NDA approval is the requirement that each prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practice standards and requirements. Although the Company expects to contract with third parties for the manufacture of any products that are approved, these manufacturers must meet and continue to comply with the standards set forth in the good manufacturing practices regulations. Manufacturing establishments are subject to periodic inspections by the FDA and by other federal, state or local agencies.

*(e) Marketing Approval:* If the NDA is approved, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may require post-marketing studies, also known as Phase 4 studies, as a condition of approval. In addition, the FDA may require distribution to patients of a medication guide for products that the FDA determines pose a serious and significant health concern. The FDA requires distribution of medication guides with Rebetrin and Peg-Intron/Rebetol.

*(f) Phase 4 Clinical Trials and Post-Marketing Studies:* In addition to studies required by the FDA after approval, these trials and studies are often conducted to explore new indications and increase acceptance of the drug in the business medical community. In addition, some post-market studies are done at the request of the FDA to develop additional information regarding the safety of a product. For example, when the FDA approved the Rebetrin combination therapy in 1998, it requested that Schering-Plough conduct a five-year follow-up study of all patients who had participated in the Phase 3 studies.

*(g) Post-Marketing Regulation:* Approved drug products are subject to continuing post-market review, monitoring, and surveillance by the FDA and foreign regulatory bodies. In addition, approved drug products that are also biological products may be subject to lot-by-lot release testing by the FDA before they can be commercially distributed. Newly discovered or developed safety or efficacy data may result in withdrawal of products from marketing. Other areas of ongoing FDA regulation for marketed drugs include compliance with current good manufacturing practices requirements, adverse event reporting, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, being subject to FDA inspections, complying with electronic records and signature requirements, and complying with FDA promotion and advertising requirements. In addition, as a result of certain legal proceedings involving ICN, the Company may for a period of time be required to pre-clear with the FDA any public communication concerning any matter subject to FDA regulation. See Note 11 of Notes to Financial Statements regarding Commitments and Contingencies.

***Orphan Drug Designation:***

## Edgar Filing: RIBAPHARM INC - Form 10-K

The FDA may grant orphan drug designation to drug candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United

States. An applicant must request orphan drug designation before submitting a new drug application. After the FDA grants orphan drug designation, the FDA publicly discloses the identity of the sponsor, generic identity of the therapeutic agent and its potential orphan use. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation is the first to receive FDA approval for the indication for which it had been designated, the product receives orphan exclusivity. This means the FDA may not approve for seven years any other application to market the same drug for the same indication, except in very limited circumstances.

***Approvals Outside of the United States:***

Steps similar to those in the United States must be undertaken before the Company can commercialize its products in other countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. The relevant authorities may not grant approvals on a timely basis or at all. In addition, most countries other than the United States require regulatory approval of prices. There can be no assurance that the resulting prices would be sufficient to generate an acceptable return to the Company.

***Other Government Regulations:***

The Food and Drug Administration Modernization Act of 1997 was enacted, in part, to ensure the timely availability of safe and effective drugs, biologics and medical devices by expediting the FDA review process for new products. This act establishes a statutory program for the approval of fast track products. The fast track provisions essentially codified existing FDA accelerated approval regulations for drug candidates and biologics. A fast track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs. Under the fast track program, the sponsor of a drug candidate or biologic may request the FDA to designate the drug candidate or biologic as a fast track product at any time during the clinical development of the product. The act specifies that the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. Approval of a new drug application for a fast track product can be based on an effect, on a clinical endpoint, or on a surrogate endpoint that is reasonably likely to predict clinical benefit. Approval of a fast track product may be subject to post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint. If a preliminary review of the clinical data suggests efficacy, the FDA may initiate review of sections of an application for a fast track product before the application is complete. This rolling review is available if the applicant provides a schedule for submission of remaining information and pays applicable user fees.

The Company is also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with its research, including radioactive compounds and infectious disease agents. The Company believes it is currently in compliance with all these laws and regulations. The extent of governmental regulation that might result from any legislative or administrative action cannot be accurately predicted.

**Litigation, Government Investigations and Other Matters**

*Litigation:* See Notes 11 and 13 of Notes to Financial Statements regarding Commitments and Contingencies and Subsequent Events respectively.

*Product Liability Insurance:* The Company is currently self-insured with respect to product liability claims. The Company could be exposed to possible claims for personal injury resulting from allegedly defective products both pre- and post-regulatory approval. While to date, no material adverse claim for personal injury resulting from allegedly defective products has been successfully maintained against the Company, a

substantial claim, if successful, could have a negative impact on the Company's financial position, results of operations and cash flows.

**Item 2. *Properties***

The Company currently leases 61,490 square feet from ICN in its Costa Mesa headquarters. The lease primarily covers the second floor research and development facilities in which the Company conducts substantially all of its operations. The lease has an initial term of 5 years, expires in April 2007, and can be renewed at the Company's option for an additional five years. The lease calls for the Company to pay ICN rent of \$5,000,000 per year, with annual adjustments based on the Orange County, California, consumer price index, as well as a pro rata portion of facility and central service costs, including utilities, security, parking, building maintenance, cleaning services, insurance premiums and other facility costs.

In the opinion of the Company's management, the facility occupied by the Company is adequate for present requirements, and the Company's current equipment is considered to be in good condition and suitable for the operations involved. Since the Company does not own its laboratory and office facilities, if the Company becomes unable to use its facilities, it would be costly and disruptive to find other facilities.

**Item 3. *Legal Proceedings***

See Note 11 and Note 13 of Notes to Financial Statements regarding Commitments and Contingencies and Subsequent Events, respectively.

**Item 4. *Submission of Matters to a Vote of Security Holders***

The Registrant did not submit any matters to a vote of security holders during the quarter ended December 31, 2002.

**Item 5. *Market for Registrant's Common Equity and Related Stockholder Matters***

**Price Range of Common Stock**

On April 17, 2002, ICN completed the sale, through an underwritten IPO, of 29,900,000 shares of the Company's common stock at \$10.00 per share representing 19.93% of the total outstanding common stock of 150,000,000 shares. Upon completion of the IPO, ICN owned the remaining 120,100,000, or 80.07%, of the Company's common stock. The Company's common stock began trading on the New York Stock Exchange (Symbol: RNA) on April 17, 2002. As of March 14, 2003, there were 2,911 holders of record of the Company's common stock.

The following table sets forth the high and low sales prices of the Company's common stock on the New York Stock Exchange Composite Transactions reporting system.



Edgar Filing: RIBAPHARM INC - Form 10-K

Fiscal Quarters	2002	
	High	Low
First	\$	\$
Second	\$ 11.85	\$ 8.61
Third	\$ 9.05	\$ 3.69
Fourth	\$ 7.00	\$ 2.54

**Dividend Policy**

The Company currently does not pay dividends and does not anticipate paying dividends in the foreseeable future. The Board of Directors will continue to review the Company's dividend policy, and will make all future determinations relating to the dividend policy. The amount and timing of any future dividends will depend upon the financial condition and profitability of the Company, capital requirements, the need to retain earnings for use in research and development, and such other factors that the Board of Directors may deem relevant.

**Item 6. Selected Financial Data**

The following table sets forth certain financial data for the five years ended December 31, 2002. The Company derived the Statement of Income data for the years ended December 31, 2002, 2001 and 2000 and the Balance Sheet data as of December 31, 2002 and 2001 from audited financial statements which are included elsewhere in this Form 10-K. The Company derived the Statement of Income data for the years ended December 31, 1999 and 1998 and balance sheet data as of December 31, 2000, 1999 and 1998 from audited financial statements which are not included in this Form 10-K. Basic and diluted earnings per share have been calculated using the 150,000,000 shares that were outstanding after completion of the IPO, and which remain outstanding as of December 31, 2002. Historical results are not necessarily indicative of the results to be expected in the future. This information should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as the financial statements included elsewhere in this Form 10-K.

	Year Ended December 31,				
	2002(4)	2001(4)	2000(4)	1999(4)	1998(4)
	(In thousands, except per share data)				
<b>Statements of Income:(1)</b>					
Revenues	\$ 270,265	\$ 143,622	\$ 154,818	\$ 109,592	\$ 36,830
Operating expenses:					
Research and development	47,480	25,595	12,552	5,638	9,517
General and administrative	18,803	5,562	11,566	5,493	7,405
Total costs and expenses	66,283	31,157	24,118	11,131	16,922
Income from operations	203,982	112,465	130,700	98,461	19,908
Interest income	(322)				
Interest expense	1,004				
Income before income taxes	203,300	112,465	130,700	98,461	19,908
Provision for income taxes	74,059	40,487	48,717	35,446	7,167
Net income	\$ 129,241	\$ 71,978	\$ 81,983	\$ 63,015	\$ 12,741
<b>Per share information:(2)</b>					
Net income basic	\$ 0.86	\$ 0.48	\$ 0.55	\$ 0.42	\$ 0.08
Shares used in basic earnings per share computation	150,000	150,000	150,000	150,000	150,000
Net income diluted	\$ 0.86	\$ 0.48	\$ 0.55	\$ 0.42	\$ 0.08
Shares used in diluted earnings per share computation	150,010	150,000	150,000	150,000	150,000

## As of December 31,

2002	2001	2000	1999	1998
------	------	------	------	------

Edgar Filing: RIBAPHARM INC - Form 10-K

**Balance Sheet Data:(3)**

Working capital (deficit)	\$ 92,569	\$ 10,813	\$ 527	\$ (1,112)	\$ (626)
Total assets	199,075	26,634	9,853	1,048	2,854
Total current liabilities	96,002	5,415	3,073	1,112	626
Total debt	465,590				
Stockholders' equity (deficit)	(363,224)	21,219	6,780	(64)	(2,095)

See accompanying Notes to Selected Financial Data.

**Notes to Selected Financial Data:**

- (1) The statements of income for the periods until April 17, 2002 are derived from the historical books and records of ICN and present the results of operations applicable to the Company. For the periods prior to April 17, 2002, the statements of income include corporate allocation of costs between the Company and ICN of shared services (including legal, finance, corporate development, information systems and corporate office expenses). These costs were allocated to the Company on a basis that is considered by management to reflect fairly or reasonably the utilization of services provided to or benefit obtained by the Company, such as the square footage, headcount or actual utilization. For the periods subsequent to April 17, 2002, the statements of income include a corporate allocation of costs between the Company and ICN in accordance with the terms of a management services and facilities agreement. It is not practicable to determine the costs specifically attributable to either ICN or the Company with respect to the U.S. Attorney investigation or the SEC litigation. (See Note 11 of Notes of Financial Statements regarding Commitments and Contingencies contained elsewhere in the Form 10-K.) Additionally, allocation methods of these costs based upon revenue, net income, assets, equity or headcount are not reflective of the nature of the costs incurred. Therefore, ICN and the Company used a joint responsibility approach in allocating these costs such that 50% of the costs, including any reserve settlement, are allocated to each of ICN and the Company. Management believes the method used to allocate these amounts is reasonable.
- (2) The Company's IPO occurred on April 17, 2002; therefore, per share information as of December 31, 2001, 2000, 1999 and 1998 is included for information purposes. Refer to (4) below.
- (3) The balance sheet data as of December 31, 2001, 2000, 1999 and 1998 was prepared using the historical basis of accounting and includes all of the assets and liabilities specifically identifiable to the Company.
- (4) The Company's financial information as of and for the years ended December 31, 2001, 2000, 1999 and 1998, as well as for the period until April 17, 2002, does not necessarily reflect what the Company's financial position or results of operation would have been had the Company operated as a stand-alone public entity, and may not be indicative of future results of operation or financial position.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

**Critical accounting policies and estimates**

The discussion and analysis of Ribapharm Inc.'s (the Company) financial condition and results of operations are based upon its financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States. The Company believes the following critical accounting policies affect its more significant judgments and estimates used in the preparation of the Company's financial statements:

*Revenue Recognition:* The Company earns royalty revenue at the time the product and technology subject to the royalty are sold by a third party. Accordingly, the Company accrues for earned royalty revenue, net of estimated returns and discounts. Royalty payments received from Schering-Plough Ltd. (Schering-Plough) are reduced by Schering-Plough's cash payments for discounts, rebates and similar deductions. The Company recognizes as revenue up-front nonrefundable fees associated with royalty and license agreements when all performance obligations under the agreements are completed. Milestone payments received, if any, related to scientific achievement are recognized as revenue when the milestone is accomplished by the third party. All of the Company's revenues for the years ended December 31, 2002 and 2000, and approximately 97% of the Company's revenues for the year ended December 31, 2001, were derived from Schering-Plough.

*Accrual of rebates and other concessions:* The Company estimates the commercial and governmental rebates that will be paid in subsequent periods for those products sold during the current period, and accrues those estimated amounts as a liability and a reduction of royalty revenue.

*Research and Development:* Research and development costs, including milestone payments and purchased research and development, are expensed as incurred.

*Income Taxes:* The Company's operations are included in ICN Pharmaceuticals, Inc.'s (ICN) consolidated tax returns. Income tax provision and benefits have been calculated on a separate return basis for federal income tax purposes and are based upon ICN's worldwide apportioned rate for the State of California.

**Results of Operations**

The following discussion of the Company's financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this report.

The Company's financial statements for the periods until April 17, 2002, are derived from the historical books and records of ICN and present the assets and liabilities, results of operations and cash flows applicable to the Company. For the periods prior to April 17, 2002, the statements of income include corporate allocation of costs between the Company and ICN of shared services (including legal, finance, corporate development, information systems and corporate office expenses). These costs were allocated to the Company on a basis that is considered by management to reflect most fairly or reasonably the utilization of services provided to or benefit obtained by the Company, such as the square footage, headcount or actual utilization. For the periods subsequent to April 17, 2002, the statement of income includes a corporate allocation of costs between the Company and ICN in accordance with the terms of the management services and facilities agreement. It is not practicable to determine the costs specifically attributable to either ICN or the Company with respect to the U.S. Attorney investigation or the SEC litigation.

## Edgar Filing: RIBAPHARM INC - Form 10-K

See Note 11 of Notes to Financial Statements regarding Commitment and Contingencies. Additionally, allocation methods of these costs based upon revenue, net income, assets, equity or headcount are not reflective of the nature of the costs incurred. Therefore, ICN and the Company used a joint responsibility approach in allocating these costs such that 50% of the costs, including any reserve settlement, are allocated to each of ICN and the Company. Management believes the methods used to allocate these amounts are reasonable.

### *Royalties*

Royalties represent amounts earned under the Company's License Agreement with Schering-Plough. Under the License Agreement, Schering-Plough licensed all oral forms of ribavirin for the treatment of hepatitis C virus ( HCV ) in combination with Schering-Plough's interferon alpha (the Combination Therapy ). Schering-Plough markets the Combination Therapy in the United States, Europe, Japan, and many other countries around the world based on the U.S. and European Union regulatory approvals.

Schering-Plough has informed ICN that it believes royalties paid under the License Agreement should not include royalties on products distributed as part of its indigent patient marketing program. Schering-Plough claims that because it receives no revenue from products given to indigent patients, it should not have to pay royalties on these products under the License Agreement. In August 2001, Schering-Plough withheld approximately \$11,628,000 from its royalty payment relating to the second quarter of 2001. The amount withheld was purportedly intended by Schering-Plough to be a retroactive adjustment of royalties previously paid to ICN through the third quarter of 2000 on products distributed as part of this indigent patient marketing program. Since the fourth quarter of 2000, Schering-Plough has withheld on a current basis all royalty payments purportedly related to this indigent patient marketing program. The Company recognized the \$11,628,000 of withheld royalty payments for the retroactive adjustment and \$3,050,000 of royalty payments withheld for the fourth quarter of 2000 and the first quarter of 2001 as income. These amounts appear on the Company's balance sheet as a receivable. The Company has not established a reserve for these amounts because, in the opinion of the Company's management, collectibility is reasonably assured based upon management's interpretation of the License Agreement and its understanding of the circumstances. Since the second quarter of 2001, the Company no longer recognizes any of these withheld royalty payments as income since such amounts can no longer be determined due to lack of information provided by Schering-Plough. ICN and the Company have initiated arbitration with Schering-Plough to collect these royalties and prevent Schering-Plough from withholding royalty payments on future sales. The parties have selected an arbitrator and the Company currently expects the arbitration will take place in May or June of 2003. If ICN and the Company do not succeed in the arbitration process, the Company may have to write off all or a portion of this receivable. If ICN and the Company do succeed, the Company will be entitled to receive the royalty payments on these indigent sales withheld by Schering-Plough.

In April 2002, Schering-Plough asserted a counterclaim against ICN and the Company in this arbitration, based on ICN's alleged failure to assist Schering-Plough in securing certain distribution rights in Egypt. ICN and the Company intend to vigorously contest this counterclaim.

Schering-Plough announced in early November 2002 that it was served with two grand jury subpoenas by the United States Attorney for the District of Massachusetts, which has been investigating certain of Schering-Plough's sales and marketing practices. Among other information, the subpoenas seek a broad range of information concerning Schering-Plough's sales, marketing and clinical trial practices and programs with respect to Rebetron, its sales and marketing contacts with managed care organizations and doctors and its offering or provision of grants, honorariums or other items or services of value to managed care organizations, physician groups, doctors and educational institutions. According to Schering-Plough, it is not possible to predict the outcome of the investigation, which could include the commencement of civil or criminal proceedings involving the imposition of fines, penalties and injunctive or administrative remedies, including exclusion from government reimbursement programs, or to predict whether the investigation will affect Schering-Plough's marketing, sales or clinical trial practices.

Additionally, Schering-Plough announced that the U.S. Attorney's Office in New Jersey, along with the FDA's Office of Criminal Investigation, is conducting an investigation which may focus on one or more of its products, including ribavirin manufactured in Puerto Rico. Schering-Plough has stated that it is cooperating with the government in the investigation.

The Company, which is not a party to, or otherwise involved in this investigation of Schering-Plough, cannot predict the impact, if any, of this investigation on royalty revenues under the License Agreement with Schering-Plough.

On January 6, 2003, the Company, ICN and F. Hoffmann-LaRoche, Ltd. ( Roche ) reached agreement on a settlement regarding pending patent disputes over Roche's combination anti-viral product containing Roche's version of ribavirin, known as Copegus. The terms of this settlement agreement include a license by the Company of ribavirin to Roche. Roche will pay royalty fees to the Company on all sales of the combination product containing Copegus. No royalties under the Roche agreement were earned by, or paid to, the Company in fiscal year 2002.

***Year Ended December 31, 2002 Compared to 2001***

***Revenues:*** Revenues for the year ended December 31, 2002 were \$270,265,000 compared to \$143,622,000 for 2001, an increase of \$126,643,000 or 88%. Revenues for 2002 are net of approximately \$9,829,000 for estimated rebates and price concessions related to current period sales of ribavirin that are projected to be paid in subsequent periods. The revenue increase is primarily due to Schering-Plough's launch of its Peg-Intron/Rebetol Combination Therapy in the United States in October 2001, and the launch of its Rebetron Combination Therapy in Japan in December 2001. Revenues for the fourth quarter of 2002 increased by \$29,249,000 as compared to the similar period in 2001.

***Research and Development:*** Research and development expenses for the year ended December 31, 2002 were \$47,480,000, compared to \$25,595,000 in 2001, an increase of \$21,885,000 or 86%. The increase reflects the Company's expanded and intensified research and development efforts, primarily in the areas of antiviral and anticancer drugs. The Company increased spending on the antiviral drug Viramidine, which is in Phase 1 clinical trials in the United States and Europe, and on the antiviral drug Hepavir B, which is in Phase 1 clinical trials in Europe. The Company commenced Phase 2 clinical trials in the United States on Viramidine during December 2002. Additionally, the Company increased research and development expenses on other initiatives, including work on anti-hepatitis C, anti-hepatitis B and anticancer compounds, and expects research and development expenses to increase in the foreseeable future, most significantly to support the product development programs for Viramidine, Hepavir B and IL-12.

***General and Administrative Expenses:*** General and administrative expenses were \$18,803,000 for the year ended December 31, 2002, compared to \$5,562,000 for 2001, an increase of \$13,241,000 or 238%. The increase is primarily due to a charge of \$6,116,000 relating to severance costs associated with the departure of former management, and legal expenses of \$5,643,000 to defend patents and address general business issues. The remainder of the increase is primarily comprised of costs incurred to establish new administrative departments and an infrastructure for the Company subsequent to the IPO. These expenses include corporate allocations from ICN of \$3,885,000 and \$3,594,000 for the years ended December 31, 2002 and 2001, respectively. Corporate allocations include legal expenses and professional fees, facility and central service charges, corporate development expenses and other general and administrative expenses.

***Income Taxes:*** The Company's effective tax rate was approximately 36% for the years ended December 31, 2002 and 2001. The Company's operations were included in the consolidated ICN tax returns. Income tax provisions and benefits have been calculated on a separate return basis for federal income tax purposes and based upon ICN's worldwide apportioned rate for the State of California of 1% for the years ended December 31, 2002 and 2001.

***Year Ended December 31, 2001 Compared to 2000***



## Edgar Filing: RIBAPHARM INC - Form 10-K

*Revenues:* Revenues for the year ended December 31, 2001 were \$143,622,000 compared to \$154,818,000 for 2000, a decrease of \$11,196,000 or 7%. Revenues for 2001 include other revenues of \$5,000,000 in connection with the licensing of Levovirin to Roche; the Company licensed Levovirin to Roche in June 2001 on

an exclusive basis. Royalties on ribavirin sales for 2001 were \$138,622,000. The Company believes that the \$16,196,000 (or 10%) decrease in royalties compared to 2000 is primarily reflective of a slowdown in sales of ribavirin by Schering-Plough, as physicians awaited marketing authorization pending FDA review and clearance for the use of pegylated interferon with ribavirin, which occurred in August 2001. The launch of this combination therapy in the United States and Japan was delayed until October 2001 and December 2001, respectively. Royalties from Schering-Plough for the fourth quarter of 2001 increased by \$25,319,000 as compared to the similar period in 2000.

*Research and Development:* Research and development expenses were \$25,595,000 for 2001 and \$12,552,000 in 2000. The increase of \$13,043,000 or 104% reflects the Company's expanded and intensified research and development efforts in 2001, primarily in the area of antiviral and anticancer drugs. The Company increased spending on the antiviral drugs Levovirin and Viramidine during the period due to the initiation of Phase 1 clinical trials. Additionally, research and development expenses increased on other initiatives, including work on the drug Tiazole as well as work on anti-hepatitis C, anti-hepatitis B, anticancer and antiviral compounds. Also, in 2001, the Company expensed the purchase of Hepavir B from Metabasis Therapeutics, Inc. as in-process research and development for which no alternative use exists.

*General and Administrative Expenses:* General and administrative expenses were \$5,562,000 for 2001 compared with \$11,566,000 for 2000, a decrease of \$6,004,000 or 52%. These expenses include corporate allocations from ICN of \$3,594,000 for 2001 and \$10,098,000 for 2000. Allocated legal expenses and professional fees were \$876,000 for 2001 and \$7,637,000 for 2000, a decrease of \$6,761,000. The decrease in legal expenses and professional fees was mainly related to a decrease in activity involving SEC litigation against ICN and the investigation by the U.S. Attorney's Office of ICN during 2001 as compared to 2000.

*Income Taxes:* The Company's effective tax rate was 36% for 2001 compared to 37% for 2000. The decrease in the effective rate of 1% in 2001 is because the effective tax rate in 2000 reflects \$4,625,000 of expenses not deductible for income taxes.

## **Liquidity and Capital Resources**

During the year ended December 31, 2002, cash provided by operating activities totaled \$81,916,000 compared to \$44,546,000 in 2001. The increase in operating cash flows primarily reflects the increase in royalty revenues in 2002 compared to 2001.

Cash used in investing activities was \$2,943,000 for the year ended December 31, 2002 and \$6,358,000 for the same period in 2001. The investment in capital expenditures reflects the purchase of state-of-the-art research equipment to be used for research and development.

Cash provided by financing activities was \$777,000 for the year ended December 31, 2002 compared to cash used in financing activities of \$38,188,000 for the same period in 2001. In 2002, cash provided by financing activities reflects net cash retained by ICN of \$34,223,000 offset by borrowings of \$35,000,000 on the line of credit from ICN.

At the time of the IPO, ICN agreed to provide the Company with working capital financing which the Company could draw upon until August 31, 2002. As of December 31, 2002, the Company had an outstanding borrowing of \$35,000,000 from ICN under the credit facility, payable on or before December 31, 2003, which was required to fund the initial operations of the Company after the IPO. Interest is charged based upon LIBOR (1.37% at December 31, 2002) plus 200 basis points. On March 28, 2003, the Company entered into an amendment to the line of credit facility with ICN which allows the Company to make draws against the line of credit, if needed, to the extent of cumulative repayments made by the Company, up to a maximum available credit limit of \$35,000,000. Subject to approval by ICN's Board of Directors, the amended expiration date would be the earlier of December 29, 2005 or the date on which ICN ceases to be the beneficial owner of at least 80%



of the issued and outstanding common stock of the Company; however, unless and until such approval is obtained, the expiration date will remain at December 31, 2003. Additionally, it was the Company's desire, and ICN agreed as a condition to the amendment, to repay ICN on the date of the amendment the aggregate outstanding principal balance and related accrued interest, without requirement to comply with a prior notice obligation. Accordingly, on March 28, 2003, the Company repaid principal and interest in the amounts of \$35,000,000 and \$984,000, respectively.

Management believes the Company's existing cash and cash equivalents and funds generated from royalties will be sufficient to meet its operating requirements at least through December 31, 2003 and to fund the continued development of its research and development programs, as well as potential acquisitions and capital expenditures for the medium term. The Company may seek debt financing or issue equity securities to finance future acquisitions.

The Company and ICN are involved in a dispute with Schering-Plough over the payment of royalties on products distributed as part of Schering-Plough's indigent patient marketing program. Also, in February and March 2003, Schering-Plough announced that it has entered into license agreements with three generic pharmaceutical companies which granted to each company a non-exclusive, non-sublicensable license to Schering-Plough's U.S. ribavirin patents. The outcome of the dispute regarding royalties from the indigent marketing program and Schering-Plough's licenses to the three generic pharmaceutical companies could have a material negative impact on the Company's future royalty revenue. See Management's Discussion and Analysis Results of Operations Royalties, and Notes 3 and 11 of Notes to Financial Statements regarding Schering-Plough License Agreement and Commitments and Contingencies, respectively.

No royalties under the Roche agreement were earned by or paid to the Company in fiscal year 2002. The Company understands that Roche may sell ribavirin at prices below those charged by Schering-Plough. If that were to occur, the Company could experience a decline in royalty revenues from Schering-Plough, and it is uncertain if royalty revenues from Roche will offset the effect of any such decline.

As a result of the IPO, the Company became jointly and severally liable for the principal and interest obligations under \$525,000,000 of 6 1/2% convertible subordinated notes due 2008 (the Notes) issued by ICN in July 2001. In July and August 2002, ICN repurchased \$59,410,000 principal amount of the Notes. As between the Company and ICN, ICN agreed to make all interest and principal payments on the Notes and to make any payments due upon a change of control of ICN or the Company (upon a change of control of the Company, as defined in the indenture governing the Notes, the Company must make an offer to repurchase all of the Notes). The Company can only amend this agreement, in a manner adverse to the Company, with the approval of holders of a majority of our outstanding shares of common stock, excluding shares held by ICN. See Note 6 of Notes to Financial Statements regarding Long-term Debt. Therefore, the Company does not expect its obligations under the Notes to have an impact on its liquidity or capital resources. The obligation and accrued interest payable under the Notes are recorded as a receivable from ICN within stockholder's equity, which offsets the related debt in long-term liabilities and interest payable in current liabilities. This receivable from ICN will remain as a component of the Company's equity to the extent that an obligation for principal and interest for these notes remains outstanding or until ICN can no longer make principal and interest payments as discussed above. See Note 7 of Notes to Financial Statements regarding Related Party Transactions.

The lease agreement with ICN provides for a lease payment of \$5,000,000 per year, plus consumer price index increases, for five years, with a five-year option to renew. The lease expires in April 2007. The lease is accounted for as an operating lease by the Company. In connection with the lease agreement, the Company pays ICN, in addition to the lease payment, for its pro rata portion of common charges for the building.

In connection with the resignations of the Company's three former executives on January 22, 2003, and in accordance with the terms of the executives' pre-existing employment agreements, the Company became obligated to make cash payments to the executives totaling \$5,334,000 in the aggregate, and may be required to



make additional cash payments covering any excise tax payable under the Internal Revenue Code in connection with such payments. The \$5,334,000 in severance payments is accrued at December 31, 2002. The Company also incurred approximately \$696,000 and \$86,000 in related legal costs and professional services, respectively, which are also included in the Company's financial results for the year ended December 31, 2002. In addition, the vesting of options granted to the executives pursuant to the Company's 2002 Stock Option and Award Plan was accelerated in accordance with provisions in their employment agreements; however, such options were not in-the-money and therefore were not recognized as compensation expense in accordance with Accounting Principles Board Opinion No. 25, Accounting for Employee Stock Options. These former executives terminated their employment with the Company as part of the settlement of litigation between the Company and ICN. See Note 13 of Notes to Financial Statements regarding Subsequent Events.

### **Costs of Products in Development**

The Company expects its research and development expenses to increase in the future, of which a large percentage will be to support product development programs for Viramidine, Hepavir B and IL-12. The Company has conducted Phase 1 clinical trials for Viramidine in Europe and the United States, and commenced Phase 2 clinical trials in the United States in December of 2002. The Company's external research and development expenses for Viramidine are approximately \$13,400,000 from inception through December 31, 2002. The Company initiated a Phase 1 clinical trial of Hepavir B in Europe in August 2002, and filed an Investigational New Drug (IND) application with the FDA in October 2002. Its external research and development expenses for Hepavir B are approximately \$10,700,000 from inception through December 31, 2002. On December 19, 2002, the Company applied to the FDA to reactivate the IND to initiate human clinical trials for IL-12. The Company is currently in the process of manufacturing IL-12.

The Company licensed Levovirin to Roche in June 2001 on an exclusive basis. Roche is responsible for all future development costs of Levovirin.

It is not unusual for the clinical development of these types of products to take five years or more and to cost over \$200,000,000. The time and cost of completing the clinical development of these product candidates will depend on a number of factors, including the disease or medical condition to be treated, clinical trial design, availability of patients to participate in trials and the relative efficacy of the product versus treatments already approved and whether or when the Company license the product candidates to third parties. Due to these many uncertainties, the Company is unable to estimate the length of time or the costs that will be required to complete the development of these product candidates. In addition, the Company cannot provide assurance that these product candidates will receive regulatory approval for use for the proposed indications or that these product candidates will be commercially successful.

### **Inflation and Changing Prices**

The effects of inflation are experienced by the Company through increases in the costs of services and supplies.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

The Company's business and financial results are affected by fluctuations in world financial markets. The Company evaluates its exposure to such risks on an ongoing basis, and reviews its risk management policy to manage these risks to an acceptable level, based on management's judgment of the appropriate trade-off between risk, opportunity and costs. The Company does not hold any significant amount of market risk sensitive instruments whose value is subject to market price and currency risk.

In the normal course of business, the Company also faces risks that are either non-financial or non-quantifiable. Such risks principally include credit risk and legal risk. See Notes 2 and 11 of Notes to Financial Statements regarding Summary of Significant Accounting Policies Concentration of Credit Risk and Commitments and Contingencies, respectively.

*Interest Rate Risk:* The Company currently does not hold financial instruments for trading or speculative purposes. The financial assets of the Company are not subject to significant interest rate risk due to their short duration. The Company does not use any derivatives or similar instruments to manage interest rate risk. The Company's principal financial liabilities subject to interest rate risk are its joint and several obligation with ICN for fixed-rate long-term debt, comprised of the Notes issued by ICN totaling \$465,590,000, and borrowings under a \$35,000,000 line of credit from ICN.

For financial reporting, the Company gives effect to its joint and several obligation for the Notes by recording the Notes and related interest as a receivable from ICN within the Company's stockholders' equity section of the balance sheet. (See Note 6 of Notes to Financial Statements regarding Long-term Debt. ) The Notes bear a 6½% fixed rate of interest. A hypothetical 100 basis point increase in interest rates (an approximate 15% increase compared to the fixed rate) affecting the Notes would reduce the fair value of the Notes by approximately \$16,100,000.

On the \$35,000,000 line of credit borrowing, the Company is charged a variable interest rate, comprised of LIBOR plus 200 basis points. The weighted average LIBOR was 1.65% during the period of time the borrowing was outstanding in 2002. A hypothetical 100 basis point increase in interest rates would increase the 1.65% weighted average LIBOR, plus 200 basis points, to 4.65%, which on an annualized basis would have a \$350,000 adverse effect on the Company's pre-tax earnings, assuming the Company borrowed the full \$35,000,000 on the line of credit.

### **FORWARD LOOKING STATEMENTS**

This Annual Report on Form 10-K contains statements that constitute forward-looking statements. Those statements appear in a number of places in this Annual Report on Form 10-K and include statements regarding, among other matters, the Company's growth opportunities, the Company's acquisition strategy, the Company's continued royalty revenue stream, expectations regarding research and development costs, the prospects for regulatory approval and commercialization of the Company's product candidates, other regulatory matters pertaining to the Company's products and other factors affecting the Company's financial condition or results of operations. Stockholders are cautioned that any such forward looking statements are not guarantees of future performance and involve risks, uncertainties and other factors which may cause actual results, performance or achievements to differ materially from the future results, performance or achievements, expressed or implied in such forward looking statements. Such factors are discussed in this Annual Report on Form 10-K and also include, without limitation, that the Company's revenues to date have largely come from a license agreement with one company for a single product, the risk of potential claims against certain of the Company's research compounds; the Company's ability to successfully develop and commercialize future products; the limited protection afforded by the patents relating to ribavirin, and possibly on future drugs, techniques, processes or products the Company may develop or acquire; the results of lawsuits or the outcome of investigations pending against ICN and the Company; the Company's potential product liability exposure and lack of any insurance coverage therefor; government regulation of the pharmaceutical industry (including review and approval for new pharmaceutical products by the FDA in the United States and comparable agencies in other countries); industry competitors; and its status as a consolidated subsidiary of ICN, which has indicated it is exploring various strategic alternatives with respect to the Company.



### QUARTERLY FINANCIAL DATA

Following is a summary of quarterly financial data for the years ended December 31, 2002 and 2001

(table in thousands, except per share amounts):

	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>
	<b>(Unaudited)</b>			
<b>2002(1)(3)</b>				
Revenues	\$ 57,001	\$ 66,000	\$ 63,395	\$ 83,869
Net income	29,975	31,120	28,892	39,254
Basic earnings per share(2)	0.20	0.21	0.19	0.26
Diluted earnings per share(2)	0.20	0.21	0.19	0.26
<b>2001(1)(3)</b>				
Revenues	\$ 29,234	\$ 38,294	\$ 21,474	\$ 54,620
Net income	14,808	19,233	8,141	29,796
Basic earnings per share(2)	0.10	0.13	0.05	0.20
Diluted earnings per share(2)	0.10	0.13	0.05	0.20

- (1) The statements of income for the periods until April 17, 2002 are derived from the historical books and records of ICN and present the results of operations applicable to the Company. For the periods prior to April 17, 2002, the statements of income include corporate allocation of costs between the Company and ICN of shared services (including legal, finance, corporate development, information systems and corporate office expenses). These costs were allocated to the Company on a basis that is considered by management to reflect fairly or reasonably the utilization of services provided to or benefit obtained by the Company, such as the square footage, headcount or actual utilization. For the periods subsequent to April 17, 2002, the statement of income includes a corporate allocation of costs between the Company and ICN in accordance with the terms of the management services and facilities agreement. It is not practicable to determine the costs specifically attributable to either ICN or the Company with respect to the U.S. Attorney investigation or the SEC litigation. (See Note 11 of Notes to Financial Statements regarding Commitments and Contingencies.) Additionally, allocation methods of these costs based upon revenue, net income, assets, equity or headcount are not reflective of the nature of the costs incurred. Therefore, ICN and the Company used a joint responsibility approach in allocating these costs such that 50% of the costs, including any reserve settlement, are allocated to each of ICN and the Company. Management believes the methods used to allocate these amounts are reasonable.
- (2) The Company's IPO occurred on April 17, 2002; therefore, per share information for the quarter ended March 31, 2002 and for each quarter of 2001 is included for information purposes only. Refer to (3) below.
- (3) The Company's financial information as of and for the years ended December 31, 2001, and for the period prior to April 17, 2002, does not necessarily reflect what the Company's financial position or results of operation would have been had the Company operated as a stand-alone public entity and may not be indicative of future results of operation or financial position.

**Item 8. *Financial Statements and Supplementary Data***

**INDEX TO FINANCIAL STATEMENTS**

**December 31, 2002**

	<b>Page</b>
Report of Independent Accountants	35
Financial statements:	
Balance sheets at December 31, 2002 and 2001	36
For the years ended December 31, 2002, 2001 and 2000:	
Statements of income	37
Statements of stockholders' equity	38
Statements of cash flows	39
Notes to financial statements	40

---

**REPORT OF INDEPENDENT ACCOUNTANTS**

To the Board of Directors and

Stockholders of Ribapharm Inc.:

In our opinion, the accompanying balance sheets and the related statements of income, stockholder's equity and cash flows present fairly, in all material respects, the financial position of Ribapharm Inc. (the Company), a Delaware corporation which was formerly a division of ICN Pharmaceuticals, Inc., at December 31, 2002 and 2001, and the results of its operations and 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. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion.

/s/ PRICEWATERHOUSECOOPERS LLP

---

Los Angeles, California

February 25, 2003

## RIBAPHARM INC.

## BALANCE SHEETS

December 31, 2002 and 2001

(In thousands, except per share data)

	<u>2002</u>	<u>2001</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 79,750	\$
Royalty receivable	105,496	16,228
Prepaid expenses and other current assets	591	
Deferred income taxes	2,734	
	<u>188,571</u>	<u>16,228</u>
Total current assets	188,571	16,228
Property, plant and equipment, net	10,504	10,406
	<u>\$ 199,075</u>	<u>\$ 26,634</u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Trade payables	\$ 1,286	\$ 1,069
Accrued liabilities	24,129	4,346
Accrued interest on 6 1/2% subordinated notes due 2008	13,871	
Due to ICN Pharmaceuticals, Inc.	4,266	
Income taxes payable to ICN Pharmaceuticals, Inc.	17,450	
Line of credit from ICN Pharmaceuticals, Inc.	35,000	
	<u>96,002</u>	<u>5,415</u>
Total current liabilities	96,002	5,415
6 1/2% subordinated notes due 2008	465,590	
Deferred income taxes.	707	
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, \$0.01 par value; 10,000 shares authorized; none issued and outstanding		
Common stock, \$0.01 par value; 400,000 shares authorized; 150,000 shares outstanding at December 31, 2002 and 2001	1,500	1,500
Advances due from ICN Pharmaceuticals, Inc.		(188,017)
Receivable from ICN Pharmaceuticals, Inc.	(479,461)	
Retained earnings	114,737	207,736
	<u>(363,224)</u>	<u>21,219</u>
Total stockholders' equity (deficit)	(363,224)	21,219
	<u>\$ 199,075</u>	<u>\$ 26,634</u>

The accompanying notes are an integral part of these financial statements.



## RIBAPHARM INC.

## STATEMENTS OF INCOME

For the years ended December 31, 2002, 2001 and 2000

(In thousands, except per share data)

	2002	2001	2000
Revenues	\$ 270,265	\$ 143,622	\$ 154,818
Operating expenses:			
Research and development	47,480	25,595	12,552
General and administrative	18,803	5,562	11,566
Total operating expenses	66,283	31,157	24,118
Income from operations	203,982	112,465	130,700
Interest income	(322)		
Interest expense	1,004		
Income before income taxes	203,300	112,465	130,700
Provision for income taxes	74,059	40,487	48,717
Net income	\$ 129,241	\$ 71,978	\$ 81,983
Basic net income per share	\$ 0.86	\$ 0.48	\$ 0.55
Shares used in basic earnings per share computation	150,000	150,000	150,000
Diluted net income per share	\$ 0.86	\$ 0.48	\$ 0.55
Shares used in diluted earnings per share computation	150,010	150,000	150,000

The accompanying notes are an integral part of these financial statements

## RIBAPHARM INC.

## STATEMENTS OF STOCKHOLDERS EQUITY

For the years ended December 31, 2002, 2001 and 2000

(In thousands)

	Preferred Stock		Common Stock		Advances		Retained Earnings (Deficit)	Total
	Shares	Amount	Shares	Amount	Due to (from) ICN	Receivable From ICN		
<b>Balance at December 31, 1999</b>		\$	150,000	\$ 1,500	\$ (55,339)	\$	\$ 53,775	\$ (64)
Net income							81,983	81,983
Advances due from ICN, net					(75,139)			(75,139)
<b>Balance at December 31, 2000</b>			150,000	1,500	(130,478)		135,758	6,780
Net income							71,978	71,978
Advances due from ICN, net					(57,539)			(57,539)
<b>Balance at December 31, 2001</b>			150,000	1,500	(188,017)		207,736	21,219
Net income							129,241	129,241
6 ½% subordinated notes and accrued interest						(479,461)		(479,461)
Advances due from ICN, net					(34,223)			(34,223)
April 17, 2002 IPO adjustment					222,240		(222,240)	
<b>Balance at December 31, 2002</b>		\$	150,000	\$ 1,500	\$	\$ (479,461)	\$ 114,737	\$ (363,224)

The accompanying notes are an integral part of these financial statements.

## RIBAPHARM INC.

## STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2002, 2001 and 2000

(In thousands)

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Cash flows from operating activities:			
Net income	\$ 129,241	\$ 71,978	\$ 81,983
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	2,845	2,205	684
Deferred income taxes, net	(2,027)		
Change in assets and liabilities:			
Royalty receivable transferred to ICN		(19,351)	(614)
Royalty receivable	(89,268)	(12,628)	(3,600)
Prepays and other current assets	(591)		
Trade payables and accrued liabilities	20,000	2,342	1,961
Due to ICN	4,266		
Income taxes payable to ICN	17,450		
Net cash provided by operating activities	<u>81,916</u>	<u>44,546</u>	<u>80,414</u>
Cash flows from investing activities:			
Capital expenditures	(2,943)	(6,358)	(5,889)
Net cash used in investing activities	<u>(2,943)</u>	<u>(6,358)</u>	<u>(5,889)</u>
Cash flows from financing activities:			
Borrowings on line of credit from ICN	35,000		
Payment of excess earnings to ICN prior to April 17, 2002, net	(34,223)	(38,188)	(74,525)
Net cash provided by (used in) financing activities	<u>777</u>	<u>(38,188)</u>	<u>(74,525)</u>
Net increase in cash and cash equivalents	79,750		
Cash and cash equivalents at beginning of year			
Cash and cash equivalents at end of year	<u>\$ 79,750</u>	<u>\$</u>	<u></u>

The accompanying notes are an integral part of these financial statements.





**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS**

**December 31, 2002**

**1. Organization and Background**

Ribapharm Inc. (the Company or Ribapharm) seeks to discover, develop, acquire and commercialize innovative products for the treatment of significant unmet medical needs, principally in the antiviral and anticancer areas. The Company's primary product, ribavirin, is an antiviral drug that was licensed to Schering-Plough Ltd. (Schering-Plough) for the treatment of chronic hepatitis C (HCV) in combination with Schering-Plough's interferon alfa-2b or pegylated interferon alfa-2b. Substantially all of the Company's revenue is currently derived from this licensing agreement.

Until April 17, 2002, the Company was a wholly owned subsidiary of ICN Pharmaceuticals, Inc. (ICN). In anticipation of an Initial Public Offering (IPO), on April 10, 2002, the Company effected a recapitalization of its common stock in the form of a 1,500,000 for 1.0 stock split. The Certificate of Incorporation provides for authorized capital stock of 410,000,000 shares, including 400,000,000 shares of common stock, \$.01 par value per share, and 10,000,000 shares of preferred stock, \$.01 par value per share. No preferred stock was sold or is currently outstanding. The financial statements give effect to the recapitalization and stock split, applied retroactively to all periods presented.

On April 17, 2002, ICN completed the sale, through an underwritten IPO, of 29,900,000 shares of common stock, representing 19.93% of the total outstanding common stock of 150,000,000 shares. Shares sold in the IPO were owned by ICN, and ICN received net cash proceeds of \$278,070,000. The Company received no proceeds from the IPO. Upon consummation of the IPO, advances due from ICN of \$222,240,000 were treated similar to a dividend and recorded by the Company as a reduction of its retained earnings. The Company was not repaid any of the advances due from ICN.

At the time of the IPO, ICN announced that, as part of its restructuring plan, it would consider distributing its remaining interest in the Company's common stock to ICN's stockholders in a tax-free spin-off no later than six months after completion of the IPO. In June 2002, ICN announced that, in light of changed circumstances and market conditions, ICN's newly-reconstituted Board of Directors was reviewing certain strategic decisions, including the decision to distribute its interest in the Company to ICN's stockholders in a tax-free spin-off. In order for the spin-off to be tax free to ICN's stockholders, ICN must distribute to its stockholders at least 80% of the issued and outstanding common stock of the Company. This requirement limits the number of shares of the Company's common stock that can be sold. In July 2002, ICN announced that the Internal Revenue Service issued to ICN a private letter ruling that ICN's distribution of its interest in the Company to ICN's stockholders would qualify as a tax-free spin-off. ICN's commitment to effect the spin-off does not constitute a binding legal obligation to do so; therefore, there can be no assurance that the spin-off will occur. ICN is continuing to explore its options with regard to the Company.

The accompanying financial statements for the periods until April 17, 2002 are derived from the historical books and records of ICN and present the assets and liabilities, results of operations and cash flows applicable to the Company. For periods prior to April 17, 2002, the statements of income include a corporate allocation of costs between the Company and ICN of shared services (including legal, finance, corporate development, information systems and corporate office expenses). These costs were allocated to the Company on a basis that is considered by management to reflect fairly or reasonably the utilization of services provided to or the benefit obtained by the Company, such as the square footage, headcount, or actual utilization. For the periods subsequent to April 17, 2002, the income statements include a corporate allocation of

## Edgar Filing: RIBAPHARM INC - Form 10-K

costs between the Company and ICN in accordance with the terms of the management services and facilities agreement. It is not practicable to determine the costs specifically attributable to either ICN or the Company with respect to the U.S. Attorney investigation or the SEC litigation. (See Note 11 of Notes to Financial Statements regarding Commitments)

---

**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

and Contingencies .) Additionally, allocation methods of these costs based upon revenue, net income, assets, equity or headcount are not reflective of the nature of the costs incurred. Therefore, ICN and the Company used a joint responsibility approach in allocating these costs such that 50% of the costs, including any reserve for settlement, are allocated to each ICN and the Company. Management believes the methods used to allocate these amounts are reasonable.

**2. Summary of Significant Accounting Policies**

**Use of Estimates:** The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an on-going basis, the Company evaluates its estimates, including those related to accruals for discounts and returns, rebates and concessions, income taxes, and contingencies and litigation. Actual results could differ from those estimates.

**Cash and Cash Equivalents:** Cash equivalents include money market funds and auction rate securities which have maturities of three months or less. For the purposes of the statements of cash flows, the Company considers highly-liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents. The carrying amount of these assets approximates fair value due to the short-term maturity of these instruments. At December 31, 2002, cash and cash equivalents totaled \$79,750,000. For the year ended December 31, 2001 and through April 17, 2002, the Company transferred all excess cash to ICN and did not maintain a cash equivalent balance.

**Property, Plant and Equipment:** Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment is calculated, primarily using the straight-line method over the estimated useful lives of the assets. Furniture and fixtures are depreciated over 5 years, and machinery and equipment are depreciated over 5 to 10 years. Amortization of leasehold improvements is calculated over the shorter of the lease term or the estimated useful lives of the assets. The Company follows the policy of capitalizing expenditures that materially increase the lives of the related assets and charges maintenance and repairs to expense. Upon sale or retirement, the costs and related accumulated depreciation or amortization are eliminated from the respective accounts, and the resulting gain or loss is included in income.

**Revenue Recognition:** The Company earns royalties as a result of the sale of product rights and technology to third parties. Royalty revenue is earned at the time the products subject to the royalty are sold by the third party; accordingly, the Company accrues for earned royalty revenue, net of estimated discounts and returns. Royalty payments from Schering-Plough are reduced by Schering-Plough's cash payments for discounts, rebates and similar deductions. The Company recognizes as revenue up-front nonrefundable fees associated with royalty and license agreements when all performance obligations under the agreements are completed. Milestone payments received, if any, related to scientific achievement are recognized as revenue when the milestone is accomplished by the third party. See the discussion below in Note 3, Schering-Plough License Agreement, regarding Schering-Plough's dispute relating to the royalty receivables due under an indigent patient marketing program.

**Accrual of rebates and other concessions:** The Company estimates the commercial and governmental rebates that will be paid in subsequent periods for those products sold during the current period, and accrues those estimated amounts as a liability and a reduction of royalty revenues.

**Research and Development:** Research and development costs, including milestone payments and purchased research and development, are expensed as incurred.

## RIBAPHARM INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

**Income Taxes:** The Company's operations are included in the consolidated ICN tax returns. The Company and ICN are parties to a tax sharing agreement. Income tax provisions and benefits have been calculated on a separate return basis for federal income tax purposes and based upon ICN's worldwide apportioned rate for the State of California, which was estimated to be 1% for the twelve months ended December 31, 2002, 2001 and 2000.

The provision for income taxes is accounted for under the asset and liability method specified in Statements of Financial Accounting Standard (SFAS) No. 109, Accounting for Income Taxes. Deferred income taxes are calculated using the estimated future tax effects or differences between financial statement carrying amounts and the tax bases of assets and liabilities. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

**Concentration of Credit Risk:** Financial instruments that subject the Company to concentrations of credit risk consist principally of accounts receivable. The Company performs an ongoing credit evaluation of its customers' financial condition and generally does not require collateral to secure accounts receivable. The Company's exposure to credit risk associated with nonpayment is affected principally by conditions or occurrences within its primary customer, Schering-Plough. The Company historically has not experienced losses relating to accounts receivable from its primary customer. All of the Company's revenues for the years ended December 31, 2002 and 2000 and approximately 97% of the Company's revenues for the year ended December 31, 2001, were derived from Schering-Plough.

**Stock-Based Compensation:** The Company has adopted the disclosure only provisions of SFAS No. 123 and SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure. Compensation cost for stock-based compensation issued to employees has been measured using the intrinsic value method provided by Accounting Principles Board Opinion (APB) No. 25. Accordingly, no compensation cost has been recognized for options granted under the stock option and award plan as all options granted under the plan had an exercise price equal to the market value of the underlying common stock on the date of grant. Had compensation cost for the plan been determined based on the fair value at the grant date for awards in 2002, consistent with the provisions of SFAS No. 123, the Company's net income and earnings per share would have been the unaudited pro forma amounts indicated below (table in thousands, except per share data):

	<u>2002</u>
Net income as reported	\$ 129,241
Stock based employee compensation expense determined under fair value based method, net of related tax effects	3,375
Pro forma net income	<u>\$ 125,866</u>
Earnings per share:	
Basic as reported	<u>\$ 0.86</u>
Basic pro forma	<u>\$ 0.84</u>

Edgar Filing: RIBAPHARM INC - Form 10-K

Diluted as reported	\$	0.86
Diluted pro forma	\$	0.84

The Company's stock option and award plan was not adopted until April 10, 2002; therefore, related disclosure information for fiscal years 2001 and 2000 is not applicable and is not included.

---

**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**Earnings per share:** Earnings per share has been calculated for all periods presented using the 150,000,000 shares outstanding after the IPO, which occurred on April 17, 2002. Earnings per share is calculated in accordance with SFAS No. 128 Earnings per Share. Basic earnings per share excludes the dilutive effects of options, compared with the diluted earnings per share which reflects the potential dilution of options. Diluted earnings per share for the year ended December 31, 2002 excludes the effect of 3,996,050 shares of common stock from options, because their effect was antidilutive.

**Reclassifications:** Certain prior period amounts have been reclassified to conform to current period presentation, with no effect on net income or stockholders' equity.

**3. Schering-Plough License Agreement**

On July 28, 1995, ICN entered into an Exclusive License and Supply Agreement (the License Agreement) and a Stock Purchase Agreement (the Agreement) with Schering-Plough Ltd. (Schering-Plough). Under the License Agreement, Schering-Plough licensed all oral forms of ribavirin for the treatment of chronic hepatitis C (HCV) in combination with Schering-Plough's interferon alpha-2b. The License Agreement provided the Company an initial non-refundable payment and future royalty payments to the Company from sales of ribavirin by Schering-Plough, including certain minimum royalty rates. As part of the initial License Agreement, the Company retained the right to co-market ribavirin capsules in the European Union under its trademark Virazole®. Under the License Agreement, Schering-Plough is responsible for all clinical developments worldwide. In 1998, ICN sold to Schering-Plough its right to co-market oral ribavirin for the treatment of HCV in the European Union, in exchange for increased royalty rates on sales of ribavirin worldwide. ICN contributed the License Agreement and its future royalty income stream to the Company prior to April 17, 2002 in order to facilitate the Company's IPO on April 17, 2002.

Schering-Plough has informed ICN that it believes royalties paid under the License Agreement should not include royalties on products distributed as part of its indigent patient marketing program. Schering-Plough claims that because it receives no revenue from products given to indigent patients, it should not have to pay royalties on these products under the License Agreement. In August 2001, Schering-Plough withheld approximately \$11,628,000 from its royalty payment relating to the second quarter of 2001. The amount withheld was purportedly intended by Schering-Plough to be a retroactive adjustment of royalties previously paid to ICN through the third quarter of 2000 on products distributed as part of this indigent patient marketing program. Since the fourth quarter of 2000, Schering-Plough has withheld on a current basis all royalty payments purportedly related to this indigent patient marketing program. The Company recognized the \$11,628,000 of withheld royalty payments for the retroactive adjustment and \$3,050,000 of royalty payments withheld for the fourth quarter of 2000 and the first quarter of 2001 as income. These amounts appear on the Company's balance sheet as a receivable. The Company has not established a reserve for these amounts because, in the opinion of the Company's management, collectibility is reasonably assured. Since the second quarter of 2001, the Company no longer recognizes any of these withheld royalty payments as income since such amounts can no longer be determined due to lack of information provided by Schering-Plough. ICN and the Company have initiated arbitration with Schering-Plough to collect these royalties and prevent Schering-Plough from withholding royalty payments on future sales. The parties have selected an arbitrator, and the Company currently expects that the arbitration will take place in May or June of 2003. If ICN and the Company do not succeed in the arbitration process, the Company may have to write off all or a portion of this receivable. If ICN and the Company do succeed, the Company will be entitled to receive the royalty payments on these indigent sales withheld by Schering-Plough.



## Edgar Filing: RIBAPHARM INC - Form 10-K

In November 2000, the Company entered into an agreement that provides Schering-Plough with certain rights to license various products the Company may develop. Under the terms of the strategic agreement,

**RIBAPHARM INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Schering-Plough has the option to exclusively license on a worldwide basis up to three compounds that the Company may develop for the treatment of hepatitis C on terms specified in the agreement. The option does not apply to Levovirin or Viramidine. The option is exercisable as to a particular compound at any time prior to the start of Phase 2 clinical studies for that compound. Once it exercises the option with respect to a compound, Schering-Plough is required to take over all developmental costs and responsibility for regulatory approval for that compound.

Under the terms of the agreement, the Company also granted Schering-Plough the right of first/last refusal to license compounds relating to the treatment of infectious diseases (other than hepatitis C) or cancer or other oncology indications as well as the right of first/last refusal with respect to Levovirin and Viramidine (collectively, the "Refusal Rights"). Under the terms of the Refusal Rights, if the Company intends to offer a license or other rights with respect to any of these compounds to a third party, the Company is required to notify Schering-Plough. At Schering-Plough's request, the Company is required to negotiate in good faith with Schering-Plough on an exclusive basis the terms of a mutually acceptable exclusive worldwide license or other form of agreement on commercial terms to be mutually agreed upon. If the Company cannot reach an agreement with Schering-Plough, the Company is permitted to negotiate a license agreement or other arrangement with a third party. Prior to entering into any final arrangement with the third party, the Company is required to offer substantially similar terms to Schering-Plough, which terms Schering-Plough has the right to match.

If Schering-Plough does not exercise its option or Refusal Rights as to a particular compound, the Company may continue to develop that compound or license that compound to other third parties. The agreement with Schering-Plough will terminate the later of 12 years from the date of the agreement or the termination of the 1995 license agreement with Schering-Plough. The agreement was entered into as part of the resolution of claims asserted by Schering-Plough against the Company, including claims regarding the Company's alleged improper hiring of former Schering-Plough research and development personnel and claims that the Company was not permitted to conduct hepatitis C research.

In June 2001, the Company licensed Levovirin to Roche. The Company's agreement with Schering-Plough granted Schering-Plough Refusal Rights for Levovirin. Although the Company believes it has complied with the Refusal Rights, Schering-Plough may allege that the Company has not complied with the Refusal Rights to Levovirin.

**4. Property, Plant and Equipment**

Property, plant and equipment at December 31, 2002 and 2001 consists of the following (table in thousands):

	<u>2002</u>	<u>2001</u>
Machinery and equipment	\$ 17,501	\$ 14,577
Furniture and fixtures	1,011	992
Leasehold improvements	77	77
	<u>18,589</u>	<u>15,646</u>
Accumulated depreciation	(8,085)	(5,240)

	<u>\$ 10,504</u>	<u>\$ 10,406</u>
--	------------------	------------------

## RIBAPHARM INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## 5. Accrued Liabilities

Accrued liabilities at December 31, 2002 and 2001 consists of the following (table in thousands):

	2002	2001
Payroll, benefits and related items	\$ 5,834	\$ 311
Accrued consulting fees	5,366	4,035
Accrued legal fees	2,690	
Accrued royalty rebates and concessions	9,829	
Other	410	
	<u>\$ 24,129</u>	<u>\$ 4,346</u>

The Company estimates the amounts of commercial and governmental rebates and concessions that will be paid in subsequent periods for those products sold during the current period, and accordingly accrues those estimated amounts as a liability.

## 6. Long-term Debt

Long-term debt at December 31, 2002 and 2001 consists of the following (table in thousands):

	2002	2001
6 ½% subordinated notes, due 2008	\$ 465,590	\$

In July 2001, ICN completed an offering of \$525,000,000 of 6½% convertible subordinated notes due 2008 (the "Notes"). In July and August 2002, ICN repurchased \$59,410,000 principal amount of the Notes. The Notes, as they relate specifically to ICN's obligation, are convertible into ICN's common stock at a conversion rate of 29.1924 shares per \$1,000 principal amount of Notes, subject to adjustment. Upon completion of the IPO on April 17, 2002, the Company became jointly and severally liable for the principal and interest obligations under the Notes. Under an agreement between the Company and ICN originally entered into on July 18, 2001, and amended and restated on April 8, 2002, ICN has agreed to make all interest and principal payments related to the Notes. However, the Company is responsible for these payments to the extent ICN defaults under that agreement and does not make these payments. In that event, the Company would have a claim against ICN for any payments

## Edgar Filing: RIBAPHARM INC - Form 10-K

ICN does not make. The Company can only amend this agreement, in a manner adverse to it, with the approval of holders of a majority of its outstanding shares of common stock, excluding shares held by ICN. In the event of a spin-off of the Company, the Notes will be convertible into common stock of both the Company and ICN. The converting note holders would receive ICN's common stock and the number of shares of the Company's common stock the note holders would have received had the Notes been converted immediately prior to the spin-off. If the spin-off had occurred as of December 31, 2002, and assuming 84,066,259 shares of ICN common stock were outstanding at December 31, 2002, the Notes would have been convertible into the equivalent of approximately 19,417,563 shares of common stock, which would be issuable by the Company.

The balance sheet as of December 31, 2002 gives effect to the joint and several obligations under the Notes to which the Company became liable upon completion of the IPO. Upon completion of the IPO, the Company recorded the obligation under the Notes as a receivable from ICN within stockholders' equity. This receivable from ICN will remain as a reduction of the Company's equity to the extent that an obligation for principal and interest for the Notes remains outstanding or until ICN can no longer make principal and interest payments as discussed above. The amount of the receivable from ICN will increase as the Company accrues interest on the Notes. Correspondingly, the amount of the receivable and the accrued interest will decrease as interest payments

---

**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

are made by ICN. If the Company is required to make a principal or interest payment because of a default by ICN and the Company is not reimbursed for this payment, the Company will record a provision for doubtful accounts against the receivable from ICN with an offsetting charge to bad debt expense. To the extent ICN defaults on an interest payment before the Notes become due, the Company would assess the overall collectibility of the receivable from ICN, which may result in an additional charge to bad debt expense. See Note 7 of Notes to Financial Statements regarding Related Party Transactions.

There were no machinery and equipment recorded under capital leases at December 31, 2002 and 2001.

**7. Related Party Transactions**

At the time of the IPO, the Company and ICN entered into an affiliation and distribution agreement, which places restrictions on the Company's ability to issue capital stock to ensure that the Company remains part of ICN's consolidated group for tax purposes; a management services and facilities agreement, which details ICN's agreement to provide the Company with interim administrative and corporate services; a lease agreement, which provides the Company a long-term lease in ICN's Costa Mesa facility; a confidentiality agreement, which provides that the Company and ICN will not disclose to third parties confidential and proprietary information concerning each other; a registration rights agreement, which grants ICN rights to require the Company to register shares of the Company common stock owned by ICN; and a tax sharing agreement, which allocates liability for taxes between ICN and the Company.

The lease agreement with ICN provides for a lease payment of \$5,000,000 per year, plus consumer price index increases, for five years, with a five-year option to renew. The lease expires in April 2007. The lease is accounted for as an operating lease by the Company. In connection with the lease agreement, the Company pays, in addition to the lease payment, ICN for its pro rata portion of common charges for the building.

Prior to the IPO, all amounts receivable from the license agreement with Schering-Plough were transferred to ICN on a quarterly basis. Additionally, all excess cash remaining after payment by the Company of its costs were transferred to ICN. All royalties earned subsequent to the IPO were retained by the Company.

At the time of the IPO, ICN agreed to provide the Company with working capital financing which the Company could draw upon until August 31, 2002. At December 31, 2002 the Company has an outstanding borrowing of \$35,000,000 from ICN under the credit facility, payable on or before December 31, 2003, which was required to fund the initial operations of the Company after the IPO. Interest is charged based upon LIBOR (1.37% at December 31, 2002) plus 200 basis points.

**RIBAPHARM INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Following is a summary of transactions between the Company and ICN for 2002, 2001 and 2000 (table in thousands):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Allocation of costs of shared services:			
Legal expenses and professional services	\$ 1,359	\$ 876	\$ 7,637
Facility and central service costs	1,682	1,967	2,425
Corporate development		635	
Information systems	378	116	36
Shared services	466		
Income taxes, net	74,059	40,487	48,717
Decrease in royalty receivable transferred to ICN	(2,546)	(19,351)	(614)
Rent charge	3,750		
Interest on line of credit	1,004		
Draw on line of credit	35,000		
Payments by ICN on behalf of the Company	1,342		
Cash transferred to or retained by ICN	(96,028)	(82,269)	(133,340)
Transfer to retained earnings	222,240		
	<u>242,706</u>	<u>(57,539)</u>	<u>(75,139)</u>

For the years ended December 31, 2002, 2001 and 2000, allocated costs amounted to \$3,885,000, \$3,594,000 and \$10,098,000 respectively, and are included in operating expenses. For the years ended December 31, 2002, 2001 and 2000, the legal expenses and professional fees allocation includes amounts related to the U.S. Attorney investigation and SEC litigation of \$735,000, \$323,000 and \$6,190,000, respectively.

Following is a summary of transactions between the Company and ICN for the period from January 1, 2002 to April 17, 2002 (the completion of the IPO (table in thousands)):

	<u>Advances due</u>
	<u>from ICN</u>
Balance, December 31, 2001	\$ (188,017)
Allocation of costs of shared services:	
Legal expenses and professional services	1,298
Facility and central service costs	371
Information systems	37
Shared services	56
Allocation of current income tax expense	22,844

Edgar Filing: RIBAPHARM INC - Form 10-K

Decrease in royalty receivable transferred to ICN	(2,546)
Royalty allocated to ICN	(11,478)
Cash transferred to or retained by ICN	(44,805)
	<hr/>
	(222,240)
Transfer to retained earnings	222,240
	<hr/>
Balance, April 17, 2002	\$
	<hr/>



**RIBAPHARM INC.****NOTES TO FINANCIAL STATEMENTS (Continued)**

Following is a summary of transactions between the Company and ICN for the period from April 18, 2002 to December 31, 2002 (table in thousands):

	<b>Due</b>
	<b>to ICN</b>
	<b>_____</b>
Balance, April 18, 2002	\$
Allocation of costs of shared services:	
Legal expenses and professional services	61
Facility and central service costs	1,311
Information systems	341
Shared services	410
Royalty allocated to ICN	11,478
Rent charge	3,750
Interest on line of credit	1,004
Payments by ICN on behalf of the Company	1,342
Cash transferred to ICN	(15,431)
	<b>_____</b>
Balance December 31, 2002	<b>\$ 4,266</b>
	<b>_____</b>

	<b>Income</b>
	<b>Taxes</b>
	<b>Payable to</b>
	<b>ICN</b>
	<b>_____</b>
Balance, April 18, 2002	\$
Allocation of current income tax expense	53,242)
Payments to ICN	(35,792)
	<b>_____</b>
Balance, December 31, 2002	<b>\$ 17,450</b>
	<b>_____</b>

**Deferred****Income****Tax**

Edgar Filing: RIBAPHARM INC - Form 10-K

Balance, April 18, 2002	\$
Allocation of deferred income tax benefit	(2,027)
	<hr/>
Deferred tax asset, net	\$ (2,027)
	<hr/>

	<b>Line of</b>
	<b>Credit</b>
	<b>from ICN</b>
	<hr/>
Balance, April 18, 2002	\$
Draw on line of credit	35,000
	<hr/>
Balance, December 31, 2002	\$ 35,000
	<hr/>

**8. Income Taxes**

The Company's operations are included in the consolidated ICN tax returns. Income tax provisions and benefits have been calculated on a separate return basis for federal income tax purposes and based upon ICN's worldwide apportioned rate for the State of California. The worldwide apportioned rate for the State of California was estimated to be 1% for the twelve months ended December 31, 2002, 2001 and 2000. Deferred income taxes are calculated using the estimated future tax effects or differences between financial statement carrying amounts and the tax bases of assets and liabilities. The Company and ICN are parties to a tax sharing agreement.

## RIBAPHARM INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

The Company's effective tax rate for the years ended 2002, 2001 and 2000 was 36%, 36% and 37%, respectively. The income tax provision for each of the years ended December 31, consists of the following (table in thousands):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Current			
Federal	\$ 71,628	\$ 39,363	\$ 47,364
State	4,458	1,124	1,353
	<u>76,086</u>	<u>40,487</u>	<u>48,717</u>
Deferred			
Federal	(2,000)		
State	(27)		
	<u>(2,027)</u>		
	<u>\$ 74,059</u>	<u>\$ 40,487</u>	<u>\$ 48,717</u>

The primary components of the Company's net deferred tax asset at December 31, 2002 and 2001 are as follows (table in thousands):

	<u>2002</u>	<u>2001</u>
Deferred tax assets:		
State income tax benefit	\$ 1,536	\$
Accrued expenses	1,049	
Other	149	
	<u>2,734</u>	<u>\$</u>
Total deferred tax asset		
Deferred tax liabilities:		
Fixed assets, due to depreciation	(707)	
	<u>(707)</u>	
Total deferred tax liability		
	<u>\$ 2,027</u>	<u>\$</u>
Net deferred tax asset		

## Edgar Filing: RIBAPHARM INC - Form 10-K

The Company's effective tax rate differs from the applicable U.S. statutory federal income tax rate due to the following:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Statutory rate	35%	35%	35%
State taxes, net of federal benefit	1	1	1
Other, net			1
Effective rate	<u>36%</u>	<u>36%</u>	<u>37%</u>

**RIBAPHARM INC.****NOTES TO FINANCIAL STATEMENTS (Continued)****9. Earnings Per Share**

The following table sets forth the computation of basic and diluted earnings per share (table in thousands, except per share data):

	<u>2002</u>	<u>2001</u>	<u>2000</u>
<b>Income:</b>			
Numerator for basic and diluted earnings per share	\$ 129,241	\$ 71,978	\$ 81,983
<b>Shares:</b>			
Denominator for basic earnings per share	150,000	150,000	150,000
Effect of potential dilutive securities:			
Employee stock options	10		
Denominator for diluted earnings per share	150,010	150,000	150,000
Basic earnings per share	\$ 0.86	\$ 0.48	\$ 0.55
Diluted earnings per share	\$ 0.86	\$ 0.48	\$ 0.55

The above calculation does not give effect to shares that could become issuable to holders of the convertible Notes in the event of a spin-off of the Company.

**10. Common Stock**

The 2002 Stock Option and Award Plan (the "2002 Plan") was adopted on April 10, 2002 by the Company's Board of Directors and approved by ICN as the sole shareholder. Accordingly, disclosure information for 2001 and 2000 is not applicable and it is not included. The 2002 Plan provides for the granting of options to purchase a maximum of 22,500,000 shares of the Company's common stock to directors, officers, employees and consultants of the Company, ICN and ICN's other affiliates. Options granted under the 2002 Plan will have an exercise price not less than the fair market value of the Company's common stock at the date of grant and a term not exceeding 10 years. Options granted to the Company's employees, officers, directors and consultants will vest ratably over a four year period from the date of the grant. Options granted to officers and employees of ICN will vest immediately upon being granted. No options will be exercisable until the earlier of the completion of a spin-off of the Company, a change of control of the Company, or September 30, 2003. As of December 31, 2002, 3,996,050 options have been granted under the 2002 Plan.

Edgar Filing: RIBAPHARM INC - Form 10-K

The following table sets forth information relating to the 2002 Plan during the year ended December 31, 2002 (table in thousands, except per share data):

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Shares under option, December 31, 2001		\$
Granted	4,017	8.91
Exercised		
Canceled	(21)	10.00
	<u>          </u>	
Shares under option, December 31, 2002	3,996	8.91
Exercisable at December 31, 2002		\$
	<u>          </u>	
Options available for grant at December 31, 2002	<u>18,504</u>	

## RIBAPHARM INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

The schedule below reflects the number of outstanding options as of December 31, 2002, segregated by price range (table in thousands, except per share data and years):

Range of Exercise Prices	Outstanding		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
\$4.06 to \$5.60	972	\$ 5.52	9.92
\$9.35 to \$10.00	3,024	\$ 10.00	9.28
	3,996		

Based on the terms of the 2002 Plan, no options were exercised at December 31, 2002.

The pro forma included in Note 2 were estimated using the Black-Scholes option-pricing model with the following assumptions:

	2002
Weighted-average life in years	4.17
Volatility	77.00%
Expected dividend per share	\$ 0.00
Risk-free interest rate	2.55%
Weighted-average fair value of options granted	\$ 5.28

The Black-Scholes option valuation model was developed for estimating the fair value of traded options that have no vesting restricting and are fully transferable. Because option valuation models require the use of subjective assumptions, changes in these assumptions can materially affect the fair value of the options, and the Company's options do not have the characteristics of traded options, the option valuation models do not necessarily provide a reliable measure of the fair value of its options.

## 11. Commitments and Contingencies

## Edgar Filing: RIBAPHARM INC - Form 10-K

*SEC:* On August 11, 1999, the United States Securities and Exchange Commission (the SEC) filed a civil complaint in the United States District Court for the Central District of California captioned Securities and Exchange Commission v. ICN Pharmaceuticals, Inc., Milan Panic, Nils O. Johannesson, and David C. Watt, Civil Action No. SACV 99-1016 DOC (ANx) (the SEC Complaint). The SEC Complaint alleges that ICN and the individual named defendants made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading and engaged in acts, practices, and courses of business which operated as a fraud and deceit upon other persons in violation of Section 10(b) of the Securities Exchange Act of 1934 (the Exchange Act) and Rule 10b-5 promulgated thereunder. The SEC Complaint concerned the status and disposition of ICN's 1994 New Drug Application for ribavirin as a monotherapy treatment for chronic hepatitis C (the NDA). The United States Food and Drug Administration (the FDA) did not approve this NDA. The SEC Complaint sought injunctive relief, unspecified civil penalties, and an order barring Mr. Panic from acting as an officer or director of any publicly traded company, which would include the Company.

In the fall of 2002, counsel for the defendants and the SEC reached an agreement to settle the SEC Complaint. The court issued a final judgment embodying the terms of the settlement with ICN on November 27, 2002. Under the terms of the settlement, ICN, without admitting or denying liability, consented to the entry of a



---

**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

consent judgment permanently enjoining it from violating Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, and consented to various corporate governance undertakings regarding FDA-related press releases (the Undertakings). Because the settlement agreement explicitly acknowledged that a change of control of ICN occurred on May 29, 2002, ICN can apply for termination of the Undertakings upon a showing of good cause eighteen months after entry of the judgment. ICN has advised the Company that the Undertakings also apply to the Company unless, after a spin-off or other change in control of the Company, the court grants the Company, upon application, early termination of these restrictions.

The Undertakings generally require ICN to establish a Board Committee responsible for establishing policies and procedures regarding the issuance of FDA-related press releases in general, and approving specific contents of such press releases. ICN must also retain an expert to review such policies and procedures, train the Board and Board-appointed officers, and conduct an annual review of ICN's FDA-related disclosure policies. ICN must pre-clear all FDA-related press releases with the FDA, and submit copies of such press releases to the expert. ICN is in the process of implementing the Undertakings, and has retained for purposes of the Undertakings the same expert it has retained for purposes of the compliance program described below.

*U.S. District Court:* On December 17, 2001, ICN pleaded guilty in the United States District Court for the Central District of California to a single felony count for securities fraud for omitting to disclose until February 17, 1995, the existence and content of a letter ICN received from the FDA in late 1994 regarding the not approvable status of the NDA. This guilty plea was entered pursuant to a plea agreement with the office of the United States Attorney for the Central District of California (the Office) to settle a six-year investigation. ICN paid a fine of \$5,600,000 and became subject to a three-year term of probation. The plea agreement provides that the Office will not further prosecute ICN and will not bring any further criminal charges against ICN or any individuals, relating to any matters that have been the subject of the investigation and will close its investigation of these matters.

The conditions of the probation require ICN to create a compliance program to ensure no future violations of the federal securities laws and to pre-clear with the FDA any public communication by ICN concerning any matter subject to FDA regulation. The terms of the compliance program include ICN retaining an expert to review its procedures for public communications regarding matters subject to FDA regulation and to develop written procedures for these communications. The compliance program also requires preparation of an annual report by the expert on ICN's compliance with the written procedures and annual certification by ICN management that ICN is complying with the expert's recommendations. ICN has advised the Company that these conditions of probation also apply to the Company unless, after a spin-off or other change in control of the Company occurs, the District Court grants the Company, upon application, early termination of the probation. Due to the results of ICN's 2002 Annual Stockholders meeting and the resulting change of control, as defined in the plea agreement, ICN has requested early termination of the probation. There can be no assurance that the court will grant the request.

*Generic Litigation:* Three generic pharmaceutical companies, Geneva Pharmaceuticals Technology Corporation, which was recently merged into its parent, Geneva Pharmaceuticals, Inc. (Geneva), Three Rivers Pharmaceuticals, LLC (Three Rivers) and Teva Pharmaceuticals USA, Inc. (Teva), have filed Abbreviated New Drug Applications (ANDA) with the FDA to market generic forms of ribavirin for use as part of a combination therapy for the treatment of hepatitis C. ICN and the Company have sued all three of these pharmaceutical companies to prevent them from marketing a generic form of ribavirin. The cases are all before the same judge, and have been coordinated with respect to a common trial date, which is currently set for June 2, 2003 in the Geneva lawsuit. Summary judgment motions were filed by the defendants, with hearing set for March 31, 2003. Schering-Plough also sued all three of these companies to prevent them from marketing a generic form of ribavirin. The Federal Food, Drug and Cosmetic Act, as amended by the Drug Price Competition



---

**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, generally prohibits the FDA from giving final marketing approval to these abbreviated new drug applications for 30 months after the applicants notify the Company of their intent to seek approval from the FDA. However, the FDA could grant marketing approval prior to expiration of this 30-month stay if a court rules that the Company's patents are invalid or unenforceable or that a generic manufacturer of ribavirin would not infringe the Company's patents, or if a court determines that a party has unreasonably delayed the progress of the patent litigation.

On February 7, 2003, Schering-Plough announced that it had entered into a licensing agreement with Three Rivers that will settle all patent litigation between the two companies regarding Schering-Plough's U.S. patents relating to ribavirin and its use in treating hepatitis C. Three Rivers has an ANDA currently pending with the FDA that seeks approval to market a generic ribavirin product. Schering-Plough markets ribavirin, USP capsules under the brand name Rebetol®. Under terms of the agreement, Schering-Plough granted to Three Rivers a non-exclusive, non-sublicensable license to its U.S. ribavirin patents. Three Rivers will pay to Schering-Plough a royalty on its ribavirin sales. The agreement does not affect Three Rivers' litigation with the Company. The agreement is subject to the courts' dismissal of the relevant lawsuits. Schering-Plough also reported that patent litigation with Geneva and Teva relative to Schering-Plough's U.S. ribavirin patents has been temporarily stayed while the parties seek to reach a settlement. The Company believes its patent position to be unchanged by Schering-Plough's settlement with Three Rivers, and intends to vigorously defend its own position in court. Schering-Plough's settlement is only relevant to the United States market.

*Name Infringement:* On June 11, 2002 a company called RiboPharm, Inc. filed a suit in the United States District Court for the Central District of California against the Company alleging trademark infringement under the Lanham Act and false advertising, unfair business practices and unfair competition under California law. In December 2002, the Company agreed upon a settlement with RiboPharm, that allows the Company to use the Ribapharm name. As part of the settlement, the Company paid \$700,000 to RiboPharm.

*Product Liability Insurance:* The Company is currently self-insured with respect to product liability claims and could be exposed to possible claims for personal injury resulting from allegedly defective products pre- and post-regulatory approval. While to date no material adverse claim for personal injury resulting from allegedly defective products has been successfully maintained against the Company, a substantial claim, if successful, could have a negative impact on the results of operations and cash flows of the Company.

*Benefits Plans:* The Company has a defined contribution plan that provides all U.S. employees the opportunity to defer a portion of their compensation for payout at a subsequent date. The Company can voluntarily make matching contributions on behalf of participating and eligible employees. The Company's expense related to such defined contribution plan was not material in 2002, 2001 and 2000.

**12. Supplemental Cash Flow Disclosures**

The following table sets forth the amount of income taxes paid during 2002, 2001 and 2000 (table in thousands):

Edgar Filing: RIBAPHARM INC - Form 10-K

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Income taxes paid	\$ 35,792	\$	\$

No interest payments were made in 2002. All interest and income taxes cash payments are owed or were paid to ICN. Additionally, upon consummation of the IPO, advances due from ICN of \$222,240,000 were treated similar to a dividend and recorded by the Company as a reduction of its retained earnings. The Company received no repayments of the advances.

---

**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**13. Subsequent Events**

*Roche:* Roche has developed and is in the process of marketing its own version of ribavirin, known as Copegus, for use in combination therapy with Roche's version of pegylated interferon, called Pegasys, for the treatment of hepatitis C. In order to protect its patent rights, in August 2002, the Company initiated legal action against a subsidiary of Roche in the Netherlands and against Roche in Germany and the United States for infringement of the Company's ribavirin patents. Roche initiated legal action in Switzerland seeking a declaratory judgment that Roche's marketing of ribavirin does not infringe the Company's patents. The Company filed a counter-claim against Roche in the Swiss action for patent infringement.

On January 6, 2003, the Company, ICN, and Roche reached agreement on a settlement regarding pending patent disputes over Roche's combination anti-viral product containing Copegus. The companies agreed to stop all legal actions regarding ribavirin, including the lawsuits filed in the United States. Under the agreement, Roche will continue to register and commercialize Copegus globally. The financial terms of this settlement agreement include a license by the Company of ribavirin to Roche. The license authorized Roche to make, have made and to sell Copegus under the Company's patents. Roche will pay royalty fees to the Company on all sales of the combination product containing Copegus. No royalties under the Roche agreement were earned by or paid to the Company in fiscal year 2002.

*Change in Management:* On December 13, 2002, the Company's Board of Directors adopted an amendment to the amended and restated bylaws of the Company to add a new Section 8(C) (4) to Article I, which sets forth the manner in which advance notice of a proposal of business by shareholders required by the Company's certificate of incorporation must be given and that purports to require the delivery of written notice to the Company of an action to be taken by written shareholder consent at least 35 days prior to the proposed effective date of such action. Further, in early December 2002, the Compensation Committee of the Company's Board of Directors granted significant cash bonuses and stock option awards to the Company's senior management. Such a grant came at a time when the employment agreements with the Company's three senior management personnel entitled them to voluntarily terminate their employment (at any time during the 60-day window period from December 11th to February 9th) and to (a) receive a cash severance payment equal to 300% of their base salary and highest bonus paid during the three years ended prior to the year in which they separate from the Company (including the newly granted bonuses) and (b) obtain accelerated vesting and extended term for all of their options, as well as other benefits. In response, ICN expressed its concern about the timing of the granting of bonuses and options, as it occurred only seven months following the Company's IPO and prior to finalization of 2002 financial results.

Accordingly, on December 23, 2002, ICN acted by written consent pursuant to Section 228 of the Delaware General Corporation Law to remove all directors on the Company's Board, other than Roberts A. Smith, Ph.D., and to amend the Company's bylaws by rescinding the new bylaw provision, effective as of January 27, 2003 or such earlier date as may be ordered by a court of competent jurisdiction. ICN commenced a lawsuit against the Company's directors to be removed in the Chancery Court of the State of Delaware. In connection with this litigation, ICN sought a temporary restraining order to prevent the Company and its Board from taking actions outside the ordinary course of business prior to the effectiveness of ICN's action by written consent. ICN also asked the Court to shorten or eliminate the 35-day notice.

On January 22, 2003, the Company and ICN settled the outstanding litigation involving ICN, the Company and certain of their officers and directors. At that time, the Company's Chairman, President and Chief Executive Officer, Johnson Y.N. Lau, M.D., resigned as an officer and director of the Company, board members Kim Campbell, Arnold H. Kroll, Hans Thierstein and John Vierling, M.D., resigned as directors, and

Edgar Filing: RIBAPHARM INC - Form 10-K

the Company's Senior Vice President and Chief Financial Officer, Thomas Stankovich, and Senior Vice President, General

---

**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

Counsel and Secretary, Roger D. Loomis, Jr., also resigned their positions, effective immediately. On January 23, 2003, the Company announced that the following additional individuals had been elected by Roberts A. Smith, Ph.D., its sole remaining director, to serve as members of its Board of Directors, effective immediately: Daniel J. Paracka, Santo J. Costa, Esquire, Gregory F. Boron and James J. Pieczynski. Mr. Paracka was also elected to serve as Chairman. The Company also announced on January 23, 2003, the appointment of Kim D. Lamon, M.D., Ph.D., to the position of President and Chief Executive Officer and, on February 3, 2003, the appointments of William M. Comer, Jr., CPA, to the position of Vice President and Chief Financial Officer, and Mel D. Deutsch, Esquire, to the position of Vice President, General Counsel and Secretary. A sixth director, Andre C. Dimitriadis, Ph.D., was elected to the Board on February 21, 2003.

Effective January 27, 2003, the Amended and Restated Bylaws of the Company were amended (by action of ICN as its majority stockholder, taken on December 23, 2002) rescinding the new bylaw provision adopted by the board of directors of the Company on December 13, 2002, which required notice of any action by written consent of stockholders to be made to the Company at least 35 days prior to effectiveness thereof.

In connection with the resignations of the Company's three former executives on January 22, 2003, and in accordance with the terms of the executives' pre-existing employment agreements, which were previously disclosed in connection with the Company's initial public offering and in several subsequent filings by both ICN and the Company, the Company became obligated to make cash payments to the executives totaling \$5,334,000 in the aggregate, and may be required to make additional cash payments covering any excise tax payable under the Internal Revenue Code in connection with such payments. The \$5,334,000 in severance payments is accrued at December 31, 2002. In addition, the vesting of options granted to the executives pursuant to the Company's 2002 Stock Option and Award Plan was accelerated in accordance with provisions in their employment agreements; however, such options were not in-the-money and therefore were not recognized as compensation expense in compliance with APB 25, Accounting for Employee Stock Options.

**14. Subsequent Events Unaudited**

*Generic Litigation:* On March 26, 2003, Schering-Plough announced that it had entered into licensing agreements with the remaining two generic pharmaceutical companies, Geneva and Teva, thereby settling all patent litigation between Schering-Plough and the two companies regarding Schering-Plough's U.S. patents relating to ribavirin and its use in treating hepatitis C. Geneva, Three Rivers and Teva each has an ANDA currently pending with the FDA that seeks approval to market a generic ribavirin product. Schering-Plough markets ribavirin, USP capsules under the brand name Rebetol®. As with Three Rivers, under terms of the agreements, Schering-Plough granted to Geneva and Teva a non-exclusive, non-sublicensable license to its U.S. ribavirin patents. The licensees will pay to Schering-Plough a royalty on their ribavirin sales. Schering-Plough's agreements do not affect the three companies' litigation with the Company. The agreements are subject to the courts' dismissal of the relevant lawsuits. The Company believes its patent position to be unchanged by Schering-Plough's settlement with Geneva, Three Rivers and Teva, and intends to vigorously defend its own position in court. Schering-Plough's settlement is only relevant to the United States market.

*Line of Credit with ICN:* On March 28, 2003, the Company entered into an amendment to the line of credit facility with ICN which allows the Company to make draws against the line of credit, if needed, to the extent of cumulative repayments made by the Company, up to a maximum available credit limit of \$35,000,000. Subject to approval by ICN's Board of Directors, the amended expiration date would be the earlier of December 29, 2005 or the date on which ICN ceases to be the beneficial owner of at least 80% of the issued and outstanding common stock of the Company; however, unless and until such approval is obtained, the expiration date will remain at





**RIBAPHARM INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

December 31, 2003. Additionally, it was the Company's desire, and ICN agreed as a condition to the amendment, to repay ICN on the date of the amendment the aggregate outstanding principal balance and related accrued interest, without requirement to comply with a prior notice obligation. Accordingly, on March 28, 2003, the Company repaid principal and interest in the amounts of \$35,000,000 and \$984,000, respectively. Prior to this amendment, ICN was obligated to make loans to the Company only prior to August 31, 2002, and the Company was required to repay all loans in full no later than December 31, 2003.

**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

**PART III**

**Item 10. *Directors and Executive Officers of the Registrant***

The information required under this Item is set forth under the captions "Information Concerning Nominees and Directors" and "Executive Officers" in the Company's definitive Proxy Statement to be filed in connection with the Company's 2003 annual meeting of stockholders (the "Proxy Statement") and is incorporated by reference.

**Item 11. *Executive Compensation***

The information required under this Item is set forth under the caption "Executive Compensation and Related Matters" in the Proxy Statement and is incorporated by reference.

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

The information required under this Item is set forth under the captions "Ownership of the Company's Securities" and "Equity Compensation Plan Information" in the Proxy Statement and is incorporated by reference.

**Item 13. *Certain Relationships and Related Transactions***

The information required under this Item is set forth under the captions "Executive Compensation and Related Matters" and "Certain Transactions" in the Proxy Statement and is incorporated by reference.

**Item 14. *Controls and Procedures***

## Edgar Filing: RIBAPHARM INC - Form 10-K

Within 90 days prior to the date of this report, the Company carried out an evaluation, under the supervision and with the participation of management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that Ribapharm's disclosure controls and procedures are effective in timely alerting them to material information relating to the company required to be included in the Company periodic SEC filings. There were no significant changes in the Company's internal controls or other factors that could significantly affect these controls subsequent to the date of their evaluation and there were no corrective actions with regard to significant deficiencies and material weakness.

### PART IV

#### **Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

##### (a) 1. *Financial Statements*

Financial Statements of the Registrant are listed in the index to Financial Statements and filed under Item 8, Financial Statements and Supplementary Data, included elsewhere in this Form 10-K.

## 3. Exhibits

<b>Exhibit</b>	
<b>Number</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of Ribapharm Inc. Previously filed as Exhibit 3.1 to Ribapharm's Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Ribapharm Inc.
4.1	Indenture, dated as of July 18, 2001, by and among ICN Pharmaceuticals, Inc., Ribapharm Inc. and The Bank of New York, as trustee, relating to the 6 ½% Convertible Subordinated Notes due 2008. Previously filed as Exhibit 4.1 to ICN Pharmaceuticals, Inc.'s Registration Statement No. 333-67376 on Form S-3 and incorporated herein by reference.
4.2	Registration Rights Agreement, dated as of July 18, 2001, by and among ICN Pharmaceuticals, Inc., Ribapharm Inc. and UBS Warburg LLC. Previously filed as Exhibit 4.2 to ICN Pharmaceuticals Inc.'s Registration Statement No. 333-67376 on Form S-3 and incorporated herein by reference.
4.3	Registration Rights Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.1	Affiliation and Distribution Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.2	Management Services Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.3	Confidentiality Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.4	Tax Sharing Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.5	Form of Indemnification Agreement between Ribapharm Inc. and its directors and executive officers. Previously filed as Exhibit 10.8 to Ribapharm's Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.6	Lease between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.7	Interdebtor Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc. with respect to the 6 ½% Convertible Subordinated Notes, due 2008.
10.8	Exclusive License and Supply Agreement between ICN Pharmaceuticals, Inc. and Schering-Plough Ltd. dated July 28, 1995. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.10 to Ribapharm Inc.'s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.9	Amendment to Exclusive License and Supply Agreement between ICN Pharmaceuticals, Inc. and Schering-Plough Ltd. dated January 20, 1998. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.11 to Ribapharm Inc.'s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.10	Amendment to Exclusive License and Supply Agreement between ICN Pharmaceuticals, Inc. and Schering-Plough Ltd. dated July 16, 1998. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.12 to Ribapharm Inc.'s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.

<u>Exhibit</u>	
<u>Number</u>	<u>Description</u>
10.11	Agreement among Schering Corporation, ICN Pharmaceuticals, Inc. and Ribapharm Inc. dated as of November 14, 2000. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.13 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.12	Exchange Agreement among Hoffmann-La Roche, Inc., F. Hoffmann-La Roche Ltd., Ribapharm Inc. and ICN Puerto Rico, a division of ICN Dutch Holdings, B.V., dated as of June 29, 2001. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.15 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.13	Transfer Agreement among F. Hoffmann-La Roche Ltd., Hoffmann-La Roche, Inc., and ICN Puerto Rico, dated as of June 29, 2001. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.16 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.14	License Agreement among Ribapharm Inc., Hoffmann-La Roche, Inc. and F. Hoffmann-La Roche Ltd., dated as of June 29, 2001. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Previously filed as Exhibit 10.1 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 and incorporated herein by reference.
10.15	Development and License Agreement between Metabasis Therapeutics, Inc. and ICN Pharmaceuticals, Inc., dated as of October 1, 2001. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.18 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.16	Agreement by and among Ribapharm Inc., ICN Pharmaceuticals, Inc., Hoffmann-LaRoche Inc., and F. Hoffmann-LaRoche Ltd. dated as of January 6, 2003.*
10.17	Ribapharm Inc. 2002 Stock Option and Award Plan. Previously filed as Exhibit 10.1 to Ribapharm s Registration Statement No. 333-39350 on Form S-1 and incorporated hereby by reference.
10.18+	Amendment No. 1 to 2002 Stock Option and Award Plan. Previously filed as Exhibit 4.5 to Ribapharm s Registration Statement No. 333-9116 on Form S-8 and incorporated herein by reference.
10.19+	Ribapharm Inc. Employee Stock Purchase Program.
10.20+	Employment Agreement between Ribapharm Inc. and Johnson Yiu-Nam Lau dated as of April 17, 2002. Previously filed as Exhibit 10.19 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.21+	Employment Agreement between Ribapharm Inc. and Thomas Stankovich dated as of April 17, 2002. Previously filed as Exhibit 10.20 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.22+	Employment Agreement between Ribapharm Inc. and Roger D. Loomis, Jr. dated as of April 17, 2002. Previously filed as Exhibit 10.21 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.

<u>Exhibit</u>	
<u>Number</u>	<u>Description</u>
10.23+	Ribapharm Inc. 2002 Amended and Restated Nonemployee Director Retainer Fee Plan. Previously filed as Exhibit 10.2 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 and incorporated herein by reference.
10.24+	Amendment No. 1 to Employment Agreement between Ribapharm Inc. and Johnson Yiu-Nam Lau dated May 17, 2002. Previously filed as Exhibit 10.1 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 and incorporated herein by reference.
10.25+	Amendment No. 1 to Employment Agreement between Ribapharm Inc. and Thomas Stankovich dated May 17, 2002. Previously filed as Exhibit 10.1 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 and incorporated herein by reference.
10.26+	Amendment No. 1 to Employment Agreement between Ribapharm Inc. and Roger D. Loomis, Jr. dated May 17, 2002. Previously filed as Exhibit 10.3 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 and incorporated herein by reference.
10.27+	Settlement Agreement and Mutual Release dated as of January 22, 2003 by and among ICN Pharmaceuticals, Inc., Ribapharm, Inc., Johnson Y.N. Lau, Hans Thierstein, Kim Campbell, Arnold H. Knoll, John Vierling, Roberts A. Smith, Thomas Stankovich, Roger D. Loomis, Jr., and Robert W. O Leary.
10.28	First Amendment to Affiliation and Distribution Agreement dated April 8, 2002, by and between ICN Pharmaceuticals, Inc. and Ribapharm Inc.
23	Consent of PricewaterhouseCoopers LLP, independent accountants

\* Portions of this exhibit have been omitted pursuant to a request for confidential treatment.  
Management Compensation.

(b) *Reports on Form 8-K*

During the quarter ended December 31, 2002, the following reports on Form 8-K were filed by the Registrant.

1. On December 20, 2002, the Registrant filed a current report on Form 8-K to report certain information under Item 5.
2. On December 31, 2002, the Registrant filed a current report on Form 8-K to report certain information under Item 5.
3. On January 3, 2002, the Registrant filed a current report on Form 8-K/A to correct certain information previously reported under Item 5.

**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.

RIBAPHARM INC.

By:           /s/ KIM D. LAMON          

**Kim D. Lamon, M.D.,  
Ph.D.  
Chief Executive Officer  
and President**

Date: March 31, 2003

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

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>          /s/ KIM D. LAMON          </u> <b>Kim D. Lamon, M.D., Ph.D.</b>	Chief Executive Officer and President	Date: March 31, 2003
<u>          /s/ WILLIAM M. COMER, JR.          </u> <b>William M. Comer, Jr.</b>	Vice President and Chief Financial Officer (principal financial and accounting officer)	Date: March 31, 2003
<u>          /s/ DANIEL J. PARACKA          </u> <b>Daniel J. Paracka</b>	Chairman of the Board	Date: March 31, 2003
<u>          /s/ GREGORY F. BORON          </u> <b>Gregory F. Boron</b>	Director	Date: March 31, 2003
<u>          /s/ SANTO J. COSTA          </u> <b>Santo J. Costa</b>	Director	Date: March 31, 2003
<u>          /s/ ANDRE C. DIMITRIADIS          </u> <b>Andre C. Dimitriadis, Ph.D.</b>	Director	Date: March 31, 2003

Edgar Filing: RIBAPHARM INC - Form 10-K

/s/ JAMES J. PIECZYNSKI

---

**James J. Pieczynski**

Director

Date: March 31, 2003

/s/ ROBERTS A. SMITH

---

**Roberts A. Smith, Ph.D.**

Director

Date: March 31, 2003



---

**Form 10-K Certifications**

I, Kim D. Lamon, the President and Chief Executive Officer of Ribapharm Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Ribapharm Inc.;
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 officer 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 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 officer 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 officer 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.

Date: March 31, 2003

/s/ KIM D. LAMON

---

Kim D. Lamon, M.D., Ph.D.

President and Chief Executive Officer

I, William M.Comer, Jr., the Vice President and Chief Financial Officer of Ribapharm Inc., certify that:

1. I have reviewed this annual report on Form 10-K of Ribapharm Inc.;
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 officer 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 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 officer 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 officer 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.

Date: March 31, 2003

/s/ WILLIAM M. COMER, JR.

---

William M. Comer, Jr.



---

**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of Ribapharm Inc. Previously filed as Exhibit 3.1 to Ribapharm's Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Ribapharm Inc.
4.1	Indenture, dated as of July 18, 2001, by and among ICN Pharmaceuticals, Inc., Ribapharm Inc. and The Bank of New York, as trustee, relating to the 6 ½% Convertible Subordinated Notes due 2008. Previously filed as Exhibit 4.1 to ICN Pharmaceuticals, Inc.'s Registration Statement No. 333-67376 on Form S-3 and incorporated herein by reference.
4.2	Registration Rights Agreement, dated as of July 18, 2001, by and among ICN Pharmaceuticals, Inc., Ribapharm Inc. and UBS Warburg LLC. Previously filed as Exhibit 4.2 to ICN Pharmaceuticals Inc.'s Registration Statement No. 333-67376 on Form S-3 and incorporated herein by reference.
4.3	Registration Rights Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.1	Affiliation and Distribution Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.2	Management Services Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.3	Confidentiality Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.4	Tax Sharing Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.5	Form of Indemnification Agreement between Ribapharm Inc. and its directors and executive officers. Previously filed as Exhibit 10.8 to Ribapharm's Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.6	Lease between ICN Pharmaceuticals, Inc. and Ribapharm Inc., dated as of April 8, 2002.
10.7	Interdebtor Agreement between ICN Pharmaceuticals, Inc. and Ribapharm Inc. with respect to the 6 ½% Convertible Subordinated Notes, due 2008.
10.8	Exclusive License and Supply Agreement between ICN Pharmaceuticals, Inc. and Schering-Plough Ltd. dated July 28, 1995. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.10 to Ribapharm Inc.'s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.9	Amendment to Exclusive License and Supply Agreement between ICN Pharmaceuticals, Inc. and Schering-Plough Ltd. dated January 20, 1998. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.11 to Ribapharm Inc.'s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.10	Amendment to Exclusive License and Supply Agreement between ICN Pharmaceuticals, Inc. and Schering-Plough Ltd. dated July 16, 1998. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.12 to Ribapharm Inc.'s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.

Edgar Filing: RIBAPHARM INC - Form 10-K

<u>Exhibit Number</u>	<u>Description</u>
10.11	Agreement among Schering Corporation, ICN Pharmaceuticals, Inc. and Ribapharm Inc. dated as of November 14, 2000. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.13 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.12	Exchange Agreement among Hoffmann-La Roche, Inc., F. Hoffmann-La Roche Ltd., Ribapharm Inc. and ICN Puerto Rico, a division of ICN Dutch Holdings, B.V., dated as of June 29, 2001. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.15 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.13	Transfer Agreement among F. Hoffmann-La Roche Ltd., Hoffmann-La Roche, Inc., and ICN Puerto Rico, dated as of June 29, 2001. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.16 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.14	License Agreement among Ribapharm Inc., Hoffmann-La Roche, Inc. and F. Hoffmann-La Roche Ltd., dated as of June 29, 2001. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended. Previously filed as Exhibit 10.1 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 and incorporated herein by reference.
10.15	Development and License Agreement between Metabasis Therapeutics, Inc. and ICN Pharmaceuticals, Inc., dated as of October 1, 2001. Portions of this exhibit have been omitted pursuant to an application for confidential treatment pursuant to Rule 406 under the Securities Act of 1933, as amended. Previously filed as Exhibit 10.18 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.16	Agreement by and among Ribapharm Inc., ICN Pharmaceuticals, Inc., Hoffmann-LaRoche Inc., and F. Hoffmann-LaRoche Ltd. dated as of January 6, 2003.*
10.17	Ribapharm Inc. 2002 Stock Option and Award Plan. Previously filed as Exhibit 10.1 to Ribapharm s Registration Statement No. 333-39350 on Form S-1 and incorporated hereby by reference.
10.18+	Amendment No. 1 to 2002 Stock Option and Award Plan. Previously filed as Exhibit 4.5 to Ribapharm s Registration Statement No. 333-9116 on Form S-8 and incorporated herein by reference.
10.19+	Ribapharm Inc. Employee Stock Purchase Program.
10.20+	Employment Agreement between Ribapharm Inc. and Johnson Yiu-Nam Lau dated as of April 17, 2002. Previously filed as Exhibit 10.19 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.21+	Employment Agreement between Ribapharm Inc. and Thomas Stankovich dated as of April 17, 2002. Previously filed as Exhibit 10.20 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.
10.22+	Employment Agreement between Ribapharm Inc. and Roger D. Loomis, Jr. dated as of April 17, 2002. Previously filed as Exhibit 10.21 to Ribapharm Inc. s Registration Statement No. 333-39350 on Form S-1 and incorporated herein by reference.

Edgar Filing: RIBAPHARM INC - Form 10-K

<u>Exhibit Number</u>	<u>Description</u>
10.23+	Ribapharm Inc. 2002 Amended and Restated Nonemployee Director Retainer Fee Plan. Previously filed as Exhibit 10.2 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 and incorporated herein by reference.
10.24+	Amendment No. 1 to Employment Agreement between Ribapharm Inc. and Johnson Yiu-Nam Lau dated May 17, 2002. Previously filed as Exhibit 10.1 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 and incorporated herein by reference.
10.25+	Amendment No. 1 to Employment Agreement between Ribapharm Inc. and Thomas Stankovich dated May 17, 2002. Previously filed as Exhibit 10.1 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 and incorporated herein by reference.
10.26+	Amendment No. 1 to Employment Agreement between Ribapharm Inc. and Roger D. Loomis, Jr. dated May 17, 2002. Previously filed as Exhibit 10.3 to Ribapharm Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002 and incorporated herein by reference.
10.27+	Settlement Agreement and Mutual Release dated as of January 22, 2003 by and among ICN Pharmaceuticals, Inc., Ribapharm, Inc., Johnson Y.N. Lau, Hans Thierstein, Kim Campbell, Arnold H. Knoll, John Vierling, Roberts A. Smith, Thomas Stankovich, Roger D. Loomis, Jr., and Robert W. O Leary.
10.28	First Amendment to Affiliation and Distribution Agreement dated April 8, 2002, by and between ICN Pharmaceuticals, Inc. and Ribapharm Inc.
23	Consent of PricewaterhouseCoopers LLP, independent accountants

\* Portions of this exhibit have been omitted pursuant to a request for confidential treatment. Management Compensation.