CYTRX CORP
Form 10-K/A
May 07, 2003
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO

SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended December 31, 2002

OR

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

Commission File No. 0-15327

CYTRX CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	58-1642740
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11726 San Vicente Blvd Suite 650 Los Angeles, California	**90049**
(Address of principal executive offices)	**(Zip Code)**

(310) 826-5648

(Registrant s telephone number, including area code)

Securities registered pursuant to Section l2(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $.001 par value per share

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 and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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 with the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). YES ¨ NO x

The aggregate market value of the Registrant s common stock held by non-affiliates on March 25, 2003 was approximately $8,445,000. On March 25, 2003, there were 21,510,111 shares of the Registrant s common stock outstanding, exclusive of treasury shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SAFE HABOR STATEMENT UNDER THE

PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

From time to time, we make oral and written statements that may constitute forward looking statements (rather than historical facts) as defined in the Private Securities Litigation Reform Act of 1995 or by the Securities and Exchange Commission (the SEC) in its rules, regulations and releases, including Section 27A of the Securities Act of 1933, as amended (the Securities Act) and Section 21E or the Securities Exchange Act of 1934, as amended (the Securities and Exchange Act). We desire to take advantage of the safe harbor provisions in the Private Securities Litigation Reform Act of 1995 for forward looking statements made from time to time, including, but not limited to, the forward looking statements made in this Annual Report on Form 10-K (the Annual Report), as well as those made in other filings with the SEC.

All statements in this Annual Report, including in Management s Discussion and Analysis of Financial Condition and Results of Operations, other than statements of historical fact are forward-looking statements for purposes of these provisions, including any projections of financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates estimates, potential, or could or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein and in documents incorporated by this Annual Report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth in the Risk Factors and for the reasons described elsewhere in this Annual Report. All forward looking statements and reasons why results may differ included in this Annual Report are made as of the date hereof, and we assume no obligation to update any such forward-looking statement or reason why actual results might differ.

We do not have, and expressly disclaim, any obligation to release publicly any updates or any changes in our expectations or any changes in events, conditions or circumstances on which any forward looking statement is based.

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PART I

Item 1. Business

General

We are a Delaware corporation that was incorporated in 1985 and is engaged in the development and commercialization of pharmaceutical products. Our current products are FLOCOR, an intravenous agent for treatment of sickle cell disease and other acute vaso-occlusive disorders, and TranzFect, a delivery technology for DNA and conventional-based vaccines. Sickle cell disease is an inherited disease caused by a genetic mutation of hemoglobin in the blood, and acute vaso-occlusive disorders are a blockage of blood flow caused by deformed or sickled red blood cells which can cause intense pain in sickle cell disease patients. We are currently seeking strategic partners or licensees to complete the development of FLOCOR, and TranzFect is currently being developed by our two licensees for this technology. We are seeking to license our TranzFect technology to a strategic partner or licensee for development as a potential DNA-based prostate cancer adjuvant and may also seek to license this technology as a potential conventional adjuvant for hepatitis B and C, flu, malaria and other viral diseases. (Adjuvants are agents added to a vaccine to increase its effectiveness.) Our technologies also have potential applications in the areas of spinal cord injury, vaccine delivery and gene therapy. In addition, we own minority interests in two development stage genomics companies, which are described under Recent Developments.

Certain financial information concerning the industry segments in which we operate can be found in Note 17 to our Consolidated Financial Statements.

Product Development

Subsequent to our merger with Global Genomics Capital, Inc. in July 2002, we modified our corporate business strategy by discontinuing any additional internal research and development efforts for any of our existing products or technologies. We have, instead, more recently focused our efforts on obtaining strategic alliances, license partners or other collaborative arrangements with larger pharmaceutical companies for FLOCOR and TranzFect. Our spending for each of these technologies now will primarily relate to maintaining patents and other agreements as required under our existing license agreements and to support our additional licensing efforts. We may also pursue product acquisition opportunities. These product acquisition activities could include our acquisition through a merger of one or more privately held companies possessing existing or potential products or technologies that we consider to be attractive, although we have not entered into any commitments to merge with or acquire any other company.

Therapeutic Copolymer Programs

General. The primary focus of our internal development activities has been on CRL-5861 (purified poloxamer 188), which we also call FLOCOR for purposes of our potential sickle cell disease product. CRL-5861 is a novel, intra-vascular agent with pharmacological properties that can be characterized as related to improved blood flow, protective of certain cells during chemotherapy and preventive of blood clot formation. CRL-5861 is an intravenous solution that has the unique property of improving micro-vascular blood flow. Extensive preclinical and

clinical studies suggest CRL-5861 may be of significant benefit in acute ischemic vascular disorders such as stroke, heart attack, or vaso-occlusive disorder crisis. These disorders are marked by a decrease in the blood supply to a bodily organ, tissue or part caused by constriction or obstruction of the blood vessels. CRL-5861 may also provide benefit in cancer when used in combination with radiation or cytotoxic drugs, which are drugs that can produce a toxic effect in cells. Through its effect on increasing blood flow, CRL-5861 is thought to (1) increase delivery of cytotoxic drugs to ischemic portions of tumors, and (2) increase oxygen delivery, thus increasing the sensitivity of tumor cells to drug and radiation therapy.

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We believe CRL-5861 may have significant potential in treating a variety of vascular-occlusive diseases, including sickle cell disease, spinal cord compression injury, muscular dystrophy and delivery of anti-cancer agents. The safety profile of CRL-5861 is well established. It has been investigated in over 17 clinical studies representing administration to approximately 4,000 patients and healthy volunteers.

Sickle Cell Disease. Sickle cell disease is a devastating disorder originating from an inherited abnormality of hemoglobin, the oxygen-carrying molecule in red blood cells, which is typically seen in African-Americans and others of African descent. Approximately 72,000 individuals suffer from this disease in the United States. Under conditions of low blood oxygen, which is generally caused by dehydration or stress, the sickle cell victim s hemoglobin becomes rigid, causing red blood cells to become rough, sticky and irregularly shaped, often looking like sickles, which gives the disease its name.

The most common problem sickle cell patients face is episodic pain, also referred to as vaso-occlusive crisis, or VOC. These episodes can last anywhere from days to weeks, and can vary significantly in their severity. Aside from causing considerable pain and suffering, these crisis episodes slowly destroy vital organs as they are deprived of oxygen. As a result, the life expectancy of sickle cell victims is about twenty years shorter than those without the disease. Patients suffering from sickle cell disease may experience several crisis episodes each year. Hospitalization is required when pain becomes too much to bear. Currently, there is no disease modifying treatment for acute crisis of sickle cell disease and treatment is limited to narcotics, fluids and bed rest.

In sickle cell disease, the application of FLOCOR can best be described as an intravenous blood lubricant. FLOCOR s unique surface-active properties decrease blood viscosity and enable the rigid sickled cells to become more flexible, thus allowing easier passage of blood cells through narrow blood vessels. We believe FLOCOR can provide limited periods of relief from pain by shortening the episodes of vaso-occlusive crises and, most importantly, preserve organ function.

In December 1999, we reported results from a Phase III clinical study of FLOCOR for treatment of acute sickle cell crisis. Although the study did not demonstrate statistical significance in the primary endpoint (objective of the study), which was duration of the vaso-occlusive crisis, statistically significant and clinically important benefits associated with FLOCOR were observed in certain subgroups, principally the subgroup of 15 years of age and under. In order to assess when patients were achieving crisis resolution, the data on achievement of crisis resolution were distributed by time. For patients 15 years of age and younger, a statistically significant number of patients achieving resolution of crisis was higher for FLOCOR-treated patients at all time periods than for placebo-treated patients. The Phase III study also demonstrated that FLOCOR is well tolerated.

Following completion of this Phase III study, our Data and Safety Monitoring Board (composed of five independent scientists and two statisticians that we had retained to evaluate the overall safety issues associated with this study) and a group of six well recognized hematologists associated with leading medical centers who we retained as consultants recommended that we continue with clinical development of FLOCOR for the treatment of sickle cell disease. Based on our conversations with the United States Food and Drug Administration (FDA), we believe it is likely that either two small additional pivotal trials or one large trial will be required for FLOCOR s approval, along with one to two additional safety studies. We expect total costs for these additional studies to be in the range of $10,000,000-$12,000,000, although the actual costs could vary substantially, depending on the nature and number of trials that the FDA ultimately would require.

Because of the substantial expenditures that will be required to conduct the required additional clinical testing of FLOCOR, we are not at this time continuing our internal efforts to develop FLOCOR but are, consistent with our new business strategy, seeking a strategic alliance or license arrangement with a larger company to complete the development of FLOCOR and market this product.

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FLOCOR has been granted Orphan Drug designation by the FDA for the treatment of sickle cell crises. The Orphan Drug Act of 1983, as amended, provides incentive to drug manufacturers to develop drugs for the treatment of rare diseases (for example, diseases that affect less than 200,000 individuals in the United States, or diseases that affect more than 200,000 individuals in the United States where the sponsor does not reasonably anticipate that its product will become profitable). As a result of the designation of FLOCOR as an Orphan Drug, if we are the first sponsor to obtain FDA approval to market FLOCOR for treatment of sickle cell crises, we will obtain a seven-year period of marketing exclusivity beginning from the date of FLOCOR s approval. During this period, the FDA may not approve the same drug for the same use from another sponsor.

Spinal Cord Injury. Traumatic spinal cord damage is one of the most devastating injuries imaginable and, unfortunately, occurs primarily in young people, often resulting in complete paralysis. Researchers believe that a significant portion of spinal cord damage results from a secondary progression of damage after the initial injury. This secondary injury results from membrane injury to nerve cells, causing them to lose function over time.

Scientists associated with a major university medical center are currently testing compounds related to CRL-5861 for their ability to interact with damaged nerve membranes in such a way as to seal the damage and restore membrane integrity. If successful, this treatment could limit the progression of secondary, post-injury damage, thereby maintaining or restoring spinal cord function. Assuming the successful outcome of these preliminary studies in animals, which would need to be confirmed in clinical trials, we believe it could be possible for any strategic partner or licensee that we might be able to secure to be able to proceed very quickly with the clinical development of this agent since the program could benefit from the existing safety data and manufacturing capabilities already in place from our FLOCOR program. To proceed with this development, we or our potential strategic partner or licensee would need to enter into a license or other arrangement with the medical center.

Vaccine Enhancement and Gene Therapy

DNA Vaccines & Gene Therapy.

Gene therapy and gene based vaccines are mediated through the delivery of DNA containing selected genes into cells by a process known as transfection. We refer to our gene delivery technology as TranzFect. A common class of materials used to enhance the transfection process are known as cationic lipids, which are fatty molecules that can bind with cell membranes. This type of lipid can associate with and alter the integrity of a cell membrane, thus increasing the uptake of the complexed DNA. Unfortunately, cationic lipids are toxic to cells and are readily metabolized. Thus, the effect of these agents in transfection protocols is not readily reproducible when used in vivo.

We have identified a series of non-ionic block copolymers known as poloxamers that share several physico-chemical traits with the cationic lipids in that they associate with DNA and cell membranes. (Block copolymers are composed of short segments of two different kinds of polymer, while non-ionic block copolymers do not have any cations (e.g. Na+ or Ca++) attached to them.) However, the block copolymers are significantly less toxic than the cationic lipids and are not metabolized in vivo. In addition, the poloxamer family of non-ionic block copolymers have a significant history of being safely used in a wide variety of oral, injectable, and topical pharmaceutical products. Importantly, a poloxamer known as CRL-1005, which is among the most active in transfection protocols and is adjuvant active, has been studied in a Phase I clinical trial that we sponsored. In that trial, CRL-1005 was well tolerated at doses significantly higher than those anticipated to be useful in gene therapy or DNA vaccine studies.

In addition to the ability of poloxamers to enhance transfection, these compounds have significant immuno-adjuvant activity. This activity results from an immunological agent being added to a vaccine to increase its antigenic response. Accordingly, we believe that an optimal application for this technology may be in the field of DNA vaccines. We believe that in this application, the activity of poloxamers will be two-fold. First, the

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poloxamers will act as delivery/transfection agents to facilitate the intracellular delivery and protection of the DNA from enzymatic digestion. Second, the poloxamer will act as an immuno-adjuvant. Since the poloxamer is not metabolized and has surface active properties, it is likely to remain on the surface of the transfected cell awaiting expression of the gene. When the gene product is excreted from the cell, the poloxamer is likely to associate with the antigen and exert immuno-adjuvant actions. (The antigen being a substance that, when introduced into the body, stimulates the production of an antibody.) Numerous preclinical have demonstrated that conventional vaccines adjuvanted with poloxamers are well tolerated and result in significantly enhanced antibody and cellular immune responses.

License fees paid to us with respect to our TranzFect technology have represented 78%, 85% and 60% of our total revenues for the years ended December 31, 2002, 2001 and 2000, respectively.

Merck License.

In November 2000, we entered into an exclusive, worldwide license agreement with Merck & Co., Inc. whereby we granted Merck the right to use our TranzFect technology in DNA-based vaccines targeted to four infectious diseases, one of which is HIV. To date, Merck has focused its efforts on the HIV application, which is still at an early stage of clinical development.

In November 2000, Merck paid us an upfront payment of $2,000,000 and in February 2002, Merck paid us an additional $1,000,000 milestone fee related to the commencement by Merck of the first FDA Phase I Study for the first product incorporating TranzFect designed for the prevention and treatment of HIV. Merck will also pay us up to $3,000,000 in $1,000,000 increments within 30 days of the occurrence of each of the following: (1) the commencement by Merck of the earlier of the first FDA Phase IIb Study or Phase III Study for such HIV product; (2) the filing by Merck of the first U.S. Public Health Service Act Product License Application in one of the countries mentioned below for such HIV product; and (3) notification from a regulatory authority in the United States, Canada, France, Germany, Italy, Spain, the United Kingdom or Japan that all approvals for the marketing of such HIV product, including pricing approvals, have been granted. Merck will also pay us an annual fee of $50,000 the first year, $75,000 the second year, and $100,000 the third year and each additional year thereafter until Merck receives notification from a regulatory authority as mentioned above. These annual payments by Merck may be used by Merck to offset future royalty payments that they may owe us.

For the products incorporating TranzFect targeting the other diseases, Merck will pay us milestone payments of up to $2,850,000 in the following increments: (1) $100,000 for the commencement by Merck of the first FDA Phase I Study; (2) $250,000 for the commencement by Merck of the earlier of the first FDA Phase IIb Study or Phase III Study; (3) $500,000 for the filing by Merck of the first U.S. Public Health Service Act Product License Application in one of the countries mentioned below; and (4) $2,000,000 for notification from a regulatory authority in the United States, Canada, France, Germany, Italy, Spain, the United Kingdom or Japan that all approvals for the marketing of such product, including pricing approvals, have been granted.

Merck also will pay to us royalties of between 2% and 4%, on a country-by-country basis, based on net sales. Merck will pay an additional 1% royalty on net sales if certain conditions are met regarding patent protection and Merck s competitive position. The royalty payments are subject to certain reductions.

The receipt of the additional milestone and royalty payments is dependent upon the activities of Merck, and therefore we cannot predict the amount or likelihood of these payments that we will receive.

This agreement remains effective unless terminated according to its terms by either party or until the expiration of all royalty obligations thereunder. Merck s obligation to pay royalties to us pursuant to the license agreement extends for a minimum of five years from the date of first commercial sale of the product in the applicable country or until the expiration of the last applicable patent in the country in which sales are made, whichever is longer. Merck may terminate this agreement at any time in its sole discretion by giving 90 days

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written notice. Upon termination by Merck, the rights and obligations under the agreement, including any licenses and payment obligations not yet due, also terminate. The agreement may also be terminated for cause by either party. All amounts previously paid to us through the date of termination are non-refundable upon termination of the agreement and require no additional efforts on our part.

Vical License.

In December 2001, we entered into a license agreement with Vical Incorporated granting Vical exclusive, worldwide rights to use or sublicense our TranzFect poloxamer technology to enhance viral or non-viral delivery of polynucleotides (such as DNA and RNA) in all preventive and therapeutic human and animal health applications, except for (1) four infectious disease vaccine targets previously licensed by us to Merck, and (2) DNA vaccines or therapeutics based on prostate-specific membrane antigen (PSMA). In addition, the Vical license permits Vical to use TranzFect poloxamer technology to enhance the delivery of proteins in prime-boost vaccine applications that involve the use of polynucleotides. Vical has not yet commenced any clinical development work with our TranzFect technology.

Under the Vical license, we received a nonrefundable up-front payment of $3,750,000, and we have the potential to receive total aggregate additional milestone payments of up to $3,600,000, plus royalty payments in the future based on criteria described in the agreement. The receipt of the additional milestone payments is dependent upon the activities of Vical, and therefore, we cannot predict the amount or likelihood of these payments that we will receive.

This agreement remains effective unless terminated according to its terms by either party or until the expiration of all royalty obligations under this agreement. Vical s obligation to pay royalties to CytRx pursuant to the license agreement extends for a minimum of five years from the date of first commercial sale of the product or until the expiration of the last applicable patent in the country in which sales are made. Vical may terminate this agreement at any time in its sole discretion by giving 90 days written notice. Upon termination by Vical, the rights and obligations under the agreement, including any licenses and payment obligations not yet due, also terminate. The agreement may also be terminated for cause by either party. All amounts previously paid to us through the date of termination are nonrefundable upon termination of the agreement and require no additional efforts on our part.

PSMA Development Company Option Agreement.

In December 2002, we granted an option to PSMA Development Company (PDC) to license TranzFect, our vaccine adjuvant technology. PDC would utilize TranzFect in this strategic alliance in a prostate cancer vaccine being developed by PDC. Under the terms of the option agreement, PDC has a 24 month right of first refusal to enter into a license agreement for TranzFect under pre-negotiated terms.

Conventional Vaccines.

As part of our TranzFect program, we have developed a library of compounds, many of which have been shown to enhance the activity of conventional vaccines. We refer to this program as Optivax. We are seeking other potential licensees for Optivax applications. We may, under certain circumstances, be required to pay a royalty fee to Emory University if we utilize certain intellectual property of that university in connection with our Optivax program. The royalty, if applicable, would be equal to 4% of the first $1,000,000 and 2.5% of any additional revenues that we receive on our sales of Optivax products or on royalties that we receive from any licensees of our Optivax technology.

Other Product Development Efforts.

Food Animal Growth Promotant. The FDA has expressed a growing concern about the use of low level antibiotics in animal feed and the possibility of resultant antibiotic resistance in human pathogens. Pending

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regulations at the FDA could suspend farmers use of any antibiotics found to promote the spread of resistant human pathogens. In experimental studies, our compound, CRL-8761, has been shown to have a consistent effect to improve the rate of weight gain and feed efficiency in well-controlled studies in poultry and swine. CRL-8761 as a feed additive consistently provides the same growth performance benefits as antibiotics but, since it has no antibiotic activity, it is free from human health concerns over the use of antibiotics.

Ivy Animal Health License.

In February 2001, we entered into a license agreement with Ivy Animal Health, Inc. under which we granted Ivy a worldwide exclusive license to CRL-8761. As part of the license, we received a nominal up-front payment, and will receive a milestone fee of $100,000 upon regulatory approval in the United States and a future royalty equal to 5% of net sales.

Recent Developments

On July 19, 2002, we completed the acquisition of Global Genomics. The acquisition of Global Genomics was accomplished through a merger of our wholly owned subsidiary, GGC Merger Corporation, with and into Global Genomics. Global Genomics was the surviving corporation in the merger with GGC Merger Corporation and is now our wholly-owned subsidiary. We have changed Global Genomics name to GGC Pharmaceuticals, Inc., but for purposes of this Annual Report, we will continue to refer to the company as Global Genomics. For accounting purposes, we were deemed the acquiror of Global Genomics.

In the Global Genomics merger, each outstanding share of common stock of Global Genomics was converted into 0.765967 shares of our common stock. Accordingly, a total of 8,948,204 shares of our common stock, or approximately 41.7% of our common stock outstanding immediately after the merger, were issued to the common stockholders of Global Genomics, and an additional 1,014,677 shares of our common stock were reserved for issuance upon the exercise of the outstanding Global Genomics warrants that we assumed in the merger. Other than the foregoing stock, we paid no other consideration to the Global Genomics shareholders.

Global Genomics is a development stage company that has been engaged principally in investing in or acquiring companies that develop and commercialize healthcare products driven by genomics technologies. Global Genomics primary assets are a 40% equity interest in Blizzard Genomics, Inc. and a 5% equity interest in Psynomics, Inc. (Psynomics).

Blizzard Genomics is developing instrumentation, software and consumable supplies for the growing genomics industry. Blizzard Genomics is the exclusive sublicensee of a technology that it believes allows for cheaper, faster and more portable analysis of DNA, through the use of its own readers and DNA chips, as compared to other currently available technology. Subject to having sufficient financial resources, Blizzard Genomics has plans to commercially launch its first product, a chip reader, during 2003. Blizzard Genomics I-Scan Imager chip reader acquires the image of labeled DNA attached to a DNA chip. It is a portable, flexible, easy-to-use instrument with DNA detection and analysis capabilities that Blizzard Genomics believes are comparable to those of DNA chip readers that are more expensive. Blizzard Genomics T-Chip thermal hybridization station produces a stable, reproducible temperature gradient across the surface of Blizzard Genomics T-Chip DNA chip. This innovation enables researchers and clinicians to use straightforward temperature versus position analyses to detect the smallest changes in a DNA strand. Most importantly, Blizzard Genomics thermal gradient technology can distinguish previously undetectable genetic variants in disease and pathogenic agents. Pending receipt of additional funding to complete the development of the T-Chip thermal hybridization station and T-Chip DNA chip, Blizzard Genomics anticipates commercial sales of these products commencing in 2004. Since Blizzard Genomics currently planned products are primarily for use in research laboratories, they will not need to be approved by the FDA before they can be marketed.

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Psynomics is an early stage psychiatric genomics company. Psynomics is currently operating out of the University of California, San Diego as a virtual company with no full-time or salaried employees, facilities or other corporate or research infrastructure and has had an ongoing research collaboration with its founders at that university. Psynomics short-term goal is to identify the genes that cause common neuropsychiatric diseases, such as bipolar disorder, schizophrenia and depression and to develop diagnostic tests for these diseases. Initial research by the founders of Psynomics has resulted in patent applications being filed for discoveries in the bipolar disorder area. Psynomics long-term goal is to provide the tools to the pharmaceutical industry to develop novel drug and gene therapy products for neuropsychiatric diseases, but Psynomics has not yet commenced any work in this area.

At the time of the Global Genomics merger, there were no material relationships between Global Genomics or any of its shareholders or affiliates and us, except that on July 16, 2002, Global Genomics three designees to our Board of Directors, Steven A. Kriegsman, Louis J. Ignarro, Ph.D. and Joseph Rubinfeld, Ph.D., were elected directors and Steven A. Kriegsman became our Chief Executive Officer. Mr. Kriegsman was Global Genomics Chairman and Dr. Ignarro was a director of Global Genomics at that time. On the date of the merger, the controlling shareholder of Global Genomics was Steven A. Kriegsman, who beneficially owned, on a fully diluted basis, approximately 41.3% of Global Genomics equity interest.

The shares of our common stock that we issued in the merger with Global Genomics or that we will issue upon exercise of warrants issued by Global Genomics that we assumed in the merger were not registered under the Securities Act. As a result, resale of these shares is restricted under the Securities Act. However, pursuant to a registration rights agreement that we signed with the former shareholders of Global Genomics, we recently filed a registration statement with the SEC to register these shares.

Research and Development Expenditures

Expenditures for research and development activities related to continuing operations were $767,000, $1,844,000 and $1,962,000 during the years ended December 31, 2002, 2001 and 2000, respectively.

Manufacturing

The manufacture of CRL-5861 requires the following:

- a supply of the raw drug substance
- a supply of the purified drug which is refined from the raw drug substance
- formulation and sterile filling of the purified drug substance into the finished drug product

A number of suppliers and manufacturers can provide the raw drug substance and the finished drug product. Prior to the change in our business strategy to now seek a strategic partner or licensee for CRL-5861 (who we anticipate would be responsible for the manufacture of CRL-5861), we entered into an agreement with Organichem Corp. to provide us with commercial supplies of the purified drug substance. However, this agreement will expire by the end of 2003, which will be well before any potential strategic partner or licensee that we secure will need commercial supplies of this substance. There can be no assurance that any strategic partner or licensee that we secure will either have the specific equipment expertise to purify the CRL-5861 drug substance or will be able to enter into an agreement with Organichem or another supplier on acceptable terms. An inability to obtain purified drug substance in sufficient amounts and at acceptable prices could have a material adverse effect on our ability to secure a strategic partner or licensee or on the ability of that partner or licensee to commercialize CRL-5861.

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If we or our strategic partner or licensee modify the manufacturing process or change the source or location of supply for any of our products, regulatory authorities will require us or our strategic partner or licensee to demonstrate that the material produced from the modified or new process or facility is equivalent to the material used in clinical trials for that product. Moreover, any manufacturing facility and the quality control and manufacturing procedures used by us or our strategic partner or licensee for the commercial supply of a product must comply with applicable Occupational Safety and Health Administration, Environmental Protection Agency, and FDA standards, including Good Manufacturing Practice regulations. See Government Regulation below.

Patents and Proprietary Technology

We actively seek patent protection for our technologies, processes, uses, and ongoing improvements and consider our patents and other intellectual property to be critical to our business.

We continually evaluate the patentability of new inventions and improvements developed by us or our collaborators. Whenever appropriate, we will endeavor to file United States and international patent applications to protect these new inventions and improvements. However, there can be no assurance that any of the current pending patent applications or any new patent applications that may be filed will ever be issued in the United States or any other country.

We also attempt to protect our proprietary products, processes and other information by relying on trade secrets and non-disclosure agreements with our employees, consultants and certain other persons who have access to such products, processes and information. Under the agreements, all inventions conceived by employees are our exclusive property. Nevertheless, there can be no assurance that these agreements will afford significant protection against misappropriation or unauthorized disclosure of our trade secrets and confidential information.

We believe we have significant intellectual property in the United States and the other commercially significant territories covering the use of poloxamers in a number of therapeutic areas. We have patents claiming broad areas of the use of these compounds currently pending or issued in Canada, Japan, South Korea, the European Patent Office and the United States. On November 23, 1999, the U.S. Patent Office issued patent No. 5,990,241 Polyoxypropylene/Polyoxyethylene Copolymers With Improved Biological Activity to us. We believe the issue of this patent provides important exclusivity protection for FLOCOR since it contains composition of matter claims for purified poloxamers used in our products and technologies, including purified poloxamer 188, the active ingredient in CRL-5861. This patent will expire in 2017. We also own a comprehensive group of patents that broadly claim the use of poloxamers as vaccine adjuvants that will provide additional coverage for DNA vaccines utilizing our TranzFect technology. Additional United States patents that cover the vaccine area for our TranzFect technology are No. 6,086,899, Novel Vaccine Adjuvant and Vaccine, which expires in 2015; No. 5,696,298, Polyoxypropylene/Polyoxyethylene Copolymers With Improved Biological Activity, which expires in 2017; No. 5,567,859, Polyoxypropylene/Polyoxyethylene Copolymers With Improved Biological Activity, which expires in 2014; and No. 5,554,372, Methods and Vaccines Comprising Surface-Active Copolymers, which expires in 2016.

Competition

Many companies, including large pharmaceutical, chemical and biotechnology firms with financial resources, research and development staffs, and facilities that may, in certain cases, be substantially greater than those of our strategic partners or licensees, are engaged in the research and development of pharmaceutical products that could compete with our potential products. To the extent that we seek to acquire, through license

or otherwise, existing or potential new products, we will be competing with numerous other companies, many of which will have substantially greater financial resources, large acquisition and research and development staffs that may give those companies a competitive advantage over us in identifying and evaluating these drug acquisition opportunities. Any products that we acquire will be competing with products marketed by

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companies that in many cases will have substantially greater marketing resources than we have. The industry is characterized by rapid technological advances and competitors may develop their products more rapidly and such products may be more effective than those currently under development or that may be developed in the future by our strategic partners or licensees. Competitive products may include in addition to those products currently under development that we are not aware of or products that may be developed in the future.

Although we do not expect FLOCOR to have direct competition from other products currently available or that we are aware of that are being developed related to FLOCOR s ability to reduce blood viscosity in the cardiovascular area, there are a number of anticoagulant products that FLOCOR would have to compete against, such as tissue plasminogen activator (t-PA) and streptokinase (blood clot dissolving enzymes) as well as blood thinners such as heparin and coumatin, even though FLOCOR acts by a different mechanism to prevent damage due to blood coagulation. In the sickle cell disease area, we would compete against companies that are developing or marketing other products to treat sickle cell disease, such as Droxia (hydroxyurea) marketed by Bristol-Myers Squibb Co. and Decitabine, which is being developed by SuperGen, Inc.

Our TranzFect technology will compete against a number of companies that have developed adjuvant products, such as the adjuvant QS-21 marketed by Aquila Biopharmaceuticals, Inc. and adjuvants marketed by Corixa. Blizzard Genomics products will compete with a number of currently marketed products, including those offered by Axon Instruments, Affymetrix, Applied Precision, Perkin Elmer and Agilent Technologies.

Government Regulation

The marketing of pharmaceutical products requires the approval of the FDA and comparable regulatory authorities in foreign countries. The FDA has established guidelines and safety standards which apply to the pre-clinical evaluation, clinical testing, manufacture and marketing of pharmaceutical products. The process of obtaining FDA approval for a new drug product generally takes several years and involves the expenditure of substantial resources. The steps required before such a product can be produced and marketed for human use in the United States include preclinical studies in animal models, the filing of an Investigational New Drug (IND) application, human clinical trials and the submission and approval of a New Drug Application (NDA). The NDA involves considerable data collection, verification and analysis, as well as the preparation of summaries of the manufacturing and testing processes, preclinical studies, and clinical trials. The FDA must approve the NDA before the drug may be marketed. There can be no assurance that we or our strategic alliance partners or licensees will be able to obtain the required FDA approvals for any of our products.

The manufacturing facilities and processes for our products, which we anticipate will be manufactured by our strategic partners or licensees or other third parties, will be subject to rigorous regulation, including the need to comply with Federal Good Manufacturing Practice regulations. Our manufacturers also will be subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Nuclear Energy and Radiation Control Act, the Toxic Substance Control Act and the Resource Conservation and Recovery Act.

Employees

As of December 31, 2002, we had three full-time employees who are each employed in our management and administrative operations.

Item 2. Properties

We currently lease administrative office space at 11726 San Vicente Blvd, Los Angeles, California. These facilities are in satisfactory condition and suitable for our purposes and present operations.

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Item 3. Legal Proceedings

We are not a party to any material litigation. We are occasionally involved in other claims arising out of our operations in the normal course of business, none of which are expected, individually or in the aggregate, to have a material adverse affect on us.

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

None.

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PART II

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

Our Common Stock is traded on the Nasdaq SmallCap Market under the symbol CYTR. The following table sets forth the high and low sale prices for our Common Stock for the periods indicated as reported by NASDAQ Such prices represent prices between dealers without adjustment for retail mark-ups, mark-downs, or commissions and may not necessarily represent actual transactions.

	High	Low
COMMON STOCK:		
2003		
January 1 to March 12	.56	.21
2002		
Fourth Quarter	.41	.21
Third Quarter	.75	.34
Second Quarter	1.05	.52
First Quarter	1.00	.57
2001		
Fourth Quarter	.94	.45
Third Quarter	1.12	.61
Second Quarter	1.35	.79
First Quarter	1.22	.75

On March 25, 2003, the closing price of our Common Stock as reported on The NASDAQ Stock Market, was $0.48 and there were approximately 1,120 holders of record of our Company s Common Stock. The number of record holders does not reflect the number of beneficial owners of our Common Stock for whom shares are held by brokerage firms and other institutions. We have not paid any dividends since our inception and do not contemplate payment of dividends in the foreseeable future.

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Item 6. Selected Financial Data

	2002	2001	2000	1999	1998
Statement of Operations Data:					
Revenues					
Service revenues	$ 22,453	$ 101,463	$ 451,031	$ 322,536	$ 350,789
License fees	1,051,000	3,751,000	2,000,000		
Interest and other income	268,456	546,947	876,827	1,068,924	1,762,747
Total revenues	1,341,909	4,399,410	3,327,858	1,391,460	2,113,536
Loss from continuing operations	(6,175,636)	(931,341)	(1,147,457)	(15,269,918)	(7,737,296)
Income from discontinued operations			799,355	240,627	2,943,937
Extraordinary item					(325,120)
Net loss	$ (6,175,636)	$ (931,341)	$ (348,102)	$ (15,029,291)	$ (5,118,479)
Basic and diluted loss per common share:					
Loss from continuing operations	$ (0.39)	$ (0.09)	$ (0.12)	$ (1.99)	$ (1.01)
Income from discontinued operations			0.08	0.03	0.38
Extraordinary item					(0.04)